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Drug Class Literature Scan: Otic Antibiotics

Date of Review: October 2026

Literature Search: 01/01/2017 – 06/08/2026
Date of Last Review: May 2017

Current Status of PDL Class:
See **Appendix 1**.

Plain Language Summary:

- The purpose of this review is to find current evidence for medicines used in the treatment of ear infections.
- Infections of the middle ear or after ear tube placement are common and often treated with medications placed directly into the ear.
- Antibiotic ear drops may help clear ear drainage (otorrhea) in the short term, but adding steroids to antibiotic ear drops may not provide extra benefit.
- Antibiotic ear drops may work better to clear ear drainage than oral antibiotics.
- Non-antibiotic treatments may work just as well as antibiotic treatments for treating outer ear infections.
- For ear drainage after ear tube surgery, topical ear drops are preferred.
- The Drug Use Research and Management (DURM) group recommends making no changes to the preferred drug list based on recent comparative evidence.

Conclusions:

- Topical antibiotics may improve short-term resolution of otorrhea, particularly as an adjunct to systemic therapy, but evidence is insufficient to identify the most effective agent or adequately assess long-term safety.[1]
- Adding topical steroids to topical antibiotics does not appear to improve resolution of ear discharge compared with antibiotics alone, and available evidence is low certainty with limited safety and hearing outcome data.[2]
- Topical quinolone antibiotics may be more effective than systemic antibiotics for achieving short-term resolution of ear discharge, although confidence in the evidence is limited by small, high-risk-of-bias studies.[3]
- Non-antibiotic treatments, including antiseptics and corticosteroids, appear to be as effective as topical antibiotics for clinical cure and may offer an antibiotic-sparing alternative for acute otitis externa.[4]
- For uncomplicated otorrhea following tympanostomy tube placement, the National Institute for Health and Care Excellence (NICE) recommends short-course non-ototoxic topical antibiotic ear drops (such as ciprofloxacin) rather than oral antibiotics, with evidence suggesting topical antibiotic-glucocorticoid combinations may provide the greatest likelihood of clinical cure.[5]
- The Agency for Healthcare Research and Quality (AHRQ) supports topical ear drops, particularly antibiotic-corticosteroid combinations, as the most effective treatment for tympanostomy tube otorrhea, with better clinical outcomes than oral antibiotics or watchful waiting.[6]
- Since the prior review, there was one new otic antifungal agent approved by the Food and Drug Administration (FDA) and one new safety alert.[7,8]

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Recommendations:

- No changes to the preferred drug list (PDL) are recommended based on the review of recently published evidence.
- After evaluation of costs in executive session, neomycin-polymyxin-hc solution was made preferred and Xtoro (finafloxacin) drops susp were made non-preferred.

Summary of Prior Reviews and Current Policy

- For the treatment of acute otitis externa or otitis media in patients with or without tympanostomy tubes, there is insufficient evidence to determine differences in safety or efficacy between ototopical antibiotics or antibiotic/corticosteroid combinations.[8]
- At least one preferred antibiotic/corticosteroid combination product and at least one ototopical aminoglycoside antibiotic is available as an option for the treatment of acute otitis media or otitis externa.[8] Current preferred products include ofloxacin, Cortisporin-TC™ (colistin /neomycin / thonzonium/ hydrocortisone), and neomycin/polymyxin B/hydrocortisone (see **Appendix 1**).

Methods:

A Medline literature search for new systematic reviews and randomized controlled trials (RCTs) assessing clinically relevant outcomes to active controls, or placebo if needed, was conducted. Abstracts of new comparative trials are listed in **Appendix 2**. The Medline search strategy used for this literature scan is available in **Appendix 3**, which includes dates, search terms and limits used. The OHSU Drug Effectiveness Review Project, Agency for Healthcare Research and Quality (AHRQ), National Institute for Health and Clinical Excellence (NICE), Department of Veterans Affairs, the Scottish Intercollegiate Guidelines Network (SIGN), and the Canada's Drug Agency (CDA-AMA) resources were manually searched for high quality and relevant systematic reviews. When necessary, systematic reviews are critically appraised for quality using the AMSTAR tool and clinical practice guidelines using the AGREE tool. The FDA website was searched for new drug approvals, indications, and pertinent safety alerts.

The primary focus of the evidence is on high-quality systematic reviews and evidence-based guidelines. Randomized controlled trials will be emphasized if evidence is lacking or insufficient from those preferred sources.

