BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

BIOLOGIC AND IMMUNOLOGICAL AGENTS – ORAL:
CIBINQO™ (abrocitinib)
ICOTYDE™ (icotrokinra)
LEQSELVI™ (deuruxolitinib)
LITFULO™ (ritlecitinib)
OLUMIANT® (baricitinib)
OTEZLA® (apremilast)
OTEZLA XR™ (apremilast)
RINVOQ® (upadacitinib)
RINVOQ® LQ (upadacitinib)
SOTYKTU™ (deucravacitinib)
VELSIPITY™ (etrasimod)
XELJANZ® (tofacitinib)
XELJANZ® XR (tofacitinib)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

ORIGINAL EFFECTIVE DATE: 04/01/2019 | ARCHIVE DATE: | LAST REVIEW DATE: 02/19/2026 | LAST CRITERIA REVISION DATE: 05/21/2026

PHARMACY COVERAGE GUIDELINE

BIOLOGIC AND IMMUNOLOGICAL AGENTS – ORAL

Section A: Alopecia Areata (AA)

Medical Necessity Requirements for LEQSELVI (deuruxolitinib) tablet, LITFULO (ritlecitinib) capsule, and OLUMIANT (baricitinib) tablet

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Dermatologist

Indication
- Severe alopecia areata

Age Requirement
- **ONE** of the following:
  - Litfulo: 12 years or older
  - Leqselvi or Olumiant: 18 years or older

Baseline Clinical Evaluation
- Chronic, relapsing nonscarring scalp hair loss
- Smooth, round or uneven patches of complete scalp hair loss that develop within weeks, sometimes affecting other areas like eyebrows, eyelashes, beard, or limbs
- Scalp hair loss of at least 50 percent for more than 6 months

Alternative Therapies
- Failure, contraindication, intolerance, or not a candidate for **BOTH** of the following:
  - Intralesional corticosteroid injection
  - High potency topical corticosteroid
- **For Leqselvi and Litfulo**: Failure, contraindication, intolerance, or not a candidate for **Olumiant**

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - **Additional criteria for Leqselvi:**

1. Use in poor CYP2C9 metabolizer
2. Use with moderate or strong CYP2C9 inhibitors or inducers
3. Severe renal impairment or end stage renal disease (estimated glomerular filtration rate less than 30 mL/min)

- **Additional criteria for Leqselvi and Litfulo:** Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
- **Additional criteria for Olumiant:** Severe renal impairment (estimated glomerular filtration rate less than 30 mL/min)

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification

- Continues care under a Dermatologist or care is in consultation with a Dermatologist

Clinical Response

- First renewal: At least 50 percent recovery of scalp hair
- Subsequent renewals: Disease stability or improvement with no evidence of disease progression

Adherence

Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
  - Myocardial infarction
  - Stroke
  - **Additional criteria for Leqselvi:**
    1. Use in poor CYP2C9 metabolizer
    2. Use with moderate or strong CYP2C9 inhibitors/inducers
    3. Severe renal impairment or end stage renal disease (estimated glomerular filtration rate less than 30 mL/min)
    4. Gastrointestinal perforation

- **Additional criteria for Leqselvi and Litfulo:** Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
- **Additional criteria for Olumiant:**
  1. Severe renal impairment (estimated glomerular filtration rate less than 30 mL/min)
  2. Gastrointestinal perforation

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section B: Ankylosing Spondylitis (AS)

Medical Necessity Requirements for RINVOQ (upadacitinib) tablet, XELJANZ (tofacitinib) tablet, and XELJANZ XR (tofacitinib) tablet

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Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Rheumatologist or in consultation with a Rheumatologist

Indication

- Moderately to severely active ankylosing spondylitis

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- Back pain that began at age 45 years or younger lasting at least 3 months
- Sacroiliitis on x ray imaging with definite structural damage of sacroiliac joints
- A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 or more
- Spinal pain rated as at least 4 or more on a 0 to 10 numerical rating scale
- Spondyloarthritis signs or symptoms indicated by **ONE** or more of the following:
  - Arthritis
  - C reactive protein elevation
  - Enthesitis (i.e., inflammation at sites where tendons and ligament attach to bone)
  - HLA B27
  - Limited chest expansion
  - Morning stiffness greater than or equal to 1 hour

Alternative Therapies

- Failure, contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
  - **TWO** nonsteroidal anti inflammatory drugs (e.g., ibuprofen, naproxen, indomethacin, others) at maximum recommended doses each trial used for greater than or equal to 4 weeks duration

- **ONE** tumor necrosis factor inhibitor drugs (e.g., adalimumab product, Cimzia, Enbrel, Simponi) used for greater than or equal to 3 months duration

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (If available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - **Additional criteria for Rinvoq:** Woman of childbearing potential who is pregnant

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification
- Continues care under a Rheumatologist or care is in consultation with a Rheumatologist

Clinical Response
- First renewal: At least a 20 percent improvement in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)
- Subsequent renewals: Disease stability or improvement with no evidence of disease progression

Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (If available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines

- Severe hepatic impairment (Child Pugh Class C)
- Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
- Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
- Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
- Myocardial infarction
- Stroke
- Gastrointestinal perforation
- **Additional criteria for Rinvoq:** Woman of childbearing potential who is pregnant

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section C: Non radiographic Axial Spondyloarthritis (nr axSpA)

Medical Necessity Requirements for RINVOQ (upadacitinib) tablet

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Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Rheumatologist or in consultation with a Rheumatologist

Indication

- Moderately to severely active non radiographic axial spondyloarthritis

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- Back that began at age 45 years or younger lasting at least 3 months
- Sacroiliitis on x ray imaging does not show definitive structural damage of sacroiliac joints
- A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 or more
- Spinal pain rated as at least 4 or more on a 0 to 10 numerical rating scale
- Spondyloarthritis signs or symptoms indicated by **ONE** or more of the following:
  - Arthritis
  - C reactive protein elevation
  - Enthesitis (i.e., inflammation at sites where tendons and ligament attach to bone)
  - HLA B27
  - Limited chest expansion
  - Morning stiffness greater than or equal to 1 hour

Alternative Therapies

- Failure, contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
  - **TWO** nonsteroidal anti inflammatory drugs (e.g., ibuprofen, naproxen, indomethacin, others) at maximum recommended doses each trial used for greater than or equal to 4 weeks duration

- **ONE** tumor necrosis factor inhibitor drugs (e.g., adalimumab product, Cimzia, Enbrel, Simponi) used for greater than or equal to 3 months duration

Brand Specific Criteria
- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - Woman of childbearing potential who is pregnant

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification
- Continues care under a Rheumatologist or care is in consultation with a Rheumatologist

Clinical Response
- First renewal: At least a 20 percent improvement in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score
- Subsequent renewals: Disease stability or improvement with no evidence of disease progression

Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines

- Severe hepatic impairment (Child Pugh Class C)
- Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
- Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
- Myocardial infarction
- Stroke
- Gastrointestinal perforation
- Woman of childbearing potential who is pregnant

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section D: Atopic Dermatitis

