Original Effective Date: 06/2012
Current Effective Date: 08/30/2023
Last P&T Approval/Version: 7/26/2023
Next Review Due By: 07/2024
Policy Number: C2437-A

Filgrastim

PRODUCTS AFFECTED

Neupogen (filgrastim); Zarxio (filgrastim-sndz); Nivestym (filgrastim-aafi); Granix (tbo-filgrastim), Releuko (filgrastim-ayow)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Febrile neutropenia prophylaxis, Peripheral blood progenitor cell collection, Chronic neutropenia, Treatment of febrile neutropenia, Hepatitis C treatment related neutropenia, HIV related neutropenia, Felty's syndrome, Acute radiation syndrome

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

FOR ALL INDICATIONS:
1. (a) IF THIS IS A PHARMACY BENEFIT REQUEST FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary alternatives for the given diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.

AND

(b) If request is for reference product with a biosimilar available for initial or continuation of therapy requests: Documentation of a trial and failure, intolerance or contraindication to a majority (not more than 3) biosimilar product(s) is required (unless otherwise specified per applicable state regulations and/or there is data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs).

[DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period, Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache)]

OR

2. FOR INITIAL OR CONTINUATION OF THERAPY REQUESTS OF A PHYSICIAN ADMINISTERED MEDICATION: BIOSIMILAR DRUGS are preferred when requested as a physician administered drug per applicable state regulations and/or there is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication is approved under the following conditions:
   a. Treatment with at least two (2) associated biosimilar drug(s) has been ineffective, not tolerated, or is contraindicated (i.e. an allergic reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR an adverse reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure while taking the preferred biologic product or biosimilar documented by patient diary or medical charted notes)

   [DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period, Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache)]

A. FEBRILE NEUTROPENIA PROPHYLAXIS IN NON-MYELOID MALIGNANCIES:
   1. Documented diagnosis of non-myeloid malignancy
      AND
   2. Documentation that filgrastim is being used following myelosuppressive chemotherapy
      [DOCUMENTATION REQUIRED of current chemotherapy regimen, any previous chemotherapy regimens, and anticipated treatment plan]
      AND
   3. (a) Member has a risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors [See Appendix])
      OR
      (b) Member has a risk of febrile neutropenia of 10-20% based on chemotherapy regimen, and at least ONE of the following risk factors apply:
         (i) Prior chemotherapy or radiation therapy
         (ii) Persistent neutropenia (defined as neutrophil count less than 500 neutrophils/mcL or less than 1,000 neutrophils/mcL and a predicted decline to less than or equal to 500 neutrophils/mcL over next 48 hours)
         (iii) Bone marrow involvement by tumor
         (iv) Recent surgery and/or open wounds
         (v) Liver dysfunction (bilirubin greater than 2.0 mg/dL)
         (vi) Renal dysfunction (creatinine clearance less than 50 mL/min)
         (vii) Age greater than 65 receiving full chemotherapy dose intensity

      OR
      (c) Previous neutropenic fever complication from a prior cycle of similar chemotherapy

OR

(d) The member is receiving a dose-dense chemotherapy regimen

B. FEBRILE NEUTROPENIA PROPHYLAXIS IN ACUTE MYELOID LEUKEMIA (AML):
1. Documented diagnosis of acute myeloid leukemia (AML)
   AND
2. Documentation that member is receiving either induction chemotherapy OR consolidation chemotherapy [DOCUMENTATION REQUIRED]

C. FEBRILE NEUTROPENIA PROPHYLAXIS FOLLOWING HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT):
1. Documented diagnosis of non-myeloid malignancy
   AND
2. Documentation member is undergoing or must have had a hematopoietic stem cell transplant (HSCT) (e.g., bone marrow transplant, peripheral-blood progenitor cell (PBPC) transplant) for a non-myeloid malignancy [DOCUMENTATION REQUIRED]

D. PERIPHERAL BLOOD PROGENITOR CELL COLLECTION:
1. Prescriber attests that member is in need of filgrastim therapy for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis and will be initiated before leukapheresis (e.g., prescribed for 6 to 7 days with leukapheresis on days 5, 6 and 7)

E. FEBRILE NEUTROPENIA PROPHYLAXIS DURING RADIATION THERAPY:
1. Documentation member is receiving radiation therapy alone or caution will be used if member is receiving concomitant chemotherapy [DOCUMENTATION REQUIRED of current radiation therapy, any previous or current chemotherapy regimens, and anticipated treatment plan] *NOTE: ASCO guidelines state that CSFs should be avoided in patients receiving concomitant chemotherapy and radiation therapy, particularly involving the mediastinum. The NCCN guidelines for myeloid growth factors (version 1.2023) state that caution should be exercised when administering prophylactic G-CSF in patients given concurrent chemotherapy and radiation.*

