Addressing Quality With Dario Diabetes Solution

The Aim of Quality Measures in Diabetes

Quality measures quantify healthcare processes, outcomes, and systems, with the goal of guiding the delivery of care in line with the **Institute of Medicine's 6 domains of health quality**[1,2]:

Safety   **Effectiveness**   **Patient centeredness**   **Timeliness**   **Efficiency**   **Equity**

Health quality outcome data are crucial to healthcare decision making in the United States.[3]

>90% **of US health plans** use the **National Committee for Quality Assurance's HEDIS®** to measure performance on dimensions of care and service[3,4]

CMS publishes the **Medicare Advantage (Part C) and Medicare Prescription Drug (Part D) Star Ratings** each year to evaluate the quality of health and drug services received by consumers[5]

These tools allow assessments of quality outcomes in disease states, including T2D[3]

Quality Measures Associated With Dario Diabetes Solution

Dario Diabetes Solution is a **non-prescription digital health platform** linked to a blood glucose meter that tracks physiological parameters to facilitate personalized diabetes management and behavioral changes through remote self-monitoring of blood glucose, data visualization, and disease education.[3]

HEDIS Measurement Year 2024 Measures[6]

Glycemic Status Assessment for Patients With Diabetes (GSD)	The percentage of members 18-75 years of age with diabetes (T1D and T2D) whose most recent glycemic status (HbA1C or glucose management indicator) was at the following levels during the measurement year: glycemic <8.0% or >9.0%.
Emergency Department (ED) Visits for Hypoglycemia in Older Adults With Diabetes (EDH)	For members 67 years of age and older with diabetes (T1D and T2D), the risk-adjusted ratio of observed-to-expected ED visits for hypoglycemia during the measurement year.
Acute Hospital Utilization (AHU)	For members 18 years of age and older, the risk-adjusted ratio of observed-to-expected acute inpatient and observation stay discharges during the measurement year.
Emergency Department Utilization (EDU)	For members 18 years of age and older, the risk-adjusted ratio of observed-to-expected ED visits during the measurement year.
Hospitalization for Potentially Preventable Complications (HPC)	For members 67 years of age and older, the rate of discharges for ACSC per 1000 members and the risk-adjusted ratio of observed-to-expected discharges for ACSC by chronic and acute conditions.
Hospitalization Following Discharge From a Skilled Nursing Facility (HFS)	For members 65 years of age and older, the percentage of skilled nursing facility discharges to the community that were followed by an unplanned acute hospitalization for any diagnosis within 30 and 60 days.
Plan All-Cause Readmissions (PCR)	For members 18 years of age and older, the number of acute inpatient and observation stays during the measurement year that were followed by an unplanned acute readmission for any diagnosis within 30 days and the predicted probability of an acute readmission.

2024 Star Rating Measures[7]

Diabetes Care – Blood Sugar Controlled (C10)	Percentage of plan members with diabetes who had an HbA1C lab test during the year that showed their average blood sugar is under control.
Plan All-Cause Readmissions (C15)	Percentage of plan members aged 18 and older discharged from a hospital stay who were readmitted to a hospital within 30 days, either for the same condition as their recent hospital stay or for a different reason.

ACSC, ambulatory care sensitive conditions; CMS, Centers for Medicare & Medicaid Services; FD&C, Federal Food, Drug, and Cosmetic; HEDIS, Healthcare Effectiveness Data and Information Set; T1D, type 1 diabetes; T2D, type 2 diabetes; US, United States.

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# Dario Diabetes Solution's Relation to Quality Measures Associated With Glycemic Control in Patients With T2D

Sanofi has sponsored **2 retrospective, observational real-world cohort studies** to clearly understand the **clinical** and **economic** impact of using Dario Diabetes Solution to manage T2D compared with non-use.[8,9] Results from these 2 studies indicate that Dario Diabetes Solution may have an **impact on multiple quality measures.**[3,6-9] This study used a combination of Dario user activity data as well as claims data, lab data, and EMR data.[10]

HbA1C Results

Observed Results at 6 Months[8]
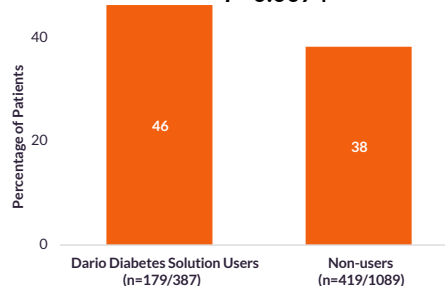**Proportion of Observed HbA1C Measures <8% at 6 Months**
P=0.002

Bar chart — Percentage of Patients:
- Dario Diabetes Solution Users (n=174/387): 45
- Non-users (n=393/1089): 36.1
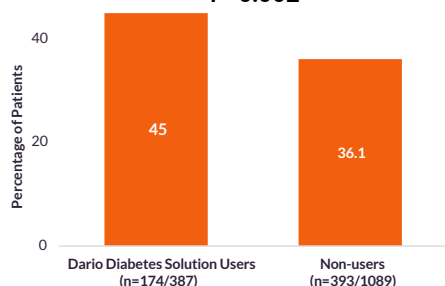
Observed Results After 12 Months[11]
Proportion of Observed HbA1C Measures <8% at 12 Months
P=0.0074

Bar chart — Percentage of Patients:
- Dario Diabetes Solution Users (n=179/387): 46
- Non-users (n=419/1089): 38

Proportion of Observed HbA1C Measures >9% at 12 Months: 36% for Dario Diabetes Solution users (n=86/237) vs 49% for non-users (n=347/713); *P*=0.0009[11]

Study Design: A retrospective cohort study in adults with T2D comparing cohorts of 568 Dario Diabetes Solution users and 1699 non-users. User and non-user cohorts were sequentially matched 1:3 using exact and propensity score matching. The primary endpoint was the change in HbA1C from baseline during a 180-day follow-up period, with subgroup analyses of people with baseline HbA1C >7.5%, >8%, and >9%. Exploratory analyses were conducted to evaluate whether Dario Diabetes Solution use could facilitate reductions in baseline HbA1C from ≥8% to <8% and from >9% to <9% in adults with T2D. Secondary endpoints included severe hypoglycemia (an event requiring medical intervention) rates for all included users and non-users and for those with a baseline HbA1C ≥8% who achieved a predefined target HbA1C <8%.[3,8]
Limitations: Given the retrospective study design, limitations include potential residual confounding differences between groups. Non-users in the study may also be more motivated than the general population, leading to underestimation of the comparative effect size.[10,12,13] No clinical conclusions should be inferred from these data.

> **With reference to HEDIS *Glycemic Status Assessment for Patients With Diabetes (GSD)* and Medicare *Diabetes Care – Blood Sugar Controlled (C10)*[6,7]**

***C10* average Star Rating in 2023**
4.1[5]

***C10* average Star Rating in 2024**
3.6[5]

The average Star Rating for the Medicare ***C10*** measure declined to 3.6 for 2024, the lowest it has been since 2015, indicating a need for improved glycemic control among members across health plans[5,14,15]

Annual diabetes-related total costs of care are significantly lower for patients with T2D with an HbA1C <8% than for those above the target ($16,399 vs $20,223, respectively).[16]

Incidence of Severe Hypoglycemia Observed at 6 Months (n=567)[8]

Severe hypoglycemia in patients with a baseline HbA1C ≥8% with an HbA1C <8% at 6 months

Patients With Severe Hypoglycemia in the Subgroup With an HbA1C <8% at 6 Months		
	Dario Diabetes Solution Users (n=174)	**Non-users (n=393)**
Severe hypoglycemia, n (%)	1 (0.57)	3 (0.76)

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> **With reference to HEDIS *Emergency Department Visits for Hypoglycemia in Older Adults With Diabetes (EDH)*[6]**

The average cost of a hypoglycemia-related hospitalization in adults with T2D is $21,000. Advisory panels for the National Committee for Quality Assurance agree that hypoglycemia is a high-priority issue for health plans among older adults with diabetes.[17,18]

EMR, electronic medical record.

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Dario Diabetes Solution Could Contribute to Lower Utilization Rates, With Reference to Multiple HCRU-Related Quality Measures

This was a retrospective, observational real-world cohort study using Dario user activity data and claims data.[13]
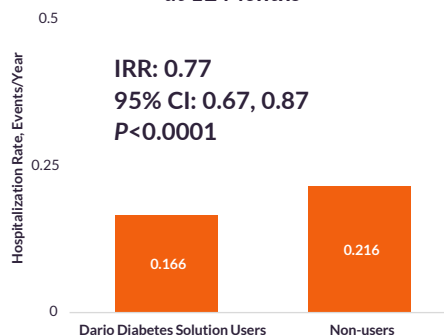
Economic Results

Results observed were a 9.3%-lower **all-cause HCRU** rate (inpatient hospitalizations and ER visits) and a 23.5%-lower **all-cause inpatient hospitalization** rate for Dario Diabetes Solution users vs non-users after 12 months.[9]

