Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.029	**Effective Date: 01/01/2020** **Revision Date: 10/2021**
Policy Name: Hypoglycemics, Insulin and Related Agents	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2022 annual review: no changes.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Hypoglycemics, Insulin and Related Agents

Reference Number: PHW.PDL.029
Effective Date: 01/01/2020
Last Review Date: 10/2021

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Insulin and Related Hypoglycemic Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Hypoglycemics, Insulin and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Insulin and Related Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemics, Insulin and Related Agent that does not contain a glucagon-like peptide-1 (GLP-1) receptor agonist.

2. A Hypoglycemics, Insulin and Related Agents combination agent that contains a glucagon-like peptide-1 (GLP-1) receptor agonist.

3. A Hypoglycemics, Insulin and Related Agents combination agent that contains a glucagon-like peptide-1 (GLP-1) receptor agonist with a prescribed quantity that exceeds the quantity limit.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemics, Insulin and Related Agent, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For a non-preferred Hypoglycemics, Insulin and Related Agent that does not contain a glucagon-like peptide-1 (GLP-1) receptor agonist, whether the beneficiary:

   a. Has a diagnosis of type 1 or type 2 diabetes mellitus

      AND

   b. Has a documented history of contraindication or intolerance to the preferred Hypoglycemics, Insulin and Related Agents that would not be expected to occur with the requested medication

AND

2. For Afrezza, whether the beneficiary:

   a. Is 18 years of age or older

      AND

   b. Is prescribed the medication by or in consultation with an endocrinologist

      AND

   c. Has a documented history of therapeutic failure, contraindication, or intolerance to short- and rapid-acting injectable Hypoglycemics, Insulin and Related Agents

      AND

   d. Has been evaluated for lung function, including a documented detailed medical history, physical examination, and spirometry testing

      AND

   e. Does not have any contraindications to Afrezza

      AND

   f. Does not have active lung cancer or a history of lung cancer

      AND

   g. Has a documented medical history of abstinence from smoking for at least 6 months and is not currently a smoker

      AND

   h. Will be assessed for lung function using spirometry testing six (6) months after initiating Afrezza and annually thereafter

      AND

   i. Has a documented baseline hemoglobin A1c (HbA1c)

      AND

   j. For type 1 diabetes mellitus, will be using Afrezza in conjunction with a long-acting insulin

OR

k. For type 2 diabetes mellitus, has a documented history of:

i. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using maximum tolerated doses of metformin in combination with maximum tolerated doses of the second line agents used to treat type 2 diabetes in accordance with the most recent American Diabetes Association (ADA) guidelines

OR

ii. A contraindication or intolerance to metformin and the second line agents used to treat type 2 diabetes in accordance with the most recent ADA guidelines

AND

3. For a Hypoglycemics, Insulin and Related Agents combination agent that contains a glucagon-like peptide-1 (GLP-1) receptor agonist, whether the beneficiary:

a. Has a diagnosis of type 2 diabetes mellitus

AND

b. Has a documented history of:

i. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using maximum tolerated doses of metformin

OR

ii. A contraindication or intolerance to metformin

AND

iii. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using basal insulin

OR

iv. Failure to achieve glycemic control as evidenced by the beneficiary's HbA1c values using a GLP-1 receptor agonist

AND

c. Will not be using the requested agent in combination with any other product containing a GLP-1 receptor agonist

AND

d. For a non-preferred agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Hypoglycemics, Insulin and Related Agents combination agent that contains a GLP-1 receptor agonist

AND

e. If a prescription for a Hypoglycemics, Insulin and Related Agents combination agent that contains a GLP-1 receptor agonist is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPTIONS FOR HYPOGLYCEMICS, INSULIN AND RELATED AGENTS: The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Hypoglycemics, Insulin and Related Agents that were previously approved will take into account the following:

1. For Afrezza, whether the beneficiary:

   a. Has improved glycemic control as evidenced by a recent documented HbA1c value

   AND

   b. Is prescribed the medication by or in consultation with an endocrinologist

   AND

   c. Has been evaluated for lung function using spirometry testing approximately 6 months after starting Afrezza, and, if applicable, annually thereafter

   AND

   d. Did not have a decline in FEV_1 of >20% from baseline since starting Afrezza

AND

e. Has a documented medical history of abstinence from smoking for at least 6 months and is not currently a smoker

AND

f. Does not have any contraindications to Afrezza

AND

g. Does not have active lung cancer

AND

h. Did not experience any bronchospasm, wheezing, or other respiratory difficulties after using Afrezza

AND

2. For a Hypoglycemics, Insulin and Related Agents combination agent that contains a glucagon-like peptide-1 (GLP-1) receptor agonist, whether the beneficiary:

   a. Has improved glycemic control as evidenced by a recent HbA1c value

   AND

   b. Will not be using the requested agent in combination with any other product containing a GLP-1 receptor agonist

   AND

   c. If a prescription for a Hypoglycemics, Insulin and Related Agents combination agent that contains a GLP-1 receptor agonist is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemics, Insulin and Related Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **Approval duration: 12 months**

E. References

1. Afrezza (human insulin) package insert. Danbury, CT: MannKind Corporation; October 2014.
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4. Beaser RS, Hollander PA, Silvestri R. Inhaled insulin: pulmonary considerations. Medscape. http://www.medscape.org/viewarticle/556041. Accessed February 9, 2015.
5. American Diabetes Association. Pharmacologic approaches to glycemic treatment. Sec. 8. In Standards of Medical Care in Diabetes – 2018. Diabetes Care. 2018;41(Suppl. 1):S73-S85. https://doi.org/10.2337/dc18-S008.
6. American Diabetes Association. Cardiovascular disease and risk management. Sec. 9. In Standards of Medical Care in Diabetes – 2018. Diabetes Care. 2018;41(Suppl. 1):S86-S104. https://doi.org/10.2337/dc18-S009.
7. Soliqua 100/33 [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; November 2016.
8. Xultophy 100/3.6 [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; November 2016.
9. McCulloch DK. Initial management of blood glucose in adults with type 2 diabetes mellitus. In: UpToDate [internet database]. Nathan DM, Mulder JE, eds. Waltham, MA: UpToDate. Revised October 18, 2017. Accessed January 24, 2018.
10. Dungan K, DeSantis A. Glucagon-like peptide-1 receptor agonists for the treatment of type 2 diabetes mellitus. In: UpToDate [internet database]. Nathan DM, Mulder JE, eds. Waltham, MA: UpToDate. Revised January 17, 2018. Accessed January 25, 2018.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022 annual review: no changes.	10/2021