Fulphila®
(pegfilgrastim-jmdb) injection

Coding and Billing Guide

for FULPHILA®

Available as 6 mg/0.6 mL in a single-dose prefilled syringe for manual use only

Fulphila®

(pegfilgrastim-jmdb) injection

Table of Contents

Please see Important Safety Information on back cover and accompanying Full Prescribing Information.

Purpose of Guide and Disclaimer

This Coding and Billing Guide for FULPHILA (pegfilgrastim-jmdb) is intended to support medically appropriate patient access by providing general information on coding, coverage, billing, and reimbursement to healthcare professionals and their staff who prescribe and administer FULPHILA at physician office and hospital outpatient sites of care. FULPHILA is biosimilar to NEULASTA® (pegfilgrastim) for the indication listed.

The content provided in this guide is for informational purposes only and is not intended as legal advice or to replace a medical provider's professional judgment.

It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure FULPHILA claims are accurate, complete, and supported by documentation in the patient's medical record. Biocon Biologics does not guarantee that payers will consider all codes appropriate for all encounter scenarios, and Biocon Biologics does not guarantee FULPHILA coverage or reimbursement.

Please note that information specific to coding, coverage policies, and payment methodologies is subject to change and should be verified for each patient prior to treatment. The information in this guide is current as of December 2021.

My Biocon Biologics™

My Biocon Biologics provides patient access support and can assist with patient-specific verification of benefits for FULPHILA and its associated professional services, such as product administration. For assistance:

Call
1 (833) 695-2623

Log on to
www.mybioconbiologicsportal.com

FULPHILA (pegfilgrastim-jmdb) Injection[1]

Indications and Usage: FULPHILA 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

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

Dosing: Patients with cancer receiving myelosuppressive chemotherapy are administered 6 mg subcutaneously once per chemotherapy cycle. FULPHILA should not be administered either 14 days before or 24 hours after administration of cytotoxic chemotherapy. Weight-based dosing is used for pediatric patients weighing less than 45 kg.

How Supplied: FULPHILA injection is available as a 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only.

Contraindication: Do not administer FULPHILA to patients with a history of serious allergic reactions, including anaphylaxis, to pegfilgrastim or filgrastim.

Coding

It is critical to report medical codes that accurately reflect a patient's condition, treatment, and the services that are rendered on the claim form submitted to a payer. The codes in this section may be appropriate to report administration of FULPHILA.

Reporting Use of FULPHILA

Healthcare Common Procedure Coding System (HCPCS) Level II Codes

FULPHILA has a unique HCPCS code, **Q5108 Injection, pegfilgrastim-jmdb, biosimilar (FULPHILA), 0.5 mg**.

Table 1. HCPCS Codes Appropriate for FULPHILA

Code[2]	Description	Site of Service	Payers
Q5108	Injection, pegfilgrastim-jmdb, biosimilar (FULPHILA), 0.5 mg	Physician office and hospital outpatient	Most payers

Please note that Q5108 describes a billing unit of 0.5 mg and the FULPHILA injection is available as a 6 mg/0.6 mL solution in a single-dose prefilled syringe. For a 6 mg dose, 12 billing units should be reported (see sample claim forms).

Modifiers for Product Acquired via 340B Drug Discount Program

The Centers for Medicare & Medicaid Services (CMS) established modifiers that must be reported on claims that meet the following criteria[3]:

The drug was furnished to a patient enrolled in fee-for-service (FFS) Medicare Part B

The drug was administered in the hospital outpatient setting

The drug was acquired via the 340B Drug Discount Program

The following modifiers may be appropriate to bill along with the HCPCS code for FULPHILA:

Table 2. Medicare Modifiers for 340B Drugs[3]

Modifier	Description	Site of Service
-JG	Drug or biological acquired with 340B drug pricing program discount	Hospital outpatient
-TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	Hospital outpatient

National Drug Codes (NDCs)

Medications approved by the Food and Drug Administration (FDA) are assigned a 3-segment number known as the NDC that is specific to the labeler (manufacturer), product (identifies a specific drug, strength, and dosage formulation), and package size. FULPHILA (pegfilgrastim-jmdb) has been assigned a 10-digit NDC as listed in the prescribing information.[1] The 11-digit format is required by HIPAA (the Health Insurance Portability and Accountability Act) for claims submission and is typically reported on claims without hyphens or other punctuation marks.

