Insulin degludec: No hint of added benefit in children and adolescents

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Insulin degludec (trade name: Tresiba) has been approved since January 2015 for adolescents and children from the age of one year with type 1 or type 2 diabetes mellitus. In an early benefit assessment pursuant to the Act on the Reform of the Market for Medicinal Products (AMNOG), the German Institute for Quality and Efficiency in Health Care (IQWiG) has now examined whether this new drug, alone or in combination with other blood-glucose lowering drugs, offers an added benefit over the appropriate comparator therapy.

No added benefit of insulin degludec for adolescents and children with type 1 diabetes mellitus can be derived from the dossier. However, in girls there is a hint of greater harm regarding serious adverse events. Since the manufacturer presented no data for adolescents and children with type 2 diabetes, no conclusion on greater or lesser benefit can be drawn for this therapeutic indication.

Type 1 and type 2 diabetes mellitus are different diseases

In contrast to its dossier for the benefit assessment of insulin degludec in adults in summer 2014, the manufacturer did not differentiate between type 1 and type 2 diabetes in the analysis of study data in its current dossier. It justified this by claiming that the therapeutic indication was not differentiated in the Summary of Product Characteristics, which generally recommended intensive insulin therapy for adolescents and

children.

IQWiG, in contrast, differentiated between type 1 and type 2 diabetes mellitus in the dossier assessment because these are two different diseases: In type 1 diabetes, there is an absolute insulin deficiency so that substitution of insulin is vital. In type 2 diabetes, there is a relative insulin deficiency, which can also be (partly) compensated by other interventions or drugs. This results in different treatment recommendations for the two diseases in the Summary of Product Characteristics, from which children and adolescents are not exempt.

No advantages for children and adolescents with type 1 diabetes

The only study presented by the manufacturer in its dossier investigated children and adolescents with type 1 diabetes. The results showed no differences between the treatment groups regarding mortality, symptoms and complaints, as well as most side effects (discontinuation due to side effects, severe and symptomatic hypoglycaemia, ketoacidosis). Health-related quality of life was not investigated. Hence no hint of an added benefit of insulin degludec could be derived for these outcomes.

More side effects in girls with type 1 diabetes

Neither positive nor negative effects were determined for boys. In girls with type 1 diabetes mellitus who were treated with insulin degludec, however, serious adverse events occurred more frequently than in the comparator group: Within 52 weeks, severe side effects occurred in approximately 15 of 100 girls who received insulin degludec. In girls who received standard treatment, this was the case in approximately 3 of 100 girls. Hence there is a hint of lesser benefit of insulin degludec versus the appropriate comparator therapy in the treatment of girls.

No data for type 2 diabetes mellitus

The manufacturer presented no data in its dossier for adolescents and children from the age of one year with type 2 diabetes mellitus. No hint of an added benefit of insulin degludec in comparison with the appropriate comparator therapy can therefore be derived.

More information: www.iqwig.de/download/A15-10_I … ertung-35a-SGB-V.pdf

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