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

Last Review Date: January 1, 2019	Number: MG.MM.PH.126

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 ≤ 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) †

† 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 – 10-20 kg = 1.5 mg – 21-30 kg = 2.5 mg – 31-44 kg = 4 mg – 45 kg and up = 6 mg 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, biosimiliar, (udenyca), 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 then 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.