
National Institute for Health and Clinical Excellence

Adalimumab, Etanercept and Infliximab for the treatment of rheumatoid arthritis after failure of a previous TNF- α Inhibitor

Royal College of Nursing

Introduction

With a membership of over 400,000 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. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

Final Appraisal Determination – Response to Letter from Appeals Committee Chair

We are pleased to note that the issues raised under Ground 2 are valid and you will be referring them to the Appeal Panel. With respect to the issues raised under Ground 3, we would make the following points:

1. The Discrimination Issue: You are minded to refer this issue in so far as it relates to the Race Relations Act 1976 but are not so minded with respect to the Disability Discrimination Act and ECHR points which you say you are struggling to understand. We must apologise for not making the points more clear. Section 21 of the DDA provides as follows:

21 Duty of providers of services to make adjustments

- (1) Where a provider of services has a practice, policy or procedure which makes it impossible or unreasonably difficult for disabled persons to make use of a service which he provides, or is prepared to provide, to other members of the public, it is his duty to take such steps as it is reasonable, in all the circumstances of the case, for him to have to take in order to change that practice, policy or procedure so that it no longer has that effect.

This places a duty on public bodies to ensure that their policies do not impact adversely on any cohort of disabled persons when compared with other

members of the public. A policy that provides for treatment to be given in trials to patients with RA will necessarily discriminate against patients with RA who are also learning disabled because as you will be aware drug trial protocols do not permit patients with learning disability who do not have the capacity to consent to take part in such trials. Accordingly the proposed policy will unlawfully discriminate against the learning disabled. The issue is of considerable importance and in our view it is plainly appropriate for it to be referred to the Appeal Panel.

With regards to the ECHR point, you will be aware that article 8 ECHR provides a positive obligation on state bodies such as NICE to promote the physical and psychological integrity of citizens. You will also be aware that in order to establish a breach of the anti-discrimination provisions of article 14 ECHR it is necessary that another of the Convention articles is engaged, but not necessary for it to be breached. Accordingly in the present case article 8 is engaged and so article 14 is in play. In considering the proposed NICE policy with respect to these drugs we are strongly of the view that the RRA and DDA points raised by us also raise Convention discrimination points under article 14. In this regard you will be aware that to promulgate a policy that breaches article 14 will be contrary to section 6 of the Human Rights Act 1998 and unlawful. Accordingly we are strongly of the view that the ECHR point is also valid and should be referred to the Appeal Panel.

2. The EC Directive Issue: In response to this proposed ground of appeal you say that the "Appeal Panel has consistently ruled that such arguments are bad as a matter of law". We were not aware that this issue had been raised before the Appeal Panel and do not know on what grounds it has been rejected in the past. Our view is that the point is a good one and without being informed why you think it is "bad as a matter of law" are unable to make further representations. We do however understand that the point is being taken in judicial review proceedings in the High Court on abatacept for rheumatoid arthritis.

In the light of the above we would invite you to refer the RCN's grounds of appeal in their entirety to the Appeal Panel.