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
2690	SSC 2690 - NICE Technology Appraisal TA 988: Ivacaftor–tezacaftor–elexacaftor, tezacaftor–ivacaftor and lumacaftor–ivacaftor for treating cystic fibrosis	Royal Cornwall Hospital, Royal Devon University Hospitals, University Hospitals Bristol and Weston, University Hospital of Plymouth.

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

All Chief Executives

All Medical Directors

All Chief Pharmacists

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

9 August 2024

Dear Colleagues,

NICE Technology Appraisal TA 988: Ivacaftor–tezacaftor–elexacaftor, tezacaftor–ivacaftor and lumacaftor–ivacaftor for treating cystic fibrosis.

I am writing to advise you regarding the funding position on the recently published NICE Technology Appraisal (TA) for ivacaftor–tezacaftor–elexacaftor, tezacaftor–ivacaftor and lumacaftor–ivacaftor for treating cystic fibrosis.

The TA988 can be found at: https://www.nice.org.uk/guidance/ta988

NICE in their Technology Appraisal published on 24th July 2024 state that:

> 1.1 Ivacaftor–tezacaftor–elexacaftor (IVA–TEZ–ELX) plus ivacaftor (IVA) alone is recommended within its marketing authorisation, as an option for treating cystic fibrosis (CF) in people 2 years and over who have at least 1 F508del mutation in the CF transmembrane conductance regulator (CFTR) gene.
> 1.2 Tezacaftor–ivacaftor (TEZ–IVA) plus IVA alone is recommended, within its marketing authorisation, for treating CF in people 6 years and over who have:
> - 2 copies of the CFTR gene with F508del mutations or
> - a copy of the CFTR gene with an F508del mutation and a copy of the CFTR gene with 1 of the mutations listed in section 2.2 of TA988.
>
> 1.3 Lumacaftor–ivacaftor (LUM–IVA) is recommended, within its marketing authorisation, for treating CF in people 1 year and over who have 2 copies of the CFTR gene with F508del mutations.
> 1.4 IVA–TEZ–ELX, TEZ-IVA and LUM–IVA are only recommended if the company provides it according to the commercial arrangement.

Ivacaftor–tezacaftor–elexacaftor, tezacaftor–ivacaftor and lumacaftor–ivacaftor for treating cystic fibrosis will be routinely commissioned from 24 July 2024 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.

In addition, NHS England will commission the above drugs for patients with mutations authorised by the Federal Drug Agency as off-label indications.
The NHS England Clinical Commissioning Statement Ivacaftor, tezacaftor/ivacaftor, and elexacaftor/tezacaftor/ivacaftor for licensed and off-label use in patients with cystic fibrosis who have named mutations can be found at:
https://www.england.nhs.uk/publication/commissioning-statement-ivacaftor-tezacaftor-ivacaftor-lumacaftor-ivacaftor-and-elexacaftor-tezacaftor-ivacaftor-for-cystic-fibrosis/
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 and lumacaftor–ivacaftor 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 price.
- Trusts must ensure that only invoices for the drug procurement costs of ivacaftor, ivacaftor–tezacaftor–elexacaftor, tezacaftor–ivacaftor and lumacaftor–ivacaftor for in this indication are invoiced to NHSE.
- In line with the terms and conditions included in the NHS Standard Contract and as per the agreement that Cancer Services are commissioned with Trusts, Schedule 6a Reporting Requirements for drugs will apply. Payment of Trust invoices will be contingent on the completion of the drugs 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.

Yours sincerely

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

Tracey Williams
Principal Pharmacist