# Clinical Policy: Ciprofloxacin/Fluocinolone (Otovel)

Reference Number: CP.PMN.249
Effective Date: 12.01.20
Last Review Date: 11.24
Line of Business: Commercial, HIM, Medicaid Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Ciprofloxacin/fluocinolone (Otovel®) otic solution is a combination of fluoroquinolone antibacterial and a corticosteroid.

## FDA Approved Indication(s)

Otovel is indicated for the treatment of acute otitis media with tympanostomy tubes (AOMT) in pediatric patients (aged 6 months and older) due to *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, and Pseudomonas aeruginosa*.

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Otovel is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Otitis Media** (must meet all)**:**

1. Diagnosis of otitis media;
2. Age ≥ 6 months;
3. For brand Otovel requests, member must use generic ciprofloxacin/fluocinolone otic suspension, unless contraindicated or clinically significant adverse effects are experienced (e.g., contraindications to excipients);
4. Recent (within the last 3 months) use of a systemic antibiotic indicated for otitis media (*see Appendix B*);
5. Presence of tympanostomy tubes;
6. Dose does not exceed 1 carton (14 single-dose vials) per affected ear.

**Approval duration: 7 days (2 cartons total – one per affected ear)**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

### A. Otitis Media

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

**Approval duration: Not applicable**

### B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

AOMT: acute otitis media with tympanostomy tubes

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| amoxicillin | 80 to 90 mg/kg PO per day in 2 divided doses | 1,750 mg/day |
| amoxicillin-clavulanate (Augmentin®) | 90 mg/kg per day amoxicillin and 6.4 mg/kg per day clavulanate PO in 2 divided doses | 1,750 mg/day of amoxicillin component |
| cefdinir | 14 mg/kg PO per day in 1 or 2 doses | 600 mg/day |
| cefuroxime axetil | 30 mg/kg PO per day in 2 divided doses | 1,000 mg/day |
| cefpodoxime proxetil | 10 mg/kg PO per day in 2 divided doses | 400 mg/day |
| ceftriaxone | 50 mg IM or IV per day for 1 or 3 days | 4 g/day |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*
*Note: Choice of antibiotic therapy includes but is not limited to the agents listed here.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Patients with known hypersensitivity to fluocinolone acetonide or other corticosteroids, ciprofloxacin, or other quinolones, or to any other components of Otovel
  - Viral infections of the external ear canal, including varicella and herpes simplex infections and fungal otic infections
- Boxed warning(s): none reported

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Otitis media | Instill the contents of one single-dose vial (0.25 mL) into the affected ear canal BID for 7 days | 0.5 mL/day/ear |

## VI. Product Availability

Single-use vials (14 of 0.25 mL vials in a carton): ciprofloxacin 0.3% (3 mg/mL) with fluocinolone acetonide 0.025% (0.25 mg/mL)

## VII. References

1. Otovel Prescribing Information. Ridgeland, MS: WraSer Pharmaceuticals; April 2016. Available at: https://www.otovel.com. Accessed July 25, 2024.
2. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2024. Available at: https://www.clinicalkey.com/pharmacology/. Accessed July 25, 2024.
3. American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. Reaffirmed 2019; *Pediatrics*. 2013;131:e964-e999.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created (adopted from HIM.PA.14, policy to retire); added Medicaid line of business; references reviewed and updated. | 08.21.20 | 11.20 |
| 4Q 2021 annual review: added that request should be for generic formulation; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated. | 08.11.21 | 11.21 |
| 4Q 2022 annual review: added Commercial line of business; clarified that generic requirement applies to brand Otovel requests; clarified approval duration of 2 cartons allows for one carton per affected ear; references reviewed and updated. Template changes applied to other diagnoses/indications. | 07.05.22 | 11.22 |
| 4Q 2023 annual review: no significant changes; references reviewed and updated. | 07.11.23 | 11.23 |
| 4Q 2024 annual review: clarified member must use otic formulation of generic ciprofloxacin/fluorocinolone; references reviewed and updated. | 07.25.24 | 11.24 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or

regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.