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This document applies to the following Participating Organizations:

Priority Partners

Keywords: afrezza

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I. POLICY

- A. Afrezza (rapid-acting insulin human inhalation powder) requires prior authorization to ensure this medication is used only when clinically appropriate. All other necessary procedures for initiation of prior authorization review can be found in the process for initiating a prior authorization request can be found in policy PHARM 20.
 - 1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
 - 2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

- A. Afrezza may be approved for patient meeting the following:
 - 1. Patient is 18 years of age or older
 - 2. Documentation has been submitted showing the patient has a predicted FEV₁>80%
 - 3. Documentation has been submitted showing one of the following:
 - a. Patient has type 1 diabetes AND the following:
 - I. prior inadequate response to a short-acting insulin
 - II. Afrezza will be used concurrently with a long-acting insulin
 - b. Patient has type 2 diabetes and had prior trial and inadequate response with a short-acting insulin

III. AUTHORIZATION PERIOD/LIMITATIONS

- A. Initial approval will be limited to 12 months of therapy
- B. Continuation of therapy may be approved in 12-month intervals with clinical documentation showing an annual FEV₁, as well as evidence that the patient has had a beneficial response to treatment

IV. EXCLUSIONS

- A. Afrezza will not be approved for the following:
 - 1. Patients with any of the following:
 - a. Chronic obstructive pulmonary disease (COPD) or Asthma
 - b. History of lung cancer
 - c. Allergy or hypersensitivity to insulin or any component of Afrezza

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- 2. Patients who are current smokers
- 3. Treatment of diabetic ketoacidosis
- 4. Any indications or uses that are not FDA-approved or guideline-supported
- B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Afrezza [prescribing information]. Danbury, CT: MannKind Corp.; February 2020

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Clarified authorization duration
07/27/2017	Updated Exclusions section regarding physician samples
07/01/2018	Removed EHP Line of Business
12/07/2021	Updated layout

Review Dates: 04/15/2015, 4/20/2016

Revision Dates: 04/20/2016, 07/27/2017, 07/01/2018, 12/07/2021

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