Section B: Pathway to COVID-19 vaccination

Section B: Pathway to COVID-19 vaccination - summary of changes

Version	Date	Section	Summary of Changes
55.0	29/05/23	17	Deleted section as no Comirnaty purple cap COVID-19 vaccine vials are left in the warehouses or providers' inventory.

Section guidance

This section provides operational guidance on the vaccination pathway COVID-19 vaccines, from booking and scheduling to vaccine preparation onto vaccine administration and observation. The first line vaccines where there are no contraindications is the Pfizer-BioNTech Comirnaty vaccines.

Purpose

The purpose of this section is guiding the vaccinating workforce to *do the right thing* and have the right resources and information available to provide a safe quality vaccination journey for every consumer. It is designed to be applicable to all sites delivering the COVID-19 vaccine and provide guidance and assistance to providers, to maintain public safety and ensure consistent and equitable vaccination practices are in place across New Zealand/Aotearoa.

This section should be read and interpreted alongside the **COVID-19 immunisation policy**, **Immunisation Handbook 2020,** the Standards, and **IMAC resources**.

Appendices relevant to this section

- **Appendix G: Vaccination site screening questions**
- **Appendix H: Supported decision-making process**
- **Appendix I: Serious Adverse Event Process** (process steps, SAC examples, notification form)

13 Booking and scheduling

The National Immunisation Booking System known as Book My Vaccine (BMV) supports a national-led approach to immunising New Zealand/Aotearoa against COVID-19. Book My Vaccine supports vaccination sites down to Community Hub level. Use by primary care sites is optional where they only service their own enrolled populations.

For more information, see **Section C: Additional Programme Guidance, Variations, and Incidents**.

Ensure that the scheduling of vaccination appointments avoid over-crowding and allow for physical distancing and other IPC measures. Also, limit the number of accompanying people to only those who need assistance, whether physical or psychosocial.

13.1 Booking second doses

Do not vaccinate less than 21 days

- **The administration of a COVID-19 vaccine second dose at an interval of less than 21 days is not approved by Medsafe and is considered off-label use and must be reported to CARM.**
- **New bookings made through bookmyvaccine.nz and the COVID-19 vaccine Whakarongorau Aotearoa 0800 28 29 26 is set to three weeks between the two doses.**
- **If consumers have existing vaccination bookings, they can keep their second appointment as it is, or choose to change it. Either way the important thing is that consumers receive two doses of the vaccine to be fully vaccinated.**
- **Consumers should select the appropriate age range when making an appointment**
- **Second doses can be booked for any time after day 21.**
- **The administration of a COVID-19 vaccine at an interval of less than 21 days is not approved by Medsafe and is considered off label use and must be reported to CARM. See Appendix I for more information on incidents.**

Note: A prescription from an authorised prescriber is required when using Nuvaxovid as a second primary dose following a non-Nuvaxovid COVID-19 vaccine for a first primary dose, in accordance with Section 25 of The Medicines Act 1981, as it is considered off-label use. This must be documented clearly including the rationale and the informed consent process. A CARM report does not need to be completed if the vaccine has been prescribed by an authorised prescriber.

For more information on dose intervals please see the **COVID-19 Immunisation policy statement on the Ministry of Health website.**

Administering leftover vaccines

To minimise wastage, the Programme recommends the preparation of a back-up/stand-by list of consumers aligning to the sequencing framework. Leftover diluted and/or drawn vaccine unused at the end of the shift that would expire before the next clinic, may be administered to consumers on the back-up/stand-by list.

The Programme does not require visibility of the back-up/stand-by list; use best judgement to manage this list as to align with the sequencing framework.

14 Protecting security and privacy

The vaccination process requires personal, identifying information be collected. In the health sector, NHIs are considered identifiable information as well as standard identifiers such as name, address, and date of birth.

Protecting and treating sensitive health information with respect is important.

- All medical records (such as written consent forms) at vaccination sites are required to be securely stored out of the sight (for example, in a drawer).
  - It is preferable this storage area is locked, or in the constant presence of an authorised person, such as an administrator, a security guard, or a vaccinator.
- At the conclusion of the vaccination event, the Programme recommends that the personal information documentation is taken directly (that is, no transit points) by an authorised person (such as an administrator, a security guard, or a vaccinator) to the site where the record will be held.

In addition to ensuring the security of health records as per above, the following security and privacy factors should be considered:

- Informing consumers why their information is being collected and what it will be used for (for example, that it will not be used for immigration or law-enforcement purposes)
- Consider who may be able to the see computer screens that are likely to be used to input personal information
- Ensure passwords and log-in details are kept confidential
- In the event of a likely security or privacy breach advise the relevant Health District or provider privacy officer or contact the Programme's Privacy team as soon as possible
- Securely dispose unnecessary duplicate information
- Ensure confidential conversations occur away from areas where other consumers or members of the public might also access.
- Ensure staff accessing consumer data have completed the appropriate privacy training (e.g., see the **Privacy Commissioner courses link**).

