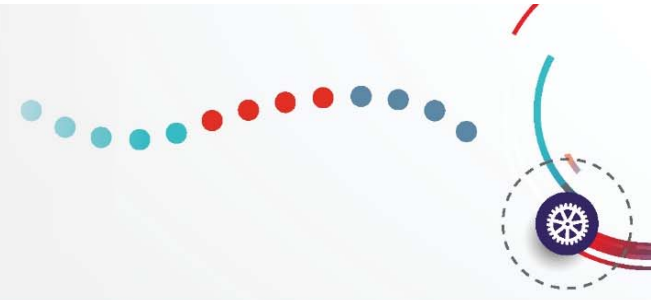


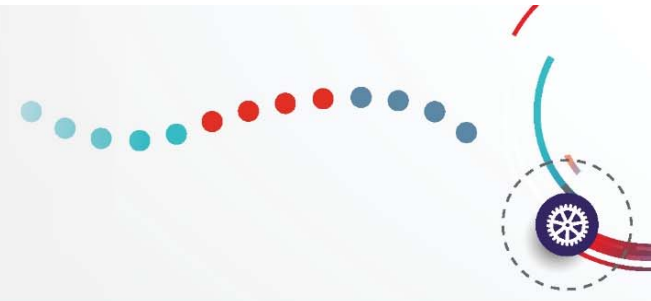
Continuous Glucose Monitoring and the Opportunities for OPTIMAL DIABETES CARE AND COST MANAGEMENT



Learning Objectives



- Characterize the clinical and economic burden of diabetes in terms of health care resource utilization, indirect costs, and member quality of life
- Describe the value of appropriate, evidence-based clinical interventions for managing morbidity and minimizing direct expenditures in other categories
- Review the available consensus recommendations regarding evidence-based care in the management of diabetes
- Characterize the role and value of CGM as part of a comprehensive diabetes management strategy
- Discuss the adverse effect of specific benefit design schema and excess cost-sharing on patient access and adherence to clinical interventions
- Employ pharmacy and medical benefit design strategies that account for the heterogeneity of patient populations and optimize outcomes



Evidence-based Diabetes Management and Monitoring Recommendations

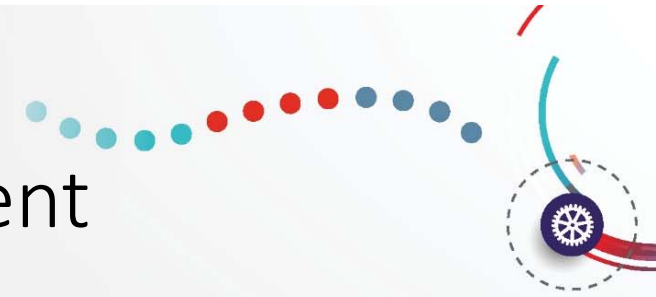
Anita Swamy, MD

Medical Director, Chicago Children's Diabetes Center

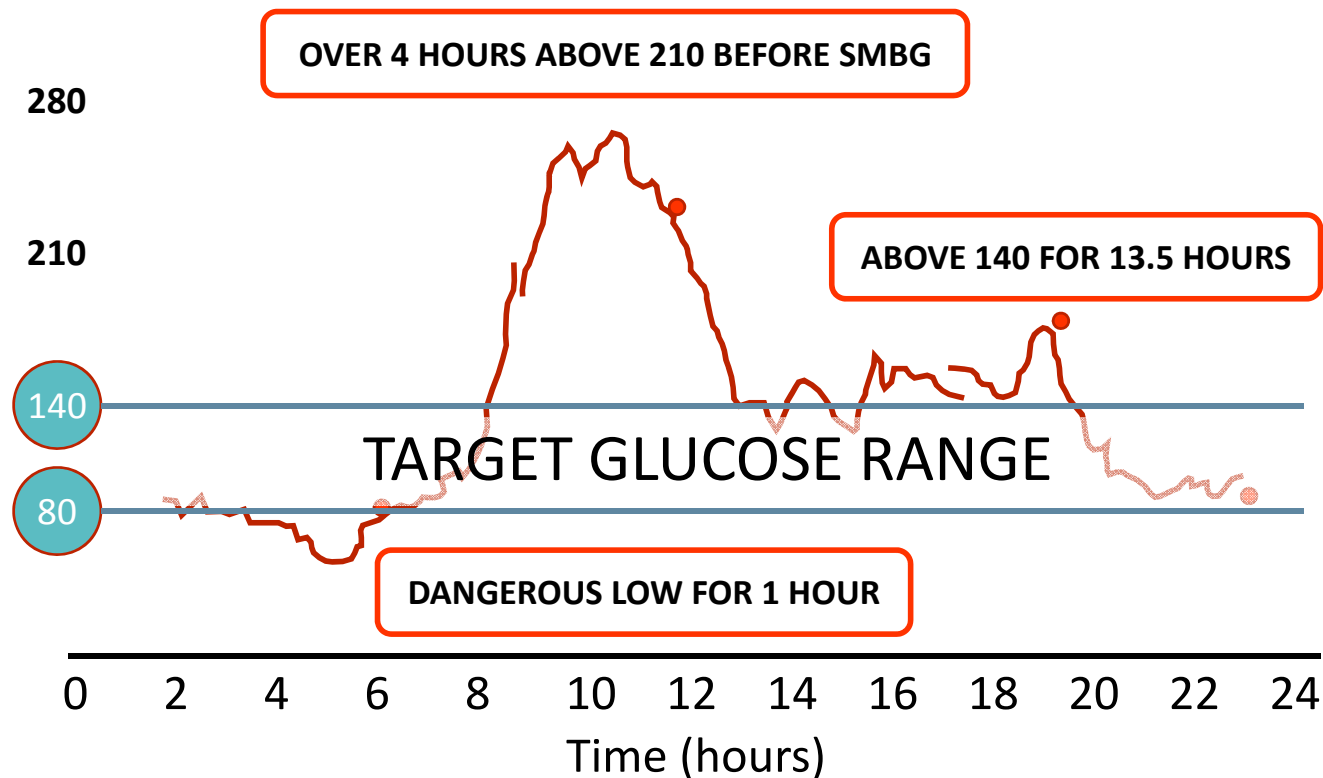
Associate Clinician, Lurie Children's

Assistant Professor of Pediatrics, Northwestern Feinberg School of Medicine

Continuous, Temporally Sensitive Measurement of Blood Glucose: A New Paradigm in Diabetes Management



Intermittent Monitoring is Not Adequate for Optimal Outcomes



New Definitions of Glycemic Control

- Time in Range
 - % of time in “safe” range (70-180 mg/dL)
- Hypoglycemia (Level 1)
 - % of time spent <70 mg/dL
- Hypoglycemia (Level 2)
 - % of time spent <54 mg/dL
- Hypoglycemia Unawareness
 - Autonomic/neuropathic complication due to extended time spent in hypoglycemia
 - Patients no longer have autonomic symptoms of hypoglycemia
 - 20%-25% T1 patients hypoglycemia unaware
- Hyperglycemia (Level 1)
 - % time spent >180 mg/dL
- Hyperglycemia (Level 2)
 - % time spent >250 mg/dL

Standards of Medical Care in Diabetes – 2019



- Insulin Delivery
- Self-Monitoring of Blood Glucose
- Continuous Glucose Monitors (CGM)
- Automated Insulin Delivery

1. Improving Care and Promoting Health in Populations
2. Classification and Diagnosis of Diabetes
3. Prevention or Delay of Type 2 Diabetes
4. Comprehensive Medical Evaluation and Assessment of Comorbidities
5. Lifestyle Management
6. Glycemic Targets
7. *Diabetes Technology*
8. Obesity Management for the Treatment of Type 2 Diabetes
9. Pharmacologic Approaches to Glycemic Treatment
10. Cardiovascular Disease and Risk Management
11. Microvascular Complications and Foot Care
12. Older Adults
13. Children and Adolescents
14. Management of Diabetes in Pregnancy
15. Diabetes Care in the Hospital
16. Diabetes Advocacy

CGM is the New Standard of Care for Glucose Monitoring in All Intensive Insulin Therapy (IIT) Patients



AACE and ATTD Guidelines for CGM Presented at ATDC 2017



Endocrine
Society

American Association
of Diabetes Educators

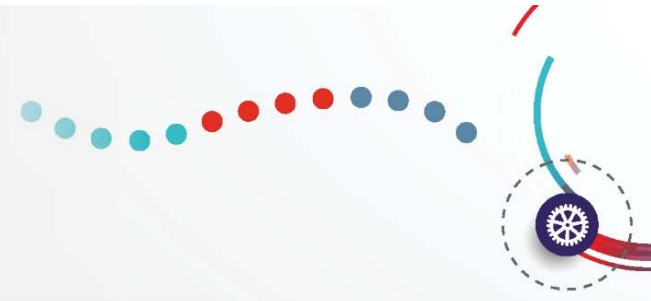


Take Away Message

- *CGM is here to stay*
- *It is standard of care for patients on intensive insulin therapy*
- *It is high time to reach out and teach both professionals and patients (and payers!) how to use it*

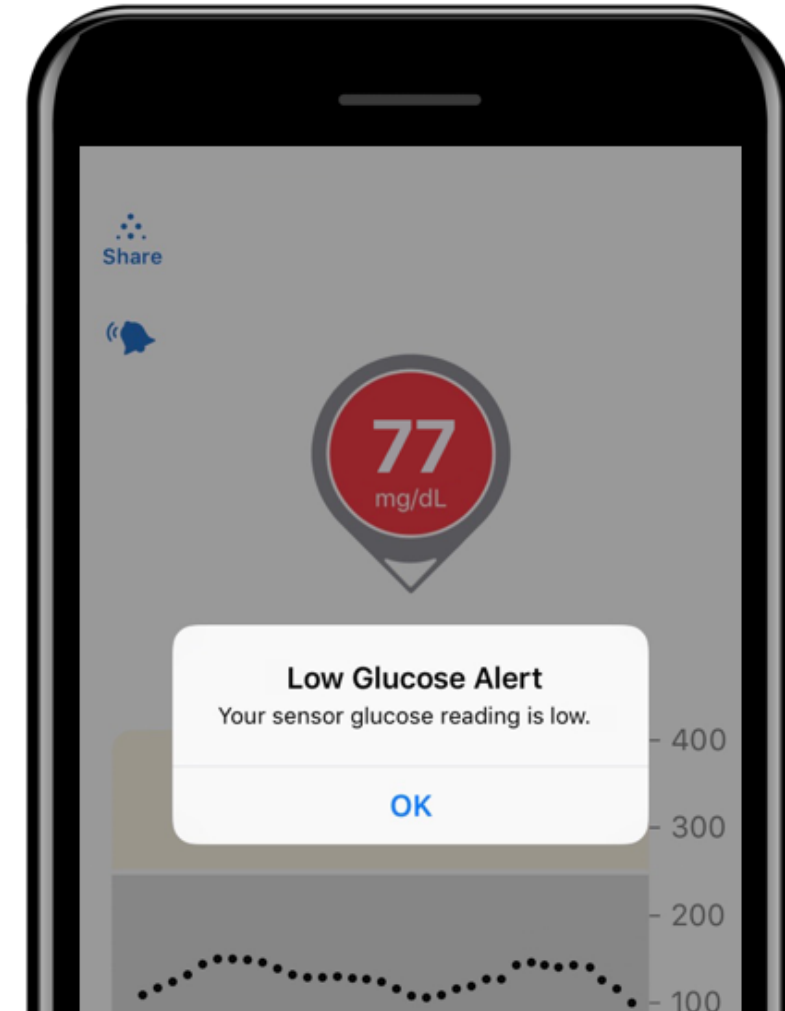
George Grunberger, MD, FACP, FACE

Past President, American Association of Clinical Endocrinologists

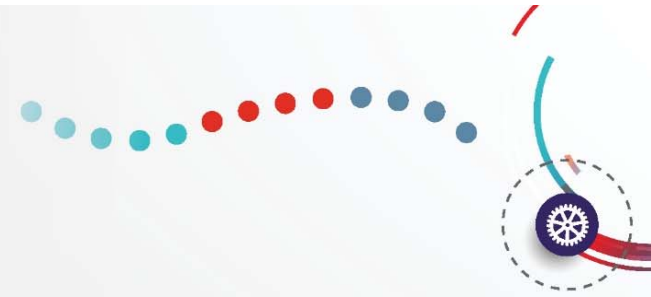


Opportunities With CGM

- Knowledge of speed and direction of glucose decreases uncertainty and improves decision making
- Alerts provide protection and inform users when action is needed
- Reduces glycemic variability
- Enhances patient/family confidence in self-care
- Reduces worry related to fear of hypoglycemia and/or hyperglycemia
- Improves provider-delivered care



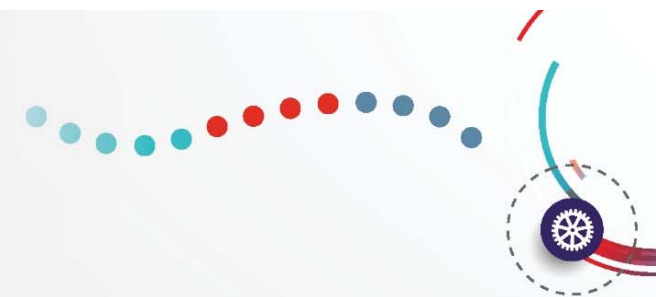
New FDA Classification - iCGM



- FDA has created a new classification for the Dexcom G6 – iCGM (Integrated Continuous Glucose Monitoring – Class II with Special Controls)
- Benefits:
 - Streamlined premarket review process
 - Minimizes the FDA review time for new products
- Key criteria:
 - Performance and accuracy standards are robust and stringent
 - Can be used alone or integrated with digitally connected devices (e.g., insulin pumps, insulin pens, automated insulin dosing (AID) systems for diabetes management)



Comparison of Available CGM Systems

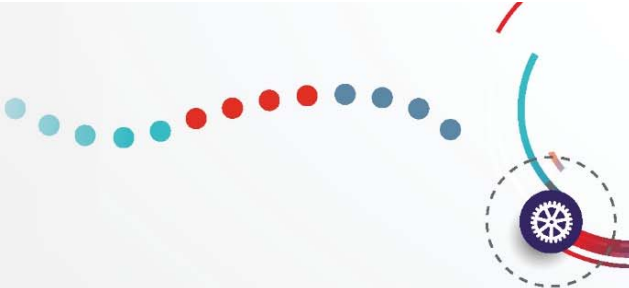


	Dexcom G6	FreeStyle Libre 14 Day (Abbott)	Guardian Connect CGM System (Medtronic)	Eversense CGM System (Senseonics)
Features				
Routine fingersticks needed	No	No	Yes	Yes
Continuous data availability	Yes	No (user must scan sensor)	Yes	Yes
Factory-calibrated	Yes (can be manually calibrated)	Yes	No (minimum of 2 fingerstick calibrations/day; 3-4 recommended)	No (2 calibrations/day required)
Indicated for use in diabetes treatment decisions	Yes	Yes	No	No
Age indication (years)	2+	18+	14-75	18+
Self-insertion and removal of sensor	Yes	Yes	Yes	No (requires surgical incision and removal by a trained physician)
Proactive/predictive alerts	Yes	No	Yes	Yes
Known interfering substances	None	Ascorbic acid (vitamin C) Salicylic acid (found in aspirin)	Acetaminophen	Mannitol (diuretic) and tetracycline (antibiotic)
Warm-up period	2 hours	1 hour (confirmatory fingerstick required during first 12 hours of sensor use)	2 hours	24 hours; daily 15-minute transmitter recharge
Sensor life	10 days	14 days	7 days	90 days
Meets requirements for integrated CGM device	Yes	No	No	No
Real-time data sharing	Yes	No	Yes	Yes
Mobile device connectivity	Yes (iOS and Android)	Yes (iOS only)	Yes (iOS only)	Yes
Medicare coverage	Yes	Yes	No	No
Performance				
Published MARD	9.0% (overall)	10.1%	10.6% (abdomen) 9/1% (arm)	8.5%, 9.6%

Performance data is not from head-to-head studies.

