


ISSUE DATE December 13, 2018	EFFECTIVE DATE December 17, 2018	NUMBER *See below
SUBJECT Prior Authorization of Hypoglycemics, Insulin and Related Agents – Pharmacy Services	BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs	

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at:
http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Hypoglycemics, Insulin and Related Agents submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services under the MA managed care delivery system should address any questions related to Hypoglycemics, Insulin and Related Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (DHS) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and

*01-18-30	09-18-31	27-18-30	33-18-30
02-18-25	11-18-25	30-18-25	
03-18-26	14-18-26	31-18-31	
08-18-33	24-18-27	32-18-25	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

quality and to recommend interventions for prescribers and pharmacists through the DHS Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

Soliqua (insulin glargine/lixisenatide) and Xultophy (insulin degludec/liraglutide) are combination agents that contain a basal insulin and a glucagon-like peptide-1 (GLP-1) receptor agonist. They are U.S. Food and Drug Administration approved for the treatment of adults with type 2 diabetes mellitus who are inadequately controlled on basal insulin or a GLP-1 receptor agonist alone. In November 2017, Soliqua (insulin glargine/lixisenatide) and Xultophy (insulin degludec/liraglutide) were added to the Hypoglycemics, Insulin and Related Agents class on the DHS Preferred Drug List. During the September 25, 2018, DUR Board meeting, the DUR Board recommended revisions to the thresholds for prior authorization and corresponding medical necessity guidelines for Hypoglycemics, Insulin and Related Agents to ensure appropriate patient selection and drug utilization of these combination agents. The proposed revisions, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of Hypoglycemics, Insulin and Related Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Hypoglycemics, Insulin and Related Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Hypoglycemics, Insulin and Related Agents

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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. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Insulin and Related Agents at: <https://papdl.com/preferred-drug-list>.
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. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

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:

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- 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

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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

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- 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 the Quantity Limits Chapter.

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

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- 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 FEV₁ 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

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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 the Quantity Limits Chapter.

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. References

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