# Clover Assistant Use and Diagnosis, Treatment, and Progression of Diabetes

Kumar Dharmarajan MD, Chief Medical Officer of Clover Assistant, Clover Health Peter Loscutoff PhD, Data Science Fellow, Clover Health Molly Inglish, Director of UX, Clover Health Devi Ramanan, Vice President of Data, Clover Health

## Summary

- Diabetes is a common and progressively worsening chronic condition that can lead to blindness, kidney failure, lower extremity amputation, and cardiovascular disease as well as treatment-related complications such as hypoglycemia.
- 2. Primary care practitioner (PCP) use of Clover Assistant is correlated with earlier diagnosis and treatment of diabetes with oral diabetes medications.
- 3. Blood sugar, insulin use, and documented hypoglycemia are all lower among patients having Clover Assistant visits.

## Background

Diabetes is a common health condition that can result in <u>major complications</u> such as blindness, kidney failure, amputation involving the lower extremities, and cardiovascular disease including heart attacks and strokes. Its diagnosis is <u>frequently delayed</u> even in <u>high-performing health systems</u>, resulting in undertreatment of elevated blood sugars, higher risk of downstream complications, and increased reliance on insulin that can cause unintended consequences including <u>hypoglycemia and</u> <u>weight gain</u>. These adverse outcomes can be lowered with early diagnosis and <u>appropriate treatment</u> of diabetes.

Clover Assistant is a scalable technology platform designed to help primary care practitioners (PCPs) diagnose and treat chronic conditions. The platform ingests large amounts of clinical data from disparate sources and surfaces key clinical insights that are intended to improve patient care and outcomes. Practitioners submit treatment plans for all conditions diagnosed with Clover Assistant.

Improvement in diabetes care has been an important goal of Clover Assistant from its inception. This analysis examines if the use of Clover Assistant is associated with (1) earlier diagnosis of diabetes; (2) earlier treatment of diabetes with oral diabetes medications; (3) reduction of hyperglycemia (elevated blood sugar); (4) reduction in treatment with insulin; and (5) reduction of hypoglycemia (low blood sugar), a major insulin-related complication.

#### Methods

All analyses examined data from Clover Health Medicare Advantage plan members from 2013 onwards, for whom we have diagnosis data, medication prescription data, and laboratory data relevant to this work. Analytic samples and methods were tailored to the specific research aims as described below.

#### Timeliness of diabetes diagnosis (Analysis 1)

To determine if Clover Assistant use is associated with earlier diagnosis of diabetes we calculated the proportion of Clover Health Medicare Advantage plan members previously enrolled in a non-Clover Medicare Advantage plan who were newly diagnosed with diabetes in healthcare claims data in the first year, first two years, and first three years after joining a Clover Health plan. These members had no pre-existing claims-based diagnoses of diabetes in the data shared with Clover Health from the Centers for Medicare & Medicaid Services (CMS). Results were compared between members receiving Clover Assistant visits with a PCP and members not receiving Clover Assistant visits.

#### Timeliness of diabetes treatment with oral diabetes medications (Analysis 2)

To determine if Clover Assistant use is associated with earlier treatment with oral diabetes medications we examined Clover Health members who (1) did not have a diagnosis of diabetes within healthcare claims data in the year after they joined a Clover Health Medicare Advantage plan and (2) were first diagnosed with diabetes within healthcare claims data in connection with a PCP visit in which Clover Assistant suggested diabetes may be present using its proprietary machine learning (ML) algorithms. Clover Assistant's ML algorithms are designed to surface potentially undiagnosed and unmanaged conditions for further evaluation and management by practitioners. As a result, this population would be expected to have low rates of diabetes diagnosis and treatment prior to the Clover Assistant visit and therefore serves as a good model to test the relationship between Clover Assistant use and the initiation of treatment with oral diabetes medications.

To identify evidence of treatment, we leveraged the fact that Clover Health is a Medicare Advantage Prescription Drug (MAPD) plan and therefore pays for oral diabetes medications for its members. These oral medications include metformin (biguanide medication), sulfonylureas (e.g. glipizide), DPP-4 inhibitors (e.g. sitagliptin), GLP-1 receptor agonists (e.g. liraglutide), SGLT2 inhibitors (e.g. empagliflozin), thiazolidinediones (e.g. pioglitazone), and alpha-glucosidase inhibitors (e.g. acarbose). We intentionally did not assay for insulin since insulin is very rarely the initial choice for longitudinal treatment of diabetes newly diagnosed in older adults, which is <u>almost always type 2 diabetes</u>.

New treatment with an oral diabetes medication was defined by the first prescription fill of a medication included in the <u>Pharmacy Quality Alliance (PQA) medication tables</u> used in the CMS diabetes medication adherence measure. This value set includes biguanides like metformin,

sulfonylureas, DPP-4 inhibitors, GLP-1 receptor agonists, SGLT2 inhibitors, and other oral medications used to treat diabetes. Using this approach, we identified new treatment of diabetes in the 90 days before and 90 days after Clover Assistant visits where diabetes was newly diagnosed.

#### Diabetes blood sugar control, insulin use, and hypoglycemia rates (Analyses 3-5)

To determine if Clover Assistant use is associated with a reduction in hyperglycemia (high blood sugar), reduced rates of insulin use, and reduced rates of hypoglycemia (low blood sugar), we examined Clover Health Medicare Advantage plan members newly started on diabetes treatment with oral diabetes medications as defined previously. As in our analysis of the timeliness of diabetes diagnosis, results were compared between members receiving Clover Assistant visits with a PCP and members not receiving Clover Assistant visits.

#### Analysis of diabetes blood sugar control (Analysis 3)

We identified all in-scope members' laboratory measurements of hemoglobin A1c (HbA1c), which is also referred to as <u>glycohemoglobin</u>, <u>glycated hemoglobin</u>, <u>or glycosylated hemoglobin</u>. The HbA1c is the most common measure of blood sugar and diabetes control, with higher HbA1c levels indicating higher blood sugar and worse diabetes control. A HbA1c value of <u>6.5% or higher is consistent with a diagnosis of diabetes</u>. As diabetes progresses, HbA1c levels rise.

From these data, we calculated (1) HbA1c at the time of first treatment of diabetes with oral diabetes medications, (2) the rate of increase in HbA1c before diabetes treatment, and (3) the rate of decline in HbA1c after treatment. Measurements were calculated separately for members receiving Clover Assistant visits with a PCP and members not receiving Clover Assistant visits, and differences in these measurements were determined for these two groups.

To make these measurements, we paired each HbA1c value to the time between this test result and the first treatment of diabetes with oral diabetes medications. These pairs were then fitted to a kinked line function to identify potential changes in the slope of HbA1c following the initiation of diabetes treatment.

#### Treatment rates with insulin (Analysis 4)

Insulin is generally used in older adults to treat <u>later stages of type 2 diabetes</u> when hyperglycemia can no longer be effectively managed with exclusively oral medications. Greater insulin use can therefore be viewed as a possible consequence of delayed diagnosis and treatment of diabetes, especially since early treatment of diabetes may <u>help preserve pancreatic beta cell function</u> and reduce future insulin requirements. Beta cells naturally produce insulin important for blood sugar control.

For this analysis, we identified a new treatment with any short or long-acting insulin preparation in healthcare claims data using Medi-Span General Product Identifier (GPI) code 2710, <u>as others have</u> <u>done</u>. We calculated rates of new treatment with insulin over time following treatment with oral diabetes medications and compared results between members receiving Clover Assistant visits with a PCP and members not receiving Clover Assistant visits.

#### Documented rates of hypoglycemia (Analysis 5)

Hypoglycemia is a potential complication of diabetes treatment that can be harmful for patients. We therefore examined healthcare claims data to identify new diagnoses of hypoglycemia from any source following the initiation of diabetes treatment. We then compared rates of documented hypoglycemia over time between members receiving Clover Assistant visits with a PCP and members not receiving Clover Assistant visits.

