

Adult and Paediatric pre-vaccination screening and guidance

Comirnaty 10mcg (Pfizer 5-11 years, orange top, mRNA-CV) Paediatric and Comirnaty 30mcg (Pfizer 12+ years, purple top, mRNA-CV) Adult

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 the CIR. Confirm child's age verbally. 5-11 years require Comirnaty 10 mcg. Those who turn 12 after the first dose should continue with 10mcg except if they require a 3rd primary dose, when 30mcg dose is recommended, taking account of clinical circumstances, and experience following previous doses. Those aged 12+ will need Comirnaty 30mcg. First and second booster doses are only approved for those aged 16+.
Are you/your child feeling well today?	Postpone vaccine if: fever >38°C or acute systemic illness. For very frail or elderly with comorbid condition, 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 SARS-CoV-2 infection, is advised to wait 3 months before any dose of COVID-19 vaccine, to ensure best response. Clinical discretion can be applied for those at risk of severe disease.
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 for those with precautions.
Is this your/your child's first COVID-19 vaccination?	Check spacing between vaccines: at least 3 weeks between first and second doses for those aged 12+. For those aged 5-11 years, 8 week spacing is recommended (see comment on back page). Day 0 is the vaccination day. No maximum spacing. See back page re: spacing for first and second boosters and 3rd primary doses.
For any COVID-19 vaccines after initial dose: Did you/your child have any problems after your last vaccines?	Check for any cardiac symptoms (particularly chest pain, palpitations, dizziness) post the previous vaccine, and refer for further advice if there were any potential concerns not previously considered. Precaution: A person who has developed myocarditis or pericarditis after their Comirnaty vaccine should not have any further doses of Comirnaty without specialist review and advice. If they are 18+, they could be prescribed Vaxzevria (AstraZeneca) or Nuvaxovid (Novavax) as an alternative vaccination. See IMAC 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 $\geq 30 \times 10^9/L$. 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 lymph clearance: Vaccine can be given in the vastus lateralis. Seek help from experienced vaccinator or call 0800 if unsure.
Other vaccines in the last 7 days	Any National Schedule vaccines can be given at the same time as Comirnaty with any interval spacing. The only exception to this is for older people receiving Zostavax (shingles vaccine). It is recommended to allow 7 days between Zostavax and any dose of Comirnaty.

Our message is 'don't delay'. Before turning anyone away, please consult with your clinical lead or IMAC on 0800 IMMUNE (0800 466 863) Weekdays: 8.30am – 6pm Weekends: 8.45am – 3.30pm



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 and guardian via phone if child attends with a different family member. Document parents name in CIR if not using a written 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, including information around those who do not have the capacity to consent, refer to the Immunisation Handbook (section 2.1.2). Also see Informed Consent for Young People Aged 12-15 Years Policy Statement (tinyurl.com/zkhrhf3).

Preparation of vaccines

- Staff preparing and administering vaccines should have completed the online COVID-19 education course. Additional online education is required for vaccine for 5-11 year olds.
- Prepare Comirnaty 10mcg and Comirnaty 30mcg vaccines separately, ideally in separated dedicated spaces. It is essential that every dose of vaccine is clearly labeled, and that the vaccine preparation guidance is followed, including record keeping. It is recommended that all doses are prepared at once, to allow diluent volume to be cross checked. For more detailed instructions please see IMAC Comirnaty multi-dose vial preparation and administration guidance documents.
- DO NOT interrupt the vaccine preparation process

Third primary dose of Comirnaty

Third primary dose is recommended for those who are severely immunocompromised aged 5+. 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 are off label so will require a prescription and a written consent form.

Booster dose

First booster doses are approved for those aged 16+. Spacing after primary course is 3 months for those aged 18+, and 6 months for those aged 16-17 years. The vaccine used is Comirnaty 30 mcg, the same vaccine as for their previous doses. Make sure incomplete schedules are completed first i.e. third primary.

Booster doses for those aged 12-15 are not currently part of the programme. See IMAC for more information.

Second booster dose

Second booster doses are recommended for those at increased risk of severe illness from COVID-19 a minimum of 6 months after a first booster. See IMAC for more information.

Pregnancy vaccines

Pregnant women are at higher risk of complications from COVID-19 disease compared to those who are not pregnant. Comirnaty 30mcg is recommended at all stages of pregnancy. First booster doses can be given from 3 months after completion of the primary course. Second booster doses are not recommended for healthy pregnant women as they are well protected with their primary course and first booster. If pregnant AND have eligible co-morbid conditions, and are therefore at higher risk of severe disease from COVID-19, they can receive a second booster 6 months after the first booster.

Paediatric vaccine spacing

The recommended spacing is 8 weeks between first and second dose of Comirnaty 10mcg. This provides an optimal immune response for 5-11 year olds. This can be reduced to 21 days in situations where an earlier interval is important for quicker protection, eg, significant medical issues such as immunosuppression.

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.

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