**DRUG GUIDELINE- TIXAGEVIMAB PLUS CILGAVIMAB (EVUSHIELD®) FOR COVID-19 PRE-EXPOSURE PROPHYLAXIS**

Tixagevimab plus cilgavimab (Evusheld®) is provisionally registered (February 2022) by the Therapeutic Goods Administration (TGA) for use in Australia for pre-exposure prophylaxis of COVID-19 in adults and adolescents (age equal or greater than 12 years of age and weighing at least 40 kg), who are at risk of disease progression to hospitalisation or death. The decision was made on the basis of short-term efficacy and safety data. Evusheld® appears to retain activity against Alpha; Beta; Gamma; Epsilon; Iota; and Delta variants of SARS-CoV-2 while some activity is expected to be retained against Omicron.

The National COVID-19 Clinical Evidence Taskforce (NCCET) provides a consensus recommendation for use of Evusheld®.

Do not routinely use Evusheld® as pre-exposure prophylaxis, however use may be considered in exceptional circumstances, in individuals who are severely immunocompromised. Given the limited evidence of benefit or safety, for prevention of infection by SARS-CoV-2 variants of concern, the NCCET recommends that rigorous data collection should be undertaken on indications and key outcomes for adults who receive pre-exposure prophylaxis with Evusheld®. Evidence regarding the potential effectiveness of Evusheld® in preventing SARS-CoV-2 infection is very limited, with small sample sizes and low event rates. Results are based on the PROVENT² trial [AZ CSR], in which 5197 unvaccinated adults were administered a single 300 mg dose of Evusheld® consisting of two intramuscular injections (150 mg tixagevimab and 150 mg cilgavimab).

NB: Pregnant & breastfeeding women and children & adolescents were not included in the trial.

This medication is regulated by the National Medical Stockpile. Access to stock requires completion of a WA Emergency COVID-19 Treatment Approval Form for tixagevimab plus cilgavimab (Evusheld®) and confirmation by the prescriber that the patient fulfils required criteria.

Supply of COVID-19 therapeutics via the National Medical Stockpile (NMS) is uncertain and availability is expected to fluctuate with demand and constraints in the supply chain.

To ensure equity of access and to conserve tixagevimab plus cilgavimab (Evusheld®) therapy for those patients at the highest risk of progression, priority level criteria are in place to allocate stock based upon current supply.

This guideline should be used in conjunction with the Evusheld® resources available:

- WA Emergency COVID-19 Treatment Approval for tixagevimab plus cilgavimab (Evusheld®) Form
- Patient Consent Form and further information regarding consent, and
- Patient Information Leaflet.
**Drug Class**

Tixagevimab and cilgavimab are two recombinant human IgG1 monoclonal antibodies which work by targeting the spike protein of SARS-CoV-2, which is thought to prevent membrane fusion after the virus binds to the human ACE2 receptor.

**Clinical Criteria**

The TGA have granted provisional registration for Evusheld® for the pre-exposure prophylaxis (prevention) of COVID-19 in people aged 12 years and older weighing at least 40 kg:

- who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments that make it likely that they will not mount an adequate immune response to COVID-19 vaccination; or
- for whom vaccination is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine or COVID-19 vaccine component (PEG).

Pre-exposure prevention with Evusheld® is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended.

**Priority of use**

Due to supply uncertainty, priority of use criteria that is required to be met may vary according to available stock numbers.

Patients will be prioritised for treatment according to the following:

1. **Access criteria for medicines to treat COVID-19 that are part of the National Medical Stockpile**
2. If supply of Evusheld® is limited, priority is allocated according to severity of immunocompromise
   - Degree of immunocompromise (e.g., severe, moderate) as defined by Access criteria for medicines to treat COVID-19 that are part of the National Medical Stockpile
   - Severe immunocompromising conditions have priority over moderate.
   - Other immunocompromising conditions have lowest priority.
3. If supply of Evusheld® is further limited, assign next level of priority within a restricted tier of immunocompromise according to the Table 1 below.

Note: In this scenario, applications will open for Priority 1 patients first. When applications have been processed for all patients in this group, applications will open to include the next highest priority level.

