Kresladi™ (marnetegragene autotemcel)
(Intravenous)

Effective Date: 11/01/2026
Review Date: 8/18/2026
Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

Coverage will be provided for one treatment course (1 dose of Kresladi) and may not be renewed**.**

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1 dose up to 3.22 x10^8 CD34+ cells

III. Summary of Evidence:

Kresladi is an autologous hematopoietic stem cell (HSC)-based gene therapy approved for the treatment of pediatric patients with severe leukocyte adhesion deficiency type I (LAD-I) due to biallelic variants in *ITGB2* without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplantation (HSCT). The efficacy of Kresladi was evaluated in the Phase 1/2 open-label, single-arm multicenter study, which enrolled nine pediatric patients with molecularly confirmed severe LAD-I. Patients received a single intravenous infusion of Kresladi at a median dose of 4.3 × 10^6 CD34+ cells/kg. The primary efficacy assessment focused on restoration of neutrophil CD18 and CD11a expression, biomarkers that reflect correction of the disease pathway. Among the seven evaluable patients with baseline CD18 expression below 2%, all demonstrated increased CD18 expression following treatment. Median CD18 expression reached 50% at Month 12 and 54% at Month 24, with sustained expression through at least Month 42. All nine patients experienced an increase in CD11a expression, with median levels of 45% at Month 12 and 39% at Month 24, also maintained through at least Month 42. The most common adverse reactions occurring in at least 30% of patients were mucositis, upper respiratory tract infection, viral infection, febrile neutropenia, skin lesions, nausea and vomiting, rash or dermatitis, pyrexia, device-related infection, and skin infection.

Neighborhood Health Plan of Rhode Island ©2026
Proprietary & Confidential – Not for Distribution

IV. Initial Criteria

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Coverage is provided in the following conditions:

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Leukocyte Adhesion Deficiency-I (LAD-I) † Φ [1-3]

- Member is ≥3 months of age
- Member has a confirmed diagnosis of severe LAD-I by a specialist provider (e.g., Hematologist/oncologists, immunologists, geneticists, or infectious disease specialists) and defined as all of the following:
    - Neutrophil CD18 expression <2% or CD11a and/or CD11b expression <2% (if neutrophil CD18 expression ≥2%); **AND**
    - Documented biallelic *ITGB2* mutations; **AND**
    - Clinical history consistent with severe LAD-I or a known family history; **AND**
- Member has ≥ 1 prior significant, medically documented bacterial or fungal infection; **AND**
- Member is a candidate for autologous hematopoietic stem cell transplant (HSCT) and has not had prior HSCT; **AND**
- Member does not have a known and available suitable 10/10 human leukocyte antigen (HLA)-matched related donor willing to participate in an allogeneic HSCT; **AND**
- Member will undergo mobilization with granulocyte-colony-stimulating factor (G-CSF) and plerixafor prior to apheresis; **AND**
- Member has no active or clinically significant systemic infection and will be monitored for signs and symptoms of infection before and after infusion, with prophylactic antimicrobials administered per institutional guidelines; **AND**
- Member will be monitored for signs and symptoms of veno-occlusive disease including assessment of liver function tests during the first month following infusion; **AND**

Neighborhood Health Plan of Rhode Island ©2026
Proprietary & Confidential – Not for Distribution

- Member has been screened and found negative for human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to mobilization and apheresis *(**Note:** Members 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 possible false-positive PCR assay test result for HIV. Therefore, members who have received Kresladi should not be screened for HIV infection using a PCR-based assay.)*; **AND**
- Member will not receive prophylactic HIV anti-retroviral therapy (ART) *(**Note:** Members receiving prophylactic ART should stop therapy 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)*; **AND**
- Member will be monitored for lentiviral vector (LVV)-mediated insertional oncogenic hematologic malignancies following treatment as clinically indicated; **AND**
- Member will be monitored and managed according to clinical practice for severe hypersensitivity reactions to dimethyl sulfoxide (DMSO) during and after infusion; **AND**
- Member will undergo treatment at an Authorized Treatment Center (ATC)
- Member has not received any prior gene therapies used for the treatment of LAD-I including treatment with Kresladi (marnetegragene autotemcel) §

§ Note: Retreatment with marnetegragene autotemcel is considered investigational. While limited retreatment was reported for a single patient in the pivotal clinical study, the available evidence is insufficient to establish the safety and effectiveness of repeat administration. Requests for retreatment will therefore be reviewed on a case-by-case basis, taking into account the totality of clinical circumstances and supporting documentation.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

V. Renewal criteria

Coverge cannot be renewed.

VI. Dosage/Administration

Indication	Dose
LAD-I	The recommended minimum dose of Kresladi is a single intravenous infusion of 2.8 × 10^6 CD34+ cells/kg. • For autologous use only. For one-time single-dose intravenous use only.

Neighborhood Health Plan of Rhode Island ©2026
Proprietary & Confidential – Not for Distribution

- *Before mobilization, apheresis, and conditioning are initiated, confirm that autologous hematopoietic stem cell (HSC) transplantation is appropriate for the member.*
- *Consider administering ustekinumab prior to mobilization and apheresis and/or prior to Kresladi infusion.*
- *Kresladi contains human blood cells that are genetically modified with replication-incompetent, self-inactivating lentiviral vector (LVV). Follow universal precautions and local institutional biosafety guidelines for handling and disposal to avoid potential transmission of infectious diseases.*
- *Vaccination is not recommended during the 6 weeks prior to the start of myeloablative conditioning and until hematologic recovery following treatment with Kresladi.*

VII. Billing Code/Availability Information

HCPCS Code(s):

J3590 – Unclassified biologics

C9399 – Unclassified drugs or biologicals *(Hospital Outpatient Use Only)*

NDC:

- Kresladi 50 mL infusion bag and metal cassette *(supplied in one or two infusion bags containing a frozen suspension of genetically modified autologous cells enriched for CD34+ cells with each infusion bag containing approximately 30 mL and is individually packed within an overwrap in a metal cassette for protection)*: 83537-0034-xx

VIII. References

1. Kresladi [package insert]. Cranbury, NJ; Rocket Pharmaceuticals, Inc; March 2026. Accessed April 2026.
2. ClinicalTrials.gov. NCT03812263. A Clinical Trial to Evaluate the Safety and Efficacy of RP-L201 in Subjects With Leukocyte Adhesion Deficiency-I. | ClinicalTrials.gov.
3. Booth C, Sevilla J, Almarza E, et al. Lentiviral Gene Therapy for Severe Leukocyte Adhesion Deficiency Type 1. N Engl J Med. 2025 May 1;392(17):1698-1709. doi: 10.1056/NEJMoa2407376.

Neighborhood Health Plan of Rhode Island ©2026
Proprietary & Confidential – Not for Distribution

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D71.1	Leukocyte adhesion deficiency

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY,	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Neighborhood Health Plan of Rhode Island ©2026
Proprietary & Confidential – Not for Distribution

Policy Rationale:

Kresladi was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use O Kresladi according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Neighborhood Health Plan of Rhode Island ©2026
Proprietary & Confidential – Not for Distribution