

DPP-4 Inhibitors and Combinations Step Therapy with Quantity Limit Program Summary

Florida Blue/Truli does not accept the use of samples to satisfy prerequisite requirements in any of the step therapy or prior authorization programs. Samples would also include any type of prescription or copay assistance rendered to the patient by the drug manufacturer or any other organization that would allow the patient to get the drug without a paid claim through billing Florida Blue/Truli.

For a complete list of Florida Blue step therapy programs, please refer to the following link:
http://www.bcbsfl.com/DocumentLibrary/Providers/Content/Rx_ResponsibleSteps.pdf

For a complete list of Truli step therapy programs, please refer to the following link:
<https://www.myprime.com/en/forms/coverage-determination/step-therapy.html>

POLICY REVIEW CYCLE

Effective Date
04-01-2025

Date of Origin

FDA LABELED 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 		7

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

Agent(s)	FDA Indication(s)	Notes	Ref#
	<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 Has not been studied in patients with a history of pancreatitis 		
Zituvimet™ (sitagliptin free base/metformin) Tablet	<p>Indicated as an 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"> Zituvimet is not recommended in patients with type 1 diabetes mellitus Zituvimet has not been studied in patients with a history of pancreatitis 		15
Zituvimet™ XR (sitagliptan free base/metformin) Tablet	<p>Indicated as an 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"> Zituvimet is not recommended in patients with type 1 diabetes mellitus Zituvimet has not been studied in patients with a history of pancreatitis 		16
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, Kombiglyze XR, Zituvimet, and Zituvimet XR carry a black box warning for lactic acidosis:(7-10,15)</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. • 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, Kombiglyze XR, Zituvimet, and Zituvimet XR have the following contraindications:(5,6,9,15)</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.
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	<ul style="list-style-type: none"> 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 2023.
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.
10	Kazano prescribing information. Takeda Pharmaceuticals America, Inc. July 2023.
11	Oseni prescribing information. Takeda Pharmaceuticals America, Inc. June 2024.
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. August 2024.
15	Zituvimet prescribing information. Zydus Pharmaceuticals (USA) Inc. July 2024.
16	Zituvimet XR prescribing information. Zydus Pharmaceuticals (USA) Inc. July 2024.

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
2-Step Edit						
Alogliptin ; Nesina	alogliptin benzoate tab	12.5 MG ; 25 MG ; 6.25 MG	M ; N ; O	M ; N		
Alogliptin/metformin hcl ; Alogliptin/metformin hydr ; Kazano	alogliptin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG	M ; N ; O	M ; N		
Alogliptin/pioglitazone ; Oseni	alogliptin-pioglitazone tab	12.5-30 MG ; 25-15 MG ; 25-30 MG ; 25-45 MG	M ; N ; O	M ; N		
Janumet ; Janumet xr	sitagliptin-metformin hcl tab ; sitagliptin-metformin hcl tab er	100-1000 MG ; 50-1000 MG ; 50-500 MG	M ; N ; O	N		
Januvia	sitagliptin phosphate tab	100 MG ; 25 MG ; 50 MG	M ; N ; O	N		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
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	M ; N ; O	N		
Kombiglyze xr ; Saxagliptin hydrochloride	saxagliptin-metformin hcl tab er	2.5-1000 MG ; 5-1000 MG ; 5-500 MG	M ; N ; O	O ; Y		
Onglyza ; Saxagliptin hydrochloride	saxagliptin hcl tab	2.5 MG ; 5 MG	M ; N ; O	O ; Y		
Sitagliptin ; Zituvo	sitagliptin tab	100 MG ; 25 MG ; 50 MG	M ; N ; O	N		
Sitagliptin/metformin hyd ; Zituvimet ; Zituvimet xr	sitagliptin free base-metformin hcl tab ; sitagliptin free base-metformin hcl tab er	100-1000 MG ; 50-1000 MG ; 50-500 MG	M ; N ; O	N		
Tradjenta	linagliptin tab	5 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
Alogliptin ; Nesina	alogliptin benzoate tab	12.5 MG ; 25 MG ; 6.25 MG	30	Tablets	30	DAYS			
Alogliptin/metformin hcl ; Alogliptin/metformin hydr ; Kazano	alogliptin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG	60	Tablets	30	DAYS			
Alogliptin/pioglitazone ; Oseni	alogliptin-pioglitazone tab	12.5-30 MG ; 25-15 MG ; 25-30 MG ; 25-45 MG	30	Tablets	30	DAYS			
Janumet	sitagliptin-metformin hcl tab	50-1000 MG ; 50-500 MG	60	Tablets	30	DAYS			
Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 100-1000 MG	100-1000 MG	30	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			
Jentadueto	Linagliptin-Metformin HCl Tab 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS			
Jentadueto	Linagliptin-Metformin HCl Tab 2.5-500 MG	2.5-500 MG	60	Tablets	30	DAYS			
Jentadueto	Linagliptin-Metformin HCl Tab 2.5-850 MG	2.5-850 MG	60	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
Jentaduetto xr	Linagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS			
Jentaduetto xr	Linagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS			
Kombiglyze xr ; Saxagliptin hydrochloride	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS			
Kombiglyze xr ; Saxagliptin hydrochloride	Saxagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS			
Kombiglyze xr ; Saxagliptin hydrochloride	Saxagliptin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS			
Onglyza ; Saxagliptin hydrochloride	saxagliptin hcl tab	2.5 MG ; 5 MG	30	Tablets	30	DAYS			
Sitagliptin ; Zituvio	sitagliptin tab	100 MG ; 25 MG ; 50 MG	30	Tablets	30	DAYS			
Sitagliptin/metformin hyd ; Zituvimet	sitagliptin free base-metformin hcl tab	50-1000 MG ; 50-500 MG	60	Tablets	30	DAYS			
Tradjenta	linagliptin tab	5 MG	30	Tablets	30	DAYS			
Zituvimet xr	sitagliptin free base-metformin hcl tab er	50-500 MG	60	Tablets	30	DAYS			
Zituvimet xr	sitagliptin free base-metformin hcl tab er	50-1000 MG	60	Tablets	30	DAYS			
Zituvimet xr	sitagliptin free base-metformin hcl tab er	100-1000 MG	30	Tablets	30	DAYS			

CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Alogliptin ; Nesina	alogliptin benzoate tab	12.5 MG ; 25 MG ; 6.25 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Alogliptin/metformin hcl ; Alogliptin/metformin hydr ; Kazano	alogliptin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Alogliptin/pioglitazone ; Oseni	alogliptin-pioglitazone tab	12.5-30 MG ; 25-15 MG ; 25-30 MG ; 25-45 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Janumet ; Janumet xr	sitagliptin-metformin hcl tab ; sitagliptin-metformin hcl tab er	100-1000 MG ; 50-1000 MG ; 50-500 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Januvia	sitagliptin phosphate tab	100 MG ; 25 MG ; 50 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
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	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Kombiglyze xr ; Saxagliptin hydrochloride	saxagliptin-metformin hcl tab er	2.5-1000 MG ; 5-1000 MG ; 5-500 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Onglyza ; Saxagliptin hydrochloride	saxagliptin hcl tab	2.5 MG ; 5 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Sitagliptin ; Zituvio	sitagliptin tab	100 MG ; 25 MG ; 50 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Sitagliptin/metformin hyd ; Zituvimet ; Zituvimet xr	sitagliptin free base-metformin hcl tab ; sitagliptin free base-metformin hcl tab er	100-1000 MG ; 50-1000 MG ; 50-500 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Tradjenta	linagliptin tab	5 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Alogliptin ; Nesina	alogliptin benzoate tab	12.5 MG ; 25 MG ; 6.25 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Alogliptin/metformin hcl ; Alogliptin/metformin hydr ; Kazano	alogliptin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Alogliptin/pioglitazone ; Oseni	alogliptin-pioglitazone tab	12.5-30 MG ; 25-15 MG ; 25-30 MG ; 25-45 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Janumet	sitagliptin-metformin hcl tab	50-1000 MG ; 50-500 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 100-1000 MG	100-1000 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-1000 MG	50-1000 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-500 MG	50-500 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Januvia	sitagliptin phosphate tab	100 MG ; 25 MG ; 50 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Jentadueto	Linagliptin-Metformin HCl Tab 2.5-1000 MG	2.5-1000 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Jentadueto	Linagliptin-Metformin HCl Tab 2.5-500 MG	2.5-500 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Jentadueto	Linagliptin-Metformin HCl Tab 2.5-850 MG	2.5-850 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Kombiglyze xr ; Saxagliptin hydrochloride	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Kombiglyze xr ; Saxagliptin hydrochloride	Saxagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Kombiglyze xr ; Saxagliptin hydrochloride	Saxagliptin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Onglyza ; Saxagliptin hydrochloride	saxagliptin hcl tab	2.5 MG ; 5 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Sitagliptin ; Zituvio	sitagliptin tab	100 MG ; 25 MG ; 50 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Sitagliptin/metformin hyd ; Zituvimet	sitagliptin free base-metformin hcl tab	50-1000 MG ; 50-500 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Tradjenta	linagliptin tab	5 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Zituvimet xr	sitagliptin free base-metformin hcl tab er	50-500 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Zituvimet xr	sitagliptin free base-metformin hcl tab er	50-1000 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Zituvimet xr	sitagliptin free base-metformin hcl tab er	100-1000 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
2-Step Edit	

Module	Clinical Criteria for Approval	
	Preferred Agents Januvia (sitagliptin) Janumet (sitagliptin/metformin) Janumet XR (sitagliptin/metformin ER)	Non-preferred Agents Alogliptin Alogliptin/metformin Alogliptin/pioglitazone Jentadueto (linagliptin/metformin) Jentadueto XR (linagliptin/metformin ER) Kazano (alogliptin/metformin) Kombiglyze XR (saxagliptin/metformin ER) Nesina (alogliptin) Onglyza (saxagliptin) Oseni (alogliptin/pioglitazone) Tradjenta (linagliptin) Zituvimet (sitagliptin free base/metformin) Zituvimet XR (sitagliptin free base/metformin ER) Zituvio, Sitagliptin
	<p>Preferred Agent(s) will be approved when ALL of the following is met:</p> <ol style="list-style-type: none"> ONE of the following: <ol style="list-style-type: none"> The patient has been treated with the requested preferred agent within the past 90 days OR The prescriber states the patient has been treated with the requested preferred agent within the past 90 days AND is at risk if therapy is changed OR The patient's medication history includes use of an agent containing metformin or insulin within the past 90 days* OR The patient has an intolerance or hypersensitivity to ONE of the following: metformin or insulin OR The patient has an FDA labeled contraindication to ALL of the following: metformin and insulin OR The patient is switching to a preferred DPP-4 inhibitor agent and the patient's medication history includes use of a non-preferred DPP-4 inhibitor agent within the past 90 days AND The patient will NOT be using the requested agent in combination with another DPP-4 inhibitor/combination agent (e.g., Alogliptin, Alogliptin/metformin, Alogliptin/pioglitazone, Januvia, Janumet, Janumet XR, Jentadueto, Jentadueto XR, Kazano, Kombiglyze XR, Nesina, Onglyza, Oseni, Tradjenta, Zituvio, Zituvimet, Zituvimet XR) for the requested indication AND The patient will NOT be using the requested agent in combination with a GLP-1 or GLP-1/GIP receptor agonist (e.g., Saxenda, Wegovy, Zepbound, Adlyxin, Bydureon, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza) <p>Non-Preferred Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> ONE of the following: <ol style="list-style-type: none"> The patient's medication history includes use of an agent containing metformin or insulin* OR The patient has an intolerance or hypersensitivity to ONE of the following: metformin or insulin OR The patient has an FDA labeled contraindication to ALL of the following: metformin and insulin AND ONE of the following: <ol style="list-style-type: none"> The patient's medication history includes use of a preferred DPP-4 inhibitor agent* OR The patient has an intolerance or hypersensitivity to sitagliptin that is not expected to occur with the requested agent sitagliptin OR The patient has an FDA labeled contraindication to sitagliptin that is not expected to occur with the requested agent AND The patient will NOT be using the requested agent in combination with another DPP-4 inhibitor/combination agent (e.g., Alogliptin, Alogliptin/metformin, Alogliptin/pioglitazone, Januvia, 	

Module	Clinical Criteria for Approval
	<p>Janumet, Janumet XR, Jentadueto, Jentadueto XR, Kazano, Kombiglyze XR, Nesina, Onglyza, Oseni, Tradjenta, Zituvio, Zituvimet, Zituvimet XR) for the requested indication AND</p> <p>4. The patient will NOT be using the requested agent in combination with a GLP-1 or GLP-1/GIP receptor agonist (e.g., Saxenda, Wegovy, Zepbound, Adlyxin, Bydureon, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza)</p> <p>Length of Approval: 12 months</p> <p>* Step therapy requirement may not apply if a prior health plan paid for the medication - documentation of a paid claim may be required</p> <p>NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal QL	<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"> The requested quantity (dose) does NOT exceed the program quantity limit OR The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> BOTH of the following: <ol style="list-style-type: none"> The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND There is support for therapy with a higher dose for the requested indication OR BOTH of the following: <ol style="list-style-type: none"> The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND There is support for 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 BOTH of the following: <ol style="list-style-type: none"> The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND There is support for therapy with a higher dose for the requested indication <p>Length of Approval: up to 12 months</p>