

## NC Medicaid and NC Health Choice Pharmacy Prior Approval Request for Hereditary Angioedema (HAE) Agents

**Beneficiary Information** 1. Beneficiary Last Name: \_\_\_\_ 2. First Name: 4. Beneficiary Date of Birth: \_\_\_\_ \_\_\_\_\_5. Beneficiary Gender: \_\_\_ 3. Beneficiary ID #: \_ Prescriber Information 6. Prescribing Provider NPI #: \_\_\_\_\_ Ext.\_\_\_ 7. Requester Contact Information - Name: \_\_\_\_ Drug Information 10. Quantity Per 30 Days: 8. Drug Name: Strength: 11. Length of Therapy (in days):  $\ \square$  up to 30 Days  $\ \square$  60 Days  $\ \square$  90 Days  $\ \square$  120 Days  $\ \square$  180 Days  $\ \square$  365 Days  $\ \square$  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)?  $\square$  Yes  $\square$  No 2. Is this request for prophylaxis of acute HAE attacks? \( \subseteq \text{Yes} \subseteq \text{No} \) 3. Is the beneficiary at least 6 years of age?  $\square$  Yes  $\square$  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 ?  $\square$  Yes  $\square$  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?  $\square$  Yes  $\square$  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)?  $\square$  Yes  $\square$  No 8. Is this request for prophylaxis of acute HAE attacks?  $\square$  Yes  $\square$  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.)?  $\square$  Yes  $\square$  No 11. Will it be prescribed by, or in consultation with, a specialist in: allergy, immunology, hematology, pulmonology, or medical genetics?  $\square$  Yes  $\square$  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)?  $\square$  Yes  $\square$  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?  $\square$  Yes  $\square$  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?  $\square$  Yes  $\square$  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?  $\square$  Yes  $\square$  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?  $\square$  Yes  $\square$  No

## NC Medicaid and NC Health Choice



Pharmacy PA Call Center: (866) 246-8505

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 coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, mutation in the kininogen 1 gene, mutation 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 been been producted and the preferred products cannot be tried?   Yes  No	ave a clinical
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 coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, mutation in the kininogen 1 gene, mutation 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 coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, mutation in the kininogen 1 gene, mutation 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? $\square$ Yes $\square$ 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 tindication or have a clinical reason that preferred products cannot be tried?   Yes  No	he same
Renewal Criteria for ALL AGENTS:	

44. Does the beneficiary continue to meet the initial criteria?  $\square$  Yes  $\square$  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?  $\square$  Yes  $\square$  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.