Insulin (analogue, long-acting)

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

EMLc ATC codes: A10AE06 A10AE05 A10AE04

Indication	Type 1 diabetes mellitus ICD11 code: 5A10
Medicine type	Biological agent
List type	Core
Additional notes	Including quality-assured biosimilars
Formulations	**Parenteral > General injections > SC:** 100 IU per mL in 3 mL cartridge solution ; 100 IU per mL in 3 mL pre-filled pen solution ; 100 IU per mL in 10 mL vial solution
EML status history	Application rejected in 2011 (TRS 965) Application rejected in 2017 (TRS 1006) Application rejected in 2019 (TRS 1021) Added in 2021 (TRS 1035) Changed in 2025 (TRS 1064)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	insulin degludec (ATC codes: A10AE06) insulin detemir (ATC codes: A10AE05) insulin glargine (ATC codes: A10AE04)
Patent information	Patents have expired in most jurisdictions Read more about patents.
Tags	Biological
Wikipedia	Insulin (analogue, long-acting)

Expert Committee recommendation

The Expert Committee recognized the importance of affordable and equitable access to insulin products as a public health priority. The Committee considered that the inclusion of long-acting insulin analogues in 10 mL vials on the Model Lists would provide an additional formulation choice and delivery option for people with diabetes who use these insulins and would be consistent with the current listings for human insulins on the Model Lists. The Committee therefore recommended that the listings for long-acting insulin analogues on the EML and EMLc be extended to include 10 mL vial formulations containing 100 IU/mL. Following the review of the age-appropriateness of formulations on the EMLc, the Expert Committee recommended the medicine description be updated to replace 'Long-acting insulin analogues' with 'Insulin (analogue, long-acting).

Background

The application proposed the addition of 10 mL vial formulations of long-acting insulin analogues (insulin degludec, insulin detemir and insulin glargine) to the core list of the EML and EMLc for the treatment of diabetes. Long-acting insulin analogues were added to the EML and EMLc in 2021 as 3 mL cartridges or prefilled pen formulations containing 100 IU/mL.

Public health relevance

The public health relevance of insulin for the treatment of type 1 and type 2 diabetes mellitus is well established.

Benefits

Evidence for the benefits of long-acting insulin analogues was evaluated in 2021.

Harms

Evidence for the harms of long-acting insulin analogues was evaluated in 2021.

Cost / cost effectiveness

The application reported that limited data were available on price differences between long-acting analogues in vials, prefilled pens and cartridges in low- and middle-income countries. In private pharmacies in Peru in 2022, the median price of 1000 IU of insulin glargine in vials was US$ 47.72 and in prefilled pens was US$ 70.39 (an increase of 48%). Similar findings were found in 2023. In Vietnam in 2022, the median price of 1000 IU of insulin glargine in vials was US$ 22.30 and in prefilled pens was US$ 42.51.

WHO guidelines

The 2018 WHO guidelines on second- and third-line medicines and type of insulin for the control of blood glucose levels in non-pregnant adults with diabetes include a weak recommendation (moderate-quality evidence) to consider using long-acting insulin analogues to control blood glucose levels in adults with type 1 or type 2 diabetes who have frequent severe hypoglycaemia with human insulin (1). In developing the guidelines, studies of comparisons of preferences between various insulin injection devices were excluded. The WHO guidelines for the management of type 1 diabetes in children are expected to be available in 2025.

Availability

Long-acting insulin analogues in 10 mL vials have wide global marketing approval. Insulin glargine in 10 mL vials is prequalified by WHO.

Other considerations

The department of Noncommunicable Diseases, Rehabilitation and Disability reviewed the application and supported the inclusion of long-acting insulin analogue 10 mL vial formulations on the Model Lists.

1. Guidelines on second-and third-line medicines and type of insulin for the control of blood glucose levels in non-pregnant adults with diabetes mellitus. Geneva: World Health Organization; 2018 (https://iris.who.int/handle/10665/272433). Licence: CC BY-NC-SA 3.0 IGO.

