DOSING AND MONITORING GUIDE

INDIVIDUALIZED TREATMENT FOR YOUR PATIENTS WITH ADA-SCID.

Meet each patient's unique needs with individualized dosing and careful lab monitoring.[1]

Revcovi®
elapegademase-lvlr
injection 1.6 mg/mL

Josh, actual Revcovi patient

There for the journey with ADA-SCID

The only enzyme-replacement therapy (ERT) for pediatric and adult patients with adenosine deaminase severe combined immune deficiency (ADA-SCID).

Revcovi

INDICATION

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- Injection site bleeding in patients with thrombocytopenia: Increased risk of local bleeding in patients with thrombocytopenia; should not be used if thrombocytopenia is severe.
- Delay in improvement of immune function: Protect immune deficient patients from infections until improvement in immune function.

ADVERSE REACTIONS

The most commonly reported adverse reactions were cough (50%) and vomiting (33%).

In addition, the following post-marketing reports for the same class of enzyme replacement therapy used in the treatment of ADA-SCID may also be seen with Revcovi treatment:

- Hematologic events: hemolytic anemia, autoimmune hemolytic anemia, thrombocythemia, thrombocytopenia and autoimmune thrombocytopenia
- Dermatological events: injection site erythema, urticaria
- Lymphomas

Please see Important Safety Information throughout and accompanying full Prescribing Information.

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Ashley and Josh, actual Revcovi patients

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ACHIEVE THERAPEUTIC DOSING THROUGH MAINTENANCE[1]

Improvement in the general clinical status of the patient may be gradual but should be apparent by the end of the first year of therapy[1]

Ashley, actual Revcovi patient

Recommended starting dose[1]

0.4 mg/kg/wk based on ideal body weight or actual weight, whichever is greater

Divided into 2 weekly doses for a minimum of 12-24 weeks

Until immune reconstitution is achieved

Recommended maintenance dose[1]

Once immune reconstitution is achieved, dose may be gradually adjusted down to maintain trough ADA activity, trough deoxyadenosine levels and/or clinical assessment.

ADA activity >30 mmol/hr/L

Trough dAXP levels <0.02 mmol/L

To maintain adequate immune reconstitution based on the clinical assessment of the patient

IMPORTANT SAFETY INFORMATION
IMPORTANT MONITORING INFORMATION

Treatment with Revcovi should be monitored by measuring trough plasma ADA activity and trough dAXP levels for maintenance of therapeutic targets. If a persistent decline in plasma ADA activity occurs, immune function and clinical status should be monitored closely, and precautions should be taken to minimize the risk of infection.

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DOSING

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THERAPEUTIC MONITORING HELPS ACHIEVE APPROPRIATE DOSING[1]

Monitoring schedule[1]

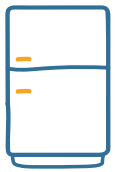
Measurement	First 3 months of treatment: monitor patients **every 2 weeks**	4-12 months of treatment: monitor patients **every 1-2 months**	1 year+ of treatment: monitor patients **every 3-6 months**	Target
ADA Activity	Every 2 weeks	Every 3-6 months	Every 3-6 months	Trough plasma ADA activity ≥30 mmol/h/L*
Erythrocyte dAXP	At week 8	Every 6 months	Every 6 months	Trough dAXP levels <0.02 mmol/L
Total & Subset Lymphocytes	At weeks 4, 8, and 12	Every 1-2 months	Every 3-6 months	General improvement†

* A decrease of ADA activity below 30 mmol/hr/L might suggest noncompliance or a development of antibodies (anti-drug, anti-PEG, and neutralizing antibodies). Test for antibodies to Revcovi if pre-injection trough plasma ADA activity falls below 15 mmol/hr/L consistently. If there is a decline in ADA activity levels, monitor immune function and clinical status more closely and take precautions to minimize the risk of infection.[1]

† Immune function, including the ability to produce antibodies, generally improves after 2-6 months of therapy, and matures over a longer period. Improvement in the general clinical status of the patient may be gradual (as evidenced by improvement in various clinical parameters) but should be apparent by the end of the first year of therapy.[1]

How supplied

- Each single-use vial of Revcovi contains 2.4 mg of elapegademase-lvlr in a 1.5 mL solution[1]
- The concentration of elapegademase-lvlr is 1.6 mg/mL[1]
- The solution is clear and colorless and contains no preservatives[1]
- The vial stopper is not made with natural rubber latex[1]



Storage & handling

- Store in the refrigerator between 2°C to 8°C (36°F to 46°F) in the original carton to protect from light[1]
- Do not freeze or shake. Do not use if there are any indications that vials were frozen[1]
- Single-dose vial; do not reuse the vial. Discard unused portions[1]
- Discard if solution is discolored, cloudy or contains particulate matter[1]

ONE-STOP PATIENT SUPPORT

Chiesi Total Care℠ is a comprehensive support program that provides exceptional service to healthcare providers and their patients.

A single call to your dedicated Chiesi Total Care team is all it takes, and they will guide you through the process of getting a patient started on Revcovi therapy. The Chiesi Total Care Program provides assistance to patients with or without commercial insurance, Medicaid, and Medicare. The program also offers injection support for patients who receive Revcovi injections at home.†

1. **Assess patient eligibility**
2. **Insurance assistance**
3. **Access to medication**

The Revcovi copay program:

Patients may pay as little as $0 for their prescription.†

Program eligibility:

- Patient must be enrolled in Chiesi Total Care. Enrollment form can be found at ChiesiTotalCare.com.
- Patient has commercial insurance and a valid prescription for a US Food and Drug Administration (FDA)-approved indication.
- Patient must be a resident of the United States or one of its territories.

† Please refer to the accompanying full Terms and Conditions for additional eligibility requirements.

Lesa, Chiesi Total Care Pharmacist

Visit chiesitotalcare.com or call 1-866-272-7078 if you have any questions

Revcovi ordering and support

Please visit **ChiesiTotalCare.com** to access the Revcovi Order/Prescription Form and the Chiesi Total Care Enrollment Form.

Scan the QR code to download forms to your device.
Please fax completed forms to Chiesi Total Care at **1-866-272-7079**.

Medical information and adverse event reporting

For adverse event reporting, product complaints, or medical information inquiries:

Phone: **1-888-661-9260**
Fax: **1-866-443-3092**
Email: **us.medical@chiesi.com**

Privacy policy

Where applicable, personal information shared and processed for adverse events reporting, product orders, reimbursement support, and patient assistance is subject to Chiesi's Privacy Policy available at **https://www.chiesiusa.com/privacy-policy/**.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

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Reference: 1. Revcovi® Prescribing information. Chiesi USA, Inc.; 2021.

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