Alaska Medicaid

BERINERT°(C1 Esterase Inhibitor, Human)

Available 500iu single-use vial

INDICATIONS and USAGE:

"Berinert is a plasma-derived C1 Esterase Inhibitor (Human) indicated for the treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema (HAE) in adult and adolescent patients.

The safety and efficacy of Berinert for prophylactic therapy have not been established."1

Criteria for Approval:

The prescriber must submitted a letter of medical necessity along with all necessary documentation substantiating all of the criteria below.

- 1. The patient has a documented diagnosis of hereditary angioedema (HAE) by an immunologist; AND
- 2. The recipient's history of HAE attacks is consistent with monthly abdominal or respiratory attack that require hospital ER intervention in the previous 6 months (ER documentation is required); **AND**
- 3. The recipient is NOT concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; **AND**
- 4. The recipient has had an insufficient response or contraindication to BOTH of the following classes of preventative medication:
 - a. $17\dot{\alpha}$ alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone) any contraindication must be documented by an endocrinologist.
 - b. Antifibrinolytic agents (e.g. aminocaproic acid, tranexamic acid)

References:

¹ Berinert package insert is available at: < http://labeling.cslbehring.com/PI/US/Berinert/EN/Berinert-Prescribing-Information.pdf > Accessed 1/7/13