

## **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 11/01/2025. 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.** Pharmacy Services is available Monday through Friday, from 8 a.m. to 5 p.m.

## **Abatacept (Orencia)**

## **Products Affected**

• Orencia PFS

• Orencia Clickjet

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not</li> </ul>
	otherwise excluded by plan design
	<ul> <li>Juvenile Idiopathic Arthritis</li> </ul>
	<ul> <li>Psoriatic Arthritis</li> </ul>
	<ul> <li>Rheumatoid Arthritis</li> </ul>
Required Medical	All diagnoses
Information and	<ul> <li>Initial testing for latent TB and treatment, if necessary, before starting</li> </ul>
Criteria	treatment.
	<ul> <li>No current active infection at initiation of therapy.</li> </ul>
	Risks and benefits documented in cases of chronic or recurrent
	infection.
	Will NOT be used in combination with another biologic or Otezla
	This is a sea in combination with another prologic or otolic
	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
	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> <li>NSAIDs for 3 months at maximum recommended or tolerated anti- inflammatory dose unless contraindicated</li> </ul>
	<ul> <li>At least 6 months of 2 of Methotrexate, leflunomide, sulfasalazine,</li> </ul>
	hydroxychloroquine, or systemic corticosteroids
	Documented intolerance or contraindication to DMARDs OR DMARD
	will be continued
	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:
	<ul> <li>Psoriasis (1 point for personal or family history, 2 points for</li> </ul>
	current)
	Psoriatic nail dystrophy
L	

	Negative test result for RF
	Dactylitis (current of history)
	<ul> <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</li> <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> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
	Di anno ancid Anthritis (DA)
	<ul> <li>Rheumatoid Arthritis (RA)</li> <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> </ul>
	<ul> <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> </ul>
	Trial and failure of both infliximab and adalimumab
Renewal Criteria	<ul> <li>JIA: 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>PsA: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> </ul>
	• <b>RA:</b> Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
Exclusion Criteria	and on onen joint oddin.
Age Restriction	
Prescriber Restriction	<ul> <li>Psoriatic Arthritis: Dermatologist or Rheumatologist</li> <li>Rheumatoid Arthritis, Juvenile Idiopathic Arthritis: Rheumatologist</li> </ul>
Coverage Duration	All diagnoses     Initial: 6 months     Renewal: 12 months

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

## **Acne Combo Products**

## **Products Affected**

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

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Acne vulgaris</li> </ul>
Required Medical	Acne Vulgaris
Information and	Documentation of trial and failure, intolerance, or contraindication to
Criteria	clindamycin/benzoyl peroxide 1.2-5% gel
Renewal Criteria	Documentation of positive clinical response to therapy
<b>Exclusion Criteria</b>	
Age Restriction	
Prescriber	
Restriction	
Coverage Duration	Initial: 12 months
	Renewal: 12 months

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

## **Adalimumab**

#### **Products Affected**

- Adalimumab-adaz 40mg/0.4mL, 80mg/0.8mL (auto-injector and prefilled syringe)
- Adalimuimab-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

#### **Covered Uses**

- All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
  - Ankylosing Spondylitis/Axial Spondyloarthritis
  - Crohn's Disease
  - o Hidradenitis Suppurativa
  - Juvenile Idiopathic Arthritis
  - Plaque Psoriasis
  - Psoriatic Arthritis
  - Rheumatoid Arthritis
  - Ulcerative Colitis
  - Uveitis

### Required Medical Information and Criteria

### All diagnoses

- Initial testing for latent TB and treatment, if necessary, before starting treatment.
- No current active infection at initiation of therapy.
- Risks and benefits documented in cases of chronic or recurrent infection.
- Will NOT be used in combination with another biologic or Otezla.

#### Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)

- 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
- 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 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: 6mercaptopurine, 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
  - o 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:

- o At least 10% of body surface area involved
- o 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 of history)
  - o 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:

- 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

### **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).

#### **Uveitis:**

- Documentation of non-infectious, intermediate-, posterior- or panuveitis
- Documented trial and failure of all the following:
  - Topical glucocorticoids for at least 1 month OR periocular steroid injection, and
  - o Oral corticosteroids, and
  - At least one of the following: mycophenolate, tacrolimus, cyclosporine, azathioprine, or methotrexate

### **Renewal Criteria**

- Ankylosing Spondylitis/Axial Spondyloarthritis: Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.
- **Crohn's Disease:** Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.
- Hidradenitis Suppurativa: Evidence of a reduction of 25% or more of the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas.
- Juvenile Idiopathic Arthritis: Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.
- Plaque Psoriasis: 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.
	Psoriatic Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	Rheumatoid Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	Ulcerative Colitis: Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.
	Uveitis: 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.
Prescriber Restriction	<ul> <li>Crohn's Disease and Ulcerative Colitis: Gastroenterologist.</li> <li>Hidradenitis Suppurativa and Plaque Psoriasis: Dermatologist.</li> <li>Psoriatic Arthritis: Dermatologist or Rheumatologist.</li> <li>Rheumatoid Arthritis, Juvenile Idiopathic Arthritis: Rheumatologist.</li> <li>Ankylosing Spondylitis, Axial Spondyloarthritis: Rheumatologist.</li> <li>Uveitis: Ophthalmologist or Rheumatologist.</li> </ul>
Coverage Duration	<ul> <li>All diagnoses:</li> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul>

Effective Date:	11/01/2023
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P&T Revision Date:	07/11/2023

## Alpelisib (Vijoice)

## **Products Affected**

• Vijoice tab

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>PIK3CA-related overgrowth spectrum (PROS)</li> </ul>
Required Medical	PIK3CA-related overgrowth spectrum (PROS)
Information and	Confirmed diagnosis of PROS
Criteria	At least one severe clinical manifestation of PROS
	A PIK3CA mutation that is confirmed by genetic testing.
Renewal Criteria	<ul> <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>	
Age Restriction	Two years of age and older
Prescriber Restriction	Prescribed by or in consultation with a provider who specializes in treatment of genetic disorders.
Coverage Duration	Initial: 24 weeks
	Renewal: 6 months

Effective Date:	10/01/2022
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P&T Revision Date:	09/13/2022

## **Anakinra (Kineret)**

## **Products Affected**

• Kineret 100MG/0.67ML

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Rheumatoid Arthritis</li> </ul>
Required Medical Information and Criteria	<ul> <li>All Diagnoses</li> <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>
	<ul> <li>Rheumatoid Arthritis (RA)</li> <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>
Renewal Criteria	Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
<b>Exclusion Criteria</b>	
Age Restriction	
Prescriber Restriction	Rheumatoid Arthritis: Rheumatologist.
Coverage Duration	Rheumatoid Arthritis     Initial: 6 months     Renewal: 12 months

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

## **Apremilast (Otezla)**

## **Products Affected**

• Otezla tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Plaque Psoriasis</li> <li>Psoriatic Arthritis</li> </ul>
Required Medical	All Diagnoses
Information and	<ul> <li>Initial testing for latent TB and treatment, if necessary, before starting</li> </ul>
Criteria	treatment.
Officeria	
	No current active infection at initiation of therapy.
	Risks and benefits documented in cases of chronic or recurrent
	infection.
	Will NOT be used in combination with another biologic
	<ul> <li>Plaque Psoriasis</li> <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> <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> <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:</li></ul></li></ul>

	Psoriatic Arthritis
	Documentation of psoriatic arthritis based on at least 3 out of 5 of the
	following:
	<ul> <li>Psoriasis (1 point for personal or family history, 2 points for</li> </ul>
	current)
	<ul> <li>Psoriatic nail dystrophy</li> </ul>
	<ul> <li>Negative test result for RF</li> </ul>
	<ul> <li>Dactylitis (current or history)</li> </ul>
	One of the following:
	<ul> <li>The member is transitioning to the requested treatment from a</li> </ul>
	different biologic product previously approved by the plan OR
	Documented trial and failure of all the following:
	NSAIDs for 3 months at maximum recommended or tolerated      satisfactory does upleas assets indicated.
	<ul> <li>anti-inflammatory dose unless contraindicated</li> <li>Methotrexate or other DMARD such as leflunomide,</li> </ul>
	sulfasalazine, or cyclosporine
	Trial and failure of both infliximab and adalimumab
	- marana ranare or both inniximab and adaminamab
Renewal Criteria	Plaque Psoriasis: 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.
	improvement.
	Psoriatic Arthritis: Evidence of a 20% or greater improvement in tender
	joint count and swollen joint count.
<b>Exclusion Criteria</b>	
Age Restriction	
Prescriber	Plaque Psoriasis: Dermatologist.
Restriction	Psoriatic Arthritis: Dermatologist or Rheumatologist.
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Coverage Duration	All diagnoses:     Initials Companies.
	<ul><li>Initial: 6 months</li><li>Renewal: 12 months</li></ul>
	o Renewal: 12 months
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Effective Date:	09/01/2023
P&T Approval Date:	07/11/2023
P&T Revision Date:	07/11/2023, 01/11/2022

## **Aprepitant (Emend)**

## **Products Affected**

• Aprepitant Capsule

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <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>
Required Medical	Prevention of chemotherapy induced nausea and vomiting
Information and	Documentation of patient receiving treatment with a moderate to
Criteria	highly emetogenic chemotherapy agent.
	Documentation patient is receiving concurrent treatment with all the
	following:
	<ul> <li>IV or oral ondansetron, granisetron or palonosetron</li> </ul>
	<ul> <li>Dexamethasone</li> </ul>
Renewal Criteria	Positive clinical response to therapy
<b>Exclusion Criteria</b>	
Age Restriction	
Prescriber	
Restriction	
<b>Coverage Duration</b>	Initial: 12 months
	Renewal: 12 months

Effective Date:	10/01/2021
P&T Approval Date:	09/14/2021
P&T Revision Date:	09/14/2021

## **Asthma Triple Combination Inhaler Step Therapy**

## **Products Affected**

• Trelegy

• Breztri

Step Therapy	Trial and failure of at least 4 weeks of 2 of the following	
Criteria	<ul> <li>A Long-Acting Beta Agonist (LABA)</li> </ul>	
	<ul> <li>An Inhaled Corticosteroid (ICS)</li> </ul>	
	<ul> <li>A Long-Acting Muscarinic Antagonist (LAMA)</li> </ul>	

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

## **Atovaquone-proguanil (MALARONE)**

## **Products Affected**

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

Covered Uses  All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design  Prevention of malaria infection  Treatment of malaria infection:  Travel to a location where CDC recommends the use of atovaquone-proguanil  Clinical contraindication to doxycycline OR doxycycline is not recommended by CDC for the travel location.  Treatment of malaria infection:  Recommended by the CDC  Renewal Criteria  Age Restriction  Refer to FDA label  Coverage Duration  Prevention of malaria infection:  Initial: 3  Renewal: N/A  Treatment of malaria infection:  Initial: 1		
Prevention of malaria infection:   Travel to a location where CDC recommends the use of atovaquone-proguanil   Clinical contraindication to doxycycline OR doxycycline is not recommended by CDC for the travel location.   Treatment of malaria infection:   Recommended by the CDC	Covered Uses	otherwise excluded by plan design  O Prevention of malaria infection
o Travel to a location where CDC recommends the use of atovaquone-proguanil	D ' 134 !' I	
Criteria  proguanil  Clinical contraindication to doxycycline OR doxycycline is not recommended by CDC for the travel location.  Treatment of malaria infection: Recommended by the CDC  Renewal Criteria  N/A  Age Restriction Refer to FDA label  Coverage Duration Prevention of malaria infection: Initial: 3 Renewal: N/A  Treatment of malaria infection: Initial: 1	I -	
Clinical contraindication to doxycycline OR doxycycline is not recommended by CDC for the travel location.  Treatment of malaria infection: Recommended by the CDC  Renewal Criteria N/A  Refer to FDA label  Overage Duration Prevention of malaria infection: Initial: 3 Renewal: N/A  Treatment of malaria infection: Initial: 1		<ul> <li>Travel to a location where CDC recommends the use of atovaquone-</li> </ul>
recommended by CDC for the travel location.  Treatment of malaria infection:  Recommended by the CDC  Renewal Criteria  N/A  Age Restriction  Refer to FDA label  Coverage Duration  Prevention of malaria infection:  Initial: 3  Renewal: N/A  Treatment of malaria infection:  Initial: 1	Criteria	proguanil
recommended by CDC for the travel location.  Treatment of malaria infection:  Recommended by the CDC  Renewal Criteria  N/A  Age Restriction  Refer to FDA label  Coverage Duration  Prevention of malaria infection:  Initial: 3  Renewal: N/A  Treatment of malaria infection:  Initial: 1		Clinical contraindication to doxycycline <b>OR</b> doxycycline is not
Renewal Criteria  N/A  Age Restriction  Refer to FDA label  Coverage Duration  Prevention of malaria infection:  Initial: 3  Renewal: N/A  Treatment of malaria infection:  Initial: 1		
Renewal Criteria  N/A  Age Restriction  Refer to FDA label  Coverage Duration  Prevention of malaria infection:  Initial: 3  Renewal: N/A  Treatment of malaria infection:  Initial: 1		Treatment of malaria infection:
Renewal Criteria  Age Restriction  Coverage Duration  Prevention of malaria infection:  Initial: 3  Renewal: N/A  Treatment of malaria infection:  Initial: 1		
Age Restriction  Coverage Duration  Prevention of malaria infection:  Initial: 3  Renewal: N/A  Treatment of malaria infection:  Initial: 1		Recommended by the CDC
Overage Duration  O Initial: 3 O Renewal: N/A  Treatment of malaria infection: O Initial: 1	Renewal Criteria	N/A
<ul> <li>Initial: 3</li> <li>Renewal: N/A</li> <li>Treatment of malaria infection:</li> <li>Initial: 1</li> </ul>	Age Restriction	Refer to FDA label
<ul> <li>Renewal: N/A</li> <li>Treatment of malaria infection:         <ul> <li>Initial: 1</li> </ul> </li> </ul>	Coverage Duration	Prevention of malaria infection:
<ul> <li>Treatment of malaria infection:</li> <li>Initial: 1</li> </ul>		o Initial: 3
<ul> <li>Treatment of malaria infection:</li> <li>Initial: 1</li> </ul>		O Renewal: N/A
o Initial: 1		
		Treatment of malaria infection:
		o Initial: 1
o Renewal: N/A		D 1 N/4

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

## **Baricitinib (OLUMIANT)**

## **Products Affected**

• Olumiant tablet

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Rheumatoid Arthritis (RA)</li> </ul>
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Required Medical	All diagnoses:
Information and Criteria	<ul> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> </ul>
	No current active infection at initiation of therapy.
	Risks and benefits documented in cases of chronic or recurrent infection.
	Will NOT be used in combination with another biologic or Otezla
	Rheumatoid Arthritis (RA):
	<ul> <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> </ul>
	<ul> <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> </ul>
	Trial and failure of both infliximab and adalimumab
	Trial and failure of Actemra, Cimzia, Kineret, Orencia, and rituximab
Renewal Criteria	Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
<b>Exclusion Criteria</b>	
Prescriber Restriction	Rheumatoid Arthritis: Rheumatologist
Coverage Duration	Rheumatoid Arthritis
	o Initial: 6 months
	Renewal: 12 months
	o nemerical removals

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

## **Bedaquiline (Sirturo)**

## **Products Affected**

• Sirturo Tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Pulmonary Tuberculosis</li> </ul>
Required Medical	Pulmonary Tuberculosis
Information and Criteria	<ul> <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> </ul>
	Sirturo is prescribed as part of a guideline recommended multi-drug treatment regimen.
Renewal Criteria	Renewal not appropriate
Exclusions	<ul> <li>Medication is being received though a county clinic with a state funded TB program.</li> </ul>
Age Restriction	5 years of age and older.
Prescriber Restriction	Pulmonary Tuberculosis: Infectious Disease
Coverage Duration	Pulmonary Tuberculosis:
	o Initial: 24 weeks
	o Renewal: N/A

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)**

## **Products Affected**

• Rezurock tablet

Covered Uses	All Food and Drug Administration (FDA)-approved indications not
	otherwise excluded by plan design
	<ul> <li>Chronic graft-versus-host disease</li> </ul>
Required Medical	Chronic graft-versus-host disease
Information and	Trial and failure of at least two prior lines of systemic therapy for
Criteria	cGVHD
	Not currently taking Imbruvica (ibrutinib)
Renewal Criteria	Documented positive clinical response to therapy
<b>Exclusion Criteria</b>	
Age Restriction	12 years of age or older
Prescriber	cGVHD: oncologist or transplant specialist
Restriction	
<b>Coverage Duration</b>	• cGVHD:
	o Initial: 3 months
	o Renewal: 6 months

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

## **Bempedoic acid (Nexletol/Nexlizet)**

## **Products Affected**

Nexletol tablet

Nexlizet tablet

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Clinical ASCVD</li> <li>Primary or familial hyperlipidemia</li> </ul>
Required Medical	Clinical ASCVD
Information and Criteria	<ul> <li>Documentation of very high risk ASCVD as evidenced by either:</li> <li>History of multiple major ASCVD events</li> </ul>
	One major ASCVD event AND multiple high-risk conditions
	Documentation of a current LDL greater than or equal to 55 mg/dl
	<ul> <li>Documentation of all the following         <ul> <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>
	Documentation of failure of PCSK9 inhibitor (Repatha or Prluent)
	Primary or familial hyperlipidemia
	Documentation of an untreated (i.e., prior to lipid lowering therapy) LDL greater than 190 mg/dL
	<ul> <li>Documentation of current LDL greater than 100 mg/dL</li> <li>Documentation of all the following</li> </ul>
	<ul> <li>Patient is receiving maximally tolerated statin therapy (atorvastatin 40-80mg, rosuvastatin 20-40mg) or has a documented clinical intolerance to statins</li> </ul>
	<ul> <li>Is receiving ezetimibe or has a documented intolerance to ezetimibe.</li> </ul>
	Documentation of failure of PCSK9 inhibitor (Repatha or Prluent)
Renewal Criteria	Documented positive clinical response to therapy (significant decrease in lipid levels).
<b>Exclusion Criteria</b>	
Age Restriction	
Prescriber	ASCVD & Primary or familial hyperlipidemia: Cardiologist,
Restriction	Endocrinologist, or lipid specialist

<b>Coverage Duration</b>	ASCVD & Primary or familial hyperlipidemia:
	<ul> <li>Initial: 6 months</li> </ul>
	<ul> <li>Renewal: 12 months</li> </ul>

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

## Bimekizumab (Bimzelx)

#### **Products Affected**

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

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

## **Covered Uses** All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design Plaque Psoriasis Psoriatic Arthritis Ankylosing Spondylitis/Axial Spondyloarthritis o Hidradenitis Suppurativa Required Medical **Plaque Psoriasis** Information and Defined as having functional impairment as indicated by Dermatology Criteria Life Quality Index (DLQI) = 11 or Children's Dermatology Life Quality Index (CDLQI) = 13 (or severe score on other validated tool) One or more of the following: At least 10% of body surface area involved Hand, foot, face, or mucous membrane involvement The patient on a current biologic product and experiencing intolerable side effects The patient tried and failed or have contraindications to ALL of 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 Trial and failure of Cosentyx and ustekinumab **Psoriatic Arthritis** Documentation of psoriatic arthritis based on at least 3 out of 5 of the following: o Psoriasis (1 point for personal or family history, 2 points for current) Psoriatic nail dystrophy

- Negative test result for RF
- Dactylitis (current of history)
- o 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 antiinflammatory 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:
  - o 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:
  - o 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

Renewal Criteria	Plaque Psoriasis: 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.
	Psoriatic Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	Ankylosing Spondylitis/Axial Spondyloarthritis: Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.
	Hidradenitis Suppurativa: Evidence of a reduction of 25% or more of the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas.
Exclusion Criteria	Not to be used in combination with other biologics for the same indication
Age Restriction	Refer to FDA label
Prescriber	Plaque Psoriasis, Hidradenitis Suppurativa: Dermatologist.
Restriction	Psoriatic Arthritis: Dermatologist or Rheumatologist.
	Ankylosing Spondylitis, Axial Spondyloarthritis: Rheumatologist.
Coverage Duration	o Initial: 6 months
	Renewal: 12 months

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

### References

- Bimzelx (bimekizumab-bkzx). Prescribing Information. UCB, Inc. Smyrna, GA 2024.
- 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.
- 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.

