

**Subject: Specialised Services Circular (SSC 2362)**  
**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
SSC 2362	<p><b>Early Access to Medicines Scheme – Lutetium (177Lu) 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.</b></p>	<ul style="list-style-type: none"> <li>• University Hospitals Bristol and Weston NHS Foundation Trust</li> <li>• University Hospitals Plymouth NHS Trust</li> </ul>

**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](mailto:england.speccomm-southwest@nhs.net)





**England**

Specialised Commissioning South West  
NHS England  
South Plaza  
Marlborough Street  
Bristol  
BS1 3NX

Email: [england.speccomm-southwest@nhs.net](mailto:england.speccomm-southwest@nhs.net)  
26/04/2022

**All Chief Executives**

**All Medical Directors**

**All Chief Pharmacists**

Dear Colleague,

**Re: Early Access to Medicines Scheme – Lutetium (177Lu) 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.**

I am writing to advise you regarding NHS England's position on the recent positive scientific opinion for lutetium (177Lu) vipivotide tetraxetan 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 lutetium (177Lu) vipivotide tetraxetan on 24<sup>th</sup> August 2021 (EAMS Step 1), MHRA issued a positive scientific opinion on 5<sup>th</sup> April 2022 which states:

Lutetium (177Lu) 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.

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 5<sup>th</sup> April 2022, Trusts who provide chemotherapy services should use the EAMS application process to apply for access to lutetium (177Lu) vipivotide tetraxetan for eligible patients from this date. A list of centres that currently use Lutetium is provided in appendix 1.

For patients wishing to access lutetium (177Lu) vipivotide tetraxetan, trusts must complete a Blueteq form to register each patient with NHS England once the application form has been submitted to Advanced Accelerator Applications 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](mailto:england.eams@nhs.net).

**Patients must be informed that lutetium (177Lu) vipivotide tetraxetan is being made available ahead of a marketing authorisation decision through EAMS. Patients should be made aware that if lutetium (177Lu) vipivotide tetraxetan 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 will need to submit an initial request via the Novartis Grants, External Studies and Managed Access System (GEMS) via [Managed Access Programs | Novartis](#).

Lutetium (177Lu) vipivotide tetraxetan 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 Lutetium (177Lu) vipivotide tetraxetan EAMS must be completed and submitted to Advanced Accelerator Applications in order 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 lutetium (177Lu) vipivotide tetraxetan for this indication (anticipated in Q2 2022), 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 Advanced Accelerator Applications 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 lutetium ( $^{177}\text{Lu}$ ) vipivotide tetraxetan 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,



Dr Peter Wilson  
Medical Director (Commissioning)



Tracey Williams  
Principal Pharmacist

## **Annex - List of eligible sites that currently use lutetium**

BUCKINGHAMSHIRE HEALTHCARE NHS TRUST  
CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST  
GUY'S AND ST THOMAS' NHS FOUNDATION TRUST  
IMPERIAL COLLEGE HEALTHCARE NHS TRUST  
KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST  
LEEDS TEACHING HOSPITALS NHS TRUST  
MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST  
MEDWAY NHS FOUNDATION TRUST  
OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST  
ROYAL FREE LONDON NHS FOUNDATION TRUST  
ROYAL LIVERPOOL AND BROADGREEN UNIVERSITY HOSPITALS NHS TRUST  
ROYAL SURREY COUNTY HOSPITAL NHS FOUNDATION TRUST  
SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST  
THE CHRISTIE NHS FOUNDATION TRUST  
THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST  
UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST  
UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST  
UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST  
UNIVERSITY HOSPITALS COVENTRY AND WARWICKSHIRE NHS TRUST  
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST  
UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST