MASSACHUSETTS

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Pharmacy Medical Policy
Supportive Care Treatments for Patients with Cancer

Policy Number: 105
BCBSA Reference Number: None

Related Policies
- Quality Care Dosing guidelines apply to the following medications and can be found in Medical Policy #621
- Blue Cross Blue Shield of Massachusetts' Medicare HMO Blue and Medicare PPO Blue Formulary

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Overview
Effective July 1, 2021, BCBSMA has delegated Medical Utilization Management of Colony Stimulating Factors to AIM Specialty Health for Commercial and Medicare Advantage products.

The National Cancer Quality Program (NCQP) requires prior authorization for Colony Stimulating Factors per the medical necessity criteria reflected in the AIM clinical guideline below (Medical Claims only).

The AIM Clinical Appropriateness Guidelines are based on peer-reviewed literature and recommendations from evidence-based research centers such as (but not limited to): the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN).

Note: Medicare Retail Pharmacy Part D claims are excluded from this program and should be directed to BCBSMA Pharmacy Operations Department at (800) 366-7778.

Policy

Commercial Managed Care (HMO and POS), Commercial PPO/EPO and Medicare Advantage (HMO Blue and PPO Blue)

Please refer to the chart below for the formulary status of the medications affected by this policy.

The following Medications may be approved when there is a contraindication or an adverse reaction to the use of TWO of the Preferred agents listed in the appropriate sections below: Nivestym ® (filgrastim-aafi), Nyvepria ™ (pegfilgrastim-apgf), Neupogen ® (filgrastim), Neulasta ® (pegfilgrastim) or Neulasta ® OnPro® (pegfilgrastim) and relevant medical benefit (clinical appropriateness) criteria is met.

Preferred Drug	Status	Non-Preferred
Granix ® (Tbo-filgrastim) Zarxio ® (filgrastim-sndz)	PA required	Neupogen ® (filgrastim) Nivestym (filgrastim-aafi)
Fulphila ® (pegfilgrastim-jmdb) Udenyca ™(pegfilgrastim-cbqv)	PA required	Neulasta ® / OnPro® (pegfilgrastim) Ziextenzo ™ (pegfilgrastim-bmez) Nyvepria ™ (pegfilgrastim-apgf)
Leukine ® (sargramostim)	PA required	

Neulasta OnPro (pegfilgrastim), may ALSO be approved if **ALL** of the following are met AND the relevant medical benefit criteria is met:

1. The member cannot use preferred product pre-filled syringes due to inability to return to clinic for injection AND does not have access to home health for administration, **AND**
2. A caregiver is present, or the patient has the ability to trouble shoot issues independently, **AND**
3. The patient does not have a secondary need to come to clinic (e.g., for evaluation, hydration, or pump disconnect) and **ONE** of the following is met:
    a. the member lives more than 50 miles from the healthcare facility
    b. the clinic is not open, and the dose cannot be delayed until reopening
    c. the member is wheelchair
    d. the member is stretcher dependent.

Medicare Advantage (HMO Blue and PPO Blue) Part D Pharmacy Benefit Coverage Criteria

To reference the criteria, click Blue Cross Blue Shield of Massachusetts' Medicare HMO Blue and Medicare PPO Blue Formulary.

Commercial Managed Care (HMO and POS), Commercial PPO/EPO and Medicare Advantage (HMO Blue and PPO Blue) Part B Medical Benefit Coverage Criteria

Note: Consideration should be given to equally effective and safe alternative chemotherapy treatment options that do not require colony stimulating factor (CSF) support, when available.

We may cover Fulphila® (pegfilgrastim-jmdb), Granix® (Tbo-filgrastim), Udenyca™ (pegfilgrastim-cbqv), and Zarxio® (filgrastim-sndz) for primary prophylaxis of febrile neutropenia when **ALL** of the following criteria are met:

- The individual has a **non-myeloid malignancy** and is **NOT receiving chemotherapy with radiation concurrently**; **AND**
- Chemotherapy intent must include **ONE** of the following:
    a. Curative intent (for example adjuvant treatment for early-stage disease), **OR**
    b. Intent is survival prolongation, and the **use of a different regimen or dose reduction would reduce the likelihood of reaching the treatment goal, OR**
    c. Intent is symptom management, and the **use of a different regimen or dose reduction would reduce the likelihood of reaching the treatment goal; AND**
- The individual falls into **ONE** of the following risk categories for febrile neutropenia:
    a. High risk of febrile neutropenia **(≥ 20%)** based on chemotherapy regimen risk (per AIM Febrile Neutropenia Risk Guideline), **OR**
    b. Intermediate risk of febrile neutropenia **(≥ 10% but < 20%)** based on chemotherapy regimen risk (per AIM Febrile Neutropenia Risk Guideline), and **at least ONE** of the following significant risk factors:
        I. Age > 65
        II. Poor performance status (ECOG 3 or 4, but chemotherapy still indicated)
        III. Preexisting neutropenia, for example resulting from bone marrow damage or tumor infiltration (ANC < 1500 mm^3)
        IV. Previous febrile neutropenia episode
        V. Liver dysfunction, with bilirubin ≥ 1.0 or liver enzymes ≥ 2x upper limit of normal
        VI. Presence of open wounds or active infections, when chemotherapy cannot be delayed in order to accommodate recovery
        VII. Renal dysfunction with creatinine clearance of less than 50 mL/min
        VIII. Poor nutritional status (baseline albumin less ≤ 3.5 g/dL or BMI less than 20)
        IX. HIV infection (active) requiring ongoing antiviral therapy
        X. High tumor volume and/or high symptom burden from disseminated or unresectable malignancy
        XI. Multiple serious comorbid conditions in addition to the treated malignancy.

We may cover Fulphila® (pegfilgrastim-jmdb), Granix® (Tbo-filgrastim), Udenyca™ (pegfilgrastim-cbqv), and Zarxio® (filgrastim-sndz) for secondary prophylaxis of febrile neutropenia when **ALL** of the following criteria are met:

Secondary prophylaxis of febrile neutropenia is considered clinically appropriate when there has been a previous neutropenic complication (in the absence of primary prophylaxis), and a change to the regimen (including dose reduction, schedule change, or change in therapy) would be expected to compromise patient outcome, particularly in the setting of curative intent.

We may cover Fulphila® (pegfilgrastim-jmdb), Granix® (Tbo-filgrastim), Udenyca™ (pegfilgrastim-cbqv), and Zarxio® (filgrastim-sndz) for adjunctive treatment of febrile neutropenia (primary prophylaxis not given) when **ALL** of the following criteria are met:

Adjunctive treatment of febrile neutropenia is considered clinically appropriate when **ANY** of the following risk factors are present (in the absence of prior growth factor use within the same cycle of treatment):

1. Age > 65
2. Neutrophil recovery is expected to be delayed (greater than 10 days)
3. Neutropenia is profound (less than 0.1 x 10^9)
4. Active pneumonia
5. Sepsis syndrome (hypotension and/or multi-organ damage/dysfunction noted)
6. Invasive fungal or opportunistic infection
7. Onset of fever during inpatient stay.

Note: *Febrile neutropenia is defined as an oral temperature > 38.3°C (101.0°F) or 2 consecutive readings of 38.0°C (100.4°F) for 1 hour, with an absolute neutrophil count less than 500 cells/microL (0.5 x 10^9/L) or less than 1000 cells/microL and expected to fall below 500 cells/microL over the next 48 hours.*

We may cover Granix® (Tbo-filgrastim), and Zarxio® (filgrastim-sndz) for the following indications by growth factor type when the requirements below are met:

1. Acute lymphocytic leukemia (ALL)
    a. After start of induction or first post-remission chemotherapy course; **OR**
    b. As an alternate or adjunct to donor leukocyte infusions (DLI) for relapsed disease after transplant
2. Acute myeloid leukemia (AML)
    a. After induction, reinduction, or consolidation; **OR**
    b. As an alternate or adjunct to donor leukocyte infusions (DLI) for relapsed disease after transplant
3. Aplastic anemia, moderate or severe
4. Hairy cell leukemia
    a. To treat severe neutropenia
5. Hematopoietic stem cell transplant
    a. To promote bone marrow myeloid recovery, **OR**
    b. To treat delayed or failed engraftment, **OR**
    c. To mobilize stem cells for collection by pheresis
6. Myelodysplastic syndrome (MDS)
    a. To treat recurrent infection, **OR**
    b. To treat neutrophil count < 500 mm^3
7. Radiation exposure
    a. Following radiation therapy in the absence of chemotherapy, if prolonged delays are expected, **OR**
    b. After accidental or intentional body irradiation of doses greater than 2 Gy (hematopoietic syndrome of acute radiation syndrome)
8. Support for dose dense or dose intensive chemotherapy in **ANY** of the following scenarios:
    a. Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel, **OR**
    b. High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer; **OR**
    c. Chemotherapy intensification for newly diagnosed localized Ewing sarcoma.

