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

Rapid to Intermediate Acting Insulin Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
04-15-2025

OBJECTIVE

The intent of the Rapid to Intermediate Acting Insulin prior authorization criteria is to encourage use of cost-effective preferred Rapid to Intermediate Acting insulin agents over the non-preferred Rapid to intermediate Acting insulin agents. The program will also support a quantity limit of 100 mL of preferred and non-preferred insulin agent per 30 days.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Apidra ; Apidra solostar	insulin glulisine inj ; insulin glulisine soln pen-injector inj	100 UNIT/ML	M ; N ; O ; Y	N		
Admelog ; Insulin lispro	insulin lispro inj soln	100 UNIT/ML	M ; N ; O ; Y	N		
Admelog solostar ; Insulin lispro kwikpen	insulin lispro soln pen-injector	100 UNIT/ML	M ; N ; O ; Y	N		
Fiasp pumpcart	insulin aspart (with niacinamide) soln cartridge	100 UNIT/ML	M ; N ; O ; Y	N		
Insulin aspart	insulin aspart inj soln	100 UNIT/ML	M ; N ; O ; Y	N		
Insulin aspart flexpen ; Novolog flexpen relion	insulin aspart soln pen-injector	100 UNIT/ML	M ; N ; O ; Y	N		
Insulin aspart penfill	insulin aspart soln cartridge	100 UNIT/ML	M ; N ; O ; Y	N		
Insulin aspart protamine/	insulin aspart prot & aspart (human) inj	(70-30) 100 UNIT/ML	M ; N ; O ; Y	N		
Insulin aspart protamine/	insulin aspart prot & aspart sus pen-inj	(70-30) 100 UNIT/ML	M ; N ; O ; Y	N		
Insulin lispro junior kwi	insulin lispro soln pen-injector	100 UNIT/ML	M ; N ; O ; Y	N		
Insulin lispro protamine/	insulin lispro prot & lispro sus pen-inj	(75-25) 100 UNIT/ML	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
Admelog ; Admelog solostar ; Humalog ; Humalog junior kwikpen ; Humalog kwikpen ; Humalog tempo pen ; Insulin lispro ; Insulin lispro junior kwi ; Insulin lispro kwikpen ;	insulin lispro inj soln ; insulin lispro soln cartridge ; insulin lispro soln pen-inj w/transmitter port ; insulin lispro soln pen-injector ; insulin lispro-aabc inj ; insulin lispro-aabc	100 UNIT/ML ; 200 UNIT/ML	100	mLs	30	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
Lyumjev ; Lyumjev kwikpen ; Lyumjev tempo pen	soln pen-inj ; insulin lispro-aabc soln pen-inj w/transmit port ; insulin lispro-aabc soln pen-injector								
Apidra ; Apidra solostar	insulin glulisine inj ; insulin glulisine soln pen-injector inj	100 UNIT/ML	100	mLs	30	DAYS			
Fiasp ; Fiasp flextouch ; Fiasp penfill ; Fiasp pumpcart ; Insulin aspart ; Insulin aspart flexpen ; Insulin aspart penfill ; Novolog ; Novolog flexpen ; Novolog flexpen relion ; Novolog penfill ; Novolog relion	insulin aspart (with niacinamide) inj ; insulin aspart (with niacinamide) sol pen-inj ; insulin aspart (with niacinamide) soln cartridge ; insulin aspart inj soln ; insulin aspart soln cartridge ; insulin aspart soln pen-injector	100 UNIT/ML	100	mLs	30	DAYS			
Humalog mix 50/50 ; Humalog mix 50/50 kwikpen ; Humalog mix 75/25 ; Humalog mix 75/25 kwikpen ; Insulin lispro protamine/	insulin lispro prot & lispro inj ; insulin lispro prot & lispro sus pen-inj ; insulin lispro protamine & lispro inj	(50-50) 100 UNIT/ML ; (75-25) 100 UNIT/ML	100	mLs	30	DAYS			
Humulin 70/30 ; Humulin 70/30 kwikpen ; Novolin 70/30 ; Novolin 70/30 flexpen ; Novolin 70/30 flexpen rel ; Novolin 70/30 relion	insulin nph & regular susp pen-inj ; insulin nph isophane & regular human inj	(70-30) 100 UNIT/ML	100	mLs	30	DAYS			
Humulin n ; Humulin n kwikpen ; Novolin n ; Novolin n flexpen ; Novolin n flexpen relion ; Novolin n relion	insulin nph (human) (isophane) inj ; insulin nph (human) (isophane) susp pen-injector	100 UNIT/ML	100	mLs	30	DAYS			
Humulin r ; Novolin r ; Novolin r relion	Insulin Regular (Human) Inj 100 Unit/ML	100 UNIT/ML	100	mLs	30	DAYS			
Humulin r u-500 (concentr	Insulin Regular (Human) Inj 500 Unit/ML	500 UNIT/ML	100	mLs	30	DAYS			
Humulin r u-500 kwikpen	Insulin Regular (Human) Soln Pen-Injector 500 Unit/ML	500 UNIT/ML	100	mLs	30	DAYS			
