

# Prior Authorization Criteria

InterCommunity Health Network

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**PLEASE READ: This document contains information about the criteria for coverage of this plan**

Updated on 01/01/2026. For more recent information or other questions, please contact Pharmacy Services at **541-768-7863 or toll free at 866-203-3435 (TTY 800-735-2900 or 711)** or visit [samhealthplans.org](http://samhealthplans.org). Pharmacy Services is available Monday through Friday, from 8 a.m. to 5 p.m.

# Abatacept (Orencia)

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## Products Affected

- Orencia PFS
- Orencia Clickjet

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Juvenile Idiopathic Arthritis</li><li>○ Psoriatic Arthritis</li><li>○ Rheumatoid Arthritis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>All diagnoses</u></b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy.</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic or Otezla</li></ul> <p><b><u>Juvenile Idiopathic Arthritis (JIA)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features</li><li>• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of the following:<ul style="list-style-type: none"><li>○ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated</li><li>○ At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids</li></ul></li><li>• Documented intolerance or contraindication to DMARDs OR DMARD will be continued</li><li>• Trial and failure of both infliximab and adalimumab</li></ul> <p><b><u>Psoriatic Arthritis (PsA)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:<ul style="list-style-type: none"><li>○ Psoriasis (1 point for personal or family history, 2 points for current)</li><li>○ Psoriatic nail dystrophy</li></ul></li></ul>

	<ul style="list-style-type: none"> <li>○ Negative test result for RF</li> <li>○ Dactylitis (current or history)</li> <li>○ Radiological evidence of juxta-articular new bone formation</li> <li>● The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of conventional therapy with both of the following <ul style="list-style-type: none"> <li>○ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>○ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine</li> </ul> </li> <li>● Trial and failure of both infliximab and adalimumab</li> </ul> <p><b>Rheumatoid Arthritis (RA)</b></p> <ul style="list-style-type: none"> <li>● Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)</li> <li>● The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine</li> <li>● Trial and failure of both infliximab and adalimumab</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>● <b>JIA:</b> Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.</li> <li>● <b>PsA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>● <b>RA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> </ul>
<b>Exclusion Criteria</b>	
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>● <b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist</li> <li>● <b>Rheumatoid Arthritis, Juvenile Idiopathic Arthritis:</b> Rheumatologist</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>● <b>All diagnoses</b> <ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	09/01/2023
P&T Approval Date:	07/11/2023

P&T Revision Date: | 07/11/2023

# Acne Combo Products

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## Products Affected

- Clindamycin/Benzoyl Peroxide 1-5% Gel
- Erythromycin/Benzoyl Peroxide 3-5% Gel

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Acne vulgaris</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Acne Vulgaris</u></b> <ul style="list-style-type: none"><li>• Documentation of trial and failure, intolerance, or contraindication to clindamycin/benzoyl peroxide 1.2-5% gel</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of positive clinical response to therapy</li></ul>
<b>Exclusion Criteria</b>	
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• Initial: 12 months</li><li>• Renewal: 12 months</li></ul>

Effective Date:	02/01/2023
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# Adalimumab

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## Products Affected

- Adalimumab-adaz 40mg/0.4mL, 80mg/0.8mL (auto-injector and prefilled syringe)
- Adalimumab-fkjp 40mg/0.8mL, 20 mg/0.4mL, (auto-injector and prefilled syringe)
- Hadlima 40mg/0.4mL, 40mg/0.8mL (auto-injector and prefilled syringe)
- Yusimry 40mg/0.8mL
- Simlandi 40mg/0.4mL

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Ankylosing Spondylitis/Axial Spondyloarthritis</li><li>○ Crohn's Disease</li><li>○ Hidradenitis Suppurativa</li><li>○ Juvenile Idiopathic Arthritis</li><li>○ Plaque Psoriasis</li><li>○ Psoriatic Arthritis</li><li>○ Rheumatoid Arthritis</li><li>○ Ulcerative Colitis</li><li>○ Uveitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>All diagnoses</b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy.</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic or Otezla.</li></ul> <p><b>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</b></p> <ul style="list-style-type: none"><li>• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:<ul style="list-style-type: none"><li>○ Back pain and stiffness for more than 3 months AND</li><li>○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND</li><li>○ BASDAI score of &gt;=4</li></ul></li><li>• One of the following:<ul style="list-style-type: none"><li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li></ul></li></ul>

- Documented failure of conventional therapy with both of the following:
  - At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND
  - Physical therapy/exercise program

**Crohn's Disease (CD)**

- Documentation of moderate-to-severe Crohn's Disease
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of at least 1 of the following: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate.

**Hidradenitis Suppurativa (HS)**

- Documentation of a diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III)
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented failure of conventional therapy (e.g. oral antibiotics).

**Juvenile Idiopathic Arthritis (JIA)**

- Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of the following:
    - NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
    - At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids
- Documented intolerance or contraindication to DMARDs OR DMARD will be continued with adalimumab.

**Plaque Psoriasis (PP):**

- Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index

(DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:

- At least 10% of body surface area involved
- Hand, foot, face, or mucous membrane involvement
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of all the following:
    - High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)
    - At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)
    - PUVA or UVB Phototherapy
    - Methotrexate
    - At least 1 other second line systemic agent such as cyclosporine or acitretin.

**Psoriatic Arthritis (PsA):**

- Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:
  - Psoriasis (1 point for personal or family history, 2 points for current)
  - Psoriatic nail dystrophy
  - Negative test result for RF
  - Dactylitis (current or history)
  - Radiological evidence of juxta-articular new bone formation
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of conventional therapy with both of the following:
    - NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
    - Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine.

**Rheumatoid Arthritis (RA):**

- Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)
- One of the following:

	<ul style="list-style-type: none"> <li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li> <li>○ Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine</li> </ul> <p><b><u>Ulcerative Colitis (UC):</u></b></p> <ul style="list-style-type: none"> <li>● Documentation of moderate-to-severe ulcerative colitis</li> <li>● One of the following: <ul style="list-style-type: none"> <li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li> <li>○ Documented trial and failure of at least 1 of the following: mesalamine, sulfasalazine, mercaptopurine, azathioprine, or corticosteroids (prednisone, methylprednisolone).</li> </ul> </li> </ul> <p><b><u>Uveitis:</u></b></p> <ul style="list-style-type: none"> <li>● Documentation of non-infectious, intermediate-, posterior- or pan-uveitis</li> <li>● Documented trial and failure of all the following: <ul style="list-style-type: none"> <li>○ Topical glucocorticoids for at least 1 month OR periocular steroid injection, and</li> <li>○ Oral corticosteroids, and</li> <li>○ At least one of the following: mycophenolate, tacrolimus, cyclosporine, azathioprine, or methotrexate</li> </ul> </li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>● <b>Ankylosing Spondylitis/Axial Spondyloarthritis:</b> Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.</li> <li>● <b>Crohn's Disease:</b> Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.</li> <li>● <b>Hidradenitis Suppurativa:</b> Evidence of a reduction of 25% or more of the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas.</li> <li>● <b>Juvenile Idiopathic Arthritis:</b> Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.</li> <li>● <b>Plaque Psoriasis:</b> Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g.</li> </ul>

	<p>pruritus, inflammation) from baseline, or evidence of functional improvement.</p> <ul style="list-style-type: none"> <li>• <b>Psoriatic Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>• <b>Rheumatoid Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>• <b>Ulcerative Colitis:</b> Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.</li> <li>• <b>Uveitis:</b> Evidence that that disease activity has been controlled, such as a lack of inflammation, no new inflammatory vascular lesions, no vitreous haze or decreases in visual acuity.</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Crohn's Disease and Ulcerative Colitis:</b> Gastroenterologist.</li> <li>• <b>Hidradenitis Suppurativa and Plaque Psoriasis:</b> Dermatologist.</li> <li>• <b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist.</li> <li>• <b>Rheumatoid Arthritis, Juvenile Idiopathic Arthritis:</b> Rheumatologist.</li> <li>• <b>Ankylosing Spondylitis, Axial Spondyloarthritis:</b> Rheumatologist.</li> <li>• <b>Uveitis:</b> Ophthalmologist or Rheumatologist.</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>All diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	11/01/2023
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# Alpelisib (Vijoice)

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## Products Affected

- Vijoice tab

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ PIK3CA-related overgrowth spectrum (PROS)</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>PIK3CA-related overgrowth spectrum (PROS)</u></b> <ul style="list-style-type: none"><li>• Confirmed diagnosis of PROS</li><li>• At least one severe clinical manifestation of PROS</li><li>• A PIK3CA mutation that is confirmed by genetic testing.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of a reduction in volume from baseline in at least one lesion AND</li><li>• Improvement in at least one symptom of PROS from baseline</li></ul>
<b>Exclusion Criteria</b>	
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Two years of age and older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• Prescribed by or in consultation with a provider who specializes in treatment of genetic disorders.</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• Initial: 24 weeks</li><li>• Renewal: 6 months</li></ul>

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P&T Revision Date:	09/13/2022

# Anakinra (Kineret)

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## Products Affected

- Kineret 100MG/0.67ML

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Rheumatoid Arthritis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>All Diagnoses</b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic or Otezla</li></ul> <p><b>Rheumatoid Arthritis (RA)</b></p> <ul style="list-style-type: none"><li>• Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)</li><li>• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine</li><li>• Trial and failure of both infliximab and adalimumab</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li></ul>
<b>Exclusion Criteria</b>	
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Rheumatoid Arthritis:</b> Rheumatologist.</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Rheumatoid Arthritis</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	09/01/2023
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# Anticholinergic Overactive Bladder Step Therapy

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## Products Affected

- Trospium IR tablets
- Fesoterodine
- Tolterodine ER capsules
- Trospium ER capsules
- Tolterodine IR tablets

Step Therapy Criteria	• Trial and failure of ○ Oxybutynin IR or ER
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P&T Revision Date:	5/13/2025

# Apremilast (Otezla)

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## Products Affected

- Otezla tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Plaque Psoriasis</li><li>○ Psoriatic Arthritis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>All Diagnoses</u></b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy.</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic</li></ul> <p><b><u>Plaque Psoriasis</u></b></p> <ul style="list-style-type: none"><li>• Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:<ul style="list-style-type: none"><li>○ At least 10% of body surface area involved</li><li>○ Hand, foot, face or mucous membrane involvement</li></ul></li><li>• One of the following:<ul style="list-style-type: none"><li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li><li>○ Documented trial and failure of all the following:<ul style="list-style-type: none"><li>▪ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)</li><li>▪ At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)</li><li>▪ PUVA or UVB Phototherapy</li><li>▪ Methotrexate</li><li>▪ At least 1 other second line systemic agent such as cyclosporine or acitretin.</li></ul></li></ul></li><li>• Trial and failure of both infliximab and adalimumab.</li></ul>

	<p><b>Psoriatic Arthritis</b></p> <ul style="list-style-type: none"> <li>Documentation of psoriatic arthritis based on at least 3 out of 5 of the following: <ul style="list-style-type: none"> <li>Psoriasis (1 point for personal or family history, 2 points for current)</li> <li>Psoriatic nail dystrophy</li> <li>Negative test result for RF</li> <li>Dactylitis (current or history)</li> </ul> </li> <li>One of the following: <ul style="list-style-type: none"> <li>The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li> <li>Documented trial and failure of all the following: <ul style="list-style-type: none"> <li>NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated</li> <li>Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab</li> </ul> </li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li><b>Plaque Psoriasis:</b> Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement.</li> <li><b>Psoriatic Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> </ul>
<b>Exclusion Criteria</b>	
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li><b>Plaque Psoriasis:</b> Dermatologist.</li> <li><b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist.</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li><b>All diagnoses:</b> <ul style="list-style-type: none"> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul> </li> </ul>

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P&T Approval Date:	07/11/2023
P&T Revision Date:	07/11/2023, 01/11/2022

# Aprepitant (Emend)

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## Products Affected

- Aprepitant Capsule

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Prevention of nausea and vomiting associated with initial and repeat courses of highly emetogenic chemotherapy</li><li>○ Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Prevention of chemotherapy induced nausea and vomiting</u></b> <ul style="list-style-type: none"><li>• Documentation of patient receiving treatment with a moderate to highly emetogenic chemotherapy agent.</li><li>• Documentation patient is receiving concurrent treatment with all the following:<ul style="list-style-type: none"><li>○ IV or oral ondansetron, granisetron or palonosetron</li><li>○ Dexamethasone</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Positive clinical response to therapy</li></ul>
<b>Exclusion Criteria</b>	
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• Initial: 12 months</li><li>• Renewal: 12 months</li></ul>

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# Asthma Triple Combination Inhaler Step Therapy

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## Products Affected

- Trelegy
- Breztri

<b>Step Therapy Criteria</b>	<ul style="list-style-type: none"><li>• Trial and failure of at least 4 weeks of 2 of the following<ul style="list-style-type: none"><li>○ A Long-Acting Beta Agonist (LABA)</li><li>○ An Inhaled Corticosteroid (ICS)</li><li>○ A Long-Acting Muscarinic Antagonist (LAMA)</li></ul></li></ul>
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# Atovaquone-proguanil (MALARONE)

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## Products Affected

- Atovaquone-proguanil 62.5mg-25mg tablet
- Atovaquone-proguanil 250mg-100mg tablet

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Prevention of malaria infection</li><li>○ Treatment of malaria infection</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Prevention of malaria infection:</b></p> <ul style="list-style-type: none"><li>• Travel to a location where CDC recommends the use of atovaquone-proguanil</li><li>• Clinical contraindication to doxycycline <b>OR</b> doxycycline is not recommended by CDC for the travel location.</li></ul> <p><b>Treatment of malaria infection:</b></p> <ul style="list-style-type: none"><li>• Recommended by the CDC</li></ul>
<b>Renewal Criteria</b>	N/A
<b>Age Restriction</b>	Refer to FDA label
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Prevention of malaria infection:</b><ul style="list-style-type: none"><li>○ Initial: 3</li><li>○ Renewal: N/A</li></ul></li><li>• <b>Treatment of malaria infection:</b><ul style="list-style-type: none"><li>○ Initial: 1</li><li>○ Renewal: N/A</li></ul></li></ul>

Effective Date:	11/1/2024
P&T Approval Date:	9/10/2024
P&T Revision Date:	9/10/2024

# Baricitinib (OLUMIANT)

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## Products Affected

- Olumiant tablet

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Rheumatoid Arthritis (RA)</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>All diagnoses:</b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy.</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic or Otezla</li></ul> <p><b>Rheumatoid Arthritis (RA):</b></p> <ul style="list-style-type: none"><li>• Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)</li><li>• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine</li><li>• Trial and failure of both infliximab and adalimumab</li><li>• Trial and failure of Actemra, Cimzia, Kineret, Orencia, and rituximab</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li></ul>
<b>Exclusion Criteria</b>	
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Rheumatoid Arthritis:</b> Rheumatologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Rheumatoid Arthritis</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023; 1/11/2022

# Bedaquiline (Sirturo)

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## Products Affected

- Sirturo Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Pulmonary Tuberculosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Pulmonary Tuberculosis</b> <ul style="list-style-type: none"><li>• Evidence of active pulmonary tuberculosis caused by mycobacterium tuberculosis that is resistant to at least rifampin and isoniazid</li><li>• The member weighs at least 15kg</li><li>• Sirturo is prescribed as part of a guideline recommended multi-drug treatment regimen.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Renewal not appropriate</li></ul>
<b>Exclusions</b>	<ul style="list-style-type: none"><li>• Medication is being received through a county clinic with a state funded TB program.</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 5 years of age and older.</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Pulmonary Tuberculosis:</b> Infectious Disease</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Pulmonary Tuberculosis:</b><ul style="list-style-type: none"><li>○ Initial: 24 weeks</li><li>○ Renewal: N/A</li></ul></li></ul>

Effective Date:	5/1/2025
P&T Approval Date:	3/11/2025
P&T Revision Date:	3/11/2025

## References

- Sirturo [package insert]. Horsham, PA: Janssen Products, LP; 2024.

# Belumosudil (Rezurock)

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## Products Affected

- Rezurock tablet

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Chronic graft-versus-host disease</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	Chronic graft-versus-host disease <ul style="list-style-type: none"><li>• Trial and failure of at least two prior lines of systemic therapy for cGVHD</li><li>• Not currently taking Imbruvica (ibrutinib)</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Exclusion Criteria</b>	
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 12 years of age or older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>cGVHD:</b> oncologist or transplant specialist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>cGVHD:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal: 6 months</li></ul></li></ul>

Effective Date:	4/1/2022
P&T Approval Date:	3/8/2022
P&T Revision Date:	3/8/2022

# Bempedoic acid (Nexletol/Nexlizet)

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## Products Affected

- Nexletol tablet
- Nexlizet tablet

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>◦ Clinical ASCVD</li><li>◦ Primary or familial hyperlipidemia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Clinical ASCVD</b></p> <ul style="list-style-type: none"><li>• Documentation of very high risk ASCVD as evidenced by either:<ul style="list-style-type: none"><li>◦ History of multiple major ASCVD events</li><li>◦ One major ASCVD event AND multiple high-risk conditions</li></ul></li><li>• Documentation of a current LDL greater than or equal to 55 mg/dl</li><li>• Documentation of all the following<ul style="list-style-type: none"><li>◦ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins</li><li>◦ Is receiving ezetimibe or has a documented intolerance to ezetimibe.</li></ul></li><li>• Documentation of failure of PCSK9 inhibitor (Repatha or Prluent)</li></ul> <p><b>Primary or familial hyperlipidemia</b></p> <ul style="list-style-type: none"><li>• Documentation of an untreated (i.e., prior to lipid lowering therapy) LDL greater than 190 mg/dL</li><li>• Documentation of current LDL greater than 100 mg/dL</li><li>• Documentation of all the following<ul style="list-style-type: none"><li>◦ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins</li><li>◦ Is receiving ezetimibe or has a documented intolerance to ezetimibe.</li></ul></li><li>• Documentation of failure of PCSK9 inhibitor (Repatha or Prluent)</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy (significant decrease in lipid levels).</li></ul>
<b>Exclusion Criteria</b>	
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>ASCVD &amp; Primary or familial hyperlipidemia:</b> Cardiologist, Endocrinologist, or lipid specialist</li></ul>

<b>Coverage Duration</b>	<b>ASCVD &amp; Primary or familial hyperlipidemia:</b> <input type="radio"/> Initial: 6 months <input type="radio"/> Renewal: 12 months
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Effective Date:	11/1/2024
P&T Approval Date:	9/10/2024
P&T Revision Date:	9/10/2024

# Bimekizumab (Bimzelx)

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## Products Affected

- Bimzelx 160mg/mL PFS
- Bimzelx 320mg/2mL PFS
- Bimzelx 160mg/mL auto-injector
- Bimzelx 320mg/2mL auto-injector

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Plaque Psoriasis</li><li>○ Psoriatic Arthritis</li><li>○ Ankylosing Spondylitis/Axial Spondyloarthritis</li><li>○ Hidradenitis Suppurativa</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Plaque Psoriasis</u></b></p> <ul style="list-style-type: none"><li>• Defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool)</li><li>• One or more of the following:<ul style="list-style-type: none"><li>○ At least 10% of body surface area involved</li><li>○ Hand, foot, face, or mucous membrane involvement</li><li>○ The patient on a current biologic product and experiencing intolerable side effects</li></ul></li><li>• The patient tried and failed or have contraindications to ALL of the following<ul style="list-style-type: none"><li>○ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)</li><li>○ At least one other topical agent: calcipotriene, tazarotene, anthralin, tar, etc.</li><li>○ PUVA or UVB Phototherapy</li><li>○ Methotrexate</li><li>○ At least 1 other second line systemic agent such as cyclosporine or acitretin</li></ul></li><li>• Trial and failure of both infliximab and adalimumab</li><li>• Trial and failure of Cosentyx and ustekinumab</li></ul> <p><b><u>Psoriatic Arthritis</u></b></p> <ul style="list-style-type: none"><li>• Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:<ul style="list-style-type: none"><li>○ Psoriasis (1 point for personal or family history, 2 points for current)</li><li>○ Psoriatic nail dystrophy</li></ul></li></ul>

- Negative test result for RF
  - Dactylitis (current or history)
  - Radiological evidence of juxta-articular new bone formation
- The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of conventional therapy with both of the following:
  - NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
  - Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine
- Trial and failure of both infliximab and adalimumab
- Trial and failure of Cosentyx, ustekinumab, and Taltz

#### **Ankylosing Spondylitis/Axial Spondyloarthritis**

- Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:
  - Back pain and stiffness for more than 3 months AND
  - Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND
  - BASDAI score of >=4
- The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of conventional therapy with both of the following:
  - At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
  - Physical therapy/exercise program
- Trial and failure of both infliximab and adalimumab
- Trial and failure of Cosentyx, and Taltz

#### **Hidradenitis Suppurativa**

- Documentation of one of the following:
  - Moderate to severe hidradenitis suppurative (Hurley Stage II or Hurley Stage III)
  - Patient is on a current biologic product and experiencing intolerable side effects.
- The patient is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of the following:
  - 90-day trial of conventional therapy (e.g. oral antibiotics)
- Trial and failure of both infliximab and adalimumab
- Trial and failure of both Cosentyx and ustekinumab

<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>• <b>Plaque Psoriasis:</b> Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement.</li> <li>• <b>Psoriatic Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>• <b>Ankylosing Spondylitis/Axial Spondyloarthritis:</b> Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.</li> <li>• <b>Hidradenitis Suppurativa:</b> Evidence of a reduction of 25% or more of the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas.</li> </ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>• Not to be used in combination with other biologics for the same indication</li> </ul>
<b>Age Restriction</b>	Refer to FDA label
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Plaque Psoriasis, Hidradenitis Suppurativa:</b> Dermatologist.</li> <li>• <b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist.</li> <li>• <b>Ankylosing Spondylitis, Axial Spondyloarthritis:</b> Rheumatologist.</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: 12 months</li> </ul>

Effective Date:	9/1/2025
P&T Approval Date:	5/13/2024
P&T Revision Date:	7/8/2025, 5/13/2024

<b>References</b>
<ul style="list-style-type: none"> <li>• Bimzelx (bimekizumab-bkzx). Prescribing Information. UCB, Inc. Smyrna, GA 2024.</li> </ul>
<ul style="list-style-type: none"> <li>• Gordon KB, et al. Bimekizumab efficacy and safety in moderate to severe plaque psoriasis (BE READY): a multicentre, double-blind, placebo-controlled, randomised withdrawal phase 3 trial. Lancet. 2021; 37:475-86.</li> </ul>
<ul style="list-style-type: none"> <li>• Gordon KB, et al. Bimekizumab safety in patients with moderate to severe plaque psoriasis: Pooled results from Phase 2 and Phase 3 randomized clinical trials. JAMA Dermatol. 2022;158(7):735-744.</li> </ul>

- Gordon KB, et al. Bimekizumab safety in patients with moderate-to-severe plaque psoriasis: pooled data from up to 3 years of treatment in randomized phase III trials. *Br J Dermatol* 2024; 190: 477-485.

# Buprenorphine Patch (Butrans)

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## Products Affected

- Buprenorphine Patch

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Cancer or End-of-life Care</li><li>○ Other Chronic Pain</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Cancer or End-of-life Care</b></p> <ul style="list-style-type: none"><li>• Patient is being treated for cancer related pain or pain associated with end-of-life</li><li>• Documented trial and failure of scheduled short-acting opioid therapy</li><li>• Documented trial and failure of, or contraindication to long-acting morphine sulfate therapy</li><li>• Documented trial/failure of, or reason why fentanyl is not appropriate.</li></ul> <p><b>Other Chronic Pain</b></p> <ul style="list-style-type: none"><li>• Documented above the line diagnosis, FDA indicated, or guideline supported condition</li><li>• Documented chronic pain (greater than 3mo) that is severe enough to require around the clock analgesic therapy</li><li>• Documented trial and failure or contraindication to short-acting opioid therapy</li><li>• Documented trial and failure of, or contraindication to long-acting morphine sulfate therapy</li><li>• Documented trial and failure of, or reason why fentanyl is not appropriate.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Cancer or End-of-Life Care:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li><li>• <b>Other Chronic Pain:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	10/1/2021
P&T Approval Date:	9/14/2021
P&T Revision Date:	9/14/2021

# Calcitonin Gene Related Peptide (CGRP) Antagonists

## Products Affected

- Aimovig (erenumab)
- Emgality (galcanezumab)
- Ajovy (fremanezumab)

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Migraine prophylaxis</li><li>○ Cluster headache (Emgality only)</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Migraine Prophylaxis</u></b></p> <ul style="list-style-type: none"><li>• Documentation showing member experiences at least 4 migraines per month.</li><li>• For members with chronic migraine (<math>\geq 15</math> headache days &amp; 8 migraine episodes per month) Trial and failure of at least 8 weeks of:<ul style="list-style-type: none"><li>○ 3 or more prophylactic medications from at least 2 of the following classes:<ul style="list-style-type: none"><li>▪ beta blockers</li><li>▪ antidepressants</li><li>▪ anticonvulsants</li></ul></li><li>○ Botox.</li></ul></li><li>• For members without a diagnosis of chronic migraine:</li><li>• Trial and failure of:<ul style="list-style-type: none"><li>○ at least 3 prophylactic medications from 2 or more of the following classes:<ul style="list-style-type: none"><li>▪ beta blockers</li><li>▪ antidepressants</li><li>▪ anticonvulsants</li></ul></li></ul></li><li>• The requested treatment will not be used in combination with another CGRP inhibitor.</li></ul> <p><b><u>Cluster Headache</u></b></p> <ul style="list-style-type: none"><li>• The request is for Emgality 300mg dose</li><li>• The member does not have any of the following exclusions:<ul style="list-style-type: none"><li>○ ECG abnormalities compatible with an acute CV event,</li><li>○ history of unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism within the past 6 months,</li></ul></li></ul>

	<ul style="list-style-type: none"> <li>○ history of stroke, intracranial or carotid aneurysm, intracranial hemorrhage, vasospastic angina, or peripheral vascular disease</li> <li>● Trial and failure of at least a 3-month trial of both of the following: <ul style="list-style-type: none"> <li>○ Verapamil</li> <li>○ Topiramate</li> </ul> </li> <li>● The requested treatment will not be used in combination with another CGRP inhibitor.</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>● <b>Migraine Prophylaxis:</b> <ul style="list-style-type: none"> <li>○ Reduction in monthly headache days by at least 2 days from pre-CGRP treatment baseline</li> <li>○ Clinical documented improvement in migraine-related disability</li> </ul> </li> <li>● Cluster Headache <ul style="list-style-type: none"> <li>○ Documented positive clinical response to therapy</li> </ul> </li> </ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"> <li>● 18 years of age and older</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>● <b>Migraine Prophylaxis and Cluster Headache:</b> Prescribed by or in consultation with a neurologist</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>● <b>Migraine Prophylaxis:</b> <ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: 12 months</li> </ul> </li> <li>● <b>Cluster Headache:</b> <ul style="list-style-type: none"> <li>○ Initial: 3 months</li> <li>○ Renewal: 6 months</li> </ul> </li> </ul>

Effective Date:	9/1/2025
P&T Approval Date:	11/08/2022
P&T Revision Date:	7/8/2025, 12/1/2022, 1/11/2022

References
<ul style="list-style-type: none"> <li>● Qaseem A, et al. Prevention of Episodic Migraine Headache Using Pharmacologic Treatment in Outpatient Settings: A Clinical Guideline From the American College of Physicians. Ann Intern Med. 2025;178:426-433.</li> <li>● Ailani J., et al. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61:1021-1039.</li> </ul>

- Timotheussen Lund NL, et al. Current treatment options for cluster headache: limitations and the unmet need for better and specific treatments—a consensus article. *The Journal of Headache and Pain*. 2023;24:121.

