



# Reimbursement and Billing Guide

# Patient Access and Reimbursement Support Services



1-844-4-UDENYCA (1-844-483-3692)  
Monday through Friday  
8:00 AM-8:00 PM ET



Fax 1-877-226-6370



[www.CoherusCOMPLETE.com](http://www.CoherusCOMPLETE.com)

## Contents

### Getting Started With UDENYCA® (pegfilgrastim-cbqv)

About the Reimbursement and Billing Guide.....	4
UDENYCA® Coding Overview.....	5

### Securing UDENYCA® Treatment Approval

<b>STEP 1:</b> Verify the Patient’s Insurance Benefits.....	6
<b>STEP 2:</b> Establish Medical Necessity.....	8
<b>STEP 3:</b> Identify the Patient’s Co-Pay.....	8

### UDENYCA® Reimbursement Process

<b>STEP 4:</b> Submit the Claims Form.....	9
Sample CMS-1500 Claims Form.....	10
Sample CMS-1450 (UB-04) Claims Form.....	11
<b>STEP 5:</b> Receive Reimbursement for Injectable Drugs.....	12
Payment Rates for Injectable Drugs in Freestanding Infusion Centers/Physician Offices.....	12
Payment Rates for Injectable Drugs in Hospital Outpatient Departments.....	13
<b>STEP 6:</b> Submit for Co-Pay Assistance.....	14
<b>STEP 7:</b> Address Claims Denials.....	14
Tips for Appealing Claims Denials.....	14

References.....	15
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Coherus BioSciences is pleased to provide you with this reimbursement and billing guide. The information included herein is general coding, billing, and coverage information, and is not intended to suggest coverage for any individual patient or treatment. It is not a guarantee of coverage or reimbursement for any product or service. All final decisions on diagnosis, the need for treatment, and the appropriateness of UDENYCA® for a particular patient rest with you as the patient’s healthcare provider. Coherus BioSciences is committed to supporting accurate claims submissions and endorses the use of its products only where medically necessary and appropriate. Given the constantly evolving nature of the healthcare reimbursement environment, this reimbursement and billing guide is intended as a set of general guidelines and is current as of May 2019.

# Getting Started With UDENYCA®

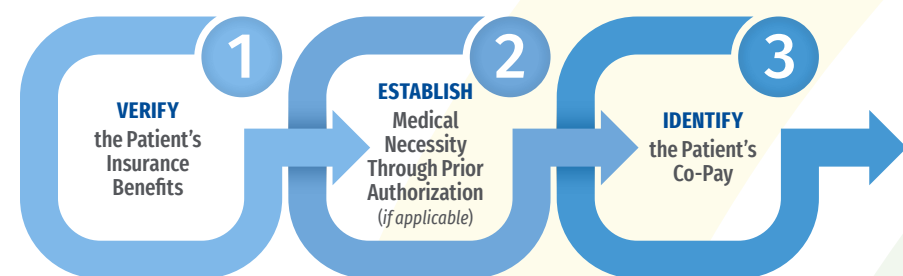
## About the Reimbursement and Billing Guide

The UDENYCA® (pegfilgrastim-cbqv) Reimbursement and Billing Guide supports healthcare providers in their efforts to understand the essential components of UDENYCA® reimbursement. This step-by-step guide includes key coding and coverage details that may help facilitate appropriate billing and reimbursement for UDENYCA® therapy.

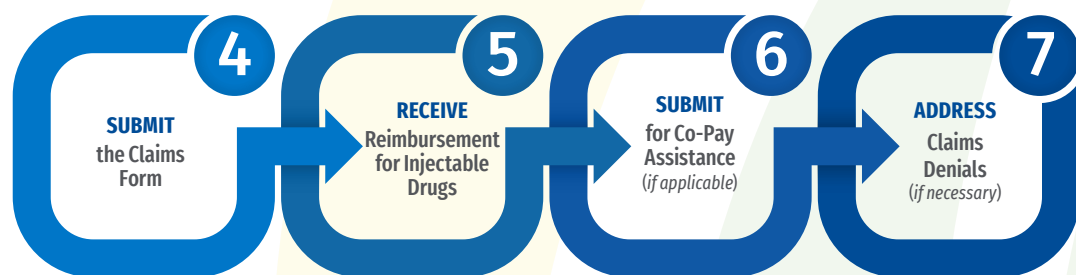
Coverage refers to the health plan's decision to provide benefits for a specific product or medical service. These coverage policies vary by payer and will specify whether a proposed course of treatment is medically necessary and eligible for reimbursement.

