

# Comirnaty 30mcg (12+ years) screening guide

QUESTIONS	RATIONALE FOR QUESTIONS AND ADVICE ON ACTIONS REQUIRED
Please tell me your full name and date of birth	Check you have the correct patient records on AIR. Confirm age verbally. Ensure you have the correct vaccine: Comirnaty 30mcg vaccine.
Are you feeling well today?	Postpone vaccine if: fever >38°C or acute systemic illness. For very frail or elderly with comorbidities, ensure they are stable or as well as possible before vaccination and advise carer on need for post-vaccination observation and hydration.
Are you severely immunocompromised?	If yes, consider 2-dose primary course with Comirnaty 30mcg vaccine.
Have you had a serious allergic reaction to anything, including a previous Comirnaty vaccine?	<b>Contraindications: A history of anaphylaxis to a 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 if anaphylaxis to the reagent polyethylene glycol (PEG) has occurred previously.</b> <b>Precaution: A definite history of anaphylaxis-type reaction to any other product.</b> 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 30mcg vaccine. 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. <b>All vaccination sites are set up with age-appropriate medical equipment to manage anaphylaxis.</b>
Have you had a previous COVID-19 vaccination?	For those previously unvaccinated aged 12 years and over, give a single dose of Comirnaty 30mcg. A further dose can be given from age 16 years, with a minimum of 6 months between doses. <b>Note:</b> Clinical discretion can be applied – see ‘Additional doses’ information on following page. Individuals aged 12 years and over who are at higher risk of severe COVID-19 infection are eligible for additional doses to be given at least 6 months after a previous dose. For more details on recommended groups, spacing and eligibility, see Tables 5.2 and 5.3 in the Immunisation Handbook. Everyone aged 30 years and over is eligible for annual doses (funded every 6 months but not recommended unless at very high risk of severe COVID-19).
For any COVID-19 vaccines after initial dose: Did you 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. <b>Precaution:</b> 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. Call 0800 IMMUNE (0800 466 863) for further vaccination guidance.
Do you have a bleeding problem or blood disorders?	Vaccines can be administered to people on anticoagulants. <b>For patients with haemophilia, vaccinations should be given as soon as possible after receiving clotting factor replacement or similar medicine.</b> 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	<b>Cardiac concerns:</b> 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 non-inflammatory heart disease or structural cardiac abnormalities are recommended to receive the vaccine. Any concerns seek medical advice. <b>Immunosuppression:</b> 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. <b>Bilateral axillary lymph node clearance:</b> Vaccine can be given in the vastus lateralis. Seek help from experienced vaccinator or call 0800 IMMUNE (0800 466 863) if unsure.
Co-administration of other vaccines	There are no restrictions to administration of other National Immunisation Schedule vaccines either before or at same time as Comirnaty vaccines. If timing of COVID-19 and mpox vaccines is not urgent, consider spacing apart by 4 weeks.

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Comirnaty 30mcg vaccines come in a single dose glass prefilled syringe.

### Schedule

Comirnaty 30mcg vaccine is available free for those aged 12-17 regardless of immigration status, and for those aged 18 and over who are eligible for funded vaccines.

**Primary course:** A single dose of Comirnaty 30mcg from 12 years of age.

**Two-dose primary course - severely immunocompromised:** Two doses of Comirnaty 30mcg vaccine are recommended 8 weeks apart. However, the second vaccination may be given any time from 3 weeks after dose one, depending on planned immunosuppression. Swap to the most current variant-matched Comirnaty 30mcg vaccine to complete a course started with original Comirnaty 30mcg vaccine.

For more information, see the Immunisation Handbook.

### Additional doses

A **single additional dose** of Comirnaty 30mcg is available for those aged 16 to 29 (minimum 6 months from previous dose.) No further doses are funded for this age group unless they have underlying medical conditions.

Additional doses of Comirnaty 30mcg continue to be **recommended once or twice yearly** for those aged 12 and over who are eligible because of a higher risk of severe infection and for anyone aged ≥75 years and older or with severe immunocompromise. They continue to be **available** for healthy people aged 30 and over if requested. For more details on recommended groups, spacing and eligibility, see Tables 5.2 and 5.3 in the Immunisation Handbook.

It is advised to wait 6 months after COVID-19 infection before receiving a recommended dose of COVID-19 vaccine. However, there are no safety concerns if giving it to someone with recent infection.

Clinical discretion can be applied to spacing rules, following a documented informed consent discussion, for clinical reasons or to allow equitable access to vaccinations, e.g., mass vaccinations. A minimum spacing of 3 months is required after the most recent dose of a COVID-19 vaccine, per the data sheet, so vaccine given sooner than this will require a prescription.

Additional vaccine doses may also be required, following clinical advice, in situations where an invalid dose of vaccine has been administered.

### Gaining informed consent

- Confirm person has received adequate information about the vaccine, including benefits, common side effects and rare but serious adverse events, including anaphylaxis and myocarditis. Offer them opportunity for questions and remind them of the need to wait 15 after vaccination.
- Those aged 12-15 years would usually attend with a parent. If they attend on their own and are 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).

### Preparation of vaccines

- Staff preparing and administering vaccines are recommended to have completed the relevant online COVID-19 education courses and should follow the IMAC vaccine preparation guidelines
- Prepare vaccine as required. Do not shake the syringe
- Administer the full amount of the vaccine in the syringe

### Pregnancy vaccines

Pregnant people 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. An additional dose is particularly recommended for those who are pregnant with medical conditions putting them at risk of severe COVID-19.

Observational data following vaccination in pregnancy with original monovalent Comirnaty 30mcg, given as primary course or additional doses with original or subsequent variant-matched vaccines, show no increased risk for adverse pregnancy or neonatal outcomes. There is limited data for use of the Comirnaty 30mcg LP.8.1 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, this vaccine 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 any expected side effects and how to manage them with the use of paracetamol or other analgesia for pain or discomfort, and if unwell rest, drink 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. If the consumer has any breathing difficulties, they should call 111.
- Cardiac problems are extremely rare but can be serious, so ensure the consumer understands 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 consumers 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 additional appointments.

### 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 - call 0800 IMMUNE (0800 466 863). Also contact site lead or Immunisation Coordinator for support.