

Subject: Specialised Services Circular (SSC 2504)
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
SSC 2504	Re: NICE Highly specialised technologies guidance: Onasemnogene abeparvovec for treating pre-symptomatic spinal muscular atrophy [HST24].	<p style="text-align: center;">University Hospitals Bristol and Weston NHS Foundation Trust</p>

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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27 April 2023

All Chief Executives

All Medical Directors

All Chief Pharmacists

Dear Colleagues,

Re: NICE Highly specialised technologies guidance: Onasemnogene abeparvovec for treating pre-symptomatic spinal muscular atrophy [HST24].

I am writing to advise you regarding the funding position on the recently published NICE highly specialised technologies guidance for onasemnogene abeparvovec for treating pre-symptomatic spinal muscular atrophy (SMA).

The guidance can be found at: <https://www.nice.org.uk/guidance/hst24/chapter/1-Recommendations>

NICE in their guidance published on 19 April 2023 has stated that onasemnogene abeparvovec is recommended as an option for treating presymptomatic 5q SMA with a biallelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene in babies aged 12 months and under. It is only recommended if the company provides it according to the commercial arrangement.

The Managed Access Agreement (MAA) for onasemnogene abeparvovec, that has been in place since July 2021, expires on 19 April 2023. Onasemnogene abeparvovec for this subgroup will be routinely commissioned from 19 April 2023, in line with the NICE recommendations and according to a set of treatment criteria which translates the NICE recommendation into a clinical guide as to use in practice. This is in addition to the existing routine commissioning position for babies that are symptomatic: <https://www.nice.org.uk/guidance/hst15/chapter/1-Recommendations>

In addition:

- Trusts must ensure that they are purchasing onasemnogene abeparvovec 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 must ensure that only invoices for the drug procurement costs of onasemnogene abeparvovec in this indication are invoiced to NHSE. All other on costs are in block arrangements.
- Patients must be registered via Blueteq and meet the clinical criteria on the registration form.
- Payment of Trust invoices will be contingent on Blueteq registration, the full 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,



Vinay Takwale (VT)
Medical Director NHS England South West
Region & Consultant Orthopaedic Surgeon



Tracey Williams
Principal Pharmacist