

Initial REMS approval: 09/2014

Most recent modification: 07/2015

**BLA 125469 TRULICITY™
(Dulaglutide)
Glucagon-like Peptide-1 (GLP-1) Receptor Agonist**

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

The goal of the TRULICITY REMS is to mitigate the potential risk of medullary thyroid carcinoma and the risk of pancreatitis associated with the use of TRULICITY by:

- Informing healthcare providers (HCPs) about the potential risk of medullary thyroid carcinoma associated with TRULICITY.
- Informing HCPs about the risk of pancreatitis associated with TRULICITY.

II. REMS Elements

A. Communication Plan

Eli Lilly and Company (Lilly) will implement the following communication plan to HCPs likely to prescribe TRULICITY. The communication plan will include:

1. REMS Letters

Lilly will send a *REMS Letter for Healthcare Providers* and a *REMS Letter for Professional Societies* within 60 days of product approval and again after 12 months of product approval. The REMS Letters will address the potential risk of medullary thyroid carcinoma and the risk of pancreatitis.

Distribution of the REMS Letters will be via electronic mail (email). If the email or fax is marked as undeliverable, a follow-up hard copy of the REMS Letter will be sent within 30 days of the undeliverable date. For those HCPs who do not prefer to receive electronic communications and for those HCPs whose e-mail and/or fax communications fail, a direct mail REMS Letter will be sent.

A copy of (or a link to) the Prescribing Information (PI), Medication Guide, and REMS Factsheet will accompany the REMS Letters.

REMS Letter for Healthcare Providers

The intended audience for the *REMS Letter for Healthcare Providers* will be endocrinologists as well as those HCPs (including physicians in internal medicine and family practice, nurse practitioners, and physician assistants) who have prescribed a glucagon-like peptide-1 (GLP-1) receptor agonist in the 12 months prior to dissemination of the letter.

The *REMS Letter for Healthcare Providers* will also be available through The Lilly Answers Center, and from Eli Lilly sales and medical representatives upon request for one year after approval of the most recent REMS modification.

REMS Letter for Professional Societies

Lilly will send the *REMS Letter for Professional Societies* to the leadership of the following professional societies and organizations and will request that the letter or the content be provided to their membership:

- American College of Physicians
- American Medical Association
- American Academy of Family Physicians
- American College of Osteopathic Family Physicians
- American College of Clinical Pharmacy
- American Pharmacists Association
- American Society of Health-System Pharmacists
- American Academy of Nurse Practitioners
- American Association of Clinical Endocrinologists
- Endocrine Society
- American Diabetes Association
- American Association of Diabetes Educators
- American Academy of Physician Assistants
- Association of Managed Care Pharmacy
- National Association of Managed Care Physicians

2. REMS Factsheet

A REMS Factsheet for HCPs will be distributed with the REMS Letters and will be made available to HCPs through Lilly's sales and medical representatives during the initial product discussion of TRULICITY with all HCPs visited and upon request for one year after approval of the most recent REMS modification.

3. REMS Website

The TRULICITY REMS website (www.TRULICITYREMS.com) will continue for 3 years after the initial approval of the REMS. The TRULICITY REMS website will include downloadable

versions of the REMS Letter for Healthcare Providers, REMS Factsheet, the Prescribing Information, and Medication Guide. The TRULICITY website for healthcare providers (<https://www.trulicity.com/healthcare-professionals-treating-patients-with-type-2-diabetes.aspx>) will include a prominent REMS-specific link to the TRULICITY REMS website. All website information will be updated within 60 days post approval of the most recent modification.

The following are part of the TRULICITY REMS and are appended:

- The *REMS Letter for Healthcare Providers* (print and email versions)
- The *REMS Letter for Professional Societies* (print and email versions)
- The REMS Factsheet
- The TRULICITY REMS Website

B. Timetable for Submission of Assessments

Lilly will submit REMS assessments to the Food and Drug Administration (FDA) at 18 months, 3 years, and 7 years from the date of the initial approval of the REMS. The reporting interval covered by each assessment will conclude no earlier than 60 days before the submission date for that assessment time interval. Lilly will submit each assessment so that it will be received by the FDA on or before the due date.