

## 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: 0076		APCBSSE/0076
Drug name and formulations:		Tresiba® (insulin degludec)
Criteria	Example	Committee Consensus
Patient Safety	<i>Potential for abuse, toxicity, significant drug interactions</i>	Some evidence of reduced risk of hypoglycaemia
Clinical effectiveness	<i>Established licensed product</i>	Shown to be effective in type 2 diabetes. Marginal reduction in risk of hypoglycaemia, no statistically significant benefit in severe hypoglycaemia
Strength of evidence		Cross over clinical trial
Cost effectiveness or resource impact	£	2 per 10,000 patients in primary care. Cost of preparation may increase relative to alternatives available. Lantus® is approximately 75% the cost of Tresiba®.
Place of therapy relative to available treatments	<i>1/2<sup>nd</sup> tier</i>	4 <sup>th</sup> tier for Type 2 diabetes. Recurrent severe hypoglycaemia (requiring third party intervention) where glargine has been ineffective.
National guidance and priorities	<i>NICE, MTRAC</i>	Type 2 diabetes high priority.
Local health priorities	<i>CCG views</i>	Concerns about creep in prescribing
Equity of access	<i>Equality assessment</i>	N/A
Stakeholder views	<i>Define wider groups to be engaged</i>	N/A
Implementation requirements	<i>Requires, RICAD ESCA etc.</i>	RED – Applicant to be invited to provide full application in 6 months with internal clinical data and/or more trial evidence.

### Decision Summary

Resubmission is recommended to complete the information to enable a decision:	N/A
Not approved and rationale:	N/A
Formulary status (RAG) and rationale	RED status. <u>Rationale</u> : There were concerns over the lack of statistically significant evidence that supported the claim of reduction in severe hypoglycaemia and reduction in hospitalisations. The committee noted that local clinical experience suggests better results than those shown in the trial data.
Implementation requirements:	N/A
Implementation monitoring:	N/A