#### Sensitivity/Systematics analyses

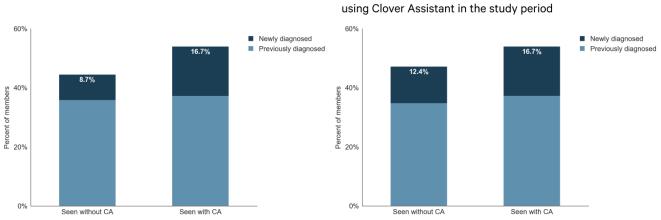
To ensure the robustness of our findings, we performed a number of additional "sensitivity" or "systematics" analyses. Firstly, we recalculated findings only including members who were patients of practitioners who would eventually use Clover Assistant. Specifically, we compared all measurements described above for the time period before and the time period after a practitioner started using Clover Assistant. In this way, we addressed the potential risk of bias from differences between practitioners who do and do not use Clover Assistant. All practitioners in this analysis used Clover Assistant for some time during the study period.

We also recalculated results related to the timeliness of diabetes treatment after excluding members who had a diabetes diagnosis within the first six months of joining a Clover Health Medicare Advantage plan, or within the first two years of joining a Clover Health Medicare Advantage plan, rather than the one year we used in the primary analysis. In addition, while Clover has access to HbA1c data starting in 2013, we repeated all analyses only looking at data from 2018 onward, when Clover Assistant was launched, to minimize the risk of potential temporal biases impacting findings.

#### Results

#### **Timeliness of diabetes diagnosis (Analysis 1)**

We identified 46,085 members who joined a Clover Health Medicare Advantage plan from a different Medicare Advantage plan. Of these, 19,705 received care from 2,109 practitioners using Clover Assistant, and 26,380 received care from 6,443 practitioners not using Clover Assistant. While similar rates of each cohort were previously diagnosed with diabetes prior to joining Clover Health, members receiving Clover Assistant visits with a PCP were much more likely to receive a new diagnosis of diabetes within the first year after joining the health plan compared to members not receiving Clover Assistant visits (16.7% vs 8.7%, P<0.0001 for difference) as shown in Figure 1, Panel Α.



#### Figure 1: Clover Assistant is associated with earlier diabetes diagnosis

Panel A: All members

Panel B: Members of primary care practitioners who started

Panel A: Results are presented for 46,085 members in the year after joining the Clover Health Medicare Advantage plan from a different Medicare Advantage plan. Of these, 26,380 received care from 6,443 PCPs not using Clover Assistant and 19,705 received care from 2,109 PCPs using Clover Assistant.

Panel B: Results are presented for 24,636 members in the year after joining the Clover Health Medicare Advantage plan from a different Medicare Advantage plan and who received care from 2,172 providers who used Clover Assistant at some time during the study period. Of these members, 4,931 received care prior to the PCPs' use of Clover Assistant and 19,705 received care after the PCPs' use of Clover Assistant.

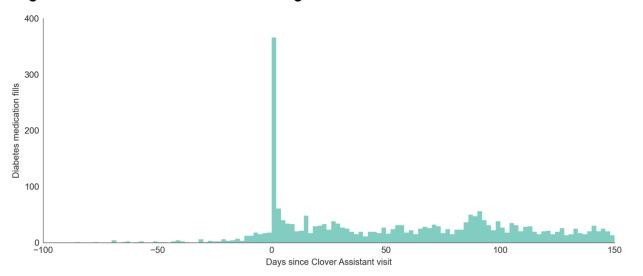
#### CA = Clover Assistant and PCP = primary care practitioner

Our findings were similar when we calculated new diabetes diagnoses within 2 years and 3 years of joining a Clover Health Medicare Advantage plan. At 2 years, rates of diabetes diagnosis for members receiving Clover Assistant visits with a PCP were 19.7% vs 10.2% for members not receiving Clover Assistant visits (P<0.0001 for difference). Similarly, at 3 years, rates of diabetes diagnosis for members receiving Clover Assistant visits with a PCP were 21.2% vs 10.9% for members not receiving Clover Assistant visits (P<0.0001 for difference).

