Clinical Policy: Diabetes – Non-Insulin

Reference Number: OH.PHAR.PPA.50
Effective Date: 01.20 Revision Log
Last Review Date: 11.21
Line of Business: Medicaid

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

Description
Refer to *Appendix A* for drug coverage table.

FDA approved indication(s)
All non-insulin diabetes products are indicated for treatment of type 2 diabetes mellitus (T2DM).

Jardiance is also indicated for reduction of cardiovascular mortality due to major cardiovascular events (MACE) and the reduction of heart failure hospitalizations in T2DM patients with established cardiovascular disease.

Farxiga and Xigduo XR are also indicated for reduction of heart failure hospitalizations in adults with T2DM and established cardiovascular (CV) disease or multiple CV risk factors.

Invokana is also indicated for the reduction of cardiovascular mortality and MACE in T2DM patients with established cardiac disease; also to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, and reduction of heart failure hospitalizations and CV death in adults with T2DM and diabetic nephropathy with albuminuria more than 300 mg/day.

Symlin is also indicated for adjunct treatment of type 1 diabetes mellitus in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.

Victoza is also indicated for reduction of cardiovascular mortality and CV events (e.g., non-fatal myocardial infarction or non-fatal stroke) in type 2 diabetes mellitus patients who also have established CV disease and for the treatment of obesity as an adjunct to a reduced-calorie diet and increased physical activity.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation® that Non-Insulin products are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. If request is for a non-preferred medication, member meets the following:

a. Inadequate clinical response or failure (i.e., inability to reach HbA1C goal) of ≥ 60 days of recommended therapeutic dose with documented adherence of at least three preferred products, unless member meets one of the following (i, ii, or iii);
   i. Allergy to medications not requiring prior approval;
   ii. Contraindication to or drug interaction with medications not requiring prior approval;
   iii. History of unacceptable/toxic side effects to medications not requiring prior approval;

4. If request is for Glyxambi®, Qtern®, or Steglujan®, failure of ≥ 90 days of at least one preferred Dipeptidyl Peptidase-4 (DPP-4) inhibitor and Sodium-Glucose Co-Transporter 2 (SGLT2) inhibitor;
5. If request is for Soliqua® or Xultophy®, documentation must address inability to use the individual components.

Approval Duration: 12 months

II. Continued Therapy

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose.

Approval duration: 12 months

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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Drug Coverage Table

DIABETES – ORAL HYPOGLYCEMICS, BIGUANIDES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
METFORMIN (generic of Glucophage®) METFORMIN ER (generic of Glucophage XR®)	GLUCOPHAGE®, GLUCOPHAGE® XR (metformin) METFORMIN ER (generic of Fortamet®) METFORMIN SOLUTION (generic of Riomet®)

DIABETES – ORAL HYPOGLYCEMICS, BIGUANIDE/SULFONYLUREA COMBO

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"

GLIPIZIDE/METFORMIN (generic of Metaglip®) GLYBURIDE/METFORMIN (generic of Glucovance®)	METAGLIP® (glipizide/metformin) GLUCOVANCE® (glyburide/metformin)

DIABETES – ORAL HYPOGLYCEMICS, TZD / BIGUANIDE COMBO

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ACTOPLUS MET XR® (pioglitazone/metformin) PIOGLITAZONE/ METFORMIN (generic of ActoPlus Met®)	

DIABETES – DIPEPTIDYL PEPTIDASE-4 INHIBITOR

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
JANUVIA® (sitagliptin) TRADJENTA™ (linagliptin)	ALOGLIPTIN (generic of Nesina®) ONGLYZA® (saxagliptin)

DIABETES – DIPEPTIDYL PEPTIDASE-4 INHIBITOR COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
JANUMET™ (sitagliptin/ metformin) JANUMET XR™ (sitagliptin/ metformin) JENTADUETO™ (linagliptin/ metformin)	JENTADUETO® XR (linagliptin/ metformin) ALOGLIPTIN/METFORMIN (generic of Kazano®) KOMBIGLYZE XR® (saxagliptin/metformin)

DIABETES – ORAL HYPOGLYCEMICS, TZD / DPP-4 COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	PIOGLITAZONE/ALOGLIPTIN (generic of Oseni®)

DIABETES – ORAL HYPOGLYCEMICS, SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
FARXIGA® (dapagliflozin) INVOKANA® (canagliflozin) JARDIANCE® (empagliflozin)	STEGLATRO™ (ertugliflozin)

DIABETES – ORAL HYPOGLYCEMICS, SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"

INVOKAMET® (canagliflozin/ metformin) SYNJARDY® (empagliflozin and metformin)	INVOKAMET® XR (canagliflozin/ metformin) SEGLUROMET™ (ertugliflozin/metformin) SYNJARDY® XR (empagliflozin and metformin) TRIJARDY® XR (empagliflozin/linagliptin/ metformin) XIGDUO XR® (dapagliflozin/ metformin)

DIABETES – ORAL HYPOGLYCEMICS, SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR AND DPP-4 COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
No less than 90 days of at least one preferred DPP-4 and SGLT product	GLYXAMBI® (empagliflozin/ linagliptin) QTERN® (dapaglifozin-saxagliptin) STEGLUJAN™ (ertugliflozin/sitagliptin)

DIABETES – ORAL HYPOGLYCEMICS, ALPHA-GLUCOSIDASE INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ACARBOSE (generic of Precose®) MIGLITOL (generic of Glyset®)	

DIABETES – ORAL HYPOGLYCEMICS, MEGLITINIDES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
NATEGLINIDE (generic of Starlix®) REPAGLINIDE (generic of Prandin®)	

DIABETES – ORAL HYPOGLYCEMICS, MEGLITINIDE/BIGUANIDE COMBO

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
REPAGLINIDE/ METFORMIN (generic of Prandimet®)	

DIABETES – ORAL HYPOGLYCEMICS, SULFONYLUREAS SECOND GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
GLIMEPIRIDE (generic of Amaryl®) GLIPIZIDE (generic of Glucotrol®) GLIPIZIDE ER (generic of Glucotrol XL®) GLYBURIDE (generic of Diabeta®, Micronase®) GLYBURIDE MICRONIZED (generic of Glynase PresTabs®)	

DIABETES – ORAL HYPOGLYCEMICS, THIAZOLIDINEDIONES

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PIOGLITAZONE (generic of Actos®)		

DIABETES – ORAL HYPOGLYCEMICS, TZD/SULFONYLUREAS COMBO

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	GLIMEPIRIDE/PIOGLITAZONE (generic of Duetact®)

ENDOCRINE AGENTS: DIABETES – AMYLIN ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	SYMLIN® (pramlintide)

ENDOCRINE AGENTS: DIABETES –GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BYETTA™ (exenatide) VICTOZA® (liraglutide) TRULICITY® (dulaglutide)	ADLYXIN™ (lixisenatide) BYDUREON® (exenatide) BYDUREON® BCISE (exenatide) OZEMPIC® (semaglutide) RYBELSUS® (semaglutide)

ENDOCRINE AGENTS: DIABETES – GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS & INSULIN COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	SOLIQUA™(insulin glargine/lixisenatide) XULTOPHY®(insulin degludec and liraglutide)

Appendix B: Abbreviation Key
CV: cardiovascular
DPP-4: Dipeptidyl Peptidase-4
ESKD: end stage kidney disease
FDA: Food and Drug Administration
MACE: major cardiovascular events
SGLT2: Sodium-Glucose Co-Transporter 2
T2DM: type 2 diabetes mellitus
TZD: thiazolidinedione

Appendix C: Therapeutic Alternatives

- Dosing varies by drug product. See FDA approved dosing and administration.

Appendix D: Contraindications/Boxed Warnings

- Refer to Clinical Pharmacology or other appropriate clinical resource.

V. Dosage and Administration

A. Varies by drug product. See FDA approved dosing and administration.

VI. Product Availability

A. Varies by drug product. Please refer to Clinical Pharmacology or other appropriate clinical resource for product availability.

VII. References

Refer to package inserts.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10.19	
Added Rybelsus as a non-preferred Glucagon-Like Peptide-1 Receptor Agonist	03.20	
Added continued therapy criteria (section II)	04.20	
Added Trijardy XR (empagliflozin/linagliptin/metformin) to the list of non-preferred SGLT2 inhibitor and combinations	07.20	
Added Farxiga and Invokana as step therapy, preferred SGLT2 inhibitors; added step therapy requirements for SGLT2 inhibitors are waived for members with a diagnosis of heart failure, chronic kidney disease, cardiovascular disease, or with multiple Cardiovascular disease risk factors; added Invokamet as a step therapy, preferred SGLT2 Inhibitor combination product; added miglitol as step therapy, preferred alpha-glucosidase inhibitor	10.20	
Removed requirement that HbA1c drawn within the past 3 months is > 8.5%; and replaced with statement: has there been inadequate clinical response to metformin products (either single-ingredient or in a sulfonylurea/metformin or TZD/metformin combination); changed timeframe of trial and failure of preferred metformin to ≥ 60 days instead of ≥ 90 days	05.21	
Added the following medications to preferred: Actoplus Met XR, Januvia, Tradjenta, Janumet, Janumet XR, Jentadueto, Jardiance, Farxiga, Invokana, Synjardy, Invokamet, Victoza, Trulicity, Byetta, Miglitol. Added Symlin to non-preferred and removed step therapy of insulin. Removed Avandia as product is no longer on the market. Removed criteria for step therapy. Removed requirement of inadequate clinical response to metformin products for non-preferred agents and replaced with statement: Inadequate clinical response or failure of ≥ 60 days of recommended therapeutic dose with documented adherence of at least three preferred products.	11.21	

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.