I. POLICY

Neulasta (pegfilgrastim), Fulphila (pegfilgrastim-jmdb), and Udenyca (pegfilgrastim-cbqv) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. **Fulphila** or **Udenyca** may be approved for patients who meet the following:
   1. **Prevention of chemotherapy-induced neutropenia:**
      - Documented diagnosis of a non-myeloid malignancy, which is being treated with myelosuppressive chemotherapy AND one of the following:
        - The chemotherapy regimen is expected to result in a 20% or greater risk for febrile neutropenia
        - The patient has at least one of the following factors associated with an increased risk for developing febrile neutropenia:
          - 65 years of age or older
          - Previous regimen of chemotherapy or radiation therapy
          - Preexisting neutropenia (ANC less than or equal to 1,000/mm$^3$) or bone marrow involvement with tumor
          - A condition that can potentially increase the risk of serious infection (i.e. current infection/open wounds, HIV/AIDS, recent surgery)
          - Poor performance status
          - Poor nutritional status
          - Poor renal function
          - Liver dysfunction
          - Prescriber is, or in consultation with, an oncologist or hematologist

B. **Neulasta** may be approved for patients who meet the following:
   1. **Prevention of chemotherapy-induced neutropenia:**
• Documented diagnosis of a non-myeloid malignancy, which is being treated with myelosuppressive chemotherapy AND one of the following:
  • The chemotherapy regimen is expected to result in a 20% or greater risk for febrile neutropenia
  • The patient has at least one of the following factors associated with an increased risk for developing febrile neutropenia:
    • 65 years of age or older
    • Previous regimen of chemotherapy or radiation therapy
    • Preexisting neutropenia (ANC less than or equal to 1,000/mm$^3$) or bone marrow involvement with tumor
    • A condition that can potentially increase the risk of serious infection (i.e. current infection/open wounds, HIV/AIDS, recent surgery)
    • Poor performance status
    • Poor nutritional status
    • Poor renal function
    • Liver dysfunction
  • Patient has had trial and inadequate response to either Fulphila or Udenyca
  • Prescriber is, or in consultation with, an oncologist or hematologist

C. **Neulasta** may be approved for patients who meet the following:
   1. **Acute Hematopoietic radiation injury syndrome**:
      • Documentation that the patient was acutely exposed to myelosuppressive doses of radiation
      • Requested quantity is not greater than two doses, which will be taken 1 week apart

### III. AUTHORIZATION PERIOD/LIMITATIONS

• Initial approval will be limited to 6 months of therapy for prophylaxis of chemotherapy-induced neutropenia (dosed no more frequently than every 14 days).
• Initial approval of Neulasta will be restricted to 2 doses when used for acute radiation exposure.
• Continuation of therapy may be approved for neutropenia prophylaxis in 6-month intervals with documentation showing a beneficial response to treatment.

### IV. EXCLUSIONS

Neulasta, Fulphila, Udenyca will **not** be covered for the following:

• Patients with history of serious allergic reaction to human granulocyte colony-stimulating factors
• Any indications that are not FDA-approved or guideline-supported including, but not limited to:
  • Acute myeloid leukemia,
  • Aplastic anemia
  • Hepatitis C treatment-induced neutropenia,
  • HIV-associated neutropenia
  • Agranulocytosis

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V. RECOMMENDED DOSAGE

Prevention of chemotherapy-induced neutropenia: 6mg subcutaneously once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy; should NOT be administered in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy

- For pediatric patients with a weight of less than 45 kilograms, dosing is weight-based once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy:
  - Patients <10 kg: 0.1 mg/kg (0.01 mL/kg volume)
  - Patients 10 to 20 kg: 1.5 mg (0.15 mL volume)
  - Patients 21 to 30 kg: 2.5 mg (0.25 mL volume)
  - Patients 31 to 44 kg: 4 mg (0.4 mL volume)

Acute Hematopoietic radiation injury syndrome: 6 mg subcutaneously once weekly for 2 doses.

- For pediatric patients with a weight of less than 45 kilograms, dosing is weight-based for two doses one week apart:
  - Patients <10 kg: 0.1 mg/kg (0.01 mL/kg volume)
  - Patients 10 to 20 kg: 1.5 mg (0.15 mL volume)
  - Patients 21 to 30 kg: 2.5 mg (0.25 mL volume)
  - Patients 31 to 44 kg: 4 mg (0.4 mL volume)

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member’s specific benefit plan determines coverage.

