

# DRUG DETERMINATION POLICY

**Title:** DDP-43 Non-Insulin Diabetic Agents

**Effective Date:** 11/10/2020



Physicians Health Plan  
PHP Insurance Company  
PHP Service Company

## Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

### 1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

### 2.0 Background or Purpose:

GLP-1 agonists, DPP-4 inhibitors, and SGLT-2 inhibitors are traditional non-insulin drugs indicated for the treatment of diabetes. These criteria were developed and implemented to ensure these drugs are used at the appropriate place in therapy and severity of disease.

### 3.0 Clinical Determination Guidelines:

Document the following with chart notes:

- A. Diagnosis and severity: Diabetes Melitus Type II
- B. Preferred Agents (refer to 3.0.F) [must meet one listed below]:
  1. Metformin step therapy [must one or both listed below]:
    - a. Dosage regimen: 1000 mg twice daily for three months.
    - b. Gastrointestinal side effects from metformin immediate release (IR): uses metformin extended release (ER)
- C. Prior authorized agents (refer to 3.0.F):
  1. All preferred formulary agents in specific drug class are contraindicated; inadequate response after three month trial or significant adverse effects.

D. Excluded agents (refer to 3.0.F) [must meet one listed below]:

1. All preferred formulary anti-diabetic agents are contraindicated; inadequate response after three month trial or significant adverse effects.

E. Approval.

1. Hgb A1c: measured after three months of consistent use of the preferred agent(s).
  - a. GLP-1: at least 7 percent.
  - b. DPP-4 Inhibitors and SGLT-2 inhibitors: 7 to 9 percent (these agents will not sufficiently decrease Hgb A1c if more than 9 percent).
2. Duration:
  - a. Initial: six months.
  - b. Reapproval: one year (reduced Hgb A1c).

F. Non-Insulin diabetic agents dosage and formulary status.

CATEGORY	DRUG NAME	DOSAGE	COMMENTS
GLP-1 AGONISTS	Trulicity SC (dulaglutide)	0.75 mg once weekly; up to 1.5 mg once weekly.	Preferred, step therapy
	Victoza SC (liraglutide)	0.6 mg once daily for one week, then 1.2 mg once daily	Preferred, step therapy
	Ozempic SC (semaglutide)	0.25 mg once weekly for four weeks then increase to 0.5 mg once weekly for at least four weeks; maximum dose 1 mg once weekly.	Preferred, step therapy
	Adlyxin (lixisenatide)	10 mcg once daily times 14 days, then increase to 20 mcg once daily.	Non-preferred, PA required
	Rybelsus		Preferred, step therapy
	Byetta/Bydureon (exenatide)		Excluded
DPP-4 INHIBITORS	Januvia oral (sitagliptin)	100 mg once daily.	Preferred, step therapy
	Alogliptin oral (generic)	25 mg once daily	Non-preferred, PA required
	Nesina (alogliptin), Tradjenta (linagliptin), Onglyza (saxagliptin).		Excluded
SGLT-2 INHIBITORS	Jardiance oral (empagliflozin)	10 mg once daily; up to 25 mg once daily.	Preferred, step therapy
	Farxiga oral (dapagliflozin):	5 mg once daily; up to 10 mg once daily	Preferred, Step therapy
	Invokana (canagliflozin), Steglatro (ertugliflozin).		Excluded

**4.0 Coding:**

None.

**5.0 References, Citations & Resources:**

1. [https://care.diabetesjournals.org/content/42/Supplement\\_1/S61](https://care.diabetesjournals.org/content/42/Supplement_1/S61) accessed 11/19.
2. Lexicomp Lexicomp Online® Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Trulicity, Victoza, Ozempic, Januvia, Jardiance, Farxiga accessed September 2020.

**6.0 Appendices:**

See page 4.

**7.0 Revision History:**

Original Effective Date: 11/10/2020

Next Review Date: 09/15/2021

Revision Date	Reason for Revision
10/20	Annual review, put formulary status of each agent/dosage in a table and simplified other criteria, formatting, replace abbreviations; added diagnosis of DM-2; clarified metformin trial

**Appendix I: Monitoring and Patient Safety**

<b>Drug</b>	<b>Adverse Reactions</b>	<b>Monitoring</b>	<b>REMS</b>
GLP-1 agents Trulicity (dulaglutide) Victoza (liraglutide) Ozempic (semaglutide) Adlyxin (lixisenatide)	<ul style="list-style-type: none"> <li>• Endocrien/metabolic: increased amylase (Ozempic: 10-13%), hypoglycemia (Ozempic: 16%)</li> <li>• Cardiovascular: increased heart rate (Victoza: 34%)</li> <li>• Central Nervous System: headache (Victoza: 14%)</li> <li>• Gastrointestinal: increased lipase (Ozempic: 22-34%) nausea/vomitting (6-39%), diarrhea (9-21%), abdominal pain (Ozempic: 6-11%), constipation (Victoza 19%)</li> <li>• Local: injection site reaction (Victoza: 3-14%)</li> </ul>	<ul style="list-style-type: none"> <li>• Labs: HbA1c, trglyceride</li> <li>• Renal: renal fuction</li> <li>• Gastrointestinal: signs and symptoms of pancreatitis or gallbladder disease</li> <li>• Psyche (Victoza): worsening depression, suicidal ideation, change in behavior</li> </ul>	None needed
DPP-4 Inhibitors Januvia (sitagliptin)	<ul style="list-style-type: none"> <li>• Respiratory: nasopharyngitis (5%)</li> </ul>	<ul style="list-style-type: none"> <li>• Labs: HbA1c, serum glucose</li> <li>• Renal: renal function</li> <li>• Cardiovascular: signs and symptoms of heart failure</li> </ul>	None needed
SGLT-2 Inhibitors Jardiance (empagliflozin) Farxiga (dapagliflozin)	<ul style="list-style-type: none"> <li>• Gentourinary: urinary tract infection (UTI) (6-9%),</li> <li>• Respiratory: nasopharyngitis (6%)</li> </ul>	<ul style="list-style-type: none"> <li>• Labs: HbA1c, LDL</li> <li>• Renal: renal function</li> <li>• Volume status (blood pressure, hematocrit, electrolytes)</li> <li>• Infections: genetic mycotic infections, UTI</li> </ul>	None needed