

SESLHD PROCEDURE

Safe Handling and Management of Monoclonal Antibodies

SESLHDPR/368

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	P12 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	P12 respiratory mask Eyewear Rubber/latex/butyl or nitrile gloves	No additional precautions

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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

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	<p>*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</p>	
Ipilimumab	<p>Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate</p>	<p>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</p>
Mepolizumab	<p>Dermal – Likely/low Oral – Unlikely/low Inhalation – Unlikely/low (preparation and administration)</p>	<p>Highest risk classification – moderate Preparation of doses – Protective eyewear and rubber/latex gloves (in addition to SOPs) Administration – no additional precautions</p>
Natalizumab	<p>Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate</p>	<p>Highest risk classification – moderate Preparation of doses – protective gown and eyewear (in addition to SOPs), impervious gloves. Administration – no additional precautions</p>
Nivolumab	<p>Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate</p>	<p>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</p>
Ocrelizumab	<p>Dermal – Likely/low Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate</p>	<p>Highest risk classification – moderate Preparation of doses – protective mask and eyewear (in addition to SOPs), impervious nitrile or rubber gloves. Administration – no additional precautions</p>

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

Monoclonal Antibody	Risk Level (likelihood/consequence)	Handling Precautions
Panitumumab	<p>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</p>	<p>Highest risk classification – moderate Preparation of doses – Protective mask, eyewear and rubber/latex gloves (in addition to SOPs) Administration – no additional precautions</p>
Pembrolizumab	<p>Dermal – Likely/low *skin contact may cause irritation Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration) Mucosal – Possible/moderate</p>	<p>Highest risk classification – moderate Preparation of doses – protective mask and eyewear (in addition to SOPs), nitrile gloves. Administration – no additional precautions</p>
Rituximab	<p>Dermal – Likely/low *skin contact may cause irritation, pain and rash Oral – Unlikely/low Inhalation – Possible/moderate (preparation), unlikely/moderate (administration)</p>	<p>Preparation of doses – Protective mask, eyewear and rubber/latex gloves (in addition to SOPs) *MSDS (ChemAlert) {reviewed 29/8/2014} recommends preparation in a biological safety</p>

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

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