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

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MEDICAL EDUCATION RESOURCES

This activity is supported by an independent educational grant from Dexcom.

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

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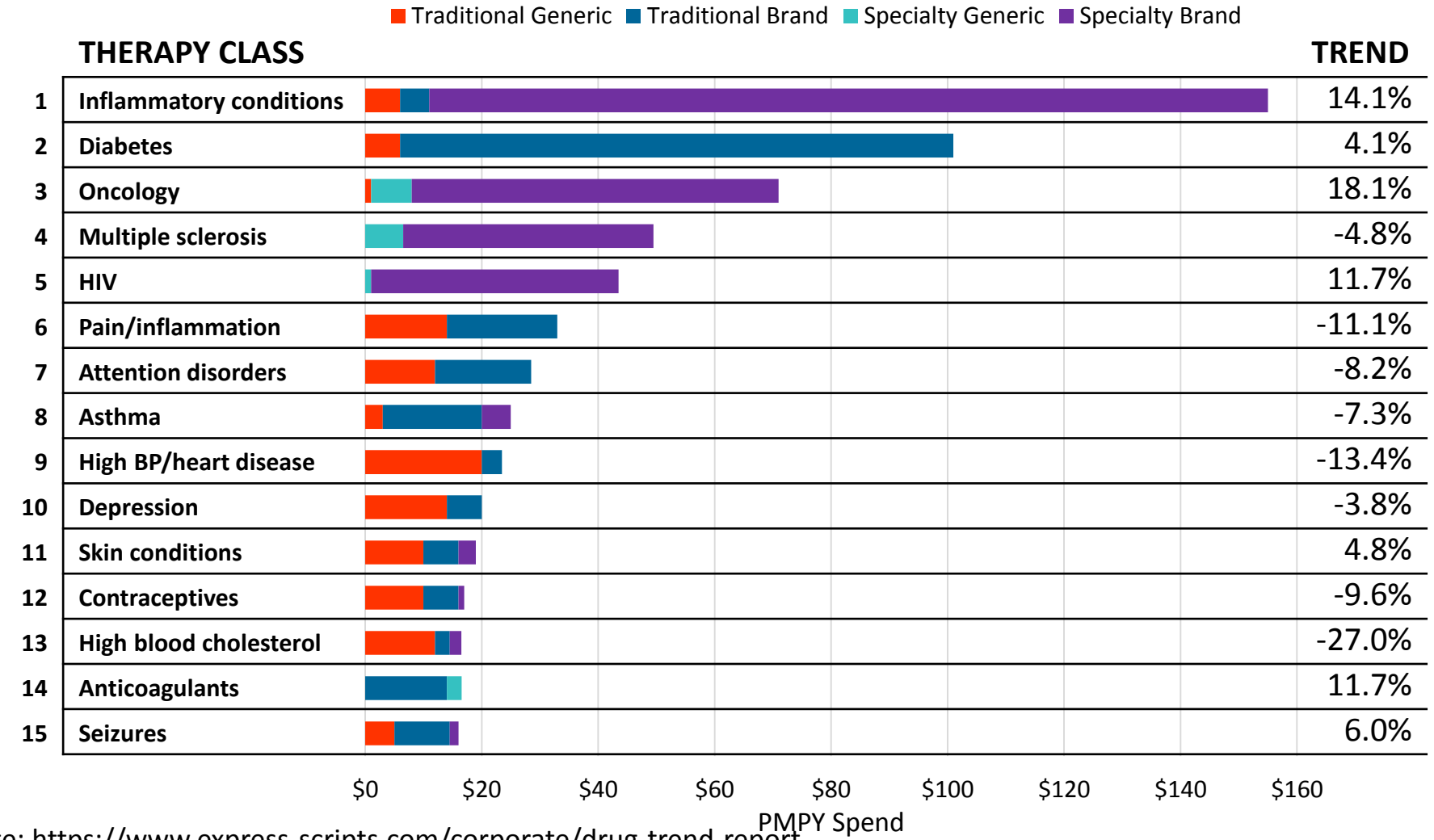
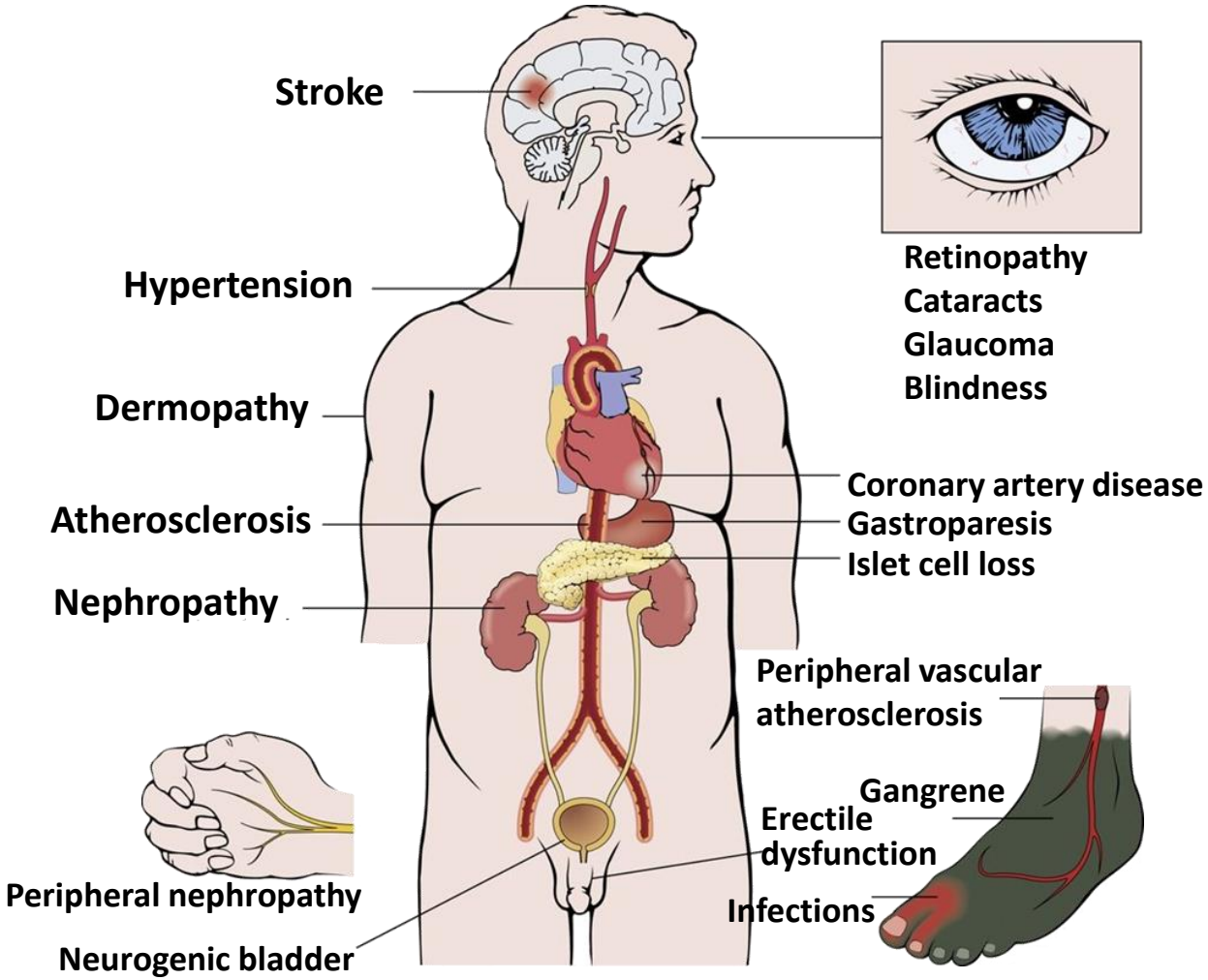
Diabetes is a Significant Driver of Health Care Resource Utilization and Drug Trend for Payers

