Dipeptidyl Peptidase-4 Inhibitors & Combinations
Policy Number: C5169-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
6/1/2016	3/11/2020	3/11/2021
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
	RxPA	Q2 2020 20200422C5169-A

PRODUCTS AFFECTED:
KAZANO (alogliptin/metformin), KOMBIGLYZE XR (saxagliptin/metformin extended-release), NESINA (alogliptin), ONGLYZA (saxagliptin), OSENI (alogliptin/pioglitazone), JANUMET (sitagliptin/metformin), JANUMET XR (sitagliptin/metformin extended-release), JANUVIA (sitagliptin), JENTADUETO (linagliptin/metformin), JENTADUETO XR (linagliptin/metformin extended-release), KAZANO (alogliptin/metformin), KOMBIGLYZE XR (saxagliptin/metformin extended-release), NESINA (alogliptin), ONGLYZA (saxagliptin), OSENI (alogliptin/pioglitazone) TRADJENTA (linagliptin), JANUVIA (sitagliptin)

DRUG CLASS:
Dipeptidyl Peptidase-4 Inhibitor-(Biguanide Combinations), DPP-4 Inhibitor- Thiazolidinedione Combinations

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Retail Pharmacy

AVAILABLE DOSAGE FORMS:
Alogliptin Benzoate TABS 12.5MG, Alogliptin Benzoate TABS 25MG, Alogliptin Benzoate TABS 6.25MG, Alogliptin-Metformin HCl TABS 12.5-1000MG; Alogliptin-Metformin HCl TABS 12.5-500MG, Janumet TABS 50-1000MG, Janumet TABS 50- 500MG, Janumet XR TB24 100-1000MG, Janumet XR TB24 50-1000MG, Janumet XR TB24 50-500MG, Januvia TABS 100MG, Januvia TABS 25MG, Januvia TABS 50MG, Jentadueto TABS 2.5- 1000MG, Jentadueto TABS 2.5-500MG, Jentadueto TABS 2.5-500MG, Jentadueto TABS 2.5- 850MG, Jentadueto XR TB24 2.5-1000MG, Jentadueto XR TB24 5-1000MG, Jentadueto XR TB24 5-1000MG, Kazano TABS 12.5-1000MG, Kazano TABS 12.5-500MG, Kombiglyze XR TB24 2.5-1000MG, Kombiglyze XR TB24 5-1000MG, Kombiglyze XR TB24 5-500MG, Nesina TABS 12.5MG, Nesina TABS 25MG, Nesina TABS 6.25MG, Onglyza TABS 2.5MG, Onglyza TABS 5MG, Tradjenta TABS 5MG, Tradjenta TABS 5MG, Tradjenta TABS 5MG Oseni TABS 12.5-15MG, Oseni TABS 12.5-30MG, Oseni TABS 12.5-45MG, Oseni TABS 25-15MG, Oseni TABS 25-30MG, Oseni TABS 25-45MG, Alogliptin-Pioglitazone TABS 12.5-15MG, Alogliptin-Pioglitazone TABS 12.5-30MG, Alogliptin-Pioglitazone TABS 12.5-45MG, Alogliptin-Pioglitazone TABS 25-15MG, Alogliptin- Pioglitazone TABS 25-30MG, Alogliptin-Pioglitazone TABS 25-45MG

FDA-APPROVED USES:
Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

COMPENDIAL APPROVED OFF-LABELED USES:
None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
Type 2 Diabetes Mellitus

REQUIRED MEDICAL INFORMATION:
A. TYPE 2 DIABETES MELLITUS:

