

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Berinert (C1 esterase inhibitor (human))
BILLING CODE	J0597 or NDC
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Berinert is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) indicated for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adult and pediatric patients. HAE is a rare autosomal dominant disease characteriz

08/25/2017	New policy for Berinert created. Criteria for each type of HAE specified. Criteria of documentation of attacks, discontinuation of meds that can cause HAE, and restriction on combinations with other meds for acute attacks were added.
01/15/2021	Updated references. Removed age limit. Removed hematology as specialist. Simplified the diagnostic criteria. Removed specific body locations from indication, per clinical guidelines. Removed log book requirement. Reworded the renewal criteria. Extended initial approval duration to 6 months and renewal to 12 months. Removed statement about causative meds. Deleted monthly quantity limit.
06/29/2022	Transferred to new template. Updated references. Added pharmacy as benefit option. Added trial of icatibant for adults.

References:

1. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; 2021.
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3. Craig TJ, Levy RJ, Wasserman RL, et al. Efficacy of human C1 esterase inhibitor concentrate compared with placebo in acute hereditary angioedema attacks. *J Allergy Clin Immunol.* 2009;124(4):801-808. doi:10.1016/j.jaci.2009.07.017
4. Betschel S, Badiou J, Binkley K, et al. The International/Canadian Hereditary Angioedema Guideline [published correction appears in Allergy Asthma Clin Immunol. 2020 May 6;16:33]. *Allergy Asthma Clin Immunol.* 2019;15:72. Published 2019 Nov 25. doi:10.1186/s13223-019-0376-8
5. Bork K, Bernstein JA, Machnig T, Craig TJ. Efficacy of Different Medical Therapies for the Treatment of Acute Laryngeal Attacks of Hereditary Angioedema due to C1-esterase Inhibitor Deficiency. *J Emerg Med.* 2016;50(4):567-80.e1. doi:10.1016/j.jemermed.2015.11.008
6. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline pTw 24.748 0 TdM0.001.5 (o)6.A36.1 (der