F. CHRONIC NEUTROPENIA:
1. Documentation of a diagnosis of congenital, cyclic, or idiopathic neutropenia [DOCUMENTATION REQUIRED]
   AND
2. Prescriber attests that member is symptomatic (e.g., fever, infections, oropharyngeal ulcers)

G. TREATMENT OF FEBRILE NEUTROPENIA:
1. Documentation member has a diagnosis of febrile neutropenia [DOCUMENTATION REQUIRED]
   AND
2. Prescriber attests that member is concurrently receiving appropriate antibiotics, if member is at high-risk for developing infection-associated complications

H. HEPATITIS C TREATMENT RELATED NEUTROPENIA:
1. Documented diagnosis of Hepatitis C
   AND
2. Prescriber attests or clinical reviewer has found member is undergoing treatment with peginterferon
   AND
3. Documentation of neutropenia as evidenced by ANC ≤ 500 cells/mm3 after dose reduction of peginterferon [DOCUMENTATION REQUIRED]

I. HIV RELATED NEUTROPENIA:
1. Documented diagnosis of HIV infection
   AND
2. Documentation member has an ANC ≤ 1,000 cells/mm3 [DOCUMENTATION REQUIRED]

J. FELTYS SYNDROME:
1. Documented diagnosis for Felty's syndrome [DOCUMENTATION REQUIRED]
   AND
2. Documentation of a history of recurrent or severe infections
   AND
3. Documentation member has tried and failed ONE of the following:
   a. Methotrexate (at maximum tolerated dose of up to 25mg weekly)
      OR
   b. Leflunomide if unable to tolerate methotrexate AND concurrent use of another DMARD for at least two months

K. ACUTE RADIATION SYNDROME:
1. Documentation that member has had suspected or confirmed acute exposure to myelosuppressive doses of radiation [greater than 2 Grays (Gy)] [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:
A. FOR ALL INDICATIONS:
1. Documentation of clinical benefits to support continuation of treatment including positive response to therapy (i.e., member did not become neutropenic mid-cycle requiring G-CSF), low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
   AND
2. Prescriber attests to regular lab monitoring (i.e., CBC) as clinically appropriate and rationale for medical necessity for continuation of therapy
   AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Initial Authorization: 12 weeks; For oncology/chemotherapy related indications: Up to 12 weeks or up to length of chemotherapy approval date- whichever is shorter,
Continuation of Therapy: 12 weeks; For oncology/chemotherapy related indications: Up to 6 months or up to length of chemotherapy approval date-whichever is shorter
NOTE: Continuation of therapy is not applicable to acute radiation syndrome, febrile neutropenia prophylaxis following hematopoietic stem cell transplant (HSCT), and peripheral blood progenitor cell collection. All requests for this indication must process through initial criteria.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified hematologist, oncologist, rheumatologist (Felty's Syndrome), infectious disease (HIV or Hep C treatment related neutropenia), or transplant specialist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
One month of age and older

QUANTITY:
14 doses per 28 days

Maximum Quantity Limits – based on FDA label

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous or Subcutaneous

DRUG CLASS:
Granulocyte Colony-Stimulating Factors (G-CSF)

FDA-APPROVED USES:
ALL PRODUCTS:
Myelosuppressive chemotherapy recipients with non-myeloid malignancies: To decrease the incidence of infection (neutropenic fever) in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy associated with a significant incidence of severe neutropenia with fever

NEUPOGEN ONLY:
Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)

NEUPOGEN/ZARXIO/NIVESTYM/RELEUKO ONLY:
Acute myeloid leukemia following induction or consolidation chemotherapy: To reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy in adults with acute myeloid leukemia (AML)

Bone marrow transplantation: To reduce the duration of neutropenia and neutropenia-related events (e.g., neutropenic fever) in patients with non-myeloid malignancies receiving myeloablative chemotherapy followed by bone marrow transplantation.

Severe chronic neutropenia: Long-term administration to reduce the incidence and duration of neutropenic complications (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

NEUPOGEN/ZARXIO/NIVESTYM ONLY:
Peripheral blood progenitor cell collection and therapy: Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for apheresis collection

COMPENDIAL APPROVED OFF-LABELED USES:
Neutropenia in Cytokine Release Syndrome (CRS) (See NCCN Management of Immunotherapy-Related Toxicities CART-3)

APPENDIX

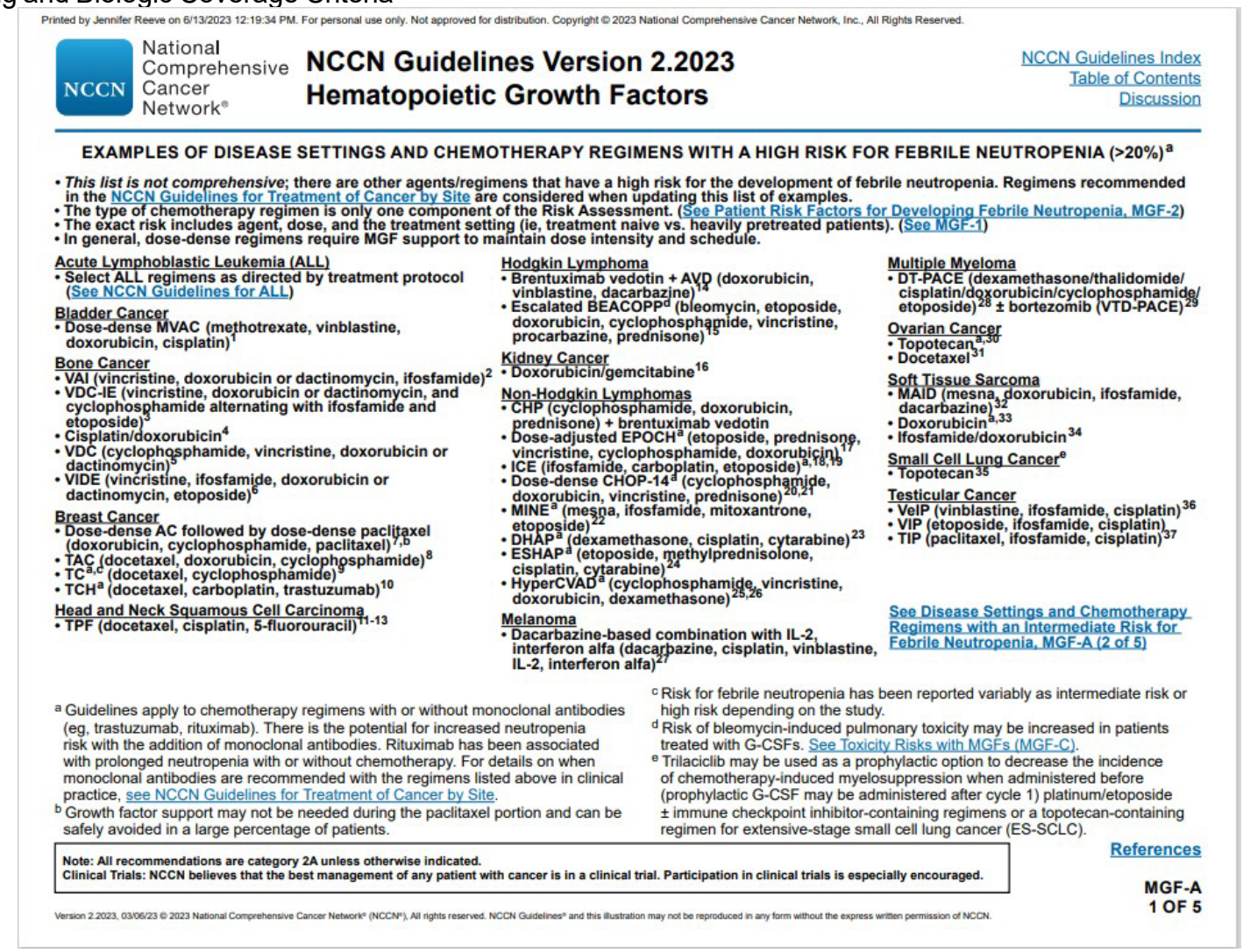
APPENDIX:
A biosimilar is highly similar version of a brand name biological drug that meets strict controls for structural,

pharmaceutical, and clinical consistency. A biosimilar manufacturer must demonstrate that there are no meaningful clinical differences (i.e., safety and efficacy) between the biosimilar and the reference product. Clinical performance is demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies.1 As costs for biological specialty drugs continue to rise, the growing biosimilar market will benefit providers and patients by broadening biological treatment options and expanding access to these medications at lower costs. Molina Healthcare, Inc. continues to be committed to continually reevaluating Preferred strategies and applying innovative cost-controls to ensure patients receive safe, effective, and quality healthcare. This commitment includes potentially creating a preference for biosimilars when value can be added without compromising patient satisfaction and safety.