*The information and data contained in this table were obtained from each manufacturer's product user guide: (Dexcom G6 CGM System user Guide, 2018); Abbott FreeStyle Libre 14 Day Flash Glucose Monitoring System, Summary of Safety and Effectiveness Data (SSED), July 2018; Medtronic (Guardian Connect System User Guide, 2018); Senseonics (Eversense CGM User Guide, 2018). *If glucose alerts and readings from the G6 do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions. *Fingersticks are required for treatment decisions when you see Check Blood Glucose symbol, during the first 12 hours of sensor use, when symptoms do not match system readings, when you suspect readings may be inaccurate or when you experience symptoms that may be due to high or low blood glucose. *As identified in the product user guide from each manufacturer ((G6 readings can be used to make diabetes treatment decisions when taking up to a maximum acetaminophen dose of 1,000 mg every 6 hours. Taking a higher dose may affect the G6 readings. \$MARD data shown based on calibrations every 12 hours; published MARD with calibration 3-4 times/day; 9.6% (abdomen); 8.9% (arm). *Both MARD figures are included in the product user guide. 8.5% (blinded-use study); 9.6% (unblinded-use study)

Available Integrated CGM Systems for Personal Use



Tandem t:slim X2 with Basal IQ



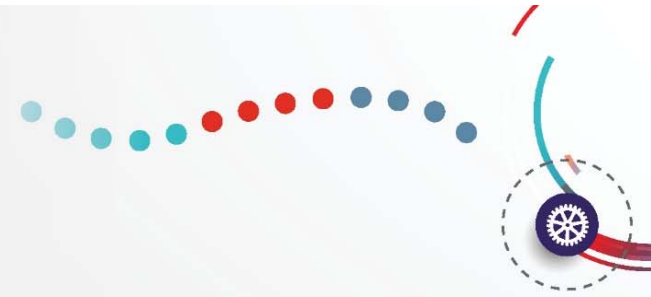
Medtronic 630G



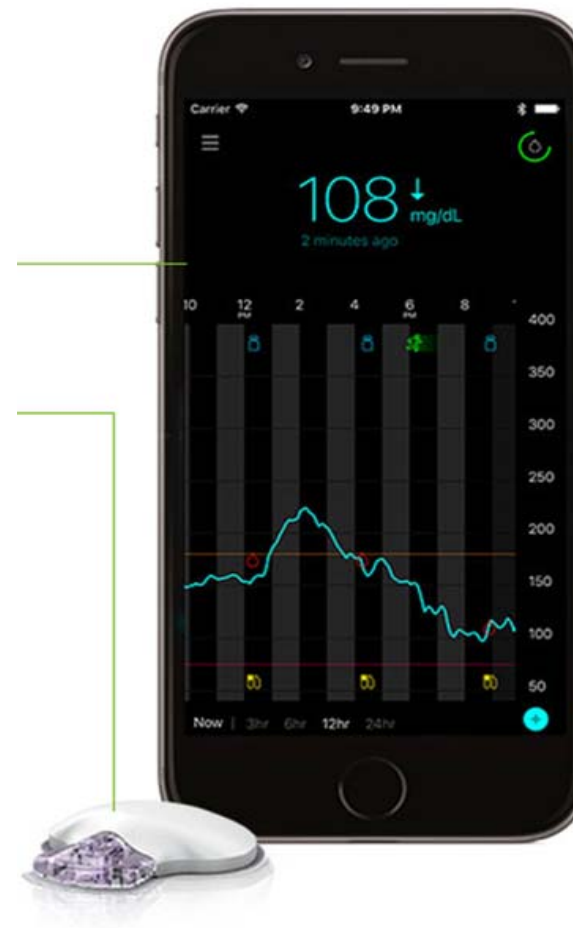
Medtronic 670G



Medtronic CGM

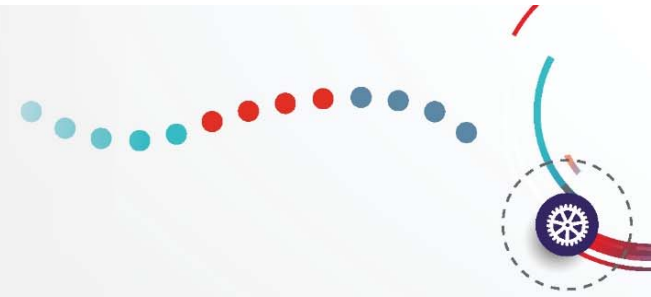


Medtronic 670G

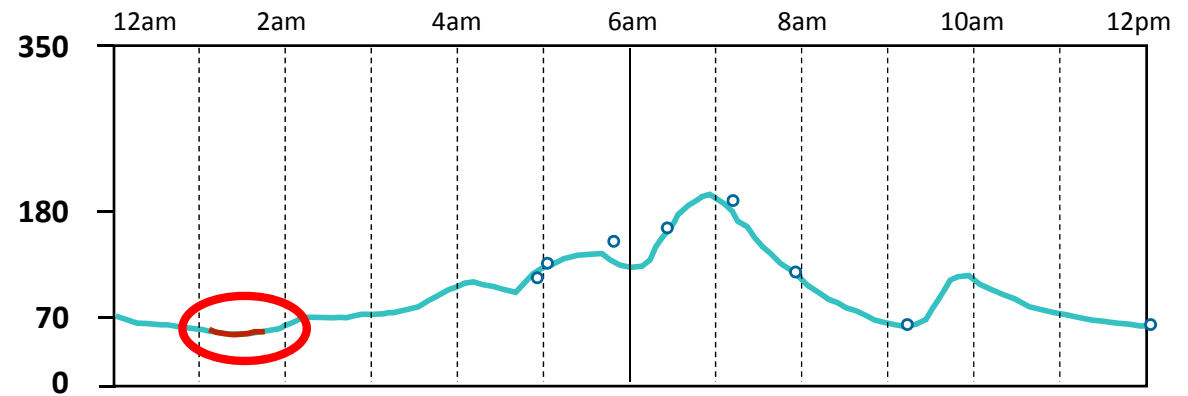


Medtronic Guardian Connect

Abbott Freestyle Libre Flash Glucose Monitoring System



Approved for patients aged ≥ 18 years



No Alerts for Hypoglycemia (≤ 70 mg/dL)

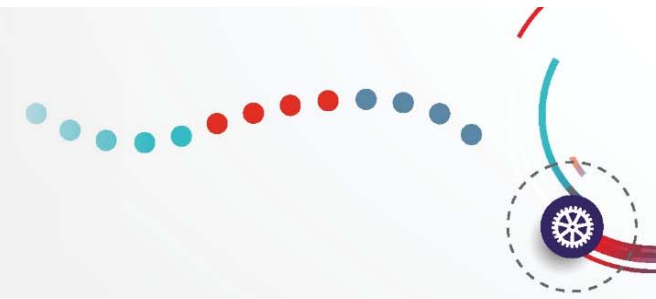
No Alerts for Impending hypoglycemia

No Alerts for Rapidly changing blood glucose

1-hour warm-up period

*Confirmation
fingersticks
required per
FDA label*

CGM has Consistent, Beneficial Effects in RCTs in Multiple Patient Populations



DEXCOM G5	Significant between Groups Difference in favor of Intervention Group?			
	↓ A1C?	↓ Hypo?	↓ Hyper?	↑ TIR?
Patient population				
Adult T1D on MDI ¹	Yes	Yes	Yes	Yes
Adult T1D on MDI ²	Yes	Yes ^c	Yes ^a	Yes ^a
Adult T1D Pump cohort ³	No	No	Yes	Yes
Adult T2D on MDI ⁴	Yes	N.A. ^b	Yes	Yes
Older Adult (>60) T1D/T2D ⁵	Yes	N.A.	Yes	Yes
Adult T1D on MDI Hypo. Unaware ⁶	No	Yes	No	Yes
Adult T1D on MDI Hypo. Unaware ⁷	No	Yes	Yes	Yes

ABBOTT LIBRE	Significant between Groups Difference in favor of Intervention Group?			
	↓ A1C?	↓ Hypo?	↓ Hyper?	↑ TIR?
Patient population				
Adult T1D ⁸	No ^c	Yes	Yes (>240 mg/dL) No (>180mg/dL)	Yes
Adult Overall T2D ^{9,10}	No	Yes ^d	No	No
Older Adult (>65) T2D ⁹	No	Yes ^e	No	No

- a. Time in hypoglycemia, hyperglycemia and range were not explicitly discussed because they were not primary outcomes; average BG, SD of BG, and amplitude of glycemia excursions all reduced significantly (P<0.05)
- b. Minutes spent low per day at baseline were too low to evaluate a meaningful difference at endpoint
- c. Both groups started w/a baseline HbA1C of ~6.7%
- d. Time in hypoglycemia did decrease significantly when it was evaluated as time (h) <70 mg/dL and when it was evaluated as # events <55 mg/dL
- e. Time in hypoglycemia did not decrease significantly when it was evaluated as # events <70 mg/dL

7. Reddy M, Jugnee N, Anantharaja S, Oliver N. *Diabetes Technol Ther.* 2018;20(11):751-757.

8. Bolinder J, Antuna R, Geelhoed-duijvestijn P, Kröger J, Weitgasser R. *Lancet.* 2016;388(10057):2254-2263.

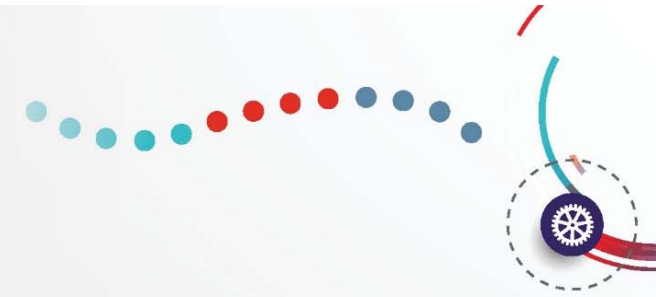
9. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. *Diabetes Ther.* 2017;8(1):55-73.

10. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. *Diabetes Ther.* 2017;8(3):573-586.

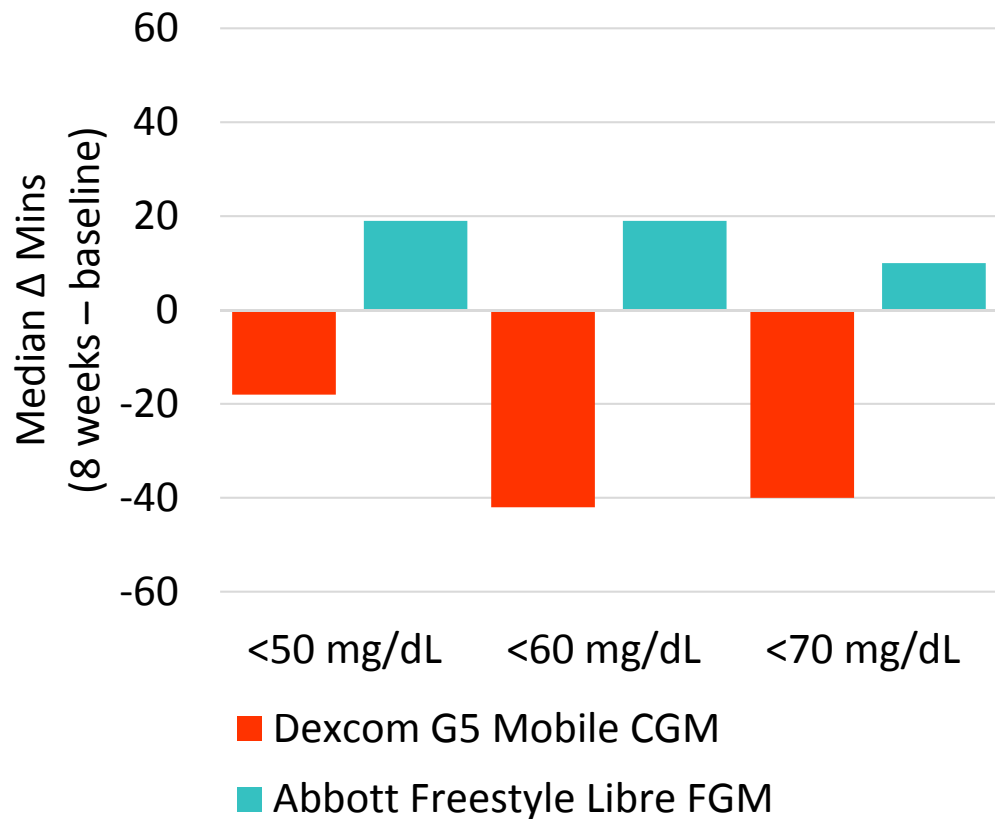
1. Beck RW, Riddlesworth T, Ruedy K, et al. *JAMA.* 2017;317(4):371-378.
 2. Lind M, Polonsky W, Hirsch IB, et al. *JAMA.* 2017;317(4):379-387.
 3. Beck RW, Riddlesworth TD, Ruedy KJ, et al. *Lancet Diabetes Endocrinol.* 2017;5(9):700-708.

4. Beck RW, Riddlesworth TD, Ruedy K, et al. *Ann Intern Med.* 2017;167(6):365-374.
 5. Ruedy KJ, Parkin CG, Riddlesworth TD, Graham C. *J Diabetes Sci Technol.* 2017;11(6):1138-1146.
 6. Heinemann L, Freckmann G, Ehrmann D, et al. *Lancet.* 2018;391(10128):1367-1377.

2017 iHART



Randomized Dexcom G5 vs. Abbott Libre in 40 patients with T1 and High Hypoglycemia Risk



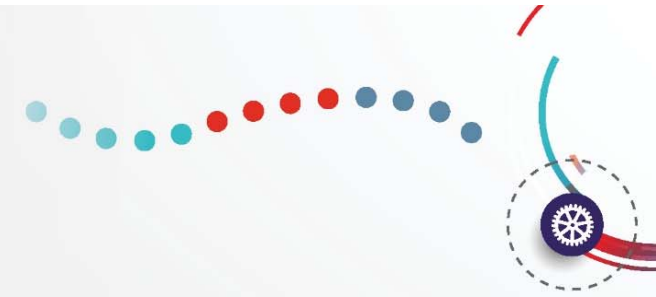
Change in time <60mg/dL vs. baseline

- Continuous ↓3% (43 min/day)
- Flash ↑1.3% (19 min/day)

Fear of Hypoglycemia

- Decreased with Dexcom
- No change with Abbott Libre

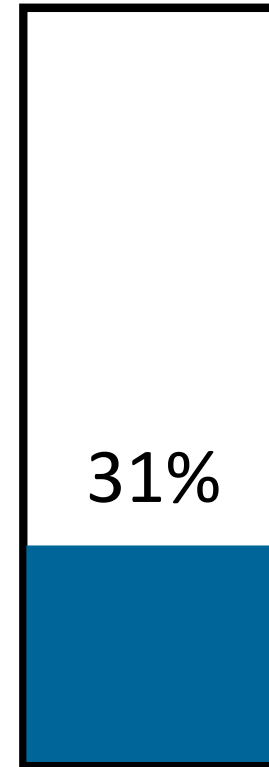
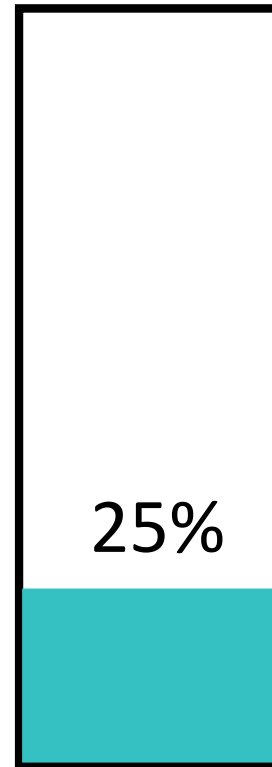
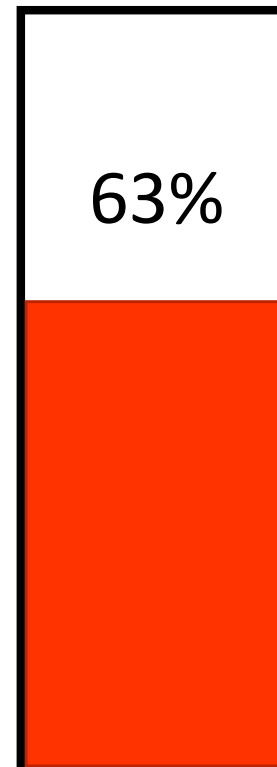
CGM and Flash Systems' Accuracy During Critical Low Glucose Ranges (40-60 mg/dL)



Dexcom sensor readings matching reference value (YSI)¹

Abbott Libre sensor readings matching reference value (YSI)²

Medtronic 670G sensor readings matching reference value (YSI)³

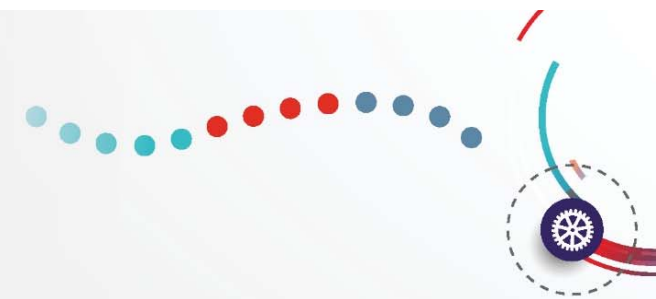


¹Dexcom G6 CGM System User Guide, 2018.

²Summary of Safety and Effectiveness Data (SSED), Abbott FreeStyle Libre, Oct 2017.

³Medtronic 670G User Guide, 2017.

