

National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

NBTXR-3 for treating soft tissue sarcoma

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	Sarcoma UK	Yes	Comment noted
Wording	Sarcoma UK	Wording of the technology section incorrect see below	Thank you this has now been corrected to 'NBTXR-3 does not currently have a CE mark for treating soft tissue sarcoma.'
Timing issues	Sarcoma UK	There are limited options available for sarcoma patients, this has real potential to enhance existing limited standard treatments and improve outcomes for our patients.	Comment noted.
Additional comments on the draft remit		No additional comments received	

Comment 2: the draft scope

National Institute for Health and Care Excellence

Consultation comments on the draft remit and draft scope for the technology appraisal of NBTXR-3 for treating soft tissue sarcoma
Issue date: October 2018

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Sarcoma UK	It would be clearer to say 'The tumour is removed with a margin of normal tissue with the aim of removing all cancer cells and lowering the chance of local relapse.'	Thank you for this comment. The scope has been updated to state "...with the aim of removing all cancer cells and lowering the chance of local relapse".
The technology/ intervention	Sarcoma UK	'NBTXR-3 does not currently have a CE mark for treating soft tissue sarcoma'	Thank you, this has been corrected in the scope.
Population	Sarcoma UK	<p>This is currently unclear and needs further clarification:</p> <p>Are there any age restrictions? Will it be available for example to the TYA community?</p> <p>Does the treatment only apply to certain sub- types?</p> <p>Will it only be available in certain centres or will all units currently providing sarcoma RT have access? For example could patients in Cornwall have access to NBTXR-3?</p>	<p>Comment noted. The technology will be appraised for the population as stipulated in the CE marked indications for use. Availability to the teenage and young adult community (TYA) will be dependent on the eligibility criteria in the CE marking.</p> <p>If NBTXR-3 is recommended by NICE NHS England will be mandated to provide</p>

Section	Consultee/ Commentator	Comments [sic]	Action
			funding and access to this technology.
Comparators	Sarcoma UK	<p>Radiotherapy – further clarity</p> <p>Will the comparison be made to pre op RT 55gy alone or will it look at post op RT 66gy which is often used to achieve the same outcome.</p> <p>Post RT is more labour intensive for patients and has added costs because of more visits. In some centres it remains the standard treatment.</p> <p>Neoadjuvant chemotherapy – is occasionally used for some sub types.</p>	<p>Comment noted. In the clinical trials NBTXR-3 was used preoperatively. NBTXR-3 will be appraised within its CE marked indication and the radiotherapy dosage it is used with will be determined during the appraisal.</p> <p>It is unclear whether NBTXR-3 can be used in people receiving chemotherapy in addition to radiotherapy and chemotherapy. Chemotherapy has not been added as a comparator in the scope, but it is noted that there may be some people who receive chemotherapy in clinical practice.</p>
Outcomes	Sarcoma UK	<p>Would the necrosis rate be considered?</p> <p>Would local recurrence rate be measured?</p>	Comments noted. It is anticipated that wound

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		<p>Did the neoadjuvant treatment allow the patient to have surgery that was not possible before?</p> <p>Patients have real issues with wound infection with pre op RT, this can have a real impact on their quality of life, will this measured?</p> <p>Is there any increase in lymphedema a significant longer term side effect?</p>	<p>infection and side effects would be considered as part of adverse effects of treatment, which is listed as an outcome in the scope. It is further anticipated that local recurrence rate would be covered by the outcome relapse rate and that necrosis rate would be covered by the outcome response rate.</p> <p>Likelihood of surgery was not added as an outcome because it is anticipated that radiotherapy (with or without NBTXR-3) would be initiated in people for whom surgery would be carried out after treatment. Success of surgery would be captured by relapse rate.</p>

Section	Consultee/ Commentator	Comments [sic]	Action
Additional comments on the draft scope		No additional comments on the draft scope received	

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

None