#### Timeliness of diabetes treatment with oral diabetes medications (Analysis 2)

We identified 2,234 Clover Health members who (1) did not have a diagnosis of diabetes within healthcare claims data in the year after they joined a Clover Health Medicare Advantage plan and (2) were first diagnosed with diabetes in connection with a Clover Assistant visit that suggested diabetes may be present using its proprietary machine learning (ML) algorithms. These members were associated with 600 practitioners using Clover Assistant.

Treatment of this group with oral diabetes medications is shown in **Figure 2**. Treatment spikes on the day of the Clover Assistant visit (Day 0, 236 new prescription fills) and continues at a higher rate compared with the time period prior to the Clover Assistant visit. In total, 27%, 31%, and 32% of members started treatment with oral diabetes medications within 30 days, 60 days, and 90 days of the Clover Assistant visit with a new diabetes diagnosis. In contrast, only 5% of members received treatment with a diabetes medication in the 90 days prior to the Clover Assistant visit (P<0.0001 for difference). The average HbA1c value associated with treatment initiation with an oral diabetes medication was 7.57%.



#### Figure 2: Clover Assistant diabetes diagnosis is associated with medication treatment

Results are presented for 2,234 Clover Health members who (1) did not have a diagnosis of diabetes within healthcare claims data in the year after they joined the Clover Health Medicare Advantage plan and (2) were first diagnosed with diabetes during a Clover Assistant visit that suggested diabetes may be present using its proprietary machine learning (ML) algorithms. These members were associated with 600 PCPs using Clover Assistant.

New treatment with a diabetes oral medication was defined by the first prescription of a medication in the Pharmacy Quality Alliance (PQA) value set used by CMS to measure diabetes medication adherence. This value set includes biguanides like metformin, sulfonylureas, DPP-4 inhibitors, GLP-1 receptor agonists, SGLT2 inhibitors, and other oral medications used to treat diabetes.

CA = Clover Assistant and PCP = primary care practitioner

Diabetes blood sugar control, insulin use, and documented hypoglycemia rates (Analyses 3-5)

We identified 6,299 members newly treated for diabetes with oral diabetes medications, of which 3,445 received Clover Assistant visits with a PCP and 2,854 did not receive a Clover Assistant visit.

#### Analysis of diabetes blood sugar control (Analysis 3)

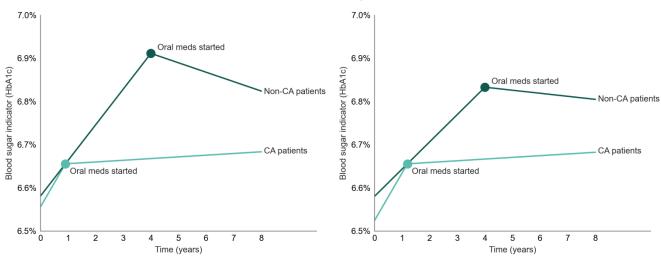
We found that the average HbA1c at the initiation of diabetes treatment with oral medications was 6.65% for members having a Clover Assistant visit with a PCP and 6.91% for members not having a

Clover Assistant visit (P<0.0001 for difference) [**Figure 3, Panel A**]. Diabetes was treated an average of 36 months earlier with Clover Assistant use (P<0.0001 for difference). Even at 36 months after initiation of diabetes treatment, HbA1c levels were 0.20% absolute percentage points lower in the group of members having Clover Assistant visits (P<0.0002 for difference).

## Figure 3: Clover Assistant is associated with earlier diabetes treatment and improved blood sugar control



Panel B: Members of primary care practitioners who started using Clover Assistant in the study period



**Panel A**: Results are presented for 6,299 members newly treated for diabetes with oral diabetes medications, of which 3,445 were seen by PCPs using Clover Assistant (CA patients) and 2,854 by PCPs not using Clover Assistant (Non-CA patients). Blood sugar is measured using the hemoglobin A1c (HbA1c) test, with higher numbers indicating higher blood sugar levels.

