The Immunisation Advisory Centre

COVID-19 EDUCATION

VERSION 19

Orange cap and Grey cap Comirnaty Vaccination Screening

Comirnaty 10mcg 5-11 years orange cap
Comirnaty 30mcg 12+ years grey cap
Comirnaty 15/15mcg grey cap booster/additional dose

QUESTIONS	RATIONALE FOR QUESTIONS AND ADVICE ON ACTIONS REQUIRED
Please tell me your/ your child's full name and date of birth.	Check you have the correct patient records on CIR/AIR. Confirm child's age verbally. Ensure you have the correct vaccine. Children 5-11 years Comirnaty 10mcg orange cap. Those who turn 12 years before their second dose will have Comirnaty 30mcg grey cap. Comirnaty 30mcg (12+) grey cap is used for primary doses, and Comirnaty 15/15mcg grey cap is used for all booster/additional doses.
Are you/your child feeling well today?	Postpone vaccine if: fever >38°C or acute systemic illness. For very frail or elderly with comorbidites, ensure they are stable or as well as possible before vaccination and advise carer on need for post vaccination observation and hydration.
Have you/your child had COVID-19?	Anyone who has had COVID-19 infection, is advised to wait 3 months before any primary dose, and 6 months before any booster/additional doses of Comirnaty vaccine. Clinical discretion can be applied, from three month after illness, following informed consent.
Have you/your child had a serious allergic reaction to anything including previous Comirnaty (Pfizer) vaccine?	**Contraindications: A history of anaphylaxis to previous dose of the Comirnaty vaccine or to any component of the vaccine. Anaphylaxis to reagent polyethylene glycol (PEG)** (vaccine may still be given under specialist guidance). **Precaution: A definite history of anaphylaxis-type reaction to any other product**. A slightly increased risk of anaphylaxis has been noted in individuals who have had a previous anaphylaxis-type reaction to any other product. These individuals can still receive Comirnaty. They should be well observed for at least 30 minutes and be given clear post vaccination advice. It is important that the observation staff are specifically alerted to this history by the vaccinator. **All vaccination sites are set up to manage anaphylaxis.**
How many COVID-19 vaccines have you/your child already had?	Check spacing: **Primary doses:** eight weeks between first and second doses of both vaccines, is recommended. This can be reduced down to a minimum of 21 days for quicker protection, for those with significant medical issues (eg immunosuppression). **Booster/additional doses:** for those 16 and over, from 6 months after COVID-19 vaccination or COVID-19 infection. See back page. Day 0 is vaccination day. No maximum spacing.
For any COVID-19 vaccines after initial dose: Did you/your child have any problems after your last vaccines?	Check for any cardiac symptoms after a previous COVID-19 vaccine (particularly chest pain, palpitations, dizziness) and refer for further advice if there were any potential concerns not previously considered. **Precaution:** A person who has developed confirmed vaccine associated myocarditis or pericarditis after their Comirnaty vaccine should not have any further doses of Comirnaty without specialist review and advice. They can be referred to IMAC for further vaccination guidance.
Do you/your child have a bleeding problem or blood disorders?	Vaccines can be administered to people on anticoagulants. **For patients with haemophilia, vaccinations should be given as soon as possible after receiving clotting factor replacement or similar medicine**. It is recommended that the platelet count is kept ≥30 x 10^9/L. Specialist advice is recommended. After vaccination, apply firm pressure over the injection site, without rubbing, for 10 minutes to reduce the risk of bruising.
Do you have any other questions? See responses to medical concerns.	**Cardiac concerns**: People with a history of myocarditis and pericarditis unrelated to COVID-19 may receive Comirnaty vaccine after the episode of myocarditis or pericarditis has completely resolved (ie, no symptoms and no evidence of ongoing heart inflammation). Those with heart disease or cardiac abnormalities are recommended to receive the vaccine. **Immunosuppression**: The antibody response to the vaccine may be reduced and protection may be suboptimal, but it is still likely to be adequate to protect against severe disease and there are no safety concerns. Patients may have been advised on specific timing of vaccinations to fit into other treatment regimens. Where possible accommodate this. **Bilateral axillary lymph node clearance**: Vaccine can be given in the vastus lateralis. Seek help from experienced vaccinator or call 0800 if unsure.
Co-administration of other vaccines	There are no restrictions to the administration of other NIS vaccines either before or at the same time as these vaccines. Spacing of 28 days may be considered between JYNNEOS and a subsequent Comirnaty vaccine for individuals at increased risk of myocarditis and/or pericarditis following a Comirnaty (males aged 16 to 40) in an abundance of caution

DON'T DELAY - IF IN DOUBT CALL 0800 IMMUNE (466 863)

Grey cap vaccines

Comirnaty 30mcg is the vaccine of choice for primary vaccinations, option to use as a booster if requested.

Comirnaty 15/15mcg is licensed as BOOSTER/ADDITIONAL DOSE only.

Using Comirnaty 15/15mcg for primary vaccination is not recommended and would require a prescription.

