DRUG DETERMINATION POLICY

Title: DDP-43 Non-Insulin Diabetic Agents

Effective Date: 03/17/2020

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. GLP-1 agonists: Adlyxin (lixisenatide).

1. Other therapies: are contraindicated, were tried and failed; or experienced significant adverse effects to both categories below:

   a. Metformin (both below):

      i. Dosage regimen: 1000 mg twice daily for three months.

      ii. Dosage form: use extended release metformin for gastrointestinal symptoms.

   b. Preferred agents: 3-month trial (all agents below):

      i. Trulicity SC (dulaglutide): 0.75 mg once weekly; up to 1.5 mg once weekly,

      ii. Victoza SC (liraglutide): 0.6 mg once daily for one week, then 1.2 mg once daily.

iii. 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.

2. Excluded: Byetta/Bydureon (exenatide)

   a. All preferred formulary agents are contraindicated; were tried and failed, or resulted in significant adverse effects.

3. Dosage regimen:

   a. Adlyxin SC (lixisenatide): 10 mcg once daily times 14 days, then increase to 20 mcg once daily.

B. DPP-4 inhibitors: alogliptin (generic).

1. Other therapies: are contraindicated, were tried and failed; or experienced significant adverse effects to both categories below:

   a. Metformin (tried both agents below):

      i. Dosage regimen: 1000 mg twice daily.

      ii. Dosage form: use extended release metformin for GI symptoms.

   b. Preferred agents: 3-month trial (tried one agent below):

      i. Januvia oral (sitagliptin): 100 mg once daily.

2. Excluded: Nesina (alogliptin), Tradjenta (linagliptin), Onglyza (saxagliptin).

   a. All preferred formulary agents are contraindicated; were tried and failed, or resulted in significant adverse effects.

3. Dosage regimen:

   a. Alogpliptin oral (generic): 25 mg once daily.

C. SGLT-2 inhibitors:

1. Other therapies: are contraindicated tried and failed; or experienced significant adverse effects to both categories below:

   a. Metformin (tried both below).

      i. Dosage regimen: 1000 mg twice daily.

      ii. Dosage form: use extended release metformin for GI symptoms.

   b. Preferred agents: three-month trial (both agents below):

      i. Jardiance oral (empagliflozin): 10 mg once daily; up to 25 mg once daily.

      ii. Farxiga oral (dapagliflozin): 5 mg once daily; up to 10 mg once daily.

2. Excluded: Invokana (canagliflozin), Steglartro (ertugliflozin).

    a. All preferred formulary agents are contraindicated; were tried and failed, or resulted in significant adverse effects.

D. Approval.

1. Hgb A1c: after three months of consistent use of the preferred agent(s)

    a. GLP-1: at least 7%.

    b. DPP-4 Inhibitors and SGLT-2 inhibitors: 7 to 9% (these agents will not sufficierntly decrease Hgb A1c if more than 9%).

2. Duration:

    a. Initial: six months.

    b. Reapproval: one year (reduced Hgb A1c).

4.0 Coding:

None.

5.0 References, Citations & Resources:

1. https://care.diabetesjournals.org/content/42/Supplement_1/S61 accesssed 11/19.

2. Lexicomp Lexicomp Online® Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Trulicity, Victoza, Ozempic, Januvia, Jardiance, Farxiga accessed January 2020.

6.0 Appendices:

Appendix I: Monitoring and Patient Safety

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

Drug	Adverse Reactions	Monitoring	REMS
(empagliflozin) Farxiga (dapagilflozin)		pressure, hematocrit, electrolytes • Infections: genetic mycotic infections, UTI	

7.0 Revision History:

Original Effective Date: 03/17/2020

Next Review Date: 09/23/2020

Revision Date	Reason for Revision