AREA PRESCRIBING COMMITTEE – Birmingham, Sandwell, Solihull and environs

Decision Making Support Tool

The following document supports the committee to consider formulary applications against defined criteria.

Formulary application reference:		APCBSSE/0030- reconsidered April 2017
Drug name and formulations:		Insulin glargine 300 units/mL – Toujeo®
Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	Three-fold concentrated insulin and potential misuse of device pose considerable risks; however these can be mitigated by implementing recommendations in risk assessment tool presented.
Clinical effectiveness	*Established licensed product*	Non-inferior to insulin glargine 100 units/mL in terms of HbA1c. Evidence for reduction in hypoglycaemia, especially nocturnal hypos, was a secondary endpoint as part of a sub-group post hoc analysis.
Strength of evidence		Sufficient to gain licence from EMA; the manufacturer had to demonstrate that Toujeo® had a similar safety and efficacy profile to that of the reference product, Lantus®
Cost effectiveness or resource impact	*£*	15% more expensive than Abasaglar®, cost neutral vs Lantus®.
Place of therapy relative to available treatments	*1/2nd tier*	Patient cohort identified, could be 2% of all diabetics.
National guidance and priorities	*NICE, MTRAC*	MTRAC issued commissioning guidance in July 2015, SMC accepted for restricted use within NHS Scotland in September 2015.
Local health priorities	*CCG views*	Risk is largely in secondary care.
Equity of access	*Equality assessment*	N/A
Stakeholder views	*Define wider groups to be engaged*	N/A
Implementation requirements	*Requires, RICAD ESCA etc.*	Supporting ESCA or RICaD to transfer prescribing to primary care.

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	

Formulary status (RAG) and rationale	Approved as AMBER with RICaD, for patients who require more than 80 units of insulin glargine per day and who are troubled by nocturnal hypos. Transfer to Primary Care should not happen until specialists can demonstrate reduction in nocturnal hypos (e.g. after 3-4 months). Specialist initiation.
Implementation requirements:	
Implementation monitoring:	