Subject: Specialised Services Circular (SSC 2534)
Sent on behalf of: Chair of the SW Specialised Service Circular Group
Dear Colleagues,

Please find attached the following Specialised Services Circular(s):

SSC Number	SSC Title	Trusts approved to prescribe in accordance with the SSC, providing appropriate internal governance arrangements are in place
2534	Dostarlimab	All South West Acute Trusts

Is an implementation plan required from all SW trusts (regardless of commissioned status) for this SSC? No

For all other South West region trusts this is for information only.

Trusts should ensure that use is registered on the Blueteq system (if appropriate).

Treatment will only be funded where the drugs minimum dataset is fully and accurately populated.

Please direct any queries to: england.speccomm-southwest@nhs.net

Specialised Commissioning South West
NHS England
360 Bristol
Marlborough Street
Bristol
BS1 3NX
Email: england.speccomm-southwest@nhs.net

17 July 2023

All Chief Executives

All Medical Directors

All Chief Pharmacists

Dear Colleagues,

Re: Early Access to Medicines Scheme – Dostarlimab in combination with platinum-containing chemotherapy for the treatment of adult patients with mismatch repair deficient (dMMR) / microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy.

I am writing to advise you regarding NHS England's position on the recent positive scientific opinion for dostarlimab published by the Medicines and Healthcare products Regulatory Agency (MHRA). It advises on where activity associated with the technology will be commissioned by NHS England and under what circumstances.

The Early Access to Medicines Scheme (EAMS) was launched in April 2014. More information about the scheme can be found here: https://www.gov.uk/apply-for-the-early-access-to-medicines-scheme-eams)

Further to the of Promising Innovative Medicine (PIM) designation for dostarlimab on 27th May 2022 (EAMS Step 1), MHRA issued a positive scientific opinion on 29th June 2023 which states:

> Dostarlimab in combination with platinum-containing chemotherapy for the treatment of adult patients with mismatch repair deficient (dMMR) / microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy.

A summary of the MHRA EAMS Public Assessment Report (PAR) is available here:

https://www.gov.uk/government/collections/early-access-to-medicines-scheme-eams-scientific-opinions

Following the publication of the positive scientific opinion on 29th June 2023, Trusts who provide chemotherapy services should use the EAMS application process to apply for access to dostarlimab for eligible patients from this date.

For patients wishing to access dostarlimab, trusts must complete a Blueteq form to register each patient with NHS England once the application form has been submitted to GSK and the patient has been considered eligible for this EAMS. Further information regarding this can be requested from the dedicated EAMS email address: england.eams@nhs.net.

Patients must be informed that dostarlimab is being made available ahead of a marketing authorisation decision through EAMS. Patients should be made aware that if dostarlimab does not receive a marketing authorisation, or if NICE publishes negative guidance, or guidance that restricts the licensed population, then this will affect their continued treatment. They should also be made aware that if future recommendations are made restricting the length of the course of treatment, then treatment provided during EAMS will count toward the recommended course length.

To register a patient with the EAMS, healthcare professionals should first make contact by sending an email to ukeams.request@gsk.com to begin the registration process.

Dostarlimab is made available free of charge for EAMS patients during the EAMS period and administration costs will be covered by NHS England.

There are three main criteria along with meeting the clinical criteria Trusts should agree when applying for EAMS on the NHS England patient application form:

1. Application made by, and first cycle of systemic anti-cancer therapy to be prescribed by, a consultant specialist trained and accredited in the use of systemic anti-cancer therapy.
2. A specific patient access form for the dostarlimab EAMS must be completed and submitted to GSK to initiate new patient enrolments.
3. The treating Trust has to formally agree to comply with full SACT dataset completion.

NOTE: SACT returns will be monitored on a regular basis and Trusts failing to comply with point 3 may have their access to the EAMS for new patients restricted.

Following marketing authorisation of dostarlimab for this indication (anticipated in September 2023), centres that register patients for this EAMS prior to marketing authorisation will be able to continue to receive free of charge supply for existing patients registered from GSK between marketing authorisation and a funding recommendation from NICE.

For centres who have NOT registered patients prior to marketing authorisation, free of charge supply under the EAMS arrangements will not be available for any patients.

NICE are appraising the product as a priority. Should NICE issue a positive draft technology appraisal guidance on dostarlimab for this indication it will be funded initially through the interim Cancer Drug Fund once it has received marketing authorisation (if this has not been received prior to NICE draft guidance). Funding will usually transfer to routine commissioning 30 days after the final guidance has been published unless NICE recommend that it is funded via the CDF.

Providers of chemotherapy services should engage with their local specialised commissioning team to consider the implications of implementing this scheme.

I would be grateful if you could cascade this information to relevant clinical teams within your organisation to support the consistent adoption of the policy nationally.

With best wishes

Vinay Takwale (VT),
Medical Director NHS England, South West Region

Tracey Williams,
Clinical Pharmacist