

Vaccination policy for HSCT and CAR-T recipients

This document has been produced by Anthony Nolan and the BSBMTCT Vaccination Sub-Committee to relay information on the financial arrangements for all post-transplant vaccinations, which has been provided to us by NHS England.

It also updates transplant centres on recent changes to the NHS vaccination programmes for shingles and COVID-19, as relevant to stem cell transplant and CAR-T recipients.

The information in this document is correct as of September 2023. For further information, please contact Yasmin.Sheikh@anthonymolan.org.

Financial arrangements for revaccination post-transplant

NHS England has provided the advice below, relevant to vaccinations for patients in England. Arrangements in Scotland, Wales and Northern Ireland will differ.

- GP practices use the legal framework of a Patient Group Direction to deliver routine vaccinations under the UK vaccination programme. Some of the vaccines recommended for patients with a specific medical condition (for example, patients post stem cell transplant) fall under the off-license protocol; meaning a Patient Group Direction is not possible for these vaccines. Instead, a **Patient Specific Direction is needed**, alongside a detailed clinical assessment, to enable vaccination.
- NHSE acknowledges some GP practices may be reluctant to undertake the responsibility of managing a personalised immunisation pathway for a patient who is under the duty of a specialist secondary care team. GP practices also may not feel comfortable writing a Patient Specific Direction.
- **NHSE advises that the specialist clinician leading on the care of the patient affected has a conversation with the patient's GP practice** to discuss the clinical need of the patient and the current contractual position for practices. The GP practice can also discuss with their local commissioning team.
- Ultimately, it is **up to individual GP practices to decide if they are willing to provide vaccination for patients outside of the national vaccination schedule** age requirements and other criteria, and up to the commissioner whether GP practices receive payment for vaccination delivered outside national schedules.
- Anthony Nolan and the BSBMTCT recognise that many transplant centres will have developed arrangements with local GP practices that facilitate the delivery of post-transplant vaccines. However, there have been numerous examples of GP practices refusing to provide post-transplant vaccinations due to the uncertainty around compensation. This is highly inequitable, requires considerable resource from transplant centres to rectify, and causes distress and anxiety to patients and families.
- We are working to request NHSE simplify the guidance and arrangements for reimbursing GP practices for the delivery of post-transplant vaccinations.

Access to Shingrix® vaccine for HSCT and CAR-T recipients

- In October 2022 the JCVI updated its advice to recommend that adult HSCT and CAR-T recipients should be offered the Shingrix® vaccine, in response to a joint request from Anthony Nolan and the BSBMTCT.
- **Clinicians can now prescribe two doses of the Shingrix® vaccine to all individuals aged 18 years and over who have received HSCT or CAR-T therapy**, in line with the Shingrix® label and Green Book. For recent or new HSCT recipients, advice on when to commence Shingrix® vaccination as part of the broader post-transplant revaccination programme is detailed in the BSBMTCT, CCLG and BIA [consensus statement](#).
- This directive can now be found in the [Green Book chapter 28a \(pg. 9\)](#): *“Individuals who have received a stem cell transplant are at a particularly increased risk of developing herpes zoster which may have severe and debilitating effects. This risk is elevated regardless of patient age. Studies have shown that within immunosuppressed populations, stem cell transplant patients are at the highest risk of herpes zoster (McKay et al.). In recognition of this, it is reasonable to give adult stem cell transplant recipients who are not otherwise eligible two doses of Shingrix® vaccine as part of their overall treatment plan. This includes adult recipients of allogeneic transplant, autologous transplant or a CAR-T (chimeric antigen receptor T-Cell) therapy. The second dose of Shingrix® should be given 8 weeks - 6 months after the first dose.”*
- NHSE has confirmed that **centrally supplied stocks of Shingrix® cannot be used for HSCT and CAR-T recipients**. Vaccination of these individuals does not fall under the National Routine Vaccination Schedule or Patient Group Direction, and **GP practices or any secondary care provider will need to procure the vaccine and claim reimbursement accordingly**.
- NHSE suggests that the **clinician leading the care of the patient discusses Shingrix® vaccination with the patient’s GP**, considering the clinical need of the patient and the current contractual position for GP practices. Should any clinicians experience challenges in obtaining access to Shingrix® for their patients, please inform Prof. Thushan de Silva T.DeSilva@sheffield.ac.uk, Yasmin Sheikh Yasmin.Sheikh@anthonymolan.org, and Niamh Buckingham Niamh.Buckingham@anthonymolan.org.
- Note that from September 2023 there will also be a national rollout of Shingrix® to severely immunosuppressed people aged 50+. These patients will be proactively contacted. **HSCT and CAR-T recipients aged 50 and above do not need to wait to be contacted** as part of the national programmes. Also from 1 September, immunocompetent people turning 65 and 70 will be contacted and offered access to Shingrix® via the national immunisation programme, in addition to those already aged over 70.
- The JCVI has agreed to consider whether to extend access to Shingrix® for other immunocompromised patients aged 18+ and is modelling the impact of an extension.

