DPP-4 Inhibitor and Combo Products
Alogliptin
Alogliptin/metformin
Nesina (aloglitin)
Kazano (alogliptin/metformin)
Oseni (alogliptin/pioglitazone)
Effective 11/01/2022

Plan	☐ MassHealth ☒ MH UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

No PA	PA required
Januvia® (sitagliptin)	Alogliptin
Onglyza® (saxagliptin) §	Alogliptin/metformin
Tradjenta® (linagliptin)	Alogliptin/pioglitazone
Janumet® (sitagliptin/metformin)	Nesina® (alogliptin)†§
Janumet XR® (sitagliptin/metformin extended-release)	Kazano® (alogliptin/metformin) † §
Jentadueto® (linagliptin/metformin)	Oseni® (alogliptin/pioglitazone) †§
Jentadueto XR® (linagliptin/metformin extended release)	
Kombiglyze XR ® (saxagliptin/metformin extended release) §	

†Authorized generic available. Both brand and authorized generic require PA.
§ Brand Preferred over generic equivalents. In general, a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

Coverage Guidelines

Authorizations requests will be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Alogliptin and **Nesina®** (alogliptin) †§
Prescriber provides documentation of the following:

1. Member has a diagnosis of Type 2 Diabetes Mellitus
2. **ONE** of the following:
    a. Pharmacy claims or prescriber documentation of inadequate response (defined as at least 90 days of therapy within a 120-day time period) to metformin used in combination with **ONE** of the following:
        i. Januvia® (sitagliptin)
        ii. Onglyza® (saxagliptin)
        iii. Tradjenta® (linagliptin)
    b. **BOTH** of the following:
        i. Adverse reaction or contraindication to metformin
        ii. Pharmacy claims or prescriber documentation of inadequate response (defined as at least 90 days of therapy within a 120-day time period) to **ONE** of the following:
            a) Januvia® (sitagliptin)
            b) Onglyza® (saxagliptin)
            c) Tradjenta® (linagliptin)
    c. **BOTH** of the following:
        i. Pharmacy claims or prescriber documentation of inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin
        ii. Adverse reaction to **ONE** of the following:
            a) Januvia® (sitagliptin)
            b) Onglyza® (saxagliptin)
            c) Tradjenta® (linagliptin)
    d. **BOTH** of the following:
        i. Pharmacy claims or prescriber documentation of inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin
        ii. Contraindication to **ALL** of the following:
            a) Januvia® (sitagliptin)
            b) Onglyza® (saxagliptin)
            c) Tradjenta® (linagliptin)
3. If requested quantity exceeds 1 tablet/day, clinical rationale for exceeding FDA-approved dosing schedule

† Authorized generic available. Both brand and authorized generic require PA.
§ Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

Alogliptin/metformin and **Kazano®** (alogliptin/metformin) †§
Prescriber provides documentation of the following:

1. Member has a diagnosis of Type 2 Diabetes Mellitus
2. **ONE** of the following:
    a. Pharmacy claims or prescriber documentation of inadequate response (defined as at least 90 days of therapy within a 120-day time period) to metformin used in combination with at least one of the non-metformin agents in the requested combination
    b. **BOTH** of the following:
        i. Adverse reaction or contraindication to metformin
        ii. Pharmacy claims or prescriber documentation of inadequate response (defined as at least 90 days of therapy within a 120-day time period) to at least one of the non-metformin agents in the requested combination
    c. **BOTH** of the following:
        i. Pharmacy claims or prescriber documentation of inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin
        ii. Adverse reaction to at least one of the non-metformin agents in the requested combination

† Authorized generic available. Both brand and authorized generic require PA.
§ Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

Alogliptin/pioglitazone and **Oseni®** (alogliptin/pioglitazone) †§
Prescriber provides documentation of the following:
1. Member has a diagnosis of Type 2 Diabetes Mellitus
2. **ONE** of the following:
    a. Pharmacy claims or prescriber documentation of inadequate response (defined as at least 90 days of therapy within a 120-day time period) to metformin used in combination with at least one of the non-metformin agents in the requested combination
    b. **BOTH** of the following:
        i. Adverse reaction or contraindication to metformin
        ii. Pharmacy claims or prescriber documentation of inadequate response (defined as at least 90 days of therapy within a 120-day time period) to at least one of the non-metformin agents in the requested combination
    c. **BOTH** of the following:
        i. Pharmacy claims or prescriber documentation of inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin
        ii. Adverse reaction to at least one of the non-metformin agents in the requested combination

† Authorized generic available. Both brand and authorized generic require PA.
§ Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

