Amneal PATHways
Patient Access To Health

Fylnetra® (pegfilgrastim-pbbk)

Coding and Billing Guide for FYLNETRA® (pegfilgrastim-pbbk)

Disclaimer

Amneal developed this guide to support healthcare professionals (HCPs) in assisting their patients to access therapy with Fylnetra® (pegfilgrastim-pbbk) in physician offices and hospital outpatient clinics. The content in this guide is provided for informational purposes. This information is not legal advice and it does not 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. HCPs should ensure that information reported to payers accurately reflects the services that were rendered and documented in the patient's medical record. The information here is current as of February 2023.

IMPORTANT SAFETY INFORMATION

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Indication: FYLNETRA 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.

Limitations of Use: FYLNETRA is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

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

Before taking FYLNETRA, 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 FYLNETRA in patients with ARDS.
- Serious allergic reactions, including anaphylaxis: Permanently discontinue FYLNETRA in patients with serious allergic reactions.
- Fatal sickle cell crises: Serious sickle cell crises have been reported in patients with sickle cell disorders receiving FYLNETRA. Discontinue FYLNETRA if sickle cell crisis occurs.
- Kidney injury (Glomerulonephritis): Kidney injury have been reported in patients on FYLNETRA. Consider dose-reduction or interruption of FYLNETRA in patients with kidney injury.
- White blood cell (WBC) counts of 100 x 109/L or greater have been observed in patients receiving pegfilgrastim products. Monitoring of complete blood count (CBC) during FYLNETRA therapy is recommended.
- Decreased platelet count (thrombocytopenia) has been reported in patients receiving pegfilgrastim. Monitor platelet counts.
- Capillary leak syndrome has been reported after G-CSF administration, including pegfilgrastim products, and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration.
- 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): Monitor patients with breast and lung cancer using FYLNETRA in conjunction with chemotherapy and/or radiotherapy for signs and symptoms of MDS/AML.
- Aortitis has been reported in patients receiving pegfilgrastim products.
- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes.

Adverse Reactions: Most common adverse reactions (≥ 5% difference in incidence compared to placebo) are bone pain and pain in extremity.

Table of Contents

Support for Patient Access

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

Amneal PATHways Patient Access To Health

There are 3 ways to get started:

Download or print a patient enrollment form at https://amnealbiosciences.com/pathways/ 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/pathways/

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 diagnosis codes on claims to help substantiate medical necessity for treatment with Fylnetra. 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 Fylnetra

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 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

Physician Office Setting

This section covers **coding for the physician office** site of care. Facilities should skip to pages 9-13.

Drug

Fylnetra may be reported on medical claims effective for dates of service on and after April 1, 2023, with the following product-specific Healthcare Common Procedure Coding System (HCPCS) code:

HCPCS Code for Fylnetra[3]

HCPCS[3]	Description
Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg

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.

HCPCS code Q5130 represents 0.5 mg of Fylnetra, for 12 units per 6 mg, single-use prefilled syringe.

Medicare and many other payers allow HCPs to bill the entire amount of medication taken from a single-use prefilled syringe, 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[4,5]:

- 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 prefilled syringe.

Modifier -JW identifies the amount of discarded drug from a single-use vial. The modifier should be appended to the HCPCS code on a separate line of the claim, along with the amount of discarded product. The amounts administered and discarded should be documented in the patient's medical chart. If no amount of drug is discarded from a single-use vial, Medicare requires use of modifier -JZ.

Medicare Modifiers for Reporting Amount of Drug Discarded or Not Discarded[3]

HCPCS Modifier	Description
-JW	Drug amount discarded/not administered to any patient
-JZ*	Zero drug amount discarded/not administered to any patient

* Modifier -JZ is effective for claims with dates of service on and after January 1, 2023, and is required on claims no later than July 1, 2023.

Payers commonly require that HCPs use a National Drug Code (NDC), in combination with the appropriate HCPCS code, on medical claims to help identify the product[6,7]:

Fylnetra NDC

Package Size	Dosage Strength	11-Digit NDC[1]
One 0.6 mL single-dose prefilled syringe	6 mg/0.6 mL	70121-1627-01

Payer guidance varies on where the NDC information should go on claim forms; however, this information is often reported in the shaded area of Item 24A. Payers may request the following types of information along with the NDC on claim forms for Fylnetra:

Drug-Identifying Information for Fylnetra

Type of Drug-Identifying Information		Fylnetra Specifics
Drug name (brand/generic)		FYLNETRA (pegfilgrastim-pbbk)
NDC and NDC qualifiers:		
NDC qualifier: "N4"	• Put in front of NDC	N470121162701 ML0.6
11-digit NDC: 70121162701	• Do not include hyphens or other punctuation marks	
NDC unit of measure qualifier ML	• Put a single space after the NDC, then follow with the unit of measure qualifier	
NDC quantity: 0.6	• Put immediately after the unit of measure qualifier • You will need to adjust the NDC quantity based on the amount administered and any amount discarded which, together, should total the full quantity of 0.6 mL • Use 2 claim lines, if needed	

See the sample CMS-1500 Claim Form on page 8 for more information.

Professional Services

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

Product Administration for Fylnetra

CPT[8,*]	Descriptor
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

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 Fylnetra 6 mg 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

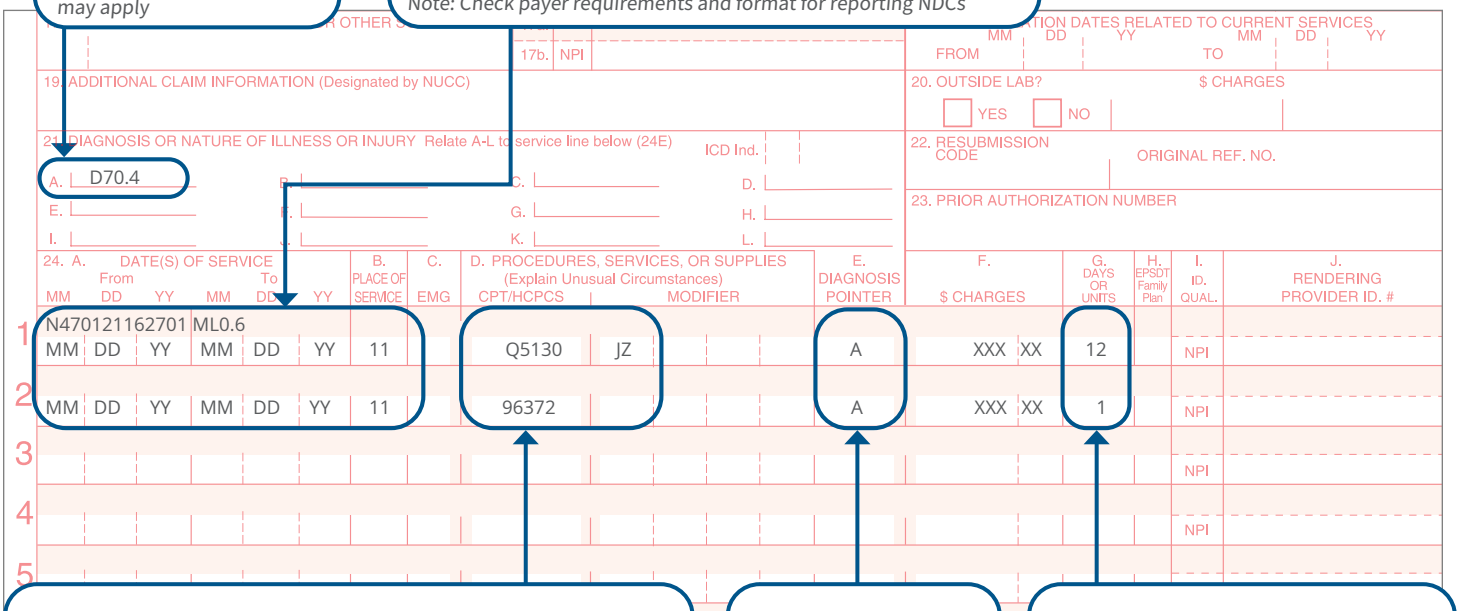
Note: Other diagnosis codes may apply

Item 24A: Date(s) of Service

Enter the NDC in the shaded area above the date:

- The "N4" qualifier is required before the NDC
- Follow the 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 prefilled syringe

Note: Check payer requirements and format for reporting NDCs



Item 24D: Procedures/Services/Supplies

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

- Drug: Q5130 for Fylnetra and modifier JZ to indicate no amount of drug was discarded
- 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 Q5130, 1 billing unit is equal to 0.5 mg; therefore, 12 billing units represent 1, 6 mg single-use prefilled syringe of Fylnetra
- 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 6-8.

Drug

Fylnetra may be reported on medical claims effective for dates of service on and after April 1, 2023, with the following product-specific Healthcare Common Procedure Coding System (HCPCS) code:

HCPCS Code for Fylnetra[3]

HCPCS	Description
Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg

The HCPCS code should be reported in Form Locator (FL) 44 of the CMS-1450 Claim Form (or its electronic equivalent), along with the appropriate number of units.

HCPCS code Q5130 represents 0.5 mg of Fylnetra, for 12 units per 6 mg, single-use prefilled syringe.

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

- 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.

Modifier -JW identifies the amount of discarded drug from a single-use vial. The modifier should be appended to the HCPCS code on a separate line of the claim, along with the amount of discarded product. The amounts administered and discarded should be documented in the patient's medical chart. If no amount of drug is discarded from a single-use vial, Medicare requires use of modifier -JZ.

Medicare Modifiers for Reporting Amount of Drug Discarded or Not Discarded[3]

HCPCS Modifier	Description
-JW	Drug amount discarded/not administered to any patient
-JZ*	Zero drug amount discarded/not administered to any patient

* Modifier -JZ is effective for claims with dates of service on and after January 1, 2023, and is required on claims no later than July 1, 2023.

The Centers for Medicare & Medicaid Services (CMS) has determined that Fylnetra should be reported with a modifier when it is acquired via the 340B Drug Pricing Program and furnished to a Medicare beneficiary.[9]

Modifier	Descriptor	Comments	Location
-TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities	Once Fylnetra is awarded temporary pass-through status	Added to HCPCS code in FL 44

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[10]:

Fylnetra NDCs

Package Size	Dosage Strength	11-Digit NDC[1]
One 0.6 mL prefilled syringe	6 mg/0.6 mL	70121-1627-01

Payer guidance varies on where this information should go on claim forms; however, this information is often reported in FL 43. Payers may request the following type of information along with the NDC on claim forms for Fylnetra:

Drug-Identifying Information for Fylnetra

Type of Drug-Identifying Information		Fylnetra Specifics
Drug name (brand/generic)		FYLNETRA (pegfilgrastim-pbbk)
NDC and NDC qualifiers		
NDC qualifier: "N4"	• Put in front of NDC	N470121162701 ML0.6
11-digit NDC: 70121162701	• Do not include hyphens or other punctuation marks	
NDC unit of measure qualifier: ML	• Put a single space after the NDC, then follow with the unit of measure qualifier	
NDC quantity: 0.6	• Put immediately after the unit of measure qualifier • You will need to adjust the NDC quantity based on the amount administered and any amount discarded which, together, should total the full quantity of 0.6 mL • Use 2 claim lines, if needed	

Payers may also ask for a revenue code 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 Fylnetra[10,11]:

Sample Revenue Code for Drug Billing

Revenue code[11]	Descriptor	Placement
0636	Drugs requiring detailed coding	FLs 42-43

Professional Services

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

Product Administration for Fylnetra

CPT[8,*]	Descriptor
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

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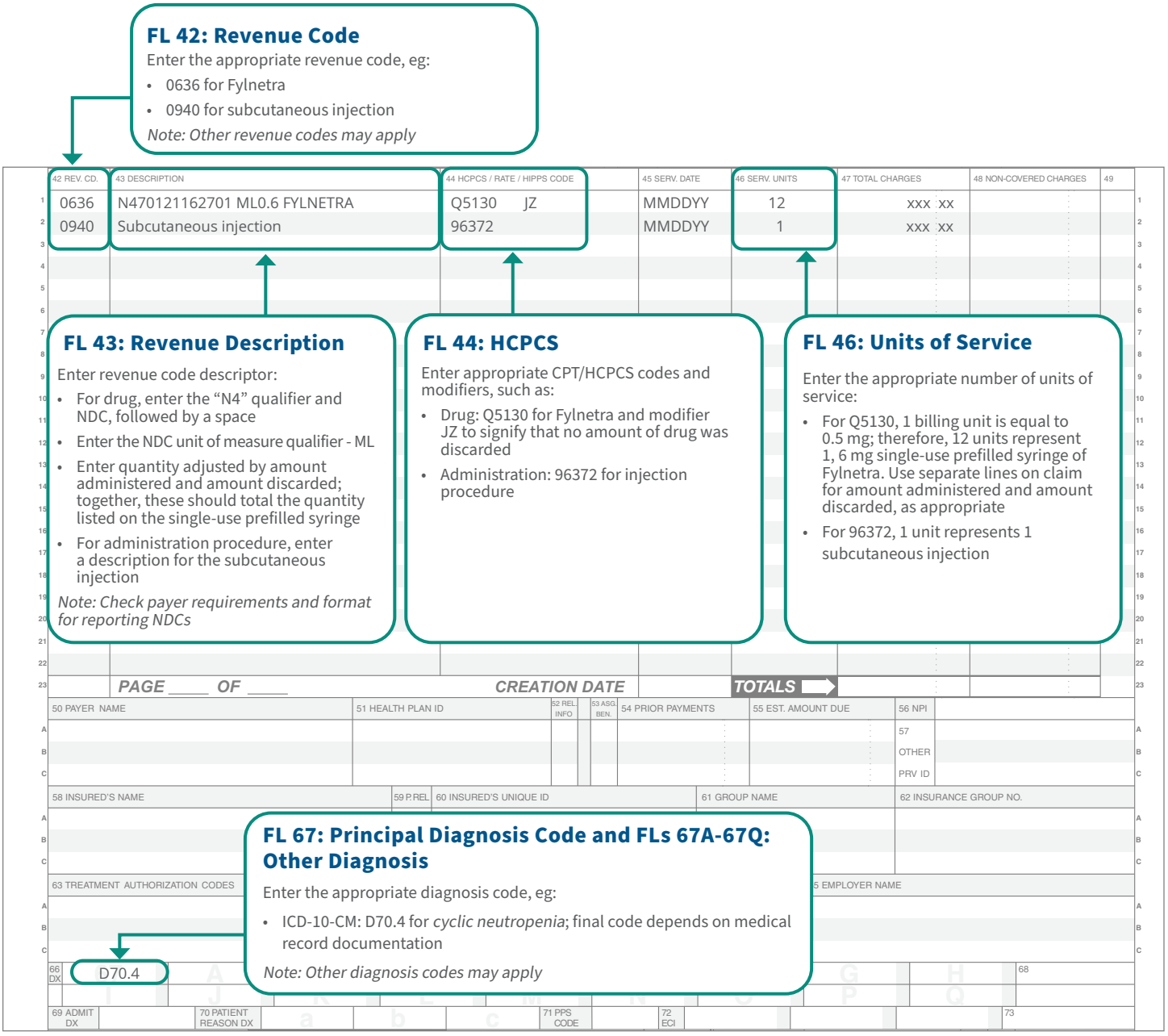
The following revenue codes may be appropriate to report Fylnetra's administration in the hospital outpatient department setting to some Medicare contractors[11]:

Revenue code[11]	Descriptor	Placement
0940	Other therapeutic services - general	FLs 42-43
0510	Clinic visit	

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 Fylnetra 6 mg in a hospital outpatient department.



Coverage

Medicare Fee-for-Service

Fylnetra and its administration procedure are generally covered under the Medicare Part B benefit when the product is[12]:

- 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

Fee-for-service Medicare does not require prior authorization. However, claims are subject to review and should follow local and national published coverage guidance.

Other Payers

Payers including private commercial insurers, Medicare Advantage (Medicare managed care), and Medicaid may cover Fylnetra 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 Fylnetra. 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)
  - Consider whether the patient has 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 Fylnetra 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

High-Level Overview of Potential Payment Methodologies for Fylnetra

Payer Type	Site of Care	
	Physician Office	**Hospital Outpatient Department**
Fee-for-service Medicare	• WAC + 3% (until ASP is established) • Biosimilar ASP + 8% of reference product's ASP[4,*]	• 95% of AWP (until WAC is available) • WAC + 3% (until ASP is established) • Biosimilar ASP + 8% of reference product's ASP (once ASP is established and product is awarded temporary pass-through status)[9,*]
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 – Contracted rate; Medicaid, state, or plan fee schedule; Medicare fee schedule; ASP (+/- a percentage); WAC (+/- percentage); AAC (+/- 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.

* ASP + 8% is a temporary payment methodology that applies for a 5-year period as long as the cost of the biosimilar does not exceed the cost of the reference product. The 5-year period starts on the first day of the first quarter that the drug is paid based on ASP. The payment methodology reverts to ASP + 6% after the 5-year period expires.

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. Fylnetra. Prescribing information. Amneal Pharmaceuticals LLC; 2022.
2. CMS. 2023 International Classification of Diseases, 10th Revision, Clinical Modification. Updated June 7, 2022. Accessed February 6, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm
3. CMS. HCPCS quarterly update. April 2023 alpha-numeric HCPCS file. Updated March 8, 2023. Accessed March 9, 2023. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update
4. 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
5. CMS. Medicare claims processing manual. Chapter 17. Drugs and biologicals. §40. Pub 100-04. Updated May 12, 2022. February 6, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf
6. NUCC. 1500 health insurance claim form reference instruction manual for form version 02/12. Version 10.0 7/22. Updated July 2022. Accessed February 6, 2023. https://www.nucc.org/images/stories/PDF/1500_claim_form_instruction_manual_2022_07-v10a.pdf
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8. American Medical Association. 2023 Current Procedural Terminology. AMA; 2022.
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10. CMS. Medicare claims processing manual. Chapter 25. Completing and processing the Form CMS-1450 data set. §75.4, §75.5. Pub 100-04. Accessed February 6, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/ Downloads/clm104c25.pdf
11. Noridian Healthcare Solutions. Revenue codes. Accessed February 6, 2023. https://med.noridianmedicare.com/web/ jea/topics/claim-submission/revenue-codes#:~:text=Revenue%20Codes%201%200020-0021%20Reserved%202%20 0022%20-,Rehabilitation%20Facility%20%28IRF%29%20PPS%205%200025-0029%20-%20Reserved
12. 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 February 6, 2023. 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