Medicine Protocol for the administration of the

Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine to Vaccine Recipients aged 12 years and older

(Ready to use – Grey cap- Do not dilute)

by

General Practice Nurse(s) employed at

Medigroup Medical Centre

- This medicine protocol is a specific written instruction for the administration of **Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine** by the General Practice Nurse(s) to persons attending Medigroup Medical Centre who are included in the target population to receive COVID-19 booster vaccination.

- This medicine protocol is valid for the 2023/2024 COVID-19 Vaccination Programme and is guided by the National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics for **Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine** as detailed by the European Medicines Agency (EMA).

- NMBI defines medicine protocols as "written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medication to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medicine protocol is in effect" (An Bord Altranais, 2007, p35).

This sample medicine protocol is based on the HSE template for this medication in the current season https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/comirnatyxbb1512yrs.pdf

It is important to be familiar with the professional guidance on Medication Management and Medication Administration from NMBI www.nmbi.ie and HSE National Immunisation Office (NIO) https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/ for information specific to the vaccine respectively.

The following is a minimum recommended list of professional guidance documents relating to the use of Medicine protocols:

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais https://www.nmbi.ie/nmbi/media/NMBI/Publications/Guidance-Medicines-Management.pdf?ext=.pdf
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*. Royal College of Physicians Ireland (RCSI) online update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/
- National Immunisation Office (2018) *Supporting Documentation for Vaccinations in General Practice* https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf
- Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Midwives on Medication Administration*: Dublin. NMBI https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020.pdf?ext=.pdf
- Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice*. *Professional Guidance* Dublin: NMBI https://www.nmbi.ie/nmbi/media/NMBI/Publications/recording-clinical-practice-professional-guidance.pdf?ext=.pdf
- Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework*. Dublin: NMBI https://www.nmbi.ie/nmbi/media/NMBI/Publications/Scope-of-Nursing-Midwifery-Practice-Framework.pdf?ext=.pdf
- Nursing and Midwifery Board of Ireland (2014) *The Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Dublin: NMBI https://www.nmbi.ie/NMBI/media/NMBI/Code-of-Professional-Conduct-and-Ethics.pdf?ext=.pdf

Learning resources:

The National Immunisation Office

- COVID-19 information for HCPs - https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/

- eLearning Programmes available on HSeLanD for all HSeLanD learners including :

    - **Immunisation Foundation Programme**
    - **Storing and Managing Vaccines**
    - **COVID-19 Vaccination Programme for competent Vaccinators**

MEDICINE PROTOCOL FOR THE ADMINISTRATION OF Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine TO VACCINE RECIPIENTS (READY TO USE – GREY CAP- DO NOT DILUTE)

1.0 Critical Elements	
1.1 Name of Organisation where protocol applies	Medigroup Medical Centre, Cathedral Road, Cork.
1.2 Date the protocol comes into effect	From September 2023
1.3 Date for review of protocol	To April 2024
1.4 Document adapted from the HSE 2022/2023 Medicine Protocol	Medicine Protocol for the Administration of Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine to vaccine recipients (Ready to use – Grey cap- Do not dilute), to nurses, midwives, healthcare workers, agency staff, contract workers and volunteers by registered nurses and registered midwives https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/comirnatyxbb1512yrs.pdf
1.5 Name and signature of the employing authority who is authorising the implementation of the protocol **Document prepared in collaboration with**	"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medication protocol and authorise its implementation" Name: _____(Employer/Principal GP) Title: _____ Signature: _____ MCRN: _____ Name: _____(GP Nurse) Title: _____ Signature: _____ NMBI: _____

1.6.1 Names and signatures of general practice nurses agreeing to work within the protocol	"I have read the medicine protocol and I am competent under my Scope of Nursing and Midwifery Practice Framework (NMBI, 2015) to administer vaccines using this protocol" Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____
	Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____
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	Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____
	Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____

2.0 Clinical Criteria	
2.1 Clinical Condition for use of the medicine protocol	The clinical condition for which this medicine protocol has been developed is for the immunisation of vaccine recipients (see Inclusion Criteria) against COVID-19.
2.2 Circumstances in which the medicine protocol applies	Targeted immunisation programme for vaccine recipients against COVID-19 as identified in the DoH policy, based on the NIAC recommendations. The World Health Organization declared COVID-19 outbreak as a pandemic on 11th March 2020 which is still ongoing
2.3 Inclusion criteria for patient treatment using the medicine protocol*	**Inclusion Criteria:** • Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older **for Booster vaccination only** • Note: This vaccine is not currently recommended for primary course or additional dose of Covid 19 mRNA vaccine.

2.3a Precautions	• Acute severe febrile illness: defer until recovery
	• Consider non mRNA vaccination for those aged 18 years and older, including pregnant women, with:
	  • Anaphylaxis after multiple, different drug classes, with no identified allergen (may indicate PEG allergy)
	  • Anaphylaxis after a vaccine, or a medicine which contained PEG
	  • Idiopathic anaphylaxis (may indicate PEG allergy)
	• Specialist advice should be sought prior to vaccination for those with a history of pericarditis after a previous dose of an mRNA vaccine
	• There should be an interval of four weeks between monkeypox/smallpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis
	• For those receiving a booster dose of vaccine, who have had breakthrough COVID-19 infection (laboratory-confirmed/antigen-positive with symptoms) since completion of the primary vaccination, the booster dose should be deferred until at least 4 months following diagnosis (3 months in exceptional circumstances)
	• Vaccination is not contraindicated for those with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration
	• Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM (intramuscular) injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopoenia (platelet count <50 x 10^9/ml) consult the supervising consultant
	• Those with inherited coagulopathies who require factor replacement therapy should receive it on the day of vaccination, prior to the IM vaccination. If there is uncertainty about the need for cover, contact the patient's Comprehensive Care Centre
	• COVID-19 vaccines and other vaccines (except monkeypox / smallpox) may be administered at the same time or at any interval. As it is not known if COVID-19 vaccine reactogenicity is increased with coadministration, vaccines should preferably be given in different limbs.
	• Patients with planned immunosuppressive therapy should ideally receive booster dose two weeks before treatment. The recommended minimum interval may be used.
	
	Pregnancy:
	• All pregnant women should have received a primary COVID-19 vaccination course as well as a 1st booster dose, in line with the recommendations for the general population. If a pregnant woman has not already received the primary course vaccines, she should receive the required

	vaccines at the recommended intervals, which can be given at any stage of pregnancy. • Pregnant women who have already completed primary and 1st booster vaccination, are recommended a 2nd mRNA vaccine booster dose in pregnancy. The timing of this 2nd booster dose should be at 16 weeks gestation or later. This timing is to enhance protection to the mother and the infant. If a 1st booster mRNA vaccine dose has already been administered earlier in the pregnancy, a 2nd booster dose is not required. **Breastfeeding:** There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping. **Individuals who are immunocompromised due to disease or treatment:** (see the NIAC chapter 5a, Table 2) • Those aged 12 and older with immunocompromise condition due to disease or treatment who have completed their primary course and additional dose may then receive a booster dose at least 4 months after their additional dose (3 months in exceptional circumstances)
2.4 Exclusion criteria for patient treatment using the medicine protocol	**Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine** should not be given under this medicine protocol if the vaccine recipient has: • Anaphylaxis (serious systemic allergic reaction requiring medical intervention following a previous dose of the vaccine or any of its constituents including polyethylene glycol (PEG) and trometamol). • Anaphylaxis following another mRNA vaccine. • A history of myocarditis after a previous dose of an mRNA vaccine • Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine.
2.5 Actions to be taken for those who are excluded from the medicine protocol	• Refer to/discuss with the relevant GP for an individual medical assessment. Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine. Consideration may be given to a non-mRNA vaccine for people aged 12 years and older • The GP can consider referring the individual to an allergist/Immunologist for a further assessment • Document action in clinical record or IT system • Where Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine is prescribed following medical assessment, the vaccinator may administer the vaccine within his/her scope of practice. **Note:** In determining their scope of practice, vaccinators must make judgements about their competency to carry out a role or activity in accordance with the guidance from their regulator
2.6 Actions to be followed for eligible persons who do <u>not</u> wish to receive vaccination	1. Advise on the risks of not having the vaccine, including risk of possible severe COVID-19 disease 2. Advice regarding the minimisation of risk 3. Document in clinical notes

2.7 Documentation required to support implementation of the medicine protocol	1. Evidence/record that consent has been received 2. Vaccine Information Leaflets 3. Patient-held record cards 4. Practice clinical record- electronic or paper patient file 5. Health Products Regulatory Authority Adverse Reaction Reporting Forms https://www.hpra.ie/homepage/about-us/report-an-issue It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine which includes the following: • Medicine Protocol for the Administration of Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine to vaccine recipients (Ready to use – Grey cap- Do not dilute) • Anaphylaxis: Immediate Management in the community. National Immunisation Advisory Committee, Immunisation Guidelines for Ireland. https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf • HSE Clinical Guidance for Covid-19 Vaccination https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pd • COVID-19 chapter from NIAC immunisation Guidelines for Ireland (2020) (available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/) • Immunisation Bulletins from national Immunisation Office https://www.hse.ie/eng/health/immunisation/infomaterials/newsletter/

3.0 Details of Medication to be supplied	
3.1 Name of Medication	**Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine (**Ready to use-Grey cap-Do not dilute)
3.2 Dose and Route of administration	• The dose is 0.3ml Note: Currently recommended for booster dose only • Route of administration: Intramuscular (IM) • Site: The preferred site is the deltoid muscle • Do not inject the vaccine intravascularly, subcutaneously or intradermally
3.2a Booster dose of COVID-19 Vaccine See the NIAC chapter Table 5a.1 Recommendations for COVID-19 vaccines by age and immune status	**1st booster dose** People aged 12 years and older who have completed their primary course with any COVID-19 vaccine type are recommended a single dose (0.3ml) of an Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine as a booster dose • The recommended interval for the booster dose is at least 4 months following the last dose of an authorised COVID-vaccine (3 months in exceptional circumstances) **Aged 12 years and older who are immunocompromised:** • at least 4 months following the last dose of an authorised COVID-19 vaccine (3 months in exceptional circumstances) For those who have had a breakthrough infection following a first booster vaccine, it is recommended to defer the second booster vaccine for at least 4 months following infection onset (3 months in exceptional circumstances) The booster dose can be given at the same time or at any interval before or after seasonal influenza vaccine. This applies whether the primary course was an mRNA or viral vector vaccine or a protein subunit vaccine. **2nd Booster dose:** Second booster dose of an mRNA vaccine is recommended for the following: ➢ those aged 50 years and older ➢ those aged 12-49 years who are residents of long-term care facilities ➢ those aged 12 -49 years with medical conditions which put them at high risk of severe disease of COVID-19 ➢ healthcare workers ➢ those aged 12 years and older with immunocompromise associated with a sub optimal response to vaccines ➢ Pregnant women: The timing of this 2nd booster dose should be at 16 weeks gestation or later. If a 1st booster mRNA vaccine dose has already been administered earlier in the pregnancy, a 2nd booster dose is not required Recommended interval: • The second booster vaccine is recommended at least 4 months after the first booster. (3 months in exceptional circumstances) • For those who have had a breakthrough infection following a first booster vaccine, it is recommended to defer the second booster vaccine for at least 4 months following infection onset. (3 months in exceptional circumstances) **3rd Booster dose:** ➢ those aged 65years and older ➢ those aged 12 years and older with immunocompromise associated with a sub optimal response to vaccines

	Recommended interval: • The 3rd booster vaccine is recommended at least 4 months after the 2nd booster. (3 months in exceptional circumstances) • For those who have had a breakthrough infection following a 2nd booster vaccine, it is recommended to defer the 3rd booster vaccine for at least 4 months following infection onset. (3 months in exceptional circumstances) The booster dose can be given at the same time or at any interval before or after seasonal influenza vaccine. This applies whether the primary course was an mRNA or viral vector vaccine or a protein subunit vaccine.
3.3 Link to Medicine **Details of product information and other data including instructions for supply and administration is available on the Health Product Regulatory Authority at www.hpra.ie**	**Link to Summary of Product Characteristics and Patient Information Leaflet** available at: https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf **Legal Classification:** POM (Prescription Only Medication) (includes prescription under this medicine protocol)

3.4 Possible Side Effects	See SPC and information provided in Patient Information leaflet (PIL) for this specific vaccine in respect of possible side effects. *(Note: The patient / parent / guardian should be reassured there may be no side effects following the vaccination)*
3.5 Potential adverse reactions and procedures for treatment of same	Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction 1. Vaccine recipients: 15 minutes 2. Those with a history of mastocytosis: 30 minutes 3. Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated Vaccine recipients should be advised to seek urgent medical attention if they have symptoms suggestive of an allergic reaction such as difficulty breathing, feeling faint, rapid heartbeat or a skin rash. NIAC will continue to closely monitor relevant data and will update this advice as necessary. The vaccine recipient should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine after the above period of observation.
3.6 Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)	All adverse drug reactions or suspected adverse drug reactions following administration of the vaccine must be reported as soon as possible in accordance with criteria outlined by the HPRA. Adverse Reaction Reporting Forms can be accessed at the following link: https://www.hpra.ie/homepage/about-us/report-an-issue The incident and all actions taken must be promptly recorded in accordance with Anaphylaxis: Treatment in the Community (NIAC, 2016) available on line at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf Record actions in patient file
3.7 Procedure for the	In the case of medication errors that directly involve the patient, i.e. wrong

