Releuko® (filgrastim-ayow)

Now Approved
with Pass-through Status

- Biosimilar to Neupogen®
- Made in the U.S.A.
- Preservative free
- Covered by Amneal PATHways® patient support program
- CMS Outpatient Prospective Payment System (OPPS) pass-through indicator status of G

Unit of Sale	Unit of Sale NDC	Inner NDC	Quantity	List (WAC) Price[1]
300 mcg/0.5 mL	70121-1568-01	70121-1568-01	1 Prefilled Syringe	$159.00
	70121-1568-07	70121-1568-01	10 Prefilled Syringes	$1,590.00
300 mcg/mL	70121-1569-07	70121-1569-01	10 Single-dose Vial	$1,590.00
480 mcg/0.8 mL	70121-1570-01	70121-1570-01	1 Prefilled Syringe	$254.40
	70121-1570-07	70121-1570-01	10 Prefilled Syringes	$2,544.00
480 mcg/1.6 mL (300 mcg/mL)	70121-1571-07	70121-1571-01	10 Single-dose Vial	$2,544.00

HCPCS Code[2]	Descriptor
Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram

Pack sizes and presentations available at launch may vary.

IMPORTANT SAFETY INFORMATION

Indications and Usage

Releuko® is a leukocyte growth factor indicated to:

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
- Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
- Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
- Reduce the incidence and duration of sequelae of severe neutropenia, (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

Releuko is not indicated to:

- Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)

Contraindications

Patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim products.

1. Wholesale Acquisition Cost (WAC) as of 9/30/2022
2. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations; Second Quarter, 2022 HCPCS Coding Cycle

amneal

Storage & Handling

Store Releuko® refrigerated at 2°C to 8°C (36°F to 46°F) in the original pack to protect from light.
Do not leave Releuko in the direct sunlight. DO NOT freeze Releuko.
Avoid shaking. Transport via pneumatic tube has not been studied.

Amneal PATHways Patient Access To Health

1-866-4AMNEAL (426-6325)

Amneal is pleased to offer reimbursement access and patient support services through the PATHways program.

PATHways Patient Access Specialists are available to assist healthcare providers and patients with:

- Benefit investigation
- Prior authorization support
- Affordability options like co-pay savings
- Claims assistance

Call toll-free Monday through Friday, 8 AM to 8 PM ET.

IMPORTANT SAFETY INFORMATION (continued)

Before you take Releuko® (filgrastim-ayow) injection, tell your healthcare provider if you are pregnant or plan to breast feed, and if you have sickle cell disorder, kidney problems or receiving radiation therapy.

Warnings and Precautions

- Fatal splenic rupture: Patients may experience enlarged spleen which can rupture and cause death.
- Acute respiratory distress syndrome (ARDS): Patients may develop fever and lung infiltrates or respiratory distress for ARDS. Discontinue Releuko in patients with ARDS.
- Fatal sickle cell crises: Serious sickle cell crises have been reported in patients with sickle cell disorders receiving Releuko. Discontinue Releuko if sickle cell crisis occurs.
- Serious allergic reactions, including anaphylaxis: Permanently discontinue Releuko in patients with serious allergic reactions.
- Kidney injury (Glomerulonephritis): Kidney injury have been reported in patients on Releuko. Consider dose-reduction or interruption of Releuko in patients with kidney injury.
- Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML): Monitor patients with breast and lung cancer using Releuko in conjunction with chemotherapy and/or radiotherapy for signs and symptoms of MDS/AML.
- Decreased platelet count (thrombocytopenia); increased white blood cell count (leukocytosis) and inflammation of your blood vessels (cutaneous vasculitis) have been reported. Monitor platelet counts and white blood cell count.

Adverse Reactions

Most common adverse reactions in patients:

- With nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs are pyrexia, pain, rash, cough, and dyspnea.
- With AML are pain, epistaxis and rash.
- With nonmyeloid malignancies undergoing myeloablative chemotherapy followed by Bone Marrow Transplant is rash.
- With severe chronic neutropenia are pain, anemia, epistaxis, diarrhea, hypoesthesia and alopecia.

Visit Releuko.us for full Prescribing Information.

Releuko® (filgrastim-ayow)

amneal

Order from your wholesaler or contact Amneal: Toll Free 866.525.7270 | CustomerRelations@amneal.com

RELPS-05 11.23.22