Blue Cross Blue Shield Blue Care Network of Michigan

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RETIRED
Effective Date: 06/09/2022

ITCA 650 (exenatide implant)

HCPCS:

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. Must be 18 years and older
   b. The member's hemoglobin A1c must be greater than 7.5% which is obtained within the last 3 months
   c. Experienced intolerance or treatment failure to at least two preferred therapies; one of which is metformin unless contraindicated
   d. Member has experienced intolerance or treatment failure to all preferred GLP-1 receptor agonist products

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: FDA recommended dosing
   b. Initial Authorization Period: 6months
   c. Renewal Criteria:
      I. Documentation that the member's A1c has remained stable or decreased from the previous value

C. ITCA 650 is considered investigational when used for all other conditions, including but not limited to:
   a. First line therapy for type 2 diabetes
   b. Treatment of type 1 diabetes

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Type 2 diabetes mellitus is characterized by hyperglycemia, insulin resistance, and relative impairment in insulin secretion. Individuals at high-risk of type 2 diabetes include those with impaired fasting glucose (IFG), impaired glucose tolerance (IGT), obesity, close relatives with type 2 diabetes, or who are members of certain ethnic groups (asian, hispanic, african american).

- 29.1 million people in the United States have diabetes, but 8.1 million may be undiagnosed. About 1.4 million new cases of diabetes are diagnosed in United States every year. Cases of diagnosed diabetes cost the United States an estimated $245 billion in 2012. This cost is expected to rise with the increasing diagnoses.

- Of the 29.1 million Americans affected with diabetes, 95% have the type 2 form which is characterized by insulin resistance leading to hyperglycemia. While all treatment plans consist of diet and exercise, many oral and injectable medications are available for disease management including metformin, sulfonylureas, thiazolidinediones, sodium-glucose co-transporter 2 (SGLT-2) inhibitors, glucagon-like peptide-1 (GLP-1) receptor agonists, insulin, and dipeptidyl peptidase 4 (DPP-4) inhibitors.

- ITCA 650 is a continuous subcutaneous delivery of exenatide. Exenatide is an analog of the hormone incretin (GLP-1) which increases glucose-dependent insulin secretion, decreases inappropriate glucagon secretion, increases B-cell growth/replication, slows gastric emptying, and decreases food intake.

- ITCA 650 is placed in an office procedure in which the matchstick-sized pump is placed just under the skin of a patient's abdomen. Once in place under the skin, water from the extracellular fluid enters the pump device at one end by diffusing through a semi-permeable membrane directly into a salt osmotic engine which expands to drive a piston at a controlled rate. This allows the drug within the pump to be released in a steady, consistent fashion at the other end of the device. Each osmotic mini-pump is designed to hold an appropriate volume of drug, to treat a patient for up to a full year and beyond.

References:

1. Rosenstock J, Denham D, Prabhakar R, Azeem R, Kjehms L, Baron M. Superior efficacy of ITCA 650 vs. sitagliptin in uncontrolled type 2 diabetes on metformin: the FREEDOM 2 randomized, double-blind, 1-year study. *Diabetes.* 2016; 65(suppl1):183
2. Intracia Therapeutics, Inc. Intracia announces two positive phase 3 trials for ITCA 650 in type 2 diabetes: Freedom – 1 and Freedom -1 high baseline (HBL) study results. October 1, 2014. Available at : https://www.intarcia.com/media/press-releases.html
3. Whitson A. ITCA 650: A novel therapeutic approach to treating type 2 diabetes (T2D). *Diabetes.* 2016; 65(suppl1):1027-P
4. Intarcia announces successful cardiovascular safety results in Phase 3 FREEDOM –CVO trial for ITCA 650, an investigational therapy for type 2 diabetes [press release]. Boston, MA: Intarcia Therapeutics; June 12, 2016. http://www.intarcia.com/media/press-releases/2016-may-6-cardiovascular-safety.html
5. Caffrey M. Sanofi's lixisenatide approved, paving way for OK of combo therapy. The American Journal of Managed Care website. http://www.ajmc.com/newsroom/sanofis-lixisenatide-approved paving-way-for-ok-of-combo-therapy. Published July 28, 2016
6. American Diabetes Association. Approaches to glycemic treatment. Sec. 7. In Standards of Medical Care in Diabetes 2016. Diabetes Care 2016;39 (Suppl. 1):S52–S59

Policy History		
#	Date	Change Description
1.1	06/09/2022	Policy to be retired as drug manufacturer is no longer pursuing FDA approval
1.0	08/10/2017	Preliminary Review