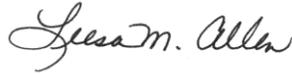




ISSUE DATE May 11, 2015	EFFECTIVE DATE May 18, 2015	NUMBER *See below
SUBJECT Prior Authorization of Hypoglycemics, Insulin – Pharmacy Service	BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs	

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers about new requirements for prior authorization of Afrezza.
2. Issue handbook pages that include instructions on how to request prior authorization of Hypoglycemics, Insulin, including the type of medical information needed to evaluate requests for medical necessity.

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 (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND:

The Department of Human Services’ (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department’s Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

*01-15-10	09-15-09	27-15-08	33-15-09
02-15-08	11-15-08	30-15-08	
03-15-08	14-15-08	31-15-09	
08-15-10	24-15-08	32-15-08	

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.state.pa.us/provider/healthcaremedicalassistance/index.htm>

DISCUSSION:

During the March 18, 2015, meeting, the DUR Board recommended guidelines to determine medical necessity of Afrezza, a medication in the Preferred Drug List (PDL) class of Hypoglycemics, Insulin. The delivery system for Afrezza is vastly different from that of conventional insulin or inhalers used for other indications, necessitating intensive patient counseling regarding use of the device, with reinforcement by both the prescriber and the dispensing pharmacist. The proposed guidelines to determine medical necessity address appropriate patient selection and drug utilization. The guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of Afrezza are included in the attached updated provider handbook pages.

PROCEDURE:

The procedures for prescribers to request prior authorization of Hypoglycemics Insulin are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapters related to Hypoglycemics, Insulin) 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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Hypoglycemics, Insulin

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Insulin that meet the following condition must be prior authorized:

1. A prescription for a non-preferred Hypoglycemic, Insulin. See Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Insulin at:
www.providersynergies.com/services/documents/PAM_PDL.pdf

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Hypoglycemic, Insulin, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Has a diagnosis of Diabetes Mellitus Type 1 or Type 2

AND

2. Has a documented history of intolerance to the preferred Hypoglycemics, Insulin

AND

3. For Afrezza, the recipient:

- 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

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

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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 Diabetes Mellitus Type I, will be using Afrezza in conjunction with a long-acting insulin

OR

- k. For Diabetes Mellitus Type II, has a documented history of:

- i. Failure to achieve glycemic control as evidenced by the recipient'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

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OR

4. Does not meet the clinical review guidelines listed above, but in the professional judgment of the physician reviewer, the therapy is medically necessary to meet the medical needs of the recipient.

**FOR RENEWALS OF PRESCRIPTIONS FOR HYPOGLYCEMICS,
INSULIN**

The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Hypoglycemics, Insulin that were previously approved will take into account whether the recipient:

1. For Afrezza:

- 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 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

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g. Does not have active lung cancer

AND

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

OR

2. Does not meet the clinical review guideline listed above, but in the professional judgment of the physician reviewer, the therapy is medically necessary to meet the medical needs of the recipient.

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 the request for a prescription for a Hypoglycemic, Insulin. 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 recipient.

References:

1. Afrezza (human insulin) package insert. Danbury, CT: MannKind Corporation; October 2014.
2. McCormack MC. Office spirometry. In: UpToDate [Internet Database]. Hollingsworth H (ed). UpToDate: Waltham, MA. Updated June 13, 2013. Accessed February 6, 2015.
3. Klonoff, DC. Afrezza inhaled insulin: the fastest-acting FDA-approved insulin on the market has favorable properties. *J Diabetes Sci Technol*. 2014; 8(6):1071-1073.
4. Beaser RS, Hollander PA, Silvestri R. Inhaled insulin: pulmonary considerations. Medscape. <http://www.medscape.org/viewarticle/556041>. Accessed February 9, 2015.

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