Limitations
1. Initial approval and reauthorizations will be granted for 12 months.
2. The following quantity limits apply:

Alogliptin	30 tablets per 30 days
Alogliptin/metformin	30 tablets per 30 days
Alogliptin/pioglitazone	30 tablets per 30 days
Nesina	30 tablets per 30 days

Kazano	30 tablets per 30 days
Oseni	30 tablets per 30 days

Appendix

Appendix A: Brand Preferred over Generic

In addition to any prior authorization requirements that may be listed above, generic medications listed below have Brand name products that are Brand Name Preferred Over Generic

- alogliptin
- alogliptin/metformin
- alogliptin/pioglitazone
- saxagliptin
- saxagliptin/metformin extended release

References

1. Januvia® [package insert]. Whitehouse Station (NJ): Merck & Co; 2019 Mar.
2. Janumet® [package insert]. Whitehouse Station (NJ): Merck & Co; 2019 Mar.
3. Janumet® XR [package insert]. Whitehouse Station (NJ): Merck & Co; 2019 Mar.
4. Onglyza® [package insert]. Wilmington (DE): AstraZeneca Pharmaceuticals LP; 2018 Apr.
5. Kombiglyze® XR [package insert]. Wilmington (DE): AstraZeneca Pharmaceuticals LP; 2018 Nov.
6. Tradjenta® [package insert]. Ridgefield (CT): Boehringer Ingelheim Pharmaceuticals, Inc.; 2017 Aug.
7. Jentadueto® [package insert]. Ridgefield (CT): Boehringer Ingelheim Pharmaceuticals, Inc.; 2017 Aug.
8. Rodbard HW, et al. Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology Consensus Panel on Type 2 Diabetes Mellitus: An Algorithm for Glycemic Control. Endocrine Practice. 2009;15(6):541-549. http://www.aace.com/pub/pdf/GlycemicControlAlgorithm.pdf
9. Nathan DM, Buse JB, Davidson MB, Ferrannini E, Holman RR, Sherwin R, et al. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. Diabetes Care. 2009 Jan;32(1):193-203.
10. Qaseem A, Humphrey LL, Sweet DE, Starkey M, Shekelle P; Clinical Guidelines Committee of the American College of Physicians. Oral pharmacologic treatment of type 2 diabetes mellitus: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2012;156(3):218-31.
11. The American Diabetes Association. Standards of medical care in diabetes – 2016. Diabetes Care.2016(Jan);38(suppl 1):S1-S112.
12. Inzucchi SE, BergenstalRM, Buse JB, Diamant M, Ferrannini E, Nauck M, et al. Management of hyperglycemia in type 2 diabetes, 2015: A patient-centered approach. Diabetes Care. 2015;38:140-9.
13. Kazano (alogliptin and metformin) [product monograph]. Oakville, Ontario, Canada: Takeda Canada Inc; March 2020.
14. Nesina (alogliptin) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America Inc; June 2019.

Review History

03/05/07 – Reviewed
04/23/07 – Reviewed
04/28/08 – Reviewed

07/16/08 – Tier 2 status
08/21/08 – Metformin-containing products
02/01/09 – Prandimet
04/27/09 – Reviewed
04/26/10 – Reviewed
12/15/10 – Disclaimer
01/03/11 – Kombiglyze XR
04/25/11 – Reviewed
06/06/11 – Tradjenta
03/19/12 – Jentadueto
04/17/19 – Reviewed
10/04/2020 – Updated; retired ST DDP-4 criteria replaced with P
04/23/12 – Updated
04/22/13 – Reviewed
04/28/14 – Updated
04/27/15 – Reviewed
04/25/16 – Reviewed
04/24/17 – Updated criteria; references updated; Match Masshealth partial unified formulary requirements for implementation on 1/1/21
11/17/2021 – Reviewed and Updated for Nov P&T; Nesina® is now brand preferred, criteria updates to Nesina and alogliptan. Effective 1/1/2022
03/16/2022 – Reviewed and Updated for March P&T; updated to reflect Onglyza® (saxagliptin) and Kombiglyze® XR (saxagliptin/metformin extended-release) are now brand preferred. Changes reflected in reference table and brand preferred over generic section. Effective 05/01/2022
11/16/2022 – Reviewed and updated for Nov P&T. Matched MH UPPL. Removed "If the request is for BRAND NAME Kazano®, the member must meet the above criteria and provide medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic formulation". Added authorized generic of Oseni, Alogliptin/pioglitazone, to reference table. Minor updates to verbiage/formatting. Effective 11/01/2022.

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