

**Pharmacy Policy**

**Pegfilgrastim Agents**

**Policy Number:** 9.622

**Revision Number:** R0

**Version Effective Date:** 1/1/2021

<p>Product Applicability <input type="checkbox"/> All Plan+ Products</p>	
<p><b>Well Sense Health Plan</b></p> <p><input checked="" type="checkbox"/> New Hampshire Medicaid</p>	<p><b>Boston Medical Center HealthNet Plan</b></p> <p><input type="checkbox"/> MassHealth - MCO</p> <p><input type="checkbox"/> MassHealth - ACO</p> <p><input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

**Products Affected:**

- Ziextenzo
- Udenyca
- Fulphila

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

<b>Covered Use</b>	All FDA approved indications not otherwise excluded
<b>Required Medical Information</b>	<p>Documentation of the following:</p> <ol style="list-style-type: none"> <li>1. Primary prophylaxis of chemotherapy induced neutropenia; <b>AND</b> <ol style="list-style-type: none"> <li>a. Chemotherapy is expected to be of curative intent; <b>AND</b></li> <li>b. The chemotherapy regimen being used has an anticipated incidence of neutropenic fever 20 percent or higher; <b>OR</b></li> <li>c. The chemotherapy regimen being used has an anticipated incidence of neutropenic</li> </ol> </li> </ol>

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	<p>fever of 10-20 percent; <b>AND</b></p> <p>One of the following risk factors:</p> <ul style="list-style-type: none"> <li>• Member is of advanced age (65 and older)</li> <li>• Member has advanced disease</li> <li>• Eastern Cooperative Oncology Group (ECOG) performance score of <math>\geq 2</math></li> <li>• Pre-existing neutropenia or bone marrow involvement with tumor</li> <li>• Renal or hepatic dysfunction</li> <li>• Recent surgery and or open wounds</li> <li>• HIV infection</li> <li>• Multiple comorbid conditions (example- COPD, heart failure (NY III-IV) and autoimmune disease)</li> <li>• Chronic immunosuppression</li> <li>• Prior chemotherapy or radiation; <b>OR</b></li> </ul> <p>2. Secondary prophylaxis of chemotherapy induced neutropenia; <b>AND</b></p> <ol style="list-style-type: none"> <li>a. Chemotherapy is expected to be of curative intent; <b>AND</b></li> <li>b. Member has experienced neutropenic fever from prior chemo cycle; <b>OR</b></li> <li>c. Neutropenia (ANC less than 500) with or without fever</li> </ol>
<b>Prescriber Restriction</b>	Prescriber must be a specialist appropriate to the disease state being treated (e.g. oncologist, hematologist, etc.)
<b>Coverage Duration</b>	Initial: 6 months

**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. 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, NH DHHS

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<b>Policy Revisions History</b>			
<b>Review Date</b>	<b>Summary of Revisions</b>	<b>Revision Effective Date</b>	<b>Approved by</b>
9/10/2020	Created policy for September 2020 P&T	1/1/2021	P&T Committee, NH DHHS

### **Next Review Date**

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2021

### **Other Applicable Policies**

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### **Reference to Applicable Laws and Regulations, If Any**

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#### **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.

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