# Carbamazepine ER Capsules

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## Products Affected

- Carbamazepine Cap ER 12HR

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<b>All Diagnoses</b> <ul style="list-style-type: none"><li>• Confirmation that carbamazepine is FDA indicated, or guideline supported for the treatment of the condition for which it is being requested</li><li>• One of the following: Trial and failure of carbamazepine ER tablets or patient is currently stable on capsules<ul style="list-style-type: none"><li>◦ Trial and failure of carbamazepine ER tablets</li><li>◦ Patient is currently stable on ER capsules</li></ul></li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>◦ Initial: Lifetime</li></ul></li></ul>

Effective Date:	01/01/2026
P&T Approval Date:	11/11/2025
P&T Revision Date:	11/11/2025

## References

- Epilepsy: Presented by Grinalds, McKenzie. ACSAP 2025

# Cenegermin (Oxervate)

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## Products Affected

- Oxervate Ophthalmic

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Neurotrophic Keratitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Neurotrophic Keratitis</u></b> <ul style="list-style-type: none"><li>• Confirmed diagnosis of stage 2 or 3 neurotrophic keratitis.</li><li>• Trial and failure of at least one ocular lubricant used for at least 2 weeks.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Maximum treatment duration of 8 weeks. Renewal is not allowed.</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Neurotrophic Keratitis:</b> Ophthalmologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Neurotrophic Keratitis:</b><ul style="list-style-type: none"><li>○ Initial: 8 weeks</li><li>○ Renewal: N/A</li></ul></li></ul>

Effective Date:	11/1/2025
P&T Approval Date:	9/9/2025
P&T Revision Date:	9/9/2025

## References

- Oxervate [package insert]. San Mateo, CA: Dompe U.S. Inc.; 2024

# Certolizumab (Cimzia)

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## Products Affected

- Cimzia PFS
- Cimzia Auto-injector

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>◦ Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</li><li>◦ Crohn's Disease (CD)</li><li>◦ Juvenile Idiopathic Arthritis (JIA)</li><li>◦ Plaque Psoriasis (PsO)</li><li>◦ Psoriatic Arthritis (PsA)</li><li>◦ Rheumatoid Arthritis (RA)</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>All diagnoses</b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment</li><li>• No current active infection at initiation of therapy</li><li>• Risks and benefits documented in cases of chronic or recurrent infection</li><li>• Will NOT be used in combination with another biologic or Otezla</li></ul> <p><b>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</b></p> <ul style="list-style-type: none"><li>• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by<ul style="list-style-type: none"><li>◦ Back pain and stiffness for more than 3 months</li><li>◦ Signs of active inflammation on MRI</li><li>◦ Radiological evidence of sacroiliitis OR HLA-B27 positive</li><li>◦ BASDAI score of &gt;=4</li></ul></li><li>• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR Documented failure of conventional therapy with both of the following<ul style="list-style-type: none"><li>◦ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated</li><li>◦ Physical therapy/exercise program</li></ul></li><li>• Trial and failure of both infliximab and adalimumab</li></ul> <p><b>Crohn's Disease (CD)</b></p> <ul style="list-style-type: none"><li>• Documentation of moderate-to-severe Crohn's Disease</li></ul>

<ul style="list-style-type: none"> <li>• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR Documented trial and failure of at least 1 of the following: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate</li> <li>• Trial and failure of both infliximab and adalimumab</li> </ul>	<p><b>Juvenile Idiopathic Arthritis (JIA)</b></p> <ul style="list-style-type: none"> <li>• Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features</li> <li>• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of the following: <ul style="list-style-type: none"> <li>○ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>○ At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids</li> </ul> </li> <li>• Documented intolerance or contraindication to DMARDs OR DMARD will be continued</li> <li>• Trial and failure of both infliximab and adalimumab</li> </ul> <p><b>Plaque Psoriasis (PsO)</b></p> <ul style="list-style-type: none"> <li>• Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool)</li> <li>• One or more of the following <ul style="list-style-type: none"> <li>○ At least 10% of body surface area involved</li> <li>○ Hand, foot, face, or mucous membrane involvement</li> </ul> </li> <li>• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of all the following <ul style="list-style-type: none"> <li>○ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)</li> <li>○ At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)</li> <li>○ PUVA or UVB Phototherapy</li> <li>○ Methotrexate</li> </ul> </li> </ul>
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	<ul style="list-style-type: none"> <li>○ At least 1 other second line systemic agent such as cyclosporine or acitretin</li> <li>● Trial and failure of both infliximab and adalimumab</li> </ul> <p><b>Psoriatic Arthritis (PsA)</b></p> <ul style="list-style-type: none"> <li>● Documentation of psoriatic arthritis based on at least 3 out of 5 of the following <ul style="list-style-type: none"> <li>Psoriasis (1 point for personal or family history, 2 points for current)</li> <li>○ Psoriatic nail dystrophy</li> <li>○ Negative test result for RF</li> <li>○ Dactylitis (current or history)</li> <li>○ Radiological evidence of juxta-articular new bone formation</li> </ul> </li> <li>● The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of conventional therapy with both of the following <ul style="list-style-type: none"> <li>○ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated</li> <li>○ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine</li> </ul> </li> <li>● Trial and failure of both infliximab and adalimumab</li> </ul> <p><b>Rheumatoid Arthritis (RA)</b></p> <ul style="list-style-type: none"> <li>● Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)</li> <li>● The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine</li> <li>● Trial and failure of both infliximab and adalimumab</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>● <b>AS/SpA:</b> Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.</li> <li>● <b>CD:</b> Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.</li> </ul>

	<ul style="list-style-type: none"> <li>• <b>JIA:</b> Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.</li> <li>• <b>PsO:</b> Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement.</li> <li>• <b>PsA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>• <b>RA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> </ul>
<b>Exclusion Criteria</b>	
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Ankylosing Spondylitis/Axial Spondyloarthritis:</b> Rheumatologist.</li> <li>• <b>Crohn's Disease:</b> Gastroenterologist</li> <li>• <b>Juvenile Idiopathic Arthritis:</b> Rheumatologist</li> <li>• <b>Plaque Psoriasis:</b> Dermatologist</li> <li>• <b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist</li> <li>• <b>Rheumatoid Arthritis:</b> Rheumatologist</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>All diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023

# Chloroquine Phosphate

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## Products Affected

- Chloroquine tablet

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>Treatment of malaria</li><li>Extraintestinal amebiasis</li><li>Prevention of malarial infection</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Prevention of malaria infection:</b></p> <ul style="list-style-type: none"><li>Travel to a location where CDC recommends the use of chloroquine</li></ul> <p><b>Treatment of malaria</b></p> <ul style="list-style-type: none"><li>Confirmed diagnosis of Malaria</li></ul> <p><b>Extraintestinal amebiasis</b></p> <ul style="list-style-type: none"><li>Confirmed diagnosis of amebiasis</li></ul>
<b>Renewal Criteria</b>	N/A
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li><b>Treatment of malaria &amp; extraintestinal amebiasis:</b><ul style="list-style-type: none"><li>Initial: 3 months</li><li>Renewal: N/A</li></ul></li></ul>

Effective Date:	11/01/2024
P&T Approval Date:	7/15/2013
P&T Revision Date:	7/15/2013, 9/10/2024

# Cinacalcet Hydrochloride

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## Products Affected

- Cinacalcet tablet

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Treatment of secondary hyperparathyroidism in patients with CKD on dialysis</li><li>○ Treatment of hypercalcemia in patients with parathyroid carcinoma.</li><li>○ Treatment of severe hypercalcemia in patients with primary hyperparathyroidism</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Secondary hyperparathyroidism in patients with CKD</b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of secondary hyperparathyroidism in patients with CKD on dialysis.</li></ul> <p><b>Hypercalcemia in patients with parathyroid carcinoma</b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of hypercalcemia in patients with parathyroid carcinoma</li></ul> <p><b>Severe hypercalcemia in patients with primary hyperparathyroidism</b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of severe hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 18 years of age and older</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

# Clobazam (Onfi)

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## Products Affected

- Clobazam tablets
- Clobazam suspension

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Lennox-Gastaut Syndrome</li><li>○ Refractory Seizures</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Lennox-Gastaut Syndrome</u></b></p> <ul style="list-style-type: none"><li>• Confirmation of diagnosis</li><li>• <b>Suspension only:</b> Member under age 10 or unable to use tablets</li></ul> <p><b><u>Refractory Seizures</u></b></p> <ul style="list-style-type: none"><li>• Documentation showing appropriate trial of 2 or more tolerated anticonvulsant therapies</li><li>• <b>Suspension only:</b> Member under age 10 or unable to use tablets</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of positive clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Age 2 or older</li><li>• <b>Suspension only:</b> Member under age 10 or unable to use tablets</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b> Neurologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: Lifetime</li></ul></li></ul>

Effective Date:	05/01/2025
P&T Approval Date:	07/11/2023
P&T Revision Date:	03/12/2024, 03/11/2025

## References

- Onfi [package insert]. Deerfield, IL: Lundbeck.; 2024.

# Clotrimazole Troche Step Therapy

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## Products Affected

- Clotrimazole Troche

<b>Step Therapy Criteria</b>	<ul style="list-style-type: none"><li>• Trial and failure of<ul style="list-style-type: none"><li>○ Formulary nystatin</li></ul></li></ul>
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Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

# Colony-Stimulating Factors (Filgrastim, Pegfilgrastim)

## Products Affected

- Nivestym Syringe and Inj.
- Zarxio Syringe
- Udenyca Syringe, Pen and Onbody
- Neulasta Syringe, Onpro
- Zixtenzo Syringe

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Bone Marrow/Stem Cell Transplant</li><li>○ Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy</li><li>○ Febrile Neutropenia Prophylaxis</li><li>○ Treatment of High-Risk Febrile Neutropenia</li><li>○ Severe Chronic Neutropenia</li><li>○ Acute Radiation Syndrome</li><li>○ Human Immunodeficiency Virus (HIV) Related Neutropenia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Bone Marrow/Stem Cell Transplant</u></b></p> <ul style="list-style-type: none"><li>• One of the following<ul style="list-style-type: none"><li>○ Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)</li><li>○ Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis</li><li>○ Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy</li></ul></li></ul> <p><b><u>Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy</u></b></p> <ul style="list-style-type: none"><li>• Diagnosis of acute myeloid leukemia (AML)</li><li>• Patient has completed induction or consolidation chemotherapy</li></ul> <p><b><u>Febrile Neutropenia Prophylaxis</u></b></p> <ul style="list-style-type: none"><li>• Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:<ul style="list-style-type: none"><li>○ Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer.</li><li>○ Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown.</li></ul></li></ul>

	<ul style="list-style-type: none"> <li>○ Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN.</li> <li>○ Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN and has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia.</li> <li>○ Patient is receiving myelosuppressive anticancer drugs associated with neutropenia and has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis).</li> </ul>
	<p><b><u>Treatment of High-Risk Febrile Neutropenia</u></b></p> <ul style="list-style-type: none"> <li>● Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia.</li> <li>● Diagnosis of febrile neutropenia (FN).</li> <li>● Patient is at high risk for infection-associated complications.</li> </ul>
	<p><b><u>Severe Chronic Neutropenia (SCN)</u></b></p> <ul style="list-style-type: none"> <li>● For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm<sup>3</sup>)</li> </ul>
	<p><b><u>Acute Radiation Syndrome (ARS)</u></b></p> <ul style="list-style-type: none"> <li>● Patient was/will be acutely exposed to myelosuppressive doses of radiation cells/mm<sup>3</sup>)</li> </ul>
	<p><b><u>Human Immunodeficiency Virus (HIV) Related Neutropenia</u></b></p> <ul style="list-style-type: none"> <li>● Patient is infected with HIV virus.</li> <li>● ANC less than or equal to 1,000 (cells/mm<sup>3</sup>).</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>● Renewal criteria</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>● <b>HIV Related Neutropenia:</b> Hematologist, Oncologist, or Infectious Disease Specialist</li> <li>● <b>All Other Diagnoses:</b> Hematologist or Oncologist</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>● <b>Severe Chronic Neutropenia:</b> <ul style="list-style-type: none"> <li>○ Initial: 12 months</li> <li>○ Renewal: 12 months</li> </ul> </li> <li>● <b>Acute Radiation Syndrome:</b> <ul style="list-style-type: none"> <li>○ Initial: 1 month</li> <li>○ Renewal: N/A</li> </ul> </li> <li>● <b>All other Diagnoses:</b></li> </ul>

	<ul style="list-style-type: none"><li><input type="radio"/> Initial: 3 months or duration of therapy</li><li><input type="radio"/> Renewal: 3 months or duration of therapy</li></ul>
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Effective Date:	9/1/2024
P&T Approval Date:	7/9/2024
P&T Revision Date:	7/9/2024

#### **References**

- Neulasta Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2021.
- Neupogen Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2021.

# Compounds (standard criteria for all compounded medications)

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## Products Affected

- All compounded medications

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>All diagnoses</b></p> <ul style="list-style-type: none"><li>• The requested medication is being used to treat an above the line diagnosis on the OHA Prioritized list OR the member has an above the line comorbid condition that will be treated indirectly by the requested medication OR the member is under the age of 21.</li><li>• Each active ingredient in the compounded drug is FDA-approved or national compendia supported for the condition being treated.</li><li>• The requested amounts are supported by national compendia or at least two peer-reviewed studies for the condition being treated in the requested route of delivery.</li><li>• If any prescription ingredients require prior authorization and/or step therapy, all drug-specific criteria must be also met.</li><li>• The patient has tried and failed therapy, or had an intolerance to all FDA-approved commercially available prescription therapeutic alternatives, unless one of the following criteria are met:<ul style="list-style-type: none"><li>○ Patient has a contraindication to all commercially available products.</li><li>○ No other therapeutic alternatives are commercially available.</li><li>○ Prepared strength(s) is/are not commercially available or currently in short supply and the strength is medically necessary.</li><li>○ Prepared in a different dosage form for a patient who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does NOT meet this criteria).</li><li>○ Patient has an allergy or sensitivity to inactive ingredients (e.g. dyes, preservatives, sugars, etc.) that are found in commercially available products.</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li></ul></li></ul>

	<input type="radio"/> Renewal: 12 months
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Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

# Conjugated Estrogens (Premarin Tablets)

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## Products Affected

- Premarin TAB 0.3MG, 0.45MG, 0.625MG, 0.9MG, 1.25MG

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<b>All FDA indicated or guideline supported diagnoses</b> <ul style="list-style-type: none"><li>• Trial and failure of generic estradiol tablets and patches</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All FDA indications</b><ul style="list-style-type: none"><li>○ Initial: Lifetime</li></ul></li></ul>

Effective Date:	3/1/2024
P&T Approval Date:	1/9/2024
P&T Revision Date:	

# Conjugated estrogens and medroxyprogesterone acetate (Prempro/Premphase)

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## Products Affected

- Prempro
- Premphase

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<b>All FDA indicated or guideline supported diagnoses</b> <ul style="list-style-type: none"><li>• One of the following:<ul style="list-style-type: none"><li>○ Trial and failure of generic combination products</li><li>○ Estradiol tablets/patches used in combination with medroxyprogesterone capsules.</li></ul></li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All FDA indications:</b><ul style="list-style-type: none"><li>○ Initial: Lifetime</li></ul></li></ul>

Effective Date:	3/1/2024
P&T Approval Date:	1/9/2024
P&T Revision Date:	1/9/2024

# Continuous Glucose Monitors (CGM)

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## Products Affected

- Dexcom G6/G7
- Freestyle Libre 2/3

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Type 1 Diabetes Mellitus</li><li>○ Type 2 Diabetes</li><li>○ Gestational Diabetes</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Type 1 Diabetes Mellitus</b></p> <ul style="list-style-type: none"><li>• One of the following:<ul style="list-style-type: none"><li>○ Use of continuous insulin infusion via pump</li><li>○ Child or adolescent under the age of 21</li><li>○ Member is pregnant or plans to become pregnant within 6 months</li><li>○ Using short or intermediate acting insulin</li></ul></li><li>• The criteria listed under "applies to all requests" has been met.</li></ul> <p><b>Type 2 Diabetes Mellitus OR Gestational Diabetes</b></p> <ul style="list-style-type: none"><li>• Using short or intermediate acting insulin</li><li>• The criteria listed under "applies to all requests" has been met.</li></ul> <p><b>Applies to all requests</b></p> <ul style="list-style-type: none"><li>• Must meet at least one of the following:<ul style="list-style-type: none"><li>○ Baseline HbA1c levels greater than or equal to 8%</li><li>○ Frequent or severe hypoglycemia</li><li>○ Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM)</li><li>○ Diabetes related complications (e.g. peripheral neuropathy, end-organ damage, etc.)</li></ul></li><li>• Member has received or will receive diabetes education specific to the use of the CGM device.</li></ul> <p>** If the request is for a <b>Dexcom</b> one of the following criteria must apply:</p> <ul style="list-style-type: none"><li>• Use of an insulin pump compatible with the requested Dexcom and not Freestyle</li><li>• Pediatric member under the age of 16 years old</li><li>• Inability to use preferred Freestyle CGM device</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Use of CGM device for at least 50% of the time for a 90-day period by the time of first follow-up visit (within 3-6 months) and provider visits</li></ul>

	within the last 6 months. **Note: two trials per year of CGM are allowed to meet adherence for continuation of coverage.
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	6/1/2022
P&T Approval Date:	5/8/2022
P&T Revision Date:	5/8/2022

# Cyclosporine Oral

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## Products Affected

- Cyclosporine capsules
- Cyclosporine solution
- Cyclosporine Modified capsules

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Solid Organ Transplant</li><li>○ Rheumatoid Arthritis</li><li>○ Psoriasis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>All diagnoses</b> <ul style="list-style-type: none"><li>• Documentation of an FDA approved indication</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• <b>Liquid only:</b> Member is under age 10 or unable to use tablets/capsules.</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

## References

- Gengraf [package insert]. North Chicago, IL: Abbvie.; 2024.
- Sandimmune/Neoral [package insert]. East Hanover, NJ: Novartis.; 2020.

# Cyclosporine ophthalmic (Restasis)

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## Products Affected

- Cyclosporine 0.05% emulsion

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Dry eye syndrome or keratoconjunctivitis sicca for EPSDT members</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Dry Eye Syndrome or Keratoconjunctivitis Sicca for members under age 21</u></b></p> <ul style="list-style-type: none"><li>• Clinically documented trial and failure of both:<ul style="list-style-type: none"><li>○ Ocular lubricants in solution form</li><li>○ Ocular lubricants in ointment form.</li></ul></li><li>• Clinical documentation that topical and systemic contributors to dry eye disease have been discussed and either:<ul style="list-style-type: none"><li>○ Eliminated <b>or</b></li><li>○ Contributing agents are medically necessary.</li></ul></li></ul> <p><b><u>Dry Eye Syndrome or Keratoconjunctivitis Sicca for members age 21 or older</u></b></p> <ul style="list-style-type: none"><li>• Documented clinical evidence of a funded (above the line) comorbid condition for which the following applies:<ul style="list-style-type: none"><li>○ Clinical evidence shows that the funded treatments are not working or are contraindicated</li><li>○ Treating dry eye syndrome or keratoconjunctivitis sicca would significantly improve the outcome of treating the funded condition.</li></ul></li><li>• Clinically documented trial and failure of both:<ul style="list-style-type: none"><li>○ Ocular lubricants in solution form.</li><li>○ Ocular lubricants in ointment form.</li></ul></li><li>• Clinical documentation that topical and systemic contributors to dry eye disease have been discussed and either:<ul style="list-style-type: none"><li>○ Eliminated <b>or</b></li><li>○ Contributing agents are medically necessary.</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Clinical documentation of efficacy.</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 16 years of age or older.</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

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Effective Date:	7/1/2025
P&T Approval Date:	5/13/2025
P&T Revision Date:	5/13/2025

### References

- Dermatologic and Eyes, Ears, Nose, and Throat, and Immunologic Disorders: Presented by Jamie L. McConaha.
- <https://www.aao.org/education/preferred-practice-pattern/dry-eye-syndrome-ppp-2023>
- Restasis [package insert]. North Chicago, IL: Abbvie.; 2024.

# Deferasirox

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## Products Affected

- Deferasirox 125MG, 250MG, 500MG tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Chronic iron overload due to blood transfusion</li><li>○ Non-transfusion-dependent thalassemia syndromes</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Chronic iron overload due to blood transfusion</b></p> <ul style="list-style-type: none"><li>• One of the following:<ul style="list-style-type: none"><li>○ A creatinine clearance of greater than or equal to 40 mL/minute</li><li>○ Serum creatinine less than or equal to 2 times the age-appropriate level</li></ul></li><li>• Patient has a serum ferritin levels consistently greater than 1,000 mcg/L (as demonstrated with at least two lab values within the previous two months)</li><li>• Patient has had a failure or contraindication to deferoxamine injection</li></ul> <p><b>Non-transfusion-dependent thalassemia syndromes</b></p> <ul style="list-style-type: none"><li>• One of the following:<ul style="list-style-type: none"><li>○ A creatinine clearance of greater than or equal to 40 mL/minute</li><li>○ Serum creatinine less than or equal to 2 times the age-appropriate level</li></ul></li><li>• Patient has a serum ferritin levels consistently greater than 1,000 mcg/L (as demonstrated with at least two lab values within the previous two months)</li><li>• Patient has had a failure or contraindication to deferoxamine injection</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Patient is 2 years of age or older</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Both Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	



# Desmopressin

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## Products Affected

- Desmopressin Acetate Nasal Spray & Injections

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Diabetes Insipidus</li><li>○ Maintenance of hemostasis and control of bleeding in hemophilia A with factor VIII coagulant activity levels greater than 5%</li><li>○ Mild-to-moderate classic von Willebrand's disease (type 1) with factor VIII coagulant activity greater than 5%.</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>All diagnoses</u></b> <ul style="list-style-type: none"><li>• Documentation of one of the conditions listed under "covered uses"</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of positive clinical response to therapy.</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023

## References

- Stimate [package insert]. King of Prussia, PA: CSL Behring LLC.; 2015.

# Deutetrabenazine (Austedo)

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## Products Affected

- Austedo tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Chorea associated with Huntington's Disease</li><li>○ Tardive Dyskinesia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Chorea associated with Huntington's Disease</u></b></p> <ul style="list-style-type: none"><li>• Documentation of the degree of chorea present and the impact on functional ability and/or quality of life.</li><li>• Documentation of mental status, specifically depression and suicidality.</li></ul> <p><b><u>Tardive Dyskinesia</u></b></p> <ul style="list-style-type: none"><li>• Clinical documentation of tardive dyskinesia including:<ul style="list-style-type: none"><li>○ At least one month of past or current exposure to a dopamine receptor blocker</li><li>○ Dyskinetic or dystonic involuntary movements</li><li>○ Exclusion of other causes of abnormal movements</li></ul></li><li>• Clear documentation that tardive dyskinesia causes functional impairment</li><li>• Documentation of the degree of tardive dyskinesia with the AIMS scale as a baseline</li><li>• One of the following:<ul style="list-style-type: none"><li>○ Discontinuation of the medication precipitating TD</li><li>○ Documentation that the patient has tried and failed an 8-week trial of at least 2 other agents within the same therapeutic category at a clinically effective and maximally tolerated dose for the patient's primary neuropsychiatric diagnosis</li><li>○ Evidence the medications precipitating tardive dyskinesia are medically necessary</li></ul></li><li>• Trial and failure of both of the following:<ul style="list-style-type: none"><li>○ Clonazepam</li><li>○ Amantadine</li></ul></li></ul>
<b>Renewal Criteria</b>	<b>Huntington's Chorea</b>

	<ul style="list-style-type: none"> <li>• Clinical response such as improvement in chorea, ability to perform ADLs, reduction in falls, or increase in quality of life. AND</li> <li>• Documentation of continued monitoring of mental status specifically for depression and suicidality.</li> </ul> <p><b>Tardive Dyskinesia</b></p> <ul style="list-style-type: none"> <li>• Follow-up AIMS assessment showing improvement from Baseline AND</li> <li>• Documented improvement in functioning such as ability to perform ADLs, reduction in falls and increase in quality of life.</li> </ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"> <li>• Age 18 and older</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Huntington's Chorea:</b> Neurologist</li> <li>• <b>Tardive Dyskinesia:</b> Neurologist or Psychiatrist</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>All diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 3 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	7/1/2023
P&T Approval Date:	5/9/2023
P&T Revision Date:	5/9/2023

<b>References</b>
<ul style="list-style-type: none"> <li>• Austedo [package insert]. Parsippany, NJ: Teva Neuroscience, Inc.; 2025.</li> </ul>

# Dihydroergotamine Injection

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## Products Affected

- Dihydroergotamine Inj

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Acute treatment of migraine</li><li>○ Acute treatment of cluster headaches</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Acute treatment of migraine</u></b></p> <ul style="list-style-type: none"><li>• Diagnosis of migraine with or without aura</li><li>• Trial and failure of, or contraindication to 5-HT1B/1D agonist (triptans)</li></ul> <p><b><u>Acute treatment of cluster headaches</u></b></p> <ul style="list-style-type: none"><li>• Diagnosis of cluster headache</li><li>• Trial and failure of, or contraindication to 5-HT1B/1D agonist (triptans)</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	7/1/2023
P&T Approval Date:	
P&T Revision Date:	5/9/2023

## References

- Migranal [package insert]. Bridgewater, NJ: Bausch Health US, LLC; 2022.

