29 August 2014

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Ms Kate Moore
Technology Appraisals Project Management – Committee D
National Institute of Health and Care Excellence
Leval 1A, City Tower
Piccadilly Plaza
Manchester M1 4BD

04 SEP 2014

Dear Ms Moore

Re: **NICE Appraisal of Degarelix**

Ferring welcome the Appeals Panel decision to uphold two of our appeal points of NICE's draft guidance on Prostate Cancer (advanced, hormone dependent) - Degarelix depot.

The points on which Ferring and other stakeholders were successful related to the wording of the patient population in which degarelix may be used. We would very much now like to work with NICE to ensure that the wording of the eventual guidance is such that the drug is used where it will benefit patients most and without the inappropriate use of NHS resources. It is also essential that the panel receives input from urology and uro-oncology experts to help define the patient population most appropriately and in relevance to clinical practice.

Equally, we are keen that due consideration is given to the range of arguments that were rehearsed during the appeal hearing. Indeed at paragraph 42 of its judgment the Appeal Panel states

"In the hope that it may assist the Committee and Consultees, the Panel observes that it felt that the NICE clinical guideline 75 was helpful but not necessarily determinative on this point in this population group. It felt that efforts should be made in any future ACD/FAD to accurately define the patient population if the technology is to be approved for a particular patient group, so that the NHS will be able to effectively operationalise such a decision. The Appeal Panel does not under-estimate the challenge of doing this. The Committee may want to consider whether the better way forward is to consult on the wording now contained in the FAD, or to offer some other wording informed by the discussion at the appeal and unconstrained by past drafting".

We are clear that waiting until spinal cord compression is already evident is not an acceptable way to approach treatment in this group. Spinal cord compression is a neurological emergency and thereby a devastating complication of the illness. It is associated with severe pain and paralysis. By the time patients are presented with spinal cord compression, the disease consequences were much different to an earlier disease stage and a substantial proportion of patients may not make it to the oncologists for definitive therapy. Spinal cord compression can be an end of life event in an elderly patient, which would otherwise (if prevented), be eligible for other therapy options.

Degarelix is not indicated to treat spinal cord compression, whilst it is effective in controlling the cancer and thereby slowing or stopping the progression to spinal cord compression. It has been shown significantly to reduce cancer activity in the bone, compared to agonists.

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Our view is that degarelix should therefore be used in patients who are at risk of developing spinal cord compression, with a view to preventing them from going on to that catastrophic event. By "at risk" we mean anybody who is showing evidence of having boney metastases in the spine.

The TNM (Tumour/Nodal/Metastases) grading is an accepted means by which to grade the progression of prostate cancer and would be the means by which you would assess a patient's suitability in this situation. We believe that this drug would suit T-3 (or T-4) N-0 (or N-1) M-1b, which would normally be above the threshold at which you would wish to intervene with it.

We are very clear that the Appraisal Committee, quite rightly, does not wish to make a recommendation that will leave the door open for indiscriminate and inappropriate use of this product. Ferring's own promotion of it recommends its use only in high-risk metastatic patients and it is of no benefit to Ferring for degarelix to be used where it won't work at its best.

In those areas of the country where access to the product is currently unrestricted, clinicians have limited its use to no more than 13% of patients. In Scotland and Wales, where approval has been given for all indications, its use has been very restrained. Ferring estimate that in England only around 3,520 patients (less than 10% of new patients diagnosed each year) are at risk of spinal cord compression and would benefit from use of this drug.

We would ask that the Committee gives careful consideration to the points that we have put forward here with a view to producing a wording that balances the needs of patients with that of ensuring sensible use of NHS resources.

We would also ask that, in reaching its conclusions as to the relevant wording to be used, the Committee draws on advice from clinicians who have had some experience of using degarelix, so that it is privy to first hand experience of the drug and the value that it brings.

Yours sincerely

Copy:

Professor Gary McVeigh, Chairman of Appraisal Committee D
Sir Andrew Dillon, Chief Executive NICE