Rinvoq (upadacitinib)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. 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.

2. Adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.

3. 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

4. Rinvoq is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers.

POLICY

Required Documentation

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

A. Rheumatoid arthritis (RA)

1. For initial requests:
   i. Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
   ii. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Psoriatic arthritis (PsA):

1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Atopic dermatitis

1. For initial requests:
   i. Chart notes or medical records showing affected areas and affected body surface area
   ii. Chart notes, medical record documentation, or claims history of prerequisite therapies, including response to therapy. If therapy is not advisable, documentation of why therapy is not advisable.
2. For continuation requests: Documentation (e.g., chart notes) that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

D. Ulcerative colitis (UC)

1. Initial requests
   i. 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.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Criteria for Initial Approval

A. Moderately to severely active rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD (e.g., Xeljanz, Olumiant) indicated for moderately to severely active rheumatoid arthritis.
2. Authorization of 12 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:
   a.) Member meets either of the following criteria:
      i. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      ii. Member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP
         3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
      iii. Member has experienced an inadequate response or intolerance to at least one tumor necrosis factor (TNF) inhibitor.

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted to members who have previously received Otezla or any biologic indicated for the treatment of active psoriatic arthritis (PsA) when the member has experienced an inadequate response or intolerance to at least one TNF inhibitor.

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:

a. 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.
b. Member has had an inadequate response to treatment with a topical corticosteroid or topical calcineurin inhibitor, or topical corticosteroids and topical calcineurin inhibitors are not advisable for the member.
c. Member has had an inadequate response to treatment with other systemic drug products, including biologics, or use of these therapies is not advisable for the member.
d. Member is 12 years of age or older.

D. Moderately to severely active ulcerative colitis (UC)

a) Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active ulcerative colitis.
b) Authorization of 12 months may be granted for the treatment of moderately to severely active ulcerative colitis when the member has had an inadequate response, intolerance or contraindication to at least one tumor necrosis factor inhibitor (TNF-i)

Continuation of Therapy

A. **Moderately to severely active rheumatoid arthritis (RA)**

Authorization of 12 months may be granted for all members (including new members) who are 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 (PsA)**

Authorization of 12 months may be granted for all members (including new members) 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 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 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).

D. **Moderately to severely active ulcerative colitis (UC)**

1. 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.

2. 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:

    1. Stool frequency
    2. Rectal bleeding
    3. Urgency of defecation
    4. C-reactive protein (CRP)
    5. Fecal calprotectin (FC)
    6. Endoscopic appearance of the mucosa
    7. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Other
For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs 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. 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 DMARD, targeted synthetic DMARD, or potent immunosuppressants 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.

Quantity Limits Apply
Rinvoq - 30 tablets per 30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

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*Some content reprinted from CVSHealth

POLICY HISTORY

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