Table 3. NDC for FULPHILA

Product	NDC (10-Digit Format)	NDC (11-Digit Format)
FULPHILA (pegfilgrastim-jmdb) 6 mg/0.6 mL single-dose prefilled syringe	83257-005-41	83257-0005-41

Report the NDC as required by payers and/or your billing system. For example, state Medicaid agencies usually require 11-digit NDCs on claims, even after a unique HCPCS code has been assigned. Some state Medicaid agencies require healthcare providers to bill the NDC and other information (e.g., an NDC qualifier, a unit of measure, and a unit of measure qualifier, in addition to the HCPCS code). Furthermore, the NDC location on the claim form may vary by payer. Please contact payers directly to verify requirements or call **My Biocon Biologics** at 1 (833) 695-2623 for assistance.

FULPHILA is administered once per chemotherapy cycle. **Do not administer FULPHILA between 14 days before and 24 hours after administration of cytotoxic chemotherapy.**

Reporting FULPHILA's Injection Administration Procedure

If a treating healthcare professional decides to administer FULPHILA in either the physician office or hospital outpatient sites of care, drug administration services are reported to most payers with Current Procedural Terminology (CPT®*)[4] codes. The following CPT code may be used to report the subcutaneous injection of FULPHILA in physician offices or hospital outpatient clinics.

Table 4. CPT Code for FULPHILA Injection Procedure

Code	Description	Sites of Service
96372	Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular	• Physician office • Hospital outpatient

Diagnosis Coding

The diagnosis related to the patient's treatment with FULPHILA is reported on physician and hospital claims with *International Classification of Diseases, 10th Revision, Clinical Modification* (ICD-10-CM) codes.[5] Allowable ICD-10-CM diagnosis codes may vary by payer. ICD-10-CM codes have 3 to 7 digits and must be reported to the highest level of specificity. This means that if there is a fourth-digit option in the diagnosis category, the code must be reported out to the fourth digit. Truncated codes (e.g., reporting only 3 digits when a fourth-digit option exists) are not valid and will be rejected by most payers.

Some payers require more than 1 ICD-10-CM code and may require 1 to be selected as the primary diagnosis code. For example, in addition to the code for neutropenia, some payers may require concurrent reporting of a code for the nonmyeloid malignancy and/or the type of myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. **Please contact the payer or My Biocon Biologics to confirm payer-specific requirements.**

Reporting Revenue Codes

Revenue codes categorize hospital services by revenue center to capture cost data. For many payers, claims must include a revenue code for each service provided in the hospital. The following is a sample of revenue codes that may be relevant for FULPHILA and its administration in the hospital outpatient site of care.

Table 5. Sample Revenue Codes

Code[6]	Description	Appropriate Use
0636	Drugs requiring detailed coding	Used in combination with HCPCS drug code
0510	Clinic visit	Used in combination with CPT injection code

INDICATIONS AND USAGE

FULPHILA 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

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

Coverage

Importance of Benefit Verifications

It is important to complete a thorough investigation of insurance benefits to determine coverage each and every time a patient presents for an injection of FULPHILA (pegfilgrastim-jmdb). This will verify whether the patient's coverage is in effect at the time of service and will help determine if drugs are a covered benefit and any applicable utilization management or acquisition requirements.

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Coverage for Medicare

Medicare Part B Coverage

FULPHILA meets the criteria for coverage under Part B when it is reasonable and medically necessary for the beneficiary and certain criteria are met.[7] Drugs may be subject to coverage restrictions spelled out in local or national Medicare coverage guidance.

In general, Medicare coverage for Part B drugs includes the following requirements:

The drug must be furnished "incident to"[7] a physician's service: The drug is furnished by a physician and administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision. In addition, the charge for the drug or biologic must be included in the physician's bill, representing an expense to the physician

The product must **meet the definition of a drug or biologic**

The treatment must be **reasonable and necessary for the diagnosis or treatment of the illness or injury for which it is administered**, according to accepted standards of medical practice

The drug is **not usually self-administered**

The drug must **be safe and effective**

Medicare Part C Coverage (Medicare Advantage)

Medicare Part C, or Medicare Advantage, offers Medicare-covered medical benefits through managed care plans that are administered by commercial payers. These plans may also offer an outpatient prescription drug benefit (under Medicare Part D). Coverage for FULPHILA under Medicare Advantage can be under a medical benefit or pharmacy benefit. It could also require prior authorization (PA) or have other utilization management restrictions. Access options may include buy-and-bill, specialty pharmacy, or both, depending on the plan. Providers should refer to each patient's plan policy to determine coverage and access options.

Coverage for Private Commercial Payers

Commercial plans may cover FULPHILA under the medical benefit, pharmacy benefit, or both. Some payer plans may allow physicians and hospitals to buy and bill FULPHILA, while others may stipulate that FULPHILA must be ordered through a network specialty pharmacy provider. Specialty pharmacies may bill the payer through the medical or pharmacy benefit, depending on the benefit design of a patient's insurance plan.

Coverage for Medicaid

Medicaid may be an important payer for patients prescribed FULPHILA, either as a primary or secondary source of coverage. The Medicaid program is jointly funded by federal and state governments and is administered at the state level. Medicaid coverage varies by state and also by the Medicaid plan type (e.g., FFS or administered through a managed care organization).

Like private payers, Medicaid FFS and managed Medicaid plans may cover FULPHILA under a medical benefit (buy-and-bill), a pharmacy benefit (specialty, retail, or mail-order), or both. Step-therapy edits, PA requirements, and preferred drug lists (PDLs) are used by Medicaid plans as a means to control access to certain prescription drugs. Drugs not listed on a PDL may have PA requirements or they may not be covered at all.

Since access processes vary significantly by state and plan, it is important to thoroughly investigate and understand the individual patient's coverage requirements prior to acquiring and administering FULPHILA to Medicaid patients.

For assistance with individual patient benefit information or questions regarding patient access to FULPHILA, please contact My Biocon Biologics at 1 (833) 695-2623.

Prior Authorization Overview

A prior authorization (PA) is a requirement imposed by a payer for the provider to obtain approval prior to administering a drug or performing a procedure or service. It is used to help payers ensure that the therapy is medically necessary. Payers typically have standard processes that must be followed for healthcare providers to submit a PA request. These may include calling a specific department, filling out and faxing a form, or writing a letter of medical necessity.

Please see Important Safety Information on back cover and accompanying Full Prescribing Information.

Tips for Submitting PAs for FULPHILA (pegfilgrastim-jmdb)

PA requirements for FULPHILA vary by payer and by plan type, and healthcare providers should contact each health plan directly to determine specific guidelines and documentation requirements. Providers may also contact My Biocon Biologics for assistance with understanding payer-specific PA requirements.

The following checklist may help you determine PA requirements for patients prescribed FULPHILA:

Is a PA required for FULPHILA?

What is the process for requesting a PA?
- By fax, by phone, or by letter of medical necessity?
- Is a specific form required?

What is the contact information (phone, fax, and/or address) for the PA department?

What information should be included as part of the PA request?
- ICD-10-CM diagnosis for primary rationale for the treatment? Or are there additional requirements (such as other diagnosis)?
- Drug billing code (e.g., HCPCS) and/or other drug-identifying information (e.g., NDC)?
- CPT procedure/service codes and descriptions?
- Chart notes and/or laboratory test results?
- List of current medications and other therapies tried and failed?
- Prescribing information and/or FDA approval letter?

What is the typical turnaround time for a PA decision?

How will the decision be communicated to the practice or facility?
- By phone/fax/mail?

If approved, how long does the PA approval last?
- 30 days/6 months/1 year?

What is the process to appeal a denied request for a PA?

Reimbursement

Medicare

Medicare provides separate payment for Part B-covered drugs in outpatient settings.

Physician Office

Medicare reimburses for Part B-covered drugs administered in the physician office setting based on average sales price (ASP), which is reported quarterly by manufacturers and updated by CMS.

Table 6. Medicare Reimbursement Methodology for a Part B-Covered Biosimilar in the Physician Office Setting[8]

Medicare Physician Office Payment Methodology[8]	When This Applies
ASP of biosimilar + 6% of reference product's ASP	For drugs with an established ASP

Hospital Outpatient Departments

Medicare payment for Part B-covered biosimilar drugs administered in hospital outpatient clinics varies based on multiple factors, including whether the biosimilar[9]:

- Has an established ASP
- Has temporary pass-through status

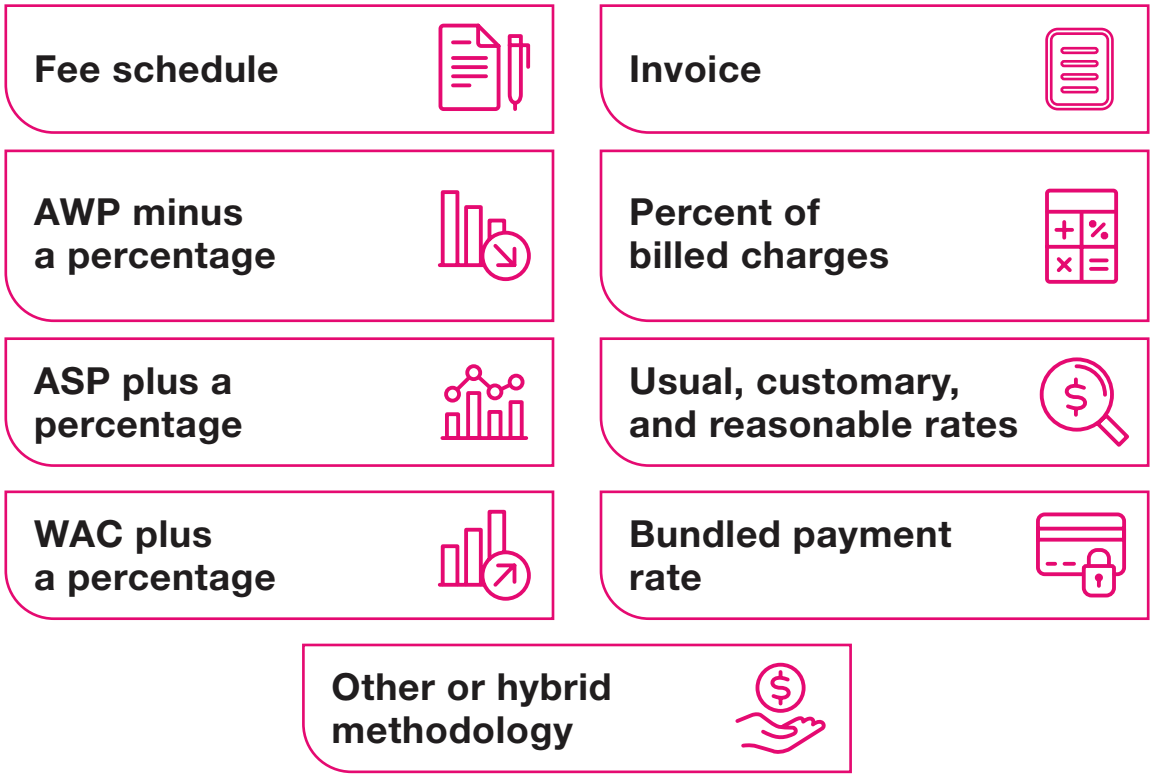
For more information, please refer to the flashcard "Medicare Payment for Biosimilars in Outpatient Settings" or contact My Biocon Biologics.

Please consult with your Medicare Administrative Contractor for more information on Medicare policies that may affect reimbursement for FULPHILA

Commercial Payers, Medicare Advantage, and Medicaid Plans

Many payers, including commercial insurance providers, Medicare Advantage, and managed Medicaid plans, reimburse physicians and hospitals based on individual contracts that are set up between the healthcare provider and the payer. It is particularly important for physician practices and hospital outpatient facilities to review their contracts for language that specifies how the payer will calculate reimbursement for new drugs. FFS Medicaid plans, like FFS Medicare, typically publicize their payment rates via a fee schedule.

Payers may reimburse physician-administered drugs and associated services in a variety of ways, including:



ASP – average sales price; AWP – average wholesale price; WAC – wholesale acquisition cost.

Claims

Sample CMS-1500 Claim Form

Products and services provided in the physician office setting are billed using the CMS-1500 claim form or the electronic claim file (837P). Required information includes patient demographic and insurance information, insurance policy number, codes to indicate the services and products provided to the patient, and the provider's National Provider Identifier (NPI). Reported codes (e.g., ICD-10-CM, CPT, and HCPCS codes) must be supported by the information in the patient's medical record. Filling out an accurate and complete claim form is critical for timely processing and reimbursement of your claim. A sample CMS-1500 claim form for billing FULPHILA (pegfilgrastim-jmdb) is provided on the next page.

Please note that information specific to coding, coverage policies, and payment methodologies is subject to change and should be verified for each patient prior to treatment. The information here is current as of December 2021.

