STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GRANULOCYTE COLONY-STIMULATING FACTORS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-SNDZ	ZARXIO	41814		GPI-10 (8240152060)	
FILGRASTIM	NEUPOGEN	06070		GPI-10 (8240152000)	
PEGFILGRASTIM	NEULASTA	23255		GPI-10 (8240157000)	
PEGFILGRASTIM-JMDB	FULPHILA	45010		GPI-10 (8240157020)	
PEGFILGRASTIM-CBQV	UDENYCA	45445		GPI-10 (8240157010)	
TBO-FILGRASTIM	GRANIX	40426		GPI-10 (8240152070)	
FILGRASTIM-AAFI	NIVESTYM	45154		GPI-10 (8240152010)	
PEGFILGRASTIM-BMEZ	ZIEXTENZO	46183		GPI-10 (8240157005)	
PEGFILGRASTIM-APGF	NYVEPRIA	46612		GPI-10 (8240157002)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

ZARXIO

1. Is Zarxio prescribed by or given in consultation with a hematologist or oncologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is Zarxio prescribed for **ONE** of the following indications?
   - Patients with acute myeloid leukemia (AML) undergoing induction or consolidation chemotherapy treatment
   - Patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) who are experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - Mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis
   - Patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

   If yes, **approve Zarxio for 12 months by HICL or GPI-10.**
   If no, continue to #3.

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GUIDELINES FOR USE - ZARXIO (CONTINUED)

3. Is Zarxio prescribed for a patient with a nonmyeloid malignancy who is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient less than 1 month of age?

   If yes, **approve Zarxio for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Is the patient 1 month of age or older **AND** has had a previous trial of Granix?

   If yes, **approve Zarxio for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

NEUPOGEN

1. Is Neupogen prescribed by or given in consultation with a hematologist or oncologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is Neupogen prescribed for **ONE** of the following indications?
   - Patients with acute myeloid leukemia (AML) undergoing induction or consolidation chemotherapy treatment
   - Patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) who are experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - Mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis
   - Patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
   - Increasing survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)

   If yes, **approve Neupogen for 12 months by HICL or GPI-10.**
   If no, continue to #3.

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GRANULOCYTE COLONY-STIMULATING FACTORS

GUIDELINES FOR USE - NEUPOGEN (CONTINUED)

3. Is Neupogen prescribed for a patient with a nonmyeloid malignancy who is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient less than 1 month of age?

   If yes, **approve Neupogen for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Is the patient 1 month of age or older **AND** has had a previous trial of Granix?

   If yes, **approve Neupogen for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

NEULASTA

1. Is Neulasta prescribed by or given in consultation with a hematologist or oncologist for **ONE** of the following indications?
   - Patients with a nonmyeloid malignancy who is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - Increasing survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)

   If yes, **approve Neulasta for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

FULPHILA

1. Is Fulphila prescribed by or given in consultation with a hematologist or oncologist for the following indication?
   - Patients with a nonmyeloid malignancy who is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

   If yes, **approve Fulphila for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GRANULOCYTE COLONY-STIMULATING FACTORS

GUIDELINES FOR USE (CONTINUED)

UDENYCA OR ZIEXTENZO

1. Is Udenyca or Ziextenzo prescribed by or given in consultation with a hematologist or oncologist for the following indication?
   - Patients with a nonmyeloid malignancy who is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

     If yes, **approve Udenyca or Ziextenzo for 12 months by HICL or GPI-10.**
     If no, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

GRANIX

1. Is Granix prescribed by or given in consultation with a hematologist or oncologist for the following indication?
   - Adult and pediatric patients 1 month of age and older with a nonmyeloid malignancy who is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

     If yes, **approve Granix for 12 months by HICL or GPI-10.**
     If no, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

NIVESTYM

1. Is Nivestym prescribed by or given in consultation with a hematologist or oncologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is Nivestym prescribed for **ONE** of the following indications?
   - Patients with acute myeloid leukemia (AML) undergoing induction or consolidation chemotherapy treatment
   - Patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) who are experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - Patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

     If yes, **approve Nivestym for 12 months by HICL or GPI-10.**
     If no, continue to #3.

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GUIDELINES FOR USE - NIVESTYM (CONTINUED)

3. Is Nivestym prescribed for a patient with a nonmyeloid malignancy who is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient less than 1 month of age?

   If yes, **approve Nivestym for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Is the patient 1 month of age or older **AND** has had a previous trial of Granix?

   If yes, **approve Nivestym for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

NYVEPRIA

1. Is Nyvepria prescribed by or given in consultation with a hematologist or oncologist for the following indication?
   - Patients with a nonmyeloid malignancy who is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

   If yes, **approve Nyvepria for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GRANULOCYTE COLONY-STIMULATING FACTORS

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GRANULOCYTE COLONY-STIMULATING FACTORS (GCSF)** requires the following rule(s) be met for approval:

A. The requested medication is prescribed by or recommended by a hematologist (blood doctor) or oncologist (cancer/tumor doctor)
B. **Requests for Zarxio also require ONE of the following:**
   1. You have acute myeloid leukemia (blood and bone marrow cancer with too many immature white blood cells) undergoing induction or consolidation chemotherapy treatment (you're starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   2. You have a nonmyeloid malignancy and are undergoing myeloablative chemotherapy (high-dose chemotherapy that kills cells in the bone marrow) followed by bone marrow transplantation and are experiencing neutropenia (low count of a type of white blood cell) and/or neutropenia-related clinical symptoms such as febrile neutropenia
   3. You are using the requested drug for mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   4. You have congenital neutropenia (low number of a type of white blood cell), cyclic neutropenia, or idiopathic neutropenia
   5. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and you are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect the bone marrow and cause low levels of a type of white blood cell) with fever. If you are 1 month of age or older, you must also have previously tried Granix for this indication.

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GRANULOCYTE COLONY-STIMULATING FACTORS

GUIDELINES FOR USE (CONTINUED)

C. **Requests for Neupogen also require ONE of the following:**
   1. You have acute myeloid leukemia (blood and bone marrow cancer with too many immature white blood cells) undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   2. You have a nonmyeloid malignancy and are undergoing myeloablative chemotherapy (high-dose chemotherapy that kills cells in the bone marrow) followed by bone marrow transplantation (BMT) and you are experiencing neutropenia (low count of a type of white blood cell) and/or neutropenia-related clinical symptoms such as febrile neutropenia)
   3. You are using the requested drug for mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   4. You have congenital neutropenia (low number of a type of white blood cell), cyclic neutropenia, or idiopathic neutropenia
   5. You are using the requested drug for increasing survival if you have been acutely exposed to myelosuppressive doses of radiation (you have radiation that affects your blood and bone marrow such as Hematopoietic Syndrome of Acute Radiation Syndrome)
   6. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever. If you are 1 month of age or older, you must have previously tried Granix for this indication

D. **Requests for Neulasta also requires ONE of the following:**
   1. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever
   2. You are using the requested drug for increasing survival if you have been acutely exposed to myelosuppressive doses of radiation (you have radiation that affects your blood and bone marrow such as Hematopoietic Syndrome of Acute Radiation Syndrome

E. **Requests for Fulphila, Nyvepria, Udenyca, or Ziextenzo also requires the following:**
   1. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever

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GRANULOCYTE COLONY-STIMULATING FACTORS

GUIDELINES FOR USE (CONTINUED)

F. **Requests for Granix also requires the following:**
   1. You are 1 month of age or older
   2. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever

G. **Requests for Nivestym also requires ONE of the following:**
   1. You have acute myeloid leukemia (blood and bone marrow cancer with too many immature white blood cells) undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   2. You have a nonmyeloid malignancy and are undergoing myeloablative chemotherapy (high-dose chemotherapy that kills cells in the bone marrow) followed by bone marrow transplantation and are experiencing neutropenia (low count of a type of white blood cell) and/or neutropenia-related clinical sequelae (symptoms such as febrile neutropenia)
   3. You are using the requested drug for mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   4. You have congenital neutropenia (low number of a type of white blood cell), cyclic neutropenia, or idiopathic neutropenia
   5. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever. If you are 1 month of age or older, you must also have previously tried Granix for this indication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GRANULOCYTE COLONY-STIMULATING FACTORS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Granulocyte Colony-Stimulating Factors.

REFERENCES

- Fulphila [Prescribing Information]. Zurich, Switzerland: Mylan GmbH; June 2018.
- Zarxio [Prescribing Information]. Princeton, NJ: Sandoz Inc.; December 2017.
- Granix [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals; July 2018.
- Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; June 2018.
- Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; June 2018.
- Nivestym [Prescribing Information]. Lake Forest, IL: Pfizer (Hospira); July 2018.
- Nyvepria [Prescribing Information]. New York, NY: Pfizer; June 2020.
- Udenyca [Prescribing Information]. Redwood City, CA: Coherus BioSciences Inc.; November 2018.
- Ziextenzo [Prescribing Information]. Princeton, NJ: Sandoz Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 02/03
Client Approval: 12/20
P&T Approval: 07/20