

Policy: MBP 193.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Revcovi (elapegademase-lvlr)

I. Policy:

Revcovi (elapegademase-lvlr)

II. Purpose/Objective:

To provide a policy of coverage regarding Revcovi (elapegademase-lvlr)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Revcovi (elapegademase-lvlr) is an exogenous source of adenosine deaminase enzyme. Adenosine deaminase is an enzyme that catalyzes the deamination of both adenosine and deoxyadenosine. Hereditary lack of adenosine deaminase activity results in severe immunodeficiency disease, an often fatal disorder. Elapegademase-lvlr in effect, reduces levels of toxic adenosine and deoxyadenosine and increases lymphocytes.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Revcovi (elapegademase-lvlr) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- If the patient is Adagen-naïve, medical record documentation that Revcovi dosing is based on ideal body weight (IBW) or actual body weight (ABW) whichever is greater **AND**
 - Medical record documentation that Revcovi is prescribed by or in consultation with an immunologist, geneticist, or a physician who specializes in inherited metabolic disorders **AND**
 - Medical record documentation of a diagnosis of adenosine deaminase deficiency-associated severe combined immune deficiency (ADA-SCID) as confirmed by the following:
 - Very low presence or absence of ADA (adenosine deaminase) activity in red blood cells or other samples **AND** Increase in adenosine, deoxyadenosine, and deoxyadenosine triphosphate (dATP) levels in red blood cells, plasma, or urine
- OR**
- Biallelic mutations in the *ADA1* gene

AUTHORIZATION DURATION:

- Approval for new starts of Revcovi will be given for an initial duration of six (6) months.
- After the initial six (6) month approval, subsequent approvals for coverage will be for an additional six (6) months. Reevaluation of coverage will be every six (6) months and will require:
 - Medical record documentation of continued or sustained improvement in trough plasma ADA and dAXP (deoxyadenosine nucleotides) levels while on Revcovi therapy **AND**
 - Medical record documentation of planned hematopoietic cell transplantation or gene therapy **OR** medical record documentation that the patient is not a suitable candidate for hematopoietic cell transplantation and gene therapy at the time of the request.

Reference for reviewing pharmacist:

- Males IBW = 50 kg + 2.3 kg for each inch over 5 feet
- Females IBW = 45.5 kg + 2.3 kg for each inch over 5 feet

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Revcovi [package insert]. Cary, NC: Chiesi USA Inc; August 2022.
2. ADA gene. NIH. Available from: <https://ghr.nlm.nih.gov/gene/ADA>
3. Adenosine deaminase deficiency: Pathogenesis, clinical manifestations, and diagnosis. UpToDate. Dec 14, 2018
4. Kohn, Hershfield, Puck, et al. Consensus approach for the management of severe combined immune deficiency caused by adenosine deaminase deficiency. Journal of Allergy and Clinical Immunology. 2018

This policy will be revised as necessary and reviewed no less than annually.

Devised: 3/19/19

Revised: 1/27/21 (ABW), 12/16/22 (LOB carve out, Medicaid PARP statement), 12/6/23 (Medicaid business segment, dAXP, references)

Reviewed: 1/1/20, 1/1/21, 12/17/21