



Hemlibra Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date

11-01-2025

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
Hemlibra	emicizumab-kxwh subcutaneous soln	105 MG/0.7ML ; 12 MG/0.4ML ; 150 MG/ML ; 30 MG/ML ; 300 MG/2ML ; 60 MG/0.4ML	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

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
85105030202007	Hemlibra	emicizumab-kxwh subcutaneous soln	12 MG/0.4 ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance		08-15-2024	
85105030202060	Hemlibra	emicizumab-kxwh subcutaneous soln	300 MG/2ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance		08-15-2024	
85105030202030	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 105 MG/0.7ML (150 MG/ML)	105 MG/0.7 ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance		08-15-2024	
85105030202040	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 150 MG/ML	150 MG/ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance		08-15-2024	
85105030202010	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 30 MG/ML	30 MG/ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance		08-15-2024	
85105030202020	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 60 MG/0.4ML (150 MG/ML)	60 MG/0.4 ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance		08-15-2024	

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Hemlibra	emicizumab-kxwh subcutaneous soln	105 MG/0.7ML ; 12 MG/0.4ML ; 150 MG/ML ; 30 MG/ML ; 300 MG/2ML ; 60 MG/0.4ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; 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
Hemlibra	emicizumab-kxwh subcutaneous soln	12 MG/0.4ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Hemlibra	emicizumab-kxwh subcutaneous soln	300 MG/2ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Hemlibra	Emicizumab-kxwh Subcutaneous Soln 105 MG/0.7ML (150 MG/ML)	105 MG/0.7ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Hemlibra	Emicizumab-kxwh Subcutaneous Soln 150 MG/ML	150 MG/ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Hemlibra	Emicizumab-kxwh Subcutaneous Soln 30 MG/ML	30 MG/ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Hemlibra	Emicizumab-kxwh Subcutaneous Soln 60 MG/0.4ML (150 MG/ML)	60 MG/0.4ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval		
	<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: <table border="1" style="width: 100%;"> <tr> <td>Agents Eligible for Continuation of Therapy</td> </tr> <tr> <td>Hemlibra (emicizumab-kxwh)</td> </tr> </table> <ol style="list-style-type: none"> 1. The prescriber states the patient has been treated with the requested agent within the past 90 days (starting on samples is not approvable) AND is at risk if therapy is changed OR B. The patient has a diagnosis of hemophilia A with or without inhibitors OR C. The patient has another FDA labeled or compendia supported indication for the requested agent and route of administration AND 2. The requested agent will be used as prophylaxis to prevent or reduce the frequency of bleeding episodes AND 3. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., prescriber working in a hemophilia treatment center [HTC], hematologist with hemophilia 	Agents Eligible for Continuation of Therapy	Hemlibra (emicizumab-kxwh)
Agents Eligible for Continuation of Therapy			
Hemlibra (emicizumab-kxwh)			

Module	Clinical Criteria for Approval
	<p>experience), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <ol style="list-style-type: none"> 4. The patient will NOT be using the requested agent in combination with any of the following while on maintenance dosing with the requested agent: <ol style="list-style-type: none"> A. Prophylaxis with a Factor VIIa product (e.g., NovoSeven RT) OR B. Prophylaxis with a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) OR C. Prophylaxis with a bypassing agent (e.g., Feiba, NovoSeven) OR D. Immune Tolerance Therapy (ITT) (Immune Tolerance Induction [ITI]) AND 5. If the patient is receiving Feiba (activated prothrombin complex concentrate [aPCC]) for breakthrough bleeds, BOTH of the following: <ol style="list-style-type: none"> A. The patient will be monitored for thrombotic microangiopathy and thromboembolism AND B. The prescriber has counseled the patient on the maximum dosages of Feiba to be used (i.e., no more than 100 u/kg/24 hours) AND 6. The patient does NOT have any FDA labeled contraindications to the requested agent AND 7. The requested quantity (dose) is within the FDA labeled dosing based on the patient's weight and dosing interval <p>Compendia Allowed: AHFS, DrugDex, 1a, 2a, or 2b level of evidence</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL, BCBSMT, and BCBSTX: 12 months</p> <p>BCBSNM: 3 months for induction therapy and 12 months for maintenance therapy (or remainder of 12 months if requesting induction therapy and maintenance therapy)</p> <p>ALL other plans:</p> <p style="padding-left: 40px;">approve 1 month for induction therapy</p> <p style="padding-left: 40px;">approve 12 months for maintenance therapy (or remainder of 12 months if requesting induction therapy and maintenance therapy)</p> <p>NOTE: If Quantity Limit applies, please see 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,

