| Reference number(s) |
| --- |
| 3173-A |

# Specialty Guideline Management
# Rinvoq

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Rinvoq | upadacitinib |

## 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[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.

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

# 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.

## 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, and polyarticular juvenile idiopathic arthritis: 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 (e.g., Xeljanz, Olumiant) 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 (e.g., Xeljanz, Otezla) 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 (e.g., Xeljanz) 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 (e.g., Xeljanz) 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.

# 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

# 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

## Table. Relative potency of select topical corticosteroid products[17]

| 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% |
| I. Super-high potency (group 1) | Fluocinonide | Cream | 0.1% |
| I. Super-high potency (group 1) | Flurandrenolide | Tape | 4 mcg/cm$^2$ |

| Potency | Drug | Dosage form | Strength |
|---|---|---|---|
| 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% |
| 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% |

| Potency | Drug | Dosage form | Strength |
|---|---|---|---|
| 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% |
| 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% |

| Potency | Drug | Dosage form | Strength |
|---|---|---|---|
| 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% |
| 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% |

| Potency | Drug | Dosage form | Strength |
|---|---|---|---|
| V. Lower-mid potency (group 5) | Triamcinolone acetonide | Lotion | 0.1% |
| V. Lower-mid potency (group 5) | Triamcinolone acetonide | Ointment | 0.025% |
| 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% |
| VII. Least potent (group 7) | Hydrocortisone acetate | Cream | 1% |

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