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Eflapegrastim-xnst (ROLVEDON) for Chemotherapy-Induced Neutropenia

Description: The purpose of this PQI is to outline key clinical and operational considerations to help optimize outcomes for patients receiving eflapegrastim-xnst (ROLVEDON) for the prevention of chemotherapy-induced neutropenia.

Background: Eflapegrastim-xnst is a long-acting granulocyte colony-stimulating factor (G-CSF) analog indicated to decrease the incidence of infection, as manifested by febrile neutropenia (FN), in adult patients with non-myeloid malignancies receiving myelosuppressive chemotherapy associated with a clinically significant incidence of FN.

Most common adverse reactions (≥20%): fatigue, nausea, diarrhea, bone pain, headache, pyrexia, anemia, rash, myalgia, arthralgia, and back pain.

PQI Process:

- Verify eligibility criteria:
  - Diagnosis of a non-myeloid malignancy.
  - Receiving chemotherapy regimen associated with >20% risk of febrile neutropenia (or 10–20% with additional risk factors).
  - Not receiving concurrent radiation to the bone marrow.
  - ANC is within acceptable range prior to administration (e.g., ANC < 500).
  - Eflapegrastim-xnst is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
- Dosing & administration:
  - Administer 13.2 mg/0.6 mL via subcutaneous injection once per chemotherapy cycle.
  - Dose should be given at least 24 hours after chemotherapy completion and not within 14 days prior to the next chemotherapy cycle.
  - Discard any prefilled syringe left at room temperature for greater than 72 hours.
- Scheduling & logistics:
  - Coordinate injection with post-chemotherapy follow-up visit.
  - Store refrigerated at 2°C to 8°C (36°F to 46°F). Protect from light. Do not freeze.
- Order entry:
  - Use the appropriate J-code (J1449) for Eflapegrastim-xnst when billing Medicare or payers.
- Product selection:
  - Confirm no other G-CSF agents are selected in patient's treatment plan.
  - Ensure payer and prior authorization status is verified in advance of administration.

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Patient-Centered Activities:

- Provide verbal and written education:
  - Rationale for G-CSF prophylaxis with chemotherapy.
  - Expected benefit: reduced risk of infection and hospitalization from FN.
  - Expected timing of injection (not the same day as chemo; usually day +1).
- Counsel on common side effects:
  - Possible injection site discomfort, bone pain, back pain, headache, fatigue.
    - Recommend allowing the syringe to sit at room temperature for ~30 minutes prior to administration to decrease possible burning with injection
  - Instruct patients to report symptoms of:
    - Allergic reactions (rash, facial swelling, difficulty breathing).
    - Left upper abdominal or shoulder pain (may indicate splenic rupture).
    - Shortness of breath or fever (possible pulmonary or infectious complications).
- Reinforce adherence and follow-up:
  - Emphasize importance of timely administration per cycle.
  - Ensure patients have transportation or support to return for injection when required.
  - Discuss insurance coverage or co-pay support programs if needed.
- Financial Assistance Options:
  - Patients may qualify for various patient support programs through the manufacturer's ACCESS4Me program at www.ACCESS4Me.com or third-party organizations.

References:

1. FDA. Eflapegrastim-xnst (Rolvedon®) injection [Prescribing Information]. Spectrum Pharmaceuticals, Inc. Revised 8/2025. Available at: https://www.accessdata.fda.gov.
2. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Hematopoietic Growth Factors. Version 1.2025. National Comprehensive Cancer Network, Inc. Accessed July 2025. https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf.

Supplemental Information:

Adverse Reaction Management

Adverse Reaction	Severity	Management Recommendations
Bone pain	Mild to Moderate	Manage with NSAIDs or acetaminophen as first-line agents.
Injection site reactions	Mild to Moderate	Apply cold compresses; consider oral antihistamines.
Hypersensitivity reactions	Any	Discontinue immediately if serious allergic reaction occurs.
Splenic rupture	Severe	Discontinue permanently; monitor for left upper quadrant pain.
Acute respiratory distress syndrome (ARDS)	Severe	Discontinue and provide supportive care. Monitor oxygenation status.
Leukocytosis (ANC > 100,000/µL)	Severe	Monitor CBC; usually resolves without intervention.

Capillary leak syndrome	Rare but life threatening	Discontinue permanently; initiate supportive care.

Note: Eflapegrastim-xnst has not been studied in patients with severe renal or hepatic impairment. Caution is advised.