Clinical Guidance: Vaccination of Citizens with Severe Immunosuppression: Delivery Through Vaccination Centres

22 October 2021

On 1 Sept 21 JCVI published guidance on additional vaccination requirements for citizens with severe immunosuppression, specifically that an additional or third dose of COVID-19 vaccination should be offered at a time from 8 weeks following their second dose. Details are contained within the COVID-19 vaccination chapter of the Green Book [here]. NHS England wrote to providers on 2nd and 30th Sept 21 with guidance on how the JCVI guidance was to be implemented. Details are available here. Whilst delivery of vaccine is progressing, there is a need to widen the opportunities for citizens to access vaccination and especially via Vaccination Centres.

NHS Digital estimates that there are approximately 510,000 citizens in England who are eligible for a third dose based upon JCVI guidance. The Green Book provides guidance that individuals outlined at Annex A, below, should be offered a third dose of an mRNA vaccine from 8 weeks following their second dose.

In accordance with already published guidance, individuals are to be identified and offered vaccination as a matter of urgency and where necessary prioritised as part of the vaccination planning process. Vaccination delivery will continue to be mainly delivered via hospital hubs and PCNs. However, where an individual attends a mass vaccination centre as a "walk in" patient or referred by a health provider such as their GP or hospital consultant, they should be strongly considered for vaccination. Key points for vaccination centres are as follows:

- Where an individual has received a referral for a 3rd dose from their GP or specialist then they must bring this letter with them to confirm they are eligible for the vaccine
- Where an individual is self-referring to the site It is required that they provides some information regarding their medical condition and medication that would make them immunosuppressed and thus eligible for a third dose of the primary course. This might include a copy of relevant hospital letters, proof of medication.
- For all individuals the pre-screening/ assessment of the individual should be undertaken by the clinical team on site and as necessary in conjunction with a more senior clinical colleague. This may require advice from a prescriber[1] who may or may not be at the same geographical location. See below for legal mechanisms of delivery.
- At present the Pinnacle IT system does not allow for the documentation of the reasons for a third dose of vaccine. Until this is resolved, the additional dose of vaccine should be entered as a booster into the IT system, irrespective of the underlying reason for the vaccination. Reasons for vaccination should be documented in the free text box.
- JCVI recommendations are that a mRNA vaccine is preferred. This would be a full dose or 0.3mls of Comirnaty (Pfizer) or a full dose 0.5 mls of Spikevax (Moderna). To note that the recommended booster dose for Spikevax (Moderna) vaccine is 0.25mls. For those aged 12 to 17 years, the Comirnaty (Pfizer-BioNTech) vaccine is preferred. **It is essential that for those who are immunosuppressed receive a full dose ie 0.5mls of Spikevax (Moderna), not the half dose being used for boosters. The dose for Comirnaty (Pfizer) for the third dose of the primary course or for boosters is the same ie 0.3mls**

[1] Note that a prescriber can be a medical prescriber or independent nurse or pharmacist prescriber.

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Legal Mechanisms of Delivery

Details of the legal mechanisms of delivery of vaccine are available here. The Patient Group Directions for the mRNA COVID-19 vaccines gives the following on inclusion criteria on page 10. Identical wording is in the equivalent National Protocol.

- *individuals referred for a third primary dose of COVID-19 vaccine in accordance with patient specific recommendations from their specialist, GP or prescriber, who has assessed the individual's indication for a third primary dose of COVID-19 vaccine in accordance with current recommendations from the JCVI and Chapter 14a of the Green Book. Note: The decision on the timing of the third dose should be undertaken by the specialist involved in the care of the patient.*

In accordance with the above requirement, where an individual attends a mass vaccination centre following a referral or a recommendation from their specialist or GP for the individual to receive the third dose of their primary course, vaccination can proceed either under the PGD or National Protocol.

Where an individual self-refers and attends with information as outlined above supporting that vaccination would be clinically indicated, such as other hospital letters or proof of medication that would place the individual in the immunosuppressed category, then a clinical assessment will be required, most likely by the clinical supervisor on site.

Once reviewed by a prescriber (this role can be on sight or remote) then vaccination can take place either under the PGD or Protocol or via a PSD or direct administration by the prescriber. (Note that a prescriber can be a medical prescriber or independent nurse or pharmacist prescriber)

Mass Vaccination sites are to ensure that clinical staff with prescribing rights are available, which maybe remotely, for advice and to provide authorisation to vaccinate under the PGD/Protocol as outlined above.

Annex A. Source Chapter 14a, page 21 of Immunisation Against Infectious Diseases.

Box: Criteria for a third primary dose of COVID-19 vaccine

Individuals with primary or acquired immunodeficiency states at the time of vaccination due to conditions including:

- acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who were under treatment or within 12 months of achieving cure
- individuals under follow up for a chronic lymphoproliferative disorders including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias (Note: this list is not exhaustive)
- immunosuppression due to HIV/AIDS with a current CD4 count of <200 cells/µl for adults
- Primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (<1,000 lymphocytes/ul) or with a functional lymphocyte disorder
- those who had received an allogeneic (cells from a donor) or an autologous (using their own cells) stem cell transplant in the previous 24 months
- those who had received a stem cell transplant more than 24 months ago but had ongoing immunosuppression or graft versus host disease (GVHD)
- persistent agammaglobulinaemia (IgG < 3g/L) due to primary immunodeficiency (e.g. common variable immunodeficiency) or secondary to disease / therapy

Individuals on immunosuppressive or immunomodulating therapy at the time of vaccination including:

- those who were receiving or had received immunosuppressive therapy for a solid organ transplant in the previous 6 months
- those who were receiving or had received in the previous 3 months targeted therapy for autoimmune disease, such as JAK inhibitors or biologic immune modulators including B-cell targeted therapies (including rituximab but in this case the recipient would be considered immunosuppressed for a 6 month period), T-cell co-stimulation modulators, monoclonal tumour necrosis factor inhibitors (TNFi), soluble TNF receptors, interleukin (IL)-6 receptor inhibitors., IL-17 inhibitors, IL 12/23 inhibitors, IL 23 inhibitors. (Note: this list is not exhaustive)
- those who were receiving or had received in the previous 6 months immunosuppressive chemotherapy or radiotherapy for any indication

Individuals with chronic immune-mediated inflammatory disease who were receiving or had received immunosuppressive therapy prior to vaccination including:

- high dose corticosteroids (equivalent to ≥ 20mg prednisolone per day) for more than 10 days in the previous month
- long term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the previous 3 months
- non-biological oral immune modulating drugs, such as methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day; 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day) in the previous 3 months
- certain combination therapies at individual doses lower than above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous 3 months

Individuals who had received high dose steroids (equivalent to >40mg prednisolone per day for more than a week) for any reason in the month before vaccination