This guide provides an overview of the following:

### Securing UDENYCA® Treatment Approval



### UDENYCA® Reimbursement Process



For reimbursement assistance for UDENYCA®, please contact



- Coherus COMPLETE™ at **1-844-4-UDENYCA (1-844-483-3692)** or **www.CoherusCOMPLETE.com**
- Your Coherus Field Reimbursement Specialist
- Individual payers for payer-specific information

## UDENYCA® Coding Overview

The coding information contained herein is for informational purposes only, and is not a guarantee of coverage or reimbursement for any product or service. This information is not intended to substitute for the physician's independent diagnosis or treatment of each patient. The inclusion of the codes is not intended to suggest or imply that such codes reflect appropriate diagnoses for any particular patient.

HCPCS Code	Description
Q5111*	Injection, pegfilgrastim-cbqv, biosimilar, (UDENYCA®), 0.5 mg
Billable Units	Description
12	<b>Billable units for administration of one syringe</b> For administration of less than one syringe, please use the billable units and JW modifier as appropriate
Modifier	Description
JG Modifier†	Modifier for drug or biological acquired with 340B drug pricing program discount
TB Modifier†	Modifier for drug or biological acquired with 340B drug pricing program discount; reported for informational purposes
JW Modifier	Modifier to report the amount of drug or biological that is discarded and eligible for payment under the discarded drug policy
CPT® Code	Description
96372‡	Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular
Patient Diagnosis Code	Description
ICD-10-CM	Appropriate diagnosis codes for patient condition
	Allowable diagnosis codes vary by payer
Hospital Services and Supplies Revenue Code	Description
0636§	Drugs requiring detailed coding
0510	Clinic visit
NDC	Description
70114-101-01 (10-digit)	6 mg/0.6 mL single-dose prefilled syringe
70114-0101-01 (11-digit)	6 mg/0.6 mL single-dose prefilled syringe

\*Effective for UDENYCA® administered on or after January 1, 2019.

†The use of informational modifier "TB" for pass-through drugs acquired with a 340B discount is required.

‡"JG" modifier is for use with each separately payable, non-pass-through, 340B-acquired drug.

§Please contact the payer to determine appropriate HCPCS coding for UDENYCA®.

||Used in combination with HCPCS drug code.

Used in combination with CPT® injection.

CPT®=Current Procedural Terminology. HCPCS=Healthcare Common Procedure Coding System. NDC=National Drug Code.

# Securing UDENYCA® Treatment Approval

## 1 VERIFY the Patient's Insurance Benefits

### Benefits Verification Process

Before administering UDENYCA®, complete a product-specific benefits verification. This will determine if additional information must be submitted in order to obtain coverage.

During benefits verification, confirm the following information with the patient's health insurance plan:

- ✓ **Patient is actively covered**
- ✓ **Name of the insured and the relationship of the insured to the patient**
- ✓ **Insurance coverage dates** (effective date and end date of policy)
- ✓ **In-network or out-of-network coverage**
  - » Network providers: Some payers have exclusive contracts with in-network or participating providers to provide infusion therapies
- ✓ **UDENYCA® Q code, CPT® code for administration, diagnosis code, and number of units are covered**
- ✓ **Whether a prior authorization (PA) is required**
  - » If no PA is required, request predetermination or precertification
  - » Understand medical necessity requirements
  - » Request a copy of the PA form, if necessary
- ✓ **Patient's financial responsibility**
  - » Co-pay
  - » Co-insurance percentage
  - » Deductible amounts and if deductible has been met for the year
- ✓ **Limitations of policy, including exclusions or documentation requirements**
  - » Understand payer policies, including setting of care restrictions
- ✓ **If uninsured, the patient may be eligible for the Patient Assistance Program**





## Conducting a Benefits Verification

Coherus COMPLETE™ can assist provider offices with benefits verification. To ensure your patients receive the appropriate support services, enroll your patients online.

The Coherus COMPLETE™ Provider Portal provides a streamlined process:

- Allows online access to monitor the approval status of patients
- Facilitates efficient communication with Patient Access Specialists
- Avoids duplication of administrative efforts when patients require additional treatment

To initiate the enrollment process

-  **1.** Log in to the Coherus COMPLETE™ Provider Portal at <http://login.CoherusCOMPLETE.com/>.
-  **2.** Select **Patient Enrollment** and complete the enrollment form.
-  **3.** Before submitting, confirm patient consent by checking attestation.
-  **4.** Click **Save and Leave** to submit the form.

Please document the results of the benefits verification in the patient's medical record.



## 2 ESTABLISH Medical Necessity

### Prior Authorization (PA)

During the benefits verification process, the payer may request a PA and will likely provide a specific PA form to be completed prior to a coverage determination. Insurers that are unfamiliar UDENYCA® (pegfilgrastim-cbqv) may require additional information in order to process the claim.

To complete this step, provider offices may use the comprehensive PA services provided by Coherus COMPLETE™:

- Identification of payer PA requirements
- Send prefilled PA form to the provider\*
- PA submissions
- PA tracking by following up with payers on PA determinations
- Sample Letter of Medical Necessity
- Other UDENYCA®-specific information requested by the payer, including the Prescribing Information and FDA Approval Letter

## 3 IDENTIFY the Patient's Co-Pay

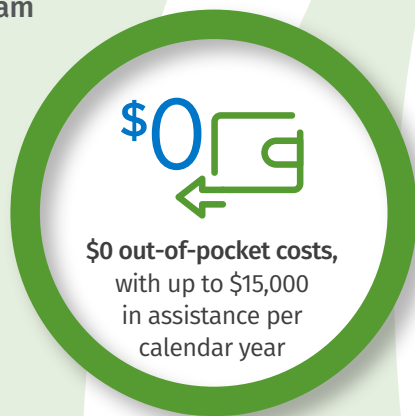
### Coherus COMPLETE™ Co-Pay Assistance Program

The Coherus COMPLETE™ Co-Pay Assistance Program can help eligible patients who are commercially insured† with out-of-pocket costs for UDENYCA®.‡

\*Provider is responsible for completing all clinical information.

†Patients covered by Medicare, Medicaid, or any federal- or state-funded program are not eligible for the Coherus COMPLETE™ Co-Pay Assistance Program.

‡For additional details, please see back cover or visit [www.CoherusCOMPLETE.com](http://www.CoherusCOMPLETE.com).



To enroll your patient in the Coherus COMPLETE™ Co-Pay Assistance Program, please visit [www.CoherusCOMPLETE.com](http://www.CoherusCOMPLETE.com).

## UDENYCA® Reimbursement Process

### 4 SUBMIT the Claims Form

Following administration of UDENYCA® (pegfilgrastim-cbqv) to the patient, submit a claim to the insurance provider. Coherus COMPLETE™ can provide information on the buy-and-bill process to aid in claims submissions on behalf of patients.

**REMINDER**  
Billable Units=12

- 1. Verify codes submitted.**  
Most claims delays and denials are due to coding errors or failure to complete the form.
- 2. Verify the patient's diagnosis.**  
Verify that the claims diagnosis code matches the diagnosis code provided in the PA form.
- 3. File claims properly.**  
Most payers have a time limit for filing claims after services are provided.

**Freestanding Infusion Center/Physician Office**

Patients may receive UDENYCA® in a freestanding infusion center or a physician office. In this setting, use a CMS-1500 Claims Form. For an overview of the CMS-1500 Claims Form, see page 10.

**Hospital Outpatient Department**

Patients may receive UDENYCA® in the hospital outpatient department. In this setting, use a CMS-1450 (UB-04) Claims Form. For an overview of the CMS-1450 (UB-04) Claims Form, see page 11.

# Sample CMS-1500 Claims Form

**HEALTH INSURANCE CLAIM FORM**  
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

**ITEM 21**  
Specify appropriate ICD-10-CM diagnosis code(s).

**ITEM 23. Prior Authorization**  
Enter the PA number as obtained before services were rendered.

**ITEM 24A. Date(s) of Service**  
Enter NDC qualifier "N4", and the NDC.

**ITEM 24D**  
Indicate appropriate HCPCS and CPT codes, for example:  

- Drug: Q5111 for UDENYCA®
- Administration: 96372 for subcutaneous injection

**ITEM 24G**  
Specify the billing units. For example, **12 billing units** for administration of 1 syringe of pegfilgrastim-cbqv, biosimilar, (UDENYCA®), 0.5 mg.  
 For administration of less than one syringe, please use the billable units and JW modifier as appropriate.

