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Month/Year of Review: January 2015
PDL Classes: Ophthalmic Antibiotic/Corticosteroids

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Current Status of PDL Class:

Preferred	Non-Preferred
Gentamicin/prednisolone 0.3/1% susp (PRED-G)	Neomycin/bacitracin/polymyxin B/hydrocortisone oint
Gentamicin/prednisolone 0.3/0.6% oint (PRED-G)	Neomycin/dexamethasone susp (NEO-DEXAIR)
Neomycin/polymyxin B/dexamethasone oint (MAXITROL)	Neomycin/polymyxin B/hydrocortisone susp
Neomycin/polymyxin B/dexamethasone susp (DEXASPORIN; MAXITROL)	Sulfacetamide/prednisolone sol
Sulfacetamide sodium/prednisolone acetate oint (BLEPHAMIDE SOP)	Tobramycin/loteprednol (ZYLET) susp
Sulfacetamide sodium/prednisolone acetate susp (BLEPHAMIDE)	
Tobramycin/dexamethasone oint (TOBRADEX)	
Tobramycin/dexamethasone susp (TOBRADEX)	

Previous Conclusions and Recommendations:

- There is insufficient evidence of difference in efficacy/effectiveness or in safety between agents.
- There is insufficient evidence to make a specific recommendation.

Conclusions and Recommendations:

- There is no significant new comparative evidence on the efficacy and safety of agents that changes the previous conclusions.
- Make gentamicin/prednisolone ophthalmic suspension and ointment products and Maxitrol (neomycin/polymyxin B/dexamethasone) ophthalmic ointment preferred on the PDL based on cost effectiveness.

Methods:
A Medline literature search for new systematic reviews and randomized controlled trials (RCTs) comparing fixed combinations of ophthalmic antibiotic/corticosteroid to placebo or active controlss was conducted with limits for humans and English. The Agency for Healthcare Research and Quality (AHRQ), Cochrane Collection, National Institute for Health and Care Excellence (NICE), Department of Veterans Affairs, Clinical Evidence, Dynamed, and the Canadian Agency for Drugs and Technologies in Health (CADTH) resources were manually searched for high quality and relevant systematic reviews. The FDA website was searched for new drugs, indications, and safety alerts, and the AHRQ National Guideline Clearinghouse (NGC) was searched for updated and recent evidence-based guidelines. The primary focus of the evidence is on high quality systematic reviews and evidence based guidelines for this class update. Randomized controlled trials will be emphasized if evidence is lacking or insufficient from those preferred sources.

New Systematic Reviews:
None identified.

New Guidelines:
None identified.

New drugs:
None.

New Formulations/Indications:
None.

New FDA safety alerts:
None.

New Trials:

20 potentially relevant RCTs were evaluated from the literature search. After further review, only one placebo-controlled trial was identified relevant to this scan. The abstract is provided below:

Comstock T, Paterno M, Bateman K, et al. Safety and Tolerability of Loteprednol Etabonate 0.5% and Tobramycin 0.3% Ophthalmic Suspension in Pediatric Subjects. *Pediatr Drugs*. 2012;14:119-30.

Background: Loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension (LE/T) is indicated for steroid-responsive inflammatory ocular conditions where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. LE/T was shown to be safe in healthy volunteers and patients aged 18 years and older with minimal effect on intraocular pressure (IOP).
Objective: The aim of the study was to evaluate the safety of LE/T in pediatric subjects by examining data from two clinical studies.
Methods: Two randomized, multicenter, double-masked, parallel-group (one two-arm, the other four-arm) studies were conducted in subjects aged 0–6 years (N = 245). One study assessed LE/T compared with vehicle in the management of lid inflammation (n = 108) and the other compared LE/T with loteprednol etabonate ophthalmic suspension 0.5% (LE), tobramycin ophthalmic solution 0.3% (tobramycin), and vehicle in the treatment of blepharoconjunctivitis (n = 137). In the first study, subjects were randomized to LE/T or vehicle administered four times daily (qid) for the first 7 days followed by twice daily (bid) for 7 days along with warm compresses bid for the entire 2 weeks. In the second study, subjects were randomized to LE/T, LE, tobramycin, or vehicle administered qid for 14 days. Treatment-emergent ocular and non-ocular adverse events (AEs) and bilateral vision were assessed at all study visits in both studies. In addition, in the lid inflammation study, IOP was assessed at all visits. The primary safety endpoint in both studies was the incidence of treatment emergent AEs.
Results: The incidence of LE/T treatment-emergent AEs was low. A total of four ocular AEs were reported for three LE/T-treated subjects in the first study (conjunctivitis [two events], meibomian gland dysfunction, and corneal staining), and one ocular AE was reported for an LE/T-treated subject in the second study (eye pain). A total of 13 non-ocular AEs were reported for eight LE/T-treated subjects in the two trials. The most prevalent non-ocular AEs were pyrexia (three events) and rash (two events). There were no differences in the incidence of specific ocular and non-ocular AEs between the LE/T group and the comparator treatment group. In both studies, there were no clinically meaningful reductions in vision at follow-up visits. Mean IOP and IOP changes from baseline, assessed in the lid inflammation study, were not different between LE/T and vehicle treatment groups at any study visits.
Conclusion: The results of these two clinical trials demonstrate the short-term safety of treatment with topical LE/T in pediatric subjects (0–6 years of age) with lid inflammation or blepharoconjunctivitis.