KRESLADI™
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Billing and Coding Guide

A RESOURCE TO SUPPORT REIMBURSEMENT FOR KRESLADI™

INDICATION AND USAGE

KRESLADI is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of pediatric patients with severe leukocyte adhesion deficiency-I (LAD-I) due to biallelic variants in *ITGB2* without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplant.

This indication is approved under accelerated approval based on increase in neutrophil CD18 and CD11a surface expression. Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infections

Serious infections have occurred with KRESLADI administration. Increased susceptibility to infections may occur due to administration of myeloablative conditioning prior to KRESLADI infusion.

Monitor patients for signs and symptoms of infection before and after KRESLADI infusion and treat appropriately. Administer prophylactic antimicrobials according to institutional guidelines.

Avoid administration of KRESLADI in patients with active bloodstream infections or other serious, untreated infections.

Any blood products required after KRESLADI infusion should be irradiated.

The information included in this resource is for informational purposes only and is subject to change. It is not to be used as legal advice or as a substitute for a health professional's judgment. It is important to verify code accuracy when submitting claims. Please contact payers for specific details regarding their coding, coverage, and payment policies. Rocket Pharma does not ensure coverage or reimbursement, and payer coverage is not guaranteed.

To connect with a Rocket Pharma Cares™ Case Navigator for more information, contact Rocket Pharma Cares at 844-725-8227 or email at support@rocketpharmacares.com.

Please see Indication and Important Safety Information for KRESLADI throughout as well as Full Prescribing Information at www.KRESLADI.com.

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Introduction

The purpose of this guide is to support Qualified Treatment Centers with billing and coding for KRESLADI. This resource is intended to equip providers and their staff with the knowledge and tools necessary to navigate KRESLADI reimbursement, Rocket Pharma Cares, relevant billing codes for each stage of treatment, and other key considerations.

Disclaimer

The information included in this resource is for informational purposes only and is subject to change. It is not to be used as legal advice or as a substitute for a health professional's judgment. It is important to verify code accuracy when submitting claims. Please contact payers for specific details regarding their coding, coverage, and payment policies. Rocket Pharma does not ensure coverage or reimbursement, and payer coverage is not guaranteed.

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Product Information[1]

Indications and Usage

KRESLADI is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of pediatric patients with severe leukocyte adhesion deficiency-I (LAD-I) due to biallelic variants in *ITGB2* without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplant.

This indication is approved under accelerated approval based on increase in neutrophil CD18 and CD11a surface expression. Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Recommended Dosing

The recommended minimum dose of KRESLADI is a single intravenous infusion of 2.8×10^6 CD34+ cells/kg.

The dose is calculated based on the patient's weight prior to first apheresis. See the Lot Information Sheet provided with the product shipment for additional information pertaining to dose.

How Supplied/Storage and Handling

KRESLADI is supplied in one or two infusion bags containing a frozen suspension of genetically modified autologous cells enriched for CD34+ cells in a cryo-preservative medium containing 5% DMSO and dextran 40. Each infusion bag contains approximately 30 mL and is individually packed within an overwrap in a metal cassette for protection. KRESLADI is shipped from the manufacturing facility to the infusion center in a cryoshipper, which may contain one or two cassettes intended for treatment of a single patient. A Lot Information Sheet is affixed inside the shipper.

- 50 mL infusion bag and metal cassette (NDC 83537-034-01)
- Match the identity of the patient with the patient identifiers on the cassette(s) and Lot Information Sheet upon receipt.
- Keep the infusion bag(s) in the cassette(s) and store KRESLADI frozen in the vapor phase of liquid nitrogen at less than or equal to -150°C (≤ -238°F) until ready for thaw and administration.
- Thaw KRESLADI prior to infusion.
- Do not re-freeze after thawing.
- Do not irradiate KRESLADI, as this could lead to inactivation.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Veno-Occlusive Disease

Veno-occlusive disease has occurred with KRESLADI treatment. Increased susceptibility to veno-occlusive disease may occur due to administration of myeloablative conditioning prior to KRESLADI infusion. Monitor patients for signs and symptoms of veno-occlusive disease including assessment of liver function tests during the first month following KRESLADI infusion.

Please see Indication and Important Safety Information for KRESLADI throughout as well as Full Prescribing Information at www.KRESLADI.com.

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Treatment Process Overview

The overall KRESLADI treatment process is highly specialized and takes approximately 4-6 months. Additional time may be required.[1,2]

Understand the Treatment Pathway



Patient referral and evaluation

- Patient referral*
- Pre-screening tests†



Pre-treatment

- Anti-inflammatory preparation
- Mobilization
- Leukapheresis
- Manufacturing*



Treatment

- Anti-inflammatory preparation
- Chemotherapy conditioning
- KRESLADI infusion



Post-treatment

- Post-infusion*
- Long-term follow-up*

*This resource does not list billing codes for these steps.
†Please see the appendix for pre-screening test codes.

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Treatment Process Overview (cont'd)

Patient referral and evaluation

- Patient referral*
- Pre-screening tests†

Pre-treatment

- **Anti-inflammatory preparation**
  - Consider administering ustekinumab prior to mobilization and apheresis and/or prior to KRESLADI infusion[1]
- **Mobilization**
  - Mobilization occurs over 6-7 days at a Qualified Treatment Center. On Days 1-4, patients will receive granulocyte colony-stimulating factor (G-CSF), and on Days 5 and 6 they will receive G-CSF and plerixafor. If needed, G-CSF and plerixafor dosing will be extended to Days 6 and 7[1,2]
- **Leukapheresis**
  - At a Qualified Treatment Center, patients' hematopoietic stem cells will be collected and shipped to the manufacturing lab[1,2]
- **Manufacturing***
  - The patients' hematopoietic stem cells will be genetically modified and then these genetically modified stem cells (KRESLADI) will be quality checked before they are cryopreserved and returned to the Qualified Treatment Center for infusion[1,2]

Treatment

- **Anti-inflammatory preparation**
  - One to 2 weeks before KRESLADI infusion, patients will begin receiving a second dose of anti-inflammatory ustekinumab[1,2]
- **Chemotherapy conditioning**
  - Four days before KRESLADI infusion, patients will receive chemotherapy conditioning with busulfan at a Qualified Treatment Center[1,2]
- **KRESLADI infusion**
  - KRESLADI is administered as a single infusion 25-69 hours after the last dose of busulfan at a Qualified Treatment Center[1,2]

Post-treatment

- Post-infusion*
- Long-term follow-up*

*This resource does not list billing codes for these steps.
†Please see the appendix for pre-screening test codes.

