Calendar Year 2011 Annual Review of Glaucoma Products

Oklahoma HealthCare Authority

April 2012

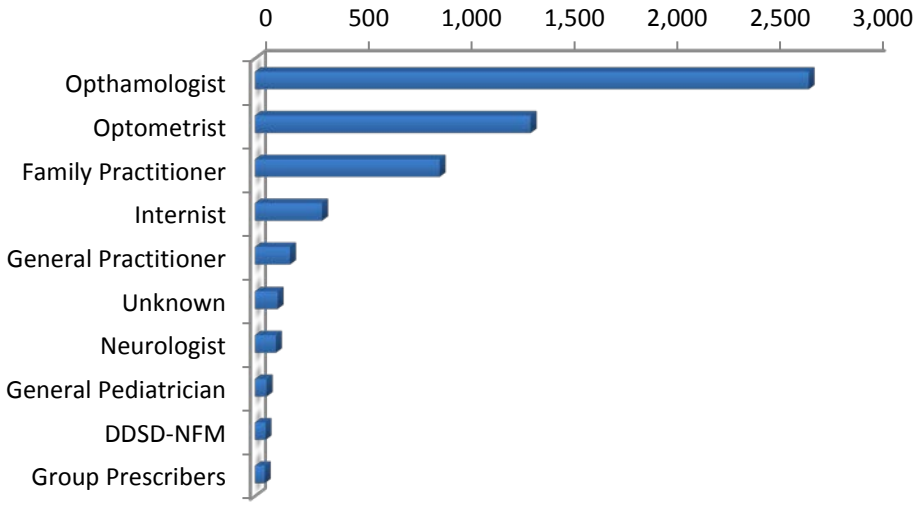
Current Prior Authorization Criteria

- FDA approved diagnosis.
- Member must attempt at least one Tier-1 trial of a minimum of 4 weeks duration within the last 90 days. Tier-1 trial may be from any pharmacologic class.
- Approval may be granted if there is a documented adverse effect, drug interaction, or contraindication to Tier-1 products.
- Approval may be granted if there is a unique FDA approved indication not covered by Tier-1 products.
- Member must have had a comprehensive dilated eye exam within the last 365 day period as recommended by the National Institute of Health.
- Approval duration will be for 1 year.

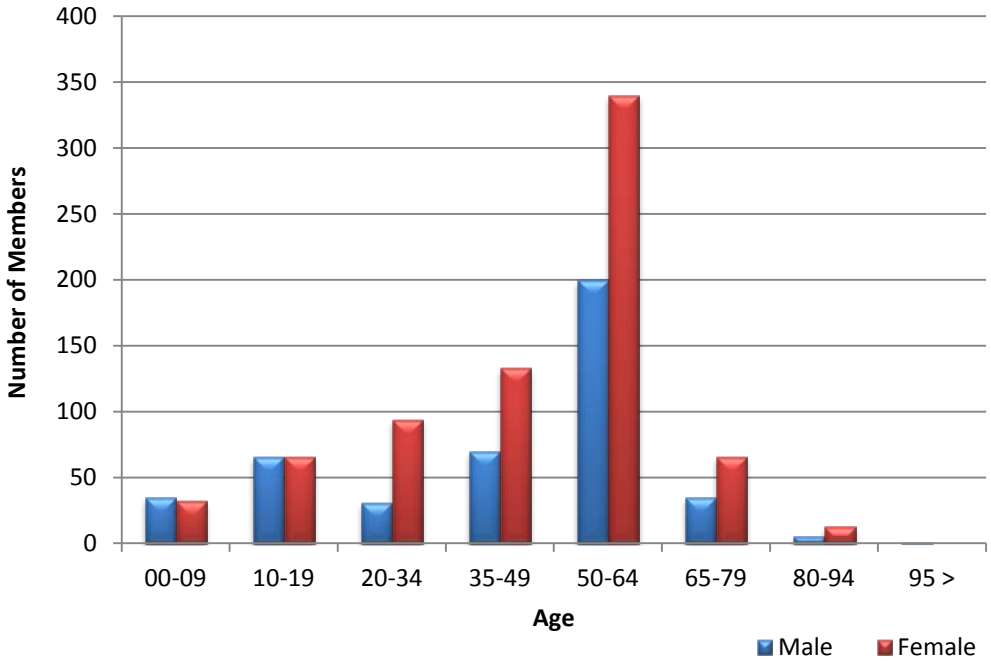
Utilization Comparison: Fiscal Year 2010 and 2011

