Appendix G – patient/carer organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Degarelix for treating advanced hormone-dependent prostate cancer

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: [redacted]

Name of your organisation: Prostate Cancer UK

Are you (tick all that apply):

- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc)

Prostate Cancer UK is the UK's leading charity for men with prostate cancer and prostate problems. We support men and provide information, find answers through funding research and lead change to raise awareness and improve care. The charity is committed to ensuring the voice of people affected by prostate disease is at the heart of all we do.

We conducted an online survey of people affected by prostate cancer about their opinions on degarelix for treating advanced hormone-dependent prostate cancer and access to the drug. 41 people replied to the survey and quotes from the respondents are included in this submission. Of the 41 respondents, one man said he had been treated with degarelix.

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What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. Advantages

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

A 2008 clinical trial demonstrated that degarelix achieved a significantly faster suppression of testosterone and PSA than leuprolide. This suppression was maintained throughout the 1-year treatment period.[i]

More recent research has shown degarelix to be associated with a lower risk of a cardiovascular (CV) event or death, especially in those with a history of CVD (more than 50% reduction in risk), compared to commonly prescribed LHRH agonists (goserelin or leuprolide)[ii]. These data are based on a pooled analysis of 2,328 men with prostate cancer from six prospective randomised trials, over one year of treatment. Further analysis of the data revealed that the men in the studies treated with degarelix had significantly higher overall survival (98.3% vs. 96.7%, p=0.0329) and improved disease control as evidenced by fewer fractures and a lower incidence of renal or urinary tract adverse events compared to men treated with LHRH agonists.[iii]

Should the STA recommend degarelix for use for this indication it will help to provide standardised access to the drug, increase the range of clinically effective treatment options available to all patients for whom it is appropriate and provide them with greater choice.

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above

Of the 41 people affected by prostate cancer who responded to our survey, 40 people believe it is ‘very important’ (34) or ‘important’ (6) for degarelix to become a treatment option available to all men for whom it is clinically appropriate – one respondent was unsure. When asked about the benefits of degarelix, 32 people said it would improve long-term control of the disease, 30 said that it would prolong survival and 25 said that it would provide another treatment option.

Quotes on advantages include:

"I developed drug induced hepatitis in early 2009 (interaction between Malarone and Casodex) degarelix was available in April 2009 and saved my life."

"Less cardiovascular risk"

"Immediate reduction in testosterone levels with no flare"

"This disease breaks the hearts of many men and their partners. Not knowing when the hormone therapy will stop working and knowing there is no alternative to turn to is a sickening feeling. The fear we have when we have to wait for the results of the next PSA test is unimaginable. Just to know there was some form of back up in degarelix would help so much..."

2. Disadvantages

Please list any problems with or concerns you have about the technology.
Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or thier family (for example cost of travel needed to access the technology, or the cost of paying a carer)

Some of the side effects may include:
Hot flushes
Weight gain
A drop in the number of red blood cells (anaemia)
Tiredness
Bone thinning
Breast swelling or tenderness
Loss of sex drive and erection problems

Other side effects may include:

- chills, fever or a feeling like you have the flu straight after the injection
- feeling dizzy or sick
- loose or watery stools (diarrhoea)
- headaches, or pain in the back, joints or bones
- a rash on the skin

40 people responded to a question about potential side effects of degarelix. 21 were concerned, but no more so than with any other standard treatment. 10 were concerned, but expected the benefits of degarelix to outweigh the side effects. 9 people had no concerns about the side effects of degarelix.

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Comments included:

"When your life is in the balance anything that can control or extend prognosis really does outweigh the side effects."

"If there are side effects, these would pale into insignificance if in the long term life expectancy is increased."

"Would not want more side effects than at present."

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

Not from our survey and research.

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

Two healthcare professionals who responded to our survey said that those men with extensive bone mets would benefit from degarelix.

As demonstrated in the trail above, those men with pre-existing cardiovascular problems may benefit from degarelix.

Comparing the technology with alternative available treatments or technologies
NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:
- improvement of the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc)

Please see comments above

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(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:
- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

Please see above comments.

Research evidence on patient or carer views of the technology
If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

Prostate Cancer UK is not aware of any adverse effects.

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

As per our survey.

Availability of this technology to patients in the NHS
What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

Of the 41 people affected by prostate cancer that we surveyed, the most common benefits of making degarelix available on the NHS were identified as living longer/improved survival, providing more treatment options, better quality of life and rapid effect of degarelix.

Comments included:

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"[Degarelix] would be good for patients who have heart disease and who cannot undertake recent trials because of the associated risks."

"Very important for patients presenting at diagnosis with a malignant spinal cord compression or extensive metastatic disease."

"Less visits to the hospital and GP. Initially, no risk of tumour flare either"

"Having used Degarelix for a considerable number of patients with prostate cancer we have seen very prompt responses in terms of improvement in bone pain."

"It would be a welcome alternative to the very few interventions currently available."

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

The overwhelming majority who responded to our survey expressed disappointment or anger if degarelix was not made available on the NHS.

A man who is receiving degarelix said:

"There is no other hormone treatment available to me my life expectancy would then be reduced to less than 12 months".

Other comments included:

"It would be a crying shame, if there is a drug to help the suffering and [it] is not made available to all men."

"Disappointed and would have a lowering of confidence in the NHS."

"Cheated if it is available in Scotland - that is outrageous."

"Concerned that the newly diagnosed will be confronted with lack of choice. I found this to be [the] most devastating and bleak aspect of going from being asymptomatic to discovering I had a life shortening illness with few treatment options."

Are there groups of patients that have difficulties using the technology?

Equality
NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could lead to recommendations that have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

It will be important to ensure that access to this technology is equitable and discrimination does not occur inappropriately on the basis of age, ethnicity or socio-economic status. Three quarters of all prostate cancers diagnoses are in men aged 65 and over[iv] and African Caribbean men are three times more likely to develop prostate cancer[v] than white men of the same age in the UK. Furthermore, men from lower socioeconomic backgrounds are less likely to survive prostate cancer than men from more affluent backgrounds[vi]. It will be important to ensure that eligible patients from these populations are not denied access to this technology (if approved) because of factors related to their age, ethnicity and socio-economic status. Information and communication strategies must also be considered and patients consulted to ensure that access can be as equitable as possible.

Other Issues

Please consider here any other issues you would like the Appraisal Committee to consider when appraising this technology.

It is important that health-related quality of life and adverse effects are considered with an equal standing to the other outcomes, such as patient-reported outcomes. Consideration of patient-reported outcomes will ensure that the agent is not only clinically effective but also improves outcomes of importance to this patient population, such as the extension of life.

References

[i] Klotz L, Boccon-Gibod L, Shore ND, Andreou C, Persson B-E, Cantor P, et al. The efficacy and safety of degarelix: a 12-month, comparative, randomized, open-label, parallel-group phase III study in patients with prostate cancer. BJU Int. 2008 Dec;102(11):1531–8.

[ii] Tombal B, Albertsen P, De La Taille A, Van Der Meulen E, Persson B-E, Olesen TK, et al. 677 Lower risk of cardiovascular (CV) events and death in men receiving ADT by gonadotropin releasing hormone (GnRH) antagonist, degarelix, compared with luteinising hormone-releasing (LHRH) agonists. Eur Urol Suppl. 2013 Mar;12(1):e677–e678.

[iii] Miller K, Crawford ED, Shore N, Karup C, Van Der Meulen E, Persson B-E. 678 Disease control-related outcomes from an analysis of six comparative randomised clinical trials of degarelix versus luteinising hormone-releasing hormone (LHRH) agonists. Eur Urol Suppl

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[v] Ben-Shlomo Y, Evans S, Ibrahim F, Patel B, Anson K, Chinegwundoh F, et al. The risk of prostate cancer amongst black men in the United Kingdom: the PROCESS cohort study. Eur Urol. 2008 Jan;53(1):99–105.

[vi] Rowan S, Rachet B, Alexe DM, Cooper N, Coleman MP. Survival from prostate cancer in England and Wales up to 2001. Br J Cancer. 2008 Sep 23;99(Suppl 1):S75–S77.