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Pre-Treatment

Anti-inflammatory preparation

Consider administering ustekinumab prior to mobilization and apheresis and/or prior to KRESLADI infusion.[1]

The following codes may be relevant for billing and coding for anti-inflammatory preparation[3-5]:

Code Type	Code	Description
ICD-10-CM	D71.1	Leukocyte adhesion deficiency
ICD-10-PCS	3E013GC	Introduction of other therapeutic substance into subcutaneous tissue, percutaneous approach
HCPCS	J3357	Ustekinumab, for subcutaneous injection, 1 mg
CPT	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug), subcutaneous or intramuscular

CPT and HCPCS codes are typically utilized for hospital outpatient procedures while ICD-10-PCS codes are used to code for procedures performed in inpatient settings.

The selection of appropriate codes varies with each individual case. Providers are responsible for ensuring correct and accurate coding. Providers should verify specific coding requirements with individual payers.

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CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ICD-10-PCS=International Classification of Diseases 10th Revision, Procedure Coding System.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Neutrophil Engraftment Failure

Neutrophil engraftment failure may occur after treatment with KRESLADI. Neutrophil engraftment failure is defined as failure to achieve three consecutive absolute neutrophil counts (ANC) ≥ 500 cells/microliter obtained on different days by Day 43 after infusion of KRESLADI. Monitor neutrophil counts until engraftment has been achieved. If neutrophil engraftment failure occurs in a patient treated with KRESLADI, provide rescue treatment with the back-up collection of CD34+ cells.

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Pre-Treatment

Mobilization

Mobilization occurs over 6-7 days at a Qualified Treatment Center. On Days 1-4, patients will receive granulocyte colony-stimulating factor (G-CSF), and on Days 5 and 6 they will receive G-CSF and plerixafor. If needed, G-CSF and plerixafor dosing will be extended to Days 6 and 7.[1,2]

The following codes may be relevant for billing and coding for mobilization[3-5]:

Code Type	Code	Description
ICD-10-CM	D71.1	Leukocyte adhesion deficiency
ICD-10-PCS	3E013GC	Introduction of other therapeutic substance into subcutaneous tissue, percutaneous approach
HCPCS	J1442	Injection, filgrastim (G-CSF), excludes biosimilars, 1 microgram
	Q5101	Injection, filagrastim-sndz, biosimilar, (Zarxio), 1 microgram
	Q5110	Injection, filagrastim-aafi, biosimilar, (Nivestym), 1 microgram
	Q5125	Injection, filagrastim-ayow, biosimilar, (Releuko), 1 microgram
	J1447	Injection, TBO-filgrastim, 1 microgram
	J2562	Injection, plerixafor, 1 mg
CPT	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug), subcutaneous or intramuscular

CPT and HCPCS codes are typically utilized for hospital outpatient procedures while ICD-10-PCS codes are used to code for procedures performed in inpatient settings.

The selection of appropriate codes varies with each individual case. Providers are responsible for ensuring correct and accurate coding. Providers should verify specific coding requirements with individual payers.

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IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Delayed Platelet Engraftment

Delayed platelet engraftment may occur after treatment with KRESLADI. Monitor platelet counts and bleeding until platelet engraftment and platelet recovery are achieved.

Please see Indication and Important Safety Information for KRESLADI throughout as well as Full Prescribing Information at www.KRESLADI.com.

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Pre-Treatment

Leukapheresis

At a Qualified Treatment Center, patients' hematopoietic stem cells (HSCs) will be collected and shipped to the manufacturing lab.[1,2]

The following codes may be relevant for billing and coding for leukapheresis[3-5]:

Code Type	Code	Description
ICD-10-CM	D71.1	Leukocyte adhesion deficiency
ICD-10-PCS	3E013GC	Introduction of other therapeutic substance into subcutaneous tissue, percutaneous approach
	6A550Z1	Pheresis of leukocytes, single
	6A551Z1	Pheresis of leukocytes, multiple
CPT	38999*	Unlisted procedure, hemic or lymphatic system
	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug), subcutaneous or intramuscular

CPT and HCPCS codes are typically utilized for hospital outpatient procedures while ICD-10-PCS codes are used to code for procedures performed in inpatient settings.

The selection of appropriate codes varies with each individual case. Providers are responsible for ensuring correct and accurate coding. Providers should verify specific coding requirements with individual payers.

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*There is no code for apheresis (used to collect cells for manufacturing cell therapies) as this process is typically incorporated into the code for the product itself. CPT code 38999 (unlisted procedure, hemic or lymphatic system) may be used to report apheresis, but it may not be covered by the payer.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

LVV-Mediated Insertional Oncogenesis

Lentiviral vector (LVV)-mediated insertional oncogenesis may occur after treatment with KRESLADI. Hematologic malignancy is a lifelong risk and patients treated with KRESLADI may develop hematologic malignancy at any time following treatment.

Monitor for hematologic malignancies clinically, and with a complete blood count (with differential) at least annually and integration site analysis as warranted for at least 15 years after treatment with KRESLADI and as clinically indicated. If malignancy is detected in any patient who received KRESLADI, contact Rocket Pharmaceuticals, Inc. at 1-800-982-2410 for reporting and to obtain instructions on collection of samples for testing.

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Treatment

Chemotherapy conditioning*

Four days before KRESLADI infusion, patients will begin receiving chemotherapy conditioning with busulfan at a Qualified Treatment Center.[1,2]

The following codes may be relevant for billing and coding for chemotherapy conditioning[3-5]:

Code Type	Code	Description
ICD-10-CM	D71.1	Leukocyte adhesion deficiency
	Z51.11	Encounter for antineoplastic chemotherapy
ICD-10-PCS	3E04305	Introduction of other antineoplastic into central vein, percutaneous approach
HCPCS	J0594	Injection, busulfan, 1 mg
CPT	96413	Chemotherapy administration, intravenous infusion technique: up to 1 hour, single or initial substance/drug
	96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)

CPT and HCPCS codes are typically utilized for hospital outpatient procedures while ICD-10-PCS codes are used to code for procedures performed in inpatient settings.

The selection of appropriate codes varies with each individual case. Providers are responsible for ensuring correct and accurate coding. Providers should verify specific coding requirements with individual payers.

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*One to 2 weeks before KRESLADI infusion, patients will receive a second dose of anti-inflammatory ustekinumab. This may overlap with the manufacturing time frame. The codes associated with this treatment step are listed on page 7.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Hypersensitivity Reactions

Hypersensitivity reactions including anaphylaxis may occur with the infusion of KRESLADI. The dimethyl sulfoxide (DMSO) in KRESLADI may cause hypersensitivity reactions which may occur in patients with and without prior exposure to DMSO.

Monitor patients for signs and symptoms of hypersensitivity reactions during and after KRESLADI infusion. If a hypersensitivity reaction occurs, pause infusion if ongoing and manage according to clinical practice.

Please see Indication and Important Safety Information for KRESLADI throughout as well as Full Prescribing Information at www.KRESLADI.com.

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Treatment

KRESLADI infusion

KRESLADI is administered as a single infusion 25-69 hours after the last dose of busulfan at a Qualified Treatment Center.[1,2]

The following codes may be relevant for billing and coding for KRESLADI infusion[1,3-5]:

Code Type	Code	Description
ICD-10-CM	D71.1	Leukocyte adhesion deficiency
ICD-10-PCS	XW1337A	Transfusion of marnetegragene autotemcel into peripheral vein, percutaneous approach, new technology group 10
	XW1437A	Transfusion of marnetegragene autotemcel into central vein, percutaneous approach, new technology group 10
HCPCS	C9399	Unclassified drugs or biologicals
	J3490	Unclassified drugs
	J3590	Unclassified biologics
CPT	96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push
	96409	Chemotherapy administration; intravenous, push technique
NDC	83537-034-01	50 mL infusion bag and metal cassette

CPT and HCPCS codes are typically utilized for hospital outpatient procedures while ICD-10-PCS codes are used to code for procedures performed in inpatient settings.

The selection of appropriate codes varies with each individual case. Providers are responsible for ensuring correct and accurate coding. Providers should verify specific coding requirements with individual payers.

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NDC=National Drug Code.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Anti-retroviral Use

Anti-retroviral medications may interfere with manufacturing of KRESLADI. If a patient requires anti-retrovirals for HIV prophylaxis, mobilization and apheresis of CD34+ cells for KRESLADI manufacturing should be delayed until HIV infection is adequately ruled out. Patients should not take anti-retroviral medications for at least one month prior to mobilization, or for the expected duration required for the elimination of the anti-retroviral medications, and until all cycles of apheresis are completed.

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Treatment

KRESLADI infusion (cont'd)

Revenue Codes

Revenue codes track costs related to hospital admission along with services and items provided.

Below is a list of revenue codes that may be associated with KRESLADI infusion[6]:

Revenue Code	Description
0250	Pharmacy - general
0500	Outpatient services - general
0510	Clinic - general
0636	Pharmacy - drugs requiring detailed coding
0870	Cell/Gene Therapy – general
0871	Cell/Gene Therapy – cell collection
0872	Cell/Gene Therapy – specialized biologic processing and storage – prior to transport
0873	Cell/Gene Therapy – storage and processing after receipt of cells from manufacturer
0874	Cell/Gene Therapy – infusion of modified cells (Effective 4/1/19)
0891	Special Processed Drugs – cell therapy (Effective 4/1/19)
0892	Special Processed Drugs – gene therapy (Effective 4/1/20)

The selection of appropriate codes varies with each individual case. Providers are responsible for ensuring correct and accurate coding. Providers should verify specific coding requirements with individual payers.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Interference with Serology Testing

Patients who have received KRESLADI are likely to test positive by polymerase chain reaction (PCR) assays for HIV due to LVV provirus insertion resulting in a false-positive test for HIV. Therefore, patients who have received KRESLADI should not be screened for HIV infection using a PCR-based assay.

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Treatment

KRESLADI infusion (cont'd)

Payment Groups

Drug administration codes map various payment groups, such as APCs, APR-DRGs, and MS-DRGs.

Below is a list of payment groups that may map to KRESLADI infusion[5]:

Payment Group	Payment Group #	Description
Hospital Outpatient Payment Groups		
APC	5692	Level 2 drug administration
	0859/0869/0895	Ustekinumab, subcutaneous injection, 1 mg
	1469	Injection, filgrastim, excludes biosimilars
	1748	Injection, tbo-filgrastim, 1 microgram
	9252	Plerixafor injection
	9193	Nivestym
	9447	Injection, Releuko, 1 microgram
	1178	Busulfan injection
	5694	Level 4 drug administration
	5693	Level 3 drug administration

APC=Ambulatory Payment Classification.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Blood, organ, tissue, and cell donation

Patients treated with KRESLADI should not donate blood, organs, tissues, or cells for transplantation at any time in the future.

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KRESLADI infusion (cont'd)

Payment Groups

Drug administration codes map various payment groups, such as APCs, APR-DRGs, and MS-DRGs.

Below is a list of payment groups that may map to KRESLADI infusion[7,8]:

Payment Group	Payment Group #	Description
Hospital Inpatient Payment Groups		
APR-DRG	008	Autologous bone marrow transplant
	011	Chimeric antigen receptor (CAR) T-Cell and other immunotherapies
	651	Other procedures of blood and blood-forming organs
	660	Major hematologic or immunologic diagnoses except sickle cell crisis and coagulation
	663	Other anemia and disorders of blood and blood-forming organs
MS-DRG	016	Autologous bone marrow transplant with CC/MCC
	017	Autologous bone marrow transplant without CC/MCC
	808	Major hematological and immunological diagnoses except sickle cell crisis and coagulation disorders with MCC
	809	Major hematological and immunological diagnoses except sickle cell crisis and coagulation disorders with CC
	810	Major hematological and immunological diagnoses except sickle cell crisis and coagulation disorders without CC/MCC

APR-DRG=All Patients Refined Diagnosis-Related Group; CC=complication or comorbidity; MCC=major complication or comorbidity; MS-DRG=Medicare Severity Diagnosis-Related Group.

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS

The most common non-laboratory adverse reactions (≥ 30% of patients) include: mucositis, upper respiratory tract infection, viral infection, febrile neutropenia, skin lesion, nausea/vomiting, rash/dermatitis, pyrexia, device related infection, and skin infection.

The most common laboratory adverse reactions (≥ 30% of patients) include: hemoglobin decreased, platelet count decreased, neutrophil count decreased, leukocyte count decreased, aspartate aminotransferase increased, and alanine aminotransferase increased.

For additional safety information, refer to the full Prescribing Information.

Please see Indication and Important Safety Information for KRESLADI throughout as well as Full Prescribing Information at www.KRESLADI.com.

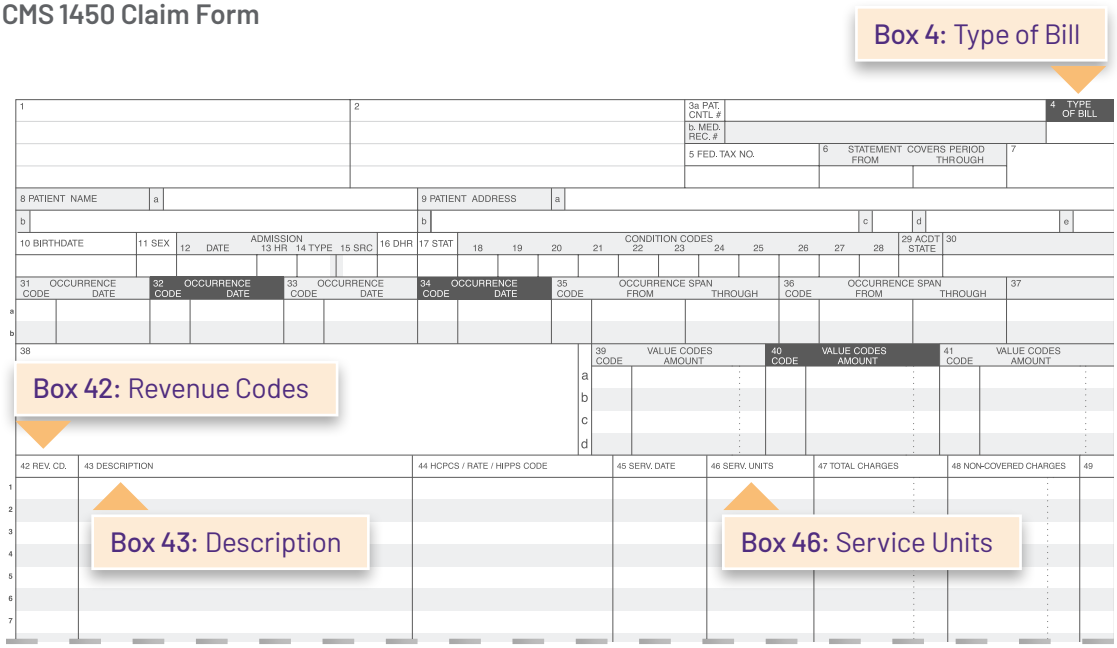
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Sample Claim Forms

CMS 1450 Claim Form



Box 4: Type of Bill

Enter the appropriate type of bill code

Type of bill codes describe the facility and care type.

Box 43: Description

Enter description

Add revenue code descriptions and associated drugs.

Box 42: Revenue Codes

Enter revenue codes

Revenue codes describe accommodations, services, and procedures.

Box 46: Service Units

Enter the total amount of units of service administered

Provide total amount for each line item.

This is a sample form. It is the responsibility of the provider to code accurately for product and service. Please review and confirm all appropriate codes with each individual payer.

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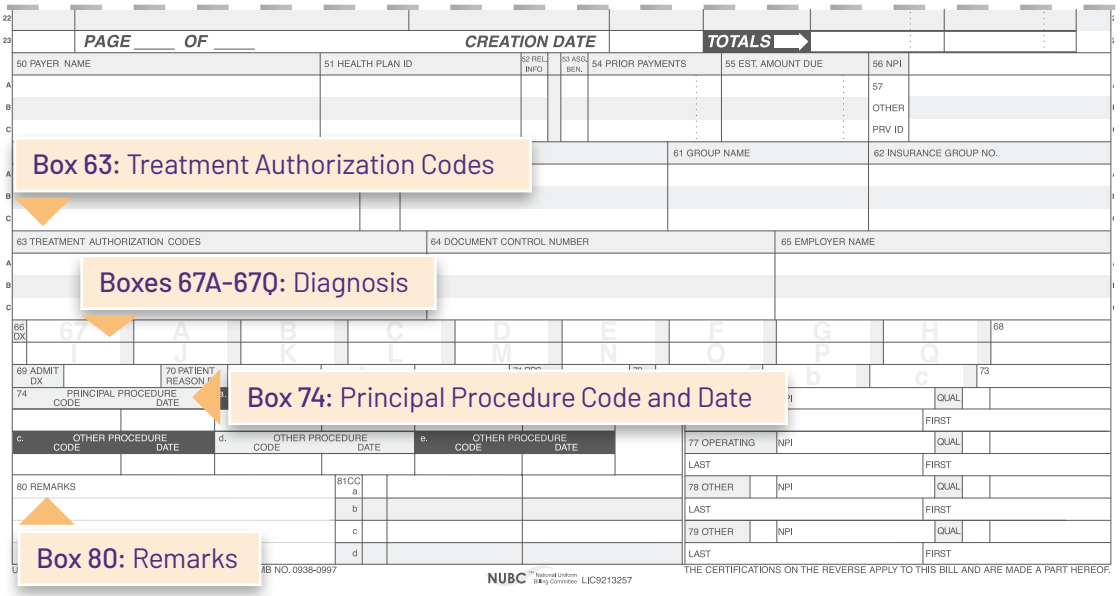
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Sample Claim Forms

CMS 1450 Claim Form (cont'd)



Box 63: Treatment Authorization Codes

Enter the authorization number

Provide the PA number as required by payer.

Box 74: Principal Procedure Code and Date

Enter the primary ICD-10-PCS and date

This field may be required on inpatient claims.

Boxes 67A-67Q: Diagnosis

Enter ICD-10-CM diagnosis codes

List all relevant codes accurately.

Box 80: Remarks

Enter additional information

Use this field to provide any additional information that a payer may require, such as any other billing codes.

This is a sample form. It is the responsibility of the provider to code accurately for product and service. Please review and confirm all appropriate codes with each individual payer.

PA=prior authorization.

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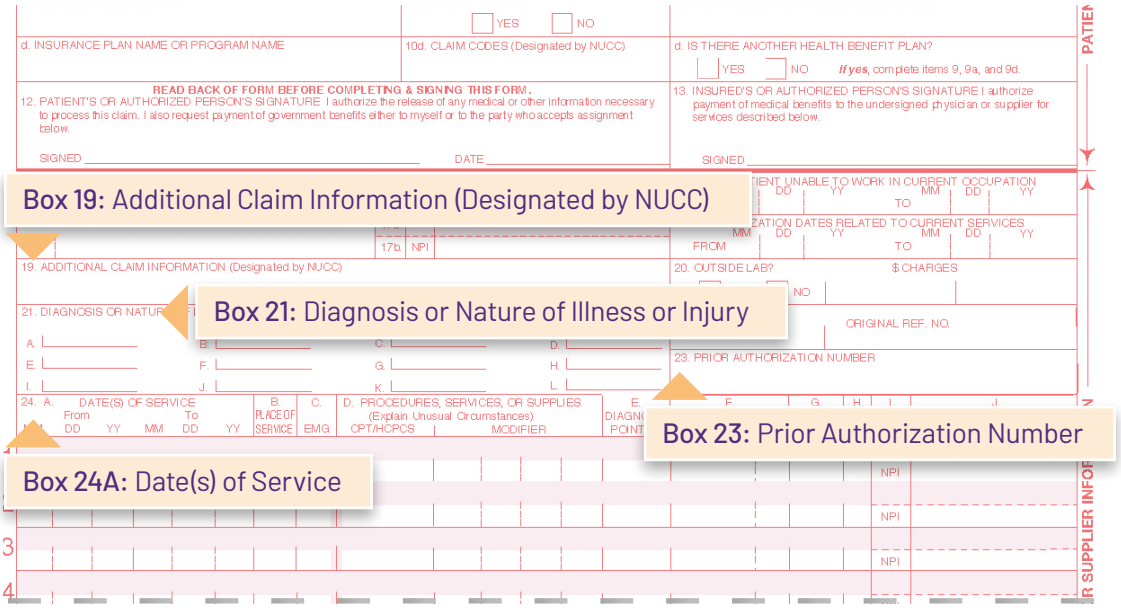
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Sample Claim Forms

CMS 1500 Claim Form



Box 19: Additional Claim Information (Designated by NUCC)

Enter additional information (as required by payer)

Enter drug information, including but not limited to the NDC code, any HCPCS codes, method of administration, and dose/units.

Box 23: Prior Authorization Number

Enter the prior authorization number

Provide the PA number as required by payer.

Box 21: Diagnosis or Nature of Illness or Injury

Enter all appropriate diagnosis codes

List all relevant ICD-10-CM diagnosis codes accurately.

Box 24A: Date(s) of Service

Enter the date of service of drug and/or procedure

Enter using the MM/DD/YY format. Some payers may require the NDC to be added to shaded portion above the dates of service. Enter the N4 qualifier followed by the 11-digit NDC, quantity, and any qualifiers.

This is a sample form. It is the responsibility of the provider to code accurately for product and service. Please review and confirm all appropriate codes with each individual payer.

NUCC=National Uniform Claim Committee.

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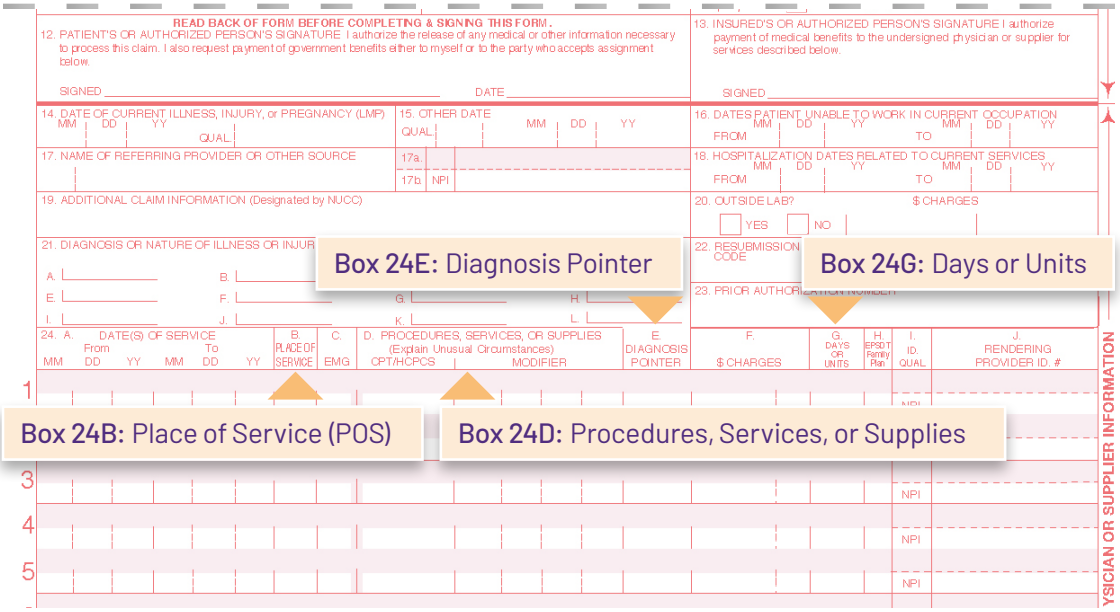
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Sample Claim Forms

CMS 1500 Claim Form (cont'd)



Box 24B: Place of Service (POS)

Enter the relevant POS codes

POS codes are 2 digits and describe the setting of the service.

Box 24E: Diagnosis Pointer

Enter the appropriate diagnosis pointer

The diagnosis pointer corresponds to the diagnosis entered in Box 21.

Box 24D: Procedures, Services, or Supplies

Enter the appropriate HCPCS and CPT codes

Modifier codes may be also be listed. Check with payers to see if modifier codes are needed.

Box 24G: Days or Units

Enter the appropriate days or units

This field describes the duration of treatment, or units of product administered in reference to the codes entered in Box 24D.

This is a sample form. It is the responsibility of the provider to code accurately for product and service. Please review and confirm all appropriate codes with each individual payer.

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CPT=Current Procedural Terminology.

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Ordering and Distribution

KRESLADI is made from each patient's own cells. Every order is patient-specific: there is no stock inventory. The order sets a manufacturing slot and the delivery date. Enroll your patient for treatment and complete the required consent forms, in accordance with your agreement with Rocket Pharmaceuticals and the Guide for Patient Treatment Enrollment and Ordering. Your patient will be issued a Patient ID. Rocket Pharma Cares provides insurance and coverage support, financial assistance, and travel support to the patient and family. Refer patients to Rocket Pharma Cares at any point; it is not a step in the ordering process.

Buy and Bill — Ordering Through CuraScript SD, the Specialty Distributor for Rocket

1. Place a Distributor Purchase Order with CuraScript SD using CSD Order Form.



Phone
877-900-9223



Fax
866-628-8942



Email
RareCSDCS@express-scripts.com

2. Rocket and your center schedule cell collection, the manufacturing slot and an estimated delivery date. Product is delivered no more than 14 days before administration.
3. Rocket delivers the Product to the Destination named in your agreement. The shipping address and any initial check-in location are not the Destination.
4. Perform the incoming receipt and inspection under the Guide for Drug Product Receipt and Storage. Inspection covers external packaging, shipping documentation, chain-of-custody verification and in-transit tracking data. It does not include inspecting frozen Product or unwrapping bulk packaging.
5. On acceptance you will receive the In Good Condition Notice. Do not initiate patient conditioning before you receive it.
6. CuraScript SD invoices your center. No invoice is issued before acceptance.

Specialty Pharmacy — Fulfillment Through Accredo

1. Submit the KRESLADI Treatment Referral Form, completed and signed by the prescriber and by the patient's parent or legal guardian, each in their own section.



Phone
844-725-8227



Fax
609-228-7927



Email
support@rocketpharmacares.com

2. Accredo verifies benefits and coordinates coverage for the patient.
3. Rocket and your center schedule cell collection, the manufacturing slot and an estimated delivery date. Product is delivered no more than 14 days before administration.
4. KRESLADI is dispensed for the named patient and delivered to your center for administration.
5. Confirm receipt under the Guide for Drug Product Receipt and Storage. Do not initiate patient conditioning before Rocket confirms the Product is in good condition.
6. Notify Accredo when administration is complete.

KRESLADI is distributed through a limited network. Access is available through the specialty pharmacy and specialty distributor identified above. Rocket Pharmaceuticals does not guarantee coverage or reimbursement by any payer.

This overview is a summary provided for convenience. The requirements for ordering, shipment, delivery, receipt, inspection, acceptance, storage and administration of KRESLADI are set out in your center's Master Agreement with Rocket Pharmaceuticals, Inc., in the Rocket Operational Guides, and in your agreement with the specialty pharmacy or specialty distributor you use. Where this overview and those documents differ, those documents control.

Please see Indication and Important Safety Information for KRESLADI throughout as well as Full Prescribing Information at www.KRESLADI.com.

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Rocket Pharma Cares

One-time administration. A world of support.

Rocket Pharma Cares can support patients, caregivers, and healthcare professionals along every step of the treatment journey.

Rocket Pharma Cares Case Navigators can help to:

Enroll a Patient

Rocket Pharma Cares can help you and your enrolled patients and their caregivers navigate the coverage process, work with insurance companies, and receive resources and support.

Patients can be enrolled by a Qualified Treatment Center. For any additional questions about enrolling a patient, contact Rocket Pharma Cares at 844-725-8227 or email support@rocketpharmacares.com

Find a Qualified Treatment Center

KRESLADI is offered by a select network of Qualified Treatment Centers that have been carefully selected and trained to administer KRESLADI.

Understand the Treatment Pathway

The overall KRESLADI treatment process takes approximately 4-6 months. Times may vary per patient.

Navigate the Access and Reimbursement Process

Rocket Pharma Cares can provide KRESLADI access and reimbursement information and support for qualifying patients. Case Navigators can:

- Conduct a benefits investigation to determine and understand your patient's insurance coverage for KRESLADI
- Provide prior authorization and appeals information
- Address logistical questions around distribution and delivery of KRESLADI
- Offer billing and coding guidance
- Provide assistance in identifying support services for your patients

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Support along every step of the treatment journey

To connect with a Rocket Pharma Cares Case Navigator for more information, contact Rocket Pharma Cares at 844-725-8227 or email at support@rocketpharmacares.com.

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Pre-Screening Tests

Patients must be screened for hepatitis B and C, HTLV, and HIV prior to starting treatment.[1]

The following codes may be relevant for billing and coding pre-screening tests prior to KRESLADI infusion[5]:

CPT Code	Description
86704	Hepatitis B core antibody (HBcAb); total
86706	Hepatitis B surface antibody (HBsAb)
87340	Hepatitis B surface antigen (HBsAg)
86803	Hepatitis C antibody test
86687	HTLV-I antibody test
86688	HTLV-II antibody test
87806	HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies

The table above may not be inclusive of all tests and codes that are required prior to administration of KRESLADI.

The selection of appropriate codes varies with each individual case. Providers are responsible for ensuring correct and accurate coding. Providers should verify specific coding requirements with individual payers.

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CPT=Current Procedural Terminology; HIV=human immunodeficiency virus; HTLV=human T-lymphotropic virus.

IMPORTANT SAFETY INFORMATION (CONT'D)

DRUG INTERACTIONS

No formal drug interaction studies have been performed. KRESLADI is not expected to interact with the hepatic cytochrome P-450 family of enzymes or drug transporters.

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Summary[1,3-5]

Code Type	Code	Description
ICD-10-CM	D71.1	Leukocyte adhesion deficiency
	Z51.11	Encounter for antineoplastic chemotherapy
ICD-10-PCS	3E013GC	Introduction of other therapeutic substance into subcutaneous tissue, percutaneous approach
	3E04305	Introduction of other antineoplastic into central vein, percutaneous approach
	6A550Z1	Pheresis of leukocytes, single
	6A551Z1	Pheresis of leukocytes, multiple
	XW1337A	Transfusion of marnetegragene autotemcel into peripheral vein, percutaneous approach, new technology group 10
	XW1437A	Transfusion of marnetegragene autotemcel into central vein, percutaneous approach, new technology group 10
HCPCS	J3357	Ustekinumab, for subcutaneous injection, 1 mg
	J1442	Injection, filgrastim (G-CSF), excludes biosimilars, 1 microgram
	Q5101	Injection, filagrastim-sndz, biosimilar, (Zarxio), 1 microgram
	Q5110	Injection, filagrastim-aafi, biosimilar, (Nivestym), 1 microgram
	Q5125	Injection, filagrastim-ayow, biosimilar, (Releuko), 1 microgram
	J1447	Injection, TBO-filgrastim, 1 microgram
	J2562	Injection, plerixafor, 1 mg
	J0594	Injection, busulfan, 1 mg
	C9399	Unclassified drugs or biologicals
	J3490	Unclassified drugs
	J3590	Unclassified biologics
CPT	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug), subcutaneous or intramuscular
	96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push
	96409	Chemotherapy administration; intravenous, push technique
	96413	Chemotherapy administration, intravenous infusion technique: up to 1 hour, single or initial substance/drug
	96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
	38999	Unlisted procedure, hemic or lymphatic system
NDC	83537-034-01	50 mL infusion bag and metal cassette

CPT and HCPCS codes are typically utilized for hospital outpatient procedures while ICD-10-PCS codes are used to code for procedures performed in inpatient settings.

