

# MEDICATION COVERAGE POLICY

## PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

<b>POLICY</b>	Eye & Ear Anti-Inflammatory Disorders	<b>P &amp; T DATE</b>	12/08/2020
<b>THERAPEUTIC CLASS</b>	Topical Anti-Inflammatory Agents	<b>REVIEW HISTORY</b> (MONTH/YEAR)	12/19, 12/18, 9/17, 2/08, 9/10, 11/15, 12/16
<b>LOB AFFECTED</b>	Medi-Cal		

*This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.*

## OVERVIEW

Eye and ear infections are among the most common reasons for patient self-referral. A wide variety of conditions can lead to ocular and ophthalmic inflammation. Inflammation of the eye is mostly caused by allergens, bacteria, and viral infections. On the other hand, ear infections are mostly caused by bacterial infections, although viral infections are also possible. Most infections are mild. However, severe cases can rapidly progress to permanent visual/hearing loss if not cared for properly. This review will examine the recommended use of topical anti-inflammatory agents and their coverage criteria.

### Available Agents: (Current as of 09/2020)

GENERIC NAME (BRAND NAME)	AVAILABLE STRENGTHS	FORM. LIMITS	AVG COST PER 30 DAYS	NOTES
<b>OPHTHALMIC AGENTS</b>				
<b>CORTICOSTEROIDS</b>				
<b>DEXAMETHASONE (MAXIDEX, OZURDEX)</b>	0.1% SOLUTION	--	\$54.76	--
	MAXIDEX 0.1% SUSPENSION	NF	\$88.31	--
	DEXYCU 9% SUSPENSION	NF		
	OZURDEX 0.7 MG IMPLANT	NF	--	--
<b>DIFLUPREDNATE (DUREZOL)</b>	0.05% EMULSION	NF	--	--
<b>FLUOCINOLONE (ILUVIEN, RETISERT)</b>	IMPLANT:			
	0.19 MG	NF	--	--
	0.59 MG	NF	--	--
<b>FLUOROMETHOLONE (FML, FLAREX, FML FORTE, FML LIQUIFILM)</b>	FLUOROMETHOLONE 0.1% SUSPENSION	--	\$60.62	--
	FML S.O.P. 0.1 % OINTMENT	--	\$135.65	--
	FLAREX 0.1% ACETATE SUSPENSION	NF	--	--
	FML FORTE 0.25% SUSPENSION	--	\$149.29	--
<b>LOTEPREDNOL (LOTEMAX, ALREX)</b>	LOTEMAX 0.5% GEL	PA	\$159.54	RESTRICTED TO PATIENTS WITH GLAUCOMA OR AGE 10 OR LESS; MUST BE PRESCRIBED BY OPHTHALMOLOGIST
	LOTEMAX 0.5% OINTMENT	PA	--	
	LOTEMAX 0.5% SUSPENSION	PA	\$209.86	
	ALREX 0.2% SUSPENSION	PA	\$199.16	
<b>PREDNISOLONE (OMNIPRED, PRED FORTE, PRED MILD)</b>	PREDNISOLONE SODIUM PHOSPHATE 1% DROPS	--	\$45.29	--
	PREDNISOLONE ACETATE 1% DROPS	--	\$53.18	--
	PRED MILD 0.12% SUSPENSION	--	\$129.19	--
<b>TRIAMCINOLONE (TRIESENCE)</b>	4 MG/ML INTRAVITREAL SUSPENSION	NF	--	--
<b>NSAIDs</b>				

