Safe Handling, Preparation and Administration of Monoclonal Antibodies Policy

1. Purpose

Monoclonal antibodies are large protein medicines that have an affinity for a specific antigen. They are used in the management of cancer and non-cancer conditions, e.g. immunological diseases. Administration is usually via the subcutaneous or intravenous route.[1]

Monoclonal antibodies are not cytotoxic (unless they are conjugated to a cytotoxic molecule) and do not need to be handled with cytotoxic precautions.[1,2,3,4,5,6] Monoclonal antibodies which are conjugated to a cytotoxic molecule, radioisotope or complex proteins such as fusion proteins are considered hazardous and are not included in the scope of this policy. Within this policy the term monoclonal antibodies refers to non-hazardous, non-cytotoxic monoclonal antibodies.

Although monoclonal antibodies have been available for decades, newer agents are continuously being developed, and there may be limited information about the long term effects of occupational (staff) exposure to them. Therefore, best practice principles exist [1,2,3,4,5,6, 7] for handling, preparation and administration of monoclonal antibodies, which may require additional precautions compared to other groups of medicines.

This policy outlines the minimum requirements for the safe handling, preparation and administration of monoclonal antibodies by staff. It does not include evaluation of clinical appropriateness of monoclonal antibody therapy for the patient, or clinical monitoring of the patient during and after administration.

A consistent approach to handling, preparation and administration will ensure that:

- occupational (staff) exposure is managed according to best practice standards
- to optimise patient access to monoclonal antibody therapies across the WA Country Health Service (WACHS), and
- a financially sustainable service is delivered across WACHS.

Where monoclonal antibodies are used for systemic anticancer therapy, refer to the WACHS Anticancer Therapy Prescribing Procedure. Additional support can be provided by contacting the WACHS Cancer Services team: WACHSCCGGRecommendations@health.wa.gov.au.

2. Policy

2.1 Occupational Exposure Risk Assessment of Monoclonal Antibodies

Precautions for the handling of non-hazardous monoclonal antibodies relate to uncertainty over the effects of potential occupational exposure to this diverse group of medicines. Factors associated with the risk of occupational exposure include the actions of the medicine, the methods used to prepare and administer the medicine, staff experience, potential route of exposure and likely level of exposure.[1,4,5]

Potential routes of exposure	Summary of literature
Inhaled	Animal models have shown that there can be systemic absorption of monoclonal antibodies through inhalation. The generation of aerosolised particles are greatest during preparation or when connecting / disconnecting 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 monoclonal antibodies 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 1: Potential routes of occupational exposure of monoclonal antibodies[1,3,4,6]

All monoclonal antibodies need to be risk assessed for workplace exposure before staff handle, prepare and administer these medicines. A critical part of this risk assessment is determining if the monoclonal antibody is hazardous or not. The workplace health and safety risk of handling, preparing and administering non-hazardous monoclonal antibodies is dependent on the risk of internal exposure as well as the toxicity and immunogenicity of the monoclonal antibody. Although each monoclonal antibody is unique, the safe handling requirements of these medicines can be considered as a class.[1,2,3]

The risk assessment for each individual monoclonal antibody:

- includes evaluation of whether it is appropriate for preparation on site (i.e. within the clinical area)
- can be completed using the WACHS Monoclonal Antibodies Workplace Exposure Risk Assessment Tool – Handling & Preparation which is based on the best practice[1, 5,7] and adapted for the WACHS setting (template accessible via the Pharmacy Services (sharepoint.com))
- should be completed with input from medical, nursing and pharmacy[1]
- must be endorsed by the WACHS Medication Safety Committee for use across WACHS.

Endorsed risk assessments are available via the Pharmacy Services (sharepoint.com). For monoclonal antibodies which do not yet have a completed risk assessment, use the risk assessment tool template.

2.2 Handling of Monoclonal Antibodies

Handling includes transport, disposal, and management of spills. No specific requirements apply for transport of non-hazardous monoclonal antibodies. For disposal and management of spills, refer to section 2.6.

2.3 Minimum Personal Protective Equipment Requirements for Preparation and Administration

Monoclonal antibodies which are not cytotoxic do not need be handled with cytotoxic precautions, however, they do require additional handling precautions compared to other non-hazardous injectable medications.

Table 2 outlines the recommended safeguards to minimise the exposure risk to healthcare workers when non-hazardous monoclonal antibodies are prepared outside of an aseptic manufacturing unit and during administration.[1,2,3,4,6]

Personal Protective Equipment	Preparation	Administration
Gloves and effective hand hygiene	Required	Required
Respirator (N95)	Required	Not mandated during administration but may be considered when connecting / disconnecting administration lines during intravenous administration due to potential aerosolisation risk.
Protective eyewear	Required	

Gowns are not required for preparation or administration.

Table 2: Minimum Personal Protective Equipment for Preparation and Administration[1,2,3,4,6]

2.4 Preparation of Suitable Monoclonal Antibodies

Preparation refers to reconstitution or dilution of the medicine, or other steps such as measuring and dose calculations, in readiness for administration to the patient. The preparation of non-hazardous monoclonal antibodies is essentially the same as for other medicines, however consideration may be given to:

- potential preparation error (monoclonal antibodies are usually high cost)
- potential dose calculation error
- occupational exposure risk assessment for preparation.

Monoclonal antibodies which are suitable for preparation within the clinical area should be prepared as such (i.e. by staff, within, e.g. a medication room), rather than being sourced from an external compounding service (e.g. Baxter). Endorsed risk assessments (available via the Pharmacy Services (sharepoint.com)) outline which monoclonal antibodies are suitable for preparation within the clinical area.

Advantages of preparation within the clinical area may include:

- ease of supply for timely administration to the patient
- less waste (cost) if administration does not occur as planned.

If prepared within the clinical area:
- preparation should be undertaken in a dedicated area away from patients and carers, ensure adequate space for preparation
- ensure robust surface cleaning of preparation areas.
- monoclonal antibodies should be prepared as close to the time of administration as practicable, they should not be prepared in advance and stored in a refrigerator.

Equipment for preparation includes:
- personal protective equipment (PPE)
- equipment required for spills and disposal
- **Note**: closed system devices should not be routinely used if there is no evidence to support its use. Use only if outlined in the completed risk assessment.

Staff preparing and administering monoclonal antibodies must comply with the WACHS Aseptic Technique Policy and be competent in performing aseptic technique. Pregnant or immunocompromised staff are not to be involved in the preparation of monoclonal antibodies for administration.[1,2,3]

For guidance on the preparation of individual monoclonal antibodies refer to the completed risk assessment, product information (PI), the Australian Injectable Drugs Handbook (AIDH), or seek the advice of a pharmacist. When the product for administration is supplied via a community pharmacy by a patient, liaise with the Regional Chief Pharmacist to confirm suitability to prepare and administer.

2.5 Administration of Monoclonal Antibodies

For guidance on the administration of individual monoclonal antibodies refer to the:
- completed risk assessment (Pharmacy Services (sharepoint.com))
- the Australian Injectable Drugs Handbook
- product information (PI), or
- seek the advice of a pharmacist.

For monoclonal antibodies used for non-cancer indications, see also:
- Medication chart (MR860 Fiona Stanley Standard Order Set)
- Specialised guidelines (FSH Pharmacy Department Medication Administration Guidelines or WACHS Specialised Medication Guidelines).

For monoclonal antibodies used for systemic anticancer therapy, see also:
- medication chart (MR860 Fiona Stanley Hospital Standard Order Set or MR170G WACHS Cancer Treatment Chart) or electronic medication chart in the Oncology Management System (OMS) - Charm®
- specialised guidelines (Cancer Institute NSW, Cancer Treatments Online – eviQ).

2.6 Disposal of Waste Spills Management

Non-hazardous monoclonal antibodies should be disposed of in the same manner as other non-hazardous injectable medications.[1,3,4] If a spill occurs during handling, preparation, administration or disposal, manage in the same manner as other non-hazardous injectable medications.[1,3,4]

Exposure to waste products, including waste and / or bodily fluids of patients, does not present any additional occupational health and safety risk to healthcare workers. Waste products should be disposed of in accordance with the disposal of clinical waste. Refer to the WA Health - Code of Practice for Clinical and Related Waste Management and the WACHS Waste Management Policy.

Patients do not require additional transmission-based contact precautions when receiving treatment with non-hazardous monoclonal antibodies, however appropriate use of standard precautions is required at all times, i.e. use of relevant PPE including the gloves, aprons or gowns if exposure to blood, body fluids or chemicals is anticipated.[1,3,4]

3. Roles and Responsibilities

Staff who complete risk assessments for monoclonal antibodies (including pharmacists, nurses and doctors) are responsible for:

- completing risk assessments in a complete and thorough manner.

The **WACHS Medication Safety Committee** is responsible for**:**

- endorsing completed risk assessments for monoclonal antibodies
- ensuring completed risk assessments are accessible to all WACHS staff (via the Pharmacy Services (sharepoint.com))
- facilitating regular review of completed risk assessments (minimum every 3 years).

Staff who prepare and administer monoclonal antibodies are responsible for**:**

- ensuring they are competent in aseptic technique and have access to the required PPE
- completing the Monoclonal antibodies and immune check-point inhibitors online course developed by Cancer Institute NSW, eviQ Education. This includes a module on the principles of safe handling and preparation of immunotherapies.
- considering their own individual factors such as pregnancy status, skin integrity, allergies and immune status and report these to their line manager if relevant.

Workers are responsible for**:**

- reporting all hazards, incidents, injuries, dangerous occurrences and system failures which occur or have the potential to occur
- taking action, in the event of an injury or unsafe situation, that will as far as is practicable ensure the safety of themselves and others.

Supervisors and managers are responsible for**:**

- providing a safe place of work for workers as far as practicable
- taking action, in the event of an injury or unsafe situation, that will as far as is practicable ensure the safety of themselves and others
- ensuring all hazards, incidents, injuries, dangerous occurrences and systems failures are appropriately reported for areas under their supervision.

All staff are required to comply with the directions in WACHS policies and procedures as per their roles and responsibilities. Guidelines are the recommended course of action for WACHS and staff are expected to use this information to guide practice. If staff are unsure which policies procedures and guidelines apply to their role or scope of practice, and/or are unsure of the application of directions they should consult their manager in the first instance.

4. Monitoring and Evaluation

Adverse events and clinical incidents relating to the handling, preparation and administration of monoclonal antibodies are to be notified via the approved clinical incident management system (CIMS), and managed as per the WACHS Medication Prescribing and Administration Policy and the MP 0122/19 Clinical Incident Management Policy 2019. The WACHS Medication Safety Committee and local Medicines and Therapeutics Committees review clinical incident data relevant to medications. Incidents reported to Work Health and Safety will be reviewed and managed as per the WACHS Work Health and Safety Policy. This policy will be reviewed as required to determine effectiveness, relevance and currency. At a minimum it will be reviewed every five years by the WACHS Medication Safety Committee.

5. References

1. M. Alexander, J. King, A. Bajel, C. Doecke, P. Fox, S. Lingaratnam, J.D. Mellor, L. Nicholson, I. Roos, T, Saunders, J. Wilkes, R. Zielinski, J. Byrne, K. MacMillan, A. Mollo, S. Kirsa, and M. Green (2014). Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel.
2. S. Langford, S. Fradgley, M. Evans, C. Blanks. Assessing the risk of handling monoclonal antibodies. Hospital Pharmacist. February 2008
3. J. Siderov. Position statement: Safe handling of monoclonal antibodies in healthcare settings. Clinical Oncology Society of Australia September 2013
4. J. King, M. Alexancer, J. Byrne, K. MacMillan, A. Mollo, S. Kirsa and M. Gree. A review of the evidence for occupational exposure risks to novel anticancer agents – a focus on monoclonal antibodies. J Oncol Pharm Pract 2016,Vol 22(1) 121-134
5. T. Bauters, J. Vandenbroucke. Development of a flowchart for risk assessment and allocation of preparation of monoclonal antibodies. J Oncol Pharm Pract 2019, Vol25(1) 187-191
6. Cancer Institute NSW, eviQ Cancer Education Immunotherapies, Viewed 17 January, 2020. http://education.eviq.org.au/courses/immunotherapies
7. Position statement: 2022 update to the safe handling of monoclonal antibodies in healthcare settings. Clinical Oncology Society of Australia March 2023

6. Definitions

Term	Definition
Oncology Management System	An end-to-end Electronic Medication Management (eMM) System supporting treatment for haematology and oncology patients. The system includes a central library of systemic anticancer therapy pathways, pharmacy management, patient scheduler, electronic medical record (EMR) and reporting. An Oncology Management System (OMS) improves patient safety by removing paper and related prescribing and administration errors. For the purposes of prescribing and administration, following systems are endorsed for use in WACHS: • Oncology Management System (OMS) Charm®

7. Document Summary

Coverage	WACHS-wide
Audience	Nurses, midwives, doctors, pharmacists, pharmacy staff
Records Management	Clinical: Health Record Management Policy
Related Legislation	*Health Practitioner Regulation National Law (WA) Act 2010* (WA) *Medicines and Poisons Act 2014* (WA) Medicines and Poisons Regulations 2016 (WA) *Health Services Act 2016* (WA) Quality of Care Principles 2014 (Cth) *Work Health and Safety Act 2020* (WA) *Work Health and Safety (General) Regulations 2022* (WA)
Related Mandatory Policies / Frameworks	• MP 0183/24 Access to Care for Country Residents Policy • MP 0122/19 Clinical Incident Management Policy • MP 0131/20 High Risk Medication Policy • MP 139/20 Medicines Handling Policy • MP 0172/22 Personal Protective Equipment in Healthcare Facilities Policy • Clinical Governance, Safety and Quality Framework • Clinical Services Planning and Programs Policy Framework • Public Health Policy Framework
Related WACHS Policy Documents	• Aseptic Technique Policy • Anticancer Therapy Prescribing Procedure • Cancer Institute NSW- Cancer Treatments Online - EviQ - Endorsed for use in Clinical Practice Policy • Hand Hygiene Policy • Hazard and Incident Management Procedure • High Risk Medications Procedure • Medication Prescribing and Administration Policy • Work Health and Safety Policy • Personal Protective Equipment (PPE) Procedure • Systemic Anticancer Therapy Procedure • Waste Management Policy
Other Related Documents	• Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare professionals • Australian Injectable Drugs Handbook • NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2016 • NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2020 (draft) • WA Health - Code of Practice for Clinical and Related Waste Management
Related Forms	• MR170G WACHS Cancer Treatment Chart • MR860 Fiona Stanley Hospital Standard Order Set

	• WACHS Monoclonal Antibodies Workplace Exposure Risk Assessment Tool – Handling & Preparation
Related Training	Available from MyLearning: • High Risk Medications: Introduction (HRMINT EL2) Other: • eviQ Monoclonal antibodies and immune check-point inhibitors
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 3648
National Safety and Quality Health Service (NSQHS) Standards	1.03, 1.07, 1.27, 3.9, 4.13, 4.15
Aged Care Quality Standards	Nil
Chief Psychiatrist's Standards for Clinical Care	Nil
Other Standards	Nil

8. Document Control

Version	Published date	Current from	Summary of changes
1.02	2 September 2024	2 November 2020	• updates to facilitate WACHS OMS - Charm® implementation including: administration of MABs updated to separate non-cancer and cancer forms and include electronic means of administration; and addition of OMS in definition section • Risk Assessment of MABs sentence updated to “Cytotoxic MABs include but are not limited to”.
2.00	21 February 2025	21 February 2025	• change of title and scope • clarity added in relation to monoclonal antibodies used for systemic anticancer therapy • clearer position statement on preparation of suitable monoclonal antibodies • changed Job Hazard Analysis form to risk assessment template • link added to completed risk assessments on SharePoint.

9. Approval

Policy Owner	Executive Director, Clinical Excellence
Co-approver	Executive Director, Nursing and Midwifery
Contact	WACHS Chief Pharmacist
Business Unit	Clinical Excellence Medical Services
EDRMS #	ED-CO-20-84336

This document can be made available in alternative formats on request.