

Subject: Specialised Services Circular (SSC 2587)
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 2587	<p>Cystic Fibrosis Modulator Therapies Commissioning Statement: Changes in licensed access to ivacaftor for patients aged 1 - 4 months, weighing 3 kg to less than 25 kg, with cystic fibrosis and homozygous for F508del combined with any other mutation.</p> <p>AND</p> <p>Changes in licensed access to elexacaftor/tezacaftor/ivacaftor for patients aged 2- 5 years with cystic fibrosis and homozygous for F508del combined with any other mutation.</p>	<ul style="list-style-type: none"> • University Hospitals Bristol and Weston NHS Foundation Trust • Royal Devon University Healthcare NHS Foundation Trust • University Hospitals Plymouth NHS Trust • Royal Cornwall Hospitals NHS 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

Specialised Commissioning South West
NHS England
360 Bristol
Marlborough Street
Bristol
BS1 3NX
Email: england.speccomm-southwest@nhs.net

30 November 2023

All Chief Executives

All Medical Directors

All Chief Pharmacists

Dear Colleagues,

Re: Cystic Fibrosis Modulator Therapies Commissioning Statement: Changes in licensed access to ivacaftor for patients aged 1 - 4 months, weighing 3 kg to less than 25 kg, with cystic fibrosis and homozygous for F508del combined with any other mutation.

AND

Changes in licensed access to elexacaftor/tezacaftor/ivacaftor for patients aged 2- 5 years with cystic fibrosis and homozygous for F508del combined with any other mutation.

The MHRA has granted a licence extension for ivacaftor for patients aged 1 - 4 months, weighing 3 kg to less than 25 kg, with cystic fibrosis and homozygous for F508del combined with any other mutation.

AND

The MHRA has granted a licence for elexacaftor/tezacaftor/ivacaftor granules for patients aged 2- 5 years with cystic fibrosis and homozygous for F508del combined with any other mutation.

NHS England will commission these changes once appropriate lower dose presentations become available. This is expected to be within the next few weeks. The commissioning statement on the approved therapies has been updated. There has been no change to the specific mutations eligible for this treatment.

The link to the commissioning statement is below.

[NHS England » Commissioning statement: Ivacaftor, tezacaftor/ivacaftor, lumacaftor/ivacaftor and elexacaftor/tezacaftor/ivacaftor for cystic fibrosis](#)

Prescribing of this drug will only be through commissioned CF centres (Appendix 1).

Trusts are reminded that data needs submitting to the CF Registry.

In addition:

- Trusts must ensure that they are purchasing ivacaftor and elexacaftor/tezacaftor/ivacaftor at the agreed discounted prices. This discounted price will be applied automatically at point of invoice and applies to all indications.
- Trusts must ensure that only invoices for the drug procurement costs of ivacaftor and elexacaftor/tezacaftor/ivacaftor in this indication are invoiced to NHSE and that they are also submitting complete and accurate information via the high cost drugs minimum dataset (MDS). All other on cost are in block arrangements.
- 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.
- Trusts must 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,



Luke Culverwell
Deputy Director of Specialised
Commissioning



Tracey Williams
Clinical Pharmacist

Appendix 1: CF Centres and shared care provider sites April 2023

North West

1. Alder Hey Children's NHS Foundation Trust
2. Liverpool Heart & Chest Hospital NHS Foundation
3. Blackpool Teaching Hospitals NHS Foundation Trust
4. Manchester University Hospitals NHS Foundation Trust

North East and Yorkshire

5. Newcastle upon Tyne Hospitals NHS Foundation Trust
6. Leeds Teaching Hospitals NHS Trust
7. York Teaching Hospital NHS Trust
8. Sheffield Teaching Hospitals NHS Foundation Trust
9. Sheffield Children's NHS Trust
10. South Tees Hospitals NHS Trust

Midlands

11. Birmingham Women's and Children's NHS Foundation Trust
12. University Hospital Birmingham NHS Foundation Trust
13. Nottingham University Hospitals NHS Trust
14. University Hospitals Leicester NHS Trust
15. University Hospitals of North Midlands NHS Trust

East of England

16. Cambridge University Hospitals NHS Trust
17. Royal Papworth Hospital NHS Foundation Trust
18. Norfolk and Norwich University Hospital NHS Foundation Trust

London

19. Kings College Hospital NHS Foundation Trust
20. Guys & St Thomas' NHS Foundation Trust
21. Bart's Health NHS Trust & The Heart Hospital
22. Great Ormond Street Hospital NHS Foundation Trust
23. Lewisham and Greenwich NHS Trust

South West

24. University Hospitals Bristol and Weston NHS Foundation Trust
25. Royal Devon University NHS Foundation Trust
26. University Hospitals Plymouth NHS Trust
27. Royal Cornwall Hospitals NHS Trust

South East

28. Frimley Health NHS Trust
29. Oxford University Hospitals NHS Trust
30. University Hospital Southampton NHS Foundation Trust
31. University Hospitals Sussex NHS Foundation Trust