

**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  |
|------------|--|---|
| 2801       | <b>NICE Technology Appraisal Final Draft Guidance: Leniolisib for activated phosphoinositide 3-kinase delta syndrome in people 12 years and over</b> | Adults:<br>North Bristol Trust<br>University Hospitals Bristol and Weston<br>University Hospital Plymouth<br><br>Children:<br>University Hospitals Bristol and Weston |

**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)

**Please note that the SmPC for leniolisib does not have a recommended dosage for people who weigh less than 45kg, therefore people weighing less than 45kg are outside of the scope of this HST appraisal.**

**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)

31 March 2025

Dear Colleagues,

**Re: NICE Technology Appraisal Final Draft Guidance: Leniolisib for activated phosphoinositide 3-kinase delta syndrome in people 12 years and over**

I am writing to advise you regarding the funding position on the recently published NICE Technology Appraisal Final Draft Guidance (FDG) for leniolisib for activated phosphoinositide 3-kinase delta syndrome in people 12 years and over.

The FDG can be found at: <https://www.nice.org.uk/guidance/indevelopment/gid-hst10059>.

NICE in their FDG published on 13<sup>th</sup> March 2025 has stated that:

Leniolisib is recommended, within its marketing authorisation, for treating activated phosphoinositide 3-kinase delta syndrome (APDS) in people 12 years and over.

Leniolisib will be available via the Innovative Medicines Fund (IMF) from 27<sup>th</sup> March 2025 in line with these recommendations and according to a set of treatment criteria which translates the NICE recommendation into a clinical guide as to use in practice. These treatment criteria can be found on the application form(s) on the Blueteq site.

NHS England will then routinely commission leniolisib in patients 12 years and over with activated phosphoinositide 3-kinase delta syndrome via specialised immunology centres (Appendix 1), incorporating these treatment criteria, including those contained within this letter from 90 days after the day of publication of the final guidance.

In addition, commissioned centres must:

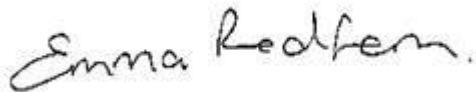
- Ensure that they are purchasing leniolisib at the agreed proposed patient access scheme (PAS) discounted price. This discounted price will be applied automatically at point of invoice and applies to all indications.
- Ensure that any patients registered on the company led compassionate use programme who meet the clinical criteria for the drug are registered via Blueteq in order for the IMF to pick up the costs of their ongoing treatment. Patients who do not meet the clinical criteria should continue to receive the drug via the manufacturer.

- Ensure that, until 90 days after publication of the final guidance from NICE, only invoices for the drug procurement costs of leniolisib in this indication are directed to the IMF and that they are also submitting complete and accurate information via the IMF minimum dataset (MDS).
- In line with the terms and conditions included in the NHS Standard Contract, Schedule 6a Reporting Requirements for drugs will apply. Payment of Trust invoices will be contingent on the completion of the MDS record and this information being made available in a timely way.
- Patients are registered via Blueteq (LENI1) and meet the clinical criteria on the registration form during the interim funding period.
- **Payment of Trust invoices will be contingent on Blueteq registration and IMF MDS record applicable to the drug being completed and this information being made available in timely way.**
- Ensure that local governance aspects (e.g. technical issues, education & training, patient information) have been identified and addressed for all staff groups (as appropriate) in order to permit the safe delivery of this therapy.

Trusts should refer to the CAP portal for further information on the PAS price. The CAP portal is available at <https://nhsengland.sharefile.eu/Authentication/Login>

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

## **Appendix 1 – Specialised immunology centres**

- ALDER HEY CHILDREN'S NHS FOUNDATION TRUST
- BARTS HEALTH NHS TRUST
- CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
- EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST
- FRIMLEY HEALTH NHS FOUNDATION TRUST
- GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST
- GUY'S AND ST THOMAS' NHS FOUNDATION TRUST
- HULL UNIVERSITY TEACHING HOSPITALS NHS TRUST
- IMPERIAL COLLEGE HEALTHCARE NHS TRUST
- KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST
- LANCASHIRE TEACHING HOSPITALS NHS FOUNDATION TRUST
- LEEDS TEACHING HOSPITALS NHS TRUST
- LIVERPOOL UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
- MANCHESTER UNIVERSITY NHS FOUNDATION TRUST
- NORFOLK AND NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
- NORTH BRISTOL NHS TRUST
- NORTHERN CARE ALLIANCE NHS FOUNDATION TRUST
- NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST
- OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
- ROYAL FREE LONDON NHS FOUNDATION TRUST
- ROYAL PAPWORTH HOSPITAL NHS FOUNDATION TRUST
- ROYAL SURREY COUNTY HOSPITAL NHS FOUNDATION TRUST
- SANDWELL AND WEST BIRMINGHAM HOSPITALS NHS TRUST
- SHEFFIELD CHILDREN'S NHS FOUNDATION TRUST
- SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST
- THE DUDLEY GROUP 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 AND WESTON NHS FOUNDATION TRUST
- UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
- UNIVERSITY HOSPITALS OF NORTH MIDLANDS NHS TRUST
- UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST
- WHITTINGTON HEALTH NHS TRUST