Pharmacy Policy Bulletin

Title: Tafluprost (Zioptan)
Policy #: Rx.01.123

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:
Tafluprost is approved for reducing elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

The use of Tafluprost (Zioptan) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

Description:
Tafluprost belongs to a group of drugs classified as selective FP prostanoidreceptor agonists. The pharmacologic activity of tafluprost is hypothesized to be comparable with other prostaglandin analogues.

Tafluprost is a fluorinated analogue of prostaglandin F2alpha. Corneal esterases rapidly convert tafluprost into its active metabolite, tafluprost acid, and subsequently penetrate into the anterior chamber of the eye. Studies have indicated that tafluprost has potent and selective agonistic activity of the human prostanoid FP receptor, with minimal activity at other receptors. It has been reported to have 2.8- to 12-times greater affinity to the prostanoid FP receptor compared with latanoprost. Tafluprost lowers IOP by stimulating the increase of aqueous humor outflow through the uveoscleral passage.

Policy:
Tafluprost (Zioptan) is approved when all of the following inclusion criteria are met:

- Documentation of a trial and failure/contraindication/intolerance/allergy to Latanoprost
- Documentation of a trial and failure/contraindication/intolerance/allergy to Lumigan or Travatan Z

Guidelines:
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company’s products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:
Zioptan [package insert]. Whitehouse Station, NJ: Merck & Co Inc; February 2012.


Schnober D, Hofmann G, Maier H, Scherzer ML, Ogundele AB, Jasek MC. Diurnal IOP-lowering efficacy and safety of travoprost 0.004% compared with timolol 0.0015% in patients with primary open-angle glaucoma or ocular hypertension. *Clin Ophthalmol*. 2010; 4:1459-1463.


Merck announces FDA acceptance of new drug application for investigational ophthalmic medication SAFLUTAN.
Applicable Drugs:
Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zioptan</td>
<td>Tafluprost</td>
</tr>
</tbody>
</table>

Cross References: