



nras

National Rheumatoid  
Arthritis Society

Cathryn Hall  
Project Manager  
National Institute for Health and Clinical Excellence  
MidCity Place  
71 High Holborn  
London WC1V 6NA

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Dear Ms. Hall

**NRAS submission in respect of ACD - Abatacept for the treatment of rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs**

Thank you for the opportunity to submit on behalf of NRAS in respect of the above Appraisal Consultation Document. The National Rheumatoid Arthritis Society was disappointed with NICE's decision not to issue a positive Appraisal Consultation Document for the use of abatacept in rheumatoid arthritis patients who have failed to respond, or are intolerant to, DMARDs including methotrexate and in answer to the Committee's specific questions, and we would reply as follows:

**1 Has all of the relevant evidence been taken into account? Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?**

We do not think that all the relevant evidence has been taken into account and agree with the British Society for Rheumatology's response to the ACD that some of trial evidence has been either misinterpreted or simply not adequately factored into the health economic calculations in respect of cost effectiveness. Also, we do not believe that the Committee have adequately taken into account the quality of life issues for someone with RA who may be contra-indicated for Anti TNF post DMARD failure.

I know first hand how vital biologic therapies are for those who have failed on standard DMARDs. The majority of people are able to start Anti-TNF treatment in line with NICE guidance, however, for a small minority, for whom Anti-TNF is contra-indicated, Abatacept is a potential lifeline and I hope that NICE will look again at the data and some of their assumptions.

I believe the Committee is well aware that for this group of patients, asking them to continue on DMARDs when they have failed at least two including methotrexate and have a DAS score of greater than 5.1 is condemning them to a life of pain and misery, with worsening disease which delivers no quality of life. I had to come off my treatment for 12 weeks last year and found that my pain levels increased so significantly that even morphine was inadequate. I could not imagine remaining in that state for any length of time, let alone for the rest of my life. Steroids are not recommended to be taken long term and this is reinforced in the NICE RA guidelines, quite rightly so, as we are now very aware of their unacceptable side effects over time. Yet high dose steroids is likely to be the only course of action to relieve the pain for someone meeting the threshold for Anti-TNF, but unable to have one of these drugs.

## **2 Are the provisional recommendations sound and a suitable basis for guidance to the NHS?**

In point 4.12 the BSR have addressed in their response the argument which has been prosecuted many times about the difference in responsiveness to HAQ of patients with short duration disease whose disease is being driven by inflammation against those with much longer duration whose HAQ is being driven by mechanical damage and therefore less likely to respond to treatment. We support their assertion that HAQ changes derived from these trials will be an underestimate of the changes seen in patients with earlier disease in routine care today, and thus the ICER for routine care today is likely to be lower than the base case ICER of £29,700.

The committee questioned the patient experts during the Appraisal about the scenario where having a quality of life could be worse than being dead and this is certainly the case. I know of people who have attempted suicide and have certainly had letters and emails from people who are experiencing a 'living hell' when no suitable and effective treatment can be found which is extremely hard to bear, especially when you know there are treatments which, if available, might be effective.

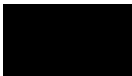
There are two additional benefits to Abatacept which we would like to reinforce, firstly that it can be taken as monotherapy if methotrexate is also counter-indicated or not tolerated, and the evidence that it delivers increased benefit after 12 months which should be taken into account.

## **3 Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?**

Whilst NICE may not be discriminating against the group of patients for whom Anti-TNF is contra-indicated on any of the above grounds, we believe that they would suffer discrimination on grounds of health which we feel is equally unfair. Clinical guidelines from BSR, EULAR and

ACR allow the use of Abatacept as a first line biologic post DMARD failure and we are talking about a relatively small group of people so costs would be contained. We agree with the BSR that there is a significant body of evidence to support the use of Abatacept in this important group of patients and we hope that the Committee will re-consider their guidance and allow at least this restricted use of Abatacept.

Yours sincerely



National Rheumatoid Arthritis Society  
Unit B1, Westacott Business Centre  
Westacott Way, Littlewick Green,  
Maidenhead SL6 3RT

Phone:  email: 

Website: [www.nras.org.uk](http://www.nras.org.uk)