Medical Policy:

Revcovi® (elapegademase-lvlr) intramuscular

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.306	February 21, 2025	2018

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Revcovi, a recombinant adenosine deaminase, is indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.

Length of Authorization

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

Dosing Limits [Medical Benefit]

Approve up to a maximum weekly dose of 0.4 mg/kg by intramuscular route.

Note: Doses may be divided into multiple injections as long as weekly cumulative maximum of 0.4 mg/kg is not exceeded.

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

• 23 mg twice weekly

Guideline

I. INITIAL

1. **Adenosine Deaminase Severe Combined Immunodeficiency (ADA-SCID).** Approve if the patient meets the following criteria:
   A. Patient has a diagnosis of ADA-SCID confirmed by one of the following criteria (i or ii):
      i. At baseline (i.e., prior to initiating enzyme replacement therapy), the patient has had absent or very low (< 1% of normal) adenosine deaminase (ADA) catalytic activity; **OR**
      ii. Patient has had molecular genetic testing confirming bi-allelic mutations in the *ADA* gene; **AND**
   B. Patient has elevated deoxyadenosine triphosphate (dATP) or total deoxyadenosine nucleotides (dAXP) in red blood cells; **AND**
      i. Patient is not a candidate for or has failed definitive therapy with bone marrow transplantation (BMT); **OR**
      ii. Patient is a candidate for definitive therapy with BMT and elapegademase will be used as bridge therapy; **AND**
   C. Patient has baseline values for trough plasma ADA activity, red blood cell dATP, trough red blood cell dAXP, and/or total lymphocyte counts; **AND**
   D. The medication is prescribed by or in consultation with an immunologist, hematologist/oncologist, or physician who specializes in ADA-SCID or related disorders.

II. RENEWAL

Coverage may be renewed based on the following criteria:

A. 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 Initial Criteria; **AND**

B. 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**

C. Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in **ONE** or more of the following:
   i. Increase in plasma ADA activity (target trough level ≥ 15 mmol/hr/L)
   ii. Decrease in red blood cell dATP level (target ≤ 0.005 to 0.015 mmol/L)
   iii. Improvement in immune function with diminished frequency/complications of infection as evidenced in improvement in the ability to produce antibodies
   iv. Decrease in red blood cell dAXP level (target trough level ≤ 0.02 mmol/L)
   v. Increase in total lymphocyte counts

Applicable Procedure Codes

Code	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Applicable NDCs

Code	Description
10122-0502-01	Revcovi 2.4mg/1.5mL Solution
57665-0002-01	Revcovi 2.4mg/1.5mL Solution

ICD-10 Diagnoses

Code	Description
D81.30	Adenosine deaminase deficiency, unspecified
D81.31	Severe combined immunodeficiency due to adenosine deaminase deficiency
D81.32	Adenosine deaminase 2 deficiency
D81.39	Other adenosine deaminase deficiency

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/21/2025	Annual Review: added D81.30, D81.32, D81.39. Initial Criteria: added: "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; AND "Renewal Criteria: added: "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 Initial Criteria; 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"
EmblemHealth & ConnectiCare	1/10/2024	Annual Review: No Criteria Changes
EmblemHealth & ConnectiCare	4/7/2023	Transfer from CCUM template to Co-Branded Medical template Retired MG.MM.PH.190
EmblemHealth & ConnectiCare	11/16/2022	Annual Revision: no criteria changes
EmblemHealth & ConnectiCare	11/10/2021	Annual Revision: no criteria changes

References

1. Revcovi® [prescribing information]. Gaithersburg, MD: Leadiant Biosciences; December 2020.