Clinical Policy: Glucagon-like Peptide-1 (GLP-1) Receptor Agonists
Reference Number: HIM.PA.53
Effective Date: 12/14
Last Review Date: 08/17
Line of Business: Health Insurance Marketplace Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

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

I. Initial Approval Criteria

A. Type 2 Diabetes Mellitus (must meet all)**:**

1. Diagnosis of type 2 diabetes mellitus;
2. HbA1c drawn within the past 3 months is ≥ 6.5%;
3. Failure of ≥ 3 consecutive months of metformin at doses ≥ 2000 mg/day in combination with a sulfonylurea, unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of ≥ 3 consecutive months of metformin at doses ≥ 2000 mg/day in combination with pioglitazone, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed:
   a. Byetta: 20 mcg/day;
   b. Tanzeum: 50 mg/week;
   c. Trulicity: 1.5 mg/week;
   d. Victoza: 1.8 mg/day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Type 2 Diabetes Mellitus (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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 in pretreatment level;
   c. HbA1c is ≥ 8.5%, and member will be managed on a three-drug regimen titrated to therapeutic doses or an insulin containing regimen, unless contraindicated or intolerant;
3. If request is for a dose increase, new dose does not exceed:
   a. Byetta: 20 mcg/day;
   b. Tanzeum: 50 mg/week;
   c. Trulicity: 1.5 mg/week;
   d. Victoza: 1.8 mg/day.

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 health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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

A. 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 – HIM.PHAR.21 or evidence of coverage documents
B. Type 1 diabetes mellitus
C. Prediabetes
D. Diabetic ketoacidosis
E. Obesity

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ADA: American Diabetes Association
DPP-4: dipeptidyl peptidase-4
FDA: Food and Drug Administration
GLP-1: glucagon-like peptide-1
HbA1c: glycated hemoglobin

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. References

1. American Diabetes Association. Standards of medical care in diabetes—2017. Diabetes Care. 2017; 40(suppl 1): S1-S135.
2. Byetta Prescribing Information. San Diego, CA: Amylin Pharmaceuticals, Inc.; February 2015. Available at: www.byetta.com. Accessed April 27, 2017.
3. Tanzeum Prescribing Information. Wilmington, DE: GlaxoSmithKline; September 2016. Available at: www.tanzeum.com. Accessed April 27, 2017.
4. Trulicity Prescribing Information. Indianapolis, IN: Eli Lilly and Company, Inc.; February 2017. Available at: www.trulicity.com. Accessed April 27, 2017.
5. Victoza Prescribing Information. Princeton, NJ: Novo Nordisk Inc.; April 2016. Available at: www.victoza.com. Accessed April 27, 2017

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guideline to new format. Extended approval period from 6 months to 12 months.	08/16	08/16
Removed age restriction. Modified A1c requirement from > 7% to > 6.5% and specified time frame for lab. Added specific dose and duration for metformin trial. Clarified criterion for failure of other anti-diabetic agents to specifically require a sulfonylurea and pioglitazone be used concurrently with metformin for 3 consecutive months. Removed criterion regarding concurrent insulin use as it is not an absolute contraindication. Modified initial approval duration from 12 months to 6 months to allow for earlier assessment of therapeutic response. Added criteria surrounding required therapeutic response for re-auth.	04/17	08/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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