20 Hallcroft Avenue, Countesthorpe
Leicester, LE8 5SL
0116 277 5330
[redacted]
treasurer@prostatecancerfederation.org.uk

www.tackleprostate.org

10 March 2014

Dr Maggie Helliwell
Vice Chair of NICE
National Institute for Health and Care Excellence
10 Spring Gardens
London SW1A 2BU
Monday, 16 June 14

Dear Dr Helliwell,

Final Appraisal Determination: Degarelix for treating advanced hormone dependent prostate cancer

Thank you for your letter of 12th May.

I confirm that my organisation, 'Tackle Prostate Cancer' would like to put forward points for an appeal of the final appraisal determination (FAD) of degarelix in advance hormone dependent prostate cancer, as you suggest. We would also ask that this appeal be heard in person by NICE's Appeal Panel.

We have four points of appeal in all, under grounds 1a and 2. These are as follows:

1. Ground 1a – the Institute has acted unfairly. We note that the wording of the proposed guidance has changed significantly between the Appraisal Consultation Document (ACD) and the FAD.

In the ACD, the guidance stated:

"Degarelix is recommended as an option for treating advanced hormone-dependent prostate cancer only for people with spinal metastases who are at risk of impending spinal cord compression."

In the FAD this reads as:

"Degarelix is recommended as an option for treating advanced hormone-dependent prostate cancer, only in people with spinal metastases who present with signs or symptoms of spinal cord compression."

The effect of this alteration is materially to change the nature of the guidance that the Institute has provided, in a way that will have a negative impact on some patients with prostate cancer. We believe that this should have led to a further stage of consultation, in the form of a second ACD. The fact that this did not happen is, in our view, unfair and we should therefore like to appeal this point.

2. Ground 1a – the Institute has acted unfairly. Second, we are unclear as to what prompted the wording of the recommendation to change. No additional evidence is presented to prompt a change from the original (and, in our view, correct) wording to the current wording in the FAD. Nor can we can see any argumentation in the FAD to justify this change, which therefore lacks transparency. Again, we believe this is unfair and we should like to appeal it.

I should also note that in commenting on the ACD, we realise that we may have characterised the then recommendation as being only for patients presenting with signs and symptoms of spinal compression. We very much hope that our misstatement has not in any way contributed to the current recommendation and that it is not too late to correct this, because that was certainly not what we meant.

3. Ground 1a – the Institute has acted unfairly. We also feel the recommendation may lead to consequences that weren't intended by the Appraisal Committee. The guidance as it stands ignores the fact that it is very rare for newly diagnosed patients to present with signs or symptoms of spinal cord compression, the only circumstances in which Degarelix could be used under the proposed guidance. This means that many patients who might benefit from it will not receive it. Under the ACD wording, clinicians would have been able to prescribe it to patients with spinal mestastases who are at risk of spinal compression, which makes a great deal more sense in the context of how patients present. We believe that producing guidance that will, in effect, debar treatment from the very patients it is intended to help (by the fact of making a requirement that is unrealistic for the stage of the disease in question) is inherently unfair.

4. Ground 2 The recommendation is unreasonable in light of the evidence submitted to NICE.

Finally, we do not believe that the recommendation in the FAD takes full account of the evidence in support of this drug.

The appraisal committee has either ignored or given insufficient weight to the many positive benefits of this drug as stated in various studies, both in terms of the effect on the disease itself and not least with respect to its cardiovascular benefits. A few of these are set out below, as examples:

Van Poppel and Klotz. Int J Urol 2012, states that on average, the use of Degarelix increased PSA PFS by 7 months in patients with a baseline PSA>20ng/ml. It also states that the bone formation marker S-ALP was better controlled with Degarelix and therefore the onset of SREs could be significantly delayed.

Albertsen et al. Eur Urol 2014, states that GnRH antagonists appear to halve the risks of cardiovascular events in men with pre-existing cardiovascular disease, one of the major causes of death in patients with advanced prostate cancer. There is an absolute reduction in risk of 8.2%.

Klotz et al Eur Urol 2014. In a study involving 1225 advanced patients, degarelix improved disease control when compared with LHRH agonists. This data confirmed data from five previously pooled studies and suggests better overall survival, better PSA progression free survival. It also confirmed a decrease in joint, musculoskeletal and urinary tract events when compared to LHRH agonists.

All of these benefits will not only save the NHS money in the long run, but will greatly improve the survivability and quality of life of patients with this disease. Our view is that the Committee has been dismissive of these and, in consequence, produced what is an unreasonable recommendation. We should therefore like to appeal this point too.

I do hope that you will give serious consideration to the issues that we have raised and grant us the opportunity to amplify these points directly to the Appeal Panel.

Yours sincerely

[redacted]
Hon Treasurer
tackle prostate cancer Action for patients
Prostate Cancer Support Federation