Clinical Policy: Lunsotogene Parvec-cwha (Otarmeni)

Reference Number: CP.PHAR.757
Effective Date: 04.23.26
Last Review Date: 12.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Lunsotogene parvec-cwha (Otarmeni™) is a dual adeno-associated virus 1 (AAV1) vector-based gene therapy.

FDA Approved Indication(s)

Otarmeni is indicated for the treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency > 90 dB HL) associated with molecularly confirmed biallelic variants in the *OTOF* gene, preserved outer hair cell function, and no prior cochlear implant in the same ear.

This indication is approved under accelerated approval based on the improvement of hearing sensitivity assessed by average pure tone audiometry (PTA) at Week 24. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory clinical trial.

Limitation(s) of use: Otarmeni is not recommended in patients in whom preoperative imaging demonstrates that 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

All requests reviewed under this policy **require Precision Drug Action Committee (PDAC) Utilization Management Review**. Refer to CC.PHAR.21 for process details.

The medical necessity of Otarmeni may be determined by the clinical criteria as stated below, in addition to other factors implemented by the covering entity (Regeneron) as part of its free-of-cost drug program:

I. Initial Approval Criteria

A. Sensorineural Hearing Loss (must meet all)**:**

1. Diagnosis of severe-to-profound sensorineural hearing loss as evidenced by both of the following (a and b):
   a. Genetic testing confirms biallelic pathogenic or likely pathogenic *OTOF* variants;
   b. Member meets all of the following in the requested treatment ear(s) (i, ii, and iii):

i. Severe-to-profound hearing loss defined by an average audiometric threshold of > 90 dB HL;
ii. Absent auditory brainstem response (ABR);
iii. Intact outer hair cell function as evidenced by one of the following (1 or 2, *see Appendix D*):
1) Presence of otoacoustic emissions (OAE);
2) Presence of a cochlear microphonic;

2. Prescribed by or in consultation with an otolaryngologist;
3. Member does not have a history of a cochlear implant in the requested treatment ear(s);
4. Member has not previously been treated with Otarmeni in the requested treatment ear(s);
5. Member has not received prior gene therapy;
6. Dose does not exceed a single intracochlear infusion of 7.2×10^{12} vector genomes (vg) per ear.

Approval duration: 3 months (one lifetime intracochlear infusion per ear)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Sensorineural Hearing Loss

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ABR: auditory brainstem response
db HL: decibel hearing level
FDA: Food and Drug Administration
OAE: otoacoustic emissions
OTOF: otoferlin gene
PTA: pure tone audiometry
vg: vector genomes

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- There is currently no clinical data available on repeat administration of Otarmeni to treat an individual ear.
- Patients who did not show intact outer hair cell function were excluded from the clinical studies of Otarmeni and may not benefit from treatment based on its mechanism of action. Intact outer hair cell function can be determined by any of the following:
  - Prescence of OAE in patients generally up to 2 years of age
  - Prescence of the cochlear microphonic in patients generally older than 2 years of age

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Severe-to-profound and profound sensorineural hearing loss associated with biallelic *OTOF*-mutations	7.2×10^{12} vg administered one time by intracochlear infusion in a total volume of 0.24 mL per ear	7.2×10^{12} vg/ear

VI. Product Availability

Single-dose vial: 3 x 10^{13} vg/mL

VII. References

1. Otarmeni Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; April 2026. Available at: https://www.fda.gov/media/192098/download?attachment. Accessed April 29, 2026.
2. Valayannopoulos V, Bance M, Carvalho DS, et al; CHORD study group. DB-OTO gene therapy for inherited deafness. *N Engl J Med.* 2025 Oct 12. doi: 10.1056/NEJMoa2400521.
3. Bower C, Reilly BK, Richerson J, et al; Hearing assessment in infants, children, and adolescents: Recommendations beyond neonatal screening. *Pediatrics*. 2023 Sep 1;152(3):e2023063288. doi: 10.1542/peds.2023-063288.
4. Li MM, Tayoun AA, DiStefano M, et al; ACMG Professional Practice and Guidelines Committee. Clinical evaluation and etiologic diagnosis of hearing loss: A clinical practice resource of the American College of Medical Genetics and Genomics (ACMG). *Genet Med.* 2022 Jul;24(7):1392-1406. doi: 10.1016/j.gim.2022.03.018.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	11.04.25	12.25
Drug is now FDA-approved – criteria updated per labeling: clarified congenital hearing loss to sensorineural hearing loss, clarified hearing loss threshold from profound to severe-to-profound (> 90 dB HL), removed age restriction; references reviewed and updated.	04.29.26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.