Third primary dose - use Comirnaty 30mcg grey cap

Third primary dose is recommended for those who are severely immunocompromised aged 5 and over, using age appropriate vaccine (10mcg or 30mcg). Administer from 8 weeks after 2nd dose (vaccine can be given from 4 weeks if medically indicated). For more information including eligibility, see the immunisation Handbook. A third primary dose may also be required, following clinical advice, in situations where an invalid dose of vaccine has been administered. Third primary doses require a prescription and written consent.

Boosters- use Comirnaty 15/15mcg grey cap

First booster: 6 months after primary course for those 16+ years. Booster doses for those 12-15 years are not currently part of the programme, but may be considered if clinically indicated - this dose will require a prescription and written consent.

Additional booster doses: Additional doses are available from 6 months after last COVID-19 vaccination for those aged 30 and over, and for those aged 16 and over who are at higher risk of severe infection. For full details see https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines

Clinical discretion can be applied when considering vaccination from 4 months to 6 months after a previous booster dose, or 5 months after a primary dose. A shorter spacing may be appropriate for those individuals considered to be at high risk of severe disease from COVID-19 re-infection, or for practical reasons to allow equitable access to vaccinations.

Gaining informed consent

- Confirm person has received adequate information about the vaccine, including the benefits, the common side effects and the rare but serious adverse events, including anaphylaxis and myocarditis. Offer them opportunity for questions and remind them of the need to wait 15 min.
- **Consent from parent or legal guardian is required for children under 12 years. It is acceptable to gain verbal consent from parent or legal guardian via phone if child attends with a different family member. Document parents name in CIR/AIR or on consent form.**
- Those aged 12-15 years would usually attend with parent. If they attend on their own and assessed as competent by an appropriately trained health professional, they can self-consent. Record any discussion regarding competency, higher risk of anaphylaxis or other significant issues.
- For further information on informed consent, see the Immunisation Handbook (section 2.1.2) and Informed Consent for Young People Aged 12-15 Years Policy Statement (tinyurl.com/zkhrhvf3).

Preparation of vaccines

- Staff preparing and administering vaccines should have completed the relevant online COVID-19 education courses and follow the IMAC vaccine preparation guidelines.
- Store and prepare Comirnaty vaccines separately, ideally in separated dedicated spaces.
- Warning: both grey cap vaccines are very similar. Take care to ensure you have the correct one and always attach syringe labels. Always follow guidance and use an independent second checker.
- It is recommended that all doses are prepared at once. This allows for a check of dilution volume for orange cap and reduces the risk of selecting incorrect grey cap vaccine.
- For more detailed instructions please see IMAC Comirnaty preparation and administration guidance documents.
- DO NOT interrupt the vaccine preparation process.

Pregnancy vaccines

Pregnant women are at higher risk of complications from COVID-19 infection compared to those who are not pregnant. Comirnaty vaccines can be given at all stages of pregnancy. First boosters are recommended for all pregnant persons and additional doses are aavailable for those in risk groups or aged 30 and over.

Observational data following vaccination with original monovalent Comirnaty 30mcg (purple cap), given as primary course or additional doses in pregnancy, show no increased risk for adverse pregnancy or neonatal outcomes. There is limited data for use of the bivalent formulation in pregnancy, but because the differences between these formulations are confined to the spike protein sequences and no clinical meaningful difference in reactogenicity has been reported between these vaccines in non-pregnant people, both vaccines can be used in pregnancy and when breastfeeding.

Post Vaccination advice to be given by Vaccinator

It is important that every consumer is given clear post vaccination advice verbally and in writing. This advice is needed for each dose of vaccine and for all ages and must include the following information:

- Discussion of potential minor side effects as well as the rare but serious ones. The advice should include expected side effect and how to manage them with the use of paracetamol or other analgesia for pain, or discomfort, and if unwell rest, drinking fluids and avoid vigorous activities, such as going to the gym.
- Awareness that anaphylaxis, although very unlikely, could occur within a few hours of vaccination and should they have any breathing difficulties, they should dial 111.
- Cardiac problems are extremely rare but can be serious, so ensure they understand the importance of seeking medical advice early for any out of character symptoms such as: Chest pain, heavy feeling in chest, discomfort, sensation of heart fluttering, racing or skipping beats, difficulty breathing, dizziness and fainting. These symptoms should not be ignored. It is important that they seek advice from a doctor or Healthline.
- For those who are insulin dependent diabetics, discuss the need to closely monitor blood glucose for next few days, as high or low glucose can occasionally be a side effect of the vaccine.
- Supply information on how and when to make a second appointment.

Incident management

- It is the site clinical and quality lead's responsibility to record, report and investigate vaccine administration incidents.
- IMAC will continue to offer support and guidance in the event of such incidents.
- Please contact 0800 IMMUNE (466 863) or your IMAC Regional Immunisation Advisor.

DON'T DELAY - IF IN DOUBT CALL 0800 IMMUNE (466 863)