E.g., Applications will initially only be accepted for patients within priority level 1 patients. When all priority level 1 patients have received therapy, applications will open for any patient who meets priority level 1 or 2, and so on.
Table 1

| Priority 1 | Severe immunocompromised eligibility AND incomplete vaccination, where vaccination is medically contraindicated or delayed due to illness where concurrent vaccination is not clinically recommended.  
• PLUS additional risk factors for severe COVID-19** |
|------------|--------------------------------------------------------------------------------------------------|
| Priority 2 | Severe immunocompromised eligibility AND incomplete vaccination, where vaccination is medically contraindicated or delayed due to illness where concurrent vaccination is not clinically recommended.  
• NO additional risk factors for severe COVID-19** |
| Priority 3 | Severe immunocompromised eligibility AND vaccination status up to date  
• PLUS additional risk factors relating to immunocompromise condition (e.g. new or recent severely immunocompromising treatment).  
• AND/OR additional risk factors for severe COVID-19** |
| Priority 4 | Moderate immunocompromised eligibility AND incomplete vaccination where vaccination is medically contraindicated or delayed due to illness where concurrent vaccination is not clinically recommended.  
• PLUS additional risk factors for severe COVID-19** |
| Priority 5 | Moderate immunocompromised eligibility AND incomplete vaccination where vaccination is medically contraindicated or delayed due to illness where concurrent vaccination is not clinically recommended.  
• PLUS additional risk factors for severe COVID-19** |
| Priority 6 | Any individual (immunocompromised or immunocompetent) where vaccination is medically contraindicated.  
• PLUS additional risk factors for severe COVID-19** |

** Additional risk factors for severe COVID-2:  
• age greater than 60 years of age (or 35 years ATSI),  
• BMI > 30kg/m2,  
• congestive heart failure, (New York Heart Association [NYHA] class II or greater)  
• chronic obstructive pulmonary disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion)  
• chronic kidney disease (i.e. eGFR < 60 mL/minute)  
• chronic liver disease

Severe immunocompromise:  
• Patients who are within 1 year of receiving B-cell depleting therapies (e.g. rituximab, ocrelizumab, ofatumumab, alemtuzumab)  
• Patients receiving Bruton tyrosine kinase inhibitors  
• Chimeric antigen receptor T cell recipients  
• Post-hematopoietic stem cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication  
• Patients with hematologic malignancies who are on active therapy  
• Lung transplant recipients  
• Patients who are within 1 year of receiving a solid-organ transplant or haematopoietic stem cell transplant  
• Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents  
• Patients with certain primary immunodeficiencies  
  - Primary Immunodeficiencies (PID) affecting cellular and humoral immunity (severe and other combined immunodeficiencies)  
  - PIDs with profoundly decreased or absent B cell number or function  
  - PIDs with impaired interferon responses  
• Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm3  
• Patients on any of the following agents not already listed  
  - Anti-CD20 antibodies rituximab, obinutuzumab, ocrelizumab, ofatumumab  
  - Bruton’s tyrosine kinase (BTK) inhibitors ibrutinib, acalabrutinib, zanubrutinib  
  - Sphingosine 1- phosphate receptor modulators fingolimod, siponimod  
  - Anti-CD52 antibodies alemtuzumab  
  - Anti-complement antibodies eculizumab  
  - Anti-thymocyte globulin

Continued on next page
Table 1 (continued)

**Moderate immunocompromise:**
- Primary immunodeficiency including combined immunodeficiency and syndromes, major antibody deficiency (e.g. common variable immune deficiency (CVID) or agammaglobulinemia), defects of innate immunity (including phagocytic cells), defects of immune regulation, complement deficiencies and phenocopies of primary immunodeficiencies
- Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes
- Greater than 12 months post-transplant: haematopoietic stem cell transplant.
- Advanced or untreated HIV with CD4 counts <200/microL, or those with a higher CD4 count unable to be established on effective anti-retroviral therapy, recent (within 12 months) AIDS-defining condition, or persistent/recurrent viraemia OR not on antiretroviral therapy (excluding elite controllers).
- Haemodialysis or peritoneal dialysis
- Immunosuppressive therapy (current or recent) examples include:
  - Chemotherapy or radiotherapy
  - Janus kinase (JAK) inhibitors - tofacitinib, baricitinib, ruxolitinib
  - High-dose corticosteroids (≥20 mg of prednisone per day, or equivalent) for ≥14 days in a month, or pulse corticosteroid therapy.
  - Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDS): leflunomide, azathioprine (≥3 mg/kg day), mycophenolate, methotrexate (>0.4 mg/kg/week), 6-mercaptopurine (≥1.5 mg/kg/day), alkylating agents (e.g., cyclophosphamide, chlorambucil), systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus).
  - Solid organ transplant recipient

