STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - HAEGARDA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR	HAEGARDA	18568		GPI-10 (8580202200)	FDB & MEDI-SPAN: BRAND = HAEGARDA

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?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient's diagnosis of HAE is confirmed via documentation of complement testing
   - Haegarda is being used for prophylaxis against HAE attacks
   - Haegarda will NOT be used concurrently with alternative prophylactic agent for HAE (e.g., Takhzyro, Cinryze, danazol)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   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 - HAEGARDA** 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. You are 6 years of age or older
   C. 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)
   D. Your diagnosis of HAE is confirmed by documented complement testing (a type of lab test)
   E. Haegarda is being used for prevention of hereditary angioedema attacks
   F. You will not be using Haegarda concurrently (at the same time) with an alternative preventive agent for HAE (such as Takhzyro, Cinryze, danazol)

   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 - HAEGARDA

GUIDELINES FOR USE (CONTINUD)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - The patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks
   - Haegarda will NOT be used concurrently with alternative prophylactic agent for HAE (e.g., Takhzyro, Cinryze, danazol)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   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 - HAEGARDA** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks
   C. You will NOT be using Haegarda concurrently (at the same time) with alternative prophylactic (preventive) agent for HAE (such as Takhzyro, Cinryze, danazol)

   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 Haegarda.

REFERENCES

- Haegarda [Prescribing Information]. Marburg, German: CSL Behring LLC. September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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