**Panel B**: Results are presented for 4,931 members newly treated for diabetes with oral diabetes medications who received care from 1,210 PCPs who used Clover Assistant at some time during the study period. Of these members, 1,486 received care prior to the PCPs' use of Clover Assistant (non-CA patients) and 3,445 received care after the PCPs' use of Clover Assistant (CA patients). Blood sugar is measured using the hemoglobin A1c (HbA1c) test, with higher numbers indicating higher blood sugar levels.

CA = Clover Assistant and PCP = primary care practitioner

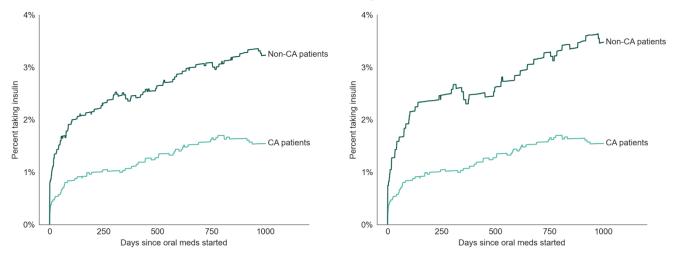
#### Treatment rates with insulin (Analysis 4)

New treatment with insulin following initiation of treatment with oral diabetes medications was lower among members having Clover Assistant visits **[Figure 4, Panel A]**. At 1000 days, 1.55% of members having Clover Assistant visits with a PCP were receiving insulin compared to 3.23% of members not having a Clover Assistant visit (P<0.0003 for difference).

#### Figure 4: Clover Assistant is associated with delayed need for insulin

#### Panel A: All members

Panel B: Members of primary care practitioners who started using Clover Assistant in the study period



**Panel A**: Results are presented for 6,299 members newly treated for diabetes with oral diabetes medications, of which 3,445 were seen by PCPs using Clover Assistant (CA patients) and 2,854 by PCPs not using Clover Assistant (Non-CA patients). New treatment with insulin is measured using Medicare Part D administrative claims data.

**Panel B**: Results are presented for 4,931 members newly treated for diabetes with oral diabetes medications who received care from 1,210 PCPs who used Clover Assistant at some time during the study period. Of these members, 1,486 received care prior to the PCPs' use of Clover Assistant (non-CA patients) and 3,445 received care after the PCPs' use of Clover Assistant (CA patients). New treatment with insulin is measured using Medicare Part D administrative claims data.

CA = Clover Assistant and PCP = primary care practitioner

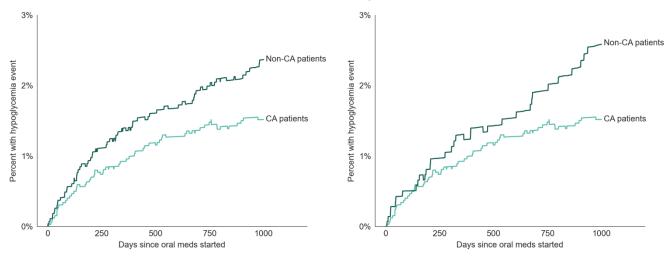
#### Documented rates of hypoglycemia (Analysis 5)

Documented rates of hypoglycemia following initiation of treatment with oral diabetes medications were lower among members having a Clover Assistant visit **[Figure 5, Panel A]**. At 1000 days, 1.5% of members having a Clover Assistant visit with a PCP had documented hypoglycemia in healthcare claims data compared to 2.4% of members not having a Clover Assistant visit (P<0.05 for difference).

#### Figure 5: Clover Assistant is associated with lower risk of hypoglycemia



Panel B: Members of primary care practitioners who started using Clover Assistant in the study period



**Panel A:** Results are presented for 6,299 members newly treated for diabetes with oral diabetes medications, of which 3,445 were seen by PCPs using Clover Assistant (CA patients) and 2,854 by PCPs not using Clover Assistant (Non-CA patients). Hypoglycemia was identified when documented in healthcare claims data from any source.

**Panel B:** Results are presented for 4,931 members newly treated for diabetes with oral diabetes medications who received care from 1,210 PCPs who used Clover Assistant at some time during the study period. Of these members, 1,486 received care prior to the PCPs' use of Clover Assistant (non-CA patients) and 3,445 received care after the PCPs' use of Clover Assistant (CA patients). Hypoglycemia was identified when documented in healthcare claims data from any source.

CA = Clover Assistant and PCP = primary care practitioner

#### Sensitivity/systematics analyses

Results were similar in our additional sensitivity/systematics analyses. For example, when we restricted analyses to 24,636 members who joined Clover Health from a different Medicare Advantage plan and who also received care from one of 2,172 practitioners who used Clover Assistant at some point during the study period, we again found that diabetes diagnosis was more frequent after the practitioner started using Clover Assistant (16.7% vs 12.4%, P<0.0001 for difference) [Figure 1, Panel B]. We also found that the average HbA1c at the initiation of diabetes treatment with oral diabetes medications was 6.65% after the practitioner started using Clover Assistant and 6.83% before this time (P<0.0001 for difference) [Figure 3, Panel B]. Diabetes was treated an average of 33 months earlier with Clover Assistant use (P<0.0001 for difference). Both insulin treatment rates and hypoglycemia rates were also lower after the use of Clover Assistant [Figures 4 and 5, Panels B, respectively]. As noted above, this approach eliminated the potential risk of bias from differences between practitioners who do and do not use Clover Assistant.

#### Discussion

The use of Clover Assistant is associated with significant improvements in diabetes care including earlier diagnosis of diabetes, earlier treatment of diabetes with oral diabetes medications, reduction in hyperglycemia, reduced treatment with insulin, and reduced rates of hypoglycemia, a major insulin-related complication. These findings were replicated in multiple sensitivity analyses, including those restricting findings to the same practitioners before and after they started using Clover Assistant.

Results from this diabetes analysis are consistent with our previous white paper showing improved early diagnosis and attenuated progression of chronic kidney disease (CKD) associated with the use of Clover Assistant. As noted in this previous white paper, Clover Assistant ingests large volumes of data from disparate sources including healthcare claims data, laboratory data, electronic health record (EHR) data, hospital data, and Health Information Exchange (HIE) data and is able to surface key insights to practitioners regarding their patients. With regard to diabetes in particular, Clover Assistant surfaces HbA1c data from sources such as specialist visits and hospital stays that practitioners may not regularly access. Clover Assistant also employs proprietary machine learning algorithms to identify the presence of early stages of disease that may not be evident to clinicians. It is well known that hyperglycemia frequently exists for many years before it is formally recognized and appropriately treated. The use of Clover Assistant is associated with a marked reduction in this latency and improved blood sugar control.

Importantly, this analysis also demonstrates that Clover Assistant use is associated with lower deleterious downstream effects of diabetes such as disease progression requiring insulin as well as hypoglycemia serious enough to be documented by doctors in administrative claims data. From a patient perspective, daily insulin administration and associated blood sugar testing have been associated with lower health-related quality of life. In addition, insulin use is a major cause of hypoglycemia, including severe hypoglycemic events that can have long-lasting consequences on patient health including brain damage and death. Older adults are particularly susceptible to severe hypoglycemic events due to common physiologic changes with aging.

Diabetes is a common chronic condition whose <u>prevalence is nonetheless rising</u> with increasing rates of obesity in the United States. Fortunately, <u>hyperglycemia in diabetes can be well controlled</u> with appropriate lifestyle changes and medications, leading to <u>reduced downstream complications</u> such as blindness, kidney failure, and cardiovascular disease. In this context, the use of Clover Assistant can increasingly promote improved patient outcomes by helping practitioners better diagnose and treat diabetes in its earliest stages.

## Endnotes

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