Pharmacy Policy

Kineret

Policy Number: 9.124
Revision Number: R1
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:

- Kineret (anakinra)

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 Kineret in combination with another biologic
Required Medical Information	Diagnosis of one of the following: 1. Cryopyrin-Associated Periodic Syndromes (CAPS) including: Neonatal-onset multisystem inflammatory disease (NOMID); **AND** a. Symptoms consistent with the above diagnoses are present (i.e. recurrent intermittent fever and urticarial rash, or amyloidosis) 2. Rheumatoid arthritis (RA); ***AND***

[+] *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.

	a. An inadequate response or adverse reaction to a 3 month trial with 1 formulary non-biologic DMARD or contraindication to non-biologic DMARDs; AND b. An inadequate response, intolerance, or contraindication to Enbrel OR Humira or a clinical rationale for the use Kineret instead of Enbrel OR Humira.
Age Restrictions	RA: 18 years of age or older
Prescriber Restriction	CAPS: Prescriber has experience in the treatment of the condition indicated for use RA: 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:

None

Clinical Background Information and References

1. Agency for Healthcare Research and Quality. Choosing Medications for Rheumatoid Arthritis. Available at effectivehealthcare.ahrq.gov/ehc/products/14/85/RheumArthritisClinicianGuide.pdf. Accessed August 24, 2011.
2. Enbrel prescribing information. Thousand Oaks, CA: Amgen Inc. and Pfizer Inc.; May 2018.
3. Finetti, M., Omenetti, A., Federici, S. et al. Chronic Infantile Neurological Cutaneous and Articular (CINCA) syndrome: a review. Orphanet J Rare Dis 11, 167 (2016).
4. Humira prescribing information. North Chicago, IL: AbbVie Inc.; December 2017.
5. Kineret (anakinra) [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2018.
6. McEvoy GK, ed. AHFS 2012 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc. 2012.
7. Nuki G, Bresnihan B, Bear MB, McCabe D. Long-term safety and maintenance of clinical improvement following treatment with anakinra (recombinant human interleukin-1 receptor antagonist) in patients with rheumatoid arthritis: extension phase of a randomized, double-blind, placebo-controlled trial. Arthritis Rheum 2002; 46:2838-46.
8. Saag KG, Teng GG, Patkar NM, Anuntiyo J, Finney C, Curtis JR. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum. Jun 15 2008; 59(6):762-84.

9. Sibley CH, Plass N, Snow J, et al. Sustained response and prevention of damage progression in patients with neonatal-onset multisystem inflammatory disease treated with anakinra: a cohort study to determine three- and five-year outcomes. Arthritis Rheum. 2012 Jul;64(7):2375-86.
10. 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.
11. 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.
12. 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.
13. Tosh JC, Wailoo AJ, Scott DL, Deighton CM. Cost-effectiveness of combination nonbiologic diseasemodifying antirheumatic drug strategies in patients with early rheumatoid arthritis. J Rheumatol. Aug 2011; 38(8):1593-600.

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	9.187 Kineret Policy retired, new policy created, updated trial/fail requirements to reflect 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.