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5.30.060

Section:	Prescription Drugs	Effective Date:	April 1, 2024
Subsection:	Endocrine and Metabolic Drugs	Original Policy Date:	October 12, 2018
Subject:	Revcovi	Page:	1 of 4

Last Review Date: March 8, 2024

Revcovi

Description

Revcovi (elapegademase-lvlr)

Background

Severe combined immune deficiency (SCID) associated with a deficiency of ADA (adenosine deaminase) enzyme is a rare, inherited, and often fatal disease. ADA enzyme is involved in purine metabolism, catalyzing the irreversible hydrolytic deamination of adenosine or deoxyadenosine to inosine or deoxyinosine, respectively, as well as several naturally occurring methylated adenosine compounds. Maintaining a low level of 2'-deoxyadenosine and adenosine is crucial for proper number and function of immune cells as well as decreasing the frequency of opportunistic infections. Elevated adenosine levels, as occurring in ADA deficiency, contribute to apoptosis and a block in the differentiation of thymocytes, causing severe T-lymphopenia (1).

Revcovi (elapegademase-lvlr) provides an exogenous source of ADA enzyme that is associated with a decrease in toxic adenosine and deoxyadenosine nucleotides levels as well as an increase in lymphocyte number (1).

Regulatory Status

FDA-approved indication: Renvovi is a recombinant adenosine deaminase, indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients (1).

Revcovi is administered by IM injection and thus it should be used with caution in patients with thrombocytopenia due to risk of injection site bleeding and should not be used if the thrombocytopenia is severe (1).

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There may be a delay in the improvement of immune function following administration of Revcovi. Precautions should be maintained to protect immune deficient patients from infections until improvement in immune function has been achieved. The timing and degree of improvement in immune function may vary from patient to patient (1).

Once treatment with Revcovi has been initiated, a target trough plasma ADA activity should be at least 30 mmol/hr/L. A decrease of ADA activity below this level suggests noncompliance to treatment or a development of antibodies. Antibodies to Revcovi should be suspected if a persistent fall in pre-injection levels of trough plasma ADA activity below 15 mmol/hr/L occurs. If a persistent decline in trough plasma ADA activity occurs, immune function and clinical status should be monitored closely, and precautions should be taken to minimize the risk of infection. In these situations, testing for Revcovi antibodies should be undertaken (1).

Two months after starting Revcovi treatment, trough erythrocyte dAXP levels should be maintained below 0.02 mmol/L and monitored at least twice a year. Total and subset lymphocytes should also be monitored periodically (1).

The safety and effectiveness of Revcovi in pediatric patients have been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Revcovi may be considered **medically necessary** if the conditions indicated below are met.

Revcovi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Adenosine deaminase severe combined immune deficiency (ADA-SCID)

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AND ALL of the following:

1. Prescriber agrees to monitor **ALL** of the following:
 - a. Trough plasma ADA activity
 - b. Trough erythrocyte dAXP levels
 - c. Total and subset lymphocyte counts

Prior – Approval *Renewal* Requirements

Diagnosis

Patient must have the following:

Adenosine deaminase severe combined immune deficiency (ADA-SCID)

AND ALL of the following:

1. Trough plasma ADA activity ≥ 30 mmol/hr/L
2. Trough erythrocyte dAXP level < 0.02 mmol/L
3. Prescriber agrees to monitor **ALL** of the following:
 - a. Trough plasma ADA activity
 - b. Trough erythrocyte dAXP levels
 - c. Total and subset lymphocyte counts

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary

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Revcovi (elapegademase-IVr) provides an exogenous source of ADA enzyme that is associated with a decrease in toxic adenosine and deoxyadenosine nucleotides levels as well as an increase in lymphocyte number. The safety and effectiveness of Revcovi in pediatric patients have been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Revcovi while maintaining optimal therapeutic outcomes.

References

1. Revcovi [package insert]. Indianapolis, IN: Chiesi USA, Inc.; December 2020.

Policy History

Date	Action
October 2018	Addition to PA
November 2018	Annual review
March 2019	Annual review. Reworded regulatory status and added requirement to monitor for total and subset lymphocyte counts per SME
December 2020	Annual review and reference update
September 2021	Annual review and reference update
September 2022	Annual review
September 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.