Fiscal Year	Total Members	Total Claims	Total Paid	Paid/ Claim	Per-Diem	Total Units	Total Days
2010	1,179	5,874	$485,241.53	$82.61	$2.81	71,915	172,389
2011	1,189	5,998	$478,330.72	$79.75	$2.64	78,667	181,104
% Change	**0.80%**	**2.10%**	**-1.40%**	**-3.50%**	**-6.00%**	**9.40%**	**5.10%**
Change	**10**	**124**	**($6,910.81)**	**($2.86)**	**($0.17)**	**6,752**	**8,715**

Prescribers of Glaucoma: Calendar 2011



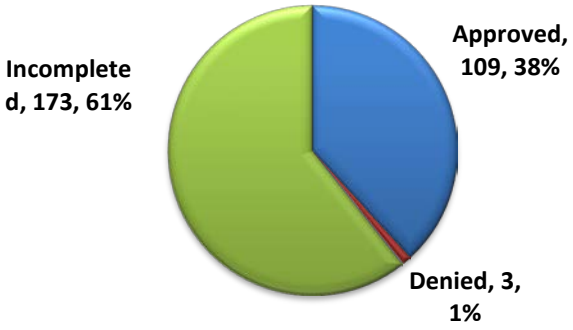
Demographics Calendar 2011



Prior Authorization Totals

There were a total of 285 petitions submitted for this PBPA category during calendar year 2011. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Update

- Tafluprost(Zioptan®) 0.0015% ophthalmic solution was approved by the FDA on February 2012 for ocular hypertension and open-angle glaucoma. It is the first preservative-free prostaglandin analog ophthalmic solution.
- Effective 3/30/11, generic Xalatan bottle cost is ~$12.
- Anticipated patent expiration:
  - Azopt 4/13,
  - Travatan Z 12/14,

- Lumigan 0.03% 9/12-8/14,
- Lumigan 0.01% 9/12-6/27,
- Alphagan P 12/12-1/22,
- Combigan 4/22-1/23.

Recommendations

The college of pharmacy recommends Zioptan® to be added to Tier-2 and Xalatan to be moved to tier-1.

Ophthalmic Glaucoma Medications	
Tier-1 (no PA required)	**Tier-2 (requires PA)**
Beta-Blockers	
betaxolol (Betoptic® 0.5%)	betaxolol (Betoptic-S®)
carteolol (Ocupress®)	brimonidine/timolol (Combigan®)
dorzolamide/timolol (Cosopt®)	timolol maleate (Timoptic® 0.5% dropperette)
levobunolol (Betagan®)	
metipranolol (OptiPranolol®)	
timolol maleate (Betimol®, Istalol®, Timoptic®, Timoptic Ocudose®, Timoptic-XE®)	
Prostaglandin Analogs	
travoprost (Travatan®, Travatan-Z®)	bimatoprost (Lumigan®)
latanoprost (Xalatan®)	**tafluprost (Zioptan®)**
Adrenergic Agonists	
dipivefrin (Propine®)	
Alpha-2 Adrenergic Agonists	
*brimonidine 0.2%	brimonidine (Alphagan-P® 0.1%, 0.15%)
	apraclonidine (Iopidine® 1%)
Carbonic Anhydrase Inhibitors	
dorzolamide/timolol (Cosopt®)	brinzolamide (Azopt®)
acetazolamide (Diamox®)*	
dichlorphenamide (Daranide®)*	
methazolamide (Neptazane®)*	
dorzolamide (Trusopt®) **(moved T1 12/2011 generic)**	
* (Indicates Available Oral Products)	
Cholinergic Agonists/Cholinesterase Inhibitors	
pilocarpine (Isopto Carpine®, Pilopine HS®, 0.5%, 1%, 2%, 4%, 6%)	carbachol (Isopto®, Miostat® 1.5%, 3%)
	*echothiophate iodide (Phospholine Iodide®)

Utilization Details of Glaucoma Medications for Calendar Year 2011

GENERIC NAME	BRAND NAME	CLAIMS	DAYS	MEMBERS	COST	CLAIMS/ MEMBER	COST/ DAY	PERCENT COST
Travoprost	TRAVATAN Z DRO 0.004%	1,738	50,524	480	$197,969.35	3.62	$3.92	41.39%
Latanoprost	LATANOPROST SOL 0.005%	660	19,530	167	$11,976.33	3.95	$0.61	2.50%
Dorzolamide -Timolol	DORZOL/TIMOL SOL 2-0.5%OP	449	15,049	134	$22,473.57	3.35	$1.49	4.70%
Timolol Maleate	TIMOLOL MAL SOL 0.5% OP	378	13,356	158	$3,470.04	2.39	$0.26	0.73%
Brimonidine -Timolol	COMBIGAN SOL 0.2/0.5%	342	9,352	77	$33,033.48	4.44	$3.53	6.91%
Bimatoprost	LUMIGAN SOL 0.03%	315	10,964	82	$46,350.31	3.84	$4.23	9.69%
Brimonidine	BRIMONIDINE SOL 0.2% OP	293	8,226	103	$4,703.66	2.84	$0.57	0.98%
Latanoprost	XALATAN SOL 0.005%	207	6,166	112	$21,352.96	1.85	$3.46	4.46%
Brimonidine Tartrate	BRIMONIDINE SOL 0.15%	190	4,962	42	$19,869.62	4.52	$4.00	4.15%
Brinzolamide	AZOPT SUS 1% OP	162	5,482	46	$18,589.27	3.52	$3.39	3.89%
Brimonidine Tartrate	ALPHAGAN P SOL 0.1%	143	4,135	40	$15,026.46	3.58	$3.63	3.14%
Dorzolamide HCl	DORZOLAMIDE SOL 2% OP	93	2,983	28	$3,053.02	3.32	$1.02	0.64%
Timolol Maleate	TIMOLOL GEL SOL 0.5% OP	82	2,519	29	$3,409.24	2.83	$1.35	0.71%
Brimonidine Tartrate	ALPHAGAN P SOL 0.15%	69	1,972	14	$8,313.73	4.93	$4.22	1.74%
Bimatoprost	LUMIGAN SOL 0.01%	69	2,273	20	$7,927.64	3.45	$3.49	1.66%
Timolol Maleate	TIMOLOL MAL SOL 0.25% OP	59	1,919	13	$409.19	4.54	$0.21	0.09%
Levobunolol HCl	LEVOBUNOLOL SOL 0.5% OP	33	885	8	$502.50	4.13	$0.57	0.11%
Betaxolol HCl	BETOPTIC-S SUS 0.25% OP	16	646	6	$2,395.71	2.67	$3.71	0.50%
Timolol	BETIMOL SOL 0.5%	11	620	4	$1,219.44	2.75	$1.97	0.25%
Pilocarpine HCl	PILOCARPINE SOL 1% OP	10	404	7	$166.68	1.43	$0.41	0.03%
Pilocarpine HCl	PILOCARPINE SOL 4% OP	7	247	2	$195.41	3.5	$0.79	0.04%
Travoprost	TRAVATAN DRO 0.004%	7	162	6	$817.94	1.17	$5.05	0.17%
Timolol	BETIMOL SOL 0.25%	6	164	3	$289.26	2	$1.76	0.06%
Levobunolol HCl	LEVOBUNOLOL SOL 0.25% OP	6	72	1	$57.91	6	$0.80	0.01%
Dorzolamide -Timolol	COSOPT SOL 2-0.5%OP	6	360	1	$1,479.60	6	$4.11	0.31%
Timolol Maleate	TIMOLOL GEL SOL 0.25% OP	5	230	2	$153.03	2.5	$0.67	0.03%
Echothiophate Iodide	PHOSPHOLINE SOL 0.125%OP	4	60	2	$299.28	2	$4.99	0.06%
Pilocarpine HCl	PILOCARPINE SOL 2% OP	3	105	2	$71.10	1.5	$0.68	0.01%
Betaxolol HCl	BETAXOLOL SOL 0.5% OP	3	130	2	$222.24	1.5	$1.71	0.05%
Timolol Maleate	ISTALOL SOL 0.5% OP	1	25	1	$149.89	1	$6.00	0.03%
Acetazolamide	ACETAZOLAMID TAB 125MG	41	1,352	8	$1,468.22	5.13	$1.09	0.31%
Acetazolamide	ACETAZOLAMID TAB 250MG	348	9,686	110	$11,009.33	3.16	$1.14	2.30%
Acetazolamide	ACETAZOLAMID CAP 500MG ER	164	4,428	65	$32,956.71	2.52	$7.44	6.89%
Acetazolamide	DIAMOX SEQUE CAP 500MG CR	8	192	4	$1,893.95	2	$9.86	0.40%
Methazolamide	METHAZOLAMID TAB 25MG	22	485	8	$229.05	2.75	$0.47	0.05%
Methazolamide	METHAZOLAMID TAB 50MG	48	1,439	12	$4,825.60	4	$3.35	1.01%
TOTAL		**5,998**	**181,104**	***1,189**	**$478,330.72**	**5.04**	**$2.64**	**100%**

*Total number of unduplicated members

PRODUCT DETAILS OF ZIOPTAN™ (TAFLUPROST OPHTHALMIC SOLUTION)
FDA-APPROVED IN FEBRUARY 2012

INDICATIONS:

- Elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

DOSAGE FORMS:

- Zioptan™ is supplied as an ophthalmic solution containing tafluprost 0.015 mg/mL.

ADMINISTRATION:

- The recommended dose is one drop of Zioptan™ in the conjunctival sac of the affected eye(s) once daily in the evening.
- The dose should not exceed once daily since it has been shown that more frequent administration of prostaglandin analogs may lessen the intraocular pressure lowering effect.
- Reduction of the intraocular pressure starts approximately 2 to 4 hours after the first administration with the maximum effect reached after 12 hours.
- Zioptan™ may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic product is being used, each one should be administered at least 5 minutes apart.

CONTRAINDICATIONS:

- None.

SPECIAL POPULATIONS:

- **Pregnancy:** Pregnancy Category C. In embryo-fetal development animal studies, tafluprost administered intravenously was teratogenic. Tafluprost caused increases in post-implantation losses and reductions in fetal body weights. Tafluprost also increased the incidence of vertebral skeletal abnormalities and the incidence of skull, brain and spine malformations. There are no adequate and well-controlled studies in pregnant woman. Although animal reproduction studies are not always predictive of human response, Zioptan™ should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Women of childbearing age/potential should have adequate contraceptive measures in place.

- **Nursing Mothers:** A study in lactating rats demonstrated that radio-labeled tafluprost and/or its metabolites were excreted in milk. It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Zioptan™ is administered to a nursing woman.

- **Pediatrics**: Use in pediatric patients is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

- **Geriatrics:** No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

WARNINGS AND PRECAUTIONS:

- **Pigmentation:** Tafluprost ophthalmic solution has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelid) and eyelashes. Pigmentation is expected to increase as long as tafluprost is administered. After discontinuation of tafluprost, pigmentation of the iris is likely to

be permanent, while pigmentation of the periorbital tissue has been reported to be reversible in some patients. The long-term effects of increased pigmentation are not known. Iris color change may not be noticeable for several months to years. While treatment with Zioptan™ can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

- **Eyelash changes:** Zioptan™ may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, color, thickness, shape and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment.

- **Intraocular Inflammation:** Zioptan™ should be used with caution in patients with active intraocular inflammation (e.g., iritis/uveitis) because the inflammation may be exacerbated.

- **Macular edema:** Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin F2α analogs. Zioptan™ should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

ADVERSE REACTIONS:

- **Common adverse reactions:** The most commonly observed adverse reaction associated with the use of tafluprost was conjunctival hyperemia.

- **Other adverse reactions:** Stinging/irritation, ocular pruritis including allergic conjunctivitis, cataract, drye eye, ocular pain, eyelash darkening, growth of eyelashes, blurred vision, headache, common cold, cough, urinary tract infection, and lid changes including deepening of the eyelid sulcus.

DRUG INTERACTIONS:

- None.

PATIENT COUNSELING INFORMATION:

- Patients should be advised to not exceed once daily dosing since more frequent administration may decrease the intraocular pressure lowering effect of tafluprost.

- Patients should be advised that tafluprost is a sterile solution that does not contain a preservative. The solution from one individual unit is to be used immediately after opening. Since sterility cannot be maintained after the individual unit is opened, the remaining contents should be discarded immediately after administration.

- Patients should be advised about the potential for increased brown pigmentation of the iris, which may be permanent. Patients should also be informed about the possibility of eyelid skin darkening, which may be reversible after discontinuation of tafluprost.

- Patients should also be informed of the possibility of eyelash and vellus hair changes in the treated eye during treatment with tafluprost. These changes may result in a disparity between eyes in length, thickness, pigmentation, number of eyelashes or vellus hairs, and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.
- Patients should be advised that if they develop a new ocular condition (eg, trauma or infection), experience a sudden decrease in visual acuity, have ocular surgery, or develop any ocular

reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their health care provider's advice concerning the continued use of tafluprost.

- If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes between applications.

REFERENCES:

1. Zioptan™ Prescribing Information. Zioptan™ (tafluprost ophthalmic solution) 0.0015%. Merck & Co., Inc. Available online at: http://zioptan.com/zioptan/hcp/secure/index.html. Last revised: February 2012; Accessed Mar 8, 2012.