



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	DPP-IV Inhibitors & Combination Agents PDL Edit
<b>First Implementation Date:</b>	January 22, 2004
<b>Revised Date:</b>	October 5, 2023
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Type 2 diabetes mellitus is a significant health problem associated with excessive morbidity and mortality. As the prevalence of this metabolic disorder is rapidly increasing and as older treatments fail to stabilize the disease in many participants, prevention and control are considered key objectives. Selective dipeptidyl peptidase-4 (DPP-IV) inhibitors are used in the treatment of type 2 diabetes mellitus and work by enhancing the levels of active incretin hormones. Glucagon-like peptide 1 (GLP-1) is rapidly degraded by DPP-IV, a serine protease. A DPP-IV inhibitor increases the half-life of active GLP-1 and prolongs the beneficial effects of the incretin hormones. GLP-1 is a glucose-dependent stimulator of insulin synthesis and secretion, and an inhibitor of glucagon release. The activity of GLP-1 is limited by the DPP-IV enzyme, which rapidly degrades incretins to metabolites that are no longer active as incretins. These agents act to prevent inactivation of the incretins by the enzyme DPP-IV, thus increasing active incretin plasma concentrations. DPP-IV inhibitors enhance the body's natural ability to lower blood glucose when it is elevated. This group of agents, including any other GLP-1 based therapies, do not cause hypoglycemia unless combined with other therapies that can. DPP-IV inhibitors can be used as monotherapy in those who cannot tolerate or have contraindications to metformin. These agents can also be used as an add-on therapy to help better control their glucose levels. Generally, all DPP-IV inhibitors have similar glycemic effects and improvement in A1C measurements.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>• Janumet®</li> <li>• Janumet® XR</li> <li>• Januvia®</li> <li>• Jentadueto®</li> <li>• Kombiglyze® XR</li> <li>• Onglyza®</li> <li>• Tradjenta®</li> </ul>	<ul style="list-style-type: none"> <li>• Alogliptin</li> <li>• Alogliptin/Metformin</li> <li>• Alogliptin/Pioglitazone</li> <li>• Glyxambi®</li> <li>• Jentadueto® XR</li> <li>• Kazano®</li> <li>• Nesina®</li> <li>• Oseni</li> <li>• Qtern®</li> <li>• Saxagliptin</li> </ul>

	<ul style="list-style-type: none"> <li>• Saxagliptin/Metformin</li> <li>• Steglujan®</li> </ul>
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Type of Criteria:  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

Data Sources:  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: DPP-IV Inhibitors & Combination Agents
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on **2** or more preferred agents
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents

## Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Lack of adequate trial on required preferred agents
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
GLYXAMBI 10 MG-5 MG TABLET	EMPAGLIFLOZIN/LINAGLIPTIN	1 tablet per day
GLYXAMBI 25 MG-5 MG TABLET	EMPAGLIFLOZIN/LINAGLIPTIN	1 tablet per day
JANUMET 50-500 MG TABLET	SITAGLIPTIN/METFORMIN	2 tablets per day
JANUMET 50-1000 MG TABLET	SITAGLIPTIN/METFORMIN	2 tablets per day
JANUMET XR 50-500 MG TABLET	SITAGLIPTIN/METFORMIN	1 tablet per day
JANUMET XR 50-1000 MG TABLET	SITAGLIPTIN/METFORMIN	2 tablets per day
JANUMET XR 100-1000 MG TABLET	SITAGLIPTIN/METFORMIN	1 tablet per day
JANUVIA 25 MG TABLET	SITAGLIPTIN	1 tablet per day
JANUVIA 50 MG TABLET	SITAGLIPTIN	1 tablet per day
JANUVIA 100 MG TABLET	SITAGLIPTIN	1 tablet per day
JENTADUETO 2.5 MG-500 MG TABLET	LINAGLIPTIN/METFORMIN	2 tablets per day
JENTADUETO 2.5 MG-850 MG TABLET	LINAGLIPTIN/METFORMIN	2 tablets per day
JENTADUETO 2.5 MG-1000 MG TABLET	LINAGLIPTIN/METFORMIN	2 tablets per day
JENTADUETO XR 2.5 MG-1000 MG TABLET	LINAGLIPTIN/METFORMIN	2 tablets per day
JENTADUETO XR 5 MG-1000 MG TABLET	LINAGLIPTIN/METFORMIN	1 tablet per day
KAZANO 12.5-500 MG TABLET	ALOGLIPTIN/METFORMIN	2 tablets per day
KAZANO 12.5-1000 TABLET	ALOGLIPTIN/METFORMIN	2 tablets per day
KOMBIGLYZE XR 2.5-1000 MG TABLET	SAXAGLIPTIN/METFORMIN	2 tablets per day
KOMBIGLYZE XR 5-500 MG TABLET	SAXAGLIPTIN/METFORMIN	1 tablet per day
KOMBIGLYZE XR 5-1000 MG TABLET	SAXAGLIPTIN/METFORMIN	1 tablet per day
NESINA 25 MG TABLET	ALOGLIPTIN	1 tablet per day
NESINA 12.5 MG TABLET	ALOGLIPTIN	1 tablet per day
NESINA 6.25 MG TABLET	ALOGLIPTIN	1 tablet per day
ONGLYZA 2.5 MG TABLET	SAXAGLIPTIN	1 tablet per day
ONGLYZA 5 MG TABLET	SAXAGLIPTIN	1 tablet per day
OSANI 12.5-15 MG TABLET	ALOGLIPTIN/PIOGLITAZONE	1 tablet per day

OSENI 12.5-30 MG TABLET	ALOGLIPTIN/PIOGLITAZONE	1 tablet per day
OSENI 12.5-45 MG TABLET	ALOGLIPTIN/PIOGLITAZONE	1 tablet per day
OSENI 25-15 MG TABLET	ALOGLIPTIN/PIOGLITAZONE	1 tablet per day
OSENI 25-30 MG TABLET	ALOGLIPTIN/PIOGLITAZONE	1 tablet per day
OSENI 25-45 MG TABLET	ALOGLIPTIN/PIOGLITAZONE	1 tablet per day
QTERN 5 MG-5 MG TABLET	DAPAGLIFLOZIN/SAXAGLIPTIN	1 tablet per day
QTERN 10 MG-5 MG TABLET	DAPAGLIFLOZIN/SAXAGLIPTIN	1 tablet per day
STEGLUJAN 5 MG-100 MG TABLET	ERTUGLIFLOZIN/SITAGLIPTIN	1 tablet per day
STEGLUJAN 15 MG-100 MG TABLET	ERTUGLIFLOZIN/SITAGLIPTIN	1 tablet per day
TRADJENTA 5 MG TABLET	LINAGLIPTIN	1 tablet per day

## Required Documentation

Laboratory Results:

Progress Notes:

MedWatch Form:

Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)

Rule Type: PDL

## Default Approval Period

1 year

## References

- Evidence-Based Medicine Analysis: "Dipeptidyl Peptidase-4 Inhibitors", UMKC-DIC; March 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Oral Hypoglycemics DPP-IV" – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
- Dungan, K., (2020). Dipeptidyl peptidase 4 (DPP-4) inhibitors for the treatment of type 2 diabetes mellitus. In J.E. Mulder (Ed.), *UptoDate*.
- American Diabetes Association (ADA). Standards of Medical Care in Diabetes – 2022. *Diabetes Care*. 2022;45(suppl 1): S1-S264.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.