AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Otarmeni™ (lunsotogene parvec-cwha) **(C9399/J3590) MEDICAL**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

A. Quantity Limit (max daily dose) [NDC Unit]:

- Each single-dose vial of contains a nominal titer of 3.0×10^{13} vg/mL of OTARMENI and has an extractable volume of 0.63 mL
- Recommended dose of OTARMENI for each ear is 7.2×10^{12} vector genomes (vg) in a total volume of 0.24 mL, administered by a single-dose intracochlear infusion.

B. Max Units (per dose and over time) [HCPCS Unit]:

- 7.2×10^{12} vg (0.24 mL) one time only (Max units is based on administration to each ear)

(Continued on next page)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Coverage will be provided for one treatment course and may NOT be renewed. An authorization length of 3 months for one dose total per ear may be granted for OTOF-related hearing loss when ALL the following criteria is met:

- ❑ Member is at least 10 months of age to ≤ 17 years of age
- ❑ Prescribed by or in consultation with an otolaryngologist or a surgeon experienced in intracochlear surgery and trained in the administration process
- ❑ Member must meet **ALL** the following:
  - ❑ Member has biallelic pathogenic (or likely pathogenic) variants in the OTOF-gene as identified by molecular genetic testing **(submit testing)**
  - ❑ Member has a diagnosis of severe-to-profound or profound sensorineural hearing loss (any frequency >90 dB HL) either unilaterally or bilaterally
  - ❑ Member has an absent auditory brainstem response (ABR)
  - ❑ Member has preserved outer hair cell function as evidenced by **ONE** of the following **(submit documentation)**:
    - ❑ Presence of otoacoustic emissions (OAE)
    - ❑ Presence of a cochlear microphonic
- ❑ Member does **NOT** have, or has **NOT** had, a prior cochlear implant in the ear planned for treatment
- ❑ Member does **NOT** have evidence of preoperative imaging demonstrating access to the inner ear is not feasible including those with abnormal mastoid pneumatization or clinically significant anatomic variations of the middle ear and inner ear
- ❑ Member does **NOT** have a history or presence of the following:
  - Other permanent or untreatable hearing loss conditions
  - Cochlear implants in the ear(s) to be injected
  - Malignancies
  - Meningitis
- ❑ Member has **NOT** received Ortameni in the same ear or any other gene therapy previously
- ❑ Prophylaxis for infection will be followed according to standard institutional guidelines
- ❑ Requested medication will be used in combination with corticosteroids for prophylaxis against inflammatory and immunological responses
- ❑ Provider will confirm that member is up to date with all vaccinations (including against meningitis), in accordance with current vaccination guidelines, prior to initiating therapy **(NOTE: Administer vaccines at least 1 month before the first corticosteroid dose and at least 1 month after the last dose)**

(Continued on next page)

- ❑ Requested dose does **NOT** exceed a single intracochlear infusion of 7.2×10^{12} vector genomes (vg) per ear
- ❑ The use of this product has satisfied Regeneron's clinical eligibility for the member to receive Otarmeni at no cost; to receive treatment through a designated otolaryngology treatment center

Reauthorization: Coverage may NOT be renewed.

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee**: 7/23/2026
REVISED/UPDATED/REFORMATTED: 8/28/2026