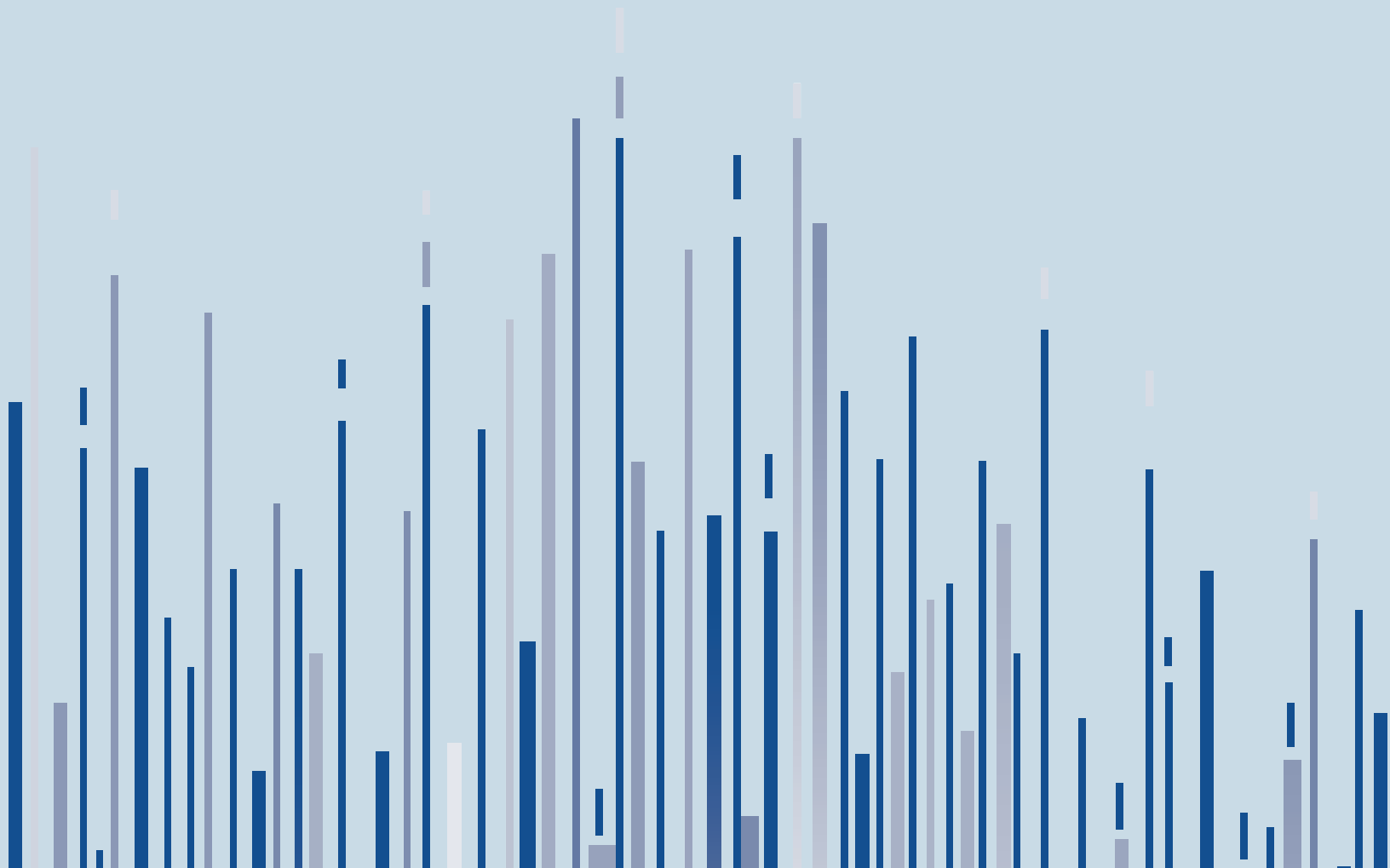


Coding and Billing Guide for **RELEUKO**[®] (filgrastim-ayow)