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

## **Buprenorphine Patch (Butrans)**

## **Products Affected**

• Buprenorphine Patch

Required Medical Information and Criteria	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design         <ul> <li>Cancer or End-of-life Care</li> <li>Other Chronic Pain</li> </ul> </li> <li>Cancer or End-of-life Care         <ul> <li>Patient is being treated for cancer related pain or pain associated with end-of-life</li> </ul> </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>
	<ul> <li>Other Chronic Pain</li> <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>
Renewal Criteria Coverage Duration	<ul> <li>Documented positive clinical response to therapy</li> <li>Cancer or End-of-Life Care:         <ul> <li>Initial: 12 months</li> <li>Renewal: 12 months</li> </ul> </li> <li>Other Chronic Pain:         <ul> <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)

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Migraine prophylaxis</li> <li>Cluster headache (Emgality only)</li> </ul>
Required Medical	Migraine Prophylaxis
Information and	Documentation showing member experiences at least 4 migraines per
Criteria	month.
	<ul> <li>For members with chronic migraine (≥ 15 headache days &amp; 8 migraine episodes per month) Trial and failure of at least 8 weeks of:         <ul> <li>3 or more prophylactic medications from at least 2 of the following classes:</li></ul></li></ul>
	CGRP inhibitor.
	Cluster Headache
	The request is for Emgality 300mg dose
	The member does not have any of the following exclusions:
	<ul> <li>ECG abnormalities compatible with an acute CV event,</li> </ul>
	<ul> <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>

	<ul> <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> <li>Verapamil</li> <li>Topiramate</li> </ul> </li> <li>The requested treatment will not be used in combination with another CGRP inhibitor.</li> </ul>
Age Restriction Prescriber Restriction	Migraine Prophylaxis:     Reduction in monthly headache days by at least 2 days from pre-CGRP treatment baseline     Clinical documented improvement in migraine-related disability     Cluster Headache     Documented positive clinical response to therapy     18 years of age and older     Migraine Prophylaxis and Cluster Headache: Prescribed by or in consultation with a neurologist
Coverage Duration	<ul> <li>Migraine Prophylaxis:         <ul> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul> </li> <li>Cluster Headache:         <ul> <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

- 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.
- Ailani J., et al. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61:1021-1039.

• 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.

## **Cenegermin (Oxervate)**

## **Products Affected**

• Oxervate Ophthalmic

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Neurotrophic Keratitis</li> </ul>
Required Medical	Neurotrophic Keratitis
Information and	<ul> <li>Confirmed diagnosis of stage 2 or 3 neurotrophic keratitis.</li> </ul>
Criteria	Trial and failure of at least one ocular lubricant used for at least 2 weeks.
Renewal Criteria	Maximum treatment duration of 8 weeks. Renewal is not allowed.
Prescriber Restriction	Neurotrophic Keratitis: Ophthalmologist
Coverage Duration	Neurotrophic Keratitis:
	o Initial: 8 weeks
	o Renewal: N/A

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)

## **Products Affected**

• Cimzia PFS

• Cimzia Auto-injector

<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <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> </ul>
<ul><li>Psoriatic Arthritis (PsA)</li><li>Rheumatoid Arthritis (RA)</li></ul>
Required Medical All diagnoses
Information and • Initial testing for latent TB and treatment, if necessary, before starting
<b>Criteria</b> treatment
No current active infection at initiation of therapy
Risks and benefits documented in cases of chronic or recurrent
infection
Will NOT be used in combination with another biologic or Otezla
Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)
<ul> <li>Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by</li> </ul>
<ul> <li>Back pain and stiffness for more than 3 months</li> </ul>
<ul> <li>Signs of active inflammation on MRI</li> </ul>
<ul> <li>Radiological evidence of sacroilitis OR HLA-B27 positive</li> <li>BASDAI score of &gt;=4</li> </ul>
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
<ul> <li>Physical therapy/exercise program</li> <li>Trial and failure of both infliximab and adalimumab</li> </ul>
That and range of both inniximab and adailmumab
Crohn's Disease (CD)
Documentation of moderate-to-severe Crohn's Disease

- 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: 6mercaptopurine, azathioprine, corticosteroid, methotrexate
- Trial and failure of both 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
- The member is transitioning to the requested treatment from a different biologic product previously approved by the plan OR documented failure of the following:
  - NSAIDs for 3 months at maximum recommended or tolerated antiinflammatory 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
- Trial and failure of both infliximab and adalimumab

### Plaque Psoriasis (PsO)

- 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)
- · One or more of the following
  - At least 10% of body surface area involved
  - Hand, foot, face, or mucous membrane involvement
- 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 of history)
  - o 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 antiinflammatory dose unless contraindicated
  - 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)
- 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
- Trial and failure of both infliximab and adalimumab

#### **Renewal Criteria**

- AS/SpA: Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.
- **CD:** Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.

	<ul> <li>JIA: 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>Ps0: 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>PsA: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>RA: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> </ul>
Fuelusian Onitania	and swonen joint count.
<b>Exclusion Criteria</b>	
Age Restriction	
Prescriber	Ankylosing Spondylitis/Axial Spondyloarthritis: Rheumatologist.
Restriction	Crohn's Disease: Gastroenterologist
	Juvenile Idiopathic Arthritis: Rheumatologist
	Plaque Psoriasis: Dermatologist
	Psoriatic Arthritis: Dermatologist or Rheumatologist
	Rheumatoid Arthritis: Rheumatologist
Coverage Duration	All diagnoses:
	o Initial: 6 months
	Renewal: 12 months
1	O Renetial IZ IIIOIIIII

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

# **Chloroquine Phosphate**

#### **Products Affected**

• Chloroquine tablet

Covered Uses	All Food and Drug Administration (FDA)-approved indications not
	otherwise excluded by plan design
	<ul> <li>Treatment of malaria</li> </ul>
	<ul> <li>Extraintestinal amebiasis</li> </ul>
	<ul> <li>Prevention of malarial infection</li> </ul>
Required Medical	Prevention of malaria infection:
Information and	Travel to a location where CDC recommends the use of chloroquine
Criteria	T
	Treatment of malaria
	Confirmed diagnosis of Malaria
	Extraintestinal amebiasis
	Confirmed diagnosis of amebiasis
Renewal Criteria	N/A
<b>Coverage Duration</b>	Treatment of malaria & extraintestinal amebiasis:
	o Initial: 3 months
	o Renewal: N/A

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

# **Cinacalcet Hydrochloride**

#### **Products Affected**

• Cinacalcet tablet

Required Medical Information and Criteria	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design     Treatment of secondary hyperparathyroidism in patients with CKD on dialysis     Treatment of hypercalcemia in patients with parathyroid carcinoma.     Treatment of severe hypercalcemia in patients with primary hyperparathyroidism  Secondary hyperparathyroidism in patients with CKD     Confirmed diagnosis of secondary hyperparathyroidism in patients with CKD on dialysis.  Hypercalcemia in patients with parathyroid carcinoma     Confirmed diagnosis of hypercalcemia in patients with parathyroid carcinoma  Severe hypercalcemia in patients with primary hyperparathyroidism     Confirmed diagnosis of severe hypercalcemia in patients with primary
	Confirmed diagnosis of severe hypercalcemia in patients with primary
	hyperparathyroidism who are unable to undergo parathyroidectomy
Renewal Criteria	Documented positive clinical response to therapy
Age Restriction	18 years of age and older
Coverage Duration	All diagnoses:
	o Initial: 12 months
	Renewal: 12 months

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

### Clobazam (Onfi)

#### **Products Affected**

• Clobazam tablets

• Clobazam suspension

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Lennox-Gastaut Syndrome</li> <li>Refractory Seizures</li> </ul>
	- Kernadiory delizated
Required Medical	Lennox-Gastaut Syndrome
Information and	Confirmation of diagnosis
Criteria	Suspension only: Member under age 10 or unable to use tablets
	Refractory Seizures
	Documentation showing appropriate trial of 2 or more tolerated anticonvulsant therapies
	Suspension only: Member under age 10 or unable to use tablets
Renewal Criteria	Documentation of positive clinical response to therapy
Age Restriction	Age 2 or older
	Suspension only: Member under age 10 or unable to use tablets
Prescriber	All Diagnoses: Neurologist
Restriction	<b>3</b>
Coverage Duration	All Diagnoses:
	o Initial: 12 months
	o Renewal: Lifetime

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**

#### **Products Affected**

• Clotrimazole Troche

Step Therapy Criteria	<ul> <li>Trial and failure of</li> <li>Formulary nystatin</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
- Ziextenzo Syringe

#### **Covered Uses**

- All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
  - Bone Marrow/Stem Cell Transplant
  - Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
  - Febrile Neutropenia Prophylaxis
  - Treatment of High-Risk Febrile Neutropenia
  - Severe Chronic Neutropenia
  - Acute Radiation Syndrome
  - o Human Immunodeficiency Virus (HIV) Related Neutropenia

#### Required Medical Information and Criteria

#### **Bone Marrow/Stem Cell Transplant**

- One of the following
  - Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)
  - Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
  - Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

#### **Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy**

- Diagnosis of acute myeloid leukemia (AML)
- Patient has completed induction or consolidation chemotherapy

#### Febrile Neutropenia Prophylaxis

- Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:
  - Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer.
  - Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown.

	Patient is receiving chemotherapy regimen(s) associated with
	greater than 20% incidence of FN.
	<ul> <li>Patient is receiving chemotherapy regimen(s) associated with 10-</li> </ul>
	20% incidence of FN and has one or more risk factors associated
	with chemotherapy induced infection, FN, or neutropenia.
	<ul> <li>Patient is receiving myelosuppressive anticancer drugs associated</li> </ul>
	with neutropenia and has a history of FN or dose-limiting event
	during a previous course of chemotherapy (secondary prophylaxis).
	Treatment of High-Risk Febrile Neutropenia
	Patient has received or is receiving myelosuppressive anticancer drugs
	associated with neutropenia.
	Diagnosis of febrile neutropenia (FN).
	Patient is at high risk for infection-associated complications.
	and the state of t
	Severe Chronic Neutropenia (SCN)
	<ul> <li>For patients with severe chronic neutropenia (SCN) (i.e., congenital,</li> </ul>
	cyclic, and idiopathic neutropenias with chronic absolute neutrophil
	count [ANC] less than or equal to 500 cells/mm^3)
	Acute Radiation Syndrome (ARS)
	Patient was/will be acutely exposed to myelosuppressive doses of
	radiation cells/mm^3)
	Human Immunodeficiency Virus (HIV) Related Neutropenia
	Patient is infected with HIV virus.
	ANC less than or equal to 1,000 (cells/mm3).
	And less than of equal to 1,000 (cells/filling).
Renewal Criteria	Renewal criteria
Prescriber	HIV Related Neutropenia: Hematologist, Oncologist, or Infectious
Restriction	Disease Specialist
	All Other Diagnoses: Hematologist or Oncologist
Coverage Duration	Severe Chronic Neutropenia:
	o Initial: 12 months
	o Renewal: 12 months
	Acute Radiation Syndrome:
	o Initial: 1 month
	o Renewal: N/A
	All other Diagnoses
	All other Diagnoses:

<ul> <li>Initial: 3 months or duration of therapy</li> <li>Renewal: 3 months or duration of therapy</li> </ul>

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)

#### **Products Affected**

• All compounded medications

Covered Uses	•	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	·	I diagnoses  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.  Each active ingredient in the compounded drug is FDA-approved or national compendia supported for the condition being treated.  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.  If any prescription ingredients require prior authorization and/or step therapy, all drug-specific criteria must be also met.  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:  Patient has a contraindication to all commercially available products.  No other therapeutic alternatives are commercially available.  Prepared strength(s) is/are not commercially available or currently in short supply and the strength is medically necessary.  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).  Patient has an allergy or sensitivity to inactive ingredients (e.g. dyes, preservatives, sugars, etc.) that are found in commercially available products.
Renewal Criteria	•	Documented positive clinical response to therapy
Coverage Duration	•	All diagnoses:
		o Initial: 6 months

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

Renewal: 12 months

### **Conjugated Estrogens (Premarin Tablets)**

#### **Products Affected**

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

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and	<ul> <li>All FDA indicated or guideline supported diagnoses</li> <li>Trial and failure of generic estradiol tablets and patches</li> </ul>
Criteria Coverage Duration	All FDA indications     Initial: Lifetime

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

# Conjugated estrogens and medroxyprogesterone acetate (Prempro/Premphase)

#### **Products Affected**

• Prempro

Premphase

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical	All FDA indicated or guideline supported diagnoses
Information and	One of the following:
Criteria	<ul> <li>Trial and failure of generic combination products</li> </ul>
	<ul> <li>Estradiol tablets/patches used in combination with</li> </ul>
	medroxyprogesterone capsules.
<b>Coverage Duration</b>	All FDA indications:
	o Initial: Lifetime

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

### **Continuous Glucose Monitors (CGM)**

#### **Products Affected**

• Dexcom G6/G7

• Freestyle Libre 2/3

Covered Uses	All Food and Drug Administration (FDA)-approved indications not
	otherwise excluded by plan design
	<ul> <li>Type 1 Diabetes Mellitus</li> </ul>
	o Type 2 Diabetes
	<ul> <li>Gestational Diabetes</li> </ul>
Required Medical	Type 1 Diabetes Mellitus
Information and	One of the following:
Criteria	<ul> <li>Use of continuous insulin infusion via pump</li> </ul>
	<ul> <li>Child or adolescent under the age of 21</li> </ul>
	<ul> <li>Member is pregnant or plans to become pregnant within 6 months</li> </ul>
	<ul> <li>Using short or intermediate acting insulin</li> </ul>
	The criteria listed under "applies to all requests" has been met.
	Type 2 Diabetes Mellitus OR Gestational Diabetes
	Using short or intermediate acting insulin
	The criteria listed under "applies to all requests" has been met.
	Applies to all requests
	Must meet at least one of the following:
	<ul> <li>Baseline HbA1c levels greater than or equal to 8%</li> </ul>
	<ul> <li>Frequent or severe hypoglycemia</li> </ul>
	<ul> <li>Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM)</li> </ul>
	,
	<ul> <li>Diabetes related complications (e.g. peripheral neuropathy, end- organ damage, etc.)</li> </ul>
	<ul> <li>Member has received or will receive diabetes education specific to the use of the CGM device.</li> </ul>
	** If the request is for a <b>Dexcom</b> one of the following criteria must apply:
	Use of an insulin pump compatible with the requested Dexcom and not Freestyle
	<ul> <li>Pediatric member under the age of 16 years old</li> </ul>
	Inability to use preferred Freestyle CGM device
Renewal Criteria	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
	The time of mot follow up visit (within 5 6 months) and provider visits

	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>	All diagnoses:
	o Initial: 6 months
	o Renewal: 12 months

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

### **Cyclosporine Oral**

#### **Products Affected**

- Cyclosporine capsules
- Cyclosporine solution

• Cyclosporine Modified capsules

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Solid Organ Transplant</li> <li>Rheumatoid Arthritis</li> <li>Psoriasis</li> </ul>
Required Medical	All diagnoses
Information and	Documentation of an FDA approved indication
Criteria	
Renewal Criteria	Documented positive clinical response to therapy
Age Restriction	Liquid only: Member is under age 10 or unable to use
	tablets/capsules.
<b>Coverage Duration</b>	All diagnoses:
	o Initial: 12 months
	o Renewal: 12 months

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)**

#### **Products Affected**

• Cyclosporine 0.05% emulsion

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	<ul> <li>Dry eye syndrome or keratoconjunctivitis sicca for EPSDT members</li> </ul>
Required Medical Information and Criteria	<ul> <li>Dry Eye Syndrome or Keratoconjunctivitis Sicca for members under age 21</li> <li>Clinically documented trial and failure of both:         <ul> <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> <li>Eliminated or</li> <li>Contributing agents are medically necessary.</li> </ul> </li> </ul>
	<ul> <li>Dry Eye Syndrome or Keratoconjunctivitis Sicca for members age 21 or older</li> <li>Documented clinical evidence of a funded (above the line) comorbid condition for which the following applies:         <ul> <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> <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> <li>Eliminated or</li> <li>Contributing agents are medically necessary.</li> </ul> </li> </ul>
Renewal Criteria	Clinical documentation of efficacy.
Age Restriction	16 years of age or older.
Coverage Duration	<ul> <li>All diagnoses:</li> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul>

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**

#### **Products Affected**

 Deferasirox 125MG, 250MG, 500MG tablets

	T
Covered Uses	All Food and Drug Administration (FDA)-approved indications not
	otherwise excluded by plan design
	<ul> <li>Chronic iron overload due to blood transfusion</li> </ul>
	<ul> <li>Non-transfusion-dependent thalassemia syndromes</li> </ul>
Required Medical	Chronic iron overload due to blood transfusion
Information and	One of the following:
Criteria	<ul> <li>A creatinine clearance of greater than or equal to 40 mL/minute</li> </ul>
	<ul> <li>Serum creatinine less than or equal to 2 times the age-appropriate</li> </ul>
	level
	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)
	Patient has had a failure or contraindication to deferoxamine injection
	,
	Non-transfusion-dependent thalassemia syndromes
	One of the following:
	<ul> <li>A creatinine clearance of greater than or equal to 40 mL/minute</li> </ul>
	<ul> <li>Serum creatinine less than or equal to 2 times the age-appropriate</li> </ul>
	level
	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)
	Patient has had a failure or contraindication to deferoxamine injection
Renewal Criteria	Documented positive clinical response to therapy
Age Restriction	Patient is 2 years of age or older
Coverage Duration	Both Diagnoses:
	o Initial: 12 months
	Renewal: 12 months
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Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

### Desmopressin

#### **Products Affected**

• Desmopressin Acetate Nasal Spray & Injections

Required Medical Information and Criteria	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design         <ul> <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> <li>All diagnoses         <ul> <li>Documentation of one of the conditions listed under "covered uses"</li> </ul> </li> </ul>
Renewal Criteria	Documentation of positive clinical response to therapy.
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</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)**

#### **Products Affected**

• Austedo tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Chorea associated with Huntington's Disease</li> <li>Tardive Dyskinesia</li> </ul>
Required Medical	Chorea associated with Huntington's Disease
Information and	Documentation of the degree of chorea present and the impact on
Criteria	functional ability and/or quality of life.
	Documentation of mental status, specifically depression and suicidality.
	Tardive Dyskinesia
	Clinical documentation of tardive dyskinesia including:
	<ul> <li>At least one month of past or current exposure to a dopamine receptor blocker</li> </ul>
	<ul> <li>Dyskinetic or dystonic involuntary movements</li> </ul>
	<ul> <li>Exclusion of other causes of abnormal movements</li> </ul>
	Clear documentation that tardive dyskinesia causes functional
	impairment
	<ul> <li>Documentation of the degree of tardive dyskinesia with the AIMS scale as a baseline</li> </ul>
	One of the following:
	<ul> <li>Discontinuation of the medication precipitating TD</li> </ul>
	<ul> <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> </ul>
	Evidence the medications precipitating tardive dyskinesia are
	medically necessary
	Trial and failure of both of the following:
	<ul> <li>Clonazepam</li> </ul>
	<ul> <li>Amantadine</li> </ul>
Renewal Criteria	Huntington's Chorea

	<ul> <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> <li>Tardive Dyskinesia</li> <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>
Age Restriction	Age 18 and older
Prescriber	Huntington's Chorea: Neurologist
Restriction	Tardive Dyskinesia: Neurologist or Psychiatrist
Coverage Duration	All diagnoses:     Initial: 3 months     Renewal: 12 months

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

#### References

• Austedo [package insert]. Parsippany, NJ: Teva Neuroscience, Inc.; 2025.

### **Dihydroergotamine Injection**

#### **Products Affected**

• Dihydroergotamine Inj

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Acute treatment of migraine</li> <li>Acute treatment of cluster headaches</li> </ul>
Required Medical	Acute treatment of migraine
Information and	Diagnosis of migraine with or without aura
Criteria	<ul> <li>Trial and failure of, or contraindication to 5-HT1B/1D agonist (triptans)</li> </ul>
	<ul> <li>Acute treatment of cluster headaches</li> <li>Diagnosis of cluster headache</li> <li>Trial and failure of, or contraindication to 5-HT1B/1D agonist (triptans)</li> </ul>
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</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**

#### **Products Affected**

• Dimethyl Fumarate DR Capsules

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Multiple sclerosis</li> </ul>
Required Medical Information and Criteria	<ul> <li>Multiple Sclerosis</li> <li>Documented diagnosis of one of the following:         <ul> <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>
Renewal Criteria	Documented positive clinical response to therapy
Prescriber Restriction	Multiple sclerosis: Neurologist
Coverage Duration	Multiple sclerosis:

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

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Insulin dependent diabetes mellitus</li> </ul>
Required Medical	Insulin Dependent Diabetes Mellitus - Pediatric
Information and Criteria	<ul> <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</li> </ul>
	<ul> <li>program in the last 12 months (member or caregiver/parent)</li> <li>Insulin Dependent Diabetes Mellitus - Adult</li> <li>All of the above pediatric requirements AND</li> <li>Documentation of one of the following:         <ul> <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>
Renewal Criteria	Clinical documentation of positive clinical response to therapy, and an in-person visit with the prescribing provider within the last 6 months
Coverage Duration	All diagnoses:     Initial: 6 months     Renewal: 12 months

Effective Date:	3/1/2024

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

References	
•	

### Donepezil

#### **Products Affected**

• Donepezil 5mg tablets

Donepezil 10mg tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Alzheimer's disease – dementia</li> <li>Alzheimer's disease, prophylaxis – Impaired cognition</li> <li>Multi-Infarct dementia</li> </ul>
Required Medical Information and Criteria	All diagnoses  Confirmed diagnosis of one of the above listed conditions
Renewal Criteria	Positive clinical response to therapy
Coverage Duration	<ul> <li>All diagnoses:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</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**

#### **Products Affected**

- Janumet
- Janumet XR
- Januvia

- Kombiglyze XR
- Onglyza
- Tradjenta

Step Therapy Criteria	<ul> <li>Clinical diagnosis of Type 2 Diabetes Mellitus (T2DM)</li> <li>Trial and failure of the following:         <ul> <li>Metformin</li> <li>Sulfonylurea or insulin</li> </ul> </li> </ul>

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

### **Dronabinol**

#### **Products Affected**

• Dronabinol capsules

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Nausea and vomiting associated with cancer chemotherapy (CINV)</li> <li>AIDS anorexia</li> </ul>
Required Medical	Nausea and Vomiting Associated with Cancer Chemotherapy
Information and	Confirmation of treatment with chemotherapy
Criteria	Trial and failure or contraindication to all of the following:
	<ul> <li>At least one 5HT-3 receptor antagonist (e.g. ondansetron, granisetron, etc.)</li> <li>At least one of:</li> </ul>
	<ul> <li>Prochlorperazine</li> </ul>
	<ul> <li>Dexamethasone</li> </ul>
	<ul><li>Haloperidol</li></ul>
	<ul> <li>Olanzapine</li> </ul>
	AIDS Anorexia
	Confirmed diagnosis of anorexia with weight loss in patients with AIDS
	Patient is on antiretroviral therapy
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	All diagnoses:
	o Initial: 12 months
	o Renewal: 12 months

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

#### **Covered Uses**

- All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
  - Moderate to Severe Asthma
  - Atopic Dermatitis
  - Eosinophilic Esophagitis
  - Chronic Rhinosinusitis with Nasal Polyps
  - Prurigo Nodularis
  - Chronic Obstructive Pulmonary Disease

#### Required Medical Information and Criteria

#### **Moderate to Severe Asthma**

- Confirmed diagnosis of moderate to severe asthma
- Inadequate control of asthma symptoms despite fully maximized treatment with one of the following:
  - o Inhaled corticosteroids combined with long-acting beta-2 agonist
  - Inhaled corticosteroids combined with long-acting muscarinic antagonist

#### **Atopic Dermatitis**

- Diagnosed with severe atopic dermatitis 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 another validated tool)
- One or more of the following:
  - At least 10% of body surface area involvement
  - Hand, foot, or mucous membrane involvement
- 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.

#### **Eosinophilic Esophagitis**

Confirmed diagnosis of Eosinophilic Esophagitis

- Weight ≥ 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 and 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 ≥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.

	Pland againaphil agust (PEC) > 200 calle (ul. within the past 2 months
	<ul> <li>Blood eosinophil count (BEC) ≥300 cells/µL within the past 3 months.</li> <li>Chronic bronchitis, defined as a chronic productive cough for ≥ 3</li> </ul>
	months in the past year, in the absence of other known causes of
	chronic cough.
	• ≥ 2 moderate COPD exacerbation (defined as requiring treatment with
	either systemic corticosteroids and/or antibiotics) or ≥ 1 severe COPD
	exacerbation (defined as requiring hospitalization or observation for
	over 24 hours in emergency department of 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].
Renewal Criteria	Documentation of positive clinical response to therapy
Age Restriction	Moderate to Severe Asthma: 6 years and older
	Atopic Dermatitis: 6 months and older
	Eosinophilic Esophagitis: 1 years and older
	CRSwNP: 12 years and older
	Prurigo Nodularis: 18 years and older
	COPD: 18 years and older
Prescriber	Atopic dermatitis: Dermatologist
Restriction	Eosinophilic Esophagitis: Gastroenterologist or Immunologist
	CRSwNP: ENT or Immunologist
	Prurigo Nodularis: Dermatologist
	Asthma, COPD: Pulmonologist
Coverage Duration	All Diagnoses:
	o Initial: 6 months
	o Renewal: 12 months

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

### References

• Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals Inc.; 2024.

# **Elagolix (Orilissa)**

#### **Products Affected**

• Orilissa tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Moderate to Severe Pain Associated with Endometriosis</li> </ul>
Required Medical Information and Criteria	<ul> <li>Moderate to Severe Pain Associated with Endometriosis</li> <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> <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>Additional info required for 200mg twice daily dosing:         <ul> <li>Documentation of coexisting dyspareunia</li> </ul> </li> </ul>
Renewal Criteria	<ul> <li>Renewal only allowed for 150mg dose</li> <li>Criteria requires documentation of:         <ul> <li>A positive clinical response to therapy</li> <li>Total therapy duration is 24 months or less</li> </ul> </li> </ul>
Age Restriction	At least 18 years of age or older but not yet through menopause
Prescriber Restriction	All Diagnoses: Obstetrician or Gynecologist
Coverage Duration	<ul> <li>150mg dose:         <ul> <li>Initial: 6 months</li> <li>Renewal: 18 months (maximum treatment duration of 24 months)</li> </ul> </li> <li>200mg dose:         <ul> <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)**

#### **Products Affected**

• Iqirvo tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Primary Biliary Cholangitis</li> </ul>
Required Medical	Primary Biliary Cholangitis
Information and	Diagnosis of primary biliary cholangitis (PBC) confirmed by two of the
Criteria	following:
	Biochemical evidence of cholestasis based on ALP elevation
	<ul> <li>Presence of AMA or other PBC-specific autoantibodies</li> </ul>
	Histology confirmation after biopsy
	Trial and failure of 12 months of ursodiol.
	No current decompensated cirrhosis.
Renewal Criteria	Documented positive clinical response to therapy
Prescriber	Primary Biliary Cholangitis: Gastroenterologist or Hepatologist
Restriction	
Coverage Duration	Primary Biliary Cholangitis:
	o Initial: 6 months
	o Renewal: 12 months

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

References	
<ul> <li>Iqirvo [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals Inc.; 2024.</li> </ul>	

### **Elexacaftor-tezacaftor-ivacaftor (Trikafta)**

#### **Products Affected**

• Trikafta

<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.</li> <li>Cystic Fibrosis</li> </ul>
Cystic Fibrosis
Documentation of cystic fibrosis diagnosis with at least one F508del
mutation
Not used in combination with other CFTR modulator treatments
Documented clinical response to therapy
2 years of age and older
Cystic Fibrosis: Pulmonologist
Cystic Fibrosis:
o Initial: 6 months
o Renewal: 12 months

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.

# **Endothelin Receptor Antagonists**

## **Products Affected**

Ambrisentan tablets

Bosentan tablets

<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Pulmonary Arterial Hypertension</li> </ul>
Pulmonary Arterial Hypertension
Clinically documented diagnosis of Pulmonary Arterial Hypertension
(WHO group 1 pulmonary hypertension)
Documented positive clinical response to therapy
Ambrisentan: 18 years of age and over
Bosentan: 3 years and up
Pulmonary Arterial Hypertension: Cardiologist or Pulmonologist
Pulmonary Arterial Hypertension:
o Initial: 6 months
o Renewal: 12 months

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

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

# **Erythromycin Gel and Solution**

## **Products Affected**

• Erythromycin 2% gel

• Erythromycin 2% solution

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	<ul> <li>All Diagnoses</li> <li>Documentation of trial and failure, intolerance, or contraindication to clindamycin 1% gel or solution</li> </ul>
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</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**

#### **Products Affected**

Retacrit

## **Covered Uses** All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design Anemia Due to Chronic Kidney Disease (CKD) Anemia Due to Chemotherapy o Anemia Associated with HIV Infection o Preoperative Use for Reduction of Allogeneic Blood Transfusion in Patients Undergoing Surgery Anemia in Myelodysplastic Syndrome (MDS) **Required Medical Anemia Due to Chronic Kidney Disease (CKD)** Information and Confirmed diagnosis of anemia with hematocrit less than 30% or Criteria hemoglobin less than 10g/dL within 30 days of request Verification of iron evaluation for adequate iron stores One of the following: Patient is on dialysis 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. **Anemia Due to Chemotherapy** Verification that other causes of anemia have been ruled out Verification of anemia with hematocrit less than 30% or hemoglobin less than 10g/dL within the prior 2 weeks Verification of iron evaluation for adequate iron stores Verification that the cancer is a non-myeloid malignancy Patient is receiving chemotherapy Anemia Associated with HIV Infection Verification of anemia with hematocrit less than 36% or hemoglobin less than 12 g/dL within the prior 30 days Verification of iron evaluation for adequate iron stores Serum erythropoietin level less than or equal to 500 mU/mL One of the following: o Patient is receiving zidovudine

Diagnosis of HIV infection

# <u>Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery</u>

- Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery
- Hemoglobin (Hgb) is greater than 10 to less than or equal to 13 g/dL
- Patient is at high risk for perioperative transfusions
- Patient is unwilling or unable to donate autologous blood preoperatively
- Verification of iron evaluation for adequate iron stores

#### **Anemia in Myelodysplastic Syndrome (MDS)**

- Diagnosis of MDS
- One of the following:
  - Serum erythropoietin level less than or equal to 500 mU/mL
  - Diagnosis of transfusion-dependent MDS
- Verification of iron evaluation for adequate iron stores

#### **Renewal Criteria**

#### **Anemia Due to CKD**

- There is a documented response to treatment
- One of the following:
  - o Patient is on dialysis and Hgb is 11g/dL or less
  - o Patient is NOT on dialysis and Hgb is 10g/dL or less

#### **Anemia Due to Chemotherapy**

- There is a documented response to treatment as indicated by a decrease in the need to blood transfusion or Hgb increase from pretreatment level
- Documented Hct less than 30% or Hgb less than 10 g/dL
- Patient is receiving chemotherapy

#### **Anemia Associated with HIV Infection**

- There is a documented response to treatment as indicated by a decrease in the need to blood transfusion or Hgb increase from pretreatment level
- Documented Hct less than 36% or Hgb less than 12 g/dL

#### **Anemia in Myelodysplastic Syndrome**

 There is a documented response to treatment as indicated by a decrease in the need to blood transfusion or Hgb increase from pretreatment level

	Documented Hct less than 36% or Hgb less than 12 g/dL
Coverage Duration	Anemia due to CKD:     Initial: 3 months     Renewal: 12 months
	<ul> <li>Anemia Due to Chemotherapy:</li> <li>Initial: 3 months</li> <li>Renewal: 3 months</li> </ul>
	<ul> <li>Anemia Associated with HIV:</li> <li>Initial: 3 months</li> <li>Renewal: 12 months</li> </ul>
	<ul> <li>Anemia in MDS:</li> <li>Initial: 3 months</li> <li>Renewal: 12 months</li> </ul>
	<ul> <li>Preoperative:</li> <li>Initial: 1 months</li> <li>Renewal: N/A</li> </ul>

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

## References

• Oregon Health Authority. (2024). *Guideline Note GN7: Erythropoiesis-Stimulating Agent (ESA) Guideline*. Health Evidence Review Commission.

# **Estradiol Ring (Estring)**

## **Products Affected**

• Estring 2mg vaginal ring

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical	All FDA approved diagnoses
Information and Criteria	Trial and failure of estradiol vaginal cream and estradiol vaginal tablet
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 6 months</li> <li>Renewal: 12 months</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)**

#### **Products Affected**

Enbrel Auto-Injector

Enbrel Prefilled Syringe

## **Covered Uses** All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design Ankylosing Spondylitis/Axial Spondyloarthritis Plaque Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis **Required Medical All diagnoses** Information and Initial testing for latent TB and treatment, if necessary, before starting Criteria treatment. No current active infection at initiation of therapy. Risks and benefits documented in cases of chronic or recurrent infection. Will NOT be used in combination with another biologic or Otezla. Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA) 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 One of the following: o 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.

