BlueCross BlueShield
Federal Employee Program

ROLVEDON
(eflapegrastim-xnst)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Rolvedon (eflapegrastim-xnst) is a recombinant human granulocyte growth factor that binds to granulocyte colony-stimulating factor (G-CSF) receptors on myeloid progenitor cells and neutrophils, triggering signaling pathways that control cell differentiation, proliferation, migration, and survival (1).

Regulatory Status

FDA-approved indication: Rolvedon is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia (1).

Limitations of Use: Rolvedon is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation (1).

Rolvedon contains warnings for the following: splenic rupture, acute respiratory distress syndrome, serious allergic reactions, sickle cell crisis in patients with sickle cell disorders, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulatory effects on malignant cells, myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) in patients with breast and lung cancer, aortitis, and nuclear imaging (1).

The safety and effectiveness of Rolvedon in pediatric patients less than 18 years of age have not been established (1).

Summary

Rolvedon is a recombinant human granulocyte growth factor that binds to granulocyte colony-stimulating factor (G-CSF) receptors and is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. The safety and effectiveness of Rolvedon in pediatric patients less than 18 years of age have not been established (1).

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Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Rolvedon while maintaining optimal therapeutic outcomes.

References

1. Rolvedon [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; November 2023.
2. NCCN Clinical Practice Guidelines in Oncology® Hematopoietic Growth Factors 2025. National Comprehensive Cancer Network, Inc. Accessed on January 13, 2025.