

National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Naldemedine for treating opioid-induced constipation

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	Action
Appropriateness	The Clatterbridge Cancer Centre	This is an appropriate appraisal in so far as it addresses a prevalent clinic problem with significant quality of life implications for patients.	Comment noted. No action required.
Wording	The Clatterbridge Cancer Centre	The wording is appropriate.	Comment noted. No action required.

Section	Consultee/ Commentator	Comments	Action
Timing Issues	The Clatterbridge Cancer Centre	Given the current availability of other peripheral opioid receptor antagonists for this specific indication (Naloxegol and methylnatrexone) which have proven efficacy and are embedded in clinic practice, the appraisal of naldemedine is not urgent as it will not remedy a currently unaddressed clinical need.	Comment noted. No action required.
Additional comments on the draft remit	The Clatterbridge Cancer Centre		

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	The Clatterbridge Cancer Centre	This information accurately describes the clinical prevalence of opioid-induced constipation. It perhaps lacks any focus on the impact of OIC on patients' quality of lives.	Comment noted. The background section notes the debilitating nature of opioid-induced constipation. This section is intended to be a brief summary for the condition. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
The technology/ intervention	The Clatterbridge Cancer Centre	The technology is adequately described.	Comment noted. No action required.
Population	The Clatterbridge Cancer Centre	As this class of medications is not used first line for opioid induced constipation, the selection of a population which has already tried a different class of laxatives before trying naldemedine is most appropriate.	Comment noted. No action required.
Comparators	The Clatterbridge Cancer Centre	This seems to be a complete list. Of particular importance is the use of naloxegol as a comparator as they have identical functions so a cost-effectiveness comparison with naloxegol is of high importance.	Comment noted. No action required.
Outcomes	The Clatterbridge Cancer Centre	The list of outcomes provided appears complete.	Comment noted. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
Economic analysis	The Clatterbridge Cancer Centre	Given the similarity to naloxegol, an economic analysis comparing these two medications is important. The wording of this section and the proposed time horizon is therefore appropriate with this in mind.	Comment noted. No action required.
Equality and Diversity	The Clatterbridge Cancer Centre	There is nothing within this proposal which indicates a risk of exclusion of certain populations.	Comment noted. No action required.
Other considerations	The Clatterbridge Cancer Centre		
Innovation	The Clatterbridge Cancer Centre	This is not a new and unique technology so is unlikely to result in a step-change in the management of opioid induced constipation. If shown to be more clinically effective than naloxegol +/- more cost effective, then it may replace naloxegol as the preferred medication for this indication (although not first line), however robust evidence around this is likely to be lacking.	Comment noted. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
NICE Pathways [Delete section if not relevant]	The Clatterbridge Cancer Centre		
Questions for consultation	The Clatterbridge Cancer Centre	Currently naloxegol and methylnaltrexone are considered established treatments for opioid induced constipation in the NHS. These would be the preferred comparators in any appraisal of naldemedine using all of the outcomes described in the proposal.	Comment noted. No action required.
Additional comments on the draft scope	The Clatterbridge Cancer Centre		

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

- Kyowa Kirin International