

**Subject: Specialised Services Circular (SSC 2644)**  
**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
2644	<b>NICE Technology Appraisal Final Draft Guidance: Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 25 years and under (MA review of TA554)</b>	University Hospitals Bristol and Weston NHS FT

**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](mailto:england.speccomm-southwest@nhs.net)

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12 April 2024

**All Chief Executives**

**All Medical Directors**

**All Chief Pharmacists**

Dear Colleagues,

**Re: NICE Technology Appraisal Final Draft Guidance: Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 25 years and under (MA review of TA554)**

I am writing to advise you regarding the funding position on the recently published NICE Technology Appraisal Final Draft Guidance (FDG) for tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 25 years and under (MA review of TA554).

The FDG can be found at: <https://www.nice.org.uk/guidance/indevelopment/gid-ta11381>.

NICE in their FDG published on 11 April 2024 has stated that:

Tisagenlecleucel is recommended, within its marketing authorisation, as an option for people 25 years and under for treating B-cell acute lymphoblastic leukaemia that is relapsed after a transplant, or relapsed for a second or later time, or refractory.

Tisagenlecleucel has been available in this indication via the Cancer Drugs Fund (CDF) since 16 November 2018 (TA554). NICE has reviewed the evidence collected as part of the CDF managed access agreement and has recommended tisagenlecleucel for use in routine commissioning. Tisagenlecleucel will receive interim funding via the Cancer Drugs Fund (CDF) from 11 April 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.

*High quality care for all, now and for future generations*

NHS England will then routinely commission tisagenlecleucel in patients aged 25 and under with relapsed or refractory B-cell acute lymphoblastic leukaemia, 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 tisagenlecleucel 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 tisagenlecleucel 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 tisagenlecleucel 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 (TIS01a and TIS01b) 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.

Yours sincerely,



Luke Culverwell  
Deputy Director of Specialised



Tracey Williams  
Principal Pharmacist

Commissioning