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

Afrezza Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
02-01-2025

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Afrezza	insulin regular (human) inh powd ; insulin regular (human) inhal powd ; insulin regular (human) inhalation powder	12 UNIT ; 4 UNIT ; 60x4 &60x8 & 60x12 UNIT ; 8 UNIT ; 90 x 4 UNIT & 90x8 UNIT ; 90 x 8 UNIT & 90x12 UNIT	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
Afrezza	Insulin Regular (Human) Inh Powd 4 & 8 & 12 Unit/Cart (60)	60x4 &60x8 & 60x12 UNIT	1260	Cartridges	30	DAYS			
Afrezza	Insulin Regular (Human) Inh Powd 90 x 8 Unit & 90 x 12 Unit	90 x 8 UNIT & 90x12 UNIT	1080	Cartridges	30	DAYS			
Afrezza	Insulin Regular (Human) Inhal Powd 90 x 4 Unit & 90 x 8 Unit	90 x 4 UNIT & 90x8 UNIT	1800	Cartridges	30	DAYS			
Afrezza	Insulin Regular (Human) Inhalation Powder 12 Unit/Cartridge	12 UNIT	900	Cartridges	30	DAYS			
Afrezza	Insulin Regular (Human) Inhalation Powder 4 Unit/Cartridge	4 UNIT	2520	Cartridges	30	DAYS	1 pack = 90 cartridges		
Afrezza	Insulin Regular (Human) Inhalation Powder 8 Unit/Cartridge	8 UNIT	1260	Cartridges	30	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
27104010002940	Afrezza	Insulin Regular (Human) Inhalation Powder 4 Unit/Cartridge	4 UNIT	1 pack = 90 cartridges			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Afrezza	insulin regular (human) inh powd ; insulin regular (human) inhal powd ; insulin regular (human) inhalation powder	12 UNIT ; 4 UNIT ; 60x4 &60x8 & 60x12 UNIT ; 8 UNIT ; 90 x 4 UNIT & 90x8 UNIT ; 90 x 8 UNIT & 90x12 UNIT	Basic ; Basic Annual ; Enhanced ; Enhanced Annual

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Afrezza	Insulin Regular (Human) Inh Powd 4 & 8 & 12 Unit/Cart (60)	60x4 &60x8 & 60x12 UNIT	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
Afrezza	Insulin Regular (Human) Inh Powd 90 x 8 Unit & 90 x 12 Unit	90 x 8 UNIT & 90x12 UNIT	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
Afrezza	Insulin Regular (Human) Inhal Powd 90 x 4 Unit & 90 x 8 Unit	90 x 4 UNIT & 90x8 UNIT	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
Afrezza	Insulin Regular (Human) Inhalation Powder 12 Unit/Cartridge	12 UNIT	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
Afrezza	Insulin Regular (Human) Inhalation Powder 4 Unit/Cartridge	4 UNIT	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
Afrezza	Insulin Regular (Human) Inhalation Powder 8 Unit/Cartridge	8 UNIT	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

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. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** 12 months

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Preferred Agent(s) | **Non-Preferred Agent(s)**

Module	Clinical Criteria for Approval

Fiasp (insulin aspart) **Humalog** (insulin lispro) **Humalog U200** (insulin lispro) **Lyumjev** (insulin lispro-aabc) **NovoLog** (insulin aspart)	**Admelog** (insulin lispro) **Apidra** (insulin glulisine) **Insulin aspart** **Insulin lispro**

Initial Evaluation

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

1. ONE of the following:
   A. The patient has a diagnosis of diabetes mellitus type 1 AND the patient is currently on long acting insulin therapy **OR**
   B. The patient has a diagnosis of diabetes mellitus type 2 **AND**
2. The patient has received ALL of the following to identify any potential lung disease:
   A. Detailed medical history review **AND**
   B. Physical examination **AND**
   C. Spirometry with Forced Expiratory Volume in 1 second (FEV1) **AND**
3. The patient has not smoked in the past 6 months **AND**
4. If the patient has an FDA labeled indication, then ONE of the following:
   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**
5. ONE of the following:
   A. The prescriber states the patient is currently being treated with a requested agent **AND** the patient is currently stable on the requested agent **OR**
   B. The patient has tried and had an inadequate response to ONE preferred agent **OR**
   C. ONE preferred agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR**
   D. The patient has an intolerance or hypersensitivity to ONE preferred agent (that is not expected to occur with the requested agent **OR**
   E. The patient has an FDA labeled contraindication to ALL preferred agents, that is not expected to occur with the requested agent **OR**
   F. ONE preferred agent 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**
   G. ONE preferred agent is not in the best interest of the patient based on medical necessity **OR**
   H. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR**
   I. The requested agent is medically necessary and appropriate for the patient **OR**
   J. There is support that the patient has a physical or a mental disability that would prevent them from using a preferred rapid acting insulin agent **OR**
   K. The patient has a documented needle phobia **AND**

Module	Clinical Criteria for Approval
	6. The patient does NOT have any FDA labeled contraindications to the requested agent **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 **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 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. The patient has received ALL of the following to identify any potential lung disease: A. Detailed medical history review **AND** B. Physical examination **AND** C. Spirometry with Forced Expiratory Volume in 1 second (FEV1) **AND** 4. The patient has not smoked in the past 6 months **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.