Molina Clinical Policy
Otarmeni (Lunsotogene Parvec-cwha): MEDICARE
Policy No. 485b

Last Approval: 06/17/2026
Next Review Due By: June 2027

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the Federal government or CMS for Medicare. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

This policy reviews the use of Otarmeni (Lunsotogene Parvec, or DB-OTO) for the treatment of congenital hearing loss due to pathogenic variants in the otoferlin gene. Otoferlin related congenital hearing loss results from bi-allelic pathogenic variants in the otoferlin gene (OTOF) & subsequent loss of functional otoferlin protein. Otoferlin protein is expressed in inner hair cells of the ear. Otoferlin functions as a sensor for calcium signaling required for neurotransmitter release into the synapse formed between the inner hair cells and the cochlear nerve (see concept diagram in supplemental information section below for visual detail). Otoferlin related hearing loss is initially suggested when OAE (oto-acoustic emission) based newborn screening is normal, but ABR testing (Auditory Brain stem Response) is abnormal. OAE is not sensitive to otoferlin related hearing loss because OAE picks up outer hair cell dysfunction, not inner hair cell function. ABR testing does pickup inner hair cell dysfunction, and ensuing genetic testing can confirm otoferlin related hearing loss.

Most cases of hearing loss due to biallelic pathogenic variants in *OTOF* present at birth and are severe to profound. Profound hearing loss is defined by the average audiometric threshold of > 90 decibel hearing level (dB HL) before sound is perceived (a tone burst heard 50% of the time). Low thresholds indicate better hearing sensitivity. This value is measured by pure-tone audiometry (PTA). This hearing threshold not only defines the severity of hearing loss, it is also the level at which cochlear implants may be considered. Cochlear implants bypass the auditory synapse and directly signal the auditory nerve, but they can limit speech understanding and are difficult to use in various settings.

It's important to note other less severe types of otoferlin related hearing loss because treatment options differ among the subclasses. One atypical form is the temperature-sensitive subtype where high temperatures lead to profound hearing loss but normalize when body temperature normalizes. Another atypical form is progressive, with hearing loss occurring months to years after the initial onset. In early onset profound hearing loss, intervention is critical to speech and language development.

Otarmeni (Lunsotogene Parvec, or DB-OTO) is a new gene therapy recently approved to treat OTOF related profound hearing loss. The functional OTOF gene is carried by two adeno associated virus type 1 (AAV-1) vectors, each delivering a portion of the large otoferlin gene. Intracochlear infusion of DB-OTO restores calcium sensing and subsequently neurotransmitter release from inner hair cells to the cochlear nerve allowing sound perception. DB-OTO is surgically infused directly into the cochlea.

COVERAGE POLICY

All Gene Therapy requests require Molina Medical Director review.

Otarmeni (Lunsotogene Parvec, or DB-OTO) gene therapy may be **considered medically necessary** for the treatment of otoferlin related congenital hearing loss when ALL the following criteria are met:

1. Member is less than 18 years of age

2. Presence of biallelic, likely pathogenic or pathogenic variants in the otoferlin gene

3. Diagnoses of profound sensorineural hearing loss by either
    a. Average audiometric threshold on behavior pure tone audiometry (PTA) > 90dBHL (decibel hearing level) (requires member participation not possible in infants)
    b. Absence of an auditory brainstem response (ABR) neural signal in response to a click stimulus at or below 85 decibels normalized Hearing Level (dB nHL) in the ear(s) to be injected with Otarmeni (No member participation required)

4. Distortion product otoacoustic emission (DPOAE) present with ≥ 6 dB signal-to-noise ratio at ≥ 3 frequencies in a distortion product (DP) Gram measured from 1 to 8 kHz in the ear(s) to be injected with Otarmeni. (Alternatively, for children >24 months to <18 years of age, outer hair cell function can be confirmed via presence of the cochlear microphonic in the ear(s) to be injected with DB-OTO.)

5. Member is eligible but has not yet received a cochlear implant in the ear planned for gene therapy

6. No evidence from measures of hearing loss that show a dependence on body temperature

7. No clinically significant abnormal findings in the following laboratory tests. Significant lab values are as follows:
    a. Gamma glutamyl- transpeptidase (GGT) >2 × upper limit of normal (ULN)
    b. Alanine aminotransferase (ALT), and aspartate aminotransferase (AST) >2 × (ULN)
    c. Bilirubin ≥2.0 mg/dL
    d. Creatinine ≥1.0 mg/dL or estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m2
    e. Hemoglobin (Hgb) <10 or >18 g/dL
    f. White blood cell (WBC) count >18,000 per mm3
    g. Platelet count <100,000 per µL

8. No history of prior treatment with gene therapy

9. No aberrant anatomy that would meaningfully impact the planned surgical approach (e.g. 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 with Otarmeni

10. No history or presence of any other permanent/untreatable hearing loss conditions

11. No history or presence of malignancies

12. No history or presence of meningitis

13. No history or presence of treatment with ototoxic drugs

14. No history of risk factor(s) for auditory neuropathy not caused by pathogenic variants in the otoferlin gene

15. Members with childbearing potential must agree to highly effective contraception for at least 12 months post-gene therapy administration

ADMINISTRATION SETTING: This gene therapy is administered in vivo. For in-vivo route, *outpatient administration* is generally anticipated. Inpatient admission is not required in the absence of complicating factors.

QUANTITY LIMITATIONS: FDA approved dosing with *one-time dose per lifetime*. Additional infusions of Otarmeni will not be authorized.

CONTINUATION OF THERAPY: Otarmeni is indicated as a one-time infusion only. Repeat treatment or re-administration of a dose is not supported by labeling or compendia and is not considered medically necessary.

DOCUMENTATION REQUIREMENTS: Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

FDA approval is supported by the CHORD study, a Phase ½ open label, single group, clinical trial examining the efficacy of DB-OTO in 12 children with profound hearing loss (NCT05788536, Valayannopoulos et al, 2026). This trial is ongoing with the intention of enrolling 30 participants. Treated ears did not have cochlear implants. Some participants were treated in both ears and others just the ear without a cochlear implant. All participants were between 10 months and 16 years of age and had bi allelic pathogenic variants in the otoferlin gene. Data from untreated individuals in a natural history study were used as comparators in this study.

Pure-tone audiometry (PTA) measured at 24 weeks defines the primary endpoint. Otarmeni is considered efficacious if after treatment, the participant perceives sound at less than 70 dB. All participants had a baseline of 90 dB HL or greater. Twenty six weeks after one infusion of Otarmeni, 75% (9 of 12) participants achieved sound perception at 70 dB or less. Six could hear soft speech and 3 had average normal hearing sensitivity. The secondary endpoint was an auditory brain stem response at or below 90dB by week 24. After Otarmeni therapy 9 out of 12 participants met this threshold for efficacy.

Three of 4 children reaching the 48-week mark in follow-up were found to have speech perception and produced words and sounds for the first time.

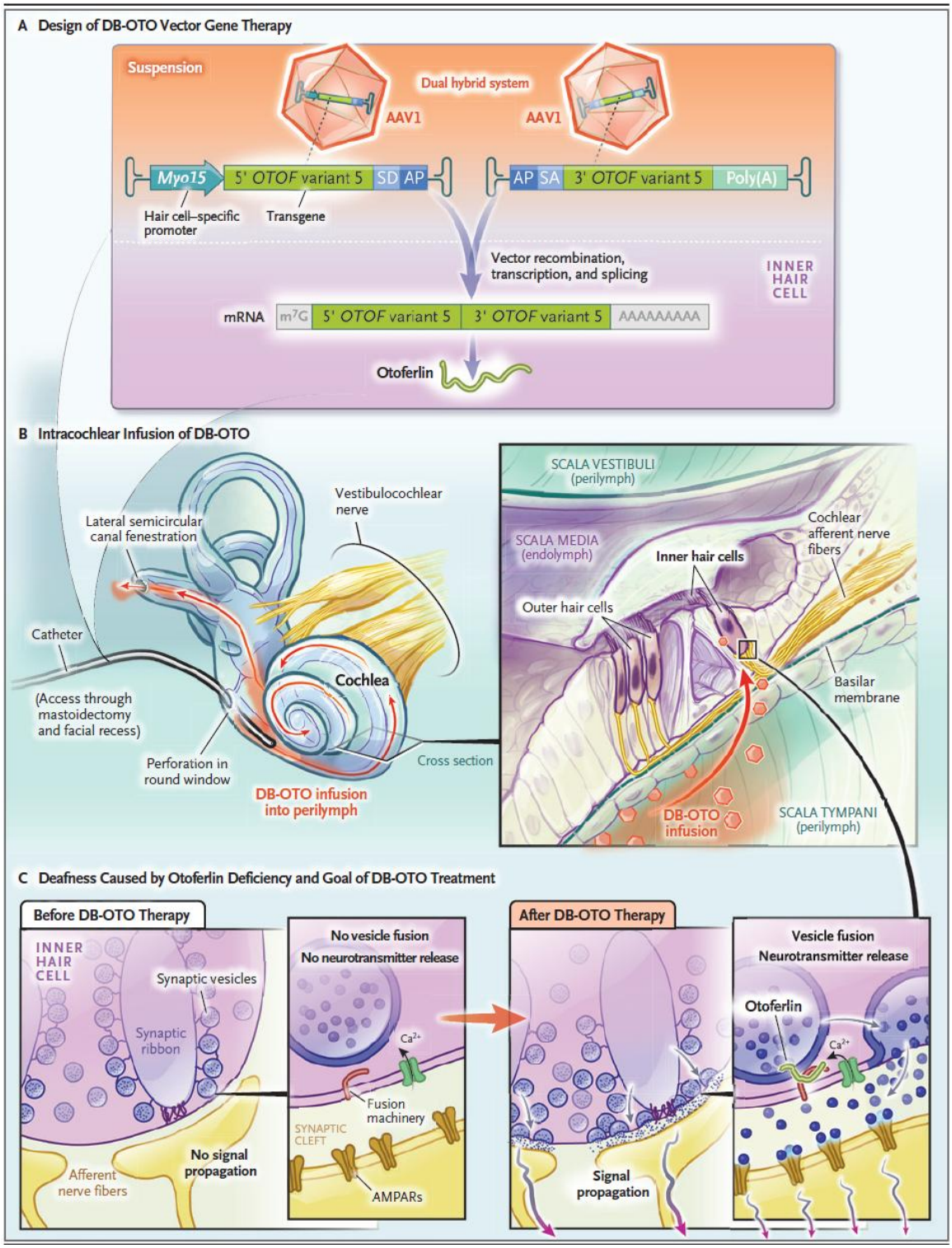
Adverse events were primarily related to the surgery and not the gene therapy. 67 adverse events were noted, all of which were transient. All participants completed the study. Anti-AAV1 titers were only transiently elevated for approximately 12 weeks after treatment.

National and Specialty Organizations

There are no current guidelines for the use of Otarmeni (lunsotogene parvec) at the present time.

SUPPLEMENTAL INFORMATION

Otarmeni gene therapy concept diagram (Valayannopoulos, 2026)



CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
69949	Unlisted procedure, inner ear [when specified as intracochlear infusion]

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
C9399	Unclassified drugs or biologicals [when specified as Otarmeni (lunsotogene parvec-cwha)]
J3590	Unclassified biologics [when specified as Otarmeni (lunsotogene parvec-cwha)]

CODING DISCLAIMER: Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

06/17/2026 New policy. IRO Peer Review June 4, 2026, by practicing board certified physician in otolaryngology.

REFERENCES

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2. Clinical Trials.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. https://clinicaltrials.gov/study/NCT05788536?term=NCT05788536&viewType=Table&rank=1
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