**NOTE** — The following agents are not considered to impart risk:
- Anti-integrins natalizumab, vedolizumab
- Anti-TNF-α antibodies infliximab, adalimumab, etanercept, golimumab, certolizumab
- Anti-IL1 antibodies anakinra
- Anti-IL6 antibodies tocilizumab
- Anti-IL17 antibodies secukinumab, ixekizumab
- Anti-IL4 antibodies dupilumab Anti-IL23 antibodies ustekinumab
- Immune checkpoint inhibitors nivolumab, pembrolizumab, ipilimumab, atezolizumab *

**Mild immunocompromise:**
All other immunocompromising conditions or treatments that do not meet criteria for severe or moderate immunocompromise.

**Please note:** Caution in patients with high risk of cardiovascular or thromboembolic events, and also not recommended for patients with polysorbate hypersensitivity.

**Contraindications and Precautions**

- **Hypersensitivity**: Serious hypersensitivity reactions, including anaphylaxis, have been observed rarely with other IgG1 monoclonal antibodies. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration, and initiate appropriate medicinal products and/or supportive therapy. Product excipients include histidine, sucrose and polysorbate 80.

- **Pregnancy and breastfeeding**: Evusheld® is pregnancy category B2¹. There is potential for placental transfer of Evusheld® from the mother to the developing foetus. It should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the foetus. No information is available on the use of Evusheld® during breastfeeding. The amount present in breastmilk is likely to be very low as Evusheld® is a large protein molecule. Discontinuation of breastfeeding may be considered.

For management of pregnant and breastfeeding women with COVID-19, contact King Edward Memorial Hospital Obstetric Medicines Information Service for advice on (08) 6458 2723.
• **Paediatric population**: The safety and efficacy of Evusheld® has not been established in children less than 12 years of age or 12 years and over weighing less than 40 kg.

• **Clinically significant bleeding disorders**
  As with any other intramuscular injections, Evusheld® should be given with caution to patients with thrombocytopenia or any coagulation disorder.

• **Cardiovascular and thromboembolic events**
  In PROVENT², there was a higher rate of cardiac serious adverse events (SAEs), including myocardial infarction (one fatal SAE) and cardiac failure, in subjects who received Evusheld® compared to placebo. All subjects who experienced cardiac SAEs had cardiovascular risk factors and/or a prior history of cardiovascular disease.

  In PROVENT², there was a higher rate of thromboembolic serious adverse events (SAEs) in subjects who received Evusheld®, compared to placebo. One event of mesenteric artery thrombosis was reported as a SAE, 6 days after injection in a subject without a known medical history of coagulation disorders. A computerised tomography (CT) scan of the abdomen and pelvis at the time of the event showed atheromatous overload of vascular vessels. A possible relationship with Evusheld® cannot be ruled out.

  A causal relationship between Evusheld® and these events has not been established.

  Consider the risks and benefits prior to initiating Evusheld® in individuals at high risk for cardiovascular events and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.

**Drug Interactions**¹

No formal interaction studies have been conducted with Evusheld®.

Evusheld® is not renally excreted or metabolised by the CYP450 enzymes, therefore, interactions with concomitant medications that are renally excreted or that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely.

Contact the local pharmacy department or medicines information service for further advice.

**Presentation and Storage**¹,¹⁰

• Available as single use vials of tixagevimab 150mg in 1.5mL and cilgavimab 150mg in 1.5mL (Evusheld® 300 mg dose)

• The solution in the vial should be clear and colourless to slightly yellow.

• Store refrigerated at 2°C to 8°C in original package. Do not freeze.

• Protect from light.

• Do not shake.
Dose 1,2

Evusheld® is given as two (2) separate intramuscular injections. They are to be administered as sequential injections (given one after the other). Tixagevimab 150mg and cilgavimab 150mg are to be injected into the gluteal muscle (one medication in each buttock) by a doctor or nurse. The recommended dose of Evusheld® is 300mg and consists of two (2) separate injections, one (1) into each buttock:

- tixagevimab 150mg in 1.5mL
- cilgavimab 150mg in 1.5mL

No dose adjustments for renal or hepatic function or age are required. There are no safety and efficacy data available with repeat dosing.

