

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## HEALTH TECHNOLOGY APPRAISAL PROGRAMME

### Equality impact assessment – Guidance development

### STA Darvadstrocel for treating complex perianal fistula in Crohn's disease

The impact on equality has been assessed during this appraisal according to the principles of the NICE equality scheme.

#### Consultation

1. Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?

Attendees at the scoping workshop noted that the expansion of the Cx601 in bovine serum may affect the decision of people from religious groups to choose this treatment.

Attendees at the workshop noted that the presence of perianal fistula can affect whether pregnant women are suitable for vaginal delivery. This treatment if effective may be beneficial in women of childbearing age.

These issues have been brought to the committee's attention at the meeting, but the committee did not consider these to be potential equality issues. The population of the decision problem and the recommendations do not exclude people who are unable or unwilling to take darvadstrocel.

The complications for women of childbearing age are complications of the condition and the recommendation or non-recommendation of darvadstrocel would not address these issues.

2. Have any other potential equality issues been raised in the submissions, expert statements or academic report, and, if so, how has the committee addressed these?

No additional equality issues were raised in the submissions, expert statements or academic report.

3. Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?

No applicable.

4. Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

The preliminary recommendation is negative, however it does not make it more difficult in practice for a specific group to access the technology compared with other groups.

5. Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

No the preliminary recommendations do not have an adverse impact on people with disabilities.

6. Are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?

No applicable.

7. Have the committee's considerations of equality issues been described in the appraisal consultation document, and, if so, where?

Yes, in section 3.19 of the ACD.

**Approved by Associate Director (name):** ...Janet Robertson.....

**Date:** 08 August 2018

## Final appraisal determination

(when an ACD issued)

1. Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?

In response to consultation, a patient group stated that some equality issues needed to be considered by the committee in terms of leaving patients with no option but to have defunctioning surgery or a proctectomy. It was noted that having pelvic surgery may be an issue for people who have not completed their family and whose fertility may be affected, and that the condition and potentially having defunctioning surgery or a proctectomy may raise particular issues for certain religious groups. The committee acknowledged that having Crohn's disease presents certain difficulties for some groups, but considered that due to the lack of clear evidence on long term clinical effectiveness of darvadstrocel and not recommending darvadstrocel does not exclude or impact differently on any populations. It also discussed that it is not proven by the clinical evidence that subsequent surgery will be avoided in any of the patient groups as an outcome of treatment with darvadstrocel. Therefore the committee concluded that this did not represent an equalities issue and that there was no need to alter its recommendations.

2. If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

The recommendation did not change after consultation.

3. If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

The recommendation did not change after consultation.

4. If the recommendations have changed after consultation, are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?

The recommendation did not change after consultation.

5. Have the committee's considerations of equality issues been described in the final appraisal determination, and, if so, where?

Yes, in section 3.22.

**Approved by Associate Director (name):** ...Janet Robertson.....

**Date:** 24 October 2018