

# Otarmeni™ (Lunsotogene Parvec-Cwha)

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[Instructions for Use](#)

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## Commercial Policy

- [Otarmeni™ \(Lunsotogene Parvec-Cwha\)](#)

## Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

| State          | Policy/Guideline |
|----------------|------------------|
| Kansas         | None             |
| North Carolina | None             |
| Ohio           | None             |

## Coverage Rationale

**Otarmeni is proven and medically necessary for the treatment of pediatric and adult patients with sensorineural hearing loss when all the following criteria are met:**

- Diagnosis of severe-to-profound or profound sensorineural hearing loss defined as any frequency > 90 decibel hearing level (dB HL); **and**
- Molecularly confirmed biallelic variants in the *OTOF* gene; **and**
- Preserved outer hair cell function; **and**
- No prior cochlear implant in the same ear; **and**
- Preoperative imaging demonstrates access to the inner ear is feasible (i.e., no abnormal mastoid pneumatization or clinically significant anatomic variations of the middle ear or inner ear); **and**
- Dosing is in accordance with the U.S. Food and Drug Administration (FDA)–approved labeling; **and**
- Authorization will be issued for no more than one treatment per ear per lifetime and for no longer than 60 days from approval

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

| HCPCS Code | Description                       |
|------------|-----------------------------------|
| C9399      | Unclassified drugs or biologicals |
| J3590      | Unclassified biologics            |

| Diagnosis Code | Description                                                                                            |
|----------------|--------------------------------------------------------------------------------------------------------|
| H90.3          | Sensorineural hearing loss, bilateral                                                                  |
| H90.41         | Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side |
| H90.42         | Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side  |
| H90.5          | Unspecified sensorineural hearing loss                                                                 |
| H90.A21        | Sensorineural hearing loss, unilateral, right ear, with restricted hearing on the contralateral side   |
| H90.A22        | Sensorineural hearing loss, unilateral, left ear, with restricted hearing on the contralateral side    |

## Background

Congenital deafness affects 1.7 per 1,000 babies born in the United States and is predominantly caused by genetic deficiencies. Biallelic pathogenic variants in *OTOF*, the gene encoding otoferlin, account for 1 to 3% of cases of congenital genetic deafness. Otoferlin functions as a calcium sensor expressed in inner hair cells and regulates synaptic transmission between sensory inner hair cells and the cochlear nerve.

Otarmeni is a dual adeno-associated virus (AAV)-1 gene therapy that delivers a functional copy of *OTOF* specifically to cochlear hair cells to enable synaptic transmission between sensory inner hair cells and the cochlear nerve. Otarmeni is administered as a single intracochlear infusion in the ear, under general anesthesia, using a surgical approach similar to that used for cochlear implantation.

## Clinical Evidence

The efficacy of Otarmeni was established in an ongoing, multicenter, single-arm study (Study DB-OTO-001; NCT05788536) in pediatric patients with molecularly confirmed *OTOF* gene associated profound sensorineural hearing loss (defined as > 90 dB HL on pure tone audiometry averaged across 0.5, 1, 2, and 4 kHz and auditory brainstem response), evidence of outer hair cell activity by otoacoustic emissions testing, and who were considered candidates for cochlear implant. Patients with cochlear implants in the same ear to be treated with Otarmeni were excluded from the study. A total of 24 patients (10 patients received unilateral treatment and 14 patients received bilateral treatment) received a single dose of Otarmeni at a dose of  $7.2 \times 10^{12}$  vector genomes (vg) in 0.24 mL per ear. The median age of the participants was 2 years (range 10 months to 16 years). Of the 24 patients, 20 had completed efficacy assessments at 24 weeks. Among these 20 patients, five had a contralateral cochlear implant in place prior to enrollment, and two received a cochlear implant in the contralateral ear during the same surgical session for Otarmeni administration. Two patients had bilateral hearing aids before Otarmeni treatment.

The primary efficacy endpoint was the achievement of a hearing sensitivity threshold  $\leq 70$  dB HL assessed by average pure tone audiometry (i.e., average of PTA thresholds at 0.5, 1.0, 2.0, and 4.0 kHz) at Week 24 after product administration. The key secondary efficacy endpoint was the presence of auditory brainstem response (ABR) to a click (broadband sound) stimulus of  $\leq 90$  dB nHL at Week 24 after product administration. At Week 24, a total of 9/20 (45%) patients achieved an average PTA threshold  $\leq 45$  dB HL (ability to hear soft conversational speech level) and 3/20 (15%) achieved  $\leq 25$  dB HL (normal hearing level i.e., ability to hear whispers). One patient received a cochlear implant as rescue treatment approximately 8 months after Otarmeni administration in the same ear following determination of treatment failure.

Among the 20 patients, 12 patients were evaluated at Week 48 after product administration. Of these, all 9 patients who previously had a response at Week 24 and who were evaluated at Week 48 maintained their response. One additional patient who had not initially achieved response at Week 24, achieved an average PTA threshold  $\leq 70$  dB HL by Week 48, resulting in a total of 10/12 (83%) patients who achieved an average PTA threshold  $\leq 70$  dB HL by Week 48. Eight of the 12 (67%) patients achieved an average PTA threshold  $\leq 45$  dB HL and 5 of the 12 patients (42%) achieved  $\leq 25$  dB HL by Week 48. Additionally, 9 of the 12 patients (75%) demonstrated presence of auditory brainstem response (ABR) to a click (broadband sound) stimulus of  $\leq 90$  dB nHL by Week 48.

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Otarmeni is an adeno-associated virus vector-based gene therapy 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.

### Limitations 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.

## References

1. Otarmeni [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; April 2026.
2. Valayannopoulos V, Bance M, Carvalho DS, et al. DB-OTO Gene Therapy for Inherited Deafness. *n Engl J Med*. 2026;394(11):1074-1083.
3. Regeneron Pharmaceuticals, Inc. Otarmeni™ (lunsotogene parvec-cwha) approved by FDA as first and only gene therapy for genetic hearing loss; Regeneron to provide Otarmeni for free in the U.S. Published April 2026. Accessed June 23, 2026. <https://investor.regeneron.com/news-releases/news-release-details/otarmenitm-lunsotogene-parvec-cwha-approved-fda-first-and-only>.

## Policy History/Revision Information

| Date       | Summary of Changes                                                                |
|------------|-----------------------------------------------------------------------------------|
| 10/01/2026 | <ul style="list-style-type: none"><li>• New Medical Benefit Drug Policy</li></ul> |

## Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.