

# Comirnaty 10mcg (5-11 years) blue cap screening guide

QUESTIONS	RATIONALE FOR QUESTIONS AND ADVICE ON ACTIONS REQUIRED
What is your child's name and birth date?	Check you have the correct patient records on AIR. Confirm child's age verbally. Ensure you have the correct vaccine: Children 5-11 years use Comirnaty 10mcg (5-11 years).
Is your child feeling well today?	Postpone vaccine if: fever >38°C or acute systemic illness.
Does your child have a medical condition, putting them at risk of severe COVID-19 infection?	Severe immunocompromise: Consider 3-dose primary course with Comirnaty 10mcg vaccine.  Other risk factors: Check eligibility for an additional dose.  See back page for more information, including eligibility criteria and advice on swapping from older vaccines.
Does your child have a heart condition?	Children with a history of inflammatory heart disease, discuss with cardiologist/specialist paediatrician.
Has your child had COVID-19?	It is advised to wait 6 months after COVID-19 infection before receiving a dose of COVID-19 vaccine.  However, clinical discretion can be applied and there are no safety concerns with doses given earlier.
Has your child had a serious allergic reaction to anything, including previous Comirnaty (Pfizer) vaccine?	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 occured previously.
	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 10mcg 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.
	All vaccination sites are set up with age-appropriate medical equipment to manage anaphylaxis.
Has your child already had any doses of COVID-19 vaccines?	Check spacing between doses.  Primary course: A single dose of Comirnaty 10mcg.  3-dose primary course – severely immunocompromised only: 3 doses, 8 weeks apart. If clinically indicated, minimum of 3 weeks between dose 1 and 2.
	Additional doses - high risk only: Minimum 6 months post-vaccine or infection. See back page for more information.
Did your child have any problems after any previous COVID-19 vaccine?	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.  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. Refer to IMAC for further vaccination guidance – call 0800 IMMUNE (0800 466 863).
Does 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°/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 structural cardiac abnormalities are recommended to receive the Comirnaty 10mcg vaccine. If you need further information please contact 0800 IMMUNE (0800 466 863).  Immunosuppression: The antibody 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.
Co-administration of other vaccines	There are no restrictions to administration of other National Immunisation Schedule vaccines either before or at the same time as Comirnaty vaccines. If COVID-19 and mpox vaccines are not urgent, consider spacing apart by 4 weeks.

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Comirnaty 10mcg blue cap vaccines come in a single dose (light blue) vial. Dose is 0.3mL.

#### Schedule - 5-11 years

**Primary course:** A single dose of Comirnaty 10mcg is used as a primary course.

**Incomplete primary course:** Incomplete primary course of original Comirnaty 10mcg, or other overseas COVID-19 vaccines – can have a single Comirnaty 10mcg from 3 months after their most recent dose.

Three dose primary course - severely immunocompromised: Three primary doses are recommended for those who are severely immunocompromised. A primary course of 3 doses of Comirnaty 10mcg vaccine is recommended 8 weeks apart. This can be given at a minimum spacing of 3 weeks between the first and second dose; and 8 weeks between the second and third dose, if clinically indicated. Complete courses with the current Comirnaty 10mcg vaccine.

Those turning 12 years old during a 3-dose primary course, complete the course using Comirnaty 10mcg. Exception to this rule is when more than 3 months have elapsed since last dose, when 30mcg should be used.

### **Additional doses**

Healthy children: No additional doses.

Severely immunocompromised and at-risk children: One additional dose of Comirnaty 10mcg at least 6 months after completion of primary course or COVID-19 infection.

Identifying those at highest risk of severe disease: Children with severe immunocompromise and complex and/or multiple health conditions are at highest risk of severe disease from COVID-19 infection. They are are described in the Starship guidelines for COVID-19 in children (see <a href="starship.org.nz/guidelines/covid-19-disease-in-children/">starship.org.nz/guidelines/covid-19-disease-in-children/</a>).

# These are:

- On immunosuppressive treatment including chemotherapy, high-dose corticosteroids, biologics or DMARDS.
- Chronic or congenital airway/lung issues including bronchiectasis, cystic fibrosis, BiPAP for OSA.
- Complex congenital heart disease, acquired heart disease or congestive heart failure.
- · Diabetes (insulin-dependent).
- · Chronic kidney disease (GFR <15 ml/min/1.73m<sup>2</sup>).
- Severe neurodisability including severe neuromuscular conditions.
- Complex genetic, metabolic and/or liver disease or multiple congenital anomalies, including Trisomy 21.
- · Primary or acquired immunodeficiency.
- Haematologic malignancy and post-transplant (solid organ or HSCT in last 24 months).

For more information, including eligibility, see the Immunisation Handbook.

#### **Gaining informed consent**

 Confirm parent/legal guardian 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 minutes.

- 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 parent's name in PMS system if possible, or on a consent form.
- 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**

- It is highly recommended that staff preparing and administering vaccines should have completed the relevant online COVID-19 education courses
- · Follow the IMAC vaccine preparation guidelines
- · Follow expiry date on box not vial
- Measure each 0.3mL dose, as vial can have excess volume.
   Discard vial with any excess vaccine

## Post-vaccination advice to be given by vaccinator

It is important that every parent/guardian 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 playing sport.
- 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 parent/guardian 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.
   Note: Children may not be able to describe cardiac symptoms caregivers should be advised to look for signs such as child being pale, lethargic, and having shortness of breath, or odd feelings in their chest or stomach. It is important parents/guardians 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.