# Dimethyl Fumarate

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## Products Affected

- Dimethyl Fumarate DR Capsules

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Multiple sclerosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Multiple Sclerosis</b> <ul style="list-style-type: none"><li>• Documented diagnosis of one of the following:<ul style="list-style-type: none"><li>○ A relapsing form of multiple sclerosis.</li><li>○ A secondary progressive form of multiple sclerosis.</li></ul></li><li>• Medication is intended for use as monotherapy.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Multiple sclerosis:</b> Neurologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Multiple sclerosis:</b><ul style="list-style-type: none"><li>○ Initial: lifetime</li></ul></li></ul>

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

## References

- Tecfidera [package insert]. Cambridge, MA: Biogen INC.; 2024.
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.
- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

# Disposable Insulin Pump (Omnipod)

## Products Affected

- Omnipod 5
- Omnipod Dash

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Insulin dependent diabetes mellitus</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Insulin Dependent Diabetes Mellitus – Pediatric</u></b></p> <ul style="list-style-type: none"><li>• Documentation of Type 1 Diabetes Mellitus or Diabetes with C-reactive protein levels indicating insulin dependence</li><li>• On intensive insulin therapy (&gt;3 daily insulin injections) requiring frequent self-adjustments for at least 6 months prior to initiation of the insulin pump</li><li>• Documentation self-testing of blood glucose at least 4 times per day during the previous 2 months</li><li>• Evidence of completion of a comprehensive diabetes education program in the last 12 months (member or caregiver/parent)</li></ul> <p><b><u>Insulin Dependent Diabetes Mellitus – Adult</u></b></p> <ul style="list-style-type: none"><li>• All of the above pediatric requirements AND</li><li>• Documentation of one of the following:<ul style="list-style-type: none"><li>○ HbA1c &gt;7%</li><li>○ History of recurring hypoglycemia</li><li>○ Wide fluctuations in blood glucose before mealtime</li><li>○ Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL</li><li>○ History of severe glycemic excursions</li></ul></li><li>• Inability to use a traditional (non-disposable) insulin pump</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Clinical documentation of positive clinical response to therapy, and an in-person visit with the prescribing provider within the last 6 months</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	3/1/2024
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P&T Approval Date:	1/9/2024
P&T Revision Date:	1/9/2024

References
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# Donepezil

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## Products Affected

- Donepezil 5mg tablets
- Donepezil 10mg tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Alzheimer's disease – dementia</li><li>○ Alzheimer's disease, prophylaxis – Impaired cognition</li><li>○ Multi-Infarct dementia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>All diagnoses</u></b> <ul style="list-style-type: none"><li>• Confirmed diagnosis of one of the above listed conditions</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	8/1/2013
P&T Approval Date:	4/5/2011
P&T Revision Date:	7/15/2013, 4/5/2011

## References

- Aricept [package insert]. Woodcliff Lake, NJ: Eisai Inc.; 2013.

# Dipeptidyl Peptidase 4 (DPP-4) Inhibitor Step Therapy

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## Products Affected

- Janumet
- Janumet XR
- Januvia
- Kombiglyze XR
- Onglyza
- Tradjenta

<b>Step Therapy Criteria</b>	<ul style="list-style-type: none"><li>• Clinical diagnosis of Type 2 Diabetes Mellitus (T2DM)</li><li>• Trial and failure of the following:<ul style="list-style-type: none"><li>○ Metformin</li><li>○ Sulfonylurea or insulin</li></ul></li></ul>
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Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

# Dronabinol

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## Products Affected

- Dronabinol capsules

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Nausea and vomiting associated with cancer chemotherapy (CINV)</li><li>○ AIDS anorexia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Nausea and Vomiting Associated with Cancer Chemotherapy</u></b></p> <ul style="list-style-type: none"><li>• Confirmation of treatment with chemotherapy</li><li>• Trial and failure or contraindication to all of the following:<ul style="list-style-type: none"><li>○ At least one 5HT-3 receptor antagonist (e.g. ondansetron, granisetron, etc.)</li><li>○ At least one of:<ul style="list-style-type: none"><li>▪ Prochlorperazine</li><li>▪ Dexamethasone</li><li>▪ Haloperidol</li><li>▪ Olanzapine</li></ul></li></ul></li></ul> <p><b><u>AIDS Anorexia</u></b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of anorexia with weight loss in patients with AIDS</li><li>• Patient is on antiretroviral therapy</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

## References

- Marinol [package insert]. North Chicago, IL: Abbvie; 2017.

# Dupilumab (Dupixent)

## Products Affected

- Dupixent Prefilled Syringe
- Dupixent Auto-Injector

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Moderate to Severe Asthma</li><li>○ Atopic Dermatitis</li><li>○ Eosinophilic Esophagitis</li><li>○ Chronic Rhinosinusitis with Nasal Polyps</li><li>○ Prurigo Nodularis</li><li>○ Chronic Obstructive Pulmonary Disease</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Moderate to Severe Asthma</u></b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of moderate to severe asthma</li><li>• Inadequate control of asthma symptoms despite fully maximized treatment with one of the following:<ul style="list-style-type: none"><li>○ Inhaled corticosteroids combined with long-acting beta-2 agonist</li><li>○ Inhaled corticosteroids combined with long-acting muscarinic antagonist</li></ul></li></ul> <p><b><u>Atopic Dermatitis</u></b></p> <ul style="list-style-type: none"><li>• Diagnosed with severe atopic dermatitis defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) <math>\geq 11</math> or Children's Dermatology Life Quality Index (CDLQI) <math>\geq 13</math> (or severe score on another validated tool)</li><li>• One or more of the following:<ul style="list-style-type: none"><li>○ At least 10% of body surface area involvement</li><li>○ Hand, foot, or mucous membrane involvement</li></ul></li><li>• Documented contraindication or failed trial to ALL of the following:<ul style="list-style-type: none"><li>○ Moderate-high potency corticosteroid (e.g., clobetasol, fluocinonide, fluticasone)</li><li>○ Topical calcineurin inhibitor (e.g. tacrolimus)</li><li>○ Oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil) <b>OR</b> the member is oral corticosteroid dependent.</li></ul></li></ul> <p><b><u>Eosinophilic Esophagitis</u></b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of Eosinophilic Esophagitis</li></ul>

- Weight  $\geq 15$  kg
- Two or more episodes of dysphagia per week
- Inadequate response to an 8-week trial, intolerance, or contraindication to high-dose PPI therapy
- Inadequate response to an 8-to-12-week trial, intolerance, or contraindication to swallowed inhaled respiratory corticosteroid therapy.

**Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**

- Diagnosis of CRSwNP, including objective evidence of the presence of bilateral nasal polyps
- Will not be used in combination with other biologics for eosinophilic indications.
- Trial and failure to adequately reduce symptoms with:
  - At least 2 months of saline nasal irrigations and inhaled nasal corticosteroids used at doses appropriate for nasal polyp treatment.
  - Systemic corticosteroid treatment for nasal polyps at least once within the last 2 years or prior nasal polyp removal surgery.
- Inhaled nasal corticosteroids will be used concomitantly with dupilumab (unless not tolerated or contraindicated).

**Prurigo Nodularis**

- Funded condition (as defined by guideline note 21 of the prioritized list) or age under 21.
- Diagnosis of PN verified by a dermatologist and the patient has had the diagnosis for at least 3 months.
- Severe or very severe itch (WI-NRS score  $\geq 7$ ) reported within the past week.
- At least 20 PN lesions in total on both legs and/or both arms and/or trunk
- Trial and failure (inadequate efficacy after 4-week trial, intolerable side effects) or contraindication to recommended first line agents for the treatment of PN including:
  - High potency topical steroids
  - Phototherapy
  - At least one systemic agent (immunosuppressant, gabapentinoid, or antidepressant).

**Chronic Obstructive Pulmonary Disease (COPD)**

- Diagnosis of COPD confirmed by post-bronchodilator FEV1/FVC  $< 0.7$  on spirometry.

	<ul style="list-style-type: none"> <li>• Blood eosinophil count (BEC) <math>\geq 300</math> cells/<math>\mu</math>L within the past 3 months.</li> <li>• Chronic bronchitis, defined as a chronic productive cough for <math>\geq 3</math> months in the past year, in the absence of other known causes of chronic cough.</li> <li>• <math>\geq 2</math> moderate COPD exacerbation (defined as requiring treatment with either systemic corticosteroids and/or antibiotics) or <math>\geq 1</math> severe COPD exacerbation (defined as requiring hospitalization or observation for over 24 hours in emergency department or urgent care) within the past year despite the adherent use of inhaled LABA + LAMA+ ICS triple therapy [or LABA + LAMA dual therapy if ICS are contraindicated].</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>• Documentation of positive clinical response to therapy</li> </ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Moderate to Severe Asthma:</b> 6 years and older</li> <li>• <b>Atopic Dermatitis:</b> 6 months and older</li> <li>• <b>Eosinophilic Esophagitis:</b> 1 years and older</li> <li>• <b>CRSwNP:</b> 12 years and older</li> <li>• <b>Prurigo Nodularis:</b> 18 years and older</li> <li>• <b>COPD:</b> 18 years and older</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Atopic dermatitis:</b> Dermatologist</li> <li>• <b>Eosinophilic Esophagitis:</b> Gastroenterologist or Immunologist</li> <li>• <b>CRSwNP:</b> ENT or Immunologist</li> <li>• <b>Prurigo Nodularis:</b> Dermatologist</li> <li>• <b>Asthma, COPD:</b> Pulmonologist</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>All Diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	3/1/2025
P&T Approval Date:	11/8/2022
P&T Revision Date:	1/14/2025, 1/9/2024, 11/8/2022

<b>References</b>
<ul style="list-style-type: none"> <li>• Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals Inc.; 2024.</li> </ul>

# Elagolix (Orilissa)

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## Products Affected

- Orilissa tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Moderate to Severe Pain Associated with Endometriosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Moderate to Severe Pain Associated with Endometriosis</b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of endometriosis with documentation of moderate to severe pain associated with the condition</li><li>• Trial and failure of, or contraindication to, both of the following:<ul style="list-style-type: none"><li>○ A 3-month trial of prescription strength NSAIDs</li><li>○ Two 3-month trials of hormonal therapies (e.g. combined oral contraceptives, progestins, or levonorgestrel IUD, etc.)</li></ul></li><li>• <b>Additional info required for 200mg twice daily dosing:</b><ul style="list-style-type: none"><li>○ Documentation of coexisting dyspareunia</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• <b>Renewal only allowed for 150mg dose</b></li><li>• Criteria requires documentation of:<ul style="list-style-type: none"><li>○ A positive clinical response to therapy</li><li>○ Total therapy duration is 24 months or less</li></ul></li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• At least 18 years of age or older but not yet through menopause</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b> Obstetrician or Gynecologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>150mg dose:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 18 months (maximum treatment duration of 24 months)</li></ul></li><li>• <b>200mg dose:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: no renewals allowed</li></ul></li></ul>

Effective Date:	2/1/2023
P&T Approval Date:	1/10/2023
P&T Revision Date:	1/10/2023

**References**

- Orilissa [package insert]. North Chicago, IL: Abbvie.; 2023.

# Elefibranor (Iqirvo)

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## Products Affected

- Iqirvo tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>Primary Biliary Cholangitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Primary Biliary Cholangitis</b></p> <ul style="list-style-type: none"><li>Diagnosis of primary biliary cholangitis (PBC) confirmed by two of the following:<ul style="list-style-type: none"><li>Biochemical evidence of cholestasis based on ALP elevation</li><li>Presence of AMA or other PBC-specific autoantibodies</li><li>Histology confirmation after biopsy</li></ul></li><li>Trial and failure of 12 months of ursodiol.</li><li>No current decompensated cirrhosis.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>Documented positive clinical response to therapy</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li><b>Primary Biliary Cholangitis:</b> Gastroenterologist or Hepatologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li><b>Primary Biliary Cholangitis:</b><ul style="list-style-type: none"><li>Initial: 6 months</li><li>Renewal: 12 months</li></ul></li></ul>

Effective Date:	11/1/2024
P&T Approval Date:	9/10/2024
P&T Revision Date:	9/10/2024

## References

- Iqirvo [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals Inc.; 2024.

# Elexacaftor-tezacaftor-ivacaftor (Trikafta)

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## Products Affected

- Trikafta

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.<ul style="list-style-type: none"><li>○ Cystic Fibrosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Cystic Fibrosis</b> <ul style="list-style-type: none"><li>• Documentation of cystic fibrosis diagnosis with at least one F508del mutation</li><li>• Not used in combination with other CFTR modulator treatments</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 2 years of age and older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Cystic Fibrosis:</b> Pulmonologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Cystic Fibrosis:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	05/01/2025
P&T Approval Date:	05/01/2021
P&T Revision Date:	09/01/2021, 03/11/2025

## References

- Trikafta [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; 2024.

# Eltrombopag (Promacta)

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## Products Affected

- Eltrombopag tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Aplastic Anemia, Severe</li><li>○ Chronic hepatitis C-associated thrombocytopenia</li><li>○ Immune thrombocytopenia (persistent or chronic)</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Immune Thrombocytopenia (ITP)</u></b></p> <ul style="list-style-type: none"><li>• Diagnosis of immune thrombocytopenia</li><li>• Member is not pregnant</li><li>• One of the following:<ul style="list-style-type: none"><li>○ Member is less than 18 years of age</li><li>○ Member is 18 years of age or older with persistent or chronic ITP (3+ months since diagnosis)</li></ul></li><li>• Documentation of one of the following:<ul style="list-style-type: none"><li>○ Platelet count less than 20,000/mcL (mm<sup>3</sup>)</li><li>○ Platelet count less than 30,000/mcL (mm<sup>3</sup>) with symptoms of bleeding</li></ul></li><li>• The member is considered steroid dependent or unresponsive to steroids</li><li>• One of the following:<ul style="list-style-type: none"><li>○ Member is less than 18 years of age</li><li>○ Member has tried and failed rituximab<ul style="list-style-type: none"><li>▪ History of splenectomy is allowed in place of rituximab but is not required if rituximab can't be used</li></ul></li></ul></li></ul> <p><b><u>Aplastic Anemia</u></b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of aplastic anemia</li><li>• Documentation of platelet count less than 30,000/mcL (mm<sup>3</sup>)</li><li>• One of the following:<ul style="list-style-type: none"><li>○ Trial and failure of the following immunosuppressive therapies:<ul style="list-style-type: none"><li>▪ Antithymocyte globulin (ATG)</li><li>▪ Cyclosporine</li></ul></li><li>○ Eltrombopag will be used as part of triple therapy with ATG and cyclosporine (Triple IST)</li></ul></li></ul>

<b>Renewal Criteria</b>	<p><u>Immune Thrombocytopenia</u></p> <ul style="list-style-type: none"> <li>Documentation shows maintenance platelet counts between 30,000/mcL and 100,000/mcL or a doubling of platelet counts from baseline with resolution of bleeding episodes</li> </ul> <p><u>Aplastic Anemia</u></p> <p>Documentation that hematologic response has occurred with treatment</p>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>Use in combination with another medication in the TPO-RA class or Travatisse</li> </ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"> <li>1 year of age and older</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li><b>Immune Thrombocytopenia:</b> Hematologist</li> <li><b>Aplastic Anemia:</b> Hematologist</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li><b>Immune Thrombocytopenia:</b> <ul style="list-style-type: none"> <li>Initial: 3 months</li> <li>Renewal: 3 months</li> </ul> </li> <li><b>Aplastic Anemia:</b> <ul style="list-style-type: none"> <li>Initial: 16 weeks</li> <li>Renewal: 6 months</li> </ul> </li> </ul>

Effective Date:	1/1/2026
P&T Approval Date:	11/11/2025
P&T Revision Date:	11/11/2025

<b>References</b>
<ul style="list-style-type: none"> <li>Neunert C. et al. American Society of Hematology 2019 Guidelines for immune thrombocytopenia. Blood Advances 10 December 2019;Vol 3 (23): 3829-3866.</li> <li>Neunert CE, et al. The 2022 review of the 2019 American Society of Hematology guidelines on immune thrombocytopenia. Blood Advances. 9 July 2024;Vol 8(13):3578-3582.</li> <li>Neunert C., et al. Management of Immune Thrombocytopenia (ITP): A pocket guide for the clinician. Based on the American Society of Hematology 2019 Guideline for Immune Thrombocytopenia. November 2019.</li> <li>Kulasekarraraj A. et al. Guidelines for the diagnosis and management of adult aplastic anaemia: A British Society of Haematology Guideline. B J Haematol. 2024;204:784-804.</li> </ul>

- Scheinberg P. and Kulasekararaj A. Consensus recommendations for severe aplastic anemia. *Blood advances*. 12 November 2024. Vol 8(21):5719-5720.
- ASH Draft Recommendations for Aplastic Anemia. 2025 American Society of Hematology.

# Endothelin Receptor Antagonists

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## Products Affected

- Ambrisentan tablets
- Bosentan tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Pulmonary Arterial Hypertension</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Pulmonary Arterial Hypertension</b> <ul style="list-style-type: none"><li>• Clinically documented diagnosis of Pulmonary Arterial Hypertension (WHO group 1 pulmonary hypertension)</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Ambrisentan: 18 years of age and over</li><li>• Bosentan: 3 years and up</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Pulmonary Arterial Hypertension:</b> Cardiologist or Pulmonologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Pulmonary Arterial Hypertension:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	9/1/2025
P&T Approval Date:	7/13/2021
P&T Revision Date:	7/8/2025, 7/13/2021

## References

- Tracleer [package insert]. Titusville, NJ: Actelion Pharmaceuticals Inc; 2024.
- Letairis [package insert]. Foster City, CA: Gilead Sciences Inc; 2025.

# Erythromycin Gel and Solution

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## Products Affected

- Erythromycin 2% gel
- Erythromycin 2% solution

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>All Diagnoses</u></b> <ul style="list-style-type: none"><li>• Documentation of trial and failure, intolerance, or contraindication to clindamycin 1% gel or solution</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	3/1/2023
P&T Approval Date:	1/10/2023
P&T Revision Date:	1/10/2023

## References

- Acne clinical guideline (aad.org)

# Erythropoietic Agents

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## Products Affected

- Retacrit

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Anemia Due to Chronic Kidney Disease (CKD)</li><li>○ Anemia Due to Chemotherapy</li><li>○ Anemia Associated with HIV Infection</li><li>○ Preoperative Use for Reduction of Allogeneic Blood Transfusion in Patients Undergoing Surgery</li><li>○ Anemia in Myelodysplastic Syndrome (MDS)</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Anemia Due to Chronic Kidney Disease (CKD)</u></b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of anemia with hematocrit less than 30% or hemoglobin less than 10g/dL within 30 days of request</li><li>• Verification of iron evaluation for adequate iron stores</li><li>• One of the following:<ul style="list-style-type: none"><li>○ Patient is on dialysis</li><li>○ Patient is not on dialysis, but the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal.</li></ul></li></ul> <p><b><u>Anemia Due to Chemotherapy</u></b></p> <ul style="list-style-type: none"><li>• Verification that other causes of anemia have been ruled out</li><li>• Verification of anemia with hematocrit less than 30% or hemoglobin less than 10g/dL within the prior 2 weeks</li><li>• Verification of iron evaluation for adequate iron stores</li><li>• Verification that the cancer is a non-myeloid malignancy</li><li>• Patient is receiving chemotherapy</li></ul> <p><b><u>Anemia Associated with HIV Infection</u></b></p> <ul style="list-style-type: none"><li>• Verification of anemia with hematocrit less than 36% or hemoglobin less than 12 g/dL within the prior 30 days</li><li>• Verification of iron evaluation for adequate iron stores</li><li>• Serum erythropoietin level less than or equal to 500 mU/mL</li><li>• One of the following:<ul style="list-style-type: none"><li>○ Patient is receiving zidovudine</li></ul></li></ul>

	<ul style="list-style-type: none"> <li>○ Diagnosis of HIV infection</li> </ul> <p><b><u>Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery</u></b></p> <ul style="list-style-type: none"> <li>● Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery</li> <li>● Hemoglobin (Hgb) is greater than 10 to less than or equal to 13 g/dL</li> <li>● Patient is at high risk for perioperative transfusions</li> <li>● Patient is unwilling or unable to donate autologous blood pre-operatively</li> <li>● Verification of iron evaluation for adequate iron stores</li> </ul> <p><b><u>Anemia in Myelodysplastic Syndrome (MDS)</u></b></p> <ul style="list-style-type: none"> <li>● Diagnosis of MDS</li> <li>● One of the following: <ul style="list-style-type: none"> <li>○ Serum erythropoietin level less than or equal to 500 mU/mL</li> <li>○ Diagnosis of transfusion-dependent MDS</li> </ul> </li> <li>● Verification of iron evaluation for adequate iron stores</li> </ul>
<b>Renewal Criteria</b>	<p><b>Anemia Due to CKD</b></p> <ul style="list-style-type: none"> <li>● There is a documented response to treatment</li> <li>● One of the following: <ul style="list-style-type: none"> <li>○ Patient is on dialysis and Hgb is 11g/dL or less</li> <li>○ Patient is NOT on dialysis and Hgb is 10g/dL or less</li> </ul> </li> </ul> <p><b>Anemia Due to Chemotherapy</b></p> <ul style="list-style-type: none"> <li>● There is a documented response to treatment as indicated by a decrease in the need to blood transfusion or Hgb increase from pre-treatment level</li> <li>● Documented Hct less than 30% or Hgb less than 10 g/dL</li> <li>● Patient is receiving chemotherapy</li> </ul> <p><b>Anemia Associated with HIV Infection</b></p> <ul style="list-style-type: none"> <li>● There is a documented response to treatment as indicated by a decrease in the need to blood transfusion or Hgb increase from pre-treatment level</li> <li>● Documented Hct less than 36% or Hgb less than 12 g/dL</li> </ul> <p><b>Anemia in Myelodysplastic Syndrome</b></p> <ul style="list-style-type: none"> <li>● There is a documented response to treatment as indicated by a decrease in the need to blood transfusion or Hgb increase from pre-treatment level</li> </ul>

	<ul style="list-style-type: none"> <li>Documented Hct less than 36% or Hgb less than 12 g/dL</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li><b>Anemia due to CKD:</b> <ul style="list-style-type: none"> <li>Initial: 3 months</li> <li>Renewal: 12 months</li> </ul> </li> <li><b>Anemia Due to Chemotherapy:</b> <ul style="list-style-type: none"> <li>Initial: 3 months</li> <li>Renewal: 3 months</li> </ul> </li> <li><b>Anemia Associated with HIV:</b> <ul style="list-style-type: none"> <li>Initial: 3 months</li> <li>Renewal: 12 months</li> </ul> </li> <li><b>Anemia in MDS:</b> <ul style="list-style-type: none"> <li>Initial: 3 months</li> <li>Renewal: 12 months</li> </ul> </li> <li><b>Preoperative:</b> <ul style="list-style-type: none"> <li>Initial: 1 months</li> <li>Renewal: N/A</li> </ul> </li> </ul>

Effective Date:	9/1/2024
P&T Approval Date:	7/9/2024
P&T Revision Date:	7/9/2024

<b>References</b>
<ul style="list-style-type: none"> <li>Oregon Health Authority. (2024). <i>Guideline Note GN7: Erythropoiesis-Stimulating Agent (ESA) Guideline</i>. Health Evidence Review Commission.</li> </ul>

# Estradiol Ring (Estring)

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## Products Affected

- Estring 2mg vaginal ring

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<b>All FDA approved diagnoses</b> <ul style="list-style-type: none"><li>• Trial and failure of estradiol vaginal cream and estradiol vaginal tablet</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	7/1/2023
P&T Approval Date:	5/9/2023
P&T Revision Date:	5/9/2023

## References

- Estring [package insert]. New York, NY: Pfizer; 2023.

# Etanercept (Enbrel)

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## Products Affected

- Enbrel Auto-Injector
- Enbrel Prefilled Syringe

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Ankylosing Spondylitis/Axial Spondyloarthritis</li><li>○ Plaque Psoriasis</li><li>○ Psoriatic Arthritis</li><li>○ Rheumatoid Arthritis</li><li>○ Ulcerative Colitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>All diagnoses</u></b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy.</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic or Otezla.</li></ul> <p><b><u>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:<ul style="list-style-type: none"><li>○ Back pain and stiffness for more than 3 months AND</li><li>○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND</li><li>○ BASDAI score of &gt;=4</li></ul></li><li>• One of the following:<ul style="list-style-type: none"><li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li><li>○ Documented failure of conventional therapy with both of the following:<ul style="list-style-type: none"><li>▪ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND</li><li>▪ Physical therapy/exercise program</li></ul></li></ul></li><li>• Trial and failure of both infliximab and adalimumab.</li></ul> <p><b><u>Plaque Psoriasis (PP):</u></b></p>

- Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:
  - At least 10% of body surface area involved
  - Hand, foot, face, or mucous membrane involvement
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of all the following:
    - High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)
    - At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)
    - PUVA or UVB Phototherapy
    - Methotrexate
    - At least 1 other second line systemic agent such as cyclosporine or acitretin.
- Trial and failure of both infliximab and adalimumab.

**Psoriatic Arthritis (PsA):**

- Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:
  - Psoriasis (1 point for personal or family history, 2 points for current)
  - Psoriatic nail dystrophy
  - Negative test result for RF
  - Dactylitis (current or history)
  - Radiological evidence of juxta-articular new bone formation
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of conventional therapy with both of the following:
    - NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
    - Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine.
- Trial and failure of both infliximab and adalimumab.

**Rheumatoid Arthritis (RA):**

	<ul style="list-style-type: none"> <li>Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)</li> <li>One of the following: <ul style="list-style-type: none"> <li>The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li> <li>Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine</li> </ul> </li> <li>Trial and failure of both infliximab and adalimumab.</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li><b>Ankylosing Spondylitis/Axial Spondyloarthritis:</b> Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.</li> <li><b>Plaque Psoriasis:</b> Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement.</li> <li><b>Psoriatic Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li><b>Rheumatoid Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li><b>Ankylosing Spondylitis, Axial Spondyloarthritis:</b> Rheumatologist.</li> <li><b>Plaque Psoriasis:</b> Dermatologist.</li> <li><b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist.</li> <li><b>Rheumatoid Arthritis:</b> Rheumatologist.</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li><b>All diagnoses:</b> <ul style="list-style-type: none"> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	11/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023

## References

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# Etrasimod arginine (Velsipity)

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## Products Affected

- Velsipity tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Ulcerative Colitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Ulcerative Colitis</u></b></p> <ul style="list-style-type: none"><li>• Documentation of moderate-to-severe ulcerative colitis</li><li>• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of at least 1 of the following:<ul style="list-style-type: none"><li>○ Mesalamine, sulfasalazine OR</li><li>○ Mercaptopurine, azathioprine, OR</li><li>○ Corticosteroids (prednisone, methylprednisolone)</li></ul></li><li>• Trial and failure of both infliximab and adalimumab</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 18 years of age or older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Ulcerative colitis:</b> Gastroenterologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Ulcerative colitis:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	3/1/2024
P&T Approval Date:	1/9/2024
P&T Revision Date:	1/9/2024

## References

- Velsipity [package insert]. New York, NY: Pfizer Inc.; 2024.