This sample claims form is for informational purposes only and does not replace a medical provider's professional judgment. Before initiating UDENYCA® treatment, the patient's health insurance provider should be contacted to confirm coverage, coding, and claims submission procedures. All claims should be reviewed for completeness, accuracy, and correct documentation from the patient's medical record. Coherus BioSciences does not guarantee UDENYCA® coverage or reimbursement.

# Sample CMS-1450 (UB-04) Claims Form

- CMS-1450 (UB-04) Claim Form -

**FORM LOCATOR (FL) 42 AND 43**  
Specify revenue codes and describe procedures, for example:  

- 0636: Drugs requiring detailed coding
- 0510: Clinic visit

 Note: Other revenue codes may apply.

**FL 44**  
Specify appropriate HCPCS and CPT codes and modifiers, for example:  

- Drug: Q5111 for UDENYCA®
- Administration: 96372 for subcutaneous injection

**FL 46**  
Specify the billing units. For example, **12 billing units** for administration of 1 syringe of pegfilgrastim-cbqv, biosimilar, (UDENYCA®), 0.5 mg.  
 For administration of less than one syringe, please use the billable units and JW modifier as appropriate.

**FL 66**  
Identify the type of ICD diagnosis code used (eg, enter a "0" for ICD-10-CM).

**FL 67**  
Specify appropriate ICD-10-CM diagnosis code(s).

This sample claims form is for informational purposes only and does not replace a medical provider's professional judgment. Before initiating UDENYCA® treatment, the patient's health insurance provider should be contacted to confirm coverage, coding, and claims submission procedures. All claims should be reviewed for completeness, accuracy, and correct documentation from the patient's medical record. Coherus BioSciences does not guarantee UDENYCA® coverage or reimbursement.

## 5 RECEIVE Reimbursement for Injectable Drugs

Injectable physician-administered products are typically covered under the medical or Part B benefit, though some payers may require coverage under the pharmacy or Part D benefit. Coverage details can be determined in the benefits verification process.

The reimbursement rates of injectable physician-administered drugs covered under the medical or Part B benefit may depend on site of care, payer, and drug-specific information.

Regularly review insurance provider payments to the office, and reconcile reimbursement of both primary and secondary insurance providers.

### Payment Rates\* for Injectable Drugs in Freestanding Infusion Centers/Physician Offices

Payer	Rate†
Medicare <sup>3,4</sup>	At launch, prior to ASP being established: <b>WAC + 3%</b> [3% of the UDENYCA® (pegfilgrastim-cbqv) WAC] After ASP is established: <b>ASP + 6%</b> [6% of the Neulasta® (pegfilgrastim) ASP]‡
Private Commercial Payers, Medicare Advantage, and Managed Medicaid	Payers typically reimburse injectable drugs based on proprietary contracts between the provider and the payer; payment rates will vary based on agreed terms
Medicaid	Each Medicaid state agency will determine its own payment rate; typically, Medicaid state agencies will publish payment rates via a fee schedule

\*CMS payment rates are subject to change by CMS from time to time.

†ASP or WAC references are exclusive of any government sequestration on reimbursement rates.

‡Due to across-the-board cuts in federal spending known as sequestration, Medicare covers 80% of the payment to providers, which is reduced by 2%. This affects payment for Part B-covered drugs along with payment for professional services, such as the administration of the UDENYCA® injection. Sequestration does not affect the patient's share of costs.

ASP=average sales price. WAC=wholesale acquisition cost.

