

## PHARMACY PRE-AUTHORIZATION CRITERIA



<b>DRUG (S)</b>	Afrezza (insulin human inhalation powder)
<b>POLICY #</b>	12101
<b>INDICATIONS</b>	Afrezza is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus.
<b>CRITERIA</b>	<p>ConnectiCare considers Afrezza to be medically necessary for patients 18 years of age or older diagnosed with Type 1 or Type 2 Diabetes Mellitus who meet all of the following criteria:</p> <p><b>Diabetes Mellitus Type 1:</b></p> <ul style="list-style-type: none"><li>• Patient is currently using a long-acting insulin</li><li>• Patient has failed to achieve HbA1c goal defined as &lt;6.5% on a short-acting insulin in combination with a longer-acting insulin</li><li>• Patient does not have underlying lung disease (Asthma, COPD)</li><li>• Baseline spirometry (FEV1) completed prior to initiation of therapy to identify potential lung disease with a documented result of FEV1 <math>\geq</math>70%</li><li>• Patient is a non-smoker or has stopped smoking more than six months prior to starting Afrezza</li></ul> <p><b>Diabetes Mellitus Type 2:</b></p> <ul style="list-style-type: none"><li>• Patient is intolerant to, or is not a candidate for, or has failed to achieve HbA1c goal, defined as &gt;6.5% on two or more oral hypoglycemic agents in combination (documentation required)</li></ul> <p><b>AND</b></p> <ul style="list-style-type: none"><li>• Treatment with an injectable insulin regimen containing a prandial insulin is ineffective for reducing A1C to goal of 7% or less after 90 days of therapy, unless contraindicated Patient does not have underlying lung disease (Asthma, COPD)</li><li>• Baseline spirometry (FEV1) completed prior to initiation of therapy to identify potential lung disease with a documented result of FEV1 <math>\geq</math>70%</li><li>• Patient is a non-smoker or has stopped smoking more than six months prior to starting Afrezza</li></ul>
<b>LIMITATIONS</b>	<p>If the above criteria are met approval of Afrezza will be granted for an initial 3 months. Subsequent approval (up to 1 year) will be based on current progress notes from the physician documenting disease status and a repeat pulmonary function test which confirms that patient has NOT experienced a decline of <math>\geq</math>20% in FEV1.</p> <p><b>Limitations of Use:</b></p> <ul style="list-style-type: none"><li>• Not a substitute for Long-Acting insulin</li><li>• Must be used in combination with LA insulin in Type 1 diabetics</li></ul>

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<b>DRUG (S)</b>	Afrezza (insulin human inhalation powder)
	<ul style="list-style-type: none"><li>• Not recommended for the treatment of diabetic ketoacidosis</li><li>• Not recommended in patients who smoke</li><li>• Contraindicated in patients with asthma or COPD (Chronic Obstructive Pulmonary Disease)</li></ul> <p>Needle phobia- ConnectiCare does not consider the drug delivery system (injection device) to be a clinical reason to use Afrezza over injectable insulins</p>
<b>REFERENCES</b>	1. Afrezza prescribing information, Sanofi Aventis, Bridgewater, NJ. October 2018
<b>P&amp;T REVIEW HISTORY</b>	4/15, 2/16, 11/16, 5/17, 5/18, 5/19
<b>REVISION RECORD</b>	9/15, 1/16, 11/16, 5/19