Medical Necessity Requirements for CIBINQO (abrocitinib) tablet and RINVOQ (upadacitinib) tablet

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Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Dermatologist or in consultation with a Dermatologist

Indication

- Moderate to severe atopic dermatitis

Age Requirement

- 12 years or older

Baseline Clinical Evaluation

- Chronic, refractory, relapsing inflammatory skin disease indicated by **ALL** of the following:
  - Lesions involve at least 10 percent of body surface area or involve sensitive areas of the face, head, neck, hands, feet, groin, or intertriginous areas
  - Weekly averaged Worst Daily Peak Pruritus Numeric Rating Scale (NRS) of at least 3
  - **ONE** of the following disease intensity measures:
    1. Investigator Global Assessment score greater than or equal to 3
    2. Eczema Area and Severity Index score greater than or equal to 7

Alternative Therapies

- **For Cibinqo:** Individual has documented failure (used for greater than 2 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ONE** medication from **EACH** of the following categories:
  - **ONE** topical medium to very high potency corticosteroid
  - **ONE** topical calcineurin inhibitor (e.g., Protopic (tacrolimus) or Elidel (pimecrolimus))
  - **ONE** topical phosphodiesterase 4 inhibitor (e.g., Eucrisa (crisaborole))

- **For Rinvoq:** Individual has documented failure (used for greater than 2 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following:
  - Topical medium to very high potency corticosteroid
  - Topical calcineurin inhibitor (e.g., Protopic (tacrolimus) or Elidel (pimecrolimus))
  - Topical phosphodiesterase 4 inhibitor (e.g., Eucrisa (crisaborole))
- **For Cibinqo and Rinvoq:** Failure, contraindication, intolerance, or not a candidate for **ONE** biologic immunomodulator (such as dupilumab or nemolizumab)

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number or platelets, neutrophils, lymphocytes, hemoglobin
  - **Additional criteria for Cibinqo:**
    1. Moderate to strong inhibitors of both CYP2C19 and CYP2C9 (e.g., abiraterone, efavirenz, voriconazole, fluconazole)
    2. Strong inducers of CYP2C19 or CYP2C9 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin, aprepitant, primidone, rifapentine)
    3. Antiplatelet drugs: NSAIDS, SSRIs, etc.
    4. Severe renal impairment (estimated creatinine clearance less than 30 mL/minute) or end stage renal disease (estimated creatinine clearance less than 15 mL/minute) including those on renal replacement therapy
  - **Additional criteria for Rinvoq:**
    1. Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
    2. End stage renal disease (estimated glomerular filtration rate less than 15 mL/min)
    3. Woman of childbearing potential who is pregnant

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification

- Continues care under a Dermatologist or care is in consultation with a Dermatologist

Clinical Response

- First renewal: At least 20 percent improvement in Investigator's Global Assessment (IGA) score or Eczema Area and Severity Index (EASI) score

- Subsequent renewals **ALL** of the following:
  - Disease stability or improvement with no evidence of disease progression
  - Achieved and maintains improvement in **ONE** of the following disease intensity scores:
    1. IGA of 0 or 1 (clear or almost clear)
    2. EASI 50 (improvement of at least 50 percent in score from baseline)
  - Achieved and maintains a decrease of 4 or more from baseline in Pruritus Numeric Rating Scale (NRS)

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
  - Myocardial infarction
  - Stroke
  - **Additional criteria for Cibinqo:**
    1. Moderate to strong inhibitors of both CYP2C19 and CYP2C9 (e.g., abiraterone, efavirenz, voriconazole, fluconazole)
    2. Strong inducers of CYP2C19 or CYP2C9 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin, aprepitant, primidone, rifapentine)
    3. Antiplatelet drugs: NSAIDS, SSRIs, etc.
    4. Severe renal impairment (estimated creatinine clearance less than 30 mL/minute) or end stage renal disease (estimated creatinine clearance less than 15 mL/minute) including those on renal replacement therapy
  - **Additional criteria for Rinvoq:**
    1. Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
    2. End stage renal disease (estimated glomerular filtration rate less than 15 mL/min)
    3. Gastrointestinal perforation
    4. Woman of childbearing potential who is pregnant

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

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Section E: Crohn's Disease (CD)

Medical Necessity Requirements for RINVOQ (upadacitinib) tablet

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Gastroenterologist or in consultation with a Gastroenterologist

Indication
- Moderately to severely active Crohn's Disease

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Moderate to severe active Crohn's disease as indicated by **ONE** of the following:
  - Crohn's disease activity index (CDAI) greater than 220 in adults
  - **At least 5** of the following signs and symptoms:
    1. Anemia
    2. Chronic intermittent diarrhea (with or without food)
    3. Crampy abdominal pain
    4. Elevated serum C reactive protein level and/or fecal calprotectin
    5. Extraintestinal manifestations such as arthritis or arthropathy, eye and skin disorders, biliary tract involvement, and kidney stones
    6. Fatigue
    7. Fistulas
    8. Perianal disease (e.g., anal fissures, anorectal abscess)
    9. Weight loss

Alternative Therapies
- Failure (trial for at least three consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
  - **ONE** trial of an oral corticosteroid or **ONE** trial of an immunomodulator (such as 6 mercaptopurine, azathioprine, methotrexate) [**Note** this criterion is waived if the individual already has tried an FDA approved Crohn's disease biologic]
  - **ONE** tumor necrosis factor (TNF) inhibitor (e.g., adalimumab product, Cimzia, infliximab) or if TNF treatment is clinically inadvisable **ONE** trial of a systemic therapy approved for CD (e.g., guselkumab, mirikizumab mrkz, risankizumab rzaa, ustekinumab)

Brand Specific Criteria
- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

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Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - Woman of childbearing potential who is pregnant

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy:
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification
- Continues care under a Gastroenterologist care is in consultation with a Gastroenterologist

Clinical Response
- First renewal: **ONE** of the following:
  - AT LEAST a 20 percent improvement in the signs and symptoms of Crohn's disease
  - Decrease in Crohn's disease activity index of more than 70 from baseline or a Crohn's disease activity index of less than 150 (in remission) in adults
- Subsequent renewals: Disease stability or improvement with no evidence of disease progression

Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
  - Myocardial infarction
  - Stroke
  - Gastrointestinal perforation

- Woman of childbearing potential who is pregnant

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section F: Plaque Psoriasis (Ps also as PsO)

Medical Necessity Requirements for ICOTYDE (icotrokindra) tablet, OTEZLA (baricitinib) tablet, OTEZLA XR (baricitinib) tablet, and SOTYKTU (deucravacitinib) tablet

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Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Dermatologist or in consultation with a Dermatologist

Indication

- Moderate to severe plaque psoriasis and is a candidate for phototherapy or systemic therapy

Age Requirement

- **ONE** of the following:
  - **For Icotyde**: 12 years of age or older and weighing at least 40 kg
  - **For Otezla**: 6 years of age or older and weighing at least 20 kg
  - **For Otezla XR**: 6 years of age or older and weighing at least 50 kg
  - **For Sotyktu**: 18 years of age or older