Insulin aspart protamine/ ; Novolog mix 70/30 ; Novolog mix 70/30 prefill ; Novolog mix 70/30 relion	insulin aspart prot & aspart (human) inj ; insulin aspart prot & aspart sus pen-inj	(70-30) 100 UNIT/ML	100	mLs	30	DAYS			
Novolin r flexpen ; Novolin r flexpen relion	Insulin Regular (Human) Soln Pen-Injector 100 Unit/ML	100 UNIT/ML	100	mLs	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Admelog ; Admelog solostar ; Humalog ; Humalog junior kwikpen ; Humalog kwikpen ; Humalog tempo pen ; Insulin lispro ; Insulin lispro junior kwi ; Insulin lispro kwikpen ; Lyumjev ; Lyumjev kwikpen ; Lyumjev tempo pen	insulin lispro inj soln ; insulin lispro soln cartridge ; insulin lispro soln pen-inj w/transmitter port ; insulin lispro soln pen-injector ; insulin lispro-aabc inj ; insulin lispro-aabc soln pen-inj ; insulin lispro-aabc soln pen-inj w/transmit port ; insulin lispro-aabc soln pen-injector	100 UNIT/ML ; 200 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Admelog ; Insulin lispro	insulin lispro inj soln	100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Admelog solostar ; Insulin lispro kwikpen	insulin lispro soln pen-injector	100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Apidra ; Apidra solostar	insulin glulisine inj ; insulin glulisine soln pen-injector inj	100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Fiasp ; Fiasp flextouch ; Fiasp penfill ; Fiasp pumpcart ; Insulin aspart ; Insulin aspart flexpen ; Insulin aspart penfill ; Novolog ; Novolog flexpen ; Novolog flexpen relion ; Novolog penfill ; Novolog relion	insulin aspart (with niacinamide) inj ; insulin aspart (with niacinamide) sol pen-inj ; insulin aspart (with niacinamide) soln cartridge ; insulin aspart inj soln ; insulin aspart soln cartridge ; insulin aspart soln pen-injector	100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Fiasp pumpcart	insulin aspart (with niacinamide) soln cartridge	100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Humalog mix 50/50 ; Humalog mix 50/50 kwikpen ; Humalog mix 75/25 ; Humalog mix 75/25 kwikpen ; Insulin lispro protamine/	insulin lispro prot & lispro inj ; insulin lispro prot & lispro sus pen-inj ; insulin lispro protamine & lispro inj	(50-50) 100 UNIT/ML ; (75-25) 100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Humulin 70/30 ; Humulin 70/30 kwikpen ; Novolin 70/30 ; Novolin 70/30 flexpen ; Novolin 70/30 flexpen rel ; Novolin 70/30 relion	insulin nph & regular susp pen-inj ; insulin nph isophane & regular human inj	(70-30) 100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Humulin n ; Humulin n kwikpen ; Novolin n ; Novolin n flexpen ; Novolin n flexpen relion ; Novolin n relion	insulin nph (human) (isophane) inj ; insulin nph (human) (isophane) susp pen-injector	100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Insulin aspart	insulin aspart inj soln	100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Insulin aspart flexpen ; Novolog flexpen relion	insulin aspart soln pen-injector	100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Insulin aspart penfill	insulin aspart soln cartridge	100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Insulin aspart protamine/	insulin aspart prot & aspart (human) inj	(70-30) 100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Insulin aspart protamine/	insulin aspart prot & aspart sus pen-inj	(70-30) 100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Insulin aspart protamine/ ; Novolog mix 70/30 ; Novolog mix 70/30 prefill ; Novolog mix 70/30 relion	insulin aspart prot & aspart (human) inj ; insulin aspart prot & aspart sus pen-inj	(70-30) 100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Insulin lispro junior kwi	insulin lispro soln pen-injector	100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual
Insulin lispro protamine/	insulin lispro prot & lispro sus pen-inj	(75-25) 100 UNIT/ML	Basic ; Basic Annual ; Enhanced ; Enhanced Annual