<table>
<thead>
<tr>
<th>Medication</th>
<th>HCPCS/CPT Code</th>
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<tbody>
<tr>
<td>Neulasta 6 MG/0.6ML SOSY Injection, pegfilgrastim, 6 mg</td>
<td>J2505</td>
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<tr>
<td>Neulasta Onpro 6 MG/0.6ML PSKT Injection, pegfilgrastim, 6 mg</td>
<td>J2505</td>
</tr>
<tr>
<td>Fulphila Injection, pegfilgrastim-jmdb, biosimilar,0.5 mg</td>
<td>Q5108</td>
</tr>
<tr>
<td>Udenyca 6 MG/0.6ML SOSY Injection, Pegfilgrastim-cbqv, biosimilar, 0.5 mg</td>
<td>Q5111</td>
</tr>
</tbody>
</table>

Examples of Disease Settings and Chemotherapy Regimens* with a High Risk for Febrile Neutropenia (>20%):

*Please Note: This is not an all-inclusive list, as additional regimens may be listed in current NCCN guidelines. The regimens listed are associated with a greater than 20% risk of febrile neutropenia, regardless of cancer type.

Acute Lymphoblastic Leukemia (ALL)
• ALL induction regimens, including, but not limited to:
  • Imatinib or dasatinib and cyclophosphamide, vincristine, doxorubicin, dexamethasone
  • Imatinib and daunorubicin, vincristine, prednisone, cyclophosphamide
  • Daunorubicin, vincristine, prednisone, pegaspargase, cyclophosphamide

Bladder Cancer

• MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)

Breast Cancer

• Dose-dense AC followed by T (doxorubicin, cyclophosphamide, paclitaxel)
• TAC (docetaxel, doxorubicin, cyclophosphamide)
• TC (docetaxel, cyclophosphamide)
• TCH (docetaxel, carboplatin, trastuzumab)

Hodgkin Lymphoma

• BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)

Kidney Cancer

• Doxorubicin/gemcitabine

Non-Hodgkin’s Lymphomas

• Dose-adjusted EOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubin)
• ICE (ifosfamide, carboplatin, etoposide)
• Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone)
• MINE (mesna, ifosfamide, Novantrone, etoposide)
• DHAP (dexamethasone, cisplatin, cytarabine)
• ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine)
• HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone)

Melanoma

• Dacarbazine-based combination with IL-2, interferon alfa (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)

Multiple Myeloma

• DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide) ±bortezomib (VTD-PACE)

Ovarian Cancer

• Topotecan
• Docetaxel

Soft Tissue Sarcoma

• MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
• Doxorubicin
• Ifosfamide/doxorubicin

Small Cell Lung Cancer

• Topotecan

Testicular cancer
- VeIP (vinblastine, ifosfamide, cisplatin)
- VIP (etoposide, ifosfamide, cisplatin)
- BEP (bleomycin, etoposide, cisplatin)
- TIP (paclitaxel, ifosfamide, cisplatin)

VII. REFERENCES
1. Neulasta [Prescribing Information]. Thousand Oaks, CA; Amgen Inc.; 2018 June
2. Fulphila [Prescribing Information]. Rockford, IL; Mylan Institutional LLC; 2018 June
3. Udenyca [Prescribing Information]. Redwood City, CA; Coherus BioSciences, Inc.; 2018 November

VIII. APPROVALS
Signature on file at JHHC

<table>
<thead>
<tr>
<th>DATE OF REVISION</th>
<th>SUMMARY OF CHANGE</th>
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<tbody>
<tr>
<td>12/19/2018</td>
<td>Policy Creation</td>
</tr>
<tr>
<td>01/16/2019</td>
<td>Added clinical criteria for Udenyca</td>
</tr>
<tr>
<td>07/17/2019</td>
<td>Modified clinical criteria to reflect Fulphila and Udenyca as preferred Nuelasta-biosimilar products</td>
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Review Date: 12/19/2018, 01/16/2019, 07/17/2019

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