Granulocyte Colony Stimulating Factor (G-CSF) Products

Medicare Advantage Medical Policy No.: MNG-014

The Health Plan reserves the right to amend this policy and procedure at any time. Exceptions to this policy and procedure will be made on a case-by-case basis at the total discretion of the Health Plan.

Original Effective Date: March 1, 2023
Current Effective Date: April 16, 2024

Medicare Advantage Members

Coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria will be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of the coverage criteria and is to be used by all plans and lines of business unless Federal or State law, contract language, including member or provider contracts, take precedence over the policy.

Basic Requirements for Clinical Appropriateness:

1. Before diagnostic or therapeutic intervention, a clinician must confirm the diagnosis or establish the likelihood based on a history and physical exam and, when appropriate, a review of laboratory studies, previous diagnostic testing and response to any prior interventions, specifically relevant to the clinical situation.
2. An alternative treatment or other appropriate intervention should not offer any greater benefit based on standards of medical practice and/or current literature.
3. The potential benefit to the patient should outweigh the risk of the diagnostic or therapeutic intervention.
4. A reasonable likelihood of the intervention changing management and/or leading to an improved outcome for the patient must exist, based on the clinical evaluation, current literature and standards of medical practice.

If these requirements are not apparent in the request for authorization, including the clinical documentation provided, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Simultaneous ordering of multiple diagnostic or therapeutic interventions and/or repeated diagnostic or therapeutic interventions in the same anatomic area may be denied, unless individual circumstances support the medical necessity of performing interventions simultaneously or repeatedly. This should be apparent in the clinical documentation or in peer-to-peer conversations.

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When Services May Be 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®‡), and the pegfilgrastim products (Neulasta®‡, Fulphila®‡, Udenyca®‡, Ziextenzo™‡, Nyvepria™‡, Fylnetra®‡, and Stimufend®‡) covered for all FDA approved indications.

Background/Overview

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

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.

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.

13. Rolvedon [package insert]. Spectrum Pharmaceuticals, Inc. Irvine, CA. June 2023.

Policy History

Chief Medical Officer Review: 03/10/2023

Original Effective Date: 03/01/2023

**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.

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