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SMH & JPOCSC Pre-Printed Orders for C1 Esterase Inhibitor and Enrolment Notice – Home Infusion Program



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DRUG & FOOD ALLERGIES

- **Mandatory** **Optional: Prescriber check (✓) to initiate, cross out and initial any orders not indicated.**

Physician's Order for C1 Esterase Inhibitor

Patient's Diagnosis: **Hereditary AngioEdema**

Date: _____ Informed consent completed (**proven C1 Esterase Inhibitor deficiency**)

Patient weight: _____ kg

Select one of the following options:

- BERINERT _____ units IV _____ times a week (usual dose BERINERT 20 units per kg)
- BERINERT _____ units IV as required
- CINRYZE _____ units IV _____ times a week (usual dose CINRYZE 1000 units twice a week)
- Other: _____

C1 Esterase Inhibitor Home Infusion Program Notification for Transfusion Medicine Service (TMS)

Hospital/TMS name: _____ TMS/Lab telephone: _____

Product will be required for the following:

- _____ vials BERINERT (500 units per vial) Other: _____
- _____ vials BERINERT (1500 units per vial)
- _____ vials CINRYZE (500 units per vial)

- every 1 month every 2 months every 3 months as required

Clinic RN Signature: _____ Order expires on (date): _____

Home infusion nurse will fax TMS/Lab notification of product pickup approximately two weeks before the required date.

TMS use only

Reviewed by: _____ Notes: _____

- Patient's TMS computer/record updated
- Order expiry date: _____ C1 Esterase Inhibitor ordered from Canadian Blood Services

Date (dd/mm/yyyy)	Time	Prescriber Signature	Printed Name and College ID#

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Enrolment Criteria

The patient must have a confirmed diagnosis of hereditary angioedema (proven C1 Esterase Inhibitor deficiency) with recurrent attacks of clinically significant angioedema. This method may be particularly appealing or useful for patients who:

- desire greater convenience and/or independence from hospital ER
- have difficulty attending the ER due to time and distance;
- have frequent/severe attacks;
- are pregnant/breast feeding;
- have adverse reaction or contraindication to alternative treatments.

The patient or caregiver who will be infusing the patient must be capable of being trained to administer C1 Esterase Inhibitor safely and accurately in the home setting. When considering which patients will be good candidates, attention should be given to a patient's/caregiver's:

- ability to read and follow instructions,
- ability to learn,
- self-motivation,
- probable compliance,
- physical limitations (especially for manual dexterity).

Informed consent must be obtained from the patient. The patient (or guardian) must be made aware that C1 Esterase is a blood product with associated risks and that infusion in the home is associated with additional risk.

The patient (or guardian) must sign a Patient Consent & Participation Agreement.

The patient or caregiver must be trained to administer C1 Esterase Inhibitor. This training must include a minimum of two sessions of supervised C1 Esterase Inhibitor or normal saline self-injections.

The patient's home infusion setting must have a working telephone and should have access to emergency assistance. Medical assistance must be available by telephone for immediate consultations should urgent medical care be required.

For patients under age 19, and for all patients during their first month and/or first three C1 Esterase inhibitor home infusions, a competent adult must be available in the home infusion setting to assist the patient for the entire period of the infusion and must remain available to the patient for at least 60 minutes thereafter. For patients aged 19 and older, the requirement for another competent adult to be in attendance during the procedure and for at least 60 minutes thereafter should be reviewed following the first month and/or a minimum of three C1 Esterase inhibitor home infusions. If, after the first month and/or a minimum of three C1 Esterase inhibitor home infusions, the patient has experienced no serious adverse events, it may be sufficient to have another competent adult available via telephone.

Contraindications:

- C1 Esterase Inhibitor is contraindicated in individuals with a history of anaphylactic or severe systemic response to C1 Esterase Inhibitor preparations.
- **Children:** The safety and efficacy of C1 Esterase Inhibitor has not been studied in children.
- **Pregnancy:** Animal reproduction studies have not been conducted with C1 Esterase Inhibitor. It is not known whether C1 Esterase Inhibitor can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. C1 Esterase Inhibitor should be given to a pregnant woman only if clearly needed.
- **Labour and Delivery:** The safety and effectiveness of C1 Esterase Inhibitor administration prior to or during labour and delivery have not been established. Use only if clearly needed.
- **Nursing Mothers:** It is not known whether C1 Esterase Inhibitor is excreted in human milk. Because many drugs are excreted in human milk, use only if clearly needed when treating a nursing woman.