Baseline Clinical Evaluation

- Chronic, relapsing inflammatory skin disease involving trunk and extremities with **ALL** of the following:
  - Plaque psoriasis involves greater than or equal to 10 percent body surface area (BSA) **or** involves less than 10 percent BSA but includes sensitive areas or areas that significantly impact daily function (e.g., palms, soles of feet, head/neck, or genitalia)
  - A Psoriasis Area and Index (PASI) of at least 10

Alternative Therapies

- Failure (used for at least 3 consecutive months), contraindication, intolerance, or is not a candidate for **BOTH** of the following: [**Note**: a product that contains betamethasone and calcipotriene will satisfy the criteria]
  - **ONE** topical corticosteroid
  - **ONE** topical vitamin D analog
- Failure (used for at least 3 consecutive months), contraindication, intolerance, or is not a candidate for **ONE** systemic therapy (such as methotrexate, cyclosporine, acitretin)
- **Additional criteria for Otezla XR:** Failure (used for at least 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **Otezla**

- **Additional criteria for Sotyktu and Icotyde:** Failure (used for at least 3 consecutive months), contraindication, intolerance, or is not a candidate for **BOTH** of the following**:**
  - A trial of **THREE** biologic immunomodulator:
    1. Adalimumab product
    2. Cimzia
    3. Enbrel
    4. Skyrizi
    5. Tremfya
    6. Ustekinumab product
  - A trial of Taltz

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - **For Otezla and Otezla XR:** Use with strong inducers of CYP3A4 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - **For Otezla XR:** Severe renal impairment (creatinine clearance of less than 30 mL/minute)
  - **For Sotyktu**:
    1. Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
    2. Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
    3. Use with live vaccines
    4. Severe hepatic impairment (Child Pugh Class C)
  - **For Icotyde:**
    1. Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
    2. Use with live vaccines

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification

- Continues care under a Dermatologist or care is in consultation with a Dermatologist

Clinical Response

- First renewal: At least 20 percent improvement in Psoriasis Area and Severity Index score (PASI)
- Subsequent renewals: Disease stability or improvement with no evidence of disease progression

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Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - **For Otezla and Otezla XR:** Use with strong inducers of CYP3A4 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - **For Otezla XR:** Severe renal impairment (creatinine clearance of less than 30 mL/minute)
  - **For Sotyktu**:
    1. Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
    2. Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
    3. Use with live vaccines
    4. Severe hepatic impairment (Child Pugh Class C)
    5. Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
    6. Markedly elevated CPK levels or myopathy, unexplained muscle pain, tenderness, or weakness
  - **For Icotyde:**
    1. Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
    2. Use with live vaccines

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

Section G: Juvenile Idiopathic Arthritis (JIA) subtype: Polyarticular (pJIA)

Medical Necessity Requirements for RINVOQ (upadacitinib) tablet, RINVOQ LQ (upadacitinib) oral solution, XELJANZ (tofacitinib) tablet, and XELJANZ oral solution

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Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Rheumatologist or in consultation with a Rheumatologist

Indication
- Active polyarticular course juvenile idiopathic arthritis

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BIOLOGIC AND IMMUNOLOGICAL AGENTS – ORAL

Age Requirement
- 2 years or older

Baseline Clinical Evaluation
- Active disease with involvement of five or more joints during the first 6 months of disease
- There is **NONE** of the following:
  - Fever, rash, lymphadenopathy, hepatosplenomegaly
  - Arthritis starting after 6 years of age in male individual who is positive for HLA B27
  - Personal history or first degree relative with psoriasis, ERA, ankylosing spondylitis, sacroiliitis with IBD, reactive arthritis, anterior uveitis

Alternative Therapies
- Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for methotrexate
- Failure (trial for at least three months duration), contraindication, intolerance to **ONE** tumor necrosis factor (TNF) inhibitor (e.g., adalimumab product, etanercept, Simponi Aria)

Brand Specific Criteria
- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - **Additional criteria for Rinvoq and Rinvoq LQ:** Woman of childbearing potential who is pregnant

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification
- Continues care under a Rheumatologist or care is in consultation with a Rheumatologist

Clinical Response
- First renewal: At least a 30 percent improvement in JIA Core Set (see Definitions section)
- Subsequent renewals: Disease stability or improvement with no evidence of disease progression

BIOLOGIC AND IMMUNOLOGICAL AGENTS – ORAL

Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
  - Myocardial infarction
  - Stroke
  - Gastrointestinal perforation
  - **Additional criteria for Rinvoq and Rinvoq LQ:** Woman of childbearing potential who is pregnant

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

Section H: Psoriatic Arthritis (PsA)

Medical Necessity Requirements for OTEZLA (baricitinib) tablet, OTEZLA XR (baricitinib) tablet, RINVOQ (upadacitinib) tablet, RINVOQ LQ (upadacitinib) oral solution, SOTYKTU (deucravacitinib) tablet, XELJANZ (tofacitinib) tablet, XELJANZ (tofacitinib) oral solution, and XELJANZ XR (tofacitinib) tablet

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Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by Rheumatologist or Dermatologist or in consultation with one

Indication
- Moderately to severely active psoriatic arthritis

Age Requirement
- **ONE** of the following:

- **Otezla**: 6 years of age or older and weighing at least 20 kg
- **Otezla XR**: 6 years of age or older and weighing at least 50 kg
- **Rinvoq and Rinvoq LQ**: 2 years of age or older
- **Sotyktu**: 18 years of age or older
- **Xeljanz tab and Xeljanz oral solution**: 2 years of age or older
- **Xeljanz XR tab**: 18 years of age or older

Baseline Clinical Evaluation

- **ONE** of the following:
  - Predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by **ALL** of the following:
    1. Radiographic evidence of axial disease (e.g., sacroiliac joint space narrowing or erosions, vertebral syndesmophytes)
    2. Symptoms (e.g., limited spinal range of motion, spinal morning stiffness more than 30 minutes) present for more than 3 months' duration
  - Predominantly non axial disease

Alternative Therapies

- Failure (used for greater than or equal to 3 consecutive months at maximum recommended doses), contraindication per FDA label, intolerance, or is not a candidate for:
  - **For all agents listed:** methotrexate or nonsteroidal anti inflammatory drug (NSAIDs)
  - **Additional criteria for Otezla XR**: **Otezla**
  - **Additional criteria for Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR, Xeljanz oral solution**: **ONE** tumor necrosis factor (TNF) inhibitor (e.g., adalimumab product, certolizumab, etanercept, Simponi, Simponi Aria)
- **For Sotyktu**:
  - Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for **TWO** of the following:
    1. Adalimumab product
    2. Cimzia
    3. Enbrel
    4. Rinvoq or Rinvoq LQ
    5. Simponi or Simponi Aria
    6. Skyrizi
    7. Tremfya
    8. Ustekinumab product
    9. Xeljanz tab or Xeljanz XR
  - Failure (used for 3 or more consecutive months), contraindication, intolerance, or is not a candidate for **BOTH** of the following:
    1. Orencia (IV or SQ)
    2. Taltz

