



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

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### Medical Guideline Disclaimer

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### Related Medical Guideline

[Off-Label Use of FDA-Approved Drugs and Biologicals](#)

### Length of Authorization

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

### Dosing Limits

#### 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

### Guideline

#### I. INITIAL APPROVAL CRITERIA

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

- The patient is continuing previously established therapy with **Udenyca** for their current chemotherapy regimen; **OR**
- 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**
- Udenyca 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)

**Coverage for Udenyca® (pegfilgrastim-cbqv) 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<sup>3</sup>) 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(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.

**Limitations/Exclusions**

Udenyca 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.

### Dosage/Administration

| Indication               | Dose   |
|--------------------------|--|
| Acute radiation exposure | – 6 mg subcutaneously weekly for 2 doses (Use weight based dosing below for pediatrics weight < 45 kg)   |
| 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 |

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

### Applicable Procedure Codes

|       |   |
|-------|---|
| Q5111 | Injection, pegfilgrastim-cbqv, biosimilar, (udenycya), 0.5 mg; 1 billable unit = 0.5 mg |
|-------|---|

### Applicable NDCs

|               |                                |
|---------------|--------------------------------|
| 70114-0101-01 | Udenyca 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              |
| T66.XXXA | Radiation sickness, unspecified, initial encounter                                |
| 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  |
| Z52.091  | Other blood donor, stem cells   |
| Z94.81   | Bone marrow transplant status   |

Z94.84

Stem cells transplant status

## References

1. Udenyca [package insert]. Redwood City, CA; Coherus BioSciences Inc; December 2018. Accessed December 2018.