(1) Does the application adequately address the issue of the public health need for the medicine?

Yes [x] No [ ]

Please provide brief details:

Uncontrolled diabetes results almost invariably with acute and chronic complications which separately are expensive to manage and carry a high morbidity and mortality.

(2) Have all important studies/evidence of which you are aware been included in the application?

Yes [x] No [ ]

Please provide brief comments on any relevant studies that have not been included:

(3) Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed use?

Yes [x] No [ ]

(a) Briefly summarise the reported benefits (e.g. clinical versus surrogate) and comment, where possible, on the actual magnitude of benefit associated with use of the medicine:

Provides clinically and statistically significant lower fasting plasma glucose and lower risk of minor hypoglycaemia, including nocturnal hypoglycaemia, than NPH human insulin and overall better glycaemic control (HbA1c) in some clinical trials. (PD Home et al, Diabetes Care 2004 May; 27(5): 1081-1087)

However, systematic reviews of these agents (e.g. Singh et. al. CMAJ 2009;180(4):385-97) suggest long-acting insulin analogues offer little benefit relative to conventional insulins in terms of glycemic control or reduced hypoglycemia and long term studies are lacking to shed light on their impact on preventing long term diabetes complications.

(b) Is there evidence of efficacy in diverse settings and/or populations? Please provide brief details:

(4) Has the application adequately considered the safety and adverse effects of the medicine? Are there any adverse effects of concern, or that may require special monitoring?

Yes [x] No [ ]
Please provide brief details:

(5) Please comment on the overall benefit to risk ratio of the medicine (e.g., favourable, uncertain etc).

Favourable
ADDITIONAL CONSIDERATIONS:

(6) Are there special requirements or training needed for the safe, effective and/or appropriate use of the medicine?
- Yes ☐ No ☒

Please provide brief details:

(7) Are there any issues regarding the registration of the medicine by regulatory authorities? (e.g., recent registration, new indications, off-label use)
- Yes ☐ No ☒

Please provide brief details:

Already registered on several markets in high as well as LMICs.

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?
- Yes ☐ No ☒

Please provide brief details:
Recommended in 2015 NICE Guidelines (Published: 26 August 2015 nice.org.uk/guidance/ng17) and ADA Standards of Care 2017

(9) Please comment briefly on issues regarding cost and affordability of this medicine.
Long-acting insulin analogues are more expensive, (Detemir (£407/yr), Glargine (£402/yr) and NPH (£222/yr) from Regional Drug and Therapeutics Centre (Newcastle) October 2016.

(10) Any additional comments?
A paper by Iskandar et al. (Journal of Medical Economics. Volume 18, 2015 - Issue 4), albeit, based on a study in type 2 diabetes patients, looked at the cost differences between insulin analogues and NPH and noted that they were not significantly different after 3 years of treatment when considered from the viewpoint of total healthcare costs. They observed a reduced cost of self-monitoring of blood glucose (SMBG) in the analogue group and an increase in the cost of bolus insulin in the NPH group.

(11) Please frame the decisions and recommendations that the Expert Committee could make.
Recommended for inclusion in EML and EMLc to be considered as an alternative to NPH insulin as basal insulin therapy, particularly when twice daily basal insulin (with NPH) is not acceptable by the patient who is unable to achieve glycaemic targets on the NPH basal-bolus insulin regime.

(12) References (if required)
- Iskandar Idris, Jason Gordon, Carl Tilling & Jiten Vora. A cost comparison of long-acting insulin analogs vs NPH insulin-based treatment in patients with type
Type 1 diabetes in adults: diagnosis and management. NICE guideline [NG17] Published date: August 2015 Last updated: July 2016