

ISSUE DATE September 30, 2016	EFFECTIVE DATE October 3, 2016	NUMBER *See below
SUBJECT Prior Authorization of Incretin Mimetic/Enhancer Hypoglycemics - Pharmacy Services		BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate their MA enrollment every 5 years. Providers should log into PROMISE to check their revalidation date and submit a revalidation application at least 60 days prior. Enrollment (revalidation) applications may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Providers who enrolled on or before SEPTEMBER 25, 2011 must complete the revalidation process as soon as possible. DHS must complete the revalidation for all providers enrolled on or before September 25, 2011 by September 25, 2016.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the type of information needed to evaluate requests for prior authorization of prescriptions for Incretin Mimetic/Enhancer Hypoglycemics 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/DISCUSSION:

The Department of Human Services (Department) is adding references to lixisenatide (brand name Adlyxin), saxagliptin (brand name Onglyza), and some combination agents containing an SGLT2 Inhibitor to the current guidelines to determine medical necessity of Incretin Mimetic/Enhancer Hypoglycemics. All prescriptions for Incretin Mimetic/Enhancer.

*01-16-30	09-16-28	27-16-27	
02-16-26	11-16-26	30-16-26	
03-16-26	14-16-27	31-16-32	
08-16-28	24-16-29	32-16-25	33-16-27

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</p>

Hypoglycemics require prior authorization. The guidelines to determine medical necessity for lixisenatide and saxagliptin are the same as the guidelines for other drugs within this class that have the same warnings for impaired renal function, gastroparesis, and pancreatitis in their Food and Drug Administration (FDA) approved package inserts. The guidelines to determine medical necessity of combination agents containing an SGLT2 Inhibitor include a cross reference to the guidelines for Hypoglycemics, SGLT2 Inhibitors. There are no other changes to the medical necessity guidelines.

PROCEDURE:

The procedures for prescribers to request prior authorization of Incretin Mimetic/Enhancer Hypoglycemics 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 chapter related to Incretin Mimetic/Enhancer Hypoglycemics) 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
Incretin Mimetic/Enhancer Hypoglycemics

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Incretin Mimetic/Enhancer Hypoglycemics (formerly referred to as Other Hypoglycemics)

A. Thresholds for Prior Authorization

Prescriptions for Incretin Mimetic/Enhancer Hypoglycemics that meet the following conditions must be prior authorized:

1. A prescription for a preferred or a non-preferred Incretin Mimetic/Enhancer Hypoglycemic, regardless of the quantity prescribed. See Preferred Drug List (PDL) for the list of preferred and non-preferred Incretin Mimetic/Enhancer Hypoglycemics at: www.papdl.com
2. A prescription for a preferred or non-preferred Incretin Mimetic/Enhancer Hypoglycemic with a prescribed quantity that exceeds the quantity limit.
See Quantity Limits for the list of drugs with quantity limits at: <http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacyservices/quantitylimitslist/index.htm>

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Incretin Mimetic/Enhancer Hypoglycemic, the determination of whether the requested prescription is medically necessary will take into account the following:

1. Whether the recipient:
 - a. Has a diagnosis of Type 2 Diabetes Mellitus

AND

 - b. Is 18 years of age or older

AND

 - c. 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 a sulfonylurea

OR

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- ii. A contraindication or intolerance to metformin and sulfonylurea

AND

- d. Does not have a HbA1c \geq 12% in absence of ketosis

AND

- e. Does not have a documented history of contraindication to the requested medication

AND

- f. Is being prescribed a dose of the requested medication that is appropriate for his/her renal function according to package labeling

AND

- g. For exenatide and lixisenatide, has a CrCl \geq 30mL/minute

AND

- h. For agents containing a TZD, has no evidence of heart failure, renal insufficiency, or bladder cancer

AND

- i. For agents containing alogliptin, does not have liver function tests (LFTs) greater than 3 times the upper limit of normal

AND

- j. For albiglutide, dulaglutide, exenatide, liraglutide, and lixisenatide, does not have a history, or is not presenting symptoms, of gastroparesis

AND

- k. For agents containing albiglutide, alogliptin, dulaglutide, exenatide liraglutide, linagliptin, lixisenatide, saxagliptin and sitagliptin, does not have a history or is not presenting symptoms of pancreatitis

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

AND

- I. For a combination agent containing an SGLT2 inhibitor, meets the guidelines in the handbook chapter for Hypoglycemics, SGLT2 Inhibitors

Note for renewals: Requests for prior authorization of renewals of prescriptions for an Incretin Mimetic/Enhancer Hypoglycemic that were previously approved will take into account whether the recipient:

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

AND

- b. Does not have a documented history of contraindication to the requested medication

AND

- c. Is being prescribed a dose of the requested medication that is appropriate for the renal function according to package labeling

AND

- d. For exenatide and lixisenatide, has a CrCl \geq 30mL/minute

AND

- e. For albiglutide, dulaglutide, exenatide, liraglutide, and lixisenatide, does not have a documented history or is not presenting symptoms of gastroparesis

AND

- f. For agents containing albiglutide alogliptin, dulaglutide, exenatide, liraglutide, linagliptin, lixisenatide, saxagliptin and sitagliptin, does not have a documented history or is not presenting symptoms of pancreatitis

