Mass General Brigham
Health Plan

Rinvoq (upadacitinib)
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

Rinvoq is a Janus kinase (JAK) inhibitor FDA indicated for:

1. Treatment of adults 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. Treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more 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. 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
5. Treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers
6. 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
7. Treatment of moderate to severe Crohn disease in adults who have had an inadequate response or intolerance to one or more TNF blockers.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment and are stable with Rinvoq excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

<u>Rheumatoid arthritis (RA)</u>

Authorization may be granted for members when all of the following criteria are met, and documentation has been provided:

1. The member has diagnosis of moderately to severely active rheumatoid arthritis
2. The member has a minimum duration of 3-month trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses:
    a. Methotrexate
    b. Leflunomide
    c. Sulfasalazine
3. The member has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

Psoriatic arthritis (PsA)

Authorization may be granted for members when all of the following criteria are met, and documentation has been provided:

1. The member has been diagnosed with active psoriatic arthritis
2. The member meets ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement
3. The member has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

Atopic dermatitis (AD)

Authorization may be granted for members when ALL the following criteria are met, and documentation has been provided:

1. The member has a diagnosis of refractory, moderate to severe atopic dermatitis
2. The member is at least 12 years of age
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 had trial and failure of a minimum 30-day supply (14-day supply for topical steroids), intolerance, or contraindication to at least ONE of the following:
    a. Medium or higher potency topical corticosteroid
    b. Pimecrolimus cream
    c. Tacrolimus ointment
    d. Eucrisa (crisaborole) ointment
5. Member has had inadequate response to treatment with other systemic drug products, including biologics, or use of these therapies is not advisable

Crohn's Disease

Authorization may be granted for members when all of the following criteria are met, and documentation has been provided:

1. The member has been diagnosed with moderate to severe Crohn's disease
2. ONE of the following:
    a. Frequent diarrhea and abdominal pain

   b. At least 10% weight loss
   c. Complications such as obstruction, fever, abdominal mass
   d. Abnormal lab values (e.g., C-reactive protein [CRP])
   e. CD Activity Index (CDAI) great than 220
3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies
   a. 6-mercaptopurine
   b. Azathioprine
   c. Corticosteroids (e.g., prednisone)
   d. methotrexate
4. The member has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., adalimumab, certolizumab pegol)

<u>Ulcerative Colitis (UC)</u>
Authorization may be granted for members when all of the following criteria are met, and documentation has been provided:
1. The member has been diagnosed with moderate to severe ulcerative colitis
2. ONE of the following:
   a. Greater than 6 stools per day
   b. Frequent blood in stools
   c. Frequent urgency
   d. Presence of ulcers
   e. Abnormal lab values (e.g., hemoglobin, ESR, CRP)
   f. Dependent on, or refractory to, corticosteroids
3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies
   a. 6-mercaptopurine
   b. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
   c. Azathioprine
   d. Corticosteroids (e.g., prednisone)
4. The member has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., adalimumab, golimumab)

<u>Ankylosing Spondylitis (AS)</u>
Authorization may be granted for members when all of the following criteria are met, and documentation has been provided:
1. The member has been diagnosed with active ankylosing spondylitis
2. Member has minimal duration of 1-month trial and failure, contraindication, or intolerance to TWO different non-steroidal anti-inflammatory drugs (NSAIDs) at maximally tolerated doses.
3. The member has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

<u>Non-Radiographic Axial Spondyloarthritis (nr-axSpA)</u>

Authorization may be granted for members when all of the following criteria are met, and documentation has been provided:

1. The member is at least 18 years of age
2. The member has been diagnosed with active non-radiographic axial spondyloarthritis with objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imagine [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joint)
3. The member has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., certolizumab pegol)

Continuation of Therapy

Atopic dermatitis: Reauthorizations may be granted when documentation has been submitted supporting clinical improvement in member's condition as evidenced by low disease activity (e.g., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).
All Other Indications: Reauthorization may be granted when documentation has been submitted supporting clinical improvement in member's condition.

Limitations

1. Initial authorizations and reauthorizations will be approved for 24 months
2. The following quantity limits apply:

Rinvoq 15mg, 30mg, and 45mg	30 tablets per 30 days

References

1. Rinvoq (upadacitinib) [prescribing information]. North Chicago, IL: AbbVie Inc; January 2022
2. O'Dell JR, Curtis JR, Mikuls TR, et al. Validation of the methotrexate-first strategy in patients with early, poor-prognosis rheumatoid arthritis: results from a two-year randomized, double-blind trial. Arthritis Rheum 2013; 65:1985
3. Food and Drug Administration Center for Drug Evaluation and Research. Summary Minutes of the Arthritis Advisory Committee Meeting. August 2, 2017 https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM575678.pdf (Accessed on October 02, 2018
4. Bonilla-Hernán MG, Miranda-Carús ME, Martin-Mola E. New drugs beyond biologics in rheumatoid arthritis: the kinase inhibitors. Rheumatology (Oxford) 2011; 50:1542

Review History

11/20/2019 – Reviewed at P&T
03/18/2020 – Reviewed and Updated Mtg; added MH LOB; checked off QL (effective 6/1/20)
01/01/2021 – Moved MH onto its own policy
01/19/2022 – Reviewed and Updated for Jan P&T; added new indication of psoriatic arthritis to criteria; references updated
03/16/2022 Reviewed and Updated for March P&T; added new indication of atopic dermatitis to criteria as preferred agent; references updated
06/22/2022 – Reviewed and Updated for June P&T; added new indication of ulcerative colitis. Effective 9/01/2022

09/21/2022 – Reviewed and Updated for Sept P&T; added new indication of ankylosing spondylitis. Effective 11/1/22
01/11/2023 – Reviewed and Updated for Jan P&T; added new indication of non-radiographic axial spondyloarthritis and 45mg strength. Effective 03/01/2023
03/15/2023 – Reviewed and Updated for March P&T; Removed requirement of Dupixent for atopic dermatitis. Added "Member has had inadequate response to treatment with other systemic drug products, including biologics, or use of these therapies is not advisable". Effective 6/1/23
7/12/2023 – Reviewed and Updated for July P&T; Added new indication of Crohn's disease. Effective 8/12/23.
11/15/2023 – Reviewed and Updated for Nov P&T; removed TB requirement. Added additional treatment options for conventional therapies for Rheumatoid arthritis. Psoriatic arthritis – removed conventional therapies and added member meets one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis – changed from 5% BSA to 3% BSA. Removed appendix with contraindications to methotrexate. Consolidated conventional therapies for plaque psoriasis. Separated out criteria for Crohn's disease vs. Ulcerative Colitis. Removed Appendix. Effective 1/1/24