National Institute for Health and Care Excellence

Trifluridine–tipiracil for treating metastatic gastric or gastro-oesophageal junction cancer after 2 or more therapies

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	Servier Laboratories	Not applicable	Comment noted. No action required.
Wording	Servier Laboratories	Please note that this is to 'extend' not 'within' trifluridine/tipiracils marketing authorisation for patients with metastatic gastric cancer who have received 2 prior lines of treatment.	Comment noted. This wording is standard to the remit section. The proposed amendment does not substantively change the remit of the appraisal. No changes made.
Timing Issues	Servier Laboratories	Trifluridine/tipiracil has had positive results in a Phase III trial, with a significant improvement in overall survival in heavily pre-treated patients with metastatic gastric cancer. [redacted]	Comment noted. No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Servier Laboratories	Please note that the background information on treatment for patients with previously treated metastatic disease refers to patients who have received 1 (not 2) prior treatment lines	Comment noted. The background section states that 'There is no standard treatment for previously treated advanced or metastatic disease', this includes second and third line treatment. This section of the scope aims to provide a brief overview of the background for the appraisal; additional details may be considered by the committee at the time of the appraisal. No action required.
The technology/ intervention	Servier Laboratories	*Is the description of the technology or technologies accurate?* Yes	Comment noted. No action required.
Population	Servier Laboratories	Yes (subject to final indication) Patients who have not received prior ramicurimab should be considered separately as a group	Comment noted. No action required. If a subgroup of the population eligible for treatment within the marketing authorisation needs separate consideration this

Section	Consultee/ Commentator	Comments [sic]	Action
			should be detailed in the company submission. Any evidence and analysis to support this would be welcomed.
Comparators	Servier Laboratories	Servier does not believe that 'Chemotherapy (such as docetaxel or paclitaxel monotherapy or combination chemotherapy)' should be considered as a direct comparator	Comment noted. The comparator section reflects current clinical practice and is kept broad to encompass the entire population that may be eligible for treatment within the marketing authorisation. If the company does not believe this comparator is used in clinical practice for any patients, the evidence to support this should be provided in the company submission.
Outcomes	Servier Laboratories	*Will these outcome measures capture the most important health related benefits (and harms) of the technology?* Yes	Comment noted. No action required.
Economic analysis	Servier Laboratories	No comment	Comment noted. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
Equality and Diversity	Servier Laboratories	Not applicable	No action required.
Other considerations	Servier Laboratories	Not applicable	No action required.
Questions for consultation	Servier Laboratories	Not applicable	No action required.

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

The Department of Health and Social Care