Insulin analogues

REJECTED

The Expert Committee, after evaluation, declines to list the medicine proposed in the application.
The Model List of Essential Medicines reports reasons that Committee Members have identified for denying listing.

Section: 18. Medicines for endocrine disorders > 18.5. Medicines for diabetes > 18.5.1. Insulins

EMLc ATC codes: A10AE04 A10AE05 A10AB05 A10AD05 A10AB04 A10AC04 A10AD04 A10AB06 A10AE06

Indication	Type 1 diabetes mellitus ICD11 code: 5A10
Medicine type	Biological agent
List type	Core (EML) (EMLc)
Formulations	Not specified
EML status history	Application rejected in 2011 (TRS 965)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Main patents have expired but secondary patents might remain active in some jurisdictions. For more information on specific patents and license status for developing countries visit www.MedsPal.org Read more about patents.
Wikipedia	Insulin analogues

Summary of evidence and Expert Committee recommendations

As part of the development of WHO advice concerning noncommunicable diseases (for the United Nations summit in September 2011) and diabetes in particular, questions have been raised by low- and middle-income countries about the role of insulin analogues compared to standard recombinant human insulin. The main concern is whether insulin analogues are cost effective or affordable, compared to recombinant human insulin. Some countries are spending significant proportions of the pharmaceutical budget on analogue insulins and at the same time, there are problems with lack of availability of standard recombinant human insulin. Insulins derived from animals are no longer available in most markets. The Secretariat has therefore commissioned a review, prepared by Ms Patti Whyte, of the comparative effectiveness and cost– effectiveness of analogue insulins compared to recombinant human insulin. The products considered are: insulin glargine, insulin detemir, insulin aspart, insulin lispro, and insulin glulisine. Expert reviews were provided by Professor Noël Cranswick and Professor Rohini Fernandopulle. The review updates a published systematic review (1). An additional 35 published trials were identified, 8 of which could be included in an updated meta-analysis. Populations covered in the review include both adults and children with type 1 diabetes and adults with type 2 diabetes. Most studies were carried out in high-income country settings. The outcomes evaluated were standard surrogates for diabetic control (change in HbA1c), severe hypoglycaemic episodes or nocturnal hypoglycaemic episodes, and the risk of malignancy. While many of the comparisons show a statistically significant difference between analogue insulin and standard recombinant human insulin, there is no evidence of a clinically significant difference in most outcomes for the majority of the studies. The Committee noted that the overall quality of evidence is low or of very-low quality for all outcomes for all comparisons. The reasons for downgrading the quality of evidence include limitations in the design of the studies, the potential for reporting bias as well as some inconsistency of results. Comparative cost data were evaluated. The cost–effectiveness estimates vary widely, from €500/QALY to £412 000/QALY, due to very uncertain estimates of the clinical effect as well as variation in costs and resources used in the different models. The Committee considered that the insulin analogues currently offer no clinical advantage over recombinant human insulin and there is still concern about possible long-term adverse effects. References: 1. Singh SR et al. Efficacy and safety

of insulin analogues for the management of diabetes mellitus: A meta-analysis. Canadian Medical Association Journal, 2009, 180(4):385–397.