



Hereditary Angioedema Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date

04-01-2026

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Orladeyo	berotralstat hcl cap ; berotralstat hcl pellet pack	108 MG ; 110 MG ; 132 MG ; 150 MG ; 72 MG ; 96 MG	M ; N ; O ; Y	N		
Cinryze	C1 Esterase Inhibitor (Human) For IV Inj 500 Unit	500 UNIT	M ; N ; O ; Y	N		
Berinert	C1 Esterase Inhibitor (Human) For IV Inj Kit 500 Unit	500 UNIT	M ; N ; O ; Y	N		
Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 2000 Unit	2000 UNIT	M ; N ; O ; Y	N		
Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 3000 Unit	3000 UNIT	M ; N ; O ; Y	N		
Ruconest	C1 Esterase Inhibitor (Recombinant) For IV Inj 2100 Unit	2100 UNIT	M ; N ; O ; Y	N		
Dawnzera	donidalorsen sodium subcutaneous soln auto-inj	80 MG/0.8ML	M ; N ; O ; Y	N		
Andembry	garadacimab-gxii soln auto-injector	200 MG/1.2ML	M ; N ; O ; Y	N		
Firazyr	icatibant acetate inj 30 mg/3ml (base equivalent)	30 MG/3ML	M ; N ; O ; Y	O ; Y		
Takhzyro	Lanadelumab-flyo Inj 300 MG/2ML (150 MG/ML)	300 MG/2ML	M ; N ; O ; Y	N		
Takhzyro	lanadelumab-flyo soln pref syringe	150 MG/ML	M ; N ; O ; Y	N		
Takhzyro	Lanadelumab-flyo Soln Pref Syringe	300 MG/2ML	M ; N ; O ; Y	N		
Ekterly	sebetralstat tab	300 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Andembry	garadacimab-gxii soln auto-injector	200 MG/1.2 ML	1	Pen	30	DAYS			
Berinerit	C1 Esterase Inhibitor (Human) For IV Inj Kit 500 Unit	500 UNIT	10	Vials	30	DAYS	QL calculation based on CDC 90th percentile for men and women averaged to 247.5 lbs or 112.5 kg (112.5 kg * 20 IU/kg=2,250 IU/500 IU/bottle=4.5 or 5 bottles or 2500 units/attack x 2 attacks/month = 10 vials/28 days		
Cinryze	C1 Esterase Inhibitor (Human) For IV Inj 500 Unit	500 UNIT	20	Vials	30	DAYS	1,000 IU every 3 days = 10,000 IU/30 days/500 u/vial = 20 vials		
Dawnzera	donidalorsen sodium subcutaneous soln auto-inj	80 MG/0.8 ML	1	Pen	28	DAYS			
Ekterly	sebetralstat tab	300 MG	8	Tablets	30	DAYS			
Firazyr	icatibant acetate inj 30 mg/3ml (base equivalent)	30 MG/3ML	6	Syringes	30	DAYS	18 mLs = 6 syringes		
Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 2000 Unit	2000 UNIT	27	Vials	28	DAYS	*QL calculation based on CDC 90 percentile for weight in adults, averaged for men and women, and rounded to the nearest even dose to reduce waste (112.5 kg individual). See Special Clinical Criteria Table		
Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 3000 Unit	3000 UNIT	18	Vials	28	DAYS	*QL calculation based on CDC 90 percentile for weight in adults, averaged for men and		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
							women, and rounded to the nearest even dose to reduce waste (112.5 kg individual). See Special Clinical Criteria Table		
Orladeyo	Berotrastat HCl Cap	110 MG	30	Capsules	30	DAYS			
Orladeyo	Berotrastat HCl Cap	150 MG	30	Capsules	30	DAYS			
Orladeyo	berotrastat hcl pellet pack	72 MG	28	Packets	28	DAYS			
Orladeyo	berotrastat hcl pellet pack	96 MG	28	Packets	28	DAYS			
Orladeyo	berotrastat hcl pellet pack	108 MG	28	Packets	28	DAYS			
Orladeyo	berotrastat hcl pellet pack	132 MG	28	Packets	28	DAYS			
Ruconest	C1 Esterase Inhibitor (Recombinant) For IV Inj 2100 Unit	2100 UNIT	8	Vials	30	DAYS			
Takhzyro	Lanadelumab-flyo Inj 300 MG/2ML (150 MG/ML)	300 MG/2ML	2	Vials	28	DAYS			
Takhzyro	lanadelumab-flyo soln pref syringe	150 MG/ML	2	Syringes	28	DAYS			
Takhzyro	Lanadelumab-flyo Soln Pref Syringe	300 MG/2ML	2	Syringes	28	DAYS			

