CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Granix (tbo-filgrastim)
BILLING CODE	J1447
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Zarxio QUANTITY LIMIT— N/A
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Granix (tbo-filgrastim) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PREVENTION OF FEBRILE NEUTROPENIA

For **initial** authorization:

1. Member is 18 years of age or older with a non-myeloid malignancy; AND
2. Member must have tried and failed treatment with Zarxio; AND
3. Medication will not be administered within 24 hours of myelosuppressive chemotherapy and will be administered for at least 5 days until neutrophil recovery (ANC ≥1,000/mm^3) up to a maximum of 14 days; AND
4. Chart notes with length of chemotherapy cycle, the days of the cycle on which chemotherapy will be administered, and the day of the cycle on which Granix will be administered, are submitted with prior authorization request; AND
5. Member has a documented history of febrile neutropenia following a previous course of chemotherapy and is receiving myelosuppressive chemotherapy; OR
6. Member is receiving myelosuppressive anti-cancer drugs associated with a high risk (>20%, see Appendix for description) for incidence of febrile neutropenia; OR
7. Member is receiving myelosuppressive anti-cancer drugs associated with at intermediate risk (10-20%, see Appendix for description) for incidence of febrile neutropenia including **one** of the following:
   a) Previous chemotherapy or radiation therapy;
   b) Persistent neutropenia;
   c) Bone marrow involvement with tumor;
   d) Recent surgery and/or open wounds;
   e) Liver dysfunction (bilirubin >2.0);
   f) Renal dysfunction (creatinine clearance <50);
   g) Age >65 years receiving full chemotherapy dose intensity.
8. **Dosage allowed:** 5 mcg/kg per day administered as a subcutaneous injection.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND

2. Chart notes have been provided that show the member is stable or has shown improvement on Granix therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Granix (tbo-filgrastim) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acute myeloid leukemia
- Hematopoietic Subsyndrome of Acute Radiation Syndrome
- Mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplant
- Myeloid recovery following autologous or allogenic bone marrow transplant
- Nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplant
- Severe chronic neutropenia

DATE	ACTION/DESCRIPTION
10/19/2017	New policy for Granix created. Criteria coverage for Prevention of Febrile Neutropenia was expanded. List of not covered diagnoses was added.

References:

1. Granix (tbo-filgrastim) [prescribing information]. North Wales, PA: Teva; February 2017.
2. Del Giglio A, Eniu A, Ganea-Motan D, Tupozov E, Lubenau H. XM02 is superior to placebo and equivalent to Neupogen in reducing the duration of severe neutropenia and the incidence of febrile neutropenia in cycle I in breast cancer patients receiving docetaxel/doxorubicin in chemotherapy. BMC Cancer. 2008;8:332-339. Doi: 10.1186/1471-2407-8-332.

Effective date: 01/01/2018
Revised date: 10/19/2017

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Appendix

Chemotherapy Regimens with a High Risk for Febrile Neutropenia (>20%)

Cancer Type	Regimen
Acute Lymphoblastic Leukemia (ALL)	ALL induction regimens (see NCCN guidelines)
Bladder Cancer	MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) (neoadjuvant, adjuvant, metastatic)
Breast Cancer	Docetaxel + trastuzumab (metastatic or relapsed)
	Dose-dense AC followed by T (doxorubicin, cyclophosphamide, paclitaxel) (adjuvant)
	TAC (docetaxel, doxorubicin, cyclophosphamide) (adjuvant)
Esophageal and Gastric Cancers	Docetaxel/cisplatin/fluorouracil
Hodgkin Lymphoma	BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)
Kidney Cancer	Doxorubicin/gemcitabine
Non-Hodgkin's Lymphoma	ICE (ifosfamide, carboplatin, etoposide) (diffuse large B-cell lymphoma [DLBCL], peripheral T-cell lymphomas [PTCL], 2nd line)
	RICE (rituximab, ifosfamide, carboplatin, etoposide)
	CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab
	MINE (mesna, ifosfamide, novantrone, etoposide) (DLBCL, 2nd line, refractory)
	DHAP (dexamethasone, cisplatin, cytarabine)
	ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine (Ara-C)) (DLBCL, PTCL, 2nd line, recurrent)
	HyperCVAD + rituximab (cyclophosphamide, vincristine, doxorubicin, dexamethasone + rituximab)
Melanoma	Dacarbazine-based combination (dacarbazine, cisplatin, vinblastine) (advanced, metastatic, or recurrent)
	Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alpha) (advanced, metastatic, or recurrent)
Ovarian Cancer	Topotecan
	Paclitaxel
	Docetaxel
Soft Tissue Sarcoma	MAID (mesna, doxorubicin, ifosfammide, dacarbazine)
	Doxorubicin
	Ifosfamide/doxorubicin
Small Cell Lung Cancer	topotecan
Testicular cancer	VelP (vinblastine, ifosfamide, cisplatin)
	VIP (etoposide, ifosfamide, cisplatin)
	BEP (bleomycin, etoposide, cisplatin)