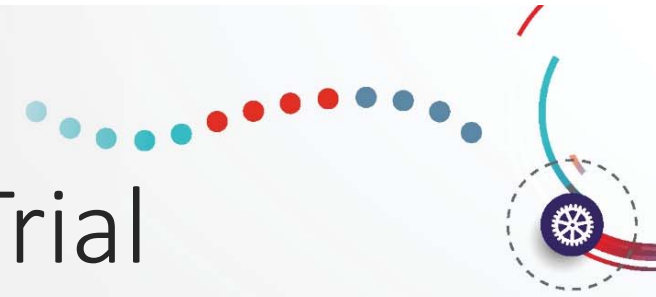
Sensor System Performance



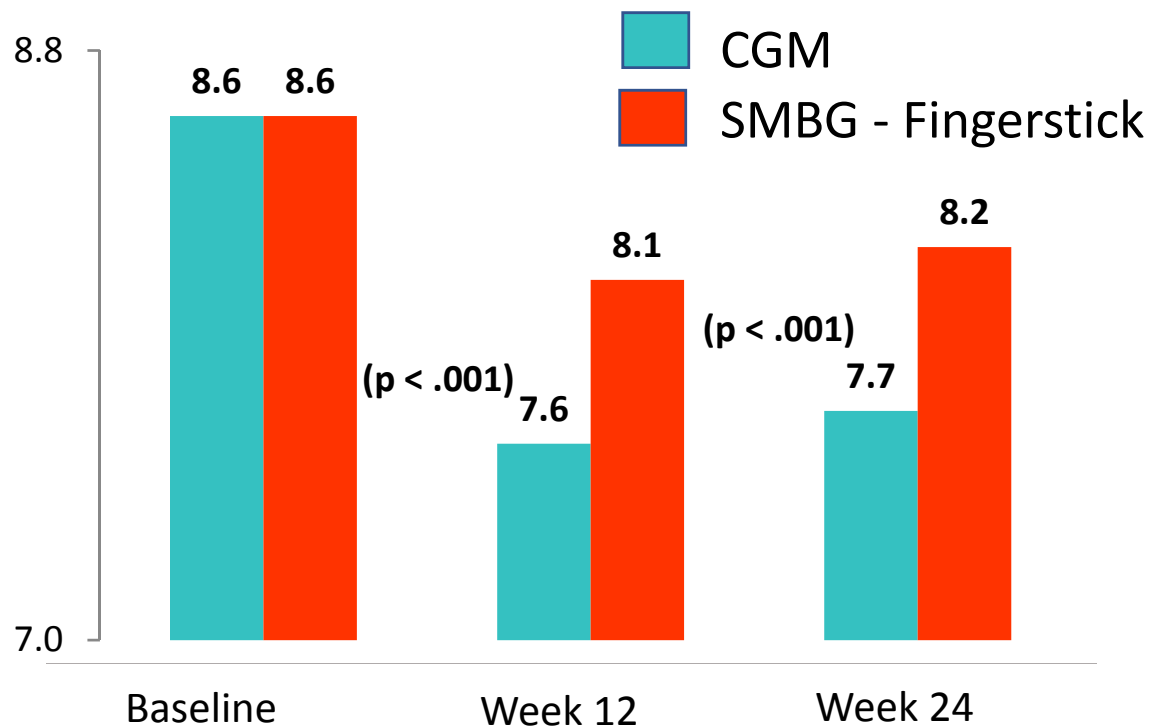
When glucose LOW < 70 mg/dL:	Detection rate (%)	False notification rate (%)	Missed rate (%)
Abbott Libre 10 Day	85.4	39.9	14.6
Dexcom G5	91.0	8.0	9.0
Medtronic Enlite 2	93.2	33.0	6.8

When glucose HIGH > 240 mg/dL:	Detection rate (%)	False notification rate (%)	Missed rate (%)
Abbott Libre 10 Day	95.1	22.1	4.9
Dexcom G5	95.0	7.0	5.0
Medtronic Enlite 2	94.6	14.5	5.4

CGM Reduces A1C and Time Spent in Hypoglycemia: The DIAMOND Randomized Trial



Effect of CGM on glycemic control in T1 adults on MDI
MDI ± CGM vs. MDI ± SMBG 158 T1 (105 CGM, 53 MDI)



A1C

↓ 1.0 % vs. baseline in CGM group

↓ 0.6% between groups

Time in Hypoglycemia < 70 mg/dL

↓ 37 minutes/day less time hypo with CGM

43 min./day with CGM (27-69)

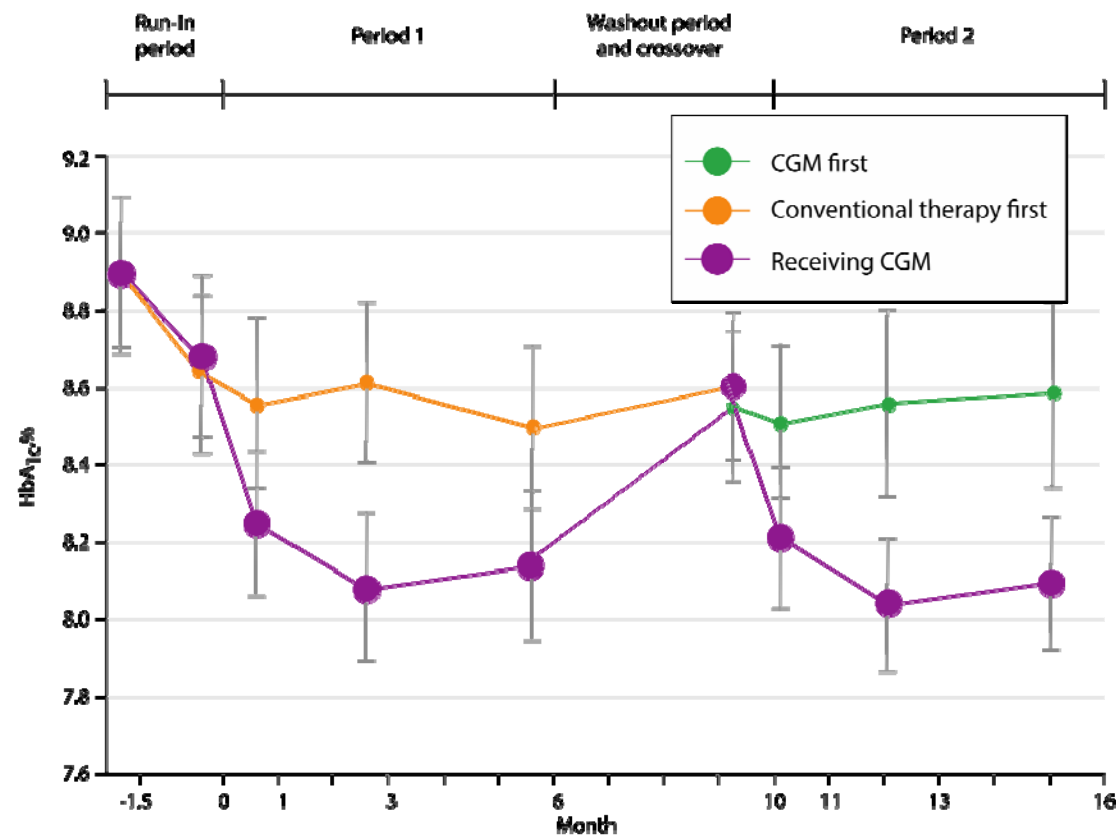
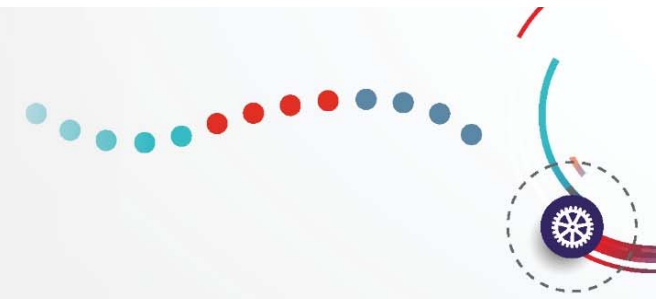
80 min./day with SMBG (36-111)

93% used system at least 6 days/week

SMBG: Self Monitoring Blood Glucose

MDI: Multiple Dose Injections

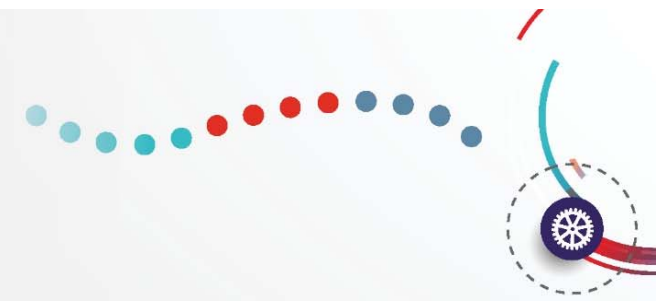
CGM Lowers A1C and Time Spent in Hypoglycemia: The GOLD Study



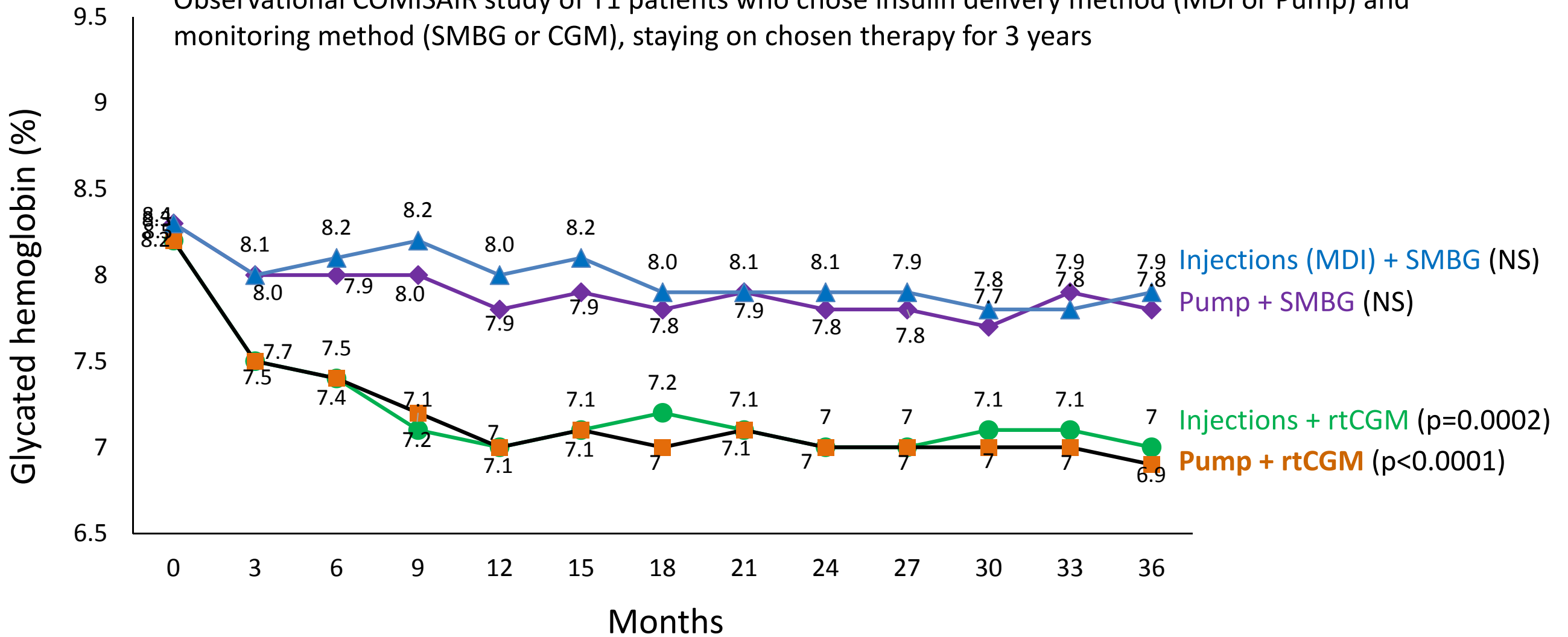
2017 GOLD Study Results:

- A1C - 0.8% reduction
- Hypoglycemia reduction
- Alerts/alarms set & necessary
- Finger-sticks didn't work
 - Regardless of diabetes education, similar study visits, and previous CGM use
 - SMBG had 12 SH events throughout course of the study vs 1 with CGM
- Included only patients on MDI
 - CGM as first technology application

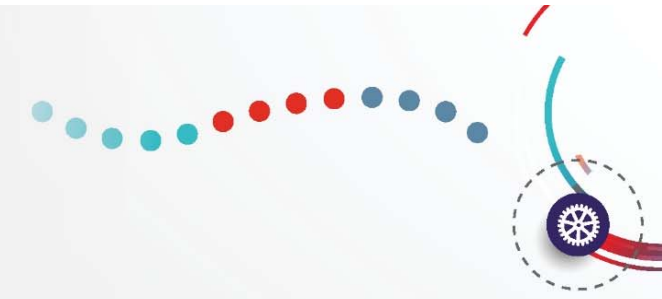
A1C Decreases With CGM Regardless of Insulin Delivery Method



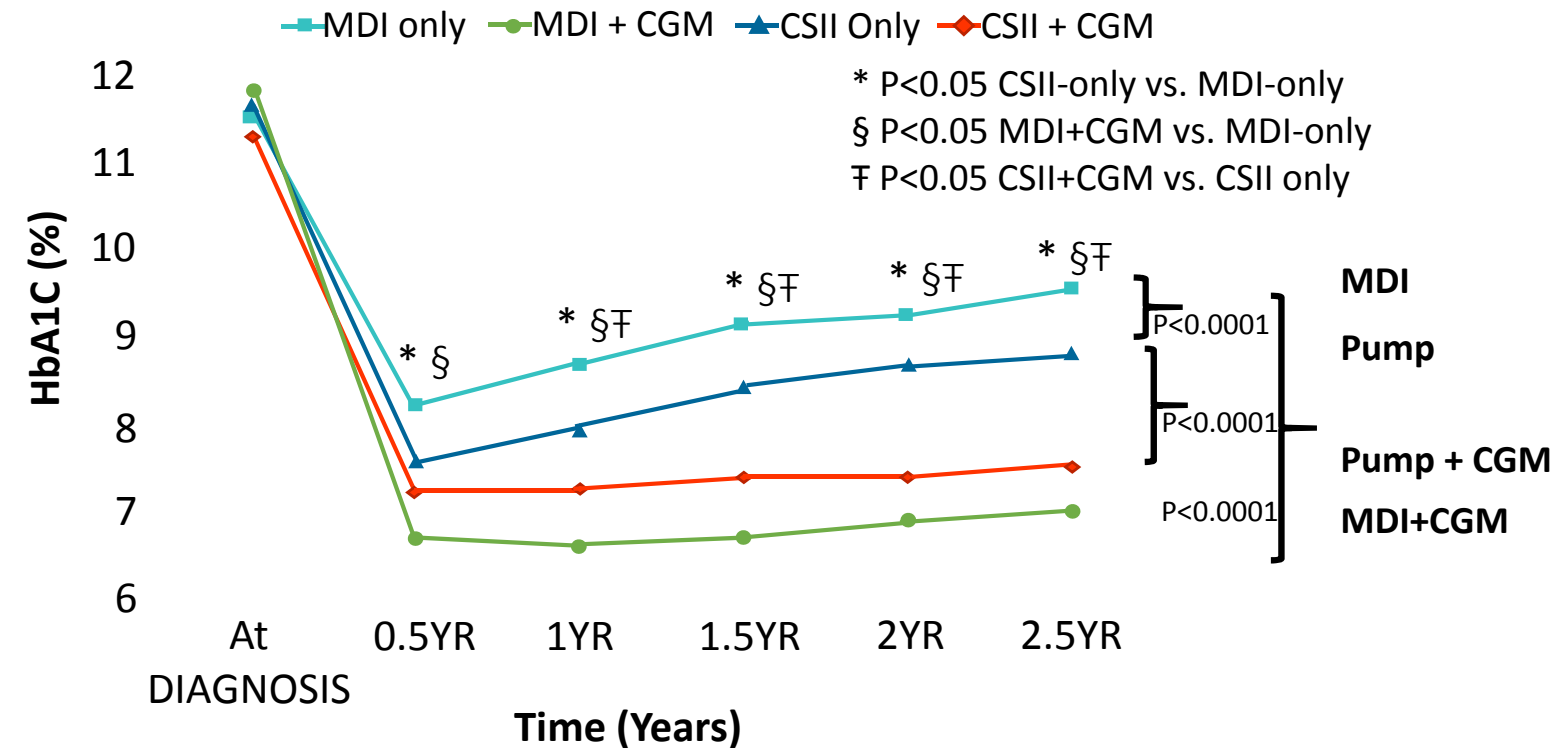
Observational COMISAIR study of T1 patients who chose insulin delivery method (MDI or Pump) and monitoring method (SMBG or CGM), staying on chosen therapy for 3 years