Disclaimer



This guide was developed by Amneal to support healthcare professionals (HCPs) in assisting their patients to access therapy with Releuko® (filgrastim-ayow) in physician offices and hospital outpatient clinics. It is provided for informational purposes and is not intended as legal advice or to guarantee reimbursement for any product or service. Payer guidance changes frequently and varies by health insurance plan. Contact the **Amneal PATHways®** Patient Support Program or payers directly to confirm the latest coding, billing, and coverage guidance. Information reported to payers should be substantiated by the services that are rendered and documented in the patient's medical record. The information here is current as of December 2022.

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. Before you take RELEUKO®, 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.

Table of Contents

Support for Patient Access	4
Coding	5
Diagnosis	5
Physician Office Setting	7
Drug	7
Professional Services	9
Sample CMS-1500 Claim Form	10
Hospital Outpatient Department Setting	11
Drug	11
Professional Services	14
Sample CMS-1450 Claim Form	15
Coverage	16
Fee-for-Service Medicare	16
Other Payers	16
Reimbursement	17
References	18

Support for Patient Access



The **Amneal PATHways**® Patient Support Program walks beside your patients on the path to more accessible and affordable treatment.



There are 3 ways to get started:



Download or print a patient enrollment form at <https://amnealbiosciences.com/support/> and fax it to the number provided on the form



Call 1-866-4-AMNEAL (1-866-426-6325) Monday–Friday, 8 AM–8 PM ET, for live support



Log onto the secure **Amneal PATHways**® Provider Portal at <https://www.pathwaysproviderportal.com/> (First-time users must register)

Available Support

- Benefit investigation
- Prior authorization research
- Coding and billing information
- Claims assistance
- Appeals assistance
- Field reimbursement specialists
- Replacement program
- Sample letters of medical necessity and appeal
- Affordability programs
 - Commercial copay support
 - Patient assistance program
 - Alternate coverage research



Learn more at <https://amnealbiosciences.com/support/>

Coding



Diagnosis

The following International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes may be appropriate to report the patient's medical condition. Codes should be billed to the maximum specificity—or greatest number of alpha-numeric characters—available. Payer guidance regarding diagnosis coding varies. For example, payers may require different primary, secondary—or even more—diagnosis codes on claims to help substantiate medical necessity for treatment with Releuko. Please note the sample list provided below is not all-inclusive; other codes could apply. You can review payer-specific coverage policies by calling the number on the back of the patient's insurance card and by checking plan websites. You can also contact **Amneal PATHways®** at 1-866-4-AMNEAL (1-866-426-6325) for additional information.

Sample Diagnosis Coding for Releuko

Indication ¹	ICD-10-CM Code Range Descriptor	ICD-10-CM Code Range ²
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	Nonmyeloid malignancies	C00.0–C96.9
	Neutropenia	D70.0–D70.9
	Fever	R50.2–R50.9
	Certain infections and parasitic diseases	A00.0–B99.9
	Adverse effect of antineoplastic and immunosuppressive drug	T45.1X5A–T45.1X5S
	Other complications following infusion, transfusion, and therapeutic injection	T80.89XA–T80.89D
Reduce the time to neutrophil recovery and the duration of fever following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia	Acute myeloid leukemia	C92.00–C92.02
		C92.30–C92.32
		C92.40–C92.42
		C92.50–C92.52
		C92.60–C92.62
		C92.90–C92.92
		C92.A0–C92.A2
		C92.Z0–C92.Z2
	Fever	R50.2–R50.9
Adverse effect of antineoplastic and immunosuppressive drug	T45.1X5A–T45.1X5S	
Other complications following infusion, transfusion, and therapeutic injection	T80.89XA–T80.89D	

Coding

Sample Diagnosis Coding for Releuko (cont.)