Note: Use secure methods when transferring information outside of the core vaccine systems such as USB encryption or accredited online services. Data should be password protected.

15 COVID-19 vaccines operational phase

- Use a daily checklist to monitor and ensure IPC and other safety measures are adhered to.
- Consider a daily 'huddle' to enhance teamwork and to highlight any IPC issues.
- Screen all staff for signs and symptoms of COVID-19 at the start of each shift.
- Screen all people arriving for vaccination for COVID signs and symptoms. For additional screening questions see **Appendix G**.
- Ensure the scheduling of vaccination appointments avoids over-crowding and allows for physical distancing and other IPC measures. Also, limit the number of accompanying people to only those who need assistance, whether physical or psychosocial.
- Ensure the appropriate processes are in place to prevent under-age vaccinations – **this is a never event**.
- Ensure the appropriate processes are in place to prevent second dose vaccinations earlier than 21 days – **this is a never event**.
- **Ensure the appropriate processes are in place to ensure consumers are receiving the age-appropriate vaccine.**

Note: In the rare occurrence where an authorised prescriber deems the vaccine clinically indicated for a consumer, the authorised prescriber can prescribe the vaccine as off label/ unapproved use. This must be documented clearly including the rationale for early second dose and the informed consent process. A CARM report does not need to be completed if the vaccine has been prescribed by an authorised prescriber. Written consent is advised.

Key IPC measures to implement

Prepare each injection in a clean, designated area.

Hand hygiene

- At the start of the shift, all vaccination team members are required to wash their hands thoroughly with soap and water and dry them thoroughly or use hand sanitiser.
- Facilitate attending consumers' hand hygiene (as above).
- Vaccinators should perform hand hygiene before putting on and removing PPE, before preparing the vaccine, and between each vaccine administration, preferably using alcohol-based hand sanitisers.
- Gloves are not required and, if used, do not replace the need for hand hygiene between each vaccine administration and for other indications. The use of alcohol hand sanitisers on gloves is strongly discouraged.

PPE

- PPE is to be selected based on risk assessment as a part of standard precautions.
- In the context of the COVID-19 pandemic, vaccinators should wear PPE appropriate to the area they are working in. For more information visit the **Te Whatu Ora website** .

Preparation and administration IPC

- Sterile, single use syringes and needles should be used. These should only be removed from their packaging immediately before use.
- Perform hand hygiene before preparing vaccine for delivery
- Prevent contamination of the vials by wiping the access diaphragm (septum) with 70% alcohol (isopropyl alcohol or ethanol) on a swab or cotton wool ball before piercing the vial and allow to air dry. If the top of the vial is accidentally touched during drawing up it must be re-wiped (repeat this step).
- Adhere to IMAC guidance for the drawing up of vaccine and skin preparation at the site of injection.
- Discard used syringes and needles as a single unit into a sharps container immediately after administering the vaccine

16 Obtaining informed consent

Prior to administering the vaccination, the registered health professional must obtain informed consent, per the *Code of Health and Disability Services Consumers' Rights* (the Code). The steps to recording the outcome of the informed consent question is:

- The vaccinator or an administrative support person must record in CIR the consumer's consent to approve or decline the administration of the vaccine.
- The Programme assumes verbal consent is agreeable in most situations.
- Written consent can be considered in the following situations below:
    a. where there are significant risk of adverse effects to the consumer, per **clause 7(6c) of the Code**
    b. if it is being prescribed. For more information, please refer to the below 'Prescription' section.
    c. if this is the provider's or vaccinator's preference, for example, in aged residential care settings.
- Where written consent is recorded under points a. b. and/or c. above, the forms do not need to be uploaded to CIR; rather, the provider is responsible for ensuring the forms are archived as a part of that consumer's clinical record.
- If written consent forms are unable to be archived in the consumer's clinical record, then this must be uploaded onto CIR. Once this is complete the record can be destroyed.

Where a consumer is not competent to make an informed choice and give consent for their vaccine, someone who has the legal right can make decisions on the consumer's behalf; namely a legal guardian or someone who currently holds Enduring Power of Attorney for personal care and welfare.

See **Appendix H** which displays the process for consumers requiring support to consent to the COVID-19 Vaccination. Any supported decision-making conversations should be documented in the notes section of CIR. For more information regarding obtaining informed consent, see the ***Immunisation Handbook*, chapter 2**.

For more information regarding supported decision making, or to access the training module specific to COVID-19 Vaccine Supported Decision Making, see IMAC Learning Courses at **IMAC Learning**.

