Medical Policy

BlueCross BlueShield Kansas
An Independent licensee of the Blue Cross Blue Shield Association

Title: Otarmeni

Professional / Institutional
Original Effective Date: August 13, 2026
Latest Review Date:
Current Effective Date: August 13, 2026

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

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.	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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**
- 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.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CLINICAL RATIONALE

See package insert for FDA preshttps://dailymed.nlm.nih.gov/dailymed/index.cfm

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

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

REVISIONS	
Posted: 07-14-2026 Effective: 08-13-2026	New medical policy added to the bcbsks.com web site. Policy is maintained by Prime Therapeutics LLC.

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..