Indication ¹	ICD-10-CM Code Range Descriptor	ICD-10-CM Code Range ²
Reduce the duration of neutropenia and neutropenia-related clinical sequelae (eg, febrile neutropenia) in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation	Bone marrow transplantation	T86.03 Z48.290 Z76.82 Z94.81
	Nonmyeloid malignancies	C00.0–C96.9
	Neutropenia	D70.0–D70.9
	Fever	R50.2–R50.9
	Adverse effect of antineoplastic and immunosuppressive drugs	T45.1X5A– T45.1X5S
	Other complications following infusion, transfusion, and therapeutic injection	T80.89XA–T80.89D
	Reduce the incidence and duration of sequelae of severe neutropenia (eg, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia	Neutropenia
Fever		R50.2–R50.9
Certain infections and parasitic diseases		A00.0–B99.9
Oropharyngeal ulcers		K12.30–K12.39

Physician Office Setting

This section covers **coding for the physician office site of care**. Facilities should skip to pages [11-15](#).



Drug

Releuko is reported on medical claims using the product-specific Healthcare Common Procedure Coding System (HCPCS) billing code:

Suggested HCPCS Code for Releuko

HCPCS ^{3,4}	Description	Comments
Q5125	Q5125 Injection, filgrastim-ayow, biosimilar (Releuko), 1 mcg	Use for dates of service starting October 1, 2022, in physician offices

The HCPCS code should be reported in Item 24D of the CMS-1500 Claim Form (or its electronic equivalent), along with the appropriate number of units.



When billing Releuko, 1 billing unit is equal to 1 microgram of Releuko.

Medicare and many other payers allow HCPs to bill the entire amount of medication taken from a single-use vial, even if some of the drug was discarded after the patient received a clinically appropriate dosage. The following should be reported on separate lines of the claim form^{5,6}:

- The amount of product given to the patient
- The amount of product that was discarded (also known as “wastage”)



The total amount eligible for reimbursement is equivalent to the quantity indicated on the vial.

Medicare requires use of modifier -JW to identify unused drug from a single-use vial that is appropriately discarded. The modifier should be listed in Item 24D, next to Releuko’s HCPCS code, on a separate line of the claim, along with the amount of discarded drug. HCPs must record the amount that was discarded in the patient’s medical record. If no drug has been discarded from a single-use vial, Medicare requires use of modifier -JZ.^{5,6}

Modifiers to Report Amount of Drug Discarded/Not Discarded From a Single-Use Vial

Modifier	Descriptor	Placement
-JW	Drug amount discarded/not administered to any patient	In Item 24D, added to Q5125, on the same line of the claim indicating the amount of drug that was discarded from a single-use vial. The amount administered to the patient should go on a separate line of the claim form
-JZ*	Zero drug amount discarded/not administered to any patient	In Item 24D, added to Q5125, when no amount of drug was discarded from a single-use vial

*Modifier -JZ is effective January 1, 2023, but will not be required on claims until July 1, 2023.

Other modifiers may be applicable. Modifiers are subject to change so check with individual payers to confirm the latest guidance.

Please see [Full Prescribing Information](#), including Important Safety Information, for RELEUKO.

Payers commonly request that HCPs use a National Drug Code (NDC), in combination with the appropriate HCPCS code, on medical claims to help identify the product^{7,8}:

Releuko NDCs

Package Size	Dosage Strength	11-Digit NDC ¹
1 x 0.5 mL prefilled syringe	300 mcg/0.5 mL	70121-1568-01
1 x 0.8 mL prefilled syringe	480 mcg/0.8 mL	70121-1570-01
1 x 1 mL single-dose vial	300 mcg/1 mL	70121-1569-01
1 x 1.6 mL single-dose vial	480 mcg/1.6 mL	70121-1571-01

General billing guidance suggests HCPs should use the shaded area of Item 24A on the CMS-1500 Claim Form to list the product's NDC, along with other qualifiers. Payers may require other supplemental information not reflected here^{7,8}:

Example Format for Reporting Releuko's NDC on the CMS-1500 Claim Form

Information Type	Format	Position
Qualifier	N4	In front of NDC
NDC	70121157001	After N4 qualifier. Use the 11-digit version of the NDC. Do not enter a space between the qualifier and the NDC. Do not enter hyphens or spaces within the NDC
Units/basis of measurement qualifier	ML	After the NDC. Add 1 space between the NDC and the unit of measurement qualifier
Quantity	0.8	Immediately after the unit of measurement qualifier. Please note you will need to adjust the quantity based on the amount administered and any amount discarded (which, together, should total the full quantity of 0.8 mL).

The example below shows a patient who received 0.583 mL of Releuko. The HCP discarded 0.217 mL – equivalent to the amount left over from the 0.8 mL single-use vial.

Sample Format for Reporting Releuko's NDC in Shaded Area of Item 24A

	24. A. DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG
	From			To				
	MM	DD	YY	MM	DD	YY		
1	N470121157001	ML0.583					11	
2	N470121157001	ML0.217					11	
3							11	
4								

Professional Services

These Current Procedural Terminology (CPT®*) codes may be appropriate to report professional services associated with administering the product:

Product Administration for Releuko

CPT ^{9,*}	Descriptor	May be appropriate if:
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Releuko is administered subcutaneously
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	The intravenous infusion time is ≤15 minutes and is the key reason for the encounter
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (list separately in addition to code for primary procedure)	The intravenous infusion time is ≤15 minutes and is NOT the key reason for the encounter
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	The intravenous infusion time is 16-90 minutes and is the key reason for the encounter
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (list separately in addition to code for primary procedure)	The intravenous infusion time is 16-90 minutes and is NOT the key reason for the encounter
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion	If the intravenous infusion is continuous. NOTE: A medical record note is typically required with the claim as supporting documentation

*CPT Copyright 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

Sample CMS-1500 Claim Form

Services rendered in physician offices are billed using the CMS-1500 claim form (electronic claim file 837P). This sample claim form shows potential coding for a patient who received Releuko in a physician office.

ITEM 21 DIAGNOSIS

Enter the appropriate diagnosis code, eg:

- ICD-10-CM: D70.4 for *cyclic neutropenia*; final code depends on medical record documentation

Note: Other diagnosis codes may apply

ITEM 24A DATE(S) OF SERVICE

Enter NDC in the shaded area above the date:

- The “N4” qualifier is required before the NDC
- Follow NDC with a space, then the unit of measure qualifier and quantity
- Adjust quantity for amounts administered and discarded; these should total the same amount listed on the single-use vial

Note: Check payer requirements and format for reporting NDCs

24. A. DATE(S) OF SERVICE										B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES		E. DIAGNOSIS POINTER	F. \$ CHARGES		G. DAYS OR UNITS	H. EPSTD Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #		
From	To	MM	DD	YY	MM	DD	YY	MM	DD	YY	MM	DD	YY	MM	DD	YY	MM	DD	YY	MM	DD	YY
1	N470121157001	ML0.583																				
2	N470121157001	ML0.217																				
3																						

ITEM 24D PROCEDURES/SERVICES/SUPPLIES

Enter the appropriate CPT/HCPCS codes and modifiers, eg:

- Drug: Q5125 for Releuko Injection per 1 mcg
- Modifier: -JW for discarded drug
- Administration: 96372 for injection procedure

Note: Other codes may apply

ITEM 24E DIAGNOSIS POINTER

Enter the letter (A-L) that corresponds to the diagnosis in Item 21A

ITEM 24G UNITS

Enter the appropriate number of units of service, eg:

- For Q5125, 1 billing unit is equal to 1 mcg of Releuko. Use separate lines on claim to denote amount administered and amount discarded
- For 96372, 1 unit represents 1 subcutaneous injection

Hospital Outpatient Department Setting

This section covers **coding for the hospital outpatient department** site of care. Physician offices should refer to pages [7-10](#).



Drug

Releuko is reported on medical claims using the product-specific Healthcare Common Procedure Coding System (HCPCS) billing code:

Suggested HCPCS Code for Releuko

HCPCS ^{3,4}	Description	Comments
Q5125	Q5125 Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg	Use for dates of service starting October 1, 2022, in hospital outpatient clinics



Please note the code descriptor for Q5125 specifies that 1 billing unit is equal to 1 microgram of Releuko.

Medicare and many other payers allow HCPs to bill the entire amount of medication taken from a single-use vial, even if some of the drug was discarded after the patient received a clinically appropriate dosage. The following should be reported on the claim form, on separate lines⁶:

- The amount of product given to the patient
- The amount of product that was discarded (also known as “wastage”)



The total amount eligible for reimbursement is equivalent to the quantity indicated on the vial.

Medicare requires use of modifier -JW to identify unused drug from a single-use vial that is appropriately discarded. The modifier should be billed on a separate line of the claim along with the amount of discarded drug. HCPs must record the amount that was discarded in the patient’s medical record. If no drug has been discarded, Medicare requires use of modifier -JZ.

Modifiers to Report Amount of Drug Discarded/Not Discarded From a Single-Use Vial^{5,6,10}

Modifier	Descriptor	Placement
-JW	Drug amount discarded/not administered to any patient	Added to Q5125 on the same line of the claim indicating the amount of drug that was discarded from a single-use vial
-JZ*	Zero drug amount discarded/not administered to any patient	Added to Q5125, when no amount of drug was discarded from a single-use vial

*Modifier -JZ is effective January 1, 2023, but will not be required on claims until July 1, 2023.

The Centers for Medicare & Medicaid Services (CMS) has determined that Releuko should be reported with the following modifier when it is acquired via the 340B Drug Pricing Program¹⁰:

Modifier to Indicate Releuko's 340B Acquisition Status

Modifier	Descriptor	Placement
-TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities	Added to Q5125

Claims for Releuko may be subject to other coding requirements, such as additional modifiers. Modifiers are subject to change.

Payers commonly request that HCPs use a National Drug Code (NDC), along with an appropriate HCPCS code, on medical claims to help identify the product¹¹:

Releuko NDCs

Package Size	Dosage Strength	11-Digit NDC ¹
1 x 0.5 mL prefilled syringe	300 mcg/0.5 mL	70121-1568-01
1 x 0.8 mL prefilled syringe	480 mcg/0.8 mL	70121-1570-01
1 x 1 mL single-dose vial	300 mcg/mL	70121-1569-01
1 x 1.6 mL single-dose vial	480 mcg/1.6 mL	70121-1571-01

General billing guidance suggests HCPs should use Form Locator (FL) 43 on the CMS-1450 Claim Form to list the product's NDC, along with other qualifiers. The NDC quantities should reflect the amounts administered and discarded. Keep in mind that payers may require other supplemental information not reflected here¹¹:

Example Format for Reporting Releuko's NDC on the CMS-1450 Claim Form

Information Type	Format	Position
Qualifier	N4	In front of NDC
NDC	70121157001	After N4 qualifier. Use the 11-digit version of the NDC. Do not enter a space between the qualifier and the NDC. Do not enter hyphens or spaces within the NDC
Units/basis of measurement qualifier	ML	After the NDC. Add 1 space between the NDC and the unit of measurement qualifier
Quantity	0.8	Immediately after the unit of measurement qualifier. You will need to adjust the quantity based on the amount administered and any amount discarded (which, together, should total the full quantity of 0.8 mL)

The example below shows a patient who received 0.583 mL of Releuko. The HCP discarded 0.217 mL – equivalent to the amount left over from the 0.8 mL single-use vial.