# Ferrous Sulfate

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## Products Affected

- Ferrous Sulfate 300mg/5mL

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>All Diagnoses</u></b> <ul style="list-style-type: none"><li>• Documentation of inability to use ferrous sulfate tabs or 200mg/5mL liquid</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: Lifetime</li></ul></li></ul>

Effective Date:	1/11/2024
P&T Approval Date:	11/14/2023
P&T Revision Date:	11/14/2023

# Fezolinetant (Veoza<sup>h</sup>)

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## Products Affected

- Veozah tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Vasomotor Symptoms Associated with Menopause</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Vasomotor Symptoms Associated with Menopause</u></b> <ul style="list-style-type: none"><li>• Diagnosis of moderate to severe vasomotor symptoms due to menopause.</li><li>• Documented contraindication, intolerance, or inadequate response to at least 2 hormonal therapies.</li><li>• Documented contraindication, intolerance, or inadequate response to two nonhormonal therapies (e.g., one SNRI and one SSRI).</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of at least 50% reduction in VMS from baseline.</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b> Gynecologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023

## References

- Veozah [package insert]. Northbrook, IL: Astellas Pharma US Inc.; 2023

# Fingolimod

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## Products Affected

- Fingolimod 0.5mg capsules

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Treatment of Multiple Sclerosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Multiple Sclerosis</b> <ul style="list-style-type: none"><li>• Documented diagnosis of one of the following:<ul style="list-style-type: none"><li>○ A relapsing form of multiple sclerosis.</li><li>○ A secondary progressive form of multiple sclerosis.</li></ul></li><li>• Medication is intended for use as monotherapy.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Positive clinical response to therapy</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Multiple Sclerosis:</b> Neurologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Multiple Sclerosis:</b><ul style="list-style-type: none"><li>○ Initial: lifetime</li></ul></li></ul>

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

## References

- Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Co.; 2023
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.
- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

# Fluorouracil, topical

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## Products Affected

- Fluorouracil 5% cream
- Fluorouracil 2% solution
- Fluorouracil 5% solution

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Superficial Basal Cell Carcinoma</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Basal Cell Carcinoma</b> <ul style="list-style-type: none"><li>• Documentation confirming a diagnosis of superficial basal cell carcinoma with multiple lesions and/or difficult to treat areas.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Basal Cell Carcinoma:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

## References

- Efudex [package insert]. Sugar Land, TX: Bausch Health Inc.; 2021

# Glatiramer

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## Products Affected

- Glatiramer 20mg/mL inj
- Glatiramer 40mg/mL inj

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Treatment of Multiple Sclerosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Multiple Sclerosis</u></b> <ul style="list-style-type: none"><li>• Documented diagnosis of one of the following:<ul style="list-style-type: none"><li>○ A relapsing form of multiple sclerosis.</li><li>○ A secondary progressive form of multiple sclerosis.</li></ul></li><li>• Medication is intended for use as monotherapy.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Positive clinical response to therapy</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Multiple Sclerosis:</b> Neurologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Multiple Sclerosis:</b><ul style="list-style-type: none"><li>○ Initial: lifetime</li></ul></li></ul>

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

## References

- Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; 2023
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.
- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

# Glucagon-Like Peptide-1 (GLP1) Receptor Agonist

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## Products Affected

- Trulicity Auto-Injector
- Liraglutide Pen-Injector

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Type 2 Diabetes</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Type 2 Diabetes</b></p> <ul style="list-style-type: none"><li>• Documentation of clinically diagnosed Type 2 Diabetes</li><li>• Documentation of adequate trial of maximally tolerated dose of metformin</li><li>• Documentation of trial and failure of one of the following (or contraindication to both):<ul style="list-style-type: none"><li>○ An SGLT-2 inhibitor (e.g. Farxiga, Jardiance, etc.)</li><li>○ A DPP-4 inhibitor (e.g. saxagliptin, Tradjenta, Januvia, etc.)</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy such as a decrease in A1c</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Type 2 Diabetes:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

<b>References</b>
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# Golimumab (Simponi)

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## Products Affected

- Simponi Auto-Injector
- Simponi Prefilled Syringe

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Ankylosing Spondylitis/Axial Spondyloarthritis</li><li>○ Psoriatic Arthritis</li><li>○ Rheumatoid Arthritis</li><li>○ Ulcerative Colitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>All diagnoses</u></b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy.</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic or Otezla.</li></ul> <p><b><u>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:<ul style="list-style-type: none"><li>○ Back pain and stiffness for more than 3 months AND</li><li>○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND</li><li>○ BASDAI score of &gt;=4</li></ul></li><li>• One of the following:<ul style="list-style-type: none"><li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li><li>○ Documented failure of conventional therapy with both of the following:<ul style="list-style-type: none"><li>▪ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND</li><li>▪ Physical therapy/exercise program</li></ul></li></ul></li><li>• Trial and failure of both infliximab and adalimumab.</li></ul> <p><b><u>Psoriatic Arthritis (PsA):</u></b></p>

- Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:
  - Psoriasis (1 point for personal or family history, 2 points for current)
  - Psoriatic nail dystrophy
  - Negative test result for RF
  - Dactylitis (current or history)
  - Radiological evidence of juxta-articular new bone formation
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of conventional therapy with both of the following:
    - NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
    - Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine.
- Trial and failure of both infliximab and adalimumab.

**Rheumatoid Arthritis (RA):**

- Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine
- Trial and failure of both infliximab and adalimumab.

**Ulcerative Colitis (UC):**

- Documentation of moderate-to-severe ulcerative colitis
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of at least 1 of the following: mesalamine, sulfasalazine, mercaptopurine, azathioprine, or corticosteroids (prednisone, methylprednisolone).
- Trial and failure of both infliximab and adalimumab.

<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>• <b>Ankylosing Spondylitis/Axial Spondyloarthritis:</b> Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.</li> <li>• <b>Psoriatic Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>• <b>Rheumatoid Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>• <b>Ulcerative Colitis:</b> Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Ankylosing Spondylitis, Axial Spondyloarthritis:</b> Rheumatologist.</li> <li>• <b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist.</li> <li>• <b>Rheumatoid Arthritis:</b> Rheumatologist.</li> <li>• <b>Ulcerative Colitis:</b> Gastroenterologist.</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>All diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	11/01/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023

<b>References</b>
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# Gonadotropin-Releasing Hormone Agonists

## Products Affected

- Lupron

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Endometriosis</li><li>○ Uterine Leiomyomata (Fibroids) – For the reduction of the size of fibroids</li><li>○ Uterine Leiomyomata (Fibroids) – Anemia</li><li>○ Central Precocious Puberty (CPP)</li><li>○ Prostate Cancer</li><li>○ Gender Dysphoria/Gender Incongruence</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Endometriosis</u></b></p> <ul style="list-style-type: none"><li>• One of the following:<ul style="list-style-type: none"><li>○ History of inadequate pain control response following and trial of at least 6 months or history of intolerance or contraindication to one of the following:<ul style="list-style-type: none"><li>▪ Danazol</li><li>▪ Combination (estrogen/progestin) oral contraceptive</li><li>▪ Progestins</li></ul></li><li>○ Patient has had surgical ablation to prevent recurrence</li></ul></li></ul> <p><b><u>Uterine Leiomyomata (Fibroids) – For the reduction of the size of fibroids</u></b></p> <ul style="list-style-type: none"><li>• For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy)</li></ul> <p><b><u>Uterine Leiomyomata (Fibroids) – Anemia</u></b></p> <ul style="list-style-type: none"><li>• Anemia is caused by uterine leiomyomata (fibroids)</li><li>• Patient has tried and had an inadequate response to at least 1 month of monotherapy with iron</li><li>• Used in combination with iron therapy</li><li>• For use prior to surgery</li></ul> <p><b><u>Central Precocious Puberty (CPP)</u></b></p> <ul style="list-style-type: none"><li>• Diagnosis of central precocious puberty (idiopathic or neurogenic)</li><li>• Early onset of secondary sexual characteristics in one of the following:<ul style="list-style-type: none"><li>○ Females less than 8 years of age</li></ul></li></ul>

	<ul style="list-style-type: none"> <li>○ Males less than 9 years of age</li> <li>● Advanced bone age of at least one year compared with chronological age</li> <li>● One of the following: <ul style="list-style-type: none"> <li>○ Patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing and peak luteinizing hormone (LH) level above pre-pubertal range</li> <li>○ Patient has a random LH level in the pubertal range</li> </ul> </li> <li>● One of the following: <ul style="list-style-type: none"> <li>○ Patient had one of the following diagnostic evaluations to rule out tumors, when suspected: <ul style="list-style-type: none"> <li>■ Diagnostic imaging of the brain (MRI or CT scan) (in patients with symptoms suggestive of a brain tumor or in those 6 years of age or younger)</li> <li>■ Pelvic/testicular/adrenal ultrasound (if steroid levels suggest suspicion)</li> <li>■ Adrenal steroids to rule out congenital adrenal hyperplasia (when pubarche precedes thelarche or gonadarche)</li> </ul> </li> <li>○ Patient has no suspected tumors</li> </ul> </li> </ul> <p><b><u>Prostate Cancer</u></b></p> <ul style="list-style-type: none"> <li>● Diagnosis of advanced or metastatic prostate cancer</li> </ul> <p><b><u>Gender Dysphoria/Gender Incongruence</u></b></p> <ul style="list-style-type: none"> <li>● Using gonadotropin for suppression of puberty</li> <li>● Diagnosis of gender dysphoria/gender incongruence</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>● <b>Endometriosis:</b> Recurrence of symptoms following a trial of at least 6 months with leuprolide acetate AND used in combination with one of the following: Norethindrone 5mg daily, other "add-back" sex-hormones (e.g. estrogen, medroxyprogesterone), other bone-sparing agents (e.g., bisphosphonates).</li> <li>● <b>Central Precocious Puberty (CPP):</b> LH levels have been suppressed to pre-pubertal levels.</li> <li>● <b>Prostate Cancer:</b> Patient does not show evidence of progressive disease while on therapy.</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>● <b>Central Precocious Puberty (CPP):</b> Pediatric endocrinologist</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>● <b>Endometriosis:</b> <ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: up to 6 months</li> </ul> </li> </ul>

	<ul style="list-style-type: none"><li>● <b>Uterine Leiomyomata (Fibroids Reduction):</b><ul style="list-style-type: none"><li>○ Initial: 4 months</li></ul></li><li>● <b>Uterine Leiomyomata (Fibroids Anemia):</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li></ul></li><li>● <b>Central Precocious Puberty (CPP):</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: up to 12 months</li></ul></li><li>● <b>Prostate Cancer:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: up to 12 months</li></ul></li><li>● <b>Gender Dysphoria:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li></ul></li></ul>
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Effective Date:	7/1/2024
P&T Approval Date:	5/14/2024
P&T Revision Date:	5/14/2024, 1/10/2023

References
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# Grass Pollen Allergen Extract -Timothy Grass (Grastek)

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## Products Affected

- Grastek

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Grass pollen-induced allergic rhinitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Grass Pollen-Induced Allergic Rhinitis</u></b> <ul style="list-style-type: none"><li>• Confirmed diagnosis of grass pollen induced allergic rhinitis</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Grass Pollen-Induced Allergic Rhinitis:</b> Allergist or Immunologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Grass Pollen-Induced Allergic Rhinitis:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal: 3 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

## References

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# Hepatitis C Antivirals

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## Products Affected

- Mavyret
- Vosevi
- Sofosbuvir-Velpatasvir

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Treatment of Hepatitis C Infection</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Hepatitis C Infection</u></b></p> <p><b>*PA for Mavyret and Sofosbuvir-Velpatasvir is only required if there is a history of prior treatment (treatment experienced). Vosevi requires PA in all cases. *</b></p> <ul style="list-style-type: none"><li>• All appropriate pre-treatment testing has been done:<ul style="list-style-type: none"><li>○ Genotype testing in the past 3 years is required if the patient has decompensated cirrhosis, prior treatment experience with DAA regimen, and if prescribed a regimen which is not pan-genotypic</li><li>○ History of previous HCV treatment, viral load after treatment, and outcome are required only if there is documentation of treatment experience</li></ul></li><li>• Documentation of prior treatment history</li><li>• Documentation of whether the patient achieved a sustained virological response (SVR) at week 12 or longer following the completion of their last DAA regimen</li><li>• Documentation if this is likely a reinfection, indicated by at least one of the following:<ul style="list-style-type: none"><li>○ Does the patient have ongoing risk factors for hepatitis C reinfection (e.g. sexually active men who have sex with men, persons who inject drugs)</li><li>○ Is the hepatitis C infection due a different genotype than previous</li></ul></li><li>• If the request is for elbasvir/grazoprevir for GT 1a, ledipasvir/sofosbuvir for GT 1a treatment experienced or sofosbuvir for GT 3 with cirrhosis or treatment experience has the patient had a baseline NS5a resistance test. (Note: baseline NS5A resistance testing is required per OHA in this situation)</li><li>• The prescribed drug regimen a recommended regimen based on the patient's genotype, age, treatment status (retreatment or treatment naïve) and cirrhosis status (see table 1 and 2)?</li></ul>

*\*Per OHA: treatment experienced are patients who received more than 4 weeks of HCV DAA therapy.*

**Table 1. Recommended Regimens for Adults and adolescents 12 years of age and older**

Treatment History	Cirrhosis Status	Recommended Regimen
<b>Treatment Naïve (Genotype 1-6)</b>		
Treatment naïve	Non-cirrhotic	SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	G/P x 8 weeks SOF/VEL x 12 weeks (baseline resistance testing recommended for GT3)
	Decompensated cirrhosis	SOF/VEL + RBV x 12 weeks SOF/VEL x 24 weeks (if RBV ineligible)
<b>Treatment Experienced (Genotype 1-6)</b>		
<u>Sofobuvir based regimen treatment failures, including:</u> sofosbuvir + ribavirin Ledipasvir/Sofobuvir Velpatasvir/sofobuvir	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks G/P x16 weeks (except GT3)
Elbasvir/grazoprevir treatment failures	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks
Glecaprevir/pibrentasvir treatment failures	Non-cirrhotic or compensated cirrhosis	G/P + SOF + RBV x 16 weeks SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis)
<u>Multiple DAA Treatment Failures, including:</u> Sofobuvir/velpatasvir/voxilaprevir Glecaprevir/pibrentasvir + sofobuvir	Non-Cirrhotic or compensated cirrhosis	G/P + SOF + RBV x 16-24 weeks SOF/VEL/VOX x24 weeks

**Table 2. Recommended Regimens for children 3-12 years of age**

Treatment History	Cirrhosis Status	Recommended Regimen
<b>Treatment Naïve (Genotype 1-6)</b>		
Treatment Naive	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 8 weeks
	Decompensated cirrhosis	SOF/VEL + RBV x 12 weeks

Abbreviations: DAA = direct acting antiviral; EBV/GZR = elbasvir/grazoprevir; G/P = glecaprevir and pibrentasvir; PEG = pegylated interferon; RBV = ribavirin; SOF = sofosbuvir; SOF/VEL = sofosbuvir/velpatasvir; SOF/VEL/VOX = sofosbuvir/velpatasvir/voxilaprevir

There is limited data supporting DAA regimens in treatment-experienced patients with decompensated cirrhosis. These patients should be handled on a case by case basis with the patient, prescriber, and CCO or FFS medical director

Ribavirin ineligible/intolerance may include: 1) neutrophils < 750 mm<sup>3</sup>, 2) hemoglobin < 10 g/dl, 3) platelets < 50,000 cells/mm<sup>3</sup>, autoimmune hepatitis or other autoimmune condition, hypersensitivity or allergy to ribavirin

<b>Coverage Duration</b>	<ul style="list-style-type: none"><li><b>Hepatitis C Infection:</b><ul style="list-style-type: none"><li>Initial: 8-24 weeks. Duration of approval depends on the specifics of the infection.</li></ul></li></ul>
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P&T Approval Date:	11/8/2022
P&T Revision Date:	11/8/2022

**References**

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# Inclisiran (Leqvio)

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## Products Affected

- Leqvio Prefilled Syringe

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>Established clinical ASCVD</li><li>Primary or Familial Hyperlipidemia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Established Clinical ASCVD</u></b></p> <ul style="list-style-type: none"><li>Documentation of very high risk ASCVD as evidenced by either:<ul style="list-style-type: none"><li>History of multiple major ASCVD events <b>OR</b></li><li>One major ASCVD event AND multiple high-risk conditions.</li></ul></li><li>Documentation of a current LDL greater than or equal to 55 mg/dl.</li><li>Documentation of all the following:<ul style="list-style-type: none"><li>Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins</li><li>Is receiving ezetimibe or has a documented intolerance to ezetimibe.</li></ul></li><li>Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).</li></ul> <p><b><u>Primary or Familial Hyperlipidemia</u></b></p> <ul style="list-style-type: none"><li>Documentation of an untreated (i.e., prior to lipid lowering therapy) LDL greater than 190 mg/dL.</li><li>Documentation of current LDL greater than 100 mg/dL.</li><li>Documentation of all the following:<ul style="list-style-type: none"><li>Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins</li><li>Is receiving ezetimibe or has a documented intolerance to ezetimibe.</li></ul></li><li>Documentation of failure of PCSK9 inhibitor (Repatha or Praluent).</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>Documented positive clinical response to therapy (significant decrease in lipid levels).</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li><b>All Diagnoses:</b> Cardiologist, Endocrinologist, or Lipid Specialist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li><b>All Diagnoses:</b></li></ul>

	<ul style="list-style-type: none"><li><input type="radio"/> Initial: 6 months</li><li><input type="radio"/> Renewal: 12 months</li></ul>
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Effective Date:	11/1/2024
P&T Approval Date:	9/10/2024
P&T Revision Date:	9/10/2024

References
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# Insulin Degludec

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## Products Affected

- Insulin Degludec FlexTouch 100 unit/mL
- Insulin Degludec FlexTouch 200 unit/mL

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Type 1 Diabetes</li><li>○ Type 2 Diabetes</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>All Diagnoses</b> <ul style="list-style-type: none"><li>• Trial and failure of Insulin Glargine or documented intolerance or contraindication to Insulin Glargine</li><li>• Documentation of significant barriers to standardized administration requiring flexibility in dose timing</li><li>• For U-200 concentration only:<ul style="list-style-type: none"><li>○ Insulin requirements of greater than 160 units of insulin per dose</li><li>○ Difficulty with multiple daily injections</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Renewal criteria</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

<b>References</b>
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# Insulin U-500 (Humulin R U-500)

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## Products Affected

- Humulin R U-500 Pens
- Humulin R U-500 Vials

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Type 1 Diabetes</li><li>○ Type 2 Diabetes</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>All Diagnoses</u></b> <ul style="list-style-type: none"><li>• Attestation that the use of U-500 insulin is medically safe and appropriate</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: Lifetime</li></ul></li></ul>

Effective Date:	3/1/2025
P&T Approval Date:	1/14/2025
P&T Revision Date:	1/14/2025

## References

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# Interferon beta-1a (Avonex)

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## Products Affected

- Avonex Pen
- Avonex prefilled syringe

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Treatment of Multiple Sclerosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Multiple Sclerosis</b></p> <ul style="list-style-type: none"><li>• Documented diagnosis of one of the following:<ul style="list-style-type: none"><li>○ A relapsing form of multiple sclerosis.</li><li>○ A secondary progressive form of multiple sclerosis.</li></ul></li><li>• Medication is intended for use as monotherapy.</li><li>• Trial and failure of all the following:<ul style="list-style-type: none"><li>○ Dimethyl fumarate</li><li>○ Fingolimod</li><li>○ Glatiramer</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Multiple Sclerosis:</b> Neurologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Multiple Sclerosis:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

## References

- Avonex [package insert]. Cambridge, MA: Biogen; 2023
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice

Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.

- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

# Interferon beta-1a (Rebif)

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## Products Affected

- Rebif Inj.
- Rebif Rebido

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Treatment of Multiple Sclerosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Multiple Sclerosis</b></p> <ul style="list-style-type: none"><li>• Documented diagnosis of one of the following:<ul style="list-style-type: none"><li>○ A relapsing form of multiple sclerosis.</li><li>○ A secondary progressive form of multiple sclerosis.</li></ul></li><li>• Medication is intended for use as monotherapy.</li><li>• Trial and failure of all the following:<ul style="list-style-type: none"><li>○ Dimethyl fumarate</li><li>○ Fingolimod</li><li>○ Glatiramer</li><li>○ Avonex</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Multiple Sclerosis:</b> Neurologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Multiple Sclerosis:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

## References

- Rebif [package insert]. Rockland, MA: EMD Serono Inc.; 2023
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice

Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.

- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

# Interferon beta-1b (Betaseron)

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## Products Affected

- Betaseron Inj.

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Treatment of Multiple Sclerosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Multiple Sclerosis</b></p> <ul style="list-style-type: none"><li>• Documented diagnosis of one of the following:<ul style="list-style-type: none"><li>○ A relapsing form of multiple sclerosis.</li><li>○ A secondary progressive form of multiple sclerosis.</li></ul></li><li>• Medication is intended for use as monotherapy.</li><li>• Trial and failure of all the following:<ul style="list-style-type: none"><li>○ Dimethyl fumarate</li><li>○ Fingolimod</li><li>○ Glatiramer</li><li>○ Avonex</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Multiple Sclerosis:</b> Neurologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Multiple Sclerosis:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	11/1/2025
P&T Approval Date:	1/10/2023
P&T Revision Date:	9/9/2025, 1/10/2023

## References

- Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2021
- Practice guideline: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Approved by the Guideline Development, Dissemination, and Implementation Subcommittee on October 9, 2017; by the Practice

Committee on October 21, 2017; and by the AAN Institute Board of Directors on March 6, 2018.

- The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A consensus Paper by the Multiple Sclerosis Coalition. Updated June 2019.

# Isotretinoin

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## Products Affected

- Amnesteem capsules
- Isotretinoin capsules
- Myorisan capsules
- Claravis capsules
- Zenetane capsules

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Severe nodulocystic acne</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Severe Nodulocystic Acne</b> <ul style="list-style-type: none"><li>• Confirmed diagnosis of severe nodulocystic acne</li><li>• Documentation of trial and failure, intolerance, or contraindication to combined therapy with an oral antibiotic and topical therapy (benzoyl peroxide or retinoid)</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• No Renewals</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 12 years and older</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Severe Nodulocystic Acne:</b><ul style="list-style-type: none"><li>○ Initial: 20 weeks</li><li>○ Renewal: No Renewals</li></ul></li></ul>

Effective Date:	2/1/2023
P&T Approval Date:	1/10/2023
P&T Revision Date:	1/10/2023

# Itraconazole

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## Products Affected

- Itraconazole Oral Solution

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>Tinea Unguium</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Tinea Unguium</b></p> <ul style="list-style-type: none"><li>Documentation of one of the following:<ul style="list-style-type: none"><li>Patient is experiencing pain which limits normal activity (i.e, unable to wear shoes, difficulty walking, etc),</li><li>Patient has diabetes,</li><li>Patient has peripheral vascular disease,</li><li>Patient is immunocompromised</li></ul></li></ul>
	<p><b>All Other Diagnoses</b></p> <ul style="list-style-type: none"><li>Diagnosis is supported by compendia and is an above the line condition</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li><b>All Diagnoses:</b><ul style="list-style-type: none"><li>Initial: 3 months</li><li>Renewal: 3 months</li></ul></li></ul>

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

## References

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# Ivacaftor (Kalydeco)

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## Products Affected

- Kalydeco Tablets
- Kalydeco Packets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.<ul style="list-style-type: none"><li>○ Cystic Fibrosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Cystic Fibrosis</u></b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of cystic fibrosis with documentation showing at least one CFTR gene mutation that has shown to be responsive to Kalydeco</li><li>• Not used in combination with other CFTR modulator treatments</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 1 month of age and older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Cystic Fibrosis:</b> Pulmonologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Cystic Fibrosis:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal: 6 months</li></ul></li></ul>

Effective Date:	05/01/2025
P&T Approval Date:	05/01/2021
P&T Revision Date:	09/01/2021, 03/11/2025

## References

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# Ivermectin

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## Products Affected

- Ivermectin Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>All Diagnoses</u></b> <ul style="list-style-type: none"><li>• Clinical documentation of a diagnosis for which ivermectin is FDA approved or compendia supported</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented reinfection</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 6 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

## References

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# Ixekizumab (Taltz)

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## Products Affected

- Taltz Auto-Injector
- Taltz Prefilled Syringe

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Ankylosing Spondylitis/Axial Spondyloarthritis</li><li>○ Plaque Psoriasis</li><li>○ Psoriatic Arthritis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>All diagnoses:</b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy.</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic or Otezla</li></ul> <p><b>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</b></p> <ul style="list-style-type: none"><li>• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:<ul style="list-style-type: none"><li>○ Back pain and stiffness for more than 3 months AND</li><li>○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND</li><li>○ BASDAI score of &gt;=4</li></ul></li><li>• One of the following:<ul style="list-style-type: none"><li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li><li>○ Documented failure of conventional therapy with both of the following:<ul style="list-style-type: none"><li>▪ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND</li><li>▪ Physical therapy/exercise program</li></ul></li></ul></li><li>• Trial and failure of infliximab and adalimumab</li></ul> <p><b>Plaque Psoriasis (PP):</b></p> <ul style="list-style-type: none"><li>• Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index</li></ul>

	<p>(DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:</p> <ul style="list-style-type: none"> <li>○ At least 10% of body surface area involved</li> <li>○ Hand, foot, face, or mucous membrane involvement</li> <li>● One of the following: <ul style="list-style-type: none"> <li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li> <li>○ Documented trial and failure of all the following: <ul style="list-style-type: none"> <li>■ High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)</li> <li>■ At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)</li> <li>■ PUVA or UVB Phototherapy</li> <li>■ Methotrexate</li> <li>■ At least 1 other second line systemic agent such as cyclosporine or acitretin.</li> </ul> </li> <li>● Trial and failure of infliximab and adalimumab</li> </ul> </li> </ul> <p><b><u>Psoriatic Arthritis (PsA):</u></b></p> <ul style="list-style-type: none"> <li>● Documentation of psoriatic arthritis based on at least 3 out of 5 of the following: <ul style="list-style-type: none"> <li>○ Psoriasis (1 point for personal or family history, 2 points for current)</li> <li>○ Psoriatic nail dystrophy</li> <li>○ Negative test result for RF</li> <li>○ Dactylitis (current or history)</li> <li>○ Radiological evidence of juxta-articular new bone formation</li> </ul> </li> <li>● One of the following: <ul style="list-style-type: none"> <li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li> <li>○ Documented trial and failure of conventional therapy with both of the following: <ul style="list-style-type: none"> <li>■ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>■ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine.</li> </ul> </li> <li>● Trial and failure of infliximab and adalimumab</li> </ul> </li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>● <b>Ankylosing Spondylitis/Axial Spondyloarthritis:</b> Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI</li> </ul>

	<ul style="list-style-type: none"> <li>• <b>Plaque Psoriasis:</b> Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement.</li> <li>• <b>Psoriatic Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Ankylosing Spondylitis, Axial Spondyloarthritis:</b> Rheumatologist.</li> <li>• <b>Plaque Psoriasis:</b> Dermatologist.</li> <li>• <b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist.</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>Hidradenitis Suppurativa and Plaque Psoriasis:</b> Dermatologist.</li> <li>• <b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist.</li> <li>• <b>Rheumatoid Arthritis, Juvenile Idiopathic Arthritis:</b> Rheumatologist.</li> <li>• <b>Ankylosing Spondylitis, Axial Spondyloarthritis:</b> Rheumatologist.</li> </ul>

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023

<b>References</b>
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# Lacosamide (Vimpat)

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## Products Affected

- Lacosamide Solution

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Focal Seizures</li><li>○ Primary Generalized Tonic-Clonic Seizures</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Focal Seizures</u></b></p> <ul style="list-style-type: none"><li>• Member under age 10 or unable to use tablets</li></ul> <p><b><u>Primary Generalized Tonic-Clonic Seizures</u></b></p> <ul style="list-style-type: none"><li>• Member under age 10 or unable to use tablets</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of positive clinical response to therapy and continued inability to use tablets</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: Lifetime</li></ul></li></ul>

Effective Date:	01/01/2026
P&T Approval Date:	07/11/2023
P&T Revision Date:	11/11/2025, 03/11/2025, 03/12/2024

## References

- Vimpat [package insert]. Smyrna, GA: UCB Inc.; 2023.

# Lanthanum Carbonate

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## Products Affected

- Lanthanum Carbonate Chew Tabs

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Hyperphosphatemia in Chronic Kidney Disease</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Hyperphosphatemia in Chronic Kidney Disease</b> <ul style="list-style-type: none"><li>• Confirmed diagnosis of hyperphosphatemia in chronic kidney disease</li><li>• Trial and failure, contraindication, or intolerance (at least 6 weeks) to both of the following at maximally tolerated doses<ul style="list-style-type: none"><li>○ Calcium acetate</li><li>○ Sevelamer carbonate</li></ul></li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 6 years of age or older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Hyperphosphatemia in CKD:</b> Nephrologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Hyperphosphatemia in CKD:</b><ul style="list-style-type: none"><li>○ Initial: Lifetime</li></ul></li></ul>

Effective Date:	7/1/2023
P&T Approval Date:	5/9/2023
P&T Revision Date:	5/9/2023

## References

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# Lasmiditan (Reyvow)

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## Products Affected

- Reyvow tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>Treatment of acute migraine</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Acute Migraine</b></p> <ul style="list-style-type: none"><li>Confirmed diagnosis of migraine</li><li>Documentation showing the member is currently on preventative therapy</li><li>Trial and failure (defined as at least 6 weeks per agent) of:<ul style="list-style-type: none"><li>At least 3 oral formulary triptans used at up to the maximally indicated dosing and in combination with NSAID therapy (e.g. naproxen).</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>Documented positive clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>18 years of age or older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li><b>Acute Migraine:</b> Neurologist or headache specialist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li><b>Acute Migraine:</b><ul style="list-style-type: none"><li>Initial: 3 months</li><li>Renewal: 12 months</li></ul></li></ul>

Effective Date:	9/1/2025
P&T Approval Date:	5/9/2023
P&T Revision Date:	7/8/2025, 5/9/2023

## References

- Reyvow [package insert]. Indianapolis, IN: Eli Lilly and Co; 2022.

# Lebrikizumab (Ebglyss)

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## Products Affected

- Ebglyss Prefilled Syringe
- Ebglyss Auto-Injector

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Atopic Dermatitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Atopic Dermatitis</b></p> <ul style="list-style-type: none"><li>• Diagnosed with severe atopic dermatitis defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) <math>\geq 11</math> or Children's Dermatology Life Quality Index (CDLQI) <math>\geq 13</math> (or severe score on another validated tool)</li><li>• One or more of the following:<ul style="list-style-type: none"><li>○ At least 10% of body surface area involvement</li><li>○ Hand, foot, or mucous membrane involvement</li></ul></li><li>• Documented contraindication or failed trial to ALL of the following:<ul style="list-style-type: none"><li>○ Moderate-high potency corticosteroid (e.g., clobetasol, fluocinonide, fluticasone)</li><li>○ Topical calcineurin inhibitor (e.g. tacrolimus)</li><li>○ Oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil) <b>OR</b> the member is oral corticosteroid dependent.</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of positive clinical response to therapy</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Atopic dermatitis:</b> Dermatologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	1/1/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

**References**

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# Lenacapavir (Sunlenca)

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## Products Affected

- Sunlenca Therapy Pack
- Sunlenca Subcutaneous

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Multi-Drug-Resistant (MDR) HIV</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Multi-Drug-Resistant HIV</b> <ul style="list-style-type: none"><li>• Diagnosis of MDR HIV-1 infection with resistance to at least two drugs in each of at least three of the following classes: NRTIs, NNRTIs, PIs, and INSTIs</li><li>• Will be used in combination with an optimized baseline regimen (OBR)</li><li>• Current ARV regimen has been stable for at least 2 months</li><li>• HIV-1 RNA is <math>\geq 400</math> copies/mL</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Continues to be used in combination with an optimized background regimen (OBR)</li><li>• Provider states that patient continues to receive clinical benefit from the treatment</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>MDR HIV Infection:</b> HIV Specialist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>MDR HIV Infection:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	4/1/2023
P&T Approval Date:	3/14/2023
P&T Revision Date:	3/14/2023

## References

- U.S. Department of Health and Human Services (DHHS): ClinicalInfo.HIV.gov. Clinical Guidelines. <https://clinicalinfo.hiv.gov/en/guidelines>.

# Lenacapavir (Yeztugo)

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## Products Affected

- Yeztugo Inj.
- Yeztugo Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Pre-Exposure Prophylaxis to reduce the risk of HIV infection</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Pre-Exposure Prophylaxis (PrEP)</b></p> <ul style="list-style-type: none"><li>• Confirmation the drug is being used for PrEP (a different product is used for treatment)</li><li>• Submission of medical records documenting both of the following U.S. Food and Drug (FDA)-approved tests prior to use of Yeztugo:<ul style="list-style-type: none"><li>○ Negative HIV-1 antigen/antibody test</li><li>○ Negative HIV-1 RNA assay</li></ul></li><li>• Trial and failure, contraindication, or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Provider attests that patient is adherent to the testing appointments and scheduled injections of Yeztugo</li><li>• Submission of medical records documenting both of the following U.S. Food and Drug (FDA)-approved tests prior to use of Yeztugo:<ul style="list-style-type: none"><li>○ Negative HIV-1 antigen/antibody test</li><li>○ Negative HIV-1 RNA assay</li></ul></li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Pre-Exposure Prophylaxis:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	11/1/2025
P&T Approval Date:	9/9/2025
P&T Revision Date:	9/9/2025

## References

- Reference Yeztugo [package insert]. Foster City, CA: Gilead Sciences Inc.; 06/2025.

- Centers for Disease Control and Prevention. Expanding PrEP Coverage in the United States to Achieve EHE Goals. October 17, 2023.
- Centers for Disease Control and Prevention: US Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 update: A Clinical Practice Guideline.
- IPD Analytics. HIV Pre-Exposure Prophylaxis: FDA approval of Yeztugo. Published July 2025.
- U.S. Department of Health and Human Services (DHHS): ClinicalInfo.HIV.gov. Clinical Guidelines. Accessed August 14, 2025. <https://clinicalinfo.hiv.gov/en/guidelines>.

# Lidocaine Patch

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## Products Affected

- Lidocaine External Patch

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Post-Herpetic Neuralgia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Post-Herpetic Neuralgia</u></b> <ul style="list-style-type: none"><li>• Documentation confirming a diagnosis of post-herpetic neuralgia</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Post-Herpetic Neuralgia:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal: 3 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

## References

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# Lisdexamfetamine

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## Products Affected

- Lisdexamfetamine Capsules

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Attention Deficit Hyperactivity Disorder</li><li>○ Binge Eating Disorder</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Attention Deficit Hyperactivity Disorder (ADHD)</u></b></p> <ul style="list-style-type: none"><li>• Prior trial of at least 30 days of both of the following:<ul style="list-style-type: none"><li>○ An extended-release amphetamine product (amphetamine salts ER, dextroamphetamine ER, etc.)</li><li>○ An extended-release methylphenidate product (dexmethylphenidate ER, methylphenidate ER, etc.)</li></ul></li></ul> <p><b><u>Binge Eating Disorder (BED)</u></b></p> <ul style="list-style-type: none"><li>• Clinical documentation confirming a diagnosis of binge eating disorder per DSM-5 criteria</li><li>• Trial and failure of 2 drugs from at least 2 of the following classes:<ul style="list-style-type: none"><li>○ Selective serotonin reuptake inhibitors (SSRI)</li><li>○ Topiramate</li><li>○ Methylphenidate</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• <b>Binge Eating Disorder:</b> 18 years of age or older</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	3/1/2025
P&T Approval Date:	1/14/2025
P&T Revision Date:	1/14/2025

## References

- [www.columbiapsychiatry.org/news/effort-underway-develop-first-u-s-guidelines-adhd-adults](http://www.columbiapsychiatry.org/news/effort-underway-develop-first-u-s-guidelines-adhd-adults)
- [www.cdc.gov/adhd/php/adults/index.html](http://www.cdc.gov/adhd/php/adults/index.html)
- [www.cdc.gov/adhd/diagnosis/index.html](http://www.cdc.gov/adhd/diagnosis/index.html)

# Long-Acting Opiates

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## Products Affected

- Fentanyl Patch
- Hydrocodone ER Capsule
- Hydrocodone ER Tablet
- Hydromorphone ER
- Methadone ER
- Morphine Sulfate ER Capsule
- Morphine Sulfate ER Tablets
- Nucynta ER
- Oxycodone ER
- Oxymorphone ER
- Xtampza ER

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Pain Related to Cancer, End of Life, or Palliative Care</li><li>○ Pain in All Other Conditions</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Pain Related to Cancer, End of Life, or Palliative Care</b></p> <ul style="list-style-type: none"><li>• Confirmation of diagnosis</li></ul> <p><b>Other Pain</b></p> <ul style="list-style-type: none"><li>• Documented use of current and/or recent usage of short-acting opioids for at least 15 days prior to long-acting opioids.</li><li>• For opioid naive (14 or fewer days filled in previous 120 days): 7-day maximum quantity limit; equal to or less than 50 MED [morphine equivalents per day].</li><li>• For opioid experienced (greater than or equal to 15 days filled in previous 120 days): equal to or less than 90 MED [morphine equivalents per day].</li><li>• Restricted to 2 fills in a 60-day period for both naive and experienced.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li><li>○</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

**References**

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# Lotilaner (Xdemvy)

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## Products Affected

- Xdemvy 0.25% Ophthalmic solution

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Demodex Blepharitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Demodex Blepharitis</u></b> <ul style="list-style-type: none"><li>• Documentation of at least mild erythema of the upper eyelid margin</li><li>• Presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• N/A</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 18 years of age and older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Demodex Blepharitis:</b> Optometrist or Ophthalmologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Demodex Blepharitis:</b><ul style="list-style-type: none"><li>○ Initial: 6 weeks</li><li>○ Renewal: Renewals are not allowed</li></ul></li></ul>

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

<b>References</b>
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# Lubiprostone

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## Products Affected

- Lubiprostone capsules

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Chronic idiopathic constipation in adults (in presence of above the line comorbid condition or if age under 21)</li><li>○ Irritable bowel syndrome in females (assigned at birth) &gt; 18 YO (in presence of above the line comorbid condition or if age under 21)</li><li>○ Opioid induced constipation (in presence of above the line comorbid condition or if age under 21)</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Chronic Idiopathic Constipation (CIC)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of a funded comorbid condition that would be improved with the treatment of CIC</li><li>• Documentation of failure to have benefit with recommended conventional first-line treatments (or contraindication to all first-line treatments):<ul style="list-style-type: none"><li>○ Dietary Modification: Increased dietary fiber (25 grams/day) and increased fluid consumption</li><li>○ Bulk-forming Laxatives: Psyllium</li><li>○ Osmotic Laxatives: Polyethylene glycol, lactulose, magnesium hydroxide, milk of magnesia</li><li>○ Stool Softener: Docusate</li><li>○ Stimulant Laxatives: Senna, bisacodyl.</li></ul></li></ul> <p><b><u>Irritable Bowel Syndrome with Constipation (IBS-C) in females (assigned at birth)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of a funded comorbid condition that would be improved with the treatment of IBS-C</li><li>• Documentation of failure to have benefit with recommended conventional first-line treatments (or contraindication to all first-line treatments):<ul style="list-style-type: none"><li>○ Dietary Modification: Increased dietary fiber (25 grams/day) and increased fluid consumption</li><li>○ Bulk-forming Laxatives: Psyllium</li><li>○ Osmotic Laxatives: Polyethylene glycol, lactulose, magnesium hydroxide, milk of magnesia</li><li>○ Stool Softener: Docusate</li></ul></li></ul>

	<ul style="list-style-type: none"> <li>○ Stimulant Laxatives: Senna, bisacodyl.</li> </ul> <p><b>Opioid Induced Constipation (OIC)</b></p> <ul style="list-style-type: none"> <li>● Documentation of a funded comorbid condition that would be improved with the treatment of OIC</li> <li>● Documentation of failure to have benefit with recommended conventional first-line treatments (or contraindication to all first-line treatments): <ul style="list-style-type: none"> <li>○ Dietary Modification: Increased dietary fiber (25 grams/day) and increased fluid consumption</li> <li>○ Osmotic Laxatives: Polyethylene glycol, lactulose, magnesium hydroxide, milk of magnesia</li> <li>○ Stool Softener: Docusate</li> <li>○ Stimulant Laxatives: Senna, bisacodyl.</li> </ul> </li> <li>● The patient is not using methadone.</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>● Documentation of efficacy and continued need</li> </ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"> <li>● 18 years of age and older</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>● <b>Chronic Idiopathic Constipation and Irritable Bowel Syndrome with Constipation:</b> Gastroenterologist, other provider after patient consultation with a dietitian</li> <li>● <b>Opioid Induced Constipation:</b> Gastroenterologist, pain management specialist, other provider after patient consultation with a dietitian</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>● <b>All diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 12 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	9/1/2025
P&T Approval Date:	7/8/2025
P&T Revision Date:	7/8/2025

<b>References</b>
<ul style="list-style-type: none"> <li>● Change L, et al. American Gastroenterological Association-American College of Gastroenterology Clinical Practice Guideline: Pharmacological Management of Chronic Idiopathic Constipation. <i>Gastroenterology</i> 2023;164:1086–1106.</li> <li>● Davids JS, et al. Clinical Practice Guidelines. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anal Fissures. <i>Dis Colon Rectum</i> 2022; 66: 190–199.</li> </ul>

- Paquette IM, et al. The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Evaluation and Management of Constipation. *Dis Colon Rectum* 2016; 59: 479–492.
- Tabbers MM, et al. Evaluation and Treatment of Functional Constipation in Infants and Children: Evidence-Based Recommendations from ESPGHAN and NASPGHAN. *JPGN* 2014;58: 258–274.
- Wald A, et al. ACG Clinical Guidelines: Management of Benign Anorectal Disorders. *Am J Gastroenterol* 2021;116:1987–2008.

# Lumacaftor-Ivacaftor (Orkambi)

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## Products Affected

- Orkambi Granules
- Orkambi Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.<ul style="list-style-type: none"><li>○ Cystic Fibrosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Cystic Fibrosis</u></b> <ul style="list-style-type: none"><li>• Documentation of cystic fibrosis diagnosis with homozygous F508del mutation</li><li>• Not used in combination with other CFTR modulator treatments</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 1 years of age and older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Cystic Fibrosis:</b> Pulmonologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Cystic Fibrosis:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	5/1/2025
P&T Approval Date:	5/1/2021
P&T Revision Date:	9/1/2021, 3/11/2025

<b>References</b>
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# Mefloquine

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## Products Affected

- Mefloquine Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Treatment of Malaria</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Malarial Treatment</u></b> <ul style="list-style-type: none"><li>• Confirmed diagnosis of malaria</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• N/A</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Malaria:</b><ul style="list-style-type: none"><li>○ Initial: 1 months</li><li>○ Renewal: N/A</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

## References

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# Memantine

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## Products Affected

- Memantine 5mg Tablets
- Memantine 10mg Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Moderate to Severe Dementia of the Alzheimer's Type</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Moderate to Severe Dementia of the Alzheimer's Type</u></b></p> <ul style="list-style-type: none"><li>• Clinical documentation confirming a diagnosis of moderate to severe dementia of the Alzheimer's type.</li></ul> <p><b>Solution only:</b> Documentation that the member is unable to use tablets</p>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• <b>Solution only:</b> Age less than 10 (or can't swallow tablets)</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

## References

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# Mesalamine Step Therapy

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## Products Affected

- Mesalamine DR tablet 1.2 gm

<b>Step Therapy Criteria</b>	<ul style="list-style-type: none"><li>• Trial and failure of<ul style="list-style-type: none"><li>○ Mesalamine 0.375gm caps</li></ul></li></ul>
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Effective Date:	11/1/2025
P&T Approval Date:	9/9/2025
P&T Revision Date:	9/9/2025

# Mirabegron (Myrbetriq)

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## Products Affected

- Mirabegron ER tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Overactive Bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency</li><li>○ Neurogenic detrusor overactivity in pediatric members</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Overactive Bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency</u></b></p> <ul style="list-style-type: none"><li>• Documented trial and failure of at least 3 of the following, or contraindication to all:<ul style="list-style-type: none"><li>○ Oxybutynin IR or ER</li><li>○ Fesoterodine</li><li>○ Solifenacina</li><li>○ Tolterodine IR or ER</li><li>○ Trospium IR or ER (requires step therapy through oxybutynin)</li></ul></li></ul> <p><b><u>Neurogenic Detrusor Overactivity in pediatric members</u></b></p> <ul style="list-style-type: none"><li>• Is there documented trial and failure, intolerance, or contraindication to both of the following:<ul style="list-style-type: none"><li>○ Oxybutynin IR or ER</li><li>○ Solifenacina</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of positive clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 3 years of age and older</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	7/1/2025
P&T Approval Date:	5/13/2025
P&T Revision Date:	5/13/2025

## References

- Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU guideline on the diagnosis and treatment of idiopathic overactive bladder. *J Urol.* Published online April 23, 2024.
- Myrbetriq [package insert]. Northbrook, IL: Astellas.; 2021.

# Mirikizumab (Omvoh)

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## Products Affected

- Omvoh 100mg/mL Auto-Injector
- Omvoh 100mg/mL Prefilled Syringe

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Ulcerative Colitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>All diagnoses</u></b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy.</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic or Otezla</li></ul> <p><b><u>Ulcerative Colitis (UC)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of moderate-to-severe ulcerative colitis</li><li>• The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of at least 1 of the following:<ul style="list-style-type: none"><li>○ Mesalamine, sulfasalazine OR</li><li>○ Mercaptopurine, azathioprine, OR</li><li>○ Corticosteroids (prednisone, methylprednisolone)</li></ul></li><li>• Trial and failure of both infliximab and adalimumab</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.</li></ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>• Not to be used in combination with other biologics for the same indication.</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Ulcerative Colitis:</b> Gastroenterologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Ulcerative Colitis:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	7/1/2024
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P&T Approval Date:	5/14/2024
P&T Revision Date:	5/14/2024

References
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# Mitapivat (Pyrukynd)

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## Products Affected

- Pyrukind Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Hemolytic Anemia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Hemolytic Anemia</b> <ul style="list-style-type: none"><li>• Diagnosis of pyruvate kinase deficiency with at least two mutations within the PKLR gene, including a missense mutation</li><li>• Confirmation of current hemoglobin <math>\leq</math> 10mg/dL</li><li>• Patient is not homozygous for the R479H mutation</li><li>• Patient does not have two non-missense variants in the PKLR gene, without the presence of another missense variant</li><li>• Patient has had at least 6 RBC transfusions within the previous year for hemolytic anemia due to PKD</li><li>• Prescriber confirmed concomitant use of daily folic acid</li><li>• Confirmation that the patient does not have moderate or severe hepatic dysfunction.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Clinical documentation showing an increase in Hb at least 1.5 mg/dL over baseline and/or a reduction in frequency of transfusions.</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 18 years of age or older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Hemolytic Anemia:</b> Hematologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Hemolytic Anemia:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal: 6 months</li></ul></li></ul>

Effective Date:	8/01/2022
P&T Approval Date:	7/12/2022
P&T Revision Date:	7/12/2022

## References

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# Mometasone Nasal Spray

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## Products Affected

- Mometasone Furoate Nasal Spray

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Nasal Congestion or Rhinitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Nasal Congestion or Rhinitis</u></b></p> <ul style="list-style-type: none"><li>• Diagnosis of asthma or an above the line comorbid condition that may worsen if not treated</li><li>• Inadequate treatment response, intolerance, or contraindication to all the following<ul style="list-style-type: none"><li>○ Fluticasone nasal spray</li><li>○ Budesonide nasal spray</li><li>○ Triamcinolone nasal spray</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	12/1/2022
P&T Approval Date:	11/8/2022
P&T Revision Date:	11/8/2022

<b>References</b>
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# Naltrexone (Vivitrol)

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## Products Affected

- Vivitrol Injection

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<b>All Diagnoses</b> <ul style="list-style-type: none"><li>○ The drug will be dispensed directly to the provider and not the member.</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	7/12/2022

## References

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# Nasal Steroids

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## Products Affected

- Budesonide 32 mcg/act nasal spray
- Triamcinolone 55 mcg/act nasal spray

<b>Step Therapy Criteria</b>	<ul style="list-style-type: none"><li>• Trial and failure of<ul style="list-style-type: none"><li>○ Fluticasone 50 mcg/act nasal spray</li></ul></li></ul>
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Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

# Nitroglycerin ointment

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## Products Affected

- Nitroglycerin 0.4% ointment

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Anal Fissure</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Anal Fissure</u></b> <ul style="list-style-type: none"><li>• Diagnosis of moderate to severe pain associated with chronic anal fissure.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• N/A</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• None</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Anal Fissure:</b><ul style="list-style-type: none"><li>○ Initial: 2 months</li><li>○ Renewal: N/A</li></ul></li></ul>

Effective Date:	9/1/2025
P&T Approval Date:	7/8/2025
P&T Revision Date:	7/8/2025

## References

- Davids JS, et al. Clinical Practice Guidelines. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anal Fissures. *Dis Colon Rectum* 2022; 66: 190–199.
- Wald A, et al. ACG Clinical Guidelines: Management of Benign Anorectal Disorders. *Am J Gastroenterol* 2021;116:1987–2008.

# Non-Formulary Criteria

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## Products Affected

- All Non-Formulary Medications

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>All FDA Approved Conditions</u></b></p> <ul style="list-style-type: none"><li>• One of the following:<ul style="list-style-type: none"><li>○ The requested medication is being used to treat an above the line diagnosis on the OHA Prioritized list</li><li>○ The member has an above the line comorbid condition that will be treated indirectly by the requested medication</li><li>○ The member under the age of 21</li></ul></li><li>• One of the following:<ul style="list-style-type: none"><li>○ The requested medication is being used for an FDA-approved indication:</li><li>○ The requested medication is being used for an off-label indication with well-established, clinical evidence supporting its use.</li></ul></li><li>• All appropriate formulary alternatives have been tried and failed or are contraindicated.</li></ul> <p><b><u>Non-Formulary alternative dosage form (e.g. a request for NF oral solution when tablets are on formulary)</u></b></p> <ul style="list-style-type: none"><li>• One of the following:<ul style="list-style-type: none"><li>○ Member is age 10 or younger</li><li>○ Member has clinically documented inability to swallow tablets/capsules</li></ul></li><li>• One of the following:<ul style="list-style-type: none"><li>○ The formulary equivalent tablet/capsule does not require PA</li><li>○ The formulary equivalent tablet/capsule requires PA and the PA criteria has been met</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Clinical documentation of follow-up indicating safety, efficacy and medication adherence over previous approval duration.</li><li>• There are not any newly added formulary alternatives, or newly added formulary alternatives have been tried and failed or are contraindicated.</li></ul>

<b>Age Restriction</b>	<ul style="list-style-type: none"> <li>FDA labeled limits</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li><b>All Diagnoses:</b> Appropriate Specialist will vary by drug and condition</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li><b>All Diagnoses:</b> <ul style="list-style-type: none"> <li>Initial: 6 months or shorter if appropriate for the drug/condition</li> <li>Renewal: 12 months or shorter if appropriate for the drug/condition</li> </ul> </li> </ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

<b>References</b>
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# Omalizumab (Xolair)

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## Products Affected

- Xolair Prefilled Syringe
- Xolair Auto-Injector

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Moderate to Severe Asthma</li><li>○ Chronic Rhinosinusitis with Nasal Polyps</li><li>○ Chronic Idiopathic Urticaria - Refractory</li><li>○ IgE-Mediated Food Allergy</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Severe Asthma</b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of moderate to severe persistent asthma.</li><li>• Positive skin test or RAST to a perennial aeroallergen.</li><li>• Baseline IgE serum level within FDA label.</li><li>• Documentation of steps taken to avoid, within reason, environmental allergens and other triggers environmental allergens and other triggers.</li><li>• Documented trial and failure, with claims history of adherence to:<ul style="list-style-type: none"><li>○ High dose inhaled corticosteroid with a long-acting beta agonist (e.g., Advair),</li><li>○ Long acting anti-muscarinic (e.g., Spiriva),</li><li>○ Leukotriene Inhibitor (e.g., Singulair).</li></ul></li><li>• Documented trial and failure of, or contraindication to allergen immunotherapy.</li></ul> <p><b>Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):</b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP).</li><li>• Documentation of recurrent nasal polyps after prior sinus surgery.</li><li>• Documented risk of another sinus surgery, or a statement why sinus surgery is not medically appropriate.</li><li>• Documented trial and failure, with claims history of adherence to:<ul style="list-style-type: none"><li>○ At least 2 intranasal corticosteroids (e.g., fluticasone, mometasone),</li><li>○ Sinuva.</li></ul></li><li>• Documentation that Xolair is intended as adjunct therapy with nasal corticosteroids.</li></ul>

	<p><b><u>Chronic Idiopathic Urticaria - refractory (CIU)</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of chronic spontaneous or idiopathic urticaria.</li> <li>• Age under 21, or a comorbid condition which would make chronic urticaria coverable under the prioritized list.</li> <li>• Documented trial and failure of at least 6 weeks of maximally tolerated doses of all the following: <ul style="list-style-type: none"> <li>○ 1<sup>st</sup> generation antihistamine – (e.g., doxepin, hydroxyzine)</li> <li>○ 2<sup>nd</sup> generation antihistamine – (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine)</li> <li>○ Histamine Type-2 Receptor Antagonists (e.g., famotidine, cimetidine)</li> <li>○ Leukotriene inhibitor (e.g., montelukast, zafirlukast)</li> </ul> </li> </ul> <p><b><u>IgE-Mediated Food Allergy</u></b></p> <ul style="list-style-type: none"> <li>• Diagnosis of IgE Mediated Food Allergy as evidenced by one of the following: <ul style="list-style-type: none"> <li>○ Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food,</li> <li>○ Positive food specific IgE (greater than or equal to 6 kUA/L),</li> <li>○ Positive oral food challenge, defined as experiencing dose-limiting symptoms at a single dose of less than or equal to 300 mg of food protein.</li> </ul> </li> <li>• Clinical history of IgE mediated food allergy.</li> <li>• Used in conjunction with food allergen avoidance.</li> <li>• Both of the following: <ul style="list-style-type: none"> <li>○ Baseline (pre-Xolair treatment) serum total IgE level is greater than or equal to 30 IU/mL and less than or equal to 1850 IU/mL,</li> <li>○ Dosing is according to serum total IgE levels and body weight.</li> </ul> </li> <li>• Xolair will not be used concomitantly with Palforzia.</li> <li>• Attestation that the member is co-prescribed epinephrine or has epinephrine at home.</li> </ul>
<b>Renewal Criteria</b>	<p><b>IgE Mediated Food Allergy:</b></p> <ul style="list-style-type: none"> <li>• Patient demonstrates positive clinical response to therapy (e.g., reduction of type 1 allergic reactions, including anaphylaxis, following accidental exposure to one or more foods).</li> <li>• Used in conjunction with food allergen avoidance.</li> <li>• Dosing will continue to be based on body weight and pretreatment IgE serum levels.</li> </ul> <p><b>All Other Diagnoses:</b></p>

	<ul style="list-style-type: none"> <li>Documentation of clinically significant improvement in symptoms.</li> </ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>Specific criteria we want reviewed. This should be blank in many cases. Do not include things like “allergy to the drug you are asking for”; this is obvious and doesn’t need to be part of the criteria.</li> </ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"> <li><b>Asthma:</b> 6 years of age and older</li> <li><b>CIU:</b> 12 years of age and older</li> <li><b>CRSwNP:</b> 18 years of age and older</li> <li><b>IgE Mediated Food Allergy:</b> 1 year of age and older</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li><b>Asthma:</b> Prescribed by or in consultation with a pulmonologist or immunologist.</li> <li><b>CIU:</b> Prescribed by or in consultation with an immunologist.</li> <li><b>CRSwNP:</b> Prescribed by or in consultation with an allergist or ENT.</li> <li><b>IgE Mediated Food Allergy:</b> Prescribed by or in consultation with an allergist or immunologist.</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li><b>Asthma:</b> <ul style="list-style-type: none"> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul> </li> <li><b>CRSwNP:</b> <ul style="list-style-type: none"> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul> </li> <li><b>CIU:</b> <ul style="list-style-type: none"> <li>Initial: 4 months</li> <li>Renewal: 6 months</li> </ul> </li> <li><b>IgE Mediated Food Allergy:</b> <ul style="list-style-type: none"> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	9/1/2024
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P&T Revision Date:	7/9/2024

<b>References</b>
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# General Oncology (Chemotherapy)

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## Products Affected

- Abemaciclib (Verzenio)
- Abiraterone
- Acalabrutinib (Calquence)
- Adagrasib (Krazati)
- Alectinib (Alecensa)
- Alpelisib (Piqray)
- Asciminib (Scemblix)
- Asparaginase Erwinia (Rylaze)
- Avutometinib/Defactinib (Avmapki/Fazynja Pak)
- Belzutifan (Welireg)
- Binimetinib (Mektovi)
- Bosutinib (Bosulif)
- Brigatinib (Alunbrig)
- Busulfan (Myleran)
- Cabozantinib (Cabometyx)
- Capivasertib (Truqap)
- Capmatinib (Tabrecta)
- Ceritinib (Zykadia)
- Chlorambucil (Leukeran)
- Crizotinib (Xalkori)
- Dabrafenib (Tafinlar)
- Dasatinib
- Darolutamide (Nubeqa)
- Dordaviprone (Modeyso)
- Elacestrant (Orserdu)
- Encorafenib (Braftovi)
- Entrectinib (Rozlytrek)
- Erlotinib
- Estramustine (Emcyt)
- Everolimus
- Fruquintinib (Fruzaqla)
- Futibatinib (Lytgobi)
- Gefitinib
- Ibrutinib (Imbruvica)
- Inavolisib (Itovebi)
- Mobocertinib (Exkivity)
- Nilotinib (Tasigna)
- Niraparib/Abiraterone (Akeega)
- Nirogacestat (Ogsiveo)
- Olaparib (Lynparza)
- Olutasidenib (Rezlidhia)
- Osimertinib (Tagrisso)
- Pacritinib (Vonjo)
- Palbociclib (Ibrance)
- Pazopanib
- Pemigatinib (Pemazyre)
- Pexidartinib (Turalio)
- Pirtobrutinib (Jaypirca)
- Ponatinib (Iclusig)
- Procarbazine (Matulane)
- Quizartinib (Vanflyta)
- Repotrectinib (Augtyro)
- Ribociclib (Kisqali)
- Sargramostim (Leukine)
- Selpercatinib (Retevmo)
- Sorafenib
- Sotorasib (Lumakras)
- Sunitinib
- Sunvozertinib (Zegfrovry)
- Talazoparib (Talzenna)
- Taletrectinib (Ibtrozi)
- Temozolomide
- Tepotinib (Tepmetko)
- Thioguanine (Tabloid)
- Tivozanib (Fotivda)
- Topotecan (Hycamtin)
- Tovorafenib (Ojemda)
- Trametinib (Mekinist)
- Trifluridine/Tipiracil (Lonsurf)
- Tucatinib (Tukysa)

- Infigratinib (Truseltiq)
- Ivosidenib (Tibsovo)
- Lazertinib (Lazcluze)
- Lenvatinib (Lenvima)
- Lomustine (Gleostine)
- Lorlatinib (Lobrena)
- Midostaurin (Rydapt)
- Mitotane (Lysodren)
- Vimseitinib (Romvimza)
- Vorasidinib (Voranigo)
- Vorinostat (Zolinza)
- Zanubrutinib (Brukinsa)
- Zongertinib (Hernexeos)
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<b>Covered Uses</b>	<ul style="list-style-type: none"> <li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> </ul>
<b>Required Medical Information and Criteria</b>	<p><b>All Diagnoses</b></p> <ul style="list-style-type: none"> <li>• One of the following is true: <ul style="list-style-type: none"> <li>○ The requested drug is being used for an FDA approved indication.</li> <li>○ The requested medication is being used according to National Comprehensive Cancer Network (NCCN) guidelines.</li> </ul> </li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>• Submission of clinical documentation supporting provider follow-up that indicates safety and efficacy of the medication and adherence to treatment.</li> </ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"> <li>• Refer to FDA indication and NCCN guidelines</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>All Diagnoses:</b> Oncologist or hematologist</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>All Diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 3 months</li> <li>○ Renewal: up to 6 months</li> </ul> </li> </ul>

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P&T Revision Date:	11/11/2025, 9/9/2025, 7/8/2025, 5/13/2025, 3/11/2025, 5/14/2024, 03/01/2024, 01/09/2024, 11/1/2023, 09/01/2023, 7/11/2023, 05/09/2023, 03/14/2023, 01/10/2023, 10/01/2022

# Oral Antifungal Agents

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## Products Affected

- Griseofulvin Ultramicrosize Tabs
- Ketoconazole Tabs
- Griseofulvin Microsize Susp

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>All Diagnoses</b></p> <ul style="list-style-type: none"><li>• The medication is being used for an FDA-approved indication OR being used for an off-label indication with well-established, clinical evidence supporting its use, including the dose being requested</li><li>• For suspension only:<ul style="list-style-type: none"><li>○ Is there a reason that a tablet form can't be used</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of positive clinical response to therapy</li><li>• Evidence of continued need for the medication</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal (non-immunocompromised): 3 months</li><li>○ Renewal (immunocompromised): 6 months</li></ul></li></ul>

Effective Date:	1/1/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

## References

- Ketoconazole tablets [package insert]. Toronto, Ontario: Apotex Inc.; 2021.
- Griseofulvin [package insert]. Bridgewater, GA: Valent LLC.; 2016.

# Oral Nutrition Supplements

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<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>All Diagnoses</b></p> <ul style="list-style-type: none"><li>• Documentation showing the prescribed oral nutritional formula and/or nutritional supplements are an integral part of treatment/medically necessary for a nutritional deficiency.</li><li>• Documentation including assessment by treating practitioner or registered dietitian that member is unable to meet their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form.</li></ul> <p><b>OR</b></p> <ul style="list-style-type: none"><li>• For age under 21<ul style="list-style-type: none"><li>◦ Documented delayed growth or failure to thrive.</li><li>◦ Documentation showing the prescribed formula/nutritional supplement is for the prevention of nutritional deficiency or malnutrition.</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of continued positive response for the requested enteral nutrition/formula with a continued need for requested supplement.</li></ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>• Supplement is to be administered via enteral tube feeding (e.g. G-tube, NG-tube).</li><li>• For tube feedings please submit via a DME vendor through the DME benefit</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>◦ Initial: 6 months</li><li>◦ Renewal: 12 months</li></ul></li></ul>

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P&T Revision Date:	11/12/2024

## References

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# Pancrelipase (Creon, Pancreaze)

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## Products Affected

- Creon Capsules
- Pancreaze Capsules

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Exocrine Pancreatic Insufficiency</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Exocrine Pancreatic Insufficiency</b></p> <ul style="list-style-type: none"><li>• Clinical documentation of one of the following:<ul style="list-style-type: none"><li>○ Confirmed diagnosis of cystic fibrosis</li><li>○ History of pancreatectomy</li><li>○ Diagnosis of exocrine pancreatic cancer</li><li>○ Diagnosis of chronic pancreatitis confirmed by imaging</li><li>○ Confirmed diagnosis of pancreatic insufficiency confirmed with one of the following methods:<ul style="list-style-type: none"><li>▪ Steatorrhea with fecal fat determination</li><li>▪ Measurement of fecal elastase</li><li>▪ Secretin or CCK pancreatic function testing</li><li>▪ Two of the following CFTR mutations (G542X, W1282X, R553X, 621+1G&gt;T, 1717-1G&gt;A, 3120+1G&gt;A, R1162X, 3659delC, 1898+1G&gt;A, 2184delA, 711+1G&gt;T, F508del, I507del, G551D, N1303K, R560T)</li></ul></li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Exocrine Pancreatic Insufficiency:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	2/1/2022
P&T Approval Date:	1/11/2022
P&T Revision Date:	1/11/2022

## References

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# Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors

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## Products Affected

- Repatha SureClick
- Repatha Prefilled Syringe
- Repatha Pushtronex
- Praluent Auto-Injector

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Established clinical ASCVD</li><li>○ Primary or Familial Hyperlipidemia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Established Clinical ASCVD</u></b></p> <ul style="list-style-type: none"><li>• Documentation of very high risk ASCVD as evidenced by either:<ul style="list-style-type: none"><li>○ History of multiple major ASCVD events</li><li>○ One major ASCVD event AND multiple high-risk conditions.</li></ul></li><li>• Documentation of a current LDL greater than or equal to 55 mg/dL.</li><li>• Documentation of all the following:<ul style="list-style-type: none"><li>○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins</li><li>○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.</li></ul></li></ul> <p><b><u>Primary or Familial Hyperlipidemia</u></b></p> <ul style="list-style-type: none"><li>• Documentation of an untreated (i.e., prior to lipid lowering therapy) LDL greater than 190 mg/dL.</li><li>• Documentation of current LDL greater than 100 mg/dL.</li><li>• Documentation of all the following:<ul style="list-style-type: none"><li>○ Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins</li><li>○ Is receiving ezetimibe or has a documented intolerance to ezetimibe.</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy (significant decrease in lipid levels).</li></ul>

<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b> Cardiologist, Endocrinologist, or Lipid Specialist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	11/1/2024
P&T Approval Date:	9/10/2024
P&T Revision Date:	9/10/2024, 1/11/2022

<b>References</b>
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# Peanut Powder (Palforzia)

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## Products Affected

- Palforzia Capsule and Powder

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Peanut Allergy</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Peanut Allergy</b></p> <ul style="list-style-type: none"><li>• Confirmed positive skin test or peanut-specific serum IgE greater than 0.35 kUA/L</li><li>• Concurrent prescription with injectable epinephrine</li><li>• Medical justification supports necessity for oral immunotherapy despite peanut avoidance.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Currently receiving medication by way of previously approved SHP authorization or documents showing <b>Initial</b> approval criteria was or has been met.</li><li>• For patients who required use of injectable epinephrine while on Palforzia, must have medical justification that supports continued need for Palforzia.</li><li>• If 18 years or older, must have medical justification that supports continued need for oral immunotherapy despite peanut avoidance and documentation that <b>Initial</b> dose escalation happened between age 4 and 17.</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Patient must be between 4 and 17 at therapy initiation</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Peanut Allergy:</b> Allergist or Immunologist enrolled in Palforzia REMS program</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Peanut Allergy:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

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<b>References</b>
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# Phosphodiesterase Type 5 (PDE5) inhibitors

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## Products Affected

- Sildenafil 20mg tablet
- Tadalafil 20mg tablet

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Pulmonary Arterial Hypertension</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Pulmonary Arterial Hypertension</b> <ul style="list-style-type: none"><li>• Clinically documented diagnosis of Pulmonary Arterial Hypertension (WHO group 1 pulmonary hypertension)</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>• Treatment of erectile dysfunction</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Tadalafil: 18 years of age and over</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Pulmonary Arterial Hypertension:</b> Cardiologist or Pulmonologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Pulmonary Arterial Hypertension:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	9/1/2025
P&T Approval Date:	7/13/2021
P&T Revision Date:	7/8/2025, 7/13/2021

## References

<ul style="list-style-type: none"><li>• Adcirca (tadalafil). Prescribing information. Eli Lilly and Co. Indianapolis, IN 2020.</li><li>• Revatio (sildenafil). Prescribing information. Viatris Specialty LLC. Morgantown, WV 2024</li></ul>
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# Phytonadione (Vitamin K) Step Therapy

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## Products Affected

- Phytonadione 5mg tab

<b>Step Therapy Criteria</b>	• Concurrent use of warfarin
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Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

# Pitolisant (Wakix)

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## Products Affected

- Wakix Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Cataplexy and Narcolepsy</li><li>○ Excessive Somnolence - Narcolepsy</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Cataplexy and Narcolepsy</u></b></p> <ul style="list-style-type: none"><li>Confirmation of diagnosis of narcolepsy based on both:<ul style="list-style-type: none"><li>○ Polysomnography</li><li>○ A multiple sleep latency test</li></ul></li><li>Documentation that CYP2D6 testing has been done, and the dosing will be adjusted if the patient is a poor metabolizer.</li><li>Diagnosis of Cataplexy confirmed by a specialist.</li><li>Trial and failure or contraindication to ALL the following:<ul style="list-style-type: none"><li>○ SSRI antidepressant (e.g. fluoxetine)</li><li>○ SNRI antidepressant (e.g. venlafaxine and duloxetine)</li><li>○ Tricyclic antidepressant (e.g. clomipramine)</li><li>○ Sodium oxybate product titrated to maximally tolerated dose.</li></ul></li></ul> <p><b><u>Excessive Somnolence - Narcolepsy</u></b></p> <ul style="list-style-type: none"><li>Confirmation of diagnosis of narcolepsy based on both:<ul style="list-style-type: none"><li>○ Polysomnography</li><li>○ A multiple sleep latency test</li></ul></li><li>Documentation that CYP2D6 testing has been done, and the dosing will be adjusted if the patient is a poor metabolizer.</li><li>Documentation of fatigue severity using a validated measure (e.g. Epworth score, Brief Fatigue Inventory, or other validated measure</li><li>Trial and failure or contraindication to ALL the following:<ul style="list-style-type: none"><li>○ Modafinil (at least 200mg dose) AND armodafinil</li><li>○ Mixed amphetamine salts, methylphenidate or dextroamphetamine, AND dextroamphetamine</li><li>○ Sunosi (solriamfetol)</li><li>○ A sodium oxybate product</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>Documentation of positive clinical response to therapy</li></ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>Severe renal or hepatic impairment</li></ul>

	<ul style="list-style-type: none"><li>• Pregnant or actively trying to conceive</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b> Sleep Specialist or Neurologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal: 6 months</li></ul></li></ul>

Effective Date:	3/1/2025
P&T Approval Date:	1/14/2025
P&T Revision Date:	1/14/2025

<b>References</b>
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# Potassium Binders

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## Products Affected

- Lokelma Powder
- Veltassa Packet

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Hyperkalemia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Hyperkalemia</b></p> <ul style="list-style-type: none"><li>• Being used for the treatment of hyperkalemia based on current potassium labs</li><li>• Failed all the following:<ul style="list-style-type: none"><li>○ Dietary changes (potassium restriction)</li><li>○ Dose modification/discontinuation of ACE-inhibitor, ARB, or other hyperkalemia causing agents</li><li>○ Diuretics titrated to maximum tolerated dose</li></ul></li><li>• If the request is for Veltassa:<ul style="list-style-type: none"><li>○ Trial and failure or contraindication to Lokelma</li></ul></li></ul>
<b>Renewal Criteria</b>	Documented positive clinical response to therapy by either of the following: <ul style="list-style-type: none"><li>• Potassium level returning to normal on therapy</li><li>• Significant drop in potassium level from baseline on therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Hyperkalemia:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	7/1/2024
P&T Approval Date:	5/14/2024
P&T Revision Date:	9/13/2022

## References

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# Pretomanid

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## Products Affected

- Pretomanid tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Pulmonary tuberculosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Pulmonary tuberculosis</b></p> <ul style="list-style-type: none"><li>• Evidence of extensively drug-resistant active pulmonary tuberculosis (XDR-TB) caused by mycobacterium tuberculosis.<ul style="list-style-type: none"><li>○ XDR-TB is defined as TB that is resistant to rifampicin and isoniazid, at least one fluoroquinolone (levofloxacin or moxifloxacin) and a second-line injectable (amikacin, capreomycin, and kanamycin) OR Isoniazid, rifampin a fluoroquinolone AND bedaquiline or linezolid.</li></ul></li><li>• Pretomanid is prescribed as part of a guideline recommended multi-drug treatment regimen.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• N/A</li></ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>• Use outside of recognized treatment guidelines.</li><li>• Medication is being received through a county clinic with a state funded TB program.</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Age of 14 or greater.</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• Infectious Disease</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Pulmonary tuberculosis:</b> 24 weeks</li></ul>

Effective Date:	5/1/2025
P&T Approval Date:	3/11/2025
P&T Revision Date:	3/11/2025

## References

- Pretomanid [package insert]. Morgantown, WV: Mylan Specialty L.P.; 2024.

# Prostacyclin Agonists

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## Products Affected

- Orenitram tablets
- Treprostinil
- Remodulin
- Tyvaso

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Pulmonary Arterial Hypertension</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Pulmonary Arterial Hypertension</b></p> <ul style="list-style-type: none"><li>• Clinically documented diagnosis of Pulmonary Arterial Hypertension (WHO group 1 pulmonary hypertension)</li><li>• Clinical documentation of WHO functional class III or IV</li><li>• Evidence of an unfavorable response or intolerance to all of the following:<ul style="list-style-type: none"><li>○ Phosphodiesterase Type 5 inhibitor (sildenafil, tadalafil)</li><li>○ Endothelin Receptor Antagonist (ambrisentan, bosentan)</li><li>○ Combination therapy with a Phosphodiesterase Type 5 inhibitor + Endothelin Receptor Antagonist (ambrisentan + tadalafil)</li></ul></li><li>• The requested medication will be an add on to an already established first line agent or agents (sildenafil, tadalafil, ambrisentan, bosentan)</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of positive clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Age 16 or older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Pulmonary Arterial Hypertension:</b> Cardiologist or Pulmonologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Pulmonary Arterial Hypertension:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	9/1/2025
P&T Approval Date:	7/13/2021
P&T Revision Date:	7/8/2025, 7/13/2021

## References

- Orenitram [package insert]. Research Triangle Park, NC: United Therapeutics Corp; 2023.

- Remodulin [package insert]. Research Triangle Park, NC: United Therapeutics Corp; 2023.
- Tyvaso [package insert]. Research Triangle Park, NC: United Therapeutics Corp; 2022.

# Quantity Limit Exception Criteria

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## Products Affected

- All Drugs with Quantity Limits

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>All FDA Approved Conditions</u></b></p> <ul style="list-style-type: none"><li>• One of the following:<ul style="list-style-type: none"><li>○ The requested medication is being used to treat an above the line diagnosis on the OHA Prioritized list</li><li>○ The member has an above the line comorbid condition that will be treated indirectly by the requested medication</li><li>○ The member under the age of 21</li></ul></li><li>• One of the following:<ul style="list-style-type: none"><li>○ The requested medication is being used for an FDA-approved indication:</li><li>○ The requested medication is being used for an off-label indication with well-established, clinical evidence supporting its use.</li></ul></li><li>• Documentation of failure of the requested medication within quantity limits, including failure of different strengths of the requested medication.</li><li>• All appropriate formulary alternatives have been tried and failed or are contraindicated.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>• Specific criteria we want reviewed. This should be blank in many cases. Do not include things like "allergy to the drug you are asking for"; this is obvious and doesn't need to be part of the criteria.</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• FDA labeled limits</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b> Appropriate Specialist will vary by drug and condition</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 6 months or shorter if appropriate for the drug/condition</li><li>○ Renewal: 12 months or shorter if appropriate for the drug/condition</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

<b>References</b>
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# Resmetirom (Rezdiffra)

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## Products Affected

- Rezdiffra Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Metabolic Dysfunction-Associated Steatohepatitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Metabolic Dysfunction-Associated Steatohepatitis</b></p> <ul style="list-style-type: none"><li>• Clinical documentation confirming a diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), formulary known as nonalcoholic steatohepatitis (NASH)</li><li>• Patient does not have cirrhosis (e.g. decompensated cirrhosis)</li><li>• Submission of medical records (e.g. chart notes) showing diagnosis has been confirmed by one of the following:<ul style="list-style-type: none"><li>○ FibroScan-aspartate aminotransferase (FAST)</li><li>○ MRI-aspartate aminotransferase (MAST)</li><li>○ Liver biopsy</li></ul></li><li>• Submission of medical records (e.g. chart notes) showing disease is fibrosis stage F2 or F3 as confirmed by one of the following:<ul style="list-style-type: none"><li>○ FibroScan</li><li>○ Fibrosis-4 index (FIB-4)</li><li>○ Magnetic resonance Elastography (MRE)</li></ul></li><li>• Presence of greater than or equal to 3 metabolic risk factors (e.g., Type 2 diabetes, hypertension, obesity)</li><li>• Submission of medical records (e.g. chart notes) confirming drug is used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Patient demonstrates positive response to therapy (e.g., MASH resolution, fibrosis stage improvement, etc.)</li><li>• Submission of medical records (e.g., chart notes) confirming drug will continue to be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• <b>!8 years of age or older</b></li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Metabolic Dysfunction-Associated Steatohepatitis:</b> Gastroenterologist, Hepatologist</li></ul>

<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Metabolic Dysfunction-Associated Steatohepatitis:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>
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Effective Date:	7/1/2024
P&T Approval Date:	5/14/2024
P&T Revision Date:	5/14/2024

<b>References</b>
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# Rifapentine (Priftin)

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## Products Affected

- Priftin tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Latent tuberculosis</li><li>○ Active tuberculosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Latent tuberculosis</u></b></p> <ul style="list-style-type: none"><li>• Used in combination with isoniazid (INH).</li></ul> <p><b><u>Active tuberculosis</u></b></p> <ul style="list-style-type: none"><li>• Used as part of a multi-drug regimen.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• N/A</li></ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>• Medication is being received through a county clinic with a state funded TB program.</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Age <math>\geq</math> 2 years old with latent TB</li><li>• Age <math>\geq</math> 12 years old with active TB</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Latent TB:</b> Not limited by specialty</li><li>• <b>Active TB:</b> Infectious disease specialist required for multidrug resistant cases only</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Latent TB:</b> 3 months</li><li>• <b>Active TB:</b> 6 months</li></ul>

Effective Date:	5/1/2025
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/11/2025, 3/12/2024

## References

- Priftin [package insert]. Bridgewater, NJ: Sanofi-Aventis.; 2021.

# Risdiplam (Evrysdi)

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## Products Affected

- Evrysdi Solution

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Spinal Muscular Atrophy</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Spinal Muscular Atrophy</b></p> <ul style="list-style-type: none"><li>• Confirmed (via genetic testing) diagnosis of 5q-autosomal recessive SMA (type 1, 2 or 3)</li><li>• Patient is not dependent on invasive ventilation or tracheostomy or use of non-invasive ventilation beyond uses for sleeping</li><li>• Patient is not receiving concomitant chronic SMN modifying therapy such as Spinraza</li><li>• Patient has not previously received gene replacement therapy for the treatment of SMA (e.g. Zolgensma)</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of clinical improvement from baseline in motor functionality confirmed by standard exams (e.g. BSID-III, CHOP INTEND, HINE-2, RULM test)</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Spinal Muscular Atrophy:</b> Neurologist with expertise in the treatment of spinal muscular atrophy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Spinal Muscular Atrophy:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023

## References

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# Roflumilast

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## Products Affected

- Product 1
- Product 3
- Product 2
- Etc.

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Chronic Obstructive Pulmonary Disorder (COPD)</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Chronic Obstructive Pulmonary Disorder (COPD)</b> <ul style="list-style-type: none"><li>• Diagnosis of moderate to severe COPD and chronic bronchitis</li><li>• Trial and failure of at least 2 previous treatments for COPD</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of positive clinical response to roflumilast therapy.</li></ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>• Specific criteria we want reviewed. This should be blank in many cases. Do not include things like "allergy to the drug you are asking for"; this is obvious and doesn't need to be part of the criteria.</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>COPD:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

## References

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# Sacubitril/Valsartan (Entresto)

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## Products Affected

- Entresto tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>Heart Failure</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Heart Failure</b></p> <ul style="list-style-type: none"><li>Diagnosis of New York Heart Association class II to IV heart failure</li><li>The patient meets one of the following:<ul style="list-style-type: none"><li>Receiving concomitant therapy with one of the following beta blockers: carvedilol, bisoprolol, sustained release metoprolol OR</li><li>Beta-blockers are contraindicated or the member has been unable to tolerate them</li></ul></li><li>The patient will discontinue use of any ACE inhibitor or ARB before initiating therapy with Entresto.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>Documented positive response to therapy.</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>Cardiologist, or in consultation with a cardiologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li><b>Heart Failure:</b><ul style="list-style-type: none"><li>Initial: Lifetime</li></ul></li></ul>

Effective Date:	9/1/2025
P&T Approval Date:	4/25/2016
P&T Revision Date:	7/8/2025

## References

- Entresto [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2024.

# Secukinumab (Cosentyx)

## Products Affected

- Cosentyx Pen 300mg Dose
- Cosentyx Prefilled Syringe 300mg Dose

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Ankylosing Spondylitis/Axial Spondyloarthritis</li><li>○ Hidradenitis Suppurativa</li><li>○ Juvenile Idiopathic Arthritis</li><li>○ Plaque Psoriasis</li><li>○ Psoriatic Arthritis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>All diagnoses</u></b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy.</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic or Otezla.</li></ul> <p><b><u>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:<ul style="list-style-type: none"><li>○ Back pain and stiffness for more than 3 months AND</li><li>○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND</li><li>○ BASDAI score of &gt;=4</li></ul></li><li>• One of the following:<ul style="list-style-type: none"><li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li><li>○ Documented failure of conventional therapy with both of the following:<ul style="list-style-type: none"><li>▪ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND</li><li>▪ Physical therapy/exercise program</li></ul></li></ul></li><li>• Trial and failure of infliximab and adalimumab</li></ul> <p><b><u>Hidradenitis Suppurativa (HS)</u></b></p>

- Documentation of a diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III)
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented failure of conventional therapy (e.g. oral antibiotics).
- Trial and failure of infliximab and adalimumab

**Juvenile Idiopathic Arthritis (JIA)**

- Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of the following:
    - NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
    - At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids
- Documented intolerance or contraindication to DMARDs OR DMARD will be continued with Cosentyx
- Trial and failure of infliximab and adalimumab

**Plaque Psoriasis (PP):**

- Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:
  - At least 10% of body surface area involved
  - Hand, foot, face, or mucous membrane involvement
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of all the following:
    - High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)
    - At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)
    - PUVA or UVB Phototherapy

	<ul style="list-style-type: none"> <li>▪ Methotrexate</li> <li>▪ At least 1 other second line systemic agent such as cyclosporine or acitretin.</li> <li>• Trial and failure of infliximab and adalimumab</li> </ul> <p><b><u>Psoriatic Arthritis (PsA):</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of psoriatic arthritis based on at least 3 out of 5 of the following: <ul style="list-style-type: none"> <li>○ Psoriasis (1 point for personal or family history, 2 points for current)</li> <li>○ Psoriatic nail dystrophy</li> <li>○ Negative test result for RF</li> <li>○ Dactylitis (current or history)</li> <li>○ Radiological evidence of juxta-articular new bone formation</li> </ul> </li> <li>• One of the following: <ul style="list-style-type: none"> <li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li> <li>○ Documented trial and failure of conventional therapy with both of the following: <ul style="list-style-type: none"> <li>▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li> <li>▪ Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine.</li> </ul> </li> </ul> </li> <li>• Trial and failure of infliximab and adalimumab</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>• <b>Ankylosing Spondylitis, Axial Spondyloarthritis:</b> Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.</li> <li>• <b>Juvenile Idiopathic Arthritis:</b> Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.</li> <li>• <b>Plaque Psoriasis:</b> Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement.</li> <li>• <b>Psoriatic Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> </ul>

<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Plaque Psoriasis:</b> Dermatologist.</li> <li>• <b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist.</li> <li>• <b>Juvenile Idiopathic Arthritis:</b> Rheumatologist.</li> <li>• <b>Ankylosing Spondylitis, Axial Spondyloarthritis:</b> Rheumatologist.</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>All Diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	7/1/2024
P&T Approval Date:	5/14/2024
P&T Revision Date:	9/1/2023, 07/11/2023, 01/11/2022

<b>References</b>
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# Seladelpar (Livdelzi)

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## Products Affected

- Livdelzi Capsules

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Primary Biliary Cholangitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Primary Biliary Cholangitis</b></p> <ul style="list-style-type: none"><li>• Diagnosis of primary biliary cholangitis (PBC) confirmed by two of the following:<ul style="list-style-type: none"><li>○ Biochemical evidence of cholestasis based on ALP elevation</li><li>○ Presence of AMA or other PBC-specific autoantibodies</li><li>○ Histology confirmation after biopsy</li></ul></li><li>• Documentation of at least 12 months of inadequate response to ursodiol</li><li>• No current decompensated cirrhosis</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented adherence to medication regimen and clinical benefit</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Age 18 or older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Primary Biliary Cholangitis:</b> Hepatologist or Gastroenterologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Primary Biliary Cholangitis:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	1/1/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

<b>References</b>
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# Semaglutide (Wegovy)

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## Products Affected

- Wegovy Injection

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Secondary Prevention of Major Adverse Events (MACE)</li><li>○ Obesity or Overweight (only applies to members under age 21)</li><li>○ Metabolic Dysfunction-Associated Steatohepatitis (MASH)</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Secondary Prevention of Major Adverse Events</u></b></p> <ul style="list-style-type: none"><li>• Wegovy is being used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.</li><li>• Wegovy is being used as adjunct to lifestyle modification (e.g., dietary, or caloric restriction, exercise, behavioral support, community-based program).</li><li>• Patient has established cardiovascular disease as evidenced by one of the following:<ul style="list-style-type: none"><li>○ Prior myocardial infarction</li><li>○ Prior stroke</li><li>○ Peripheral arterial disease (e.g., intermittent claudication with ankle-brachial index &lt;0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)</li></ul></li><li>• BMI greater than or equal to 27 kg/m<sup>2</sup></li></ul> <p><b><u>Obesity or Overweight</u></b></p> <ul style="list-style-type: none"><li>• Age 20 or younger</li><li>• BMI at or above the 95<sup>th</sup> percentile or 27kg/m<sup>2</sup>.</li><li>• Documentation of one of the following:<ul style="list-style-type: none"><li>○ Comorbidities (e.g., hypertension, dyslipidemia, fatty liver disease, depression, or sleep apnea).</li><li>○ Trial and failure of at least 3 months of a diet/exercise plan administered by a health care provider in the last 6 months.</li></ul></li><li>• The patient is, or will be, engaged in a weight management lifestyle modification program in addition to pharmacotherapy.</li></ul> <p><b><u>Metabolic Dysfunction-Associated Steatohepatitis</u></b></p>

	<ul style="list-style-type: none"> <li>• Clinical documentation of a diagnosis of MASH confirmed by one of the following: <ul style="list-style-type: none"> <li>○ FibroScan-aspartate aminotransferase (FAST)</li> <li>○ MRI-aspartate aminotransferase (MAST)</li> <li>○ Liver biopsy</li> </ul> </li> <li>• Submission of medical records showing disease is fibrosis stage F2 or F3 as confirmed by one of the following: <ul style="list-style-type: none"> <li>○ FibroScan</li> <li>○ Fibrosis-4 index (FIB-4)</li> <li>○ Magnetic resonance Elastography (MRE)</li> </ul> </li> <li>• Wegovy is being used as adjunct to lifestyle modification (e.g., dietary, or caloric restriction, exercise, behavioral support, community-based program).</li> <li>• None of the following are present: <ul style="list-style-type: none"> <li>○ Cirrhosis</li> <li>○ Viral hepatitis</li> <li>○ Ongoing significant alcohol use (e.g. more than 21 drinks per week)</li> </ul> </li> <li>• Presence of greater than or equal to 3 metabolic risk factors (e.g. obesity, hypertension, hypertriglyceridemia)</li> <li>• Member is currently treating 3 of the 5 metabolic risk factors (or treatment of at least 50% of the risk factors present) associated with MASH <ul style="list-style-type: none"> <li>○ Overweight or Obesity</li> <li>○ Hypertension</li> <li>○ Type 2 diabetes</li> <li>○ Hypertriglyceridemia</li> <li>○ Decreased level of high-density lipoprotein (HDL)</li> </ul> </li> </ul>
<b>Renewal Criteria</b>	<p><b>Secondary Prevention of Major Adverse Events (MACE):</b></p> <ul style="list-style-type: none"> <li>• Documentation of treatment success (BMI reduction of 5% or more).</li> <li>• Documentation of continuation of lifestyle modification program with reduced calorie diet and regular physical activity alongside continuous Wegovy use (80% adherence).</li> </ul> <p><b>Obesity or overweight:</b></p> <ul style="list-style-type: none"> <li>• Patient is less than 21 years old.</li> <li>• Documentation of at least a 1% decrease in BMI from baseline.</li> <li>• Patient is continuing full weight loss plan (e.g., diet and exercise program, nutritional counseling).</li> </ul>

	<p><b>Metabolic Dysfunction-Associated Steatohepatitis:</b></p> <ul style="list-style-type: none"> <li>Documentation of treatment success, e.g. lack of disease progression per fibrosis staging.</li> </ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>Coverage for weight loss is excluded for members aged 21 or older</li> <li>Use in combination with any other GLP-1 or GIP medication</li> </ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"> <li><b>Secondary Prevention of Major Adverse Events (MACE):</b> 12 years or older</li> <li><b>Obesity or overweight:</b> Age 12 to under 21 years of age</li> <li><b>Metabolic Dysfunction-Associated Steatohepatitis:</b> Age 18 or older</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li><b>Secondary Prevention of Major Adverse Events (MACE):</b> Cardiologist</li> <li><b>Metabolic Dysfunction-Associated Steatohepatitis:</b> Hepatologist or Gastroenterologist</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li><b>Secondary Prevention of Major Adverse Events (MACE):</b> <ul style="list-style-type: none"> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul> </li> <li><b>Obesity or overweight:</b> <ul style="list-style-type: none"> <li>Initial: 6 months</li> <li>Renewal: 12 months or until age 21, whichever is less</li> </ul> </li> <li><b>Metabolic Dysfunction-Associated Steatohepatitis:</b> <ul style="list-style-type: none"> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	1/1/2026
P&T Approval Date:	7/9/2024
P&T Revision Date:	11/11/2025, 7/9/2024, 5/13/2024

<b>References</b>
<ul style="list-style-type: none"> <li>Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk INC.; 2025.</li> </ul>

# Sirolimus Solution

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## Products Affected

- Sirolimus Oral Solution

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Patient is under age 10 or unable to use tablets</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

## References

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# Sodium Oxybate

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## Products Affected

- Sodium oxybate 500mg/mL

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Cataplexy and narcolepsy</li><li>○ Excessive somnolence due to narcolepsy</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Cataplexy and Narcolepsy</u></b></p> <ul style="list-style-type: none"><li>Confirmation of diagnosis of narcolepsy based on polysomnography AND a multiple sleep latency test with cataplexy</li><li>Trial and failure or contraindication to ALL the following<ul style="list-style-type: none"><li>○ SSRI antidepressant (e.g. fluoxetine)</li><li>○ SNRI antidepressant (e.g. venlafaxine or duloxetine)</li><li>○ Tricyclic antidepressant (e.g. clomipramine)</li></ul></li></ul> <p><b><u>Excessive Somnolence due to Narcolepsy</u></b></p> <ul style="list-style-type: none"><li>Confirmation of diagnosis of narcolepsy based on BOTH:<ul style="list-style-type: none"><li>○ Polysomnography</li><li>○ A multiple sleep latency test</li></ul></li><li>Baseline documentation of fatigue severity using a validated measure (e.g. Epworth score, Brief Fatigue Inventory, or other validated tool).</li><li>Trial and failure or contraindication to ALL the following:<ul style="list-style-type: none"><li>○ Modafinil (maximum recommended/tolerated dose)</li><li>○ At least 2 stimulant medications (amphetamine, methylphenidate, dextroamphetamine, etc.)</li><li>○ Sunosi (maximum recommended/tolerated dose)</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>Request for a continued maintenance dose within FDA approved limits based on indication.</li><li>Documented clinical efficacy and tolerability to therapy compared to baseline (for Epworth Sleepiness scale—improvement of at least 3 points is considered clinically significant).</li></ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>Currently pregnant or plan to conceive during treatment.</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>Age <math>\geq</math>7 years old and weight <math>\geq</math>20kg</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li><b>All diagnoses:</b> Sleep specialist, Neurologist, Pulmonologist</li></ul>

<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>All diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 3 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>
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Effective Date:	11/1/2025
P&T Approval Date:	9/9/2025
P&T Revision Date:	9/9/2025

<b>References</b>
<ul style="list-style-type: none"> <li>• Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; 2025</li> <li>• Steier et al. Recommendations for clinical management of excessive daytime sleepiness in obstructive sleep apnoea-A Delphi consensus study. <i>Sleep Med.</i> 2023 December;112:104-115.</li> <li>• Mehra R, et al. Current Management of Residual Excessive Daytime Sleepiness Due to Obstructive Sleep Apnea: Insights for Optimizing Patient Outcomes. <i>Neurol Ther</i> (2021) 10:661-672.</li> <li>• Servid and Shirley. Drug Class Review with New Drug Evaluation: Narcolepsy Agents. <i>Drug Use Research &amp; Management Program</i>. July 2029.</li> <li>• Epstein LJ, et al. Clinical Guideline for the Evaluation, Management, and Long-term Care of Obstructive Sleep Apnea in Adults. <i>Journal of Clinical Sleep Medicine</i>, Vol.5, No. 3, 2009.</li> </ul>

# Sodium-Glucose Co-Transporter 2 (Sglt2) Inhibitors

## Products Affected

- Farxiga Tablets
- Dapagliflozin Tablets
- Steglatro Tablets
- Jardiance Tablets
- Invokana Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Type 2 Diabetes</li><li>○ Chronic Kidney Disease</li><li>○ Heart Failure</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Type 2 Diabetes</b></p> <ul style="list-style-type: none"><li>• Trial and failure of, or contraindication to metformin</li><li>• Trial and failure of sulfonylurea or pioglitazone or contraindication to both</li></ul> <p><b>Chronic Kidney Disease</b></p> <ul style="list-style-type: none"><li>• Concurrent therapy with an ACEi or ARB at maximum tolerated doses, or documented contraindication to both</li><li>• Stage 2, 3, or 4 CKD or eGFR of 25 to 75 mL/min/1.73 m<sup>2</sup></li><li>• No previous use of dialysis</li><li>• No history of polycystic kidney disease, type 1 diabetes, lupus nephritis, or antineutrophil cytoplasmic antibody-associate vasculitis.</li></ul> <p><b>Heart Failure</b></p> <ul style="list-style-type: none"><li>• One of the following:<ul style="list-style-type: none"><li>○ All the following:<ul style="list-style-type: none"><li>▪ Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction (HFrEF)</li><li>▪ Documentation of concurrent use of ACEi, ARB, or ARNI, or contraindication to all</li><li>▪ Documentation of concurrent use of carvedilol, metoprolol succinate, or bisoprolol, or contraindication to all</li><li>▪ Documented eGFR &gt;30 mL/min/1.73m<sup>2</sup></li></ul></li><li>○ All of the following:<ul style="list-style-type: none"><li>▪ Diagnosis of heart failure with mildly reduced ejection fraction (HFmrEF), or heart failure with preserved ejection fraction (HFpEF)</li></ul></li></ul></li></ul>

	<ul style="list-style-type: none"><li>▪ eGFR &gt;30 mL/min/1.73m<sup>2</sup></li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: Lifetime</li></ul></li></ul>

Effective Date:	9/1/2024
P&T Approval Date:	3/8/2022
P&T Revision Date:	7/7/2024, 3/8/2022

References
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# Somatropin (Humatrop) (Somatotropin)

## Products Affected

- Humatrop Cartridge

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>Growth Hormone Deficiency (GHD)</li><li>Prader-Willi Syndrome</li><li>Noonan Syndrome</li><li>Turner Syndrome</li><li>Idiopathic Short Stature</li><li>Growth Failure secondary to chronic kidney disease (CKD)</li><li>Small for gestational age</li><li>Short stature homeobox-containing (SHOX) gene deficiency</li><li>HIV Associated Cachexia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>All Diagnoses</u></b></p> <ul style="list-style-type: none"><li>Documentation of goals of therapy and objective baseline assessment (e.g., quality of life, exercise capacity, height, body composition)</li></ul> <p><b><u>Patient Under Age 18</u></b></p> <ul style="list-style-type: none"><li>Confirmation of one of the following:<ul style="list-style-type: none"><li>Growth Hormone Deficiency (GHD) as noted by one of the following:<ul style="list-style-type: none"><li>Growth hormone deficiency is confirmed by a negative response to a growth hormone stimulation test (e.g., serum GH levels of &lt;5 ng/mL on stimulation testing with either of the following: glucagon or insulin)</li><li>Patient has had the pituitary removed or destroyed or has had panhypopituitarism since birth</li></ul></li><li>Diagnosis of Prader-Willi Syndrome and patient does not have concurrent severe obesity nor history of upper airway obstruction nor sleep apnea nor severe respiratory impairment</li><li>Diagnosis of Noonan Syndrome</li><li>Diagnosis of Turner Syndrome</li><li>Diagnosis of Idiopathic Short Stature</li><li>Diagnosis of Growth Failure secondary to chronic kidney disease (CKD)</li><li>Diagnosis of Small for gestational age</li></ul></li></ul>

	<ul style="list-style-type: none"> <li>○ Diagnosis of Short stature homeobox-containing (SHOX) gene deficiency</li> <li>○ Diagnosis of HIV Associated Cachexia</li> </ul> <p><b><u>Patients Aged 18 and Older</u></b></p> <ul style="list-style-type: none"> <li>● Confirmation of one of the following: <ul style="list-style-type: none"> <li>○ Confirmation of all the following: <ul style="list-style-type: none"> <li>■ Growth Hormone Deficiency (GHD) as noted by one of the following: <ul style="list-style-type: none"> <li>■ Growth hormone deficiency is confirmed by a negative response to a growth hormone stimulation test (e.g., serum GH levels of &lt;5 ng/mL on stimulation testing with either of the following: glucagon or insulin)</li> <li>■ Patient has had the pituitary removed or destroyed or has had panhypopituitarism since birth</li> <li>■ The prescriber certifies that the growth hormone is not being prescribed for anti-aging therapy or to enhance athletic ability or body building</li> </ul> </li> <li>○ HIV associated cachexia</li> <li>○ Short Bowel Syndrome (SBS)</li> </ul> </li> </ul> </li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>● Treatment with agent initiated in a patient prior to reaching adulthood (&lt;18 years of age) was to improve growth velocity or height and one of the following: <ul style="list-style-type: none"> <li>○ Growth velocity greater than 2.5 cm per year</li> <li>○ Growth velocity less than 2.5 cm per year</li> </ul> </li> <li>● Documentation that benefits of therapy continue to outweigh risks</li> <li>● Documentation of improvement from baseline as assessed by the prescribing provider</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>● <b>Under 18:</b> Pediatric Endocrinologist or Nephrologist</li> <li>● <b>18 and Older:</b> Endocrinologist</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>● <b>All Diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 12 months</li> <li>○ Renewal: up to 12 months</li> </ul> </li> </ul>

Effective Date:	4/1/2023
P&T Approval Date:	3/14/2023
P&T Revision Date:	3/14/2023

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<b>References</b>
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# Sotatercept (Winrevair)

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## Products Affected

- Winrevair Injection

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Pulmonary Arterial Hypertension (PAH)</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Pulmonary Arterial Hypertension (PAH)</b></p> <ul style="list-style-type: none"><li>• Diagnosis of symptomatic PAH (WHO Group 1 PH) confirmed by right heart catheterization.</li><li>• WHO functional class II or III symptoms.</li><li>• On a stable dose of both<ul style="list-style-type: none"><li>○ Endothelin-1 receptor antagonists (ERA) <b>and</b></li><li>○ Phosphodiesterase type 5 inhibitors <b>or</b> guanylate cyclase stimulant</li></ul></li><li>• Current PAH background therapies (ERA, PDE5i, etc.) will be continued unless not tolerated.</li><li>• Baseline platelet count &gt;500,000</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Pulmonary Arterial Hypertension:</b> Pulmonologist or Cardiologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Pulmonary Arterial Hypertension:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	11/1/2024
P&T Approval Date:	9/10/2024
P&T Revision Date:	9/10/2024

## References

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# Sparsentan (Filspari)

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## Products Affected

- Filspari Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Primary Immunoglobulin A Nephropathy.</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Primary Immunoglobulin A Nephropathy</b> <ul style="list-style-type: none"><li>• Urine protein-to-creatinine ratio (UPCR) <math>\geq</math> 1.5 and eGFR <math>\geq</math> 30 mL/min?1.73 m<sup>2</sup></li><li>• Biopsy-verified primary IgA nephropathy</li><li>• No history of kidney transplant and not currently receiving dialysis</li><li>• Member has failed to achieve a reduction in proteinuria to under 1 gram/day while receiving maximally tolerated doses of an ACE inhibitor or ARB for at least 12 weeks</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of improved or stable kidney function compared to baseline or reduction in proteinuria</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Age 18 or older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Primary Immunoglobulin A Nephropathy:</b> Nephrologist.</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Primary Immunoglobulin A Nephropathy:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023

<b>References</b>
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# Sumatriptan Nasal Spray Step Therapy

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## Products Affected

- Sumatriptan Nasal Spray

<b>Step Therapy Criteria</b>	<ul style="list-style-type: none"><li>• Trial and failure of<ul style="list-style-type: none"><li>○ Formulary triptan tablet</li></ul></li></ul>
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Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

# Suzetrigine (Journavx)

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## Products Affected

- Journavx tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Acute, moderate to severe pain</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Acute moderate to severe pain</u></b></p> <ul style="list-style-type: none"><li>• Clinical documentation of post-operative use following one of the following:<ul style="list-style-type: none"><li>○ Abdominoplasty</li><li>○ Bunionectomy</li></ul></li><li>• Documentation of one of the following:<ul style="list-style-type: none"><li>○ Diagnosis of opioid use disorder</li><li>○ Prescriber has a specific concern for opioid abuse.</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Not eligible for renewal, patients will need to meet initial criteria with new surgery to be eligible for a new prescription.</li></ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>• Use for more than 14 days.</li><li>• Any use outside of acute post-procedural pain.</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Age 18 or older.</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b><u>Acute moderate to severe pain:</u></b><ul style="list-style-type: none"><li>○ Initial: 14 days</li><li>○ Renewal: N/A</li></ul></li></ul>

Effective Date:	7/1/2025
P&T Approval Date:	5/13/2025
P&T Revision Date:	5/13/2025

## References

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- Journavx (suzetrigine) [Package Insert]. Vertex Pharmaceuticals, Inc; Boston, MA: 2025. Accessed at: [https://pi.vrtx.com/files/uspi\\_suzetrigine.pdf](https://pi.vrtx.com/files/uspi_suzetrigine.pdf).
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# Synthroid Step Therapy

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## Products Affected

- Synthroid

<b>Step Therapy Criteria</b>	<ul style="list-style-type: none"><li>• Trial and failure of<ul style="list-style-type: none"><li>○ Generic levothyroxine</li></ul></li></ul>
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Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

# Tacrolimus Ointment

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## Products Affected

- Tacrolimus 0.1% Ointment
- Tacrolimus 0.03% Ointment

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Atopic Dermatitis</li><li>○ Psoriasis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Atopic Dermatitis</b></p> <ul style="list-style-type: none"><li>• Clinical documentation of diagnosis of moderate to severe atopic dermatitis<ul style="list-style-type: none"><li>○ At least 10% of body surface area involved</li><li>○ Hand, foot, face, or mucous membrane involvement</li></ul></li><li>• Trial and failure of all the following (or a reason they are not appropriate):<ul style="list-style-type: none"><li>○ High potency topical steroids</li><li>○ UVB phototherapy</li></ul></li></ul> <p><b>Psoriasis</b></p> <ul style="list-style-type: none"><li>• Diagnosis of moderate to severe psoriasis as indicated by a validated tool such as the Dermatology Life Quality Index and one of the following:<ul style="list-style-type: none"><li>○ At least 10% of body surface area involved</li><li>○ Hand, foot, face, or mucous membrane involvement</li></ul></li><li>• Trial and failure of all the following (or a reason they are not appropriate):<ul style="list-style-type: none"><li>○ High potency topical steroids</li><li>○ UVB phototherapy</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	

P&T Revision Date: [ ]

**References**

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# Tazarotene

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## Products Affected

- Tazarotene 0.1% Cream

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Psoriasis</li><li>○ Acne</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Psoriasis</b></p> <ul style="list-style-type: none"><li>• Diagnosis of moderate to severe psoriasis as indicated by a validated tool such as the Dermatology Life Quality Index and one of the following:<ul style="list-style-type: none"><li>○ At least 10% of body surface area involved</li><li>○ Hand, foot, face, or mucous membrane involvement</li></ul></li></ul> <p><b>Acne</b></p> <ul style="list-style-type: none"><li>• Confirmation that the diagnosis is one of the following:<ul style="list-style-type: none"><li>○ Above the line (severe acne)</li><li>○ The member is under the 21 and acne is substantially interfering with daily life</li></ul></li><li>• Trial and Failure of at least 2 other formulary alternatives used to treat acne</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	3/1/2023
P&T Approval Date:	1/10/2023
P&T Revision Date:	1/10/2023

<b>References</b>
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# Tenofovir Alafenamide (Descovy)

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## Products Affected

- Descovy Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Treatment of HIV Infection</li><li>○ Pre-Exposure Prophylaxis of HIV Infection (PrEP)</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Treatment of HIV Infection</u></b></p> <ul style="list-style-type: none"><li>• Clinical contraindication to generic Truvada</li><li>• Documentation that the drug will be used in combination with other HIV drugs as part of a complete treatment regimen</li></ul> <p><b><u>Pre-Exposure Prophylaxis of HIV Infection (PrEP)</u></b></p> <ul style="list-style-type: none"><li>• Clinical contraindication to generic Truvada</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: Lifetime</li></ul></li></ul>

Effective Date:	9/1/2024
P&T Approval Date:	7/11/2024
P&T Revision Date:	7/11/2024

## References

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# Testosterone

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## Products Affected

- Testosterone 1% Gel (25mg & 50mg)
- Testosterone 1% Gel pump

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Gender Dysphoria.</li><li>○ AIDS Wasting Syndrome.</li><li>○ Post-Menopausal Breast Cancer.</li><li>○ Hypogonadism.</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Gender Dysphoria</u></b></p> <ul style="list-style-type: none"><li>• Diagnosis of gender dysphoria</li><li>• Trial and failure or contraindication to injectable testosterone</li></ul> <p><b><u>AIDS Wasting Syndrome</u></b></p> <ul style="list-style-type: none"><li>• Diagnosis of AIDS wasting syndrome</li><li>• Trial and failure or contraindication to injectable testosterone</li></ul> <p><b><u>Post-Menopausal Breast Cancer</u></b></p> <ul style="list-style-type: none"><li>• Diagnosis of post-menopausal breast cancer</li><li>• Trial and failure or contraindication to injectable testosterone</li></ul> <p><b><u>Hypogonadism</u></b></p> <ul style="list-style-type: none"><li>• Diagnosis of hypogonadism</li><li>• Trial and failure or contraindication to injectable testosterone</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Gender Dysphoria, AIDS Wasting Syndrome, Post-Menopausal Breast Cancer:</b><ul style="list-style-type: none"><li>○ Initial: Lifetime</li></ul></li><li>• <b>Hypogonadism:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	7/1/2024
P&T Approval Date:	9/13/2022
P&T Revision Date:	5/14/2024, 9/13/2022

References
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# Tezacaftor-Ivacaftor (Symdeko)

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## Products Affected

- Symdeko Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.<ul style="list-style-type: none"><li>○ Cystic Fibrosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Cystic Fibrosis</u></b> <ul style="list-style-type: none"><li>• Documentation of cystic fibrosis diagnosis with homozygous F508del mutation</li><li>• Not used in combination with other CFTR modulator treatments</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 1 years of age and older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Cystic Fibrosis:</b> Pulmonologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Cystic Fibrosis:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	05/01/2025
P&T Approval Date:	05/01/2021
P&T Revision Date:	09/01/2021, 03/11/2025

<b>References</b>
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# Thickener (Thick-It)

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## Products Affected

- Thick-It
- Thick-It #2

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Swallowing Disorder</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Swallowing Disorder</u></b></p> <ul style="list-style-type: none"><li>• Documented swallowing study/evaluation for the treatment of swallowing disorder due to one of the following medical conditions:<ul style="list-style-type: none"><li>○ Diagnosis of dysphagia which negatively impacts the ability to swallow</li><li>○ Chronic diseases such as, but not limited to, Parkinson's, dementia, reflux disease, stroke, neuromuscular disease/disorder, and spinal cord injury</li><li>○ Treatment of head, neck, or throat cancer</li><li>○ Documented aspiration of food or liquid associated with chronic illness or disease</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of appointment in the last 12 months confirming effectiveness of the requested thickener and continued need</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Swallowing Disorder:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	1/1/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

## References

- Oregon administrative rule 410-148-0260 (7)(a)(A-D)(b)

# Tiagabine

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## Products Affected

- Tiagabine Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Partial (Focal) Seizures</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>Partial Seizures</u></b> <ul style="list-style-type: none"><li>• Confirmation of diagnosis of Partial Seizures</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Partial Seizures:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

## References

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# Ticagrelor

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## Products Affected

- Ticagrelor tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Acute Coronary Syndrome</li><li>○ Minor Ischemic Stroke</li><li>○ Etc.</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Acute Coronary Syndrome</b></p> <ul style="list-style-type: none"><li>• Member has:<ul style="list-style-type: none"><li>○ Either non-ST-elevation acute coronary syndrome (NSTE-ACS) or ST-elevation myocardial infarction (STEMI) AND</li><li>○ Has had percutaneous coronary intervention (PCI) AND</li><li>○ Has a contraindication to prasugrel</li></ul></li></ul> <p>OR</p> <ul style="list-style-type: none"><li>• Member has NSTE-ACS and is treated with medical therapy alone (has not had PCI)</li></ul> <p><b>Minor Ischemic Stroke</b></p> <ul style="list-style-type: none"><li>• Member has had a minor non-cardioembolic ischemic stroke (NIHSS score <math>\leq 5</math>) in the immediate past</li><li>• Did not receive IV alteplase</li><li>• Has a reason that clopidogrel can't be used</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• <b>Acute Coronary Syndrome:</b> Documentation of positive clinical response to therapy and continued need for treatment</li><li>• <b>Minor ischemic stroke:</b> Renewal not appropriate</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 18 years of age and older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Acute Coronary Syndrome:</b> Cardiologist</li><li>• <b>Minor Ischemic Stroke:</b> Cardiologist, Neurologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Acute Coronary Syndrome:</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li><li>• <b>Minor Ischemic Stroke:</b><ul style="list-style-type: none"><li>○ Initial: 1 month</li><li>○ Renewal: N/A</li></ul></li></ul>

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Effective Date:	9/1/2025
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P&T Revision Date:	7/8/2025, 7/11/2023

## References

- Brilinta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2024.
- Rao SV, et al. 2025 ACC/AHA/ ACEP/NAEMSP/SCAI guideline for the management of patients with acute coronary syndromes: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2025;85(22):2135-2237.
- Powers WJ, et al.; on behalf of the American Heart Association Stroke Council. Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2019;50:e344–e418

# Tobramycin Solution

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## Products Affected

- Tobramycin Nebulization Solution

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Cystic Fibrosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Cystic Fibrosis</u></b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of cystic fibrosis</li></ul> <p><b><u>All Other Diagnoses</u></b></p> <ul style="list-style-type: none"><li>• Confirmed diagnosis of an FDA approved or compendia supported indication</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Confirmed diagnosis with clinical evidence supporting chronic use</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>Cystic Fibrosis:</b> Prescribed by or in consultation with Infectious Disease Specialist, Pulmonologist, or Cystic Fibrosis Specialist</li><li>• <b>All Other Diagnoses:</b> Prescribed by or in consultation with Infectious Disease Specialist, or Pulmonologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Cystic Fibrosis:</b><ul style="list-style-type: none"><li>○ Initial: Lifetime</li></ul></li><li>• <b>All Other Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	1/1/2025
P&T Approval Date:	11/12/2024
P&T Revision Date:	11/12/2024

## References

- Mogayzel, Jr, PJ, et al. Cystic Fibrosis Foundation Pulmonary Guidelines. Pharmacologic Approaches to Prevention and Eradication of Initial *Pseudomonas aeruginosa* Infection. *AnnalsATS* 2014; 11(10): 1640-1650.

- Mogayzel, Jr, PJ, et al. Cystic Fibrosis Foundation Pulmonary Guidelines. Chronic Medications for Maintenance of Lung Health. *Am J Respir Crit Care Med* 2013; 18 (7): 680–689.

# Tocilizumab (Actemra, Tyenne)

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## Products Affected

- Actemra Prefilled Syringe
- Actemra ActPen
- Tyenne Prefilled Syringe
- Tyenne Auto-Injector
- Tyenne IV Solution

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Juvenile Idiopathic Arthritis</li><li>○ Rheumatoid Arthritis</li><li>○ Giant Cell Arteritis</li><li>○ Systemic Sclerosis-Associated Interstitial Lung Disease</li><li>○ Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>All diagnoses</u></b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy.</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic or Otezla.</li></ul> <p><b><u>Juvenile Idiopathic Arthritis (JIA)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features</li><li>• One of the following:<ul style="list-style-type: none"><li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li><li>○ Documented trial and failure of the following:<ul style="list-style-type: none"><li>▪ NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND</li><li>▪ At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids</li></ul></li></ul></li><li>• Documented intolerance or contraindication to oral disease-modifying antirheumatic drugs (DMARD) such as methotrexate, leflunomide, etc. or DMARDs will be continued</li><li>• Trial and failure of both infliximab and adalimumab</li></ul>

	<p><b><u>Rheumatoid Arthritis (RA):</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)</li> <li>• One of the following: <ul style="list-style-type: none"> <li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li> <li>○ Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine</li> </ul> </li> <li>• Trial and failure of both infliximab and adalimumab</li> </ul> <p><b><u>Giant Cell Arteritis:</u></b></p> <ul style="list-style-type: none"> <li>• Clinical documentation confirming diagnosis of Giant Cell Arteritis</li> <li>• Trial and failure of glucocorticoid treatment</li> </ul> <p><b><u>Systemic Sclerosis-Associated Interstitial Lung Disease:</u></b></p> <ul style="list-style-type: none"> <li>• Confirmed diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD)</li> <li>• Trial and failure of mycophenolate mofetil</li> </ul> <p><b><u>Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy:</u></b></p> <ul style="list-style-type: none"> <li>• Member will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>• <b>Juvenile Idiopathic Arthritis:</b> Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.</li> <li>• <b>Rheumatoid Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>• <b>Giant Cell Arteritis:</b> Demonstrated positive clinical response to therapy.</li> <li>• <b>Systemic Sclerosis-Associated Interstitial Lung Disease:</b> Demonstrated positive clinical response to therapy.</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Giant Cell Arteritis:</b> Rheumatologist</li> <li>• <b>Systemic Sclerosis-Associated Interstitial Lung Disease:</b> Rheumatologist or Pulmonologist</li> <li>• <b>Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy:</b> Oncologist or Hematologist</li> </ul>

<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>● <b>Cytokine Release Syndrome:</b><ul style="list-style-type: none"><li>○ Initial: 2 months</li><li>○ Renewal: N/A</li></ul></li><li>● <b>All Other Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: 12 months</li></ul></li></ul>
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Effective Date:	9/1/2024
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/9/2024, 7/11/2023

<b>References</b>
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# Tofacitinib (Xeljanz)

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## Products Affected

- Xeljanz XR tablets
- Xeljanz Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Ankylosing Spondylitis/Axial Spondyloarthritis</li><li>○ Juvenile Idiopathic Arthritis</li><li>○ Psoriatic Arthritis</li><li>○ Rheumatoid Arthritis</li><li>○ Ulcerative Colitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:<ul style="list-style-type: none"><li>○ Back pain and stiffness for more than 3 months AND</li><li>○ Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND</li><li>○ BASDAI score of <math>\geq 4</math></li></ul></li><li>• One of the following:<ul style="list-style-type: none"><li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li><li>○ Documented failure of conventional therapy with both of the following:<ul style="list-style-type: none"><li>■ At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND</li><li>■ Physical therapy/exercise program</li></ul></li></ul></li><li>• Trial and failure of infliximab and adalimumab</li><li>• Trial and failure of Cosentyx and Taltz</li></ul> <p><b><u>Juvenile Idiopathic Arthritis (JIA)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement) or JIA without active systemic features</li><li>• One of the following:<ul style="list-style-type: none"><li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li></ul></li></ul>

- Documented trial and failure of the following:
  - NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
  - At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, or systemic corticosteroids
- Documented intolerance or contraindication to DMARDs OR DMARD will be continued with Xeljanz.
- Trial and failure of infliximab and adalimumab
- Trial and failure of Actemra and Orencia

**Psoriatic Arthritis (PsA):**

- Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:
  - Psoriasis (1 point for personal or family history, 2 points for current)
  - Psoriatic nail dystrophy
  - Negative test result for RF
  - Dactylitis (current or history)
  - Radiological evidence of juxta-articular new bone formation
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of conventional therapy with both of the following:
    - NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
    - Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine.
- Trial and failure of infliximab and adalimumab
- Trial and failure of ustekinumab, Cosentyx, Otezla, Orencia, and Taltz

**Rheumatoid Arthritis (RA):**

- Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine
- Trial and failure of infliximab and adalimumab

	<ul style="list-style-type: none"> <li>• Trial and failure of Actemra, Cimzia, Kineret, Orencia, and rituximab</li> </ul> <p><b><u>Ulcerative Colitis (UC):</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of moderate-to-severe ulcerative colitis</li> <li>• One of the following: <ul style="list-style-type: none"> <li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li> <li>○ Documented trial and failure of at least 1 of the following: mesalamine, sulfasalazine, mercaptopurine, azathioprine, or corticosteroids (prednisone, methylprednisolone).</li> </ul> </li> <li>• Trial and failure of infliximab and adalimumab</li> <li>• Trial and failure of ustekinumab and Entyvio</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>• <b>Ankylosing Spondylitis/Axial Spondyloarthritis:</b> Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.</li> <li>• <b>Juvenile Idiopathic Arthritis:</b> Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.</li> <li>• <b>Psoriatic Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>• <b>Rheumatoid Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>• <b>Ulcerative Colitis:</b> Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Ankylosing Spondylitis, Axial Spondyloarthritis:</b> Rheumatologist.</li> <li>• <b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist.</li> <li>• <b>Juvenile Idiopathic Arthritis:</b> Rheumatologist</li> <li>• <b>Rheumatoid Arthritis:</b> Rheumatologist.</li> <li>• <b>Ulcerative Colitis:</b> Gastroenterologist.</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>All Diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023

P&T Revision Date: 7/11/2023, 1/11/2022

**References**

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# Topical Antifungal Agents

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## Products Affected

- Ciclopirox 8% Solution
- Econazole 1% Cream
- Selenium Sulfide 2.5% Lotion
- Ketoconazole 2% Cream and Shampoo

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>All Diagnoses</b></p> <ul style="list-style-type: none"><li>• All the following have been tried and failed or are not appropriate for use:<ul style="list-style-type: none"><li>○ Clotrimazole 1% cream</li><li>○ Miconazole 2% (cream, aerosol, or powder),</li><li>○ Terbinafine 1%, cream, terbinafine tablets</li><li>○ Nystatin 100,000 units/gram (ointment, cream, or powder)</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response to therapy</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023, 1/11/2022

## References

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# Toujeo Step Therapy

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## Products Affected

- Toujeo Max Solostar
- Toujeo Solostar

<b>Step Therapy Criteria</b>	<ul style="list-style-type: none"><li>• Trial and failure of<ul style="list-style-type: none"><li>○ Any non-concentrated basal insulin product</li></ul></li></ul>
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Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

# Tranexamic Acid

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## Products Affected

- Tranexamic Acid Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>Hemophilia – Hemorrhage Prophylaxis; Tooth Extraction</li><li>Menorrhagia</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Hemophilia – Hemorrhage Prophylaxis</u></b></p> <ul style="list-style-type: none"><li>Documentation that use is intended for hemorrhage prophylaxis for tooth extraction</li></ul> <p><b><u>Menorrhagia</u></b></p> <ul style="list-style-type: none"><li>Documentation of abnormal uterine bleeding</li><li>Trail and failure of, current use of, or contraindication to all of the following:<ul style="list-style-type: none"><li>Combined Oral Contraceptive therapy</li><li>Progestin therapy (oral or LM) or Levonorgestrel IUD</li><li>NSAID therapy</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>Documentation of positive clinical response to therapy</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li><b>Hemorrhage Prophylaxis:</b> Hematologist, Hemophilia Specialist, Dentist</li><li><b>Menorrhagia:</b> Gynecologist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li><b>All Diagnoses:</b><ul style="list-style-type: none"><li>Initial: 12 months</li><li>Renewal: 12 months</li></ul></li></ul>

Effective Date:	7/1/2024
P&T Approval Date:	5/14/2024
P&T Revision Date:	5/14/2024

<b>References</b>
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# Tretinoin, Topical

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## Products Affected

- Tretinoin **0.025% cream**
- Tretinoin **0.05% cream**
- Tretinoin **0.1% cream**
- Tretinoin **0.01% gel**
- Tretinoin **0.025% gel**

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Acne</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b>Acne</b> <ul style="list-style-type: none"><li>• Documentation of trial and failure, intolerance, or contraindication to a topical product containing benzoyl peroxide.</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documentation of positive clinical response to therapy.</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All Diagnosis</b><ul style="list-style-type: none"><li>○ Initial: 12 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	02/01/2023
P&T Approval Date:	01/10/2023
P&T Revision Date:	01/10/2023

# Ubrogepant (Ubrelvy)

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## Products Affected

- Ubrelvy tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>Treatment of acute migraine</li><li>○</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Acute Migraine</b></p> <ul style="list-style-type: none"><li>Confirmed diagnosis of migraine</li><li>Documentation showing the member is currently on preventative therapy</li><li>Trial and failure (defined as at least 6 weeks per agent) of:<ul style="list-style-type: none"><li>○ At least 3 oral formulary triptans used at up to the maximally indicated dosing and in combination with NSAID therapy (e.g. naproxen).</li></ul></li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>Documented positive clinical response to therapy</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>18 years of age or older</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li><b>Acute Migraine:</b> Neurologist or headache specialist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li><b>Acute Migraine:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal: 12 months</li></ul></li></ul>

Effective Date:	9/1/2025
P&T Approval Date:	5/9/2023
P&T Revision Date:	7/8/2025, 5/9/2023

## References

- Ubrelvy [package insert]. North Chicago, IL: Abbvie Inc; 2025.

# Upadacitinib (Rinvoq)

## Products Affected

- Rinvoq Tablets
- Rinvoq LQ Solution

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>Ankylosing Spondylitis/Axial Spondyloarthritis</li><li>Atopic Dermatitis</li><li>Crohn's Disease</li><li>Psoriatic Arthritis</li><li>Rheumatoid Arthritis</li><li>Ulcerative Colitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)</u></b></p> <ul style="list-style-type: none"><li>Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:<ul style="list-style-type: none"><li>Back pain and stiffness for more than 3 months AND</li><li>Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND</li><li>BASDAI score of &gt;=4</li></ul></li><li>One of the following:<ul style="list-style-type: none"><li>The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li><li>Documented failure of conventional therapy with both of the following:<ul style="list-style-type: none"><li>At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND</li><li>Physical therapy/exercise program</li></ul></li></ul></li><li>Trial and failure of infliximab and adalimumab</li><li>Trial and failure of Cosentyx and Taltz</li></ul> <p><b><u>Atopic Dermatitis</u></b></p> <ul style="list-style-type: none"><li>Diagnosed with severe atopic dermatitis defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) <math>\geq 11</math> or Children's Dermatology Life Quality Index (CDLQI) <math>\geq 13</math> (or severe score on another validated tool)</li><li>One or more of the following:<ul style="list-style-type: none"><li>At least 10% of body surface area involvement</li><li>Hand, foot, or mucous membrane involvement</li></ul></li></ul>

- Documented contraindication or failed trial to ALL of the following:
  - Moderate-high potency corticosteroid (e.g., clobetasol, fluocinonide, fluticasone)
  - Topical calcineurin inhibitor (e.g. tacrolimus)
  - Oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil) **OR** the member is oral corticosteroid dependent.
- Failure of Dupixent

**Crohn's Disease (CD)**

- Documentation of moderate-to-severe Crohn's Disease
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of at least 1 of the following: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate.
- Trial and failure of infliximab and adalimumab
- Trial and failure of ustekinumab, Cimzia, and Entyvio

**Psoriatic Arthritis (PsA):**

- Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:
  - Psoriasis (1 point for personal or family history, 2 points for current)
  - Psoriatic nail dystrophy
  - Negative test result for RF
  - Dactylitis (current or history)
  - Radiological evidence of juxta-articular new bone formation
- One of the following:
  - The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR
  - Documented trial and failure of conventional therapy with both of the following:
    - NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
    - Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine.
- Trial and failure of infliximab and adalimumab
- Trial and failure of ustekinumab, Cosentyx, Otezla, Orencia, and Taltz

**Rheumatoid Arthritis (RA):**

	<ul style="list-style-type: none"> <li>Documentation of a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)</li> <li>One of the following: <ul style="list-style-type: none"> <li>The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li> <li>Documented trial and failure of nonbiologic DMARD therapy: methotrexate (dosed at least 20mg per week for at least 8 weeks), leflunomide or sulfasalazine</li> </ul> </li> <li>Trial and failure of infliximab and adalimumab</li> <li>Trial and failure of Actemra, Cimzia, Kineret, Orencia, and rituximab</li> </ul> <p><b><u>Ulcerative Colitis (UC):</u></b></p> <ul style="list-style-type: none"> <li>Documentation of moderate-to-severe ulcerative colitis</li> <li>One of the following: <ul style="list-style-type: none"> <li>The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li> <li>Documented trial and failure of at least 1 of the following: mesalamine, sulfasalazine, mercaptopurine, azathioprine, or corticosteroids (prednisone, methylprednisolone).</li> </ul> </li> <li>Trial and failure of infliximab and adalimumab</li> <li>Trial and failure of ustekinumab and Entyvio</li> </ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li><b>Ankylosing Spondylitis/Axial Spondyloarthritis:</b> Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.</li> <li><b>Atopic Dermatitis:</b> Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement.</li> <li><b>Crohn's Disease:</b> Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.</li> <li><b>Psoriatic Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li><b>Rheumatoid Arthritis:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> </ul>

	<ul style="list-style-type: none"> <li>• <b>Ulcerative Colitis:</b> Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Ankylosing Spondylitis, Axial Spondyloarthritis:</b> Rheumatologist.</li> <li>• <b>Atopic Dermatitis:</b> Dermatologist.</li> <li>• <b>Crohn's Disease and Ulcerative Colitis:</b> Gastroenterologist.</li> <li>• <b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist.</li> <li>• <b>Rheumatoid Arthritis:</b> Rheumatologist.</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>All Diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	9/1/2023
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/11/2023, 1/11/2022

<b>References</b>
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# Ustekinumab

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## Products Affected

- Selarsdi
- Yesintek
- Steqeyma

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Crohn's Disease</li><li>○ Plaque Psoriasis</li><li>○ Psoriatic Arthritis</li><li>○ Ulcerative Colitis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>All diagnoses</u></b></p> <ul style="list-style-type: none"><li>• Initial testing for latent TB and treatment, if necessary, before starting treatment.</li><li>• No current active infection at initiation of therapy.</li><li>• Risks and benefits documented in cases of chronic or recurrent infection.</li><li>• Will NOT be used in combination with another biologic or Otezla</li></ul> <p><b><u>Crohn's Disease (CD)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of moderate-to-severe Crohn's Disease</li><li>• One of the following:<ul style="list-style-type: none"><li>○ The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR</li><li>○ Documented trial and failure of at least 1 of the following: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate</li></ul></li><li>• Trial and failure of both infliximab and adalimumab</li></ul> <p><b><u>Plaque Psoriasis (PP)</u></b></p> <ul style="list-style-type: none"><li>• Documentation of severe plaque psoriasis, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) AND one or more of the following:<ul style="list-style-type: none"><li>○ At least 10% of body surface area involved</li><li>○ Hand, foot, face, or mucous membrane involvement</li></ul></li></ul>

- The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of all the following:
  - High-potency topical corticosteroids (augmented betamethasone, clobetasol, etc.)
  - At least one other topical agent (calcipotriene, tazarotene, anthralin, tar, etc.)
  - PUVA or UVB Phototherapy
  - Methotrexate
  - At least 1 other second line systemic agent such as cyclosporine or acitretin
- Trial and failure of both infliximab and adalimumab

#### **Psoriatic Arthritis (PsA)**

- Documentation of psoriatic arthritis based on at least 3 out of 5 of the following:
  - Psoriasis (1 point for personal or family history, 2 points for current)
  - Psoriatic nail dystrophy
  - Negative test result for RF
  - Dactylitis (current or history)
  - Radiological evidence of juxta-articular new bone formation
- The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of conventional therapy with both of the following:
  - NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, AND
  - Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine
- Trial and failure of both infliximab and adalimumab

#### **Ulcerative Colitis (UC)**

- Documentation of moderate-to-severe ulcerative colitis
- The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of at least 1 of the following:
  - Mesalamine, sulfasalazine OR
  - Mercaptopurine, azathioprine, OR
  - Corticosteroids (prednisone, methylprednisolone)
- Trial and failure of both infliximab and adalimumab

<b>Renewal Criteria</b>	<ul style="list-style-type: none"> <li>• <b>CD:</b> Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.</li> <li>• <b>PP:</b> Evidence of positive clinical response to therapy as evidenced by ONE of the following: reduction of body surface area (BSA) involvement from baseline, improvement in symptoms (e.g. pruritus, inflammation) from baseline, or evidence of functional improvement.</li> <li>• <b>PsA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>• <b>UC:</b> Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.</li> </ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>• Not to be used in combination with other biologics for the same indication.</li> </ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"> <li>• <b>Crohn's Disease and Ulcerative Colitis:</b> Gastroenterologist.</li> <li>• <b>Plaque Psoriasis:</b> Dermatologist.</li> <li>• <b>Psoriatic Arthritis:</b> Dermatologist or Rheumatologist.</li> </ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"> <li>• <b>All diagnoses:</b> <ul style="list-style-type: none"> <li>○ Initial: 6 months</li> <li>○ Renewal: 12 months</li> </ul> </li> </ul>

Effective Date:	5/1/2025
P&T Approval Date:	7/11/2023
P&T Revision Date:	3/11/2025, 7/11/2023, 1/11/2022

<b>References</b>
<ul style="list-style-type: none"> <li>• Selarsdi [package insert]. Parsippany, NJ: Teva Pharmaceuticals; 2025.</li> <li>• Yesintek [package insert]. Cambridge, MA: Biocon Biologics; 2024.</li> <li>• Steqeyma [package insert]. Jersey City, NJ: Celltrion USA Inc.; 2024.</li> </ul>

# Valacyclovir Step Therapy

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## Products Affected

- Valacyclovir tablets

<b>Step Therapy Criteria</b>	<ul style="list-style-type: none"><li>• Trial and failure of<ul style="list-style-type: none"><li>○ Acyclovir tablets</li></ul></li></ul>
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Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

# Vanzacaftor-tezacaftor-deutivacaftor (Alyftrek)

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## Products Affected

- Alyftrek Tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.<ul style="list-style-type: none"><li>○ Cystic Fibrosis</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b><u>Cystic Fibrosis</u></b></p> <ul style="list-style-type: none"><li>• Presence of at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA):<ul style="list-style-type: none"><li>○ F508del mutation</li><li>○ A mutation in the CFTR gene that is responsive based on clinical, in vitro, or extrapolated data.</li></ul></li><li>• Not to be used in combination with other CFTR modulator treatments</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Demonstrated positive clinical response to therapy.</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• Age 6 and older.</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• Pulmonologist or Specialist affiliated with a CF care center.</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• Initial: 6 months</li><li>• Renewal: 12 months</li></ul>

Effective Date:	05/01/2025
P&T Approval Date:	03/11/2025
P&T Revision Date:	03/11/2025

## References

- Alyftrek [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; 2025.

# Vonoprazan (Voquezna)

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## Products Affected

- Voquezna 10mg and 20mg tablets

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Erosive esophagitis</li><li>○ H. Pylori infection</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<p><b>Erosive Esophagitis</b></p> <ul style="list-style-type: none"><li>• Imaging confirmed LA Classification Grade C/D erosive esophagitis AND</li><li>• Documented contraindication, intolerance, or inadequate response to 2 or more PPIs (i.e., lansoprazole, omeprazole, esomeprazole, etc.) at maximum tolerated twice-daily dosing for at least 8 weeks each.</li></ul> <p><b>H. Pylori Infection</b></p> <ul style="list-style-type: none"><li>• Confirmed H. pylori positive infection</li><li>• Documented contraindication, intolerance, or inadequate response to:<ul style="list-style-type: none"><li>○ Standard first-line therapies for H.pylori infection<ul style="list-style-type: none"><li>■ PPI + clarithromycin + (amoxicillin or metronidazole)</li><li>■ Bismuth quadruple therapy</li></ul></li></ul></li><li>• Co-prescribed with antibiotics</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Renewals past the initial approved timelines are not allowed</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• 18 years of age or older.</li></ul>
<b>Prescriber Restriction</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b> Gastroenterologist or Infectious Disease specialist</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>Initial healing of erosive esophagitis:</b><ul style="list-style-type: none"><li>○ Initial: 2 months</li><li>○ Renewal: n/a</li></ul></li><li>• <b>Maintenance of healing of erosive esophagitis:</b><ul style="list-style-type: none"><li>○ Initial: 6 months</li><li>○ Renewal: n/a</li></ul></li><li>• <b>H. Pylori infection:</b><ul style="list-style-type: none"><li>○ Initial: 14 days</li><li>○ Renewal: n/a</li></ul></li></ul>

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Effective Date:	3/1/2024
P&T Approval Date:	1/9/2024
P&T Revision Date:	1/9/2024

References
<ul style="list-style-type: none"><li>• Voquezna [package insert]. Buffalo Grove, IL: Phathom Pharmaceuticals; 2022.</li></ul>

# Voriconazole

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## Products Affected

- Voriconazole tablets
- Voriconazole suspension

<b>Covered Uses</b>	<ul style="list-style-type: none"><li>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design<ul style="list-style-type: none"><li>○ Treatment of invasive aspergillosis</li><li>○ Treatment of serious fungal infections</li></ul></li></ul>
<b>Required Medical Information and Criteria</b>	<b><u>All diagnoses</u></b> <ul style="list-style-type: none"><li>• Documentation of one of the approved conditions</li></ul>
<b>Renewal Criteria</b>	<ul style="list-style-type: none"><li>• Documented positive clinical response and continued need</li></ul>
<b>Age Restriction</b>	<ul style="list-style-type: none"><li>• <b>Suspension only:</b> Member is under age 10 or unable to use tablets</li></ul>
<b>Coverage Duration</b>	<ul style="list-style-type: none"><li>• <b>All diagnoses:</b><ul style="list-style-type: none"><li>○ Initial: 3 months</li><li>○ Renewal: 3 months</li></ul></li></ul>

Effective Date:	5/1/2024
P&T Approval Date:	3/12/2024
P&T Revision Date:	3/12/2024

## References

- Vfend [package insert]. New York, NY: Pfizer.; 2025.

# Zafirlukast Step Therapy

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## Products Affected

- Zafirlukast tablets

<b>Step Therapy Criteria</b>	<input type="radio"/> Trial and failure of montelukast
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Effective Date:	9/1/2025
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P&T Revision Date:	7/8/2025