National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Cemiplimab for untreated PD-L1-postive advanced or metastatic non-small-cell lung cancer

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
Wording	Sanofi	Please update the appraisal title to specify the likely indication: Cemiplimab for untreated PD-L1 in [redacted] tumour cells with locally advanced or metastatic Non-Small-Cell Lung Cancer Please align the remit to be in line with the anticipated marketing authorisation: [redacted]	No action needed. The remit of the scope is kept broad, partly so that confidential wording is not shared and partly in case the wording of the marketing authorisation isn't what was expected. The current title and remit is consistent with previous appraisals also recommended in this indication (for examples, please see TA531 and ID1678),

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			where level of PD-L1 expression is not stated in the title.
	MSD	No comment.	No action needed.
Timing Issues	Sanofi	Despite recent advances in the treatment of NSCLC there is still a need for additional treatment options that will benefit the patient and clinical groups. Cemiplimab offers an additional treatment option to clinicians to help fill this need.	Comment noted. No action needed.
	MSD	No comment.	No action needed.
Additional comments on the draft remit	Sanofi	No comment.	No action needed.
	MSD	No comment.	No action needed.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Sanofi	The background information includes information on comparators not relevant to the likely indication i.e. patients with a PD-L1 status [redacted] Tumour Propensity Score. Reference to platinum-combination chemotherapy: Since NICE guideline 122 was published pembrolizumab (TA531) was recommended and has become the standard of care for this population.	No action needed. The remit of the scope is kept broad, partly so that confidential wording is not shared and partly in case the wording of the marketing authorisation

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		Atezolizumab with bevacizumab, carboplatin and paclitaxel: NICE TA 584 is not deemed relevant for this appraisal as - it is guidance for the second-line treatment of NSCLC following targeted treatment with EGFR or ALK inhibitors - it is indicated for patients with tumour expression of PD-L1 less than 50%.	isn't what was expected. Comment noted regarding atezolizumab with bevacizumab, carboplatin, and paclitaxel. This has now been removed from the scope.
	MSD	No comment.	No action needed.
The technology/ intervention	Sanofi	Please align the description of the technology to the anticipated marketing authorisation: [redacted]	The scope is written with information that is in the public domain. Since the anticipated wording of the marketing authorisation is confidential this can't be used. No action required.
	MSD	No comment.	No action needed.
Population	Sanofi	<u>Please align the population to the anticipated market authorisation:</u> [redacted]	The scope is written with information that is in the public domain. Since the anticipated

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		[redacted]	wording of the marketing authorisation is confidential this can't be used in the scope. The population is usually left broad in case the wording of the marketing authorisation isn't what was expected. The committee will consider the clinical evidence presented to it and make recommendations based on that. No action required.
	MSD	No comment.	No action needed.
Comparators	Sanofi	**Non-squamous:** **Pemetrexed in combination with a platinum drug (carboplatin or cisplatin) +/- pemetrexed maintenance** **Chemotherapy (docetaxel, gemcitabine, paclitaxel or vinorelbine) in combination with platinum drug (carboplatin or cisplatin) +/- pemetrexed maintenance:** We do not believe chemotherapy to constitute a significant treatment option within this population. Interviews with independent clinical experts during an advisory board suggest approximately 5-10% of NSCLC patients with PD-L1 tumour expression of at least 50% are treated with chemotherapy in this	The scope is written with information that is in the public domain. Since the anticipated wording of the marketing authorisation is confidential this can't be used in the scope. The comparators are usually left broad in case the wording of the marketing authorisation

Section	Consultee/ Commentator	Comments [sic]	Action
		population. Market research data from IPSOS (IPSOS Aug 2020) suggests that this value may even be less than 5%. **Atezolizumab + bevacizumab, carboplatin and paclitaxel:** NICE TA 584 is not deemed relevant for this submission as - it is guidance for the second-line treatment of NSCLC following targeted treatment with EGFR or ALK inhibitors - it is indicated for patients with tumour expression of PD-L1 less than 50%. **Squamous:** **Chemotherapy (docetaxel, gemcitabine, paclitaxel or vinorelbine) in combination with platinum drug (carboplatin or cisplatin) +/- pemetrexed maintenance** As highlighted above we do not believe chemotherapy to constitute a significant treatment option within this population. Sanofi intend to provide comparisons versus chemotherapy (defined as Platinum (carboplatin or cisplatin) in combination with chemotherapy (docetaxel, gemcitabine, paclitaxel, pemetrexed, or vinorelbine), with or without pemetrexed maintenance treatment) on the basis that this was the comparator in the pivotal trial for Cemiplimab. **Comparators split by histology:**	isn't what was expected. The committee will consider the clinical evidence presented to it and make recommendations based on that. No action required.

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		Interviews with clinical experts have suggested histology is not a determining factor of success when treating this population i.e. PD-L1 in ≥ 50% tumour cells. Therefore we do not believe the list of comparators should differ according to histology. Standard of care and the principal comparator for this appraisal should be pembrolizumab monotherapy.	Comparators have been kept separate for squamous and non-squamous populations because of differences in existing recommendations for both groups.
	MSD	Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic is considered standard of care for non-squamous non-small-cell lung cancer and has been available since 2018 through the CDF. The combination has now been approved for routine commissioning on the NHS and therefore should be a comparator for the non-squamous population of the indication in ID3839.	Pembrolizumab with pemetrexed and platinum chemotherapy has been added into the scope as a potential comparator for people with non-squamous NSCLC.
Outcomes	Sanofi	The outcomes listed are considered appropriate.	Comment noted.

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	MSD	No comment.	No action needed.
Economic analysis	Sanofi	Discussions with clinicians suggest that PD-L1 testing has now become routine practice for all patients. We therefore do not believe this cost would need to be accounted for in the economic model as all patients are tested as standard practice.	The statement regarding PD-L1 testing has now been removed from the scope.
	MSD	No comment.	No action needed.
Equality and Diversity	Sanofi	No equality considerations	Comment noted.
	MSD	No comment.	No action needed.
Other considerations	Sanofi	The likely indication for Cemiplimab is for patients with PD-L1 [redacted] Subgroup analyses based on PD-L1 expression are therefore inappropriate.	The scope is written with information that is in the public domain. Since the anticipated wording of the marketing authorisation is confidential this can't be used in the scope. No action needed.
	MSD	No comment.	No action needed.
Innovation	Sanofi	Sanofi anticipate cemiplimab to be an alternative option to pembrolizumab for the treatment of NSCLC in patients with PD-L1 TPS [redacted]%.	Comment noted.
	MSD	No comment.	No action needed.

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Questions for consultation	Sanofi	Sanofi anticipate cemiplimab to be an alternative option to existing PD-L1/1s currently approved for the treatment of NSCLC in patients with PD-L1 TPS [redacted] Data for cemiplimab will be available from the pivotal EMPOWER LUNG-1 trial.	Comment noted.
	MSD	No comment.	No action needed.
Additional comments on the draft scope	Sanofi	No comment.	No action needed.
	MSD	No comment.	No action needed.

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

- Asthma UK and British Lung Foundation
- Pfizer