New Systematic Reviews:

Topical antibiotics for chronic suppurative otitis media (2025)

A Cochrane review assessed the effects of topical antibiotics in the treatment of people with chronic suppurative otitis media (CSOM).[1] Literature was searched through June 2022.[1] The review included 18 RCTs involving 1,783 participants.[1] Relevant comparisons included topical antibiotics plus systemic antibiotics versus systemic antibiotics alone, and comparisons between different antibiotic classes.[1] Primary outcomes were resolution of ear discharge, quality of life, and local adverse effects assessed at three follow-up periods: 1 to 2 weeks, 2 to 4 weeks, and more than 4 weeks after treatment initiation.[1] Evidence certainty was assessed using the GRADE framework.[1]

Adding topical antibiotics to systemic antibiotic therapy may increase discharge resolution compared with systemic antibiotics alone (88% vs 60%; risk ratio [RR] 1.47; low-certainty evidence).[1] Quinolones (e.g., ciprofloxacin, ofloxacin) may be more effective than aminoglycosides (e.g., gentamicin) at resolution of ear discharge, but the evidence is highly uncertain due to substantial heterogeneity and methodological limitations of the RCTs.[1] Data on hearing outcomes, ototoxicity, ear pain, quality of life, and serious complications were sparse and inconsistently reported.[1]

Current evidence suggests that topical antibiotics may improve short-term resolution of otorrhea in CSOM, either as monotherapy or as an adjunct to systemic antibiotics.[1] However, the overall certainty of evidence is low to very low because of small sample sizes, risk of bias, and imprecise estimates.[1] There is insufficient evidence to determine the most effective topical antibiotic or to adequately assess long-term safety and adverse effects.[1] Further high-quality randomized trials are needed.[1]

Topical antibiotics with steroids for chronic suppurative otitis media (2025)

A second Cochrane review assessed the effects of adding a topical steroid to topical antibiotics in the treatment of people with CSOM.[2] Literature was searched through June 2022.[2] The review included 19 RCTs involving at least 2,044 participants.[2] Relevant comparisons included topical antibiotics alone, topical steroids alone, oral antibiotics, or topicalantiseptics.[2] The primary outcome was resolution of ear discharge, with secondary outcomes including hearing improvement, ear discomfort, adverse events, and ototoxicity.[2]

Compared with the same topical antibiotic alone, adding a steroid produced little or no improvement in resolution of ear discharge at 1 to 2 weeks (RR 1.08, 95% confidence interval [CI] 0.96 to 1.21; low or very low certainty evidence).[2] In comparisons involving different antibiotic classes, topical quinolone antibiotics alone were more effective than non-quinolone antibiotic-steroid combinations for achieving a dry ear at 1 to 2 weeks (RR 0.77, 95% CI 0.71 to 0.83).[2] Data on hearing outcomes, adverse events, quality of life, and ototoxicity were limited and inconsistently reported.[2]

Current evidence does not demonstrate a clear benefit from adding topical steroids to topical antibiotics for CSOM.[2] Some evidence suggests that topical quinolone antibiotics alone may be more effective than certain antibiotic-steroid combinations.[2] However, the overall certainty of evidence is low because of methodological limitations, small sample sizes, and incomplete reporting.[2] Further high-quality randomized trials are needed to establish the efficacy and safety of antibiotic-steroid combinations in CSOM.[2]

Topical versus systemic antibiotics for chronic suppurative otitis media (2025)

A third Cochrane review compared the effectiveness and safety of topical versus systemic antibiotics in patients with CSOM.[3] Literature was searched through June 2022.[3] The review included 6 RCTs involving 445 participants.[3] Most studies evaluated quinolone antibiotics, and all were judged to have a high risk of bias.[3] The primary outcome was the resolution of ear discharge (dry ear), which was measured at 1 to 2 weeks, 2 to 4 weeks, and beyond 4 weeks after treatment.[3]

Topical quinolone antibiotics may be more effective than oral quinolones in achieving resolution of ear discharge within 1 to 2 weeks (RR 1.50, 95% CI 1.22 to 1.84; low to very low certainty).[3] Evidence for comparisons between topical quinolones and systemic aminoglycosides or amoxicillin-clavulanic acid was limited and highly uncertain.[3] No studies adequately reported long-term outcomes, health-related quality of life, ear pain, serious complications, or hearing outcomes. Ototoxicity was not reported, but methods of assessment were poorly described.[3]

