NHS England South West

Subject: Specialised Services Circular (SSC 2649)
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
2649	**NICE Technology Appraisal Final Draft Guidance: Dabrafenib with trametinib for treating BRAF V600E mutation-positive glioma in children and young people aged 1 year and over**	University Hospitals Bristol and Weston NHS FT Only

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

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06 May 2024

All Chief Executives

All Medical Directors

All Chief Pharmacists

Dear Colleagues,

Re: NICE Technology Appraisal Final Draft Guidance: Dabrafenib with trametinib for treating BRAF V600E mutation-positive glioma in children and young people aged 1 year and over

I am writing to advise you regarding the funding position on the recently published NICE Technology Appraisal Final Draft Guidance (FDG) for dabrafenib with trametinib for treating BRAF V600E mutation-positive glioma in children and young people aged 1 year and over.

The FDG can be found at: https://www.nice.org.uk/guidance/indevelopment/gid-ta11006.

NICE in their FDG published on 24 April 2024 has stated that:

Dabrafenib with trametinib is recommended, within its marketing authorisation, as an option for treating:

- low-grade glioma (LGG) with a BRAF V600E mutation in children and young people aged 1 year and over who need systemic treatment, and
- high-grade glioma (HGG) with a BRAF V600E mutation in children and young people aged 1 year and over after at least 1 radiation or chemotherapy treatment.

This guidance relates to dabrafenib dispersible tablets (Brand name Finlee®) and trametinib liquid (Brand name Spexotras®). Please note that Novartis have informed NHS England that there is no commercial stock of dabrafenib and trametinib currently available. Dabrafenib and trametinib will be available via the Cancer Drugs Fund (CDF) from the date commercial stock is available (expected June 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 national CDF list at

https://www.england.nhs.uk/cancer/cdf/cancer-drugs-fund-list/ or on the application form(s) on the Blueteq site.

NHS England will then routinely commission dabrafenib and trametinib in patients with BRAF V600E mutation-positive glioma, incorporating these treatment criteria, including those contained within this letter from 90 days after the day of publication of the final guidance.

In addition:

- Trusts must ensure that they are purchasing dabrafenib dispersible tablets and trametinib liquid 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
- Trusts must ensure that any patients registered on the company led compassionate use programme who meet the clinical criteria for the drug are registered via Blueteq in order for the CDF to pick up the costs of their ongoing treatment.
- Trusts must ensure that, until 90 days after publication of the final guidance from NICE, only invoices for the drug procurement costs of dabrafenib and trametinib in this indication are directed to the CDF and that they are also submitting complete and accurate information via the CDF minimum dataset (MDS).
- 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 MDS record and this information being made available in a timely way.
- Trusts must ensure they are registering dabrafenib and trametinib use on SACT. The SACT dataset is a mandated dataset as part of the Health and Social Care Information Standards. This is listed as a Schedule 6 national information requirement within the NHS Standard Contract.
- Patients must be registered via Blueteq (DABTRA4) and meet the clinical criteria on the registration form during the interim funding period.
- **Payment of Trust invoices will be contingent on Blueteq registration, the full SACT and CDF MDS record applicable to the drug being completed and this information being made available in 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.

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.

NHS England South West

Yours sincerely,

Luke Culverwell
Deputy Director of Specialised Commissioning

Tracey Williams
Principal Pharmacist