

## Pharmacy Policy Bulletin

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**Title:** Injectable Antidiabetic Agents

**Policy #:** Rx.01.162

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

### ▶ **Intent:**

The intent of this policy is to communicate the medical necessity criteria for albiglutide (Tanzeum), lixisenatide (Adlyxin), insulin glargine/ lixisenatide (Soliqua) and pramlintide (Symlin Pen) as provided under the member's pharmacy benefit.

### ▶ **Description:**

Albiglutide and lixisenatide are glucagon-like peptide (GLP-1) receptor agonists. Upon activation of GLP-1 receptors on pancreatic beta cells, insulin release is stimulated and gastric emptying is delayed. GLP-1 agonists increase intracellular cyclic AMP (cAMP) in beta cells leading to glucose-dependent insulin release and slow gastric emptying.

Insulin glargine is a basal insulin analog.

Albiglutide (Tanzeum) and lixisenatide (Adlyxin) are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Insulin glargine/ lixisenatide (Soliqua) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 60 units per day) or lixisenatide.

Pramlintide is a synthetic analog of the naturally occurring beta-cell hormone amylin. Amylin is co-secreted with insulin by beta cells in response to meals, and it aids in the regulation of glucose levels. Pramlintide works by slowing gastric emptying, decreasing post-prandial glucagon secretion, and inducing weight loss.

Pramlintide (SymlinPen®) is indicated as an adjunctive treatment in patients with type 1 or type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.

▸ **Policy:**

Albiglutide (Tanzeum) and lixisenatide (Adlyxin) are approved when BOTH of the following criteria are met:

1. Documentation of Type 2 diabetes; and
2. Inadequate response or inability to tolerate ONE of the following: dulaglutide (Trulicity), exenatide (Byetta, Bydureon), or liraglutide (Victoza)

Insulin glargine/lixisenatide (Soliqua) is approved when All of the following criteria are met:

1. Documentation of type 2 diabetes; and
2. Inadequate response or inability to tolerate combination therapy with the following:
  - a. ONE of the following: dulaglutide (Trulicity), exenatide (Byetta, Bydureon), or liraglutide (Victoza) AND
  - b. ONE of the following : Lantus, Levemir, Toujeo, or Tresiba

Pramlintide (SymlinPen) is approved when there is a diagnosis of diabetes (type 1 or 2) with concurrent insulin therapy.

▸ **Black Box Warning:**

**Albiglutide (Tanzeum)**

Thyroid C-cell tumors have been observed in rodent studies with glucagonlike peptide 1 (GLP-1) receptor agonists at clinically relevant exposures. It is unknown whether albiglutide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans.

Albiglutide is contraindicated in patients with a personal or family history of MTC or in patients with multiple endocrine neoplasia type 2 (MEN2). Routine serum calcitonin or thyroid ultrasound monitoring is of uncertain value in patients treated with albiglutide. Patients should be counseled regarding the risk and symptoms of thyroid tumors.

**Pramlintide (SymlinPen)**

Pramlintide is used with insulin and has been associated with an increased risk of insulin-induced severe hypoglycemia, particularly in patients with type 1 diabetes. When severe hypoglycemia associated with pramlintide use occurs, it is seen within 3 hours following a pramlintide injection. If severe hypoglycemia occurs while operating a motor vehicle, heavy machinery, or while engaging in other high-risk activities, serious injuries may occur. Appropriate patient selection, careful patient instruction, and insulin dose adjustments are critical elements for reducing this risk.

▸ **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▸ **References:**

Cefalu WT, editor. American Diabetes Association Standards of Medical Care in Diabetes-2016. Available at: [http://care.diabetesjournals.org/content/suppl/2015/12/21/39.Supplement\\_1.DC2/2016-Standards-of-Care.pdf](http://care.diabetesjournals.org/content/suppl/2015/12/21/39.Supplement_1.DC2/2016-Standards-of-Care.pdf). Accessed November 9, 2016.


Adlyxin (lixisenatide) [package insert]. Bridgewater, NJ. Sanofi-Aventis US, LLC. July 2016. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=1727cc16-4f86-4f13-b8b5-804d4984fa8c&type=display>. Accessed April 10, 2017.

Soliqua (insulin glargine/ lixisenatide) [package insert]. Bridgewater, NJ. Sanofi-Aventis US, LLC. November 2016. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=4bba538b-cf7c-4310-ae8f-cb711ed21bcc&type=display>. Accessed April 10, 2017.

SymlinPen® (pramlintide) [package insert]. Wilmington, DE. Astra Zeneca. April 2016. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=4aea30ff-eb0d-45c1-b114-3127966328ff&type=display>. Accessed November 9, 2016.

Tanzeum (albiglutide) [package insert]. Research Triangle Park, NC. GlaxoSmithKline. September 2016. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5fcad939-76e7-49cf-af94-4e6aef17901f&type=display>. Accessed November 9, 2016.

#### Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Adlyxin	Lixisenatide
Soliqua	Insulin glargine/ lixisenatide
Tanzeum	Albiglutide
Symlin/Symlin Pen	Pramlintide

#### Cross References:

N/A

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<b>Policy Version Number:</b>	5.00
<b>P&amp;T Approval Date:</b>	April 6, 2017
<b>Policy Effective Date:</b>	May 1, 2017
<b>Next Required Review Date:</b>	October 13, 2017

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