

Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

Guideline Name	Incretin Mimetics: Adlyxin (lixisenatide), Bydureon (exenatide), Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), and Victoza (liraglutide)
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Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, the below prior authorization criteria will apply.

1. Criteria

Product Name: Adlyxin	
Approval Length	24 Month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization/Step Therapy, Non-Formulary
<p>Approval Criteria</p> <p>1 - Patient has type 2 diabetes</p> <p style="text-align: center;">AND</p> <p>2 - Patient has tried and failed or is currently taking an oral hypoglycemic agent (such as a sulfonylurea, thiazolidinedione, metformin, DPP-IV inhibitor, SGLT2 inhibitor, or combination of these agents)</p> <p style="text-align: center;">AND</p> <p>3 - Patient has tried and failed a formulary incretin mimetic (i.e. Trulicity, Byetta, Bydureon, Ozempic or Victoza)</p>	

Product Name: Bydureon, Byetta, Ozempic, Trulicity, or Victoza	
Approval Length	24 Month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization/Step Therapy
<p>Approval Criteria</p> <p>1 - Patient has type 2 diabetes</p> <p style="text-align: center;">AND</p>	

2 - Patient has tried and failed or is currently taking an oral hypoglycemic agent (such as a sulfonylurea, thiazolidinedione, metformin, DPP-IV inhibitor, SGLT2 inhibitor, or combination of these agents)

Product Name: Adlyxin, Bydureon, Byetta, Ozempic, Trulicity, or Victoza	
Approval Length	24 Month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization/Step Therapy, Non-Formulary
Approval Criteria	
1 - Patient has shown improvement or is stable on the requested medication	

2. Background

<p>Benefit/Coverage/Program Information</p> <p>Note: Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then the prescription will deny at point of service with a message indicating that prior authorization (PA) is required.</p> <p>Members who do not meet the step therapy criteria at point of service will need to submit a request for clinical review. First level drug therapy required include the following:</p> <ul style="list-style-type: none"> • Antidiabetic agents such as a sulfonylurea, thiazolidinedione, metformin, DPP-IV inhibitor, SGLT2 inhibitor or a combination product of these agents. • Lookback is 120 days. <p>RATIONALE</p> <p>To ensure that GLP-1 Agonists are not being used for weight loss and that they are being used appropriately for Type II Diabetes.</p> <p>FDA APPROVED INDICATIONS</p> <p>Bydureon is indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type II Diabetes Mellitus in multiple clinical settings.</p> <p>Byetta is indicated as an adjunct to diet and exercise to improve glycemic control and as adjunctive treatment for patients with Type II Diabetes Mellitus who are taking metformin, a sulfonylurea, a thiazolidinedione, or a combination of metformin and a sulfonylurea or thiazolidinedione but have not achieved adequate glycemic control.</p> <p>Ozempic is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.</p> <p>Tanzeum is indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type II Diabetes Mellitus.</p>
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Trulicity is indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type II Diabetes Mellitus.

Victoza is indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type II Diabetes Mellitus. It has been indicated to reduce the risk of major cardiovascular events in adults with Type II Diabetes Mellitus and established cardiovascular disease.

REFERENCES

- Byetta Product Information. Amylin Pharmaceuticals. December 2018.
- Victoza Product Information. Novo Nordisk Inc. January 2018.
- Bydureon Product Information. Amylin Pharmaceuticals. February 2019.
- Trulicity Product Information. Eli Lilly and Company. January 2019.
- Adlyxin Product Information. Sanofi-Aventis LLC. January 2019.
- Ozempic Prescribing Information. Novo Nordisk Inc. April 2019.

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