Topical quinolone antibiotics may provide a modest short-term benefit over systemic antibiotics in resolving ear discharge in CSOM.[3] However, the evidence base is limited by small sample sizes, methodological weaknesses, and inadequate reporting of adverse events and long-term outcomes.[3] Further well-designed randomized trials are required to determine the optimal route of antibiotic administration in CSOM.[3]

Antibiotics versus non-antibiotic treatments for acute otitis externa (2023)

A systematic review and meta-analysis of comparative RCTs assessed antibiotics versus non-antibiotic treatments for acute otitis externa.[4] Literature was searched through August 2022.[4] Seventeen RCTs met the inclusion criteria, with 10 studies suitable for meta-analysis.[4] Eligible studies compared topical antibiotics with non-antibiotic therapies, including antiseptics, corticosteroids, astringents, or other topical agents.[4] Clinical cure and symptom improvement were assessed, and data from comparable studies were pooled using meta-analysis.[4]

Comparisons between antiseptic or corticosteroid monotherapy and antibiotic-based treatments showed no statistically significant differences in clinical cure rates.[4] While several individual studies favored antiseptic or steroid treatments, pooled analyses did not demonstrate superiority of either non-antibiotic or antibiotic therapy.[4]

Current evidence does not support the superiority or inferiority of non-antibiotic therapies compared with topical antibiotics.[4] These findings suggest that non-antibiotic treatments may represent viable alternatives and could contribute to antimicrobial stewardship efforts.[4]

After review, 6 systematic reviews were excluded due to poor quality, wrong study design of included trials (e.g., observational), comparator (e.g., no control or placebo-controlled), or outcome studied (e.g., non-clinical).

New Guidelines:

Otitis media with effusion in under children under 12 years of age (2023)

NICE published guidelines for the treatment of otitis media with effusion in patients under 12 years old.[5] For otorrhea after tympanostomy tube placement, evidence favors topical antibiotic ear drops over oral antibiotics, with topical antibiotic-glucocorticoid combinations (for example, ciprofloxacin/dexamethasone) showing the highest likelihood of clinical cure.[5] Topical antibiotic-only drops are also effective and superior to oral antibiotics.[5] The NICE guideline specifically recommends considering non-ototoxic topical antibiotic drops such as ciprofloxacin for 5 to 7 days in children with otorrhea after grommet insertion and discourages oral antibiotics for uncomplicated cases.[5] No evidence supports one non-antibiotic agent being superior to topical antibiotics for treating tube otorrhea, and there is no compelling evidence that routine water precautions improve outcomes once tubes are in place.[5]

Tympanostomy tubes in children with otitis media **(2017)**

AHRQ published guidelines for the treatment of children with tympanostomy tubes (TTs) who developed otorrhea after tube placement, beyond the immediate postoperative period.[6] Interventions compared topical antibiotics, topical antibiotic–corticosteroid combinations, oral antibiotics, and watchful waiting.[6] For tympanostomy tube otorrhea, topical antibiotic-glucocorticoid ear drops were the most effective treatment and were superior to both oral antibiotics and watchful waiting/placebo.[6] Topical antibiotic drops alone were also more effective than watchful waiting and likely more effective than oral antibiotics, although the evidence was less certain.[6] Overall, topical preparations had the highest probability of clinical cure, with antibiotic-steroid combinations ranking first and antibiotic-only drops ranking second.[6] Therefore, current evidence supports topical ear drops, particularly antibiotic-glucocorticoid combinations, over oral antibiotics for uncomplicated tube otorrhea.[6]

New Formulations:[7]

FDA Approval Date	Brand Name	Generic Name	Indication
9/26/2025	Clotic™	clotrimazole	fungal otitis externa due to aspergillus and candida species

New FDA Safety Alerts:[8]

Table 1. Description of New FDA Safety Alerts

Generic Name	Brand Name	Month / Year of Change	Location of Change (Boxed Warning, Warnings, CI)	Addition or Change and Mitigation Principles (if applicable)
Ciprofloxacin hydrochloride; hydrocortisone	Cipro HC Otic™	3/20/2017	Warnings	Dizziness, ear canal erythema, ear congestion, hypoacusis and medication residue reported in post-approval period.