When to Start: Early initiation of CGM after T1 diagnosis



396 newly diagnosed T1, 94% < 18 years 2.5 years follow up



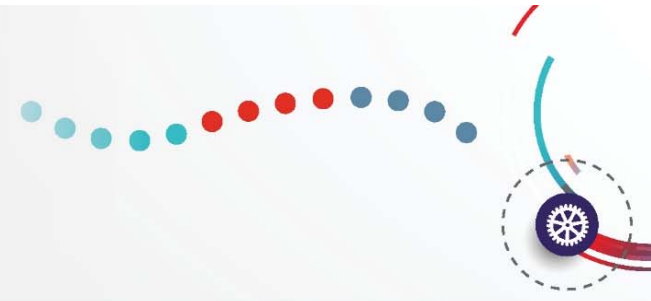
Better glucose control, fewer ER visits when CGM started within 6 months of diagnosis

A1C

MDI + CGM: 1.5% lower than MDI alone
 MDI + CGM: 0.9% lower than pump alone
 Pump + CGM: 0.7% lower than pump alone

No difference between pump + CGM and MDI + CGM

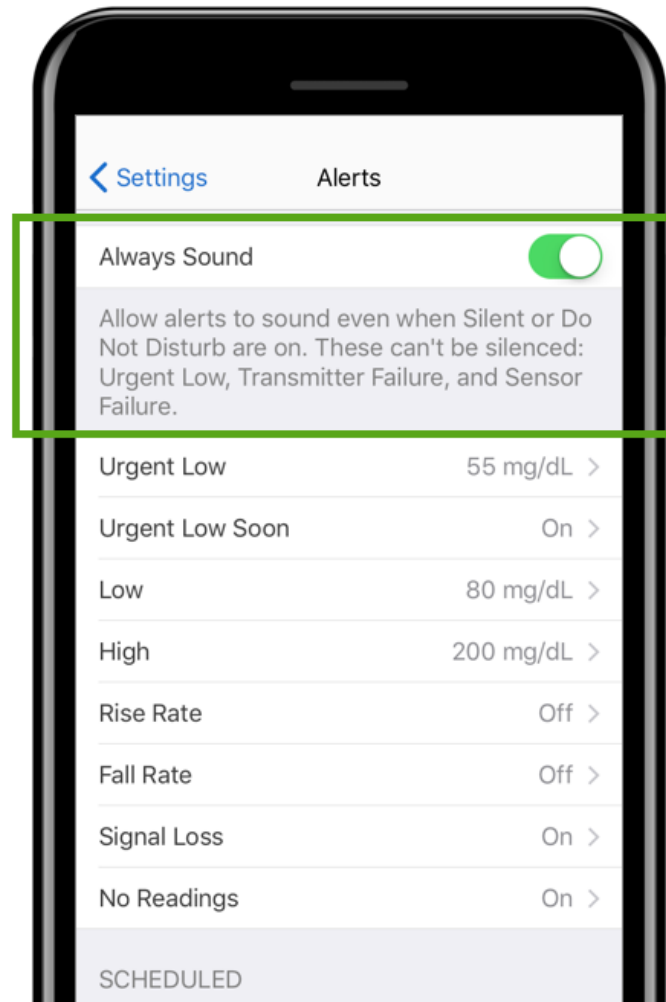
Overcoming Patient Barriers to CGM Uptake



Wearing a device (or two)



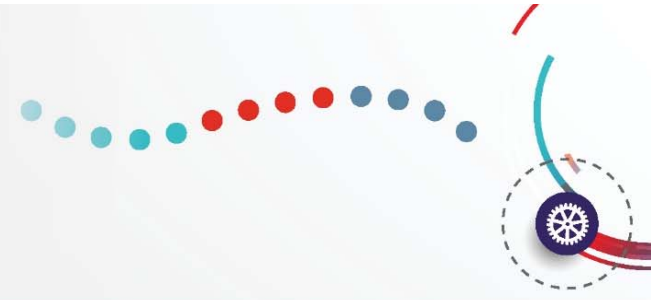
Alarms & alerts



I don't want to "share"



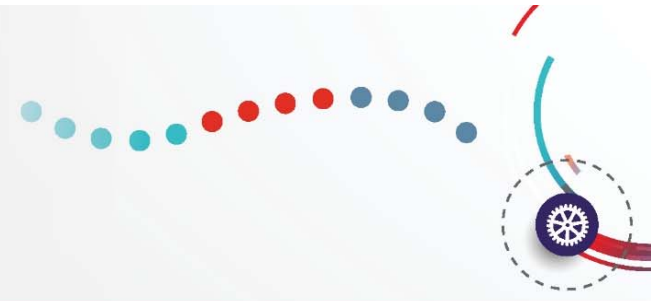
Assessing Patient Readiness for CGM



- Starting the conversation
 - At diagnosis
 - When glucose targets aren't achieved
 - Too many/too few finger-sticks
- Before or after CSII
- Setting expectations
 - CGMs are different



Overcoming Payer Barriers to CGM Uptake



“A Tale of Two Benefits”

Medical

- More effort required to manage utilization due to retroactive claims payment
- Decreased access and member convenience with potential delays at the point-of-service
- Fewer opportunities for patient contacts with trained HCPs
- Inefficiencies and potential confusion resulting from standard A-code billing

Pharmacy

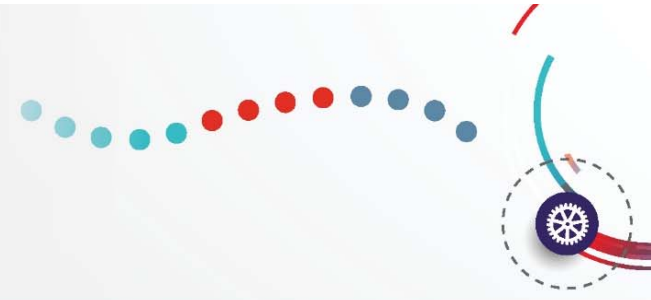
- Automated utilization management as a function of real-time claims adjudication
- Increased access and member satisfaction
- Potential cost savings for payers via management efficiencies and member cost share
- Potential to expand the integrated care team to include retail pharmacists

Pharmacy Coverage for CGM Enhances Patient Access and Integrates the Role of the Pharmacist in a Comprehensive Care Approach

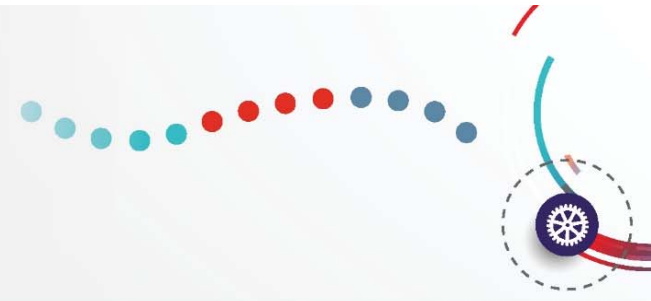


- Pharmacists are trusted health care professionals who provide the following services:
 - Assess patients' health status
 - Devise medication treatment plans
 - Select, modify, and administer interventions
 - Review current interventions and identify related problems
 - Communicate care to other providers
 - Provide patient education
 - Refer patients for broader disease management services
- 9 out of 10 Americans live within 5 miles of a community pharmacy

Summary



- CGM represents a new paradigm of care in diabetes, allowing for more precise and accurate management, with demonstrated reductions in A1C and time spent in hypoglycemia
- Clinicians must carefully weigh the benefits and disadvantages of available CGM systems before selecting the appropriate option for their patients
- Patients should be initiated on CGM as soon as possible after diagnosis, after assessing their readiness for the technology
- Insurance coverage of CGM under the pharmacy benefit allows for enhanced patient access and integration of the pharmacist as an allied health care provider



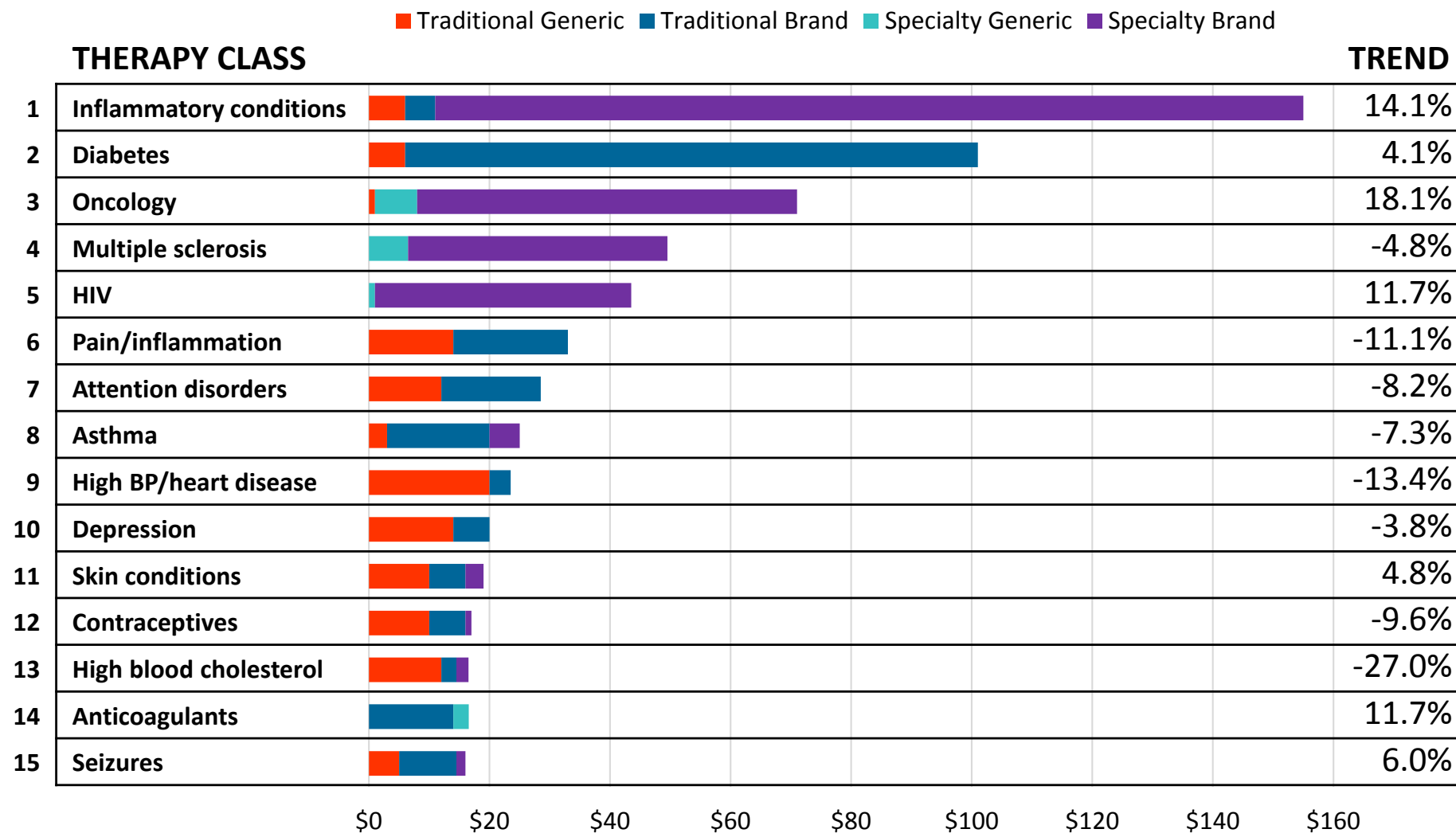
The Value of Glucose Monitoring Systems as Part of a Comprehensive Management Strategy

Sam Eisa, MD
Market Medical Executive
Cigna Medicare Advantage

Diabetes is a Significant Driver of Health Care Resource Utilization and Drug Trend for Payers



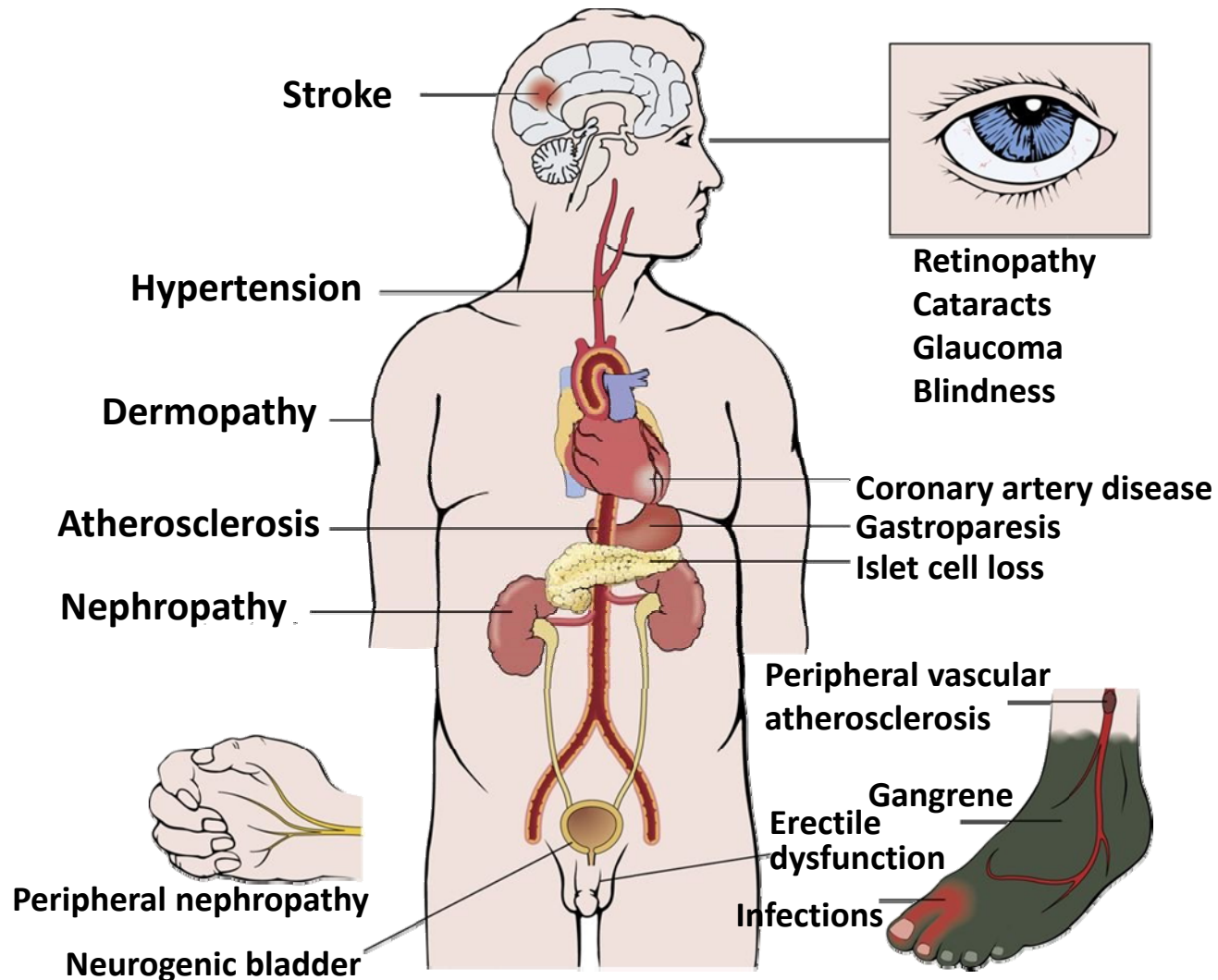
- There are more than 30 million Americans with diabetes at an estimated cost of >\$327 billion per year
- The cost to treat the complications of diabetes alone total \$44.1 billion per year



2018 Drug Trend Report. Express Scripts website: <https://www.express-scripts.com/corporate/drug-trend-report>.

Accessed October 2019. Standards of medical care in diabetes—2013. *Diabetes Care*. 2013;36 Suppl 1:S11-66.