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
  - o 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 of 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> <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> <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>
Renewal Criteria	Ankylosing Spondylitis/Axial Spondyloarthritis: Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.
	Plaque Psoriasis: 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.
	Psoriatic Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	Rheumatoid Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
Prescriber Restriction	<ul> <li>Ankylosing Spondylitis, Axial Spondyloarthritis: Rheumatologist.</li> <li>Plaque Psoriasis: Dermatologist.</li> <li>Psoriatic Arthritis: Dermatologist or Rheumatologist.</li> <li>Rheumatoid Arthritis: Rheumatologist.</li> </ul>
Coverage Duration	All diagnoses:     Initial: 6 months     Renewal: 12 months

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

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# **Etrasimod arginine (Velsipity)**

## **Products Affected**

• Velsipity tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Ulcerative Colitis</li> </ul>
Required Medical	Ulcerative Colitis
Information and	Documentation of moderate-to-severe ulcerative colitis
Criteria	<ul> <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> <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>
Renewal Criteria	Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission
Age Restriction	18 years of age or older
Prescriber	Ulcerative colitis: Gastroenterologist
Restriction	
Coverage Duration	<ul> <li>Ulcerative colitis:</li> <li>Initial: 6 months</li> <li>Renewal: 12 months</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**

## **Products Affected**

• Ferrous Sulfate 300mg/5mL

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	<ul> <li>All Diagnoses</li> <li>Documentation of inability to use ferrous sulfate tabs or 200mg/5mL liquid</li> </ul>
Coverage Duration	All Diagnoses:

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

# Fezolinetant (Veozah)

## **Products Affected**

Veozah tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Vasomotor Symptoms Associated with Menopause</li> </ul>
Required Medical	Vasomotor Symptoms Associated with Menopause
Information and Criteria	Diagnosis of moderate to severe vasomotor symptoms due to menopause.
	<ul> <li>Documented contraindication, intolerance, or inadequate response to at least 2 hormonal therapies.</li> </ul>
	<ul> <li>Documented contraindication, intolerance, or inadequate response to two nonhormonal therapies (e.g., one SNRI and one SSRI).</li> </ul>
Renewal Criteria	Documentation of at least 50% reduction in VMS from baseline.
Prescriber Restriction	All Diagnoses: Gynecologist
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 3 months</li> <li>Renewal: 12 months</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**

#### **Products Affected**

Fingolimod 0.5mg capsules

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Treatment of Multiple Sclerosis</li> </ul>
Required Medical	Multiple Sclerosis
Information and	Documented diagnosis of one of the following:
Criteria	<ul> <li>A relapsing form of multiple sclerosis.</li> </ul>
	<ul> <li>A secondary progressive form of multiple sclerosis.</li> </ul>
	Medication is intended for use as monotherapy.
Renewal Criteria	Positive clinical response to therapy
Prescriber	Multiple Sclerosis: Neurologist
Restriction	
<b>Coverage Duration</b>	Multiple Sclerosis:
	o Initial: lifetime

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

- 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

## **Products Affected**

- Fluorouracil 5% cream
- Fluorouracil 2% solution

• Fluorouracil 5% solution

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Superficial Basal Cell Carcinoma</li> </ul>
Required Medical	Basal Cell Carcinoma
Information and	Documentation confirming a diagnosis of superficial basal cell
Criteria	carcinoma with multiple lesions and/or difficult to treat areas.
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	Basal Cell Carcinoma:
	o Initial: 12 months
	o Renewal: 12 months

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

#### References

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

## **Glatiramer**

#### **Products Affected**

• Glatiramer 20mg/mL inj

Glatiramer 40mg/mL inj

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Treatment of Multiple Sclerosis</li> </ul>
Required Medical	Multiple Sclerosis
Information and	Documented diagnosis of one of the following:
Criteria	<ul> <li>A relapsing form of multiple sclerosis.</li> </ul>
	<ul> <li>A secondary progressive form of multiple sclerosis.</li> </ul>
	Medication is intended for use as monotherapy.
Renewal Criteria	Positive clinical response to therapy
Prescriber	Multiple Sclerosis: Neurologist
Restriction	
Coverage Duration	Multiple Sclerosis:
	o Initial: lifetime

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

- 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**

## **Products Affected**

• Trulicity Auto-Injector

• Liraglutide Pen-Injector

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Type 2 Diabetes</li> </ul>
Required Medical	Type 2 Diabetes
Information and	Documentation of clinically diagnosed Type 2 Diabetes
Criteria	Documentation of adequate trial of maximally tolerated dose of metformin
	<ul> <li>Documentation of trial and failure of one of the following (or contraindication to both):</li> </ul>
	<ul> <li>An SGLT-2 inhibitor (e.g. Farxiga, Jardiance, etc.)</li> </ul>
	<ul> <li>A DPP-4 inhibitor (e.g. saxagliptin, Tradjenta, Januvia, etc.)</li> </ul>
Renewal Criteria	Documented positive clinical response to therapy such as a decrease
Kenewai Onteria	Documented positive clinical response to therapy such as a decrease in A1c
<b>Coverage Duration</b>	Type 2 Diabetes:
	o Initial: 12 months
	o Renewal: 12 months

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

References	
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# Golimumab (Simponi)

## **Products Affected**

• Simponi Auto-Injector

Simponi Prefilled Syringe

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Ankylosing Spondylitis/Axial Spondyloarthritis</li> <li>Psoriatic Arthritis</li> <li>Rheumatoid Arthritis</li> <li>Ulcerative Colitis</li> </ul>			
Required Medical	All diagnoses			
Information and Criteria	<ul> <li>Initial testing for latent TB and treatment, if necessary, before starting treatment.</li> </ul>			
	No current active infection at initiation of therapy.			
	Risks and benefits documented in cases of chronic or recurrent infection.			
	Will NOT be used in combination with another biologic or Otezla.			
	Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)			
	<ul> <li>Documentation of moderate-to-severe ankylosing spondylitis or axial spondyloarthritis as defined by:</li> </ul>			
	<ul> <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> </ul>			
	<ul><li>BASDAI score of &gt;=4</li></ul>			
	<ul> <li>One of the following:         <ul> <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:</li> </ul> </li> </ul>			
	<ul> <li>At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated AND</li> </ul>			
	<ul> <li>Physical therapy/exercise program</li> </ul>			
	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 of history)
  - o 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.

Renewal Criteria	<ul> <li>Ankylosing Spondylitis/Axial Spondyloarthritis: 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>
	Psoriatic Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	Rheumatoid Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	Ulcerative Colitis: Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.
Prescriber Restriction	<ul> <li>Ankylosing Spondylitis, Axial Spondyloarthritis: Rheumatologist.</li> <li>Psoriatic Arthritis: Dermatologist or Rheumatologist.</li> <li>Rheumatoid Arthritis: Rheumatologist.</li> <li>Ulcerative Colitis: Gastroenterologist.</li> </ul>
Coverage Duration	All diagnoses:     Initial: 6 months     Renewal: 12 months

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

References	
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# **Gonadotropin-Releasing Hormone Agonists**

## **Products Affected**

• Lupron

- 1-	
Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <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>
Required Medical	Endometriosis
Information and	One of the following:
Criteria	<ul> <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> <li>Danazol</li> <li>Combination (estrogen/progestin) oral contraceptive</li> </ul> </li> </ul>
	<ul><li>Progestins</li></ul>
	<ul> <li>Patient has had surgical ablation to prevent recurrence</li> <li>Uterine Leiomyomata (Fibroids) - For the reduction of the size of fibroids</li> </ul>
	<ul> <li>For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy)</li> </ul>
	<u> Uterine Leiomyomata (Fibroids) – Anemia</u>
	Anemia is caused by uterine leiomyomata (fibroids)
	<ul> <li>Patient has tried and had an inadequate response to at least 1 month of monotherapy with iron</li> </ul>
	Used in combination with iron therapy
	For use prior to surgery
	Central Precocious Puberty (CPP)
	<ul> <li>Diagnosis of central precocious puberty (idiopathic or neurogenic)</li> <li>Early onset of secondary sexual characteristics in one of the following:</li> </ul>

o Females less than 8 years of age

	<ul> <li>Males less than 9 years of age</li> </ul>
	Advanced bone age of at least one year compared with chronological
	age
	One of the following:
	<ul> <li>Patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing and peak luteinizing hormone (LH) level above prepubertal range</li> </ul>
	<ul> <li>Patient has a random LH level in the pubertal range</li> </ul>
	One of the following:
	<ul> <li>Patient had one of the following diagnostic evaluations to rule out tumors, when suspected:</li> </ul>
	<ul> <li>Diagnostic imaging of the brain (MRI or CT scan) (in patients</li> </ul>
	with symptoms suggestive of a brain tumor or in those 6 years of age or younger
	<ul> <li>Pelvic/testicular/adrenal ultrasound (if steroid levels suggest suspicion)</li> </ul>
	<ul> <li>Adrenal steroids to rule out congenital adrenal hyperplasia (when pubarche precedes thelarche or gonadarche)</li> </ul>
	Patient has no suspected tumors
	Prostate Cancer
	Diagnosis of advanced or metastatic prostate cancer
	Gender Dysphoria/Gender Incongruence
	Using gonadotropin for suppression of puberty
	Diagnosis of gender dysphoria/gender incongruence
Renewal Criteria	Endometriosis: 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).
	Central Precocious Puberty (CPP): LH levels have been suppressed to pre-pubertal levels.
	disease while on therapy.
Prescriber Restriction	Central Precocious Puberty (CPP): Pediatric endocrinologist
Coverage Duration	Endometriosis:
	o Initial: 6 months
	Renewal: up to 6 months
	1 C

• Uterine Leiomyomata (Fibroids Reduction):

o Initial: 4 months

• Uterine Leiomyomata (Fibroids Anemia):

o Initial: 3 months

• Central Precocious Puberty (CPP):

o Initial: 12 months

o Renewal: up to 12 months

• Prostate Cancer:

o Initial: 12 months

o Renewal: up to 12 months

• Gender Dysphoria:

o Initial: 12 months

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)**

## **Products Affected**

Grastek

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design     Grass pollen-induced allergic rhinitis
Required Medical	Grass Pollen-Induced Allergic Rhinitis
Information and Criteria	Confirmed diagnosis of grass pollen induced allergic rhinitis
Renewal Criteria	Documented positive clinical response to therapy
Prescriber Restriction	Grass Pollen-Induced Allergic Rhinitis: Allergist or Immunologist
Coverage Duration	<ul> <li>Grass Pollen-Induced Allergic Rhinitis:</li> <li>Initial: 3 months</li> <li>Renewal: 3 months</li> </ul>

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

References	
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# **Hepatitis C Antivirals**

## **Products Affected**

- Mavyret
- Vosevi

• Sofosbuvir-Velpatasvir

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Treatment of Hepatitis C Infection</li> </ul>
Required Medical Information and Criteria	Hepatitis C Infection  *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. *  • All appropriate pre-treatment testing has been done:  • 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  • History of previous HCV treatment, viral load after treatment, and outcome are required only if there is documentation of treatment experience  • Documentation of prior treatment history  • Documentation of whether the patient achieved a sustained virological response (SVR) at week 12 or longer following the completion of their last DAA regimen  • Documentation if this is likely a reinfection, indicated by at least one of the following:  • 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)  • Is the hepatitis C infection due a different genotype than previous  • 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)
	patient's genotype, age, treatment status (retreatment or treatment naïve) and cirrhosis status (see table 1 and 2)?

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

<u>Table 1. Recommended Regimens for Adults and adolescents 12 years</u> of age and older

Treatment	Cirrhosis Status	Recommended Regimen
History		
Treatment Naïv	ve (Genotype 1-6)	
Treatment	Non-cirrhotic	SOF/VEL x 12 weeks
naïve		G/P x 8 weeks
	Compensated	G/P x 8 weeks
	cirrhosis	SOF/VEL x 12 weeks (baseline
		resistance testing
		recommended for GT3)
	Decompensated	SOF/VEL + RBV x 12 weeks
	cirrhosis	SOF/VEL x 24 weeks (if RBV
		ineligible)

Sofobuvir based regimen	Non-cirrhotic or	SOF/VEL/VOX x
treatment failures, including:	compensated	12 weeks G/P
sofosbuvir + ribavirin	cirrhosis	x16 weeks
Ledipasvir/Sofobuvir		(except GT3)
Velpatasvir/sofobuvir		
Elbasvir/grazoprevir treatment	Non-cirrhotic or	SOF/VEL/VOX x
failures	compensated	12 weeks
	cirrhosis	
Glecaprevir/pibrentasvir	Non-cirrhotic or	G/P + SOF + RBV
treatment failures	compensated	x 16 weeks
	cirrhosis	SOF/VEL/VOX x
		12 weeks (plus
		RBV if
		compensated
		cirrhosis)
Multiple DAA Treatment Failures,	Non-Cirrhotic or	G/P + SOF + RBV
including:	compensated	x 16-24 weeks
Sofobuvir/velpatasvir/voxilaprevir	cirrhosis	SOF/VEL/VOX
Glecaprevir/pibrentasvir +		x24 weeks
sofobuvir		

	Treatment History	Cirrhosis Status	Recommended Regimen
	Treatment Naïve (Ge	enotype 1-6)	<u> </u>
	Treatment Naive	Non-cirrhotic or	SOF/VEL x 12 weeks
		compensated cirrhosis	G/P x 8 weeks
		Decompensated	SOF/VEL + RBV x 12
		cirrhosis	weeks
	Abbreviations: DAA =	= direct acting antiviral; EBV	//GZR =
		G/P = glecaprevir and pibre	
	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		
	-	ntolerance may include: 1) n	neutrophils < 750 mm3.
	2) hemoglobin < 10 g/dl, 3) platelets <50,000 cells/mm3, autoimmune		
	, ,	toimmune condition, hypers	*
	ribavirin		-
Coverage Duration	<ul> <li>Hepatitis C Infect</li> </ul>		
		eks. Duration of approval de	epends on the specifics of
	the infection.		

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

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

References	
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# Inclisiran (Leqvio)

## **Products Affected**

• Leqvio Prefilled Syringe

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Established clinical ASCVD</li> <li>Primary or Familial Hyperlipidemia</li> </ul>
Required Medical Information and Criteria	<ul> <li>Established Clinical ASCVD</li> <li>Documentation of very high risk ASCVD as evidenced by either:         <ul> <li>History of multiple major ASCVD events OR</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> <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> <li>Primary or Familial Hyperlipidemia</li> <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> <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>
Renewal Criteria	Documented positive clinical response to therapy (significant decrease in lipid levels).
Prescriber Restriction	All Diagnoses: Cardiologist, Endocrinologist, or Lipid Specialist
<b>Coverage Duration</b>	All Diagnoses:

<ul><li>Initial: 6 months</li><li>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**

## **Products Affected**

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

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Type 1 Diabetes</li> <li>Type 2 Diabetes</li> </ul>
Required Medical	All Diagnoses
Information and	Trial and failure of Insulin Glargine or documented intolerance or
Criteria	contraindication to Insulin Glargine
Renewal Criteria	Renewal criteria
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</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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# Insulin U-500 (Humulin R U-500)

## **Products Affected**

• Humulin R U-500 Pens

• Humulin R U-500 Vials

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Type 1 Diabetes</li> <li>Type 2 Diabetes</li> </ul>
Required Medical Information and Criteria	<ul> <li>All Diagnoses</li> <li>Attestation that the use of U-500 insulin is medically safe and appropriate</li> </ul>
Coverage Duration	All Diagnoses:     Initial: Lifetime

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)**

#### **Products Affected**

Avonex Pen

Avonex prefilled syringe

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Treatment of Multiple Sclerosis</li> </ul>	
Required Medical	Multiple Sclerosis	
Information and	Documented diagnosis of one of the following:	
Criteria	A relapsing form of multiple sclerosis.	
	A secondary progressive form of multiple sclerosis.	
	Medication is intended for use as monotherapy.  This is a definition of all the fall and many the second seco	
	Trial and failure of all the following:  Dim athyl furn grate	
	<ul><li>Dimethyl fumarate</li><li>Fingolimod</li></ul>	
	Glatiramer	
	Giatilaniei	
Renewal Criteria	Documented positive clinical response to therapy	
Prescriber	Multiple Sclerosis: Neurologist	
Restriction		
Coverage Duration	Multiple Sclerosis:	
	o Initial: 12 months	
	o Renewal: 12 months	

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

- 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)

#### **Products Affected**

Rebif Inj.

Rebif Rebido

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Treatment of Multiple Sclerosis</li> </ul>		
Required Medical	Multiple Sclerosis		
Information and	Documented diagnosis of one of the following:		
Criteria	<ul> <li>A relapsing form of multiple sclerosis.</li> </ul>		
	<ul> <li>A secondary progressive form of multiple sclerosis.</li> </ul>		
	Medication is intended for use as monotherapy.		
	Trial and failure of all the following:		
	<ul> <li>Dimethyl fumarate</li> </ul>		
	o Fingolimod		
	o Glatiramer		
	o Avonex		
Renewal Criteria	Documented positive clinical response to therapy		
Prescriber	Multiple Sclerosis: Neurologist		
Restriction			
Coverage Duration	Multiple Sclerosis:		
	o Initial: 12 months		
	o Renewal: 12 months		

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

- 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)

#### **Products Affected**

Betaseron Inj.

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design     Treatment of Multiple Sclerosis		
Required Medical	Multiple Sclerosis		
Information and	Documented diagnosis of one of the following:		
Criteria	<ul> <li>A relapsing form of multiple sclerosis.</li> </ul>		
	<ul> <li>A secondary progressive form of multiple sclerosis.</li> </ul>		
	Medication is intended for use as monotherapy.		
	Trial and failure of all the following:		
	<ul> <li>Dimethyl fumarate</li> </ul>		
	<ul> <li>Fingolimod</li> </ul>		
	<ul> <li>Glatiramer</li> </ul>		
	<ul> <li>Avonex</li> </ul>		
Renewal Criteria	Documented positive clinical response to therapy		
Prescriber	Multiple Sclerosis: Neurologist		
Restriction			
Coverage Duration	Multiple Sclerosis:		
	o Initial: 12 months		
	o Renewal: 12 months		

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

- 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

#### **Products Affected**

- Amnesteem capsules
- Isotretinoin capsules
- Myorisan capsules

- Claravis capsules
- Zenetane capsules

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design     Severe nodulocystic acne
Required Medical	Severe Nodulocystic Acne
Information and	Confirmed diagnosis of severe nodulocystic acne
Criteria	Documentation of trial and failure, intolerance, or contraindication to combined therapy with an oral antibiotic and topical therapy (benzoyl peroxide or retinoid)
Renewal Criteria	No Renewals
Age Restriction	12 years and older
Coverage Duration	<ul> <li>Severe Nodulocystic Acne:</li> <li>Initial: 20 weeks</li> <li>Renewal: No Renewals</li> </ul>

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

## Itraconazole

### **Products Affected**

• Itraconazole Oral Solution

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Tinea Unguium</li> </ul>
Required Medical	Tinea Unguium
Information and	Documentation of one of the following:
Criteria	<ul> <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>
	<ul> <li>All Other Diagnoses</li> <li>Diagnosis is supported by compendia and is an above the line condition</li> </ul>
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 3 months</li> <li>Renewal: 3 months</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)

### **Products Affected**

• Kalydeco Tablets

• Kalydeco Packets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.</li> <li>Cystic Fibrosis</li> </ul>
Required Medical	Cystic Fibrosis
Information and Criteria	Confirmed diagnosis of cystic fibrosis with documentation showing at least one CFTR gene mutation that has shown to be responsive to Kalydeco
	Not used in combination with other CFTR modulator treatments
Renewal Criteria	Documented clinical response to therapy
Age Restriction	1 month of age and older
Prescriber Restriction	Cystic Fibrosis: Pulmonologist
Coverage Duration	<ul> <li>Cystic Fibrosis:</li> <li>Initial: 3 months</li> <li>Renewal: 6 months</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**

### **Products Affected**

• Ivermectin Tablets

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	All Diagnoses     Clinical documentation of a diagnosis for which ivermectin is FDA approved or compendia supported
Renewal Criteria	Documented reinfection
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 6 months</li> <li>Renewal: 6 months</li> </ul>

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

References	
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# Ixekizumab (Taltz)

