DIAGNOSTIC SERVICES MANITOBA SERVICES DIAGNOSTIC MANITOBA	*C1 Esterase Inhibitor*		**Document #** 160-65-09
			Version # 02
	Approved by:	**Effective Date:**	**Source Document:**
	Dr. Charles Musuka	27-OCT-2016	**Blood Product Administration Guidelines from Manufactures Monographs**

Other Names	• Berinert
Description	• Lyophilized, human plasma-derived concentrate of C1 esterase inhibitor • Viral inactivation steps include pasteurization and chromatography as well as screening of the plasma donors • Latex - free
Special Approvals/Authorizations	• An independent 2 person check is required for all doses, as per Manitoba standards • Approval for the product must be obtained by consult with Dr. C Kalicinsky or immunologist on call.
Classification	• Lyophilized powder enzyme
Indications	• C1 esterase inhibitor for treatment of acute abdominal, facial or laryngeal attacks of hereditary angioedema (HAE) • Geriatrics (greater than 65 years of age) safety and efficacy of Berinert® in the geriatric population has not been established. • Pediatrics (3 – 16 years of age) safety and efficacy of Berinert® in this age group has not been systematically evaluated.

Contraindications	• Patients who have experienced life-threatening hypersensitivity reactions, including anaphylaxis to C1 esterase inhibitor preparations.
	• Warnings:
	  ○ Hypersensitivity reactions may occur. Discontinue the drug. Epinephrine, hydrocortisone and diphenhydramine should be readily available and may be administered for any acute severe hypersensitivity
	  ○ Thrombotic events have occurred in patients receiving high off-label dosing.

Supplied	Vial size is 500 and 1500 international units lyophilized powder, single use vial (without preservative). Also supplied with diluent (sterile water for injection) and Mix2 vial transfer set. Keep in box and protect from light until needed.
Dosage	Usual: 20 international units/kg IV by slow IV injection Maximum single dose: 1500 international units (the maximum single dose may be increased beyond 1500 international units if authorized by an immunologist)
Reconstitution/Stability	**Reconstitution** Bring vials to room temperature. Dilute with supplied sterile water for injection and add slowly down the side of the vial. (Follow manufacturer's steps.) Do NOT shake. Gently swirl to dissolve, resulting in a clear colourless solution. Do not use if cloudy or if particulate matter is present. **Stability** • Once reconstituted, use immediately. Do not refrigerate
Compatibilities/ Incompatibilities	• When administering by IV, use a separate line with a standard IV administration set (tubing with a filter is not required). • No other drugs / solutions (including normal saline) can be co-administered in the same line
Administration, Identification	Refer to **Manitoba Best Practice Guidelines** • section 2.2 Standards- Identification and Administration
Administration, Method	• IV push: Administer undiluted slowly: 500 international units over at least 2.5 min • 1500 international units over at least 1 min • IV continuous: Not recommended • IM/subcutaneous: Not recommended • Maximum rate: IV Push 4mL/min • Maximum concentration: IV Push 500 international units vials: 500 international units/10mL • 1500 international unit vials: 1500 international units/3 mL
Adverse Events	Refer to **Manitoba Best Practice Guidelines** section 2.7 for transfusion reactions.
Resources:	For further information refer to the C1 Esterase product monograph at http://www.cslbehring.ca/docs/386/535/BerinertPMApr2015EN.pdf.