Sample Format for Reporting Releuko’s NDC in FL 43¹¹

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE
1	0636	N470121157001 ML0.583 RELEUKO	Q5125 TB
2	0636	N470121157001 ML0.217 RELEUKO	Q5125 JW TB
3			
4			
5			
6			

Payers may also ask for a revenue code¹¹ or codes in FL 42. The actual codes vary by payer. Medicare guidance allows HCPs to enter a corresponding narrative description or standard abbreviation for each revenue code listed in FL 42 on the adjacent line in FL 43. The additional description in FL 43, while not required, assists with clerical review. Below is a sample revenue code that may be accepted by some Medicare contractors to report use of Releuko¹²:

Sample Revenue Code for Drug Billing¹²

Revenue Code ¹²	Descriptor	Placement
0636	N470121157001 ML0.8 Releuko	Form Locators 42-43

Professional Services

These Current Procedural Terminology (CPT®*) codes may be appropriate to report professional services associated with administering the product:

Product Administration for Releuko

CPT ⁹	Description	May be appropriate if:
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Releuko is administered subcutaneously
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	The intravenous infusion time is ≤15 minutes
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/ drug (list separately in addition to code for primary procedure)	The intravenous infusion time is ≤15 minutes
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	The intravenous infusion time is 16-90 minutes
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (list separately in addition to code for primary procedure)	The intravenous infusion time is 16-90 minutes
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion	If the intravenous infusion is continuous. NOTE: A medical record note is typically required with the claim as supporting documentation

*CPT Copyright 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

Payers may also adopt different revenue codes. The following revenue codes may be appropriate to report Releuko's administration in the hospital outpatient department setting to some Medicare contractors¹²:

Revenue Code for Billing Drug Administration Service¹²

Revenue Code ¹²	Descriptor	Placement
0940	Subcutaneous injection	Form Locators 42-43

Sample CMS-1450 Claim Form

Services rendered in outpatient facilities including hospital outpatient departments are billed using the CMS-1450 institutional claim form (electronic claim file 837I). This sample claim form shows potential coding for a patient who received Releuko in a hospital outpatient department.

FL 42 Revenue Code
Enter the appropriate revenue code, eg:

- 0636 for Releuko
- 0940 for subcutaneous injection

Note: Other revenue codes may apply

42 REV. CL.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0636	N470121157001 ML0.583 RELEUKO	Q5125 TB	MMDDYY	350	XXX XX		1
0636	N470121157001 ML0.217 RELEUKO	Q5125 JW TB	MMDDYY	130	XXX XX		2
0940	Subcutaneous Injection	96372	MMDDYY	1	XXX XX		3

FL 43 Revenue Description
Enter revenue code descriptor:

- For drug, enter the "N4" qualifier and NDC, followed by a space and the unit of measure.
- Enter quantity adjusted by amount administered and amount discarded; together, these should total the quantity listed on the single-use vial

Note: Check payer requirements and format for reporting NDCs

FL 44 HCPCS
Enter appropriate CPT/HCPCS codes and modifiers, such as:

- Drug: Q5125 for RELEUKO per 1 mcg
- Modifier: -JW for discarded drug
- Modifier: -TB if acquired via 340B
- Administration: 96372 for injection procedure

FL 46 Units of Service
Enter the appropriate number of units of service:

- For Q5125, 1 billing unit is equal to 1 mcg of Releuko. Use separate lines on claim for amount administered and amount discarded
- For 96372, 1 unit represents 1 subcutaneous injection