<b>BROMFENAC SODIUM (PROLENSA, XIBROM)</b>	0.09% SOLUTION	NF	--	--
<b>DICLOFENAC (VOLTAREN)</b>	0.1% SOLUTION	--	\$15.56	--
<b>FLURBIPROFEN (OCUFEN)</b>	0.03% SOLUTION	--	\$6.55	-
<b>KETOROLAC (ACULAR LS, ACULAR, ACUVAIL)</b>	0.4% SOLUTION	--	\$47.11	--
	0.5 % SOLUTION	--	\$37.11	--
	ACUVAIL 0.45% SOLUTION	NF	--	--
<b>NEPAFENAC (ILEVRO, NEVANAC)</b>	ILEVRO 0.3% SUSPENSION	NF	--	--
	NEVANAC 0.1 % SUSPENSION	NF	--	--
<b>ANTIBIOTICS</b>				
<b>AZITHROMYCIN (AZASITE)</b>	AZASITE 1% SOLUTION	NF	--	--
<b>BACITRACIN</b>	500 UNITS/GRAM OINTMENT	--	\$80.89	--
<b>BESIFLOXACIN (BESIVANCE)</b>	BESIVANCE 0.6% SUSPENSION	NF	--	--
<b>CIPROFLOXACIN (CILOXAN)</b>	CILOXAN 0.3% OINTMENT	NF	--	--
	0.3% SOLUTION	--	\$13.54	--
<b>ERYTHROMYCIN</b>	0.5% OINTMENT	--	\$15.65	--
<b>GATIFLOXACIN (ZYMAR)</b>	0.5% SOLUTION	NF	--	--
<b>GENTAMICIN (GARAMYCIN, GENTAK)</b>	0.3% OINTMENT	--	\$13.46	--
	0.3% SOLUTION	--	\$6.07	--
<b>MOXIFLOXACIN (VIGAMOX)</b>	0.5 % DROPS	--	\$86.40	--
<b>OFLOXACIN (OCUFLOX)</b>	0.3% SOLUTION	--	\$15.59	--
<b>SULFACETAMIDE (BLEPH-10)</b>	10% OINTMENT	--	\$49.45	--
	10% SOLUTION	--	\$43.48	--
<b>TOBRAMYCIN (TOBREX)</b>	TOBREX 0.3% OINTMENT	--	\$206.45	--
	0.3% SOLUTION	--	\$12.58	--
<b>BACITRACIN/ POLYMYXIN B (POLYCIN)</b>	500UNITS/10,000 UNITS OINTMENT	--	\$21.40	--
<b>BACITRACIN/POLYMYXIN/ NEOMYCIN (NEO-POLYCIN)</b>	400UNITS/10,000UNITS/3.5MG OINTMENT	--	\$40.60	--
<b>BACITRACIN/POLYMYXIN/ NEOMYCIN/HC (NEO-POLYCIN HC)</b>	400UNITS/10,000UNITS/ 3.5MG/1% OINTMENT	--	\$43.08	--
<b>GENTAMICIN/ PREDNISOLONE (PRED-G)</b>	0.3%/0.6% OINTMENT	--	--	--
	0.3%/1% SUSPENSION	--	--	--
<b>NEOMYCIN/POLYMYXIN/ DEXAMETHASONE (MAXITROL)</b>	3.5MG/10,000 UNITS/0.1% OINTMENT	--	\$16.93	--
	3.5MG/10,000 UNITS/0.1% SOLUTION	--	\$16.15	--
<b>NEOMYCIN/ POLYMYXIN B/GRAMICIDIN (NEOSPORIN)</b>	1.75MG/10,000UNITS/0.025 MG SOLUTION	--	\$40.60	--
<b>NEOMYCIN/POLYMYXIN/ HC (CORTISPORIN)</b>	3.5MG/400-10,000 U/ 10MG/ML SUSPENSION	--	\$119.97	--
<b>POLYMYXIN B/ TRIMETHOPRIM (POLYTRIM)</b>	10,000 UNITS/1 MG SOLUTION	--	\$9.66	--

<b>TOBRAMYCIN/ DEXAMETHASONE (TOBRADEX)</b>	TOBRADEX 0.3%/0.1% OINTMENT	--	\$197.71	--
	TOBRADEX ST 0.3%/0.05% OINTMENT	NF		
	0.3%/0.1% SOLUTION	--	\$85.36	--
<b>TOBRAMYCIN/ LOTEPREDNOL (ZYLET)</b>	ZYLET 0.5/0.3% SUSPENSION	NF	--	--
<b>SULFACETAMIDE/PREDNI SOLONE ACETATE (BLEPHAMIDE SOP, BLEPHAMIDE)</b>	10%/0.23% SOLUTION	-	\$26.06	--
	BLEPHAMIDE 10%/0.2% SUSPENSION	--	\$192.42	--
	BLEPHAMIDE S.O.P. 10/ 0.2% OINTMENT	--	\$129.19	--
<b>ANTIFUNGALS</b>				
<b>NATAMYCIN (NATACYN)</b>	5% SUSPENSION	--	--	--
<b>ANTIVIRALS</b>				
<b>TRIFLURIDINE (VIOPTIC)</b>	0.1% SOLUTION	--	\$113.20	--
<b>GANCICLOVIR (ZIRGAN)</b>	0.15% GEL	NF	--	--
<b>H<sub>1</sub>-ANTIAGONISTS</b>				
<b>ALCAFTADINE (LASTACFT)</b>	0.25% SOLUTION	NF	--	--
<b>EMEDASTINE (EMADINE)</b>	0.05% SOLUTION	NF	--	--
<b>MAST-CELL INHIBITORS</b>				
<b>CROMOLYN SODIUM (OPTICROM)</b>	4% SOLUTION	--	\$13.07	--
<b>LODOXAMIDE (ALOMIDE)</b>	0.1% SOLUTION	NF	--	--
<b>NEDOCROMIL (ALOCRIL)</b>	2% SOLUTION	NF	--	--
<b>H<sub>1</sub>-ANTAGONIST/MAST-CELL INHIBITORS</b>				
<b>AZELASTINE (OPTIVAR)</b>	0.05% SOLUTION	ST	\$55.32	STEP THERAPY TO KETOTIFEN
<b>ALCAFTADINE (LASTACFT)</b>	0.25% SOLUTION	NF	--	
<b>BEPOTASTINE (BEPREVE)</b>	1.5% SOLUTION	NF	--	--
<b>BROMFENAC (XIBROM)</b>	0.09% SOLUTION	NF	\$202.00	
<b>EPINASTINE (ELESTAT)</b>	0.05% SOLUTION	NF	--	--
<b>KETOTIFEN (ALAWAY, ZADITOR)</b>	0.025% SOLUTION	QL	\$7.55	LIMIT 10 ML PER MONTH
<b>OLOPATADINE (PATADAY, PATANOL, PAZEO)</b>	0.1% DROPS	PA,QL	\$85.20	RESERVED FOR TREATMENT FAILURE TO AZELASTINE AND EITHER KETOTIFEN OR NAPHCN-A. LIMIT 5ML PER 30
	PATANOL 0.1% DROPS	NF	\$259.80	