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

BIOLOGIC AND IMMUNOLOGICAL AGENTS – ORAL

Safety

- There is **NONE** of the following:
  - Use with strong inducers of CYP3A4 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - **Additional criteria for Otezla XR:** Severe renal impairment (creatinine clearance of less than 30 mL/minute)
  - **Additional criteria for Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR, Xeljanz oral solution**:
    1. Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
    2. Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
    3. Use with live vaccines
    4. Severe hepatic impairment (Child Pugh Class C)
    5. Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
    6. **Additional criteria for Rinvoq and Rinvoq LQ:** Woman of childbearing potential who is pregnant
  - **For Sotyktu**:
    1. Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
    2. Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
    3. Use with live vaccines
    4. Severe hepatic impairment (Child Pugh Class C)

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification

- Continues care under a Rheumatologist or Dermatologist or care is in consultation with a Rheumatologist or Dermatologist

Clinical Response

- First renewal: AT LEAST a 20 percent improvement in **ANY** of the following: (see Definitions section)
  - American College of Rheumatology (ACR)
  - Clinical Disease Activity Index (CDAI) score greater than 10
  - Disease Activity Score 28 (DAS28) of greater than 3.2
  - Patient Activity Scale (PAS) of greater than 3.7
  - Patient Activity Scale II (PASII) of greater than 3.7
  - Routine Assessment of Patient Index Data 3 (RAPID 3) score greater than 2
  - Simplified Disease Activity Index (SDAI) score greater than 11
- Subsequent renewals: Disease stability or improvement with no evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

PHARMACY COVERAGE GUIDELINE

BIOLOGIC AND IMMUNOLOGICAL AGENTS – ORAL

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Use with strong inducers of CYP3A4 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - **Additional criteria for Otezla XR:** Severe renal impairment (creatinine clearance of less than 30 mL/minute)
  - **Additional criteria for Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR, Xeljanz oral solution**:
    1. Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
    2. Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
    3. Use with live vaccines
    4. Severe hepatic impairment (Child Pugh Class C)
    5. Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
    6. Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
    7. Myocardial infarction
    8. Stroke
    9. Gastrointestinal perforation
    10. **Additional criteria for Rinvoq and Rinvoq LQ:** Woman of childbearing potential who is pregnant
  - **For Sotyktu**:
    1. Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
    2. Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
    3. Use with live vaccines
    4. Severe hepatic impairment (Child Pugh Class C)
    5. Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
    6. Markedly elevated CPK levels or myopathy, unexplained muscle pain, tenderness, or weakness

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section I: Rheumatoid Arthritis (RA)

Medical Necessity Requirements for OLUMIANT (baricitinib) tablet, RINVOQ (upadacitinib) tablet, XELJANZ (tofacitinib) tablet, and XELJANZ XR (tofacitinib) tablet

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Criteria for Initial Therapy:

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BIOLOGIC AND IMMUNOLOGICAL AGENTS – ORAL

Prescriber Qualifications
- Prescribed by Rheumatologist or in consultation with a Rheumatologist

Indication
- Moderately to severely active rheumatoid arthritis

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Clinical evaluation and documentation with **ONE** of the following:
  - Clinical Disease Activity Index (CDAI) score greater than 10
  - Disease Activity Score 28 (DAS28) of greater than 3.2
  - Patient Activity Scale (PAS) of greater than 3.7
  - Patient Activity Scale II (PASII) of greater than 3.7
  - Routine Assessment of Patient Index Data 3 (RAPID 3) score greater than 2
  - Simplified Disease Activity Index (SDAI) score greater than 11

Alternative Therapies
- Failure (trial for at least three consecutive months duration), contraindication per FDA label, intolerance, or is not a candidate for methotrexate
- Failure (trial for at least three consecutive months duration), contraindication per FDA label, intolerance, or is not a candidate for leflunomide or sulfasalazine [**Note**: This criterion is waived if the individual already has tried an FDA approved Rheumatoid Arthritis biologic]
- **Additional criteria for Olumiant: ALL** of the following:
  - Failure (trial for at least three consecutive months duration), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following:
    1. Adalimumab product
    2. Cimzia
    3. Enbrel
    4. Rinvoq tab
    5. Simponi
    6. Xeljanz tab or Xeljanz XR tab
  - Failure (trial for at least three consecutive months duration), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
    1. **ONE** of the following:
       a. Actemra (IV&SQ)
       b. Avtozma (IV&SQ)
       c. Tofidence (IV)
       d. Tyenne (IV&SQ)
    2. Orencia (IV or SQ)
- **Additional criteria for Tofidence (IV), Tyenne (IV&SQ):** Failure (used for 3 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following:
  - Actemra
  - Avtozma (IV)
- **Additional criteria for Rinvoq, Xeljanz tab, and Xeljanz XR:** Failure (trial for at least three consecutive months duration), contraindication, intolerance, or is not a candidate for **ONE** tumor necrosis factor (TNF) inhibitor (such as adalimumab, certolizumab, etanercept, golimumab, infliximab)

PHARMACY COVERAGE GUIDELINE

BIOLOGIC AND IMMUNOLOGICAL AGENTS – ORAL

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
- **Additional criteria for Olumiant:** Severe renal impairment (estimated glomerular filtration rate less than 30 mL/min)
- **Additional criteria for Rinvoq:**
  - Woman of childbearing potential who is pregnant
  - Use with strong inducers of CYP3A4 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
- **Additional criteria for Xeljanz tab, and Xeljanz XR:**
  - Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification

- Continues care under a Rheumatologist or care is in consultation with a Rheumatologist

Clinical Response

- First renewal: At least a 20% improvement in any of the following: ACR, CDAI, DAS28, PAS, PASII, RAPID 3, SDAI
- Subsequent renewals: Disease stability or improvement with no evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
  - Myocardial infarction
  - Stroke
  - Gastrointestinal perforation
- **Additional criteria for Olumiant:** Severe renal impairment (estimated glomerular filtration rate less than 30 mL/min)
- **Additional criteria for Rinvoq:**
  - Woman of childbearing potential who is pregnant
  - Use with strong inducers of CYP3A4 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
- **Additional criteria for Xeljanz tab, and Xeljanz XR:**
  - Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section J: Ulcerative Colitis (UC)

Medical Necessity Requirements for RINVOQ (upadacitinib) tablet, VELSIPITY (etrasimod) tablet, XELJANZ (tofacitinib) tablet, and XELJANZ XR (tofacitinib) tablet

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Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by Gastroenterologist or in consultation with a Gastroenterologist

Indication

- Moderately to severely active ulcerative colitis

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- **ONE** of the following:
  - American College of Gastroenterology Ulcerative Colitis activity index rating of moderate to severe disease in adults

- Pediatric ulcerative colitis activity index (PUCAI) greater than or equal to 35
- **At least 5** of the following signs and symptoms:
  1. Anemia
  2. Bloody diarrhea or visible blood in stool
  3. Bowel movements 4 to 6 or more times per day
  4. Colicky abdominal pain
  5. Elevated fecal calprotectin
  6. Elevated serum C reactive protein or erythrocyte sedimentation rate
  7. Fatigue
  8. Fever
  9. Tenesmus
  10. Urgency
  11. Weight loss or delayed growth in children
- **For Velsipity only: ALL** of the following:
  1. Electrocardiogram
  2. Ophthalmic assessment of fundus, including macula
  3. Skin examination for skin cancer

Alternative Therapies

- Failure (trial for at least three months duration), contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following: [**Note**: This criterion is waived if the individual already has tried an FDA approved Ulcerative Colitis biologic]
  - Corticosteroid
  - Azathioprine
  - 6 mercaptopurine
  - Salicylates (such as mesalamine, sulfasalazine, balsalazide, olsalazine)
- **For Rinvoq:** Failure (trial for at least three months duration), contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following:
  - **ONE** tumor necrosis inhibitor (TNF) inhibitor. (e.g., adalimumab product, Simponi)
  - If treatment with a TNF inhibitor is clinically inadvisable, has had trial of a systemic therapy approved for ulcerative colitis (e.g., etrasimod, guselkumab, mirikizumab mrkz, risankizumab rzaa, ustekinumab)
- **For Velsipity:** Failure (trial for at least three months duration), contraindication per FDA label, intolerance, or is not a candidate for **TWO** or more of the following:
  - Adalimumab product
  - Rinvoq (upadacitinib)
  - Skyrizi (risankizumab) (IV&SQ)
  - Simponi (golimumab)
  - Ustekinumab product
  - Tremfya (guselkumab) (IV&SQ)
  - Xeljanz tab or Xeljanz XR tab
- **For Xeljanz and Xeljanz XR:** Failure (trial for at least three months duration), contraindication per FDA label, intolerance, or is not a candidate for **ONE** tumor necrosis inhibitor (TNF) inhibitor. (e.g., adalimumab product, Simponi)

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BIOLOGIC AND IMMUNOLOGICAL AGENTS – ORAL

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - **Additional for Rinvoq, Xeljanz tab, Xeljanz XR tab:**
    1. Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
    2. Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - **Additional criteria for Rinvoq and Velsipity:** Woman of childbearing potential who is pregnant
  - **Additional criteria for Velsipity:**
    1. Class Ia anti arrhythmic drugs (e.g., quinidine, procainamide)
    2. Class IIIa anti arrhythmic drugs (e.g., amiodarone, sotalol)
    3. Moderate to strong inhibitors of both CYP2C9 and CYP3A4 (e.g., fluconazole)
    4. If individual is a CYP2C9 poor metabolizer: moderate to strong inhibitors of CYP2C8 or CYP3A4
    5. Rifampin

Additional Requirements

- **For Velsipity only:**
  - There are **NO** FDA label contraindications including: History of myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or class III or IV heart failure in the last 6 months; history or presence of Mobitz type II second degree or third degree atrioventricular block, sick sinus syndrome, or sino atrial block, unless the patient has a functioning pacemaker

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification

- Continues care under a Gastroenterologist or car is in consultation with a Gastroenterologist

Clinical Response

- First renewal: **ONE of the following:**
  - AT LEAST a 20 percent improvement in signs and symptoms of ulcerative colitis
  - American College of Gastroenterology Ulcerative Colitis activity index rating of mild disease or disease in remission in adults
  - Pediatric ulcerative colitis activity index (PUCAI) of less than or equal to 34 in children indicating mild disease or disease remission

- Subsequent renewals: Disease stability or improvement with no evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - **Additional for Rinvoq, Xeljanz tab, Xeljanz XR tab:**
    1. Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
    2. Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
    3. Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
    4. Myocardial infarction
    5. Stroke
    6. Gastrointestinal perforation
  - **Additional criteria for Rinvoq and Velsipity:** Woman of childbearing potential who is pregnant
  - **Additional criteria for Velsipity:**
    1. Bradyarrhythmia or atrioventricular conduction delays, significant liver injuries, macular edema, Posterior Reversible Encephalopathy Syndrome (PRES), pulmonary decline
    2. Class Ia anti arrhythmic drugs (e.g., quinidine, procainamide)
    3. Class IIIa anti arrhythmic drugs (e.g., amiodarone, sotalol)
    4. Moderate to strong inhibitors of both CYP2C9 and CYP3A4 (e.g., fluconazole)
    5. If individual is a CYP2C9 poor metabolizer: moderate to strong inhibitors of CYP2C8 or CYP3A4
    6. Rifampin

Additional Requirements

- **For Velsipity only:**
  - There are **NO** FDA label contraindications including: History of myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or class III or IV heart failure in the last 6 months; history or presence of Mobitz type II second degree or third degree atrioventricular block, sick sinus syndrome, or sino atrial block, unless the patient has a functioning pacemaker

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

BIOLOGIC AND IMMUNOLOGICAL AGENTS – ORAL

Section K: Behcet's Disease

Medical Necessity Requirements for OTEZLA (apremilast) tablet and OTEZLA XR (baricitinib) tablet

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by Rheumatologist or in consultation with one

Indication
- Oral ulcers associated with Behcet's Disease

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Meets **ALL** of the following International Study Group (ISG) criteria for Behcet's Disease (see Definitions section) with:
  - Two or more active oral ulcer without major organ involvement
  - Oral ulcers that occurred 3 or more times in previous 12 months
  - Does not require systemic immunosuppressants (e.g., biologics, corticosteroids, azathioprine)

Alternative Therapies
- Failure (used for greater than or equal to 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
  - Topical corticosteroid
  - Colchicine
- **Additional criteria for Otezla XR:** Failure (used for greater than or equal to 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **Otezla**

Brand Specific Criteria
- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - **For Otezla and Otezla XR:** Use with strong inducers of CYP3A4 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - **For Otezla XR:** Severe renal impairment (creatinine clearance of less than 30 mL/minute)

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification
- Continues care under a Rheumatologist or care is in consultation with a Rheumatologist

Clinical Response
- First renewal: At least a 20 percent improvement in signs and symptoms of oral ulcers
- Subsequent renewals: Disease stability or improvement with no evidence of disease progression

Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. Note: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - **For Otezla and Otezla XR:** use with strong inducers of CYP3A4 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - **For Otezla XR:** severe renal impairment (creatinine clearance of less than 30 mL/minute)

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

Section L: Giant Cell Arteritis

Medical Necessity Requirements for RINVOQ (upadacitinib) tab

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by Rheumatologist or Ophthalmologist or in consultation with one

Indication
- New onset or relapsing Giant Cell Arteritis (GCA, also known as temporal arteritis)

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Age Requirement
- 50 years or older

Baseline Clinical Evaluation
- Temporal artery biopsy or evidence of large vessel vasculitis by angiography or cross sectional imaging such as ultrasound, magnetic resonance imaging (MRI), computed tomography (CT) or positron emission tomography (PET)
- History of erythrocyte sedimentation rate (ESR) of at least 50 mm/hour or high sensitivity C reactive protein (hsCRP)/CRP of at least 1 mg/dL
- **ONE** of the following:
  - Cranial symptoms (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication)
  - Symptoms of polymyalgia rheumatica (PMR) (shoulder and/or hip girdle pain associated with inflammatory morning stiffness)

Alternative Therapies
- Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for corticosteroid

Brand Specific Criteria
- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - Use with strong CYP3A4 inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin)
  - Woman of childbearing potential who is pregnant

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification
- Continues care under a Rheumatologist or Ophthalmologist or care is in consultation with a Rheumatologist or Ophthalmologist

Clinical Response
- First renewal: AT LEAST 20 percent improvement in signs and symptoms of giant cell arteritis
- Subsequent renewals: Disease stability or improvement with no evidence of disease progression

Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Use with biologic immunomodulators, other Janus kinase inhibitors, or potent immunosuppressants
  - Active serious infections (tuberculosis, Hepatitis B/C, opportunistic infections, fungal infections, clinically important localized infections)
  - Use with live vaccines
  - Severe hepatic impairment (Child Pugh Class C)
  - Abnormal number of platelets, neutrophils, lymphocytes, hemoglobin
  - Thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis)
  - Myocardial infarction
  - Stroke
  - Gastrointestinal perforation
  - Woman of childbearing potential who is pregnant

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

Section M: Measurement of Antibodies to Biologic/Immunologic Agents

Measurement of antibodies for biologic or immunologic agents in an individual receiving treatment, either alone or as a combination test, which includes the measurement of serum levels for the biologic or immunologic agents is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
3. Insufficient evidence to support improvement of the net health outcome; or
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
5. Insufficient evidence to support improvement outside the investigational setting.

These measurements include, *but are not limited to:*
- Anser™ ADA

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Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Adult: Age 18 years and older.

Laboratory Parameters that preclude use of biologic

Drug	ALC (Absolute Leukocyte Count)	ANC (Absolute Neutrophil Count)	Hemoglobin	Platelet	Renal
Cibinqo	Avoid start in patients with <500 cells/mm^3	Avoid start in patients with <1,000 cells/mm^3	Avoid start in patients with <8g/dL	Avoid start in patients with <150,000 cells/mm^3	Avoid start in severe renal impairment (<30ml/min) or in end-stage renal disease (<15ml/min) including renal replacement therapy
Litfulo	Avoid start in patients with <500 cells/mm^3	N/A	N/A	Avoid start in patients with <100,000 cells/mm^3	N/A
Olumiant	Avoid start in patients with <500 cells/mm ^{3}	Avoid start in patients with <1,000cells/mm^3	Avoid start in patients with <8g/dL	N/A	Avoid use <30ml/min
Rinvoq/ Rinvoq LQ	Avoid start in patients with <500cells/mm ^{3}	Avoid start in patients with <1,000cells/mm^3	Avoid start in patients with <8g/dL	N/A	Avoid start in patients with end stage renal disease (eGFR <15ml/min)
Xeljanz/ Xeljanz XR	Avoid start in patients with <500 cells/mm ^{3}	Avoid start in patients with <1000 cells/mm ^{3}	Avoid start in patients with <9 g/dL	N/A	Avoid start in patients with moderate and severe renal impairment

Recommendations for Discontinuation of Janus Kinase Inhibitor for Laboratory Abnormalities

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Laboratory Measure	Recommendation
Absolute neutrophil count (ANC) < 1,000mm^3 (tofacitinib: < 500mm^3)	Interrupt treatment, restart once ANC above this value
Absolute lymphocyte count (ALC) < 500/mm^3	Interrupt treatment, restart once ALC above this value
Hemoglobin (Hb) < 8g/dL (tofacitinib: < 9g/dL)	Interrupt treatment, restart once Hb above this value
Platelet count < 150,000/mm^3 (Cibinqo)	Interrupt treatment, follow until > 100,000/mm^3
Elevated hepatic transaminases suggesting drug-induced liver injury	Interrupt treatment until this diagnosis is excluded

Bath Ankylosing Spondylitis Disease Activity Index (BASDAI):

1.	How would you describe the overall level of fatigue/tiredness you have experienced? None 0 1 2 3 4 5 6 7 8 9 10 Very Severe
2.	How would you describe the overall level of ankylosing spondylitis **neck, back or hip pain** you have had? None 0 1 2 3 4 5 6 7 8 9 10 Very Severe
3.	How would you describe the overall level of pain/swelling you have had in joints other than neck, back and hips? None 0 1 2 3 4 5 6 7 8 9 10 Very Severe
4.	How would you describe the level of discomfort you have had from an area tender to touch or pressure? None 0 1 2 3 4 5 6 7 8 9 10 Very Severe
5.	How would you describe the level of morning stiffness you have had from the time you wake up? None 0 1 2 3 4 5 6 7 8 9 10 Very Severe
6.	How long does your morning stiffness last from the time you wake up? 0 hours 0 1 2 3 4 5 6 7 8 9 10 2 or more hours
Calculation of BASDAI: Compute the mean of questions 5 and 6 Calculate the sum of the values of question 1-4 and add the result to the mean of questions 5 and 6	

Atopic Dermatitis Therapies:

Topical corticosteroids (TCS):

- Low-potency corticosteroids are recommended for maintenance therapy
- Intermediate and high-potency corticosteroids should be used for the treatment of clinical exacerbation over short periods of time
- Ultra-high-potency corticosteroids should be used only for very short periods (1-2 weeks) and in non-facial non-skinfold areas.
- Do not use potent fluorinated corticosteroids on the face, eyelids, genitalia, and intertriginous areas or in young infants.

Topical calcineurin inhibitors (TCI):

- Tacrolimus ointment (Protopic and generics) is indicated as second-line therapy for moderate to severe atopic dermatitis
- Pimecrolimus cream (Elidel and generics) is indicated as second line therapy for mild to moderate atopic dermatitis

Topical phosphodiesterase 4 (PDE-4) inhibitor:

- Eucrisa (crisaborole) ointment is indicated for treatment of mild to moderate atopic dermatitis

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Relative Potency of Selected Topical Corticosteroid Products:

Product	Dosage form	Strength
Category I – Very high potency		
Augmented betamethasone dipropionate	Gel, ointment	0.05
Clobetasol propionate	Ointment, gel, cream	0.05
Fluocinonide	Cream	0.1
Diflorasone diacetate	Ointment	0.05
Halobetasol propionate	Ointment, cream	0.05
Category II – High potency		
Amcinonide	Ointment, cream, lotion	0.1
Augmented betamethasone dipropionate	Cream, lotion	0.05
Betamethasone dipropionate	Ointment, cream	0.05
Betamethasone valerate	Ointment	0.1
Desoximetasone	Ointment, cream	0.25
Desoximetasone	Gel	0.05
Diflorasone diacetate	Ointment (emollient base), cream	0.05
Fluocinonide	Ointment, gel, cream	0.05
Halcinonide	Ointment, cream	0.1

Atopic Dermatitis Disease Activity Measurement Instruments:

Investigator Global Assessment Scale (IGA):
Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf (eczemacouncil.org) [Accessed May 11, 2022]

The IGA score is selected using the morphologic descriptors that best describe the overall appearance of the lesions at a given time point. It is not necessary that all characteristics under Morphological Description be present.

