Drug Therapy Guidelines

<table>
<thead>
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<th>Afrezza® (insulin human)</th>
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<tbody>
<tr>
<td><strong>Medical Benefit</strong></td>
<td>Effective: 5/1/18</td>
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<tr>
<td><strong>Pharmacy-Formulary 1</strong></td>
<td>x Next Review: 3/19</td>
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<tr>
<td><strong>Pharmacy-Formulary 2</strong></td>
<td>x Date of Origin: 6/15</td>
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<tr>
<td><strong>Pharmacy-Formulary 3/Exclusive</strong></td>
<td>x Review Dates: 3/15, 3/17, 3/18</td>
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<td><strong>Pharmacy-Formulary 4/AON</strong></td>
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I. Medication Description

Afrezza (insulin human) is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus. Following pulmonary absorption into systemic circulation, the metabolism and elimination of Afrezza is comparable to that of regular human insulin.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is provided when the following criteria are met:

• Member must be 18 years or older AND
• Member must be diagnosed with diabetes mellitus AND
• Member is a non-smoker or has stopped smoking more than 6 months or more prior to request AND
• Member does not have a chronic lung disease (COPD, asthma, etc.) AND
• Detailed medical history, physical examination, and spirometry (FEV1) results have been provided to rule out potential lung disease AND
• For members with diabetes mellitus type 1, Afrezza must be used with a long-acting insulin

IV. Quantity Limitations

Provide enough units to allow three times daily dosing with meals.

V. Coverage Duration

Coverage is granted for six months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed for up to 12 months at a time based upon the following criteria:

• Stabilization of disease or in absence of disease progression AND
• Absence of unacceptable toxicity from the drug including absence of decrease in pulmonary function (pulmonary function assessment will be required after the first 6 months of therapy and annually thereafter even in absence of pulmonary symptoms).
VII. Billing/Coding Information

- Afrezza is available as 4 unit, 8 unit, and 12 unit cartridges
- Pertinent indications: Diabetes Mellitus, type I 250.01 (E10.9), Diabetes Mellitus, type II 250.00 (E11.9)

VIII. Summary of Policy Changes

- 6/15/15: new policy
- 7/1/15: formulary distinctions made
- 4/5/17: no policy changes
- 5/1/18: updated available products

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.