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
2726	**NICE Technology Appraisal Final Draft Guidance: Elafibranor for previously treated primary biliary cholangitis**	University Hospitals Bristol and Westen University Hospital Plymouth Royal Devon University Hospitals

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
100 Temple Street
Bristol
BS1 6AG
Email: england.speccomm-southwest@nhs.net

28 October 2024

Dear Colleagues,

Re: NICE Technology Appraisal Final Draft Guidance: Elafibranor for previously treated primary biliary cholangitis.

I am writing to advise you regarding the funding position on the recently published NICE Technology Appraisal Final Draft Guidance (FDG) for elafibranor for previously treated primary biliary cholangitis (PBC).

The FDG can be found at: https://www.nice.org.uk/guidance/indevelopment/gid-ta11378.

NICE in their FDG published on 22nd October 2024 has stated that:

> Elafibranor is recommended, within its marketing authorisation, as an option for treating primary biliary cholangitis in adults, when used with ursodeoxycholic acid (UDCA), if the primary biliary cholangitis has not responded well enough to UDCA, or alone, if UDCA cannot be tolerated.

Elafibranor will be available via the Innovative Medicines Fund (IMF) from 22nd October 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. These treatment criteria can be found on the application form(s) on the Blueteq site.

NHS England will then routinely commission elafibranor in patients with PBC via specialised hepatobiliary centres, 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 specialised hepatobiliary centres must:

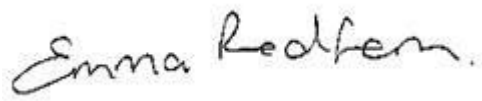
- Ensure that they are purchasing elafibranor at the agreed proposed patient access scheme (PAS) discounted price. This discounted price will be applied automatically at point of invoice and applies to all indications. Trusts should refer to the CAP portal for further information on the PAS price. The CAP portal is available at https://nhsengland.sharefile.eu/Authentication/Login
- Ensure that, until 90 days after publication of the final guidance from NICE, only invoices for the drug procurement costs of elafibranor 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.
- Ensure that patients are registered via Blueteq (ELAF1) and meet the clinical criteria on the registration form during the interim funding period.
- Ensure that patients are registered on the UK PBC registry.
- **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.

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