	0.2% DROPS	NF	\$136.95	--
	PATADAY 0.2% DROPS	NF	\$199.33	--
	PAZEO 0.7% SOLUTION	NF	\$196.86	--
<b>CALCINEURIN INHIBITOR</b>				
<b>CYCLOSPORINE (RESTASIS)</b>	RESTASIS 0.05% DROPERETTE	PA	\$427.30	RESERVED FOR TREATMENT FAILURE TO OPHTHALMIC LUBRICANTS IN THE LAST 6 MONTHS
	RESTASIS 0.05% MULTIDOSE VIALS	PA	\$ 474.44	
<b>LFA-1 ANTAGONIST</b>				
<b>LIFITEGRAST (XIIDRA)</b>	5% SOLUTION	NF	\$446.79	--
<b>OPHTHALMIC LUBRICANTS AND IRRIGATIONS</b>				
<b>HYDROXYPROPYL CELLULOSE (LACRISERT)</b>	5 MG INSERT	NF	--	--
<b>PROPYLENE GLYCOL/PEG 400 (SYSTANE, LUBRICANT EYE)</b>	0.4%/0.3% DROPS	--	\$6.72	--
<b>GLYCERIN/PROPYLENE GLYCOL (ADVANCED EYE RELIEF, ARTIFICIAL TEARS)</b>	ARTIFICIAL TEAR DROPS 0.1%/0.3%	--	\$2.50	--
<b>MINERAL OIL/PETROLATUM WHITE OINTMENT (ARTIFICIAL TEARS, REFRESH P.M.)</b>	OINTMENT	--	\$5.82	--
<b>CARBOXYMETHYL- CELLULOSE (GEN TEAL, REFRESH OPTIVE, TEARS AGAIN)</b>	0.25%, 1%, 1.5% GEL 0.25%, 0.5 %, 0.7% , 1% SOLUTION	--	--	--
	REFRESH LIQUIGEL 1% GEL DROPS	--	\$10.39	--
<b>HYPROMELLOSE (PURE AND GENTLE EYE DROPS)</b>	0.2% DROPS	--	--	--
	0.3% DROPS	--	--	--
<b>DEXTRAN 70/ HYPROMELLOSE (ARTIFICIAL TEARS, TEARS PURE, TEARS NATURALE FREE)</b>	0.1%-0.3% DROPS	NF	--	--
<b>PEG 400/ HYPROMELLOSE/ GLYCERIN (ARTIFICIAL TEARS)</b>	1%-0.2%-0.2% DROPS	--	\$1.03	--
<b>POLYVINYL ALCOHOL (HYPO TEARS, LIQUI TEARS, MURINE TEARS, TEARS AGAIN)</b>	1.4% DROPS	--	\$3.14	--
<b>POLYVINYL ALCOHOL/POVIDONE (ARTIFICIAL TEARS, REFRESH)</b>	0.5%/0.6% DROPS	--	--	--
<b>VASO-CONSTRICTORS</b>				
<b>NAPHAZOLINE</b>	<b>CLEAR EYES REDNESS RELIEF SOLUTION (NAPHAZOLINE 0.125%/ GLYCERIN 0.2%)</b>	NF	--	--

(CLEAR EYES REDNESS RELIEF, GOODSENSE REDNESS RELIEF PLUS, VASOCLEAR)	GOODSENSE REDNESS RELIEF PLUS SOLUTION (NAPHAZOLINE 0.03%/ GLYCERIN 0.5% )	NF	--	--
	0.1% SOLUTION	--	\$5.34	--
OXYMETAZOLINE (VISINE-LR)	0.025 % SOLUTION	NF	--	--
PHENYLEPHRINE (ALTAFRIN, MYDFRIN, NEOFRIN)	2.5% SOLUTION	--	--	--
	10% SOLUTION	--	--	--
TETRAHYDROZOLINE (OPTI-CLEAR, VISINE ADVANCED RELIEF)	0.05% SOLUTION	NF	--	--
NAPHAZOLINE/PHENIRAMINE (NAPHCON-A, OPCON-A, VISINE-A)	0.025%-0.3% SOLUTION	--	\$5.95	--
	0.027%-0.315% SOLUTION	--	\$3.81	--