All-Cause HCRU Rate (Inpatient Hospitalizations and ER Visits) at 12 Months

IRR: 0.91
95% CI: 0.83, 1.00
P=0.0411

HCRU Rate, Events/Year

- Dario Diabetes Solution Users: 0.475
- Non-users: 0.524

All-Cause Inpatient Hospitalization Rate at 12 Months

IRR: 0.77
95% CI: 0.67, 0.87
P<0.0001

Hospitalization Rate, Events/Year

- Dario Diabetes Solution Users: 0.166
- Non-users: 0.216

Study Design: A retrospective cohort study in adults with T2D comparing cohorts of 2445 Dario Diabetes Solution users and 7334 non-users. User and non-user cohorts were sequentially matched 1:3 using exact and propensity score matching. The primary endpoint was all-cause HCRU rates (inpatient hospitalizations and ER visits) during the follow-up period. Other endpoints included length of stay and 30-day readmission rates among users and non-users.[3,9]
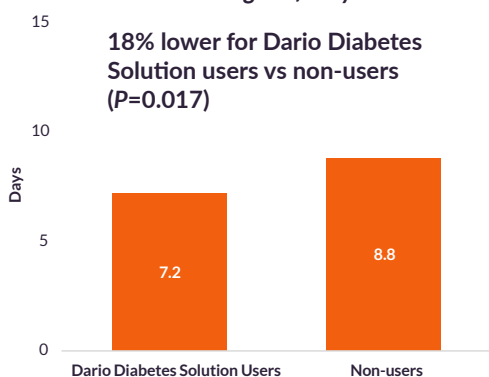
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> **With reference to HEDIS *Acute Hospital Utilization (AHU), Emergency Department Utilization (EDU), Hospitalization for Potentially Preventable Complications (HPC),* and *Hospitalization Following Discharge From a Skilled Nursing Facility (HFS)*[6]**
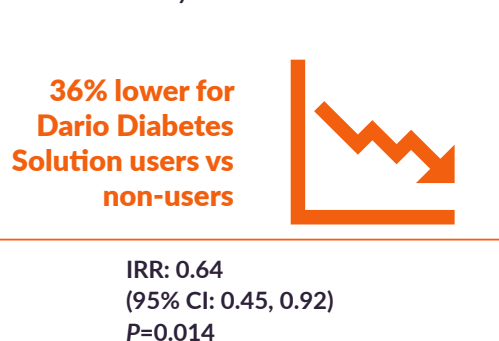
Additional Economic Results

Dario Diabetes Solution users with an inpatient event had an observed shorter **length of stay** and lower **30-day readmission rate** than non-users.[3,19]

Length of Stay

18% lower for Dario Diabetes Solution users vs non-users (*P*=0.017)

Days

- Dario Diabetes Solution Users: 7.2
- Non-users: 8.8

30-Day Readmission Rate

36% lower for Dario Diabetes Solution users vs non-users

IRR: 0.64
(95% CI: 0.45, 0.92)
P=0.014

Study Design: A retrospective cohort study in adults with T2D comparing cohorts of 2445 Dario Diabetes Solution users and 7334 non-users. User and non-user cohorts were sequentially matched 1:3 using exact and propensity score matching. The primary endpoint was all-cause HCRU rates (inpatient hospitalizations and ER visits) during the follow-up period. Other endpoints included length of stay and 30-day readmission rates among users and non-users.[3,9]

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> **With reference to HEDIS *Plan All-Cause Readmissions (PCR)* and Medicare *Plan All-Cause Readmissions (C15)*[6,7]**

People with diabetes have an excess of ~$12,000 in medical expenditures per person per year compared to those without diabetes; there is a need for strategies to improve the quality of care and reduce the economic burden of disease.[20]

CI, confidence interval; ER, emergency room; HCRU, healthcare resource utilization; IRR, incidence rate ratio.

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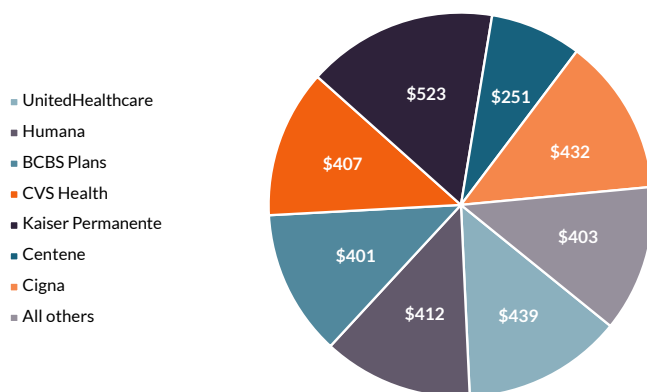
Health Plans Can Benefit by Implementing Measures to Improve Quality

Medicare Advantage Plans Can Benefit From Improved Star Ratings[21]

The Star Ratings system may reward higher-performing Medicare Advantage plans.

Average Annual Bonus per Enrollee in 2023

- UnitedHealthcare
- Humana
- BCBS Plans
- CVS Health
- Kaiser Permanente
- Centene
- Cigna
- All others

Pie chart values: $523, $251, $432, $403, $439, $412, $401, $407

All other insurers include firms with <2% of total enrollment. BCBS plans are BlueCross and BlueShield affiliates and include Anthem BCBS plans (Elevance). Non-BCBS Elevance plans are 2% of total enrollment. Plans that received at least a 4-star quality rating in 2022 (or were too new or had too little enrollment to be assigned a star rating) are eligible for quality bonus payments.

Annual bonus payments from the federal government to Medicare Advantage plans have increased every year since 2015 and will reach at least $12.8B in 2023.

~30% increase from 2022

>4x the spending in 2015

Consumers May Gain Confidence in High-Performing Plans

High performance on standardized quality measures such as HEDIS and Medicare Advantage Star Ratings helps consumers compare the quality of plans, empowering them to make the best healthcare decisions for themselves.[5,22]

Quality performance plays a critical role in patient healthcare, and health plans stand to benefit from focusing on and investing in quality improvement initiatives.[21,23] Dario Diabetes Solution can support health plans in improving quality based on HEDIS and Star Rating measures.[3,6,7]

B, billion; BCBS, Blue Cross Blue Shield.

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