



Medicaid Drug Use Criteria

Pramlintide

- Developed June 2018
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Information on indications for use or diagnosis is assumed to be unavailable. All criteria may be applied retrospectively; the prospective application is indicated with an asterisk [*]. The information contained is for the convenience of the public. The Texas Health and Human Services Commission is not responsible for any errors in transmission or any errors or omissions in the document.

Medications listed in the tables and non-FDA approved indications included in these retrospective criteria are not indicative of Vendor Drug Program formulary coverage.

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1 Dosage*

1.1 Adults

Pramlintide (Symlin®), a synthetic analog of human amylin, is FDA-approved for use as adjunct therapy in type 1 or type 2 diabetics using mealtime insulin who are not adequately controlled with optimal insulin therapy. Amylin is a neuroendocrine hormone secreted concurrently with insulin in response to food intake to decrease hepatic glucose output and slow gastric emptying, which results in reduced carbohydrate absorption and lower postprandial glucose levels. Similarly,

pramlintide works by delaying gastric emptying, decreasing postprandial increases in glucagon levels, and causing satiety, which promotes decreased caloric intake and potential weight loss. Pramlintide is available as a 1.5 ml disposable, multidose 60-pen injector or a 2.7 ml disposable, multidose 120-pen injector containing pramlintide 1000 mcg/ml. The 60-pen injector provides doses of 15 mcg, 30 mcg, 45 mcg, or 60 mcg while the 120-pen injector provides pramlintide doses of 60 mcg or 120 mcg. Recommended pramlintide dosages are summarized in Table 1.

Table 1. Adult Recommended Dosages

Treatment Indication	Dosage Form/Strength	Initial Dose	Dosage Titration	Maximum Recommended Dosage
type 1 diabetes mellitus	SymLinPen® 60 solution pen-injector (1000 mcg/mL, 1.5 mL)	15 mcg subcutaneously immediately prior to each major meal	15 mcg increments	60 mcg subcutaneously immediately prior to each major meal
type 2 diabetes mellitus (insulin-using)	SymLinPen® 120 solution pen-injector (1000 mcg/mL, 2.7 mL)	60 mcg subcutaneously immediately prior to each major meal	60 mcg increments	120 mcg subcutaneously immediately prior to each major meal

In patients with type 1 diabetes, dosage titrations should be initiated when clinically significant nausea has been absent for at least 3 days. If nausea persists with the 45 mcg or 60 mcg dose, the dosage may be reduced to 30 mcg. If patients do not tolerate the 30 mcg dose, discontinuing therapy may be necessary. In insulin-using patients with type 2 diabetes, dosage titrations may be initiated when significant nausea is absent for at least 3 days. If the 120 mcg dose is not tolerated, the dosage may be decreased to 60 mcg. For patients with type 1 or type 2 diabetes receiving pre-prandial rapid or short-acting insulin therapy, including fixed-mixed insulin, dose should be decreased by 50% when adjunctive pramlintide therapy is instigated to minimize hypoglycemic episodes. Insulin doses may be titrated upward as needed when a maintenance pramlintide dose is established. Patient profiles containing pramlintide prescription quantities of greater than 2 x 60-pen injectors or 1 x 120-pen injector per 30 days for patients with type 1 diabetes will be reviewed. Likewise, patient profiles containing pramlintide prescription quantities of greater than 2 x 120-pen injectors per 30 days for patients with type 2 diabetes will be reviewed.

Pramlintide should not be administered to patients who:

- have been diagnosed with gastroparesis within the last 2 years
- have recurrent episodes of hypoglycemia requiring intervention in the last 6 months and/or hypoglycemia unawareness
- have an HbA1c greater than 9%
- require therapy with medications that stimulate gastrointestinal motility
- are poorly compliant with insulin regimens and/or self-monitoring of blood glucose serum concentrations

1.2 Pediatrics

Safety and efficacy of pramlintide injections in pediatric patients have not been established. However, a few small, short-term crossover studies have evaluated pramlintide use in adolescents with type 1 diabetes and demonstrated significant reductions in postprandial hyperglycemia. Further long-term studies are necessary to solidify results.

2 Duration of Therapy

Pramlintide is indicated for the management of diabetes mellitus and may be continued indefinitely based on patient need to achieve desired glucose control.

3 Drug-Drug Interactions*

Patient profiles will be assessed to identify those drug regimens which may result in clinically significant drug-drug interactions. Drug-drug interactions considered clinically relevant for pramlintide are summarized in Table 2. Only those drug-drug interactions identified as clinical significance level 1 or those considered life-threatening which have not yet been classified will be reviewed:

Table 2. Pramlintide Drug-Drug Interactions

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level*
antidiabetic agents	fluoroquinolones	adjunctive administration may result in blood glucose disturbances and increased risk for hyper- or hypoglycemia due to an unknown mechanism	closely monitor blood glucose levels and adjust antidiabetic doses as needed; doses may also require adjustments with fluoroquinolone discontinuation	major (DrugReax) 3-moderate (CP)
antidiabetic agents	somatostatin analogues (SAs) (e.g., octreotide, pasireotide)	concurrent use may impair glucose regulation as SAs inhibit insulin and glucagon secretion; substantially increased blood glucose levels may result	monitor closely for changes in blood glucose control before and throughout SA therapy; adjust antidiabetic doses as needed	major (DrugReax) 2-major (CP)
pramlintide	alpha glucosidase inhibitors (e.g., acarbose, miglitol)	alpha glucosidase inhibitors slow nutritive absorption; adjunctive administration may potentiate pramlintide pharmacologic effects, increasing potential for additional blood glucose reductions and risk of hypoglycemia	concurrent administration not recommended by manufacturer	3-moderate (CP)
pramlintide	gastric stimulants (e.g., metoclopramide, tegaserod)	concurrent administration may attenuate pharmacologic effects of both agents	manufacturer states that pramlintide/gastric stimulant combination should be avoided	2-major (CP)

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level*
pramlintide	medications that slow gastrointestinal motility (e.g., tricyclic antidepressants, opiates, antimuscarinics, diphenoxylate)	adjunctive administration may enhance pramlintide pharmacologic effects, increasing potential for additional blood glucose reductions and risk of hypoglycemia	concurrent administration not recommended by manufacturer	2-major (CP)
pramlintide	insulin	adjunctive use may increase hypoglycemia risk; pramlintide pharmacokinetic parameters altered if mixed in same syringe with insulins	reduce mealtime insulin doses to minimize hypoglycemia; do not mix together; give as separate injections	2-major (CP)
pramlintide	oral medications with hypoglycemic effects (e.g., oral antidiabetic agents, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, disopyramide, fibric acid derivatives, salicylates, sulfonamide antibiotics)	concomitant administration may result in enhanced hypoglycemic pharmacologic and adverse effects	monitor blood glucose levels closely and adjust dosages as necessary if drug combination required to minimize excessive hypoglycemia and associated adverse events	moderate (DrugReax) 3-moderate (CP)
pramlintide	oral medications with rapid gastrointestinal (GI) absorption, or narrow therapeutic index	pramlintide delays gastric emptying; combined use may reduce serum levels of drugs with narrow therapeutic index, or those requiring rapid GI absorption	use cautiously together	4-minor (CP)

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level*
pramlintide	oral medications requiring threshold concentrations for effect (e.g., acetaminophen, oral contraceptives)	concurrent administration may reduce serum levels of drugs with threshold concentrations as pramlintide delays gastric emptying	use cautiously together; administer medications having threshold concentrations for effect at least 1 hour before or 2 hours after pramlintide	4-minor (CP)

4 References

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