UDENYCA® pegfilgrastim-cbqv

UDENYCA Solutions™ Product Replacement Program

UDENYCA Solutions™ is part of the Coherus Solutions™ family of programs.

Call 1-844-483-3692
Monday to Friday | 8 AM to 8 PM ET
FAX 1-877-226-6370
www.UDENYCASolutions.com

All sections/fields with an asterisk are required in order to ensure timely processing.

PRODUCT REQUEST FORM

The UDENYCA Solutions™ Product Replacement program allows physician offices or hospital outpatient departments to receive UDENYCA® (pegfilgrastim-cbqv) replacement product if all eligibility criteria is met. (See Coherus Solutions™ Product Replacement Program Terms and Conditions on pages 3-4).

Please complete this form and submit all required documentation to Coherus Solutions™ via **Fax at 1-877-226-6370**

1 PATIENT INFORMATION*

Patient's Name: Gender: ☐ Male ☐ Female ☐ Other

DOB: (MM/DD/YYYY) / / Patient's Phone #: ☐ Home ☐ Cell

Patient's Address:

City: State: ZIP:

Email:

Alternate contact name: Phone #:

Date: Date of service: Date of denial:

Please indicate which presentation of UDENYCA was administered to the patient:

☐ **UDENYCA Prefilled Syringe** (NDC 70114-0101-01) ☐ **UDENYCA Autoinjector** (NDC 70114-0120-01)
☐ **UDENYCA ONBODY™** (NDC 70114-0130-01)

2 PROVIDER INFORMATION*

Prescriber name:

Office contact name: Contact phone number:

Delivery address:

City: State: ZIP:

3 PRODUCT-SPECIFIC BENEFIT VERIFICATION (BV)*

For a patient to qualify for the Product Replacement Program, a product-specific benefit verification demonstrating active coverage must have been completed and documented prior to treatment with UDENYCA.

Please complete the following:

The product-specific benefit verification was completed by:

☐ Provider/provider office ☐ Coherus Solutions™ Date benefit verification completed:

For which presentation of UDENYCA did you complete a BV (if unsure, please select both)?

☐ **UDENYCA Prefilled Syringe** (NDC 70114-0101-01) ☐ **UDENYCA Autoinjector** (NDC 70114-0120-01) ☐ Both
☐ **UDENYCA ONBODY** (NDC 70114-0130-01) ☐ All

If a Benefit Verification was not completed by Coherus Solutions™, a legible copy of the Summary of Benefits obtained by the office, prior to injection, must be submitted.

Was a prior authorization (PA) required or a Predetermination recommended?

☐ Yes ☐ No Date PA submitted:

If a PA was required or predetermination was recommended, please submit the PA or predetermination approval documentation with this request form. If PA was NOT required, please provide reference number _____.

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4 APPEAL INFORMATION

Date of 1st appeal*: Date of 2nd appeal (If applicable):

All appeals must be completed within the appropriate payer timely filing limit. If appeals were conducted by the provider office, please provide the following documentation with this request form:

- ☐ Initial denied claim (EOB)
- ☐ Documentation of first appeal (Include second appeal documentation if applicable)
- ☐ A copy of the claim form (CMS 1500 or 1450 UB04) must be submitted to confirm that therapy was used for an on-label indication

If only one level of appeal has been completed, please contact Coherus Solutions™ to determine if a second appeal is required.

5 TO BE COMPLETED BY OFFICE*

By signing below, I attest that, where required by applicable law, regulation, or other applicable authority, I have obtained patient consent, permission and/or a HIPAA authorization ("Legal Permission") permitting me to use and disclose my patients' health, demographic, and other individually identifiable information, including insurance information, to Coherus BioSciences, Inc., its affiliates, its program administrator, and their respective agents, service providers and field reimbursement professionals for the purpose of providing patient support programs, co-pay assistance, and/or patient assistance, reimbursement support as part of the patient's treatment with UDENYCA. I maintain records of such Legal Permission consistent with applicable law. I further certify that (a) any reimbursement investigation support provided to patients through Coherus Solutions™ is not made in exchange, directly or indirectly, for my recommendation, prescription, or use of the above therapy or any other product or service for or from anyone, and (b) my decision to prescribe the above therapy was based solely on my determination of medical necessity. In addition, I attest that a benefits-verification was completed, all payer coverage requirements were followed prior to administration, and that the product was prescribed for a medically appropriate use as determined by the specific payer's policies and coverage guidelines. I also attest that I did not or will not receive payment for the product in which I am requesting a replacement nor do I belong to a physician practice that receives an all-inclusive payment for patients covered under the insurance plan. I understand the program only provides a replacement product and does not cover any costs related to the office visit or administration of the product. I understand and agree, Coherus BioSciences, Inc. may modify or discontinue its Product Replacement Program without notice at any time for any reason.

