Effective Date **1/1/2023**
Next Review Date… **1/1/2024**
Coverage Policy Number **IP0468**

Ciprofloxacin/fluocinolone for Individual and Family Plans

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for ciprofloxacin/fluocinolone otic solution (Otovel®) for Individual and Family Plans.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Ciprofloxacin/fluocinolone (Otovel) is considered medically necessary when the following are met:

1. **Acute Otitis Media with Tympanostomy Tubes (AOMT).** Individual meets **BOTH** of the following (A and B):
   A. Individual is 6 months to less than 18 years of age.
   B. Individual meets the preferred covered alternative(s) criteria as indicated in the table below.

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Individual and Family Plan Non-Covered Products and Covered Alternative(s):

Non-Covered Product	Criteria
Ciprofloxacin and fluocinolone acetonide otic solution, 0.3%/0.025%	There is documentation of **ONE** of the following (A or B): A. The individual has had an inadequate response or is intolerant to the following: i. ciprofloxacin 0.3% and dexamethasone 0.1% otic suspension B. Individual has a known hypersensitivity to a preservative (e.g., benzalkonium chloride [BAK], benzyl alcohol)
Otovel (ciprofloxacin and fluocinolone acetonide otic solution, 0.3%/0.025%)	There is documentation of **ONE** of the following (A or B): A. **BOTH** of the following (i and ii): i. Individual has tried **ciprofloxacin-fluocinolone 0.3%-0.025% otic solution [prior authorization required]** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. ii. The individual has had an inadequate response or is intolerant to ciprofloxacin 0.3% and dexamethasone 0.1% otic suspension. B. Individual has a known hypersensitivity to a preservative (e.g., benzalkonium chloride [BAK], benzyl alcohol)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: Not applicable

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
Ciprofloxacin/fluocinolone otic solution is a combination antibacterial and corticosteroid 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.*[1]

Guidelines
The American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) guidelines for the management of children with tympanostomy tubes (2013) recommend the use of ototopical antibiotics, without oral antibiotics, in children with uncomplicated acute tympanostomy tube otorrhea.[2] The guidelines do not prefer

one ototopical product over another. The advantages of ototopical products in acute otitis media with tympanostomy tubes include increased drug concentration at the site of infection, improved coverage of likely pathogens, and no systemic AEs.

References

1. Otovel [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals; April 2016.
2. Rosenfeld RM, Schwartz SR, Pynnonen MA, et al. Clinical Practice Guideline: Tympanostomy tubes in children. Otolaryngol Head Neck Surg. 2013;149(1 Suppl):S1-35.