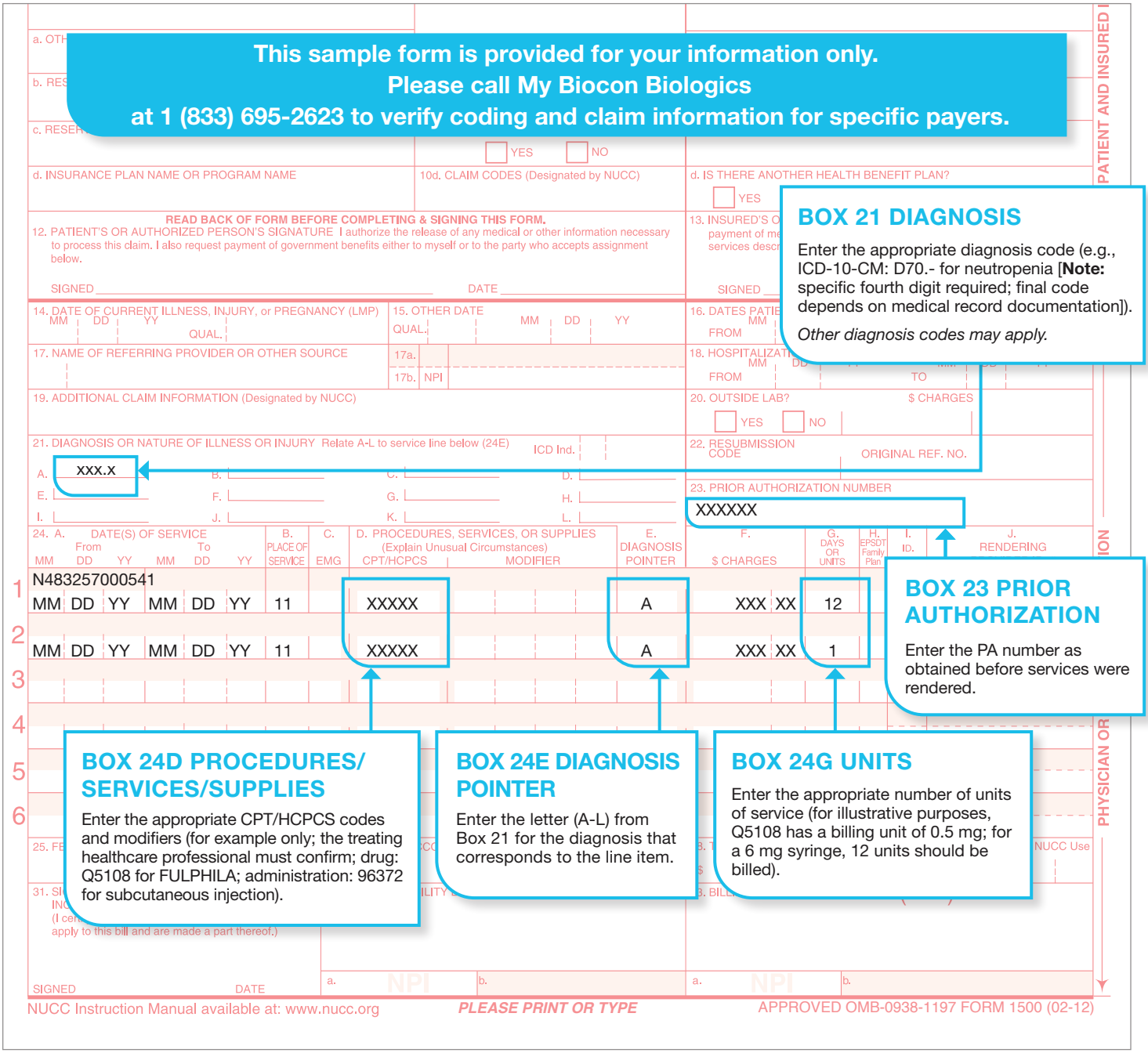
IMPORTANT SAFETY INFORMATION

Do not administer FULPHILA to patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as pegfilgrastim products or filgrastim products.

Fatal splenic rupture can occur following administration of pegfilgrastim products: Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.

Acute respiratory distress syndrome (ARDS) can occur in patients receiving pegfilgrastim products. Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue FULPHILA in patients with ARDS.

Sample CMS-1500 Claim Form



The content provided on this sample claim form is for informational purposes only and is not intended as legal advice or to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure FULPHILA (pegfilgrastim-jmdb) claims are accurate, complete, and supported by documentation in the patient's medical record. Biocon Biologics does not guarantee that payers will consider all codes appropriate for all encountered scenarios, and Biocon Biologics does not guarantee FULPHILA coverage or reimbursement.

Sample CMS-1450 (UB-04) Claim Form

Products and services provided in the hospital outpatient facility are billed using the CMS-1450 institutional claim form or the electronic claim file (837I). This form is also referred to as UB-04. Required information includes patient demographic and insurance information, insurance policy number, codes to indicate the services and products provided to the patient, revenue codes, and the provider's NPI. Reported codes (e.g., ICD-10-CM, CPT, and HCPCS codes) must be supported by the information in the patient's medical record. Filling out an accurate and complete claim form is critical for timely processing and reimbursement of your claim. A sample CMS-1450 claim form for billing FULPHILA administered to a Medicare patient is provided on the next page.

Please note that information specific to coding, coverage policies, and payment methodologies is subject to change and should be verified for each patient prior to treatment. The information here is current as of December 2021.

INDICATIONS AND USAGE

FULPHILA 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

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

IMPORTANT SAFETY INFORMATION

Serious allergic reactions, including anaphylaxis, can occur in patients receiving pegfilgrastim products. Permanently discontinue FULPHILA in patients with serious allergic reactions.

