Medical Policy:

Colony Stimulating Factors: Rolvedon™ (eflapegrastim-xnst) subcutaneous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.376	March 17, 2025	February 9, 2023

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Rolvedon, a leukocyte growth factor, is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adults with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Eflapegrastim is a long-acting recombinant human granulocyte growth factor conjugated with a recombinant human IgG Fc fragment with the Fc fragment allowing for an extended half-life. Eflapegrastim binds to granulocyte colony-stimulating factor receptors on myeloid progenitor cells and neutrophils, triggering signaling pathways to cell differentiation, proliferations, migration, and survival.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Rolvedon 13.2 mg prefilled syringe: 1 syringe per 14 days

Max Units (per dose and over time) [HCPCS Unit]:

132 billable units (13.2 mg) per 14 days

Guideline

I. Initial Approval Criteria

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

- Patient is at least 18 years of age

Neulasta and Udenyca are the preferred agents for Commercial, Medicaid, and Medicare members.

The patient has failed treatment with Neulasta AND Udenyca or they are contraindicated ††; **OR**

1. The patient is continuing previously established therapy with *Rolvedon* for their current chemotherapy regimen; **AND**
2. A member does not have access to, or benefits for, home health services; **OR**
3. A member is expected to receive G-CSF for 5 consecutive days or more

†† Commercial, Medicaid, AND Medicare members are subject to this step therapy

Prophylactic use in adult patients with solid tumors or non-myeloid malignancy*:*

1. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖ of greater than 20% §; **OR**
2. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖of 10% to 20% § **AND** one or more patient-related risk factors ¥;
3. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖ of <10% **AND** two or more patient related risk factors ¥ **

   ***Use in this setting is based on clinical judgment.*

   Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

§ Expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Hematopoietic Growth Factors Clinical Practice Guideline at NCCN.org

¥ Patient risk factors for febrile neutropenia
• Age >65 years receiving full dose intensity chemotherapy • Prior exposure to chemotherapy or radiation therapy • Persistent neutropenia (ANC ≤ 1000/mm3) • Bone marrow involvement by tumor • Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts) • Recent surgery and/or open wounds • Poor performance status • Renal dysfunction (creatinine clearance <50 mL/min) • Liver dysfunction (elevated bilirubin >2.0 mg/dL) • Chronic immunosuppression in the post-transplant setting, including organ transplant
❖ Febrile neutropenia is defined as:
• Temperature: a single temperature ≥38.3 °C orally or ≥38.0 °C over 1 hour; AND • Neutropenia: <500 neutrophils/mcL or <1,000 neutrophils/mcL and a predicted decline to ≤500 neutrophils/mcL over the next 48 hours

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II. Renewal Criteria

Same as initial prior authorization policy criteria

Applicable Procedure Codes

Code	Description
J1449	Injection, eflapegrastim-xnst, 0.1 mg

Applicable NDCs

Code	Description
76961-0101-xx	Rolvedon 13.2 mg prefilled syringe

ICD-10 Diagnoses

Code	Description
D61.810	Antineoplastic chemotherapy induced pancytopenia
D61.811	Other drug-induced pancytopenia
D61.818	Other pancytopenia
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
T66.XXXD	Radiation sickness, unspecified, subsequent encounter
T66.XXXS	Radiation sickness, unspecified, sequela
W88.1	Exposure to radioactive isotopes
W88.8	Exposure to other ionizing radiation
Z41.8	Encounter for other procedures for purposes other than remedying health state
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy
Z51.89	Encounter for other specified aftercare
Z76.89	Persons encountering health services in other specified circumstances

Revision History

Company(ies)	DATE	REVISION

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EmblemHealth & ConnectiCare	3/17/2025	Updated risk factors(patient co-morbidities) for febrile neutropenia. Added to criteria: Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of <10% AND two or more patient related risk factors ¥ ** Separated from criteria co-morbidities and created chart to reference, as well as defining febrile neutropenia. Added: Patient is at least 18 years of age Updated ICD-10 Codes
EmblemHealth & ConnectiCare	3/21/2024	Annual Review: Updated dosing limits
EmblemHealth & ConnectiCare	9/13/2023	Updated J Code- removed J3590, added J1449
EmblemHealth & ConnectiCare	02/09/2023	New Policy

References

1. Rolvedon [package insert]. Irvine, CA; Spectrum Pharmaceuticals, Inc; June 2023. Accessed March 2025.

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