

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
2821	NICE Technology Appraisal Draft Guidance: Ribociclib with an aromatase inhibitor for adjuvant treatment of hormone receptor-positive HER2-negative early breast cancer at high risk of recurrence	All South West Acute 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

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

02 May 2025

Dear Colleagues,

Re: NICE Technology Appraisal Draft Guidance: Ribociclib with an aromatase inhibitor for adjuvant treatment of hormone receptor-positive HER2-negative early breast cancer at high risk of recurrence

I am writing to advise you regarding the funding position on the recently published NICE Technology Appraisal Draft Guidance (DG) for ribociclib with an aromatase inhibitor for adjuvant treatment of hormone receptor-positive HER2-negative early breast cancer at high risk of recurrence.

The DG can be found at: <https://www.nice.org.uk/guidance/indevelopment/gid-ta11090>.

NICE in their DG published on 24th April 2025 has stated that:

Ribociclib with an aromatase inhibitor can be used as an option for the adjuvant treatment of hormone receptor-positive, HER2-negative, early breast cancer at high risk of recurrence in adults. It can only be used if the cancer is lymph-node positive and present in:

- at least 4 axillary lymph nodes, or
- 1 to 3 axillary lymph nodes and the cancer:
 - is grade 3, defined as at least 8 points on the modified Bloom–Richardson grading system or equivalent, or
 - has a primary tumour size of at least 5 cm.

For women in pre- or perimenopause, and men, combine the aromatase inhibitor with a luteinising hormone-releasing hormone (LHRH) agonist

Ribociclib will be available via the Cancer Drugs Fund (CDF) from 24th April 2025 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 ribociclib in patients with HR-positive

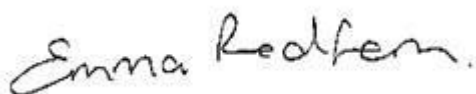
HER2-negative early breast cancer at high risk of recurrence, incorporating these treatment criteria, including those contained within this letter from 90 days after the day of publication of the final guidance.

In addition:

- Trusts must ensure that they are purchasing ribociclib 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, until 90 days after publication of the final guidance from NICE, only invoices for the drug procurement costs of ribociclib 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 ribociclib 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 (RIB3) 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.

With best wishes,



Emma Redfern
Medical Director NHS England South West
Region



Tracey Williams
Principal Pharmacist