National Institute for Health and Clinical Excellence

Adalimumab, etanercept and infliximab (review) for Rheumatoid arthritis

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Introduction

With a membership of over 380,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. The RCN promotes patient and nursing interests on a wide range of issues by working closely with Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

Assessment Report

Executive Summary

Section:

Criteria:

The UK treatment eligibility criterion is one of the hardest to achieve. In Belgium 41.3% and Norway 47.9% of patients on Biologics would not meet UK criteria \(^1\)

Lack of appropriate data

It is uncertain about how the Assessment Group considered the additional clinical issues and costs implications that can result from suboptimal patient management with DMARDs and the potential organ and systemic damage that occurs. Often these patients are admitted via other medical specialities (e.g. cardiology, respiratory) and currently the data on real life issues and cost related to the consequence of the disease remain poorly documented.
The limited evidence to evaluate traditional DMARDs should not compromise access to treatments that are more expensive but have evidence supporting their benefit (although some of this require further work to demonstrate the long term).

**Different routes of administration**

The route of administration must be seriously considered in the light of individual preferences and risks – some patients will not be appropriate for subcutaneous administration and others will. Unless this guidance adds flexibility (at all points in treatment pathway) it will be interpreted in a rigid way by some trusts and we will continue to have the ‘postcode prescribing issue’ resulting in further problems – adding to patient frustrations, lack of clarity & a greater time frame before practitioners can help the patient identify the individual patients' pathway. This will help patients recognise their long term plans (including wishing to try alternative routes of administration for methotrexate) and to have a clear understanding of the criteria for biologic assessment and be realistic about when biologics will be prescribed.

This is an area that must be considered, as unrealistic expectations have been fuelled by the ‘can't have - therefore must have’ philosophy that adds to patient distress and difficulties. It also presents additional problems for the practitioner supporting the patients who may have very little in the way of options once DMARDs have failed.

These therapies also need to be considered in the context of new therapies that will be launched in the next few years and it would be helpful if the Assessment Group can consider the placing of these in this context, for example if new equally expensive therapies are launched where will the order of treatment choices rest then?

**The costs to the individual**

Although there are difficulties in evaluation we would ask what the review considers in relation to systemic damage unrelated to joint changes (e.g. respiratory, cardiovascular etc) We would like to also stress that in clinical trial data we still are failing to research and capture the factors that make a significant difference to the individual - that is the sense of well being, loss of fatigue and overall reduction in pain. The evaluation of these therapies is complex, as many patients, once they are on biologics, reduce their other treatments that carry risks related to long term treatment (e.g. steroids, nsaids etc). Anecdotally, in clinical practice, patients who continue treatment often take up more tasks, (not necessarily captured in HAQ) become more independent and participate in social activities (including returning to work). These issues do need exploring in further research. The
social implications to the individual and the family have not, as yet, been adequately studied.  

In recent years patients have had an increasing level of understanding of the work of NICE and their guidance. It therefore, seems a travesty that the costs of the disease to the individual cannot be adequately considered in the current healthcare environment where we are expecting patients to increasingly self manage their conditions yet we have no way of weighting this to support them in treatment needs.

**Joint Replacement Issues:**

It is stated that data on joint replacements:

> 'Long-term observations show that around a quarter of patients with RA undergo a total joint arthroplasty.40 It cannot, of course, be assumed that all such surgery is directly attributable to RA, especially as osteoarthritis is the most prevalent form of arthritis.'

In addition although it has to be expected that some Osteoarthritis changes are to be expected, on average RA patients have multiple joint replacements/orthopaedic interventions and if the research in this field can be reviewed we suspect this will show that they have considerably greater amount of joint replacement surgery than the average population. James et al (2004) study demonstrated that 11% of patients with early RA underwent large or small joint surgery within five years of starting DMARD treatments.  

It is essential that in this guidance we serve patients well although have good criteria and management to use these therapies responsibly. Early data demonstrates a reduction in long term disability. It is important that we balance lack of data (DMARDs) against early evidence that has significant implications for patient outcomes.

**Cost effectiveness - resources**

 Ensuring cost effectiveness in the management of these therapies will be significantly helped by a positive response that enables units to proactively develop strategies for their patients need and can then work on long term planning to increase cost effectiveness issues in the management and treatment related to administering biologic therapies. 

There is currently no long term joined up planning between specialist units struggling to treat their patients with minimal strategic long term support and
PCTs who are forced to crisis manage their funding issues related to NICE funding.

**Factor 6.**

The great variation in use of facilities etc is compounded by the fact that implementation of first NICE guidance has been difficult because of complex issues related to funding, financial planning and the fact that despite guidance from NICE monies for such treatments they are not adequately allocated.

Experience from previous guidance has resulted in postcode prescribing. We would urge NICE to ensure that within reasonable grounds clinical decision making should enable the tailoring of treatment options to the specific and sometimes very complex needs of the individual with RA.
References:

Reference List


