BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

RINVOQ™ (upadactinib) extended release tablet

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 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 precertification 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.

Criteria:

Section A. Applies for all indications and uses:

- **Criteria for initial therapy:** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in or is in consultation with a Rheumatologist, Dermatologist, or Gastroenterologist depending upon indication or use

  2. Age of individual is consistent with the FDA approved product labeling

  3. Meets other additional initial criteria per indication or use as described below in Sections B-F below

4. Individual does **NOT** have **ANY** of the following:
    a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
        i. Serologic tests for hepatitis B and C (HB surface Ag, anti-HB surface Ab, anti-HB core Ab, and hepatitis C antibody tests) have been done within the previous 12 months
        ii. Screening for latent tuberculosis infection with a tuberculin skin test or blood test has been done and; if positive, treatment has been initiated
    b. Absolute neutrophil count less than 1,000/mm^3
    c. Absolute lymphocyte count less than 500/mm^3
    d. Hemoglobin less than 8 g/dl
    e. Severe hepatic impairment
    f. Concurrent use of live vaccines
    g. Pregnancy

5. There is no concurrent use with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (e.g., Adbry, azathioprine, Cibinqo, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, methotrexate, Otezla, Xeljanz, Xolair, etc.)

6. There are no significant interacting drugs, such as:
    a. Strong inducers or CYP3A4 inducers (e.g., rifampin)

7. There are **NO** FDA-label contraindications

- **Criteria for continuation of coverage (renewal request):** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in or is in consultation with a Rheumatologist, Dermatologist, Gastroenterologist depending upon indication or use

2. Meets other additional continuation criteria per indication or use as described in Sections B-F below

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications per FDA label or other significant adverse drug effects that may exclude continued use including:
    a. Myocardial infarction or stroke
    b. Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis
    c. Hematologic Abnormalities (see Definitions section)

5. Individual does **NOT** have **ANY** of the following:
    a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
    b. Severe hepatic impairment
    c. Concurrent use of live vaccines

6. There is no concurrent use with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (e.g., Adbry, azathioprine, Cibinqo, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, methotrexate, Otezla, Xeljanz, Xolair, etc.)

7. There are no significant interacting drugs, such as:
    a. Strong inducers or CYP3A4 inducers (e.g., rifampin)

Section B. Moderately to severely active Ankylosing Spondylitis (AS):

- **Criteria for initial therapy:** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active ankylosing spondylitis:

1. Prescriber is a physician specializing in the patient's diagnosis or Rheumatologist

2. Meets other initial criteria per indication or use as described in Section A above

3. Individual is 18 years of age or older

4. Clinical and diagnostic imaging evidence of ankylosing spondylitis as indicated by **ALL** of the following:
    a. Back pain of 3 months or more duration and age of onset of 45 years or younger
    b. Sacroiliitis on imaging
    c. Spondyloarthritis signs or symptoms as indicated by **ONE or more** of the following:
        i. Arthritis
        ii. Elevated serum C-reactive protein
        iii. Enthesitis (e.g., inflammation of Achilles tendon insertion)
        iv. HLA-B27
        v. Limited chest expansion
        vi. Morning stiffness for one hour or more

5. Disease activity and treatment scenario as indicated by **ONE or more** of the following:
    a. Axial (spinal) disease
    b. Peripheral arthritis without axial involvement, and failure, contraindication per FDA label, or intolerance of 4 or more months of therapy with sulfasalazine

6. Individual has failure, contraindication per FDA label, or intolerance to **TWO or more** different NSAIDs (at maximum recommended doses) over a total period of at least 4 or more weeks of therapy

7. Individual has failure (used for > 3 consecutive months), contraindication per FDA label, or intolerance to at least **ONE** TNF inhibitor (e.g., Cimzia, Humira, Simponi).

Approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met (**samples are not considered for continuation of therapy**):

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy
    a. **With first request for continuation**: Response is defined as AT LEAST a 20% improvement in BASDAI (see Definition section)
    b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Renewal Duration: 12 months

Section C. Atopic Dermatitis (AD):

- **Criteria for initial therapy:** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or Dermatologist

2. Meets other initial criteria per indication or use as described in Section A above

3. Individual is 12 years of age or older

4. Individual has a confirmed diagnosis of refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable

5. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate (see Definitions section):
    a. Lesions involve at least 10% of body surface area or involve sensitive areas of the face, head, neck, hands, feet, groin, or intertriginous areas
    b. Weekly averaged Worst Daily Peak Pruritus Numeric Rating Scale (NRS) of at least 3
    c. **ONE** of the following disease intensity measures:
        i. Disease severity defined by an Investigator's Global Assessment (IGA) score of at least 7
        ii. Eczema Area and Severity Index (EASI) score of at least 7

6. Individual has documented failure (used for > 2 consecutive months), contraindication per FDA label, intolerance, or not a candidate to **ONE** agent from **EACH** of the following categories:
    a. Topical medium to very high potency corticosteroid
    b. Calcineurin inhibitor (Protopic (tacrolimus) or Elidel (pimecrolimus))
    c. Phosphodiesterase 4 inhibitor (Eucrisa (crisaborole))

7. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or not a candidate to **BOTH** of the following medications:
    a. Dupixent
    b. Adbry

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. Individual's condition has responded while on therapy, defined as **ALL** of the following:
    a. Documented evidence of efficacy, disease stability and/or improvement
    b. Achieved and maintains improvement in **ONE** of the following disease intensity scores
        i. IGA of 0 or 1 (clear or almost clear)
        ii. EASI-50 (improvement of at least 50% in score from baseline)
        iii. NRS decrease of 4 or more from baseline

Renewal duration: 12 months

Section D. Moderately to severely active Psoriatic Arthritis (PsA):

- **Criteria for initial therapy:** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active psoriatic arthritis:

    1. Prescriber is a physician specializing in the patient's diagnosis or Rheumatologist or Dermatologist

    2. Meets other initial criteria per indication or use as described in Section A above

    3. Individual is 18 years of age or older

    4. Diagnosis of moderate to severe active psoriatic arthritis is identified by **ONE or more** of the following:
        a. Predominantly axial disease (i.e. sacroiliitis or spondylitis) as indicated by **ALL** of the following:
            i. Radiographic evidence of axial disease (e.g., sacroiliac joint space narrowing or erosions, vertebral syndesmophytes)
            ii. Symptoms (e.g., limited spinal range of motion, spinal morning stiffness more than 30 minutes) present for more than 3 months' duration
            iii. Failure, contraindication per FDA label, or intolerance of 1 or more different NSAIDs (at maximum recommended doses) over total period of at least 4 or more weeks of therapy
        b. Predominantly non-axial disease, and failure (used for ≥ 3 consecutive months), intolerance, or contraindication per FDA label to methotrexate or NSAIDs

    5. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to at least **ONE** TNF inhibitors (e.g., Cimzia, Humira, Simponi).

    Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met (**samples are not considered for**

continuation of therapy):

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy
   a. **With first request for continuation**: Response is defined as AT LEAST a 20% improvement in any of the following: ACR, CDAI, DAS28, PAS, PASII, RAPID-3, SDAI (see Definition section)
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Renewal Duration: 12 months

Section E. Moderately to severely active Rheumatoid Arthritis (RA):

- **Criteria for initial therapy:** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active rheumatoid arthritis:

1. Prescriber is a physician specializing in the patient's diagnosis or Rheumatologist

2. Meets other initial criteria per indication or use as described in Section A above

3. Individual is 18 years of age or older

4. Diagnosis of rheumatoid arthritis identified by **ONE** of the following:
   a. Clinical Disease Activity Index (CDAI) score greater than 10
   b. Disease Activity Score 28 (DAS28) of greater than 3.2
   c. Patient Activity Scale (PAS) of greater than 3.7
   d. Patient Activity Scale II (PASII) of greater than 3.7
   e. Routine Assessment of Patient Index Data 3 (RAPID-3) score greater than 2
   f. Simplified Disease Activity Index (SDAI) score greater than 11

5. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **methotrexate**

6. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **ONE** of the following: [Note this criterion is waived if the individual already has tried an FDA-approved Rheumatoid Arthritis biologic]
   a. Leflunomide
   b. Sulfasalazine

7. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to at least **ONE** TNF inhibitors (e.g., Cimzia, Humira, Simponi).

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met (**samples are not considered for continuation of therapy**):

  1. Meets other continuation criteria as described in Section A above

  2. Individual's condition responded while on therapy
     a. **With first request for continuation**: Response is defined as AT LEAST a 20% improvement in any of the following: ACR, CDAI, DAS28, PAS, PASII, RAPID-3, SDAI (see Definition section)
     b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

  Renewal Duration: 12 months

Section F. Moderately to severely active Ulcerative Colitis (UC):

- **Criteria for initial therapy:** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active ulcerative colitis (UC):

  1. Prescriber is a physician specializing in the patient's diagnosis or Gastroenterologist

  2. Meets other initial criteria per indication or use as described in Section A above

  3. Individual is 18 years of age or older

  4. Diagnosis of moderate to severe active ulcerative colitis, as indicated by **ONE** of the following:
     a. American College of Gastroenterology Ulcerative Colitis activity index rating of moderate to severe disease in adults

     b. **At least 5** of the following signs and symptoms:
        i. Anemia
        ii. Bloody diarrhea or visible blood in stool
        iii. Bowel movements 4-6 or more times per day
        iv. Colicky abdominal pain
        v. Elevated fecal calprotectin
        vi. Elevated serum C-reactive protein or erythrocyte sedimentation rate
        vii. Fatigue
        viii. Fever
        ix. Tenesmus
        x. Urgency
        xi. Weight loss

  5. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **ONE or more** of the following: [Note this criterion is waived if the individual already has tried an FDA-approved Ulcerative Colitis biologic]
     a. 6-mercaptopurine
     b. Azathioprine

c. Oral corticosteroids
d. Salicylates (such as mesalamine, sulfasalazine, balsalazide, olsalazine)

6. Individual has failure (used for > 3 consecutive months), contraindication per FDA label contraindication per FDA label, or intolerance to at least **ONE** TNF inhibitors (e.g., Cimzia, Remicade, Simponi).

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Rinvoq (upadactinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met (**samples are not considered for continuation of therapy**):

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy
   a. **With first request for continuation ONE of the following:**
      i. Response is defined as AT LEAST a 20% improvement in signs and symptoms of ulcerative colitis
      ii. American College of Gastroenterology Ulcerative Colitis activity index rating of mild disease or disease in remission in adults
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Renewal Duration: 12 months

Section G. Other:

- 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:

Adult: Age 18 years and older.

PHARMACY COVERAGE GUIDELINE

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Preferred and Non-Preferred Agents:

Disease State	Preferred Agents	Non-Preferred Agents
Rheumatoid Arthritis (RA)	Cimzia* Humira* Rinvoq* Simponi* Simponi Aria† Xeljanz tab* Xeljanz XR tab*	Actemra (IV)† DSE Actemra (SQ)* DSE Enbrel* QSE Kevzara* QSE Kineret* QSE Olumiant* QSE Orencia (IV)† DSE Orencia (SQ)* DSE
Psoriatic Arthritis (PsA)	Cimzia* Humira* Otezla* Rinvoq* Simponi* Simponi Aria† Skyrizi* Stelara (IV)† Stelara (SQ)* Xeljanz tab* Xeljanz XR tab*	Cosentyx* QSE Enbrel* QSE Orencia (IV)† DSE Orencia (SQ)* DSE Taltz* SSE
Psoriasis (PsO)	Cimzia* Humira* Otezla* Skyrizi* Stelara (IV)† Stelara (SQ)* Tremfya*	Cosentyx* QSE Enbrel* QSE Siliq* QSE Taltz* SSE
Juvenile Idiopathic Arthritis	Humira* Simponi Aria† Xeljanz oral solution* DSE Xeljanz tab*	Actemra (IV)† DSE Actemra (SQ)* DSE Enbrel* QSE Orencia (IV)† DSE Orencia (SQ)* DSE

SSE: Single Step Edit. Individual has failure, contraindication or intolerance to at least **one** preferred agent with a specific duration.
DSE: Double Step Edit. Individual has failure, contraindication or intolerance to at least **two** preferred agents with a specific duration.
TSE: Triple Step Edit. Individual has failure, contraindication or intolerance to at least **three** preferred agents with a specific duration
QSE: Quadruple Step Edit. Individual has failure, contraindication or intolerance to at least **four** preferred agents with a specific duration.