reporting and documentation of errors and near misses involving the vaccine	medication/patient/dose/route being administered or another medication error, the general practice nurse/general practitioner must remain with the patient and closely monitor the patient for any adverse reactions (if the reaction has occurred while the patient is still on the premises). Vital signs should be recorded and the patient should be reviewed by the general practice nurse and general practitioner. 1. The incident must be reported to the general practitioner as soon as possible. 2. The incident and all actions taken must be promptly recorded 3. The patient, parent or guardian should be informed of the nature of the incident 4. Incident Report Form must be completed by the practice and held by the authorising general practitioner (may use NIRF form https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf) 5. Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.
3.8 Mechanisms for storage of vaccines and for obtaining supply	Storage and ordering of vaccines in accordance with guidance included in Guidelines for Vaccinations in General Practice (see section 8, pages 22-27) https://www.hse.ie/eng/health/immunisation/infomaterials/gpguidelines.pdf
3.9 Resources and equipment required	1. Vaccine Fridge with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C) 2. Vaccine (ready to use- Grey cap- Do not dilute) 3. 23 gauge / 25g gauge needle for IM administration 4. Sharps bins, and bins for disposal of other hazardous materials 5. Disposable kidney dishes/trays 6. Cotton wool balls/tape/plasters 7. Alcohol hand sanitiser 8. Surgical face masks 9. Access to telephone 10. Resuscitation equipment and drugs in accordance with National Immunisation Advisory Committee (2022) Anaphylaxis: Immediate Management in the Community available online: https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf 11. Safe storage areas for medicines and equipment 12. Current medicine protocol
3.10 Audit process to identify appropriate use of the protocol or unexpected outcomes	1. All documentation to be held for review and audit purposes 2. Regular team meetings are advisable to review the use of the medication protocol

4.0 Information for Vaccine Recipients/Carers	
4.1 Advice to be given to the patient/parent/guardian before and/or after treatment* ** literature for patients whose first language is not English is available on the National Immunisations Office website and should be made available to patients if required*	**Before vaccination:** • The patient information leaflet (PIL) should be supplied in advance of obtaining informed consent. • Discuss the Comirnaty Omicron XBB.1.5 30 micrograms/dose COVID-19 mRNA Vaccine and the importance of protecting their health. Inform vaccine recipient that patient information leaflet is available online at https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf • Discuss potential side-effects. Details of adverse reactions may be found in the Summary of Product Characteristics (SmPC), available at https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf • Inquire if they have any questions before proceeding. • Obtain informed consent and a signed consent form (as per local policy) **After vaccination:** Discuss potential side effects and give advice how to manage common adverse reactions. Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction. Events of anaphylaxis have been reported therefore NIAC recommends the following monitoring for the post-vaccination period: • Vaccine recipients: 15 minutes • Those with a history of mastocytosis: 30 minutes • Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated. The vaccine recipient should not leave the healthcare facility if they are feeling unwell and must report any side effects to a member of the vaccination team. The vaccine recipient should be advised to report any side effects to the relevant medical practitioner. If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol or ibuprofen-containing products) may be used. Ibuprofen is not recommended in pregnancy. If more serious adverse or persistent effects occur, vaccine recipient should be advised to contact their GP/out of hours service.
4.1 Details of any necessary follow-up, action and referral arrangements	1. Inform patient/parent/guardian if and when a subsequent vaccine is due. 2. Document all advice/details in patients records 3. In the event of an adverse reaction, the general practice nurse must ensure that all procedures are adhered to as outlined in section 3.0 of this protocol.

5.0 Staff authorised to use medicine protocol	**** all nurses working under medicine protocol should do so guided by their scope of practice and should be supported and encouraged to achieve and maintain competence in all areas noted by the authorising general practitioner.***
5.1 **Professional qualifications, training, experience and competence required prior to using this medicine protocol**	Registered nurse or registered midwife, maintained on the active register of the Nursing and Midwifery Board of Ireland. **Required Training** • Basic Life Support for Health Care Workers within the last two years • Initial anaphylaxis programme *("National Anaphylaxis Education Programme for Health Care Professionals")* via HSELanD followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). • Subsequent updates every two years via HSELanD Anaphylaxis e-learning programme available at www.hseland.ie **Recommended Training** Having successfully completed the following programmes: • Immunisation Foundation Programme (available on www.hseland.ie) • eLearning Medication Management Programme (available from www.nmbi.ie) • Vaccinations and pregnancy (www.hseland.ie) **Required Experience** Currently employed as a general practice nurse and have had an opportunity to shadow experienced vaccinator in gaining experience. **Required Competence** Competence in injection technique Self-assessment of competency assessed as per Supporting Information for Vaccinations in General Practice https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf