Granulocyte Colony Stimulating Factor (G-CSF) Products

Policy # 00819
Original Effective Date: 12/12/2022
Current Effective Date: 12/12/2022

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the filgrastim products, Neupogen®‡, Nivestym™‡, Zarxio®‡, Releuko®‡, and Granix®‡, to be **eligible for coverage.****

Based on review of available data, the Company may consider the pegfilgrastim products, Neulasta®‡, Neulasta Onpro®‡, Fulphila®‡, Udenyca®‡, Ziextenzo™‡, Nyvepria™‡, Fylnetra®‡, and Stimufend®‡, to be **eligible for coverage.****

Background/Overview

The granulocyte colony stimulating factor (G-CSF) products include filgrastim and pegfilgrastim. These products are intended to increase white blood cell production. The filgrastim and pegfilgrastim products are covered at parity status.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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The purpose of this policy is to reflect the coverage of the filgrastim and pegfilgrastim products at parity status. It should be noted that these are not targeted medical drugs. This Medical Policy is informational in nature only.

References

1. Neupogen [package insert]. Amgen, Inc. Thousand Oaks, California. Updated February 2021.
2. Nivestym [package insert]. Hospira Inc. Lake Forest, Illinois. November 2021.
3. Zarxio [package insert]. Sandoz Inc. Princeton, New Jersey. March 2021.
4. Releuko [package insert]. Kashiv Biosciences, Inc. Piscataway, New Jersey. February 2022.
5. Granix [package insert]. Teva Pharmaceuticals USA, Inc. North Wales, Pennsylvania. November 2019.
6. Neulasta [package insert]. Amgen Inc. Thousand Oaks, California. February 2021.
7. Fulphila [package insert]. Mylan Pharmaceuticals. Morgantown, West Virginia. October 2021.
8. Udenyca [package insert]. Coherus Biosciences. Redwood City, California. June 2021.
9. Ziextenzo [package insert]. Sandoz, Inc. Princeton, New Jersey. March 2021.
10. Nyvepria [package insert]. Pfizer Oncology. Lake Forest, Illinois. October 2021.
11. Fylnetra [package insert]. Kashiv BioSciences, LLC. Piscataway, New Jersey. May 2022.
12. Stimufend [package insert]. Fresenius Kabi USA, LLC. Lake Zurich, Illinois. September 2022.

Policy History

Original Effective Date: 12/12/2022
Current Effective Date: 12/12/2022
11/03/2022 Medical Policy Committee review
11/09/2022 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 11/2023

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.