	TIP (paclitaxel, ifosfamide, cisplatin)

National Comprehensive Cancer Network (NCCN): Myeloid Growth Factors, 2016.

Chemotherapy Regimens with an Intermediate Risk of Febrile Neutropenia (10% to 19%)

Cancer Histology	**Regimen**
Occult primary - adenocarcinoma	Gemcitabine/docetaxel
Breast cancer	Docetaxel every 21 days
	CMF classic (cyclophosphamide, methotrexate, fluorouracil) (adjuvant)
	AC (doxorubicin, cyclophosphamide) + sequential docetaxel (adjuvant) (taxane portion only)
	AC + sequential docetaxel + trastuzumab (adjuvant)
	FEC (fluorouracil, epirubicin, cyclophosphamide) + sequential docetaxel
	TC (docetaxel, cyclophosphamide)
Cervical Cancer	Cisplatin/topotecan (recurrent or metastatic)
	Paclitaxel/cisplatin
	Topotecan (recurrent or metastatic)
	Irinotecan (recurrent or metastatic)
Colorectal	FOLFOX (fluorouracil, leucovorin, oxaliplatin)
Esophageal and Gastric Cancers	Irinotecan/cisplatin
	Epirubicin/cisplatin/5-fluorouracil
	Epirubicin/cisplatin/capecitabine
Multiple myeloma	DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophoaphamide/etoposide)
	DT-PACE + bortezomib (VTD-PACE)
Non-Hodgkin's lymphomas	EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) (AIDS-related NHL, Burkitt lymphoma, recurrent, otherr NHL subtypes)
	EPOCH-IT chemotherapy (AIDS-related NHL, DLBCL, recurrent)
	GDP (gemcitabine, dexamethasone, cisplatin) (DLBCL, PTCL, 2nd line)
	GDP (gemcitabine, dexamethasone, cisplatin) + rituximab (DLBCL, 2nd line, Burkitt lymphoma, other NHL subtypes)
	FMR (fludarabine, mitoxantrone, rituximab)
	CHOP + rituximab (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab) including regimens with pegylated liposomal doxorubicin or mitoxantrone substituted for doxorubicin
Non-Small Cell Lung Cancer	Cisplatin/paclitaxel (advanced/metastatic)
	Cisplatin/vinorelbine (adjuvant, advanced/metastatic)
	Cisplatin/docetaxel (adjuvant, advanced/metastatic)
	Cisplatin/etoposide (adjuvant, advanced/metastatic)

	Carboplatin/paclitaxel (adjuvant, advanced/metastatic)
	Docetaxel (advanced/metastatic)
Ovarian Cancer	Carboplatin/docetaxel
Pancreatic Cancer	FOLFIRINOX
Prostate Cancer	Cabazitaxel
Small Cell Lung Cancer	Etoposide/carboplatin
Testicular Cancer	Etoposide/cisplatin
Uterine Sarcoma	Docetaxel (advanced or metastatic)

National Comprehensive Cancer Network (NCCN): Myeloid Growth Factors, 2016.