



ISSUE DATE July 5, 2016	EFFECTIVE DATE July 11, 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 albiglutide (brand name Tanzeum) and dulaglutide (brand name Trulicity) to the current guidelines to determine medical necessity of Incretin Mimetic/Enhancer Hypoglycemics. Both are included in the Incretin Mimetic/Enhancer Hypoglycemics class of drugs, both require prior authorization, and the guidelines to determine medical necessity for both are the same as the guidelines for other drugs within this class.

*01-16-23	09-16-21	27-16-21	
02-16-20	11-16-20	30-16-20	
03-16-20	14-16-21	31-16-25	
08-16-21	24-16-23	32-16-19	33-16-20

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>

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, has a CrCl \geq 30mL/minute

AND

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

AND

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

AND

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

AND

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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, has a CrCl \geq 30mL/minute

AND

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

AND

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

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)

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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:

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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

- 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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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.

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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.
 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