# Afrezza® ([Insulin Human] Inhalation Powder)
# STATEMENT OF MEDICAL NECESSITY

## Patient Information

Last Name:______________________________ First Name: ______________________________ Date of Birth: _______________

Street Address: ______________________________ City: _________________________ State:_______ Zip Code:_____________

Preferred Contact Number: _________________________ ☐ Home ☐ Cell ☐ Work______________________________________

Medical Insurance Name (required for confirmation of payer policy):__________________________ Policy Number:__________________

Prescription Insurance Name (required for PA submission): _____________________________ Policy Number:____________________

## Diagnosis, Eligibility, and Medical Need

| | | | |
|---|---|---|---|
| Diabetes Mellitus ☐ Type 1 ☐ Type 2 | If Type 2, is patient on maximum tolerated dose or Metformin intolerant? | | ☐ Yes ☐ No |
| Is the patient over 18 years of age? | ☐ Yes ☐ No | HbA1c ≥ 7%? | ☐ Yes ☐ No |
| Has the patient been a non-smoker for at least the past 6 months? | | | ☐ Yes ☐ No |
| Does the patient have chronic lung disease?*<br>*Exclusion of chronic lung disease requires detailed medical history, physical examination and spirometry (FEV1) | | | ☐ Yes ☐ No |
| Patient is unable or unwilling to inject prandial insulin **OR**<br>Patient is non-compliant with injected insulin therapy due to unwillingness to inject or intensify injections **OR**<br>Patient has used injected prandial insulin within the last 6 months without achieving goal **OR**<br>Patient has used injected prandial insulin within the last 6 months with unacceptable post prandial hypoglycemia | | | ☐ Yes ☐ No<br>☐ Yes ☐ No<br>☐ Yes ☐ No<br>☐ Yes ☐ No |
| Additional rationale: | | | |
| Additional supporting documentation attached: | ☐ Lab Results ☐ Treatment History ☐ Other Clinical Information | | |

## Treatment Plan and Authorization

| | | | |
|---|---|---|---|
| **Medication: Afrezza® ([Insulin Human] Inhalation Powder)** | **Meal 1 ___ units***<br>**Meal 2 ___ units***<br>**Meal 3 ___ units*** | **Other ___ units***<br>**Total ___ units*** | *Afrezza is administered in 4 unit increments |
| Directions for Use: | | | |
| Prescriber Last Name: | Prescriber First Name: | Practice Name: | |
| Address: | City: | State: | Zip: |
| Tax ID#: | State License#: | NPI#: | |
| Practice Contact: | Contact Phone: | Contact Fax: | |
| **Service Requested (check all that apply)**:<br>☐ Benefit Verification (if coverage status unknown) ☐ Prior Authorization ☐ Medical Exception (if appeal required) | | | |

I certify that the information provided is current, complete, and accurate to the best of my knowledge and certify that **Afrezza® ([Insulin Human] Inhalation Powder)** is medically necessary for this patient. I certify that I have obtained from my patient all required written authorization for the release of my patient's personal identification, medical and insurance information to Sanofi US and their agents and representatives. I authorize Sanofi Patient Connection, as a program that maintains technical and administrative safeguards, policies, and procedures that meet HIPAA requirements, to provide all of the included information to the patient's insurance company for the specific purposes of benefit verification, prior authorization determination, or medical exception purposes.

| **Prescriber Signature:** | **Printed Name:** | **Date:** |
|---|---|---|
| | | |

**Please fax completed form to: 866.682.9280 or phone information to: 844.3Afrezza (844.323.7399)**

***Please note:*** *This letter is intended as an example for your consideration and may not include all the information necessary to support your prior authorization request. Requirements will vary based on the health plan guidelines and patient benefit design. Please note the requesting provider is entirely responsible for ensuring the accuracy, adequacy, and supportability of all information provided.*



Please see full Prescribing Information for Afrezza, including **Boxed WARNING** at: http://products.sanofi.us/afrezza/afrezza.pdf

SANOFI Patient Connection™

## Afrezza® ([Insulin Human] Inhalation Powder) Benefit Verification Support Services

The Sanofi Patient Connection™ (SPC) program offers an efficient and convenient service to help facilitate benefit verification as well as the prior authorization (PA) and medical exception processes that some payers require for patients who have been prescribed Afrezza®.

To initiate the support services available through SPC, the healthcare provider does the following as soon as the decision has been made to treat a patient with Afrezza®:

Complete the Afrezza® Statement of Medical Necessity (SMN) form and submit via fax to: **866.682.9280**
OR
Phone in the information to a live program counselor by calling: **844.3Afrezza (844.323.7399)**
Monday through Friday 9:00 AM to 8:00 PM ET.
The SMN template in editable PDF format can be accessed at **www.visitspconline.com**.

Be sure to:

- Complete the form in its entirety, including prescriber signature (if phoning in the SMN information the caller will be asked to provide a verbal certification matching the one located on the SMN)
  - If the patient's coverage status for Afrezza® is unknown, check all 3 services boxes
  - If it is already known that a PA is required or a prescription has been denied, check the Prior Authorization and Medical Exception boxes only
- Attach any necessary or available supporting documents (such as: actual date of A1c and the %, list of tried and discontinued prescriptions, list of current prescriptions, is the patient needle phobic?, and does patient have physical or mental problems that prevent self-administration of injectable insulin?)
- Call **844.3Afrezza (844.323.7399)** with any questions

## What SPC will do:

**Review the submitted Statement of Medical Necessity form to ensure alignment with payer requirements**

Once the SMN is **COMPLETE**, SPC will:

- Conduct a Pharmacy Insurance Verification (if calling in the SMN this will be done during the call)
- If the Pharmacy IV claim is accepted and there is nothing further to verify, SPC will communicate the outcome to the provider
- If coverage needs to be further verified or if a PA is required, SPC will proactively initiate the PA and/or Appeal as necessary with the payer, usually on the same business day
- Track the progress and status with the payer, based on the payer's normal turnaround time
- Provide an outcome report to the provider within 1 business day of payer confirmation

**If Coverage is:**

**APPROVED**, SPC will fax a product coverage summary to the provider and will call the patient to advise on next steps

**DENIED**, SPC will contact the provider to discuss appeal options and patient communication

If **INCOMPLETE**, SPC will:

- Provide a status update to the provider within 1 business day in order to facilitate completion of the payer requirements as quickly as possible

If the payer requires a special form* that **IS** available to a third party, SPC will:

- Transfer the information already submitted via the Statement of Medical Necessity to the payer's required form and will submit to the prescriber for signature and any additional information
- Submit to the payer on the prescriber's behalf
- Track the progress and provide an outcome report to the provider as described in the first column

If the payer requires a special form* that **IS NOT** available to a third party, SPC will:

- Call the prescriber to advise of the payer's requirements
- Track the progress and provide an outcome report as allowable by the payer

*SPC will continually research payer requirements for prior authorization and/or medical exception requests in order to always have the most up to date information available to avoid processing delays. This is non-patient specific research and some requirements could vary based on a patient's plan.

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