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

April 8-12 2013

Expert peer review on glibenclamide vs gliclazide, glipizide and glimepiride in the elderly.

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
   No
   1. Bollen S et al. Comparative efficacy and safety of oral diabetic medications for patients with Type 2 Diabetes AHRQ Publication No07 - EHC010- EF July 2007 Comparative effectiveness review No. 8
      A metanalysis done by these reviewers showed that there was no difference in the efficacy of Glibenclamide in reducing HbA1c as compared to Gliclazide, Glipizide and Glimepiride
      In this unblinded trial, Gliclazide was significantly better in reducing HbA1c than Glipizide
      In this study once daily sustained release Gliclazide was shown to be as effective as Glimepiride in reducing HbA1c.
   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      On metanalysis, Glibenclamide was not superior to Gliclazide, Glipizide and Glimepiride in reducing HbA1c. Gliclazide was significantly better in reducing HbA1c than Glipizide in 1 unblinded trial. Gliclazide is as effective as Glimepiride in reducing HbA1c.
   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      No, Study No 3 (above)
      This randomized controlled study showed that hypoglycaemia with blood glucose level < 3 mmol L(-1) occurred significantly less frequently (P = 0.003) with gliclazide sustained release (3.7% of patients) compared with glimepiride (8.9% of patients).
   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      Gliclazide causes significantly less hypoglycaemia events than both Glibenclamide and Glimepiride.
   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on safety 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)

Gliclazide is slightly more expensive than Glibenclamide on the MSH drug price list. There are no data on cost effectiveness.

c. Please provide any additional relevant information with reference

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

According to the WHO 2010 report, 8 – 10% of the world population suffers from diabetes, with 90 to 95% of the cases being of Type 2 diabetes.

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

Yes

NICE guidelines

5. Are there special requirements for use or training needed for safe/effective use?

No

6. Is the proposed product registered by a stringent regulatory authority?

Yes

7. Any other comments

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

I recommend that Glibenclamide 2.5mg and 5mg tablets remain on the EML with age restriction recommending against use in patients older than 60 years of age.

Gliclazide 80mg tablet should be added to the EML for use in the elderly with type 2 diabetes, with a square box designation so as to indicate that other second general sulfonylureas (other than glibenclamide) are an acceptable alternative

RATIONALE

Gliclazide is as effective as Glibenclamide and Glimepiride and more effective than Glipizide in reducing HbA1c. Gliclazide causes less hypoglycaemia than Glibenclamide and Glimepiride.