NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Patient/carer expert statement (STA)

Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy [ID690]

Thank you for agreeing to give us your views on this treatment that is being appraised by NICE and how it could be used in the NHS. Patients, carers and patient organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of receiving NHS care for the condition
- the experience of having specific treatments for the condition
- the outcomes of treatment that are important to patients or carers (which might differ from those measured in clinical studies, including health-related quality of life)
- preferences for different treatments and how they are given
- expectations about the risks and benefits of the treatment.

We have already asked your nominating organisation to provide an organisation's view. We are asking you to give your views as an individual whether you are:

- a patient
- a carer (who may be voicing views for a patient who is unable to) or
- somebody who works or volunteers for a patient organisation.

To help you give your views, we have provided a questionnaire. You do not have to answer every question — the questions are there as prompts to guide you. The response area will expand as you type. The length of your response should not normally exceed 10 pages.

1. About you

Your name: [redacted]

Name of your nominating organisation: **Crohns and Colitis UK**

Do you know if your nominating organisation has submitted a statement?

☐X Yes ☐ No

Do you wish to agree with your nominating organisation's statement?

☐X Yes ☐ No

(We would encourage you to complete this form even if you agree with your nominating organisation's statement.)

Are you:

- a patient with the condition?

☐X Yes ☐ No

- a carer of a patient with the condition?

☐ Yes **X** No

- a patient organisation employee or volunteer?
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☐ Yes ☐ **X** No

Do you have experience of the treatment being appraised? ☐X Yes ☐ No

If you wrote the organisation submission and do not have anything to add, tick here ☐ (If you tick this box, the rest of this form will be deleted after submission.)

2. Living with the condition

What is your experience of living with the condition as a patient or carer?

I was 50 and living in Canberra, Australia in September 2004 when I noticed I was becoming tired easily and found it difficult to go jogging or exercise at the gym. I had experienced no serious illnesses and no days off work apart from tonsillectomy when I was 18 and had no need to visit my Dr at all until this time. It took until January 2005 when I was hospitalised to be diagnosed with Crohns at which time I was 42 kilos with swollen joints, erythema nodossom, dreadful wind, diarrhoea, pain etc….the treatment was Prednisolone and sulfasalazine and this achieved remission within a 3 month period. I returned to work in the 4th month.

My first flare up was October 2006 and due to the various bad side effects of Prednisolone in 2005 I was put on Budesonide and Sulfasalazine. When these did not help I tried Azathioprine and Methotrexate and was taken off both due to the side effects. When these had no impact I remained taking Sulfasalazine and was put on prednisolone and then on to Infliximab in March 2007 which at the time was a trial drug in Canberra. I went on a FODMAPS diet which slows the symptoms and can stop some weight loss but ongoing deterioration leads to nausea, pain and the inability to do anything but read, sleep and go to the toilet and clean the toilet after each visit. Regular social, domestic life activites STOP… It is extremely difficult to concentrate and focus on a particular subject. I recall being at Centrelink (Social benefits office in Canberra) and bursting into tears on being asked two or three question quickly in succession. I just couldn't remember more than one question at a time and found it very difficult to cope with the stress I was experiencing. I have always been very much in control and "on top of the game". I stayed on prednisilone until the end of April. By June 2007 my symptoms had diminished and by July I was developing arthritic symptoms and asked to be taken off Infliximab in August 2007. I had 9 months off work.

I was in remission for two years until Aug/Sept 2009 when symptoms returned. Again I tried prednisilone and sulfasalazine but did not go into

remission and was unable to go on infliximab due to the fact I had built up antibodies against it. My personal life was in tatters, my partner and I separated after being together for 18 years and in December 2009 my mother died in England and I was unable to travel to the UK for the funeral as I was too ill. My condition was deteriorating and I was experiencing mild depression. In March 2010 I started Vedolizumab and have been on that and sulfasalazine ever since. I went on a liquid supplement diet as the nausea was so bad that all food made it worse. This helped me keep my weight above 50 kilos. I started introducing food by mid May and my symptoms diminished slowly and in October 2010 I came back to live in Yorkshire, to be near relatives. My health continued to improve. I had transferred my treatment to Dr James Lindsay at The Royal London/Barts and have now been on Vedulizamab for coming up to 4 years. By March 2011 I came off the mild anti depressant tablets as I felt I was back to "my old self" and had regained most of my physical energy and enthusiasm for life. I was off work for 14 months this time and I had been totally dependent on other people from February 2010 to mid May 2010.

I set up a textile company, in North Yorkshire in June 2011, and have successfully run that business with no days off ill.

From my experience there is only Vedolizumab that brings me remission with NO side effects.

3. Current practice in treating the condition

Which treatment outcomes are important to you? (That is, what would you like treatment to achieve?) Which of these are most important? If possible, please explain why.

Remission is the desirable outcome. There isn't one particular symptom that would improve ones quality of life with Crohns if it wasn't there, because there are so many.

What is your experience of currently available NHS care and of specific treatments? How acceptable are these treatments – which did you prefer and why?

Prednisilone created mood swings, lethargy and then hyper unable to sleep and thrush, my bone density was checked regularly and after the first diagnosis it didn't have any impact on my symptoms.

Budesonide did not improve my symptoms

Aziathioprine did not agree with me at all…. My vision and balance went peculiar and my Dr took me off it after two days.

Methotrexate. I couldn't get out of bed as I was dizzy with it and had to lie down with a really bad headache. My Dr took me off it.

Sulfasalazine . I have been taking this for nearly 4 years. I don't think I have any side effects except for darker urine and am told it may help stop Bowel cancer.

