


ISSUE DATE December 13, 2018	EFFECTIVE DATE December 17, 2018	NUMBER *See below
SUBJECT Prior Authorization of Hypoglycemics, Incretin Mimetics/Enhancers – 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, Incretin Mimetics/Enhancers 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, Incretin Mimetics/Enhancers 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

*01-18-29	09-18-30	27-18-29	33-18-29
02-18-24	11-18-24	30-18-24	
03-18-25	14-18-25	31-18-30	
08-18-32	24-18-26	32-18-24	

<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>

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

DISCUSSION:

During the September 25, 2018, DUR Board meeting, the DUR Board recommended removing multiple elements from the medical necessity guidelines for Hypoglycemics, Incretin Mimetics/Enhancers based on the recommendations of multiple national treatment guidelines to individualize drug therapy and the lack of compelling medical literature and guidelines that definitively support the use of specific classes of hypoglycemics as second-line choices. The DUR Board also recommended automating prior authorization of preferred Hypoglycemics, Incretin Mimetics/Enhancers (except for amylin analogs). The proposed revisions to 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 DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of Hypoglycemics, Incretin Mimetics/Enhancers 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, Incretin Mimetics/Enhancers) 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, Incretin Mimetics/Enhancers

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Hypoglycemics, Incretin Mimetics/Enhancers

A. Prescriptions That Require Prior Authorization

All prescriptions for Hypoglycemics, Incretin Mimetics/Enhancers must be prior authorized.

1. See the Preferred Drug List (PDL) for the list of preferred and non-preferred Hypoglycemics, Incretin Mimetics/Enhancers at:
<https://papdl.com/preferred-drug-list>.
2. 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, Incretin Mimetic/Enhancer, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a glucagon-like peptide-1 (GLP-1) receptor agonist or dipeptidyl peptidase-4 (DPP-4) inhibitor:
 - 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

2. For an amylin analog:
 - a. Has a diagnosis of type 1 diabetes mellitus

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

OR

- b. Has a diagnosis of type 2 diabetes mellitus and 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

- c. Failed to achieve adequate glycemic control as evidenced by the beneficiary's HbA1c values despite compliance with optimal insulin therapy

AND

- d. Will be prescribed the requested amylin analog in combination with insulin

AND

- 3. For a non-preferred Hypoglycemics, Incretin Mimetic/Enhancer, has a documented history of therapeutic failure, contraindication, or intolerance of the preferred Hypoglycemics, Incretin Mimetics/Enhancers with the same mechanism of action

AND

- 4. If a prescription for a Hypoglycemics, Incretin Mimetic/Enhancer 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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

FOR RENEWALS OF PRESCRIPTIONS FOR AN AMYLIN ANALOG:
Requests for prior authorization of renewals of prescriptions for an amylin analog that were previously approved will take into account whether the beneficiary:

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

AND

2. If a prescription for an amylin analog 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.

C. Automated Prior Authorization

Prior authorization of a prescription for a preferred Hypoglycemics, Incretin Mimetic/Enhancer (except for an amylin analog) with a prescribed quantity that does not exceed the quantity limit will be automatically approved when the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim(s) within 90 days of the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.

D. 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, Incretin Mimetic/Enhancer. 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 beneficiary.

E. References

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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. Juvисync 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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

21. 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>.
22. 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>.
23. Garber AJ, Abrahamson MJ, Barzilay JI, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm – 2017 executive summary. Endocr Pract. 2017;23(2):207-238.
24. 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.
25. 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.
26. Dungan K, DeSantis A. Dipeptidyl peptidase-4 (DPP-4) inhibitors for the treatment of type 2 diabetes mellitus. In: UpToDate [internet database]. Nathan DM, Mulder JE, eds. Waltham, MA: UpToDate. Updated October 19, 2017. Accessed January 25, 2018.