AETNA BETTER HEALTH® Coverage Policy/Guideline				
Name:	Revcovi		Page:	1 of 3
Effective Date:	2/13/2025		Last Review Date:	01/13/2025
Applies to:	☒ Illinois ☒ Florida Kids	☒ Kentucky PRMD ☒ Pennsylvania Kids	☒ Maryland ☒ Virginia	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Revcovi under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

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

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Revcovi

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests:

- Genetic or molecular test results or medical records confirming the diagnosis.
- Baseline values for plasma adenosine deaminase (ADA) activity, red blood cell deoxyadenosine triphosphate (dATP), trough deoxyadenosine nucleotide (dAXP) levels, and/or total lymphocyte counts.
- Hematologic assessment (e.g., complete blood count) demonstrating absence of severe thrombocytopenia (platelets <50,000/microL).

Continuation requests:

- Chart notes, lab values, or medical record documentation supporting positive clinical response

Prescriber Specialties

This medication must be prescribed by an or in consultation with an immunologist or a physician who specializes in the treatment of metabolic disease and/or lysosomal storage disorders

Criteria for Initial Approval:

Adenosine Deaminase Severe Combined Immune Deficiency
Authorization of 12 months may be granted for treatment of ADA-SCID when ALL the following criteria are met:

- The diagnosis is confirmed by ONE of the following:
  - Increased red blood cell deoxyadenosine triphosphate (dATP) or trough deoxyadenosine nucleotide (dAXP) concentrations and ONE of the following:
    - Absent or very low (<1% of normal) adenosine deaminase (ADA) activity in red blood cells
    - Genetically confirmed, biallelic variant in the ADA gene.
- Baseline values for plasma ADA activity, red blood cell dATP, dAXP levels, and/or total lymphocyte counts have been obtained.
- Member meets one of the following:
  - The requested medication will only be used until definitive therapy with hematopoietic stem cell transplantation (HSCT) .
  - Member is not a suitable candidate for HSCT (e.g., matched sibling or family donor not available).
  - Member has failed HSCT.
- Member does not have severe thrombocytopenia (platelets <50,000/microL).
- Member does not have autoimmune disease requiring immunosuppressive therapy.
- Member will be monitored for evidence of treatment efficacy per protocol outlined in the prescribing information during treatment with Revcovi

Continuation of Therapy
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when ALL the following criteria are met:

- Member meets the criteria for initial approval.
- Member does not have unacceptable toxicity (e.g., severe injection site reactions/bleeding, severe thrombocytopenia).
- Member is experiencing benefit from therapy (e.g., maintenance of target trough plasma ADA activity ≥30 mmol/L, trough erythrocyte dAXP levels below 0.02 mmol/L, improved or stabilized total lymphocyte counts and/or immune function).

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Revcovi [package insert]. Cary, NC: Chiesi USA, Inc.; December 2020.
2. Grunebaum E, Booth C, Cuvelier GDE, Loves R, Aiuti A, Kohn DB. Updated Management Guidelines for Adenosine Deaminase Deficiency. J Allergy Clin Immunol Pract. 2023;11(6):1665-1675. doi:10.1016/j.jaip.2023.01.032
3. 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):852-863. doi:10.1016/j.jaci.2018.08.024