### TOPICAL ANESTHETIC

LIDOCAINE (AKTEN)	3.5% GEL	NF	--	--
PROPARGACAINE (ALCANINE, PARCAINE)	0.5% SOLUTION	--	\$25.93	--
TETRACAINE (ALTACAINE, TETCAINE, TETRAVISC, TETRAVISC FORTE)	0.5% SOLUTION	NF	--	--
PROPARGACAINE/FLUORESCEIN (FLUCAINE)	0.25%-0.5% SOLUTION	NF	--	--

### MISCELLANEOUS

CYSTEAMINE (CYSTARAN)	0.44 % DROPS	NF	--	--
SODIUM CHLORIDE (MURO-128)	2 % DROPS	NF	--	--
	5 % DROPS	PA	--	PA REQUIRED. APPROVAL IS DETERMINED BY MEDICAL NECESSITY CRITERIA. MAY BE RESTRICTED TO SPECIALTY PHARMACY.
	5 % OINTMENT	PA	-	PA REQUIRED. APPROVAL IS DETERMINED BY MEDICAL NECESSITY CRITERIA. MAY BE RESTRICTED TO SPECIALTY PHARMACY.

## OTIC AGENTS

### ANTIBIOTICS

CIPROFLOXACIN (CETRAXAL, OTIPRIO)	0.2% SOLUTION	NF	--	--
	OTIPRIO 6% INTRATYMPANIC SUSPENSION	NF	--	--
OFLOXACIN (FLOXIN OTIC)	0.3% SOLUTION	--	\$21.43	--
NEOMYCIN/POLYMYXIN B/HC	3.5MG/10,000 UNITS/1% SOLUTION	--	\$47.58	--

( CORTISPORIN OTIC )	3.5MG/10,000 UNITS/1% SUSPENSION	--	\$51.92	--
CIPROFLOXACIN/ FLUOCINOLONE (OTOVEL OTIC)	0.3-0.25% SOLUTION	NF	--	--
CIPROFLOXACIN/HC (CIPRO HC)	0.2%-1% SUSPENSION	NF	\$276.51	--
CIPROFLOXACIN/ DEXAMETHASONE (CIPRODEX OTIC)	0.3%-0.1% SUSPENSION	ST	\$204.57	Step therapy to Ofloxacin Ear or Eye Drops And Dexamethasone 0.1% Eye Drops in the last 365 days.
NEOMYCIN/COLISTIN/HC/ THONZONIUM (COLY-MYCIN S, CORTISPORIN TC)	0.33%-0.3%-1%-0.05% SUSPENSION	NF	--	--
<b>ANTI-INFECTIVES</b>				
ACETIC ACID (VOSOL)	2% SOLUTION	--	\$16.25	--
ACETIC ACID/ALUMINUM ACETATE	2% SOLUTION	--	\$61.22	--
ACETIC ACID/HYDROCORTISONE (VOSOL-HC)	1%/2% SOLUTION	--	\$129.32	--
CRESYL ACETATE (CRESYLATE)	CRESYLATE 25% SOLUTION	NF	--	--
<b>CORTICOSTEROIDS</b>				
FLUOCINOLONE (DERMOTIC)	0.01% OIL	NF	\$170.82	--
PA = Prior Authorization; QL = Quantity Limit; NF = Non-Formulary				

## ⊕ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

### **Ophthalmic Corticosteroids**

*Dexamethasone (Maxidex, Ozurdex), Difluprednate (Durezol), Fluorometholone (Flarex, FML Forte, FML Liquifilm, FML SOP), Loteprednol (Lotemax, Alrex), Prednisolone (Omnipred, Pred Forte, Pred Mild), Triamcinolone (Triesence)*

**Dexamethasone (Maxidex, Ozurdex), Fluorometholone (Flarex, FML Forte, FML Liquifilm, FML SOP), Prednisolone (Omnipred, Pred Forte, Pred Mild), Triamcinolone (Triesence)**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A
- Non-Formulary:** Ozurdex, Flarex, Triesence, Maxidex

### **Loteprednol (Lotemax, Alrex)**

- Coverage Criteria:** Loteprednol is reserved for use in patients with glaucoma or for use in children ≤10 years. Must be prescribed by an ophthalmologist.
- Limits:** None
- Required Information for Approval:**
  - Charts documenting patient has glaucoma or request is for patients 10 years or younger.
  - Medication is requested by an ophthalmologist.

- Other Notes:** N/A
- Non-Formulary:** Difluprednate (Durezol)

#### **Ophthalmic NSAIDs**

*Bromfenac Sodium (Bromday, Prolensa, Xibrom), Diclofenac, Flurbiprofen (Ocufer), Ketorolac (Acular LS, Acular), Nepafenac (Ilevro, Nevanac)*

#### **Diclofenac, Flurbiprofen (Ocufer), Ketorolac (Acular LS, Acular)**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A
- Non-Formulary:** Bromfenac Sodium (Prolensa, Xibrom); Acuvail 0.45%; Ilevro 0.3%; Nevanac 0.1%

#### **Ophthalmic Antibiotics**

*Azithromycin (AzaSite), Bacitracin, Besifloxacin (Besivance), Ciprofloxacin 0.3 % solution, erythromycin 0.5 % ointment, gatifloxacin (Zymar), Gentamicin 0.3 % ointment and solution, Levofloxacin 0.5% solution, Ofloxacin 0.3% solution, Sulfacetamide (Bleph-10) 10% ointment and solution, Tobramycin 0.3% solution, Tobrex 0.3% ointment, Moxifloxacin 0.5% drops*

#### **Bacitracin, Ciprofloxacin 0.3 % solution, erythromycin 0.5 % ointment, gatifloxacin (Zymar), Gentamicin 0.3 % ointment and solution, Ofloxacin 0.3% solution, Sulfacetamide (Bleph-10) 10% ointment and solution, Tobramycin 0.3% solution, Tobrex 0.3% ointment, Moxifloxacin 0.5% drops**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A
- Non-Formulary:** AzaSite, Besivance, Ciloxan, Levofloxacin

#### **Ophthalmic Antibiotics and Corticosteroid Combination Products**

*Bacitracin/Polymyxin B (Polycin), Bacitracin/Polymyxin/Neomycin ( Neo-Polycin), Bacitracin/Polymyxin/Neomycin/HC (Neo-Polycin HC), Gentamicin/Prednisolone (Pred-G), Neomycin/Polymyxin/Dexamethasone (Maxitrol), Neomycin/Polymyxin/Gramicidin (Neosporin), neomycin/Polymyxin/HC, Polymyxin/Trimethoprim (Polytrim), Tobramycin/Dexamethasone (Tobradex), Sulfacetamide/Prednisolone Acetate (Blephamide SOP, Blephamide)*

#### **Bacitracin/Polymyxin B (Polycin), Bacitracin/Polymyxin/Neomycin ( Neo-Polycin), Bacitracin/Polymyxin/Neomycin/HC (Neo-Polycin HC), Gentamicin/Prednisolone (Pred-G), Neomycin/Polymyxin/Dexamethasone (Maxitrol), Neomycin/Polymyxin/Gramicidin (Neosporin), neomycin/Polymyxin/HC, Polymyxin/Trimethoprim (Polytrim), Tobramycin/Dexamethasone (Tobradex), Sulfacetamide/Prednisolone Acetate (Blephamide SOP, Blephamide)**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A
- Non-Formulary:** Zylet

#### **Ophthalmic Antifungals**

*Natamycin (Natacyn)*

#### **Natamycin:**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A

#### **Ophthalmic Antivirals**

*Trifluridine (Viroptic), Ganciclovir (Zirgan)*

#### **Trifluridine (Viroptic)**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A
- Non-Formulary:** Ganciclovir (Zirgan)

### Ophthalmic H<sub>1</sub>-Antagonists

*Alcaftadine (Lastacasft), Emedastine (Emadine)*

- Non-Formulary:** Alcaftadine and Emedastine
- Note:** Formulary alternatives are Ketotifen, Azelastine, and Olopatadine

### Ophthalmic Mast-Cell Inhibitors

*Cromolyn Sodium (Opticrom), Lodoxamide (Alomide), Nedocromil (Aldocril)*

#### **Cromolyn Sodium (Opticrom) 4% solution**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A
- Non-Formulary:** Alomide, Alocril

### Ophthalmic H<sub>1</sub>-Antagonist/ Mast-cell Inhibitors

*Azelastine (Optivar), Bepotastine (Bepreve), Epinastine (Elestat), Ketotifen (Alaway, Zaditor), Olopatadine (Pataday, Patanol, Pazeo)*

#### **Azelastine (Optivar)**

- Coverage Criteria:** Step therapy to previous treatment with Ketotifen in the last 30 days.
- Limits:** None
- Required Information for Approval:** Fill history of Ketotifen in the last 30 days.
- Other Notes:** N/A
- Non-Formulary:** Bepotastine (Bepreve), Epinastine (Elestat)

#### **Ketotifen**

- Coverage Criteria:** None
- Limits:** Limit 10 ml (1 bottle) per month
- Required Information for Approval:** N/A
- Other Notes:** N/A

#### **Olopatadine (Patanol 0.1%)**

- Coverage Criteria:** Olopatadine 0.1% is reserved for treatment failure or intolerance to Azelastine **and** 1 of the following: Ketotifen (Alaway, Zaditor), Naphazoline/Pheniramine (Visine-A).
- Limits:** Limit 5ml (1 bottle) per 30 days
- Required Information for Approval:** Fill history of Azelastine **and** either Ketotifen or Naphazoline/Pheniramine.
- Non-Formulary:** Olopatadine 0.2%, Pataday 0.2%, Pazeo 0.7%

### Ophthalmic Calcineurin

*Cyclosporine (Restasis)*

#### **Cyclosporine (Restasis) dropperettes and multi-dose vials:**

- Coverage Criteria:** Restasis is reserved for patients who have failed ophthalmic lubricants in the last 6 months.
- Limits:** None
- Required Information for Approval:** Clinical documentations of inadequate response to other ophthalmic lubricants in the last 6 months. Must be prescribed by Ophthalmologist.
- Other Notes:** None

### LFA-1 Antagonist

*Lifitegrast (Xiidra)*



- Non-Formulary**
- Note:** Formulary alternatives- Lubricant eye drops, Restasis

### Ophthalmic Lubricants

*Hydroxypropyl Cellulose (Lacrisert), Propylene Glycol/Peg 400, Glycerin/Propylene Glycol (Artificial Tears), Petrolatum/Mineral Oil/Sodium Chloride (Artificial Tears, Nighttime Relief), Carboxymethylcellulose (Refresh Liquigel), Dextran 70/Hypromellose (Artificial Tears, Tears Naturale, Tears pure), Polyvinyl Alcohol (Liquitears, Lubricant Eye)*

**Propylene Glycol/Peg 400 (0.4%-0.3% drops and dropperettes), Glycerin/Propylene Glycol (0.1%-0.3%), Petrolatum/Mineral Oil (42.5%-57.3%) ointment, Carboxymethylcellulose (0.5% drops, dropperettes, and 1% gel drops), Carboxymethylcellulose/glycerin (0.5%-0.9% drops and dropperettes), Hypromellose (0.3% drops), Dextran 70/Hypomellose (0.1%-0.3% drops), Peg 400/hypromellose/Glycerin (1%-0.2%-0.2% drops), Polyvinly Alcohol (1.4% drops)**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A
- Non-Formulary:** Hydroxypropyl Cellulose (Lacrisert), Carboxymethylcellulose (0.25%, 1%, 1.5% gel), 0.7% liquid, (0.25% and 1%) solution

### Ocular Vasoconstrictors

*Naphazoline (Clear Eyes, VasoClear), Naphazoline/Pheniramine (Naphcon-A, Opcon-A, Visine-A), Oxymetazoline (Visine-LR), Phenylephrine (Altafrin, Mydfrin, Neofrin), Tetrahydrozoline (Opti-Clear)*

**Naphazoline (Clear Eyes, VasoClear), Naphazoline/Pheniramine (Naphcon-A, Opcon-A, Visine-A), Oxymetazoline (Visine-LR), Phenylephrine (Altafrin, Mydfrin, Neofrin), Tetrahydrozoline (Opti-Clear)**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A
- Non-Formulary:** Naphazoline 0.125%, 0.02%, 0.03%, 0.5% solutions, Oxymetazoline (Visine-LR), Tetrahydrozoline 0.05% solution

### Miscellaneous

*Sodium Chloride 5% Eye Drops, Sodium Chloride 5% Eye Ointments*

**Sodium Chloride 5% Eye Drops, Sodium Chloride 5% Eye Ointments**

- Coverage Criteria:** PA required. Approval is determined by medical necessity criteria. May be restricted to specialty pharmacy.
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A

### Ophthalmic Anesthetics

*Lidocaine (Akten), Proparacaine (Alcaine), Tetracaine (Altacaine, Tetcaine, TetraVisc, TetraVisc Forte), Proparacaine/Fluorescein (Fluacaine)*

**Lidocaine (Akten), Proparacaine (Alcaine), Tetracaine (Altacaine, Tetcaine, TetraVisc, TetraVisc Forte), Proparacaine/Fluorescein (Fluacaine)**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A
- Non-Formulary:** Lidocaine, Tetracaine, Proparacaine/fluorescein

### Otic Antibiotics

*Ciprofloxacin (Cetraxal, Otiprio), Ciprofloxacin/ Dexamethasone (Ciprodex), Ciprofloxacin/Fluocinolone (Otovel Otic), Neomycin/Polymyxin B/HC (Cortisporin Otic), neomycin/Colistin/HC/Thonzonium (Coly-Mycin S, Cortisporin TC), Ofloxacin (Floxin Otic)*

**Ofloxacin, Neomycin/Polymyxin B/HC**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A

**Ciprofloxacin/Dexamethasone (Ciprodex)**

- Coverage Criteria:** Ciprodex is step therapy to Ofloxacin Ear or Eye Drops and Dexamethasone 0.1% Eye Drops in the last 365 days.
- Limits:** None
- Required Information for Approval:** None
- Other Notes:** N/A
- Non-Formulary:** Ciprofloxacin/Fluocinolone (Otovel Otic), Ciprofloxacin/HC (Cipro HC), Neomycin/colistin/HC/thonzonium (Coly-Mycin S, Cortisporin TC)

**Otic Anti-Infectives**

*Acetic Acid (Vosol) Acetic Acid/Aluminum Acetate (Borofair), Acetic Acid/Hydrocortisone, Cresyl Acetate (Cresylate)*

**Acetic Acid (Vosol) Acetic Acid/Aluminum Acetate (Borofair), Acetic Acid/Hydrocortisone**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** N/A
- Non-Formulary:** Cresyl Acetate (Cresylate)

**Otic Corticosteroids**

*Fluocinolone (DermOtic)*

**Non-Formulary**

**CLINICAL JUSTIFICATION**

Most eye and ear inflammatory conditions are self-limiting. However, the use of medications can quicken the time to recovery. Topical corticosteroids may help reduce local inflammation to prevent secondary problems like ocular scarring in severe cases. Chronic or recurrent infections may be indicative of an underlining malignancy and should be further examined.

Ocular inflammatory treatment recommendations are based on the 2018 American Academy of Ophthalmology are summarized below<sup>1</sup>:

**Management of Ocular Inflammatory Disorders<sup>1,8</sup>**

Type	Condition	Treatment Recommendations
Conjunctivitis	Allergic Conjunctivitis	<ul style="list-style-type: none"> <li>• Remove source of irritation</li> <li>• OTC topical antihistamine/vasoconstrictor eye drops</li> <li>• 2<sup>nd</sup> generation topical antihistamine eye drops</li> <li>• Antihistamine + mast-cell stabilizers</li> <li>• If symptoms not resolved, may utilize 1-2 weeks of topical corticosteroid +/- topical NSAIDs</li> <li>• Severe cases, topical cyclosporin</li> </ul>
	Vernal/Atopic Conjunctivitis	<ul style="list-style-type: none"> <li>• Remove source of irritation</li> </ul>

		<ul style="list-style-type: none"> <li>• Cool compresses and ocular lubricants</li> <li>• Topical and oral antihistamines +/- topical mast cell stabilizers</li> <li>• For acute exacerbations, topical corticosteroids are used to control severe symptoms +/- topical cyclosporine</li> </ul>
	Adenoviral Conjunctivitis	<ul style="list-style-type: none"> <li>• Usually self-limiting and do not require treatment</li> <li>• Artificial tears, antihistamine, and cold compresses may help relieve symptoms</li> </ul>
	Herpes Simplex Virus Conjunctivitis	<ul style="list-style-type: none"> <li>• Topical and/or oral antiviral treatment; <ul style="list-style-type: none"> <li>○ Topical trifluridine 1% solution 5-8x per day (max duration of therapy should not exceed 2 weeks)</li> <li>○ Ganciclovir 0.15% gel 3-5x per day</li> <li>○ Acyclovir 200-400mg 5x per day</li> <li>○ Valacyclovir 500mg 2-3x per day F</li> <li>○ amciclovir 250mg twice a day</li> </ul> </li> <li>• <u>Avoid topical corticosteroids as they can worsen HSV infection</u></li> </ul>
	Varicella (Herpes) Zoster Virus Conjunctivitis	<ul style="list-style-type: none"> <li>• Topical Antiviral are ineffective</li> <li>• Topical Antibiotics may be used to prevent secondary infection</li> <li>• Oral Antivirals for immunocompetent patients</li> </ul>
	Bacterial Conjunctivitis	<ul style="list-style-type: none"> <li>• Treatment not necessary for mild cases but it may be associated with earlier remission</li> <li>• Topical broad spectrum antibiotic therapy for 5-7 days</li> <li>• Severe Bacterial conjunctivitis are treated with appropriate systemic antibiotics according to culture result</li> </ul>
	Gonococcal/Chlamydial Conjunctivitis	<ul style="list-style-type: none"> <li>• Treatment is with systemic therapy. No evidence that topical therapy will confer additional benefit.</li> <li>• Gonococcal: <ul style="list-style-type: none"> <li>○ Adults: Ceftriaxone 250mg IM single dose <b>and</b> Azithromycin 1Gm PO single dose</li> <li>○ or Doxycycline 100mg PO BID x 7 days</li> <li>○ For Cephalosporin allergic patients; Azithromycin 2 gram PO as single dose</li> <li>○ Children (&lt; 18 years): Ceftriaxone 125mg IM for Wt. &lt; 45kg, Adult dose for children weighing &gt; 45 kg,</li> </ul> </li> <li>• Chlamydia: <ul style="list-style-type: none"> <li>○ Adults: Azithromycin 1Gram PO as a single dose or Doxycycline 100mg PO BID x 7 days</li> <li>○ Children (&lt;18 years): Erythromycin 50 mg/kg/day in divided doses for 14 days in children Wt.&lt;45 kg</li> <li>○ Children Wt.≥45 kg but who are &lt; 8 years old: Azithromycin 1 gram PO as single dose</li> <li>○ Children ≥ 8 years: Azithromycin 1 gram PO as single dose or Doxycycline 100 mg PO bid X 7 days</li> </ul> </li> </ul>
Keratitis	Bacterial Keratitis	<ul style="list-style-type: none"> <li>• Treatment with empiric topical therapy: FDA approved ophthalmic fluoroquinolones</li> <li>• Topical steroids may be considered to suppress inflammation in certain cases to reduce corneal scarring and associated visual loss.</li> </ul>
Dry Eyes	Dry Eyes	<ul style="list-style-type: none"> <li>• Mild: Environmental control and removing offending agents <ul style="list-style-type: none"> <li>○ Artificial tears</li> </ul> </li> <li>• Moderate: Artificial tears + topical cyclosporine, Lifitegrast corticosteroids</li> <li>• Severe: Artificial tears + topical cyclosporine , Anticholinergic agents such as pilocarpine</li> </ul>

## **ACUTE OTITIS EXTERNA (AOE)**

Topical therapy is the recommended initial treatment for AOE, but initial systemic antibiotic use is not recommended unless condition involves beyond ear canal or unless there is a specific reason for systemic antibiotic use. With high concentration of antibiotics in topical formulation, direct application to the affected area can result in 100 to 1000 stronger effect than systemic antibiotic therapy. However, if the symptoms do not resolve within 48 to 72 hours, reevaluation is recommended.

There are no significant differences in outcomes of treatment among different class of drugs. Therefore topical treatment choices are based on the physician's experience and factors such as patient preference, cost, possible side effects and adherence.<sup>7</sup>

## **ACUTE OTITIS MEDIA (AOM)<sup>3</sup>**

Systematic antibiotic therapy is recommended for children 6 months and older with severe signs or symptoms such as moderate or severe otalgia or otalgia for at least 48 hours or temperature 39°C [102.2°F] or higher. Children who fall in this age group with bilateral AOM should also be treated with antibiotic therapy. Children 6 months to 23 months of age with non-severe unilateral AOM or non-severe AOM (either unilateral or bilateral) in children 24 months of age or older, routine antibiotic therapy is not recommended. Instead, children should be closely monitored. If symptoms worsen or fail to improve within 48 to 72 hours of onset of symptoms, antibiotic therapy should be considered.

Amoxicillin is the first line antibiotic therapy unless allergic to penicillin, has received amoxicillin in the past 30 days, or the child has concurrent purulent conjunctivitis, or has a history of recurrent AOM unresponsive to amoxicillin. Prophylactic antibiotic use is not recommended. For recurrent AOM (3 episodes in 6 months or 4 episodes in 1 year with 1 episode in the preceding 6 months). Tympanostomy tube may be considered. Oral antibiotics are listed in HPSJ bacterial infections policy.

## **OTITIS MEDIA EFFUSION (OME)<sup>3</sup>**

Otitis Media Effusion (OME) is a condition when middle ear is filled with fluid without any signs and symptoms of infection. Antibiotics, antihistamines, decongestants and/or intranasal or systemic corticosteroids are not recommended to treat OME. Children at risk for OME should be routinely examined to prevent complications such as hearing loss. OME treatment involves various types of surgery.

## **REFERENCES**

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6. U.S. Food And Drug Administration. *FDA takes action against unapproved prescription ear drop products*: FDA News realises July 1. 2015.
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9. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/208694s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208694s000lbl.pdf)

## ☒ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Ophthalmics Feb 08.doc	02-2008	Allen Shek PharmD
Update to Policy	Ophthalmic Corticosteroids Class Review 9-21-10.docx	09-2010	Allen Shek PharmD
Update to Policy	Ophthalmic ABX Class Review REVISED 9-21-10.docx	09-2010	Allen Shek PharmD
Update to Policy	HPSJ Coverage Policy - Eye & Ear Anti-Inflammatory Disorders 11-2015.docx	11-2015	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Eye & Ear - Eye & Ear Inflammatory Disorders 2016-12.docx	12-2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Eye & Ear - Eye & Ear Inflammatory Disorders 2017-09.docx	9/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Eye & Ear - Eye & Ear Inflammatory Disorders 2018-12.docx	12/2018	Matthew Garrett, PharmD
Review Policy	Eye_Ear Inflammatory Disorders	12/2019	Matthew Garrett, PharmD
Review Policy	Eye_Ear Inflammatory Disorders	12/2020	Matthew Garrett, PharmD

*Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy*