

**Subject: Specialised Services Circular (SSC)**  
**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
2807	<b>Early Access to Medicines Scheme – Sebetralstat is indicated for the treatment of hereditary angioedema (HAE) attacks in adult and adolescents aged 12 years and older</b>	North Bristol Trust University Hospitals Plymouth Trust University Hospitals Bristol and Weston Trust

**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)

**All Chief Executives**

**All Medical Directors**

**All Chief Pharmacists**

Specialised Commissioning  
South West  
NHS England  
100 Temple Street  
Bristol  
BS1 6AG  
Email: [england.speccomm-southwest@nhs.net](mailto:england.speccomm-southwest@nhs.net)

16 April 2025

Dear Colleagues,

**Re: Early Access to Medicines Scheme – Sebetralstat is indicated for the treatment of hereditary angioedema (HAE) attacks in adult and adolescents aged 12 years and older.**

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

Following the publication of the positive Scientific Opinion on 19th March 2025, Trusts who provide specialised services treatment of hereditary angioedema (HAE) attacks in adult and adolescents aged 12 years and older should use the EAMS application process to apply for access to sebetralstat for eligible patients. A list of eligible sites is provided in appendix 1.

The Medicines and Healthcare Regulatory products Agency MHRA launched the Early Access to Medicines Scheme (EAMS) 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 designation of Promising Innovative Medicine (PIM) status for Sebetralstat in January 2025 (EAMS Step 1), MHRA issued a positive Scientific Opinion on 19<sup>th</sup> March 2025 which supports sebetralstat for:

The treatment of hereditary angioedema (HAE) attacks in adult and adolescents aged 12 years and older.

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 19th March 2025, Trusts should use the EAMS application process to apply for access to sebetralstat for eligible patients from this date. For patients wishing to access sebetralstat, Trusts must complete a Patient Assessment Form to register each patient, once the application form has been submitted to Kalvista Pharmaceuticals Limited and the patient has been considered eligible for this EAMS.

*High quality care for all, now and for future generations*

To register a patient with the EAMS, the physician will need to contact Kalvista Pharmaceuticals Limited via the following email addresses:

[Access@Inceptua.com](mailto:Access@Inceptua.com) & [SMiah@kalvista.com](mailto:SMiah@kalvista.com)

Cc - [rbrowne@kalvista.com](mailto:rbrowne@kalvista.com)

Note, submission of a Blueteq prior approval form is not required for this EAMS.

Patients must be informed that sebetralstat is being made available ahead of a marketing authorisation decision through EAMS and that if sebetralstat 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.

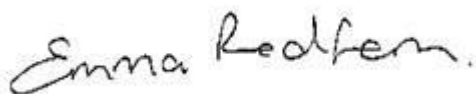
Sebetralstat is made available free of charge for EAMS patients during the EAMS period. Following marketing authorisation of sebetralstat (anticipated in October 2026), centres that register patients for this EAMS prior to marketing authorisation will be able to continue to receive free of charge supply for new patients registered with Kalvista Pharmaceuticals Limited between marketing authorisation and a funding recommendation from NICE.

NICE are appraising the product as a priority. Should NICE issue positive Technology Appraisal guidance, this guidance will usually be implemented 30 days after final guidance is published.

Providers of specialised services for the treatment of hereditary angioedema (HAE) attacks in adult and adolescents aged 12 years and older 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,



Emma Redfern  
Medical Director NHS England South West  
Region



Tracey Williams  
Principal Pharmacist

## Annex 1 - Specialised Immunology and Allergy Providers (Adults and Children)

Region	Trust
EAST OF ENGLAND	ROYAL PAPWORTH HOSPITAL NHS FOUNDATION TRUST
EAST OF ENGLAND	CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
EAST OF ENGLAND	NORFOLK AND NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
LONDON	GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST
LONDON	BARTS HEALTH NHS TRUST
LONDON	ROYAL FREE LONDON NHS FOUNDATION TRUST
LONDON	GUY'S AND ST THOMAS' NHS FOUNDATION TRUST
LONDON	KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST
LONDON	WHITTINGTON HEALTH NHS TRUST
LONDON	EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST
LONDON	IMPERIAL COLLEGE HEALTHCARE NHS TRUST
LONDON	CHELSEA AND WESTMINSTER HOSPITAL NHS FOUNDATION TRUST
LONDON	HOMERTON HEALTHCARE NHS FOUNDATION TRUST
LONDON	UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST
MIDLANDS	UNIVERSITY HOSPITALS OF NORTH MIDLANDS NHS TRUST
MIDLANDS	THE DUDLEY GROUP NHS FOUNDATION TRUST
MIDLANDS	UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST
MIDLANDS	UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
MIDLANDS	NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST
MIDLANDS	SANDWELL AND WEST BIRMINGHAM HOSPITALS NHS TRUST
NORTH EAST & YORKSHIRE	THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
NORTH EAST & YORKSHIRE	SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST
NORTH EAST & YORKSHIRE	LEEDS TEACHING HOSPITALS NHS TRUST
NORTH EAST & YORKSHIRE	HULL UNIVERSITY TEACHING HOSPITALS NHS TRUST
NORTH EAST & YORKSHIRE	SHEFFIELD CHILDREN'S NHS FOUNDATION TRUST
SOUTH EAST	FRIMLEY HEALTH NHS FOUNDATION TRUST
SOUTH EAST	UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST
SOUTH EAST	OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
SOUTH EAST	ROYAL SURREY COUNTY HOSPITAL NHS FOUNDATION TRUST
SOUTH EAST	UNIVERSITY HOSPITALS SUSSEX NHS FOUNDATION TRUST
SOUTH WEST	UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST
SOUTH WEST	NORTH BRISTOL NHS TRUST
SOUTH WEST	UNIVERSITY HOSPITALS BRISTOL AND WESTON NHS FOUNDATION TRUST
NORTH WEST	MANCHESTER UNIVERSITY NHS FOUNDATION TRUST
NORTH WEST	ALDER HEY CHILDREN'S NHS FOUNDATION TRUST
NORTH WEST	LIVERPOOL UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
NORTH WEST	NORTHERN CARE ALLIANCE NHS FOUNDATION TRUST
NORTH WEST	LANCASHIRE TEACHING HOSPITALS NHS FOUNDATION TRUST