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

SPECIALTY GUIDELINE MANAGEMENT

RINVOQ (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.

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

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

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

F. Crohn's disease

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

IV. 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), Stelara (ustekinumab), 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. 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)
    i. 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 18 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
2. Documented active disease and member has experienced an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab 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. 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. Member has tried and failed or had an inadequate response for at least 2-3 months to at least one medium-high to very high potency topical corticosteroid;
5. Member has tried and failed or had an inadequate response for at least 2-3 months to pimecrolimus, tacrolimus ointment or crisaborole (Eucrisa)
6. Member has tried and failed or had an inadequate response for at least 6 months to cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil.
7. Member has a documented inadequate response, intolerance or contraindication to Dupixent and Adbry

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. Member has previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active ulcerative colitis; AND
2. Rinvoq is prescribed by, or in consultation with, a specialist in gastroenterology; AND
3. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab 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. Member has experienced an inadequate response or has a contraindication to TWO (2) NSAIDs; AND
4. 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 corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate) at maximum tolerated doses.
4. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

V. 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

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)

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 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) who are 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) 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:

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)

VI. 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).

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.

VII. REFERENCES

1. Rinvoq [package insert]. North Chicago, IL; AbbVie, Inc.; November 2023.
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.