

**Recipient’s name**

Name

Team/Directorate

Address 1

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Address 3

Postcode

Telephone

Email address

Date

Address 1

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Address 4

Postcode

Dear <Medical Director>

**Re: NICE Technology Appraisal Final Appraisal Determination: larotrectinib for treating NTRK fusion-positive solid tumours**

I am writing to advise you regarding the funding position on the recently published NICE Technology Appraisal Final Appraisal Determination (FAD) for larotrectinib for treating NTRK fusion-positive solid tumours.

The FAD can be found at: https://www.nice.org.uk/guidance/indevelopment/gid-ta10229

NICE in their FAD published on 21st April 2020 has stated that:

1.1 Larotrectinib is recommended for use within the Cancer Drugs Fund as an option for treating neurotrophic tyrosine receptor kinase (NTRK) fusion positive solid tumours in adults and children if:

* the disease is locally advanced or metastatic or surgery could cause severe health problems and
* they have no satisfactory treatment options.

Larotrectinib will be available via the Cancer Drugs Fund (CDF) from 21st April 2020 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.

Larotrectinib will be available via the Cancer Drugs Fund (CDF) under the terms of the managed access agreement (MAA) and commercial access agreement (CAA), until NICE reviews this indication.

In addition:

* Trusts must ensure that they are purchasing larotrectinib 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 must ensure that any patients registered on the EAMS programme / 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. Patients who do not meet the clinical criteria should continue to receive the drug via the manufacturer.
* The MAA incorporates a commercial in confidence CAA which includes a discounted price for larotrectinib across all indications in use in the NHS. Trusts must ensure that they are purchasing larotrectinib at the agreed CAA discounted price. This discounted price will be applied automatically at point of invoice.
* Trusts must ensure that only invoices for the drug procurement costs of larotrectinib 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 larotrectinib 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 (LAR1) and meet the clinical criteria on the registration form.
* **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 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

<insert name and title>

Cc Provider Chief Executive

 Provider Chief Pharmacist

**Genomic testing for NTRK gene fusions implementation plan**

1. Determining eligibility for larotrectinib relies on detecting the presence of the NTRK gene fusion via a genomic test. The genomic testing will be undertaken by the NHS Genomics Laboratory Hubs (GLHs). The aim is to achieve a testing rate of 30,000 patients per year by the end of 2020/21, which would capture all those solid tumour patients who were potentially eligible for the drugs at the point at which standard therapies had failed.
2. However, currently due to the impact of the COVID-19 pandemic the NHS GLHs have a reduced testing capacity due to the redeployment of staff and equipment to support COVID-19 testing. The deployment has resulted in the slow down or suspension of developmental work to establish NTRK testing capability and reduced testing capacity where development work had already been completed.
3. A phased implementation plan will be implemented to utilise the available testing capacity where it will have the most impact. Table 1 outlines the patients who will be eligible for testing in phase 1.

**Table 1: detailed testing plan for phase 1**

|  |  |
| --- | --- |
|  | **Testing group** |
| 1 | Four cancers in which NTRK gene fusion incidence is very high (>90%):* Infantile fibrosarcoma
* Congenital mesoblastic nephroma
* Mammary-variant salivary gland cancer
* Secretory breast cancer
 |
| 2 | Three cancers in which NTRK gene fusion incidence is between 5 and 25%:* Gastro-intestinal stromal tumours (GISTs)
* Thyroid cancers
* Spitzoid neoplasms
 |
| 3 | Children (0-16) with solid tumours being treated in Principal Treatment Centres  |
| 4 | Teenagers (16-18) with solid tumours  |
| 5 | Young adults (18-25) with solid tumours |

1. The genomic testing will be carried out by four Genomic Laboratory Hubs on behalf of the whole country as outlined in Table 2 for phase 1. A document indicating the providers covered by each GLH geography will be added to this circular as annexe A .

**Table 2: genomic testing laboratories for phase 1**

|  |  |  |  |
| --- | --- | --- | --- |
| Testing GLH | Testing laboratory in GLH | Key laboratory contact | Geography covered |
| Yorkshire and North East GLH | Newcastle upon Tyne Hospitals NHS Foundation Trust | nuth.cancer.genomics@nhs.net | Yorkshire and North East GLH |
| North West GLH | Manchester University NHS Foundation Trust | Mft.pharmaco.geneticsrequests@nhs.net  | North West GLH |
| West Midlands, Oxford and Wessex GLH | Birmingham Women’s and Children’s NHS Foundation Trust | bwc.RGLMolecularPathologyTeam@nhs.net; Yvonne Wallis y.wallis@nhs.net  | West Midlands, Oxford and Wessex GLH, South West GLH |
| London North GLH | The Royal Marsden NHS Foundation Trust | rmh-tr.moleculardiagnostics@nhs.net  | London North GLH, London South GLH and East of England GLH |

1. The histopathology laboratory should use the genomic testing laboratory’s Test Request Form and send a formalin-fixed paraffin-embedded (FFPE) tumour sample directly to the genomic testing laboratory designated to perform the testing on behalf of that geography as outlined in table 2. The testing laboratory will perform the extraction, testing, interpretation and report the result back to the referring oncologist.
2. NHS England and NHS Improvement will continue to work with the Genomic Laboratory Hubs to agree a timeline for the expansion of genomic testing capacity.