

**Rinvoq (upadacitinib)
Effective 01/01/2022**

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> 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. 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 AllWays Health Partners 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:

Moderate to Severe Rheumatoid Arthritis (RA)

Prescriber provides documentation of ALL the following:

1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to ONE traditional DMARD or contraindication to traditional DMARDs
3. ONE of the following:
 - a. Paid claims or physician documented inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for RA
 - b. Contraindication to ALL biologic DMARDs FDA-approved for RA



4. Paid claims or physician documented inadequate response, adverse reaction or contraindication to Xeljanz® (tofacitinib) or Xeljanz XR® (tofacitinib extended-release)
5. Quantity requested is ≤1 tablet/day

Continuation of Therapy

Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, FDA approved indication and appropriate dosing.

Limitations

1. Initial authorizations will be approved for 6 months
2. Reauthorizations will be approved for 12 months
3. The following quantity limits apply:

Rinvoq 15mg	30 tablets per 30day
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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: Off-Label Indications

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



Atopic Dermatitis (moderate-to-severe)

Prescriber documents ALL of the following:

1. Paid claim or physician attestation of inadequate response, adverse reaction or contraindication to phototherapy
2. Paid claim or physician attestation of response, adverse reaction or contraindication to **TWO** traditional DMARDs (cyclosporine, methotrexate, mycophenolate, azathioprine) or a contraindication to all traditional DMARDs

References

1. Rinvoq (upadacitinib) [prescribing information]. North Chicago, IL: AbbVie Inc; August 2019
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, Martín-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

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