***Pharmacy Benefit:** Injectable and oral medications that can be self-administered are billed and processed through pharmacy benefit only.
† **Medical Benefit:** Injectable medications that must be administered by a healthcare professional.

Recommendations for Discontinuation for Rinvoq Discontinuation for Laboratory Abnormalities

Laboratory Measure	Recommendation
Absolute neutrophil count (ANC) <1,000mm3	Interrupt treatment if ANC is < 1000 cell/mm^3 and may restart once ANC above this value
Absolute lymphocyte count (ALC) < 500/mm3	Interrupt treatment if ALC is < 500 cell/mm^3 and may restart once ALC above this value
Hemoglobin (Hb) < 8g/dl	Interrupt treatment if Hb < 8g/dl and may restart once Hb above this value
Hepatic transaminases	Interrupt treatment if drug-induced liver injury is suspected, 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:

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:

Instrument	Threshold of Disease Activity
Investigator Global Assessment Scale (IGA): Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf (eczemacouncil.org) [Accessed August 8, 2022]	Range: 0 to 4 Clear: 0 (No inflammatory signs of AD) Mild: 2 (slight but definite signs of AD) Moderate: 3 (clearly perceptible signs of AD) Severe: 4 (marked signs of AD)
Pruritis Numerical Rating Scale (NRS) Numerical Rating Scale - Pruritus Resources (pruritussymposium.de) [Accessed August 8, 2022]	Range: 0 to 10 NRS 0 - no pruritus NRS < 3 - mild pruritus NRS ≥ 3 < 7 - moderate pruritus NRS ≥ 7 < 9 - severe pruritus NRS ≥ 9 - very severe pruritus
Eczema Area and Severity Index (EASI) score A-E Calculating Eczema Area and Severity Index | Eczema Severity Index | Eczema Less [Accessed August 8, 2022]	Range: 0-72 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 – Very Severe **Based on clinical trial data from Adbry, Cibinqo, Dupixent, and Rinvoq: moderate AD was defined as EASI ≥16*

Investigator Global Assessment Scale (IGA):
The IGA score is an outcome measure that provides an overall assessment of the severity of AD at a specific time point. It is generally a 5-point scale from 0 (clear) to 4 (severe).

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. It ranges from 0 to 72 with higher scores indicating greater severity. Total scores represent assessment of severity signs of erythema, induration/papulation/edema, excoriations, and lichenification across four body regions. e percentage area involved for each of the four body regions are assigned a proportional score from 0 to 6 (where 0= no eruption, 1 = ≤10%, 2 = 10-29%, 3 – 30-49%, 4 = 50-69%, 5= 70-89%, and 6 = 90-100%). The proportionate body surface areas assigned to adults are 10% for the head and neck (20% for children), 20% for the upper extremities (same for children), 30% for trunk (same for children) and 50% for lower extremities (30% for children). Outcomes are assessed as the change in EASI response from baseline and are categorized as the percent improvement.

Pruritus Numerical Rating Scale (NRS):
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 during the worst moment in the previous 24 hours. It features high reliability and concurrent validity and is a popular choice for all patients due to its simple format.

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Rheumatoid Arthritis and Psoriatic 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:
3. Swollen joint count
4. Tender joint count
And three of the following five variables:
5. Patient-assessed global disease activity (e.g., by VAS)
6. Evaluator-assessed global disease activity (e.g., by VAS)
7. Patient pain assessment (e.g., by VAS)
8. Functional disability (e.g., by HAQ)
9. 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].
© 2018 UpToDate, Inc. a. *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.* b. *Felson DT, Anderson JJ, Boers M, et al. American College of Rheumatology preliminary definition of improvement in rheumatoid arthritis. Arthritis Rheum 1995; 38:727.*

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

Resources:

Rinvoq (upadactinib) product information, revised by AbbVie Inc. 04-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 4, 2022.

Yu DT, van Tubergen A. Diagnosis and differential diagnosis of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondylarthritis) in adults. In: UpToDate, Sieper J, Romain RL (Eds), UpToDate, Waltham, MA.: UpToDate Inc. Available at http://uptodate.com. Accessed August 9, 2022.

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