We may cover Fulphila® (pegfilgrastim-jmdb) and Udenyca™ (pegfilgrastim-cbqv) for the following indications by growth factor type when the requirements below are met:

1. Acute lymphocytic leukemia (ALL)
    a. After start of induction or first post-remission chemotherapy course
2. Hematopoietic stem cell transplant
    a. To promote bone marrow myeloid recovery, **OR**
    b. To treat delayed or failed engraftment

3. Myelodysplastic syndrome (MDS)
    a. To treat recurrent infection, **OR**
    b. To treat neutrophil count < 500 mm^3
4. Radiation exposure
    a. After accidental or intentional body irradiation of doses greater than 2 Gy (hematopoietic syndrome of acute radiation syndrome)
5. Support for dose dense chemotherapy in **ANY** of the following scenarios:
    a. Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel, **OR**
    b. High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer; **OR**
    c. Chemotherapy intensification for newly diagnosed localized Ewing sarcoma.

We may cover Leukine® (sargramostim) for the following indications by growth factor type when the requirements below are met:

1. Acute lymphocytic leukemia (ALL)
    a. After start of induction or first post-remission chemotherapy course
2. Acute myeloid leukemia (AML)
    a. After induction, reinduction, for individuals over 55 years of age
3. Hematopoietic stem cell transplant
    a. To promote bone marrow myeloid recovery, **OR**
    b. To treat delayed or failed engraftment, **OR**
    c. To mobilize stem cells for collection by pheresis
4. Myelodysplastic syndrome (MDS)
    a. To treat recurrent infection, **OR**
    b. To treat neutrophil count < 500 mm^3
5. Radiation exposure
    a. After radiation therapy in the absence of chemotherapy, if prolonged delays are expected; **OR**
    b. After accidental or intentional body irradiation of doses greater than 2 Gy (hematopoietic syndrome of acute radiation syndrome)
6. Support for dose dense chemotherapy in **ANY** of the following scenarios:
    a. Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel, **OR**
    b. High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer; **OR**
    c. Chemotherapy intensification for newly diagnosed localized Ewing sarcoma.

The use of multiple WBC growth factor agents for prophylaxis and/or adjunctive treatment within a given chemotherapy cycle is **NOT clinically indicated.**

We do not cover the medications listed above for other conditions not listed above.

Requesting Prior Authorization Information through AIM Specialty Health:

Prior Authorization will be required when the medications are administered using a member's **medical benefit** in these settings:

- A clinician's or physician's office
- A home health care provider
- Outpatient hospital and dialysis settings
- Surgical day care.

To request prior authorization for the following products: Commercial Managed Care (HMO and POS), Commercial PPO/EPO and Medicare Advantage (HMO Blue and PPO Blue) please see instructions below.

1. Through the Blue Cross Blue Shield of Massachusetts website:
   - Log in to your Blue Cross Blue Shield of Massachusetts Provider Central account at www.bluecrossma.com/provider.
   - Click **eTools>AIM Specialty Health**
   - Press **Go Now**
2. Going directly to AIM's *ProviderPortal*℠ (registration required)
   - Go to www.providerportal.com
   - Or calling 1-866-745-1783 (when applicable).

Requesting Prior Authorization Information through BCBSMA under Retail/Specialty Pharmacy:

- All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document.
- Physicians may also call BCBSMA Pharmacy Operations Department at (800) 366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Sources of Clinical Criteria for Review of Requests for Medicare

When considering the multiple sources of clinical criteria for review of requests for Medicare Advantage members, AIM utilizes the following hierarchy to prioritize the criteria applicable to a given request:

- **First: National Coverage Determinations and other CMS guidance** (e.g., Medicare Policy Benefit Manual, Medicare Managed Care Manual, Medicare Claims Processing Manual, and the Medicare Learning Network).
- **Second: Local Coverage Determinations:** If there is no NCD, the clinical reviewers shall apply any applicable LCD. If there is an NCD but also a more specific LCD, then the LCD should be used to determine medical necessity of the request. Any LCAs containing reasonable and medically necessary indications for a particular item or service will be used along with their associated LCDs in order to make a determination.
- **Third: Health Plan Medical Policy:** If there is no applicable Coverage Determination, the clinical staff will apply any applicable Health Plan Medical Policy.
- **Fourth: Evidence-Based Medical Necessity Criteria:** In the absence of any of the above criteria or where the existing guidance provides insufficient clinical detail to help ensure that all approved services are reasonable and necessary, the physician reviewer will make a determination of medical necessity using objective, evidence-based criteria. AIM Guidelines is an internal resource available for commonly requested services.

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration.

CPT Codes / HCPCS Codes / ICD Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

Policy History

Date	Action
6/2021	Special early launch of the new policy implemented for colony stimulating factor agents to align with Quality Care Cancer Program (Medical Oncology). Effective 7/1/2021.

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To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

http://www.bluecrossma.com/common/en_US/medical_policies/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf