



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-AYOW

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-AYOW	RELEUKO	47848		GPI-10 (8240152015)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?

- The patient has a nonmyeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
- The patient has acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
- The patient has a nonmyeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
- The requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- The patient has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
- The requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?

- Therapy is prescribed by or in consultation with a hematologist or oncologist
- The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

If yes, **approve 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.

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-AYOW

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 **FILGRASTIM-AYOW (Releuko)** requires the following rule(s) be met for approval:

- A. The request is for ONE of the following:
1. You have a nonmyeloid malignancy (a type of cancer) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
 2. You have acute myeloid leukemia (AML: a type of blood cancer) and are 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)
 3. You have a nonmyeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
 4. You will be using Releuko for mobilization of autologous hematopoietic progenitor cells into the 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)
 5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low amount of a type of white blood cell at birth, in cycles, or due to unknown cause)
 6. You will be using Releuko to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)
- B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
- C. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym (filgrastim-aafi)

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.

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FILGRASTIM-AYOW

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Releuko and Neupogen.

REFERENCES

- Releuko [Prescribing Information]. Piscataway, NJ: Kashiv BioSciences, LLC; October 2022.
- Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/23

Created: 05/22

Client Approval: 05/23

P&T Approval: 04/23