Clinical Policy: Upadacitinib (Rinvoq)

Reference Number: NH.PHAR.443
Effective Date: 12.21
Last Review Date: 04.25
Line of Business: Medicaid

Revision Log

See Important Reminder **at the end of this policy for important regulatory and legal information.**

Description

Upadacitinib (Rinvoq™) is a Janus kinase (JAK) inhibitor.

FDA Approved Indication(s)

Rinvoq is indicated for treatment of:

- Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults and pediatric patients 12 years of age and older with 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.
- Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults with active ankylosing spondylitis who have had an inadequate response or intoleranace to one or more TNF blockers.
- Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.

Limitation(s) of use: Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Rinvoq is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all)**:**

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix E*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of at least ONE conventional DMARD (e.g.,

sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effect are experienced or all are contraindicated;

5. Documentation of one of the following baseline assessment scores (a or b):
   a. Clinical disease activity index (CDAI) score (*see Appendix F*);
   b. Routine assessment of patient index data 3 (RAPID3) score (*see Appendix G*);
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed 15 mg (one tablet) per day.

Approval duration: 6 months

B. Psoriatic Arthritis (must meet all)**:**

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age > 18 years;
4. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
5. Dose does not exceed 15 mg (one tablet) per day.

   Approval duration: 6 months

C. Atopic Dermatitis (must meet all)**:**

1. Diagnosis of atopic dermatitis affecting one of the following (a or b):
   a. At least 10% of the member's body surface area (BSA);
   b. Hands, feet, face, neck, scalp, genitals/groin, and/or intertriginous areas;
2. Prescribed by or in consultation with a dermatologist or allergist;
3. Age > 12 years;
4. Failure of all of the following (a, b, and c), unless contraindicated or clinically significant adverse effects are experienced:
   a. Two formulary medium to very high potency topical corticosteroids, each used for > 2 weeks;
   b. One non-steroidal topical therapy* used for > 4 weeks: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment, pimecrolimus 1% cream) or Eucrisa®;
      **These agents may require prior authorization*
   c. One systemic agent used for > 3 months: azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine;
5. Rinvoq is not prescribed concurrently with another biologic medication (e.g., Adbry®, Dupixent®) or a JAK inhibitor (e.g., Olumiant®, Cibinqo®, Opzelura™);
6. Dose does not exceed one of the following (a or b):
   a. 15 mg (one tablet) per day;
   b. 30 mg (one tablet) per day and medical justification supports inadequate response to 15 mg daily.

Approval duration: 6 months

D. Axial Spondyloarthritis (must meet all):

1. Diagnosis of AS or nr-axSpA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless clinically significant adverse effects are experienced or all are contraindicated;
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed both of the following (a and b):
   a. 15 mg per day;
   b. 1 tablet per day.

Approval duration: 6 months

E. Ulcerative Colitis (must meet all)**:**

1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
4. Documentation of a Mayo Score ≥ 6 or modified Mayo Score ≥ 5 (*see Appendix H*);
5. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Request meets one of the following (a or b):
   a. For induction (both i and ii):
      i. 45 mg once daily for 8 weeks;
      ii. 1 tablet once daily for 8 weeks;
   b. For maintenance (both i and ii):
      i. 15 mg once daily;
      ii. 1 tablet once daily.

Approval duration: 6 months

F. Polyarticular Juvenile Idiopathic Arthritis (must meet all):

1. Diagnosis of PJIA* as evidenced by ≥ 5 joints with active arthritis;
   **Overlap of diagnosis exists in children with JIA and non-systemic polyarthritis, which may include children from ILAR JIA categories of enthesitis-related arthritis*
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 2 years;
4. Member meets one of the following (a, b, c, or d):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of leflunomide or sulfasalazine at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
   c. For sacroiliitis/axial spine involvement (i.e., spine, hip), failure of a ≥ 4 week trial of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   d. Documentation of high disease activity;
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed one of the following (a, b, or c):
   a. Weight 10 kg to < 20 kg: 6 mg per day (*Rinvoq LQ*);
   b. Weight 20 kg to < 30 kg: 8 mg per day (*Rinvoq LQ*);
   c. Weight ≥ 30 kg, one of the following (i or ii):
      i. 12 mg per day (*Rinvoq LQ*);

ii. Both of the following (1 and 2) (*Rinvoq*):
1. 15 mg per day;
2. 1 tablet per day.

Approval duration: 6 months

G. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL, the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Rheumatoid Arthritis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. A decrease in CDAI (*see Appendix F*) or RAPID3 (*see Appendix G*) score from baseline;
   b. Medical justification stating inability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed 15 mg (one tablet) per day.

Approval duration: 12 months

B. Psoriatic Arthritis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed 15 mg (one tablet) per day.

Approval duration: 12 months

C. Atopic Dermatitis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by, including but not limited to, reduction in itching and scratching;
3. Rinvoq is not prescribed concurrently with another biologic medication (e.g., Adbry®, Dupixent®) or a JAK inhibitor (e.g., Olumiant®, Cibinqo®, Opzelura™);
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. 15 mg (one tablet) per day;
   b. 30 mg (one tablet) per day and medical justification supports inadequate response

to 15 mg daily.

Approval duration: 12 months

D. All Other Indications (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed (a or b):
   a. For PsA, UC, AS, nr-axSpA: both of the following (i and ii):
      i. 15 mg per day;
      ii. 1 tablet per day;
   b. For refractory, severe, or extensive UC: both of the following (i and ii):
      i. 30 mg per day;
      ii. 1 tablet per day.
   c. For pJIA: One of the following (I, ii, or iii):
      i. Weight 10 kg to <20 kg: 6mg per day (Rinvoq LQ);
      ii. Weight 20 kg to <30 kg: 8 mg per day (Rinvoq LQ);
      iii. Weight ≥30 kg, one of the following (1 or 2):
      1. 12 mg per day (Rinvoq LQ);
      2. Both of the following (a and b) (Rinvoq):
         a) 15 mg per day;
         b) 1 tablet per day.

Approval duration: 12 months

E. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents;

B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars (Avsola™, Inflectra™, Renflexis™, Zymfentra®), Simponi®], interleukin agents [e.g., Actemra® (IL-6RA), Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Stelara® (IL-12/23 inhibitor), Taltz® (IL-17A inhibitor), Tofidence™ (IL-6), Tremfya® (IL-23 inhibitor), Wezlana™ (IL-12/23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars (Riabni™, Ruxience™, Truxima®), Rituxan Hycela®], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the

additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

IV. Appendices/General Information *Appendix A: Abbreviation/Acronym Key* CDAI: clinical disease activity index DMARD: disease-modifying antirheumatic drug
FDA: Food and Drug Administration JAKi: Janus kinase inhibitors

MTX: methotrexate PsA: psoriatic arthritis RA: rheumatoid arthritis
RAPID3: routine assessment of patient index data 3

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
athioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID **AD** 1-3 mg/kg/day PO QD	3 mg/kg/day
corticosteroids	**UC*** rednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week Budesonide (Uceris®) 9 mg PO QAM for up to 8 weeks	Various
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**RA** 2.5 – 4 mg/kg/day PO divided BID **AD** *Adult:* 150-300 mg/d *Pediatric:* 3-6 mg/kg/day PO	RA: 4 mg/kg/day AD: Adult: 300 mg/day Pediatric: 6 mg/kg/day
droxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg/day PO QD Maintenance dose: 200 – 400 mg/day PO QD	600 mg/day
leflunomide (Arava®)	**RA** Initial dose (for low risk hepatotoxicity or myelosuppression): 100 mg PO QD for 3 days Maintenance dose: 20 mg PO QD	20 mg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®)	**RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week **AD**	RA: 30 mg/week AD: Adult: 25 mg/week Pediatric: 0.7 mg/kg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Adult: 7.5-25 mg/wk PO once weekly *Pediatric:* 0.2 – 0.7 mg/kg/wk PO once weekly	
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS** Varies	Varies
Ridaura® (auranofin)	**RA** 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	**RA** Initial dose: 500 mg to 1,000 mg PO QD for the first week. Increase the daily dose by 500 mg each week up to a maintenance dose of 2 g/day. Maintenance dose: 2 g/day PO in divided doses	3 g/day
mycophenolate mofetil	**AD** *Adult:* 1-1.5 g PO BID *Pediatric:* 30 – 50 mg/kg/day PO	Adult: 3 g/day Pediatric: 50mg/kg/day
Actemra® (tocilizumab)	**RA** 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response SC: Weight < 100 kg: 162 mg SC every other week, followed by an increase to every week based on clinical response Weight ≥ 100 kg: 162 mg SC every week	IV: 800 mg every 4 weeks SC: 162 mg every week
Enbrel® (etanercept)	**AS** 50 mg SC once weekly **RA, PsA** 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Cimzia® (certolizumab)	**AS, nr-axSpA** Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 200 mg SC every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks
Humira® , Amjevita™ (adalimumab)	**UC** Initial dose: 160 mg SC on Day 1, then 80 mg SC on Day 15 Maintenance dose: 40 mg SC every other week starting on Day 29	40 mg every other week
Kevzara® (sarilumab)	**RA** 200 mg SC once every two weeks	200 mg/2 weeks
Oluminat® (baricitinib)	**RA** 2 mg PO QD	2 mg/day
Taltz®	**AS, PsA**	80 mg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(ixekizumab)	nitial dose: 160 mg (two 80 mg injections) SC at week 0 Maintenance dose: 80 mg SC every 4 weeks **nr-axSpA** 80 mg SC every 4 weeks	
Xeljanz® (tofacitinib)	**AS, PsA, RA** 5 mg PO BID	10 mg/day
Xeljanz XR® tofacitinib extended-release)	**AS, PsA, RA** 11 mg PO QD	11 mg/day
Very High Potency Topical Corticosteroids		
gmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution diflorasone diacetate 0.05% (Maxiflor®, Psorcon E®) cream, ointment halobetasol propionate 0.05% (Ultravate®) cream, ointment	**AD** Apply topically to the affected area(s) BID	Varies
High Potency Topical Corticosteroids		
gmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion diflorasone 0.05% (Florone®, Florone E®, Maxiflor®,Psorcon E®) cream luocinonide acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution riamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment	**AD** Apply topically to the affected area(s) BID	Varies
Medium Potency Topical Corticosteroids		
soximetasone 0.05% (Topicort ®) cream, ointment, gel uocinolone acetonide 0.025% (Synalar®) cream, ointment mometasone 0.1% (Elocon®) cream, ointment, lotion amcinolone acetonide 0.025%, 0.1% (Aristocort®, Kenalog®) cream, ointment	**AD** Apply topically to the affected area(s) BID	Varies
Low Potency Topical Corticosteroids		
lometasone 0.05% (Aclovate®) cream, ointment desonide 0.05% (Desowen®) cream, ointment, lotion luocinolone acetonide 0.01% (Synalar®) solution ydrocortisone 2.5% (Hytone®)	**AD** Apply topically to the affected area(s) BID	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cream, ointment		
Other Classes of Agents		
tacrolimus (Protopic®), pimecrolimus (Elidel®)	**AD** Children ≥ 2 years and adults: Apply a thin layer topically to affected skin BID. Treatment should be discontinued if resolution of disease occurs.	Varies
Eucrisa® (crisaborole)	**AD** Apply to the affected areas BID	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to upadacitinib or any of the excipients in Rinvoq
- Boxed warning(s): serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis

Appendix D: General Information

- Definition of MTX or DMARD Failure
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living
- TNF blockers:
  - Etanercept (Enbrel®), adalimumab (Humira®), adalimumab-atto (Amjevita™), infliximab (Remicade®) and infliximab biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

Appendix E: The 2010 ACR Classification Criteria for RA
Add score of categories A through D; a score of ≥ 6 out of 10 is needed for classification of a patient as having definite RA.

A	**Joint involvement**	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
B	**Serology (at least one test result is needed for classification)**	
	Negative rheumatoid factor (RF) *and* negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF *or* low positive ACPA ** Low: < 3 x upper limit of normal*	2

A	**Joint involvement**	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
	High positive RF *or* high positive ACPA ** High: ≥ 3 x upper limit of normal*	3
C	**Acute phase reactants (at least one test result is needed for classification)**	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	> 6 weeks	1

Appendix F: Clinical Disease Activity Index (CDAI) Score

The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

CDAI Score	Disease state interpretation
≤ 2.8	Remission
> 2.8 to ≤ 10	Low disease activity
> 10 to ≤ 22	Moderate disease activity
> 22	High disease activity

Appendix G: Routine Assessment of Patient Index Data 3 (RAPID3) Score

The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0 – 10, and the maximum achievable score is 30.

RAPID3 Score	Disease state interpretation
≤ 3	Remission
3.1 to 6	Low disease activity
6.1 to 12	Moderate disease activity
> 12	High disease activity

Appendix H: Mayo Score

- Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 – 2	Remission
3 – 5	Mild activity
6 – 10	Moderate activity
>10	Severe activity

I. Dosage and Administration

dication	sing Regimen aximum	Dose
, nr-axSpA, RA, PsA	mg PO QD	mg/day
	• Age > 12 years and > 40 kg but < 65 years: 15 mg PO QD; if an adequate response is not achieved, consider increasing the dosage to 30 mg PO QD	• Age >12 years and > 40 kg but < 65 years: 30 mg/day

dication	sing Regimen aximum	Dose
	• Age > 65 years: 15 mg PO QD	• Age > 65 years: 15 mg/day
	• Induction: 45 mg PO Q for 8 weeks • Maintenance: 15 mg PO QD. A dosage of 30 mg PO QD may be considered for patients with refractory, severe, or extensive disease.	30 mg/day

II. Product Availability

Tablets, extended-release: 15 mg, 30 mg, 45 mg

III. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.21	10.21

2Q 2022 annual review: criteria added for new FDA indications: psoriatric arthritis, atopic dermatitis; revised Rinvoq's place in therapy after TNFi for RA and PsA per FDA labeing; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.	3.22	4.22
Annual review, no changes	01.23	01.23
Added new indications and updated references and dosing charts	06.23	06.23
2Q 2024 annual review: removed nr-axSpA supplemental guideline information in Appendix D; added Bimzelx, Zymfentra, Omvoh, Wezlana, Sotyktu, Tofidence, and Velsipity to section III.B; references reviewed and updated. Adjusted to new PDL requirements by removing trial and failure of other preferred agents	04.24 08.24	04.24 08.24
2Q 2025 annual review: for UC initial criteria, added option for documentation of modified Mayo Score ≥ 5; added indication for pJIAsis; removed criteria for "member is responding positively to therapy as evidence by decrease in cJADAS-10 from baseline" in continued therapy;	04.25	04.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely

responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exerciseindependent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan. This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited.
Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.