#### **Products Affected**

• Taltz Auto-Injector

• Taltz Prefilled Syringe

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Ankylosing Spondylitis/Axial Spondyloarthritis</li> <li>Plaque Psoriasis</li> <li>Psoriatic Arthritis</li> </ul>
Required Medical	All diagnoses:
Information and	<ul> <li>Initial testing for latent TB and treatment, if necessary, before starting</li> </ul>
Criteria	treatment.
	No current active infection at initiation of therapy.
	Risks and benefits documented in cases of chronic or recurrent
	infection.
	Will NOT be used in combination with another biologic or Otezla
	, and the second
	Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA)
	Documentation of moderate-to-severe ankylosing spondylitis or axial
	spondyloarthritis as defined by:
	<ul> <li>Back pain and stiffness for more than 3 months AND</li> </ul>
	<ul> <li>Signs of active inflammation on MRI OR radiological evidence of</li> </ul>
	sacroiliitis OR HLA-B27 positive AND
	<ul> <li>BASDAI score of &gt;=4</li> </ul>
	One of the following:
	<ul> <li>The member is transitioning to the requested treatment from a</li> </ul>
	different biologic product previously approved by the plan OR
	<ul> <li>Documented failure of conventional therapy with both of the</li> </ul>
	following:
	<ul> <li>At least two NSAIDs for 3 months at maximum recommended</li> </ul>
	or tolerated anti-inflammatory dose unless contraindicated
	AND
	<ul> <li>Physical therapy/exercise program</li> </ul>
	Trial and failure of infliximab and adalimumab
	Plaque Psoriasis (PP):
	<ul> <li>Documentation of severe plaque psoriasis, defined as having</li> </ul>
	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
  - o 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 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 of history)
  - o 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

#### **Renewal Criteria**

 Ankylosing Spondylitis/Axial Spondyloarthritis: Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI

	<ul> <li>Plaque Psoriasis: 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>Psoriatic Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> </ul>
Prescriber Restriction	<ul> <li>Ankylosing Spondylitis, Axial Spondyloarthritis: Rheumatologist.</li> <li>Plaque Psoriasis: Dermatologist.</li> <li>Psoriatic Arthritis: Dermatologist or Rheumatologist.</li> </ul>
Coverage Duration	<ul> <li>Hidradenitis Suppurativa and Plaque Psoriasis: Dermatologist.</li> <li>Psoriatic Arthritis: Dermatologist or Rheumatologist.</li> <li>Rheumatoid Arthritis, Juvenile Idiopathic Arthritis: Rheumatologist.</li> <li>Ankylosing Spondylitis, Axial Spondyloarthritis: Rheumatologist.</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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## **Lacosamide (Vimpat)**

#### **Products Affected**

• Lacosamide tablets

Lacosamide solution

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Focal Seizures</li> <li>Primary Generalized Tonic-Clonic Seizures</li> </ul>
Required Medical	Focal Seizures
Information and	Documentation confirming epilepsy or seizure disorder
Criteria	Solution only: Member under age 10 or unable to use tablets
	Primary Generalized Tonic-Clonic Seizures
	Documentation confirming epilepsy or seizure disorder
	Solution only: Member under age 10 or unable to use tablets
Renewal Criteria	Documentation of positive clinical response to therapy
Age Restriction	Solution only: Member under age 10 or unable to use tablets
Prescriber Restriction	All diagnoses: Neurologist
Coverage Duration	All diagnoses:
	o Initial: 12 months
	Renewal: Lifetime

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

### References

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

## **Lanthanum Carbonate**

### **Products Affected**

• Lanthanum Carbonate Chew Tabs

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Hyperphosphatemia in Chronic Kidney Disease</li> </ul>
Required Medical Information and Criteria	<ul> <li>Hyperphosphatemia in Chronic Kidney Disease</li> <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> <li>Calcium acetate</li> <li>Sevelamer carbonate</li> </ul> </li> </ul>
Age Restriction	6 years of age or older
Prescriber Restriction	Hyperphosphatemia in CKD: Nephrologist
Coverage Duration	<ul> <li>Hyperphosphatemia in CKD:</li> <li>Initial: Lifetime</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)

### **Products Affected**

• Reyvow tablets

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design     Treatment of acute migraine	
Required Medical	Acute Migraine	
Information and	Confirmed diagnosis of migraine	
Criteria	<ul> <li>Documentation showing the member is currently on preventative therapy</li> </ul>	
	Trial and failure (defined as at least 6 weeks per agent) of:	
	<ul> <li>At least 3 oral formulary triptans used at up to the maximally</li> </ul>	
	indicated dosing and in combination with NSAID therapy (e.g. naproxen).	
Renewal Criteria	Documented positive clinical response to therapy	
Age Restriction	18 years of age or older	
Prescriber	Acute Migraine: Neurologist or headache specialist	
Restriction		
Coverage Duration	Acute Migraine:	
	o Initial: 3 months	
	o Renewal: 12 months	

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

Refer	References		
•	Revyow [package insert]. Indianapolis, IN: Eli Lilly and Co: 2022.		

# Lebrikizumab (Ebglyss)

#### **Products Affected**

• Ebglyss Prefilled Syringe

• Ebglyss Auto-Injector

Covered Uses  Required Medical	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design     Atopic Dermatitis  Atopic Dermatitis
Information and Criteria	<ul> <li>Diagnosed with severe atopic dermatitis 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 another validated tool)</li> <li>One or more of the following:         <ul> <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> <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) OR the member is oral corticosteroid dependent.</li> </ul> </li> </ul>
Renewal Criteria	Documentation of positive clinical response to therapy
Prescriber Restriction	Atopic dermatitis: Dermatologist
Coverage Duration	All Diagnoses:     Initial: 6 months     Renewal: 12 months

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

References

## Lenacapavir (Sunlenca)

#### **Products Affected**

• Sunlenca Therapy Pack

• Sunlenca Subcutaneous

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Multi-Drug-Resistant (MDR) HIV</li> </ul>
Required Medical	Multi-Drug-Resistant HIV
Information and	Diagnosis of MDR HIV-1 infection with resistance to at least two drugs
Criteria	in each of at least three of the following classes: NRTIs, NNRTIs, PIs, and INSTIs
	Will be used in combination with an optimized baseline regimen (OBR)
	Current ARV regimen has been stable for at least 2 months
	HIV-1 RNA is ≥400 copies/mL
Renewal Criteria	Continues to be used in combination with an optimized background regimen (OBR)
	Provider states that patient continues to receive clinical benefit from the treatment
Prescriber	MDR HIV Infection: HIV Specialist
Restriction	
Coverage Duration	MDR HIV Infection:
	o Initial: 6 months
	o Renewal: 12 months

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)

#### **Products Affected**

• Yeztugo Inj.

• Yeztugo Tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Pre-Exposure Prophylaxis to reduce the risk of HIV infection</li> </ul>
Required Medical Information and Criteria	<ul> <li>Pre-Exposure Prophylaxis (PrEP)</li> <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> <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>
Renewal Criteria	<ul> <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> <li>Negative HIV-1 antigen/antibody test</li> <li>Negative HIV-1 RNA assay</li> </ul> </li> </ul>
Coverage Duration	<ul> <li>Pre-Exposure Prophylaxis:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</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**

### **Products Affected**

• Lidocaine External Patch

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Post-Herpetic Neuralgia</li> </ul>
Required Medical	Post-Herpetic Neuralgia
Information and	Documentation confirming a diagnosis of post-herpetic neuralgia
Criteria	
Renewal Criteria	Documented positive clinical response to therapy
<b>Coverage Duration</b>	Post-Herpetic Neuralgia:
	o Initial: 3 months
	o Renewal: 3 months

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

References	
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## Lisdexamfetamine

### **Products Affected**

• Lisdexamfetamine Capsules

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Attention Deficit Hyperactivity Disorder</li> <li>Binge Eating Disorder</li> </ul>
Required Medical	Attention Deficit Hyperactivity Disorder (ADHD)
Information and	Prior trial of at least 30 days of both of the following:
Criteria	<ul> <li>An extended-release amphetamine product (amphetamine salts ER, dextroamphetamine ER, etc.)</li> </ul>
	<ul> <li>An extended-release methylphenidate product</li> </ul>
	(dexmethylphenidate ER, methylphenidate ER, etc.)
	<ul> <li>Binge Eating Disorder (BED)</li> <li>Clinical documentation confirming a diagnosis of binge eating disorder per DSM-5 criteria</li> <li>Trial and failure of at least 2 of the following therapeutic alternatives:         <ul> <li>Selective serotonin reuptake inhibitors (SSRI)</li> <li>Topiramate</li> <li>Methylphenidate</li> </ul> </li> </ul>
Renewal Criteria	Documented positive clinical response to therapy
Age Restriction	Binge Eating Disorder: 18 years of age or older
Coverage Duration	All diagnoses:     Initial: 12 months     Renewal: 12 months

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-adhdadults
- www.cdc.gov/adhd/php/adults/index.html
- www.cdc.gov/adhd/diagnosis/index.html

## **Long-Acting Opiates**

#### **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

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Pain Related to Cancer, End of Life, or Palliative Care</li> <li>Pain In All Other Conditions</li> </ul>
Required Medical Information and	Pain Related to Cancer, End of Life, or Palliative Care
Criteria	Confirmation of diagnosis
	Other Pain
	Documented use of current and/or recent usage of short-acting opioids for at least 15 days prior to long-acting opioids.
	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].
	<ul> <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> </ul>
	Restricted to 2 fills in a 60-day period for both naive and experienced.
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</li> </ul>

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

References

# **Lotilaner (Xdemvy)**

### **Products Affected**

• Xdemvy 0.25% Ophthalmic solution

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Demodex Blepharitis</li> </ul>	
Required Medical	Demodex Blepharitis	
Information and	Documentation of at least mild erythema of the upper eyelid margin	
Criteria	Presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination	
Renewal Criteria	• N/A	
Age Restriction	18 years of age and older	
Prescriber Restriction	Demodex Blepharitis: Optometrist or Ophthalmologist	
Coverage Duration	Demodex Blepharitis:	
	o Initial: 6 weeks	
	Renewal: Renewals are not allowed	

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

References	
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# Lubiprostone

### **Products Affected**

• Lubiprostone capsules

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <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>	
Required Medical	Chronic Idiopathic Constipation (CIC)	
Information and Criteria	Documentation of a funded comorbid condition that would be improved with the treatment of CIC	
Criteria	<ul> <li>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> <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> <li>Irritable Bowel Syndrome with Constipation (IBS-C) in females (assigned at birth)</li> <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):</li> </ul>	
	<ul> <li>Dietary Modification: Increased dietary fiber (25 grams/day) and increased fluid consumption</li> </ul>	
	Bulk-forming Laxatives: Psyllium	
	<ul> <li>Osmotic Laxatives: Polyethylene glycol, lactulose, magnesium hydroxide, milk of magnesia</li> </ul>	
	<ul> <li>Stool Softener: Docusate</li> </ul>	

	<ul> <li>Stimulant Laxatives: Senna, bisacodyl.</li> </ul>	
	Opioid Induced Constipation (OIC)	
	Documentation of a funded comorbid condition that would be improved with the treatment of OIC	
	<ul> <li>Documentation of failure to have benefit with recommended conventional first-line treatments (or contraindication to all first-line treatments):</li> </ul>	
	<ul> <li>Dietary Modification: Increased dietary fiber (25 grams/day) and increased fluid consumption</li> </ul>	
	<ul> <li>Osmotic Laxatives: Polyethylene glycol, lactulose, magnesium hydroxide, milk of magnesia</li> </ul>	
	<ul> <li>Stool Softener: Docusate</li> </ul>	
	<ul> <li>Stimulant Laxatives: Senna, bisacodyl.</li> </ul>	
	The patient is not using methadone.	
Renewal Criteria	Documentation of efficacy and continued need	
Age Restriction	18 years of age and older	
Prescriber	Chronic Idiopathic Constipation and Irritable Bowel Syndrome with	
Restriction	Constipation: Gastroenterologist, other provider after patient	
	consultation with a dietician	
	Opioid Induced Constipation: Gastroenterologist, pain management	
	specialist, other provider after patient consultation with a dietician	
Coverage Duration	All diagnoses:	
	o Initial: 12 months	
	o Renewal: 12 months	

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

#### References

- Change L, et al. American Gastroenterological Association-American College of Gastroenterology Clinical Practice Guideline: Pharmacological Management of Chronic Idiopathic Constipation. *Gastroenterology* 2023;164:1086–1106.
- 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.

- 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)**

#### **Products Affected**

• Orkambi Granules

• Orkambi Tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.</li> <li>Cystic Fibrosis</li> </ul>
Required Medical	Cystic Fibrosis
Information and	Documentation of cystic fibrosis diagnosis with homozygous F508del
Criteria	mutation
	Not used in combination with other CFTR modulator treatments
Renewal Criteria	Documented clinical response to therapy
Age Restriction	1 years of age and older
Prescriber	Cystic Fibrosis: Pulmonologist
Restriction	
Coverage Duration	Cystic Fibrosis:
	o Initial: 6 months
	o Renewal: 12 months

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

References	
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# Mefloquine

### **Products Affected**

• Mefloquine Tablets

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design     Treatment of Malaria	
Required Medical	Malarial Treatment	
Information and	Confirmed diagnosis of malaria	
Criteria		
Renewal Criteria	• N/A	
Coverage Duration	Malaria:	
	o Initial: 1 months	
	o Renewal: N/A	

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

References	
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## **Memantine**

### **Products Affected**

• Memantine 5mg Tablets

• Memantine 10mg Tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Moderate to Severe Dementia of the Alzheimer's Type</li> </ul>
Required Medical Information and Criteria	<ul> <li>Moderate to Severe Dementia of the Alzheimer's Type</li> <li>Clinical documentation confirming a diagnosis of moderate to severe dementia of the Alzheimer's type.</li> </ul>
	Solution only: Documentation that the member is unable to use tablets
Renewal Criteria	Documented positive clinical response to therapy
Age Restriction	Solution only: Age less than 10 (or can't swallow tablets)
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</li> </ul>

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

References	
•	

# **Mesalamine Step Therapy**

#### **Products Affected**

• Mesalamine DR tablet 1.2 gm

Step Therapy	• Tr	ial and failure of
Criteria	0	Mesalamine 0.375mg caps

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

# Mirabegron (Myrbetriq)

### **Products Affected**

• Mirabegron ER tablets

	1
Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Overactive Bladder with symptoms of urge urinary incontinence,</li> </ul>
	urgency, and urinary frequency
	Neurogenic detrusor overactivity in pediatric members
Required Medical	Overactive Bladder with symptoms of urge urinary incontinence, urgency,
Information and	and urinary frequency
Criteria	<ul> <li>Documented trial and failure of at least 3 of the following, or contraindication to all:</li> </ul>
	Oxybutynin IR or ER
	<ul> <li>Fesoterodine</li> </ul>
	<ul> <li>Solifenacin</li> </ul>
	<ul> <li>Tolterodine IR or ER</li> </ul>
	<ul> <li>Trospium IR or ER (requires step therapy through oxybutynin)</li> </ul>
	Neurogenic Detrusor Overactivity in pediatric members
	Is there documented trial and failure, intolerance, or contraindication to both of the following:
	Oxybutynin IR or ER
	o Solifenacin
Renewal Criteria	Documentation of positive clinical response to therapy
Age Restriction	3 years of age and older
Coverage Duration	All Diagnoses:
	o Initial: 12 months
	o Renewal: 12 months

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)

#### **Products Affected**

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

Required Medical Information and Criteria	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design         <ul> <li>Ulcerative Colitis</li> </ul> </li> <li>All diagnoses         <ul> <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> </li> <li>Ulcerative Colitis (UC)         <ul> <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:</li></ul></li></ul>
Renewal Criteria	<ul> <li>Trial and failure of both infliximab and adalimumab</li> <li>Evidence of a significant response such as a decrease in bloody stools</li> </ul>
	per day or elimination of signs of toxicity.
Exclusion Criteria	<ul> <li>Not to be used in combination with other biologics for the same indication.</li> </ul>
Prescriber	Ulcerative Colitis: Gastroenterologist
Restriction	
Coverage Duration	Ulcerative Colitis:
	o Initial: 6 months
	o Renewal: 12 months

Effective Date:	7/1/2024

P&T Approval Date:	5/14/2024
P&T Revision Date:	5/14/2024

References	
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# Mitapivat (Pyrukynd)

### **Products Affected**

• Pyrukind Tablets

Covered Uses  Required Medical Information and	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design     Hemolytic Anemia  Hemolytic Anemia
Criteria	<ul> <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 ≤ 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>
Renewal Criteria	Clinical documentation showing an increase in Hb at least 1.5 mg/dL over baseline and/or a reduction in frequency of transfusions.
Age Restriction	18 years of age or older
Prescriber	Hemolytic Anemia: Hematologist
Restriction	
Coverage Duration	<ul> <li>Hemolytic Anemia:</li> <li>Initial: 3 months</li> <li>Renewal: 6 months</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**

#### **Products Affected**

• Mometasone Furoate Nasal Spray

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Nasal Congestion or Rhinitis</li> </ul>
Required Medical	Nasal Congestion or Rhinitis
Information and Criteria	Diagnosis of asthma or an above the line comorbid condition that may worsen if not treated
	<ul> <li>Inadequate treatment response, intolerance, or contraindication to all the following</li> <li>Fluticasone nasal spray</li> <li>Budesonide nasal spray</li> <li>Triamcinolone nasal spray</li> </ul>
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</li> </ul>

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

References	
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# **Naltrexone (Vivitrol)**

### **Products Affected**

• Vivitrol Injection

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical	All Diagnoses
Information and	<ul> <li>The drug will be dispensed directly to the provider and not the</li> </ul>
Criteria	member.
Coverage Duration	All Diagnoses:
	o Initial: 12 months
	o Renewal: 12 months

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**

### **Products Affected**

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

Step Therapy Criteria	<ul> <li>Trial and failure of</li> <li>Fluticasone 50 mcg/act nasal spray</li> </ul>

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

### **Nitroglycerin ointment**

### **Products Affected**

• Nitroglycerin 0.4% ointment

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

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**

### **Products Affected**

• All Non-Formulary Medications

<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> </ul>
One of the following:   The requested medication is being used to treat an above the line diagnosis on the OHA Prioritized list   The member has an above the line comorbid condition that will be treated indirectly by the requested medication   The member under the age of 21   One of the following:   The requested medication is being used for an FDA-approved indication:   The requested medication is being used for an off-label indication with well-established, clinical evidence supporting its use.   All appropriate formulary alternatives have been tried and failed or are contraindicated.   Non-Formulary alternative dosage form (e.g. a request for NF oral solution when tablets are on formulary)   One of the following:   Member has clinically documented inability to swallow tablets/capsules   One of the following:   The formulary equivalent tablet/capsule does not require PA   The formulary equivalent tablet/capsule requires PA and the PA criteria has been met
<ul> <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>

Age Restriction	FDA labeled limits	
Prescriber Restriction	All Diagnoses: Appropriate Specialist will vary by drug and condition	
Coverage Duration	<ul> <li>All Diagnoses:</li> <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>	

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

References	
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### **Omalizumab** (Xolair)

#### **Products Affected**

Xolair Prefilled Syringe

Xolair Auto-Injector

### **Covered Uses** All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design Moderate to Severe Asthma Chronic Rhinosinusitis with Nasal Polyps Chronic Idiopathic Urticaria - Refractory IgE-Mediated Food Allergy **Required Medical** Severe Asthma Information and Confirmed diagnosis of moderate to severe persistent asthma. Criteria Positive skin test or RAST to a perennial aeroallergen. • Baseline IgE serum level within FDA label. • Documentation of steps taken to avoid, within reason, environmental allergens and other triggers environmental allergens and other triggers. Documented trial and failure, with claims history of adherence to: • High dose inhaled corticosteroid with a long-acting beta agonist (e.g., Advair), Long acting anti-muscarinic (e.g., Spiriva). Leukotriene Inhibitor (e.g., Singulair). Documented trial and failure of, or contraindication to allergen immunotherapy. **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):** Confirmed diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP). Documentation of recurrent nasal polyps after prior sinus surgery. • Documented risk of another sinus surgery, or a statement why sinus surgery is not medically appropriate. • Documented trial and failure, with claims history of adherence to: • At least 2 intranasal corticosteroids (e.g., fluticasone, mometasone), Sinuva. Documentation that Xolair is intended as adjunct therapy with nasal corticosteroids.

