SESLHD PROCEDURE COVER SHEET

Health
South Eastern Sydney
Local Health District

NAME OF DOCUMENT	Work Health and Safety - Monoclonal Antibodies Safe Handling and Management
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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director People and Culture
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POSITION RESPONSIBLE FOR THE DOCUMENT	Manager, Health Safety and Wellbeing
KEY TERMS	Monoclonal Antibodies, MABs, Cytotoxic, Occupational Exposure
SUMMARY	The procedure has been developed to ensure processes are in place to manage the potential risk to workers health when using Monoclonal Antibodies in the workplace.

Feedback about this document can be sent to seslhd-executiveservices@health.nsw.gov.au

1. POLICY STATEMENT

The use of Monoclonal antibodies (MABs) within cancer and other services has been expanding within our organisation and as they are not like traditional anticancer agents, MABs often do not fulfil the criteria for classification as cytotoxic or hazardous substances.

As there is currently limited research on the long term effects of MABs, SESLHD has decided to adopt the risk management principles outlined in CPG Position Statement: Safe handling of monoclonal antibodies in healthcare settings.

For additional information the Safework NSW Cytotoxic Drugs and Related Waste – Risk Management guide should also be referenced.

The procedure is intended to be used by workers who are involved in the handling of MABs and is applicable to but limited to medical, pharmacy and nursing staff.

2. DEFINITIONS

Monoclonal antibodies (MABs): A type of protein made in the laboratory that can bind to substances in the body, including cancer cells. A monoclonal antibody is made so that it binds to only one substance. Monoclonal antibodies are being used to treat some types of cancer and can be used alone or to carry drugs, toxins, or radioactive substances directly to cancer cells.

NHMRC : National Health and Medical Research Council

Personal Protective Equipment (PPE): Safety equipment provided to reduce the risk of exposure to specific MABs. PPE consists of:

- Impermeable long sleeved gown
- Particulate Respirator Masks (N95 or P2)
- Safety goggles (side shields) / face shield
- Gloves – See recommendations in Appendix 1 for suitable glove types per stocking in each clinical area.

3. RESPONSIBILITIES

3.1 Clinical staff (medical officers, nurses, pharmacists) will:

- For existing MABs (at the time of writing) staff will check *Appendix 1 – Monoclonal Antibody Risk Rating and Handling Precautions Guide,* identify the risk level and PPE prior to handling or using the MAB.
- For new MABs staff will check Safety Data Sheets and/ or instructions provided by the drug manufacturer to identify the risk level and PPE prior to handling or using the MAB. In addition staff will escalate relevant information and additions to a senior manager.
- Report spills or any exposure to your manager and follow safety advice outlined by the manufacturer.

- Participate in occupational exposures program if handling High Risk MABs.

3.2 Line Managers will:

- Ensure workers are provided with appropriate PPE
- Where workers are required to handle MABs identified as high risk, arrange baseline assessments for health monitoring as per Occupational Exposures Procedure
- Report any new MABs that are not in the Monoclonal Risk Ratings to a Senior Manager.

