Effective Date:
Reviewed: 4/2020, 12/2020, 5/2021, 5/2022, 9/2022, 12/2022, 8/2023, 2/2024, 1/2025, 5/2025, 8/2026 Scope: Medicaid

RINVOQ (upadacitinib) and RINVOQ LQ (upadacitinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Rinvoq is indicated for:

1. Moderately to severely active rheumatoid arthritis (RA) in adults who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers
2. Active psoriatic arthritis (PsA) in adults who have had an inadequate response or intolerance to one or more TNF blockers
3. Refractory moderate to severe atopic dermatitis (AD) in adults and pediatric patients 12 years of age and older whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable
4. Moderately to severely active ulcerative colitis (UC) in adults who have had an inadequate response or intolerance to one or more TNF blockers
5. Active ankylosing spondylitis (AS) in adults who have had an inadequate response or intolerance to one or more TNF blockers
6. Active non-radiographic axial spondyloarthritis (nr-axSpA) in adults with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy
7. Moderately to severely active Crohn's disease (CD) in adults who have had an inadequate response or intolerance to one or more TNF blockers
8. Active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers
9. Giant cell arteritis (GCA) in adults

Rinvoq LQ is indicated for:

1. Treatment of adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers
2. Treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one or more TNF blockers

All other indications are considered experimental/investigational and are not a covered benefit.

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II. CRITERIA FOR INITIAL APPROVAL

For all indications:

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Rinvoq will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (e.g., Hadlima), Enbrel (etanercept), infliximab (e.g., Inflectra), Simponi (golimumab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Otulfi, Selarsdi, Steqeyma, and Yesintek, etc.), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), Omvoh (mirikizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), tofacitinib (Xeljanz), Olumiant (baricitinib), Velsipity (etrasimod), etc.); AND
- Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND
- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment.

A. Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted for treatment of moderately to severely active RA when all of the following criteria is met:

1. Member is 18 years of age or older; AND
2. Rinvoq is prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Documentation is submitted of one of the following criteria:
    a. Member has been tested for either of the following biomarkers and the test was positive:
        a. Rheumatoid factor (RF)
        b. Anti-cyclic citrullinated peptide (anti-CCP); OR
    ii. Member has been tested for ALL of the following biomarkers:
        a. RF
        b. Anti-CCP
        c. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR); AND
4. Documentation is submitted that the member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab AND tofacitinib at maximum tolerated doses.

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of active psoriatic arthritis in members when all of the following criteria are met:

1. Member is 2 years of age or older; AND
2. Rinvoq or Rinvoq LQ is prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND

3. Member has documented active disease; AND
4. If member is 18 years of age or older, documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab, a 6-month trial of ustekinumab biosimilar, AND a 3-month trial of tofacitinib at maximum tolerated doses.
5. If member is 6 years of age or older but under 18, documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 6-month trial of ustekinumab biosimilar AND a 3-month trial of tofacitinib at maximum tolerated doses.
6. If member is under 6 years of age, documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of tofacitinib at maximum tolerated doses.

C. Moderate-to-severe atopic dermatitis

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis when all of the following criteria are met:

1. Member is 12 years of age or older; AND
2. Rinvoq is prescribed by, or in consultation with dermatologist or allergist/immunologist; AND
3. Documentation has been submitted that the affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected; AND
4. Documentation has been submitted of ALL of the following:
    a. Member has had an inadequate response, intolerance, or contraindication to at least one medium to super-high potency topical corticosteroid for ≥ 2 consecutive weeks (see Appendix); AND
    b. Member has had an inadequate response, intolerance, or contraindication to pimecrolimus cream or tacrolimus ointment for ≥6 consecutive weeks; AND
    c. Member had an inadequate response, intolerance, or contraindication to at least a 4-month trial of Dupixent; AND
    d. Member had an inadequate response, intolerance, or contraindication to at least a 4-month trial of Adbry OR Nemluvio.

D. Moderately to severely active ulcerative colitis (UC)

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis when all the following criteria are met:

1. Member is 18 years of age or older; AND
2. Rinvoq is prescribed by, or in consultation with, a specialist in gastroenterology; AND
3. Documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of infliximab IV or adalimumab AND at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

E. Active ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

Authorization of 12 months may be granted for treatment of active ankylosing spondylitis when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Rinvoq is prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
3. Documentation has been submitted indicating member has active disease for AS or nr-axSpA; AND
4. Documentation that the member has experienced an inadequate response or has a contraindication to TWO (2) NSAIDs; AND
5. Documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses; AND
6. If requesting Rinvoq for ankylosing spondylitis (AS), documentation has been submitted that the member has also had an inadequate response, intolerance or contraindication to at least a 3-month trial of tofacitinib at maximum tolerated doses.

F. Moderately to severely active Crohn's disease (CD)

Authorization of 12 months may be granted for treatment of moderate to severe active Crohn's disease in members when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Rinvoq is prescribed by, or in consultation with, a specialist in gastroenterology; AND
3. Member has a documented diagnosis of moderate to severe active CD; AND
4. Documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of infliximab IV or adalimumab AND at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

G. Active polyarticular juvenile idiopathic arthritis (pJIA)

Authorization of 12 months may be granted for treatment of active polyarticular juvenile idiopathic arthritis in members when all of the following criteria are met:

1. Member is 2 years of age or older; AND
2. Rinvoq or Rinvoq LQ is prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab AND tofacitinib at maximum tolerated doses.

