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AETNA BE	TTER HEALTH®			
Coverage	Policy/Guideline			
Name:	lame: Liraglutide, Ozempic, and Trulicity		Page:	1 of 5
Effective Date: 2/4/2025		Last Review Date: 1/2025		
A mulion	□Illinois	□Florida	⊠Florida Kids	
Applies to:	☐New Jersey	⊠Maryland	□Michigan	
	⊠Pennsylvania Kids	□Virginia	⊠Kentucky PRMD	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Liraglutide, Ozempic, and Trulicity under the patient's prescription drug benefit.

Description:

Liraglutide

Liraglutide is indicated:

- as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use

- Liraglutide should not be used in patients with type 1 diabetes mellitus.
- Liraglutide contains liraglutide and should not be coadministered with other liraglutide-containing products.

Compendial Uses

Advanced chronic kidney disease (CKD) in adults with type 2 diabetes mellitus

Ozempic

Ozempic is indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use

- Ozempic has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Ozempic is not indicated for use in patients with type 1 diabetes mellitus.

Compendial Uses

Advanced chronic kidney disease (CKD) in adults with type 2 diabetes mellitus

Trulicity

Trulicity is indicated:

• As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus.

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 To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Limitations of Use

- Trulicity has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Trulicity should not be used in patients with type 1 diabetes mellitus.
- Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and is therefore not recommended in these patients.

Compendial Uses

Advanced chronic kidney disease (CKD) in adults with type 2 diabetes mellitus

Applicable Drug List:

Formulary with Step Therapy: Liraglutide Ozempic

Non-preferred:

Trulicity

Policy/Guideline:

If the patient has filled at least 60 days of metformin within the past 180 days under the Aetna Better Health prescription benefit and has a diagnosis of Type 2 Diabetes, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Coverage Criteria

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when the patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months when ALL of the following criteria are met:

- If the request is for a Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists [Note: Examples of GLP-1 Agonists are Ozempic, Trulicity, liraglutide.], then ONE of the following criteria is met:
 - The patient has a history of an A1C greater than or equal to 6.5 percent.
 [ACTION REQUIRED: Documentation is required for approval.]

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- The patient has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL [ACTION REQUIRED: Documentation is required for approval.] when the following criteria is met:
 - The patient fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- The patient meets ONE of the following criteria and for Trulicity has had a trial and failure or contraindication to both Ozempic AND liraglutide unless otherwise noted**:
 - The patient experienced an inadequate treatment response, intolerance, or has a contraindication to metformin
 - The patient requires combination therapy AND has an A1C of 7.5 percent or greater
 - The patient has established cardiovascular disease
 - The patient has multiple cardiovascular risk factors and the following criteria is met:
 - The request is for Trulicity (dulaglutide) (**trial and failure of Ozempic and liraglutide not required**)
 - The patient has a diagnosis of advanced chronic kidney disease (CKD)
 (estimated glomerular filtration rate [eGFR] less than 30 mL/min/1.73m2)

Continuation of Therapy

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when the patient has been receiving a stable maintenance dose of the requested drug for at least 3 months when ALL of the following criteria are met:

- If the request is for a Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists [Note: Examples of GLP-1 Agonists are Ozempic, Trulicity, liraglutide.], then ONE of the following criteria is met:
 - The patient has a history of an A1C greater than or equal to 6.5 percent.
 [ACTION REQUIRED: Documentation is required for approval.]
 - The patient has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [ACTION REQUIRED: Documentation is required for approval.]

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- The patient has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL [ACTION REQUIRED: Documentation is required for approval.] when the following criteria is met:
 - The patient fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- The patient meets ONE of the following criteria and for Trulicity has had a trial and failure or contraindication to both Ozempic AND liraglutide unless otherwise noted**:
 - The patient has demonstrated a reduction in A1C since starting this therapy
 - The patient has established cardiovascular disease
 - The patient has multiple cardiovascular risk factors and the following criteria is met:
 - The request is for Trulicity (dulaglutide) (**trial and failure of Ozempic and liraglutide not required**)
 - The patient has a diagnosis of advanced chronic kidney disease (CKD)
 (estimated glomerular filtration rate [eGFR] less than 30 mL/min/1.73m2) and
 the following criteria is met:

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

- 1. Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; September 2023.
- 2. Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2022.
- 3. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2023.
- 4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed March 4, 2024.
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- 7. Davies MJ, Aroda VR, Collins BS, et. al. Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2022;45(11):2753-2786.
- 8. American Diabetes Association Professional Practice Committee. American Diabetes Association, Standards of Care in Diabetes 2024. Diabetes Care. 2024:47(Suppl. 1):S1-S322.

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- 9. Heidenreich PA, Bozkurt B, Aguilar D et. al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2022;79:e263-e421.
- Kittleson MM, Panjrath GS, Amancherla K et. al. 2023 ACC expert consensus decision pathway on management of heart failure with preserved ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2023;81(18):1835-1878.
- 11. Maddox TM, Januzzi JL Jr, Allen LA, et. al. 2024 ACC expert consensus decision pathway for treatment of heart failure with reduced ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol* 2024;XX:XXX-XX.
- 12. Samson SL, Vellanki P, Blonde L et. al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm 2023 Update. Endocrine Practice 2023;29(5):P305-340.