I attest that I will not receive payment for UDENYCA and that I do not belong to a physician practice that receives an all-inclusive payment for patients covered under this insurance plan. **I acknowledge that this product replacement will be returned if payment is recognized at any time in the future.**

Office Contact (Name) Date:

Office Contact Signature:

*If you do not have patient consent, please utilize patient consent form at www.CoherusSolutions.com

6 TO BE COMPLETED BY FRM*

I, (FRM), hereby attest that I:

1. performed a thorough review of necessary documentation pertaining to the included claim(s)
2. certify that to the best of my ability, this PRP request complies with SOP-001977
3. believe that based upon this review, alternative steps the provider would take, beyond those outlined in section 4.2 of SOP-001977, do not seem to be warranted.
4. certify that the presentation of UDENYCA requested is:

- ☐ **UDENYCA Prefilled Syringe** (NDC 70114-0101-01)
- ☐ **UDENYCA Autoinjector** (NDC 70114-0120-01)
- ☐ **UDENYCA ONBODY** (NDC 70114-0130-01)

Field Reimbursement Manager Signature Date:

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Please review the following guidelines with terms and conditions.

PRODUCT REPLACEMENT PROGRAM DESCRIPTION

- This program allows physician offices or hospital outpatient departments to receive UDENYCA replacement product if all eligibility criteria are met
- This program does NOT require providers to utilize Coherus Solutions™ to perform benefit verifications for the patient prior to therapy
- Providers *may* register claims for product replacement after an initial claim for UDENYCA is denied by a payer

PHYSICIAN OFFICES AND HOSPITAL OUTPATIENT DEPARTMENTS ARE ELIGIBLE:

- If UDENYCA is administered for a medically appropriate use, as determined by the specific payer's policies and coverage guidelines
- If the office conducted a product-specific benefit verification and followed all payer coverage requirements prior to treatment or has used Coherus Solutions™ services to conduct the benefit verification
- If UDENYCA is not reimbursed after all eligibility criteria are met

HOW THE PROGRAM WORKS*

1. Identify the denied claim
2. Report the denied claim to Coherus Solutions™
   - Providers can register denied claims/appeals for UDENCYA with Coherus Solutions™
   - At registration, the provider receives a product replacement request form (See pages 1-2)
   - The provider is required to submit required documentation
     - » Signed product replacement request form
     - » Identify type of presentation for UDENYCA
     - » Proof of benefit verification (Copy of Summary of Benefits)
     - » When appropriate, prior authorization (PA) results
     - » Explanation of Benefits (EOB)
     - » Denied appeals
     - » Provider letter of appeal
   - If the provider meets eligibility requirements for product replacement, Coherus Solutions™ can support the remaining appeals process
3. Coordinate with Coherus Solutions™ on the appeal(s)
   - Providers work with Coherus Solutions™ on the appeal process to attempt to have the claim paid. If the claim remains unpaid after one unsuccessful appeal, the UDENYCA Field Reimbursement Manager should be contacted to help determine if a second appeal is required before the provider is eligible for product replacement
4. Your Field Reimbursement Manager (FRM) will review all necessary documentation and sign the product replacement program request form before final submission to Coherus Solutions™
5. If approved, Coherus Solutions™ ships the product to the provider's office

***Providers must adhere to all program terms and conditions (please see page 4). Provider must submit appeals in the appropriate payer timely filing limit.**

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PROGRAM TERMS AND CONDITIONS

For each claim, prior to initiation of UDENYCA therapy, providers must perform a product-specific benefit verification to confirm that UDENYCA will be covered by the payer for the intended use. The provider does not need to have this completed by Coherus Solutions™; however, Coherus Solutions™ can assist providers with the UDENYCA benefit verification process upon request if providers obtain patient consent. If required, the provider must also obtain PA approval from the payer.

The provider must keep a record of the benefit verification/PA results in the patient's record. This should include: the dates of these interactions and written information from the payer. Whether the patient's primary insurer is Medicare, Medicaid, or a private commercial payer, the patient's claim must meet the specific payer's guidelines for use of the therapy. If providers need assistance identifying the Medicare guidelines or Medicaid guidelines for their respective state, they may contact Coherus Solutions™.

Once a provider receives a denial for a properly verified claim and contacts Coherus Solutions™, Patient Access Specialists will confirm that the office is registered in the Coherus Solutions™ Product Replacement Program and will request copies of the relevant information, including but not limited to:

- The initial submitted claim
- The EOB (denial)
- Supporting documentation to show proof of a benefit verification and/or secured PA

A Field Reimbursement Manager (FRM) will review all materials and documentation. A request form must have a FRM signature.

Once these materials are received, Coherus Solutions™ will: confirm appropriate benefit verification and review the denied claim, help determine the reason for the denial, and provide support to appeal the claim. If Coherus Solutions™ confirms that the patient's coverage was verified prior to treatment, and the original claim was submitted appropriately, Coherus Solutions™ will register the claim in the Product Replacement Program.

Coherus Solutions™ can assist the provider with the first and/or second appeal. However, if a second appeal is unsuccessful, the provider must promptly notify Coherus Solutions™ to request enrollment in the Product Replacement Program for the registered claim. Coherus BioSciences will provide replacement product(s) to the provider for UDENYCA if all the above eligibility criteria are met.

The Product Replacement Program is available for outpatient use only and does not cover any costs related to office visits or administration of UDENYCA. Coherus BioSciences may modify or terminate this program at any time without notice. Nothing in this program is intended to induce or reward referrals of product.

Providers should not bill the patient for any product that was replaced under this program. If providers receive any payments for products replaced under this program, they agree to return or pay Coherus for the cost of the product.

Providers that are reimbursed under a fully capitated rate for drug products or practices that account for drug products as part of their negotiated rates, the practice assumes full risk and cannot participate in the product replacement program.

Coherus BIOSCIENCES