Reference number(s)
7475-A

Specialty Guideline Management Otarmeni

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Otarmeni	lunsotogene parvec-cwha

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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.

All other indications are considered experimental/investigational and not medically necessary.

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Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Molecular or genetic testing results demonstrating presence of biallelic, likely pathogenic or pathogenic OTOF variants.
- Audiological studies demonstrating profound sensorineural hearing loss and outer hair cell presence.

Prescriber Specialties

This medication must be prescribed by a surgeon experienced in intracochlear surgery and trained in the administration procedure.

Coverage Criteria

OTOF-related Hearing Loss[1,2]

Authorization of 3 months for one dose total per ear may be granted for OTOF-related hearing loss when all of the following criteria are met:

- Member is 17 years of age or younger.
- Presence of biallelic, likely pathogenic or pathogenic OTOF variants.
- Member has profound sensorineural hearing loss (SNHL; ≥90 dB HL) based on behavioral and physiologic measurements (auditory brainstem response [ABR]) of inner ear function.
- Outer hair cell presence is confirmed by either of the following:
    - Presence of otoacoustic emissions (≥6 dB signal-to-noise ratio) at ≥3 frequencies from 1 to 8 kHz in the ear(s) to be injected.
    - Presence of cochlear microphonics in the ear(s) to be injected.
- Member has no evidence from measures of hearing loss that show a dependence on body temperature.
- Member does not have surgical anatomy that would preclude or meaningfully impact the planned surgical approach (e.g., abnormal mastoid pneumatization, enlarged cochlear or vestibular aqueduct) as indicated by medical imaging (e.g., computed tomography [CT] or magnetic resonance imaging [MRI]) in the ear(s) to be injected.
- 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 Otarmeni in the same ear or any other gene therapy previously.

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;394:1074-1083.