# Clover

## Colony Stimulating Factors: Udenyca™ (pegfilgrastim-cbqv) (Subcutaneous)

Document Number: IC-0409

**Last Review Date: 12/04/2018**
**Date of Origin:** 12/04/2018
**Dates Reviewed:12/2018**

## I. Length of Authorization

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

## II. Dosing Limits

**A. Quantity Limit (max daily dose) [Pharmacy Benefit]:**

- Udenyca 6 mg prefilled syringe: 1 syringe per 14 days

**B. Max Units (per dose and over time) [Medical Benefit]:**

- 12 billable units weekly x 2 doses for Acute Radiation Exposure
- 12 billable units per 14 days for all other indications

## III. Initial Approval Criteria

Coverage 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 $\leq$ 1000/mm$^3$) 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) ‡**

**Bone marrow transplantation (BMT) failure or engraftment delay ‡**

**Peripheral blood progenitor cell (PBPC) mobilization and transplant ‡**

† FDA-labeled indication(s); ‡ Compendia recommended indication(s)

§ *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*

## IV. Renewal Criteria

Same as initial prior authorization policy criteria.

## V. Dosage/Administration

| Indication | Dose |
|---|---|
| All other indications* | <10 kg = 0.1 mg/kg<br>10-20 kg = 1.5 mg<br>21-30 kg = 2.5 mg<br>31-44 kg = 4 mg<br>45 kg and up = 6 mg<br>Dosed no more frequently than every 14 days. |
| Acute Radiation Exposure | 6 mg subcutaneously weekly x 2 doses (Use weight based dosing for pediatrics weighing <45 kg) |

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

## VI. Billing Code/Availability Information

HCPCS code:

- Q5111 – Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg. 1 billable unit = 0.5 mg

NDC:

- Udenyca 6 mg prefilled single-dose syringe: 70114-0101-xx

## VII. References


1. Udenyca [package insert]. Redwood City, California; Coherus Biosciences; November 2018. Accessed November 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pegfilgrastim. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL

COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2018.

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloid Growth Factors. Version 1.2018. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2018.
4. Russel N, Mesters R, Schubert J, et al. A phase 2 pilot study of pegfilgrastim and filgrastim for mobilizing peripheral blood progenitor cells in patients with non-Hodgkin's lymphoma receiving chemotherapy. Haematologica March 200893:405-412;doi:10.3324/haematol.11287
5. Isidori A, Tani M, Bonifazi F, et al. Phase II study of a single pegfilgrastim injection as an adjunct to chemotherapy to mobilize stem cells into the peripheral blood of pretreated lymphoma patients. Haematologica January 200590:225-231
6. Jagasia MH, Greer JP, Morgan DS, et al. Pegfilgrastim after high-dose chemotherapy and autologous peripheral blood stem cell transplant: phase II study. Bone Marrow Transplant. 2005 Jun;35(12):1165-9.
7. Bruns, Ingmar, et al. "A single dose of 6 or 12 mg of pegfilgrastim for peripheral blood progenitor cell mobilization results in similar yields of CD34+ progenitors in patients with multiple myeloma." Transfusion 46.2 (2006): 180-185.
8. Staber, P. B., et al. "Fixed-dose single administration of Pegfilgrastim vs daily Filgrastim in patients with haematological malignancies undergoing autologous peripheral blood stem cell transplantation." Bone marrow transplantation 35.9 (2005): 889-893.
9. Vanstraelen, Gaëtan, et al. "Pegfilgrastim compared with Filgrastim after autologous hematopoietic peripheral blood stem cell transplantation." Experimental hematology 34.3 (2006): 382-388.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---|---|
| 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 |
| T66.XXXA | Radiation sickness, unspecified, initial encounter |
| Z41.8 | Encounter for other procedures for purposes other then remedying health state |
| Z48.290 | Encounter for aftercare following bone marrow transplant |

| ICD-10 | ICD-10 Description |
|---|---|
| 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 |
| Z52.091 | Other blood donor, stem cells |
| Z94.81 | Bone marrow transplant status |
| Z94.84 | Stem cells transplant status |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |