The Immunisation Advisory Centre

COVID-19 EDUCATION

VERSION 18

Grey and Orange cap Comirnaty Vaccination Screening

Comirnaty 10mcg 5-11 years orange cap, and Comirnaty 30mcg 12+ years grey cap, and Comirnaty Original/Omicron 15mcg/15mcg grey cap booster

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. Ensure you have correct vaccine, 5-11 years require Comirnaty 10 mcg. Those aged 12 and over Comirnaty 12+ 30mcg. Those who turn 12 after the first dose should continue with Comirnaty 12+ 30mcg, age appropriate dose. 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 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 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.**
How many COVID-19 vaccines have you/your child already had?	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, but this can be reduced to 21 days when quicker protection is needed eg for significant medical issues, eg immunosupression. Day 0 is the vaccination day. No maximum spacing. See back page regarding spacing for 3rd primary doses and first and second boosters. **Discuss bivalent booster vaccines** (see IMAC factsheet).
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 the previous 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 lymph 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 asubsequent mRNA COVID vaccine for individuals at increased risk of myocarditis and/or pericarditis following an mRNA vaccine(males aged 16 to 40) in an abundance of caution

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Grey cap vaccines:

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

Comirnaty 15/15mcg is licenced as BOOSTER only.

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

Third primary dose

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 require a prescription and written consent.

Boosters- use Comirnaty 15/15mcg grey cap

First booster, 3 months after primary, for those aged 18+ and 6 months for those aged 16-17 years. Complete primary schedules first, using Comirnaty 30mcg grey cap.

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

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.

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/zkhrhvf3).

Preparation of vaccines

- Staff preparing and administering vaccines should have completed the 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 disease compared to those who are not pregnant. Comirnaty vaccines are 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.

Use of Comirnaty 15/15mcg as a booster dose in pregnancy

Although there is no data available for the bivalent formulation, observational data for the original monovalent Comirnaty shows no increased risk of adverse pregnancy outcomes or increased risk of miscarriage in first trimester. No clinically meaningful difference in reactogenicity has been reported and the differences in the vaccines are confined to spike protein sequences, bivalent can be used in pregnancy and during 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.

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