

National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Nintedanib for previously treated locally advanced or metastatic non-small cell lung cancer

Response to consultee and commentator comments on the draft scope

Section	Consultees	Comments	Action
Appropriateness	Boehringer Ingelheim	We believe that it is appropriate for NICE to consider this topic.	Comment noted.
	Roche Products	Yes	
Wording	Boehringer Ingelheim	The brand name 'vargatef' should not be used. Please use nintedanib in all instances. Boehringer Ingelheim is spelt incorrectly near the end of page 1.	Comment noted. The brand name has been removed and left as unknown.
	Roche Products	Yes	
Timing Issues	Boehringer Ingelheim	We anticipate nintedanib being an important treatment option for this patient group given the significant increase in overall survival that has been observed in RCTs. Therefore it is important for NICE to provide recommendations on its use to the NHS as close to marketing authorisation as possible.	Comment noted.
Background information	Roche Products	Best supportive care is also considered for patients who may be unwilling to receive another line of chemotherapy.	Comment noted.
The technology/ intervention	Boehringer Ingelheim	The brand name 'vargatef' should not be used. Boehringer Ingelheim is spelt incorrectly near the end of page 1.	Comment noted. The brand name has been removed and left as unknown.
Population	Boehringer Ingelheim	See comment 4 below	
Comparators	Boehringer	Best supportive care should not be a comparator as these	Comment noted. Best

Appendix D - NICE's response to consultee and commentator comments on the draft scope and provisional matrix

Section	Consultees	Comments	Action
	Ingelheim	patients would be ineligible for treatment as they would otherwise receive erlotinib or docetaxel.	supportive care has been removed from the list of comparators in the draft scope. The
	Roche Products	Best supportive care would seem an inappropriate comparator for nintedanib in combination with docetaxel, since patients who are well enough to tolerate this chemotherapy regimen are unlikely candidates to receive BSC.	See above comment.
Economic analysis	Boehringer Ingelheim	We believe that the 'End of Life' criteria may apply with the increased threshold for cost-effectiveness	Comment noted. The appraisal committee will consider evidence and analyses presented in submissions in support of nintedanib as an end-of-life treatment.
	Roche Products	A lifetime time horizon is appropriate.	Comment noted.
Innovation	Boehringer Ingelheim	Nintedanib is the first drug in this indication to show increased overall survival in over 10 years, and the first against a non-placebo comparator.	Comment noted. The appraisal committee will consider evidence presented in submissions supporting the innovation of nintedanib.
Questions for consultation	Boehringer Ingelheim	Given that a significant increase in overall survival was observed, will this meet the criteria for end-of-life? Would subgroups be considered?	See comments above regarding end-of-life treatments. Similarly, the Appraisal Committee will consider subgroup analyses presented in submissions where the treatment is shown to be more clinically or cost-effective.

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

DH
Royal College of Nursing
MHRA

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

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Response to consultee and commentator comments on the provisional matrix of consultees and commentators (pre-referral)

Version of matrix of consultees and commentators reviewed:				
Provisional matrix of consultees and commentators sent for consultation				
Summary of comments, action taken, and justification of action:				
	Proposal:	Proposal made by:	Action taken: Removed/Added/Not included/Noted	Justification:
1.	Add HAWC	NICE Secretariat	Added	This organisation's interests are closely related to the appraisal topic and as per our inclusion criteria. HAWC has been included in the matrix of consultees and commentators under 'patient groups.'
2.	Remove Independent Age	Independent Age	Removed	Independent Age have been removed from the matrix at their own request.

Appendix D - NICE's response to consultee and commentator comments on the draft scope and provisional matrix

3.	Remove British Association for Services to the Elderly	British Association for Services to the Elderly	Removed	This organisation has disbanded.
4.	Add UK Health Forum	NICE Secretariat	Add	This organisation's interests are closely related to the appraisal topic and as per our inclusion criteria. UK Health Forum has been included in the matrix of consultees and commentators under 'professional groups.'
5.	Remove Commissioning Support Appraisals Service (CSAS)	NICE Secretariat	Removed	This organisation's interests are not closely related to the appraisal topic and as per our inclusion criteria. Commissioning Support Appraisals Service has been removed from the matrix.
6.	Re-classify British Thoracic Oncology Group	NICE Secretariat	Re-classified	This organisation has been re-classified as a 'professional group-commentator'.

Appendix D - NICE's response to consultee and commentator comments on the draft scope and provisional matrix

7.	Remove Research Institute for the Care of Older People	NICE Secretariat	Removed	This organisation's interests are not closely related to the appraisal topic and as per our inclusion criteria. Research Institute for the Care of Older People has been removed from the matrix.
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