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85802022006420	Berinerst	C1 Esterase Inhibitor (Human) For IV Inj Kit 500 Unit	500 UNIT	QL calculation based on CDC 90th percentile for men and women averaged to 247.5 lbs or 112.5 kg (112.5 kg * 20 IU/kg=2,250 IU/500 IU/bottle=4.5 or 5 bottles or 2500 units/attack x 2 attacks/month = 10 vials/28 days			
85802022002120	Cinryze	C1 Esterase Inhibitor (Human) For IV Inj 500 Unit	500 UNIT	1,000 IU every 3 days = 10,000 IU/30 days/500 u/vial = 20 vials		07-15-2023	
8582004010E520	Firazyr	icatibant acetate inj 30 mg/3ml (base equivalent)	30 MG/3ML	18 mLs = 6 syringes		03-27-2023	
85802022002130	Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 2000 Unit	2000 UNIT	*QL calculation based on CDC 90 percentile for weight in adults, averaged for men and women, and rounded to the nearest even dose to reduce waste (112.5 kg individual). See Special Clinical Criteria Table		07-15-2023	
85802022002140	Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 3000 Unit	3000 UNIT	*QL calculation based on CDC 90 percentile for weight in adults, averaged for men and women, and rounded to the nearest even dose to reduce waste (112.5 kg individual). See Special Clinical Criteria Table		07-15-2023	

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Andembry	garadacimab-gxii soln auto-injector	200 MG/1.2ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Berinert	C1 Esterase Inhibitor (Human) For IV Inj Kit 500 Unit	500 UNIT	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Cinryze	C1 Esterase Inhibitor (Human) For IV Inj 500 Unit	500 UNIT	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Dawnzera	donidalorsen sodium subcutaneous soln auto-inj	80 MG/0.8ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Ekterly	sebetralstat tab	300 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Firazyr	icatibant acetate inj 30 mg/3ml (base equivalent)	30 MG/3ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 2000 Unit	2000 UNIT	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 3000 Unit	3000 UNIT	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Orladeyo	berotralstat hcl cap ; berotralstat hcl pellet pack	108 MG ; 110 MG ; 132 MG ; 150 MG ; 72 MG ; 96 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Ruconest	C1 Esterase Inhibitor (Recombinant) For IV Inj 2100 Unit	2100 UNIT	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Takhzyro	Lanadelumab-flyo Inj 300 MG/2ML (150 MG/ML)	300 MG/2ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Takhzyro	Lanadelumab-flyo Soln Pref Syringe	300 MG/2ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Takhzyro	lanadelumab-flyo soln pref syringe	150 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Andembry	garadacimab-gxii soln auto-injector	200 MG/1.2ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Berinerit	C1 Esterase Inhibitor (Human) For IV Inj Kit 500 Unit	500 UNIT	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Cinryze	C1 Esterase Inhibitor (Human) For IV Inj 500 Unit	500 UNIT	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Dawnzera	donidalorsen sodium subcutaneous soln auto-inj	80 MG/0.8ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Ekterly	sebetralstat tab	300 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Firazyr	icatibant acetate inj 30 mg/3ml (base equivalent)	30 MG/3ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 2000 Unit	2000 UNIT	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Haegarda	C1 Esterase Inhibitor (Human) For Subcutaneous Inj 3000 Unit	3000 UNIT	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Orladeyo	Berotralstat HCl Cap	150 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Orladeyo	Berotralstat HCl Cap	110 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Orladeyo	berotralstat hcl pellet pack	132 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Orladeyo	berotralstat hcl pellet pack	108 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Orladeyo	berotralstat hcl pellet pack	96 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Orladeyo	berotralstat hcl pellet pack	72 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Rucnest	C1 Esterase Inhibitor (Recombinant) For IV Inj 2100 Unit	2100 UNIT	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Takhzyro	Lanadelumab-flyo Inj 300 MG/2ML (150 MG/ML)	300 MG/2ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Takhzyro	Lanadelumab-flyo Soln Pref Syringe	300 MG/2ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Takhzyro	lanadelumab-flyo soln pref syringe	150 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Andemby, Cinryze, Dawnzera, Haegarda, Orladeyo, or Takhzyro	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is eligible for continuation of therapy AND the following: <div style="border: 1px solid black; padding: 5px; margin: 10px 0; text-align: center;"> <p>Agents Eligible for Continuation of Therapy</p> <p>All target agents are eligible for continuation of therapy</p> </div> B. ALL of the following: <ol style="list-style-type: none"> 1. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed OR 2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND 3. The requested agent is being prescribed for HAE prophylaxis AND 4. The patient has a history of at least three moderate to severe acute HAE attacks per month (e.g., airway swelling, severe abdominal pain, painful facial swelling) AND 2. If Takhzyro is requested, then ONE of the following: <ol style="list-style-type: none"> A. The patient is an adult or 12 years of age or older AND ONE of the following: <ol style="list-style-type: none"> 1. The patient is initiating therapy with the requested agent OR 2. The patient has been treated with the requested agent for less than 6 consecutive months OR 3. The patient has been treated with the requested agent for at least 6 consecutive months AND ONE of the following: <ol style="list-style-type: none"> A. The patient has been free of acute HAE attacks for at least 6 consecutive months and ONE of the following: <ol style="list-style-type: none"> 1. The patient's dose will be reduced to 300 mg every 4 weeks OR 2. There is support for therapy using 300 mg every 2 weeks OR B. The patient has NOT been free of acute HAE attacks for at least 6 consecutive months OR B. The patient is 6 to less than 12 years of age AND ONE of the following: <ol style="list-style-type: none"> 1. The patient is initiating therapy with the requested agent OR

