Implementation of a pharmacist-driven continuous glucose monitoring program for advanced diabetes management in patients with type 2 diabetes

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ABSTRACT OF PROPOSAL

Background:
Glucose monitoring is a necessary component of diabetes care to evaluate the safety and efficacy of treatment. This is often achieved through self-monitoring of blood glucose (SMBG) by patients, however detection of hypoglycemia and glucose variability can be difficult due to the limited number of times per day patients are testing. Glycated hemoglobin (A1c) is the gold standard for assessing glycemic control, but it has its limitations and cannot detect glycemic variability. Continuous glucose monitoring (CGM) measures the interstitial glucose as frequently as every five minutes and therefore, is more effective at identifying glycemic patterns day-to-day. Use of CGM has been shown to improve glycemic control compared to SMBG in both Type 1 and Type 2 diabetes, although the data is more limited in Type 2. Placement of a CGM sensor and interpretation of the data is a billable service. There are no studies to date which evaluate the impact of a pharmacist billing for CGM services and using the data to drive therapeutic decisions while working under a collaborative practice agreement.

Objectives:
The long-term goal of this study is to implement a pharmacist-driven CGM consulting service available to community physicians to improve patient outcomes while increasing revenue. The current proposal is a pilot project with a primary objective of evaluating the impact on glycemic control after utilization of CGM in patients with Type 2 diabetes. Secondary objectives are to: (1) describe the pharmacotherapy changes implemented after analyzation of CGM data, (2) assess the feasibility of a CGM program managed by clinical pharmacists, (3) develop a billing model for CGM services to obtain reimbursement.

Methods:
This pilot study is designed as a prospective cohort study at a health single center associated with Virginia Commonwealth University Health system. Patients will be enrolled if they meet the following criteria: (1) adult 18 years of age or older, (2) diagnosis of Type 2 diabetes, (3) A1c greater than 8%, (4) prescribed basal insulin plus either prandial insulin or a glucagon-like peptide-1 (GLP-1) receptor agonist. The primary outcome is the change in A1c from baseline to week 14. Secondary outcomes will evaluate the percentage of patients achieving A1c less than 7% and/or a 10% relative reduction in A1c as well as the change in total daily insulin dose, number of dose adjustments and number of new additions of diabetes-related medications. Upon enrollment, patients will wear the CGM sensor for two weeks, after which the pharmacist will review the data and implement any changes. The patient will continue meeting with the pharmacist for monthly appointments and changes will continue to be made based on review of SMBG logs. A final A1c will be collected between week 14 and 16. The primary outcome will be evaluated using the non-parametric Wilcoxon Signed Rank test. The pharmacotherapy changes implemented after analysis of CGM data will be reported descriptively. All analyses will be performed using SAS version 9.4.