

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Eye & Ear Anti-Inflammatory Disorders	P & T DATE	9/12/2017
THERAPEUTIC CLASS	Topical Anti-Inflammatory Agents	REVIEW HISTORY (MONTH/YEAR)	2/08, 9/10, 11/15, 12/16
LOB AFFECTED	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 8/2017)

Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Formulary Limits	Average Cost per 30 Days	Notes
Ophthalmic Agents					
Corticosteroids	Dexamethasone (Maxidex, Ozurdex)	0.1% Solution	--	\$49.29	--
		Maxidex 0.1% suspension	--	\$76.55	--
		Ozurdex 0.7 mg Implant	NF	--	--
	Difluprednate (Durezol)	Durezol 0.05% emulsion	NF	\$127.72	--
	Fluocinolone (Iluvien, Retisert)	0.19 mg Implant	NF	--	--
		0.59 mg implant	NF	--	--
	Fluorometholone (FML, Flarex, FML forte, FML Liquifilm)	FML 0.1% Ointment	--	\$127.70	--
		Flarex 0.1% acetate suspension	NF	--	--
		Fluorometholone 0.1% suspension	--	\$67.18	--
		FML Forte 0.25% suspension	--	\$157.99	--
	Loteprednol (Lotemax, Alrex)	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	\$210.46	
		Lotemax 0.5% suspension	PA	\$210.37	
		Alrex 0.2% suspension	PA	\$234.31	
	Prednisolone (Omnipred, Pred Forte, Pred Mild)	1% solution	--	\$47.25	--
		1% suspension	--	\$57.24	--
		Pred Mild 0.12% Suspension	--	\$163.51	--
Rimexolone (Vexol)	1% Suspension	--	--	--	

	Triamcinolone (Triesence)	4 mg/ml Intravitreal suspension	NF	--	--	
NSAIDs	Bromfenac Sodium (Prolensa, Xibrom)	0.09% solution	NF	--	--	
	Diclofenac (Voltaren)	0.1% solution	--	\$15.61	--	
	Flurbiprofen (Ocufer)	0.03% solution	--	\$6.55	-	
	Ketorolac (Acular LS, Acular, Acuvail)	0.4% solution	--	\$47.48	--	
		0.5 % solution	--	\$34.66	--	
		Acuvail 0.45% solution	NF	--	--	
	Nepafenac (Ilevro, Nevanac)	Ilevro 0.3% Suspension	NF	--	--	
		Nevanac 0.1 % Suspension	NF	--	--	
Antibiotics	Azithromycin (AzaSite)	AzaSite 1% solution	NF	--	--	
	Bacitracin	500 units/gram ointment	--	--	--	
	Besifloxacin (Besivance)	Besivance 0.6% suspension	NF	--	--	
	Ciprofloxacin (Ciloxan)	Ciloxan 0.3% ointment	NF	--	--	
		0.3% solution	--	\$13.04	--	
	Erythromycin	0.5% ointment	--	\$15.04	--	
	Gatifloxacin (Zymar)	0.5% solution	--	--	--	
	Gentamicin (Garamycin, Gentak)	0.3% ointment	--	\$16.33	--	
		0.3% solution	--	\$4.72	--	
	Levofloxacin	0.5% solution	NF	--	--	
	Ofloxacin (Ocuflox)	0.3% solution	--	\$13.81	--	
	Sulfacetamide (Bleph-10)	10% Ointment	--	\$49.45	--	
		10% Solution	--	\$43.54	--	
	Tobramycin (Tobrex)	Tobrex 0.3% Ointment	--	\$197.71	--	
		0.3% Solution	--	\$12.24	--	
	Combination Products					
		Bacitracin/Polymyxin B (Polycin)	500units/10,000 units Ointment	--	\$22.38	--
		Bacitracin/Polymyxin/Neomycin (Neo-Polycin)	400units/10,000units/3.5 mg Ointment	--	\$54.53	--
		Bacitracin/Polymyxin/Neomycin/HC (Neo-Polycin HC)	400units/10,000units/3.5 mg/1% Ointment	--	\$43.08	--
		Gentamicin/Prednisolone (Pred-G)	0.3%-0.6% Ointment	--	--	--
			0.3%-1% Suspension	--	--	--
		Neomycin/Polymyxin/Dexamethasone (Maxitrol)	3.5mg-10,000 Units/0.1% Ointment	--	\$16.54	--
	3.5mg-10,000 Units/0.1% Solution		--	\$16.15	--	
	Neomycin/Polymyxin B/Gramicidin (Neosporin)	1.75mg/10,000 units/0.025 mg solution	--	\$41.36	--	
	Neomycin/Polymyxin/HC (Cortisproin)	3.5mg-400-10,000 U-10mg/ml Suspension	--	\$113.77	--	

	Polymyxin B/Trimethoprim (Polytrim)	10,000 units/1 mg solution	--	\$9.48	--
	Tobramycin/ Dexamethasone (Tobradex)	0.3%-01% Ointment	--	\$197.71	--
		0.3%-0.1% Solution	--	\$85.36	--
	Tobramycin/Loteprednol (Zylet)	Zylet 0.5-0.3% Suspension	NF	--	--
	Sulfacetamide/Prednisolone Acetate (Blephamide SOP, Blephamide)	10%-0.23% Solution	-	\$22.67	--
		Blephamide 10%-0.2% Suspension	--	\$192.64	--
		Blephamide S.O.P. 10-0.2% Ointment,	--	\$93.79	--
Antifungals	Natamycin (Natacyn)	5% suspension	--	--	--
Antivirals	Trifluridine (Viroptic)	1% solution	--	\$120.39	--
	Ganciclovir (Zirgan)	0.15% Gel	NF	--	--
H1-Antagonists	Alcaftadine (Lastacaft)	0.25% Solution	NF	--	--
	Emedastine (Emadine)	0.05% Solution	NF	--	--
Mast-cell Inhibitors	Cromolyn Sodium (Opticrom)	4% Solution	--	\$19.27	--
	Lodoxamide (Alomide)	0.1% solution	NF	--	--
	Nedocromil (Alocril)	2% Solution	--	--	--
H1-Antagonist/ Mast-cell Inhibitors	Azelastine (Optivar)	0.05% Solution	ST	\$61.39	Step therapy to Ketotifen
	Bepotastine (Bepreve)	1.5% solution	NF	--	--
	Epinastine (Elestat)	0.05% Solution	Nf	--	--
	Ketotifen (Alaway, Zaditor)	0.025% Solution	QL	\$7.55	Limit 10 ml per month
	Olopatadine (Pataday, Patanol, Pazeo)	0.1% Drops	PA,QL	\$85.20	Reserved for treatment failure to Azelastine AND either Ketotifen or Naphcon-A. Limit 5ml per 30
		0.2% Drops	NF	\$128.65	--
		Pataday 0.2% Drops	NF	\$199.33	--
Pazeo 0.7% solution		NF	\$196.86	--	
Calcineurin Inhibitor	Cyclosporine (Restasis)	0.05% Dropperette	PA	\$429.62	Reserved for treatment failure to ophthalmic lubricants
		0.05% drops	PA	--	Reserved for treatment failure to ophthalmic lubricants
LFA-1 Antagonist	Lifitegrast (Xiidra)	5% solution	NF	\$446.79	--
Ophthalmic Lubricants and Irrigations	Hydroxypropyl Cellulose (Lacrisert)	5 mg insert	NF	--	--
	Propylene Glycol/Peg 400 (Systane, Lubricant Eye)	0.4%-0.3% drops, preservative free dropperettes	--	\$19.28	--
	Glycerin/Propylene Glycol (Advanced Eye Relief, Artificial Tears)	Artificial Tear Drops 0.1%-0.3%	--	\$3.54	--
	Petrolatum/Mineral Oil (Lubricant Eye)	42.5%-57.3% ointment	--	\$6.40	--

	Carboxymethylcellulose (Gen Teal, Refresh Optive, Tears Again)	0.25%, 1%, 1.5% gel 0.7% liquid 0.25%, 1% Solution	NF	--	--	
		0.5% drops, droperettes	--	--	--	
		Refresh Liquigel 1% gel Drops	--	\$9.23	--	
	Carboxymethylcellulose/Glycerin (Refresh Optive, Refresh Tears)	0.5%-0.9% drops, droperettes	--	--	--	
	Hypromellose (Pure and Gentle Eye Drops)	0.3% drops	--	--	--	
	Dextran 70/Hypromellose (Artificial tears)	0.1%-0.3%	--	\$5.73	--	
	Peg 400/Hypromellose/Glycerin (Artificial Tears)	1%-0.2%-0.2% drops	--	--	--	
	Polyvinyl Alcohol (Hypo Tears, Liqui Tears, Murine Tears, Tears Again)	1.4% drops	--	\$2.86	--	
	Vaso-constrictors	Naphazoline (Clear Eyes Redness Relief, VasoClear)	0.125%, 0.02%, 0.03%, 0.5% Solution	NF	--	--
			0.1% Solution	--	\$5.72	--
		Oxymetazoline (Visine-LR)	0.025 % solution	NF	--	--
		Phenylephrine (Altafrin, Mydrfrin, Neofrin)	2.5% Solution	--	--	--
			10% Solution	--	--	--
Tetrahydrozoline (Eye Drops, Opti-Clear)		0.05% Solution	NF	--	--	
Combination Products						
	Naphazoline/Pheniramine (Naphcon-A, Opcon-A, Visine-A)	0.025%-0.3% Solution	--	\$7.44	--	
		0.027%-0.315% solution	--	--	--	
Topical Anesthetic	Lidocaine (Akten)	3.5% Gel	NF	--	--	
	Proparacaine	0.5% Solution	--	\$31.34	--	
	Tetracaine (Altacaine, Tetcaine, TetraVisc, TetraVisc Forte)	0.5% Solution	NF	--	--	
	Combination Products					
	Proparacaine/Fluorescein (Flucaeine)	0.25%-0.5% Solution	NF	--	--	

Otic Agents					
Antibiotics	Ciprofloxacin (Cetraxal, Otiprio)	0.2% Solution	NF	--	--
		Otiprio 6% Intratympanic suspension	NF	--	--
	Ofloxacin (Floxin Otic)	0.3% solution	--	\$17.98	--
	Combination Products				
	Neomycin/Polymyxin B/HC (Cortisporin Otic)	3.5mg-10,000 Units/1% Solution	--	\$46.85	--

		3.5mg-10,000 Units-1% Suspension	--	\$50.59	--
	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%-1.7% Suspension	PA	\$191.07	Reserved for treatment failure to Ofloxacin and Neomycin/Polymyxin/HC in the last 30 days.
	Neomycin/colistin/HC/thonzonium (Coly-Mycin S, Cortisporin TC)	0.33%-0.3%-1%-0.05% Suspension	NF	--	--
	Acetic Acid (Vosol)	2% Solution	--	\$16.25	--
	Combination Products				
Anti-Infectives	Acetic Acid/Aluminum Acetate	2% solution	--	\$61.22	--
	Acetic Acid/Hydrocortisone	1%-2% solution	--	--	--
	Cresyl Acetate (Cresylate)	Cresylate 25% solution	NF	--	--
	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 HSPJ Medical Review Guidelines (UM06).

Ophthalmic Corticosteroids
<i>Dexamethasone (Maxidex, Ozurdex), Difluprednate (Durezol), Fluorometholone (Flarex, FML Forte, FML Liquifilm, FML SOP), Loteprednol (Lotemax, Alrex), Prednisolone (Omnipred, Pred Forte, Pred Mild), Rimexolone (Vexol), Triamcinolone (Triesence)</i>

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

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

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 (Ocufen), Ketorolac (Acular LS, Acular), Nepafenac (Ilevro, Nevanac)

Diclofenac, Flurbiprofen (Ocufen), 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

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

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

Bacitracin/Polymyxin B (Polycin), Bacitracin/Polymyxin/Neomycin (Neo-Polycin), Bacitracin/Polymyxin/Neomycin/HCl (Neo-Polycin HCl), Gentamicin/Prednisolone (Pred-G), Neomycin/Polymyxin/Dexamethasone (Maxitrol), Neomycin/Polymyxin/Gramicidin (Neosporin), neomycin/Polymyxin/HCl, 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 H₁-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 (Alocril)

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 H₁-Antagonist/ Mast-cell Inhibitors

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

Azelastine (Optivar), Ketotifen (Alaway, Zaditor), Opatadine 0.1%

- Coverage Criteria:** Optivar is step therapy to Ketotifen drops; Olopatadine 0.1% is reserved for treatment failure to Azelastine **AND** either Ketotifen or Naphcon-A
- Limits:** Ketotifen is limited to 10 ml per month; Olopatadine 0.1% is limited to 5 ml per month
- Required Information for Approval:** Fill history of Ketotifen in the last 30 days for Azelastine request; Clinical documentations indicating treatment failure to Azelastine **and** Ketotifen or Napcon-A
- Non-Formulary:** Bepreve, Elestat, Olopatadine 0.2%, Pataday (0.2%), Pazeo (0.7%)

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 droperettes), Glycerin/Propylene Glycol (0.1%-0.3%), Petrolatum/Mineral Oil (42.5%-57.3%) ointment, Carboxymethylcellulose (0.5% drops, droperettes, and 1% gel drops), Carboxymethylcellulose/glycerin (0.5%-0.9% drops and droperettes), 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

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 reserved for treatment failure to Ofloxacin and Neomycin/Polymyxin/HC in the last 30 days.
- Limits:** None
- Required Information for Approval:** Clinical documentation of treatment failure or intolerance to Ofloxacin and/or Neomycin/Polymyxin/HC.
- 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
<i>Acetic Acid (Vosol) Acetic Acid/Aluminum Acetate (Borofair), Acetic Acid/Hydrocortisone, Cresyl Acetate (Cresylate)</i>

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
<i>Fluocinolone (DermOtic)</i>
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 2013 American Academy of Ophthalmology are summarized below¹:

Management of Ocular Inflammatory Disorders¹

Type	Condition	Treatment Recommendations
Conjunctivitis	Allergic Conjunctivitis	<ul style="list-style-type: none"> Remove source of irritation OTC topical antihistamine/vasoconstrictor eye drops 2nd generation topical antihistamine eye drops Antihistamine + mast-cell stabilizers If symptoms not resolved, may utilize 1-2 weeks of topical corticosteroid +/- topical NSAIDs
	Vernal/Atopic Conjunctivitis	<ul style="list-style-type: none"> Remove source of irritation Cool compresses and ocular lubricants Topical and oral antihistamines +/- topical mast cell stabilizers For acute exacerbations, topical corticosteroids are used to control severe symptoms +/- topical cyclosporine
	Adenoviral Conjunctivitis	<ul style="list-style-type: none"> Usually self-limiting and do not require treatment

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

Management of Acute Otic Inflammatory Disorders

Acute Otitis Externa

Topical antimicrobials or antibiotics such as acetic acid, aminoglycosides, polymyxin B, and quinolones are the treatment of choice in uncomplicated acute otitis externa. There is no literature that suggests any one antimicrobial or antibiotic preparation is clinically superior to another. If the tympanic membrane is intact (hypersensitivity to aminoglycosides is not a concern), neomycin/polymyxin B/hydrocortisone otic preparation

would be a first-line therapy because of its cost-effectiveness. Ofloxacin and ciprofloxacin/dexamethasone (Ciprodex) are approved for middle ear use and should be used if the tympanic membrane is not intact or its status cannot be determined visually. The addition of corticosteroids may help resolve symptoms more quickly. Systemic antibiotics should only be used when the infection has spread beyond the ear canal.²

Acute Otitis Media (AOM)

- ❑ Systemic high-dose amoxicillin is first-line therapy unless amoxicillin was given within the last 30 days or patient is allergic to amoxicillin. Alternative regimens to patients with penicillin allergy includes: cefdinir, cefuroxime, or cefpodoxime. In patients who've tried and failed amoxicillin, amoxicillin/clavulanate or ceftriaxone is recommended.³
- ❑ Lifitegrast (Xiidra) is a recently approved medication for the treatment of signs and symptoms of dry eyes in July 2016. Thus far, there have been three randomized controlled trials investigating the clinical efficacy and safety of lifitegrast in populations ranging from mild to severe symptoms.⁴ The studies conducted were compared to placebo and showed clinical efficacy of lifitegrast ophthalmic solution for the treatment of dry eyes. The most common side effects included eye irritation/discomfort.⁵ Given that lifitegrast (Xiidra) confers no additional benefit compared to formulary alternatives cyclosporine (Restasis) and ophthalmic lubricants, Xiidra is non-formulary.

☒ REFERENCES

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3. Lieberthal AS, Carroll AE, Chonmaitree T, et al. Clinical Practice Guideline: The diagnosis and management of otitis media. Pediatrics. 2013; 131(3): 964-999.
4. Holland EJ, Whitley WO, Sall K, et al. Lifitegrast clinical efficacy for treatment of signs and symptoms of dry eye disease across three randomized controlled trials. Curr Med Res Opin. 2016;:1-7.
5. Sheppard JD, Torkildsen GL, Lonsdale JD, et al. Lifitegrast ophthalmic solution 5.0% for treatment of dry eye disease: results of the OPUS-1 phase 3 study. Ophthalmology. 2014;121(2):475-83.
6. U.S. Food And Drug Administration. *FDA takes action against unapproved prescription ear drop products*: FDA News realses July 1. 2015.

☒ 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

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

Recommended changes were approved by P&T Committee during 9/12/17 Meeting.