PAGE ____ OF ____ CREATION DATE TOTALS →

50 PAYER NAME		51 HEALTH PLAN ID		52 REL INFO	53 ASG BEN	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI
58 INSURED'S NAME		59 P.REL		60 INSURED'S UNIQUE ID		61 GROUP NAME		57 OTHER PRV ID
63 TREATMENT AUTHORIZATION CODES		65 EMPLOYER NAME						
66 DX	68							
69 ADMIT DX	70 PATIENT REASON DX	71 PPS CODE		72 ECI	73			
74 PRINCIPAL PROCEDURE CODE	75 OTHER PROCEDURE CODE	76 ATTENDING NPI	77 OPERATING NPI	QUAL		FIRST		
74 PRINCIPAL PROCEDURE DATE		75 OTHER PROCEDURE DATE		76 ATTENDING NPI		77 OPERATING NPI		
74 PRINCIPAL PROCEDURE DATE		75 OTHER PROCEDURE DATE		76 ATTENDING NPI		77 OPERATING NPI		

FL 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis
Enter the appropriate diagnosis code, eg:

- ICD-10-CM: D70.4 for *cyclic neutropenia*; final code depends on medical record documentation

Note: Other diagnosis codes may apply

66 DX: D70.4

Coverage



Fee-for-Service Medicare

Releuko and its administration procedure are generally covered under the Medicare Part B benefit when the product is¹³:

- Administered for a medically accepted purpose
- Administered in outpatient settings including physician offices and hospital outpatient departments
- Not usually self-administered
- Acquired via buy and bill, meaning that it represents an expense to the physician practice or facility where it is administered
- Administered under the supervision of a qualified HCP

Other Payers



Payers including private commercial insurers, Medicare Advantage (Medicare managed care), and Medicaid may cover Releuko under a medical benefit, prescription drug benefit, or both.

Most will also cover the drug administration procedure under a medical plan benefit.

Payers frequently change coverage policies, so it is helpful to verify a patient's health insurance plan coverage prior to administering Releuko. Key information to check includes:

- Whether the plan requires prior authorization, and, if so, the associated requirements (eg, how to submit a request, required documentation, etc)
 - Consider whether the patient may have an existing prior authorization on file for the reference drug or another biosimilar that needs to be updated
- If the plan allows product acquisition via buy and bill
- If the plan allows product acquisition via the specialty pharmacy channel, and, if so, which specialty pharmacies are considered to be in network with the patient's plan
- Published coverage guidance
- Coding or claims submission requirements
- Patient's out-of-pocket financial responsibility

Reimbursement

Most payers offer separate reimbursement for Releuko and its administration procedure. Actual payment amounts vary based on multiple factors, including:

- The patient’s individual health insurance plan benefit
- Where the patient receives care
- Whether the product is acquired via buy and bill or another way, such as through a pharmacy (specialty or retail)
- Whether the payer believes the treatment was medically necessary
- The payer’s method for determining reimbursement

The following offers a high-level overview of potential payment methodologies for Releuko:

Reimbursement Scenarios for Releuko When Acquired Via Buy and Bill

Payer Type	Site of Care
	Physician Offices and Hospital Outpatient Departments
Fee-for-service Medicare	Once ASP is established: Biosimilar ASP + 8% of reference product’s ASP ^{5,10*}
Medicare Advantage	Varies. Possible methodologies: Contracted rate; Medicare fee schedule; usual, customary, and reasonable charge; other methodology
Private commercial payer	Varies. Possible methodologies: Contracted rate; ASP (+ a percentage); WAC (+ a percentage); AWP (+/- a percentage); usual, customary, and reasonable charge; invoice-based; percent of billed charges; other methodology
Fee-for-service Medicaid	Varies. Possible methodologies: Medicaid or state fee schedule; Medicare fee schedule; ASP (+/- a percentage); WAC (+/- percentage); AAC (+/- a percentage); invoice-based; other methodology
Medicaid managed care organization	Varies. Possible methodologies: Contracted rate; Medicaid, state, or plan fee schedule; Medicare fee schedule; ASP (+/- a percentage); WAC (+/- percentage); AAC (+/- percentage); invoice-based; other methodology

Key: AAC – actual acquisition cost; ASP – average sales price; AWP – average wholesale price; WAC – wholesale acquisition cost.

