CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

Description:

DuoTravTM ophthalmic solution is a fixed dose combination of travoprost and timolol maleate that is approved for the treatment of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers, prostaglandins, or other IOP lowering agents and when the use of the fixed combination drug is considered appropriate.

Dosage Forms:

Ophthalmic solution containing travoprost 0.004% and timolol 0.5%

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that DuoTravTM ophthalmic solution be listed for use in patients who have not adequately responded to ophthalmic beta blocker drugs.

Reasons for the Recommendation:

- 1. The Committee reviewed two randomized controlled trials of three months duration which compared the fixed dose combination of travoprost 0.004%/timolol 0.5% given as one drop daily in the morning, with concomitant administration of timolol 0.5% (one drop daily in the morning) and travoprost 0.004% (one drop daily in evening). One trial included a comparison with timolol 0.5% given in the morning and evening. All regimens, including the timolol BID, achieved clinically significant reductions in IOP from baseline. The combination of travoprost and timolol, either as the fixed dose combination or given separately, produced statistically significant greater reductions in IOP compared to timolol alone.
- 2. There is no evidence of any difference in the incidence or nature of adverse effects with the fixed dose combination of travoprost/timolol versus the concomitant use of each agent alone.
- 3. The monthly drug cost of DuoTrav[™] is approximately \$20.00 compared with \$25.00 for the concomitant use of travoprost and timolol.

Of Note:

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.