Colony Stimulating Factors: Ziextenzo™ (pegfilgrastim-bmez)

Last Review Date: January 20, 2020
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Medical Guideline Disclaimer

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Definition

Ziextenzo is a colony stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

Length of Authorization

Coverage will be provided for four months and may be renewed.

Dosing Limits

a. Max Units (per dose and over time)
   • Acute radiation exposure
     – 6mg max weekly for 2 doses
   • All other indications:
     – 6mg max per 14 days for all other indications
Guideline

I. Initial Approval Criteria

**Ziextenzo** may be considered medically necessary if one of the below conditions are met AND use is consistent with the medical necessity criteria that follows:

Neulasta and Udenyca are the preferred agents for Medicare members. (Step protocol not mandated for Medicare members).

- The patient has failed treatment with Neulasta AND Udenyca or they are contraindicated;††; OR
- The patient is continuing previously established therapy with Ziextenzo for their current chemotherapy regimen; AND
- A member does not have access to, or benefits for, home health services; OR
- A member is expected to receive G-CSF for 5 consecutive days or more; OR
- Ziextenzo is used in combination with one of the following chemotherapy regimens*:
  - Bladder Cancer:
    - Dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
  - Breast Cancer:
    - Dose dense AC followed by T (doxorubicin, cyclophosphamide, paclitaxel)
  - Non-Hodgkin's Lymphoma:
    - Dose dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone)

* Pegylated filgrastim is the only G-CSF product used in the published clinical trials for these regimens. The requesting provider should provide journal citations supporting this request for regimens other than those listed.

**Coverage for Ziextenzo™ (pegfilgrastim-bmez) is provided in the following conditions:**

**Prophylactic use in patients with non-myeloid malignancy†**

- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 20% or greater §; OR
- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% or greater § AND one or more of the following co-morbidities:
  - Elderly patients (age 65 or older)
  - History of recurrent febrile neutropenia from chemotherapy
  - Extensive prior exposure to chemotherapy
  - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
  - Pre-existing neutropenia (ANC ≤ 1000/mm3) or bone marrow involvement with tumor
- Patient has a condition that can potentially increase the risk of serious infection (i.e. HIV/AIDS)
- Infection/open wounds
- Recent surgery
- Poor performance status
- Poor renal function (creatinine clearance <50)
- Liver dysfunction (elevated bilirubin >2.0)
- Chronic immunosuppression in the post-transplant setting including organ transplant

Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy ‡

Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome) ‡

†FDA-labeled indication, ‡ Compendia recommended indication

§ expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Myeloid Growth Factors Clinical Practice Guideline at NCCN.org

Limitations/Exclusions
Ziextenzo is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

II. Renewal Criteria

Same as initial prior authorization policy criteria

III. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute radiation exposure</td>
<td>6 mg subcutaneously weekly for 2 doses (Use weight-based dosing below for pediatrics weight &lt; 45 kg)</td>
</tr>
<tr>
<td>All other indications</td>
<td>&lt; 10 kg = 0.1 mg/kg</td>
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<tr>
<td></td>
<td>10-20 kg = 1.5 mg</td>
</tr>
<tr>
<td></td>
<td>21-30 kg = 2.5 mg</td>
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<tr>
<td></td>
<td>31-44 kg = 4 mg</td>
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<td>45 kg and up = 6 mg</td>
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Dosed no more frequently than every 14 days

*Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy
Revision History

| 01/20/2020 | 1. New Medical Policy
| | 2. Neulasta and Udenyca are the preferred agents for Medicare members. (Step protocol not mandated for Medicare members).
| | 3. Added Step therapy to use Neulasta AND Udenyca prior to initiating Ziextenzo therapy. |

Applicable Procedure Codes

| J3590 | Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 1 billable unit |

Applicable NDCs

| 61314-0866-01 | Ziextenzo 6 mg prefilled syringe |

Applicable Diagnosis Codes

| D70.1 | Agranulocytosis secondary to cancer chemotherapy |
| D70.9 | Neutropenia, unspecified |
| T45.1X5A | Adverse effect of antineoplastic and immunosuppressive drugs initial encounter |
| T45.1X5D | Adverse effect of antineoplastic and immunosuppressive drugs subsequent encounter |
| T45.1X5S | Adverse effect of antineoplastic and immunosuppressive drugs sequela |
| Z41.8 | Encounter for other procedures for purposes other than remedying health state |
| Z48.290 | Encounter for aftercare following bone marrow transplant |
| Z51.11 | Encounter for antineoplastic chemotherapy |
| Z51.12 | Encounter for antineoplastic immunotherapy |
| Z51.89 | Encounter for other specified aftercare |
| Z52.001 | Unspecified donor, stem cells |
| Z52.011 | Autologous donor, stem cells |
| ZZ52.091 | Other blood donor, stem cells |
| Z94.81 | Bone marrow transplant status |
| Z94.84 | Stem cells transplant status |

References