MASSACHUSETTS

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Pharmacy Medical Policy
Supportive Care Treatments for Patients with Cancer

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Policy Number: 105

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply to the following medications and can be found in Medical Policy #621A

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Prior Authorization Information

Policy	☒ Prior Authorization ☐ Step Therapy ☒ Quantity Limit	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**2/2024**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ Rx ☒ MED	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below. **Blue Cross Blue Shield of Massachusetts** **Pharmacy Operations Department** 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289 **Individual Consideration for the atypical patient:** Policy for requests that do not meet clinical criteria of this policy, see section	
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary			

• Managed Blue for Seniors with Custom BCBSMA Formulary • Medicare Advantage	labeled Individual Consideration

Summary

Effective July 1, 2021, BCBSMA has delegated Medical Utilization Management of Colony Stimulating Factors to Carelon Medical Benefits Management 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 Carelon MBM clinical guideline below (Medical Claims only).

The Carelon MBM 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

Length of Approval	12 months
Formulary Status	All requests must meet the Prior Authorizations requirement and for non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

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. All non-oncology diagnosis (i.e., Donor Medication use) will be reviewed by Blue Cross Blue Shield and can be found in Policy 033.

The below medications may be approved when there is previous use of, a contraindication to, or an adverse reaction to the use of TWO of the Preferred agents listed in the appropriate sections below and relevant medical benefit (clinical appropriateness) criteria is met.

Drug	Formulary Status (BCBSMA Commercial Plan)	Formulary Requirement
Preferred		
Granix ® (Tbo-filgrastim)	Covered, PA, QCD	PA Required. See criteria below.
Zarxio ® (filgrastim-sndz)	Covered, PA, QCD	

Non-Preferred		
Neupogen ® (filgrastim)	NCNF, PA, QCD	Requires prior use of TWO Preferred medication AND must meet PA criteria below.
N**ivestym** ™ (filgrastim-aafi)	Covered, ST, PA, QCD	
Releuko ™ (filgrastim-ayow)	Covered, PA, QCD	

QCD - Quality Care Dosing (quantity limits policy #621B); PA – Prior Authorization; NFNC – Non-formulary, Non-Covered

Drug	Formulary Status (BCBSMA Commercial Plan)	Formulary Requirement
Preferred		
Ziextenzo ™ (pegfilgrastim-bmez)	Covered, PA, QCD	PA Required. See criteria below.
Neulasta ® **/ OnPro** ® (pegfilgrastim)	Covered, PA, QCD	
Non- Preferred		
Fulphila ® (pegfilgrastim- jmdb)	Covered, PA, QCD	Requires prior use of TWO Preferred medication AND must meet PA criteria below.
Fylnetra ® (pegfilgrastim-pbbk)	Covered, PA, QCD	
Nyvepria ™ (pegfilgrastim-apgf)	Covered, PA, QCD	
Rolvedon ™ (eflapegrastim -xnst)	Covered, PA, QCD	
Stimufend ® (pegfilgrastim-fpgk)	Covered, PA, QCD	
Udenyca ™ (pegfilgrastim-cbqv)	Covered, PA, QCD	

QCD - Quality Care Dosing (quantity limits policy #621B); PA – Prior Authorization

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement
Leukine ® (sargramostim)	Covered, PA	PA required. See below for criteria.

PA – Prior Authorization

Granix (Tbo-filgrastim), Zarxio (filgrastim-sndz), Ziextenzo (pegfilgrastim-bmez), and Neulasta (pegfilgrastim)

Primary Prophylaxis of Febrile Neutropenia

Granix, Zarxio, Ziextenzo, and Neulasta may be considered **MEDICALLY NECESSARY** for primary prophylaxis of febrile neutropenia, when **ALL** of the following criteria are met:

1. The individual has a **non-myeloid malignancy** and is **NOT receiving chemotherapy with radiation concurrently**; **AND**

2. 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**

3. 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 Carelon MBM Febrile Neutropenia Risk Guideline), **OR**
b. Intermediate risk of febrile neutropenia **(≥ 10% but < 20%)** based on chemotherapy regimen risk (per Carelon MBM 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.

Secondary Prophylaxis of Febrile Neutropenia

Granix, Zarxio, Ziextenzo, and Neulasta may be considered **MEDICALLY NECESSARY** for secondary prophylaxis of febrile neutropenia, when **ALL** of the following criteria are met:

1. Previous neutropenic complication (in the absence of primary prophylaxis); **AND**
2. 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.

Adjunctive Treatment of Febrile Neutropenia

Granix, Zarxio, Ziextenzo, and Neulasta may be considered **MEDICALLY NECESSARY** for adjunctive treatment of febrile neutropenia, 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.*

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Covered Indications by Growth Factor Type - Granix (Tbo-filgrastim), and Zarxio (filgrastim-sndz)

We may cover Granix, and Zarxio 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.

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Covered Indications by Growth Factor Type - Ziextenzo (pegfilgrastim-bmez), and Neulasta (pegfilgrastim)

We may cover Ziextenzo, and Neulasta 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.

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Covered Indications by Growth Factor Type - Leukine (sargramostim)

We may cover Leukine 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.

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Requesting Prior Authorization Information

Requesting Prior Authorization Information through Carelon Medical Benefits Management:

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> Carelon Medical Benefits Management**
   - Press **Go Now**
2. Going directly to *Carelon's ProviderPortal*[SM] (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, **Carelon MBM** 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. **Carelon MBM** Guidelines is an internal resource available for commonly requested services.

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications criteria has been met.

Policy History

Date	Action
2/2024	Clarified formulary status within the policy.
1/2024	Moved Fulphila ® to non-preferred.
10/2023	Reformatted Policy and updated IC to align with 118E MGL § 51A.
7/2023	Reformatted Policy.

3/2023	Updated AIM's new name to Carelon MBM.
2/2023	Updated to add Stimufend ® to the policy.
1/2023	Updated to add Rolvedon ™ to the policy.
11/2022	Updated to add Fylnetra ® to the policy.
10/2022	Updated to add a note that Donor requests will come to Blue Cross.
7/2022	Updated to add Ziextenzo ™, and Neulasta ® / OnPro ® to preferred also to move Udenyca ™ to non-preferred.
4/2022	Updated to add Releuko (filgrastim) as non-preferred.
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.

Forms

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

Massachusetts Standard Form for Medication Prior Authorization Requests #434

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