Mass General Brigham
Health Plan

Rinvoq (upadacitinib)
Effective 03/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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

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

Rheumatoid arthritis (RA)

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 diagnosis of moderately to severely active rheumatoid arthritis
3. The member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20mg/week) **OR**
4. The member has an intolerance or contraindication to methotrexate (see Appendix A)

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 is at least 18 years of age
2. The member has been diagnosed with active psoriatic arthritis
3. Member meets ONE of the following:
    a. Paid claims or physician documented intolerance to or inadequate response after at least 3 months of treatment with methotrexate OR leflunomide
    b. Documentation of contraindication to BOTH methotrexate and leflunomide and has experienced an inadequate response, intolerance, or contraindication to sulfasalazine
4. The member has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers

Atopic dermatitis (AD)

Authorization may be granted for members when all of 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 meets ONE of the following:
    a. Paid claims or physician documented intolerance to or inadequate response to a high potency topical corticosteroid or a topical calcineurin inhibitor in the past 180 days,
    b. Physician documented contraindication to topical corticosteroids, topical calcineurin inhibitors,
5. Member meets ONE of the following:
    a. Paid claims or physician documented intolerance to or inadequate response to Dupixent
    b. Physician documented contraindication to Dupixent

Ulcerative Colitis (UC)

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 moderate to severe ulcerative colitis
3. The member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix B).
4. The member has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers

Ankylosing Spondylitis (AS)

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 ankylosing spondylitis
3. ONE of the following:
    a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
    b. Member has an intolerance or contraindication to two or more NSAIDs.

Non-Radiographic Axial Spondyloarthritis (nr-axSpA)

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
3. The member has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers

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

Appendices

Appendix A: Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix B: Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:
    a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa)

b. Rectal mesalamine (e.g., Canasa, Rowasa)
c. Alternatives: azathioprine, mercaptopurine, sulfasalazine

2. Mild to moderate disease – maintenance of remission:
    a. Oral mesalamine, rectal mesalamine
    b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
    a. Sulfasalazine
4. Severe disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: sulfasalazine
5. Pouchitis: rectal mesalamine

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