*Applies as long as the cost of the biosimilar does not exceed the cost of the reference product.

Other payment scenarios may apply.



For additional guidance, please contact the patient’s health insurance administrator or Amneal PATHways® at 1-866-4-AMNEAL (1-866-426-6325).

References

1. Releuko. Prescribing information. Amneal Pharmaceuticals LLC; 2022.
2. CMS. 2023 International Classification of Diseases, 10th Revision, Clinical Modification. Updated June 7, 2022. Accessed December 5, 2022. <https://www.cms.gov/medicare/icd-10/2023-icd-10-cm>
3. CMS. Healthcare Common Procedure Coding System (HCPCS) application summaries and coding recommendations: Second quarter, 2022 HCPCS coding cycle. Updated July 19, 2022. Accessed December 5, 2022. <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelIII-Coding-Decisions-Narrative-Summary>
4. CMS. HCPCS quarterly update. January 2023 alpha-numeric HCPCS file. Updated November 28, 2022. Accessed December 5, 2022. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>
5. CMS. Medicare and Medicaid programs; CY 2023 payment policies under the Physician Fee Schedule and other changes to Part B payment and coverage policies; Medicare Shared Savings Program requirements; implementing requirements for manufacturers of certain single-dose container or single-use package drugs to provide refunds with respect to discarded amounts; and COVID-19 interim final rules. *Fed Regist.* 2022;87(222). <https://www.federalregister.gov/d/2022-23873>
6. CMS. Medicare claims processing manual. Chapter 17. Drugs and biologicals. §40. Pub 100-04. Updated May 12, 2022. Accessed December 5, 2022. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf>
7. NUCC. 1500 health insurance claim form reference instruction manual for form version 02/12. Version 10.0 7/22. Updated July 2022. Accessed December 5, 2022. https://www.nucc.org/images/stories/PDF/1500_claim_form_instruction_manual_2022_07-v10a.pdf
8. CMS. Medicare claims processing manual. Chapter 26. Completing and processing the Form CMS-1500 data set. §10.4. Pub 100-04. Updated May 22, 2022. Accessed December 5, 2022. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf>
9. American Medical Association. 2023 Current Procedural Terminology. AMA; 2022.
10. CMS. Medicare program; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; organ acquisition; rural emergency hospitals: payment policies, conditions of participation, provider enrollment, physician self-referral; new service category for hospital outpatient department prior authorization process; overall hospital quality star rating; COVID-1. *Fed Regist.* 2022;187(225). <https://www.federalregister.gov/d/2022-23918>
11. CMS. Medicare claims processing manual. Chapter 25. Completing and processing the Form CMS-1450 data set. §75.4, §75.5. Pub 100-04. Accessed December 5, 2022. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>
12. Noridian Healthcare Solutions. Revenue codes. Accessed December 5, 2022. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes#:~:text=Revenue%20Codes%201%200020-0021%20Reserved%20%200022%20-,Rehabilitation%20Facility%20%28IRF%29%20PPS%205%200025-0029%20-%20Reserved>
13. CMS. Medicare benefit policy manual. Chapter 15, Covered medical and other health services. §50, §50.3, §60, §60.1. Pub 100-02. Updated May 20, 2022. Accessed December 5, 2022. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>

Ways to Contact the Amneal PATHways® Patient Support Program

Phone



1.866.426.6325 (866-4-AMNEAL)

Fax



1.855.690.6573

Online



<https://amnealbiosciences.com/support/>

Mail



PO Box 220303, Charlotte, NC 28222

Releuko is a registered trademark of Kashiv Biosciences, L.L.C.

© 2022 Amneal Pharmaceuticals LLC. All rights reserved. PP-HCP-RELE-US-0006 January 2023

Please see [Full Prescribing Information](#), including Important Safety Information, for RELEUKO.