FIRST AND ONLY GLP-1 RA indicated in combination with an SGLT2i[2]*

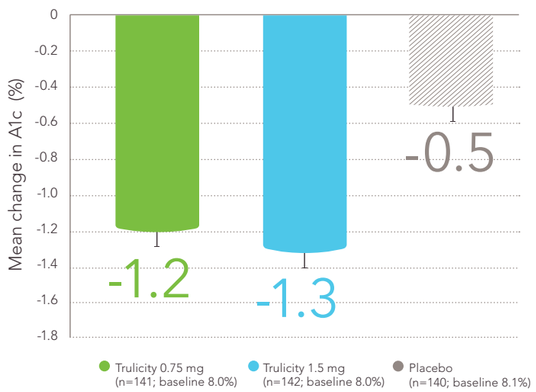
AWARD-10

NEW indication

Trulicity vs. placebo

Both in combination with SGLT2i ± metformin[1†‡]

Demonstrated A1c reduction from baseline at week 24



p<0.001 for superiority of both Trulicity doses vs. placebo.

Adapted from Product Monograph.

GLP-1 RA=glucagon-like peptide-1 receptor agonist; SGLT2i=sodium-glucose co-transporter 2 inhibitor.

* Comparative clinical significance is unknown.
† The recommended starting dose for Trulicity is 0.75 mg once weekly.
‡ 24-week, Phase 3, multicentre, randomized, parallel-arm, double-blind trial. Patients received either Trulicity 0.75 mg once weekly (n=141), Trulicity 1.5 mg once weekly (n=142), or placebo (n=140). Treatment was added to background therapy with SGLT2i with or without metformin. Primary endpoint was superiority of Trulicity vs. placebo in A1c reduction from baseline at 24 weeks.

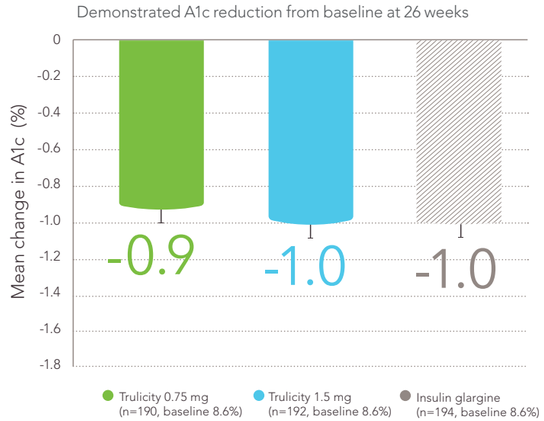
AWARD-7

NEW pivitol trial

Trulicity vs. insulin glargine in patients with moderate to severe CKD

Both in combination with insulin lispro
Non-inferiority, open-label study[1‡§]

Demonstrated A1c reduction from baseline at 26 weeks



p<0.001 for non-inferiority of both Trulicity doses vs. insulin glargine

Non-inferiority margin of 0.4%.

Adapted from Product Monograph.

‡ The recommended starting dose for Trulicity is 0.75 mg once weekly.
§ 52-week, Phase 3, multicentre, randomized, parallel-arm, open-label, active comparator trial in patients with type 2 diabetes and moderate to severe chronic kidney disease. Patients received either Trulicity 0.75 mg once weekly (n=190), Trulicity 1.5 mg once weekly (n=192), or insulin glargine (n=194). Primary endpoint was non-inferiority vs. insulin glargine in reduction in A1c from baseline at 26 weeks, margin for non-inferiority 0.4%.

The Trulicity pen has been shown to be easy to learn and easy to use[1]
Uncap, place and unlock, press and hold

Clinical use:
Trulicity is not a substitute for insulin. Trulicity should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Contraindications:
- Patients with a personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- Pregnant and nursing women

Most serious warnings and precautions:
Risk of thyroid C-cell tumors: In male and female rats, dulaglutide causes dose-dependent and treatment duration-dependent thyroid C-cell tumors after lifetime exposure. Patients should be counseled regarding the risk and symptoms of thyroid tumors.

Other relevant warnings and precautions:
- Heart rate increase
- Prolongation of PR interval
- Hypoglycemia (in combination with an insulin secretagogue or insulin)
- Severe gastrointestinal disease
- Pancreatitis
- Systemic hypersensitivity, including postmarketing reports of serious reactions (e.g., anaphylactic reactions and angioedema)
- Nausea, vomiting and diarrhea can lead to dehydration. It is important to avoid dehydration which can cause serious kidney problems even in people with normal kidney function
- Not studied in pediatric patients
- No dose adjustment required in patients over 65 years of age
- Hepatic or renal impairment
- Recent myocardial infarction, unstable angina and congestive heart failure

For more information:
Please consult the product monograph at www.lilly.ca/TrulicityPM/en for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The product monograph is also available by calling us at 1-888-545-5972.

Reference: 1. Trulicity Product Monograph. Eli Lilly Canada Inc.,August 15, 2019. **2.** Data on file. Eli Lilly Canada Inc., 2019.

To learn more about Trulicity, visit **LillyPro.ca**

MEMBER OF INNOVATIVE MEDICINES CANADA PAAB
PP-DG-CA-0169

Lilly

NEW pivotal trials & indication

once weekly
trulicity®
(dulaglutide) injection
0.75 mg/0.5 mL, 1.5 mg/0.5 mL

Trulicity® clinical trial overview

7 pivotal trials encompassing
>4,500 patients

Trulicity is indicated for the once-weekly treatment of adult patients with type 2 diabetes mellitus to improve glycemic control, in combination with:
- diet and exercise in patients for whom metformin is inappropriate due to contraindication or intolerance.
- metformin, when diet and exercise plus maximal tolerated dose of metformin do not achieve adequate glycemic control.
- metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control.
- sodium glucose co-transporter 2 inhibitor (SGLT2i) with metformin, when diet and exercise plus SGLT2i with or without metformin do not achieve adequate glycemic control.
- basal insulin with metformin, when diet and exercise plus basal insulin with or without metformin do not achieve adequate glycemic control.
- prandial insulin with metformin, when diet and exercise plus basal or basal-bolus insulin therapy (up to two injections of basal or basal *plus* prandial insulin per day) with or without oral antihyperglycemic medications, do not achieve adequate glycemic control.

Trulicity's AWARD study clinical program overview[1]

Studied in patients when diet and exercise plus maximal tolerated dose of metformin did not achieve adequate glycemic control		
AWARD-5 study Trulicity vs. placebo and vs. sitagliptin	**Primary endpoint: 52 weeks**	**972 patients**
AWARD-6 study Trulicity vs. liraglutide	**Primary endpoint: 26 weeks**	**599 patients**
Studied in patients when diet and exercise plus an SGLT2 inhibitor (SGLT2i) with or without metformin did not achieve adequate glycemic control		
AWARD-10 study Trulicity vs. placebo	**Primary endpoint: 24 weeks**	**424 patients**
Studied in patients when diet and exercise plus dual therapy with metformin and a sulfonylurea did not achieve adequate glycemic control		
AWARD-2 study Trulicity vs. insulin glargine	**Primary endpoint: 52 weeks**	**810 patients**
Studied in patients when diet and exercise plus basal insulin with or without metformin did not achieve adequate glycemic control		
AWARD-9 study Trulicity vs. placebo	**Primary endpoint: 28 weeks**	**300 patients**
Studied in patients started on mealtime insulin with or without metformin when diet and exercise plus basal insulin therapy with or without oral antihyperglycemic medications did not achieve adequate glycemic control		
AWARD-4 study Trulicity vs. insulin glargine	**Primary endpoint: 26 weeks**	**884 patients**
Studied in patients started on mealtime insulin without oral antihyperglycemic medications when diet and exercise plus basal insulin therapy with or without oral antihyperglycemic medications did not achieve adequate glycemic control		
AWARD-7 study Trulicity vs. insulin glargine in patients with moderate to severe CKD	**Primary endpoint: 26 weeks**	**577 patients**

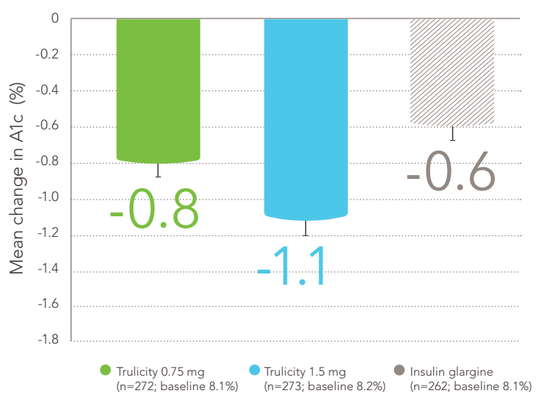
CKD=chronic kidney disease

AWARD-2

Trulicity vs. insulin glargine

Both in combination with metformin and a sulfonylurea
Non-inferiority, open-label study[1*†]

Demonstrated A1c reduction from baseline at 52 weeks[†]



p<0.001 for non-inferiority of both Trulicity doses vs. insulin glargine

Non-inferiority margin of 0.4%.
Adapted from Product Monograph.

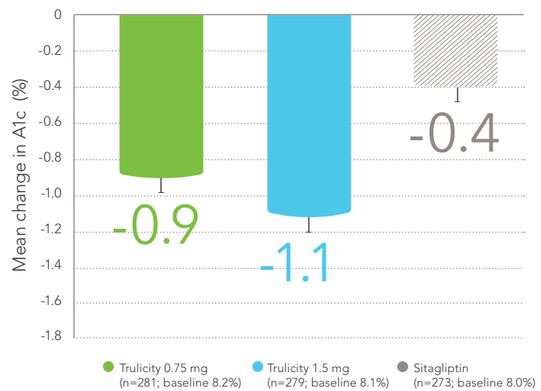
* The recommended starting dose for Trulicity is 0.75 mg once weekly.
† 78-week, Phase 3, multicentre, randomized, parallel-arm, open-label to active comparator study (double-blind with respect to Trulicity dose assignment). Patients received either Trulicity 0.75 mg once weekly (n=272), Trulicity 1.5 mg once weekly (n=273), or insulin glargine (n=262), starting dose 10 U then titrated to target, once daily. Treatment was added to background therapy with maximally tolerated dose of metformin ≥1500 mg/day and glimepiride ≥4 mg/day. Primary endpoint was non-inferiority vs. insulin glargine in reduction in A1c from baseline at 52 weeks, margin for non-inferiority 0.4%.

AWARD-5

Trulicity vs. sitagliptin

Both in combination with metformin
Non-inferiority study[1*†]

Demonstrated A1c reduction from baseline at 52 weeks



p<0.001 for superiority of both Trulicity doses vs. sitagliptin

Non-inferiority margin of 0.25%.
Adapted from Product Monograph.

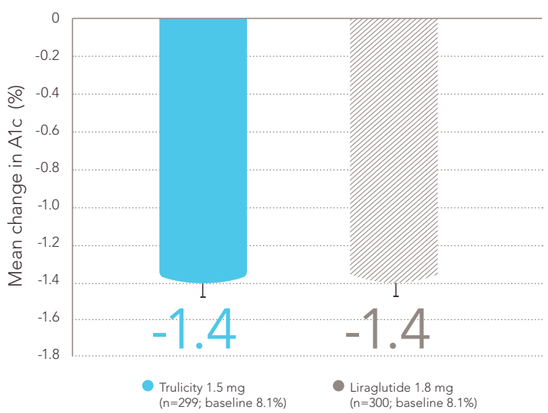
* The recommended starting dose for Trulicity is 0.75 mg once weekly.
† 104-week, Phase 2/3, adaptive, inferentially seamless, multicentre, randomized, placebo-controlled, double-blind, parallel-arm, dose finding trial. Patients received either Trulicity 0.75 mg once weekly (n=281), Trulicity 1.5 mg once weekly (n=279), sitagliptin 100 mg once daily (n=273), or placebo once daily (n=139). After 26 weeks, patients in the placebo treatment group received blinded sitagliptin 100 mg/day for the remainder of the study. Treatment was added to background therapy with metformin (≥1500 mg/day). Primary endpoint was non-inferiority vs. sitagliptin in reduction in A1c from baseline at 52 weeks, margin for non-inferiority 0.25%.

AWARD-6

Trulicity 1.5 mg once weekly vs. liraglutide 1.8 mg once daily

Both in combination with metformin
Non-inferiority, open-label study[1‡§]

Demonstrated A1c reduction from baseline at 26 weeks



p<0.001 vs. liraglutide for non-inferiority

Non-inferiority margin of 0.4%.
Adapted from Product Monograph.

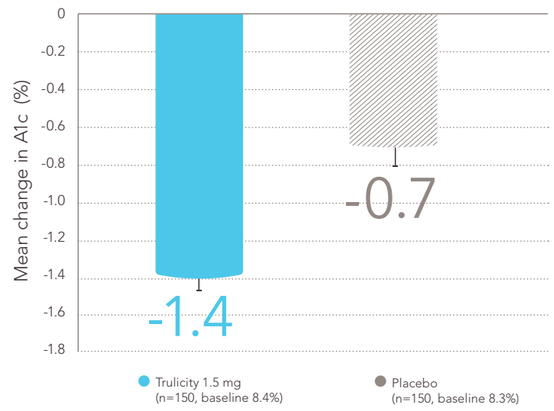
‡ The recommended starting dose for Trulicity is 0.75 mg once weekly.
§ 26-week, Phase 3, multicentre, randomized, parallel-arm, active-comparator, open-label, non-inferiority trial. Patients received either 1.5 mg Trulicity once weekly (n=299) or 1.8 mg liraglutide once daily (n=300). Treatment was added to background therapy with metformin (≥1500 mg/day). All n-values refer to intent-to-treat population. Primary endpoint was change in A1c from baseline to week 26 between once-weekly Trulicity and once-daily liraglutide, margin of non-inferiority 0.4%.

AWARD-9

Trulicity 1.5 mg vs. placebo

Both in combination with insulin glargine ± metformin[1*†]

Demonstrated A1c reduction from baseline at 28 weeks



p<0.001 vs. placebo for superiority

Adapted from Product Monograph.

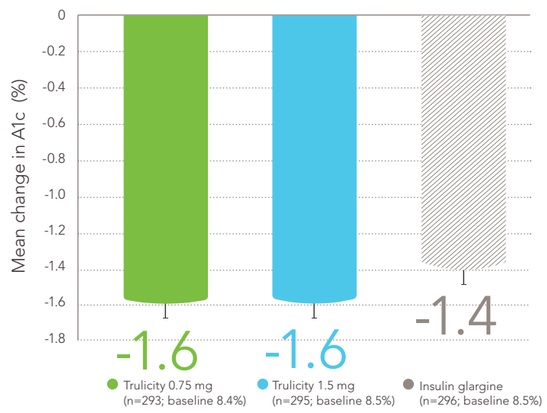
* The recommended starting dose for Trulicity is 0.75 mg once weekly.
† 28-week, Phase 3, multicentre, randomized, parallel-arm, double-blind, placebo-controlled trial. Patients received either 1.5 mg Trulicity once weekly (n=150) or placebo (n=150). All patients added assigned therapy to basal insulin glargine with/without metformin. Basal insulin glargine was titrated to target in both study arms after a 4-week initial stabilization period. All n-values refer to intent-to-treat population. Primary endpoint was change in A1c from baseline to week 28 between once-weekly Trulicity and placebo.

AWARD-4

Trulicity vs. insulin glargine

Both in combination with insulin lispro ± metformin
Open-label study[1‡§]

Demonstrated A1c reduction from baseline at 26 weeks



p<0.001 vs. for non-inferiority of both Trulicity doses vs. insulin glargine

Adapted from Product Monograph.

‡ The recommended starting dose for Trulicity is 0.75 mg once weekly.
§ 52-week, Phase 3, multicentre, randomized, parallel-arm, open-label, active comparator trial. Patients received Trulicity 0.75 mg (n=293) or 1.5 mg (n=295) once weekly or insulin glargine (n=296). All patients added insulin lispro three times daily with/without metformin. Insulin glargine was titrated based on a target fasting glucose of <5.6 mmol/L. The primary objective of the study was to demonstrate non-inferiority of Trulicity 1.5 mg once weekly compared to insulin glargine, both in combination with prandial insulin lispro, in A1c reduction from baseline at 26 weeks, with a noninferiority margin of 0.4%.