

Billing & Coding Guide



Injection, for subcutaneous use | 6 mg/0.6 mL single-dose prefilled syringe

Quick reference: HCPCS Q5169 = Injection, pegfilgrastim-unne (ARMLUPEG), biosimilar, 0.5 mg. A 6 mg syringe is reported as 12 billing units.

Intended for physician office and hospital outpatient department billing teams.

HCPCS=Healthcare Common Procedure Coding System.

IMPORTANT DISCLAIMER

This guide is for informational purposes only. It is not legal advice, does not guarantee coverage or reimbursement, and is not a substitute for payer-specific guidance. Coding, coverage, billing, and payment policies change frequently and vary by payer and site of care. Providers are responsible for selecting codes that accurately reflect the patient's diagnosis, documented services, payer requirements, and medical record. Verify current requirements with the payer, Medicare Administrative Contractor, Medicaid agency, or other applicable authority before claim submission.

INDICATION

ARMLUPEG is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Limitation of Use

ARMLUPEG is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

IMPORTANT SAFETY INFORMATION

Contraindications

- ARMLUPEG is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products
- Reactions have included anaphylaxis

Please see Important Safety Information on pages 13-14 and full [Prescribing Information](#).

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CMS= Content Management System; NDC= National Drug Code.

ValorumPRO Overview

A Comprehensive Patient Access & Support Service

ValorumPRO is a centralized access point designed to support patient access by helping providers streamline administrative processes, navigate reimbursement, identify affordability options, and promote continuity of care for Valorum products.

Provider and Office

- **Integrated eBV:** Fast, electronic benefit verification
- **Dedicated Counselors:** Assigned experts managing accounts
- **Full-Cycle Support:** BV, PA Guidance, Coding and Reimbursement Support, Appeals Support
- **Product Replacement and Valorum Commitment Program:** Safeguarding patient access

Out-of-Pocket Optimization

- **\$0 Copay & Deductible:** Eligible commercially insured patients receive financial assistance to help reduce copay and deductible costs
- **Administration Support:** Coverage tailored to specific needs
- **Point-of-Care Clarity:** Seamless coordination in real time
- **Copay Card:** Designed for pharmacy benefit adjudication

Patient Assistance Program

- **Free Product:** Available for eligible patients
- **Income-based qualifications** with eligibility determined by objective program criteria
- **Effortless Enrollment:** Simple online provider/patient workflows
- **Therapy Continuity:** Helping to avoid gaps in care

SamaCare Integration: Delivers a 29% lift in prior authorization approval rates across \$6.2B+ in managed medical drug spend.

PX Connect (CareMetx): Drives AI-enabled provider enrollment, automated workflows, and real-time benefit checks.

Stedi Integration: Real-time eligibility checks help confirm active coverage, patient benefit details, and payer requirements.

BV=Benefit Verification; eBV=Electronic Benefit Verification; PA=Prior Authorization.

ValorumPRO Commitment Program:

The ValorumPRO Commitment Program is designed to support healthcare providers and maintain patient access during reimbursement implementation and transition periods associated with Valorum product launches.

ValorumPRO Replacement Program:

ValorumPRO will replace products due to wastage and breakage include products that are mishandled at the site of care (eg, syringe dropped, refrigerator malfunction) and deemed not usable for patient treatment.

The Three Ways to Get Started:

1. Download or print a patient enrollment form at ValorumPRO.com and fax it to 833-282-7224.
2. Call 844-VALORUM Monday-Friday, 8:30 am-5:00 pm ET for live support.
3. Log on to the secure Provider Portal at ValorumPRO.com. Please note that first-time users must register.

This section is informational only. Program processes, eligibility, and documentation requirements should be confirmed with ValorumPRO.

Phone: 844-VALORUM | Fax: 833-282-7224 | Web: ValorumPRO.com | Hours: Monday-Friday, 8:30 am-5:00 pm ET

Product and Coding Snapshot

ARMLUPEG® (pegfilgrastim-unne) injection is a pegfilgrastim biosimilar supplied as a 6 mg/0.6 mL single-dose prefilled syringe for subcutaneous administration.¹ CMS established HCPCS code Q5169 for ARMLUPEG with a 0.5 mg descriptor, making a 6 mg syringe equal to 12 billing units.²

Item	ARMLUPEG Coding Detail
Product	ARMLUPEG (pegfilgrastim-unne) injection
Route	Subcutaneous
Package	One 0.6 mL single-dose prefilled syringe containing 6 mg pegfilgrastim-unne
HCPCS	Q5169
HCPCS Descriptor	Injection, pegfilgrastim-unne (ARMLUPEG), biosimilar, 0.5 mg
Billing Units	1 unit = 0.5 mg; 6 mg dose = 12 units
CPT Administration	96372: Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular
NDC	70748-273-01 (10-digit/package label); 70748-0273-01 / 70748027301 (11-digit claim format)

Diagnosis Coding Considerations

Use ICD-10-CM diagnosis codes that are supported by the patient's medical record and payer policy. The sample code ranges below are not exhaustive and may require payer-specific sequencing or additional diagnosis codes to support medical necessity.

Clinical Context	ICD-10-CM Code Descriptor ³	Sample ICD-10-CM Code Range
Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia	Nonmyeloid malignancies	C00.0-C96.9
	Neutropenia	D70.0-D70.9
	Fever	R50.2-R50.9
	Certain infectious and parasitic diseases	A00.0-B99.9
	Adverse effect of antineoplastic and immunosuppressive drugs	T45.1X5A-T45.1X5S
	Other complications following infusion, transfusion, and therapeutic injection	T80.89XA-T80.89XS

CPT=Current Procedural Terminology; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

Physician Office Setting

Services rendered in physician offices are typically billed using the CMS-1500 claim form or electronic 37P equivalent.

Drug Coding

HCPSC Code	Descriptor	Typical Units for 6 mg Syringe
Q5169	Injection, pegfilgrastim-unne (ARMLUPEG), biosimilar, 0.5 mg	12 units

Professional Service Coding

CPT Code	Descriptor	Relevant Site of Service
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Physician office and hospital outpatient department

Modifiers

Modifier	Descriptor	Common Use
JB	Subcutaneous administration	Some payers may request route-of-administration reporting. Verify payer rules.
JW	Drug amount discarded/not administered to any patient	Report discarded amount from a single-dose package on a separate line when applicable.
JZ	Zero drug amount discarded/not administered to any patient	Medicare requires JZ when no discarded amount is reported for applicable single-dose drugs.

Sample CMS-1500 Claim Checklist

Claim Item	Example/Guidance
Item 21	Enter appropriate ICD-10-CM diagnosis code(s) supported by documentation.
Item 24D	Report Q5169 for ARMLUPEG; report CPT 96372 for subcutaneous injection when appropriate. Add payer-required modifiers such as JB, JW, or JZ as applicable.
Item 24E	Enter the diagnosis pointer linking the drug and administration code lines to the applicable diagnosis.
Item 24G	Report 12 units for one 6 mg/0.6 mL syringe of ARMLUPEG. Report 1 unit for CPT 96372 when billing the injection.
NDC field shaded area	When required, report N470748027301 ML0.6 for the full 0.6 mL syringe. Payer-specific NDC placement and formatting may vary.

JB= Administered subcutaneously; JW= Amount of drug that was discarded and not given to patient; JZ=Zero waste.

Hospital Outpatient Department Setting

Services rendered in outpatient facilities, including hospital outpatient departments, are typically billed using the CMS-1450/UB-04 claim form or electronic 837I equivalent.

Drug Coding

HCPSC Code	Descriptor	Typical Units for 6 mg Syringe	UB-04 Location
Q5169	Injection, pegfilgrastim-unne (ARMLUPEG), biosimilar, 0.5 mg	12 units	FL 44

Revenue Codes and Administration

Type of Code	Code/Descriptor ³	Common Use/Placement
Revenue code	0636: Drugs requiring detailed coding	Used with the drug HCPSC code; FL 42/43
Revenue code	0500: Outpatient services - general classification	May be used with administration code; verify payer rules
Revenue code	0510: Clinic - general classification	May be used with administration code when injection is administered in a clinic setting
Revenue code	0940: Other therapeutic services - general	May be accepted by some Medicare contractors for administration services
CPT code	96372: Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular	Report when billing the subcutaneous administration service

Modifiers

Modifier	Descriptor	Common Use
JB	Subcutaneous administration	Some payers may request route-of-administration reporting. Verify payer rules.
JW	Drug amount discarded/not administered to any patient	Report discarded amount from a single-dose package on a separate line when applicable.
JZ	Zero drug amount discarded/not administered to any patient	Medicare requires JZ when no discarded amount is reported for applicable single-dose drugs.
TB	340B Acquired Drug	Modifier for drug or biological is acquired with 340B drug pricing program discount.

FL= Flu vaccine administration; TB=Drug acquired with a 340B discount.

Sample UB-04/CMS-1450 Claim Checklist

Form Locator	Example/Guidance
FL 42	Report revenue code 0636 for the drug line; report applicable administration revenue code such as 0500, 0510, or 0940 based on payer and facility policy.
FL 43	Enter narrative description and/or NDC as required, eg, N470748027301 ML0.6.
FL 44	Report Q5169 for ARMLUPEG; report 96372 for injection administration when appropriate. Include payer-required modifiers such as JB, JW, JZ, or TB (340B-related modifier when applicable).
FL 46	Report 12 units for one 6 mg/0.6 mL syringe of ARMLUPEG. Report 1 unit for CPT 96372 when billing the administration service.
FL 67	Report appropriate ICD-10-CM diagnosis code(s) supported by the medical record.

NDC conversion: Because the labeled NDC uses a 5-3-2 configuration (70748-273-01), the 11-digit 5-4-2 claim format adds a zero to the second segment: 70748-0273-01.

NDC Reporting and Claim Format

Many payers request an NDC in combination with the HCPCS code to identify the specific product dispensed and administered. Verify the payer's required NDC format, qualifier, unit of measure, and claim-field placement.

NDC Reporting Element	ARMLUPEG Example
Drug name	ARMLUPEG® (pegfilgrastim-unne) injection
Package size	One 0.6 mL single-dose prefilled syringe
Strength	6 mg/0.6 mL (when applicable)
Package label NDC	70748-273-01
11-digit claim NDC	70748-0273-01 / 70748027301
NDC qualifier	N4
NDC unit of measure	ML
NDC quantity for full syringe	0.6
Sample claim string	N470748027301 ML0.6

Coverage and Reimbursement Checklist

- Confirm payer coverage policy, medical necessity criteria, and any prior authorization or step therapy requirements before administration when feasible. For support, please contact ValorumPRO
- Confirm whether the payer requires both HCPCS and NDC on medical claims
- Confirm payer-specific modifier requirements, including JB for subcutaneous route, JW/JZ for discarded or non-discarded, single-dose drug reporting, and TB for 340B-related modifier.
- Document the dose administered, product NDC, route of administration, date of service, and any wastage or zero wastage in the medical record
- For denials or underpayments, review payer policy, units, NDC format, modifier usage, and payer system loading of Q5169. Please contact ValorumPRO for support and a sample redetermination letter

REFERENCES: **1.** DailyMed. ARMLUPEG® (pegfilgrastim-unne) injection label, updated April 1, 2026. Label lists NDC 70748-273-01, 6 mg/0.6 mL single-dose prefilled syringe, subcutaneous use, and product indications. **2.** CMS Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Determinations, First Quarter 2026 Drug and Biological HCPCS Level II code application review cycle. CMS established Q5169 for ARMLUPEG with descriptor: Injection, pegfilgrastim-unne (ARMLUPEG), biosimilar, 0.5 mg. CMS states new coding actions are effective July 1, 2026 unless otherwise indicated. **3.** CPT code descriptions are owned by the American Medical Association. CPT® is a registered trademark of the American Medical Association. Revenue code guidance may vary by payer and facility policy.

Sample CMS-1500 Professional Claim Form Entry

Highlighted ARMLUPEG Example

Illustrative example only. Do not submit sample patient/provider information. Final coding, units, modifiers, revenue codes, NDC reporting, and claim-form placement should be confirmed against payer-specific requirements, medical-record documentation, and current coding guidance.

CMS-1500/837P - Sample Professional Claim Entry for ARMLUPEG

Patient Name Jane Sample	DOB 01/01/1970	Insured ID Example only	Payer Example Medicare/ Commercial
Diagnosis A C50.912 - Malignant neoplasm of unspecified site of left female breast	Diagnosis B D70.1 - Agranulocytosis secondary to cancer chemotherapy	Diagnosis C T45.1X5A - Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter	POS 11 - Office
Drug ARMLUPEG® (pegfilgrastim-unne) 6 mg/0.6 mL PFS	HCPCS Q5169 - 0.5 mg	Dose/Units 6 mg = 12 billing units	NDC N470748027301 ML0.6
Administration 96372 - subcutaneous/ intramuscular injection	Modifiers JB and JZ shown as examples	Date of Service 07/15/2026	Charges Use actual charge master/fee schedule

Example Service Lines for Item 24/837P:

24A DOS	24B POS	24D HCPCS/CPT	Modifier(s)	24E Dx Ptr	24F Charges	24G Units	24J NPI	NDC/Shaded Line	Notes
07/15/2026	11	Q5169	JB, JZ	A, B, C	\$X,XXX.XX	12	Rendering NPI	N470748027301 ML0.6	ARMLUPEG 6 mg/0.6 mL PFS; Q5169 = 0.5 mg per unit.
07/15/2026	11	96372		A, B, C	\$XX.XX	1	Rendering NPI		Therapeutic/prophylactic/diagnostic subcutaneous or IM injection, when separately billable.

IM=Intramuscular; NPI= National Provider Identifier; POS=Place of service.

CMS-1500 Field-Level Guidance:

CMS-1500 Item	ARMLUPEG Example Entry	Practical Note
Item 21	A: C50.912; B: D70.1; C: T45.1X5A	Use diagnosis codes supported by the chart and payer policy.
Item 24D - Drug	Q5169 with payer-required modifiers, eg, JB and JZ when applicable	Q5169 descriptor is per 0.5 mg; one 6 mg syringe generally equals 12 units.
Item 24D - Admin	96372	Report administration when the service is separately billable and documented.
Item 24G	12 for Q5169; 1 for 96372	Do not report 1 unit for a full 6 mg syringe unless payer instructions differ.
NDC supplemental field	N470748027301 ML0.6	N4 qualifier + 11-digit NDC + unit of measure + quantity.

CMS-1500 / 837P - Highlighted Sample Professional Claim Entry for Armlupeg

Illustrative example only. Yellow fields show the Armlupeg-specific entries to verify on a professional claim.

Do not submit sample patient/provider data.

1a Insured ID EXAMPLE12345	2 Patient Name JANE SAMPLE	3 DOB / Sex 01/01/1970 / F	11 Insured Policy Example Medicare / Commercial	33 Billing Provider Sample Oncology Practice NPI: 1234567890
21 Diagnosis or Nature of Illness or Injury A C50.912 Malignant neoplasm, left female breast B D70.1 Agranulocytosis secondary to cancer chemotherapy C T45.1X5A Adverse effect of antineoplastic drugs, initial		19 Additional Claim Information NDC when payer requires in shaded/supplemental line: N470748027301 ML0.6		23 Prior Authorization Number Enter PA number if required by payer
241 / 24J Rendering Provider Qualifier/NPI per payer requirements Rendering NPI: 1234567890				

24. Service lines - example entries

24A Date(s)	24B POS	24D Procedures, Services, or Supplies	Modifiers	24E Dx Ptr	24F Charges	24G Units	24J NPI	Shaded/supplemental NDC line
07/15/2026	11	Q5169 Armlupeg 0.5 mg	JB, JZ	A,B,C	\$X,XXX.XX	12	1234567890	N470748027301 ML0.6
07/15/2026	11	96372 Injection admin		A,B,C	\$XX.XX	1	1234567890	

Highlighted Armlupeg coding checks

- Q5169 descriptor is per 0.5 mg; one 6 mg syringe generally equals 12 billing units.
- Use N4 + 11-digit NDC + NDC unit of measure/quantity when the payer requires NDC reporting: N470748027301 ML0.6.
- Apply JB/JW/JZ or other modifiers only when required by payer policy and documentation supports use.
- Use ICD-10-CM codes supported by the medical record; examples shown are not a coverage guarantee.

CMS-1500 placement map

Item 21 Diagnosis code pointers A/B/C	Item 24D Q5169 on drug line; 96372 on admin line	Item 24G 12 units for Q5169; 1 unit for 96372	Shaded/supplemental NDC area N470748027301 ML0.6
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Reminder: This is a teaching example. Confirm payer-specific claim form placement, electronic 837P loops, modifiers, units, and NDC formatting before submission.

Highlighted ARMLUPEG Example

Illustrative example only. Do not submit sample patient/provider information. Final coding, units, modifiers, revenue codes, NDC reporting, and claim-form placement should be confirmed against payer-specific requirements, medical-record documentation, and current coding guidance.

Sample CMS-1450/UB-04 Institutional Claim Form Entry

CMS-1450/UB-04/837I - Sample Hospital Outpatient Claim Entry for ARMLUPEG

Type of Bill 0131 - Hospital outpatient admit through discharge claim (example)	Patient Control No. Example only	Statement Covers Period 07/15/2026 - 07/15/2026	Patient Status 01 - Discharged to home/self-care (example)
Principal Diagnosis C50.912	Other Diagnosis D70.1; T45.1X5A	Drug ARMLUPEG 6 mg/0.6 mL PFS	NDC N470748027301 MLO.6
Drug Revenue Code 0636	Administration Revenue Code 0510 or 0940 example; verify payer	HCPCS/CPT Q5169 and 96372	Units Q5169 = 12; 96372 = 1

Example Revenue Code Lines for FL 42-48/837I:

FL 42 Rev Code	FL 43 Description/NDC	FL 44 HCPCS/CPT	Modifier(s)	FL 46 Units	FL 47 Charges	FL 67 Dx Link	Notes
0636	ARMLUPEG 6 mg/0.6 mL PFS; N470748027301 MLO.6	Q5169	JB, JZ	12	\$X,XXX.XX	C50.912; D70.1; T45.1X5A	Drug line. Q5169 is billed per 0.5 mg; one 6 mg syringe generally equals 12 units.
0510 or 0940	Subcutaneous injection administration	96372		1	\$XX.XX	C50.912; D70.1; T45.1X5A C50.912; D70.1; T45.1X5A	Administration line. Revenue code varies by facility, payer, and billing policy.

UB-04 Field-Level Guidance:

UB-04 Form Locator	ARMLUPEG Example Entry	Practical Note
FL 42	0636 for drug; 0510 or 0940 for administration example	Confirm facility revenue code policy and payer requirements.
FL 43	ARMLUPEG 6 mg/0.6 mL PFS; N470748027301 MLO.6	Include NDC when required by payer or state Medicaid.
FL 44	Q5169 for drug; 96372 for administration	Append payer-required modifiers such as JB/JZ when applicable.
FL 46	12 for Q5169; 1 for 96372	Billing units should align to 0.5 mg HCPCS descriptor.
FL 47	Use actual hospital charge	Charges are examples only and should come from the facility charge master.
FL 67 and 67A-Q	C50.912; D70.1; T45.1X5A	Report diagnoses supported by documentation and payer policy.

CMS-1450 / UB-04 / 837I - Highlighted Sample Institutional Claim Entry for Armlupeg

Illustrative example only. Yellow fields show the Armlupeg-specific entries to verify on an institutional claim.

Do not submit sample patient/provider data.

4 Type of Bill 0131 - Hospital outpatient claim	6 Statement Covers Period 07/15/2026 - 07/15/2026	8 Patient Name JANE SAMPLE	17 Patient Status 01 - Discharged to home/self-care	67 Principal Dx C50.912
67A-Q Other Diagnosis Codes D70.1; T45.1X5A as supported by documentation	Attending / Operating / Other Provider NPI fields per facility and payer requirements		NDC / description note Report N470748027301 MLO.6 in FL 43 or electronic equivalent when required.	

FL 42-48 Revenue-code lines - example entries

FL 42 Rev Code	FL 43 Description / NDC	FL 44 HCPCS/CPT	Modifiers	FL 46 Units	FL 47 Charges	Dx support	Notes
0636	ARMLUPEG 6MG/0.6ML PFS N470748027301 MLO.6	Q5169	JB, JZ	12	\$X,XXX.XX	C50.912; D70.1; T45.1X5A	Drug line
0510 or 0940	Subcutaneous injection administration	96372		1	\$XX.XX	C50.912; D70.1; T45.1X5A	Admin line

Highlighted UB-04 form-locator checks

FL 42 0636 for drug line; 0510/0940 example for administration	FL 43 ARMLUPEG description + N470748027301 MLO.6 when required	FL 44 Q5169 for drug; 96372 for administration	FL 46 12 units for Q5169; 1 unit for 96372	FL 67 / 67A-Q Diagnosis codes supported by chart and payer policy
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Institutional claim notes

- Hospitals should confirm the appropriate revenue code based on facility policy, payer rules, and site of service.
- For 340B acquired product, confirm whether modifier reporting is required for the payer and claim type.
- Use actual charge master amounts; dollar values shown in this guide are placeholders.
- Electronic 837I loop placement may differ from paper form location; confirm clearinghouse/payer specifications.

Reminder: This is a teaching example. Confirm claim form placement, 837I loops, modifiers, units, NDC formatting, and revenue codes with the payer before submission.

INDICATION

ARMLUPEG is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Limitation of Use

ARMLUPEG is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

IMPORTANT SAFETY INFORMATION

Contraindications

- ARMLUPEG is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products
- Reactions have included anaphylaxis

Warnings and Precautions

Splenic Rupture

- Splenic rupture, including fatal cases, can occur following the administration of pegfilgrastim products
- Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain after receiving ARMLUPEG

Acute Respiratory Distress Syndrome (ARDS)

- ARDS can occur in patients receiving pegfilgrastim products
- Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving ARMLUPEG
- Discontinue ARMLUPEG in patients with ARDS

Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis, can occur in patients receiving pegfilgrastim products
- The majority of reported events occurred upon initial exposure
- Allergic reactions, including anaphylaxis, can recur within days after the discontinuation of initial anti-allergic treatment
- Permanently discontinue ARMLUPEG in patients with serious allergic reactions

Use in Patients with Sickle Cell Disorders

- Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving pegfilgrastim products
- Discontinue ARMLUPEG if sickle cell crisis occurs

Glomerulonephritis

- Glomerulonephritis has occurred in patients receiving pegfilgrastim products
- The diagnoses were based on azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy
- Generally, events of glomerulonephritis resolved after dose-reduction or discontinuation of pegfilgrastim products
- If glomerulonephritis is suspected, evaluate for cause. If causality is likely, consider dose-reduction or interruption of ARMLUPEG

Leukocytosis

- White blood cell counts of $100 \times 10^9/L$ or greater have been observed in patients receiving pegfilgrastim products
- Monitoring of complete blood count (CBC) during ARMLUPEG therapy is recommended

Thrombocytopenia

- Thrombocytopenia has been reported in patients receiving pegfilgrastim products
- Monitor platelet counts

Capillary Leak Syndrome (CLS)

- CLS has been reported after granulocyte-colony stimulating factor (G-CSF) administration, including pegfilgrastim products, and is characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration
- Episodes vary in frequency and severity and may be life-threatening if treatment is delayed
- Patients who develop symptoms of CLS should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

- The G-CSF receptor through which pegfilgrastim and filgrastim products act has been found on tumor cell lines
- The possibility that pegfilgrastim products act as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim products are not approved, cannot be excluded

Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer

- MDS and AML have been associated with the use of pegfilgrastim products in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer
- Monitor patients for signs and symptoms of MDS/AML in these settings

Aortitis

- Aortitis has been reported in patients receiving pegfilgrastim products. It may occur as early as the first week after start of therapy
- Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (eg, c-reactive protein and white blood cell count)
- Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue ARMLUPEG if aortitis is suspected

Nuclear Imaging

- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone imaging results

Most Common Adverse Reactions

- Bone pain
- Pain in extremity

ARMLUPEG Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only

To report SUSPECTED ADVERSE REACTIONS, contact Valorum Biologics at 844-VALORUM (844-825-6786) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full [Prescribing Information](#).

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

A comprehensive patient access & support service

ValorumPRO is a centralized online portal designed to support patient access by helping providers streamline administrative processes, navigate reimbursement, identify affordability options, and promote continuity of care for Valorum products.

- **Integrated Benefits Verification:** Fast, electronic benefit verification
- **Dedicated Counselors:** Assigned experts managing accounts
- **Full-Cycle Support:** BV, PA Guidance, Coding and Reimbursement Support, Appeals Support
- **Product Replacement and Valorum Commitment Program:** Safeguarding patient access

SamaCare Integration: Delivers a 29% lift in prior authorization approval rates across \$6.2B+ in managed medical drug spend.

Stedi Integration: Real-time eligibility checks help confirm active coverage, patient benefit details, and payer requirements.

Visit [ValorumPRO.com](https://www.valorumpro.com)