Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Rinvoq under the patient's prescription drug benefit.

Description:

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[1]

- Adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- Adults and pediatric patients 2 years of age and older with active psoriatic arthritis (PsA) 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.
- Adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers.
- 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.
- Adults with moderately to severely active Crohn's disease (CD) who have had an inadequate response or intolerance to one or more TNF blockers.
- Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults with giant cell arteritis (GCA)

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Rinvoq Extended-Release Tablet and Rinvoq LQ Solution

Policy/Guideline:

Documentation for all indications:
The patient is unable to take THREE preferred products, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid arthritis (RA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and polyarticular juvenile idiopathic arthritis (pJIA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Giant cell arteritis (GCA)

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Atopic dermatitis

Initial requests

- Chart notes or medical records showing affected area(s) and affected body surface area (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy (where applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Ulcerative colitis (UC) and Crohn's disease (CD)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, polyarticular juvenile idiopathic arthritis, and giant cell arteritis: rheumatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Atopic dermatitis: dermatologist or allergist/immunologist
- Ulcerative colitis and Crohn's disease: gastroenterologist

Coverage Criteria

Rheumatoid arthritis (RA)[1-3,5,6]

- Authorization of 12 months may be granted for adult members for treatment of moderately to severely active rheumatoid arthritis (RA) when the member has experienced an inadequate response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor.

- Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for moderately to severely active RA.

Psoriatic arthritis (PsA)[1,7,14]

- Authorization of 12 months may be granted for members 2 years of age or older for treatment of active psoriatic arthritis when the member has had an inadequate response or intolerance to at least one TNF inhibitor.
- Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for active psoriatic arthritis.

Atopic dermatitis[1,9,10,21]

- Authorization of 4 months may be granted for members 12 years of age or older for treatment of moderate-to-severe atopic dermatitis when the member has had an inadequate response or intolerance to at least one biologic (e.g., Adbry, Dupixent, Ebglyss, Nemluvio) or a systemic targeted synthetic drug (e.g., Cibinqo) in the past year.
- Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:
    - 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.
    - Member meets either of the following:
        - Member has had an inadequate treatment response with one of the following in the past year:
            - A medium potency to super-high potency topical corticosteroid (see Appendix)
            - A topical calcineurin inhibitor
            - A topical Janus kinase (JAK) inhibitor
            - A topical phosphodiesterase-4 (PDE-4) inhibitor
    - The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

- Member has had an inadequate response or intolerance to treatment with a biologic (e.g., Adbry, Dupixent, Ebglyss, Nemluvio) or systemic targeted synthetic drug (e.g., Cibinqo) indicated for the treatment of atopic dermatitis.

Ulcerative colitis (UC)[1]

- Authorization of 12 months may be granted for treatment of moderately to severely active UC when the member has had an inadequate response or intolerance to at least one TNF inhibitor.
- Authorization of 12 months may be granted for members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for moderately to severely active ulcerative colitis.

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[1,13,15]

- Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when the member has experienced an inadequate response or intolerance to at least one TNF inhibitor.
- Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Crohn's disease (CD)[1]

- Authorization of 12 months may be granted for treatment of moderately to severely active CD when the member has had an inadequate response or intolerance to at least one TNF inhibitor.
- Authorization of 12 months may be granted for members who have previously received a biologic (other than a TNF inhibitor) indicated for moderately to severely active Crohn's disease.

Polyarticular juvenile idiopathic arthritis (pJIA)[1]

- Authorization of 12 months may be granted for members 2 years of age or older for treatment of active polyarticular juvenile idiopathic arthritis when the member has had an inadequate response or intolerance to at least one TNF inhibitor.

- Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for active polyarticular juvenile idiopathic arthritis.

Giant cell arteritis (GCA)[1]

Authorization of 12 months may be granted for adult members for treatment of giant cell arteritis when the member's diagnosis was confirmed by either of the following:

- Temporal artery biopsy or cross-sectional imaging
- Acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum C-reactive protein [CRP])

Continuation of Therapy

Rheumatoid arthritis (RA)[1,3,5,6]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active RA 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.

Psoriatic arthritis[1,7,16]

Authorization of 12 months may be granted for members 2 years of age or older (including new members) who are using the requested medication for 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:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Atopic dermatitis[1,8]

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis and who achieve or maintain a positive clinical response as evidenced by 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).

Ulcerative colitis (UC)[1,10-12]

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 who achieve or maintain remission.

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 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:

- Stool frequency
- Rectal bleeding
- Urgency of defecation
- C-reactive protein (CRP)
- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, 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)

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[1,13,15]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis 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:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints

- C-reactive protein (CRP)

Crohn's disease (CD)[1,18,19]

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 who achieve or maintain remission.

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 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:

- Abdominal pain or tenderness
- Diarrhea
- Body weight
- Abdominal mass
- Hematocrit
- Appearance of the mucosa on endoscopy, 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)

Polyarticular juvenile idiopathic arthritis (pJIA)[1,20]

Authorization of 12 months may be granted for members 2 years of age or older (including new members) 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 when there is improvement in any of the following from baseline:

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

Giant cell arteritis (GCA)[1,23]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for GCA 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:

- Headaches
- Scalp tenderness

- Tenderness and/or thickening of superficial temporal arteries
- Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
- Jaw and/or tongue claudication
- Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
- Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
- Limb claudication

Other[1,4]

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm^2
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%

Potency	Drug	Dosage form	Strength
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%

Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%

Potency	Drug	Dosage form	Strength
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%

Potency	Drug	Dosage form	Strength
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

Approval Duration and Quantity Restrictions:

Approval:
Initial Approval: atopic dermatitis: 4 months; all other indications: 12 months
Renewal Approval: 12 months

Quantity Level Limit:
- Rinvoq (upadacitinib) 15 mg extended-release tablet:
  - 30 tablets per 30 days
- Rinvoq (upadacitinib) 30 mg extended-release tablet:
  - 30 tablets per 30 days
- Rinvoq (upadacitinib) 45 mg extended-release tablet
  - Exception limit: 84 tablets per 84 days
- Rinvoq (upadacitinib) LQ 1 mg/mL oral solution:
  - 360 mL (2 bottles) per 30 days

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