Pharmacy Policy

Pegfilgrastim Agents

Policy Number: 9.622
Version Number: 2.0
Version Effective Date: 3/1/2022

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:

- Fulphila (pegfilgrastim-jmdb)
- Udencya (pegfilgrastim-cbqv)

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	None
Required Medical Information	1. Cancer in a Patient Receiving Myelosuppressive Chemotherapy; **AND** a. Member meets ONE of the following conditions (i, ii, or iii): i. Patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen); **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.

	ii. Member is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has at least one risk factor for febrile neutropenia according to the prescriber; **OR** Note: Examples of risk factors include age ≥ 65 years; prior chemotherapy or radiation therapy; persistent neutropenia; bone marrow involvement by tumor; recent surgery and/or open wounds; liver and/or renal dysfunction; poor performance status; or human immunodeficiency virus (HIV) infection. iii. Member has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome; 2. Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome). **OR** 3. Peripheral Blood Progenitor Cell Transplantation in Patients with Cancer.
Age Restriction	None
Prescriber Restriction	Prescriber must be a specialist appropriate to the disease state being treated (e.g. oncologist, hematologist, etc.)
Coverage Duration	6 months
Other criteria	None

Applicable Coding:

Code	Medication
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg

Clinical Background Information and References

1. American Society of Clinical Oncology (ASCO); ASCO coronavirus resources; COVID-19 patient care information. Cancer treatment and supportive care: neutropenic fever and neutropenia. https://www.asco.org/asco-coronavirus-resources/care-individuals-cancer-during-covid-19/cancer-treatment-supportive-care. Updated July 23, 2020. Accessed Oct. 2021.
2. Fulphila (pegfilgrastim-jmdb) [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc; March 2021. Accessed Oct 2021.
3. Udenyca (pegfilgrastim-cbqv) [prescribing information]. Redwood City, CA: Coherus BioSciences, Inc; May 2021. Accessed Oct 2021.

4. Ziextenzo ((pegfilgrastim-bmez) [prescribing information]. Princeton, NJ: Sandoz Inc.; November 2019.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
9/10/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
9/10/2020	Created policy for September 2020 P&T	1/1/2021	P&T Committee
11/11/2021	Recommended criteria changes to adopt ESI policy. Removed Ziextenzo from policy and moved to non-formulary. Add Undenya to policy.	3/1/2022	P&T Committee

Next Review Date

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.