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
2857	**Arrangements for access to cystic fibrosis transmembrane conductance regulator (CFTR) modulators for licensed and off-label use in patients with cystic fibrosis**	Royal Cornwall Hospital Trust University Hospitals Plymouth Trust University Hospitals Bristol and Weston Trusts Royal Devon University Hospitals Foundation Trusts

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

NHS England South West

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

15 July 2025

Dear Medical Directors,

Arrangements for access to cystic fibrosis transmembrane conductance regulator (CFTR) modulators for licensed and off-label use in patients with cystic fibrosis

I am writing to advise you regarding the funding position on both the recently published NICE Final Draft Guidance (FDG) 'Vanzacaftor–tezacaftor–deutivacaftor for treating cystic fibrosis with 1 or more F508del mutations in the CFTR gene in people aged 6 years and over' and the update to the NHS England Clinical Commissioning Statement, 'Arrangements for access to cystic fibrosis transmembrane conductance regulator (CFTR) modulators for licensed and off-label use in patients with cystic fibrosis'.

NHS England will commission vanzacaftor–tezacaftor–deutivacaftor during this interim access period, in line with the NICE FDG, from 15th July 2025.

NHS England will routinely commission vanzacaftor–tezacaftor–deutivacaftor for all patients from 30 days post publication of the NICE Technology Appraisal (TA) [ID6372] who are eligible, in line with the NICE TA.

The FDG can be found at: Project documents | Vanzacaftor–tezacaftor–deutivacaftor for treating cystic fibrosis with 1 or more F508del mutations in the CFTR gene in people aged 6 years and over [ID6372] | Guidance | NICE

In addition, from 15th July, NHS England will commission the following, in line with the NHS England Clinical Commissioning Statement, 'Arrangements for access to cystic fibrosis transmembrane conductance regulator (CFTR) modulators for licensed and off-label use in patients with cystic fibrosis'

- Vanzacaftor–tezacaftor–deutivacaftor for those patients not covered by the optimised NICE guidance within its licenced indications who have a non-F508del responsive mutation in the CFTR gene;
- Vanzacaftor–tezacaftor–deutivacaftor for patients who have at least one non-Class I mutation in the CFTR gene as outlined by the European Medicines Agency (EMA), as off-label indications;

- Ivacaftor–tezacaftor– elexacaftor, patients who have at least one non-Class I mutation in the CFTR gene as outlined by the European Medicines Agency (EMA), as off-label indications

Access for prescribers and pharmacists to the look-up table for establishing patient eligibility for off-licence indications can be sought by contacting: england.npoc-internalmedicine@nhs.net

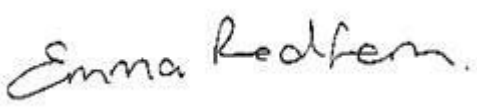
In addition:

- Trusts must ensure that they are purchasing ivacaftor, ivacaftor–tezacaftor–elexacaftor, tezacaftor–ivacaftor, lumacaftor–ivacaftor and vanzacaftor–tezacaftor–deutivacaftor at the agreed patient access scheme (PAS) discounted price. This discounted price will be applied automatically at point of invoice and applies to all indications.
- The discounted price paid by trusts remains the same as the existing discounted prices for ivacaftor, ivacaftor–tezacaftor–elexacaftor and tezacaftor–ivacaftor, lumacaftor–ivacaftor.
- Trusts must ensure that only invoices for the drug procurement costs of ivacaftor, ivacaftor–tezacaftor–elexacaftor, tezacaftor–ivacaftor, lumacaftor–ivacaftor and vanzacaftor–tezacaftor–deutivacaftor in this indication are invoiced to NHS England.
- 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 drugs Minimum Data Set 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,



Emma Redfern
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Tracey Williams
Principal Pharmacist