Kresladi™ (marnetegragene autotemcel)
(Intravenous)

Document Number: IC-0850

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for ONE dose total.
- Renewal: Prior authorization validity may NOT be renewed **§**

  § *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.*

II. Dosing Limits

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

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

III. Initial Approval Criteria [1]

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.

Prior authorization validity is provided in the following conditions:

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

- Member has a confirmed diagnosis of severe LAD-I 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 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**
- 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 has not received prior gene therapies used for the treatment of LAD-I including treatment with 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

IV. Renewal Criteria [1]

- Duration of authorization has not been exceeded (*refer to Section I*)

V. Dosage/Administration [1]

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.
– *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.*	

VI. 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

VII. 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.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior

authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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, UT, AZ	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