19th Expert Committee on The Selection and Use of Essential Medicines

April 8-12 2013

Expert peer review on application for adding latanoprost under ophthalmological preparations

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      No (if no, please provide reference and information)

   The review has given only older references of clinical trials. There have been a number of clinical trials that have proved the efficacy of once daily latanoprost in open angle glaucoma. W Y Zhang, A Li Wan Po, H S Dua, A Azuara-Blanco. Meta-analysis of randomised controlled trials comparing latanoprost with timolol in the treatment of patients with open angle glaucoma or ocular hypertension. Br J Ophthalmol 2001;85:983-990

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   Latanaoprost is more effective than timolol in open angle glaucoma. There is also the added consideration of once daily administration.

   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      No (if no, please provide reference and information)


   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   The main adverse effect is iris pigmentation which is seen in 12% of patients with light coloured irises and occurs with long term use. It is seen in 18% of the patients when used for two years. Other adverse effects are mild, not very common and does not lead to stoppage of treatment.

   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on cost been provided
      Yes
b. Summarize the data on cost and cost effectiveness, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

Latanoprost is more expensive than timolol. However, the generic version of the drug is available which has been shown to be equivalent to the branded version.

c. Please provide any additional relevant information with reference.

d. Is the product available in several low and middle income countries?

Yes

4. Assessment of public health need
a. Please provide the public health need for this product (1-2 sentences)

Glaucoma is the second leading cause of blindness globally and accounts for 12% of the total blindness.

b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable

NICE clinical guidelines (April 2009) on glaucoma does not list latanoprost specifically but states to “offer people newly diagnosed with early or moderate chronic open angle glaucoma, and at risk of significant visual loss in their lifetime, treatment with a prostaglandin analogue”

5. Are there special requirements for use or training needed for safe/effective use?
If yes, please provide details in 1-2 sentences

Treatment should be started by an ophthalmologist and after starting intra ocular pressure should be checked at regular intervals.

6. Is the proposed product registered by a stringent regulatory authority?
Yes. It has been approved by US FDA.

7. Any other comments

Latanoprost is efficacious and safe in the treatment of chronic open angle glaucoma. It is licensed for use, quality standards are in place and has been used for quite a long time with good success. It is also convenient for the patient, with once daily dosing. The only disadvantage is its cost when compared to timolol. In India latanoprost costs around 6-8 USD and timolol around 2 USD.

8. What is your recommendation to the committee (please provide the rationale)

Latanoprost should be added to the EML in the complementary list under ophthalmological preparations. This is now the drug of first choice in chronic open angle glaucoma and should be listed in the EML. It is desirable to place it in the complementary list due to its cost factor.