

DORSET MEDICINES ADVISORY GROUP

COMMISSIONING STATEMENT ON THE USE OF DEGARELIX (Firmagon®) FOR ADVANCED HORMONE-DEPENDENT PROSTATE CANCER IN ADULTS WITH SPINAL METASTASES (TA404)

SUMMARY	
<i>NHS Dorset Clinical Commissioning Group commissions in accordance with NICE TA 404 the use of Degarelix (Firmagon®) for advanced hormone-dependent prostate cancer in adults with spinal metastases.</i>	
BACKGROUND	<p>NICE TA404 states “Degarelix is recommended as an option for treating advanced hormone-dependent prostate cancer in people with spinal metastases, only if the commissioner can achieve at least the same discounted drug cost as that available to the NHS in June 2016.”</p> <p>Clinical studies have shown that testosterone suppression occurs immediately after administration, with serum testosterone levels corresponding to medical castration after 3 days and 100% after one month.</p>
RELEVANT NICE GUIDANCE	https://www.nice.org.uk/guidance/ta404
FORMULARY STATUS	Red.
PBR STATUS	Drug cost included in PbR tariff.
COMMISSIONING IMPLICATIONS	This treatment would be available in secondary care only. The therapeutic effect of Degarelix should be monitored by clinical parameters and prostate specific antigen levels (PSA).
RELEVANT CLINICAL COMMISSIONING PROGRAMME	Commissioned by Planned and Specialist Clinical Working Group of the CCG.
PATIENT PATHWAY IMPLICATIONS	See NICE pathway – Prostate cancer https://pathways.nice.org.uk/pathways/prostate-cancer
PRESCRIBING INFORMATION	<p>Degarelix (Firmagon®, Ferring Pharmaceuticals) is a selective gonadotrophin-releasing hormone antagonist that reduces the release of gonadotrophins by the pituitary, which in turn reduces the secretion of testosterone by the testes. Gonadotrophin-releasing hormone is also known as luteinising hormone-releasing hormone. Because gonadotrophin-releasing hormone antagonists do not produce a rise in hormone levels at the start of treatment, there is no initial testosterone surge or tumour stimulation, and therefore no potential for symptomatic flares. Degarelix has a marketing authorisation in the UK for the 'treatment of adult male patients with advanced hormone-dependent prostate cancer'. It is administered as a subcutaneous injection.</p> <p>The most common adverse reactions with degarelix are related to the effects of testosterone suppression, including hot flushes and weight increase, or injection site reactions (such as pain and erythema). For full details of adverse reactions and contraindications, see the summary of product characteristics.</p>

SUMMARY OF EVIDENCE TO SUPPORT FORMULARY STATUS	https://www.nice.org.uk/guidance/ta404				
ASSESSMENT OF COST IMPLICATIONS	<p>Firmagon® 80mg powder and solvent for solution for injection vials (Ferring Pharmaceuticals Ltd) x1 vial - £129.37 (BNF Sept 2016)</p> <p>Firmagon® 120mg powder and solvent for solution for injection vials (Ferring Pharmaceuticals Ltd) x2 vials - £260.00 (BNF Sept 2016)</p> <table border="1" data-bbox="507 555 1490 734"> <tr> <th data-bbox="507 555 999 629">Starting Dose</th> <th data-bbox="1003 555 1490 629">Maintenance Dose: monthly administration</th> </tr> <tr> <td data-bbox="507 636 999 734">Initially 240mg subcutaneously in the abdominal region as two injections of 120mg each.</td> <td data-bbox="1003 636 1490 734">80mg subcutaneously every 28 days as one injection.</td> </tr> </table> <p>The company's estimate of a total course of treatment (including administration) is £12,306. The company estimated that, assuming treatment with degarelix continues until disease progression, the total time spent on treatment is 5.9 years (including time spent having combined androgen blockade and anti-androgen withdrawal). Costs will increase to approximately £14,800 assuming treatment with degarelix continues until death (including administration and anti-androgen withdrawal).</p> <p>NICE states: "No resource impact is anticipated from this technology appraisal. Degarelix is another treatment option for advanced hormone-dependent prostate cancer in people with spinal metastases. Because of the small number of people who may have treatment, it is considered that clinical practice will not change substantially as a result of this guidance.</p> <p>A benefit of degarelix is that there is no testosterone flare at the start of treatment. This avoids the cost of using an anti-androgen treatment to prevent flares."</p> <p>The TA states that degarelix should be considered "only if the commissioner can achieve at least the same discounted drug cost as that available to the NHS in June 2016."</p>	Starting Dose	Maintenance Dose: monthly administration	Initially 240mg subcutaneously in the abdominal region as two injections of 120mg each.	80mg subcutaneously every 28 days as one injection.
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REFERENCES	https://www.nice.org.uk/guidance/ta404 https://www.medicinescomplete.com				
DATE	September 2016.				
REVIEW DATE	September 2018 or before in light of new information.				
CONTACT FOR THIS POLICY	Michelle Trevett, Senior Pharmacist, NHS Dorset CCG.				