



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors and Combinations Step Therapy with Quantity Limit Program Summary

Step Therapy applies to FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, and Health Insurance Marketplace formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

Quantity limits apply to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx.

POLICY REVIEW CYCLE

Effective Date
06-01-2024

Date of Origin
01-01-2021

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Janumet® (sitagliptin/m etformin) Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of use: <ul style="list-style-type: none"> Should not be used in patients with type 1 diabetes. Has not been studied in patients with a history of pancreatitis 		5
Janumet® XR (sitagliptin- metformin HCl Tab ER) Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of use: <ul style="list-style-type: none"> Should not be used in patients with type 1 diabetes. Has not been studied in patients with a history of pancreatitis 		6
Januvia® (sitagliptin) Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of use: <ul style="list-style-type: none"> Should not be used in patients with type 1 diabetes. Has not been studied in patients with a history of pancreatitis. 		1
Jentadueto® (linagliptin/m etformin) Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of use: <ul style="list-style-type: none"> Should not be used in patients with type 1 diabetes Has not been studied in patients with a history of pancreatitis 		7

Agent(s)	FDA Indication(s)	Notes	Ref#
Jentaduetto XR® (linagliptin/metformin ER) Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of use: <ul style="list-style-type: none"> Should not be used in patients with type 1 diabetes Has not been studied in patients with a history of pancreatitis 		8
Kazano™, Alogliptin/metformin Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of use: <ul style="list-style-type: none"> Should not be used in patients with type 1 diabetes mellitus 		10
Kombiglyze™ XR (saxagliptin/metformin)* Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate Limitations of use: <ul style="list-style-type: none"> Not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis 	*- generic available	9
Nesina®, Alogliptin Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of use: <ul style="list-style-type: none"> Should not be used in patients with type 1 diabetes mellitus 		2
Onglyza® (saxagliptin)* Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of use: <ul style="list-style-type: none"> Not used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis 	*-generic available	3
Oseni®, Alogliptin/pioglitazone Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of use: <ul style="list-style-type: none"> Should not be used in patients with type 1 diabetes 		11
Tradjenta® (linagliptin) Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of use: <ul style="list-style-type: none"> Should not be used in patients with type 1 diabetes, as it would not be effective in these settings 		4

Agent(s)	FDA Indication(s)	Notes	Ref#
	<ul style="list-style-type: none"> Has not been studied in patients with a history of pancreatitis 		
Zituvio™ (sitagliptin) Tablet	<p>Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus</p> <p>Limitations of Use:</p> <ul style="list-style-type: none"> Zituvio is not recommended in patients with type 1 diabetes mellitus Zituvio has not been studied in patients with a history of pancreatitis 		14

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

CLINICAL RATIONALE

Diabetes	<p>The American Diabetes Association (ADA) states that first-line therapy depends on comorbidities, patient-centered treatment factors, and management needs and generally includes metformin and comprehensive lifestyle modification. Because type 2 diabetes is a progressive disease in many patients, maintenance of glycemic targets with monotherapy is often possible for only a few years, after which combination therapy is necessary. Traditional recommendations have been to use stepwise addition of medications to metformin to maintain A1C at target.(12,13)</p> <p>Metformin is effective and safe, is inexpensive, and may reduce risk of cardiovascular events and death. Metformin is available in an immediate-release form for twice-daily dosing or as an extended-release form that can be given once daily. Compared with sulfonylureas, metformin as first-line therapy has beneficial effects on A1C, weight, and cardiovascular mortality.(13)</p>
Safety	<p>Janumet, Jentadueto, Jentadueto XR, Kazano, and Kombiglyze XR carry a black box warning for lactic acidosis:(7-10)</p> <ul style="list-style-type: none"> Post-marketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. The onset of metformin associated lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Metformin associated lactic acidosis was characterized by elevated blood lactate levels (greater than 5 mmol/Liter), anion gap acidosis (without evidence of ketonuria or ketonemia), an increased lactate/pyruvate ratio; and metformin plasma levels generally greater than 5 mcg/ml Risk factors for metformin-associated lactic acidosis include renal impairment, concomitant use of certain drugs (e.g., carbonic anhydrase inhibitors such as topiramate), age 65 years old or greater, having a radiological study with contrast, surgery and other procedures, hypoxic states (e.g., acute congestive heart failure), excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high-risk groups are provided in the full prescribing information If metformin-associated lactic acidosis is suspected, immediately discontinue the medication and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended. <p>Oseni carries a black box warning for congestive heart failure:(11)</p> <ul style="list-style-type: none"> Thiazolidinediones, including pioglitazone, cause or exacerbate congestive heart failure in some patients.

	<ul style="list-style-type: none"> • After initiation of Oseni and after dose increases, monitor patients carefully for signs and symptoms of heart failure (e.g., excessive, rapid weight gain, dyspnea and/or edema). If heart failure develops, it should be managed according to current standards of care and discontinuation or dose reduction of pioglitazone in Oseni must be considered. • Oseni is not recommended in patients with symptomatic heart failure. Initiation of Oseni in patients with established New York Heart Association (NYHA) Class III or IV heart failure is contraindicated. <p>Janumet, Janumet XR, and Kombiglyze XR have the following contraindications:(5,6,9)</p> <ul style="list-style-type: none"> • Severe renal impairment: (eGFR below 30 mL/min/1.73 m²). • Metabolic acidosis, including diabetic ketoacidosis. • History of a serious hypersensitivity reaction (e.g., anaphylaxis, angioedema, exfoliative skin conditions) to the active ingredients, metformin, or any excipients. <p>Jentadueto, Jentadueto XR, and Kazano have the following contraindications:(7,8,10)</p> <ul style="list-style-type: none"> • Severe renal impairment (eGFR below 30 mL/min/1.73 m²). • Metabolic acidosis, including diabetic ketoacidosis. • Hypersensitivity to the active ingredients or any of the excipients. <p>Januvia, Nesina, Onglyza, and Tradjenta have the following contraindication:(1-4)</p> <ul style="list-style-type: none"> • History of serious hypersensitivity to the active ingredient or any of the excipients. <p>Oseni has the following contraindication:(11)</p> <ul style="list-style-type: none"> • Serious hypersensitivity reaction to alogliptin or pioglitazone, components of Oseni, or any of the excipients. • Do not initiate Oseni in patients with established NYHA Class III or IV heart failure. <p>Zituvio has the following contraindication:(14)</p> <ul style="list-style-type: none"> • History of a serious hypersensitivity reaction to sitagliptin or any of the excipients in Zituvio, such as anaphylaxis or angioedema.
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REFERENCES

Number	Reference
1	Januvia prescribing information. Merck & Co., Inc. July 2022.
2	Nesina prescribing information. Takeda Pharmaceuticals America, Inc. July 2023.
3	Onglyza prescribing information. Astra Zeneca. October 2019.
4	Tradjenta prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. June 2023.
5	Janumet prescribing information. Merck & Co., Inc. July 2022.
6	Janumet XR prescribing information. Merck & Co., Inc. July 2022.
7	Jentadueto prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. June 2023.
8	Jentadueto XR prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. June 2023.
9	Kombiglyze XR prescribing information. Bristol-Meyers Squibb Company/AstraZeneca Pharmaceuticals LP. October 2019.

Number	Reference
10	Kazano prescribing information. Takeda Pharmaceuticals America, Inc. July 2023.
11	Oseni prescribing information. Takeda Pharmaceuticals America, Inc. March 2022.
12	American Diabetes Association. Standards of Medical Care in Diabetes-2022. Available at https://diabetesjournals.org/care/issue/45/Supplement_1 .
13	Nuha A. ElSayed, et. al, American Diabetes Association, 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2023. Diabetes Care 1 January 2023; 46 (Supplement_1): S140–S157. https://doi.org/10.2337/dc23-S009 .
14	Zituvio prescribing information. Zydus Pharmaceuticals (USA) Inc. October 2023.

POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
1-Step Through Preferred						
Jentaduetto ; Jentaduetto xr	linagliptin-metformin hcl tab ; linagliptin-metformin hcl tab er	2.5-1000 MG ; 2.5-500 MG ; 2.5-850 MG ; 5-1000 MG	M ; N ; O	N		
Kazano	alogliptin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG	M ; N ; O	M ; N		
Kombiglyze xr	saxagliptin-metformin hcl tab er	2.5-1000 MG ; 5-1000 MG ; 5-500 MG	M ; N ; O	O ; Y		
Nesina	alogliptin benzoate tab	12.5 MG ; 25 MG ; 6.25 MG	M ; N ; O	M ; N		
Onglyza	saxagliptin hcl tab	2.5 MG ; 5 MG	M ; N ; O	O ; Y		
Oseni	alogliptin-pioglitazone tab	12.5-15 MG ; 12.5-30 MG ; 12.5-45 MG ; 25-15 MG ; 25-30 MG ; 25-45 MG	M ; N ; O	M ; N		
Tradjenta	linagliptin tab	5 MG	M ; N ; O	N		
Zituvio	sitagliptin tab	100 MG ; 25 MG ; 50 MG	M ; N ; O	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Janumet	sitagliptin-metformin hcl tab	50-1000 MG ; 50-500 MG	60	Tablets	30	DAYS			
Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS			
Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-500 MG	50-500 MG	30	Tablets	30	DAYS			
Januvia	sitagliptin phosphate tab	100 MG ; 25 MG ; 50 MG	30	Tablets	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Jentadueto	linagliptin-metformin hcl tab	2.5-1000 MG ; 2.5-500 MG ; 2.5-850 MG	60	Tablets	30	DAYS			
Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS			
Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS			
Kazano	alogliptin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG	30	Tablets	30	DAYS			
Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS			
Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS			
Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS			
Nesina	alogliptin benzoate tab	12.5 MG ; 25 MG ; 6.25 MG	30	Tablets	30	DAYS			
Onglyza	saxagliptin hcl tab	2.5 MG ; 5 MG	30	Tablets	30	DAYS			
Oseni	alogliptin-pioglitazone tab	12.5-15 MG ; 12.5-30 MG ; 12.5-45 MG ; 25-15 MG ; 25-30 MG ; 25-45 MG	30	Tablets	30	DAYS			
Tradjenta	Linagliptin Tab 5 MG	5 MG	30	Tablets	30	DAYS			
Zituvio	sitagliptin tab	25 MG	30	Tablets	30	DAYS			
Zituvio	sitagliptin tab	50 MG	30	Tablets	30	DAYS			
Zituvio	sitagliptin tab	100 MG	30	Tablets	30	DAYS			

CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Jentadueto ; Jentadueto xr	linagliptin-metformin hcl tab ; linagliptin-metformin hcl tab er	2.5-1000 MG ; 2.5-500 MG ; 2.5-850 MG ; 5-1000 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Kazano	alogliptin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx
Kombiglyze xr	saxagliptin-metformin hcl tab er	2.5-1000 MG ; 5-1000 MG ; 5-500 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx
Nesina	alogliptin benzoate tab	12.5 MG ; 25 MG ; 6.25 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx
Onglyza	saxagliptin hcl tab	2.5 MG ; 5 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx
Oseni	alogliptin-pioglitazone tab	12.5-15 MG ; 12.5-30 MG ; 12.5-45 MG ; 25-15 MG ; 25-30 MG ; 25-45 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx
Tradjenta	linagliptin tab	5 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx
Zituvio	sitagliptin tab	100 MG ; 25 MG ; 50 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Janumet	sitagliptin-metformin hcl tab	50-1000 MG ; 50-500 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 100-1000 MG	100-1000 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-1000 MG	50-1000 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-500 MG	50-500 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Januvia	sitagliptin phosphate tab	100 MG ; 25 MG ; 50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Jentadueto	linagliptin-metformin hcl tab	2.5-1000 MG ; 2.5-500 MG ; 2.5-850 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Health Insurance Marketplace/BasicRx ; KeyRx
Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Kazano	alogliptin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Nesina	alogliptin benzoate tab	12.5 MG ; 25 MG ; 6.25 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Onglyza	saxagliptin hcl tab	2.5 MG ; 5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Oseni	alogliptin-pioglitazone tab	12.5-15 MG ; 12.5-30 MG ; 12.5-45 MG ; 25-15 MG ; 25-30 MG ; 25-45 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Tradjenta	Linagliptin Tab 5 MG	5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zituvio	sitagliptin tab	50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zituvio	sitagliptin tab	25 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Marketplace/BasicRx ; KeyRx
Zituvio	sitagliptin tab	100 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval				
1-Step Through Preferred	<table border="1"> <thead> <tr> <th>Preferred Agents</th> <th>Non-preferred Agents</th> </tr> </thead> <tbody> <tr> <td> Januvia (sitagliptin) Janumet (sitagliptin/metformin) Janumet XR (sitagliptin/metformin extended-release) </td> <td> Alogliptin Alogliptin/metformin Alogliptin/pioglitazone Jentaduetto (linagliptin/metformin) Jentaduetto XR (linagliptin/metformin ER) Kazano (alogliptin/metformin) Kombiglyze XR (saxagliptin/metformin ER)* Nesina (alogliptin) Onglyza (saxagliptin)* Oseni (alogliptin/pioglitazone) Tradjenta (linagliptin) Zituvio (sitagliptin) </td> </tr> </tbody> </table> <p>* available as generic; not a prerequisite or target in the step therapy program</p> <p>Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> The patient is currently being treated with the requested agent as indicated by ALL of the following: <ol style="list-style-type: none"> A statement by the prescriber that the patient is currently taking the requested agent AND A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent AND The prescriber states that a change in therapy is expected to be ineffective or cause harm OR The patient's medication history includes use of one or more of the following: Januvia, Janumet, Janumet XR OR BOTH of the following: <ol style="list-style-type: none"> The prescriber has stated that the patient has tried Januvia, Janumet, or Janumet XR AND Januvia, Janumet, or Janumet XR was discontinued due to lack of effectiveness or an adverse event OR The patient has an intolerance or hypersensitivity to a preferred sitagliptin agent OR The patient has an FDA labeled contraindication to a preferred sitagliptin agent that is not expected to occur with the requested agent OR The prescriber has provided documentation that a preferred sitagliptin agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm <p>Length of Approval: 12 months</p> <p>NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.</p>	Preferred Agents	Non-preferred Agents	Januvia (sitagliptin) Janumet (sitagliptin/metformin) Janumet XR (sitagliptin/metformin extended-release)	Alogliptin Alogliptin/metformin Alogliptin/pioglitazone Jentaduetto (linagliptin/metformin) Jentaduetto XR (linagliptin/metformin ER) Kazano (alogliptin/metformin) Kombiglyze XR (saxagliptin/metformin ER)* Nesina (alogliptin) Onglyza (saxagliptin)* Oseni (alogliptin/pioglitazone) Tradjenta (linagliptin) Zituvio (sitagliptin)
Preferred Agents	Non-preferred Agents				
Januvia (sitagliptin) Janumet (sitagliptin/metformin) Janumet XR (sitagliptin/metformin extended-release)	Alogliptin Alogliptin/metformin Alogliptin/pioglitazone Jentaduetto (linagliptin/metformin) Jentaduetto XR (linagliptin/metformin ER) Kazano (alogliptin/metformin) Kombiglyze XR (saxagliptin/metformin ER)* Nesina (alogliptin) Onglyza (saxagliptin)* Oseni (alogliptin/pioglitazone) Tradjenta (linagliptin) Zituvio (sitagliptin)				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	<p>Quantity limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 2. There is support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR C. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication <p>Length of Approval: up to 12 months</p>