

Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

Guideline Name	Incretin Mimetics: Adlyxin (lixisenatide), Bydureon (exenatide), Byetta (exenatide), Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), and Victoza (liraglutide)
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1. Criteria

Product Name: Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, or Victoza	
Approval Length	24 Month(s)
Therapy Stage	Initial Authorization
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Patient has type 2 diabetes</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure or is currently taking ONE oral hypoglycemic agent (such as a sulfonylurea, thiazolidinedione, metformin, DPP-IV inhibitor, SGLT2 inhibitor, or combination of these agents)</p>	

Product Name: Adlyxin	
Approval Length	24 Month(s)
Therapy Stage	Initial Authorization
Guideline Type	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 - Trial and failure or is currently taking ONE 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 - Trial and failure of ONE preferred incretin mimetic (i.e. Trulicity, Byetta, Bydureon, Ozempic, Victoza, or Rybelsus)</p>	

Product Name: Adlyxin, Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, or Victoza	
Approval Length	24 Month(s)
Therapy Stage	Reauthorization
Guideline Type	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>STEP THERAPY*: 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 180 days. <p><i>*Adlyxin may be Non-Formulary. Step Therapy point of service coding described above does NOT apply to Non-Formulary medications.</i></p> <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 2 diabetes mellitus.</p> <p>FDA APPROVED INDICATIONS</p> <p>Adlyxin (lixisenatide) injection is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. <i>Limitations of Use:</i> Has not been studied in patients with chronic pancreatitis or a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis; Not for treatment of type 1 diabetes or diabetic ketoacidosis; Has not been studied in combination with short acting insulin; Has not been studied and is not recommended in patients with gastroparesis.</p> <p>Bydureon BCise (exenatide extended-release) injectable is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. <i>Limitations of Use:</i> Not recommended as first-line therapy for patients inadequately controlled on diet and exercise; Should not be used to treat type 1 diabetes; Bydureon Bcise is an extended-release formulation of exenatide. Do not coadminister with other exenatide containing products; Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patient with a history of pancreatitis.</p>
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Byetta (exenatide) injection is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use: Should not be used to treat type 1 diabetes; Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patient with a history of pancreatitis.

Ozempic (semaglutide) injection is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It has been indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use: Has not been studied in patients with a history of pancreatitis (consider another antidiabetic therapy); Not for treatment of type 1 diabetes mellitus.

Rybelsus (semaglutide) tablets is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use: Not recommended as first-line therapy for patients inadequately controlled on diet and exercise; Has not been studied in patients with a history of pancreatitis; Not for treatment of type 1 diabetes mellitus.

Trulicity (dulaglutide) injection is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It has been indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Limitations of Use: Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in these patients; Not for treatment of type 1 diabetes mellitus; Not recommended in patients with severe gastrointestinal disease, including severe gastroparesis.

Victoza (liraglutide) injection is indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus. It has been indicated to reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use: Not for treatment of type 1 diabetes mellitus; Should not be coadministered with other liraglutide-containing products.

REFERENCES

- Bydureon BCise (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2020.
- Byetta (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2021.
- Victoza (liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; November 2020.
- Trulicity (dulaglutide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; April 2021.
- Adlyxin (lixisenatide) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; January 2019.
- Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; April 2021.
- Rybelsus (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; April 2021.

Created: 09/11/06
Revised: <ul style="list-style-type: none">• Annual review (effective: 1/1/20)• 5/20/20 - Clarified guideline type to include Step Therapy (effective: 6/1/20)• 10/11/20 - Annual review: background updates; increased ST lookback from 120 to 180 days; added Rybelsus (effective: 1/1/21)• 6/14/21 - Annual review: background updates; updated criteria to reflect that Rybelsus is now a preferred GLP requiring ST
P&T Approval: 6/14/21
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