Lori Farrar
Project Manager - Committee C
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8th July, 2015

Dear Lori

Response to the ACD relating to the Multiple Technology Appraisal (MTA) Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, abatacept and tocilizumab for the treatment of rheumatoid arthritis (review of TA guidance 130, 186, 224, 234 and part review of TA guidance 225 and 247) [ID537]

Thank you for the opportunity to comment on the Appraisal Consultation Document relating to the above MTA.

We welcome the publication of the draft MTA ACD provisionally recommending access to biologic medicines for patients living with severe RA, but have some real concerns which we outline below which align with those expressed by the BSR:

- Ongoing access to bDMARDS in patients with severe, active RA
- Removal of access to those patients who are intolerant to or are contra/indicated for MTX, who would previously have had access to mono-therapy bDMARDs
- Access for people with moderate disease but who have poor prognosis

Ongoing access for patients with severe, active RA

We are relieved that patients with severe active disease will have on-going access to these drugs which are so life-changing for many. We also understand in a cash-strapped NHS where rationing has to happen that only patients who are at greatest risk of poor prognosis and worsening disease should receive these therapies. We agree with the BSR clinical experts that active synovitis despite combination therapy and tight control is an indicator of poor outcomes and that this ACD does represent a more stringent threshold than previously, but one which aligns with current best practice and guidelines.

Access to bDMARDs for patients with intolerance and/or contra-indications to MTX

We are, however, dismayed to see that these two small but important groups of patients are being denied access to bDMARD monotherapy. This is in stark contrast to previous NICE TAs, flies in the face of current best practice which has been established for many years and we believe would be an unfair and retro-grade step for these patients who would be singularly disadvantaged and would have to live with progressive disease, increasing disability, pain and suffering or have to live with debilitating side effects which can all too easily lead to job loss, depression and very diminished

quality of life. We speak to people who are intolerant to MTX and call our helpline and know how disruptive and unpleasant side effects can be and it is, we believe, unreasonable and unfair to exclude this group and those who are already disadvantaged by being contra-indicated in some way. We completely agree with the BSR's comments on patients wishing to conceive.

We would strongly urge the Committee to re-consider their initial recommendations in regard to the above groups and allow monotherapy bDMARD prescription for those who are either intolerant to or have a contra-indication to methotrexate.

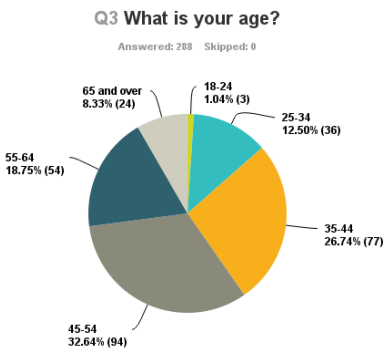
Access for people with moderate disease/poor prognosis

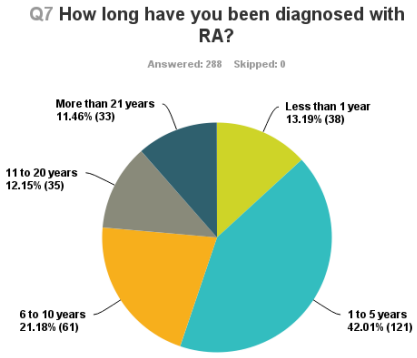
We fully support the BSR position in regard to this group. As the ICER from the exploratory analysis for the moderate group falls within the cost effective range set by NICE, we would request that NICE re-consider their initial recommendations not to extend the guidance to this group and in particular would endorse the data findings presented by the BSR, which evidence that those with moderate disease, but who have a rapidly progressing course of disease, do constitute a major clinical problem and should be eligible for bDMARDs if they fail combination therapy.

We went back to the data we presented for the meeting on 21st May, gathered from our survey and extrapolated those patients who were on cDMARDs and do not meet the current eligibility criteria for biologic treatment, so have a DAS of less than 5.1.

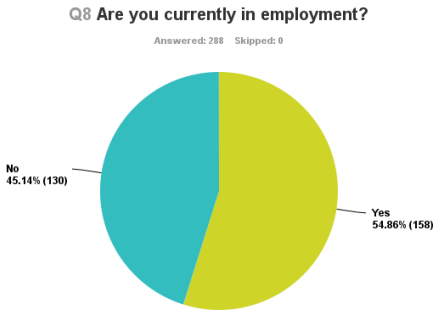
The following data reinforces the BSR position we believe and demonstrates the importance of treating this group of patients who are likely to continue to be expensive to treat if they remain unable to access the most appropriate biologic therapy to gain adequate control of their disease:

288 patients met the criteria for currently being on cDMARDs and not therefore meeting current criteria for biologic access. Of the total, 20 were male and 268 female. Out of the 288, 60% were in the age range 35-54, so in the prime of their working life, bringing up families. We asked how long people had been diagnosed and over 55% had been diagnosed within the last 5 years.