The selection of appropriate codes varies with each individual case. Providers are responsible for ensuring correct and accurate coding. Providers should verify specific coding requirements with individual payers.

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Summary[6] (cont'd)

Revenue Code	Description
0250	Pharmacy - general
0500	Outpatient services - general
0510	Clinic - general
0636	Pharmacy - drugs requiring detailed coding
0870	Cell/Gene Therapy – general
0871	Cell/Gene Therapy – cell collection
0872	Cell/Gene Therapy – specialized biologic processing and storage – prior to transport
0873	Cell/Gene Therapy – storage and processing after receipt of cells from manufacturer
0874	Cell/Gene Therapy – infusion of modified cells (Effective 4/1/19)
0891	Special Processed Drugs – cell therapy (Effective 4/1/19)
0892	Special Processed Drugs – gene therapy (Effective 4/1/20)

The selection of appropriate codes varies with each individual case. Providers are responsible for ensuring correct and accurate coding. Providers should verify specific coding requirements with individual payers.

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IMPORTANT SAFETY INFORMATION (CONT'D)

DRUG INTERACTIONS (CONT'D)

Vaccines: The safety and effectiveness of immunization with live viral vaccines during or following KRESLADI treatment has not been studied. Vaccination is not recommended during the 6 weeks preceding the start of myeloablative conditioning, and until hematological recovery following treatment with KRESLADI. Where feasible, administer childhood vaccinations prior to myeloablative conditioning for KRESLADI.

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Summary[5,7,8] (cont'd)

Payment Group	Payment Group #	Description
Hospital Outpatient Payment Groups		
APC	5692	Level 2 drug administration
	0859/0869/0895	Ustekinumab, subcutaneous injection, 1 mg
	1469	Injection, filgrastim, excludes biosimilars
	1748	Injection, tbo-filgrastim, 1 microgram
	9252	Plerixafor injection
	9193	Nivestym
	9447	Injection, Releuko, 1 microgram
	1178	Busulfan injection
	5694	Level 4 drug administration
	5693	Level 3 drug administration
Hospital Inpatient Payment Groups		
APR-DRG	008	Autologous bone marrow transplant
	011	Chimeric antigen receptor (CAR) T-Cell and other immunotherapies
	651	Other procedures of blood and blood-forming organs
	660	Major hematologic or immunologic diagnoses except sickle cell crisis and coagulation
	663	Other anemia and disorders of blood and blood-forming organs
MS-DRG	016	Autologous bone marrow transplant with CC/MCC
	017	Autologous bone marrow transplant without CC/MCC
	808	Major hematological and immunological diagnoses except sickle cell crisis and coagulation disorders with MCC
	809	Major hematological and immunological diagnoses except sickle cell crisis and coagulation disorders with CC
	810	Major hematological and immunological diagnoses except sickle cell crisis and coagulation disorders without CC/MCC

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IMPORTANT SAFETY INFORMATION (CONT'D)

DRUG INTERACTIONS (CONT'D)

Anti-retroviral medications: Patients should not take anti-retroviral medications for at least one month prior to initiating medications for stem cell mobilization and for the expected duration for elimination of the medications, and until all cycles of apheresis are completed. Anti-retroviral medications may interfere with manufacturing of KRESLADI.

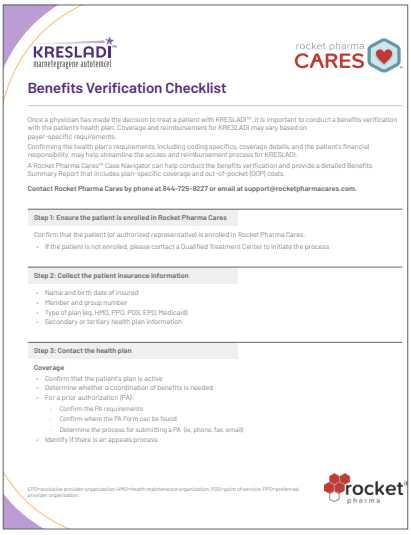
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Additional Forms and Resources



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Benefits Verification Checklist

Once a physician has made the decision to treat a patient with KRESLADI™, it is important to conduct a benefits verification with the patient's health plan. Coverage and reimbursement for KRESLADI may vary based on payer-specific requirements.

Confirming the health plan's requirements, including coding specifics, coverage details, and the patient's financial responsibility, may help streamline the access and reimbursement process for KRESLADI.

A Rocket Pharma Cares™ Case Navigator can help conduct the benefits verification and provide a detailed Benefits Summary Report that includes plan-specific coverage and out-of-pocket (OOP) costs.

Contact Rocket Pharma Cares by phone at 844-725-8227 or email at support@rocketpharmacares.com.

Step 1: Ensure the patient is enrolled in Rocket Pharma Cares

Confirm that the patient (or authorized representative) is enrolled in Rocket Pharma Cares.

- If the patient is not enrolled, please contact a Qualified Treatment Center to initiate the process

Step 2: Collect the patient insurance information

- Name and birth date of insured
- Member and group number
- Type of plan (eg, HMO, PPO, POS, EPO, Medicaid)
- Secondary or tertiary health plan information

Step 3: Contact the health plan

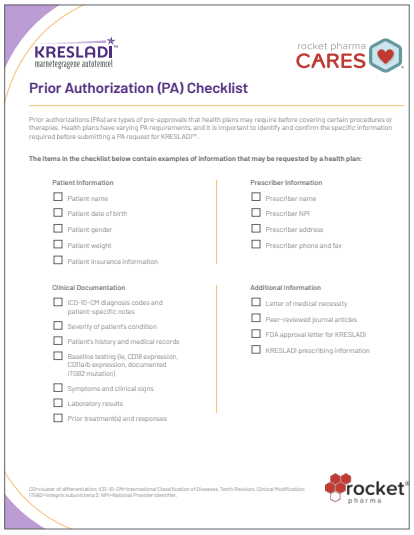
Coverage

- Confirm that the patient's plan is active
- Determine whether a coordination of benefits is needed
- For a prior authorization (PA):
  - Confirm the PA requirements
  - Confirm where the PA Form can be found
  - Determine the process for submitting a PA (ie, phone, fax, email)
- Identify if there is an appeals process

EPO=exclusive provider organization; HMO=health maintenance organization; POS=point of service; PPO=preferred provider organization.

