

Decision Support Unit Project Specification Form	
Project Number	
Appraisal title	Infliximab (review) and adalimumab for the treatment of Crohn's disease (including a review of technology appraisal guidance 40)
Synopsis of the technical issue	<p>Following consultation on the ACD a number of issues were raised by consultees relating to the cost effectiveness analysis produced by the assessment group (WMHTAC). The committee was of the opinion that an independent review of the WMHTAC model, with consideration of alternative approaches, would be helpful in reaching a conclusion.</p> <p>In particular, it was noted that the analysis is highly sensitive to the relapse rate assumed for people receiving standard care who had achieved remission following an induction course of treatment. Further evidence on the most plausible relapse rate in this population is needed.</p> <p>An alternative, unpublished analysis was put forward during consultation.</p> <p>An evaluation and comparison of these approaches by the DSU suggested that there were several issues that need to be addressed:</p> <ul style="list-style-type: none"> • whether all the benefits of treatment are being captured • the external validity of the Silverstein cohort • comparative analysis using different trials for each arm. <p>A modelling approach that reconciles these issues is required.</p>

<p>Question(s) to be answered by DSU</p>	<p>The DSU will address these questions in a stepwise fashion.</p> <ol style="list-style-type: none"> 1. Conduct a review of relapse rates in people with severe Crohn’s disease who have achieved an initial remission with treatment. This will be used to inform estimates of cost effectiveness. 2. Reconcile the different modelling approaches presented to: <ul style="list-style-type: none"> ○ capture all benefits of treatment, not just avoided relapses ○ improve the internal validity of the model ○ improve the external validity of the model – particularly in regards to relapse rates 3. If appropriate, further analysis may include consideration of different durations of maintenance treatment with reversion to standard care on discontinuation. 4. Where considered appropriate, conduct sensitivity analysis around parameters.
<p>How will the DSU address these questions</p>	<p>Review of the evidence relating to the rate of relapse in people with severe Crohn’s disease and in the post surgical state, which should then be incorporated in the cost effectiveness estimates.</p> <p>Reconcile all models submitted for estimating the cost effectiveness of TNF inhibitors in Crohn’s disease.</p>

How does this relate to the AG?	<p>Some of these analyses could have been carried out by the WMHTAC. However, the Appraisal Committee felt that a third party examination of the model and evidence base would be beneficial in responding to the critiques of the WMHTAC analysis.</p> <p>The Assessment Group will provide the DSU with analyses prepared before the Committee meeting including a critique of the analysis by Bodger et al, and a non systematic review of the relapse rates observed in studies of other interventions for Crohn's disease.</p>
Exact analyses required	<p>The DSU will prepare a report which:</p> <ul style="list-style-type: none"> reviews main clinical and economic inputs into the model provides estimates of the cost effectiveness of maintenance and episodic therapy present validation analyses around main parameters of economic model, such as relapse rates <p>If the DSU considers it appropriate, analyses in which maintenance treatment is discontinued after a fixed period should be presented.</p>

Decision Support Unit Project Administration Form	
Project Number	
DSU Lead Analyst	Allan Wailoo,
DSU Project Leader	Allan Wailoo

Date form sent to DSU	February 2009
NICE contacts <ul style="list-style-type: none"> • Technical Lead • Technical Adviser • Project manager 	Raphael Yugi Prashanth Kandaswamy Bijal Chandarana (Bijal.chandarana@nice.org.uk)
DSU contacts <ul style="list-style-type: none"> • Project Leader 	Allan Wailoo, ScHARR
Assessment Group <ul style="list-style-type: none"> • Lead reviewer 	Catherine Meads
Details of Assessment Group involvement in the project	Requests may be made by the DSU for information from the Assessment Group. All correspondence to be copied to NICE team
Appraisal committee members involved in the project	Simon Maxwell Alec Miners Philip Home David Barnett

Other experts involved in the project	
Documentation sent to DSU and date*	
Timelines:	
<ul style="list-style-type: none"> • Start date 	April 2009
<ul style="list-style-type: none"> • Date for delivery of draft report 	1st June 2009
<ul style="list-style-type: none"> • Date for delivery of report to Institute 	5th June 2009
<ul style="list-style-type: none"> • Date of appraisal Committee meeting for presentation of report 	20th August 2009
Total anticipated DSU person hours - for full details see task form	