BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Orencia

Policy Number: 9.126
Revision Number: R0
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☒ New Hampshire Medicaid	☐ 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 (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
Exclusion Criteria	Use of Orencia in combination with another biologic
Required Medical Information	Diagnosis of one of the following: 1. Polyarticular juvenile idiopathic arthritis (pJIA); ***AND*** a. An inadequate response or intolerance to a three month trial of at least one formulary non-biologic DMARD, or is currently on methotrexate; ***AND*** b. An inadequate response, intolerance, or contraindication to Enbrel OR Humira or a clinical rationale for the use Orencia instead of Enbrel OR Humira 2. Psoriatic Arthritis (PsA); ***AND***

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	a. An inadequate response or intolerance to a three month trial of at least of one formulary non-biologic DMARD, or is currently on methotrexate; ***AND*** b. An inadequate response, intolerance, or contraindication to Enbrel, Humira OR Cosentyx or a clinical rationale for the use Orencia instead of Enbrel, Humira OR Cosentyx 3. Rheumatoid arthritis (RA); ***AND*** a. An inadequate response or intolerance to a three month trial of at least one formulary non-biologic DMARD, or is currently on methotrexate; ***AND*** b. An inadequate response, intolerance, or contraindication to Enbrel OR Humira or a clinical rationale for the use Orencia instead of Enbrel OR Humira
Age Restrictions	pJIA: 2 years of age or older PsA, RA: 18 years of age or older
Prescriber Restriction	Prescribed by or in consultation with a rheumatologist
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. Clinical condition has improved or stabilized

Applicable Coding:

Code	Medication
J0129	Orencia (abatacept injection)

Clinical Background Information and References

1. Athanasakis K, Petrakis I, Kyriopoulos J. Investigating the value of abatacept in the treatment of rheumatoid arthritis: a systematic review of cost-effectiveness studies. ISRN Rheumatol. 2013 May 30;2013:256871.
2. Atzeni F, Puttini PS, Mutti A, et al. Long-term safety of abatacept in patients with rheumatoid arthritis. Autoimmun Rev. 2013 Jun 22. pii: S1568-9972(13)00115-8.
3. Enbrel prescribing information. Thousand Oaks, CA: Amgen Inc. and Pfizer Inc.; 2015 March.
4. Genovese MC, Becker JC, Schiff M, et al. Abatacept for rheumatoid arthritis refractory to tumor necrosis factor alpha inhibition. N Engl J Med. 2005;353(11):1114-23.
5. Humira prescribing information. North Chicago, IL: AbbVie Inc.; 2016 June.

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6. Kaine J, Gladstein G, Strusberg I et al. Evaluation of abatacept administered subcutaneously in adults with active rheumatoid arthritis: impact of withdrawal and reintroduction on immunogenicity, efficacy and safety (phase Iiib ALLOW study). Ann Rheum Dis. 2012 Jan; 71(1):38-44.
7. Kremer JM, Genant HK, Moreland LW et al. Effects of abatacept in patients with methotrexateresistant active rheumatoid arthritis: a randomized trial. Ann Intern Med. 2006 Jun 20;144(12):865-76.
8. Kremer JM, Russell AS, Emery P et al. Long-term safety, efficacy and inhibition of radiographic progression with abatacept treatment in patients with rheumatoid arthritis and an inadequate response to methotrexate: 3-year results from the AIM trial. Ann Rheum Dis. 2011 Oct; 70(10):1826-30.
9. McEvoy GK, ed. AHFS 2013 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc. 2013.
10. Orencia (abatacept) [package insert]. Princeton, NJ: Bristol-Myers Squibb; March 2019.
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12. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. Arthritis Rheum 2008 Jun 15; 59(6):762-84.
13. Schiff M, Pritchard C, Huffstutter JE et al. The 6-month safety and efficacy of abatacept in patients with rheumatoid arthritis who underwent a washout after anti-tumour necrosis factor therapy or were directly switched to abatacept: the ARRIVE trial. Ann Rheum Dis. 2009 Nov;68(11):1708-14.
14. Singh JA, Furst DE, Bharat A et al. Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Vol. 64, No. 5, May 2012, pp 625–639.
15. 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.
16. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs. Ann Rheum Dis 2010; 69: 964 – 75.
17. Wells AF, Westhovens R, Reed DM et al. Abatacept plus methotrexate provides incremental clinical benefits versus methotrexate alone in methotrexate-naive patients with early rheumatoid arthritis who achieve radiographic nonprogression. J Rheumatol. 2011 Nov;38(11):2362-8.

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

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.189 Orencia Policy retired, new policy created, aligned with NH PDL, removed adherence requirement. Updated DMARD trial/fail timeframe to reflect ACR and EULAR guidelines	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.