We wanted to know how many were in employment and their employment status and the following two graphs illustrate this.

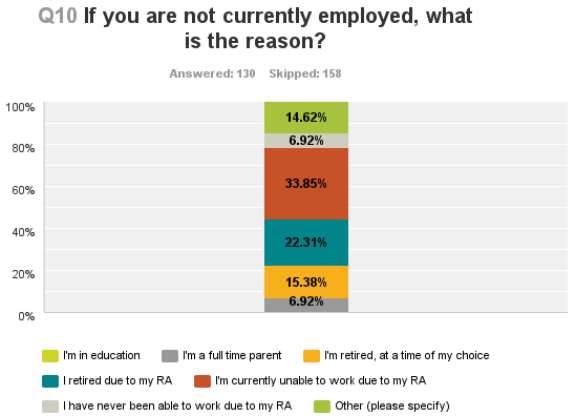


We asked of the 45.1% of participants who were not working, the reason that they were not employed and found, shockingly, that 63% were not employed due to their RA with the breakdown as follows:

33.85% were currently unable to work due to their RA

22.31% had retired due to their RA

6.92% had never been able to work due to their RA



We then asked about pain and fatigue impact during the last 6 months, using a visual analogue scale from 0-10 where 0 is not severe at all and 10 is very severe. In the case of pain, the average score for the 287 people who answered the question was 6.85 and 7.67 in respect of fatigue, both of which are relatively high, and are very debilitating symptoms to have to live with on a regular basis.

"I have tried 5 DMARDs and getting increasingly frustrated at the failures. I am not sure if biologics are the way forward for me but if the choice was not there I would be devastated".

"I'm very worried. At the moment I feel that biologics are future treatment options for when I need them. If that option were not available to me, it would be like someone telling me that I will be in pain and tired for the rest of my life and will have to try and survive on ever increasing doses of strong, addictive pain relief. I would not want to live like that with no hope of an effective treatment."

We also asked participants a question relating to identifying which of the following situations applies to them and these answers give a clear picture as to the serious way in which RA impacts on this group of patients:

Out of 284 who answered the questions:

- >60% said their disease is not well enough controlled to enable them to continue to do valued day to day activities
- Just under 60% said their disease is not well enough controlled and this is affecting their confidence and independence
- Just under 25% said their disease is not well enough controlled and is affecting their ability to remain in their current job
- Just under 10% said their disease is not well enough controlled and as a result they have lost their job

"I would be terrified. I am 30 years old, struggle to walk, to cook, have had to downgrade my job and lost a lot of income. I hope I will be put onto biologics as soon as I am eligible, and really really hope they work."

I hope that the above results from our recent survey and the attached case studies will give you and the committee an insight into the plight of those people who fall into the 'moderate' disease category, yet who have the poor prognostic markers and really need access to biologics in line with the rest of Western Europe.

We appreciate that we must be careful with precious NHS resources and cannot necessarily recommend that biologics be made accessible to all patients in the DAS 3.2-5.1 'moderate' category. We therefore confirm that we concur with the BSR proposal regarding patients in this group who have strong predictors of progressive disease as evidenced by active synovitis, persistently elevated inflammatory markers, erosions on x-ray and a positive ACPA. We strongly believe that left untreated, these patients will be more expensive to the NHS in the long run, not only in regard to treatment for their RA, including surgery and in-patient spells, but through greater co-morbidity including mental health issues such as depression, anxiety and of course to wider society through loss of work and financial independence.

In conclusion, we would like to see access to bDMARDs for those who cannot tolerate or are contra-indicated for MTX for the reasons both we and the BSR have identified and would urge the committee to consider access for those with moderate disease but restricting this to those who can be identified as having a rapidly progressive course. We believe that we are recommending actions which are fair, reasonable and whilst not fully aligning England and Wales with the level of access which those patients in the rest of Western Europe get to biologic therapies, go a crucial step further than currently exists and that this is fully justified in both humanitarian and economic terms.

Yours sincerely

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