carolina complete health

Pharmacy Prior Approval Request for Hereditary Angioedema (HAE) Agents

Beneficiary Information

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

Prescriber Information

6. Prescribing Provider NPI #: _____
7. Requester Contact Information - Name: _____ Phone #: _____ Ext. _____

Drug Information

8. Drug Name: _____ 9. Strength: _____ 10. Quantity Per 30 Days: _____
11. 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary continue to meet the initial criteria? ☐ **Yes** ☐ **No**

45. Since starting the medication, has the beneficiary experienced significant improvement in severity and duration of attacks and ahs this improvement been sustained? ☐ **Yes** ☐ **No**

46. Has the beneficiary 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.