Score	Morphological Description
0 – Clear	No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present.
1 – Almost clear	Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting.
2 – Mild	Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting.
3 – Moderate	Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present.
4 – Severe	Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.
Notes: 1. In indeterminate cases, use extent to differentiate between scores. For example: • Patient with marked erythema (deep or bright red), marked papulation and/or marked lichenification that is limited in extent (instead of widespread), would be considered "3 – Moderate". 2. Excoriations should not be considered when assessing disease severity	

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Eczema Area and Severity Index (EASI) score (A-E):
An EASI score is a tool used to measure the extent (area) and severity of atopic eczema. EASI score does not include a grade for dryness or scaling. Include only inflamed areas.

A. Body regions:
There are four body regions:

- Head and neck
  - Face occupies 33 percent (17 percent each side), neck 33 percent (17 percent front and back) and scalp 33 percent of the head and neck region
- Trunk (including genital area)
  - Front occupies 55 percent and back 45 percent of the trunk
- Upper limbs
  - Each arm occupies 50 percent of the upper limbs region (front or back of one arm is 25 percent)
- Lower limbs (including buttocks)
  - Each leg occupies 45 percent (front or back of one leg is 22.5 percent) and buttocks 10 percent of the lower limbs region

B. Area score:
Area score is recorded for each of the four regions of the body. The area score is the percentage of skin affected by eczema for each body region.

Area score	Percentage of skin affected by eczema in each region
0	No active eczema in this region
1	1-9
2	10-29
3	30-49
4	50-69
5	70-89
6	90-100: the entire region is affected by eczema

C. Severity score:
Severity score is recorded for each of the four regions of the body. The severity score is the sum of the intensity scores for four signs. The four signs are:

1. Redness (erythema, inflammation)
2. Thickness (induration, papulation, swelling—acute eczema)
3. Scratching (excoriation)
4. Lichenification (lined skin, furrowing, prurigo nodules—chronic eczema).

The *average* intensity of each sign in each body region is assessed as: none (0), mild (1), moderate (2) and severe (3). Half scores are allowed. It may be difficult to assess redness in dark skin. If in doubt, increase the average redness score by one level.

Score	Intensity of redness, thickness/swelling, scratching. lichenification
0	None, absent
1	Mild (just perceptible)
2	Moderate (obvious)

3	Severe

D. Calculations:
For each region, record the intensity for each of four signs and calculate the severity score.

- Severity score = redness intensity + thickness intensity + scratching intensity + lichenification intensity

For each region, multiple the severity score by the area score and by a multiplier. The multiplier is different for each body site.

- Head and neck: severity score x area score x 0.1 (in children 0–7 years, x 0.2)
- Trunk: severity score x area score x 0.3
- Upper limbs: severity score x area score x 0.2
- Lower limbs: severity score x area score x 0.4 (in children 0–7 years, x 0.3)

Add up the total scores for each region to determine the final EASI score. The minimum EASI score is 0 and the maximum EASI score is 72.

E. Interpretation:
The suggested severity levels for the EASI are as follows:

0	Clear
0.1-1.0	Almost clear
1.1-7.0	Mild
7.1-21.0	Moderate
21.1-50.0	Severe
50.1-72.0	Very severe

Pruritus Numerical Rating Scale (NRS):
Numerical Rating Scale - Pruritus Resources (pruritussymposium.de) [Accessed October 09, 2021]
The NRS is comprised of one item and is represented by numbers 0 (“no itch”) to 10 (“worst imaginable itch”). Patients are asked to rate the intensity of their itch using this scale. It features high reliability and concurrent validity and is a popular choice for all patients due to its simple format. Time needed for completion: 1 minute. It has been validated in several languages.

- It can be interpreted as follows:
  - NRS 0 - no pruritus
  - NRS < 3 - mild pruritus
  - NRS ≥ 3 < 7 - moderate pruritus
  - NRS ≥ 7 < 9 - severe pruritus
  - NRS ≥ 9 - very severe pruritus

On a scale from 0 (no itch) to 10 (worst imaginable itch), how would you rate your itch overall (on average) during the past 24-hour? (Select number)										
0	1	2	3	4	5	6	7	8	9	10

Diagnostic criteria for Behcet’s syndrome:

Criterion	Required features
Recurrent oral ulceration	Aphthous (idiopathic) ulceration, observed by clinician or patient, with at least three episodes in any 12-month period
Plus any two of the following:	
Recurrent genital ulceration	Aphthous ulceration or scarring, observed by clinician or patient
Eye lesions	Anterior or posterior uveitis cells in vitreous in slit-lamp examination; or retinal vasculitis documented by ophthalmologist

Skin lesions	Erythema nodosum-like lesions observed by clinician or patient; papulopustular skin lesions or pseudofolliculitis with characteristic acneiform nodules observed by clinician
Pathergy test	Interpreted at 24 to 48 hours by clinician
Adapted from International Study Group for Behcet's Disease. Criteria for diagnosis of Behcet's disease. Lancet 1990; 335:1078.	

When to suspect giant cell arteritis (GCA) — The diagnosis of giant cell arteritis (GCA) should be considered in a patient over the age of 50 years who has one or more of the following symptoms or signs, particularly in the setting of an elevated erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP):

- New headache or change in characteristics of preexisting headache
- Abrupt onset of visual disturbances, especially transient/permanent monocular visual loss
- Jaw claudication
- Unexplained fever or other constitutional symptoms and signs
- Signs/symptoms of vascular abnormalities (e.g., limb claudication; asymmetric blood pressures; abnormal radial pulse; vascular bruits; temporal artery abnormalities such as tenderness to palpation, decreased pulse amplitude, and presence of nodules)

Psoriasis Area and Severity Index (PASI):

	Head	Upper Extremities	Trunk	Lower extremities
1. Redness[1]				
2. Thickness[1]				
3. Scale[1]				
4. Sum of rows 1,2 and 3				
5. Area score[2]				
6. Score of row 4 x row 5 x the area multiplier	row 4 x row 5 x 0.1	row 4 x row 5 x 0.2	Row 4 x row 5 x 0.3	Row 4 x row 5 x 0.4
7. Sum row 6 for each column for PASI score				

Steps in generating PASI score:
(a) Divide body into four areas: head, arms, trunk to groin, and legs to top of buttocks.
(b) Generate an average score for the erythema, thickness, and scale for each of the 4 areas (0 = clear; 1–4 = increasing severity)[1].
(c) Sum scores of erythema, thickness, and scale for each area.
(d) Generate a percentage for skin covered with psoriasis for each area and convert that to a 0–6 scale (0 = 0%; 1 = <10%; 2 = 10–<30%; 3 = 30–<50%; 4 = 50–<70%; 5 = 70–<90%; 6 = 90–100%).
(e) Multiply score of item (c) above times item (d) above for each area and multiply that by 0.1, 0.2, 0.3, and 0.4 for head, arms, trunk, and legs, respectively.
(f) Add these scores to get the PASI score.

