Rinvoq (upadacitinib)
Effective 11/01/2022

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐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 moderately to severely active rheumatoid arthritis, refractory moderate to severe atopic dermatitis, active psoriatic arthritis, ulcerative colitis, and ankylosing spondylitis. Janus kinase (JAK) enzymes, are intracellular enzymes involved in stimulating hematopoiesis and immune cell function through a signaling pathway. JAKs activate signal transducers and activators of transcription (STATs) which regulate gene expression and intracellular activity. The inhibition of JAKs prevents the activation of STATs.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with Rinvoq excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

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

<u>Moderate to Severe Rheumatoid Arthritis (RA)</u>

Prescriber provides documentation of **ALL** the following:

1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** traditional DMARD
3. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for rheumatoid arthritis

b. Contraindication to **ALL** anti-TNF agents FDA-approved for rheumatoid arthritis

4. Paid claims or physician documented inadequate response, adverse reaction to **ONE** or contraindication to **BOTH** of the following:
    a. Xeljanz® (tofacitinib)
    b. Xeljanz XR® (tofacitinib extended-release)
5. Appropriate dosing
6. Quantity requested is ≤1 tablet/day

Moderate to Severe Atopic Dermatitis

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is a specialist (i.e., allergist/immunologist or dermatologist) or consult notes from a specialist are provided
3. Member is ≥ 12 years of age
4. For members ≥ 12 years of age and < 18 years of age, weight is ≥ 40 kg (weight required)
5. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** superpotent or potent topical corticosteroid*
    b. Contraindication to **ALL** superpotent or potent topical corticosteroids **
6. **ONE** of the following:
    a. Paid claims of physician documented inadequate response or adverse reaction to topical tacrolimus or Eucrisa® (crisaborole)
    b. Contraindication to **BOTH** topical tacrolimus and Eucrisa® (crisaborole)
7. Paid claims of physician documented inadequate response, adverse reaction, or contraindication to Dupixent® (dupilumab)
8. Quantity requested is ≤ 1 tablet/day
9. Appropriate dosing

Notes:
** Trials with a superpotent or potent topical corticosteroid may be bypassed if member has tried a systemic immunomodulatory therapy and/or Dupixent® (dupilumab)*
***Trials with topical corticosteroids may be bypassed if the request clearly state that the treatment area is a sensitive area (facial/groin) or the affected area is too widespread*

Psoriatic Arthritis

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** traditional DMARDs
3. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agents that are FDA-approved for psoriatic arthritis
4. Paid claims of physician documented inadequate response, adverse reaction or contraindication to Xeljanz® or Xeljanz XR®
5. Appropriate dosing
6. Quantity requested is ≤1 tablet/day

Ankylosing Spondylitis

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Paid claims or physician documented of inadequate response or adverse reaction to **TWO** or contraindication to **ALL** NSAIDs*
3. Paid claims or physician documented of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agents that are FDA-approved for ankylosing spondylitis
4. Appropriate dosing
5. **BOTH** of the following:
    a. Paid claims or physician documented of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
        i. Xeljanz® (tofacitinib)
        ii. Xeljanz XR® (tofacitinib extended-release)
    b. Requested quantity is ≤ 1 tablet/day

**If member has tried biologic therapy and trial with an NSAID has not been documented, the trial may be bypassed.*

Moderate to Severe Ulcerative Colitis

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of moderate to severe ulcerative colitis
2. Paid claims or physician documented of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agents that are FDA-approved for ulcerative colitis
3. Appropriate dosing
4. Paid claims or physician documented of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
    a. Xeljanz (tofacitinib)
    b. Xeljanz XR (tofacitinib extended-release)
5. Requested quantity is ≤ 1 tablet/day

Continuation of Therapy

Resubmission by prescriber for any of the following FDA-approved diagnoses will infer a positive response to therapy and request can be recertified if dosing is appropriate.

Limitations

1. Initial authorizations will be approved for:
    a. Ulcerative colitis: up to 2 months (to complete induction period with 45 mg tablets) OR 6 months (if member is stable on 15 or 30 mg dose)
    b. Other diagnoses: 6 months
2. Reauthorizations will be approved for 12 months
3. The following quantity limits apply:

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

Appendices

Appendix A: Traditional DMARDS

Traditional DMARDS*	
azathioprine	methotrexate*
cyclosporine	sulfasalazine*

hydroxychloroquine*	thalidomide
leflunomide	
If a member has a contraindication to **ALL** of the most commonly used traditional DMARDs* (methotrexate, sulfasalazine, and hydroxychloroquine), a trial with a traditional DMARD may be bypassed.	

Appendix B. Conventional Therapies for Plaque Psoriasis

Conventional Treatment Lines	Agents Used
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

Appendix C: More frequent/Higher doses

Requests more frequent or higher doses of injectable biologics, may be approved if ALL of the following is provided:

1. Documentation of severe disease
2. **ONE** of the following:
    a. Inadequate response or adverse reaction to **ONE** other injectable biologic which is FDA-approved for the requested indication
    b. Contraindication to **ALL** other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

References

1. Rinvoq (upadacitinib) [prescribing information]. North Chicago, IL: AbbVie Inc; March 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)
10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021
11/17/2021 –Reviewed and Updated for Nov P&T; matched MH UPPL for 1/1/2022 implementation; added appendix with higher dose/more frequent dosing and off label indication. Effective 01/01/2022

06/22/2022 – Reviewed and Updated for June P&T; matched MH UPPL. Added criteria for newly FDA-approved indications (psoriatic arthritis and refractory moderate to severe atopic dermatitis). Criteria for rheumatoid arthritis updated to require a step through at least one anti-TNF agent. Clarified note for atopic dermatitis by including Dupixent® (dupilumab) as another trial along with systemic immunomodulatory therapy. Continuation of therapy language was updated. Added new strengths of 30 mg and 45 mg. Updated references. Effective 08/01/2022.
11/16/2022 – Reviewed and updated for Nov P&T; matched MH. Added criteria for newly FDA-approved indications: ulcerative colitis and ankylosing spondylitis. Criteria will require a step through Xeljanz or Xeljanz XR for these new indications. Effective 11/01/2022

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