

**NC Medicaid and NC Health Choice
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, Haegarda, 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 angiotensin-converting enzyme 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

**NC Medicaid and NC Health Choice
Pharmacy Prior Approval Request for****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 angiotensin-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 angiotensin-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 angiotensin-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 has 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.