Module	Clinical Criteria for Approval
	<p>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. ONE of the following: <ol style="list-style-type: none"> A. The patient has had improvements or stabilization with the requested agent as indicated by the number of breakthrough bleeds as reported in the treatment log and/or chart notes (medical records including treatment log and/or chart notes required) OR

Module	Clinical Criteria for Approval
	<p>B. There is support for the continued use of the requested agent (medical record required) AND</p> <p>3. If the patient is receiving Feiba (activated prothrombin complex concentrate [aPCC]) for breakthrough bleeds, the patient will be monitored for thrombotic microangiopathy and thromboembolism AND</p> <p>4. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., prescriber working in a hemophilia treatment center [HTC], hematologist with hemophilia experience), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>5. The patient will NOT be using the requested agent in combination with any of the following:</p> <ul style="list-style-type: none"> A. Prophylaxis with a Factor VIIa product (e.g., NovoSeven RT) OR B. Prophylaxis with a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) OR C. Prophylaxis with a bypassing agent (e.g., Feiba, NovoSeven) OR D. Immune Tolerance Therapy (ITT) (Immune Tolerance Induction [ITI]) AND <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>7. The requested quantity (dose) is within the FDA labeled dosing based on the patient’s weight and dosing interval</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 see Quantity Limit criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Quantity Limit for Target Agent(s) will be approved when ONE of the following is met:</p> <ul style="list-style-type: none"> 1. The patient is requesting induction therapy only OR 2. The patient is requesting induction therapy and maintenance therapy and the requested quantity (dose) for maintenance therapy does not exceed the program quantity limit (see Hemlibra Weight-Based Approvable Quantities chart) OR 3. The patient is requesting maintenance therapy only and the requested quantity (dose) does not exceed the program quantity limit (see the Hemlibra Weight-Based Approvable Quantities chart) <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans: 1 month for induction therapy 12 months for maintenance therapy (or remainder of 12 months if requesting induction therapy and maintenance therapy)</p> <p>Renewal Evaluation</p> <p>Quantity Limit for the Target Agent(s) will be approved when the requested quantity (dose) for maintenance therapy does not exceed the program quantity limit (see the Hemlibra Weight-Based Approvable Quantities chart)</p>

Module	Clinical Criteria for Approval						
Length of Approval: 12 months							
Hemlibra Weight-Based Approvable Quantities (maintenance dosing)							
Weight (kg)	Dosing Schedule	12 mg/0.4 mL vials	30 mg/1 mL vials	60 mg/0.4 mL vials	105 mg/0.7 mL vials	150 mg/1 mL vials	300 mg/2 mL vial
less than or equal to 5 kg	1.5 mg/kg every week	1.6 mL (4 vials)/28 days	0	0	0	0	0
less than or equal to 5 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0	0	0	0
less than or equal to 5 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0	0	0	0
greater than 5 and less than or equal to 10 kg	1.5 mg/kg every week	0	4 mL (4 vials)/28 days	0	0	0	0
greater than 5 and less than or equal to 10 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0	0	0	0
greater than 5 and less than or equal to 10 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	0	0
greater than 10 and less than	1.5 mg/kg every week	0	4 mL (4 vials)/28 days	0	0	0	0

Module	Clinical Criteria for Approval							
or equal to 15 kg								
greater than 10 and less than or equal to 15 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/ 28 days	0	0	0	0
greater than 10 and less than or equal to 15 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0.4 mL (1 vial)/28 days	0	0	0	0
greater than 15 and less than or equal to 20 kg	1.5 mg/kg every week	0	4 mL (4 vials)/ 28 days	0	0	0	0	0
greater than 15 and less than or equal to 20 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/ 28 days	0	0	0	0
greater than 15 and less than or equal to 20 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/ 28 days	0	0	0	0
greater than 20 and less than or equal to 25 kg	1.5 mg/kg every week	0	0	1.6 mL (4 vials)/ 28 days	0	0	0	0

Module	Clinical Criteria for Approval							
greater than 20 and less than or equal to 25 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/ 28 days	0.8 mL (2 vials)/ 28 days	0	0	0	0
greater than 20 and less than or equal to 25 kg	6 mg/kg every 4 weeks	0	0	0	0	1 mL (1 vial)/28 days	0	0
greater than 25 and less than or equal to 30 kg	1.5 mg/kg once every week	0	0	1.6 mL (4 vials)/ 28 days	0	0	0	0
greater than 25 and less than or equal to 30 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/ 28 days	0.8 mL (2 vials)/ 28 days	0	0	0	0
greater than 25 and less than or equal to 30 kg	6 mg/kg every 4 weeks	0	0	1.2 mL (3 vials)/ 28 days	0	0	0	0
greater than 30 and less than or equal to 35 kg	1.5 mg/kg once every week	0	0	1.6 mL (4 vials)/ 28 days	0	0	0	0
greater than 30 and less than	3mg/kg every 2 weeks	0	0	0	1.4 mL (2 vials)/ 28 days	0	0	0

Module	Clinical Criteria for Approval							
or equal to 35 kg								
greater than 30 and less than or equal to 35 kg	6 mg/kg every 4 weeks	0	0	0	1.4 mL (2 vials)/ 28 days	0	0	0
greater than 35 and less than or equal to 40 kg	1.5 mg/kg once every week	0	0	1.6 mL (4 vials)/ 28 days	0	0	0	0
greater than 35 and less than or equal to 40 kg	3 mg/kg every 2 weeks	0	0	1.6 mL (4 vials)/ 28 days	0	0	0	0
greater than 35 and less than or equal to 40 kg	6 mg/kg every 4 weeks	0	0	1.6 mL (4 vials)/ 28 days	0	0	0	0
greater than 40 and less than or equal to 45 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/ 28 days	1.6 mL (4 vials)/ 28 days	0	0	0	0
greater than 40 and less than or equal to 45 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/ 28 days	0	1.4 mL (2 vials)/ 28 days	0	0	0

Module	Clinical Criteria for Approval							
greater than 40 and less than or equal to 45 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/ 28 days	0	1 mL (1 vial)/28 days	0	
greater than 45 and less than or equal to 50 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/ 28 days	1.6 mL (4 vials)/ 28 days	0	0	0	
greater than 45 and less than or equal to 50 kg	3 mg/kg every 2 weeks	0	0	0	0	2 mL (2 vials)/ 28 days	0	
greater than 45 and less than or equal to 50 kg	6 mg/kg every 4 weeks	0	0	0	0	0	2 mL (1 vial)/28 days	
greater than 50 and less than or equal to 55 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/ 28 days	1.6 mL (4 vials)/ 28 days	0	0	0	
greater than 50 and less than or equal to 55 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/ 28 days	1.4 mL (2 vials)/ 28 days	0	0	
greater than 50 and less than	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/ 28 days	1.4 mL (2 vials)/ 28 days	0	0	

Module	Clinical Criteria for Approval							
or equal to 55 kg								
greater than 55 and less than or equal to 60 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/ 28 days	1.6 mL (4 vials)/ 28 days	0	0	0	
greater than 55 and less than or equal to 60 kg	3 mg/kg every 2 weeks	0	0	2.4 mL (6 vials)/ 28 days	0	0	0	
greater than 55 and less than or equal to 60 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	0	2 mL (1 vial/28 days)	
greater than 60 and less than or equal to 65 kg	1.5 mg/kg once every week	0	0	0	2.8 mL (4 vials)/ 28 days	0	0	
greater than 60 and less than or equal to 65 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/ 28 days	0.8 mL (2 vials)/ 28 days	1.4 mL (2 vials)/ 28 days	0	0	
greater than 60 and less than or equal to 65 kg	6 mg/kg every 4 weeks	0	0	1.6 mL (4 vials)/ 28 days	0	1 mL (1 vial)/28 days	0	