3.3 Seniors Managers will:

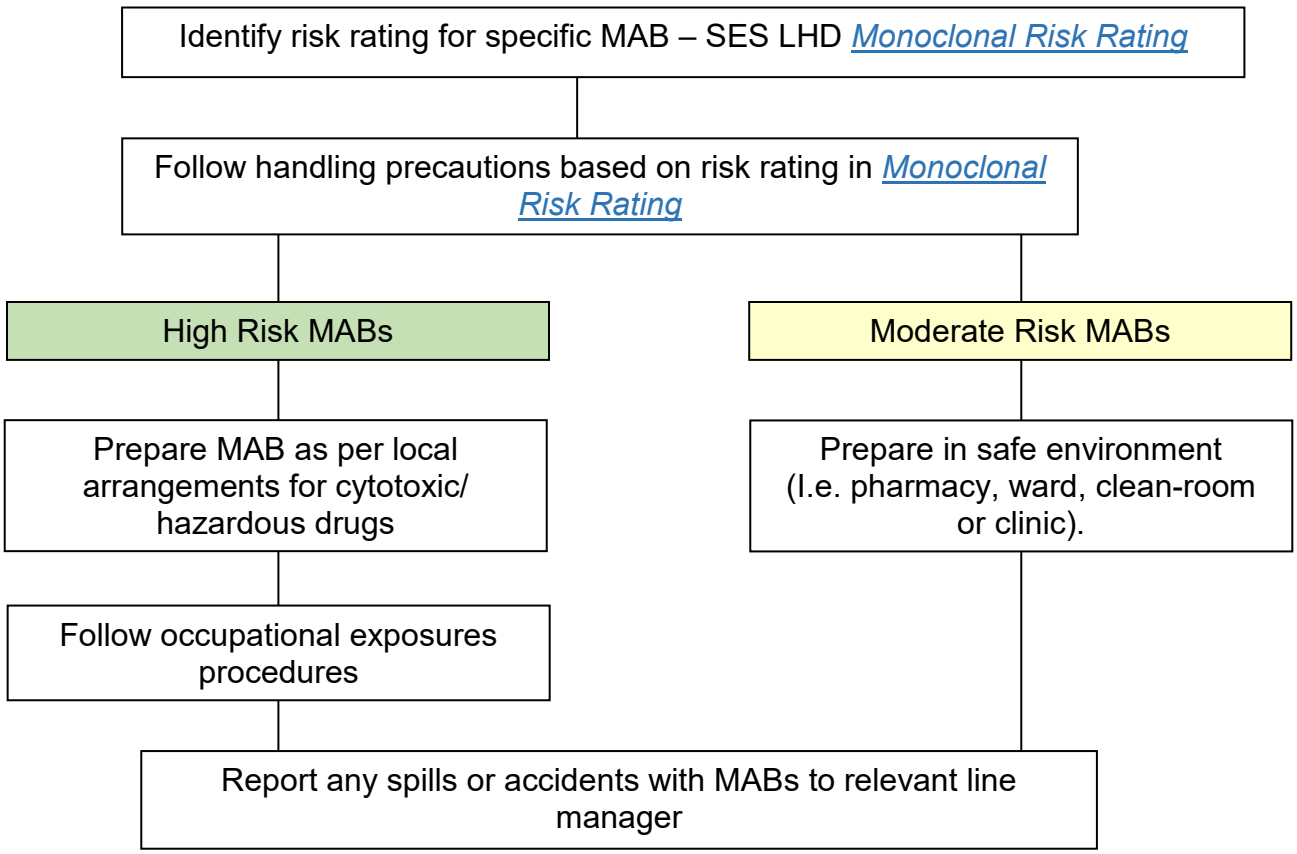
- Support the program in place for Health monitoring and safe handling of MABs
- Report any new MABs that are not in SES LHD *Appendix 1 – Monoclonal Antibody Risk Rating and Handling Precautions Guide* to SESLDH Drug and QUM Committee.

3.4 Drug and QUM Committee will:

- Review newly identified MABs to ensure appropriate risk rating occurs and the suitable controls are documented and communicated to staff.

4. PROCEDURE

Flowchart 1: General principles to implementing MAB management



4.1 Risk Identification and Controls

The Safety Data Sheets or instructions provided by the drug manufacturer can also be used to check for additional information and the highest level of controls either manufacturer or SESLHD guide are to be implemented.

4.2 Unlisted MABs

If the MAB is not listed in SESLHD monoclonal risk rating it is to be referred to the relevant line manager and the SESLHD Drug and QUM Committee for review. In this instance refer to the drug manufacturer safety instructions and Safety Data Sheets for the suggested risk rating and minimum handling precautions until otherwise advised.

4.3 Use of Personal Protective Equipment (PPE)

Current research indicates the most likely MAB absorption risks are through dermal absorption such as damaged skin (cuts, open wounds), inhalation or oral absorption. The likelihood of producing an aerosol with the required physical characteristics in the healthcare setting is limited.

For this reason the correct use of the appropriate PPE, is imperative in reducing the risk of exposure to workers. If the correct PPE is not available the relevant manager is to be notified so it can be arranged before handling or administering a MAB.

4.4 Preparation of MABs

The preparation of low and moderate risk MABs require aseptic transfer techniques and are dispensed from pharmacy to the clinical area for preparation and administration *(see Appendix 1)*.

High Risk MABs must prepared by a centralised service in the same safety cabinets as cytotoxic agents. Contact sterile manufacturing unit for further assistance.

4.5 Disposal

Disposal of waste products (including patient waste) associated with low and moderate risk MABs should be in accordance with the PD2017_026 Clinical and Related Waste Management for Health Services. This applies to waste production during preparation and administration, as well as patient waste. Disposal of high risk MABs is in accordance with cytotoxic guidelines.

4.6 Spills Management

For a medium risk MAB waste should be disposed of in accordance with clinical waste guidelines.

In the case of high risk MABs, spills are to be managed in accordance with the Safety Data Sheet provided by the manufacturer and Cytotoxic Medication Administration and Handling. If the MAB contains a cytotoxic agent then a cytotoxic spill kit is required.

This spill must be reported to local Work Health and Safety Unit who will assist with further reporting if required.

4.7 Staff Training

The relevant line manager is to ensure training is provided to workers prior conducting work with MABs . Minimum training requirements includes:

- Aware of the requirements set out in this procedure
- Training in the specific Safe Work Procedures for medium and high risk MABs
- Competency in aseptic transfer techniques (available on *My Health Learning Course Code 40027445*)
- Complex dosing calculations or complex reconstitution techniques
- Safe handling of cytotoxic drugs for workers who handle high risk and cytotoxic MABs.

Through Cancer Institute NSW, there is an Antineoplastic Drug Administration Course (ADAC) which may be a useful resource for workers. Link - eviQ Education (required free registration to access).

4.8 Health Monitoring

Where workers are handling and dispensing high risk MABs, the Manager will implement health monitoring as outlined in the SESLHDPR/378 Health Monitoring - Occupational Health Exposures other than Infectious Diseases.

5. DOCUMENTATION

Workers are required to document the use of MABs as part of their standard medication documentation processes.

6. AUDIT

Clinical incidents relating to MABs will be audited based on reports within the Incident Information Management System.

7. REFERENCES

7.1 External

- SafeWork NSW - SW08559 Cytotoxic drugs and related risk management guide
- Guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel
- SafeWork Australia - Health Monitoring for Exposure to Hazardous Chemicals
- COSA and CPG Position Statement - Safe handling of monoclonal antibodies in healthcare settings
- eviQ Resource Document - Safe Handling and Waste Management of Hazardous Drugs

7.2 Internal

- SESLHDPR/378 Health Monitoring - Occupational Health Exposures other than Infectious Diseases.

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
September 2014	1	New procedure Author - Peter Kuszelyk Endorsed by Executive Sponsor, Sharon Litchfield
February 2015	1	Endorsed by D&QUMC on 12 February 2015
March 2015	1	Endorsed by CQC on 11 March 2015
June 2015	2	Hyperlink added to SharePoint page - http://sesinet/sites/HSW/Monoclonal/Pages/default.aspx and Appendix 1 removed
May 2018	3	Content review and update of links
June 2018	3	Endorsed by Executive Council
March 2019	4	Minor review - change to glove requirement recommendations from QUM Committee incorporated into document. Endorsed by Executive Sponsor. April 2019 - Reviewed and endorsed by Amy Minett, Lead Pharmacist, QUMC
May 2019	4	Formatted by Executive Services prior to publishing.
June 2020	5	Risk rating reduced to High Risk. Review date amended to May 2021 to align with High Risk rating. Executive Sponsor updated from Director Workforce Services to Director People and Culture. Approved by Executive Sponsor.

Appendix 1 – Monoclonal Antibody Risk Rating and Handling Precautions Guide

Monoclonal Antibody	Risk Level *(Likelihood/consequence)*	Potential Response	Risk Level *(LDH Consensus)*	Handling Precautions	
				Preparation	Administration
Brentuximab Vedotin	Dermal – likely/high Oral – unlikely/high Inhalation – Possible/high Mucosal – unlikely/high		High	Use cytotoxic precautions	Use cytotoxic precautions
Trastuzumab-Emtansine	Dermal – likely/high Oral – unlikely/high Inhalation – Possible/high Mucosal – unlikely/high		High	Use cytotoxic precautions	Use cytotoxic precautions
Alemtuzumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate Mucosal – Possible/moderate	Skin contact may cause irritation, redness, pain, rash Oral: Ingestion may cause GI irritation, nausea, vomiting, abdominal pain and diarrhoea.	Moderate	P2 respiratory mask Eyewear Rubber/latex gloves	No additional precautions
Bevacizumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate Mucosal – Possible/moderate	Skin contact may cause irritation, redness, pain, rash Oral: Ingestion cause GI irritation, nausea, vomiting, abdominal pain and diarrhoea.	Moderate	P2 respiratory mask Eyewear Rubber/latex/butyl or nitrile gloves	No additional precautions

Monoclonal Antibody	Risk Level (likelihood/consequence)	Handling Precautions
Cetuximab	Dermal – Likely/low *skin contact may cause irritation, pain and rash Oral – Unlikely/low *Ingestion may result in GI irritation, nausea, vomiting, abdominal pain and diarrhoea. Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Highest risk classification – moderate Preparation of doses – Protective mask, eyewear and rubber/latex gloves (in addition to SOPs) Administration – no additional precautions
Denosumab	Dermal – Likely/none Oral – Unlikely/low Inhalation – unlikely/moderate Mucosal – unlikely/moderate	Highest risk classification – moderate Preparation of doses – protective mask and eyewear (in addition to SOPs) Administration – no additional precautions
Eculizumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Unlikely/low (preparation and administration)	Highest risk classification – moderate Preparation of doses – Protective eyewear and rubber/latex gloves (in addition to SOPs) Administration – no additional precautions
Evolocumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Unlikely/low (preparation and administration)	Highest risk classification – moderate Preparation of doses – Protective eyewear and rubber/latex gloves (in addition to SOPs) Administration – no additional precautions
Idarucizumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration)	Highest risk classification – moderate Preparation of doses – protective mask and eyewear (in addition to SOPs), impervious nitrile, rubber and latex gloves. Administration – no additional precautions
Infliximab	Dermal – Likely/low *Prolonged or repeated skin exposure may cause irritation, redness, pain and rash Oral – Unlikely/low	Highest risk classification – moderate Preparation of doses – Protective mask, eyewear and rubber/latex gloves (in addition to SOPs) Administration – no additional precautions

	*Ingestion may result in GI irritation, nausea, vomiting, headache and diarrhoea. Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) *Over exposure may result in irritation of the nose and throat, with coughing. May cause sensitisation by inhalation. Mucosal – Possible/moderate	
Ipilimumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Highest risk classification – moderate Preparation of doses – protective mask and eyewear (in addition to SOPs), impervious nitrile, rubber and latex gloves. Administration – no additional precautions
Mepolizumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Unlikely/low (preparation and administration)	Highest risk classification – moderate Preparation of doses – Protective eyewear and rubber/latex gloves (in addition to SOPs) Administration – no additional precautions
Natalizumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Highest risk classification – moderate Preparation of doses – protective gown and eyewear (in addition to SOPs), impervious gloves. Administration – no additional precautions
Nivolumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Highest risk classification – moderate Preparation of doses – protective mask and eyewear (in addition to SOPs), nitrile gloves, rubber and latex (double gloved). Administration – no additional precautions
Ocrelizumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Highest risk classification – moderate Preparation of doses – protective mask and eyewear (in addition to SOPs), impervious nitrile or rubber gloves. Administration – no additional precautions

Ofatumumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Highest risk classification – moderate Preparation of doses – protective mask and eyewear (in addition to SOPs), impervious nitrile, rubber and latex gloves. Administration – no additional precautions No MSDS available
Omalizumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Highest risk classification – moderate Preparation of doses – protective mask and eyewear (in addition to SOPs), nitrile gloves. Administration – no additional precautions

Monoclonal Antibody	Risk Level (likelihood/consequence)	Handling Precautions
Panitumumab	Dermal – Likely/low *skin contact may cause irritation, pain and rash Oral – Unlikely/low *Ingestion may result in GI irritation, nausea, vomiting, abdominal pain and diarrhoea. Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Highest risk classification – moderate Preparation of doses – Protective mask, eyewear and rubber/latex gloves (in addition to SOPs) Administration – no additional precautions
Pembrolizumab	Dermal – Likely/low *skin contact may cause irritation Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Highest risk classification – moderate Preparation of doses – protective mask and eyewear (in addition to SOPs), nitrile gloves. Administration – no additional precautions
Rituximab	Dermal – Likely/low *skin contact may cause irritation, pain and rash Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration)	Preparation of doses – Protective mask, eyewear and rubber/latex gloves (in addition to SOPs) SDS (Roche) ChemAlert 7/9/2015 recommends preparation in a biological safety cabinet.

	*Over exposure may result in irritation of the nose and throat with coughing Mucosal – Possible/moderate Highest risk classification – moderate	SDS (Roche) ChemAlert 07/09/2015} recommends respiratory protection in dusty operations. Administration – no additional precautions

Tocilizumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Highest risk classification – moderate Preparation of doses – protective eyewear (in addition to SOPs), nitrile gloves. Respiratory protection not necessary during normal operations Administration – no additional precautions

Monoclonal Antibody	Risk Level (likelihood/consequence)	Handling Precautions
Trastuzumab	Dermal – Likely/low *Prolonged or repeated skin exposure may cause irritation and rash Oral – Unlikely/low *Ingestion may result in GI irritation, nausea, vomiting, abdominal pain and diarrhoea. Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Highest risk classification – moderate Preparation of doses – protective eyewear (in addition to SOPs) and impervious nitrile, rubber and latex gloves. Prepare in well-ventilated area Administration – no additional precautions
Ustekinumab	Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration)	Highest risk classification – moderate Preparation of doses – protective eyewear (in addition to SOPs), nitrile gloves. Respiratory protection not necessary during normal operations Administration – no additional precautions
Vedolizumab	Dermal – Likely/low *skin contact may cause irritation Oral – Unlikely/low *Ingestion may result in GI irritation, nausea, vomiting and diarrhoea.	Highest risk classification – moderate Preparation of doses – Protective mask, eyewear (in addition to SOPs) impervious nitrile, rubber and latex gloves Prepare in well-ventilated area

	Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate	Administration – no additional precautions