

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION

Technology Appraisals

**Consultation on Batch 51 draft remits and draft scopes and
summary of comments and discussions at scoping workshops**

Topic ID	Topic title
993	Abatacept for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs
960	Cx601 for treating complex perianal fistula in Crohn's disease

Provisional Title	Abatacept for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs		
Topic Selection ID Number	7905	Wave / Round	R155
TA ID Number	993		
Company	Bristol Myers Squibb		
Anticipated licensing information	***Confidential information removed***		
Draft remit	To appraise the clinical and cost effectiveness of abatacept within its marketing authorisation for treating active psoriatic arthritis in adults whose disease has not responded adequately to previous disease-modifying anti-rheumatic drug therapy.		
Main points from consultation	<p>No scoping workshop was required. Following the consultation exercise, the Institute is of the opinion that an appraisal of abatacept for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs is <u>appropriate</u>.</p> <p>The proposed remit is appropriate. No changes are required.</p> <p>No changes to the scope were suggested.</p>		
Population size	<p>Approximately 2000 people in England would be eligible for treatment with abatacept.</p> <p>In 2014 it was estimated there were 42,724,917 adults in England. Based on a prevalence estimate of 0.19% of adults in England, this means an estimated 81,177 adults had psoriatic arthritis. It assumed that the population eligible for treatment will be the same as that for previously recommended drugs for psoriatic arthritis in TA199 (etanercept, infliximab and adalimumab) and TA220 (golimumab). The costing statement for TA220 states that 2.4% of people with psoriatic arthritis are eligible for treatment (based on a company submission). Using 2014 figures, this is an estimated 1,948 adults.</p>		
Process (TA/HST)	TA		
Proposed changes to remit (in bold)	None		
Costing implications of remit change	<p>Abatacept is already marketed in the UK for the treatment of rheumatoid arthritis. The list price for a 125mg pre-filled syringe (125mg/ml) of abatacept costs £302.40 and treatment with 125mg abatacept once weekly for 24 weeks would cost £7,257.60. There is a patient access scheme for abatacept which offers a simple discount (confidential) at the point of purchase or invoice.</p> <p>It is unlikely that there would be a significant resource impact because it is anticipated abatacept would be priced similarly to alternative treatment options.</p>		
Timeliness statement	Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for		

	this technology will be possible.
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Provisional Title	Cx601 for treating complex perianal fistula in Crohn's disease		
Topic Selection ID Number	7522	Wave / Round	R122
TA ID Number	960		
Company	Takeda		
Anticipated licensing information	***Confidential information removed***		
Draft remit	To appraise the clinical and cost effectiveness of Cx601 within its marketing authorisation for treating perianal fistula in non-active or mildly active luminal Crohn's disease.		
Main points from consultation	<p>Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of Cx601 for treating complex perianal fistula in Crohn's disease is <u>appropriate</u>.</p> <p>The proposed remit is not appropriate and should be amended as follows: To appraise the clinical and cost effectiveness of Cx601 within its marketing authorisation for treating perianal fistula in non-active or mildly active luminal Crohn's disease which is consistent with the anticipated marketing authorisation. Reference to the activity of luminal Crohn's disease has been removed as Cx601 only treats the perianal fistulas and not the underlying Crohn's disease.</p> <p>Cx601 does not treat the underlying Crohn's disease but is a targeted treatment for perianal fistulas. Consultees were in agreement that that Cx601 can be used in combination with biologics (where these were tolerated) or as monotherapy. Infliximab, adalimumab and vedolizumab treat the underlying Crohn's disease and if tolerated in patients with residual perianal fistula's will have Cx601 added to their treatment. Therefore biologics have not been included as comparators as they will be used in both arms. Surgical treatments (such as use of a seton, fistulotomy, advancement flap procedures or insertion of biosynthetic plugs and fibrin glue) were considered to be the most relevant comparators.</p>		
Population size	<p>Between 10,400 and 14,300 people in England would be eligible for treatment with Cx601</p> <p>Of the 115,000 people in the UK with Crohn's disease approximately 20% (23,000) develop perianal fistula. The majority patients who continue to have perianal fistula after treatment with infliximab, adalimumab or vedolizumab would be treated with Cx601 either as monotherapy (if they are unable to tolerate anti-TNF) or in combination with anti-TNF. Based on the success rate of infliximab (38-55% of fistulas are closed following infliximab treatment) between 10,400 and 14,300 people in England would be eligible for treatment with Cx601</p>		
Process (TA/HST)	TA		

Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of Cx601 within its marketing authorisation for treating perianal fistula in non-active or mildly active luminal Crohn's disease which is consistent with the anticipate .
Costing implications of remit change	***Confidential information removed*** Where treatment is successful, costs for surgery can potentially be avoided.
Timeliness statement	Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible.