Clinical Policy: Ciprofloxacin/Fluocinolone (Otovel)

Reference Number: HIM.PA.14
Effective Date: 09.04.18
Last Review Date: 11.19
Line of Business: HIM

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 actibacterial 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. Recent (within the last 3 months) use of a systemic antibiotic indicated for otitis media (*see Appendix B*);
4. Presence of tympanostomy tubes;
5. Dose does not exceed 1 carton (14 single-dose vials) per affected ear.

Approval duration: 7 days (2 cartons)

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

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 – HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
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 (Amoxil®)	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	30 mg/kg PO per day in 2 divided doses	1,000 mg/day
cefpodoxime	10 mg/kg PO per day in 2 divided doses	400 mg/day
cefriaxone	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. Atlanta, GA: Arbor Pharmaceuticals, LLC; April 2016. Available at: https://www.otovel.com/pdfs/OTOVEL_USPI_Final.pdf. Accessed August 13, 2019.
2. American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. Pediatrics. 2013;131:e964-e999.
3. Harmes KM, Blackwood RA, Burrows HL, Cooke JM, Harrison RV, and Passamani PP. Otitis media: diagnosis and treatment. Am Fam Physician 2013;88(7):435-440.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed August 13, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.04.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.13.19	11.19

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 Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.