Chiesi TOTAL care℠

Getting Started Guide

To get a patient started on Revcovi® (elapegademase-lvlr) follow **2 steps** outlined in this guide.

Visit chiesitotalcare.com or call 1-866-272-7078 – we're ready to help!

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

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.

Please see accompanying Prescribing Information.

Revcovi®
elapegademase-lvlr
injection

Step 1:

Fill out the Physician Order/Prescription & Statement of Medical Necessity Form

Chiesi TOTAL care

Physician Order/Prescription & Statement of Medical Necessity

Revcovi® elapegademase-lvlr injection 1.6 mg/mL

Please fax completed form to Chiesi Total Care℠ staff at 866-272-7079

PATIENT INFORMATION

Patient Name (Last, First) _____

Social Security # _____ - _____ - _____ Sex: ☐ Male ☐ Female Date of Birth _____/_____/_____ (mm/dd/yyyy)

Address _____ City _____ State _____ Zip _____

Primary Phone (Required) _____ Cell Phone _____ Language: ☐ English ☐ Other _____

Parent/Guardian (If applicable) _____ Relationship to Patient _____

CLINICAL INFORMATION

Diagnosis: ☐ Adenosine deaminase severe combined immune deficiency (ADA-SCID) ICD-10 code D81.31 (primary)

☐ Secondary ICD-10 _____ ☐ Other ICD-10 _____

Treatment information

☐ Initial Rx for ADA-SCID ☐ Continuation on ERT ☐ Restart after Gene Therapy ☐ Restart after HSCT

☐ New patient/returning to therapy ☐ Other _____ Allergies: ☐ None ☐ Specify _____

Height _____ inches or _____ cm Weight _____ lb or _____ kg Known Drug Allergies: _____

INSURANCE INFORMATION

Primary Prescription Insurance	**Primary Medical Insurance**	**Secondary Medical Insurance**
Policy Holder	Policy Holder	Policy Holder
Policy ID #	Policy ID #	Policy ID #
Group #	Group #	Group #
Phone	Phone	Phone

☐ Eligible for Medicare ☐ Eligible for Medicaid ☐ No Insurance

Please attach copies of patient insurance and prescription cards—front and back.

REVCOVI (elapegademase-lvlr) PRESCRIPTION/ORDER

Revcovi (elapegademase-lvlr) 2.4 mg/1.5 mL single use vial NDC 10122-502-01 QTY _____ Refills _____

Instructions: Inject _____ mg intramuscularly (IM) _____ times per week.

Provide medical supplies, including syringes and needles, to safely administer prescribed medication.

☐ Skilled nursing visits _____ times for medication administration teaching

PRESCRIBER/OFFICE INFORMATION

Prescriber's Name (Print) _____ Practice/Group Name _____

Address _____ Suite _____

City _____ State _____ Zip _____

Office Contact Person _____

Office Phone _____ Office Fax _____

License # _____ NPI # _____

By signing below, I certify that I am the prescribing provider mentioned above, that I am part of the Chiesi Total Care Program, that the therapy described above is medically necessary, and that all the medical necessity information is true, accurate, and complete. The patient's records contain supporting documentation that substantiates the utilization and medical necessity of the products marked above. I provide permission to use my personal information and the personal information of the patient provided above to facilitate this request and complete any regulatory or legal requirements associated with this request. I understand that the personal information provided herein may be shared with Chiesi, successors, and their agents and service providers as needed to support this request. I also attest that I have obtained the patient's authorization to release the above information and such other personal information as may be necessary for the Chiesi Total Care Program and/or their agents and service providers. If the patient is 18 years old or younger, I attest that I have obtained permission from the patient's legal guardian. If my patient is eligible for free product, I understand that receiving free product is not contingent on any purchase obligations. I also understand that no free product may be submitted for reimbursement to any payer, including Medicare and Medicaid; nor may I bill any payer for administration of such product. I understand that any falsification, omission, or concealment of material fact may result in criminal liability.

Prescriber's Signature _____ _____ Date _____

Substitution Permitted Dispense as Written

Revcovi is available as 2.4 mg/1.5 mL (1.6 mg/mL) intramuscular injection.

Questions? Chiesi Total Care is here to help! Please contact Chiesi Total Care at 866-272-7078 if you have questions regarding this form.

Please see Important Safety Information on the reverse side.

A

B

You may also attach separate instructions.

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

A Specify appropriate ICD-10 Diagnosis code(s) for secondary diagnosis

(Other uses are at prescriber's discretion)

ICD-10 Diagnosis Codes	
Diagnosis	**Current indication**
D81.3	Adenosine deaminase deficiency, unspecified
D81.31	Severe combined immunodeficiency due to adenosine deaminase deficiency
D81.9	Combined immunodeficiency, unspecified

Intended as a reference for coding and billing for product and associated services. Not intended to be a directive, nor does the use of the recommended codes guarantee reimbursement. Providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

B Recommended starting dose

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

- Once immune reconstitution is achieved, dose may be gradually adjusted down to maintain trough ADA activity >30 mmol/hr/L, trough dAXP levels <0.02 mmol/L, and/or to maintain adequate immune reconstitution based on the clinical assessment of the patient
- 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

Refer to administration guide for details.

Sample dosing assuming 60 kg patient @ 0.4 mg/kg/wk

Instructions: Inject 12 mg

intramuscularly (IM) 2 times per week.

Step 2:

Once you have completed the form:

1. Attach copies of patient insurance and prescription cards – front and back.
2. First prescription for the patient:

   The first copy of the form must be faxed for each patient. Fax completed form to Chiesi Total Care℠ at 1-866-272-7079. **Please complete one form per patient.**
3. Subsequent prescriptions:

   If you wish to send additional forms via e-script please search for "Eversana Life Science Services" in your EMR/HMR's e-prescribing software.

The fillable pdf can be downloaded and saved for future use.

Scan the QR code to download a copy.

FPO

Chiesi TOTAL care℠

Visit chiesitotalcare.com or call 1-866-272-7078 – we're ready to help!

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

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.

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Please see full Prescribing Information inside.

References: 1. Revcovi® (elapegademase-lvlr) Prescribing Information. Chiesi USA, Inc.; 2020.

For more information, visit revcovi.com.
Chiesi Total Care℠ Program offered through EVERSANA Life Science Services Specialty Pharmacy

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Revcovi®
elapegademase-lvlr
injection