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Click here to download the Benefits Verification Checklist



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Prior Authorization (PA) Checklist

Prior authorizations (PAs) are types of pre-approvals that health plans may require before covering certain procedures or therapies. Health plans have varying PA requirements, and it is important to identify and confirm the specific information required before submitting a PA request for KRESLADI™.

The items in the checklist below contain examples of information that may be requested by a health plan:

Patient Information

- ☐ Patient name
- ☐ Patient date of birth
- ☐ Patient gender
- ☐ Patient weight
- ☐ Patient insurance information

Prescriber Information

- ☐ Prescriber name
- ☐ Prescriber NPI
- ☐ Prescriber address
- ☐ Prescriber phone and fax

Clinical Documentation

- ☐ ICD-10-CM diagnosis codes and patient-specific notes
- ☐ Severity of patient's condition
- ☐ Patient's history and medical records
- ☐ Baseline testing (ie, CD18 expression, CD11a/b expression, documented ITGB2 mutation)
- ☐ Symptoms and clinical signs
- ☐ Laboratory results
- ☐ Prior treatment(s) and responses

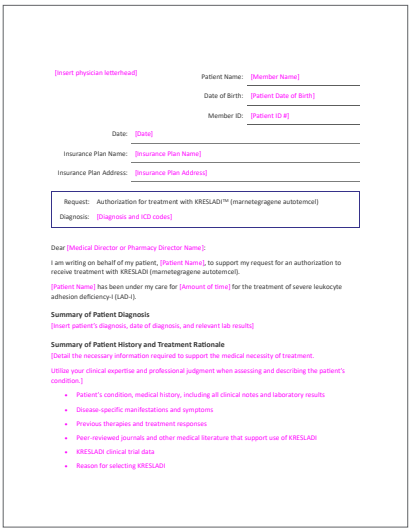
Additional Information

- ☐ Letter of medical necessity
- ☐ Peer-reviewed journal articles
- ☐ FDA approval letter for KRESLADI
- ☐ KRESLADI prescribing information

CD=cluster of differentiation; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ITGB2=integrin subunit beta 2; NPI=National Provider Identifier.

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Click here to download the Prior Authorization Checklist



[Insert physician letterhead]

Patient Name: [Member Name]

Date of Birth: [Patient Date of Birth]

Member ID: [Patient ID #]

Date: [Date]

Insurance Plan Name: [Insurance Plan Name]

Insurance Plan Address: [Insurance Plan Address]

Request: Authorization for treatment with KRESLADI™ (marnetegragene autotemcel)

Diagnosis: [Diagnosis and ICD codes]

Dear [Medical Director or Pharmacy Director Name]:

I am writing on behalf of my patient, [Patient Name], to support my request for an authorization to receive treatment with KRESLADI (marnetegragene autotemcel).

[Patient Name] has been under my care for [Amount of time] for the treatment of severe leukocyte adhesion deficiency-I (LAD-I).

Summary of Patient Diagnosis

[Insert patient's diagnosis, date of diagnosis, and relevant lab results]

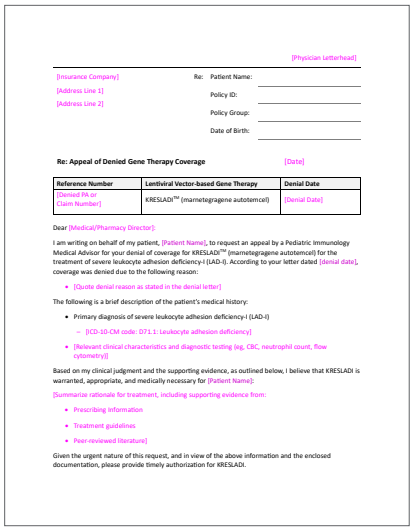
Summary of Patient History and Treatment Rationale

[Detail the necessary information required to support the medical necessity of treatment.

Utilize your clinical expertise and professional judgment when assessing and describing the patient's condition.]

- Patient's condition, medical history, including all clinical notes and laboratory results
- Disease-specific manifestations and symptoms
- Previous therapies and treatment responses
- Peer-reviewed journals and other medical literature that support use of KRESLADI
- KRESLADI clinical trial data
- Reason for selecting KRESLADI

Click here to download a sample Letter of Medical Necessity



[Physician Letterhead]

[Insurance Company]

[Address Line 1]

[Address Line 2]

Re: Patient Name:

Policy ID:

Policy Group:

Date of Birth:

Re: Appeal of Denied Gene Therapy Coverage [Date]

Reference Number	Lentiviral Vector-based Gene Therapy	Denial Date
[Denied PA or Claim Number]	KRESLADI™ (marnetegragene autotemcel)	[Denial Date]

Dear [Medical/Pharmacy Director]:

I am writing on behalf of my patient, [Patient Name], to request an appeal by a Pediatric Immunology Medical Advisor for your denial of coverage for KRESLADI™ (marnetegragene autotemcel) for the treatment of severe leukocyte adhesion deficiency-I (LAD-I). According to your letter dated [denial date], coverage was denied due to the following reason:

- [Quote denial reason as stated in the denial letter]

The following is a brief description of the patient's medical history:

- Primary diagnosis of severe leukocyte adhesion deficiency-I (LAD-I)
  - [ICD-10-CM code: D71.1: Leukocyte adhesion deficiency]
- [Relevant clinical characteristics and diagnostic testing (eg, CBC, neutrophil count, flow cytometry)]

Based on my clinical judgment and the supporting evidence, as outlined below, I believe that KRESLADI is warranted, appropriate, and medically necessary for [Patient Name]:

[Summarize rationale for treatment, including supporting evidence from:

- Prescribing Information
- Treatment guidelines
- Peer-reviewed literature]

Given the urgent nature of this request, and in view of the above information and the enclosed documentation, please provide timely authorization for KRESLADI.

Click here to download a sample Appeal Letter

Please see Indication and Important Safety Information for KRESLADI throughout as well as Full Prescribing Information at www.KRESLADI.com.

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Please see Indication and Important Safety Information for KRESLADI throughout as well as Full Prescribing Information at www.KRESLADI.com.

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