References:

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Appendix 1: Current Preferred Drug List

Generic	Brand	Form	PDL
neomyc/colist/hydrocort/thonzn	CORTISPORIN-TC	DROPS SUSP	Y
neomycin/polymyxin B/hydrocort	NEOMYCIN-POLYMYXIN-HC	DROPS SUSP	Y
ofloxacin	OFLOXACIN	DROPS	Y
ciprofloxacin HCl	CIPROFLOXACIN HCL	DROPERETTE	N
ciprofloxacin HCl/dexameth	CIPROFLOXACIN-DEXAMETHASONE	DROPS SUSP	N
ciprofloxacin HCl/fluocinolone	CIPROFLOXACIN HCL-FLUOCINOLONE	VIAL	N
ciprofloxacin HCl/fluocinolone	OTOVEL	VIAL	N
ciprofloxacin/hydrocortisone	CIPRO HC	DROPS SUSP	N
ciprofloxacin/hydrocortisone	CIPROFLOXACIN-HYDROCORTISONE	DROPS SUSP	N
neomycin/polymyxin B/hydrocort	NEOMYCIN-POLYMYXIN-HYDROCORT	SOLUTION	N

Appendix 2: New Comparative Clinical Trials

A total of 158 citations were manually reviewed from the initial literature search. After further review, 157 citations were excluded because of wrong study design (e.g., observational), comparator (e.g., no control or placebo-controlled), or outcome studied (e.g., non-clinical). The abstract of the remaining trial is summarized below.

Topical or oral antibiotics in childhood acute otitis media and ear discharge: a randomized controlled non-inferiority trial
BACKGROUND: Current guidance suggests oral antibiotics can be considered for children with acute otitis media (AOM) and ear discharge, but there is an absence of evidence regarding the relative effectiveness of antibiotic-corticosteroid eardrops., AIM: To establish whether antibiotic-corticosteroid eardrops are non-inferior to oral antibiotics in children with AOM and ear discharge., DESIGN AND SETTING: Open randomized controlled non-inferiority trial set in Dutch primary care., METHODS: Children were randomized to hydrocortisone-bacitracin-colistin eardrops (five drops, three times per day in the discharging ear(s)) or amoxicillin suspension (50 mg per kilogram of body weight per day, divided over three doses administered orally) for 7 days. The primary outcome was the proportion of children with resolution of ear pain and fever at day 3., RESULTS: Between December 2017 and March 2023, 58 of the planned 350 children were recruited due to slow accrual for various reasons. Children assigned to eardrops (n = 26) had lower resolution rates of ear pain and fever at 3 days compared to those receiving oral antibiotics (n = 31): 42% vs 65%; adjusted risk difference 20.3%, 95% confidence interval -5.3% to 41.9%), longer parent-reported ear discharge (6 vs 3 days; P = .04), and slightly higher mean ear pain scores (Likert scale 0-6) over days 1-3 (2.1 vs 1.4, P = .02), but received fewer oral antibiotic courses in 3months (11 for 25 children vs 33 for 30 children), and had less GI upset and rash (12% vs 32% and 8% vs 16%, respectively)., CONCLUSION: Early termination stopped us from determining non-inferiority of antibiotic-corticosteroid eardrops. Our limited data, requiring confirmation, suggests that oral antibiotics may be more effective than antibiotic-corticosteroid eardrops in resolving symptoms and shortening the duration of ear discharge.

Appendix 3: Medline Search Strategy

Ovid MEDLINE(R) ALL 1946 to July 08, 2026

1 exp Ciprofloxacin/16908
2 exp Ofloxacin/8985
3 exp Neomycin/8290
4 exp Colistin/6678
5 exp Polymyxin B/4001
6 exp Anti-Bacterial Agents/904090
7 exp Otitis/31369
8 exp Labyrinthitis/728
9 exp Otitis Media, Suppurative/2506
10 1 or 2 or 3 or 4 or 5 or 6/904194
11 7 or 8 or 9/31369
12 10 and 11/6638
13 limit 12 to (english language and humans and yr="2017 -Current" and (clinical study or clinical trial, all or clinical trial, phase iii or clinical trial, phase iv or clinical trial or comparative study or controlled clinical trial or meta analysis or multicenter study or practice guideline or pragmatic clinical trial or randomized controlled trial or "systematic review")) 158

Appendix 4: Key Inclusion Criteria

Population	People with otitis externa, chronic suppurative otitis media, and tympanostomy tube otorrhea
Intervention	Topical antibiotics approved for the treatment of otitis externa, otitis media, and tympanostomy tube otorrhea
Comparator	Active treatments
Outcomes	Resolution of infection
Setting	Outpatient