ELAPEGADEMASE-LVLR

Generic	Brand	HICL	GCN	Exception/Other
ELAPEGADEMASE-LVLR	REVCOVI	45340		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) as manifested by **ONE** of the following?
   - Confirmatory genetic test
   - Suggestive laboratory findings (e.g. elevated deoxyadenosine nucleotide [dAXP] levels, lymphopenia) **AND** hallmark signs/symptoms (e.g. recurrent infections, failure to thrive, persistent diarrhea)

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the requested medication prescribed by or in consultation with an immunologist, hematologist/oncologist, or physician specializing in inherited metabolic disorders?

   If yes, continue to #3.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is there physician attestation that the patient meets **ONE** of the following criteria?
   - The patient has failed or is not a candidate for hematopoietic cell transplantation (HCT)
   - The requested medication will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

   If yes, **approve for 6 months by HICL.**
   APPROVAL TEXT: Renewal requires 1) documentation of trough plasma ADA activity greater than or equal to 30 mmol/hr/L and trough dAXP levels less than 0.02 mmol/L, **AND** 2) physician attestation of improvement in/maintenance of immune function from baseline, and patient has not received successful hematopoietic cell transplant (HCT) or gene therapy.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAPEGADEMASE-LVLR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) as manifested by ONE of the following:

- Confirmatory generic test, or
- Suggestive laboratory findings (e.g. elevated deoxyadenosine nucleotide [dAXP] levels, lymphopenia) AND hallmark signs/symptoms (e.g. recurrent infections, failure to thrive, persistent diarrhea)
- In addition, the following criteria must be met:
  - The requested medication is prescribed by or in consultation with an immunologist, hematologist/oncologist, or physician specializing in inherited metabolic disorders
  - Physician attestation that the patient has failed or is not a candidate for hematopoietic cell transplant (HCT), OR the requested medication will be used as a bridging therapy prior to planned hematopoietic cell transplant (HCT) or gene therapy

RENEWAL CRITERIA

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) and meet **ALL** of the following criteria?
   - Documentation of trough plasma ADA activity ≥30 mmol/hr/L **AND** trough dAXP levels <0.02 mmol/L
   - Physician attestation of improvement in/maintenance of immune function from baseline (e.g. decrease in number and severity of infections), **AND** patient has not received successful hematopoietic cell transplant (HCT) or gene therapy

   If yes, **approve for 12 months by HICL.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID). In addition, the following criteria must be met:
   - Documentation of trough plasma ADA activity greater than or equal to 30 mmol/hr/L AND trough dAXP levels less than 0.02 mmol/L
   - Physician attestation of improvement in/maintenance of immune function from baseline (e.g. decrease in number and severity of infections), AND patient has not received successful hematopoietic cell transplantation (HCT) or gene therapy

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ELAPEGADEMASE-LVLR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revcovi.

REFERENCES

- Revcovi [Prescribing Information]. Gaithersburg, MD: Leadiant Biosciences Inc., October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/19
Created: 02/19
Client Approval: 03/19
P&T Approval: 01/19