

Subject: Specialised Services Circular (SSC 2538)
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 2538	Re: Age group licence extension to for lumacaftor/ivacaftor (Orkambi®) for patients aged 1-2 years with cystic fibrosis.	University Hospitals Bristol and Weston NHS Foundation Trust Royal Devon University 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

20 July 2023

All Chief Executives

All Medical Directors

All Chief Pharmacists

Dear Colleagues,

Re: Age group licence extension to for lumacaftor/ivacaftor (Orkambi®) for patients aged 1-2 years with cystic fibrosis.

The Medicines and Healthcare Regulatory Authority (MHRA) has granted a licence extension for lumacaftor/ivacaftor to extend the eligible age range for patients aged 1-2 years.

NHS England will commission for this age range extension once appropriate lower dose presentations become available. **The commissioning statement on the approved therapies has been updated.** There has been no change to the specific mutations eligible for this treatment.

The following therapy is now included:

Lumacaftor/ivacaftor: For people with CF aged 1-2 years who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

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 lumacaftor/ivacaftor at the agreed discounted price. 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 lumacaftor/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,



Vinay Takwale (VT)
Medical Director NHS England South West
Region & Consultant Orthopaedic Surgeon



Tracey Williams
Principal Pharmacist

Cc Trust CF Clinical Leads and CF pharmacists, home care pharmacists, Trust contract leads

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

