

Template Letter of Medical Necessity (LMN)

This letter is being provided as a sample to help you with your payer interactions concerning coverage for RUCONEST (C1 esterase inhibitor [recombinant]). Use of this template does not guarantee coverage or reimbursement. This template is designed as a framework only and should be customized appropriately by your facility.

As a healthcare professional, you are solely responsible for providing accurate information to third-party payers. The information in this document should accurately reflect your patient's history and your clinical rationale as to why RUCONEST is medically necessary.

Indication for RUCONEST

RUCONEST[®] is a C1 esterase inhibitor (recombinant) indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). Effectiveness in clinical studies was not established in HAE patients with laryngeal attacks.

Important Safety Information for RUCONEST

RUCONEST[®] (C1 esterase inhibitor [recombinant]) is contraindicated in patients with a history of allergy to rabbits or rabbit-derived products, and patients with a history of life-threatening immediate hypersensitivity reactions to C1 esterase inhibitor preparations, including anaphylaxis.

Severe hypersensitivity reactions may occur. The signs and symptoms of hypersensitivity reactions may include hives, generalized urticaria, tightness of the chest, wheezing, hypotension, and/or anaphylaxis during or after injection of RUCONEST. Should symptoms occur, discontinue RUCONEST and administer appropriate treatment. Because hypersensitivity reactions may have symptoms similar to HAE attacks, treatment methods should be carefully considered.

Serious arterial and venous thromboembolic (TE) events have been reported at the recommended dose of plasma-derived C1 esterase inhibitor products in patients with risk factors. Risk factors may include the presence of an indwelling venous catheter/access device, prior history of thrombosis, underlying atherosclerosis, use of oral contraceptives or certain androgens, morbid obesity, and immobility. Monitor patients with known risk factors for TE events during and after RUCONEST administration.

RUCONEST has not been studied in pregnant women; therefore, should only be used during pregnancy if clearly needed.

The most common adverse reactions (incidence $\geq 2\%$) were headache, nausea, and diarrhea. The serious adverse reaction in clinical studies of RUCONEST was anaphylaxis.

Please see accompanying full Prescribing Information for RUCONEST or visit www.ruconest.com.

[Blank or provider office letterhead]

[Date]

[Payer Name]

[Payer Address, City, State, Zip]

[Member ID]

[Group ID]

Re: Letter of Medical Necessity for [Patient Name] for RUCONEST[®] (C1 esterase inhibitor [recombinant])

Dear [Contact],

This is a formal Letter of Medical Necessity for **[Patient Name]** requesting coverage for RUCONEST.

As the treating physician, it is my clinical judgment that RUCONEST is the most medically appropriate treatment to treat acute HAE attacks for **[Patient Name]**. This patient has a confirmed diagnosis of HAE, and continues to have acute attacks. **[Patient Name]** is still at risk for continued attacks, hospitalizations, and suffering. Therefore, I am requesting for RUCONEST to be a covered therapy for this patient by your plan. Enclosed is additional information regarding my patient's medical history and a summary of my treatment rationale.

Patient History and Diagnosis

[Patient Name] is a **[age]** year-old **[male/female]** who has suffered from HAE for **[Insert # of years/months]**. Additionally, my patient has an average of **[#]** HAE attacks per **[week/month/year]**. These HAE attacks are difficult to manage due to the inability to predict the location or severity of the attack.

To support this request, I have included the following documentation to support medical necessity:

- [Patient's progress notes, including diagnosis of HAE]
 - C4 level _____ / C1-INH antigenic level _____
 - C1-INH functional level _____
- [Treatment history, therapies tried and failed, reason for failure, date of discontinuation and/or reason why existing therapy is not enough, length of time]
- [Frequency of attacks, date of last attack, level of severity]
- [Describe areas predominantly affected (abdomen, extremities, face, urogenital tract, other)]
- [Details from patient diary documenting patient attacks]
- [Positive response to RUCONEST trial units, as compared to existing therapy]
- [Images provided by patients during an HAE attack]

Attachments

- [RUCONEST Prescribing Information]
- [Patient Impact Letter/Testimony regarding burden of HAE and experience with other HAE therapies]
- [HAEA Practice Guidelines]
- [Relevant clinical reprints]

Additional Information regarding RUCONEST

- RUCONEST is a plasma-free, recombinant product that is indicated for the treatment of acute attacks in adult and adolescent patients diagnosed with hereditary angioedema (HAE). Efficacy has not been established in laryngeal attacks¹
- As a recombinant product, RUCONEST carries no risk of blood-borne infections or potential drug shortages

- RUCONEST is an intravenous (IV) injectable which may be self-administered by appropriately trained patients at a dose of 50 IU/kg with a maximum of 4200 IU per dose, to be given as a slow IV injection¹
- RUCONEST has demonstrated rapid symptom relief, as well as sustained response for at least 3 days in most patients;² thus, the patient may not require repeat therapy during this timeframe
- RUCONEST directly addresses the cause of HAE by replacing and/or replenishing the inadequate C1-INH levels produced by the patient's body¹
- The United States HAE Association guidelines recommend that an effective treatment strategy for acute HAE includes replenishing C1-INH levels as soon as possible at the onset of an attack³
- RUCONEST is contraindicated in patients with a history of allergy to rabbits or rabbit-derived products, and patients with a history of life-threatening immediate hypersensitivity reactions to C1 esterase inhibitor preparations, including anaphylaxis¹
- Please see accompanying full Prescribing Information for RUCONEST or visit www.ruconest.com

On behalf of **[Patient Name]**, we would appreciate your prompt approval of coverage for RUCONEST as my patient meets the medical necessary criteria. Please call me at **[Primary Treating Site Phone Number]** if I can be of further assistance or if you require additional information.

Sincerely,

[Treating Provider Name]

1. RUCONEST [Prescribing Information]. 2. Bernstein JA, Relan A, Harper JR, Riedl M. Sustained response of recombinant human C1 esterase inhibitor for acute treatment of hereditary angioedema attacks [published online March 8, 2017]. *Ann Allergy Asthma Immunol*. doi:10.1016/j.anai.2017.01.029. 3. Zuraw BL, Banerji A, Bernstein JA, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 recommendations for the management of hereditary angioedema due to C1 inhibitor deficiency. *J Allergy Clin Immunol: In Practice*. 2013;1(5):458-467.