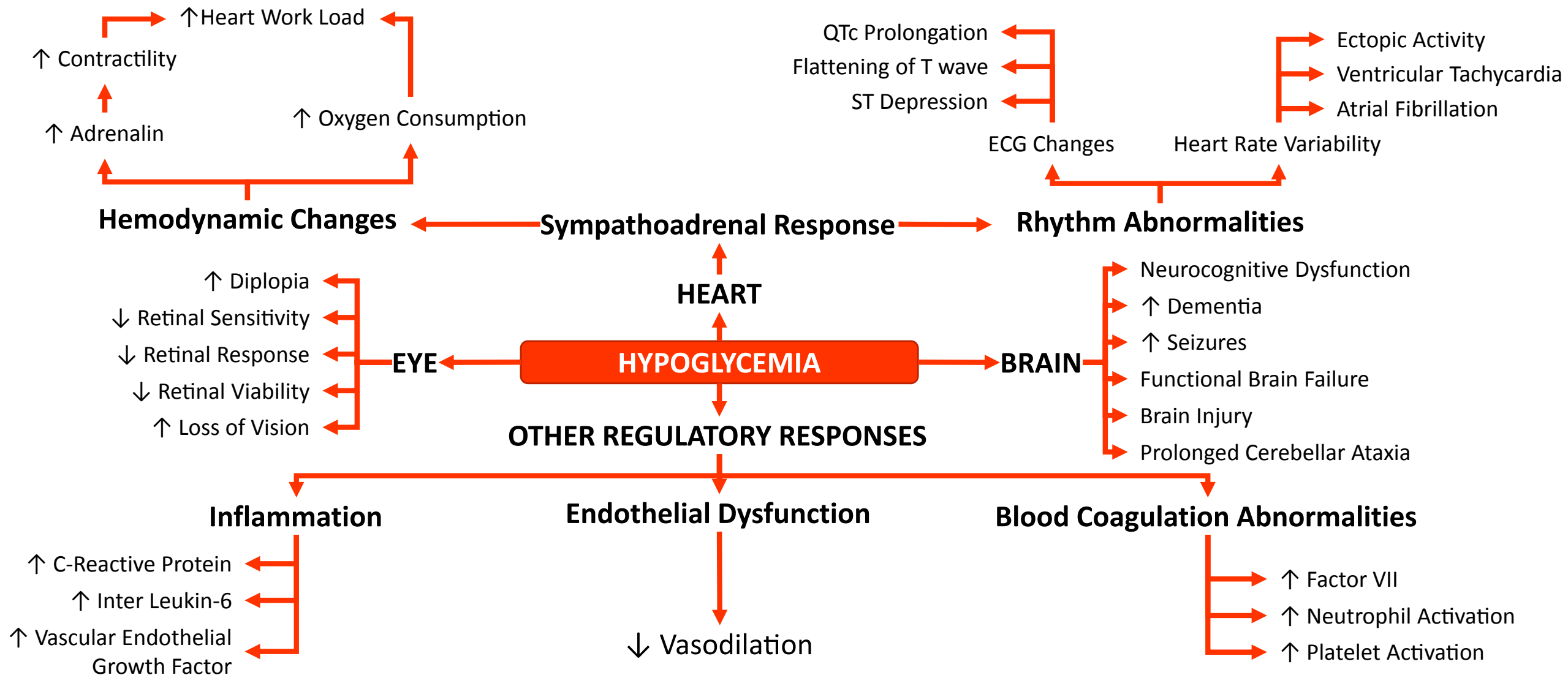
Complications of Diabetes and the Benefits of Tight Glycemic Control



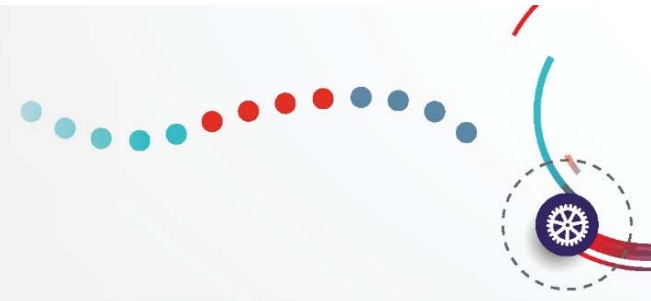
30 years of excellent vs. poor glycemic control substantially reduced the incidence of the following:

- Retinopathy requiring laser therapy (5% vs. 45%)
- End-stage renal disease (0% vs. 5%)
- Clinical neuropathy (15% vs. 50%)
- Myocardial infarction (3% vs. 5%)
- Stroke (0.4% vs. 2%)
- Death (6% vs. 20%)

Hypoglycemia: “The Greatest Limiting Factor in Diabetes Management”



How Often Does Hypoglycemia Occur?



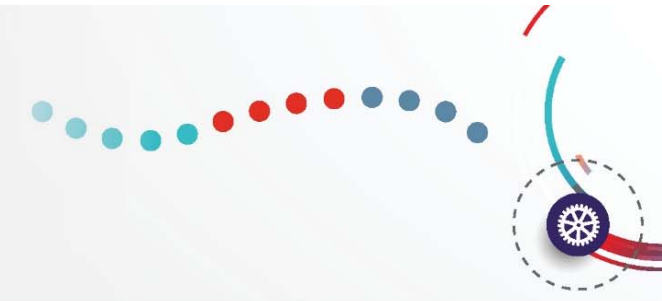
- Type 1 diabetes

- ❑ Patients with T1D report an average of up to 3 episodes of severe hypoglycemia per year (episodes requiring the assistance of another person).
- ❑ Studies using continuous glucose monitoring (CGM) show much more frequent episodes of clinically important hypoglycemia (<54 mg/dL), ranging from every 2-4 days to every 6 days.

Pedersen-Bjergaard U, Thorsteinsson B. Reporting Severe Hypoglycemia in Type 1 Diabetes: Facts and Pitfalls. *Curr Diab Rep* 2017; 17:131.

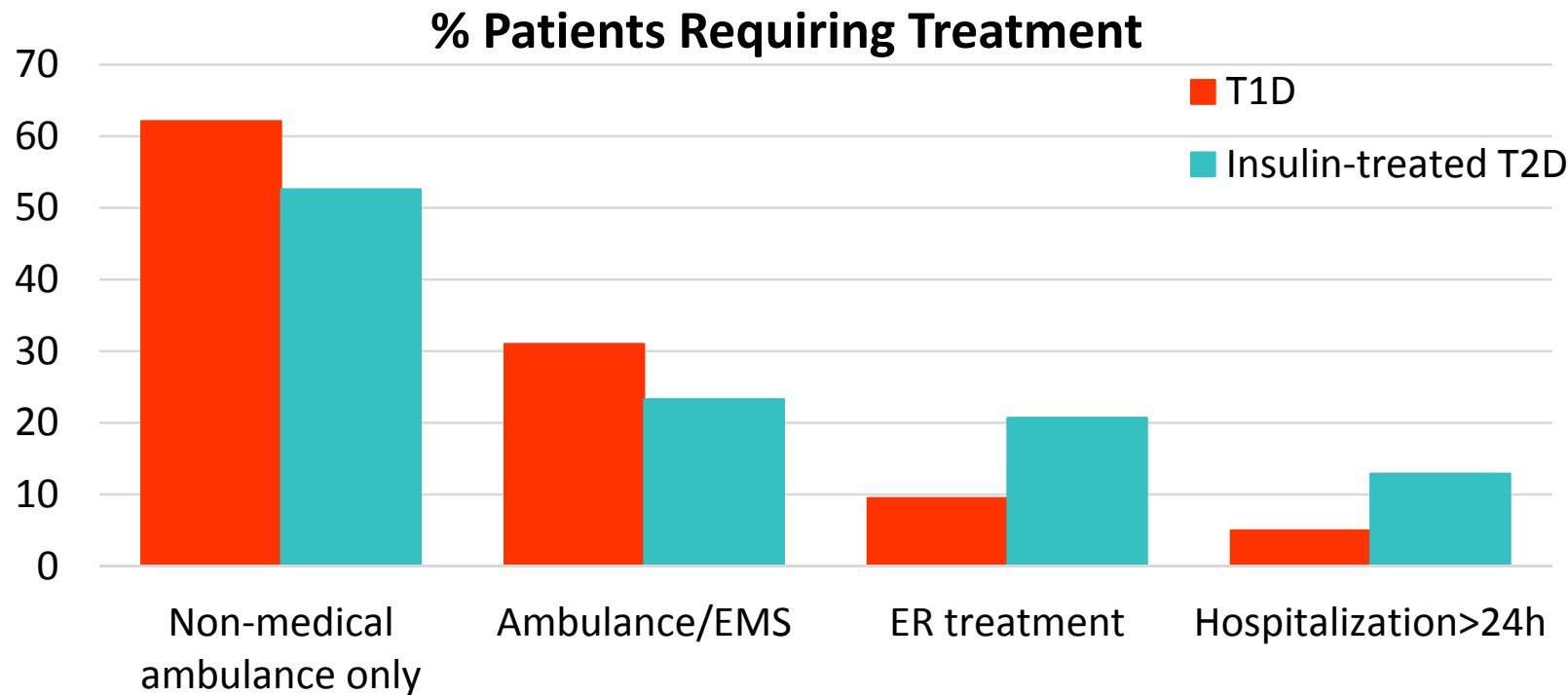
Riddlesworth T, Price D, Cohen N, Beck RW. Hypoglycemic Event Frequency and the Effect of Continuous Glucose Monitoring in Adults with Type 1 Diabetes Using Multiple Daily Insulin Injections. *Diabetes Ther* 2017; 8:947.

And It's Not Just the Type 1s



Assessment of resource allocation related to severe hypoglycemia¹

- 15 Phase 3a studies, T1D and insulin-treated T2D
- 516 severe hypoglycemic events

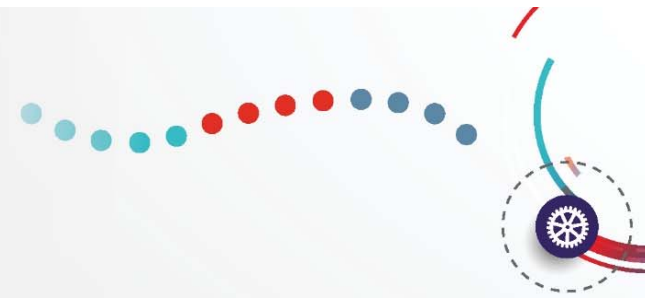


Average Costs/Event	
Ambulance transport ²	\$1704
ER visit ³	\$796
Hospitalization ³	\$13,108*

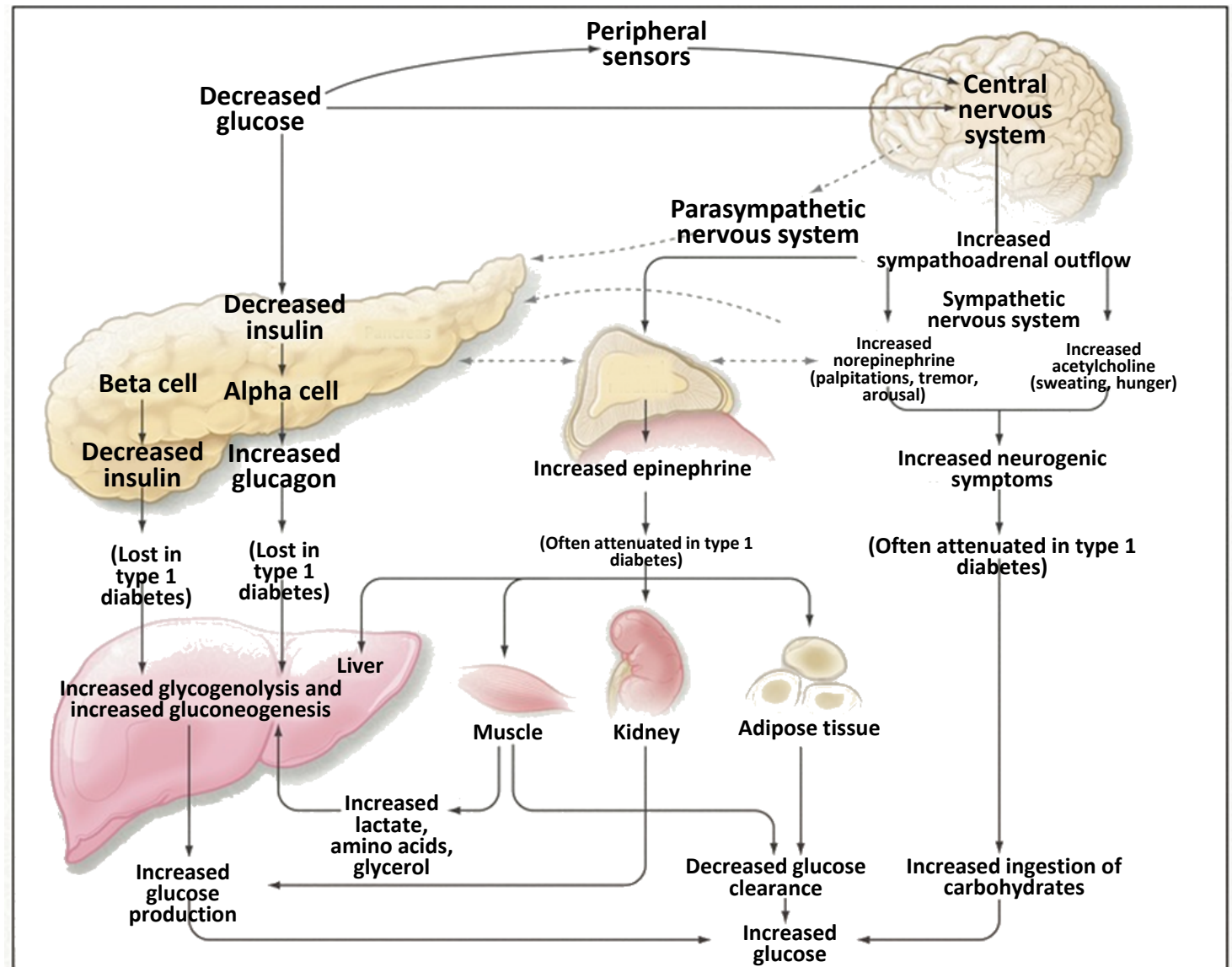
*Updated to 2017 cost using Consumer Price Index for Medical Care

1. Heller AR, et al. *Diabet Med.* 2016;33:471-7. 2. Centers for Medicare & Medicaid Services. *Ambulance Fee Schedule Public Use Files.* <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/afspuf.html>. Accessed 1/23/18. 3. Curkendall, SM. *J Clin Outcomes Manag.* 2011;18:455-62.

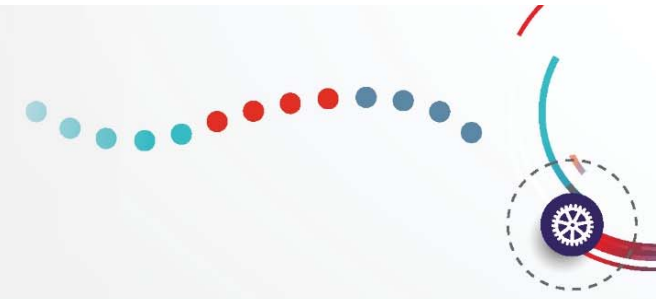
Hypoglycemia-associated Autonomic Failure (HAAF)



- Hypoglycemia causes both defective glucose counter regulation and hypoglycemia unawareness



Specific Demographics of Patients are Predisposed to Severe Hypoglycemia



Risk factors for severe hypoglycemia in individuals treated with sulfonylureas or insulin

- *Prior episode of severe or non-severe hypoglycemia*
- Current low A1C (<6.0%)
- Hypoglycemia unawareness
- Long duration of insulin therapy
- Autonomic neuropathy
- Chronic kidney disease
- Low economic status, food insecurity
- Low health literacy
- Preschool-age children unable to detect and/or treat mild hypoglycemia on their own
- Adolescence
- Pregnancy
- Elderly
- Cognitive impairment

HUA (Hypoglycemic Unawareness) is Relatively Prevalent, Particularly the Elderly and Children/Adolescents



Across 21 studies spanning 2000-2016...

Adults with T1DM

- Median Prevalence: 19%
- High/Low Prevalence: 58%/10%

Children and Adolescents with T1DM

- Median Prevalence: 25%

Adults with Insulin-treated T2DM

- Median Prevalence: 10%

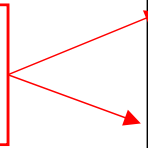


Insulin is the Second-most Commonly Implicated Medication in Hospitalizations for Adverse Drug Events (ADEs)

Table 4. National Estimates of Medications Commonly Implicated in Emergency Hospitalizations for Adverse Drug Events in Older U.S. Adults, 2007–2009.*

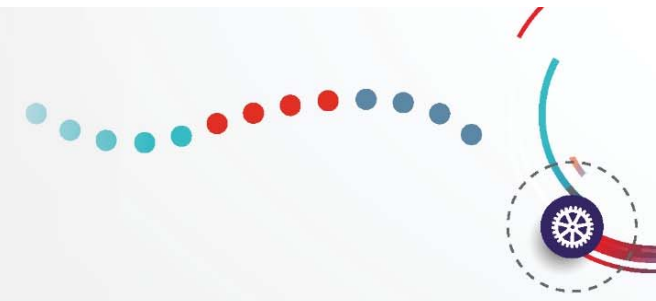
Medication	Annual National Estimate of Hospitalizations (N = 99,628)		Proportion of Emergency Department Visits Resulting in Hospitalization
	no.	% (95% CI)	%
Most commonly implicated medications†			
Warfarin	33,171	33.3 (28.0–38.5)	46.2
Insulins	13,854	13.9 (9.8–18.0)	40.6
Oral antiplatelet agents	13,263‡	13.3 (7.5–19.1)	41.5
Oral hypoglycemic agents	10,656	10.7 (8.1–13.3)	51.8
Opioid analgesics	4,778	4.8 (3.5–6.1)	32.4
Antibiotics	4,205	4.2 (2.9–5.5)	18.3
Digoxin	3,465	3.5 (1.9–5.0)	80.5
Antineoplastic agents	3,329‡	3.3 (0.9–5.8)‡	51.5
Antiadrenergic agents	2,899	2.9 (2.1–3.7)	35.7
Renin–angiotensin inhibitors	2,870	2.9 (1.7–4.1)	32.6
Sedative or hypnotic agents	2,469	2.5 (1.6–3.3)	35.2
Anticonvulsants	1,653	1.7 (0.9–2.4)	40.0
Diuretics	1,071‡	1.1 (0.4–1.8)‡	42.4

1/4 of ADE hospitalizations



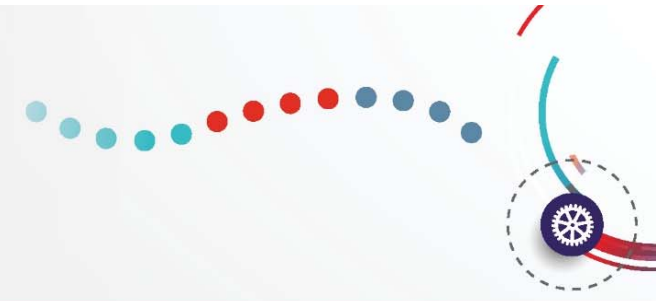
Budnitz DS, Lovegrove MC, Shehab N, Richards CL. *N Engl J Med.* 2011;365(21):2002-12.