4. What do you consider to be the advantages of the treatment being appraised?

Benefits of a treatment might include its effect on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (such as lifestyle and work)
- other people (for example, family, friends and employers)
- ease of use (for example, tablets rather than injection)
- where the treatment has to be used (for example, at home rather than in hospital)
- any other issues not listed above

Please list the benefits that you expect to gain from using the treatment being appraised.

Over time all my symptoms have gone and I am in remission

I am able to work and look after myself and my dog.

I am happy and have a good quality of life.

My friends and family don't have to look after me.

I can go for walks with my dog and jog a little

I receive my treatment for a couple of hours a month in hospital.

I don't suffer any side effects from the treatment.

Please explain any advantages that you think this treatment has over other NHS treatments in England.

As above as this drug has been successful

If you know of any differences in opinion between you and other patients or carers about the benefits of the treatment being appraised, please tell us about them.

- *I don't know of any differences of opinion.*

5. What do you consider to be the disadvantages of the treatment being appraised?

Disadvantages of a treatment might include:

- aspects of the condition that the treatment cannot help with or might make worse
- difficulties in taking or using the treatment (for example, injection rather than tablets)
- side effects (for example, type or number of problems, how often, for how long, how severe. Please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- where the treatment has to be used (for example, in hospital rather than at home)
- impact on others (for example, family, friends and employers)
- financial impact on the patient and/or their family (for example, the cost of travel to hospital or paying a carer)
- any other issues not listed above

The only disadvantage would be that I have to travel to London from Yorkshire one day a month to continue my treatment.

(I have been happy to take this journey when I moved to North Yorkshire for treatment as my health had already improved greatly over the previous 7 months of treatment in Canberra)

If I became ill again with the usual symptoms I would not be able to travel an hour to York by car,and sit for two hours on a train to London and take the tube to Whitechapel and do the same on the return journey.

(When I lived in Canberra I was only 10 minutes drive away from my hospital.)

Please list any concerns you have about current NHS treatments in England.

The only other drugs that have helped me have been prednisilone which is known to have long lasting side effects and the Infliximab helped the Crohns but I gained arthritis symptoms.

Please list any concerns you have about the treatment being appraised.

No concerns

If you know of any differences in opinion between you and other patients or carers about the disadvantages of the treatment being appraised, please tell us about them.

I know of none

6. Patient population

Do you think some patients might benefit more from the treatment than others? If so, please describe them and explain why.

I do not know

Do you think some patients might benefit less from the treatment than others? If so, please describe them and explain why.

I do not know

7. Research evidence on patient or carer views of the treatment

Are you familiar with the published research literature for the treatment?

☐X Yes ☐ No

If you answered 'no', please skip the rest of section 7 and move on to section 8.

Please comment on whether your experience of using the treatment as part of routine NHS care reflects the experience of patients in the clinical trials.

I am on a clinical trial

Do you think the clinical trials have captured outcomes that are important to patients? Are you aware of any limitations in how the treatment has been assessed in clinical trials?

I do believe the outcomes of the clinical trials have been extremely important to patients. ie remission.

I am not aware of any limitations in how the treatment has been assessed in clinical trials. During my experience on the trial I have completed many questionnaires and blood tests have been analized regularly. For the main trial I completed daily symptom records. My nurse and specialist have asked me many questions as to my health on each visit to the hospital. There has been extensive data collected

If the treatment being appraised is already available in the NHS, are there any side effects that were not apparent in the clinical trials but have emerged during routine NHS care?

n/a

Are you aware of any relevant research on patient or carer views of the condition or existing treatments?

☐ Yes ☐ **X** No

If yes, please provide references to the relevant studies.

8. Equality

NICE is committed to promoting equality of opportunity and eliminating discrimination. Please let us know if you think that recommendations from this appraisal could have an adverse impact on any particular groups of people, who they are and why.

None

9. Other issues

Do you consider the treatment to be innovative?

☐X Yes ☐ No

If yes, please explain what makes it significantly different from other treatments for the condition.

It targets specific cells within inflamed bowel tissue only.

Is there anything else that you would like the Appraisal Committee to consider?

Having a flare up of Crohns Disease is a "shocking" event because the patient knows the symptoms will only get worse and life goes on HOLD until some drug is used to stop them. A flare up induces anxiety which will only increase symptoms and therefore the wellbeing both mentally and physically is severely compromised. My GP suggested I take a light anti depressant on my third flare up as she identified that I was preparing myself for a long haul of symptoms/hospital visits/loneliness/etc… Until I was 51 I had never been ill, never took drugs, ie asprin, paracetomol etc.. of any kind and was extremely fit…. Never smoked and had an occasional glass of wine. Visited the gym regularly, ran, etc.. Crohns disease came out of the blue and so emotionally it was very difficult to get my head around that "I was ill" and would have to take drugs. I had been in Australia for 16 years when I was first diagnosed and had never had the need to visit a Dr.

This drug has given me back my life and I can live life to the full. In the four years since I returned to the UK I have only visited my GP once on arrival to register and once in 2011.

Finally, I believe I am on this maintenance trial until March 2015. If I come off the drug then I would like to know that I would be able to go on it again should I have a future flare-up. If this is not possible then my only avenue would be to try another trial drug if it was available as history has shown all other NHS drug therapies have been unsuccessful in stopping my symptoms.

10. Key messages

In no more than 5 bullet points, please summarise the key messages of your submission.

- *This drug has been very effective for me and I am in remission and feeling very well.*
- *I have experienced no adverse side effects compared to all other treatments I have experienced.*

- *Treatments once a month instead of daily pills*
- *I am back in the workforce again.*
- *Less drain on GPs time.*