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 2. The patient has been treated with the requested agent for less than 6 consecutive months OR 3. The patient has been treated with the requested agent for at least 6 consecutive months AND ONE of the following: <ol style="list-style-type: none"> A. The patient has been free of acute HAE attacks for at least 6 consecutive months AND ONE of the following: <ol style="list-style-type: none"> 1. The patient's dose will be reduced to 150 mg every 4 weeks OR 2. There is support for therapy using 150 mg every 2 weeks OR B. The patient has NOT been free of acute HAE attacks for at least 6 consecutive months OR C. The patient is 2 to less than 6 years of age AND 3. If Dawnzera is requested, then ONE of the following: <ol style="list-style-type: none"> A. The patient is initiating therapy with the requested agent OR B. The patient has been treated with the requested agent for less than 12 consecutive months OR C. The patient has been treated with the requested agent for at least 12 consecutive months AND ONE of the following: <ol style="list-style-type: none"> 1. The patient has been free of acute HAE attacks for at least 12 consecutive months AND ONE of the following: <ol style="list-style-type: none"> A. The patient's dose will be reduced to 80 mg every 8 weeks OR B. There is support for therapy using 80 mg every 4 weeks OR 2. The patient has NOT been free of acute HAE attacks for at least 12 consecutive months AND 4. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin receptor blockers) have been evaluated and discontinued when appropriate AND 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 6. The patient will NOT be using the requested agent in combination with another agent indicated for prophylaxis of HAE attacks (i.e., Andembry, Dawnzera, Cinryze, Haegarda, Orladeyo, Takhzyro) AND 7. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>All other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] AND D. There is support for an age in the patient's given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years

Module	Clinical Criteria for Approval
	<p>of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] OR</p> <ol style="list-style-type: none"> 2. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. The patient has had clinical benefit with the requested agent AND 3. If Takhzyro is requested, then ONE of the following: <ol style="list-style-type: none"> A. The patient is an adult or 12 years of age or older AND ONE of the following: <ol style="list-style-type: none"> 1. The patient is initiating therapy with the requested agent OR

