Dear Colleagues

Gateway Reference 04194

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To: CCGs

Primary Care Commissioning
National Support Centre
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Re: Early Access to Medicines Scheme (EAMS)

This letter is to raise awareness of the early access to medicines scheme (EAMS) and to alert your prescribing leads to the fact that a novel medication for heart failure has recently received approval for the EAMS scheme which will have implications for primary and secondary care prescribing next year.

The Early Access to Medicines Scheme was launched by the Medicines and Healthcare Regulatory Authority (MHRA) in April 2014. The scheme is intended to enable patient access to medicines for treatment of life threatening or seriously debilitating conditions where there is an unmet need.[1]

The scheme offers a way by which unlicensed medicines can be available to patients before approval of a licence to benefit public health. It enables companies to gain additional knowledge and the NHS to gain experience of these medicines in clinical use.

To date, EAMS has applied exclusively to treatments used in the care of cancer and have therefore been only commissioned by NHS England.

In April 2015, the MHRA issued a Promising Innovative Medicine (PIM) designation to a new drug, 'Sacubitril / Valsartan' to reduce the risk of cardiovascular mortality and morbidity in adult patients with symptomatic heart failure and reduced ejection fraction.[2] Novartis has subsequently received an EAMS positive opinion for Sacubitril / Valsartan' on 27 August 2015.

This will be the first non-oncology medicine to progress through the EAMS scheme. Participation in EAMS will be from centres with a heart failure specialist.

Through EAMS, the drug is made available free of charge to the NHS. The manufacturer (Novartis) will manage all requests from specialist heart failure services and provide NHS England and CCGs with a regular update detailing the participating centres and the number of patients entered.

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1 https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams

2 https://www.gov.uk/government/publications/early-access-to-medicines-scheme-eams-scientific-opinion-sacubitrilvalsartan

Requests for patients to join the scheme will be managed by the Novartis medical information team (contacted by email at medinfo.uk@novartis.com).

Physician prescribing guidance, information for patients and public assessment report is available through the MHRA website here.

Novartis will inform relevant Trusts and regional HTA Centres about the appropriate process to enter patients into EAMS, should they wish to do so. The EAMS scheme allows for free of charge stock to be accessed from the point of positive scientific opinion (August 2015) until the marketing authorisation is granted. This is permitted to last for a period of 12 months. Should the product receive a marketing authorisation within the 12 months, it will become chargeable from that point onwards for all new patients. For patients who started treatment during the EAMS (pre-marketing authorisation) period, stock will remain free of charge until a positive NICE TA is given (indicated as May/ June 2016) and for 30 days beyond. Given this is the first non-oncology EAMS molecule and is likely to be prescribed in primary care, CCGs will receive a series of updates to provide them with further background on EAMS and a brief on the specifics of sacubitril / valsartan. Further details will also be provided nearer to the time when NICE are publishing the technology appraisal (TAG).

Through EAMS, NHS services should become familiar with the introduction of the new drug and to be equipped to monitor its introduction in mainstream clinical practice. Pending a favorable NICE appraisal, drugs introduced through EAMS are expected to be introduced prior to the 90 day limit set out in the regulations. CCGs and Trusts will be expected to implement the NICE TA within a 30 day period.

Further information will be available in due course, however, it will be worthwhile for medicines optimisation teams being made aware of the EAMS scheme and its application to sacubitril /valsartan.

Best wishes

Yours sincerely

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cc. Regional Medical Directors – NHS England