Insulin-related Hypoglycemia Results in Nearly 100,000 ED Visits Annually



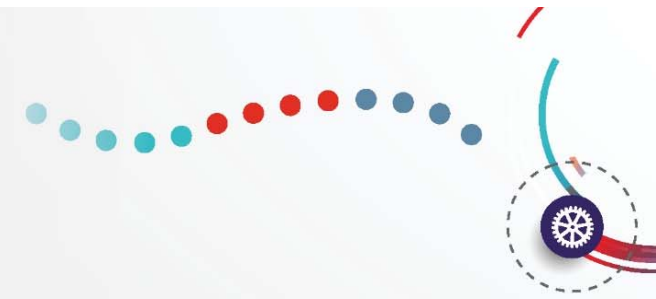
Age	Number going to ED for IHE/yr	% of insulin-only patients each year	% of insulin + oral patients each year
18-44	21,189	3.5	0.3
45-64	34,173	2.7	0.4
65-79	24,720	2.7	0.7
>80	15,479	5.0	1.6

The Cost of Insulin-related Hypoglycemia is Staggering



Based on previous cost estimates for hypoglycemia, nearly 100,000 ED visits and 30,000 hospitalizations annually, **more than \$600 million** was spent on drug-related hypoglycemia during a 5-year period (2007-2011).

How is Value in Health Care Innovation Created?



Better patient outcomes

- Clinical endpoints
- Lower toxicity
- Better Quality of Life

Healthcare system efficiencies

- Refocus resources
- Cost offsets

$$\text{Value} = \text{Quality} / \text{Cost}$$

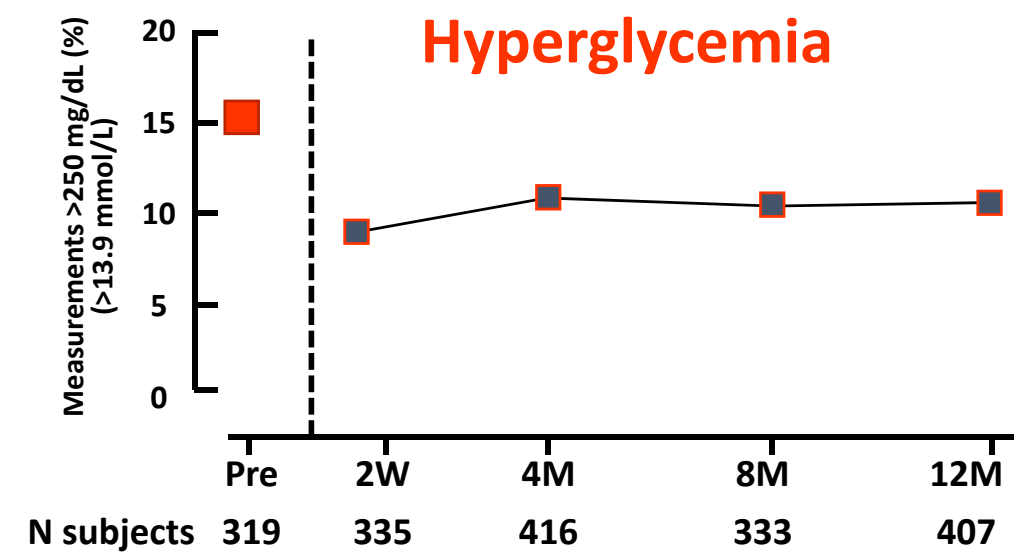
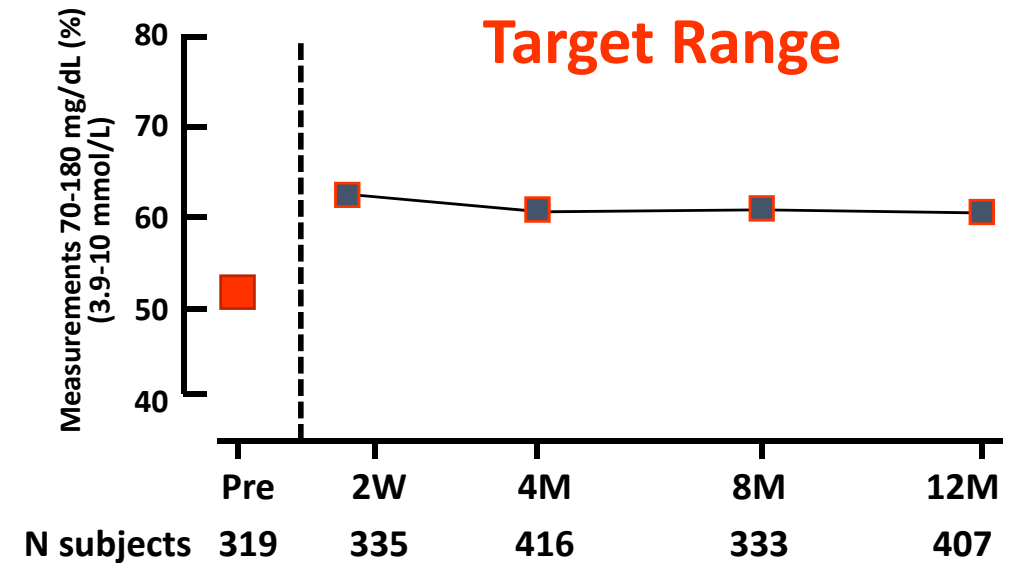
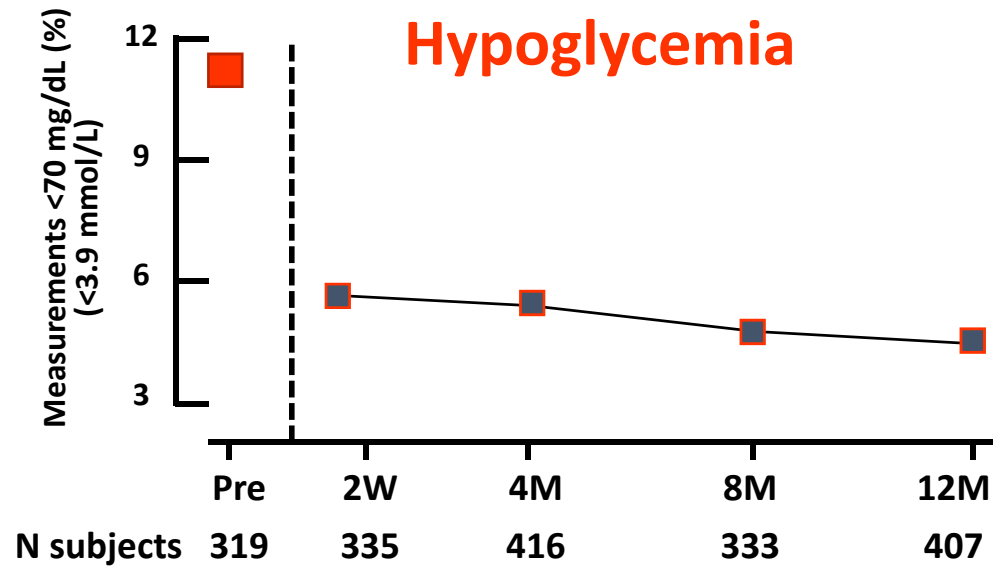
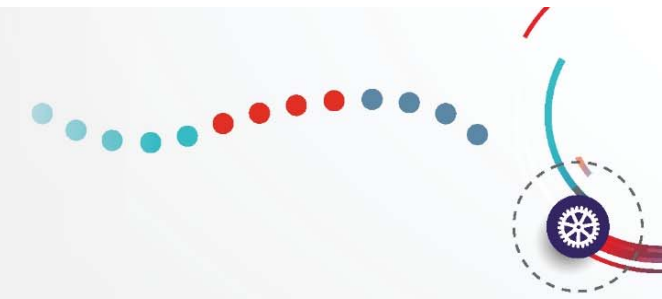
Improved societal outcomes

- Increased productivity
- Less reliance on caregivers
- Caring for others

Living longer and better

- Employment
- Productivity
- Self-worth

The Value of rtCGM: Improved Population Glycemic Control



The Value of rtCGM: Reduction in Hospitalizations and Work Absenteeism

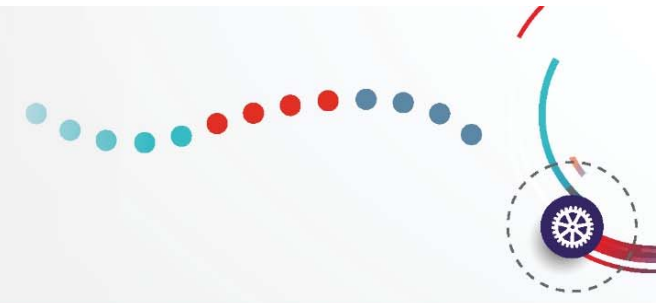


	Pre-Reimbursement for rtCGM (n = 496)	Post-Reimbursement for rtCGM (n = 379)	P Value
Patients with			
Hospitalizations due to hypoglycemia and/or ketoacidosis	77 (16%)	14 (4%)	<0.0005
Hospitalizations due to hypoglycemia	59 (11%)	12 (3%)	<0.0005
Hospitalizations due to ketoacidosis	23 (5%)	4 (1%)	0.092
Work absenteeism ^a	123 (25%)	36 (9%)	<0.0005
Days (per 100 patient years) of			
Hospitalizations due to hypoglycemia and/or ketoacidosis	53.5	17.8	<0.0005
Hospitalizations due to hypoglycemia	38.5	12.5	0.001
Hospitalizations due to ketoacidosis	14.9	5.3	0.220
Work absenteeism	494.5	233.8	0.001

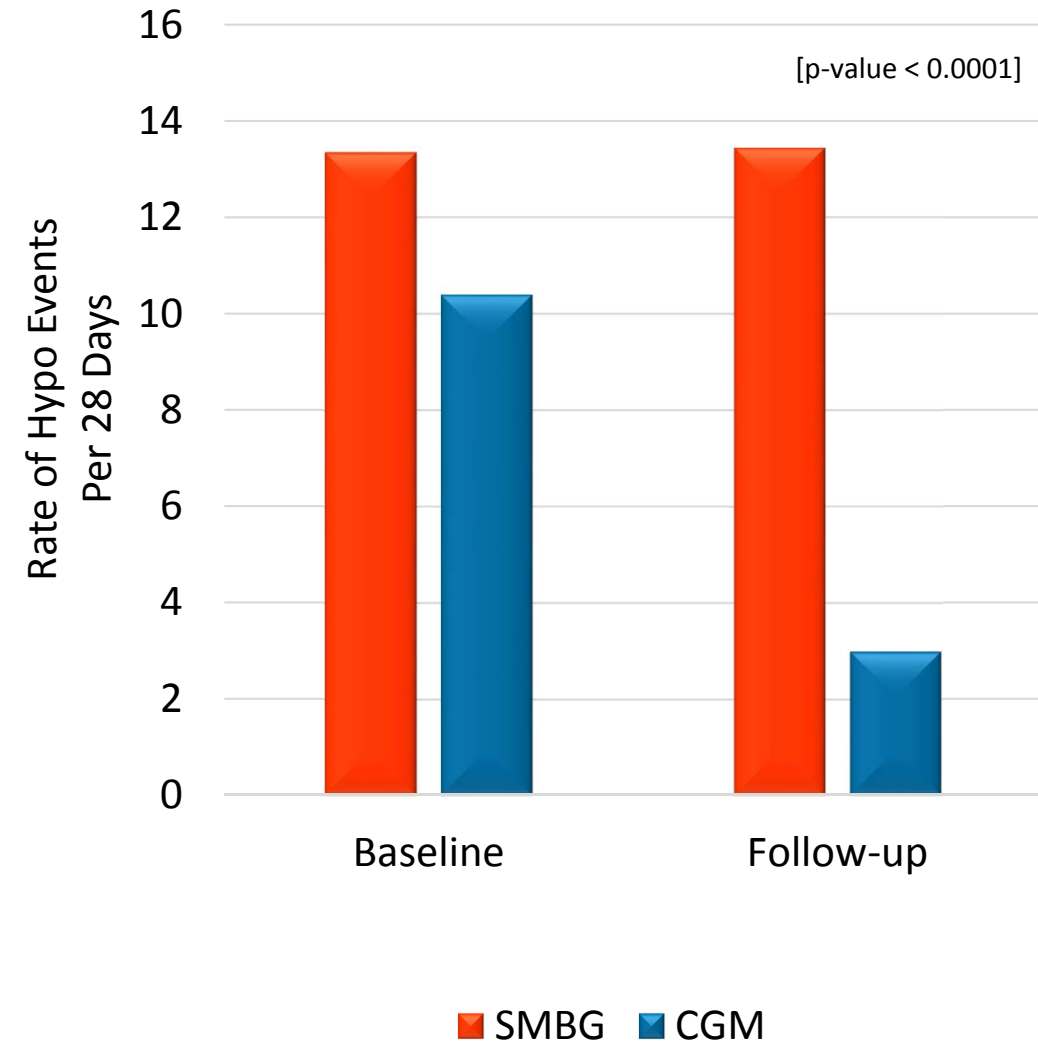
Data are n (%).

^aWork absenteeism of at least half a day. Patient-reported hospital admissions were validated by clinicians.

The Value of rtCGM: Addressing the Costly Complications of Hypoglycemia



- HypoDE was a 6-month, multicenter, open-label, parallel, randomized controlled trial
- A hypoglycemic event was defined as glucose ≤ 54 mg/dL for ≥ 20 min
- Mean number of hypoglycemic events per 28 days among participants in the rtCGM group was reduced from 10.8 to 3.5
- Reductions among control participants were negligible (from 14.4 to 13.7)
- Incidence of hypoglycemic events decreased by 72% for participants in the rtCGM group (incidence rate ratio 0.28 [95% CI 0.20–0.39], $p < 0.0001$)





Non-Severe and Severe Hypoglycemia Can Significantly Impact Hospitalizations, Readmissions, CV Events, and All-Cause Mortality

- Non-Severe Hypoglycemic Events (NSHEs)¹
 - Of 1400 responders with NSHE, 22.7% were late for work or missed a full day.
 - Productivity loss highest for NSHEs occurring during sleep, with an average of 14.7 working hours lost.
 - In the week following an NSHE, respondents required an average of 5.6 extra BG test strips and insulin-users decreased their insulin dose by 25% → Fear of hypoglycemia affecting treatment decisions

Admission for dysglycemia is a strong predictor for a readmission within 30 days due to dysglycemia^{4,5,6} and both NSHE and SH events are associated with a higher risk of CV events, hospitalization and all-cause mortality.^{7,8}

- DEVOTE T2DM trial, 2.5-fold greater risk of death anytime after an episode of SH with the risk 4-fold higher 15 days after an event.⁹

*Type 1 and type 2 diabetes combined

1. Brod M, et al. Value Health. 2011;14(5):665-71. 2. Bronstone A, et al. J Diabetes Sci Technol. 2016;10(4):905–913. 3. HCUP Nationwide Inpatient Sample (NIS). <http://hcupnet.ahrq.gov/Hcupnet.jsp>. 4. Hsieh CJ. Sci Rep. 2019;9(1):14240. 5. Rozalina G, et al. J Gen Intern Med. 2017. 6. McCoy RG, et al. J Gen Intern Med. 2017;32(10):1097–1105. 7. Davis SN, et al. Diabetes Care. 2019;42(1): 157-163. 8. Cha SA, et al. Diabetes Metab J. 2016;40(3):202–210. 9. Pieber TR, et al. Diabetologia. 2018;61(1):58–65.

