September 2015

**Insulin Glargine Biosimilars for type 1 (T1DM) and type 2 diabetes mellitus (T2DM).**

The New Therapies Subgroup discussed the above at its meeting on 15th September 2015. The recommendation of this subgroup is as follows:

The New Therapies Subgroup of the GMMMG considered the use of Insulin Glargine Biosimilars for type 1 (T1DM) and type 2 diabetes mellitus (T2DM).

The group recommends the use of insulin glargine biosimilars, as a first line option in all new patients requiring insulin glargine in line with NICE guidelines on the use of long acting insulin analogues for T1DM and T2DM.

A managed therapeutic switch programme could be considered for those patients who are not currently on a stable dose, however this would need to be carried out in conjunction with the initiating clinician and patient and monitored closely in case a dose adjustment is necessary; patients may also need to be shown how to use the pen device as these may differ.

Abasaglar® is currently the only insulin glargine biosimilar approved for use in the EU and it has been shown to be bioequivalent to Lantus® and the efficacy of the two products are comparable. Abasaglar® is approximately 15% cheaper than the reference product. The group recommends that the most cost effective product should be used first line.

All insulin glargine products (including biosimilar) must be prescribed by brand name to avoid any confusion.

According to set criteria insulin glargine biosimilar was deemed to be a high priority for funding.

1prices correct at time of publication.

Review date: September 2017

* Unless superseded by NICE guidance or substantial and significant new evidence becomes available.

▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm their risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.
Commissioning implications for CCGs

NTS Recommendation

Diabetes is a very high cost area both nationally and in all GM CCGs.

There is almost a 3-fold difference in costs per patient between GMCCGs for spend on insulin glargine but less difference when the comparison is with long acting insulins. This suggests different product mix.

Future commissioning implications

There are not expected to be any significant future financial or commissioning implications. A modest saving would be generated from starting new patients on the biosimilar. Switching existing patients would be time consuming and incur extra monitoring so all relevant factors would need to be considered before doing so.

Formulary and Interface considerations

Insulin glargine is first line in the Formulary with the Lantus brand named. Biosimilars will therefore also be placed in the Formulary.

Insulin does not have a RAG status and would be considered as "green" i.e. suitable for initiation and ongoing prescribing within primary care.

Summary of impact

Impact is expected to be minimal.

Major area of risk / implications: primary care