H. Giant Cell Arteritis (GCA)

Authorization of 12 months may be granted for treatment of giant cell arteritis in members when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Rinvoq is prescribed by, or in consultation with, a specialist in rheumatology or neurology; AND
3. Member has a documented diagnosis of giant cell arteritis that has been confirmed by biopsy or with imaging of the large vessels (e.g., color Doppler ultrasound [CDUS], MRI, PET-CT, or CT angiography); AND

4. Member has active disease with elevated C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR); AND
5. Documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to a systemic corticosteroid; AND
6. Rinvoq will be used in combination with a tapering course of corticosteroids (NOTE: Rinvoq can be used alone following discontinuation of corticosteroids).

III. CONTINUATION OF THERAPY

A. Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all adult members (including new members) with documentation who are using the requested medication for moderately to severely active rheumatoid arthritis and documentation is submitted indicating a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) with documentation who are using the requested medication for active psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

C. Moderate-to-severe atopic dermatitis

Authorization of 12 months may be granted for all members 12 years of age or older (including new members) with documentation who are using the requested medication for moderate-to-severe atopic dermatitis when both of the following are met:

1. Documentation that the member has achieved or maintained a positive clinical response as evidenced by either low disease activity (i.e., clear or almost clear skin) or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).
2. Documentation that the provider is using the lowest effective dose needed to maintain response

D. Moderately to severely active ulcerative colitis (UC)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and documentation is submitted indicating one of the following:

1. Member has achieved or maintained remission; OR
2. Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition from baseline (e.g., stool frequency, rectal bleeding, urgency of defecation, C-reactive protein (CRP), fecal calprotectin (FC), endoscopic appearance of the mucosa (e.g., computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound), improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score).

E. Ankylosing Spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

Authorization of 12 months may be granted for all adult members (including new members) with documentation who are using the requested medication for active ankylosing spondylitis or nr-axSpA and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

F. Moderately to severely active Crohn's disease (CD)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and documentation is submitted indicating one of the following:

1. Member has achieved or maintained remission; OR
2. Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition from baseline (e.g., abdominal pain or tenderness, diarrhea, body weight, abdominal mass, hematocrit, endoscopic appearance of the mucosa (e.g., computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound), improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score).

G. Polyarticular juvenile idiopathic arthritis (pJIA)

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) with documentation who are using the requested medication for active polyarticular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition from baseline:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

H. Giant cell arteritis (GCA)

Authorization of 12 months may be granted for all members (including new members) with documentation who are using the requested medication for giant cell arteritis and who achieve or maintain a positive clinical response as evidenced by improvement in signs and symptoms of the condition from baseline:

1. Headaches
2. Scalp tenderness
3. Tenderness and/or thickening of superficial temporal arteries
4. Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
5. Jaw and/or tongue claudication
6. Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
7. Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
8. Limb claudication

IV. QUANTITY LIMIT

Rinvoq ER 15mg, 30mg, 45mg tablets: 1 tablet per day
Rinvoq ER 45mg has a limit of 84 tablets per 365 days (one loading dose per year)
Rinvoq LQ 1mg/ml solution: 2 bottles per month (daily dose of 12 mL)

Rinvoq Tablets	
Indication	**Dose**
Rheumatoid arthritis, Ankylosing Spondylitis	15mg once a day
Psoriatic arthritis	Adults: 15mg once a day Pediatric patients 2 years of age and older weighing at least 10kg: Recommended dose is based on body weight <30kg: Use Rinvoq LQ ≥30kg: 15mg once a day
Atopic dermatitis	Pediatric patients 12 years of age and older weighing at least 40kg AND adults under the age of 65: Initiate treatment with 15 mg once daily. If an adequate response is not achieved, consider increasing the dosage to 30 mg once daily. Adults 65 years of age and older: 15mg once a day
Ulcerative colitis	Induction: 45mg once a day for 8 weeks

	Maintenance: 30mg once a day
Crohn's disease	Induction: 45mg once daily for 12 weeks Maintenance: 15mg once a day A maintenance dosage of 30mg once daily may be considered for patients with refractory, severe, or extensive disease.
Polyarticular juvenile idiopathic arthritis	Pediatric patients 2 years of age and older weighing at least 10kg: Recommended dose is based on body weight <30kg: Use Rinvoq LQ ≥30kg: 15mg once a day
Giant cell arteritis	15 mg once daily in combination with a tapering dose of corticosteroids. Rinvoq 15 mg once daily can be used as monotherapy following discontinuation of corticosteroids.

Rinvoq LQ	
Indication	**Dose**
Psoriatic arthritis, Polyarticular juvenile idiopathic arthritis	Patient Weight: Rinvoq LQ 10kg to less than 20kg: 3 mg (3 mL oral solution) twice daily 20kg to less than 30kg: 4 mg (4 mL oral solution) twice daily 30kg or greater: 6 mg (6 mL oral solution) twice daily

V. APPENDIX

Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
	Clobetasol propionate	Cream, Ointment, Solution, Cream (emollient)	0.05%
	Fluocinonide	Cream	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Betamethasone dipropionate	Cream	0.05%
	Betamethasone valerate	Ointment	0.1%

Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
	Mometasone furoate	Cream	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%

VI. REFERENCES

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3. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis.* 2017;*0*:1-18.
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5. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol.* 2018;113:481-517.