- 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

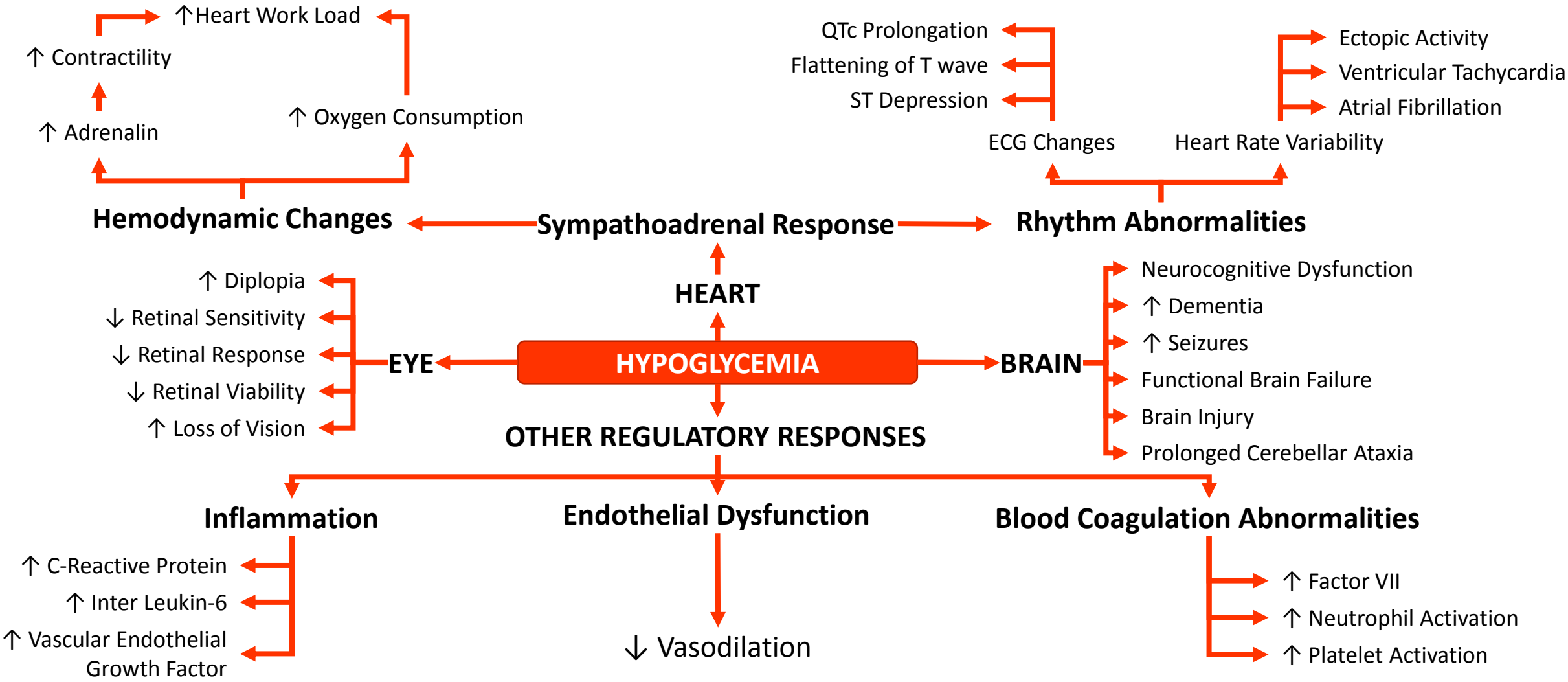


30 years of excellent vs. poor glycemic control substantially reduced the incidence of the following:

- 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%)

Herman WH, Braffett BH, Kuo S, et al. *J Diabetes Complicat*. 2018;32(10):911-915.

Hypoglycemia: "The Greatest Limiting Factor in Diabetes Management"



Kalra S, Mukherjee JJ, Venkataraman S, et al. *Indian J Endocrinol Metab*. 2013;17(5):819-34.

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).

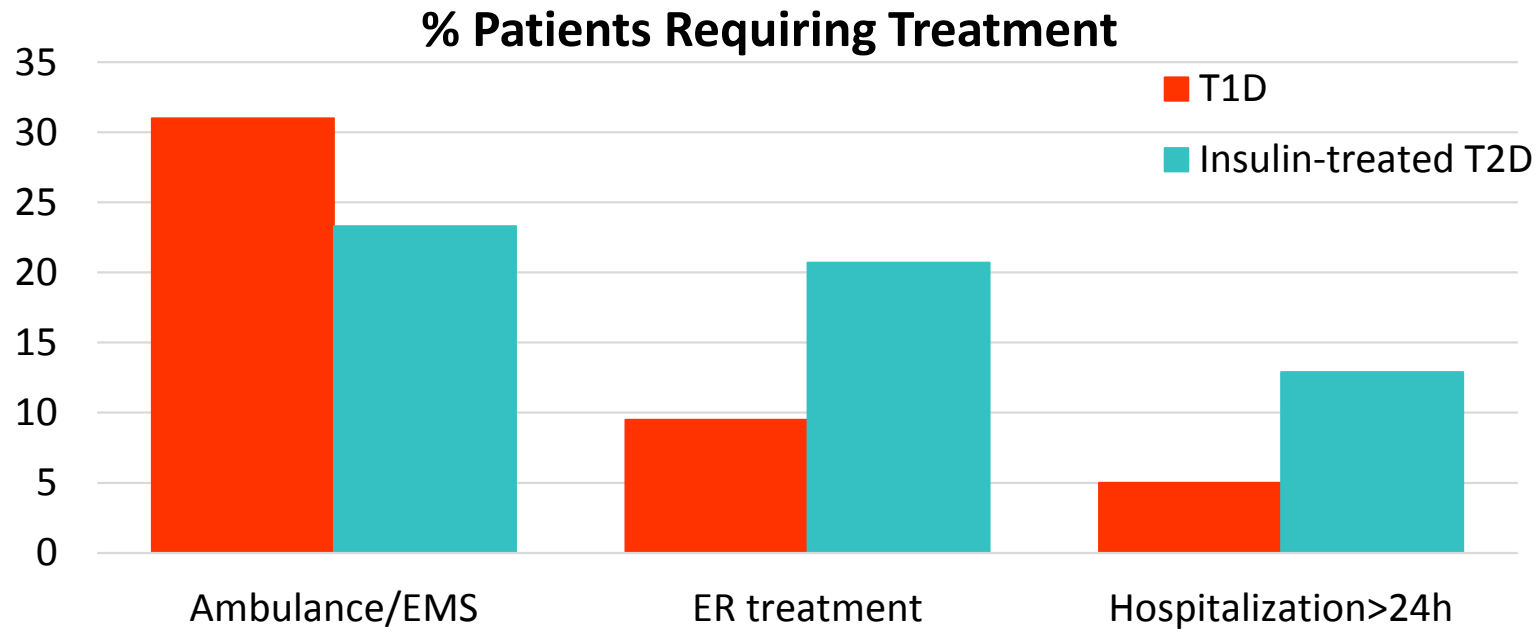
- ❑ Studies using continuous glucose monitoring (CGM) show much more frequent episodes of clinically important hypoglycemia (<54 mg/dL), ranging from every 2-4 days to every 6 days.

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.

The Cost of Hypoglycemia is Evident Across T1 and T2 Patients

Assessment of resource allocation related to severe hypoglycemia[1]

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



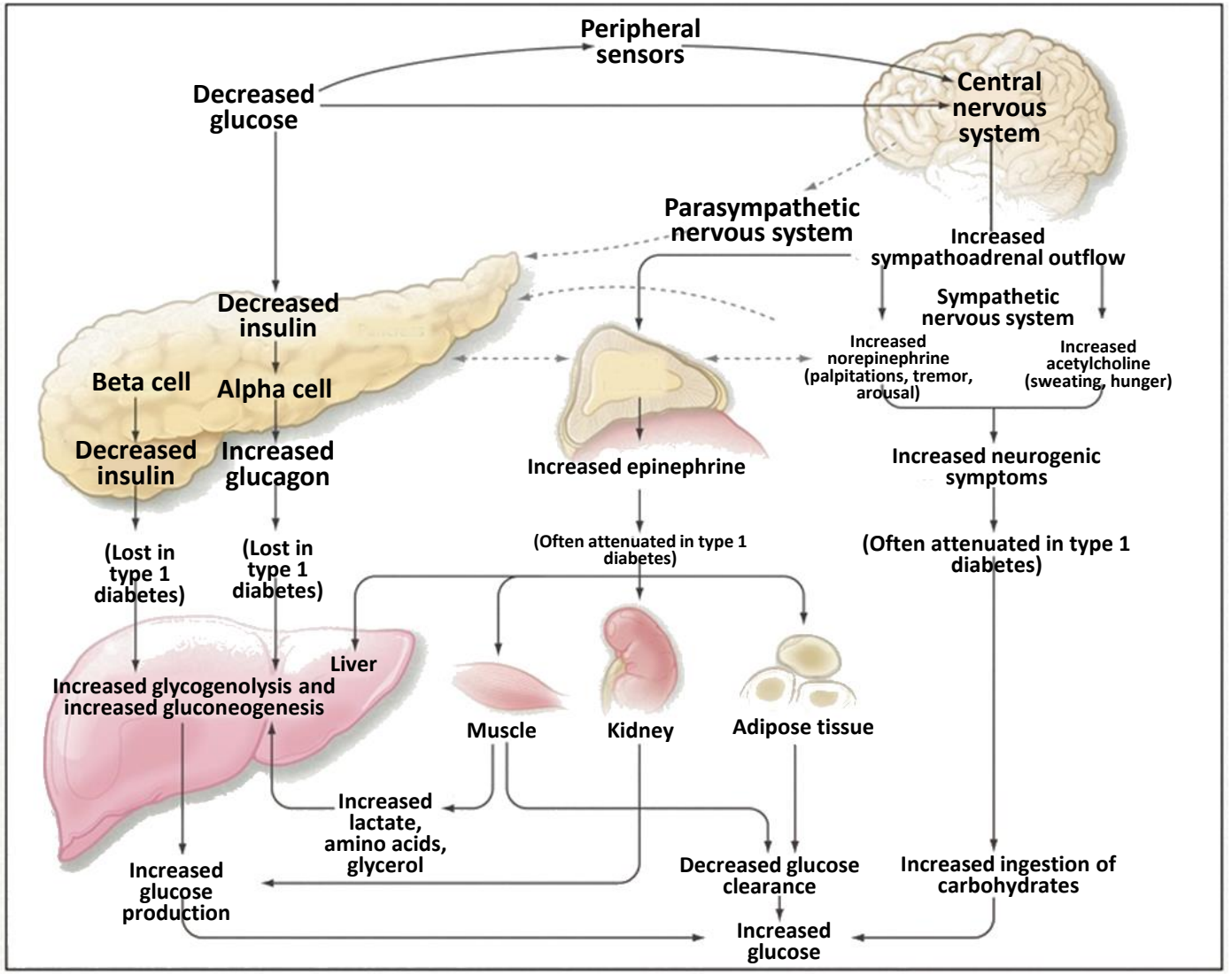
Average Costs/Event	
Ambulance transport[2]	$1704
ER visit[3]	$796
Hospitalization[3]	$13,108*

*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 November 2019. 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



Cryer PE. *N Engl J Med.* 2013; 369:362-372

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

Cariou B, et al. *Diabetes Metab*. 2015;41(2):116-25.

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%

Choudhary, 2010; Conget, 2016; Geddes, 2008; Hendrieckx, 2016; Henriksen, 2016; Hoi-Hansen, 2010; Holstein, 2003; Kulzer, 2014; Olsen, 2014; Ostenson, 2014; Pedersen-Bjergaard, 2003; Pedersen-Bjergaard, 2004; Peene, 2014; ter Braak, 2000; Abraham, 2016; Ly, 2009; Henderson, 2003; Kulzer 2014; Ostenson, 2014; Peene, 2014; Schopman, 2010.

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

¼ 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

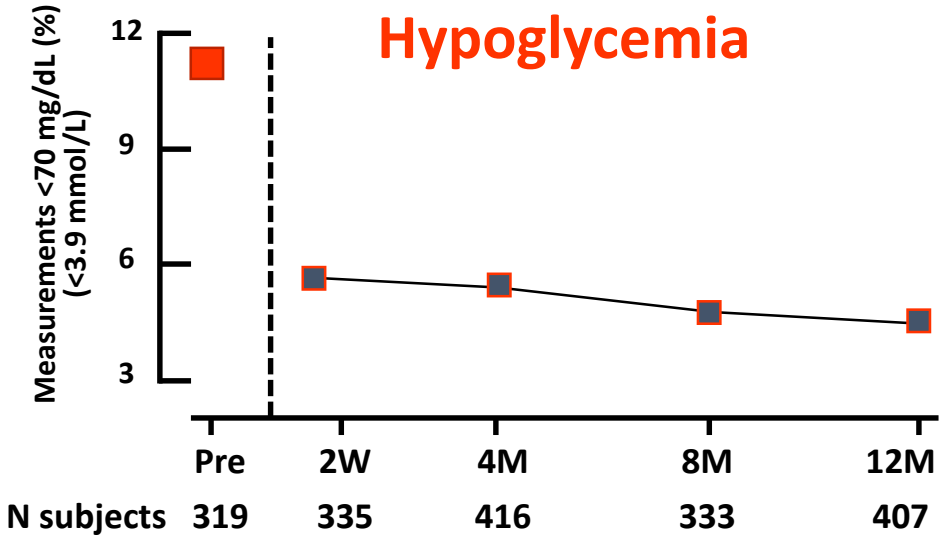
Geller KI, Shehab N, Lovegrove MC, Kegler SR, Weidenbach KN, Ryan GJ, & Budnitz DS. (2014). National estimates of insulin-related hypoglycemia and errors leading to emergency department visits and hospitalizations. *JAMA Intern Med*, *174*(5):678-686.

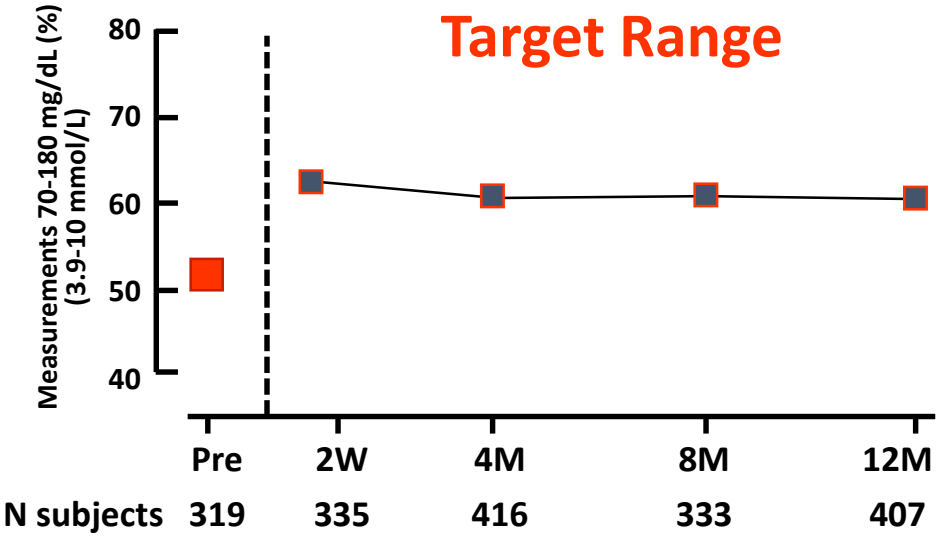
The Cost of Insulin-related Hypoglycemia is Staggering

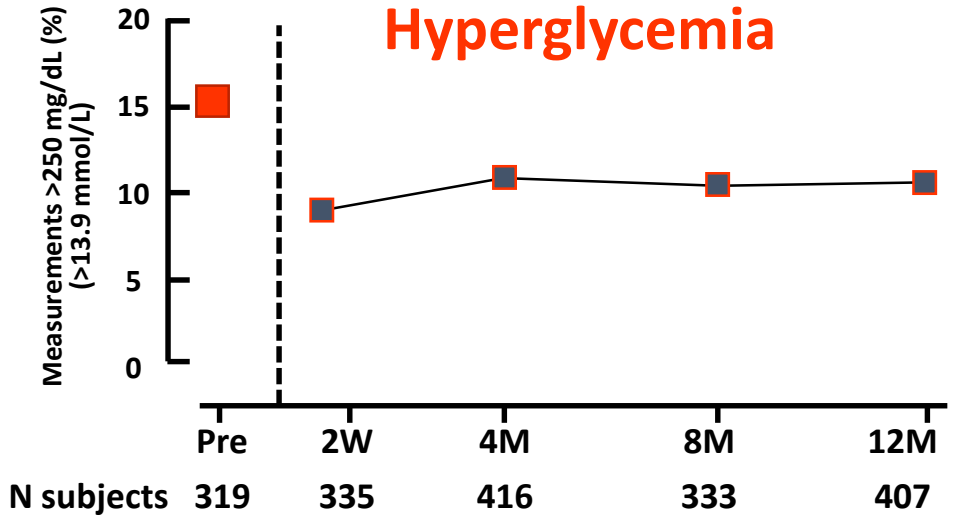
Based on previous cost estimates for hypoglycemia, nearly 100,000 ED visits and 30,000 hospitalizations annually, ***more than $600 million*** was spent on drug-related hypoglycemia during a 5-year period (2007-2011).

Geller KI, Shehab N, Lovegrove MC, Kegler SR, Weidenbach KN, Ryan GJ, & Budnitz DS. (2014). National estimates of insulin-related hypoglycemia and errors leading to emergency department visits and hospitalizations. *JAMA Intern Med*, *174*(5):678-686.

The Value of Real-Time Continuous Glucose Monitoring (rtCGM): Improved Population Glycemic Control







Charleer S, Mathieu C, Nobels F, et al. *J Clin Endocrinol Metab*. 2018;103(3):1224-1232.

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

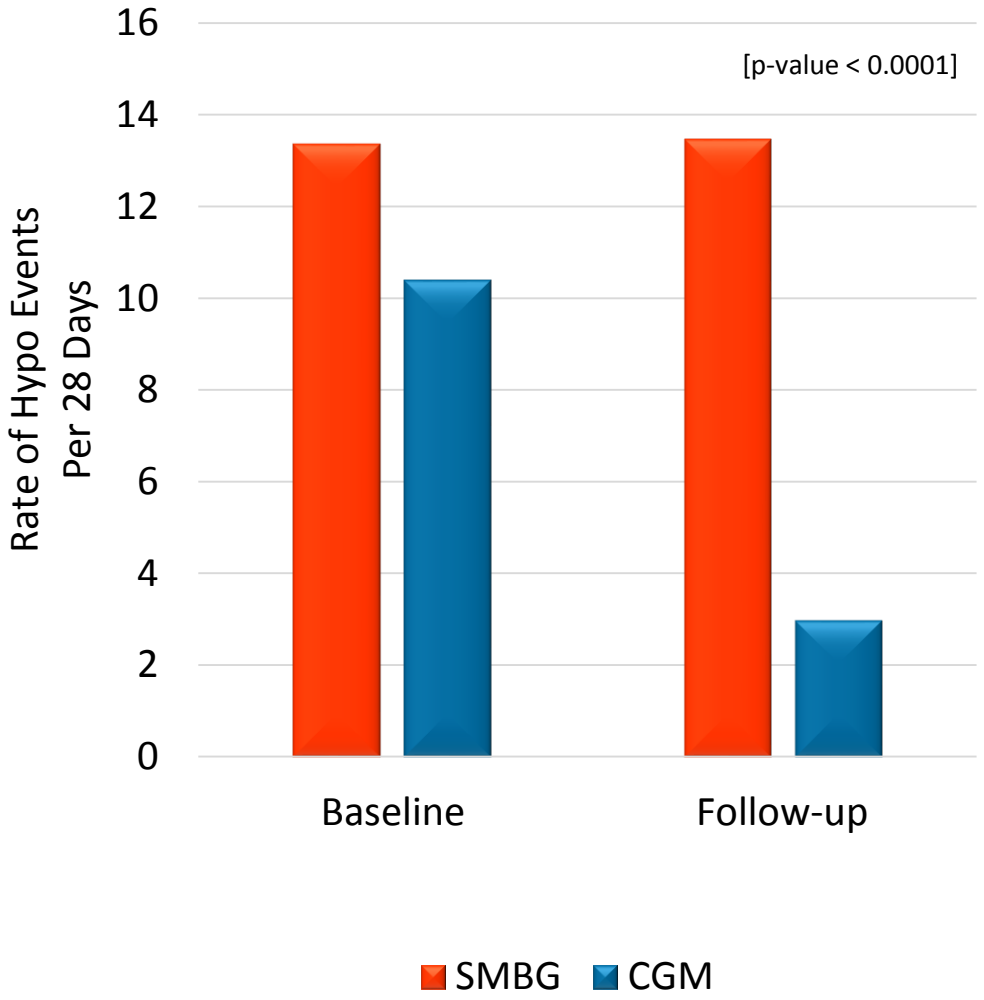
Data are n (%).

[a]Work absenteeism of at least half a day. Patient-reported hospital admissions were validated by clinicians.

Charleer S, et al. *Clin Endocrinol Metab*. 2018;103(3):1224–1232

The Value of rtCGM: Addressing the Costly Complications of Hypoglycemia

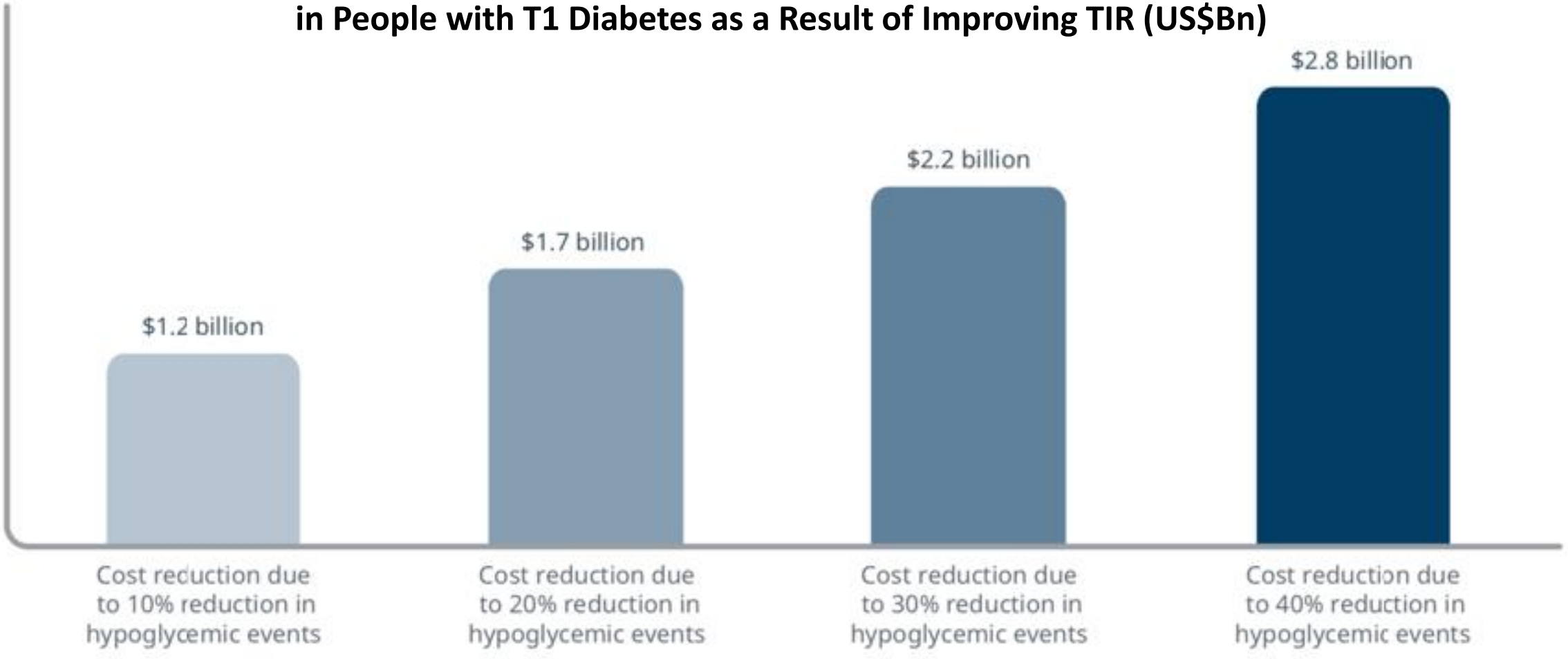
- HypoDE was a 6-month, multicenter, open-label, parallel, randomized controlled trial
- A hypoglycemic event was defined as glucose ≤54 mg/dL for ≥20 min
- Mean number of hypoglycemic events per 28 days among participants in the rtCGM group was reduced from 10.8 to 3.5
- Reductions among control participants 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)



Heinemann L, Freckmann G, Ehrmann D, et al. *Lancet*. 2018;391(10128):1367-1377.

Reducing Hypoglycemic Events via TIR Improvement Can Further Potentiate Cost Savings

Incremental 10-Year Cost Reduction from Lowering the Rate of Hypoglycemic Events in People with T1 Diabetes as a Result of Improving TIR (US$Bn)



IQVIA. Core Diabetes Model, 2019.

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*

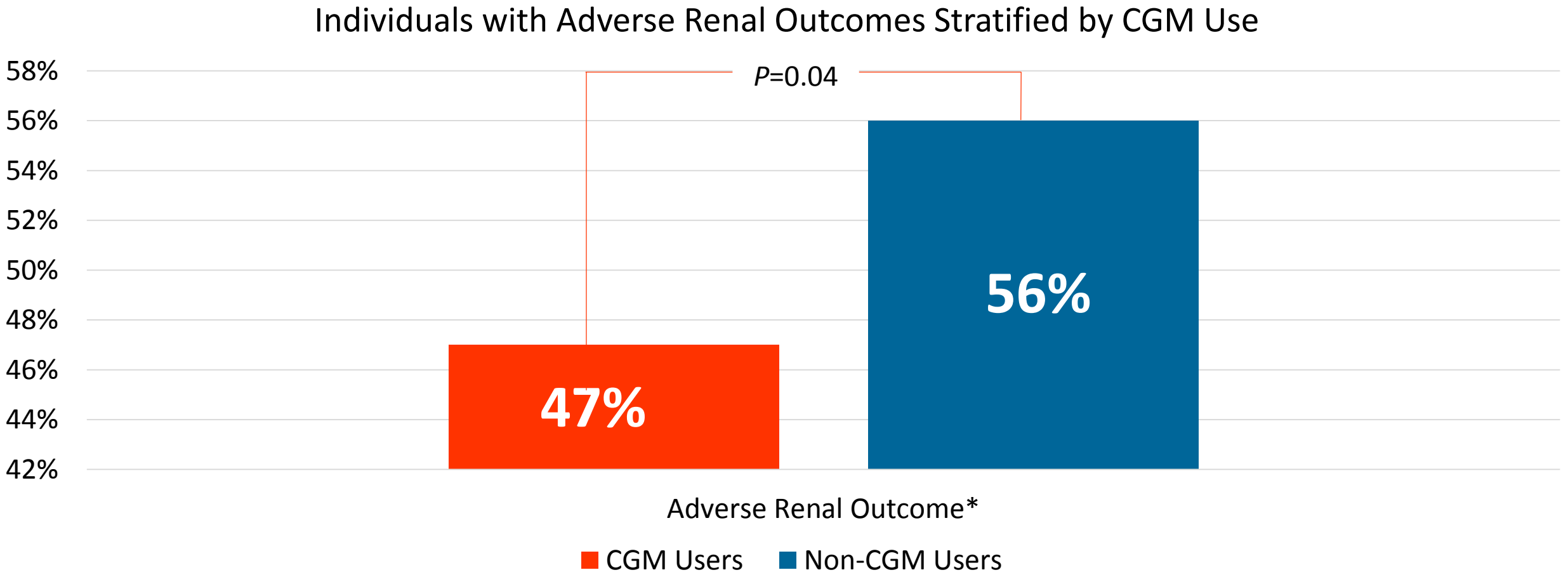
Admission for dysglycemia is a strong predictor for a readmission within 30 days due to dysglycemia [4,5,6] and both NSHE and SH events are associated with a higher risk of CV events, hospitalization and all-cause mortality.[7,8]

- 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.ahrg.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.

