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SPECIALTY GUIDELINE MANAGEMENT

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:

A. Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers
B. Treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers
C. Treatment of 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
D. Treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers
E. Treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.
F. Treatment of adults with adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.
G. Treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers.
H. 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
I. Treatment of adult patients with giant cell arteritis.

Rinvoq LQ is indicated for:

A. 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
B. 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.

II. CRITERIA FOR INTIAL AND CONTINUATION OF THERAPY

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

III. CRITERIA FOR INITIAL APPROVAL

For all indications:

- Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *[Note: Members who have received Rinvoqor any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.];* AND
- If the member is using Rinvoq for RA, PsA, UC, AS, CD, or nr-axSpA, it will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), Simponi (golimumab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab(e.g., Stelara, Wezlana, etc.), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), Omvoh (mirikizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Velsipity (etrasimod), etc.)

A. Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active rheumatoid arthritis and Rinvoq is prescribed by, or in consultation with, a specialist in rheumatology.

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

1. Rinvoq is prescribed by, or in consultation with, a specialist in rheumatology.
2. Documentation that the member meets either of the following criteria:
    i. 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)
    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)

3. Member has experienced an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of active psoriatic arthritis in members who are 2 years of age or older when all of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology
a. Member is requesting Rinvoq or Rinvoq LQ
2. Documented active disease and member has experienced an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab and 6-month trial of ustekinumab biosimilar 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.
2. Prescribed by, or in consultation with dermatologist or allergist/immunologist
3. Documentation 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.
4. Documentation that the member has had an inadequate treatment response to at least one medium to super-high potency topical corticosteroid for ≥ 2 consecutive weeks (see Appendix) or use of a topical corticosteroid is not advisable for the member (e.g., due to contraindications, prior intolerances).
5. Documentation that the member has had an inadequate treatment response to pimecrolimus cream or tacrolimus ointment for ≥6 consecutive weeks, experienced an intolerance or is contraindicated to topical calcineurin inhibitors
6. Documentation that the member has had an inadequate treatment response with a 4-month trial, intolerance or contraindication to Dupixent
7. Documentation that the member has had an inadequate treatment response with a 4-month trial, intolerance or contraindication to 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 follow criteria are met:

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

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

Authorization of 12 months may be granted for treatment of active ankylosing spondylitis in members 18 years of age or older when both of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology
2. Documented active disease for AS or (nr-axSpA)
3. Documentation that the member has experienced an inadequate response or has a contraindication to TWO (2) NSAIDs; AND
4. Documentation that the member has experienced an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab 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 who are 18 years of age or older when all of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in gastroenterology; AND
2. Documented moderate to severe disease: AND
3. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses.
4. Member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

G. Polyarticular juvenile idiopathic arthritis (pJIA)

Authorization of 12 months may be granted for treatment of polyarticular juvenile idiopathic arthritis in members who are 2 years of age or older when all of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in rheumatology
2. Member is requesting Rinvoq or Rinvoq LQ
3. Documentation that the member has experienced an inadequate response, intolerance, or contraindication to at least a 3- month trial of adalimumab at maximum tolerated doses; OR member is already established on a biologic or targeted synthetic therapy for the treatment of pJIA

H. Giant Cell Arteritis (GCA)

Authorization of 12 months may be granted for treatment of giant cell arteritis in members who are 18 years of age or older when all of the following criteria are met:

1. Patient has large vessel arteritis that has at some point been verified with biopsy or with imaging of the large vessels (color Doppler ultrasound [CDUS], MRI, PET-CT, or CT angiography); **AND**
2. Patient has active disease and an elevated c-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR); **AND**
3. Patient has had an inadequate response, contraindication, or intolerance to glucocorticoid
4. therapy alone; **AND**
5. Used in combination with a tapering course of corticosteroids (NOTE: Rinvoq(Upadacitinib) can be used alone following discontinuation of corticosteroids.)

IV. CONTINUATION OF THERAPY

A. Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all members (including new members) with documentation of using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain 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

Authorization of 12 months may be granted for all members (including new members) with documentation of 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 when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement

C. Moderate-to-severe atopic dermatitis

Authorization of 12 months may be granted for members 12 years of age or older 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) with documentation of using the requested medication for moderately to severely active ulcerative colitis when one of the following are met:

1. The member has achieved or maintained remission.
2. The member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    a. Stool frequency
    b. Rectal bleeding
    c. Urgency of defecation
    d. C-reactive protein (CRP)
    e. Fecal calprotectin (FC)
    f. Endoscopic appearance of the mucosa

g. 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 members (including new members) with documentation of using the requested medication for active ankylosing spondylitis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)

F. Moderately to severely active Crohn's disease

Authorization of 12 months may be granted for all members (including new members) with documentation of using the requested medication for moderately to severely active Crohn's disease and who achieve or
maintain remission.

Authorization of 12 months may be granted for all members (including new members) with documentation of using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

i. Abdominal pain or tenderness
ii. Diarrhea
iii. Body weight
iv. Abdominal mass
v. Hematocrit
vi. Endoscopic appearance of the mucosa
vii. 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 members 2 years of age or older (including new members) with documentation of 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 when there is improvement in any of the following 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 members 18 years of age or older (including new members) with documentation of using the requested medication for giant cell arteritis and who and

who achieve or maintain a positive clinical response as evidenced by improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Headache
2. Temporal artery tenderness
3. Visual symptoms
4. Inflammatory parameters (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein)
5. Imaging studies (color Doppler ultrasound [CDUS], MRI, PET-CT, or CT angiography)

V. QUANTITY LIMIT

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

Rinvoq Tablets	
Indication	**Dose**
Rheumatoid arthritis, Psoriatic arthritis, Atopic dermatitis, Ankylosing Spondylitis	15mg once a day
Atopic dermatitis	Pediatric Patients 12 Years of Age and Older Weighing at Least 40 kg and Adults Less Than 65 Years of Age: 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: 45 mg once daily for 12 weeks Maintenance: 15mg once a day A dosage of 30 mg once daily may be considered for patients with refractory, severe or extensive disease.
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 10 kg to less than 20 kg: 3 mg (3 mL oral solution) twice daily 20 kg to less than 30 kg: 4 mg (4 mL oral solution) twice daily 30 kg or greater: 6 mg (6 mL oral solution) twice daily

VI. 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%
III. High potency (group 3)	Betamethasone dipropionate	Cream	0.05%
	Betamethasone valerate	Ointment	0.1%
	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%

VII. REFERENCES

1. Rinvoq [package insert]. North Chicago, IL; AbbVie, Inc.; April 2025. Accessed May 2025.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1)1-26.
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.

4. Tuberculosis (TB). TB risk factors. Centers for Disease Control and Prevention. Retrieved on 21 June 2019 from: https://www.cdc.gov/tb/topic/basics/risk.htm.
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.