Otarmeni™ (lunsotogene parvec-cwha)
(Intracochlear)

Document Number: IC-0859

Last Review Date: 06/02/2026
Date of Origin: 06/02/2026
Dates Reviewed: 06/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for one dose.
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

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)

III. Initial Approval Criteria

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

Sensorineural Hearing Loss † Φ [1-3]

- Member is at least 10 months of age; **AND**
- Member has a diagnosis of severe-to-profound or profound sensorineural hearing loss (any frequency >90 dB HL) either unilaterally or bilaterally; **AND**
- Member has biallelic pathogenic (or likely pathogenic) variants in the *OTOF*-gene as identified by molecular genetic testing; **AND**
- Member has preserved outer hair cell function as evidenced by otoacoustic emissions (OAE) testing; **AND**
- Member does not have, or has not had, a prior cochlear implant in the ear planned for treatment; **AND**

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- 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; **AND**
- Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
- Used in combination with corticosteroids for prophylaxis against inflammatory and immunological responses; **AND**
- 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)*; **AND**
- 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

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity may NOT be renewed.

V. Dosage/Administration [1]

Indication	Dose
Sensorineural Hearing Loss	The recommended dose for each ear is 7.2×10^{12} vg in a total volume of 0.24 mL, administered by a single-dose intracochlear infusion.
• OTARMENI should be administered by a surgeon experienced in intracochlear surgery and trained in the administration procedure. • Administer bilateral OTARMENI, if applicable, in a single surgical session.	

VI. Billing Code/Availability Information

HCPCS code(s):

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals *(Hospital Outpatient Use Only)*

NDC:

- Otarmeni sterile suspension in a single-dose vial containing a nominal titer of 3.0×10^{13} vg/mL with an extractable volume of 0.63 mL: 61755-0062-xx

VII. References

1. Otarmeni [package insert]. Tarrytown, NY; Regeneron Pharm., Inc.; April 2026. Accessed May 2026.
2. ClinicalTrials.gov. NCT05788536. A Study of DB-OTO, an Adeno-Associated Virus (AAV) Based Gene Therapy, in Children/Infants With Hearing Loss Due to Otoferlin Mutations (CHORD). https://clinicaltrials.gov/search?intr=NCT05788536&viewType=Card.
3. Valayannopoulos V, Bance M, Carvalho DS, et al; CHORD Study Group. DB-OTO Gene Therapy for Inherited Deafness. N Engl J Med. 2026 Mar 12;394(11):1074-1083. doi: 10.1056/NEJMoa2400521. Epub 2025 Oct 12..

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	No: PA not a priority

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
H90.3	Sensorineural hearing loss, bilateral
H90.5	Unspecified sensorineural hearing loss
H91.3	Deaf nonspeaking, not elsewhere classified
H91.8X1	Other specified hearing loss, right ear
H91.8X2	Other specified hearing loss, left ear
H91.8X3	Other specified hearing loss, bilateral
H91.8X9	Other specified hearing loss, unspecified ear
H93.211	Auditory recruitment, right ear
H93.212	Auditory recruitment, left ear
H93.213	Auditory recruitment, bilateral
H93.219	Auditory recruitment, unspecified ear
H93.221	Diplacusis, right ear
H93.222	Diplacusis, left ear
H93.223	Diplacusis, bilateral
H93.229	Diplacusis, unspecified ear
H93.231	Hyperacusis, right ear
H93.232	Hyperacusis, left ear
H93.233	Hyperacusis, bilateral

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H93.239	Hyperacusis, unspecified ear
H93.241	Temporary auditory threshold shift, right ear
H93.242	Temporary auditory threshold shift, left ear
H93.243	Temporary auditory threshold shift, bilateral
H93.249	Temporary auditory threshold shift, unspecified ear
H91.3X1	Disorders of acoustic nerve, right ear
H91.3X2	Disorders of acoustic nerve, left ear
H91.3X3	Disorders of acoustic nerve, bilateral
H91.3X9	Disorders of acoustic nerve, unspecified ear

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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