Access to repeat COVID-19 primary vaccines following HSCT or CAR-T

Choice and timing of vaccine

- The [BSBMTCT statement on COVID-19 vaccination](#) provides recommendations on the choice and timing of COVID-19 vaccine for HSCT and CAR-T recipients. HSCT and CAR-T therapy recipients should receive a three-dose primary course.
- NHSE is using **bivalent vaccines for primary course doses** in addition to booster doses, including for those who have not received these vaccines previously.
- The following vaccines are available for: (i) eligible adults; and (ii) eligible children. More detail can be found in the [Green Book](#) (pg32-39).

(i) Vaccination type (adults)	Primary doses	Booster doses
Moderna (Spikevax®) bivalent Original/Omicron BA.4-5 (50/50 micrograms)/ml	0.5ml	0.5ml
Pfizer BioNTech (Comirnaty®) bivalent Original/Omicron BA.4-5 (15/15 micrograms)/dose	0.3ml	0.3ml
Sanofi Pasteur (VidPrevtyn Beta®) (5 micrograms)/dose <i>Alternative for adults 75+</i>	Not to be used for primary vaccination	0.5ml
(ii) Vaccination type (children)	Primary doses	Booster doses
12-17 years – Pfizer BioNTech (Comirnaty®) bivalent Original/Omicron BA.4-5 (15/15 micrograms)/dose	0.3ml	0.3ml
5-11 years – Pfizer BioNTech (Comirnaty®) bivalent Original/Omicron BA.4-5 (5/5 micrograms)/dose	0.2ml	0.2ml
6 months to 4 years – Pfizer BioNTech (Comirnaty®) (3 micrograms)/dose	0.2ml	0.2ml

Vaccine availability

- We are aware of instances of patients encountering delays and barriers to receiving a repeat primary COVID-19 vaccination course post-transplant. Contributing factors include issues with recording repeat primary courses in the national IT system, general lack of education amongst vaccinating sites as to the requirements of stem cell transplant recipients, and lack of clarity over reimbursement for vaccinating sites.
- NHSE has been made aware of these issues at a national level and is implementing measures with regions across England to ensure there is a **Standard Operation Procedure (SOP) in place for accessing repeat COVID-19 primary courses for HSCT and CAR-T recipients.**

- As part of the new SOP, NHSE has directed Integrated Care Boards (ICBs) to implement local pathways that enable HSCT and CAR-T recipients to be referred for COVID-19 revaccination. **ICBs are to ensure year-round pathways are in place to enable these vaccinations outside of a national campaign or seasonal booster period.** HSCT and CAR-T recipients can no longer access revaccination through the National Booking Service or by phoning 119.
- As with other revaccinations for this patient cohort, there are no national Patient Group Directions or National Protocols for these doses. A Patient Specific Direction form is needed to enable vaccination under a prescriber model, tailored to the individual. NHSE has prepared a template [Patient Specific Direction](#) for specialists and GPs to complete and advise on the timing of the Covid vaccine doses for the individual.
- Under the new SOP, **specialists and GPs managing the care of HSCT and CAR-T recipients are responsible for referring these individuals to local vaccination services.** If the ICB pathway or local vaccination offer is not known, **the specialist and GP or patient can escalate by contacting their local NHS vaccination service.** The system points of contact of each ICB can be found at www.england.nhs.uk/local-covid-19-vaccination-contacts.
- Please continue to flag any individual instances of patients unable to receive COVID-19 revaccination to Anthony Nolan by emailing Yasmin.Sheikh@anthonymolan.org and Niamh.Buckingham@anthonymolan.org, including as many details as possible.