Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 7/31/2018**
Policy Number: PA.CP.PPA.21	**Effective Date: 01/2018** **Revision Date: 07/18/2018**
Policy Name: Glucagon-like peptide-1 receptor agonists for type 2 diabetes	**HC Approval Date:**

Type of Submission – Check all that apply:

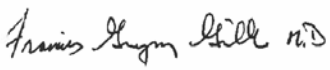
- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy** – *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

PA.CP.PST.14 Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Glucagon-like peptide-1 receptor agonists for type 2 diabetes

Reference Number: PA.CP.PPA.21
Effective Date: 01/18
Last Review Date: 11/17
Line of Business: Medicaid

Coding Implications
Revision Log

Description
The following agents are synthetic glucagon-like peptide-1 (GLP-1) receptor agonists requiring prior authorization: albiglutide (Tanzeum®), dulaglutide (Trulicity®), exenatide ER (Bydureon®), exenatide IR (Byetta®), liraglutide (Victoza®), and lixisenatide (Adlyxin®).

FDA approved indication
GLP-1 receptor agonists are indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria**

GLP-1 receptor agonists indicated for type 2 diabetes are medically **necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Diabetes Mellitus (must meet all)**:**

1. Diagnosis of type 2 diabetes;
2. Failure of ≥ 3 month trial of metformin at doses ≥ 2000 mg/day, unless member experiences clinically significant adverse effects or has contraindication(s) to metformin;
3. HbA1c drawn within the past 3 months is ≥ 6.5%;
4. Member meets one of the following (a or b):
   a. Request is for a PDL agent: Byetta, Bydureon, or Victoza;
   b. Failure of adherent use of two PDL agents: Byetta/Bydureon and Victoza, each used concurrently with metformin for ≥ 3 months, unless member experiences clinically significant adverse effect or has contraindications(s) to these agents;
5. Requested dose does not exceed FDA approved maximum recommended dose for type 2 diabetes and health plan approved quantity limit.

Approval duration: 6 months

B. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Diabetes Mellitus (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member meets one of the following (a, b, or c):
   a. Request is for a dose increase;
   b. HbA1c drawn within the past 3 months demonstrates positive response to therapy as indicated by one of the following (i or ii):
      i. Initial reauthorization: HbA1c is < 8.5% and shows reduction from pretreatment level;
      ii. Subsequent reauthorization: HbA1c is < 8.5% and shows continued reduction or maintenance of initial reduction from pretreatment level;
   c. HbA1c is ≥ 8.5% and member will be managed with one of the following, unless contraindicated or intolerant (i or ii):
      i. A three-drug regimen titrated to therapeutic doses;
      ii. A regimen containing insulin;
3. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose for type 2 diabetes and health plan approved quantity limit.

Approval duration: 12 months *(6 months if request is for a dose increase)*

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Type 1 diabetes mellitus
B. Prediabetes
C. Diabetic ketoacidosis
D. Obesity
E. All other non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy.

IV. Appendices/General Information

Appendix A: Abbreviation Key
ADA: American Diabetes Association
ER: extended-release
FDA: Food and Drug Administration
GLP-1: glucagon-like peptide-1
HbA1c: glycated hemoglobin
IR: immediate-release
PDL: preferred drug list

Appendix B: HbA1c Goals per ADA Guidelines
According to the American Diabetes Association (ADA), the goal of treatment can be as lenient as HbA1c < 8.5% depending on the patient. Per ADA, HbA1c levels above 8.5% are not recommended as they may expose patients to more frequent high glucose values and acute risks from glycosuria, dehydration, hyperglycemic hyperosmolar syndrome, and poor wound healing.

V. Dosage and Administration

- Tanzeum
  - 30 mg to 50 mg SC once weekly
- Byetta
  - 5 mcg to 10 mcg SC twice daily
- Bydureon
  - 2 mg SC once weekly
- Trulicity
  - 0.75 mg to 1.5 mg SC once weekly
- Victoza
  - Initial dose: 0.6 mg SC daily for 7 days (2 or 3 pens)
  - Maintenance dose: 1.2 mg to 1.8 mg SC daily
- Adlyxin
  - Initial dose: 10 mcg SC daily for 14 days
  - Maintenance dose: 20 mcg SC daily

VI. Product Availability

- Route of administration: injectable for subcutaneous administration
  - Tanzeum
    - Single dose prefilled pen powder: 30 mg and 50 mg
  - Byetta
    - Prefilled pen: 5 mcg/dose (0.02 ml) in 1.2 mL (60 doses)
    - Prefilled pen: 10 mcg/dose (0.04 ml) in 2.4 mL (60 doses)
  - Bydureon
    - Single-dose tray: 2 mg vial
    - Single-dose prefilled pen: 2 mg pen
  - Trulicity
    - Single-dose prefilled pen: 0.75 mg/0.5ml and 1.5 mg /0.5ml
    - Single-dose prefilled syringe: 0.75 mg/0.5ml and 1.5 mg /0.5ml
  - Victoza
    - Multi-dose prefilled pen: 6 mg/mL in 3mL (2 or 3 pens)
    - Pen delivers doses of 0.6 mg, 1.2 mg, or 1.8 mg
  - Adlyxin
    - Multi-dose prefilled pen: 50 mcg/mL in 3 mL (14 doses; 10 mcg/dose)
    - Multi-dose prefilled pen: 100 mcg/mL in 3 mL (14 doses; 20mcg/dose)

VII. References

1. American Diabetes Association. Standards of medical care in diabetes—2016. Diabetes Care. 2016; 39(suppl 1): S1-S106.
2. Adlyxin [Prescribing information]. Bridgewater, NJ: Sanofi-aventis US LLC. July 2016
3. Bydureon [Prescribing information]. San Diego, CA: Amylin Pharmaceuticals, Inc; September 2015.
4. Byetta [Prescribing information]. San Diego, CA: Amylin Pharmaceuticals, Inc; February 2015.
5. Tanzeum [Prescribing information]. Wilmington, DE: GlaxoSmithKline; September 2016.
6. Trulicity [Prescribing information]. Indianapolis, IN: Eli Lilly and Company, Inc; March 2015.
7. Victoza [Prescribing information]. Princeton, NJ: Novo Nordisk Inc; April 2016.

Reviews, Revisions, and Approvals	Date	Approval Date
This policy is being retired and replaced by the following policy: **PA.CP.PST.14 Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists**	7/18	

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