The Value of rtCGM: Patient QoL and Confidence in Treatment Decision Making

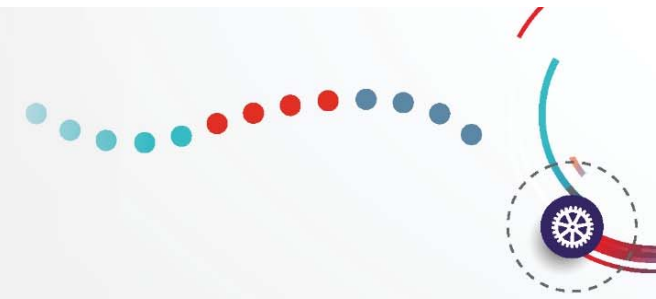


rtCGM participants reported a significantly greater increase in hypoglycemic confidence and a decrease in diabetes regimen and interpersonal distress compared to the SMBG group

CGM satisfaction was high and related to:

- Decrease in total diabetes-related distress
- Hypoglycemic worry
- Increases in hypoglycemic confidence
- Overall well-being

How is Value in Health Care Innovation Created?



Better patient outcomes

- Improved A1c and amount of time spent in range
- Reduced complications (ESRD, retinopathy, CV events, etc.)

Healthcare system efficiencies

- Reduced admissions/ER visits
- Reduced DKA
- Reduced hypoglycemia

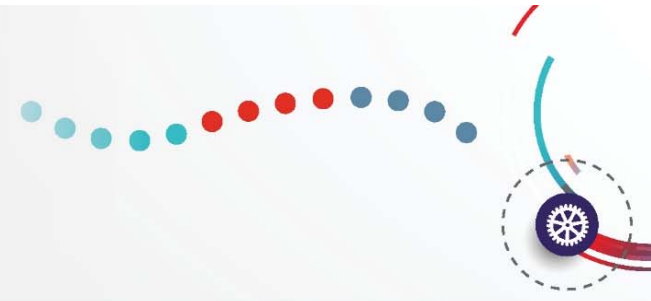
Improved societal outcomes

- Increased productivity
- Less reliance on caregivers
- Less parent anxiety over child's sugar

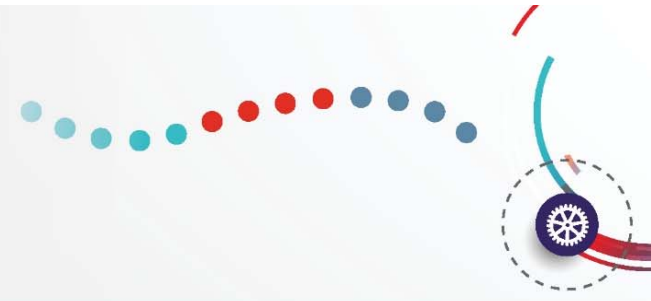
Living longer and better

- Improved quality of life
- Less fear of hypoglycemia
- Less death

Summary



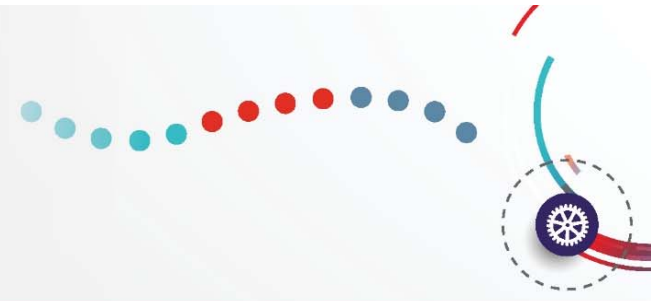
- Diabetes represents a leading driver of health care resource utilization and drug trend for payers
- While tight glycemic control is associated with improved outcomes and reduced costs, hypoglycemia remains a great limiting factor
- HUA is prevalent among a number of diabetes patient demographics and contributes to the clinical and economic burden of hypoglycemia – and it's not just Type 1's
- Self glucose monitoring has evolved from manual fingersticks to rtCGM, demonstrating a potential for value
- Reductions in A1C and rates of hypoglycemia have been demonstrated with the use of rtCGM, as well as reduced health care resource utilization and associated costs



*Pharmacy Benefit Management
Strategies to Enhance Outcomes
through Appropriate Coverage of CGM
and Other Technology Interventions*

Estay Greene, PharmD, MBA
Vice President, Pharmacy Services
Blue Cross Blue Shield of North Carolina

The Evolution of Glucometers



- Glucometers have been in use since the early 1980s for direct measurement of blood glucose
- The requisite blood sample size has decreased from 50-100 μL to 0.3-0.6 μL



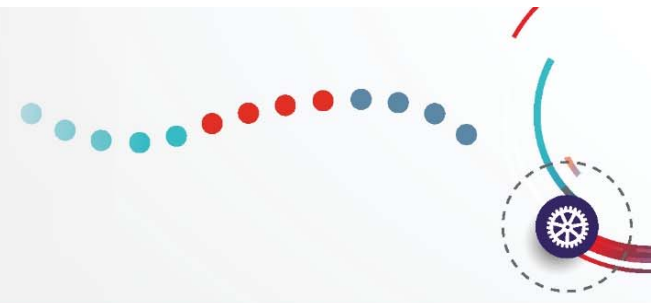
The Advent of Continuous Glucose Monitoring (CGM) Technology



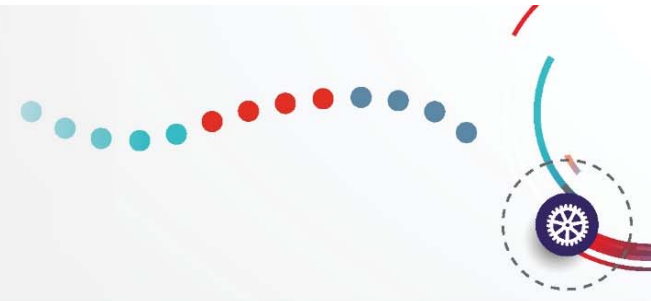
- CGM estimates BG by measuring the concentration of glucose in the interstitial fluid (ISF)
- Signals from the ISF are calibrated to the fingerstick BG level
- The delay between the BG and the CGM is the lag between ISF and BG + electrochemical sensor delay



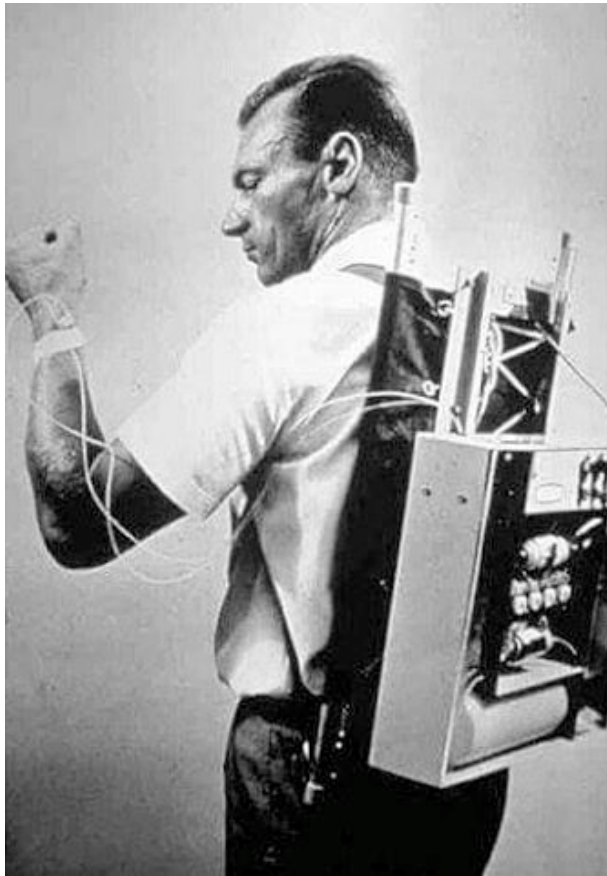
Present Day Glucose Monitoring: CGM



Evolution of Insulin Pumps



1963 - Arnold Kadish



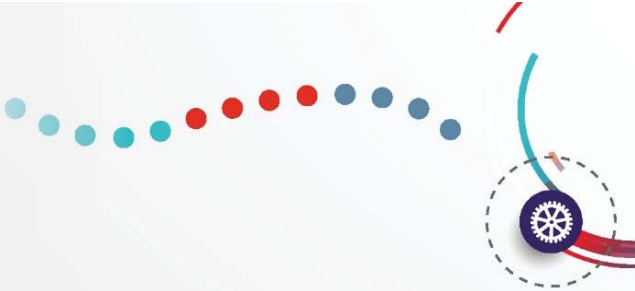
1976/78 Biostator and
Autosyringe AS2C



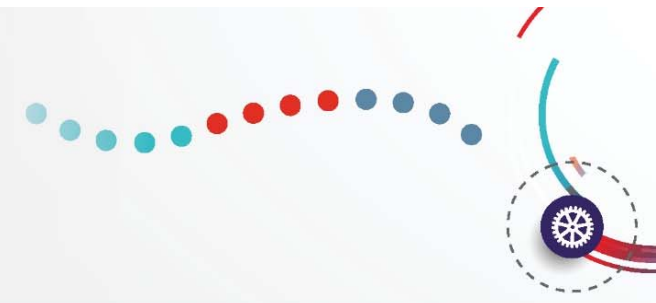
1976 Biostator (top)

1978 Autosyringe AS2C

Present Day Insulin Pumps



Characterizing the Clinical and Humanistic Value of CGM



Fear of hypoglycemia has long been recognized as the number one barrier to achieving good glycemic control¹

CGM addresses hypoglycemic unawareness

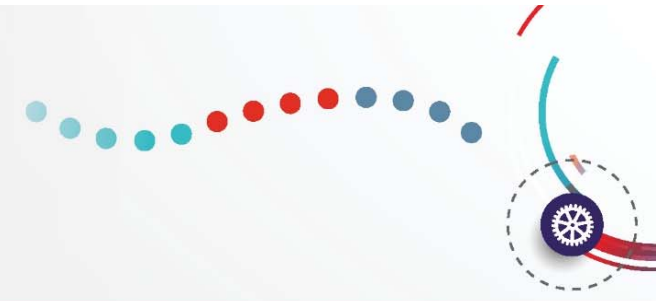
Concerns about low blood glucose lead to avoidance and suboptimal control²

Can reduce A1C and glycemic variability

Improved quality of life

1. Graveling AJ, Frier BM, *Diabetes Metab.* 2010 Oct;36 Suppl 3:S64-74.
2. Irvine AA, Cox D, Gonder-frederick L. *Health Psychol.* 1992;11(2):135-8.

As These Technologies Have Evolved, So Has Their Application



Then

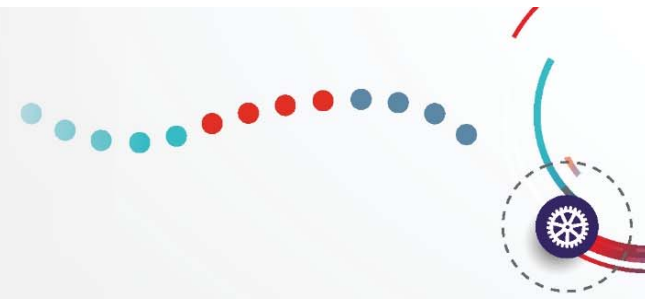
- High cost
- More complex devices
- Greater focus on patients with complex insulin needs



Now

- Cost is decreasing
- Technology is simpler and more accessible (i.e., via smartphone apps)
- Available to treat a wide variety of “average” patients

How Have These Advances Impacted Health Care from the Payer Perspective?



Population Health

Effective Intervention
for a Greater Number
of Members

Improved Outcomes
and Cost Efficacy

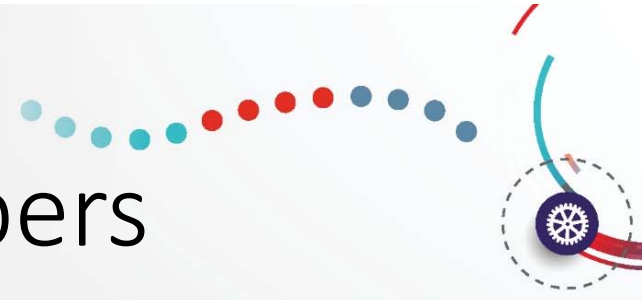
The Triple Aim of Health Care

Care Experience

Enhanced Member Access
with Appropriate Coverage
and Benefit Design

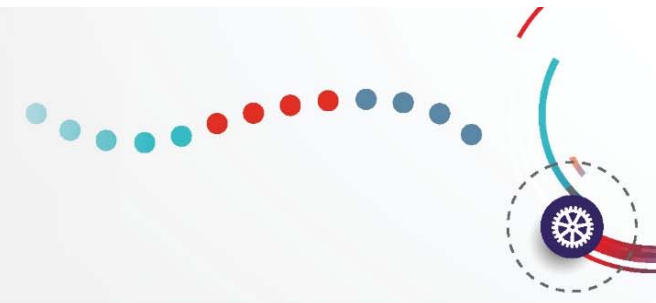
Per Capita Cost

Advances in CGM Systems Allow for Effective Interventions for a Greater Number of Members



- Payers and providers can deliver effective care to more patients with the same amount of financial resources
- The scope of care is being broadened to use CGM as a general tool of care rather than only in niche patients/pump utilizers
 - Gone is the notion that this is a “T1 issue” —now it is more of an “insulin-user issue” (and beyond?)

Advances in CGM Systems Facilitate Optimal Outcomes and Cost Efficacy



- Modernized CGM results in improved outcomes:
 - Reduced A1C
 - Reduced time in hypoglycemia and hypoglycemic events
 - More clinically appropriate and cost-effective use of insulin therapy
- CGM also improves the precision of care by revealing more specific areas of focus for management interventions (e.g., fasting levels vs prandial levels)
- CGM minimizes adherence issues with traditional blood glucose monitoring
 - While test strips create an opportunity for patients to be nonadherent several times a day, sensors need only be changed biweekly
 - <5% of patients using IIT check their glucose 9-10 times/day as recommended by ADA Standards of Care

More Sophisticated Forms of CGM Have the Potential to Increase Total Cost Savings



Real-time CGM (rtCGM) yields cost offsets versus flash CGM technologies via avoidance of complications related to imprecise management

Mean Health Care Costs by Study Group

	rtCGM (N=1023)	Non-rtCGM (N=1023)	Difference ^a	P value
Total cost (w/o DME)	\$16,194	\$20,452	-\$4,257	.0010
Medical (w/o DME)	\$7,749	\$11,583	-\$3,834	.0001
Inpatient	\$1,116	\$3,104	-\$1,987	.0002
Inpatient other facility	\$256	\$201	\$56	.6446
Outpatient office & clinic	\$2,055	\$1,787	\$268	0.282
Outpatient other facility	\$2,273	\$4,560	-\$2,287	.0002
Emergency room	\$869	\$1,282	-\$413	.0180
Post-acute care and other location	\$1,179	\$649	\$530	.0002
Pharmacy (w/o DME)	\$8,445	\$8,869	-\$424	.4444
Insulin	\$4,637	\$4,566	\$71	.5742
OAD	\$0	\$1	-\$1	.3175
Other Rx (nondiabetic)	\$3,807	\$4,301	-\$494	.3599
Utilization				
Average hospital admission	0.06	0.13	-0.07	.0001
Average LOS per admission	3.79	5.46	-1.67	.0788

T-test was used for continuous variables. Cost breakdown based on place of service. Details in the appendix.

^aRounded to the nearest dollar

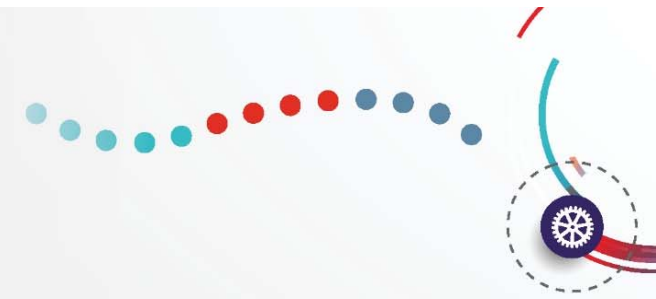
Gill M, Zhu C, Shah M, Chhabra H. *J Diabetes Sci Technol.* 2018;12(4):800-807.

