HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
10 JUNE 2020

The legally binding text is the original French opinion version

insulin glargine
TOUJEO 300 U/ml solution for injection

New indication

Key points

Favourable opinion for reimbursement in the treatment of diabetes mellitus in adolescents and children from the age of 6 years.

What therapeutic improvement?

No clinical added value compared to LANTUS (insulin glargine) in the treatment of diabetes mellitus in adolescents and children from the age of 6 years.

Role in the care pathway?

Type 1 diabetes

Children and adolescents with type 1 diabetes require insulin therapy and nutritional management.

There are a number of possible insulin therapy regimens:

- treatment with 2 injections/d: injection of a mixture of fast-acting insulin (or fast-acting analogue) and intermediate-acting insulin,
- treatment with 3, 4 or 5 injections/d: a mixture of fast-acting insulin (or fast-acting analogue) and intermediate-acting insulin is combined with a fast-acting insulin (or fast-acting analogue),

- "basal-bolus" treatment with 3, 4 or 5 injections/d: an intermediate-acting "basal insulin" (twice/d) or a long-acting insulin analogue (once to twice/d) is combined with a fast-acting "prandial insulin" (or fast-acting analogue) injected as a bolus before each of the main meals (3 times/d),
- treatment using a subcutaneous portable pump (continuous infusion with a fixed or variable basic flow rate depending on the time of day or night and bolus at mealtimes). Pump administration requires the use of fast-acting insulin (or fast-acting analogue).

The choice of insulin therapy regimen is dependent on the glycaemic targets for each child and adolescent, their preferences and lifestyle, and those of their family.

Type 2 diabetes

The initial treatment of type 2 diabetes in children and adolescents focuses on lifestyle changes, since type 2 diabetes in children and adolescents is mainly related to being overweight. If these lifestyle changes are not effective, medicinal treatment with metformin (MA in children from 10 years of age and adolescents), and sometimes insulin, may be initiated. In some cases, it may be necessary to temporarily initiate insulin at the start of treatment in the event of severe hyperglycaemia symptoms at the time of diagnosis.

Role of the medicinal product in the care pathway

In the treatment of type 1 diabetes in adolescents and children from the age of 6 years, TOUJEO (insulin glargine) is a first-line treatment.
As a long-acting human insulin analogue, the role of TOUJEO (insulin glargine) in the care pathway for the treatment of type 2 diabetes in adolescents and children from the age of 6 years is as follows:

- following the failure of lifestyle changes, medicinal treatment with metformin (MA in children from 10 years of age and adolescents), and sometimes insulin, may be initiated.
- in some cases, it may be necessary to temporarily initiate insulin at the start of treatment in the event of severe hyperglycaemia symptoms at the time of diagnosis.

Special recommendations

TOUJEO 300 IU/ml (insulin glargine) is a sustained-release formulation of insulin glargine three times more concentrated than medicinal products containing 100 units/ml of insulin glargine, i.e., LANTUS and its biosimilar ABASAGLAR. Consequently**,** TOUJEO (insulin glargine) 300 IU/ml and the other medicinal products containing insulin glargine 100 unit/ml are not bioequivalent and are not directly interchangeable therefore.

COMMITTEE'S CONCLUSIONS

Clinical benefit

◗ Diabetes is a chronic disease with potentially serious complications, particularly cardiovascular.
◗ These proprietary medicinal products are part of a symptomatic treatment regimen for hyperglycaemia.
◗ The efficacy/adverse effects ratio of these medicinal products is high.
◗ There are therapeutic alternatives.
◗ In the treatment of type 1 diabetes in adolescents and children from the age of 6 years, TOUJEO (insulin glargine) is a first-line treatment. As a long-acting human insulin analogue, the role of TOUJEO (insulin glargine) in the care pathway for the treatment of type 2 diabetes in adolescents and children from the age of 6 years is as follows:

- following the failure of lifestyle changes, medicinal treatment with metformin (MA in children from 10 years of age and adolescents,) and sometimes insulin, may be initiated.
- in some cases, it may be necessary to temporarily initiate insulin at the start of treatment in the event of severe hyperglycaemia symptoms at the time of diagnosis.

Public health impact

Considering:

- the seriousness of the disease,
- its prevalence,
- the met medical need,
- the absence of demonstration of an additional impact on morbidity and mortality and on quality of life and hence the absence of an additional response to the already met medical need,
- the absence of demonstration of a potential impact on the organisation of care,

TOUJEO (insulin glargine) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of TOUJEO (insulin glargine) is substantial in the treatment of diabetes mellitus in adolescents and children from the age of 6 years.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the treatment of diabetes mellitus in adolescents and children from the age of 6 years and at the MA dosages.

Clinical Added Value

Considering:

- **demonstration of the non-inferiority of TOUJEO (insulin glargine) compared to LANTUS (insulin glargine), in an open-label study in children aged over 6 years and adolescent with type 1 diabetes, in terms of change in HbA1c after 26 weeks of treatment, with a predefined non-inferiority margin of 0.3% (primary endpoint),**
- **the availability of efficacy results for an interim endpoint only, and the absence of morbidity and mortality data,**
- **the safety profile of TOUJEO (insulin glargine), which appears to be similar to that of LANTUS (insulin glargine) in the same study,**
- **and the absence of quality of life data,**

the Transparency Committee considers that TOUJEO (insulin glargine) provides no clinical added value (CAV V) compared to LANTUS (insulin glargine) in the management of diabetes mellitus in children from the age of 6 years and adolescents.