Module	Clinical Criteria for Approval
	<p>2. The patient has been treated with the requested agent for less than 6 consecutive months OR</p> <p>3. The patient has been treated with the requested agent for at least 6 consecutive months AND ONE of the following:</p> <p style="padding-left: 20px;">A. The patient has been free of acute HAE attacks for at least 6 consecutive months and ONE of the following:</p> <p style="padding-left: 40px;">1. The patient's dose will be reduced to 300 mg every 4 weeks OR</p> <p style="padding-left: 40px;">2. There is support for therapy using 300 mg every 2 weeks OR</p> <p style="padding-left: 20px;">B. The patient has NOT been free of acute HAE attacks for at least 6 consecutive months OR</p> <p style="padding-left: 20px;">B. The patient is 6 to less than 12 years of age AND ONE of the following:</p> <p style="padding-left: 40px;">1. The patient is initiating therapy with the requested agent OR</p> <p style="padding-left: 40px;">2. The patient has been treated with the requested agent for less than 6 consecutive months OR</p> <p style="padding-left: 40px;">3. The patient has been treated with the requested agent for at least 6 consecutive months AND ONE of the following:</p> <p style="padding-left: 60px;">A. The patient has been free of acute HAE attacks for at least 6 consecutive months and ONE of the following:</p> <p style="padding-left: 80px;">1. The patient's dose will be reduced to 150 mg every 4 weeks OR</p> <p style="padding-left: 80px;">2. There is support for therapy using 150 mg every 2 weeks OR</p> <p style="padding-left: 60px;">B. The patient has NOT been free of acute HAE attacks for at least 6 consecutive months OR</p> <p style="padding-left: 20px;">C. The patient is 2 to less than 6 years of age AND</p> <p>4. If Dawnzera is requested, then ONE of the following:</p> <p style="padding-left: 20px;">A. The patient is initiating therapy with the requested agent OR</p> <p style="padding-left: 20px;">B. The patient has been treated with the requested agent for less than 12 consecutive months OR</p> <p style="padding-left: 20px;">C. The patient has been treated with the requested agent for at least 12 consecutive months AND ONE of the following:</p> <p style="padding-left: 40px;">1. The patient has been free of acute HAE attacks for at least 12 consecutive months AND ONE of the following:</p> <p style="padding-left: 60px;">A. The patient's dose will be reduced to 80 mg every 8 weeks OR</p> <p style="padding-left: 60px;">B. There is support for therapy using 80 mg every 4 weeks OR</p> <p style="padding-left: 40px;">2. The patient has NOT been free of acute HAE attacks for at least 12 consecutive months AND</p> <p>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>6. The patient will NOT be using the requested agent in combination with another agent indicated for prophylaxis of HAE attacks (i.e., Andembry, Dawnzera, Cinryze, Haegarda, Orladeyo, Takhzyro) AND</p> <p>7. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>
<p>Berinert, Ekterly, Firazyr, icatibant , or Ruconest</p>	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <p>1. ONE of the following:</p>

Module	Clinical Criteria for Approval
	<p>A. The requested agent is eligible for continuation of therapy AND the following:</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: fit-content;"> <p style="text-align: center;">Agents Eligible for Continuation of Therapy</p> <p style="text-align: center;">All target agents are eligible for continuation of therapy</p> </div> <p>1. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) AND is at risk if therapy is changed OR</p> <p>B. ALL of the following:</p> <p>1. ONE of the following:</p> <p>A. The patient has a diagnosis of hereditary angioedema (HAE) due to C1INH deficiency (HAE-C1INH [Type 1 or Type 2]) confirmed by ONE of the following:</p> <p>1. The patient's diagnosis has been confirmed with measurements of C1-INH protein level, C1-INH function level, and C4 level as follows:</p> <p>A. Type 1 HAE: Decreased quantities of C4 level, C1-INH protein level, and C1-INH function level OR</p> <p>B. Type 2 HAE: Decreased quantities of C4 level and C1-INH function level (C1-INH protein level may be normal or elevated) OR</p> <p>2. The patient's diagnosis has been confirmed by mutation in the C1-INH gene altering protein synthesis and/or function OR</p> <p>B. The patient has a diagnosis of hereditary angioedema (HAE) with normal C1INH (HAE-nI-C1INH) evidenced by BOTH of the following:</p> <p>1. The patient has levels within the normal range for C1-INH protein level, C1-INH function level, and C4 level AND</p> <p>2. ONE of the following:</p> <p>A. The patient's diagnosis is associated with a mutation in ONE of the following genes:</p> <ol style="list-style-type: none"> 1. Coagulation factor FXII (mutation in F12) 2. Plasminogen 3. Angiotensin-converting enzyme 1 4. Kininogen-1 5. Heparan sulfate 3-O-sulfotransferase 6 gene 6. Myoferlin gene OR <p>B. The patient has a diagnosis of HAE-U that has been confirmed by an HAE specialist (medical records required) AND</p> <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <p>A. The patient's age is within FDA labeling for the requested indication for the requested agent OR</p> <p>B. There is support for using the requested agent for the patient's age for the requested indication AND</p> <p>3. If the request is for Ekterly or Ruconest, then ONE of the following:</p> <p>A. The patient is between 12 and 17 years of age OR</p> <p>B. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR</p> <p>C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR</p> <p>D. The patient has tried and had an inadequate response to generic icatibant [chart notes required] OR</p> <p>E. Generic icatibant was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>F. The patient has an intolerance or hypersensitivity to generic icatibant [chart notes required] OR</p>

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	<p>G. The patient has an FDA labeled contraindication to generic icatibant [chart notes required] OR</p> <p>H. Generic icatibant is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient’s adherence of care; OR worsen a comorbid condition; OR decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>I. Generic icatibant is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as generic icatibant and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND</p> <p>2. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate AND</p> <p>3. The requested agent will be used to treat acute HAE attacks AND</p> <p>4. If the request is for one of the following brand agents with an available generic equivalent, then ONE of the following:</p> <table border="1" data-bbox="477 856 1172 934"> <thead> <tr> <th data-bbox="477 856 824 898">Brand</th> <th data-bbox="824 856 1172 898">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="477 898 824 934">Firazyr</td> <td data-bbox="824 898 1172 934">icatibant</td> </tr> </tbody> </table> <p>A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR</p> <p>B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR</p> <p>C. The patient has tried and had an inadequate response to the generic equivalent [chart notes required] OR</p> <p>D. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>E. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the requested brand agent [chart notes required] OR</p> <p>F. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the requested brand agent [chart notes required] OR</p> <p>G. The generic equivalent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient’s adherence of care; OR worsen a comorbid condition; OR decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>H. The generic equivalent is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>J. There is support for the use of the requested brand agent over the generic equivalent AND</p> <p>5. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., allergist, immunologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>6. The patient will NOT be using the requested agent in combination with another agent indicated for the treatment of acute HAE attacks (i.e., Berinert, Ekterly, Firazyr, icatibant, Kalbitor, Ruconest) AND</p> <p>7. The patient does NOT have any FDA labeled contraindications to the requested agent</p>	Brand	Generic Equivalent	Firazyr	icatibant
Brand	Generic Equivalent				
Firazyr	icatibant				

Module	Clinical Criteria for Approval
	<p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>All other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] AND D. There is support for an age in the patient’s given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] OR 2. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p>

Module	Clinical Criteria for Approval				
	<p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. The patient has had clinical benefit with the requested agent AND 3. If the request is for one of the following brand agents with an available generic equivalent, then ONE of the following: <table border="1" data-bbox="477 978 1172 1056"> <thead> <tr> <th data-bbox="477 978 824 1012">Brand</th> <th data-bbox="824 978 1172 1012">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="477 1012 824 1056">Firazyr</td> <td data-bbox="824 1012 1172 1056">icatibant</td> </tr> </tbody> </table> <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR C. The patient has tried and had an inadequate response to the generic equivalent [chart notes required] OR D. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR E. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the requested brand agent [chart notes required] OR F. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the requested brand agent [chart notes required] OR G. The generic equivalent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR H. The generic equivalent is not in the best interest of the patient based on medical necessity [chart notes required] OR I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR J. There is support for the use of the requested brand agent over the generic equivalent AND 4. The prescriber has communicated (via any means) with the patient regarding the frequency and severity of attacks and has verified that the patient does NOT have greater than 1-month supply (sufficient for 2 acute HAE attacks) currently on-hand AND 	Brand	Generic Equivalent	Firazyr	icatibant
Brand	Generic Equivalent				
Firazyr	icatibant				

