MEDICAL MUTUAL®

Drug Policy

Policy:	**201844-MRX (2-23)**	**Initial Effective Date: 12/15/2018**
Code(s):	**HCPCS J3590, C9399**	**Annual Review Date: 02/20/2025**
SUBJECT:	**Revcovi™ (elapegademase-lvlr injection for intramuscular use – Leadiant)**	**Last Revised Date: 02/20/2025**

Subject to: ☒Site of Care
☐Medication Sourcing

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

Policy Statement
This policy involves the use of Revcovi. Prior authorization is recommended for medical benefit coverage of Revcovi Approval is recommended for those who meet the conditions of coverage in the **Initial Approval and Renewal Criteria, Preferred Drug (when applicable), Dosing/Administration, Length of Authorization, and Site of Care (when applicable)** for the diagnosis provided. The requirement that the patient meet the Criteria and Preferred Drug for coverage of the requested medication applies to the initial authorization only. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy.

I. Length of Authorization

Coverage will be provided for 12 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Revcovi 2.4 mg/1.5 mL single-dose vial: 20 vials per 7 days

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

- 23 mg twice weekly

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Universal Criteria [1]

- Patient does not have severe thrombocytopenia (i.e., platelet count <50,000/microL); **AND**

Adenosine Deaminase Severe Combined Immunodeficiency (ADA-SCID) † Φ [1,2,5]

- Patient has adenosine deaminase severe combined immunodeficiency (ADA-SCID) disease as determined by one of the following:
  - Deficient ADA catalytic activity (<1% of normal) in hemolysates (in untransfused individuals) or in extracts of other cells (e.g., blood mononuclear cells, fibroblasts); **OR**
  - Detection of biallelic pathogenic mutations in the *ADA* gene by molecular genetic testing; **AND**
- Patient has elevated deoxyadenosine triphosphate (dATP) or total deoxyadenosine nucleotides (dAXP) in red blood cells; **AND**
  - Patient is not a candidate for or has failed definitive therapy with bone marrow transplantation (BMT); **OR**
  - Patient is a candidate for definitive therapy with BMT and elapegademase will be used as bridge therapy; **AND**
- Patient has baseline values for trough plasma ADA activity, red blood cell dATP, trough red blood cell dAXP, and/or total lymphocyte counts

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

IV. Renewal Criteria [1,2,5]

Coverage may be renewed based on the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: injection site bleeding in patients with thrombocytopenia, severe thrombocytopenia, delay in improvement of immune function, etc.; **AND**
- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
  - Increase in plasma ADA activity (target trough level ≥ 15 mmol/hr/L)
  - Decrease in red blood cell dATP level (target ≤ 0.005 to 0.015 mmol/L)

- Improvement in immune function with diminished frequency/complications of infection as evidenced in improvement in the ability to produce antibodies
- Decrease in red blood cell dAXP level (target trough level ≤ 0.02 mmol/L)
- Increase in total lymphocyte counts

V. Dosage/Administration [1]

Indication	Dose
Adenosine Deaminase Severe Combined Immunodeficiency (ADA-SCID)	Patients transitioning from Adagen to Revcovi: • Weekly Adagen dose is unknown or weekly Adagen dose ≤30 U/kg – The recommended minimum starting dose of Revcovi is 0.2 mg/kg, intramuscularly (IM), once a week • Weekly Adagen dose >30 U/kg – An equivalent weekly Revcovi dose (mg/kg) should be calculated using the following conversion formula: *Revcovi dose in mg/kg = Adagen dose in U/kg ÷ 150* • Subsequent doses may be increased by increments of 0.033 mg/kg weekly if trough ADA activity <30 mmol/hr/L, trough deoxyadenosine nucleotides (dAXP) >0.02 mmol/L, and/or the immune reconstitution is inadequate based on the clinical assessment of the patient. The total weekly dose may be divided into multiple IM administrations during a week. Adagen-naïve patients: • The starting weekly dose of Revcovi is 0.4 mg/kg based on ideal body weight§ or actual weight (whichever is greater), divided into two doses (0.2 mg/kg twice a week), intramuscularly, for a minimum of 12 to 24 weeks until immune reconstitution is achieved. • The dose may be gradually adjusted down to maintain trough ADA activity >30 mmol/hr/L, trough dAXP level <0.02 mmol/L, and/or to maintain adequate immune reconstitution based on clinical assessment of the patient.

§The Devine formula for ideal body weight:
•Ideal body weight (men) = 50 kg + 2.3 kg x (height, in - 60)
•Ideal body weight (women) = 45.5 kg + 2.3 kg x (height, in - 60)

•Note: this formula is only an approximation, and is generally only applicable for people 60 inches (5 foot) tall or greater. For patients under 5 feet, one commonly-used modification is to subtract 2-5 lbs for each inch below 60 inches (Devine BJ. Gentamicin therapy. Drug Intell Clin Pharm. 1974;8:650–655.)

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals

NDC:

- Revcovi 2.4 mg/1.5 mL single-dose vial: 10122-0502-xx

VII. References

1. Revcovi [package insert]. Cary, NC; Chiesi USA, Inc.; August 2022. Accessed January 2024.
2. Hershfield, M. Adenosine Deaminase Deficiency. GeneReviews. www.ncbi.nlm.nih.gov/books/NBK1483/. Initial Posting: October 3, 2006; Last Update: March 16, 2017. Accessed January 2024.
3. Gaspar HB, Aiuti A, Porta F, et al. How I treat ADA deficiency. Blood. 2009 October 22; 114(17): 3524–3532.
4. Adenosine Deaminase Deficiency-genetic and Rare Diseases Information Center. US Department of health and human services-NIH. Available at: https://rarediseases.info.nih.gov/diseases/5748/adenosine-deaminase-deficiency
5. Flinn AM, Gennery AR. Adenosine deaminase deficiency: a review. Orphanet Journal of Rare Diseases 2018. https://doi.org/10.1186/s13023-018-0807-5
6. Dorsey MJ, Rubinstein A, Lehman H, et al. PEGylated Recombinant Adenosine Deaminase Maintains Detoxification and Lymphocyte Counts in Patients with ADA-SCID. J Clin Immunol 43, 951–964 (2023).
7. Kohn DB, Hershfield MS, Puck JM, et al. Consensus approach for the management of severe combined immune deficiency caused by adenosine deaminase deficiency. J Allergy Clin Immunol. 2019;143(3):852–63.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J3590

†When *unclassified biologics* (J3590) is determined to be Revcovi.

Edits and Denials:

Prior approval: Prior approval is required for Revcovi **(HCPCS Codes J3590)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.