Obtaining written consent for the Nuvaxovid vaccine

The Programme requires written consent to be obtained before administering the Nuvaxovid vaccine as a second primary dose after a non-Nuvaxovid vaccination.

Informed consent for consumers aged 12 to 15 years

Under the code of rights, every consumer, including a child, has the right to the information they need to make an informed choice or to give informed consent. Therefore, a young person aged 12-15 years can provide their own informed consent or refusal to consent if they are deemed competent to give consent, and a parent or guardian does not need to provide consent or be present. Some of these young people may choose to have their parent or guardian consent on their behalf and that is fine.

Verbal or written consent for consumers aged 12 to 15 years

Informed consent for consumers aged 12-15 years can be verbal. However, written consent can be required if it is the provider's or vaccinator's preference, and like with all consumers, must be obtained if there is significant risk of adverse effects.

16.1 Prescription

A prescription from an authorised prescriber is required when a vaccine is being administered off-label under **Section 25 of The Medicines Act 1981,** such as when a Medsafe approved medicine is being used for an un-approved use. However, no prescription from an authorised provider is required if the administration is authorised under **section 34A of The Medicines Act 1981** which empowers the Director-General of Health to authorise, by Notice, the use of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet.

For the list of authorised prescribers please refer to the **Medsafe website**.

When a prescription is used, it is recommended that written consent is completed. In this instance it means that the prescriber completes and signs the written consent form. However, if the prescriber is not available to sign the written consent form, the Clinical Lead can complete the form. The prescription and written consent form can be uploaded in the CIR.

16.1.1 Written consent forms

Written consent forms must be managed on-site or by a centralised administration team. Given the information on the written form contains personal information, **forms must be always held and transported securely** (for example, in a locked cabinet/drawer, a tracked courier bag, or other secure container when transported between locations). The consumer may also decide to take the written consent form with them.

If providers choose to upload written consent forms the person uploading, for example the administrator, must scan each form to their computer, locate the consumer's CIR record, then upload the scanned form/s to the consumer's CIR record; delete the local copy and securely destroy the written form. When necessary, the written form may be kept for a few days or weeks to check for inaccuracies in transcribing before the written forms are destroyed.

Note: Instructions for uploading files to CIR are included in the CIR eLearning module.

16.1.2 Variations to consent forms

As of 6 May 2021, there is now only one NPHS Te Whatu Ora consent form (the Group 1a version m has been withdrawn). The COVID-19 consent form is available via the National Immunisation Programme's Dropbox and the Ministry of Health website. Please ensure you are using the latest version.

16.1.3 Vaccine safety and additional considerations for consumers aged 12 to 15 years

Similarly, as with consumers over the age of 16 years, it is important to assess the administration site and select the correct needle length. Most commonly, the same needles used for adults would be used for consumers aged 12-15 years.

17 Comirnaty 15/15mcg Original/ Omicron BA.4/5 grey cap COVID-19 vaccine (for ages 16 years and over)

The key safety points are:

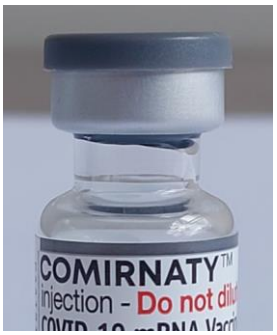
- Approved for use for consumers aged 16 years or over receiving a booster dose
- The Comirnaty 15/15mcg Original/ Omicron BA.4/5 grey cap COVID-19 vaccine **does not need** to be diluted
- There are 6 doses per vial
- For all vaccinator resources and materials related to Comirnaty 15/15mcg vaccine please refer to the **IMAC website.**

This is the first line additional booster vaccine where there are no contraindications to the Pfizer-BioNTech Comirnaty vaccine.

A prescription from an authorised prescriber is required when using the Comirnaty 15/15mcg Original/ Omicron BA.4/5 grey cap vaccine as a primary course dose, in accordance with **Section 25 of The Medicines Act 1981**, as it is considered off-label use. Written consent is required for all consumers receiving an 'off label' dose of the Comirnaty 15/15 mcg Original/ Omicron BA.4/5 grey cap vaccine.

18 Comirnaty 30mcg grey cap COVID-19 vaccine (for ages 12 years and over)

The key safety points are:



- Approved for use for consumers aged 12 years or over receiving their **primary course.**
- The Comirnaty 30 mcg grey cap COVID-19 vaccine **does not need** to be diluted.
- There are 6 doses per vial.
- To be considered as a booster dose at less than 6 months after a previous dose, then written consent and a prescription are required.
- This is the first line vaccine where there are no contraindications to the Pfizer-BioNTech Comirnaty vaccine.
- For all vaccinator resources and materials related to Comirnaty 30mcg vaccine please refer to the **IMAC website.**

A prescription from an authorised prescriber is required when using the Comirnaty 30 mcg grey cap vaccine as a booster dose administered at less than 6 months from a previous dose, in accordance with **Section 25 of The Medicines Act 1981**, as it is considered off-label use. Written consent is required for all consumers receiving an 'off label' dose of the Comirnaty 30 mcg grey cap vaccine.