Module	Clinical Criteria for Approval							
greater than 65 and less than or equal to 70 kg	1.5 mg/kg once every week	0	0	0	2.8 mL (4 vials)/ 28 days	0	0	0
greater than 65 and less than or equal to 70 kg	3 mg/kg every 2 weeks	0	0	0	2.8 mL (4 vials)/ 28 days	0	0	0
greater than 65 and less than or equal to 70 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/ 28 days	0	0	2 mL (1 vial)/28 days	0
greater than 70 and less than or equal to 75 kg	1.5 mg/kg once every week	0	0	3.2 mL (8 vials)/ 28 days	0	0	0	0
greater than 70 and less than or equal to 75 kg	3 mg/kg every 2 weeks	0	0	1.6mL (4 vials)/ 28 days	1.4 mL (2 vials)/ 28 days	0	0	0
greater than 70 and less than or equal to 75 kg	6 mg/kg every 4 weeks	0	0	0	0	3 mL (3 vials)/28 days	0	0
greater than 75 and less than	1.5 mg/kg once every week	0	0	3.2 mL (8 vials)/ 28 days	0	0	0	0

Module	Clinical Criteria for Approval							
or equal to 80 kg								
greater than 75 and less than or equal to 80 kg	3 mg/kg every 2 weeks	0	0	3.2 mL (8 vials)/28 days	0	0	0	
greater than 75 and less than or equal to 80 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	2.8 mL (4 vials)/28 days	0	0	
greater than 80 and less than or equal to 85 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	0	0	
greater than 80 and less than or equal to 85 kg	3 mg/kg every 2 weeks	0	0	0	1.4 mL (2 vials)/28 days	2 mL (2 vials)/28 days	0	
greater than 80 and less than or equal to 85 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	3 mL (3 vials)/28 days	0	
greater than 85 and less than or equal to 90 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	0	0	

Module	Clinical Criteria for Approval							
greater than 85 and less than or equal to 90 kg	3 mg/kg every 2 weeks	0	0	1.6 mL (4 vials)/ 28 days	0	2 mL (2 vials)/ 28 days	0	
greater than 85 and less than or equal to 90 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/ 28 days	2.8 mL (4 vials)/ 28 days	0	0	
greater than 90 and less than or equal to 95 kg	1.5 mg/kg once every week	0	0	0	0	4 mL (4 vials)/ 28 days	0	
greater than 90 and less than or equal to 95 kg	3 mg/kg every 2 weeks	0	0	2.4 mL (6 vials)/ 28 days	1.4 mL (2 vials)/ 28 days	0	0	
greater than 90 and less than or equal to 95 kg	6 mg/kg every 4 weeks	0	0	0	2.8 mL (4 vials)/ 28 days	1 mL (1 vial)/ 28 days	0	
greater than 95 and less than or equal to 100 kg	1.5 mg/kg once every week	0	0	0	0	4 mL (4 vials)/ 28 days	0	
greater than 95 and less than	3 mg/kg every 2 weeks	0	0	0	0	0	4 mL (2 vials)/ 28 days	

Module	Clinical Criteria for Approval							
or equal to 100 kg								
greater than 95 and less than or equal to 100 kg	6 mg/kg every 4 weeks	0	0	0	0	0	0	4 mL (2 vials)/ 28 days
greater than 100 and less than or equal to 105 kg	1.5 mg/kg once every week	0	0	1.6 mL (4 vials)/ 28 days	2.8 mL (4 vials)/ 28 days	0	0	
greater than 100 and less than or equal to 105 kg	3 mg/kg every 2 weeks	0	0	0	4.2 mL (6 vials)/ 28 days	0	0	
greater than 100 and less than or equal to 105 kg	6 mg/kg every 4 weeks	0	0	0	4.2 mL (6 vials)/ 28 days	0	0	
greater than 105 and less than or equal to 110 kg	1.5 mg/kg once every week	0	0	1.6 mL (4 vials)/ 28 days	2.8 mL (4 vials)/ 28 days	0	0	
greater than 105 and less than	3 mg/kg every 2 weeks	0	0	1.6 mL (4 vials)/ 28 days	2.8 mL (4 vials)/ 28 days	0	0	

Module	Clinical Criteria for Approval							
or equal to 110 kg								
greater than 105 and less than or equal to 110 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	0	4 mL (2 vials)/28 days)	
greater than 110 and less than or equal to 115 kg	1.5 mg/kg once every week	0	0	4.8 mL (12 vials)/28 days	0	0	0	
greater than 110 and less than or equal to 115 kg	3 mg/kg every 2 weeks	0	0	3.2 mL (8 vials)/28 days	1.4 mL (2 vials)/28 days	0	0	
greater than 110 and less than or equal to 115 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	4.2 mL (6 vials)/28 days	0	0	
greater than 115 and less than or equal to 120 kg	1.5 mg/kg once every week	0	0	4.8 mL (12 vials)/28 days	0	0	0	
greater than 115 and ≤less	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	0	0	4 mL (2 vials)/28 days	

Module	Clinical Criteria for Approval							
than or equal to 120 kg								
greater than 115 and less than or equal to 120 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/ 28 days	0	0	4 mL (2 vials)/ 28 days	
greater than 120 and less than or equal to 125 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/ 28 days	1.6 mL (4 vials)/ 28 days	2.8 mL (4 vials)/ 28 days	0	0	
greater than 120 and less than or equal to 125 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/ 28 days	4.2 mL (6 vials)/ 28 days	0	0	
greater than 120 and less than or equal to 125 kg	6 mg/kg every 4 weeks	0	0	0	0	5 mL (5 vials)/28 days	0	
greater than 125 and less than or equal to 130 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/ 28 days	1.6 mL (4 vials)/ 28 days	2.8 mL (4 vials)/ 28 days	0	0	
greater than 125 and	3 mg/kg every	0	0	3.2 mL (8 vials)/	0	2 mL (2 vials)/	0	

Module	Clinical Criteria for Approval							
less than or equal to 130 kg	2 weeks			28 days		28 days		
greater than 125 and less than or equal to 130 kg	6 mg/kg every 4 weeks	0	0	1.2 mL (3 vials)/ 28 days	0	0	4 mL (2 vials)/ 28 days	
greater than 130 and less than or equal to 135 kg	1.5 mg/kg once every week	0	0	0	5.6 mL (8 vials)/ 28 days	0	0	
greater than 130 and less than or equal to 135 kg	3 mg/kg every 2 weeks	0	0	0	1.4 mL (2 vials)/ 28 days	0	4 mL (2 vials)/ 28 days	
greater than 130 and less than or equal to 135 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	5 mL (5 vials)/28 days	0	
greater than 135 and less than or equal to 140 kg	1.5 mg/kg once every week	0	0	0	5.6 mL (8 vials)/ 28 days	0	0	
greater than 135	3 mg/kg every	0	0	1.6 mL (4 vials)/	0	0	4 mL (2 vial	

Module	Clinical Criteria for Approval							
and less than or equal to 140 kg	2 weeks			28 days			s)/28 days	
greater than 135 and less than or equal to 140 kg	6 mg/kg every 4 weeks	0	0	0	5.6 mL (8 vials)/28 days	0	0	
greater than 140 and less than or equal to 145 kg	1.5 mg/kg once every week	0	0	3.2 mL (8 vials)/28 days	2.8 mL (4 vials)/28 days	0	0	
greater than 140 and less than or equal to 145 kg	3 mg/kg every 2 weeks	0	0	1.6 mL (4 vials)/28 days	4.2 mL (6 vials)/28 days	0	0	
greater than 140 and less than or equal to 145 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/28 days	0	5 mL (5 vials)/28 days	0	
greater than 145 and less than or equal to 150 kg	1.5 mg/kg once every week	0	0	3.2 mL (8 vials)/28 days	2.8 mL (4 vials)/28 days	0	0	
greater than	3 mg/kg	0	0	0	0	6 mL (6	0	

Module	Clinical Criteria for Approval							
145 and less than or equal to 150 kg	every 2 weeks					vials)/ 28 days		
greater than 145 and less than or equal to 150 kg	6 mg/kg every 4 weeks	0	0	0	0	0	6 mL (3 vials)/ 28 days	
greater than 150 and less than or equal to 155 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/ 28 days	0	5.6 mL (8 vials)/ 28 days	0	0	
greater than 150 and less than or equal to 155 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/ 28 days	1.4 mL (2 vials)/ 28 days	0	4 mL (2 vials)/ 28 days	
greater than 150 and less than or equal to 155 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0	0	0	6 mL (3 vials)/ 28 days	
greater than 155 and less than or equal to 160 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/ 28 days	0	5.6 mL (8 vials)/ 28 days	0	0	

Module	Clinical Criteria for Approval							
greater than 155 and less than or equal to 160 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0	0	6 mL (6 vials)/28 days	0	
greater than 155 and less than or equal to 160 kg	6 mg/kg every 4 weeks	0	0	0	0.4 mL (1 vial)/28 days	0	6 mL (3 vials)/28 days	
greater than 160 and less than or equal to 165 kg	1.5 mg/kg once every week	0	0	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days	0	
greater than 160 and less than or equal to 165 kg	3 mg/kg every 2 weeks	0	0	2.4 mL (6 vials)/28 days	4.2 mL (6 vials)/28 days	0	0	
greater than 160 and less than or equal to 165 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0	1.4 mL (2 vials)/28 days	5 mL (5 vials)/28 days	0	
greater than 165 and less than or equal to 170 kg	1.5 mg/kg once every week	0	0	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days	0	

Module	Clinical Criteria for Approval							
greater than 165 and less than or equal to 170 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	0	6 mL (6 vials)/28 days	0	
greater than 165 and less than or equal to 170 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	1.4 mL (2 vials)/28 days	5 mL (5 vials)/28 days	0	
greater than 170 and less than or equal to 175 kg	1.5 mg/kg once every week	0	0	2.4 mL (4 vials)/28 days	5.6 mL (8 vials)/28 days	0	0	
greater than 170 and less than or equal to 175 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	4.2 mL (6 vials)/28 days	2 mL (2 vials)/28 days	0	
greater than 170 and less than or equal to 175 kg	6 mg/kg every 4 weeks	0	0	0	0	7 mL (7 vials)/28 days	0	
greater than 175 and less than or equal to 180 kg	1.5 mg/kg once every week	0	0	2.4 mL (4 vials)/28 days	5.6 mL (8 vials)/28 days	0	0	

Module	Clinical Criteria for Approval							
greater than 175 and less than or equal to 180 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0	2.8 mL (4 vials)/28 days	0	4 mL (2 vials)/28 days	
greater than 175 and less than or equal to 180 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0	0	7 mL (7 vials)/28 days	0	
greater than 180 and less than or equal to 185 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days	0	
greater than 180 and less than or equal to 185 kg	3 mg/kg every 2 weeks	0	0	0	1.4 mL (2 vials)/28 days	6 mL (6 vials)/28 days	0	
greater than 180 and less than or equal to 185 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	7 mL (7 vials)/28 days	0	
greater than 185 and less than or equal to 190 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days	0	

Module	Clinical Criteria for Approval							
greater than 185 and less than or equal to 190 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/ 28 days	2.8 mL (4 vials)/ 28 days	0	4 mL (2 vials)/ 28 days	
greater than 185 and less than or equal to 190 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0	1.4 mL (2 vials)/ 28 days	0	6 mL (3 vials)/ 28 days	
greater than 190 and less than or equal to 195 kg	1.5 mg/kg once every week	0	0	0	0	0	8 mL (4 vials)/ 28 days	
greater than 190 and less than or equal to 195 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/ 28 days	0	1.4 mL (2 vials)/ 28 days	6 mL (6 vials)/ 28 days	0	
greater than 190 and less than or equal to 195 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	1.4 mL (2 vials)/ 28 days	0	6 mL (3 vials)/ 28 days	
greater than 195 and less than or equal to 200 kg	1.5 mg/kg once every week	0	0	0	0	0	8 mL (4 vials)/ 28 days	

Module	Clinical Criteria for Approval							
greater than 195 and less than or equal to 200 kg	3 mg/kg every 2 weeks	0	0	0	0	0	0	8 mL (4 vials)/ 28 days
greater than 195 and less than or equal to 200 kg	6 mg/kg every 4 weeks	0	0	0	0	0	0	8 mL (4 vials)/ 28 days
greater than 200 kg	Approve quantity requested if appropriate for patient weight and dosing interval							
<p>The 12 mg and 30 mg vials are the same concentration (30 mg/mL) and may be combined for dosing</p> <p>The 60 mg, 105 mg, 150 mg, and/or 300 mg vials are the same concentration (150 mg/mL) and may be combined for dosing</p>								
<p>The 12 mg vials and 30 mg vials (30mg/mL) should NOT be combined in the same injection with the 60 mg, 105 mg, 150 mg, or 300 mg vials and should be given as a separate injection</p>								