BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Orencia Subcutaneous®

Policy Number: 9.126
Version Number: 2.2
Version Effective Date: 4/1/2022

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:

Orencia® for subcutaneious use (abatacept)

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

Covered Use	All FDA approved indications not otherwise excluded
Required Medical Information	Diagnosis of the following: 1. Rheumatoid Arthritis; **AND** Member must meet the following conditions: **i.** Documentation* showing the member has had an inadequate response, intolerance, or contraindication to at least TWO of the following: Actemra subcutaneous, Enbrel, Humira, Rinvoq, OR Xeljanz/XR [Note: a trial of either or both Xeljanz products collectively counts as ONE product]; 2. Juvenile Idiopathic Arthritis/Juvenile Rheumatoid Arthritis; **AND** Member must meet ALL the following (i, ii, iii):

[+] *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.

	i. The Member meets one of the following conditions (a, b, c, or d): a) Member has tried one other agent for this condition; **OR** ❖ Note: Examples of therapies which could have been tried include methotrexate, sulfasalazine, or leflunomide, and a nonsteroidal anti-inflammatory drug (NSAID). A biologic also counts as a trial of one agent for JIA. b) Member will be starting on therapy concurrently with methotrexate, sulfasalazine, or leflunomide; **OR** c) Member has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; **OR** Note: Examples of absolute contraindications to methotrexate include pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias **OR** d) Member has aggressive disease, as determined by the prescriber; **AND** **ii.** Member meets ONE of the following conditions (a or b): a) Documentation* showing the member has an inadequate response, intolerance, or contraindication to at least TWO of the following: Actemra subcutaneous, Enbrel, Humira, or Xeljanz [Note: a trial of either or both Xeljanz products collectively counts as ONE product]; **OR** b) According to the prescriber, the member has heart failure, a previously treated lymphoproliferative disorder, OR a previous serious infection; **AND** **iii.** The agent is prescribed by or in consultation with a rheumatologist. 3. Psoriatic Arthritis; **AND** Member must meet the following: i. Documentation* showing the member had an inadequate response, intolerance, or contraindication to TWO of the following: Enbrel, Humira, Otezla, Rinvoq, Skyrizi, Stelara subcutaneous, Taltz, Tremfya, and Xeljanz/XR [Note: a trial of either or both Xeljanz products collectively counts as ONE product]. * Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts
Age Restriction	PsA, RA: 18 years and older JIA, JRA: 2 years of age or older
Prescriber Restriction	RA/JIA/JRA Prescribed by or in consultation with a rheumatologist PsA Prescribed by or in consultation with a rheumatologist or dermatologist
Coverage Duration	Initial – 3 months Reauthorization - 1 year
Other criteria	Reauthorization criteria: i. Initial criteria are met; **AND** ii. Member's clinical condition has improved or stabilized

Applicable Coding:

Code	Medication
J0129	Injection, abatacept, 10mg

Clinical Background Information and References

1. Abrams JR, Lebwohl MG, Guzzo CA, et al. CTLA4Ig-mediated blockade of T-cell costimulation in patients with psoriasis vulgaris. *J Clin Invest.* 1999;103:1243-1252.
2. Fraenkel L, Bathon J, England, B et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis & Rheumatology. 2021 Jan;71(1):1-16.
3. Furst DE, Keystone EC, Braun J, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2011. *Ann Rheum Dis*. 2012;71 Suppl 2:i2-i45.
4. Mease PJ, Gottlieb AB, van der Heijde D, et al. Efficacy and safety of abatacept, a T-cell modulator, in a randomised, double-blind, placebo-controlled, phase III study in psoriatic arthritis. *Ann Rheum Dis.* 2017;76(9):1550-1558.
5. Ogdie A, et al. 2021 American College of Rheumatology Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2021 Jan;71(1):5-32.
6. Orencia® for injection [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2019. Accesed July 2021.
7. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Rheumatol*. 2019;71(6):717-734.
8. Sandborn WJ, Colombel JF, Sands BE, et al. Abatacept for Crohn's disease and ulcerative colitis. *Gastroenterology*. 2012;143(1):62-69.e4.
9. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken).* 2019;71(1):2-29.
10. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
11. Song IH, Heldmann F, Rudwaleit M, et al. Treatment of active ankylosing spondylitis with abatacept: an open-label, 24-week pilot study. *Ann Rheum Dis*. 2011;70(6):1108-1110.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/24/2021	7/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
5/24/2021	Policy created	7/1/2021	P&T Committee

Policy Revisions History			
8/12/2021	P&T Annual Review: Removal of trial of one formulary non-biologic DMARD for RA and PsA. Minor language updates in regards to trial time requirements, age requirements and prescriber restrictions.	1/1/2022	P&T Committee
1/20/2022	Updated policy to realign with ESI ICCV policy.	3/1/2022	P&T Committee
3/7/2022	Updated policy to realign with ESI ICCV policy designation of Skyrizi PsA preferred status	4/1/2022	P&T Committee

Next Review Date

8/2022

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.