19 Comirnaty 10mcg orange cap COVID-19 vaccine (for ages 5 to 11 years)

The key safety points are:

- Approved for use for children/tamariki aged 5 to 11 years
- The Comirnaty orange cap vaccine dose is different to the Comirnaty purple cap dose (12+ years) and the Comirnaty maroon cap dose (6 months to 4 years)
- There are 10 doses per vial
- If the consumer receives the Comirnaty orange cap dose (for ages 5-11) and then turns 12 before their second dose, they will receive the adult dose of the Comirnaty vaccine for subsequent doses.
- For all vaccinator resources and materials related to Comirnaty 10mcg vaccine please refer to the **IMAC website.**

19.1 Site readiness

If sites are new to vaccinating the Comirnaty orange cap vaccines (for ages 5 to 11 years) it is recommended a Comirnaty orange cap site, check list is completed

Comirnaty orange cap Site Checklist	**Y / N**
Site Workforce Police safety check are up to date	Y ☐ N ☐
Vaccinators administering the Comirnaty orange cap vaccine must complete the Paediatric COVID-19 Vaccinator Education Course (IMAC link)	Y ☐ N ☐
Child safe Environment	Y ☐ N ☐
SOP preparation of Comirnaty orange cap doses	Y ☐ N ☐
Child friendly resources (distraction posters can be found on the IMAC website)	Y ☐ N ☐
Child-suitable bag valve mask (BVM or 'ambu bag') resuscitator is required, airways (optional) and any other emergency equipment to respond to a serious adverse event.	Y ☐ N ☐

Note: See A4.6. Minimum staff and equipment requirements for vaccination services in **Appendix 4** of the Immunisation Handbook (2020)	
Consumer collateral	Y ☐ N ☐
Dry Run	Y ☐ N ☐
Wet Run	Y ☐ N ☐

19.2 Vaccine safety and additional considerations for consumers aged 5 to 11 years

With consumers the age of 5 to 11 years, it is important to use the correct needle length. For children/tamariki under the age of 7 years a 16 mm length needle should be used. For children/tamariki ages 7 to 11 years clinical judgement should be used to determine if a longer needle is required (25mm). Use of a shorter needle risks delivering the vaccine subcutaneously as opposed to intramuscularly, which has the potential to underdose. For more information on needle length, refer to the ***Immunisation Handbook*.**

Ensuring young people have adequate understanding of the vaccine and can provide informed consent

Training and guidance material are available to support vaccinators to gauge consumer's ability to provide informed consent. It is important that a robust conversation occurs prior to vaccination, where the child or their parent/ legal guardian/ enduring power of attorney has an opportunity to have any questions answered and concerns addressed.

20 Comirnaty 3mcg maroon cap COVID-19 vaccine (for ages 6 months to 4 years)

The key safety points are:

- Approved for use for children/tamariki aged 6 months to 4 years
- The Comirnaty maroon cap vaccine dose is different to the Comirnaty purple cap dose (12+ years) and the Comirnaty orange cap dose (5 to 11 years)
- There are 10 doses per vial
- If the consumer receives the Comirnaty maroon cap dose (for ages 6 months -4 years) and then turns 5 before their second or third dose, they will receive Comirnaty orange cap (5 to 11 years) for subsequent doses.
- For all vaccinator resources and materials related to Comirnaty 3mcg vaccine please refer to the **IMAC website**.

20.1 Vaccine safety and additional considerations for consumers aged 6 months to 4 years

With consumers the age of 6 months to 4 years, it is important to use the correct needle length for the child being vaccinated as well as the area of their body the vaccine is to be given into (ie deltoid vs vastus lateralis). For more information on needle length, refer to the ***Immunisation Handbook*.**

Ensuring young people have adequate understanding of the vaccine and can provide informed consent

Training and guidance material are available to support vaccinators to gauge consumer's ability to provide informed consent. It is important that a robust conversation occurs prior to vaccination, where the child or their parent/ legal guardian/ enduring power of attorney has an opportunity to have any questions answered and concerns addressed.

21 Nuvaxovid COVID-19 vaccine (for ages 12 years and over)

The key safety points are:

- Approved for use for consumers aged 12 years or over receiving dose 1 and dose 2 of the primary series
- Approved for use for consumers aged 18 and over receiving the primary series and booster doses
- The Nuvaxovid COVID-19 vaccine **does not need** to be diluted
- There are 10 doses per vial
- For all vaccinator resources and materials related to Nuvaxovid please refer to the **IMAC website**.

The Nuvaxovid vaccine is available as a second line vaccine for consumers who meet the eligibility criteria.

A prescription from an authorised prescriber is required when using the Nuvaxovid vaccine as dose 2 of their primary course (i.e., following a non-Nuvaxovid COVID-19 vaccine for dose 1), in accordance with **Section 25 of The Medicines Act 1981**, as it is considered off-label use. Written consent is required for all consumers receiving an 'off label' dose of the Nuvaxovid vaccine.

22 Preparation of Doses

Follow the IMAC vaccine preparation instructions for vaccine preparation. These instructions are included in vaccine shipments and are available on the **IMAC website**.

Note: These instructions are regularly updated. Please ensure you are using the most recent version.

Table 23.1

Vaccine type	Dilution required?	Draw up	Doses per vial
Comirnaty 15mcg/15mcg Original / Omicron BA.5-5 (grey cap) 16+ years	**NO**	0.3mL	6
Comirnaty 30mcg (grey cap) 12+ years	**NO**	0.3mL	6
Comirnaty 10mcg (orange cap) 5-11 years	YES	0.2mL	10
Comirnaty 3mcg (maroon cap) 6 months-4 years	YES	0.2mL	10
Nuvaxovid (blue cap) 12+ years	**NO**	0.5mL	10

For vaccines that **do not** require dilution:

Incorrect volume of vaccine may be detected by identifying you have drawn up less or more than **6 doses (Comirnaty)** OR **10 doses (Nuvaxovid)** from a vial.

Should this occur, immediately quarantine the vaccines and discard all doses from that vial if it is clear why the mistake has occurred.

If it is unclear why the error has occurred, keep the vaccines in quarantine and contact IMAC for clinical guidance. This error must be documented as waste in CIR and reported as an incident in the local organisation's quality and safety reporting system.

For vaccines that require dilution (3 mcg and 10 mcg only):

Pfizer-BioNTech COVID-19 vaccine should be brought to room temperature prior to dilution, as noted in IMAC's preparing vaccine instructions. It should not feel cold to the

touch. The actual time to get the vial to room temperature will vary depending on when you take vials out of the fridge and the temperature of the room. Approximately 30 minutes should be sufficient time.

The Medsafe data sheets confirms ten (10) doses per vial.

To avoid the Comirnaty vaccine being under or over diluted it is recommended that all doses are drawn up into syringes following dilution and double-checked by a second appropriately trained vaccinator.

If the number of doses drawn from the vial are not in line with expected number this will immediately alert to the vial having not been correctly diluted. Any vial where doses drawn up are less than or more than ten (10), should be quarantined. Use of the IMAC dilution record spreadsheet will also provide an additional check.

Please discuss with IMAC on 0800 466 863 and if advised to discard, this must be documented as waste in CIR as per guidelines and reported as an incident in the local organisation's quality and safety reporting system.

Before preparation of vaccine check:

- **That it's the right vaccine**
- Manufacturer's vaccine expiry date
- Appropriate supplies are used. **Please refer to Section 9: Vaccine and consumables ordering and delivery** for ordering consumables**.**

Number the vaccine vial and enter the number into the **dilution record**. Second person independently checks that the correct vaccine has been selected, by confirming the product name on the vial and checking the expiry date printed on vial by manufacturer. Second person also independently checks the numbering of the vial and documents these checks by signing/initialling the **dilution record**.

Syringe labels are used to help differentiate between vaccines. Please see **table 8.2** for the different syringe labels available to order.

During the preparation of the vaccine both expiry dates must be double checked. This includes the vial and the 10-week removal from ULT expiry date (in-use' expiry date label on the vaccine pack). Vaccines can be administered until the end of the expiry day.

For quality and safety purposes, it is recommended that each vial and/or syringes (made from that vial), are labelled with the:

- date and time
- expiry time

For vaccines that require dilution (3 mcg and 10 mcg only):

- diluent name
- date and time of dilution
- expiry time after dilution

Vaccine preparation precautions

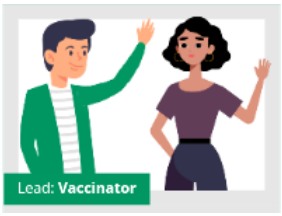
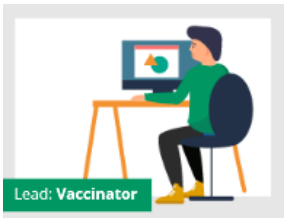
- Draw up from one vial at a time. Each vaccine dose from that vial should go into one kidney dish/ container with the empty vial for vaccine administration.
- It is recommended that a suitable covering is used when storing the drawn-up syringes. This is to ensure that **the vaccine is not exposed to direct sunlight or UV light** (both in the vial or in the drawn-up syringe) and that used syringes will not be put back with the unused syringes.
- During the preparation of the vaccine standard local IPC policies should be followed.
- **Any vaccine not used within the expiry time outlined above must be discarded.**
- The vaccine must not be shaken during preparation.
- Some liquid may remain in the vial after withdrawing the final dose. The leftover vaccine must be discarded. **Do not mix doses from different vials.**
- If during the preparation of the vaccine a foreign body (such as a black particle) or discolouration is identified, the vial should be discarded and recorded as an open vial-quality issue in CIR. The vaccine will appear colourless to slightly yellow, clear to mildly opalescent.
- **Note:** Call IMAC for clinical advice if required at any stage of preparation.

23 COVID-19 vaccine pathway to vaccination

For more information see **IMAC guidelines** found on the IMAC website and the ***Immunisation handbook*** **Section 2.2** for the correct vaccine administration process.

Please refer to the '7 Rights of COVID-19 Vaccine Administration' on the **IMAC website**.

Table 24.1 – pre-vaccination greeting and verify identity

Step	Action
 **Greet consumer, conduct COVID-19 health check**	On arrival at the vaccination site, the vaccinator/site administrator will greet the consumer and ask whether they have any COVID-19 symptoms as per standard site practices. If the consumer is underage, a parent, legal guardian, caregiver, or person with an enduring power of attorney will need to accompany a child to their appointment(s) as the responsible adult and be able to provide consent for them to be immunised. **Please note:** • People who have a confirmed COVID-19 infection, should not be vaccinated until they have had the appropriate recovery period • People who have symptoms of COVID-19 should be advised to stay at home and get a test. They can be vaccinated once they have a negative test result and symptoms are mild only. • People who live with someone who has COVID-19 are a household contact and are advised to follow the specific advice public health advice for testing and isolating. • People who are significantly unwell are advised to wait until they are better before getting the vaccine; however, note that mild symptoms are not a contraindication. People in this situation are advised to discuss their symptoms with their GP or vaccine provider. • People who have been advised to self-isolate, stay at home, are under an isolation order or are waiting on a test result, should have their appointment deferred. • Please see the **Vaccination Site screening questions** below for questions related to clinical assessment.
 **Verify consumer's identity**	The vaccinator/site administrator will also verify the consumer's identity using name, DOB, address, and locate their record in CIR. This should be done in a private and confidential manner and should not be overheard or viewed by other consumers. Check the consumer's DOB and confirm age and what vaccine they will be receiving. If underage do **not** vaccinate. • Check with the consumer and CIR to ensure they are eligible for their vaccine today.

	• Check the dose interval and timing is correct for the vaccine the consumer is receiving. For more information see the **COVID-19 immunisations policy statement.** **Note:** Photo ID is **not** required to confirm the consumer's identity. Use the **7 rights of covid vaccination** resource available on the IMAC website.

Table 24.2 – pre-vaccination provide collateral

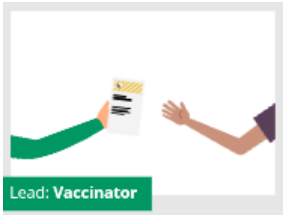
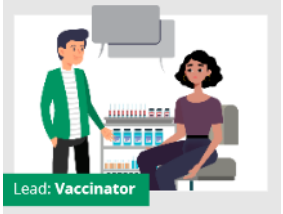
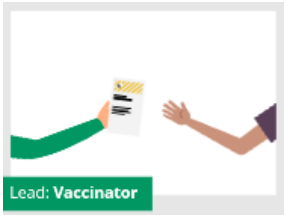
Step	Action
 **Provide collateral**	The vaccinator/site administrator will provide the consumer with the COVID-19 vaccination information and consent pack, which includes: • What you need to know about the COVID-19 vaccination • After the COVID-19 vaccination Ensure the consumer retains this information in either paper form or by taking a photo. You may also choose to provide the COVID vaccine FAQs sheet, which is available on **the Ministry's website.** You may also display the privacy statement in the reception area as well as supplying the information in hard copy.

Table 21.3 – vaccination process: pre-vaccination clinical assessment

Step	Action
 **Complete a pre-vaccination clinical assessment**	**Pre-vaccination clinical assessment** The vaccinator undertakes a pre-vaccination clinical assessment. This encompasses whether the consumer has medical reasons why they should not receive the vaccine, any history of allergy, whether they had an adverse event after receiving a previous dose of the COVID-19 vaccine, any current symptoms, are pregnant or breastfeeding, and other relevant precautions. This includes checking that the consumer is not underage for the vaccine they will be receiving, and they have scheduled the correct interval between doses. For more information on dose intervals and timing see the **COVID-19 immunisation policy statement.** **Interaction with other vaccines** If possible, the COVID-19 vaccination should be given 7-days before or after administering the live-attenuated shingles vaccine (Zostavax). Other vaccines on the National Immunisation Schedule can be given before, after or at the same time as the COVID-19 vaccination.

Step	Action
	Boosters If the consumer has presented for a COVID-19 vaccine booster, they must meet the **eligibility criteria** available on the Ministry of Health website. The outcome of this clinical assessment must be recorded in CIR (in the medical screening section). • If recording the consumer as medically unfit to receive the vaccine, CIR will prompt to either cancel or reschedule the immunisation event. If the consumer is temporarily unable to receive the vaccine (that is, they are unwell today), select reschedule to ensure you can use the same CIR case record in future to capture details of the first and second doses. • Only select cancel if the consumer will *never* be able to receive the vaccine. Cancelling the event record means it will not be possible to go back to record a first or second dose on this record in future.

Table 24.4 – vaccination process: informed consent

Step	Action
 **Obtain informed consent**	**Obtain informed consent before administering the vaccine** The vaccinator (or vaccinator support person) **must** obtain the consumer's informed consent to receive the vaccine prior to the administering of the vaccine. Where appropriate, consent may be given by a proxy such as a guardian or person with power of attorney. A parent, legal guardian, caregiver, or person with an enduring power of attorney will need to accompany a child to their appointment(s) as the responsible adult and be able to provide consent for them to be immunised. • If a child presents to their vaccination with whānau who cannot provide consent for the child to be immunised, written or verbal consent should be obtained from a parent, legal guardian, or person with an enduring power of attorney prior to administration of the paediatric vaccine. If off-label use of the vaccine, obtain **written** informed consent before administering the vaccine. **Note**: IPC guidance must be observed when dealing with hard-copy consent forms and obtaining consent. For example, consumers should use hand-sanitiser before or after handling a pen to sign the form or bring along their own pen.

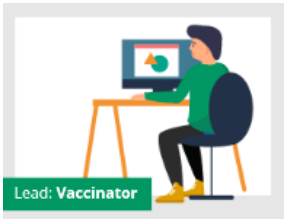
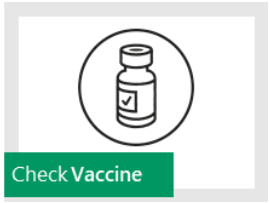
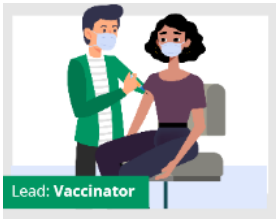
Step	Action
 **Record consent in CIR**	**Consumer consent record** The vaccinator or an administrative support person must record the consumer's consent to receive the vaccine in CIR. • Do not vaccinate if the interval is less than **21 days.** • If the person does not wish to receive the vaccine, record their decline in CIR. • Do not vaccinate with Nuvaxovid if the child is under the age of 12 years. • Nuvaxovid vaccine is not recommended for pregnant people due to lack of safety data and requires a prescription and written consent before administration.

Table 24.5 – vaccination process: administering the vaccination

Step	Action
 **Check the vaccine**	**Check the vaccine** Check: • The label and confirm that you have the correct vaccine, and that the vaccine has not expired. • The opened/punctured diluted vial is used within the appropriate time frame before expiry. Refer to the **IMAC vaccine preparation sheets** for vial expiry times after opening. • The unopened vial fridge expiry date (in-use' expiry date label on the vaccine pack).
 **Administer vaccination**	**Administer the vaccination** Before administering the vaccine verbally check the vaccine type with the consumer. Please refer to the '7 Rights of COVID-19 Vaccine Administration' on the **IMAC website**. When administering concomitant vaccines, the vaccinator should ensure that the vaccines do not require any spacing and there is no specific information required to be given to consumers regarding this. **Note**: Vaccinators should ensure the correct needle length is used for the administering the vaccine based on individual consumers being vaccinated. This includes considering body size and site vaccine will be administered (eg deltoid or vastus lateralis). For more information on needle length, refer to the ***Immunisation Handbook*.**

