Immunisation Advisory Centre

VERSION 3

Comirnaty 30mcg (12+ years)

Guidance for health care professionals

Key information

- Comirnaty 30mcg vaccine is available from 12 years, for those eligible for funded healthcare. There is currently no private-purchase option.
- Comirnaty 30mcg LP.8.1 supersedes the previous Comirnaty vaccines. As of March 2026, Comirnaty 30mcg LP.8.1 is the only COVID-19 vaccine available for those aged 12 years and older.
- A single dose of Comirnaty 30mcg is used as a primary course or as an additional dose for those who are eligible.
- The vaccine is presented as a single dose in a prefilled glass syringe.

Background

SARS-CoV-2 continues to circulate globally and to evolve rapidly with continuous changes to the spike protein to evade the immune response or to become more infectious. By using variant-matched vaccines, we can maximise vaccine effectiveness.

Numerous sub-lineages of the Omicron variant have caused, and continue to cause, global waves of infection. Early variants, such as Delta and the original strain, have largely disappeared.

In Aotearoa New Zealand, COVID-19 admissions and deaths continue year-round, with cases peaking in the summer and winter months. Although the hospital admissions and deaths are lower than in previous years, the elderly remain at particular risk. Hospital admissions are around 12 and 25 times higher in those aged over 70 and over 80 years, respectively, than in those aged under 60 years.

The WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) monitors the evolution of SARS-CoV-2 variants and assesses the performance of COVID-19 vaccines against the circulating variants. After reviewing the evidence in December 2025, the TAG-CO-VAC advised the use of monovalent LP.8.1 as the recommended vaccine antigen.

Many people have hybrid immunity from both vaccination and infection. Although protection against reinfection with Omicron variants wanes within months of COVID-19 infection or additional doses, protection remains sustained against severe disease.

For most healthy people, it appears that protection against severe disease extends beyond six months as immune memory develops.

The immune function of some people, particularly older age groups, is not as robust as it is in younger healthy people. This means that any protection they gain from the vaccine is shorter-lived, increasing the risk of severe COVID-19 as their immunity wanes. Additional doses help to bolster this immunity and protect against COVID-19-related hospitalisation and death for several months. Thus, use of COVID-19 vaccines now focuses mainly on older adults and those who have an increased risk of severe COVID-19. Depending on the group, updated vaccines are recommended twice or once a year.

Recommended schedule

Comirnaty 30mcg is administered intramuscularly as a single dose of 0.3mL to individuals 12 years of age and older for eligible individuals as a primary or additional dose.

Comirnaty 30mcg prefilled syringe
Each prefilled syringe contains a single 0.3mL dose
Each dose (0.3mL) contains: · 30mcg of modified single-stranded, 5'-capped messenger RNA (mRNA) encoding the viral spike protein of SARS-CoV-2 (embedded in lipid nanoparticles). · Tris/sucrose buffer to improve stability at +2˚C to +8˚C
DOES NOT require dilution This vaccine is latex-free, and the glass syringe has a polypropylene rigid cap with a plunger stopper made of bromobutyl rubber.

Two-dose primary course for immunocompromise

Two primary doses of Comirnaty 30mcg are recommended for those who are previously unvaccinated and severely immunocompromised, given 8 weeks apart. For groups considered to have severe immunocompromise, see IMAC factsheet '*COVID-19 vaccination recommendations for those with severe immunocompromise*'.

Additional dose eligibility and spacing

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 Table 5.2 (below) and Table 5.3 (on page 4) from the Immunisation Handbook (IHB). Or see IMAC factsheets, '*Examples of special groups recommended ongoing COVID-19 vaccination (excluding severely immunocompromised)*', and *'COVID-19 recommendations for those with severe immunocompromise'*.

Table 5.2: COVID-19 vaccination for healthy individuals aged 5 years and over (IHB)

Age	No prior vaccination Primary dose	Previously vaccinated Additional dose with most current variant-matched vaccine
Healthy population		
75 years and over	One dose	Twice yearly, from 6 months after previous dose
65 – 74 years		One dose annually
30 – 64 years		One dose is available annually, but not generally recommended (see footnote [a])
16 – 29 years		Not generally recommended (see footnote [b])
12 – 15 years		-
5 – 11 years		-
Complete vaccination course as recommended, regardless of previous SARS-CoV-2 infection		

a. *Carers, frontline healthcare, aged-care or disability workers aged 30 years and over can receive one dose of variant-matched mRNA-CV annually, with a priority for those working with frail elderly or severely immunocompromised. All other individuals aged 30 years and over can be given mRNA-CV if they request it.*

b. *A one-off booster dose is funded for those aged 16-29 years. Additional doses are only available for this age group if they have certain underlying medical conditions (see IHB Table 5.3 and section 5.5.3). Healthy frontline healthcare, aged-care or disability workers aged under 30 years are not eligible for additional doses.*

Contraindications and precautions

As with all vaccines, Comirnaty 30mg is contraindicated for those who have history of anaphylaxis to a previous dose of any Comirnaty vaccine or to any component of the vaccine.

For details on precautions when administering Comirnaty 30mcg, see the Comirnaty 30mcg screening tool. Those with any current active cardiac inflammation or who had myocarditis or pericarditis after a past dose of COVID-19 vaccine require specialist immunisation advice before receiving Comirnaty.

Co-administration

All National Immunisation Schedule vaccines can be given at the same time as the Comirnaty 30mcg, preferably in a different limb. Influenza vaccination is also highly recommended for eligible groups and can be given at the same time as any COVID-19 vaccine.

If the timing of mpox or COVID-19 vaccination is not urgent, consider allowing a gap of 4 weeks between Jynneos and Comirnaty. This is particularly relevant for young males and those who have a history of cardiac inflammation.

TST/Mantoux testing for tuberculosis can be conducted at any time before, after or simultaneously with Comirnaty 30mg.

Vaccine effectiveness

The monovalent LP.8.1 variant-matched Comirnaty 30mcg vaccine stimulates antibody responses against a range of variants, including NB.1.8.1 and XFG. This suggests LP.8.1 is likely to increase protection against severe COVID-19 caused by the circulating variants currently predominant.

The updated vaccines continue to provide protection against hospitalisation and death. For example, among adult US veterans who received an updated COVID-19 vaccine between 3 September and 31 December 2024, effectiveness at 6 months' follow up was 39% and 64% against hospital admission and death, respectively. The vaccine provided protection across age groups (<65 years, 65 to 75 years, and >75 years) and among people with and without cardiovascular disease, cerebro-vascular disease, chronic kidney disease, or chronic lung disease, and among both immunocompetent and immunocompromised persons. Another recent US study found an updated vaccine was 79% effective against invasive mechanical ventilation or death.

It is anticipated that Comirnaty 30mcg LP.8.1 will provide similar protection.

Vaccine safety

The adverse event profile of Comirnaty 30mcg LP.8.1 is expected to be like that of earlier formulations as the only change is in the mRNA spike protein sequence.

In a clinical trial of Comirnaty XBB.1.5, the most common local reaction was injection site pain, which started from one to two days and lasted one to three days. Fatigue and headache were the most common systemic adverse events. These reactions were reported less frequently by over 55-year-old participants than among 12–17 year olds.

Responses to AusVaxSafety post-vaccination surveys sent on day three after vaccination with Comirnaty 30mcg JN.1 showed that around one quarter of respondents reported at least one adverse event (local reaction, fatigue, muscle or joint pain, headache and fever). Three percent missed usual activities and 0.52% visited a doctor or ED following vaccination. This was less than observed with earlier vaccine formulations.

Myocarditis and/or pericarditis occur very rarely following a COVID-19 vaccination and have been reported following receipt of any of the current internationally available COVID-19 vaccines. The highest incidence was seen in adolescent males after a second dose of an mRNA vaccine. Cases have been reported at any age in male and female adults and after any dose of a COVID-19 vaccine. Australian reports show that myocarditis occurs after fewer than one in every 100,000 additional doses given.

A longer interval between doses reduces adverse events, including the rate of myocarditis and pericarditis following mRNA vaccines.

Despite a small cluster of ischaemic stroke cases detected following co-administration of bivalent Comirnaty vaccine with high-dose or adjuvanted influenza vaccine in people aged 65 and over in the US, further analysis of vaccine data safety showed the rate of stroke was actually reduced in vaccinated individuals. Both COVID-19 and influenza infections increase the risk of a stroke. No safety concern was confirmed by data for the XBB.1.5 vaccines.

US data identified a potential sign for Guillain-Barré syndrome (GBS) after Comirnaty XBB.1.5 in adults aged over 65 years. No signal for GBS was seen with previous formulations. The true risk is unknown and further analysis is ongoing.

Monitoring elsewhere has been reassuring. For example, in Denmark no increase was observed for any of the adverse events investigated, including strokes, GBS and myocarditis after receipt of XBB.1.5 vaccine.

There is no evidence of a higher rate of reporting of GBS following COVID-19 vaccination in people who have previously had GBS.

Use in pregnancy and breastfeeding

Comirnaty 30mcg can be used in pregnancy and while breastfeeding. Observational data for the original Comirnaty 30mcg vaccine show no increased risk of adverse pregnancy outcomes or increased risk of miscarriage in the first trimester.

Although there is no current data available for the Comirnaty 30mcg LP.8.1 formulation, there is no plausible theoretical reason for any increased risk in pregnancy. The differences between these vaccine formulations are confined to the mRNA spike protein sequences.

Additional doses in pregnancy

Pregnant people are at higher risk of complications from COVID-19 infection compared with 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 underlying medical conditions putting them at risk of severe COVID-19.

For more information see IMAC factsheet '*COVID-19 disease and COVID-19 vaccination in pregnancy*'.

Post-vaccine advice

Continue to follow post-vaccine advice as listed in the Comirnaty 30mcg screening tool.

It is essential that every consumer is given thorough and clear post-vaccination advice verbally and in writing. This advice is needed for each dose of vaccine and for all ages.

Comirnaty 30mcg 12+ years vaccine storage and administration

- Comirnaty 30mcg is presented in a prefilled glass syringe
- Vaccine is stored in the usual cold chain at +2°C to +8°C for up to 12 months
- Remove from cold chain as needed and prepare - remove the tip cap by slowly turning the cap counterclockwise
- Select and attach the correct length sterile needle for IM injection. Do not shake
- Administer the entire volume of the syringe

Strategies to minimise the risk of error

- Where possible, create a "Do not disturb" time/place when vaccines are being prepared
- Store different Comirnaty vaccines in separate areas in the fridge. Consider coloured signage, labelling, coloured baskets to differentiate between different vaccines
- Create a physical barrier between different vaccine preparation areas
- Use a second checker for key checks, such as correct vaccine strength, expiry and drawn-up dose volume

Table 5.3: COVID-19 vaccination for individuals at higher risk of severe COVID-19 aged 6 months and over (IHB)

Groups at highest risk of severe COVID-19	Age / group	No prior vaccination Primary course	Previously vaccinated Additional dose with the most current variant-matched vaccine
All older adults	75 years and over	One dose	Twice yearly, from 6 months[a] after any previous dose
Resident of aged-care facility or those with pronounced frailty and complex medical conditions	65 years and over		
Severely immune compromised[b] (see section 5.5.2)	5 years and over	Two doses, 8 weeks apart [c]	Twice yearly, from 6 months[a] after any previous dose
	6 months to 4 years	Three doses, (see footnote [d] for spacing)	Twice yearly, from 6 months[a] after any previous dose, based on clinical decision.
Other groups[c] at high risk of severe COVID-19	5 years and over	One dose	Once yearly or twice yearly, from 6 months[a] after any previous dose (see below for further details)
	6 months to 4 years[c]	Three doses (see footnote [d] for spacing)	Once yearly, from 12 months after any previous dose.
Examples of other groups at higher risk of severe COVID-19 (see Immunisation Handbook, section 5.5.3)			
Multiple comorbidities, complex medical conditions and/or profound frailty	18 – 64 years	One dose	Twice yearly, from 6 months after any previous dose [a]
	5 – 17 years		Once yearly, from 12 months[a] after any previous dose
All older adults	65 – 74 years	One dose	Once yearly, from 12 months after any previous dose
Māori or Pacific People	50 –74 years		
Resident of aged or disability care facility	16 – 64 years		
At least 1 comorbidity that increases risk from COVID-19	5 years and over		
Pregnant (see section 5.5.6)	high-risk pregnancy or with underlying health conditions	One dose, at any stage of pregnancy	One dose during pregnancy, if it is more than 6 months since previous dose
	healthy pregnancy		Personal preference, given from 12 months after any previous dose
Complete vaccination course as recommended, regardless of previous SARS-CoV-2 infection			

a. This spacing can be reduced or increased, on a case-by-case basis, where there is a clinical need or to facilitate mass vaccinations. Preferred spacing is at least 6 months between additional doses with the most current variant-matched vaccine. Once yearly vaccination can be considered for young people.

b. Certain individuals aged 5 years and over with severely immunocompromising conditions or immunosuppressive treatments are eligible for a second primary dose and additional doses. See section 5.5.2.

c. The timing of the second dose needs also to consider current or planned immunosuppressive therapies. If the period of least immunosuppression is less than eight weeks, the second vaccination can be given any time from three weeks after dose one. See section 5.5.2.

d. Give dose two 3 weeks after dose one and dose three is given 8 weeks later. See footnote c around spacing.

e. See section 5.5.4 for examples of other conditions, significant or complex health needs in children aged 6 months to 4 years eligible for mRNA-CV.