In Addition to Clinical Benefits Related to A1C and Hypoglycemia, CGM Appears to Have a Kidney-Protective Benefit in Bivariate Analyses



*Estimated glomerular filtration rate <60 or albuminuria

McGill JB, et al. *J Diabetes Complications*. 2019;33:1-4.

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

Polonsky WH, et al. *Diabetes Care*. 2017;40(6):736-741.

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

Value=Quality/Cost

Improved societal outcomes

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

Living longer and better

- Employment
- Productivity
- Self-worth

Summary

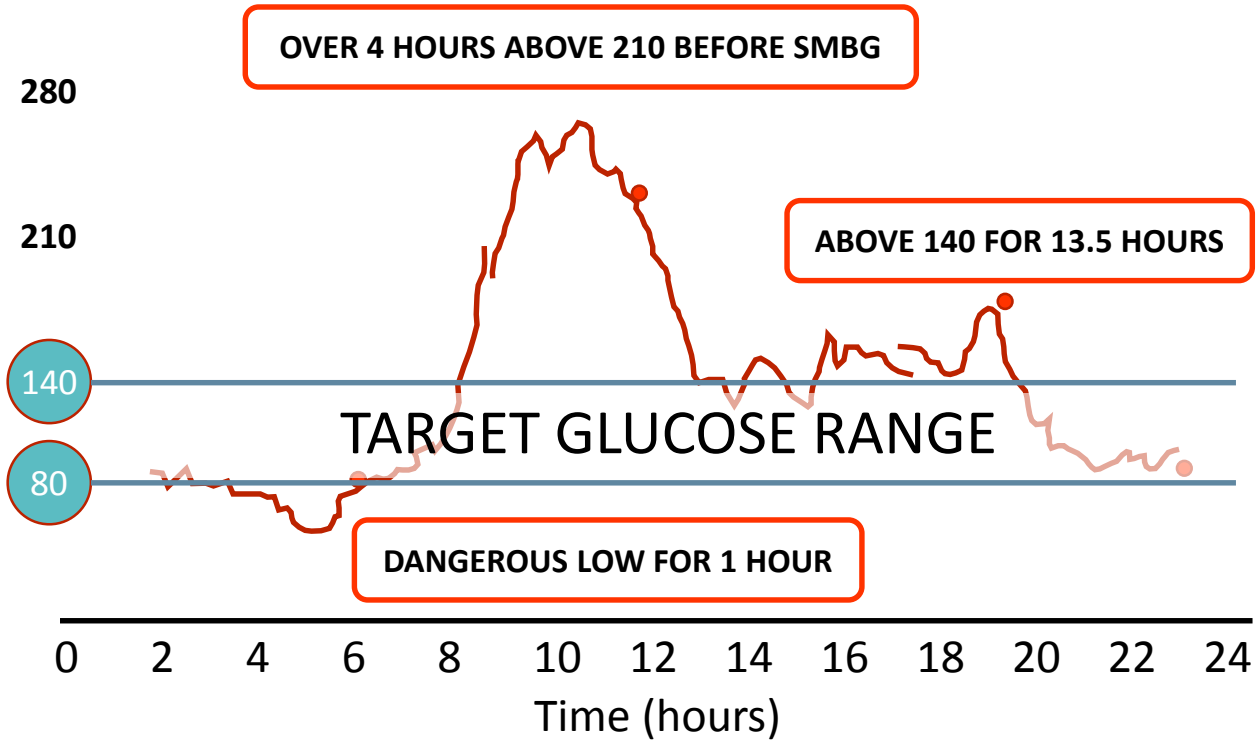
- Diabetes represents a leading driver of health care resource utilization and drug trend for payers
- While tight glycemic control is associated with improved outcomes and reduced costs, hypoglycemia remains a great limiting factor
- HUA is prevalent among a number of diabetes patient demographics and 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 rtCGM, as well as reduced health care resource utilization and associated costs
- Enhanced patient access to rtCGM via the pharmacy benefit has the potential to improve clinical outcomes and reduce adverse health care resource utilization including 30 day hospital readmissions for dysglycemia

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 Glucose Monitoring: 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

Agiostratidou G, Anhalt H, Ball D, et al. *Diabetes Care*. 2017;40(12):1622-1630.

Increased Monitoring Improves Glycemic Control and Time in Range (TIR), Which Can Lead to Reduced Disease-Related Complications

10-year Cumulative Incidence of Developing Diabetes-Related Complications After Improving TIR in PwD with T1 and T2D

TYPE 1 DIABETES

COMPLICATION	58% TIR	70% TIR	80% TIR
Myocardial infarction	3.29	2.65–2.97	2.25–2.70
End-stage renal disease	3.85	3.79–3.81	3.72–3.73
Severe vision loss	9.12	7.99–8.44	7.55–8.00
Amputation	3.96	3.73–3.82	3.57–3.73

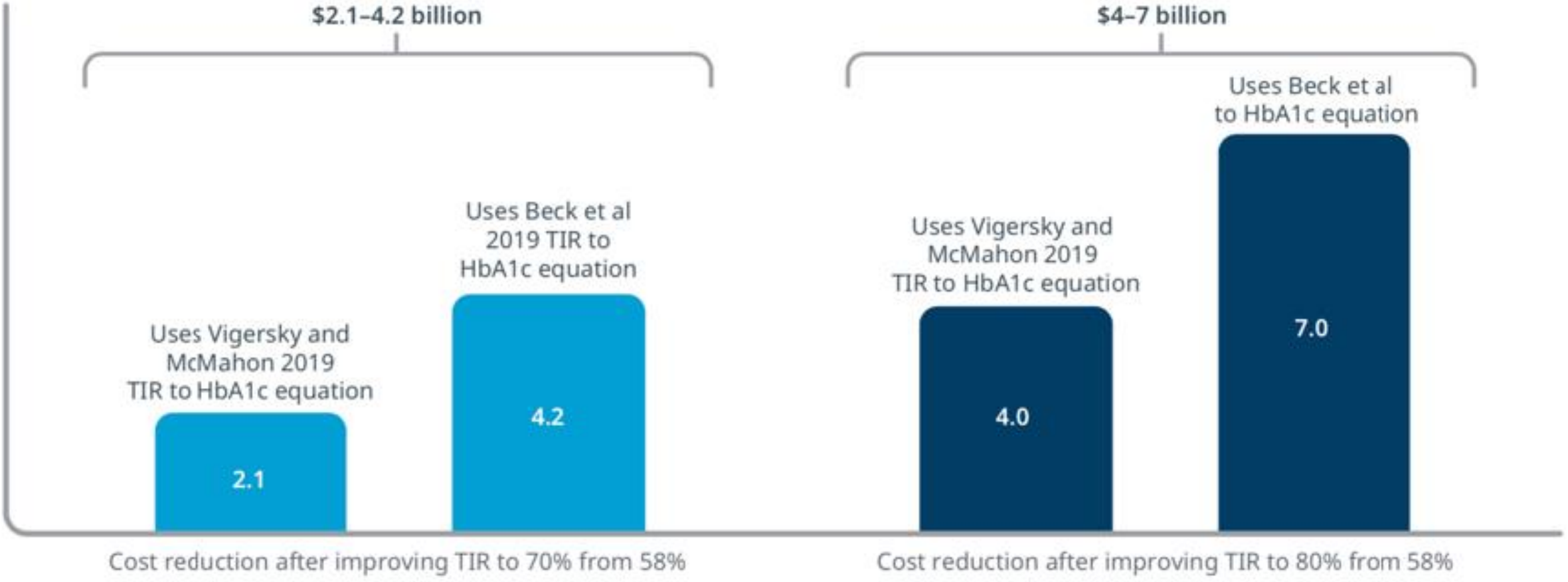
TYPE 2 DIABETES

COMPLICATION	58% TIR	70% TIR	80% TIR
Myocardial infarction	12.76	11.99–12.39	11.37–11.97
End-stage renal disease	2.84	1.94–2.34	1.42–1.98
Severe vision loss	5.18	4.78–4.98	4.56–4.83
Amputation	1.00	0.97	0.95–0.96

IQVIA. Core Diabetes Model, 2019.

The Value of rtCGM: Potential Cost Savings with Improvements in TIR

10-Year Cost Reduction by Improving TIR in People with T1 and T2 Diabetes to 70% and 80% TIR (US$Bn)



IQVIA. Core Diabetes Model, 2019.

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

American Diabetes Association Standards of Medical Care in Diabetes —2019. *Diabetes Care*. 2019;42(Suppl 1).

