National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Ertugliflozin monotherapy for treating type 2 diabetes

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Appropriateness	AstraZeneca	Yes	Comment noted
	MSD	Yes	Comment noted
	Servier	No comments, Servier agree that the draft scope is appropriate	Comment noted
Wording	AstraZeneca	Yes	Comment noted
	MSD	No, the scope has been issued as a single technology appraisal. Ertugliflozin fulfils the criteria for a fast track appraisal (FTA): • It provides similar or greater health benefit to NICE approved treatments for the same indication. • It has similar or lower costs compared to NICE approved treatments for the same indication. • It can be compared to the treatments approved in NICE technology appraisal (TA) 390.	Thank you for your comment. NICE agrees that a cost comparison for monotherapy and dual therapy would be appropriate.

Section	Consultee/ Commentator	Comments [sic]	Action
		Ertugliflozin should be appraised under the new FTA cost comparison process.	
Timing Issues	AstraZeneca	We believe that ertugliflozin will be available in early 2018.	Comments noted

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	AstraZeneca	It is adequate.	Comments noted
	MSD	It is accurate	Comments noted
The technology/ intervention	AstraZeneca	We believe it is.	Comments noted
	MSD	Yes	Comments noted
Population	AstraZeneca	Yes the population is defined appropriately and there are no groups that should be considered separately.	Comments noted
	MSD	No, The population should reflect the license indication "Monotherapy - When diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications", which is consistent with the TA390 population. There are no groups in the population that should be considered separately.	Comment noted. The scope has been updated.

Section	Consultee/ Commentator	Comments [sic]	Action
Comparators	AstraZeneca	Yes	Comment noted. The scope has been updated following consultation.
	MSD	As noted above ertugliflozin monotherapy is for patients for whom metformin is considered inappropriate and as a result metformin should be excluded as a comparator. In technology appraisals 288, 315, 336 and 418, it was concluded that the most appropriate comparators for sodium-glucose cotransporter-2 (SGLT-2) inhibitors were other SGLT-2s and dipeptidyl peptidase-4 (DPP-4) inhibitors. The list of comparators should reflect this.	Comment noted. The scope has been updated.
Outcomes	AstraZeneca	We do not believe that currently available data for this technology will be able to inform on the outcome measures of mortality or complications of diabetes including cardiovascular, renal and eye.	Comments noted. The outcomes listed include longer term outcomes such as mortality and complications as these are listed as secondary outcomes in some trials (for example the VERTIS CV study includes time to cardiovascular death and time to stroke as secondary outcome measures). The outcomes listed in the scope are examples of clinically relevant outcomes but analysis of these will depend on the availability of data.
	MSD	Yes	Comment noted
	AstraZeneca	No comments	Noted

Section	Consultee/ Commentator	Comments [sic]	Action
Economic analysis	MSD	A cost comparison analysis should be conducted as part of a fast track appraisal (FTA) rather than a cost-utility analysis as part of an STA. Ertugliflozin is likely to provide similar or greater health benefits at similar or lower cost than the other SGLT-2s already recommended in TA 390 for the same indication.	Thank you for your comment. NICE agrees that a cost comparison for monotherapy and dual therapy would be appropriate.
Equality	MSD	We have not identified any equality issues	Comment noted
Innovation	AstraZeneca	Three other SGLT-2 inhibitors are currently available and recommended by NICE. We are not aware of benefits beyond the QALY calculation for this technology.	Comment noted
	MSD	Ertugliflozin adds an additional treatment choice in the SGLT-2 inhibitor class. The SGLT2 inhibitor class provides adults with type 2 diabetes with an additional oral treatment option. The SGLT-2 mechanism of action increases renal glucose excretion providing clinically significant glucose reduction alongside a decrease in blood pressure as well as weight loss.	Comment noted
Other considerations	MSD	None	Comment noted
Questions for consultation	MSD	As noted above MSD feels that this appraisal should follow the new fast track appraisal process (FTA). Ertugliflozin fulfils the criteria for an FTA of being likely to provide similar or greater health benefits at similar or lower cost than the other SGLT-2s already recommended in TA 390 for the same indication.	Thank you for your comment. NICE agrees that a cost comparison for monotherapy and dual therapy would be appropriate.

Section	Consultee/ Commentator	Comments [sic]	Action
Additional comments on the draft scope	AstraZeneca	No further comments.	Noted

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

Sanofi, Pfizer, Department of Health and Social Care