Preparation and Administration 1,2,10

- The occupational hazard of intermittent low dose exposure to Evusheld® is not known. Wear a mask and gloves when preparing the injection to minimise exposure. Preparation in a cytotoxic hood/sterile environment is not required.
- It is recommended that the name and the batch number of the administered product is clearly recorded in the patient’s medical record in order to improve traceability if the product is prepared outside of the pharmacy department.
- The solutions for injection do not contain a preservative and therefore, the prepared syringes should be administered IMMEDIATELY.
- If immediate administration is not possible and the prepared tixagevimab and cilgavimab syringes need to be stored, the total time from vial puncture to administration should not exceed 4 hours either
  - in a refrigerator at 2°C to 8°C or
  - at room temperature up to 25°C.
- Personnel and equipment to manage anaphylaxis must be present during injection and for at least 15 minutes post-administration.

Preparation Steps

1. Remove one vial each of tixagevimab 150mg in 1.5mL and cilgavimab 150mg in 1.5mL solution from refrigerator.
2. Visually inspect vials to ensure no particulate matter is present or damage to the vials. (Discard if present).
3. Gently swirl the vials several times without creating air bubbles before using. (Do NOT shake vigorously).
4. Withdraw 1.5mL of tixagevimab solution (100mg/mL) into a syringe. Label the syringe.
5. Withdraw 1.5mL of cilgavimab solution (100mg/mL) into another syringe. Label the syringe.
6. Discard the vials including any unused solution, in line with local protocols for monoclonal antibody handling.

Administration Steps

1. Tixagevimab plus cilgavimab should be administered as separate sequential intraMUSCULAR injections at different injection sites, one in each of the gluteal muscles.
2. **Observe the patient during the injection and for 15 minutes after injection** in case of hypersensitivity reactions or anaphylaxis.
Monitoring Requirements\textsuperscript{1,5,6,10}

Monitor the patient for adverse effects (see Adverse Effects section below).

Reactions include fever, chills, dizziness, dyspnoea, pruritis and rash.
If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration, and commence treatment immediately and/or supportive therapy. Anaphylactic reactions are rare but are a medical emergency.

Adverse Effects\textsuperscript{1,5}

It may be difficult to distinguish between adverse effects of Evusheld\textsuperscript{®} and signs and symptoms of COVID-19. As the proposed use is for a provisionally approved medicine which has no relevant post-marketing data, it is important to document and report all (from possible to confirmed) adverse effects experienced by the patient during treatment to inform its safety profile and future use.

Refer to product information for complete list of possible adverse effects.

Common (> 1%):
- headache (6%),
- fatigue (4%),
- hypersensitivity reactions (includes rash, bronchospasm).

Rare:
- anaphylaxis
- cardiovascular – acute myocardial infarction, myocardial infarction, congestive cardiac failure, atrial fibrillation, angina pectoris, arrhythmia, cardiac failure, cardiomegaly, cardiomyopathy, coronary artery disease, paroxysmal atrioventricular block.
- thromboembolic events – mesenteric artery thrombosis, cerebral infarction, transient ischaemic attack, cerebrovascular accident, pulmonary embolism.

Contracting COVID-19 After Receiving Evusheld\textsuperscript{®} for Pre-exposure Prophylaxis

If a patient who has received Evusheld\textsuperscript{®} for pre-exposure prophylaxis contracts COVID-19, either within 6 months of or after 6 months of administration, they should be reviewed for the same way for eligibility to existing treatment options according to current WA Department of Health COVID-19 guidelines and access criteria. Patients who contract COVID-19 within 6 months of administration should not be excluded from assessment for treatment eligibility.

Reporting

- As Evusheld\textsuperscript{®} is a TGA provisionally registered medicine and only available through the National Medical Stockpile, prescribers must complete and submit a WA Emergency COVID-19 Treatment Approval for tixagevimab plus cilgavimab (Evusheld\textsuperscript{®}) Form, for approval for each patient they intend to treat with Evusheld\textsuperscript{®}.
- This will enable appropriate medicines governance and ensure the collection and analysis of patient outcomes and systematic monitoring of medicines use. The prescribing clinician and health professional administering Evusheld\textsuperscript{®} is responsible for reporting medication errors and adverse events occurring as a result of Evusheld\textsuperscript{®} treatment.
- Adverse events related to medicines should be reported to the TGA & via the Datix CIMS (WA Health).
APPENDIX 1: Anaphylaxis Kits

An anaphylaxis response kit must always be readily available and easily accessible by health professionals administering Evusheld®.

The recommended contents of these pre-prepared kits are based on the Australian Immunisation Handbook and the WA COVID-19 Vaccination Clinical Reference Group.

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity per kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle 23 Gauge x 25mm</td>
<td>10 per kit</td>
</tr>
<tr>
<td>1mL ‘single use only’ syringes (not insulin syringes)</td>
<td>10 per kit</td>
</tr>
<tr>
<td>Cotton wool swab</td>
<td>10 per kit</td>
</tr>
<tr>
<td>Manual resuscitator set</td>
<td>1 per kit</td>
</tr>
<tr>
<td>Adult: Mask; Flow Diverter; 4.2m Oxygen tubing; single patient use.</td>
<td></td>
</tr>
<tr>
<td>Manual resuscitator set</td>
<td>1 per kit</td>
</tr>
<tr>
<td>Paediatric: Mask; Flow Diverter; 4.2m Oxygen tubing; single patient use.</td>
<td></td>
</tr>
<tr>
<td>Adrenaline 1:1000</td>
<td>10 ampoules per kit</td>
</tr>
<tr>
<td>Guedel Airway - Adult</td>
<td>1 per kit</td>
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<tr>
<td>Guedel Airway - Paediatric</td>
<td>1 per kit</td>
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<tr>
<td>Mask – non-rebreather – Adult</td>
<td>1 per kit</td>
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<tr>
<td>Mask – non-rebreather - Paediatric</td>
<td>1 per kit</td>
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<tr>
<td>Laminated copy of ‘Recognition and Treatment of Anaphylaxis’</td>
<td>1 per kit</td>
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<tr>
<td>Australian Immunisation Handbook</td>
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<tr>
<td>Laminated copy of ‘Doses of intramuscular 1:1000 adrenaline for anaphylaxis’ – Australian Immunisation Handbook</td>
<td>1 per kit</td>
</tr>
<tr>
<td>Documentation to record treatment of anaphylaxis</td>
<td>1 per kit</td>
</tr>
<tr>
<td>Address of venue</td>
<td>1 per kit</td>
</tr>
<tr>
<td>Digital Clock/Timer (for timing of adrenaline)</td>
<td>1 per kit</td>
</tr>
<tr>
<td>Pens</td>
<td>2 per kit</td>
</tr>
<tr>
<td>A4 notebook</td>
<td>1 per kit</td>
</tr>
<tr>
<td>Anaphylaxis Response Kit Storage (e.g. backpack)</td>
<td>1 per kit</td>
</tr>
<tr>
<td>Razor</td>
<td>1 per kit</td>
</tr>
</tbody>
</table>
APPENDIX 2: Guidelines for Safe Handling and Administration of Monoclonal Antibodies
(Adapted from WACHS Safe Handling and Administration of Monoclonal Antibodies)

1. Guiding Principles
Monoclonal antibodies (MABs) are large protein drugs that have an affinity for a specific antigen. They are used in the management of cancer and non-cancer diseases. Administration is by injection and the route is usually subcutaneous, intramuscular or intravenous.\(^1\)

The action of MABs is different from traditional cytotoxic therapies and most are not inherently cytotoxic and do not need to be handled with cytotoxic precautions.\(^{11,12,13,14,15,16}\)

With the continuing development of new MABs, the advent of fixed dosing and expansion of indications for existing MABS, a universal approach is required when assessing the risk to healthcare workers as well as the management of these medications.

2. Guideline
This guideline has been developed to advise healthcare staff of the minimum level of personal protection required when preparing, handling, administering, and disposing of MABs. This guideline will also provide guidance and direction on the preparation of low risk MABs on site.

2.1 Risk Assessment of MABs
All MABs need to be risk assessed. The occupational health and safety risk of handling MABs is dependent on the risk of internal exposure as well as the toxicity and immunogenicity of the MAB. Although each MAB is unique, the safe handling requirements of these agents can be considered as a class.\(^{11,12,13}\)

Cytotoxic MABs are not included in the scope of this document.
- Any MAB conjugated to a cytotoxic molecule must be handled with cytotoxic precautions and should only be prepared in a manufacturing unit.\(^{11,13,14,16}\)
- Current cytotoxic MABs available:
  - Brentuximab vedotin (Adcetris®)
  - Trastuzumab emtansine (Kadcyla®)

If unsure about specific handling for a MAB product, please contact your pharmacist.