Advances in CGM Can Be Accessed by Members with Appropriate Coverage and Benefit Design



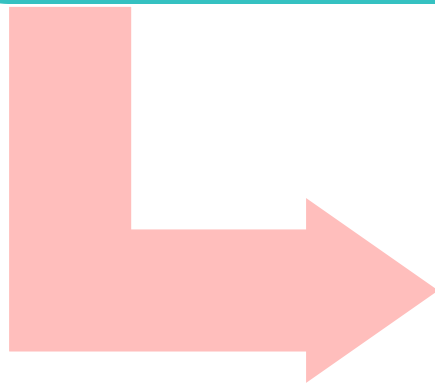
- The simplicity of modern CGM products allows for more broad distribution, utilization, and education through multiple avenues
 - Internet
 - Smartphone app
 - Community pharmacist
- In contrast, older and more complex were covered exclusively on the durable medical equipment (DME) benefit

Coverage and Benefit Design Has Largely Evolved with Advances in CGM



Traditional

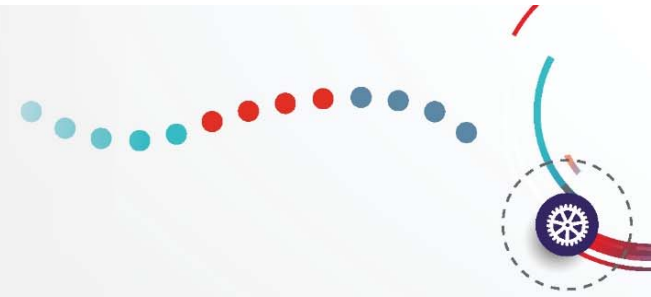
- DME typically covered under the medical benefit
- Supplies such as test strips often covered under the pharmacy benefit



Modern

- Coverage of glucose monitoring devices and supplies increasingly covered under the pharmacy benefit as a means of improving access and uptake among network providers and plan members

Channel Management: Moving CGM from the Medical Benefit to the Pharmacy Benefit



Benefits of CGM Coverage Under the Pharmacy Benefit:



Increased access to the product at the corner pharmacy



Increased specificity of data for the health plan (i.e., through DME, the details of utilization are more difficult to collect and analyze)



Increased contractual and programmatic cooperation between the manufacturer and the payer

Pharmacy Access Benefits All Stakeholders



Payer:

- Ability to implement pharmacy utilization controls
- Increased visibility to data
- Lower budget impact to pharmacy coverage vs. covered as DME



Provider:

- Ease of prescribing
- Less administrative burden
- Confidence that the patient has access to rtCGM

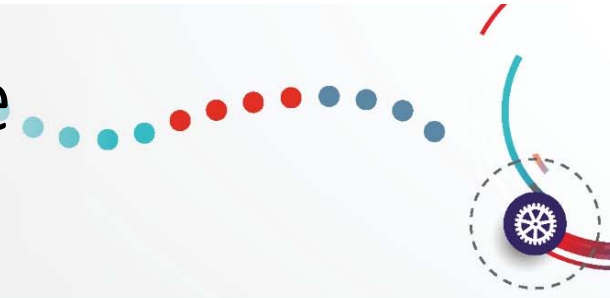


Patient:

- Potential lower out-of-pocket costs
- Quickest access to product through pharmacy coverage vs. medical benefit

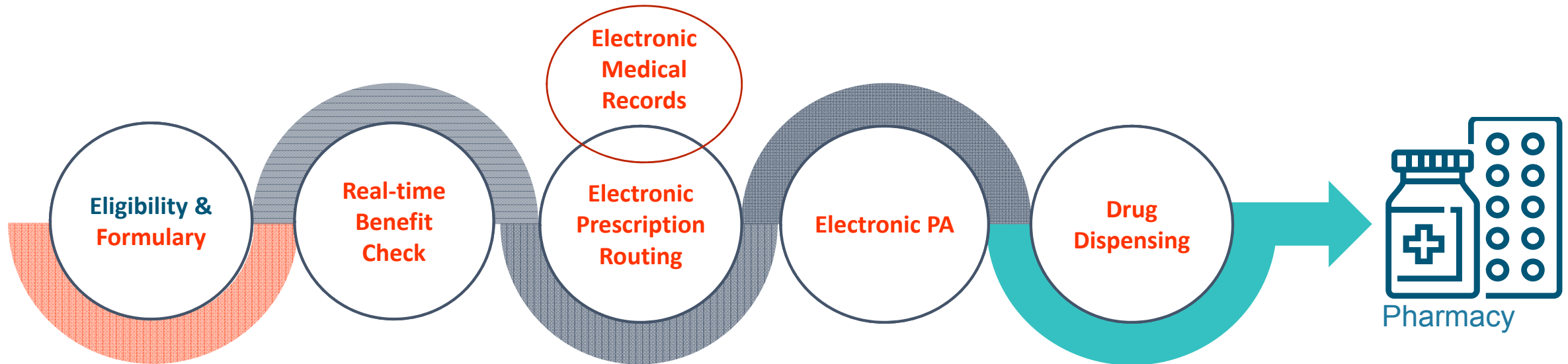
Providing convenient and cost-effective access through the pharmacy channel will lead to quicker access to the product.

The Interests of Payers, Providers, and Patients are Served by Reducing Administrative Inefficiencies



- Reducing cost and administrative inefficiencies increases value
- Patient lobbying and physician burden are leading to increased transparency in utilization management
- Each pre-authorization costs payers and providers \$50-\$100
- Methods to decrease unnecessary administrative burden:
 - Automate authorizations in workflow and deploy real-time adjudication under the pharmacy benefit
 - Limit prior authorization to interventions not in national guidelines/pathways
 - Link EHRs to medical review to streamline authorizations
 - Track trends in authorization and utilization in aggregate and by provider
 - Refine and update
 - Reflect current guidelines for care
 - Monitor provider outliers

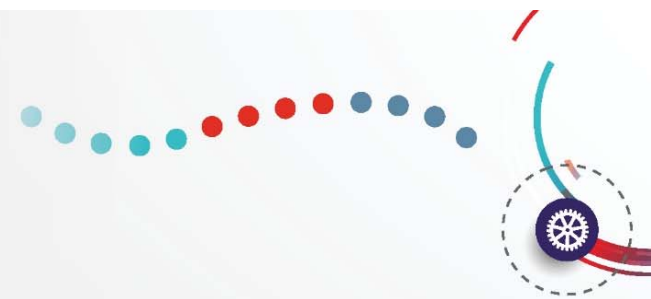
Data Management and Support Under the Pharmacy Benefit Can Streamline Patient Access and Availability



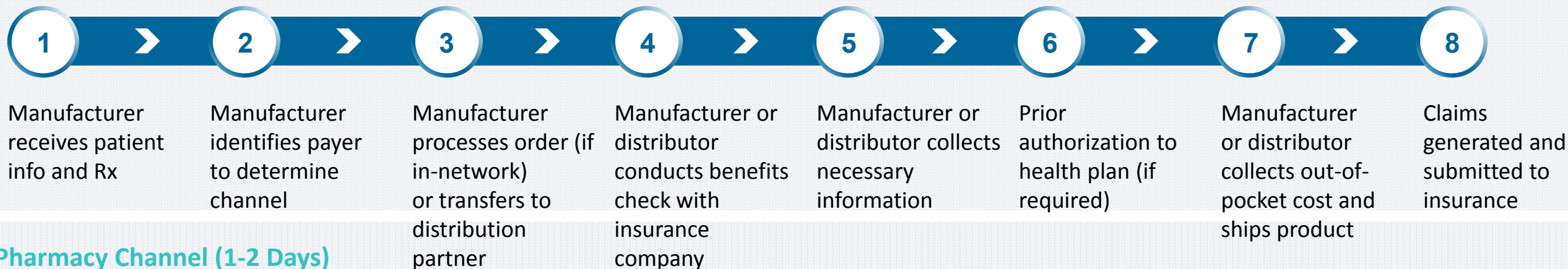
The services should:

- Exchange information, so that the prescriber (staff) only needs to enter it once
- Have a common “ID” so that the different transactions can be linked by multiple entities at different times
- Complete all actions required to get the patient on the right medication as soon as possible
- Integration of electronic medical records (EMRs) potentiates efficiency

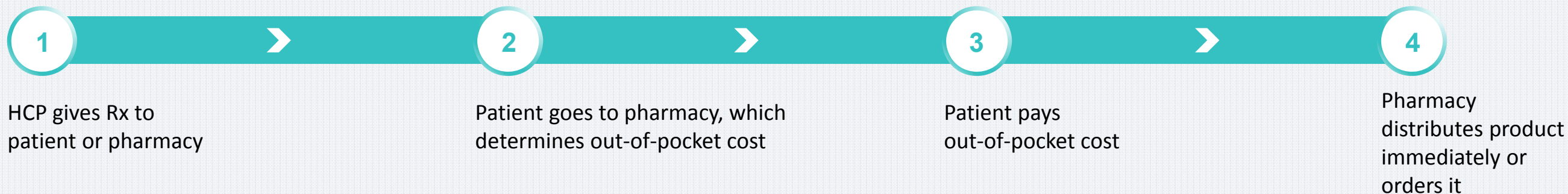
The Pharmacy Channel Improves Efficiencies and Enhances the Member Experience



DME Channel (3-4 Weeks)

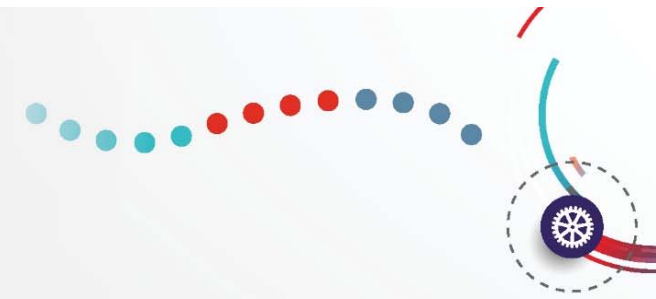


Pharmacy Channel (1-2 Days)

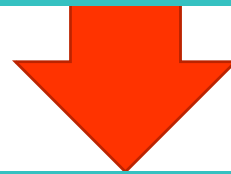


Coverage under the pharmacy channel reduces the waiting time by up to 4 weeks

CGM Coverage Trends Among CMS and Commercial Payers



In 2017, the Centers for Medicare and Medicaid Services (CMS) made a milestone ruling, establishing benefit coverage for “therapeutic” CGM—a designation applying only to those CGM systems approved for use in making treatment decisions without a fingerstick (“non-adjunctive use”)



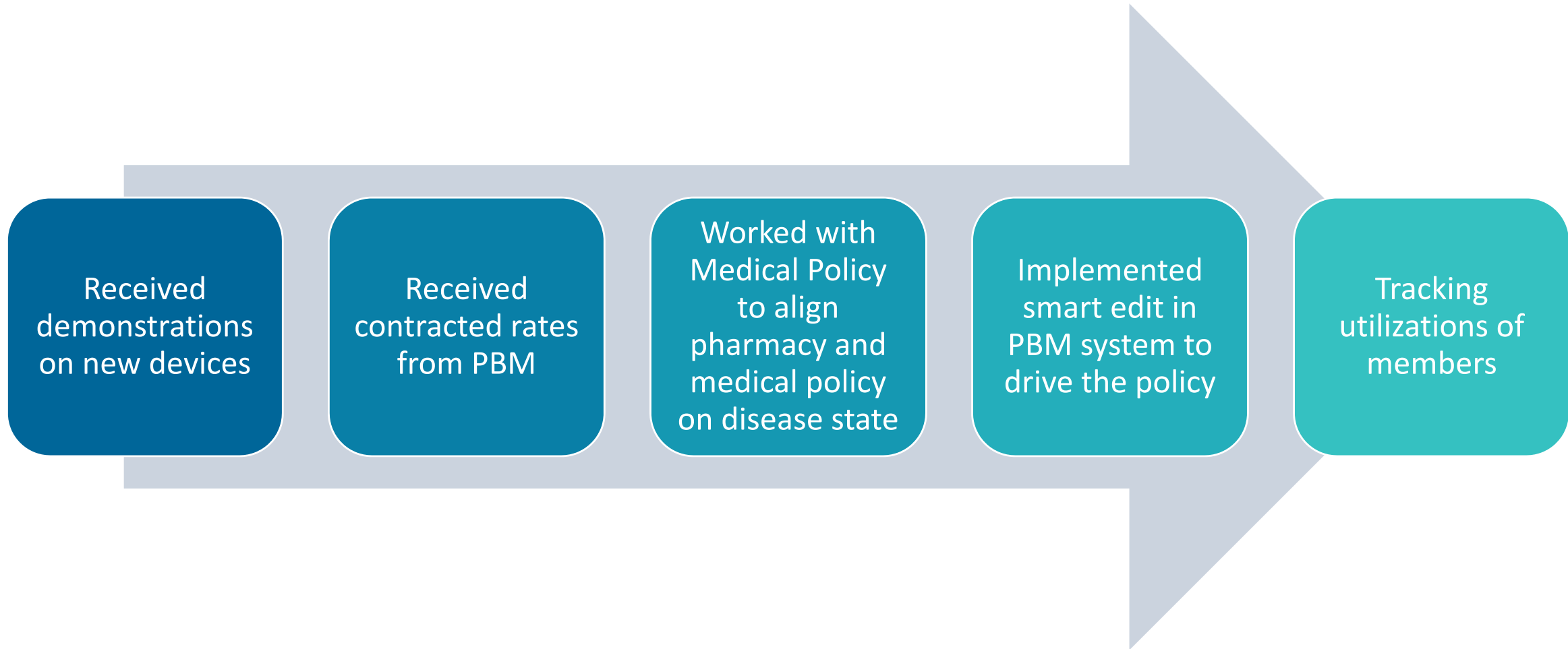
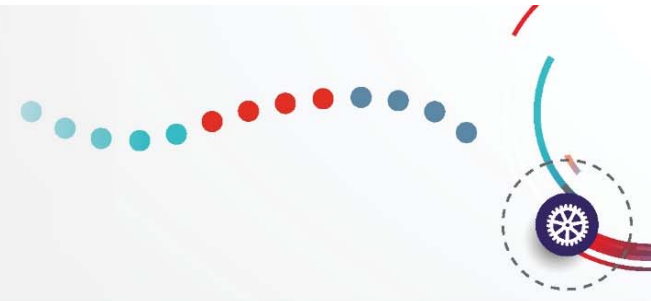
98% of commercial plans cover CGM for patients who meet medical criteria



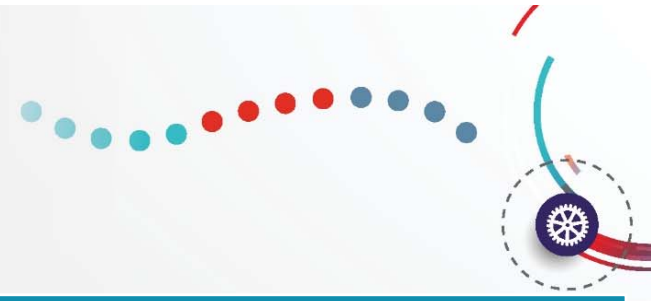
Nearly 50% of patients have coverage under their pharmacy benefit

Centers for Medicare and Medicaid Services. CMS Rulings. CMS-1682-R <https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/CMS-Rulings-Items/CMS1682R.html>. Published January 12, 2017. Accessed October 2019.

Health Plan Experience: Moving CGM to the Pharmacy Benefit



Defining Criteria for Coverage: Potential Indications for CGM



A1C above goal

Pre-conception

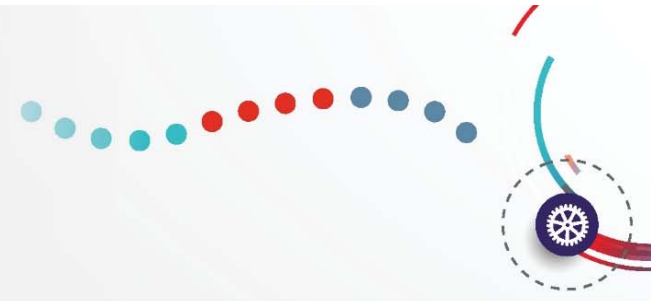
Pregnancy

History of severe hypoglycemia or hypoglycemia unawareness

Glucose variability

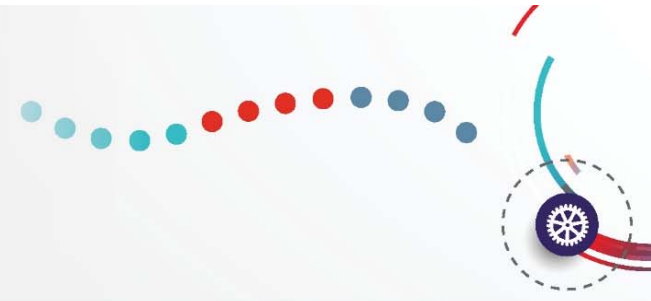
Basal/Bolus Insulin Therapy

Summary



- CGM has advanced over time and represents a comprehensive system for disease management
- CGM is recommended by the ADA and other endocrinology-related professional societies in appropriate clinical scenarios for both type 1 and type 2 diabetes but is vastly underutilized
- While tight glycemic control is beneficial, *precision* diabetes management is paramount to quality care and optimal outcomes; precision diabetes management is only achievable via CGM

Summary (cont.)



- Administrative burden and restrictive benefit design can have a detrimental effect on provider prescribing and member access to appropriate clinical interventions
- Seamless, real-time access to CGM technology under the pharmacy benefit is essential to facilitate prescribing and use of this proven intervention among patients and providers, respectively
- Coverage of CGM under the pharmacy benefit integrates the involvement of pharmacists as allied HCPs and facilitates therapeutic adherence as well as the safety and efficacy of medical interventions