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Admelog ; Admelog solostar ; Humalog ; Humalog junior kwikpen ; Humalog kwikpen ; Humalog tempo pen ; Insulin	insulin lispro inj soln ; insulin lispro soln cartridge ; insulin lispro soln pen-inj w/transmitter port ; insulin lispro soln	100 UNIT/ML ; 200 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
lispro ; Insulin lispro junior kwi ; Insulin lispro kwikpen ; Lyumjev ; Lyumjev kwikpen ; Lyumjev tempo pen	pen-injector ; insulin lispro-aabc inj ; insulin lispro-aabc soln pen-inj ; insulin lispro-aabc soln pen-inj w/transmit port ; insulin lispro-aabc soln pen-injector		Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Apidra ; Apidra solostar	insulin glulisine inj ; insulin glulisine soln pen-injector inj	100 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Fiasp ; Fiasp flextouch ; Fiasp penfill ; Fiasp pumpcart ; Insulin aspart ; Insulin aspart flexpen ; Insulin aspart penfill ; Novolog ; Novolog flexpen ; Novolog flexpen relion ; Novolog penfill ; Novolog relion	insulin aspart (with niacinamide) inj ; insulin aspart (with niacinamide) sol pen-inj ; insulin aspart (with niacinamide) soln cartridge ; insulin aspart inj soln ; insulin aspart soln cartridge ; insulin aspart soln pen-injector	100 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Humalog mix 50/50 ; Humalog mix 50/50 kwikpen ; Humalog mix 75/25 ; Humalog mix 75/25 kwikpen ; Insulin lispro protamine/	insulin lispro prot & lispro inj ; insulin lispro prot & lispro sus pen-inj ; insulin lispro protamine & lispro inj	(50-50) 100 UNIT/ML ; (75-25) 100 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Humulin 70/30 ; Humulin 70/30 kwikpen ; Novolin 70/30 ; Novolin 70/30 flexpen ; Novolin 70/30 flexpen rel ; Novolin 70/30 relion	insulin nph & regular susp pen-inj ; insulin nph isophane & regular human inj	(70-30) 100 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Humulin n ; Humulin n kwikpen ; Novolin n ; Novolin n flexpen ; Novolin n flexpen relion ; Novolin n relion	insulin nph (human) (isophane) inj ; insulin nph (human) (isophane) susp pen-injector	100 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Humulin r ; Novolin r ; Novolin r relion	Insulin Regular (Human) Inj 100 Unit/ML	100 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Humulin r u-500 (concentr	Insulin Regular (Human) Inj 500 Unit/ML	500 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Humulin r u-500 kwikpen	Insulin Regular (Human) Soln Pen-Injector 500 Unit/ML	500 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods
Insulin aspart protamine/ ; Novolog mix 70/30 ; Novolog mix 70/30 prefill ; Novolog mix 70/30 relion	insulin aspart prot & aspart (human) inj ; insulin aspart prot & aspart sus pen-inj	(70-30) 100 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Select Biosimilar ; Whole Foods
Novolin r flexpen ; Novolin r flexpen relion	Insulin Regular (Human) Soln Pen-Injector 100 Unit/ML	100 UNIT/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module: PA QL

