BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Xeljanz

Policy Number: 9.131
Version Number: 2.2
Version Effective Date: 4/5/2022

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth - MCO ☐ MassHealth - ACO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Xeljanz (tofacitinib)
- Xeljanz XR (tofacitinib extended-release)
- Xeljanz Oral Solution (tofacitinib)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Use in combination with biologic DMARDs or potent immunosuppressants.
Required Medical Information	**Xeljanz Tablets** Diagnosis of one of the following: 1. Psoriatic Arthritis (PsA); ***AND*** a. An inadequate response, adverse reaction or contraindication to a trial of Enbrel OR

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	Humira; OR b. Note: a trial of Cimzia, an infliximab product, or Simponi (Aria or subcutaneous) will also be accepted. 2. Moderate to severely active Rheumatoid Arthritis (RA); ***AND*** a. An inadequate response, adverse reaction or contraindication to a trial of Enbrel or Humira; OR b. Note: a trial of Cimzia, an infliximab product, or Simponi (Aria or subcutaneous) will also be accepted. 3. Moderate to severely active Ulcerative Colitis (UC) a. An inadequate response, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira; OR b. Note: a trial of infliximab or Simponi will also be accepted 4. Polyarticular course juvenile idiopathic arthritis (pJIA); ***AND*** a. Member has had an inadequate response, negative reaction or contraindication to a 3 month trial of Enbrel or Humira; OR b. Note: a trial of an infliximab product or Simponi Aria will also be accepted. 5. Ankylosing Spondylitis (AS); ***AND*** a. Member has had an inadequate response, negative reaction or contraindication to a 3 month trial of Enbrel or Humira; OR b. Note: a trial of Cimzia, an infliximab product, or Simponi (Aria or subcutaneous) will also be accepted. **Xeljanz Oral Solution** 1. Diagnosis of polyarticular course juvenile idiopathic arthritis (pJIA); ***AND*** Member has had an inadequate response, negative reaction or contraindication to a 3 month trial of Enbrel or Humira;
Age Restrictions	AS, PsA, RA, UC: 18 years of age or older pJIA: 2 years of age or older
Prescriber Restriction	AS, pJIA, RA: Prescribed by or in consultation with a rheumatologist PsA,: Prescribed by or in consultation with a dermatologist or rheumatologist UC: Prescribed by or in consultation with a gastroenterologist
Coverage Duration	12 months

Appendix

Diagnosis	Non-Biologic DMARD Treatment Options

Polyarticular-Course Juvenile Idiopathic Arthritis	Methotrexate Leflunomide Sulfasalazine Azathioprine Cyclosporine
Psoriatic Arthritis	Methotrexate Leflunomide Sulfasalazine Azathioprine
Rheumatoid Arthritis	Methotrexate Leflunomide Sulfasalazine Azathioprine Hydroxychloroquine

Note: other trials may be considered on a case-by-case basis

Applicable Coding:

None

Clinical Background Information and References

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3. Fleischmann R, Kremer J, Cush J, et al. Placebo-controlled trial of tofacitinib monotherapy in rheumatoid arthritis. N Engl J Med. 2012b;367:495-507.
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5. Kremer J, Li ZG, Hall S, et al. An oral JAK inhibitor, in combination with traditional DMARDs: phase 3 study in patients with active rheumatoid arthritis with inadequate response to DMARDs [abstract]. Ann Rheum Dis. 2011;70(Suppl 3):170.
6. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Rheumatol. 2016 Jan;68(1):1-26.
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11. van Vollenhoven RF, Fleischmann R, Cohen S, et al. Tofacitinib or adalimumab versus placebo in rheumatoid arthritis. N Engl J Med. 2012 Aug 9; 367(6):508-19.
12. Xeljanz (tofacitinib) [prescribing information]. New York, NY: Pfizer Labs; February 2016.
13. Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults. American College of Gastroenterology Practice Parameters Committee. 2004.
14. Sandborn W, Ghosh S, Panes J, et al. Phase 2 study of CP-690,550, an oral janus kinase inhibitor, in active ulcerative colitis. DDW abstract 594, Chicago, IL 2011.
15. Sanborn W, Gosh S, et al. Tofacitinib, an oral Janus kinase inhibitor, in active ulcerative colitis. N Engl J Med. 2012 Aug;367(7):616-24.
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Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.195 Xeljanz Policy retired, new policy created. Removed respective Olumiant, Enbrel and Humira trial requirements for the diagnosis of RA and PsA to align with ESI ICCV policy.	1/1/2021	P&T Committee
4/23/2021	Removed needle phobia criteria for diagnosis of RA to align with ESI ICCV.	4/23/2021	

Policy Revisions History			
8/12/2021	P&T Annual Review. Added diagnosis of pJIA; updated criteria to align with other policies; added table of non-biologic DMARDs; updated age and prescriber restrictions; removed reauthorization criteria.	1/1/2022	P&T Committee
1/20/2022	Policy updated to include indication of AS, Xeljanz oral solution added to policy, realigned with ESI ICCV policy.	3/1/2022	P&T Committee
4/1/2022	Updated policy to include Xeljanz solution in products affected section, specifically called out dosage form of Simponi allowed for prior trial	4/5/2022	

Next Review Date

8/2022

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.