Additional COVID vaccine for severely immunocompromised people

The COVID-19 Vaccine Technical Advisory Group recommends that those aged 12 and over who are severely immunocompromised will benefit from a third primary dose of the mRNA-CV to improve protection against COVID-19.

While awaiting sign off from Medsafe it will be necessary for these third doses to be given under prescription, and requiring written consent to be obtained.

The Ministry of Health's *Third Primary Dose of the Pfizer/BioNTech Vaccine Policy Statement and Clinical Guidance* can be found here (tinyurl.com/3mjpmr56).

Process for administration of vaccines

The third primary dose should be administered **at least 8 weeks after the second dose.**

If appropriate pay attention to current or planned immunosuppressive therapies: where possible delay the third dose until 2 weeks after the period of immunosuppression (in addition to the clearance time-period of the therapeutic).

Informed consent

These third doses can currently only be offered by an authorised prescriber after informed consent. This means that the consumer's GP or specialist will need to confirm eligibility, provide a prescription and complete a consent form with the consumer.

Completing the consent form

The consent for the third dose is now part of the standard COVID-19 vaccination consent form (HP7565, 21 October 2021). Ensure that the correct sections on page 1 are completed by the consumer and prescriber at the time of prescribing. Page 2 is completed at the vaccination site by the vaccinator and vaccination site clinical lead (these might be the same person).

How to access a consent form

The Informed consent form should be completed at the time the prescription is issued. The form will be available via the:

- Standard CVIP collateral Drop Box and print option.
- Health Pathway site along with the HP clinical guidance based on the policy statement.

Criteria for eligibility (from Immunisation Handbook)

Eligible group	Condition	Treatments or health status
Individuals with primary or acquired immunodeficiency states at the time of vaccination	Acute and chronic leukaemia and clinically aggressive lymphomas (including Hodgkin's lymphoma)	under treatment or within 12 months of achieving cure
	Chronic lymphoproliferative disorders, including haematological malignancies[a] and plasma cells dyscrasias.	under follow up
	Active HIV infection/AIDS	current CD4 count <200 cells/µl
	Primary or acquired cellular and combined immune deficiencies	lymphopenia (<1,000 lymphocytes/µl) or functional lymphocyte disorder.
	Allogenic or autologous haematopoietic stem cell transplant	received in prev. 24 months or received >24 months ago with ongoing immunosuppression or graft-vs-host disease.
	Persistent agammaglobulinaemia due to primary immunodeficiency and secondary to disease/therapy	IgG <3g/L
Individuals on immunosuppressive or immunomodulating therapy **at the time of vaccination**	Following solid organ transplant	receiving or had received therapy in previous 6 months
	Targeted therapy for autoimmune disease, such as JAK inhibitors and biologic immune modulators[b, c]	receiving or had received therapy in the previous 3 months[c]
	Immunosuppressive chemotherapy or immunosuppressive radiotherapy for any indication	receiving or had received therapy in previous 6 months
Individuals with chronic immune-mediated inflammatory disease who were receiving or had received immunosuppressive therapy **prior to vaccination**	High-dose corticosteroids (equivalent to ≥20 mg prednisolone per day)	for more than 10 days in previous month
	Long term moderate dose corticosteroids (equivalent to ≥10 mg prednisolone per day)	for more than 4 weeks in previous 3 months
	Non-biological oral immune modulating drugs eg, methotrexate (>20mg/week; oral or subcutaneous) azathioprine (>3 m/kg/day) 6-mercaptopurine (>1.5mg/kg/day) mycophenolate (>1g/day)	in previous 3 months
	Certain combination therapies at individual doses lower than above[d].	in previous 3 months.
Individuals who had received high-dose steroids	Equivalent to >40mg prednisolone per day for more than a week for any reason[e].	in the month before vaccination.

a. Such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias. **Note** this list is not exhaustive but provides an indication of conditions where a consumer should receive a third primary dose.

b. B-cell targeted therapies (including rituximab), T-cell co-stimulation modulators, monoclonal tumour necrosis factor inhibitors, soluble TNF receptors, interleukin (IL)-6 receptor inhibitors, IL-17 inhibitors, IL-2/23 inhibitors, IL-23 inhibitors. **Note** this list is not exhaustive but provides a guide on the types of scenarios where a consumer should receive a third primary dose.

c. In the case of rituximab, recipients would be considered immunosuppressed for a longer period of 6 months.

d. 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.

e. Individuals who had received brief immunosuppression (≤40mg prednisolone per day) for an acute episode (for example, asthma / chronic obstructive pulmonary disease / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination.

Information to support informed consent discussions re third doses

Rationale for the third dose

Standard vaccine schedules given to immunosuppressed individuals offers some protection from severe illness and hospitalisation from COVID-19. This protection may be low and not last as long as for those with healthy immune systems. The benefit of a third dose has been demonstrated and is standard practice in other countries for those at high risk.

Expected side effects following third dose

Currently there is limited data on third doses. The common side effects would be expected ie, muscle aches, headache, fever and fatigue. The rates and types of adverse events following a third dose are similar to prior doses.

The rates of rare but more severe events

The rates of severe events such as myocarditis and anaphylaxis after the third dose are not known. The rationale for offering this third dose is that these people are likely to have had a low response to the previous doses of vaccine, so the risk of more serious reactions is likely to be extremely rare.

Practical issues

Accessing the vaccination

If there are no vaccination facilities at the site the prescription is issued, the consumer will need to take the prescription and consent form to a COVID-19 vaccination site. They can attend any walk-in vaccination centre or ring the COVID Vaccination Healthline on 0800 28 29 26 to book an appointment.

Administering the vaccines

The vaccinator will need to confirm the consumer has a prescription and is still happy to proceed with the vaccination. The vaccinator then completes the second page section of the consent form. The consent form and prescription must be scanned into CIR and vaccination recorded as below

How to log third dose vaccination into the CIR

1. Create a **New Immunisation Case** for the Consumer (acknowledge the warning about the existing case)
2. Complete the first Immunisation Event
3. **Important:** Add a **Note** explaining the reason for administering the third dose.

Quick Step Guide to this process can be accessed from *CIR Classroom and Production* under CIR training materials or, can be accessed here: link to guide.

PLEASE NOTE: This is an **interim solution** until supporting functionality is released on Tuesday 26 October 2021 as part of the upcoming COVID Immunisation Register (CIR) release.