1. Documentation of diagnosis of type 2 diabetes mellitus
   AND
2. (a) If baseline Hemoglobin A1C < 9.0%: Documentation of an inadequate treatment response, contraindication or intolerance to metformin. Inadequate response is defined as not achieving adequate glycemic control after 3 continuous months of receiving maximal daily doses despite current treatment
   OR
   (b) If baseline A1C is > 9.0% and member is symptomatic (presenting with polyuria, polydipsia, or polyphagia), documentation that insulin use was initiated prior to the addition of a Dipeptidyl Peptidase-4 Inhibitor [if presenting without significant symptoms member may be an appropriate candidate for dual or triple therapy that could include a DPP4 agent per (AACE/ACE 2020)]
   AND
3. FOR NON-FORMULARY/NON-PREFERRED AGENTS: Documentation of an inadequate trial and failure, contraindication or intolerance to PREFERRED formulary Dipeptidyl Peptidate-4 Inhibitors and combination products (Failure is defined as not achieving expected Hemoglobin A1C lowering while adherent to therapy)

DURATION OF APPROVAL:
Initial Authorization: 12 months, Continuation of Therapy: 12 months

QUANTITY:
No requirement

PRESCRIBER REQUIREMENTS:
No requirement

AGE RESTRICTIONS:
18 years of age and older

CONTINUATION OF THERAPY:
A. TYPE 2 DIABETES:

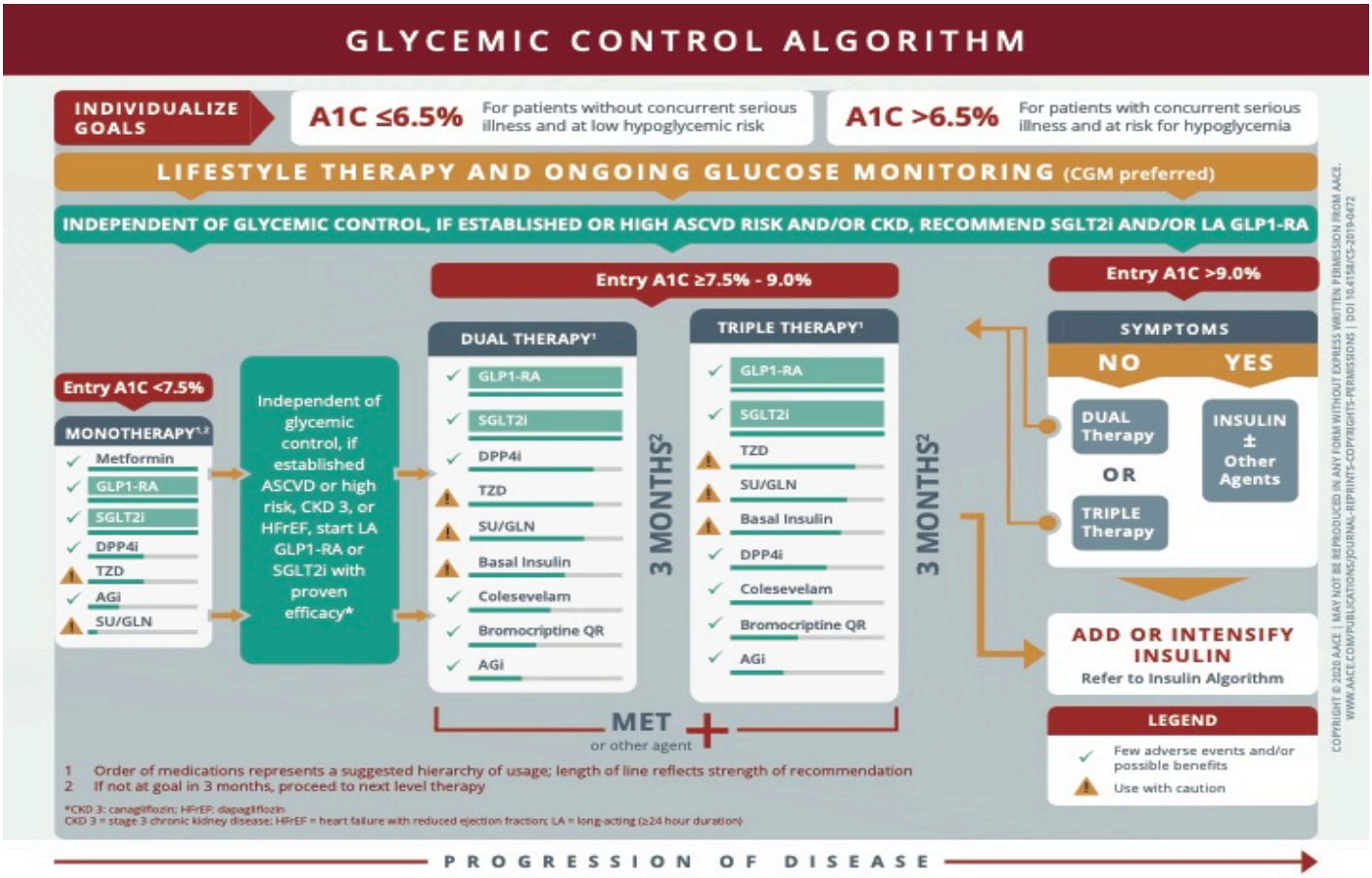
1. Documentation member has been tolerating and responding to the treatment (reduction in hemoglobin A1c)
   AND
2. Documentation of member compliance with therapy as verified by Prescriber and member's medication fill history (review Rx history for compliance)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
A) Heart failure (Oseni), B) Renal impairment (Janumet, Janumet XR, Jentadueto, Kazano, Kombiglyze XR), C) Active liver disease (Juvisync), D) Concomitant use of a strong CYP3A4 inhibitor (Juvisync), E) Concomitant use of gemfibrozil, cyclosporine, or danazol (Juvisync), F) Pregnant or nursing (Juvisync)