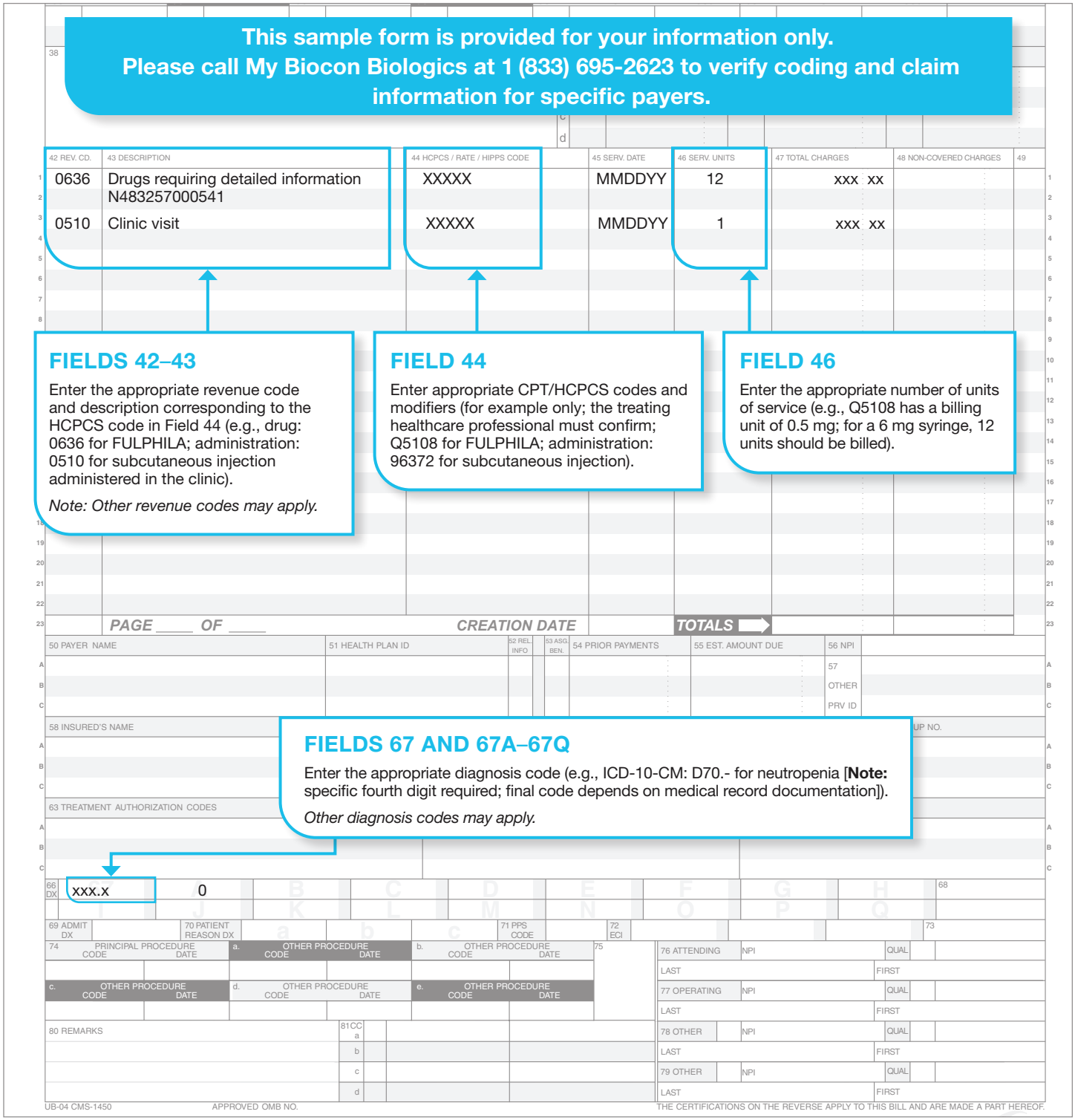
Fatal sickle cell crises can occur in patients with sickle cell disorders receiving pegfilgrastim.

Glomerulonephritis has been reported in patients receiving pegfilgrastim products. Evaluate and consider dose-reduction or interruption of FULPHILA if causality is likely.

High white blood cell counts ≥100 x 10^9/L have been found in patients receiving pegfilgrastim. Monitor Complete Blood Cell Counts (CBCs).

Please see Important Safety Information on back cover and accompanying Full Prescribing Information.

Sample CMS-1450 (UB-04) Claim Form



The content provided on this sample claim form is for informational purposes only and is not intended as legal advice or to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure FULPHILA (pegfilgrastim-jmdb) claims are accurate, complete, and supported by documentation in the patient's medical record. Biocon Biologics does not guarantee that payers will consider all codes appropriate for all encountered scenarios, and Biocon Biologics does not guarantee FULPHILA coverage or reimbursement.

Clean Claims Submission

Submitting an error-free or "clean" claim that has all the required information necessary in required fields of the claim form may facilitate timely and accurate reimbursement for services rendered.

The following are some considerations for preparing and submitting claims for FULPHILA:

Include the correct patient/subscriber information (name, date of birth, and member ID number), clinic demographic information, and required signatures

Report all of the necessary payer-specific, drug-identifying information for FULPHILA (e.g., correct codes, units, NDC, drug name, and dose)

Report a primary diagnosis code (and secondary code, if applicable) to the highest level of specificity

Include payer-specific required supplemental information (e.g., letter of medical necessity, PA number, chart notes, laboratory tests)

When filing a claim electronically, stay within any payer-mandated character limits for completing the sections that correspond to Box 19 (CMS-1500) or Field 80 (CMS-1450)

Report the drug code and the subcutaneous injection code on the same claim form; ensure that the date of service does not fall between 14 days before and 24 hours after administration of cytotoxic chemotherapy

File the claim within the payer's required time frame for submission

You may contact My Biocon Biologics for additional information about claims submissions.

IMPORTANT SAFETY INFORMATION

Thrombocytopenia has been reported in patients receiving pegfilgrastim. Monitor platelet counts.

Capillary leak syndrome (CLS) has been reported after the administration of granulocyte colony-stimulating factors (G-CSF), including pegfilgrastim, that results in hypotension, hypoalbuminemia, edema, and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients with CLS should be closely monitored and given standard symptomatic treatment, which may include a need for intensive care.

Please see Important Safety Information on back cover and accompanying Full Prescribing Information.

Sample Letter of Medical Necessity

Payers may request a letter of medical necessity to support coverage of FULPHILA (pegfilgrastim-jmdb). The letter explains why the drug was medically necessary for the specific patient and may include supporting documentation (e.g., medical records, peer-reviewed literature, prescribing information). The letter may be submitted as part of a PA request, with the claim form, or in response to a payer's additional document request.

The following is a sample letter of medical necessity; or you may use another form or format. The letter should include patient-specific information, should be on your letterhead and signed by the prescriber, and should be submitted to a payer to support a PA request or claim for FULPHILA.

[Date]
[Contact Name] [Title]
[Name of Health Insurance Company]
[Address] [City, State Zip]

Insured: [Name]
Policy Number: [Number]
Group Number: [Number]

Dear [Contact's Name]:

I am writing on behalf of my patient, [name of patient], to request that [name of health insurance company] approve coverage and appropriate reimbursement associated with [name of patient]'s treatment with FULPHILA (pegfilgrastim-jmdb), a biosimilar. FULPHILA is FDA-approved for subcutaneous use as a leukocyte growth factor indicated to 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.

Patient History and Diagnosis

[Name of patient] is a[n] [age]-year-old [male/female/other gender identification] born [MM-DD-YEAR] who has been receiving myelosuppressive anticancer drugs and is at risk of developing an infection due to febrile neutropenia since [date] for [patient's cancer diagnosis].

[Provide a brief discussion of patient's symptoms and therapy to date. It may be helpful to note whether FULPHILA, if previously administered, has decreased the incidence of infection, as manifested by febrile neutropenia, for the patient.]

Based on the above facts, I am confident you will agree that FULPHILA is indicated and medically necessary for this patient. If you have any further questions, please feel free to call me at [physician's phone number] to discuss. Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician's name]

[Physician's practice name]

[Phone number]

Enclosures [original claim form, supporting documentation]

Sample Letter of Appeal

In some cases, a claim denial may be overturned after a phone call to a payer representative. If not, an appeal letter may be submitted in response to a payer's decision for underpayment or non-payment, as detailed in the explanation of benefits (EOB) or remittance advice. In addition to filing the appeal within timely filing limits, understanding the reasons the payer denied the claim is critical for filing a successful appeal.

The following sample letter of appeal or another form may be used to submit additional documentation to the patient's payer when appealing a denied claim.

[Date]
[Contact Name] [Title]
[Name of Health Insurance Company]
[Address] [City, State Zip]

Insured: [Name]
Policy Number: [Number]
Group Number: [Number]
Claim Control Number: [Number]

Dear [Contact's Name]:

This letter serves as a request for reconsideration for payment of a denied claim representing charges for FULPHILA (pegfilgrastim-jmdb), a biosimilar administered to [name of patient] on [date of service]. [Name of patient] is a[n] [age]-year-old [male/female/other gender identification] born [MM-DD-YEAR] who has been under my treatment. [Name of patient] is under my care for [his/her] diagnosis [insert nonmyeloid diagnosis and myelosuppressive chemotherapy regimen], which puts the patient at risk of infection from febrile neutropenia. You have indicated that FULPHILA is not covered by [insurance name] because [reason for denial].

[Provide a brief discussion of patient's symptoms and therapy to date and any other pertinent information.] FULPHILA has decreased the incidence of infection, as manifested by febrile neutropenia, for this patient.

