Berkshire West Area Prescribing Committee Policy Statement

Drug Name	Insulin glargines including biosimilars (Toujeo®, Abasaglar®)
Indication under review	Type 1 and Type 2 Diabetes Mellitus (T1DM and T2DM)
Policy No:	APC 128
Date of Issue:	May 2016
Review Date:	May 2019

Policy Statement:

Toujeo® is NOT recommended for the treatment of adult patients with type 1 and type 2 diabetes.

Abasaglar® is recommended for the treatment of adult patients with type 1 and type 2 diabetes newly initiated onto a glargine. Existing patients on Lantus® may be switched onto treatment with Abasaglar®

Traffic Light Status	**Abasaglar® Green** **Toujeo® Brown**

Key Points considered:

- Abasaglar ® is the first biosimilar insulin approved in the EU and has an identical amino acid sequence to that of the active ingredient in the reference product Lantus. The licensed indication (treatment of diabetes mellitus in adults, adolescents and children aged two years and above), dosing regimen, pharmaceutical form, and strength of Abasaglar are identical to those of Lantus.
- In extensive comparability studies all major physicochemical characteristics and biological activities of Abasaglar were comparable to those of Lantus. Abasaglar was shown to be non-inferior to Lantus in reducing HBA1c in both T1DM and T2DM. The overall safety profile of Abasaglar was comparable to Lantus and was in line with the documented safety profile of the reference product. No new or unexpected safety signals were detected
- The APC recommend Abasaglar® for new all new initiations.
- Toujeo®▼ uses the same insulin glargine molecule as Lantus®, but is a higher-strength formulation (300 units/mL) than the existing insulin glargine product on the market (Lantus, 100 units/mL). Toujeo is intended to have a flatter and more prolonged pharmacodynamic profile than Lantus and offers the benefit of a smaller volume of subcutaneous injection. Toujeo is licensed for the treatment of diabetes mellitus in adults.
- Toujeo® was shown to be non-inferior to Lantus in reducing HBA1c in both T1DM and T2DM. The incidence of nocturnal severe and/or confirmed hypoglycaemia was a significantly lower with Toujeo in T2DM, but showed no difference in T1DM. The overall safety profile of Toujeo was comparable to the well-established safety profile of Lantus. No new or unexpected safety signals were detected.
- The APC decision is not to recommend Toujeo® for routine use.

References

National Institute for Health and Care Excellence. Evidence Summary-New Medicine [ESNM62]. Type 1 diabetes mellitus in adults: high-strength insulin glargine 300 units/ml (Toujeo). October 2015. RE Regional Drugs and Therapeutics Centre (Newcastle) November 2015: Insulin glargine U300 (Toujeo) and insulin glargine biosimilar (Abasaglar). Erhorn S

Date taken to APC:	4th May 2016
Date Ratified by MMC on Behalf of the Board:	18th May 2016

Berkshire West Area Prescribing Policies serve as a guide to clinicians. This does not overrule the clinical or budgetary responsibility of clinicians when considering treatment for individual patients.

Brown	Green	Amber	Red
These drugs have been reviewed and are not considered a cost effective use of scarce NHS resources	Medicines suitable for routine use. Primary care prescribers take full responsibility for prescribing	Medicines that should be initiated or recommended by a specialist and can be continued in primary care under a shared care agreement.	Medicines which should be prescribed by specialists only