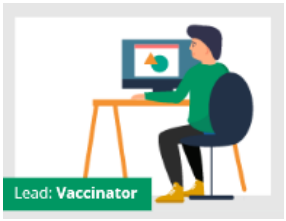
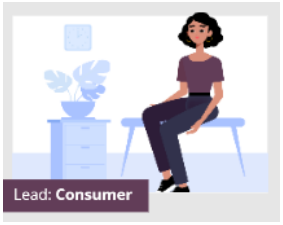
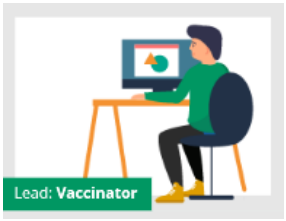
Step	Action
 **Record information**	**Record vaccination information in CIR** Once the vaccination is complete the vaccinator or administrative support person must update the consumer's record in CIR with complete and accurate record of the vaccination event. This enables accurate data for operational reports (such as number of vaccinations completed and other trend data). This must include: • The batch, sub-batch number and expiry date for the vaccine (for example AB1234-567 the first part is the batch number, the second part is the sub-batch number) these are found on the vaccine pack. • The batch number and expiry date for the diluent (these are found on the diluent vial/ampoule). • Details of the injection site and the date and time of the vaccination event. In situations where this is not possible, such as CIR being unavailable, or insufficient internet connectivity at the vaccinating location, ensure an administrative process is in place to enter information into CIR on the same day as the vaccination event. This is essential clinical information; it is a requirement to ensure it is not lost and that it is transcribed correctly.

Table 24.6 – vaccination process: after vaccination

Step	Action
 **Consumer waits 15 minutes in observation area**	**Observation** The consumer must remain on site under observation for at least 15 minutes. If the vaccinator determines it necessary, they may ask the consumer to wait for longer than 15 minutes, for example, if the individual is in a rural or remote area or has a history of anaphylaxis. If a consumer is required to wait 30 minutes the vaccinator should record this on the CIR so that the staff member observing is aware. Consumers may also be required to stay for a longer length of time (20 mins) if a non-COVID-19 vaccine is to be administered at the same time eg a childhood vaccine such as MMR, shingles or tetanus booster, Post-vaccination advice should be given to consumers both verbally and in writing. Site Clinical Leads should ensure the latest leaflets are being used (these can be downloaded from the drop box). More information and resources can be found on the Ministry's 'COVID-19 vaccine: After your vaccination' poster found on **the Ministry's website.** For further information on post vaccination, see **section 2.3** in the ***Immunisation Handbook***.

Step	Action
 **Record exit in CIR**	**Consumer exit time record** The site administrator/vaccinator must record the time of the consumer's exit from the site in CIR. If the consumer insists on leaving early the Site Clinical Lead must be notified and discuss this with the consumer to understand possible implications. A note should be added to the CIR to document the consumer leaving early and the advice given. Any hard copy forms must be entered into CIR by close of business on the following day. Ensure any printed copies are locked away when not in use.

23.1 Sharing information on the vaccine

The Medicines Regulations 1984 requires written information is provided in the form of a data sheet, available at **https://www.medsafe.govt.nz/medicines/infosearch.asp**; the COVID-19 vaccine data sheet can be found by searching 'COVID-19'. There is no legal requirement for any hard copy data sheets or medicine packaging inserts to be provided on site.

23.2 Observation following vaccination

Consumers should remain under observation for at least 15 minutes following vaccination in an observation area. This is to ensure that any adverse reactions that may occur can receive prompt treatment.

Consumers may also be required to stay for a longer length of time (20 mins) if a non-COVID-19 vaccine is to be administered at the same time eg a childhood vaccine, shingles or tetanus booster,

All vaccinators must be able to distinguish anaphylaxis from fainting, anxiety, immunisation stress-related responses, and breath-holding spells and seizures. For further information on post-vaccination procedures, see **section 2.3** in the ***Immunisation Handbook*.**

Active monitoring: Post Vaccine Symptom Check

As part of the pharmacovigilance activities for the Comirnaty vaccine, the Programme conducts active monitoring for side effects after vaccination. This is called Post Vaccine Symptom Check (PVSC) and is an SMS text-based survey sent to a randomly selected sample of the vaccinated population. When a PVSC campaign is active, a message enquiring if the consumer has experienced side effects since the vaccination is sent to up

to 25% of consumers (or their caregivers). The consumer can reply YES or NO – or reply STOP should they wish to opt out of the survey. Where the consumer replies with YES, they are sent a unique and secure link to a mobile-friendly survey form that captures the side effect/s experienced. Results are published on the Medsafe website.

A PVSC campaign for the COVID-19 Comirnaty 15/15 mcg BA.4/5 vaccine was introduced on 1 April 2023 and is expected to run until October 2023.

23.3 Consumers' record of vaccination

Consumers should be supplied with a COVID-19 Vaccination record card detailing the vaccine administered and the date their second dose is due. This card is not designed as a vaccination certificate – and as such, may not be recognised as proof of vaccination by other countries.

International Travel Vaccination Certificate

Consumers can request an International Travel Vaccination Certificate required when travelling overseas. This certificate can also be requested through **My Covid Record** or calling 0800 222 478.

For more information please see the **Ministry's website**.