1. Food and Drug Administration. Biosimilar and Interchangeable Products. Retrieved from https://www.fda.gov/drugs/biosimilars/biosimilar- and-interchangeable-products. Accessed October 8, 2019.

High risk for chemotherapy induced FN infectious complications because of bone marrow compromise OR co-morbidity with any of the following risk factors (not an all-inclusive list):

Age >65 years
Poor performance status
Previous episodes of FN
History of previous chemotherapy or radiation therapy
Completion of combined chemoradiotherapy
Bone marrow involvement by tumor producing
cytopenia Pre-existing neutropenia
Poor nutritional status
Poor renal function
Liver dysfunction (i.e., elevated bilirubin)
Presence of open wound(s) or active infection
Recent surgery (within the past 12 weeks)
More advanced cancer
Other serious co-morbidities



NCCN National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2023
Hematopoietic Growth Factors

NCCN Guidelines Index
Table of Contents
Discussion

EXAMPLES OF DISEASE SETTINGS AND CHEMOTHERAPY REGIMENS WITH A HIGH RISK FOR FEBRILE NEUTROPENIA (>20%)[a]

- ***This list is not comprehensive***; there are other agents/regimens that have a high risk for the development of febrile neutropenia. Regimens recommended in the NCCN Guidelines for Treatment of Cancer by Site are considered when updating this list of examples.
- The type of chemotherapy regimen is only one component of the Risk Assessment. (See Patient Risk Factors for Developing Febrile Neutropenia, MGF-2)
- The exact risk includes agent, dose, and the treatment setting (ie, treatment naive vs. heavily pretreated patients). (See MGF-1)
- In general, dose-dense regimens require MGF support to maintain dose intensity and schedule.

Acute Lymphoblastic Leukemia (ALL)
- Select ALL regimens as directed by treatment protocol (See NCCN Guidelines for ALL)

Bladder Cancer
- Dose-dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)[1]

Bone Cancer
- VAI (vincristine, doxorubicin or dactinomycin, ifosfamide)[2]
- VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide)[3]
- Cisplatin/doxorubicin[4]
- VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin)[5]
- VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)[6]

Breast Cancer
- Dose-dense AC followed by dose-dense paclitaxel (doxorubicin, cyclophosphamide, paclitaxel)[7,b]
- TAC (docetaxel, doxorubicin, cyclophosphamide)[8]
- TC[a,c] (docetaxel, cyclophosphamide)[9]
- TCH[a] (docetaxel, carboplatin, trastuzumab)[10]

Head and Neck Squamous Cell Carcinoma
- TPF (docetaxel, cisplatin, 5-fluorouracil)[11-13]

Hodgkin Lymphoma
- Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine)[14]
- Escalated BEACOPP[d] (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)[15]

Kidney Cancer
- Doxorubicin/gemcitabine[16]

Non-Hodgkin Lymphomas
- CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin
- Dose-adjusted EPOCH[a] (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)[17]
- ICE (ifosfamide, carboplatin, etoposide)[a,18,19]
- Dose-dense CHOP-14[a] (cyclophosphamide, doxorubicin, vincristine, prednisone)[20,21]
- MINE[a] (mesna, ifosfamide, mitoxantrone, etoposide)[22]
- DHAP[a] (dexamethasone, cisplatin, cytarabine)[23]
- ESHAP[a] (etoposide, methylprednisolone, cisplatin, cytarabine)[24]
- HyperCVAD[a] (cyclophosphamide, vincristine, doxorubicin, dexamethasone)[25,26]

Melanoma
- Dacarbazine-based combination with IL-2, interferon alfa (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)[27]

Multiple Myeloma
- DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide)[28] ± bortezomib (VTD-PACE)[29]

Ovarian Cancer
- Topotecan[a,30]
- Docetaxel[31]

Soft Tissue Sarcoma
- MAID (mesna, doxorubicin, ifosfamide, dacarbazine)[32]
- Doxorubicin[a,33]
- Ifosfamide/doxorubicin[34]

Small Cell Lung Cancer[e]
- Topotecan[35]

Testicular Cancer
- VeIP (vinblastine, ifosfamide, cisplatin)[36]
- VIP (etoposide, ifosfamide, cisplatin)
- TIP (paclitaxel, ifosfamide, cisplatin)[37]

See Disease Settings and Chemotherapy Regimens with an Intermediate Risk for Febrile Neutropenia, MGF-A (2 of 5)

[a] Guidelines apply to chemotherapy regimens with or without monoclonal antibodies (eg, trastuzumab, rituximab). There is the potential for increased neutropenia risk with the addition of monoclonal antibodies. Rituximab has been associated with prolonged neutropenia with or without chemotherapy. For details on when monoclonal antibodies are recommended with the regimens listed above in clinical practice, see NCCN Guidelines for Treatment of Cancer by Site.

[b] Growth factor support may not be needed during the paclitaxel portion and can be safely avoided in a large percentage of patients.

[c] Risk for febrile neutropenia has been reported variably as intermediate risk or high risk depending on the study.

[d] Risk of bleomycin-induced pulmonary toxicity may be increased in patients treated with G-CSFs. See Toxicity Risks with MGFs (MGF-C).

[e] Trilaciclib may be used as a prophylactic option to decrease the incidence of chemotherapy-induced myelosuppression when administered before (prophylactic G-CSF may be administered after cycle 1) platinum/etoposide ± immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

References

MGF-A
1 OF 5

Recommendations for the Use of WBC Growth Factors (ASCO, 2015)
Primary prophylaxis with a CSF starting in the first cycle and continuing through subsequent cycles of chemotherapy is recommended in patients who have an approximately20%or higher risk for febrile neutropenia on the basis of patient-, disease-, and treatment related factors. Primary CSF prophylaxis should also be administered in patients receiving dose-dense chemotherapy when considered appropriate.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of filgrastim and its biosimilars are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to filgrastim and its biosimilars include: patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim, administration in the period between 24 hours before and 24 hours after administration of cytotoxic chemotherapy, with simultaneous use with chemotherapy and radiation therapy.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J1442	Injection, filgrastim (g-csf), excludes biosimilars, 1 microgram
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram
J1447	Injection, tbo-filgrastim, 1 microgram
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram
Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram

AVAILABLE DOSAGE FORMS:
Neupogen SOLN 300MCG/ML
Neupogen SOLN 480MCG/1.6ML
Neupogen SOSY 300MCG/0.5ML
Neupogen SOSY 480MCG/0.8ML
Nivestym SOLN 300MCG/ML
Nivestym SOLN 480MCG/1.6ML
Nivestym SOSY300MCG/0.5ML
Nivestym SOSY 480MCG/0.8ML
Zarxio SOSY 300MCG/0.5ML
Zarxio SOSY 480MCG/0.8ML
Granix SOLN 300MCG/ML
Granix SOLN 480MCG/1.6ML
Granix SOSY 300MCG/0.5ML
Granix SOSY 480MCG/0.8ML
Releuko SOLN 300MCG/ML
Releuko SOLN 480MCG/1.6ML
Releuko SOSY 300MCG/0.5ML
Releuko SOSY 480MCG/0.8ML

REFERENCES

1. Neupogen [package insert]. Thousand Oaks, CA; Amgen Inc; April 2023.
2. Zarxio [prescribing information]. Princeton, NJ: Sandoz, Inc.; September 2022.
3. Granix [prescribing information]. Sunnyvale, CA; Pharmacyclics, Inc.; November 2019.
4. Nivestym [prescribing information]. Lake Forest, IL; Pfizer; March 2023.
5. Releuko (filgrastim-ayow) [package insert]. Bridgewater, NY: Amneal Pharmaceuticals LLC; April 2022.
6. National Comprehensive Cancer Network. 2022. Hematopoietic Growth Factors (Version 1.2022). [online] Available at: < growthfactors.pdf (nccn.org)> [Accessed 30 June 2022]
7. Smith, T. J., Bohlke, K., Lyman, G. H., Carson, K. R., Crawford, J., Cross, S. J., … Armitage, J. O. (2015). Recommendations for the Use of WBC Growth Factors: American Society of Clinical Oncology Clinical Practice Guideline Update. Journal of Clinical Oncology, 33(28), 3199–3212. https://doi.org/10.1200/jco.2015.62.3488
8. National Comprehensive Cancer Network. 2023. Hematopoietic Growth Factors (Version 2.2023). [online] Available at: < growthfactors.pdf (nccn.org) > [Accessed 13 June 2023].

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Duration of Approval Quantity Compendial Approved Off-Labeled Uses Appendix Contraindications/Exclusions/Discontinuation Coding/Billing Information Available Dosage Forms References	Q3 2023
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Quantity FDA-Approved Uses Coding/Billing Information Available Dosage Forms References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file