BlueCross BlueShield of Illinois
BlueCross BlueShield of Montana
BlueCross BlueShield of New Mexico
BlueCross BlueShield of Oklahoma
BlueCross BlueShield of Texas

GLP-1 (glucagon-like peptide-1) Agonists Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
1/1/2024

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5ML ; 1.5 MG/0.5ML ; 3 MG/0.5ML ; 4.5 MG/0.5ML	M ; N ; O ; Y	N		
Bydureon bcise	exenatide extended release susp auto-injector	2 MG/0.85ML	M ; N ; O ; Y	N		
Byetta	exenatide soln pen-injector	10 MCG/0.04ML ; 5 MCG/0.02ML	M ; N ; O ; Y	N		
Victoza	liraglutide soln pen-injector	18 MG/3ML	M ; N ; O ; Y	N		
Adlyxin starter pack	lixisenatide pen-inj starter kit	10 & 20 MCG/0.2ML	M ; N ; O ; Y	N		
Adlyxin	lixisenatide soln pen-injector	20 MCG/0.2ML	M ; N ; O ; Y	N		
Ozempic	semaglutide soln pen-inj	2 MG/1.5ML ; 2 MG/3ML ; 4 MG/3ML ; 8 MG/3ML	M ; N ; O ; Y	N		
Rybelsus	semaglutide tab	14 MG ; 3 MG ; 7 MG	M ; N ; O ; Y	N		
Mounjaro	tirzepatide soln pen-injector	10 MG/0.5ML ; 12.5 MG/0.5ML ; 15 MG/0.5ML ; 2.5 MG/0.5ML ; 5 MG/0.5ML ; 7.5 MG/0.5ML	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
Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2 ML	2	Pens	28	DAYS			

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
Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2 ML	2	Pens	180	DAYS			
Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85 ML	4	Pens	28	DAYS			
Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	1	Pen	30	DAYS			
Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	1	Pen	30	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5 ML	4	Pens	28	DAYS			
Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	1	Pen	28	DAYS			
Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	1	Pen	28	DAYS			
Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	1	Pen	28	DAYS			
Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5 ML	1	Pen	28	DAYS			
Ozempic	Semaglutide Soln Pen-inj 1 MG/DOSE (2 MG/1.5ML)	2 MG/1.5 ML	2	Pens	28	DAYS			
Rybelsus	semaglutide tab	14 MG ; 3 MG ; 7 MG	30	Tablets	30	DAYS			
Rybelsus	Semaglutide Tab 3 MG	3 MG	30	Tablets	180	DAYS			
Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5 ML ; 1.5 MG/0.5 ML ; 3 MG/0.5 ML ; 4.5 MG/0.5 ML	4	Pens	28	DAYS			
Victoza	liraglutide soln pen-injector	18 MG/3ML	3	Pens	30	DAYS			
Victoza	Liraglutide Soln Pen-injector 18 MG/3ML (6 MG/ML)	18 MG/3ML	3	Pens	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Adlyxin	lixisenatide soln pen-injector	20 MCG/0.2ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Adlyxin starter pack	lixisenatide pen-inj starter kit	10 & 20 MCG/0.2ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Bydureon bcise	exenatide extended release susp auto-injector	2 MG/0.85ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Byetta	exenatide soln pen-injector	10 MCG/0.04ML ; 5 MCG/0.02ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Mounjaro	tirzepatide soln pen-injector	10 MG/0.5ML ; 12.5 MG/0.5ML ; 15 MG/0.5ML ; 2.5 MG/0.5ML ; 5 MG/0.5ML ; 7.5 MG/0.5ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Ozempic	semaglutide soln pen-inj	2 MG/1.5ML ; 2 MG/3ML ; 4 MG/3ML ; 8 MG/3ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Rybelsus	semaglutide tab	14 MG ; 3 MG ; 7 MG	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5ML ; 1.5 MG/0.5ML ; 3 MG/0.5ML ; 4.5 MG/0.5ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Victoza	liraglutide soln pen-injector	18 MG/3ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Ozempic	Semaglutide Soln Pen-inj 1 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Rybelsus	semaglutide tab	14 MG ; 3 MG ; 7 MG	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Rybelsus	Semaglutide Tab 3 MG	3 MG	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5ML ; 1.5 MG/0.5ML ; 3 MG/0.5ML ; 4.5 MG/0.5ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods
Victoza	liraglutide soln pen-injector	18 MG/3ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Victoza	Liraglutide Soln Pen-injector 18 MG/3ML (6 MG/ML)	18 MG/3ML	Balanced ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2023 ; HIM Quarterly 2024 ; Performance ; Performance Annual ; Performance Select ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)

Preferred Agent(s)	Non-Preferred Agent(s)
Bydureon® (exenatide) **Ozempic®** (semaglutide) **Rybelsus®** (semaglutide) **Trulicity®** (dulaglutide) **Mounjaro™** (tirzepatide)	 **Adlyxin®** (lixisenatide) **Byetta®** (exenatide) **Victoza®** (liraglutide)

Target Agent(s) will be approved when BOTH of the following are met:

1. The patient has a diagnosis of type 2 diabetes [chart notes are required] **AND**
2. BOTH of the following:
    A. ONE of the following:
        1. The patient has tried or is currently using a diabetic agent [i.e., agents containing metformin, agents containing insulin, agents containing DPP-4 inhibitors, agents containing SGLT2 inhibitors, sulfonylureas, dopamine receptor agonists-ergot derivatives (e.g., bromocriptine), d-phenylalanine dervitives, meglitinide analogues, alpha-glucosidase inhibitors, thiazolidinediones, sulfonylurea-thiazolidinedione combinations] **OR**
        2. The patient has an intolerance or hypersensitivity to a diabetic agent [i.e., agents containing metformin, agents containing insulin, agents containing DPP-4 inhibitors, agents containing SGLT2 inhibitors, sulfonylureas, dopamine receptor agonists-ergot derivatives (e.g., bromocriptine), d-phenylalanine dervitives, meglitinide analogues, alpha-glucosidase inhibitors, thiazolidinediones, sulfonylurea-thiazolidinedione combinations] **OR**
        3. The patient has an FDA labeled contraindication to ALL diabetic agents [i.e., agents containing metformin, agents containing insulin, agents containing DPP-4 inhibitors, agents containing SGLT2 inhibitors, sulfonylureas, dopamine receptor agonists-ergot derivatives (e.g., bromocriptine), d-phenylalanine dervitives, meglitinide analogues, alpha-glucosidase inhibitors, thiazolidinediones, sulfonylurea-thiazolidinedione combinations] **OR**
        4. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **AND**
    B. ONE of the following:
        1. The requested agent is a preferred GLP-1 or GLP-1/GIP **OR**
        2. The agent is a non-preferred GLP-1 or GLP-1/GIP and TWO of the following:
            A. ONE of the following:
                1. The prescriber states the patient is currently being treated with the requested agent AND the patient is currently stable on the requested agent **OR**

Module	Clinical Criteria for Approval
	2. The patient has tried and had an inadequate response to semaqlutide (Ozempic OR Rybelsus) **OR** 3. Semaqlutide (Ozempic OR Rybelsus) was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 4. The patient has an intolerance or hypersensitivity to semaqlutide (Ozempic OR Rybelsus) **OR** 5. The patient has an FDA labeled contraindication to semaqlutide (Ozempic OR Rybelsus) AND **OR** 6. Semaqlutide (Ozempic OR Rybelsus) 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 **OR** 7. Semaqlutide (Ozempic OR Rybelsus) is not in the best interest of the patient based on medical necessity **OR** 8. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as semaglutide (Ozempic OR Rybelsus) and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 9. The requested agent is medically necessary and appropriate for the patient **OR** B. ONE of the following: 1. The prescriber states the patient is currently being treated with the requested agent AND the patient is currently stable on the requested agent **OR** 2. The patient has tried and had an inadequate response to dulaglutide (Trulicity) **OR** 3. Dulaglutide (Trulicity) was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 4. The patient has an intolerance or hypersensitivity to dulaglutide (Trulicity) **OR** 5. The patient has an FDA labeled contraindication to dulaglutide (Trulicity) **OR** 6. Dulaglutide (Trulicity) 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 **OR** 7. Dulaglutide (Trulicity) is not in the best interest of the patient based on medical necessity **OR** 8. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as dulaglutide (Trulicity) and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 9. The requested agent is medically necessary and appropriate for the patient **OR** C. ONE of the following:

Module	Clinical Criteria for Approval
	1. The prescriber states the patient is currently being treated with the requested agent AND the patient is currently stable on the requested agent **OR** 2. The patient has tried and had an inadequate response to tirzepatide (Mounjaro) **OR** 3. Tirzepatide (Mounjaro) was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 4. The patient has an intolerance or hypersensitivity to tirzepatide (Mounjaro) **OR** 5. The patient has an FDA labeled contraindication to tirzepatide (Mounjaro) **OR** 6. Tirzepatide (Mounjaro) 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 **OR** 7. Tirzepatide (Mounjaro) is not in the best interest of the patient based on medical necessity **OR** 8. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as tirzepatide (Mounjaro) and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 9. The requested agent is medically necessary and appropriate for the patient **Length of approval:** 12 months For BCBSIL members: Approve for 12 months (if approving starter pack that has separate GPI-14, approve both starter pack and maintenance product for 12 months each) NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. BOTH of the following: A. The patient has a diagnosis of type 2 diabetes mellitus **AND** B. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: 1. BOTH of the following: A. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **OR** 2. BOTH of the following: A. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. BOTH of the following:

Module	Clinical Criteria for Approval
	A. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** B. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months