National Institute for Health and Care Excellence

Health Technology Appraisal

Golimumab for treating non-radiographic axial spondyloarthritis [ID903]

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	MSD	Yes	Comment noted
	National Ankylosing Spondylitis Society	Yes	Comment noted
	British Society of Rheumatology	This is appropriate and relevant as non-radiographic axial SPA is an area of increasing recognition that requires new treatments.	Comment noted
Wording	MSD	No, the scope has been issued as a single technology appraisal. Golimumab fulfils the criteria for an abbreviated technology appraisal: • It provides similar or greater health benefit to NICE approved treatments for the same indication. • It has similar or lower costs compared to NICE approved treatments for the same indication. • It can be compared to the treatments approved in NICE TA 383. Golimumab should be appraised under the new abbreviated technology appraisal process.	Comment noted. The technology will be appraised under the Fast track: cost comparison technology process.

Section	Consultee/ Commentator	Comments [sic]	Action
	National Ankylosing Spondylitis Society	Yes	Comment noted
	British Society of Rheumatology	Yes	Comment noted
Timing Issues	MSD	It is important to appraise golimumab, and provide more treatment options for patients	Comment noted
	British Society of Rheumatology	Relatively urgent in line with publication of the recent NICE SPA guidelines in Feb 2017	Comment noted. The technology will be appraised under the Fast track: cost comparison technology appraisal process

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	MSD	The back ground information is appropriate	Comment noted
	National Ankylosing Spondylitis Society	Accurate	Comment noted
	British Society of Rheumatology	Accurate	Comment noted
	MSD	Yes	Comment noted

Section	Consultee/ Commentator	Comments [sic]	Action
The technology/ intervention	National Ankylosing Spondylitis Society	Accurate	Comment noted
	British Society of Rheumatology	Accurate	Comment noted
Population	MSD	Yes, the population is defined appropriately. There are no groups that should be considered separately	Comment noted
	National Ankylosing Spondylitis Society	Defined appropriately	Comment noted
	British Society of Rheumatology	Defined as non-radiographic axial SPA	Comment noted
Comparators	MSD	Yes, these are the standard treatments used by the NHS.	Comment noted
	National Ankylosing Spondylitis Society	Accurate	Comment noted
	British Society of Rheumatology	Comparators (other anti-TNFs) listed	Comment noted
Outcomes	MSD	Yes	Comment noted
	National Ankylosing	Yes	Comment noted

Section	Consultee/ Commentator	Comments [sic]	Action
	Spondylitis Society		
	British Society of Rheumatology	These are appropriate outcomes measures	Comment noted
Economic analysis	MSD	A cost comparison analysis should be utilised as part of an abbreviated technology appraisal rather than a cost-utility analysis as part of an STA. Golimumab fulfils the criteria for an abbreviated technology appraisal: • It provides similar or greater health benefit to NICE approved treatments for the same indication. • It has similar or lower costs compared to NICE approved treatments for the same indication. • It can be compared to the treatments approved in NICE TA 383.	Comment noted. The technology will be appraised under the Fast track: cost comparison technology process and methods.
	National Ankylosing Spondylitis Society	No comment	-
	British Society of Rheumatology	These are appropriate	Comment noted
Equality and Diversity	MSD	We have not identified any equality issues.	Comment noted
	British Society of Rheumatology	No issues	Comment noted
	MSD	None	Comment noted

Section	Consultee/ Commentator	Comments [sic]	Action
Other considerations	British Society of Rheumatology	None	-
Innovation	MSD	Golimumab has demonstrated significant and sustained improvements in signs and symptoms of nr-axial SpA. Golimumab is well tolerated in nr-axial SpA, and has a safety profile consistent with the known safety profile of golimumab across other indications. Moreover, golimumab has shown to be an effective therapy in the treatment of patients with spondyloarthropathies who have common extra-articular manifestations, such as inflammatory bowel disease. Golimumab has a once monthly frequency of administration which provides a more convenient treatment alternative to its comparators. It is particularly convenient for the economically active population. Additionally, golimumab offers a self-injectable pen, an innovation that is specifically designed for those who feel discomfort with self-injection, and those who have limited mobility in the hand.	Comment noted. At submission stage a case for innovation can be made.
	British Society of Rheumatology	Provision of choice for treatment of non-radiographic axial SPA	Comment noted
Questions for consultation	MSD	As noted above MSD feel that this appraisal should follow the new abbreviated technology appraisal process. Golimumab fulfils the criteria for an abbreviated technology appraisal: • It provides similar or greater health benefit to NICE approved treatments for the same indication. • It has similar or lower costs compared to NICE approved treatments for the same indication. • It can be compared to the treatments approved in NICE TA 383.	Comment noted. The technology will be appraised under the Fast track: cost comparison technology process and methods.

Section	Consultee/ Commentator	Comments [sic]	Action
	British Society of Rheumatology	None	-
Additional comments on the draft scope	MSD	-	-
	British Society of Rheumatology	None	-

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

AbbVie

The Royal College of Physicians endorsed comments submitted by the British Society of Rheumatology.