eflapegrastim-xnst (Rolvedon)

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

Drug Details

USP Category: BLOOD PRODUCTS AND MODIFIERS
Mechanism of Action: colony stimulating factor
HCPCS:
J1449:Injection, eflapegrastim-xnst, 0.1 mg
How Supplied:

- 13.2 mg/0.6 mL solution in a single-dose prefilled syringe

Condition(s) listed in policy (see coverage criteria for details)

- Non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

Any request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

For members enrolled in our Blue Shield Select (PPO) and Blue Shield Medicare (PPO) plans:
Rolvedon requires step therapy. Step therapy requires you to try other drug(s) first before a drug can be covered. The BSC preferred step drugs are Neulasta and Udenyca. Both of these drugs will need to be tried for members newly initiating Rolvedon therapy.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice:

Non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia
Meets medical necessity if all the following are met:

1. Administered while patient is receiving myelosuppressive chemotherapy medications
2. Administered every 14 days or more
3. Not being used concurrently with long-acting or short-acting granulocyte colony stimulating factors (e.g., filgrastim or pegfilgrastim drugs)
4. For PPO request: Treatment failure, intolerable side effect, or contraindication to the preferred long-acting granulocyte colony stimulating products (Neulasta AND Udenyca)

Covered Doses:
13.2 mg SC per chemotherapy cycle

Coverage Period:
length of chemotherapy

ICD-10:
C00.0-C91.91, D00.00-D49.9

Additional Information

Summary of Evidence

The contents of this policy were created after examining the following resources:

1. The prescribing information for Rolvedon
2. CMS approved compendium in accordance with the accepted compendia ratings listed:
   a. Micromedex DrugDex - Class I, Class IIa, of Class IIb
   b. American Hospital Formulary Service-Drug Information (AHFS-DI) - supportive narrative text
   c. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium - Category 1 or 2A
   d. Lexi-Drugs – "Use: Off-Label" and rated as "Evidence Level A" (cancer indications only)
   e. Clinical Pharmacology - supportive narrative text (cancer indications only)
3. Noridian Healthcare Solutions Medicare: Drugs, Biologics and Injections
4. NCCN Guideline: Hematopoietic Growth Factors

Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer's prescribing information.
- Beginning January 1, 2019, the Centers for Medicare & Medicaid Services (CMS) provided Medicare Advantage (MA) plans the option of applying step therapy for physician-administered and other Part B drugs to lower costs and improve the quality of care for Medicare beneficiaries
- NCCN Clinical Practice Guidelines in Oncology for the use of hematopoietic growth factors support use of granulocyte colony-stimulating factors (G-CSFs) as prophylaxis of chemotherapy-induced febrile neutropenia or other dose-limiting neutropenic events in patients at risk of febrile neutropenia with solid tumors and non-myeloid malignancies who are receiving treatment in the curative/adjuvant or palliative settings

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals

2. Medicare Coverage Database. Available at https://www.cms.gov/Medicare-Coverage-Database/search.aspx
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS®. Available by subscription at http://www.lexi.com
5. DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
6. RolvedonTM (eflapegrastim-xnst) [Prescribing information]. Lake Forest, CA: Spectrum Pharmaceuticals, Inc.; 2023.
7. National Comprehensive Cancer Network. Hematopoietic Growth Factors, v3.2024. Available at http://www.nccn.org.

Review History

Date of Last Annual Review: 4Q2024
Changes from previous policy version:

- New Part B policy

Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee