

Email:mark.sheppard1@nhs.netTelephone:0113 824 9549Our Ref:SSC1693: PasireotideDate:13 December 2016

Specialised Commissioning – Midlands & East Fosse House 6 Smith Way Grove Park Enderby Leicestershire LE19 1SX

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

Tel: 0116 206 0185

Dear Colleague

Re: Publication of New Clinical Commissioning Policy (16052/P) for Pasireotide disparate injectable medical therapy for the treatment of Cushing's disease

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 has approved the use of pasireotide diaspartate injectable medical therapy for the treatment of Cushing's disease in accordance with the criteria outlined in the published policy. Pasireotide diaspartate should be used, according to its licensed dose, for patients with Cushing's disease requiring medical therapy who have not achieved control, or who are unable to tolerate, metyrapone and ketoconazole.

As a number of treatment modalities are available, patients will have their condition managed by a full multi-disciplinary team with access to a dedicated pituitary surgeon, pituitary endocrinologist, laparoscopic adrenal surgeon and pituitary radiotherapist. The decision to use pasireotide must be endorsed by the patient's multi-disciplinary team (with experience in the management of Cushing's disease) with support from other relevant service areas.

Pasireotide may only be used where a definitive curative therapy is planned (further surgery, radiotherapy or bilateral adrenalectomy) and should only be used for a defined period (for example, while waiting for radiotherapy treatment to become effective or to stabilise prior to surgery). In all cases initial therapy will be for a defined period of 2 months. Pasireotide diaspartate therapy may continue if tolerated by the patient and if measures of cortisol production show a 50% fall compared to levels measured before commencing treatment. Cortisol production must be

1

monitored every 2 months with a trial of withdrawal as cortisol production returns to the normal range.

Exclusions: Patients who require medical therapy but have not trialed, and are not contraindicated to, metyrapone and ketoconazole. Patient's who are contraindicated to pasireotide diaspartate as per the licence.

Starting Criteria: Pasireotide diaspartate may be used as defined above.

Stopping Criteria: Pasireotide diaspartate will be stopped if treatment is not tolerated by the patient. Pasireotide diaspartate will be stopped if measures of cortisol production do not show an improvement at 2 months and a 50% fall from baseline at 4 months. Pasireotide diaspartate will be withdrawn when definitive therapy becomes effective. This may require a trial period off pasireotide therapy to demonstrate normal or low cortisol production (pasireotide may need to be reinstated if unsuccessful).

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 Interim Assistant Director of Specialised Commissioning for East Midlands NHS England – Midlands and East

Cc Medical Director Pharmacy Lead Contracts Lead