2.1.1 Occupational exposure
Concerns over the handling of MABs arose due to the uncertainty over the effects of potential occupational exposure to this diverse group of drugs. Factors associated with the risk of occupational exposure include the actions of the drug, the methods used to prepare and administer the drug, staff experience, potential route of exposure and likely level of exposure.\(^{11,14,15}\)
Table 1: Potential routes of occupational exposure of MABs

<table>
<thead>
<tr>
<th>Potential Routes of Exposure</th>
<th>Summary of literature</th>
</tr>
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</table>
| Inhaled                     | • Animal models have shown that there can be systemic absorption of MABs through inhalation  
                              • The generation of aerosolised particles are greatest during preparation or when dis/connecting lines, although the likelihood of producing a liquid aerosol in the clinical setting is low |
| Mucosal                     | • Animal models have shown that there is the potential for local and systemic absorption from mucosal uptake (nasal and ocular)  
                              • The generation of aerosolised particles are greatest during preparation or when dis/connecting lines, although the likelihood of producing a liquid aerosol in the clinical setting is low |
| Dermal                      | • Due to the molecular size of most MABs dermal absorption is considered unlikely  
                              • Healthcare workers with exposed damaged skin may be at an increased risk |
| Oral                        | • Animal and human models have shown the oral route is a potential route of absorption  
                              • Hand to mouth contamination is the most likely cause  
                              • The level of occupational exposure is unlikely to cause toxicity |

Table 2: Minimum Personal Protective Equipment

<table>
<thead>
<tr>
<th>Personal Protective Equipment</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves and effective hand hygiene</td>
<td>• Use to minimise the risk of contamination and infection as part of good aseptic technique</td>
</tr>
<tr>
<td>Gowns</td>
<td>• Not warranted for preparation or administration</td>
</tr>
</tbody>
</table>
| Mask (N95)                    | • Worn during dose preparation.  
                              • Not mandated during administration but may be considered when dis/connecting administration lines during intravenous administration due to potential aerolisation risk |
| Protective Eyewear            | • Worn during dose preparation  
                              • Not mandated during administration but may be considered when dis/connecting administration lines during intravenous administration due to potential aerolisation risk |

Table 2: Minimum Personal Protective Equipment

2.2 Minimum personal protective equipment requirements during handling

Non-cytotoxic MABs do not need be handled with cytotoxic precautions; however, they do require greater handling precautions than other non-hazardous injectable medications. Table 2 has the recommended safeguards to minimise the risk to healthcare workers when MABs are handled outside of an aseptic manufacturing unit.
2.3 Preparation of low risk MABs

There may be occasions in areas that MABs are required to be prepared on site. Preparation is the process of preparing or being prepared for use and is different to the process of administration. Examples of these include subcutaneous or intramuscular MABs or if a prepared infusion/injection has a short expiry. These should be prepared just before administration when the patient is ready to receive treatment. They should not be prepared in advance and stored in a refrigerator.

When determining the appropriate site of preparation of a MAB please refer to the occupational health and safety risk assessment in the Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare professionals or regionally endorsed assessment form for non-cancer MABs. The risk assessment must be conducted with input from medical teams, nursing and pharmacist.\textsuperscript{11}

Nursing staff preparing and administering MABs should be competent in aseptic technique. Preparation should be undertaken in a dedicated area away from patients and carers. Pregnant or currently immunocompromised staff are not to be involved in the preparation of MABs for administration.\textsuperscript{11,12,13}

2.4 Disposal of waste, patient waste and spills

MABs should be disposed of in the same manner as other non-hazardous injectable medications. Exposure to waste products including waste and/or bodily fluids of patients should not present an additional occupational health and safety risk to healthcare workers. They should be disposed of in accordance with the disposal of clinical waste. Patients do not require additional contact precautions when receiving treatment with a MAB.\textsuperscript{11,13,14}

If a spill occurs during preparation, administration or disposal of a MAB, it is recommended that the spill clean-up procedure is managed in the same manner as other non-hazardous injectable medications.\textsuperscript{11,13,14}
References

1. Australian Product Information - Tixagevimab plus cilgavimab (Evusheld®) TGA; 2022. 
5. AstraZenca Evusheld Consumer Medicines Information Summary
7. IBM Micromedex ®.
   http://education.eviq.org.au/courses/immunotherapies
Version Control

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<td>8/4/2022</td>
<td>Update on post administration monitoring as per AstraZeneca advice.</td>
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This guidance is correct at the time of publishing. However, as it is subject to updates, please use the hyperlinks to confirm the information is accurate.

WA guidance may be amended as additional national guidance is finalised and/or further information becomes available.

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