STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - RUCONEST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR, RECOMBINANT	RUCONEST	37766		GPI-10 (8580202210)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient's diagnosis of HAE is confirmed via complement testing
   - Ruconest is being used for acute attacks of hereditary angioedema
   - Ruconest will NOT be used concurrently with alternative acute treatment for HAE attacks (e.g., Berinert, Firazyr, Kalbitor)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 vials per fill.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor) or hematologist (a type of blood doctor)
   C. Your diagnosis is confirmed by complement testing (a type of lab test)
   D. Ruconest is being used for acute (short term) attacks of hereditary angioedema
   E. You will NOT be using Ruconest concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Berinert, Firazyr, Kalbitor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - RUCONEST

GUIDELINES FOR USE (CONTINED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) **AND** meet the following criterion?
   - Ruconest will NOT be used concurrently with alternative acute treatment for HAE attacks (e.g., Berinert, Firazyr, Kalbitor)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #8 vials per fill.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene
   B. You will NOT be using Ruconest concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Berinert, Firazyr, Kalbitor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ruconest.

REFERENCES

- Ruconest [Prescribing Information]. Raleigh, NC: Salix Pharmaceuticals; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
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P&T Approval: 04/22