Trillium Health Resources
Pharmacy Prior Approval Request for

Trillium HEALTH RESOURCES
Transforming Lives. Building Community Well-Being.

Hereditary Angioedema (HAE) Agents

Member Information

1. Last Name: _____ 2. First Name: _____
3. Trillium ID #: _____ 4. Date of Birth: _____ 5. Gender: _____

Prescriber Information

1. Prescriber Name: _____ 2. NPI #: _____
3. Requestor Name (Nurse/Office Staff): _____
4. Mailing Address: _____ City: _____ State: ____ Zip: _____
5. Phone #: _____ Ext. _____ Fax #: _____

Drug Information

1. Drug Name:_____ 2. Strength: _____ 3. Quantity per 30 Days: _____
4. Length of Therapy (in Days): ☐ up to 30 Days ☐ 60 Days ☐ 90 Days ☐ 120 Days ☐ 180 Days ☐ 365 Days ☐ Other _____

Clinical Information

Prophylaxis Agents:

Requests for Cinryze:

1. Does the member have a diagnosis of hereditary angioedema (HAE) I or II and Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)? ☐ **Yes** ☐ **No**
2. Is this request for prophylaxis of acute HAE attacks? ☐ **Yes** ☐ **No**
3. Is the member at least 6 years of age? ☐ **Yes** ☐ **No**
4. Will it not be used in combination with other prophylactic therapies targeting C1 inhibitor (i.e., Haegarda, etc.) or kallikrein (i.e., Takhzyro, Orladeyo, etc.)? ☐ **Yes** ☐ **No**
5. Will it be prescribed by, or in consultation with, a specialist in: allergy, immunology, hematology, pulmonology, or medical genetics? ☐ **Yes** ☐ **No**
6. In addition, for non-preferred products, has the member tried and failed or experienced an insufficient response to at least two preferred products for the same indication or have a clinical reason that preferred products cannot be tried? ☐ **Yes** ☐ **No**

Requests for Haegarda:

7. Does the member have a diagnosis of HAE I or II; AND Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)? ☐ **Yes** ☐ **No**
8. Is this request for prophylaxis of acute HAE attacks? ☐ **Yes** ☐ **No**
9. Is the member at least 6 years of age? ☐ **Yes** ☐ **No**
10. Will it not be used in combination with other prophylactic therapies targeting C1 inhibitor (i.e., Cinryze, etc.) or kallikrein (i.e., Takhzyro, Orladeyo, etc.)? ☐ **Yes** ☐ **No**
11. Will it be prescribed by, or in consultation with, a specialist in: allergy, immunology, hematology, pulmonology, or medical genetics? ☐ **Yes** ☐ **No**

Requests for Orladeyo:

12. Does the member have a diagnosis of HAE I or II; AND Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)? ☐ **Yes** ☐ **No**
13. Is this request for prophylaxis of acute HAE attacks? ☐ **Yes** ☐ **No**
14. Is the member at least 12 years of age? ☐ **Yes** ☐ **No**

15 Will it not be used in combination with other prophylactic therapies targeting C1 inhibitor (i.e., Cinryze, Haegarda, etc.) or kallikrein (i.e., Takhzyro, etc.)? ☐ **Yes** ☐ **No**

16. Will it be prescribed by, or in consultation with, a specialist in: allergy, immunology, hematology, pulmonology, or medical genetics? ☐ **Yes** ☐ **No**

Requests for Takhzyro:

17. Does the member have a diagnosis of HAE I or II; AND Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)? ☐ **Yes** ☐ **No**
18. Is this request for prophylaxis of acute HAE attacks? ☐ **Yes** ☐ **No**
19. Is the member at least 2 years of age? ☐ **Yes** ☐ **No**
20. Will it not be used in combination with other prophylactic therapies targeting C1 inhibitor (i.e., Cinryze, Haegarda, etc.) or kallikrein (i.e., Orladeyo, etc.)? ☐ **Yes** ☐ **No**
21. In addition, for non-preferred products, has the member tried and failed or experienced an insufficient response to at least two preferred products for the same indication or have a clinical reason that preferred products cannot be tried? ☐ **Yes** ☐ **No**

Treatment Agents:

Requests for Berinert:

22. Does the member have a diagnosis of HAE I or II; AND Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)? ☐ **Yes** ☐ **No**
23. Does the member have a diagnosis of HAE with normal C1-INH (formerly known as HAE III); AND does the patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, mutation in the kininogen 1 gene, mutation in the myoferlin gene, mutation in the heparan sulfate 3-O sulfotransferase 6 gene, etc.)? ☐ **Yes** ☐ **No**
24. Is the request for treatment for acute abdominal, facial, or laryngeal attacks of HAE? ☐ **Yes** ☐ **No**
25. Will it not be used in combination with other approved treatments for acute HAE attacks (e.g. Firazyr, Ruconest, and Kalbitor)? ☐ **Yes** ☐ **No**
26. Will it be prescribed by, or in consultation with, a specialist in: allergy, immunology, hematology, pulmonology, or medical genetics? ☐ **Yes** ☐ **No**

Requests for Firazyr:

27. Does the member have a diagnosis of HAE I or II; AND Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)? ☐ **Yes** ☐ **No**
28. Does the member has a diagnosis of HAE with normal C1-INH (formerly known as HAE III); AND does the patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, mutation in the kininogen 1 gene, mutation in the myoferlin gene, mutation in the heparan sulfate 3-O sulfotransferase 6 gene, etc.)? ☐ **Yes** ☐ **No**
29. Is the request for treatment of acute abdominal, facial, or laryngeal attacks of HAE? ☐ **Yes** ☐ **No**
30. Is the member at least 18 years of age? ☐ **Yes** ☐ **No**
31. Will it not be used in combination with other approved treatments for acute HAE attacks (e.g. Berinert, Ruconest, and Kalbitor)? ☐ **Yes** ☐ **No**
32. In addition, for non-preferred products, has the member tried and failed or experienced an insufficient response to at least two preferred products or have a clinical reason that preferred products cannot be tried? ☐ **Yes** ☐ **No**

Requests for Kalbitor:

33. Does the member have a diagnosis of HAE I or II; AND Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)? ☐ **Yes** ☐ **No**
34. Does the member has a diagnosis of HAE with normal C1-INH (formerly known as HAE III); AND does the patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, mutation in the kininogen 1 gene, mutation in the myoferlin gene, mutation in the heparan sulfate 3-O sulfotransferase 6 gene, etc.) or family history of HAE? ☐ **Yes** ☐ **No**
35. Is the request for treatment of acute abdominal, facial, or laryngeal attacks of HAE? ☐ **Yes** ☐ **No**
36. Will it not be used in combination with other approved treatments for acute HAE attacks (e.g. Berinert, Firazyr, and Ruconest)? ☐ **Yes** ☐ **No**
37. Will it be prescribed by, or in consultation with, a specialist in: allergy, immunology, hematology, pulmonology, or medical genetics? ☐ **Yes** ☐ **No**

Requests for Ruconest:

38. Does the member have a diagnosis of HAE I or II; AND Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)? ☐ **Yes** ☐ **No**
39. Does the member has a diagnosis of HAE with normal C1-INH (formerly known as HAE III); AND does the patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, mutation in the kininogen 1 gene, mutation in the myoferlin gene, mutation in the heparan sulfate 3-O sulfotransferase 6 gene, etc.) or family history of HAE? ☐ **Yes** ☐ **No**
40. Is the request for treatment of acute abdominal or facial attacks of HAE? ☐ **Yes** ☐ **No**
41. Will it not be used in combination with other approved treatments for acute HAE attacks (e.g. Berinert, Firazyr, and Ruconest)? ☐ **Yes** ☐ **No**
42. Will it be prescribed by, or in consultation with, a specialist in: allergy, immunology, hematology, pulmonology, or medical genetics? ☐ **Yes** ☐ **No**
43. In addition, for non-preferred products, has the member tried and failed or experienced an insufficient response to at least two preferred products for the same indication or have a clinical reason that preferred products cannot be tried? ☐ **Yes** ☐ **No**

Renewal Criteria for ALL AGENTS:

44. Does the member continue to meet the initial criteria? ☐ **Yes** ☐ **No**
45. Since starting the medication, has the member experienced significant improvement in severity and duration of attacks and has this improvement been sustained? ☐ **Yes** ☐ **No**
46. Has the member experienced any unacceptable toxicity from the medication? ☐ **Yes** ☐ **No**

Signature of Prescriber: _____ Date: _____

(Prescriber Signature Mandatory)

I certify that the information provided is accurate and complete to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.