

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
2773	NICE Technology Appraisal Final Draft Guidance: Exagamglogene autotemcel for treating severe sickle cell disease in people 12 years and over	No commissioned SW providers (see appendix for commissioned providers)

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

07 February 2025

Dear Colleagues,

Re: NICE Technology Appraisal Final Draft Guidance: Exagamglogene autotemcel for treating severe sickle cell disease in people 12 years and over

I am writing to advise you regarding the funding position on the recently published NICE Technology Appraisal Final Draft Guidance (FDG) for exagamglogene autotemcel (exa-cel) for treating severe sickle cell disease in people 12 years and over.

The FDG can be found at: <https://www.nice.org.uk/guidance/indevelopment/gid-ta11249>

NICE in their FDG published on 31st January 2025 has stated that:

Exagamglogene autotemcel (exa-cel) is recommended with managed access as an option for treating sickle cell disease (SCD) in people 12 years and over.:

- who have:
 - recurrent vaso-occlusive crises (VOCs) and
 - a β^S/β^S , β^S/β^+ or β^S/β^0 genotype, and
- when haematopoietic stem cell transplant (HSCT) is suitable, but a human leukocyte antigen-matched related haematopoietic stem cell donor is not available.

It is only recommended for people who have had at least 2 VOCs per year during the 2 previous years.

Exa-cel will be available via the Innovative Medicines Fund (IMF) from 31st January 2025 in line with these recommendations and according to a set of treatment criteria which translates the NICE recommendation into a clinical guide to use in practice. Exa-cel will be available at centres commissioned to deliver exa-cel for sickle cell disease (See Appendix A) under the terms of the managed access agreement (MAA) and commercial access agreement (CAA), until NICE reviews this guidance.

In addition, centres commissioned to deliver exa-cel for sickle cell disease must ensure that:

- They are purchasing exa-cel at the agreed 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>
- Only invoices for the drug procurement costs of exa-cel 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 and as per the agreement that 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. The commissioned service category code for IMF is 32.
 - A full overview of IMF data requirements is available in the Provider reimbursement in managed access funds SOP: <https://www.england.nhs.uk/publication/provider-reimbursement-in-managed-access-funds-standard-operating-procedure/>
- Patients are registered via Blueteq (EXA2a/b) and meet the clinical criteria on the registration form. Forms will only be enabled once the governance requirements have been met, which includes signing of regional contract variations.
 - EXA2a - to be completed on initial and subsequent cell collection, hence more than one form may be required per patient.
 - EXA2b – to be completed after treatment with exa-cel to confirm the patient received the treatment; or reason for non-treatment.
 - Both forms must be completed before Trusts can be reimbursed for the cost of exa-cel.
- The off-label use of plerixafor is required as a supportive medicine as part of cell mobilisation for sickle cell patients. Trust policy regarding the use of unlicensed medicines should be applied and the criteria for commissioning will be covered by a separate NHS England policy (Policy 2348a).
 - Trusts must ensure that patients are registered via Blueteq and meet the clinical criteria on the registration form: Initial Funding Application – Plerixafor use in patients with sickle cell disease who are eligible for treatment with exagamglogene autotemcel (Ages 12 years and above) [Policy 2348a]
- **Payment of Trust invoices will be contingent on Blueteq registration and full IMF MDS record applicable to the drug being completed and this information being made available in a timely way.**
- 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.

WWS

Emma Redfern
Medical Director NHS England South West
Region

Tracey Williams
Principal Pharmacist

Appendix A – List of centres commissioned to deliver exagamglogene autotemcel for severe sickle cell disease in people 12 years and over

- Barts Health NHS Trust (adults only)
- Imperial College Healthcare NHS Trust (paediatrics and adults)
- Kings College Hospital NHS Foundation Trust (paediatrics and adults)
- Manchester University NHS Foundation Trust (paediatrics and adults)
- Sandwell and West Birmingham NHS Trust and Birmingham Women’s and Children’s NHS Foundation Trust (sub-contract to University Hospitals Birmingham NHS Foundation Trust for adults) (paediatrics and adults)
- University College London Hospitals NHS Foundation Trust