OTHER SPECIAL CONSIDERATIONS:
None

BACKGROUND:
Per American Diabetes Association (ADA) guidelines, metformin and lifestyle changes are considered first line in the treatment of type 2 diabetes. DPP-4 inhibitors are considered add-on treatment options if glycemic targets are not achieved after approximately three months of metformin monotherapy. Sulfonylureas, thiazolidinediones, sodium-glucose co-transporter 2 (SGLT2) inhibitors, GLP-1 agonists, and basal insulin are also considered add-on treatments to metformin. The choice of add-on treatment is patient-specific.

APPENDIX:



Reference: AACE/ACE Consensus Statement. Diabetes Management Algorithm, Endocr Pract. 2020;26(1). Available at: https://www.aace.com/pdfs/diabetes/algorithm-exec-summary.pdf

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Janumet (sitagliptin and metformin) tablets [prescribing information]. Whitehouse Station, NJ: Merck & Co, Inc; August 2019.
2. Janumet XR (sitagliptin and metformin) extended-release tablets [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; June 2019.
3. Januvia (sitagliptin) [prescribing information] Whitehouse Station, NJ: Merck & Co Inc; August 2019.
4. Jentadueto (linagliptin and metformin) [prescribing information]. Ridgefield, CT: Boehringer

Ingelheim Pharmaceuticals, Inc; July 2019.
5. Jentadueto XR (linagliptin and metformin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; August 2017.
6. Kazano (alogliptin and metformin) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc; June 2019.
7. Kombiglyze XR (saxagliptin/metformin) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2019.
8. Nesina (alogliptin) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America Inc; June 2019.
9. Onglyza (saxagliptin) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; June 2019.
10. Oseni (alogliptin and pioglitazone) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc; June 2019.
11. Tradjenta (linagliptin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; July 2019.
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14. American Diabetes Association (ADA). Standards of medical care in diabetes–2020. Diabetes Care. 2020;43(suppl 1):S1-S212. Available at: https://care.diabetesjournals.org/content/43/Supplement_1. Accessed Feb 2020.
15. AACE/ACE Consensus Statement. Diabetes Management Algorithm, Endocr Pract. 2020;26(1). Available at: https://www.aace.com/pdfs/diabetes/algorithm-exec-summary.pdf Accessed Feb 2020.
16. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology – Clinical Practice Guidelines for developing a diabetes mellitus comprehensive care plan. Endocr Pract. 2015; 21(Suppl 1):1- 87