



Montana Healthcare Programs
Drug Prior Authorization Coverage Criteria

Afrezza™ (insulin human inhalation powder)

Review Criteria: Member must meet all of the following criteria specific to diagnosis:

- **For Type 1 Diabetes:**

- Initiation of Therapy:
 - Documentation is provided that treatment with an injectable preferred prandial insulin has been ineffective in reducing A1C to $\leq 7\%$ after at least 90 days of therapy
 - Must be used concurrently with a long-acting insulin
 - Documentation must be provided that patient does not smoke or, if has quit smoking, must be > 6 months prior
 - Pulmonary function tests must be performed prior to initiation of treatment
 - Limitations:
 - Initial approval x 6 months
- Continuation of Therapy:
 - Repeat pulmonary function testing (PFT) confirms the patient is not experiencing a decline of 20% or more in forced expiratory volume in the first second (FEV1)
 - Documentation is provided of positive clinical response to therapy
 - Reauthorization annually.

- **For Type 2 Diabetes:**

- Initiation of Therapy:
 - Documentation is provided that treatment with metformin has been ineffective in reducing A1C to $\leq 7\%$ after at least 90 days of therapy (should be continued unless contraindicated) AND
 - Documentation is provided that treatment with an injectable insulin regimen containing a prandial insulin is ineffective for reducing A1C goal to $\leq 7\%$ after at least 90 days of therapy
 - Documentation must be provided that patient does not smoke or if has quit smoking, must be > 6 months prior AND
 - Pulmonary function tests must be performed prior to initiation of treatment
 - Limitations:
 - Initial approval x 6 months
- Continuation of Therapy:

- Repeat PFT confirms the patient is not experiencing a decline of 20% or more in FEV1
- Patient continues to not smoke
- Documentation is provided of positive clinical response to therapy
- Reauthorization annually