Medicines and Healthcare products Regulatory Agency (MHRA): Early Access to Medicines Scheme (EAMS)

Summary of operational arrangements for Dostarlimab in NHS Scotland. EAMS number 52719/0001

The aim of the MHRA Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed and ‘off label’ medicines to UK patients that have a high unmet clinical need. The medicinal products included in the scheme are those that are intended to treat, diagnose or prevent seriously debilitating or life threatening conditions where there are no adequate treatment options. The MHRA EAMS positive opinion should not be regarded as a medicine licensed by the MHRA or a future commitment by the MHRA to license such a medicine. The opinion and EAMS documentation published by the MHRA are intended only to inform clinicians’ decision making and not to recommend use. Under EAMS the risk and legal responsibility for prescribing an EAMS medicines remains with the prescribing clinician. More information about the scheme can be found here: http://www.mhra.gov.uk/Howweregulate/Innovation/EarlyaccesstomedicinesschemeEAMS/index.htm

Dostarlimab is made available free of charge for patients via EAMS during the EAMS period. This document summarises how the medicine can be used in Scotland.

Medicine
Dostarlimab 500 mg concentrate for solution for infusion per 10ml vial

Indication and patient population
Dostarlimab is indicated 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.

Conditions for entry to EAMS
The EAMS makes free-of-charge dostarlimab for use in first-line treatment of primary advanced or recurrent endometrial cancer available to Health Boards (subject to approval by GSK) provided that the following conditions are met:

I. The patient (who is the subject of each order for EAMS dostarlimab) is an adult patient with with mismatch repair deficient dMMR/MSI-H primary advanced or recurrent EC and who are candidates for systemic therapy
II. The Health Board does not have any policies, guidelines or procedures in place which prohibit the acceptance of EAMS medicines
III. While a valid positive EAMS opinion is in place (Marketing Authorisation expected Q4 2023)
Detailed patient eligibility information is included in the Treatment Protocol – Information for Healthcare Professionals, link appended below.

**Supply arrangements**

1. Clinicians wishing to access treatment for their patients with dostarlimab need to contact the GSK medical department by email at ukeams.request@GSK.com.
2. As for all unlicensed medicines and off-label uses of licensed medicines, individual health boards will also have local governance arrangements in place to authorise medicines supplied via EAMS. This review should be expedited as a rigorous risk/benefit assessment has already been conducted by MHRA and can be accessed in the Public Assessment Report (PAR), link appended.
3. Other aspects of the supply arrangements can be accessed via EAMS documentation, links to which are appended at the end of this guidance.

**Practical considerations**

Dostarlimab 500mg is administered by intravenous infusion (IV) in combination with a platinum-containing chemotherapy every 3 weeks (Q3W) for 6 cycles (cycles 1-6), followed by dostarlimab 1000mg IV every 6 weeks (Q6W) for all subsequent cycles (cycle 7 onwards), until progression of disease, unacceptable toxicity, withdrawal of consent, or physician’s decision, up to a maximum of 3 years.

Dostarlimab is supplied as a solution in vials containing 500 mg (50 mg/mL) specifically labelled for this EAMS. Instructions for the preparation and administration of the dostarlimab infusion solution can be found in the ‘Dostarlimab EAMS Treatment Protocol – Information for Healthcare Professionals’ or in the Dostarlimab SmPC (available at: www.medicines.org.uk/emc/).

Carboplatin and paclitaxel are to be administered after administration of dostarlimab as per current local institutional practice. Further information on the administration of carboplatin and paclitaxel can be found in the current SmPCs (available at: www.medicines.org.uk/emc/).

No additional monitoring is required. The treating physician (or other HCPs involved with this EAMS) will be responsible for detecting, documenting, and reporting any adverse events (AEs) and immune related adverse events (irAEs) occurring in patients receiving dostarlimab within this EAMS programme to GSK. Information on reporting of AEs can be found in ‘Dostarlimab EAMs: Treatment protocol: Information on the pharmacovigilance system and requirements for reporting safety data’.

Dostarlimab should be stored in a refrigerator (2°C – 8°C).

There are no homecare or delivery options for dostarlimab within this EAMS.
**Pharmacovigilance and data collection**

Clinicians are required to report to GSK using specific documentation and recording mechanisms.

Specific details relating to pharmacovigilance can be found in the Dostarlimab EAMs – Treatment protocol – Information on the pharmacovigilance system and requirements for reporting safety data, a link to which is appended at the end of this guidance.
EAMS termination arrangements/exit strategy

Following Marketing Authorisation of dostarlimab for the treatment of patients with primary advanced or recurrent endometrial cancer, the EAMS programme will close in line with the MHRA regulations and no new patients will be allowed to enrol onto the scheme to access free of charge supply.

Access to treatment for new patients would be via local board processes from the point of licensing until Scottish Medicines Consortium (SMC) accepted advice is issued or, where relevant, until availability via the ultra-orphan pathway is confirmed by Scottish Government.

The provision of dostarlimab, free of charge via EAMS for any one patient enrolled in the EAMS shall end, on the earliest of the following to occur:

A. In the event that SMC accepted advice is issued for this medicine and indication, 30 days after the publication of SMC accepted advice on their website (www.scottishmedicines.org.uk).

OR

B. In the event that SMC not recommended advice is issued:
   I. until such time as GSK may receive SMC accepted advice for this medicine and indication (e.g. after a resubmission).
   II. until such time that the patient:
      a. Completes the defined course length of treatment
      b. No longer derives clinical benefit (e.g. disease progression or unacceptable toxicity)

OR

C. In the event that Marketing Authorisation is not granted, until such time as the patient no longer derives clinical benefit (disease progression or unacceptable toxicity).

OR

D. In the event of availability through the ultra-orphan pathway, 30 days after Scottish Government confirmation

Supporting documents
- Public Assessment Report
- Treatment Protocol – Information for Healthcare Professionals
- Treatment Protocol – Information for Patients
- Treatment Protocol – Information on the Pharmacovigilance System
- Information for NHS Medical Directors

NHSScotland EAMS operational guidance v4.0 November 2020, R O’Connell
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