[1] Erythema, induration and scale are measured on a 0–4 scale (none, slight, mild, moderate, severe)
[2] Area scoring criteria (score: % involvement)
0: 0 (clear)
1: <10%
2: 10–<30%
3: 30–<50%
4: 50–<70%
5: 70–<90%
6: 90–<100%

Feldman, SR and Krueger, GG. Psoriasis assessment tools in clinical trials. Ann Rheum Dis 2005; 64 (Suppl III): ii65-ii68.

JIA Core Set 30%:

At least 30 percent improvement in at least 3 of the 6 core set variables with no more than 1 remaining variable worsening by > 30%

1. Physician's global assessment of overall disease activity measured on a visual analog scale (VAS)
2. Parent or patient global assessment of overall well-being measured on VAS
3. Functional ability
4. Number of joints with active arthritis
5. Number of joints with limited range of motion
6. Erythrocyte sedimentation rate (ESR)
Giannini, EH, Ruperto, N, Ravelli A, et al. Preliminary Definition of Improvement in Juvenile Arthritis. Arthritis & Rheumatism 1997

Rheumatoid Arthritis Disease Activity Measurement Instruments:

Instrument	Threshold of Disease Activity
Clinical Disease Activity Index (CDAI)	Range: 0 to 76 Remission: ≤ 2.8 Low activity: >2.8 to ≤ 10 Moderate activity: >10 to ≤ 22 High activity: >22
Disease Activity Score 28 (DAS28)	Range: 0.5 to 9 Remission: < 2.6 Low activity: > 2.6 to ≤ 3.2 Moderate activity: > 3.2 to ≤ 5.1 High activity: > 5.1
Patient Activity Scale (PAS) Patient Activity Scale II (PASII)	Range 0 to 10 Remission: 0 to 0.25 Low activity: >0.25 to 3.7 Moderate activity: > 3.7 to < 8.0 High activity: ≥ 8.0
Routine Assessment of Patient Index Data 3 (RAPID-3)	Range: 0 to 10 Remission: 0 to 1.0 Low activity: > 1.0 to 2.0 Moderate activity: > 2.0 to 4.0 High activity: > 4.0 to 10
Simplified Disease Activity Index (SDAI)	Range: 0 to 90 Remission: ≤ 3.3 Low activity: > 3.3 to ≤ 11.0 Moderate activity: > 11.0 to ≤ 26 High activity: > 26

American College of Rheumatology 20 Percent Improvement Criteria (ACR20):

At least 20 percent improvement in the following:
1. Swollen joint count
2. Tender joint count
And three of the following five variables:
3. Patient-assessed global disease activity (e.g., by VAS)
4. Evaluator-assessed global disease activity (e.g., by VAS)
5. Patient pain assessment (e.g., by VAS)
6. Functional disability (e.g., by HAQ)
7. Acute phase response (ESR or CRP)
A 50 and 70 percent ACR response (ACR50 and ACR70, respectively) represents respective improvement of at least 50 or 70 percent[1].
 1. *Felson DT, Anderson JJ, Lange ML, et al. Should improvement in rheumatoid arthritis clinical trials be defined as fifty percent or seventy percent improvement in core set measures, rather than twenty percent. Arthritis Rheum 1998; 41:1564.* 2. *Felson DT, Anderson JJ, Boers M, et al. American College of Rheumatology preliminary definition of improvement in rheumatoid arthritis. Arthritis Rheum 1995; 38:727.*

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Crohn's Disease Activity Index:
Sum each factor after adjustment with a weighting factor

Clinical or laboratory variable	Weighting factor	Factor Sum
Number of liquid or soft stools each day for seven days	x 2	
Abdominal pain (graded 0 = none, 1 = mild, 2 = moderate, 3 = severe) each day for 7 days	x 5	
General well-being (assessed from 0 = well, 1 = slightly under par, 2 = poor, 3 = very poor, 4 = terrible) each day for 7 days	x 7	
Presence of complications†	x 20	
Taking Lomotil (diphenoxylate/atropine) or opiates for diarrhea (0 = No, 1 = Yes)	x 30	
Presence of an abdominal mass (0 = none, 2 = questionable, 5 = definite)	x 10	
Hematocrit of < 0.47 in men and < 0.42 in women	x 6	
Percentage deviation from standard weight [1 – (ideal/observed)] x 100	x 1	
† **Complications**: one point each is added for each: • the presence of joint pains (arthralgia) or frank arthritis • inflammation of the iris or uveitis • presence of erythema nodosum, pyoderma gangrenosum, or aphthous ulcers • anal fissures, fistulae or abscesses • other fistulae • fever during the previous week		
Total CDAI		
Remission of CD: CDAI < 150 Severe CD: CDAI > 450 CD response: decrease in CDAI of > 70		

Ulcerative Colitis Activity (Adults):

American College of Gastroenterology Ulcerative Colitis Activity Index				
	Remission	Mild	Moderate-severe	Fulminant
Stools (no./d)	Formed	< 4	> 6	> 10
Blood in stools	None	Intermittent	Frequent	Continuous
Urgency	None	Mild, occasional	Often	Continuous
Hemoglobin	Normal	Normal	< 75% of normal	Transfusion needed
ESR	< 30	< 30	> 30	> 30
CRP (mg/L)	Normal	Elevated	Elevated	Elevated
Fecal calprotectin (mg/g)	< 150-200	> 150-200	> 150-200	> 150-200
Endoscopy (Mayo sub-score)	0-1	1	2-3	3
UCEIS	0-1	2-4	5-8	7-8
The above factors are general guides for disease activity. With the exception of remission, a patient does not need to have all the factors to be considered in a specific category. CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; UCEIS, Ulcerative Colitis Endoscopic Index of Severity.				

Endoscopic Assessment of Disease Activity		
Endoscopic Features	UCEIS Score	Mayo Score
Normal	0	0
Erythema, decreased vascular pattern, mild friability	1-3	1
Marked erythema, absent vascular pattern, friability, erosions	4-6	2

Spontaneous bleeding, ulceration	7-8	3

Pediatric ulcerative colitis activity index (PUCAI)

Abdominal pain	No pain	0 points
	Pain can be ignored	5 points
	Pain cannot be ignored	10 points
Rectal Bleeding	None	0 points
	Small amount only, in <50% of stools	10 points
	Small amount with most stools	20 points
	Large amount (>50% of the stool content)	30 points
Stool consistency of most stools	Formed	0 points
	Partially formed	5 points
	Completely unformed	10 points
Number of stools er 24 hours	0 to 2	0 points
	3 to 5	5 points
	6 to 8	10 points
	>8	15 points
Nocturnal stools (any episode causing wakening)	No	0 points
	Yes	10 points
Activity level	No limitation of activity	0 points
	Occasional limitation of activity	5 points
	Severe restricted activity	10 points
Sum (0-85) PUCAI scores are interpreted as follows: 0 to 9 – Remission 10 to 34 – Mild disease 35 to 64 – Moderate disease 65 to 85 – Severe disease		

Resources:

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