FULPHILA is FDA-approved for subcutaneous use as a leukocyte growth factor indicated to 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. FULPHILA has been administered to this patient per the FDA-approved indication.

FULPHILA is a medically necessary part of [name of patient]'s treatment. I request that an oncology specialist who is familiar with FULPHILA review this appeal letter with additional documentation as I am confident your reconsideration of this claim would yield appropriate payment. Please contact me at [physician's phone number] if you require additional information.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician's name]

[Physician's practice name]

[Phone number]

Enclosures [original claim form, denial/EOB, supporting documentation]

Please see Important Safety Information on back cover and accompanying Full Prescribing Information.

Appeal of Denied Claims

If a claim for FULPHILA (pegfilgrastim-jmdb) is improperly reimbursed or denied, you may consider submitting an appeal. Many claim denials result from the use of incorrect codes, incorrect member identification number, or missing supplemental documentation, such as a letter of medical necessity. Many claims issues can be resolved with a single phone call to a payer representative who may be able to reprocess a corrected claim. If not, a carefully crafted appeal letter may be required.

This list offers considerations that may be helpful for appealing denied claims:

DETERMINE THE PAYER'S PROCESS FOR FILING APPEALS

- Use a designated form for the appeal if such a form is required by the payer
- Determine the timely filing limit

UNDERSTAND THE REASON FOR THE DENIAL

- Read the EOB to find the reason for the claim denial. Payers use remittance advice codes for the service in question. Remittance advice code descriptions are usually included at the bottom of the page
- If the payer cites the need for additional information, compile and submit the necessary documentation as soon as possible
- If you receive a claim denial due to a lack of medical necessity, submit additional documentation that helps to support the physician's clinical decision to prescribe FULPHILA to your patient

DRAFT THE APPEAL LETTER

- Make sure the appeal letter responds to the denial code reason
- Submit a corrected claim if the denial was due to a technical billing error (e.g., incorrect patient identification number, missing diagnosis). Write "Corrected Copy" at the top
- Include a copy of the original claim and related denial notification (EOB)
- You may need to include the patient's relevant medical records, prescribing information, FDA approval letter, and relevant journal articles supporting the use of FULPHILA
- Request that an oncology specialist who is familiar with FULPHILA review the appeal letter and additional documentation

SUBMIT AND TRACK APPEAL STATUS

- Submit the appeal as soon as possible and within required time limits
- Track claims appeal responses to ensure appeals have been processed appropriately
- Document the result (e.g., payment made or if further action is required)

References

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Notes

Notes

Please see Important Safety Information on back cover and accompanying Full Prescribing Information.

INDICATIONS AND USAGE

FULPHILA 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

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

IMPORTANT SAFETY INFORMATION

Do not administer FULPHILA to patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors, such as pegfilgrastim products or filgrastim products

Fatal splenic rupture can occur following the administration of pegfilgrastim products: Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.

Acute respiratory distress syndrome (ARDS) can occur in patients receiving pegfilgrastim products. Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue FULPHILA in patients with ARDS.

Serious allergic reactions, including anaphylaxis, can occur in patients receiving pegfilgrastim products. Permanently discontinue FULPHILA in patients with serious allergic reactions.

Fatal sickle cell crises can occur in patients with sickle cell disorders receiving pegfilgrastim.

Glomerulonephritis has been reported in patients receiving pegfilgrastim products. Evaluate and consider dose-reduction or interruption of FULPHILA if causality is likely.

High white blood cell counts ≥100 x 10^9/L have been found in patients receiving pegfilgrastim. Monitor Complete Blood Cell Counts (CBCs).

Thrombocytopenia has been reported in patients receiving pegfilgrastim. Monitor platelet counts.

Capillary leak syndrome (CLS) has been reported after the administration of granulocyte colony-stimulating factors (G-CSF), including pegfilgrastim, that results in hypotension, hypoalbuminemia, edema, and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients with CLS should be closely monitored and given standard symptomatic treatment, which may include a need for intensive care.

Pegfilgrastim and filgrastim may possibly act as growth factors for any tumor type. The G-CSF receptor, through which these products act, has been found on tumor cell lines.

Myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) have been associated with the use of pegfilgrastim: Monitor patients with breast and lung cancer using FULPHILA in conjunction with chemotherapy and/or radiotherapy for signs and symptoms of MDS/AML.

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

Growth factor therapy increases the hematopoietic activity of the bone marrow which has been associated with transient positive bone imaging changes. Consider when interpreting bone imaging results.

The most common adverse reactions (≥ 5% difference in incidence compared to placebo) are bone pain and pain in extremity.

Please see accompanying Full Prescribing Information.

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