### Payment Rates\* for Injectable Drugs in Hospital Outpatient Departments

Payer	Rate†
<b>NON-340B ENTITIES</b>	
Medicare <sup>3,4</sup>	After a product-specific code, prior to ASP being established: <b>WAC + 3%</b> [3% of UDENYCA® (pegfilgrastim-cbqv) WAC] After ASP is established: <b>ASP + 6%</b> (6% of Neulasta® (pegfilgrastim) ASP)
Private Commercial Payers, Medicare Advantage, and Managed Medicaid	Payers typically reimburse injectable drugs based on proprietary contracts between the provider and the payer; payment rates will vary based on agreed terms
Medicaid	Each Medicaid state agency will determine its own payment rate; typically, Medicaid state agencies will publish payment rates via a fee schedule

Payer	Rate†
<b>340B ENTITIES</b>	
Medicare <sup>3,4</sup>	After a product-specific code, prior to pass-through status being established: <b>WAC - 22.5%</b> (22.5% of UDENYCA® WAC) If the drug receives pass-through status: <b>WAC + 3%</b> (3% of UDENYCA® WAC) <sup>5</sup> After ASP is established <sup>¶</sup> : <b>ASP + 6%</b> (6% of Neulasta® ASP)
Private Commercial Payers, Medicare Advantage, and Managed Medicaid	Payers typically reimburse injectable drugs based on proprietary contracts between the provider and the payer; payment rates will vary based on agreed terms
Medicaid	Each Medicaid state agency will determine its own payment rate; typically, Medicaid state agencies will publish payment rates via a fee schedule

¶While pass-through status is effective.



## **SUBMIT for Co-Pay Assistance**

For patients enrolled in the Coherus COMPLETE™ Co-Pay Assistance Program, the practice submits an ANSI ASC X12N electronic secondary claim using Payer ID #56155, Group #00003633 to process the patient's co-pay assistance benefits. For information on submitting pharmacy benefit claims, please contact Coherus COMPLETE™ at 1-844-4-UDENYCA (1-844-483-3692).

## **ADDRESS Claims Denials**

If your claim is denied, review the payer-provided Explanation of Benefits (EOB) detailing the reason for the denial.

### **Common reasons for a claims denial or underpayment include**

- Lack of details on the patient's history and clinical course
- Incorrect billing codes or omission of modifiers
- Incomplete documentation supporting the medical necessity and/or codes used
- Inaccurate description of services provided

**Coherus COMPLETE™ can help manage the denied claims appeals process. Contact Coherus COMPLETE™ at 1-844-4-UDENYCA (1-844-483-3692).**

## **Tips for Appealing Claims Denials**

If there are no submission errors or the claim was denied because the payer was not convinced UDENYCA® (pegfilgrastim-cbqv) was necessary, submit additional documentation to justify the medical necessity of UDENYCA®.

**A sample Letter of Appeal is available to download at [www.CoherusCOMPLETE.com](http://www.CoherusCOMPLETE.com). The letter highlights**

- Patient's medical history
- Other therapies that have been tried unsuccessfully
- Rationale for selecting UDENYCA® for this patient

**The following information may be needed in the resubmitted claim:**

- UDENYCA® Prescribing Information, which is available through Coherus COMPLETE™
- FDA Approval Letter, which is available through Coherus COMPLETE™



**There are time limits to submit the appeal.**

## **References**

1. CMS.gov. HCPCS Quarterly Update. November 21, 2018. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.html>. Accessed December 10, 2018.
2. CMS.gov. Medicare-FFS Program Billing 340B Modifiers Under the Hospital Outpatient Prospective Payment System (OPPS) Frequently Asked Questions. April 2, 2018. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf>. Accessed September 5, 2018.
3. CMS.gov. Medicare Physician Fee Schedule CY 2019. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-F.html>. Accessed November 15, 2018.
4. CMS.gov. Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. <https://www.federalregister.gov/documents/2018/11/21/2018-24243/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center>. Accessed November 15, 2018.
5. CMS.gov. Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Correction. <https://www.federalregister.gov/documents/2018/12/28/2018-28348/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center>. Accessed May 20, 2019.



## Overview of Coherus COMPLETE™

Coherus is committed to ensuring patient access to biologics. Coherus COMPLETE™ is a suite of patient support services and programs designed to assist with patient access.

### Reimbursement support provided by Patient Access Specialists

- Product-specific benefit verification
- Comprehensive PA services—coverage, coding, and reimbursement education
- Investigating alternative financial support through independent foundations for eligible patients

### Patient support through financial assistance programs

- Coherus COMPLETE™ Co-Pay Assistance Program
- Patient Assistance Program

### Access support to simplify program utilization

- Coherus COMPLETE™ Provider Portal
- Product Replacement Program
- Access support to simplify program utilization

