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Our Ref: SSC1690: **Pegvisomant**
Date: 13 December 2016

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EMAILED TO:
EAST MIDLANDS ACUTE PROVIDERS
CHIEF EXECUTIVES AND MEDICAL DIRECTORS

Dear Colleague

Re: Publication of New Clinical Commissioning Policy (16050/P) for Pegvisomant for acromegaly as a third-line treatment (adults)

Following the outcome of a judicial review on HIV prevention (PrEP), NHS England has on the 4th December 2016 set out the results of its annual process for deciding which new specialised treatments and services, which require new investment, it will make available to patients.

The associated press release can be found at: https://www.england.nhs.uk/2016/12/hiv-prevention-pregramme/

The published policy can be found here: https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-a/a03/

NHS England will routinely commission the use of Pegvisomant for acromegaly as a third-line treatment (adults) in patients with uncontrolled acromegaly who have failed first and second-line treatment options in accordance with the criteria outlined in the published policy as outlined below:

Inclusion criteria:

i. Patient presents with continued clinical features of acromegaly (disfiguration, metabolic); AND
ii. Baseline IGF-1 ≥ 1.3 times Upper Level Normal (ULN) (adjusted for age and sex) as assessed by blood test; AND
iii. Is unsuitable for OR shows incomplete response to first-line treatment (pituitary surgery); AND
iv. Shows incomplete response to second-line treatment (medical therapy as monotherapy - SSAs, or medical therapy in combination with radiation therapy - SRS/SRT); OR
v. Has significant adverse effects as a result of second-line treatment.

Exclusion criteria:

i. Baseline hepatic alanine transaminase enzyme elevations ≥ 3 times ULN; OR
ii. Presence of severe life-limiting complications of acromegaly.

Stopping criteria:

i. Failure to normalise levels of IGF-1 AND failure to reduce IGF-1 by 50% despite maximum titration after 6 months; OR
ii. Evidence of efficacy having been achieved with normalisation of IGF-1 levels three months after withdrawal of treatment. Once IGF-1 is normalised on pegvisomant, the dose will be titrated downward and pegvisomant discontinued if IGF-1 remains normal (see Patient Pathway for further detail on process and duration); OR
iii. Serious adverse effects; OR
iv. Non-compliance indicated by elevated IGF-1, and clinical evaluation despite reasonable efforts to educate patients and/or secure regular drug administration; OR
v. Patient develops either related or unrelated severe life limiting condition(s).

In addition Trusts should ensure that:

- Patient outcomes are audited and reported.
- All patients are invited to participate in the national acromegaly database (see the UK Acromegaly register).
- Pegvisomant is purchased at the commercial in confidence discount

Treatment decisions, including assessment of disease activity, should be taken by recognised pituitary multidisciplinary teams operating to the relevant NICE clinical guideline (NICE CSG10 - "Improving outcomes for people with brain and other central nervous system tumours") and who have undergone peer review. This will ensure that all the relevant clinicians (neurosurgery and clinical oncology) are involved to ascertain that other treatment modalities have been explored.

Further information regarding the commercial in confidence discount can be obtained from James Steed at Email james.steed@pfizer.com or on 01304 616161

I would be very grateful if you could ensure this letter is shared as soon as possible with relevant clinical and contract teams within the Trust , as appropriate to aid implementation and discussion with affected patients.

Yours Sincerely

Mark Sheppard
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NHS England – Midlands and East

Cc Medical Director
Pharmacy Lead
Contracts Lead