#### **Chronic Idiopathic Urticaria - refractory (CIU)**

- Documentation of chronic spontaneous or idiopathic urticaria.
- Age under 21, or a comorbid condition which would make chronic urticaria coverable under the prioritized list.
- Documented trial and failure of at least 6 weeks of maximally tolerated doses of all the following:
  - o 1st generation antihistamine (e.g., doxepin, hydroxyzine)
  - 2<sup>nd</sup> generation antihistamine (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine)
  - Histamine Type-2 Receptor Antagonists (e.g., famotidine, cimetidine)
  - Leukotriene inhibitor (e.g., montelukast, zafırlukast)

#### **IgE-Mediated Food Allergy**

- Diagnosis of IgE Mediated Food Allergy as evidenced by one of the following:
  - Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food,
  - Positive food specific IgE (greater than or equal to 6 kUA/L),
  - 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.
- · Clinical history of IgE mediated food allergy.
- Used in conjunction with food allergen avoidance.
- Both of the following:
  - 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,
  - Dosing is according to serum total IgE levels and body weight.
- Xolair will not be used concomitantly with Palforzia.
- Attestation that the member is co-prescribed epinephrine or has epinephrine at home.

#### **Renewal Criteria**

#### **IgE Mediated Food Allergy:**

- 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).
- Used in conjunction with food allergen avoidance.
- Dosing will continue to be based on body weight and pretreatment IgE serum levels.

#### All Other Diagnoses:

	Documentation of clinically significant improvement in symptoms.	
<b>Exclusion Criteria</b>	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.	
Age Restriction	Asthma: 6 years of age and older	
	CIU: 12 years of age and older	
	CRSwNP: 18 years of age and older	
	IgE Mediated Food Allergy: 1 year of age and older	
Prescriber	Asthma: Prescribed by or in consultation with a pulmonologist or	
Restriction	immunologist.	
	CIU: Prescribed by or in consultation with an immunologist.	
	CRSwNP: Prescribed by or in consultation with an allergist or ENT.	
	IgE Mediated Food Allergy: Prescribed by or in consultation with an	
	allergist or immunologist.	
Coverage Duration	Asthma:	
	o Initial: 6 months	
	o Renewal: 12 months	
	CRSwNP:	
	o Initial: 6 months	
	o Renewal: 12 months	
	• CIU:	
	o Initial: 4 months	
	Renewal: 6 months	
	o Kenewai. o months	
	IgE Mediated Food Allergy:	
	o Initial: 6 months	
	o Renewal: 12 months	

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

References	
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### **General Oncology (Chemotherapy)**

#### **Products Affected**

- Abemaciclib (Verzenio)
- Abiraterone
- Acalabrutinib (Calquence)
- Adagrasib (Krazati)
- Alectinib (Alecensa)
- Alpelisib (Piqray)
- Ascinimib (Scemblix)
- Asparaginase Erwinia (Rylaze)
- Avutometinib/Defactinib (Avmapki/Fazynja Pak)
- Belzutifan (Welireg)
- Binimetinib (Mektovi)
- Bosutinib (Bosulif)
- Brigatinib (Alunbrig)
- Busulfan (Myleran)
- Cabozantinib (Cabometyx)
- Capivasertib (Trugap)
- Capmatinib (Tabrecta)
- Ceritinib (Zykadia)
- Chlorambucil (Leukeran)
- Crizotinib (Xalkori)
- Dabrafenib (Tafınlar)
- Dasatinib
- Darolutamide (Nubega)
- Elacestrant (Orserdu)
- Encorafenib (Braftovi)
- Entrectinib (Rozlytrek)
- Erlotinib
- Estramustine (Emcyt)
- Everolimus
- Fruguintinib (Fruzagla)
- Futibatinib (Lytgobi)
- Gefitinib
- Ibrutinib (Imbruvica)
- Inavolisib (Itovebi)
- Infigratinib (Truseltiq)

- Lorlatinib (Lobrena)
- Midostaurin (Rydapt)
- 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)
- Quizartinib (Vanflyta)
- Repotrectinib (Augtyro)
- Ribociclib (Kisqali)
- Sargramostim (Leukine)
- Selpercatinib (Retevmo)
- Sorafenib
- Sotorasib (Lumakras)
- Sunitinib
- Sunvozertinib (Zegfrovy)
- Talazoparib (Talzenna)
- Taletrectinib (Ibtrozi)
- Temozolomide
- Tepotinib (Tepmetko)
- Tivozanib (Fotivda)
- Topotecan (Hycamtin)
- Tovorafenib (Ojemda)
- Trametinib (Mekinist)
- Trifluridine/Tipiracil (Lonsurf)
- Tucatinib (Tukysa)

- Ivosidenib (Tibsovo)
- Lazertinib (Lazcluze)
- Lenvatinib (Lenvima)
- Lomustine (Gleostine)

- Vimseltinib (Romvimza)
- Vorasidinib (Voranigo)
- Vorinostat (Zolinza)
- Zanubrutinib (Brukinsa)

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design	
Required Medical Information and Criteria	<ul> <li>All Diagnoses</li> <li>One of the following is true:         <ul> <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>	
Renewal Criteria	Submission of clinical documentation supporting provider follow-up that indicates safety and efficacy of the medication and adherence to treatment.	
Age Restriction	Refer to FDA indication and NCCN guidelines	
Prescriber Restriction	All Diagnoses: Oncologist or hematologist	
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 3 months</li> <li>Renewal: up to 6 months</li> </ul>	

Effective Date:	11/1/2025
P&T Approval Date:	10/01/2022
P&T Revision Date:	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**

### **Products Affected**

- Griseofulvin Ultramicrosize Tabs
- Ketoconazole Tabs

• Griseofulvin Microsize Susp

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	<ul> <li>All Diagnoses</li> <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> <li>Is there a reason that a tablet form can't be used</li> </ul> </li> </ul>
Renewal Criteria	<ul> <li>Documentation of positive clinical response to therapy</li> <li>Evidence of continued need for the medication</li> </ul>
Coverage Duration	<ul> <li>All diagnoses:</li> <li>Initial: 3 months</li> <li>Renewal (non-immunocompromised): 3 months</li> <li>Renewal (immunocompromised): 6 months</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**

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information and Criteria	<ul> <li>All Diagnoses</li> <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> <li>OR</li> <li>For age under 21         <ul> <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>
Renewal Criteria	Documentation of continued positive response for the requested enteral nutrition/formula with a continued need for requested supplement.
Exclusion Criteria	<ul> <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>
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul>

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

### References

# Pancrelipase (Creon, Pancreaze)

### **Products Affected**

• Creon Capsules

• Pancreaze Capsules

Required Medical Information and Criteria	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design         <ul> <li>Exocrine Pancreatic Insufficiency</li> </ul> </li> <li>Clinical documentation of one of the following:         <ul> <li>Confirmed diagnosis of cystic fibrosis</li> <li>History of pancreatectomy</li> <li>Diagnosis of exocrine pancreatic cancer</li> <ul> <li>Diagnosis of chronic pancreatici insufficiency confirmed with one of the following methods:</li> <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> </ul></li> </ul>
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	<ul> <li>Exocrine Pancreatic Insufficiency:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</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

#### **Products Affected**

- Repatha SureClick
- Repatha Prefilled Syringe
- Repatha Pushtronex

Praluent Auto-Injector

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Established clinical ASCVD</li> <li>Primary or Familial Hyperlipidemia</li> </ul>
Required Medical Information and Criteria	<ul> <li>Established Clinical ASCVD</li> <li>Documentation of very high risk ASCVD as evidenced by either:         <ul> <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> <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>
	<ul> <li>Primary or Familial Hyperlipidemia</li> <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> <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>
Renewal Criteria	Documented positive clinical response to therapy (significant decrease in lipid levels).

Prescriber Restriction	All Diagnoses: Cardiologist, Endocrinologist, or Lipid Specialist
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul>

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

References	
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# **Peanut Powder (Palforzia)**

### **Products Affected**

• Palforzia Capsule and Powder

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Peanut Allergy</li> </ul>	
Required Medical Information and Criteria	<ul> <li>Peanut Allergy</li> <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>	
Renewal Criteria	<ul> <li>Currently receiving medication by way of previously approved SHP authorization or documents showing Initial 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 Initial dose escalation happened between age 4 and 17.</li> </ul>	
Age Restriction	Patient must be between 4 and 17 at therapy initiation	
Prescriber Restriction	Peanut Allergy: Allergist or Immunologist enrolled in Palforzia REMS program	
Coverage Duration	<ul> <li>Peanut Allergy:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</li> </ul>	

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

References	
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# **Phosphodiesterase Type 5 (PDE5) inhibitors**

### **Products Affected**

• Sildenafil 20mg tablet

Tadalafil 20mg tablet

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Pulmonary Arterial Hypertension</li> </ul>
Required Medical	Pulmonary Arterial Hypertension
Information and	Clinically documented diagnosis of Pulmonary Arterial Hypertension
Criteria	(WHO group 1 pulmonary hypertension)
Renewal Criteria	Documented positive clinical response to therapy
<b>Exclusion Criteria</b>	Treatment of erectile dysfunction
Age Restriction	Tadalafil: 18 years of age and over
Prescriber Restriction	Pulmonary Arterial Hypertension: Cardiologist or Pulmonologist
Coverage Duration	Pulmonary Arterial Hypertension:
	o Initial: 6 months
	o Renewal: 12 months

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

### References

- Adcirca (tadalafil). Prescribing information. Eli Lilly and Co. Indianapolis, IN 2020.
- Revatio (sildenafil). Prescribing information. Viatris Specialty LLC. Morgantown, WV 2024

# **Phytonadione (Vitamin K) Step Therapy**

### **Products Affected**

• Phytonadione 5mg tab

Step Therapy Criteria	Concurrent use of warfarin
Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

# Pitolisant (Wakix)

### **Products Affected**

• Wakix Tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Cataplexy and Narcolepsy</li> <li>Excessive Somnolence - Narcolepsy</li> </ul>
Required Medical Information and Criteria	<ul> <li>Cataplexy and Narcolepsy</li> <li>Confirmation of diagnosis of narcolepsy based on both:         <ul> <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> <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>
	<ul> <li>Excessive Somnolence - Narcolepsy</li> <li>Confirmation of diagnosis of narcolepsy based on both:         <ul> <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> <li>Modafinil (at least 200mg dose) AND armodafinil</li> <li>Mixed amphetamine salts, methylphenidate or dexmethylphenidate, AND dextroamphetamine</li> <li>Sunosi (solriamfetol)</li> <li>A sodium oxybate product</li> </ul> </li> </ul>
Renewal Criteria	Documentation of positive clinical response to therapy
<b>Exclusion Criteria</b>	Severe renal or hepatic impairment

	Pregnant or actively trying to conceive	
Prescriber Restriction	All Diagnoses: Sleep Specialist or Neurologist	
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 3 months</li> <li>Renewal: 6 months</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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### **Potassium Binders**

### **Products Affected**

• Lokelma Powder

• Veltassa Packet

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design     Hyperkalemia	
Required Medical	<u>Hyperkalemia</u>	
Information and Criteria	<ul> <li>Being used for the treatment of hyperkalemia based on current potassium labs</li> <li>Failed all the following:         <ul> <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> <li>Trial and failure or contraindication to Lokelma</li> </ul> </li> </ul>	
Renewal Criteria	Documented positive clinical response to therapy by either of the following:  Potassium level returning to normal on therapy Significant drop in potassium level from baseline on therapy	
Coverage Duration	Hyperkalemia:     Initial: 6 months     Renewal: 12 months	

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**

### **Products Affected**

Pretomanid tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Pulmonary tuberculosis</li> </ul>
Required Medical	Pulmonary tuberculosis
Information and	Evidence of extensively drug-resistant active pulmonary tuberculosis
Criteria	(XDR-TB) caused by mycobacterium tuberculosis.
	<ul> <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> <li>Pretomanid is prescribed as part of a guideline recommended multidrug treatment regimen.</li> </ul>
Renewal Criteria	• N/A
<b>Exclusion Criteria</b>	Use outside of recognized treatment guidelines.
	<ul> <li>Medication is being received through a county clinic with a state funded TB program.</li> </ul>
Age Restriction	Age of 14 or greater.
Prescriber Restriction	Infectious Disease
Coverage Duration	Pulmonary tuberculosis: 24 weeks

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**

### **Products Affected**

- Orenitram tablets
- Treprostinil

- Remodulin
- Tyvaso

Covered Uses  Required Medical	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Pulmonary Arterial Hypertension</li> </ul> Pulmonary Arterial Hypertension		
Information and Criteria	<ul> <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> <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>		
Renewal Criteria	Documentation of positive clinical response to therapy		
Age Restriction	Age 16 or older		
Prescriber Restriction	Pulmonary Arterial Hypertension: Cardiologist or Pulmonologist		
Coverage Duration	<ul> <li>Pulmonary Arterial Hypertension:</li> <li>Initial: 6 months</li> <li>Renewal: 12 months</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**

### **Products Affected**

• All Drugs with Quantity Limits

0 111	AUE I ID AIIII (FDA) IIII I		
Covered Uses	All Food and Drug Administration (FDA)-approved indications not		
	otherwise excluded by plan design		
Required Medical	All FDA Approved Conditions		
Information and			
Criteria	<ul> <li>One of the following:         <ul> <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> <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</li> </ul>		
	<ul> <li>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>		
Renewal Criteria	Documented positive clinical response to therapy		
Exclusion Criteria	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.		
Age Restriction	FDA labeled limits		
Prescriber	All Diagnoses: Appropriate Specialist will vary by drug and condition		
Restriction			
Coverage Duration	<ul> <li>All Diagnoses:</li> <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>		

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

References	
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# Resmetirom (Rezdiffra)

### **Products Affected**

• Rezdiffra Tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Metabolic Dysfunction-Associated Steatohepatitis</li> </ul>
Required Medical Information and Criteria	<ul> <li>Metabolic Dysfunction-Associated Steatohepatitis</li> <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> <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> <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>
Renewal Criteria	<ul> <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>
Age Restriction	!8 years of age or older
Prescriber Restriction	Metabolic Dysfunction-Associated Steatohepatitis:     Gastroenterologist, Hepatologist

Coverage Duration	Metabolic Dysfunction-Associated Steatohepatitis:		
	o Initial: 6 months		
	o Renewal: 12 months		

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

References	
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# **Rifapentine (Priftin)**

### **Products Affected**

• Priftin tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Latent tuberculosis</li> <li>Active tuberculosis</li> </ul>
Required Medical	<u>Latent tuberculosis</u>
Information and	Used in combination with isoniazid (INH).
Criteria	
	Active tuberculosis
	Used as part of a multi-drug regimen.
Renewal Criteria	• N/A
<b>Exclusion Criteria</b>	<ul> <li>Medication is being received through a county clinic with a state funded TB program.</li> </ul>
Age Restriction	Age ≥ 2 years old with latent TB
	<ul> <li>Age ≥ 12 years old with active TB</li> </ul>
Prescriber	Latent TB: Not limited by specialty
Restriction	Active TB: Infectious disease specialist required for multidrug
	resistant cases only
Coverage Duration	Latent TB: 3 months
	Active TB: 6 months

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.

# Rifaximin (Xifaxan)

### **Products Affected**

• Xifaxan 550mg tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Hepatic Encephalopathy</li> </ul>
Required Medical	Hepatic Encephalopathy
Information and	Confirmed diagnosis of hepatic encephalopathy
Criteria	One of the following:
	<ul> <li>Xifaxan will be used as add-on therapy to lactulose and there is documentation of failure to achieve optimal clinical response with lactulose alone</li> </ul>
	<ul> <li>Documentation of contraindication or intolerance to lactulose</li> </ul>
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	<ul> <li>Hepatic Encephalopathy:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</li> </ul>

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

References	
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# Risdiplam (Evrysdi)

### **Products Affected**

• Evrysdi Solution

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Spinal Muscular Atrophy</li> </ul>
Required Medical	Spinal Muscular Atrophy
Information and Criteria	<ul> <li>Confirmed (via genetic testing) diagnosis of 5q-autosomal recessive SMA (type 1, 2 or 3)</li> </ul>
	Patient is not dependent on invasive ventilation or tracheostomy or use of non-invasive ventilation beyond uses for sleeping
	Patient is not receiving concomitant chronic SMN modifying therapy such as Spinraza
	Patient has not previously received gene replacement therapy for the treatment of SMA (e.g. Zolgensma)
Renewal Criteria	Documentation of clinical improvement from baseline in motor functionality confirmed by standard exams (e.g. BSID-III, CHOP INTEND, HINE-2, RULM test)
Prescriber	Spinal Muscular Atrophy: Neurologist with expertise in the treatment
Restriction	of spinal muscular atrophy
Coverage Duration	Spinal Muscular Atrophy:     Initial: 12 months     Renewal: 12 months

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**

### **Products Affected**

- Product 1
- Product 3

- Product 2
- Etc.

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Chronic Obstructive Pulmonary Disorder (COPD)</li> </ul>
Required Medical	Chronic Obstructive Pulmonary Disorder (COPD)
Information and	Diagnosis of moderate to severe COPD and chronic bronchitis
Criteria	Trial and failure of at least 2 previous treatments for COPD
Renewal Criteria	Documentation of positive clinical response to roflumilast therapy.
Exclusion Criteria	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.
Coverage Duration	<ul> <li>COPD:</li> <li>Initial: 12 months</li> <li>Renewal:12 months</li> </ul>

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

References	
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## Sacubitril/Valsartan (Entresto)

### **Products Affected**

Entresto tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Heart Failure</li> </ul>
Required Medical	Heart Failure
Information and	Diagnosis of New York Heart Association class II to IV heart failure
Criteria	The patient meets one of the following:
	<ul> <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> <li>The patient will discontinue use of any ACE inhibitor or ARB before initiating therapy with Entresto.</li> </ul>
Renewal Criteria	Documented positive response to therapy.
Prescriber	Cardiologist, or in consultation with a cardiologist
Restriction	
Coverage Duration	Heart Failure:

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

### **Covered Uses** All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design Ankylosing Spondylitis/Axial Spondyloarthritis Hidradenitis Suppurativa Juvenile Idiopathic Arthritis Plaque Psoriasis Psoriatic Arthritis **Required Medical** All diagnoses Information and Initial testing for latent TB and treatment, if necessary, before starting Criteria treatment. No current active infection at initiation of therapy. Risks and benefits documented in cases of chronic or recurrent infection. Will NOT be used in combination with another biologic or Otezla. Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA) 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 One of the following: o 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 infliximab and adalimumab

**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
  - o 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

- Methotrexate
- At least 1 other second line systemic agent such as cyclosporine or acitretin.
- Trial and failure of 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 of 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

#### **Renewal Criteria**

- Ankylosing Spondylitis, Axial Spondyloarthritis: Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.
- **Juvenile Idiopathic Arthritis:** Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.
- Plaque Psoriasis: 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.
- Psoriatic Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.

Prescriber	Plaque Psoriasis: Dermatologist.
Restriction	Psoriatic Arthritis: Dermatologist or Rheumatologist.
	Juvenile Idiopathic Arthritis: Rheumatologist.
	Ankylosing Spondylitis, Axial Spondyloarthritis: Rheumatologist.
<b>Coverage Duration</b>	All Diagnoses:
	o Initial: 6 months
	o Renewal: 12 months

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

References	
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# Seladelpar (Livdelzi)

### **Products Affected**

• Livdelzi Capsules

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design     Primary Biliary Cholangitis
Required Medical	Primary Biliary Cholangitis
Information and	Diagnosis of primary biliary cholangitis (PBC) confirmed by two of the
Criteria	following:
	<ul> <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>
	Documentation of at least 12 months of inadequate response to ursodiol
	No current decompensated cirrhosis
Renewal Criteria	Documented adherence to medication regimen and clinical benefit
Age Restriction	Age 18 or older
Prescriber	Primary Biliary Cholangitis: Hepatologist or Gastroenterologist
Restriction	
Coverage Duration	Primary Biliary Cholangitis:
	o Initial: 6 months
	o Renewal: 12 months

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

References	
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# **Semaglutide (Wegovy)**

## **Products Affected**

• Wegovy Injection

Covered Uses	All Food and Dura Administration (FDA) annuaried indication and	
Covered uses	All Food and Drug Administration (FDA)-approved indications not     atherwise evaluded by plan decire.	
	otherwise excluded by plan design	
	Secondary Prevention of Major Adverse Events (MACE)	
	<ul> <li>Obesity or Overweight (only applies to members under age 21)</li> </ul>	
Required Medical	Secondary Prevention of Major Adverse Events	
Information and	Wegovy is being used to reduce the risk of major adverse	
Criteria	cardiovascular events (cardiovascular death, non-fatal myocardial	
	infarction, or non-fatal stroke) in adults with established	
	cardiovascular disease and either obesity or overweight.	
	<ul> <li>Wegovy is being used as adjunct to lifestyle modification (e.g., dietary,</li> </ul>	
	or caloric restriction, exercise, behavioral support, community-based	
	program).	
	<ul> <li>Patient has established cardiovascular disease as evidenced by one of</li> </ul>	
	the following:	
	<ul> <li>Prior myocardial infarction</li> </ul>	
	Prior stroke	
	<ul> <li>Peripheral arterial disease (e.g., intermittent claudication with</li> </ul>	
	ankle-brachial index <0.85, peripheral arterial revascularization	
	procedure, or amputation due to atherosclerotic disease)	
	BMI greater than or equal to 27 kg/m2	
	Bivil greater than or equal to 27 kg/m2	
	Obesity or Overweight	
	Age 20 or younger	
	BMI at or above the 95 <sup>th</sup> percentile or 27kg/m2.	
	Documentation of one of the following:	
	<ul> <li>Comorbidities (e.g., hypertension, dyslipidemia, fatty liver disease,</li> </ul>	
	depression, or sleep apnea).	
	<ul> <li>Trial and failure of at least 3 months of a diet/exercise plan</li> </ul>	
	administered by a health care provider in the last 6 months.	
	The patient is, or will be, engaged in a weight management lifestyle	
	modification program in addition to pharmacotherapy.	
Renewal Criteria	Secondary Prevention of Major Adverse Events (MACE):	
	Documentation of treatment success (BMI reduction of 5% or more).	
	Documentation of continuation of lifestyle modification program with	

	reduced calorie diet and regular physical activity alongside continuous Wegovy use (80% adherence).	
	Obesity or overweight:	
	Patient is less than 21 years old.	
	<ul> <li>Documentation of at least a 1% decrease in BMI from baseline.</li> </ul>	
	<ul> <li>Patient is continuing full weight loss plan (e.g., diet and exercise program, nutritional counseling).</li> </ul>	
<b>Exclusion Criteria</b>	Coverage for weight loss is excluded for members age 21 or older	
Age Restriction	Secondary Prevention of Major Adverse Events (MACE): 12 years or	
	older	
	Obesity or overweight: Age 12 to under 21 years of age	
Prescriber	Secondary Prevention of Major Adverse Events (MACE): Cardiologist	
Restriction	Diagnosis 2: Specialist 2, etc.	
	• Etc.	
<b>Coverage Duration</b>	Secondary Prevention of Major Adverse Events (MACE):	
	o Initial: 6 months	
	o Renewal: 12 months	
	<ul> <li>Obesity or overweight:</li> <li>Initial: 6 months</li> <li>Renewal: 12 months or until age 21, whichever is less</li> </ul>	
	<b>3</b> ,	

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

References	
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# **Sirolimus Solution**

### **Products Affected**

• Sirolimus Oral Solution

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design	
Age Restriction	Patient is under age 10 or unable to use tablets	
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</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**

## **Products Affected**

• Sodium oxybate 500mg/mL

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Cataplexy and narcolepsy</li> <li>Excessive somnolence due to narcolepsy</li> </ul>	
Required Medical Information and Criteria	<ul> <li>Cataplexy and Narcolepsy</li> <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> <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>	
	<ul> <li>Excessive Somnolence due to Narcolepsy</li> <li>Confirmation of diagnosis of narcolepsy based on BOTH:         <ul> <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> <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>	
Renewal Criteria	<ul> <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>	Currently pregnant or plan to conceive during treatment.	
Age Restriction	Age ≥7 years old and weight ≥20kg	
Prescriber Restriction	All diagnoses: Sleep specialist, Neurologist, Pulmonologist	

<b>Coverage Duration</b>	All diagnoses:	
	<ul><li>Initial: 3 months</li></ul>	
	<ul> <li>Renewal: 12 months</li> </ul>	

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

#### References

- Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; 2025
- Steier et al. Recommendations for clinical management of excessive daytime sleepiness in obstructive sleep apnoea-A Delphi consensus study. Sleep Med.2023 December;112:104-115.
- Mehra R, et al. Current Management of Residual Excessive Daytime Sleepiness Due to Obstructive Sleep Apnea: Insights for Optimizing Patient Outcomes. Neurol Ther (2021) 10:661-672.
- Servid and Shirley. Drug Class Review with New Drug Evaluation: Narcolepsy Agents. Drug Use Research & Management Program. July 2029.
- Epstein LJ, et al. Clinical Guideline for the Evaluation, Management, and Long-term Care
  of Obstructive Sleep Apnea in Adults. Journal of Clinical Sleep Medicine, Vol.5, No. 3,
  2009.

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

#### **Products Affected**

- Farxiga Tablets
- Dapagliflozin Tablets
- Steglatro Tablets

- Jardiance Tablets
- Invokana Tablets

#### **Covered Uses**

- All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
  - Type 2 Diabetes
  - Chronic Kidney Disease
  - Heart Failure

### Required Medical Information and Criteria

### **Type 2 Diabetes**

- Trial and failure of, or contraindication to metformin
- Trial and failure of sulfonylurea or pioglitazone or contraindication to both

#### **Chronic Kidney Disease**

- Concurrent therapy with an ACEi or ARB at maximum tolerated doses, or documented contraindication to both
- Stage 2, 3, or 4 CKD or eGFR of 25 to 75 mL/min/1.73 m2
- No previous use of dialysis
- No history of polycystic kidney disease, type 1 diabetes, lupus nephritis, or antineutrophil cytoplasmic antibody-associate vasculitis.

#### **Heart Failure**

- One of the following:
  - All the following:
    - Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction (HFrEF)
    - Documentation of concurrent use of ACEi, ARB, or ARNI, or contraindication to all
    - Documentation of concurrent use of carvedilol, metoprolol succinate, or bisoprolol, or contraindication to all
    - Documented eGFR >30 mL/min/1.73m<sup>2</sup>
  - All of the following:
    - Diagnosis of heart failure with mildly reduced ejection fraction (HFmrEF), or heart failure with preserved ejection fraction (HFpEF)

	■ eGFR >30 mL/min/1.73m <sup>2</sup>
Coverage Duration	All Diagnoses:

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 (Humatrope)**

### **Products Affected**

• Humatrope Cartridge

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Patient Under Age 18	
Confirmation of one of the following:	
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	<ul> <li>Diagnosis of Short stature homeobox-containing (SHOX) gene deficiency</li> </ul>	
	Diagnosis of HIV Associated Cachexia	
	Patients Aged 18 and Older	
	Confirmation of one of the following:  Out for a fall the following:	
	<ul> <li>Confirmation of all the following:</li> <li>Growth Hormone Deficiency (GHD) as noted by one of the following:</li> </ul>	
	<ul> <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> </ul>	
	<ul> <li>Patient has had the pituitary removed or destroyed or has had panhypopituitarism since birth</li> </ul>	
	<ul> <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>	
	HIV associated cachexia	
	<ul> <li>Short Bowel Syndrome (SBS)</li> </ul>	
Renewal Criteria	<ul> <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:</li> </ul>	
	Growth velocity greater than 2.5 cm per year	
	<ul> <li>Growth velocity less than 2.5 cm per year</li> <li>Documentation that benefits of therapy continue to outweigh risks</li> </ul>	
	<ul> <li>Documentation of improvement from baseline as assessed by the prescribing provider</li> </ul>	
Prescriber	Under 18: Pediatric Endocrinologist or Nephrologist	
Restriction	18 and Older: Endocrinologist	
Coverage Duration	All Diagnoses:	
	o Initial: 12 months	
	o Renewal: up to 12 months	

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

References	
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# **Sotatercept (Winrevair)**

## **Products Affected**

• Winrevair Injection

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Pulmonary Arterial Hypertension (PAH)</li> </ul>
Required Medical	Pulmonary Arterial Hypertension (PAH)
Information and	Diagnosis of symptomatic PAH (WHO Group 1 PH) confirmed by right
Criteria	heart catheterization.
	WHO functional class II or III symptoms.
	On a stable dose of both
	<ul> <li>Endothelin-1 receptor antagonists (ERA) and</li> <li>Phosphodiesterase type 5 inhibitors or guanylate cyclase stimulant</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>
Renewal Criteria	Documented positive clinical response to therapy
Prescriber	Pulmonary Arterial Hypertension: Pulmonologist or Cardiologist
Restriction	
Coverage Duration	<ul> <li>Pulmonary Arterial Hypertension:</li> <li>Initial: 6 months</li> <li>Renewal: 12 months</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)**

## **Products Affected**

• Filspari Tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Primary Immunoglobulin A Nephropathy.</li> </ul>
Required Medical	Primary Immunoglobulin A Nephropathy
Information and Criteria	<ul> <li>Urine protein-to-creatine ratio (UPCR) ≥ 1.5 and eGFR ≥ 30 mL/min?1.73 m2</li> </ul>
	Biopsy-verified primary IgA nephropathy
	<ul> <li>No history of kidney transplant and not currently receiving dialysis</li> </ul>
	<ul> <li>Member has failed to achieve a reduction in proteinuria to under 1</li> </ul>
	gram/day while receiving maximally tolerated doses of an ACE inhibitor or ARB for at least 12 weeks
Renewal Criteria	Documentation of improved or stable kidney function compared to baseline or reduction in proteinuria
Age Restriction	Age 18 or older
Prescriber	Primary Immunoglobulin A Nephropathy: Nephrologist.
Restriction	
Coverage Duration	Primary Immunoglobulin A Nephropathy:
	o Initial: 6 months
	o Renewal: 12 months

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

References	
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# **Sumatriptan Nasal Spray Step Therapy**

### **Products Affected**

• Sumatriptan Nasal Spray

Step Therapy	•	Trial and failure of
Criteria		<ul> <li>Formulary triptan tablet</li> </ul>

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

## **Suzetrigine (Journavx)**

### **Products Affected**

Journavx tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Acute, moderate to severe pain</li> </ul>
Required Medical	Acute moderate to severe pain
Information and	Clinical documentation of post-operative use following one of the
Criteria	following:
	<ul> <li>Abdominoplasty</li> </ul>
	<ul> <li>Bunionectomy</li> </ul>
	Documentation of one of the following:
	<ul> <li>Diagnosis of opioid use disorder</li> </ul>
	<ul> <li>Prescriber has a specific concern for opioid abuse.</li> </ul>
Renewal Criteria	Not eligible for renewal, patients will need to meet initial criteria with new surgery to be eligible for a new prescription.
<b>Exclusion Criteria</b>	Use for more than 14 days.
	Any use outside of acute post-procedural pain.
Age Restriction	Age 18 or older.
Coverage Duration	Acute moderate to severe pain:
	o Initial: 14 days
	o Renewal: N/A

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

### References

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# **Synthroid Step Therapy**

## **Products Affected**

• Synthroid

Step Therapy	• T	Trial and failure of
Criteria	C	Generic levothyroxine

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

## **Tacrolimus Ointment**

### **Products Affected**

• Tacrolimus 0.1% Ointment

• Tacrolimus 0.03% Ointment

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Atopic Dermatitis</li> <li>Psoriasis</li> </ul>
Required Medical	Atopic Dermatitis
Information and	Clinical documentation of diagnosis of moderate to severe atopic
Criteria	dermatitis
	<ul> <li>At least 10% of body surface area involved</li> </ul>
	<ul> <li>Hand, foot, face, or mucous membrane involvement</li> </ul>
	Trial and failure of all the following (or a reason they are not
	appropriate):
	<ul> <li>High potency topical steroids</li> </ul>
	<ul> <li>UVB phototherapy</li> </ul>
	<u>Psoriasis</u>
	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> <li>At least 10% of body surface area involved</li> </ul>
	<ul> <li>Hand, foot, face, or mucous membrane involvement</li> </ul>
	Trial and failure of all the following (or a reason they are not
	appropriate):
	High potency topical steroids
	<ul> <li>UVB phototherapy</li> </ul>
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	All Diagnoses:
	o Initial: 12 months
	Renewal: 12 months

Effective Date:	
P&T Approval Date:	

P&T Revision Date:	
References	
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## **Tazarotene**

### **Products Affected**

• Tazarotene 0.1% Cream

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Psoriasis</li> <li>Acne</li> </ul>
Required Medical	<u>Psoriasis</u>
Information and Criteria	<ul> <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> <li>At least 10% of body surface area involved</li> <li>Hand, foot, face, or mucous membrane involvement</li> </ul> </li> </ul>
	Acne
	<ul> <li>Confirmation that the diagnosis is one of the following:         <ul> <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>
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	<ul> <li>All Diagnoses:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</li> </ul>

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

References	
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# **Tenofovir Alafenamide (Descovy)**

### **Products Affected**

• Descovy Tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Treatment of HIV Infection</li> <li>Pre-Exposure Prophylaxis of HIV Infection (PrEP)</li> </ul>	
Required Medical	Treatment of HIV Infection	
Information and	Clinical contraindication to generic Truvada	
Criteria	Documentation that the drug will be used in combination with other HIV drugs as part of a complete treatment regimen	
	Pre-Exposure Prophylaxis of HIV Infection (PrEP)	
	Clinical contraindication to generic Truvada	
Coverage Duration	All Diagnoses:	

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**

### **Products Affected**

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

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Gender Dysphoria.</li> <li>AIDS Wasting Syndrome.</li> <li>Post-Menopausal Breast Cancer.</li> <li>Hypogonadism.</li> </ul>	
Required Medical	Gender Dysphoria	
Information and	Diagnosis of gender dysphoria	
Criteria	Trial and failure or contraindication to injectable testosterone	
	AIDS Wasting Syndrome	
	Diagnosis of AIDS wasting syndrome	
	Trial and failure or contraindication to injectable testosterone	
	Post-Menopausal Breast Cancer	
	Diagnosis of post-menopausal breast cancer	
	Trial and failure or contraindication to injectable testosterone	
	<u>Hypogonadism</u>	
	Diagnosis of hypogonadism	
	Trial and failure or contraindication to injectable testosterone	
Renewal Criteria	Documented positive clinical response to therapy	
Coverage Duration	<ul> <li>Gender Dysphoria, AIDS Wasting Syndrome, Post-Menopausal Breast Cancer:</li> <li>Initial: Lifetime</li> </ul>	
	<ul> <li>Hypogonadism:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</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)**

### **Products Affected**

• Symdeko Tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.</li> <li>Cystic Fibrosis</li> </ul>	
Required Medical	Cystic Fibrosis	
Information and	Documentation of cystic fibrosis diagnosis with homozygous F508del	
Criteria	mutation	
	Not used in combination with other CFTR modulator treatments	
Renewal Criteria	Documented clinical response to therapy	
Age Restriction	1 years of age and older	
Prescriber Restriction	Cystic Fibrosis: Pulmonologist	
Coverage Duration	Cystic Fibrosis:	
	o Initial: 6 months	
	o Renewal: 12 months	

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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# **Thickener (Thick-It)**

### **Products Affected**

• Thick-It

• Thick-It #2

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Swallowing Disorder</li> </ul>
Required Medical	Swallowing Disorder
Information and Criteria	<ul> <li>Documented swallowing study/evaluation for the treatment of swallowing disorder due to one of the following medical conditions:         <ul> <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>
Renewal Criteria	Documentation of appointment in the last 12 months confirming effectiveness of the requested thickener and continued need
Coverage Duration	<ul> <li>Swallowing Disorder:</li> <li>Initial: 6 months</li> <li>Renewal: 12 months</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

## **Products Affected**

• Tiagabine Tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Partial (Focal) Seizures</li> </ul>
Required Medical Information and Criteria	Partial Seizures     Confirmation of diagnosis of Partial Seizures
Renewal Criteria	Documented positive clinical response to therapy
Coverage Duration	<ul> <li>Partial Seizures:</li> <li>Initial: 12 months</li> <li>Renewal: 12 months</li> </ul>

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

References	
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# Ticagrelor

## **Products Affected**

• Ticagrelor tablets

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Covered Uses	All Food and Drug Administration (FDA)-approved indications not	
	otherwise excluded by plan design	
	<ul> <li>Acute Coronary Syndrome</li> </ul>	
	<ul> <li>Minor Ischemic Stroke</li> </ul>	
	o Etc.	
Required Medical	Acute Coronary Syndrome	
Information and	Member has:	
Criteria	<ul> <li>Either non-ST-elevation acute coronary syndrome (NSTE-ACS) or</li> </ul>	
	ST-elevation myocardial infarction (STEMI) AND	
	<ul> <li>Has had percutaneous coronary intervention (PCI) AND</li> </ul>	
	<ul> <li>Has a contraindication to prasugrel</li> </ul>	
	OR	
	Member has NSTE-ACS and is treated with medical therapy alone (has	
	not had PCI)	
	,	
	Minor Ischemic Stroke	
	Member has had a minor non-cardioembolic ischemic stroke (NIHSS)	
	score ≤5) in the immediate past	
	Did not receive IV alteplase	
	Has a reason that clopidogrel can't be used	
Renewal Criteria	Acute Coronary Syndrome: Documentation of positive clinical	
	response to therapy and continued need for treatment	
	Minor ischemic stroke: Renewal not appropriate	
Age Restriction	18 years of age and older	
Prescriber	Acute Coronary Syndrome: Cardiologist	
Restriction	Minor Ischemic Stroke: Cardiologist, Neurologist	
Coverage Duration	Acute Coronary Syndrome:	
	o Initial: 12 months	
	Renewal: 12 months	
	O Renewali 12 months	
	Minor Ischemic Stroke:	
	o Initial: 1 month	
	Renewal: N/A	
	O Reflewal. 14/A	
	1	

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

#### References

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- 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**

### **Products Affected**

• Tobramycin Nebulization Solution

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Cystic Fibrosis</li> </ul>
Required Medical	Cystic Fibrosis
Information and Criteria	Confirmed diagnosis of cystic fibrosis
	All Other Diagnoses
	Confirmed diagnosis of an FDA approved or compendia supported indication
Renewal Criteria	Confirmed diagnosis with clinical evidence supporting chronic use
Prescriber Restriction	<ul> <li>Cystic Fibrosis: Prescribed by or in consultation with Infectious         Disease Specialist, Pulmonologist, or Cystic Fibrosis Specialist</li> <li>All Other Diagnoses: Prescribed by or in consultation with Infectious         Disease Specialist, or Pulmonologist</li> </ul>
Coverage Duration	<ul> <li>Cystic Fibrosis:         <ul> <li>Initial: Lifetime</li> </ul> </li> <li>All Other Diagnoses:         <ul> <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)

#### **Products Affected**

- Actemra Prefilled Syringe
- Actemra ActPen

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

#### **Covered Uses**

- All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
  - Juvenile Idiopathic Arthritis
  - Rheumatoid Arthritis
  - Giant Cell Arteritis
  - Systemic Sclerosis-Associated Interstitial Lung Disease
  - Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy

### Required Medical Information and Criteria

### All diagnoses

- Initial testing for latent TB and treatment, if necessary, before starting treatment.
- No current active infection at initiation of therapy.
- Risks and benefits documented in cases of chronic or recurrent infection.
- Will NOT be used in combination with another biologic or Otezla.

### 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
  - o 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 oral disease-modifying antirheumatic drugs (DMARD) such as methotrexate, leflunomide, etc. or DMARDs will be continued
- Trial and failure of both infliximab and adalimumab

	<ul> <li>Rheumatoid Arthritis (RA):</li> <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> <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>
	<ul> <li>Giant Cell Arteritis:</li> <li>Clinical documentation confirming diagnosis of Giant Cell Arteritis</li> <li>Trial and failure of glucocorticoid treatment</li> </ul>
	<ul> <li>Systemic Sclerosis-Associated Interstitial Lung Disease:</li> <li>Confirmed diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD)</li> <li>Trial and failure of mycophenolate mofetil</li> </ul>
	<ul> <li>Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy:</li> <li>Member will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy</li> </ul>
Renewal Criteria	<ul> <li>Juvenile Idiopathic Arthritis: 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>Rheumatoid Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>Giant Cell Arteritis: Demonstrated positive clinical response to therapy.</li> <li>Systemic Sclerosis-Associated Interstitial Lung Disease:         <ul> <li>Demonstrated positive clinical response to therapy.</li> </ul> </li> </ul>
Prescriber Restriction	<ul> <li>Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Giant Cell Arteritis: Rheumatologist</li> <li>Systemic Sclerosis-Associated Interstitial Lung Disease: Rheumatologist or Pulmonologist</li> <li>Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy: Oncologist or Hematologist</li> </ul>

Coverage Duration	<ul> <li>Cytokine Release Syndrome:</li> <li>Initial: 2 months</li> <li>Renewal: N/A</li> </ul>
	<ul> <li>All Other Diagnoses:</li> <li>Initial: 6 months</li> <li>Renewal: 12 months</li> </ul>

Effective Date:	9/1/2024
P&T Approval Date:	7/11/2023
P&T Revision Date:	7/9/2024, 7/11/2023

References	
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## **Tofacitinib** (Xeljanz)

#### **Products Affected**

Xeljanz XR tablets

Xeljanz Tablets

### **Covered Uses** All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design Ankylosing Spondylitis/Axial Spondyloarthritis o Juvenile Idiopathic Arthritis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis **Required Medical** Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA) Information and Documentation of moderate-to-severe ankylosing spondylitis or axial Criteria 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 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 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 infliximab and adalimumab Trial and failure of Cosentyx and Taltz 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 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 of history)
  - o 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

	Trial and failure of Actemra, Cimzia, Kineret, Orencia, and rituximab
	Ulcerative Colitis (UC):  Documentation of moderate-to-severe ulcerative colitis
	<ul> <li>One of the following:         <ul> <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>
Renewal Criteria	Ankylosing Spondylitis/Axial Spondyloarthritis: Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.
	Juvenile Idiopathic Arthritis: Evidence of 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability.
	Psoriatic Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	Rheumatoid Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
	Ulcerative Colitis: Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.
Prescriber Restriction	<ul> <li>Ankylosing Spondylitis, Axial Spondyloarthritis: Rheumatologist.</li> <li>Psoriatic Arthritis: Dermatologist or Rheumatologist.</li> <li>Juvenile Idiopathic Arthritis: Rheumatologist</li> <li>Rheumatoid Arthritis: Rheumatologist.</li> <li>Ulcerative Colitis: Gastroenterologist.</li> </ul>
Coverage Duration	All Diagnoses:     Initial: 6 months     Renewal: 12 months

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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## **Tolterodine Step Therapy**

### **Products Affected**

• Tolterodine ER capsule

• Tolterodine tablet

Step Therapy	Trial and failure of
Criteria	o Oxybutynin

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

## **Topical Antifungal Agents**

### **Products Affected**

- Ciclopirox 8% Solution
- Econazole 1% Cream

- Selenium Sulfide 2.5% Lotion
- Ketoconazole 2% Cream and Shampoo

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical	All Diagnoses
Information and	All the following have been tried and failed or are not appropriate for
Criteria	use:
	<ul> <li>Clotrimazole 1% cream</li> </ul>
	<ul> <li>Miconazole 2% (cream, aerosol, or powder),</li> </ul>
	<ul> <li>Terbinafine 1%, cream, terbinafine tablets</li> </ul>
	Nystatin 100,000 units/gram (ointment, cream, or powder)
Renewal Criteria	Documented positive clinical response to therapy
<b>Coverage Duration</b>	All Diagnoses:
	o Initial: 3 months
	o Renewal: 12 months

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**

## **Products Affected**

• Toujeo Max Solostar

• Toujeo Solostar

Step Therapy Criteria	<ul> <li>Trial and failure of</li> <li>Any non-concentrated basal insulin product</li> </ul>

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

## **Tranexamic Acid**

## **Products Affected**

• Tranexamic Acid Tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Hemophilia – Hemorrhage Prophylaxis; Tooth Extraction</li> <li>Menorrhagia</li> </ul>
Required Medical Information and Criteria	Hemophilia – Hemorrhage Prophylaxis  O Documentation that use is intended for hemorrhage prophylaxis for tooth extraction
	<ul> <li>Menorrhagia</li> <li>Documentation of abnormal uterine bleeding</li> <li>Trail and failure of, current use of, or contraindication to all of the following:         <ul> <li>Combined Oral Contraceptive therapy</li> <li>Progestin therapy (oral or LM) or Levonorgestrel IUD</li> <li>NSAID therapy</li> </ul> </li> </ul>
Renewal Criteria	Documentation of positive clinical response to therapy
Prescriber Restriction	<ul> <li>Hemorrhage Prophylaxis: Hematologist, Hemophilia Specialist, Dentist</li> <li>Menorrhagia: Gynecologist</li> </ul>
Coverage Duration	All Diagnoses:

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

References		
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# Tretinoin, Topical

### **Products Affected**

- Tretinoin 0.025% cream
- Tretinoin **0.05% cream**

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

Covered Uses	All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design     Acne
Required Medical	Acne
Information and	Documentation of trial and failure, intolerance, or contraindication to a
Criteria	topical product containing benzoyl peroxide.
Renewal Criteria	Documentation of positive clinical response to therapy.
<b>Coverage Duration</b>	All Diagnosis
	o Initial: 12 months
	o Renewal: 12 months

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

## **Trospium Step Therapy**

## **Products Affected**

• Trospium IR tablets

• Trospium ER caps

Step Therapy Criteria	<ul> <li>Trial and failure of</li> <li>Oxybutynin IR or ER</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

# **Ubrogepant (Ubrelvy)**

## **Products Affected**

• Ubrelvy tablets

Required Medical Information and Criteria	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design         <ul> <li>Treatment of acute migraine</li> </ul> </li> <li>Acute Migraine         <ul> <li>Confirmed diagnosis of migraine</li> </ul> </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> <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>
Renewal Criteria	Documented positive clinical response to therapy
Age Restriction	18 years of age or older
Prescriber Restriction	Acute Migraine: Neurologist or headache specialist
Coverage Duration	Acute Migraine:     Initial: 3 months     Renewal: 12 months

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

Refer	ences
•	Ubrelyy [package insert]. North Chicago, IL: Abbyie Inc: 2025.

## **Upadacitinib** (Rinvoq)

#### **Products Affected**

Rinvoq Tablets

Rinvoq LQ Solution

### **Covered Uses** All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design Ankylosing Spondylitis/Axial Spondyloarthritis Atopic Dermatitis Crohn's Disease Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis **Required Medical** Ankylosing Spondylitis/Axial Spondyloarthritis (AS/SpA) Information and Documentation of moderate-to-severe ankylosing spondylitis or axial Criteria spondyloarthritis as defined by: Back pain and stiffness for more than 3 months AND o Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive AND BASDAI score of >=4 One of the following: o 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 infliximab and adalimumab Trial and failure of Cosentyx and Taltz **Atopic Dermatitis** Diagnosed with severe atopic dermatitis 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 another validated tool) One or more of the following: At least 10% of body surface area involvement Hand, foot, or mucous membrane involvement

- Documented contraindication or failed trial to ALL of the following:
  - Moderate-high potency corticosteroid (e.g., clobetasol, fluocinonide, fluticasone)
  - o 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: 6mercaptopurine, 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 of history)
  - o 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
- Trial and failure of Actemra, Cimzia, Kineret, Orencia, and rituximab

#### **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 infliximab and adalimumab
- Trial and failure of ustekinumab and Entyvio

#### **Renewal Criteria**

- Ankylosing Spondylitis/Axial Spondyloarthritis: Evidence of significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI.
- Atopic Dermatitis: 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.
- Crohn's Disease: Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.
- **Psoriatic Arthritis:** Evidence of a 20% or greater improvement in tender joint count and swollen joint count.
- Rheumatoid Arthritis: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.

	Ulcerative Colitis: Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.
Prescriber Restriction	<ul> <li>Ankylosing Spondylitis, Axial Spondyloarthritis: Rheumatologist.</li> <li>Atopic Dermatitis: Dermatologist.</li> <li>Crohn's Disease and Ulcerative Colitis: Gastroenterologist.</li> <li>Psoriatic Arthritis: Dermatologist or Rheumatologist.</li> <li>Rheumatoid Arthritis: Rheumatologist.</li> </ul>
Coverage Duration	All Diagnoses:     Initial: 6 months     Renewal: 12 months

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

Reference	
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## **Ustekinumab**

#### **Products Affected**

- Selarsdi
- Yesintek

Steqeyma

### **Covered Uses**

- All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
  - Crohn's Disease
  - o Plaque Psoriasis
  - Psoriatic Arthritis
  - Ulcerative Colitis

### Required Medical Information and Criteria

#### All diagnoses

- Initial testing for latent TB and treatment, if necessary, before starting treatment.
- No current active infection at initiation of therapy.
- Risks and benefits documented in cases of chronic or recurrent infection.
- Will NOT be used in combination with another biologic or Otezla

#### 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: 6mercaptopurine, azathioprine, corticosteroid, methotrexate
- Trial and failure of both 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
  - o Hand, foot, face, or mucous membrane involvement

- 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 of history)
  - o 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 antiinflammatory 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

Renewal Criteria	<ul> <li>CD: Evidence of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.</li> <li>PP: 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>PsA: Evidence of a 20% or greater improvement in tender joint count and swollen joint count.</li> <li>UC: Evidence of a significant response such as a decrease in bloody stools per day or elimination of signs of toxicity.</li> </ul>
Exclusion Criteria	Not to be used in combination with other biologics for the same indication.
Prescriber	Crohn's Disease and Ulcerative Colitis: Gastroenterologist.
Restriction	Plaque Psoriasis: Dermatologist.
	Psoriatic Arthritis: Dermatologist or Rheumatologist.
Coverage Duration	All diagnoses:
	o Initial: 6 months
	o Renewal: 12 months

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

## References

- Selarsdi [package insert]. Parsippany, NJ: Teva Pharmaceuticals; 2025.
- Yesintek [package insert]. Cambridge, MA: Biocon Biologics; 2024.
- Steqeyma [package insert]. Jersey City, NJ: Celltrion USA Inc.; 2024.

# **Valacyclovir Step Therapy**

## **Products Affected**

• Valacyclovir tablets

Step Therapy Criteria	<ul> <li>Trial and failure of</li> <li>Acyclovir tablets</li> </ul>
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Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

## Vanzacaftor-tezacaftor-deutivacaftor (Alyftrek)

### **Products Affected**

• Alyftrek Tablets

Covered Uses  Required Medical	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.</li> <li>Cystic Fibrosis</li> </ul> Cystic Fibrosis	
Information and		
Criteria	<ul> <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> <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>	
Renewal Criteria	Demonstrated positive clinical response to therapy.	
Age Restriction	Age 6 and older.	
Prescriber	Pulmonologist or Specialist affiliated with a CF care center.	
Restriction		
Coverage Duration	Initial: 6 months	
	Renewal: 12 months	

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: Vertx Pharmaceuticals Inc.; 2025.

# Vonoprazan (Voquezna)

## **Products Affected**

• Voquezna 10mg and 20mg tablets

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Erosive esophagitis</li> <li>H. Pylori infection</li> </ul>
Required Medical Information and Criteria	<ul> <li>Erosive Esophagitis</li> <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> <li>H. Pylori Infection</li> <li>Confirmed H. pylori positive infection</li> <li>Documented contraindication, intolerance, or inadequate response to:         <ul> <li>Standard first-line therapies for H.pylori infection</li> <li>PPI + clarithromycin + (amoxicillin or metronidazole)</li> <li>Bismuth quadruple therapy</li> </ul> </li> <li>Co-prescribed with antibiotics</li> </ul>
Renewal Criteria	Renewals past the initial approved timelines are not allowed
Age Restriction	18 years of age or older.
Prescriber Restriction	All diagnoses: Gastroenterologist or Infectious Disease specialist
Coverage Duration	<ul> <li>Initial healing of erosive esophagitis:         <ul> <li>Initial: 2 months</li> <li>Renewal: n/a</li> </ul> </li> <li>Maintenance of healing of erosive esophagitis:         <ul> <li>Initial: 6 months</li> <li>Renewal: n/a</li> </ul> </li> <li>H. Pylori infection:         <ul> <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

• Voquezna [package insert]. Buffalo Grove, IL: Phatham Pharmaceuticals; 2022.

## Voriconazole

### **Products Affected**

Voriconazole tablets

• Voriconazole suspension

Covered Uses	<ul> <li>All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design</li> <li>Treatment of invasive aspergillosis</li> <li>Treatment of serious fungal infections</li> </ul>
Required Medical Information and Criteria	<ul> <li>All diagnoses</li> <li>Documentation of one of the approved conditions</li> </ul>
Renewal Criteria Age Restriction Coverage Duration	<ul> <li>Documented positive clinical response and continued need</li> <li>Suspension only: Member is under age 10 or unable to use tablets</li> <li>All diagnoses:         <ul> <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.

# **Zafırlukast Step Therapy**

## **Products Affected**

• Zafırlukast tablets

Step Therapy	<ul> <li>Trial and failure of montelukast</li> </ul>
Criteria	

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