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Pharmacy Policy

Xeljanz

Policy Number: 9.131
Revision Number: R1
Version Effective Date: 1/1/2021

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)

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 biologics or potent immunosuppressants
Required Medical Information	Diagnosis of one of the following: 1. Psoriatic Arthritis (PsA); ***AND*** a. An inadequate response, intolerance or contraindication to methotrexate; ***AND*** b. One of the following i. An inadequate response, intolerance, or contraindication to Cosentyx, Enbrel or Humira or a clinical rationale for use of the requested agent instead of

[+] *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.

	Cosentyx, Enbrel or Humira; ***OR*** ii. Patient has documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29 for specific phobia diagnostic criteria) 2. Moderate to severely active Rheumatoid Arthritis (RA); ***AND*** a. An inadequate response, intolerance or contraindication to methotrexate; ***AND*** b. One of the following i. An inadequate response, intolerance, or contraindication to Enbrel or Humira or a clinical rationale for use of the requested agent instead of Enbrel or Humira; ***OR*** ii. Patient has documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29 for specific phobia diagnostic criteria) 3. Moderate to severely active Ulcerative Colitis (UC) a. An inadequate response, contraindication or intolerance to use of **two** of the following: i. 5-aminosalicylic acid (e.g. mesalamine) ii. 6-mercaptopurine, azathioprine, and/or cyclosporine iii. corticosteroids; ***AND*** b. One of the following: i. An inadequate response, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira; ***OR*** ii. Patient has documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29 for specific phobia diagnostic criteria)
Age Restrictions	18 years of age or older
Prescriber Restriction	PsA, RA: Prescribed by or in consultation with a rheumatologist UC: Prescribed by or in consultation with a gastroenterologist
Coverage Duration	12 months
Other criteria	Reauthorization: 1. Currently receiving medication via Well Sense benefit or member has previously met initial approval criteria; **AND** 2. Patient's clinical condition has improved or stabilized

Applicable Coding:

None

Clinical Background Information and References

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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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8. Smolen JS, Beaulieu A, Rubbert-Roth A et al. Effect of interleukin-6 receptor inhibition with tocilizumab in patients with rheumatoid arthritis (OPTION study): a double-blind, placebocontrolled, randomized trial. Lancet 2008; 371:987-97.
9. Schneider M, Krüger K. Rheumatoid arthritis-early diagnosis and disease management. Dtsch Arztebl Int. 2013 Jul;110(27-28):477-84.
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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.
16. Sanborn W, Su C, et al. Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med. 2017;376(18):1723.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.195 Xeljanz Policy retired, new policy created. Addition of Cosentyx to align with the NH PDL.	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

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.