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	<p>5. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., allergist, immunologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>6. The patient will NOT be using the requested agent in combination with another agent indicated for the treatment of acute HAE attacks (i.e., Berinert, Ekterly, Firazyr, icatibant, Kalbitor, Ruconest) AND</p> <p>7. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval																																										
Andemby, Cinryze, Dawnzer a, Haegarda, a, Orladeyo , or Takhzyro	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) is within the FDA labeled dose AND within the quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND there is support for therapy with a higher dose or quantity for the requested indication <p>Length of Approval: 12 months</p> <p>HAEGARDA WEIGHT-BASED QUANTITY LIMITS: EXTENDED DOSING TABLE</p> <table border="1" data-bbox="233 1087 1227 1988"> <thead> <tr> <th data-bbox="233 1087 367 1304">Weight (lb)</th> <th data-bbox="367 1087 488 1304">Weight (kg)</th> <th data-bbox="488 1087 675 1304">Quantity Limit of 3000 IU vials per 28 days</th> <th data-bbox="675 1087 857 1304">Quantity Limit of 2000 IU vials per 28 days</th> <th data-bbox="857 1087 1044 1304">Number of 3000 IU vials used per dose</th> <th data-bbox="1044 1087 1227 1304">Number of 2000 IU vials used per dose</th> </tr> </thead> <tbody> <tr> <td data-bbox="233 1304 367 1419">greater than 330-365</td> <td data-bbox="367 1304 488 1419">greater than 150-166</td> <td data-bbox="488 1304 675 1419">16</td> <td data-bbox="675 1304 857 1419">16</td> <td data-bbox="857 1304 1044 1419">2</td> <td data-bbox="1044 1304 1227 1419">2</td> </tr> <tr> <td data-bbox="233 1419 367 1535">greater than 293-330</td> <td data-bbox="367 1419 488 1535">greater than 133-150</td> <td data-bbox="488 1419 675 1535">24</td> <td data-bbox="675 1419 857 1535">0</td> <td data-bbox="857 1419 1044 1535">3</td> <td data-bbox="1044 1419 1227 1535">0</td> </tr> <tr> <td data-bbox="233 1535 367 1650">greater than 255-293</td> <td data-bbox="367 1535 488 1650">greater than 116-133</td> <td data-bbox="488 1535 675 1650">0</td> <td data-bbox="675 1535 857 1650">32</td> <td data-bbox="857 1535 1044 1650">0</td> <td data-bbox="1044 1535 1227 1650">4</td> </tr> <tr> <td data-bbox="233 1650 367 1766">greater than 220-255</td> <td data-bbox="367 1650 488 1766">greater than 100-116</td> <td data-bbox="488 1650 675 1766">8</td> <td data-bbox="675 1650 857 1766">16</td> <td data-bbox="857 1650 1044 1766">1</td> <td data-bbox="1044 1650 1227 1766">2</td> </tr> <tr> <td data-bbox="233 1766 367 1881">greater than 182.6-220</td> <td data-bbox="367 1766 488 1881">greater than 83-100</td> <td data-bbox="488 1766 675 1881">16</td> <td data-bbox="675 1766 857 1881">0</td> <td data-bbox="857 1766 1044 1881">2</td> <td data-bbox="1044 1766 1227 1881">0</td> </tr> <tr> <td data-bbox="233 1881 367 1988">greater than</td> <td data-bbox="367 1881 488 1988">greater than 66-83</td> <td data-bbox="488 1881 675 1988">8</td> <td data-bbox="675 1881 857 1988">8</td> <td data-bbox="857 1881 1044 1988">1</td> <td data-bbox="1044 1881 1227 1988">1</td> </tr> </tbody> </table>	Weight (lb)	Weight (kg)	Quantity Limit of 3000 IU vials per 28 days	Quantity Limit of 2000 IU vials per 28 days	Number of 3000 IU vials used per dose	Number of 2000 IU vials used per dose	greater than 330-365	greater than 150-166	16	16	2	2	greater than 293-330	greater than 133-150	24	0	3	0	greater than 255-293	greater than 116-133	0	32	0	4	greater than 220-255	greater than 100-116	8	16	1	2	greater than 182.6-220	greater than 83-100	16	0	2	0	greater than	greater than 66-83	8	8	1	1
Weight (lb)	Weight (kg)	Quantity Limit of 3000 IU vials per 28 days	Quantity Limit of 2000 IU vials per 28 days	Number of 3000 IU vials used per dose	Number of 2000 IU vials used per dose																																						
greater than 330-365	greater than 150-166	16	16	2	2																																						
greater than 293-330	greater than 133-150	24	0	3	0																																						
greater than 255-293	greater than 116-133	0	32	0	4																																						
greater than 220-255	greater than 100-116	8	16	1	2																																						
greater than 182.6-220	greater than 83-100	16	0	2	0																																						
greater than	greater than 66-83	8	8	1	1																																						

Module	Clinical Criteria for Approval					
	145-182.6					
	greater than 110-145	greater than 50-66	0	16	0	2
	greater than or equal to 75-110	greater than or equal to 34-50	8	0	1	0
	less than 75	less than 34	0	8	0	1
Berinert, Ekterly, Firazyr, icatibant, or Ruconest	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) is within the program quantity limit (allows for 2 acute HAE attacks per month) OR 2. The requested quantity (dose) exceeds the program quantity limit and there is support for therapy with a higher dose or quantity for the requested indication (e.g., frequency of attacks within the past 3 months has been greater than 2 attacks per month) <p>Length of Approval: 12 months</p>					