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

Summary of operational arrangements for Lutetium (\(^{177}\text{Lu}\)) vipivotide tetraxetan ([\(^{177}\text{Lu}\)]Lu-PSMA-617, \(^{177}\text{Lu}\)-PSMA-617) in NHS Scotland. EAMS number 35903/0001

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 medicine remains with the prescribing clinician. More information about the scheme can be found here: http://www.mhra.gov.uk/Howweregulate/Innovation/EarlyaccesstomedicinesschemeEAMS/index.htm

\(^{177}\text{Lu}\) vipivotide tetraxetan 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

Lutetium (\(^{177}\text{Lu}\)) vipivotide tetraxetan, [\(^{177}\text{Lu}\)]Lu-PSMA-617, \(^{177}\text{Lu}\)-PSMA-617, 1000 MBq/mL solution for injection/infusion

Indication and patient population

Lutetium (\(^{177}\text{Lu}\)) vipivotide tetraxetan is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy or who are not medically suitable for taxanes.

Taxane-ineligibility (including the identification of patients not medically suitable for taxanes) is to be determined by the treating physician.

Conditions for entry to EAMS

The EAMS makes free-of-charge \(^{177}\text{Lu}\) vipivotide tetraxetan for use in PSMA-positive metastatic castration-resistant prostate cancer available to Health Boards (subject to approval by Advanced Accelerator Applications, UK & Ireland Inc) provided that the following conditions are met.
I. The patient (who is the subject of each order for EAMS $^{177}$Lu vipivotide tetraxetan) is an adult patient with PSMA-positive metastatic castration-resistant prostate cancer.

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 June 2022)

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 $^{177}$Lu vipivotide tetraxetan need to contact Advanced Accelerator Applications/Novartis via the Novartis GEMS portal. Information for how to submit a request and access to the portal can be found on the Novartis website [https://www.novartis.com/healthcare-professionals/managed-access-programs](https://www.novartis.com/healthcare-professionals/managed-access-programs).

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

The recommended $^{177}$Lu vipivotide tetraxetan dose is 7400 MBq (200 mCi; ± 10%) every 6 weeks (± 1 week) for a total of 6 doses. $^{177}$Lu vipivotide tetraxetan may be administered as an injection using a disposable syringe fitted with a syringe shield (with or without a syringe pump), as an infusion using the gravity method (with or without an infusion pump), or as an infusion using the vial (with a peristaltic infusion pump).

Prior to administration, flush the intravenous catheter used exclusively for lutetium ($^{177}$Lu) vipivotide tetraxetan administration with ≥10 mL of 0.9% sterile sodium chloride solution to ensure patency and to minimise the risk of extravasation. In the event of extravasation, the injection must be stopped, the site of injection changed and the affected area irrigated with sodium chloride solution. See protocol for further instructions.

Monitoring requirements for the EAMS include a screening visit, and visits every 6 weeks (±1 week) for a maximum of 6 doses.

Before use, $^{177}$Lu vipivotide tetraxetan should be stored below 30°C in the original package to protect from ionising radiation (lead shielding). $^{177}$Lu vipivotide tetraxetan should not be frozen. $^{177}$Lu vipivotide tetraxetan has a shelf life of 5 days (120 hours) from the date and time of calibration. Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organisation.
**Pharmacovigilance and data collection**

Clinicians are required to report to Advanced Accelerator Applications using specific documentation and recording mechanisms.

Specific details relating to pharmacovigilance can be found in the Treatment Protocol for Pharmacovigilance, a link to which is appended at the end of this guidance.

**EAMS termination arrangements/exit strategy**

Following Marketing Authorisation of $^{177}$Lu vipivotide tetraxetan for the treatment of patients with PSMA-positive metastatic castration-resistant prostate cancer, the EAMS scheme 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 $^{177}$Lu vipivotide tetraxetan, 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 Advanced Accelerator Applications 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