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- g. For a combination agent containing an SGLT2 inhibitor, meets the guidelines in the handbook chapter for Hypoglycemics, SGLT2 Inhibitors

2. For **Symlin**, whether the recipient:

- a. Has a diagnosis of Type 1 Diabetes Mellitus with the following:
 - i. Requires three (3) or more insulin injections daily (using a medically acceptable regimen of insulin that is consistent with current medical standards)

OR

- ii. Is using an insulin pump

OR

- b. Has a diagnosis of Type 2 Diabetes Mellitus with the following:
 - i. A documented history of failure to respond to maximum tolerated doses of metformin as evidenced by the recipient's HbA1c value

OR

- ii. A documented history of a contraindication or intolerance of metformin

AND

- iii. Requires three (3) or more insulin injections daily (using a medically acceptable regimen of insulin that is consistent with current medical standards)

OR

- iv. Is using an insulin pump

AND

- c. Failed to achieve adequate glycemic control despite compliance with individualized insulin management, defined as:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- i. HbA1c level is greater than 7.5% and less than 9%

OR

- ii. Marked day-to-day variability in glucose levels (based on review of self-monitoring blood glucose levels)

AND

- d. Carries out home blood glucose monitoring three (3) or more times per day

AND

- e. Has no history of recurrent severe hypoglycemia requiring medical intervention during the previous six (6) months

AND

- f. Has no need for medications that stimulate GI motility

AND

- g. Is 18 years of age or older

AND

- h. Does not have a documented history of a contraindication to Symlin

Note: For renewals of prescriptions for Symlin: Requests for prior authorization of renewals of Symlin that were previously approved will take into account the following:

- a. Improved glycemic control as evidenced by HbA1c lowering from baseline

AND

- b. No recurrent, unexplained hypoglycemia that requires medical intervention

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- c. No persistent clinically significant nausea or associated abdominal pain

AND

- d. No need for medications that stimulate GI motility

AND

- e. Compliance with self-monitoring of blood glucose concentrations

AND

- f. Does not have a documented history of a contraindication to Symlin

- 3. For all non-preferred Incretin Mimetic/Enhancer Hypoglycemics, whether the recipient has a documented history of therapeutic failure, contraindication or intolerance of the preferred Incretin Mimetic/Enhancer Hypoglycemics

OR

- 4. For all Incretin Mimetic/Enhancer Hypoglycemics, if the request 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
- 5. If a prescription for an Incretin Mimetic/Enhancer Hypoglycemic 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.

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 an Incretin Mimetic/Enhancer Hypoglycemic. If the applicable guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the applicable 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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

D. References

1. Lexi-Comp Reader. Lexi-Comp, Inc., 2009.
2. Genuth S, Eastman R, and Kahn R. et al. "Implications of the United Kingdom Prospective Diabetes Study." *Diabetes Care*. 2002; 25(1); S28-32.
3. Matthew, Sheetz, and King George. "Molecular Understanding of Hyperglycemia's Adverse Effects for Diabetic Complications." *JAMA* 2002: 288; 2579-588.
4. UpToDate Online 17.2. 2009. Web. <<http://www.uptodate.com>>.
5. Nathan DM, Buse JB, Davidson MB, et al. "Medical Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy: A Consensus Statement of the American Diabetes Association and the European Association for the Study of Diabetes." *Diabetes Care*. Jan 2009; 32(1): 193 – 203.
6. Mikhail NE. "Is Exenatide a Useful Addition to Diabetes Therapy?" *Endocrine Practice*. June 2006; 12(3): 307-314.
7. UpToDate Online 17.2. 2009. Web. <<http://www.uptodate.com>>.
8. UpToDate Online 17.2. 2009. Web. <<http://www.uptodate.com>>.
9. Rodbard HW, Jellinger PS, Davidson JA et al. "Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology Consensus Panel on Type 2 Diabetes Mellitus: An Algorithm for Glycemic Control." *Endocrine Practice*. October 2009; 15(6): 540-559.
10. Food and Drug Administration. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. 2009. Web. <<http://www.fda.gov/safety/MedWatch>>.
11. American Diabetes Association: Standards of Medical Care in Diabetes – 2010. *Diabetes Care*. January 2010; 33(1): S11-S61.
12. Inzucchi, S.E, et.al. "Management of hyperglycemia in type 2 diabetes: a patient-centered approach. Position statement of the American Diabetes Association (ADA) and the European Diabetes Association (EASD)" *Diabetes Care*. June 2012; 35 (1364-1379).
13. Bydureon package insert. Amylin Pharmaceuticals, Inc., San Diego, CA; January 2012
14. Januvia [package insert]. Merck & Co. Whitehouse Station, NJ. 2007.
15. Jentadueto package insert. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT; January 2012
16. Juvisync package insert. Merck and Co., Inc. Whitehouse Station, NJ; March 2012
17. Symlin [package insert]. Amylin Pharmaceuticals. San Diego, CA. 2008.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

18. Onglyza [package insert]. Bristol-Myers Squibb. Princeton, NJ 08543.
19. Victoza [package insert]. Novo Nordisk A/S. Princeton, NJ 141522.
20. Tradjenta package insert. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT; May 2011