Clinical Criteria for Approval

Formulation	Preferred Agent(s)	Non-Preferred Target Agent(s)	Stand-Alone Agent (s)
Rapid Insulin	**Fiasp** (insulin aspart) **Fiasp Flextouch** (insulin aspart) **Fiasp Penfill** (insulin aspart) **Humalog** (insulin lispro) **Humalog U200** (insulin lispro) **Lyumjev** (insulin lispro-aabc) **NovoLog** (insulin aspart)	**Admelog** (insulin lispro) **Apidra** (insulin glulisine) **Fiasp Pumpcart** (insulin aspart) **Insulin aspart** **Insulin lispro**	**None**
Regular Insulin	**Humulin R U-100** (regular human insulin) **Novolin R** (regular human insulin)	**None**	**Humulin R U-500**(regular human insulin concentrated) **ReliOn R** (regular human insulin)
NPH Insulin	**Humulin N** (human insulin isophane suspension) **Novolin**	**None**	**None**

Module	Clinical Criteria for Approval

	N (human insulin NPH)		
Mix Insulin	**Humalog 75/25** (75% insulin lispro protamine suspension/25% insulin lispro) **Humalog 50/50** (50% insulin lispro protamine suspension/50% insulin lispro) **Humulin 70/30** (70% human insulin isophane suspension/30% human insulin) **NovoLog 70/30** (70% insulin aspart protamine/30% insulin aspart)	**Insulin aspart protamine /insulin aspart Mix 70/30 Insulin lispro protamine/insulin lispro 75/25**	**None**

Non-Preferred Insulin Target Agent(s) will be approved when ONE of the following is met:

1. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent **OR**
2. BOTH of the following:
    A. The requested agent is a rapid insulin **AND**
    B. ONE of the following:
        1. The patient is currently using an insulin pump that has an incompatibility with ALL preferred rapid insulin agents that is not expected to occur with the requested agent **OR**
        2. The patient has tried and had an inadequate response to ALL preferred rapid acting insulin agents that is not expected to occur with the requested agent **OR**
        3. ALL preferred rapid acting insulin agents were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR**
        4. The patient has an intolerance or hypersensitivity to ALL preferred rapid acting insulin agents that is not expected to occur with the requested agent **OR**
        5. The patient has an FDA labeled contraindication to ALL preferred rapid acting insulin agents that is not expected to occur with the requested agent **OR**
        6. ALL preferred rapid acting insulin agents are 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. ALL preferred rapid acting insulin agents are not in the best interest of the patient based on medical necessity**OR**

Module	Clinical Criteria for Approval
	8. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL preferred rapid acting insulin agents and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 3. BOTH of the following: A. The requested agent is a regular insulin **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ALL preferred regular insulin agents that is not expected to occur with the requested agent **OR** 2. ALL preferred regular insulin agents were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 3. The patient has an intolerance or hypersensitivity to ALL preferred regular insulin agents that is not expected to occur with the requested agent **OR** 4. The patient has an FDA labeled contraindication to ALL preferred regular insulin agents that is not expected to occur with the requested agent **OR** 5. ALL preferred regular insulin agents are 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** 6. ALL preferred regular insulin agents are not in the best interest of the patient based on medical necessity **OR** 7. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL preferred regular insulin agents and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 4. BOTH of the following: A. The requested agent is a mixed insulin **AND** B. ONE of the following: 1. The patient has tried and had an inadequate response to ALL preferred mixed insulin agents that is not expected to occur with the requested agent **OR** 2. ALL preferred mixed insulin agents were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 3. The patient has an intolerance or hypersensitivity to ALL preferred mixed insulin agents that is not expected to occur with the requested agent **OR** 4. The patient has an FDA labeled contraindication to ALL preferred mixed insulin agents that is not expected to occur with the requested agent **OR** 5. ALL preferred mixed insulin agents are 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** 6. ALL preferred mixed insulin agents are not in the best interest of the patient based on medical necessity **OR** 7. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL preferred mixed insulin agents and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** 5. The requested agent is medically necessary and appropriate for the patient **OR**

Module	Clinical Criteria for Approval
	6. The patient has a physical or a mental disability that would prevent them from using ALL preferred insulin agents **OR** 7. The patient is pregnant **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **The requested agent will also be approved when the following are met:** 1. The member resides in Ohio **AND** 2. The plan is Fully Insured or HIM Shop (SG) **AND** BOTH of the following A. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** B. ONE of the following: 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] **Non-oncology compendia allowed:** DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive) **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 **Length of Approval:** 12 months NOTE: If Quantity Limit 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. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** C. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: 12 months