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

FDA

ATTD Advanced Technologies & Treatments for Diabetes

CMS Centers for Medicare & Medicaid Services

ISPAD International Society for Pediatric and Adolescent Diabetes

AACE American Association of Clinical Endocrinologists

AADE American Association of Diabetes Educators

Endocrine Society

ADA

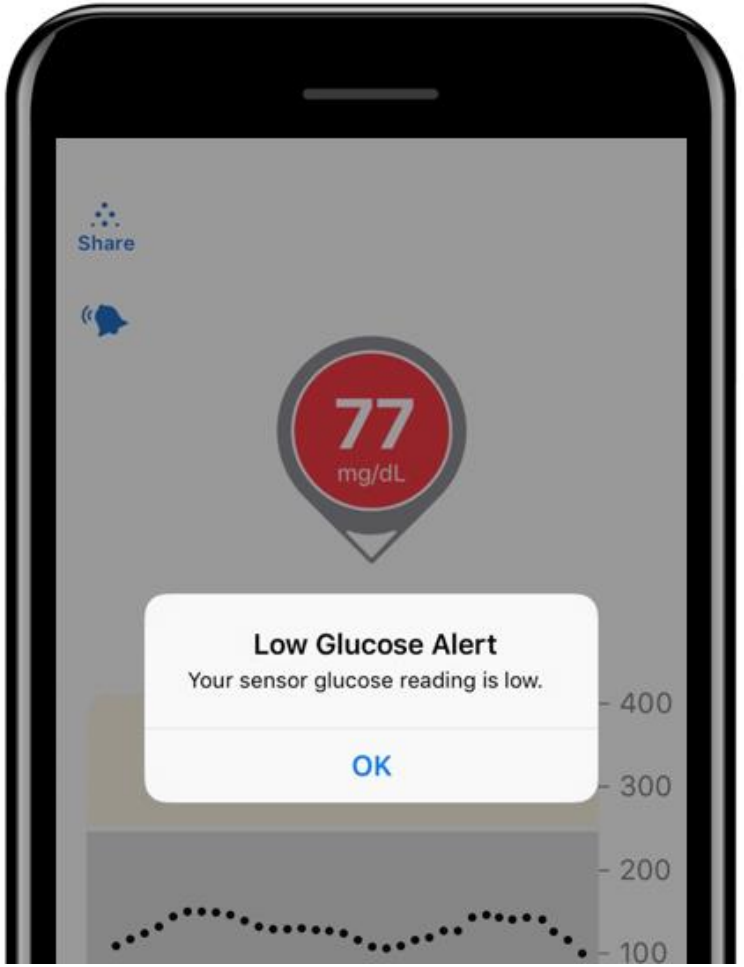
Take Away Message

- *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

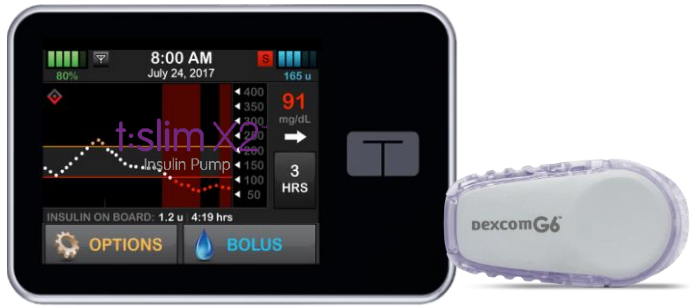
Opportunities With CGM

- 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)



Therapeutic CGM Product Comparison

Product Attributes and Performance	G6® CGM System (Dexcom)[1]	FreeStyle® Libre Flash Glucose Monitoring System (Abbott)[2]
CGM classification	Real-Time CGM	Intermittent Scan CGM
Continuous data availability	Data available without user intervention	Data available only with user intervention (i.e. user must scan sensor)
Sensor Wear	10 days	14 days
Age indication (years)	2+	18+
Factory-calibrated	Yes	Yes
Confirmatory fingerstick required per labeled indications:		
• When experiencing symptoms that do not match sensor glucose readings	No	Yes
• When experiencing symptoms that may be due to low or high blood glucose	No	Yes
• During times of rapidly changing glucose (i.e., trend arrows↑↓)	No	Yes
• To confirm hypoglycemia or impending hypoglycemia as reported by the sensor	No	Yes
• Anytime the check BG icon appears	N/A	Yes
• During first 12 hours of sensor wear	No	Yes
Ease of use/sensor insertion	No assembly required; 4 steps	No assembly required; 3 steps

Therapeutic CGM Product Comparison (cont.)

Product Attributes and Performance	G6® CGM System (Dexcom)[1]	FreeStyle® Libre Flash Glucose Monitoring System (Abbott)[2][2]
Protective Safeguards (alerts/alarms):		
• Provides updates without user interaction (i.e. during sleep)	Yes	No
• Real-time, customizable glucose alerts (low/high)	Yes	No
• Predictive hypoglycemia alert	Yes	No
• Rapidly rising/falling rate of change alerts	Yes	No
• Urgent low glucose safety alarm	Yes	No
FDA warning for use in hypoglycemia unawareness patients	No	Yes
Real-time data sharing	Yes	Limited[3]
Hypoglycemia accuracy (Concurrence of sensor readings with YSI-measured values in the critically low range 40-60 mg/dL)	63%	25%
ADA Standards of Care Recommendations & Level of Clinical Evidence[5] • A = Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered • B = Supportive evidence from well-conducted cohort studies • C = Supportive evidence from poorly controlled or uncontrolled studies	Real-time CGM is a useful tool to lower AIC in adults with TID who are not meeting glycemic targets **(A)**	Intermittent Scan CGM should be used only as a substitute for SMBG in adults that require frequent glucose testing **(C)**
	Real-time CGM may be a useful tool in those with hypo unawareness and/or frequent hypoglycemic episodes **(B)**	
	Real-time CGM should be considered in children & adolescents with TID to improve glucose control and reduce the risk of hypoglycemia **(B)**	
	Real-time CGM may be used to improve AIC levels and neonatal outcomes in pregnant women with TID **(B)**	

References: [1]Dexcom G6 CGM System User Guide 2018; [2]Abbott FreeStyle Libre 14 day System User Guide 2018; Summary of Safety and Effectiveness Data (SSED), Abbott FreeStyle Libre, July 2018; [3]Sharing function is not real-time (glucose information can only be viewed by the follower after the user scans their sensor with their smart device) https://www.librelinkup.com/; [4]Approach to Using Trend Arrows in the FreeStyle Libre Flash Glucose Monitoring Systems in Adults. Endocrine Society 2018; [5]ADA Standards of Medical Care in Diabetes- 2019. [6]FDA authorizes first Class II Interoperable CGM system. [7]Class III PMA Approval for Abbott Freestyle Libre Flash Glucose Monitoring System

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

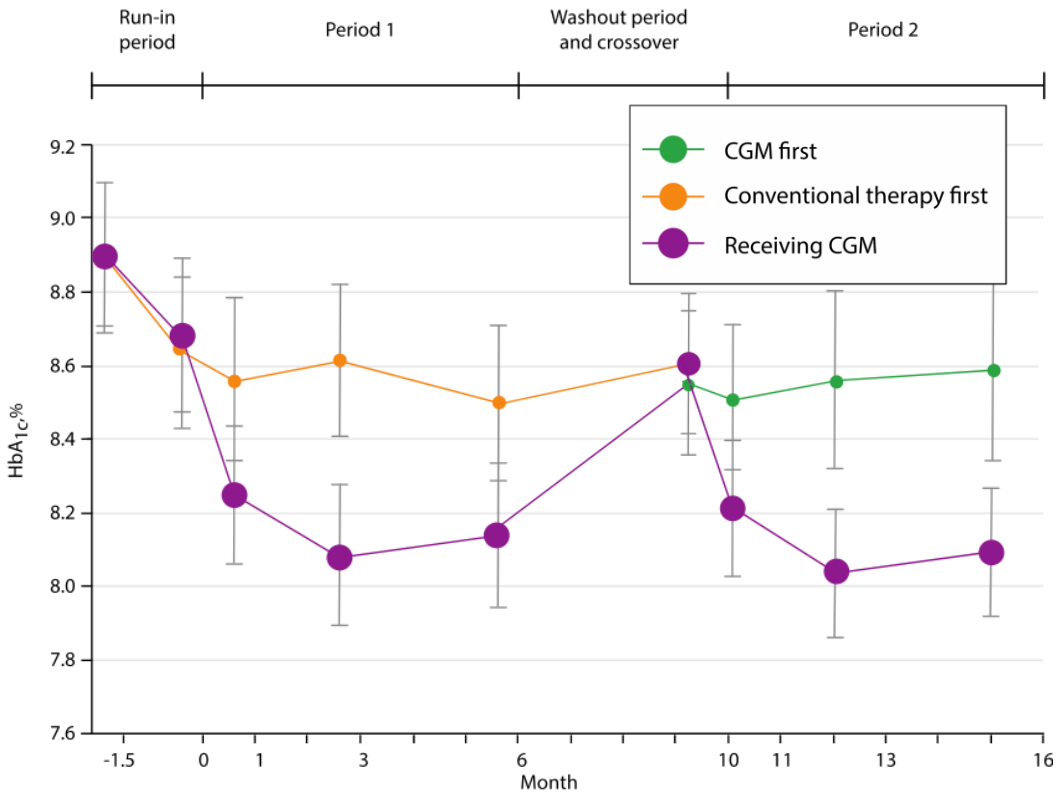
DEXCOM G5	Significant between Groups Difference in favor of Intervention Group?			
Patient population	↓ A1C?	↓ Hypo?	↓ Hyper?	↑ TIR?
Adult T1D on MDI [1]	Yes	Yes	Yes	Yes
Adult T1D on MDI[2]	Yes	Yes[c]	Yes[a]	Yes[a]
Adult T1D Pump cohort[3]	No	No	Yes	Yes
Adult T2D on MDI[4]	Yes	N.A.[b]	Yes	Yes
Older Adult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

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.
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.

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

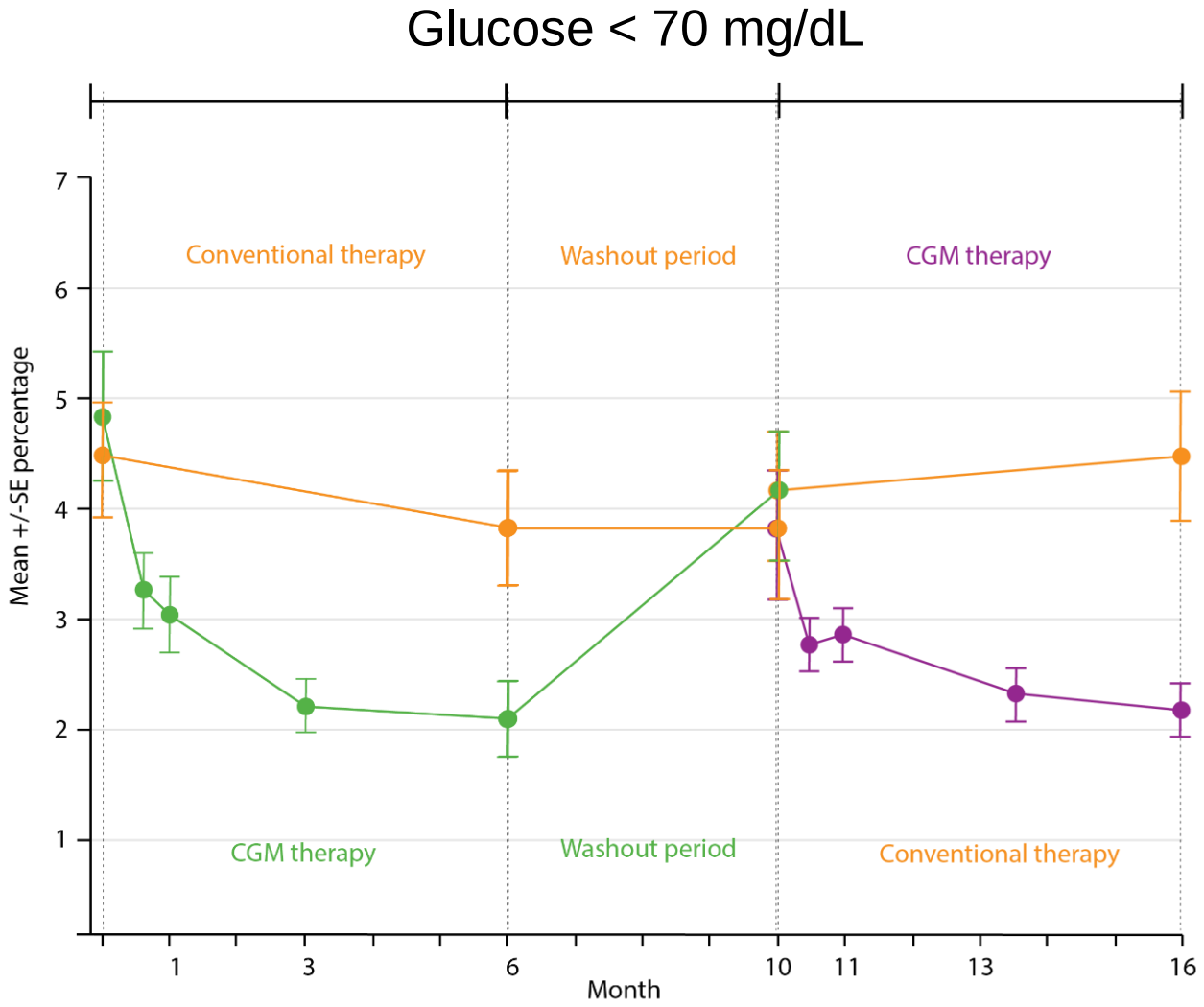


2017 GOLD Study Results:

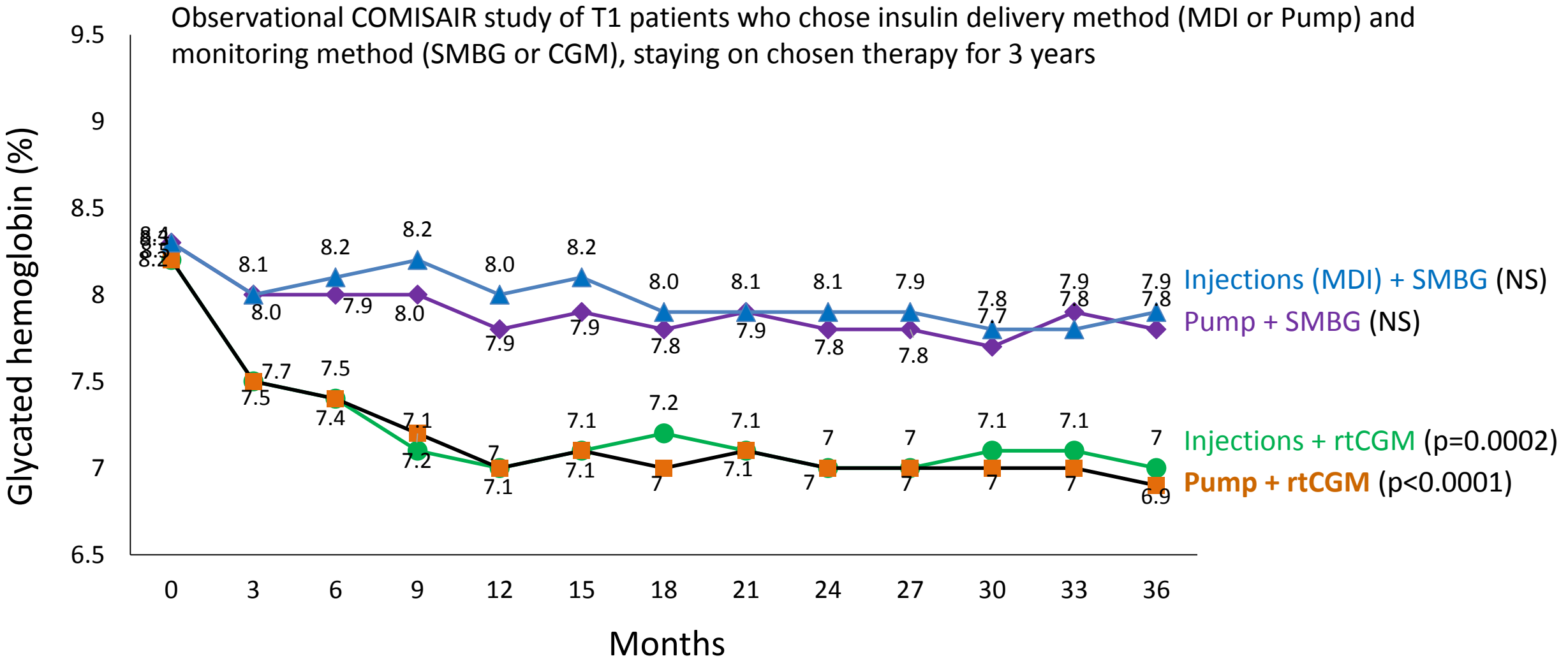
- A1C - 0.8% reduction
- Hypoglycemia reduction
- Alerts/alarms set & necessary
- Finger-sticks didn't work
  - Regardless of diabetes education, similar study visits, and previous CGM use
  - SMBG had 12 SH events throughout course of the study vs 1 with CGM
- Included only patients on MDI
  - CGM as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

Lind M, Polonsky W, Hirsch IB, et al. *JAMA*. 2017;317(4):379-387.

GOLD Study Demonstrates Considerable Reduction in Time Spent Hypoglycemic with Continuous Use of CGM



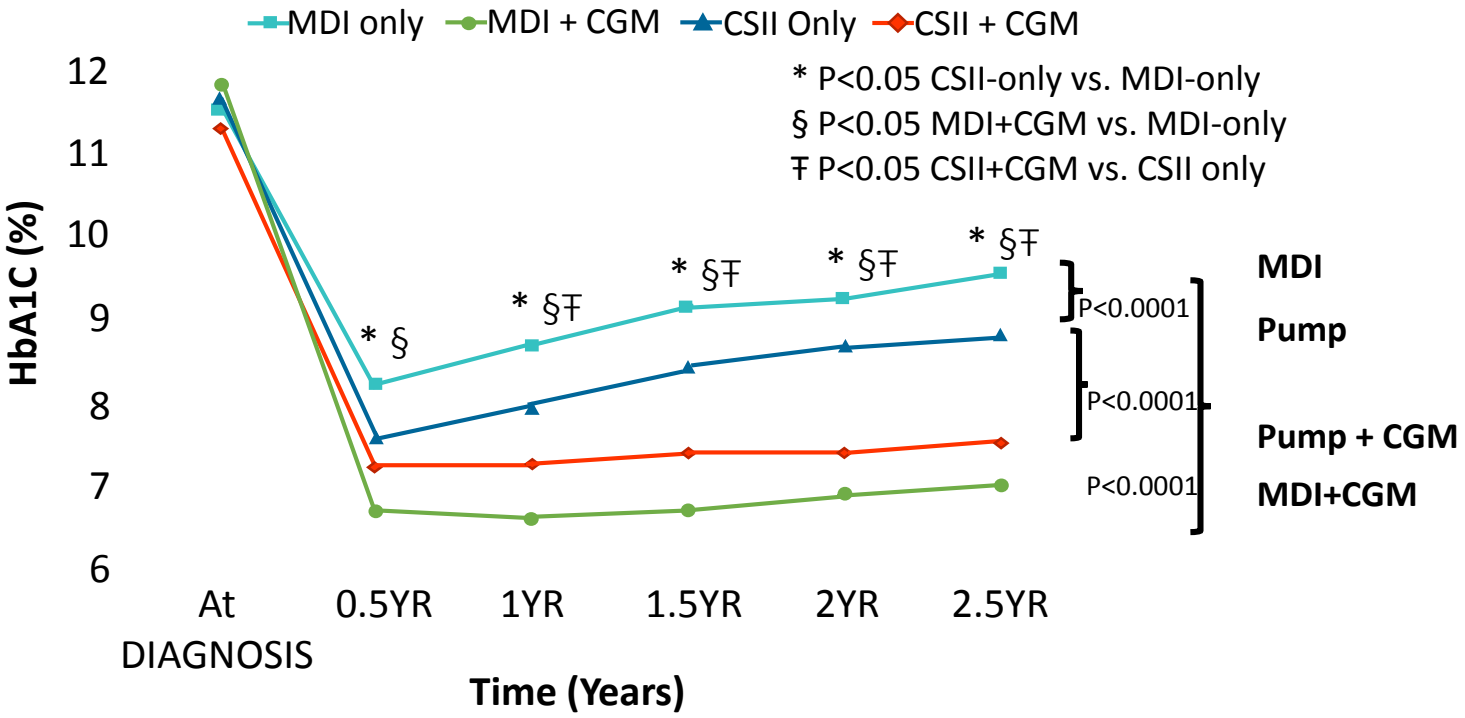
A1C Decreases With CGM Regardless of Insulin Delivery Method



Šoupal J, et al. *Diabetes Care*. ePub ahead of print; September 17, 2019.

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

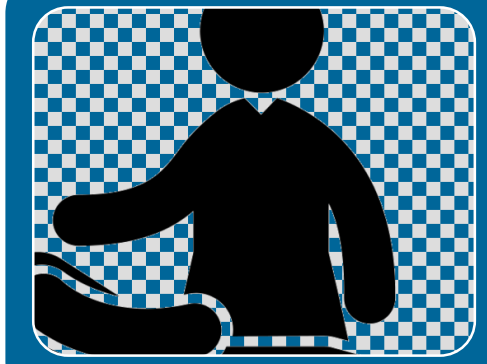
A1C

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

Mulinacci G, Alonso GT, Snell-bergeon JK, Shah VN. *Diabetes Technol Ther*. 2019;21(1):6-10.

Pharmacy Benefit Coverage for Therapeutic CGM Benefits Both Providers and Patients



Providers

- Increased ease of prescribing
- Reduced administrative burden

Patients

- Potentially lower out-of-pocket costs, particularly impactful for low-resource patients (e.g., Illinois Medicaid experience)
- Timely access to product through pharmacy coverage

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

Medication Therapy Management. American Pharmacists Association website: **https://www.pharmacist.com/sites/default/files/files/mtm_APhA-APPMMTMPayerPresentation.pdf.** Accessed October 2019.

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
- Insurance coverage of CGM under the pharmacy benefit allows for improved patient access, reduced administrative costs for payers and providers, and integrates the pharmacist as an allied health care provider

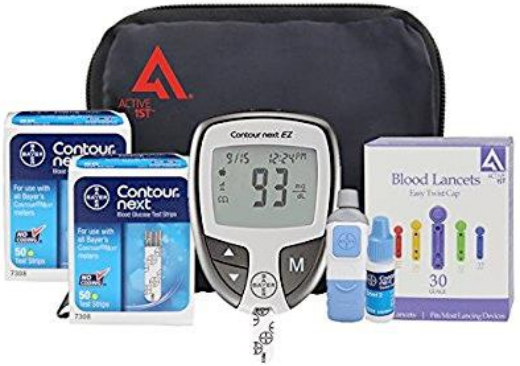
Pharmacy Benefit Management Strategies to Enhance Outcomes through Appropriate Coverage of CGM and Other Technology Interventions

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

As Glucose Monitoring 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

“A Tale of Two Benefits”

Medical

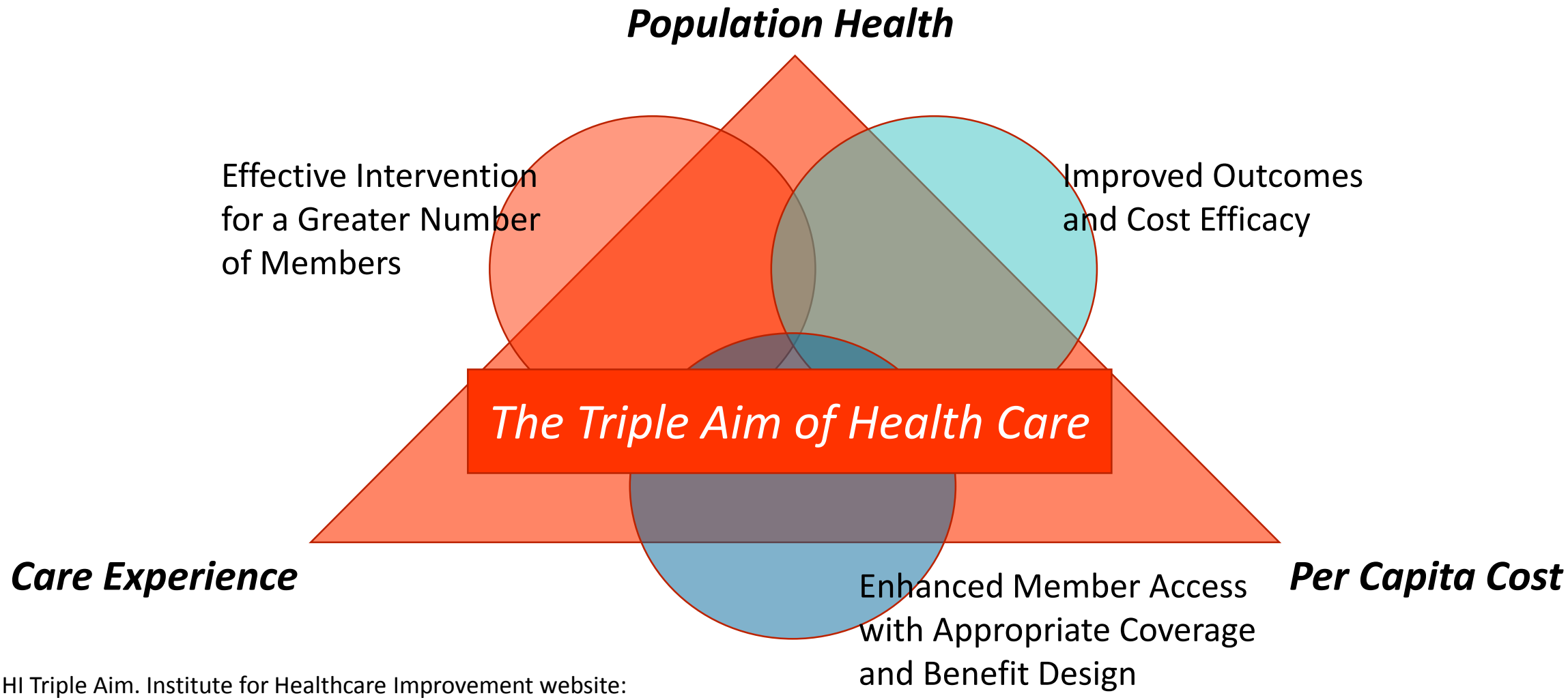
- More effort required to manage utilization due to retroactive claims payment
- Decreased access and member convenience with potential delays at the point-of-service
- Fewer opportunities for patient contacts with trained HCPs
- Inefficiencies and potential confusion resulting from standard A-code billing

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 vs. medical benefit. American Pharmacists Association website: https://www.pharmacist.com/pharmacy-vs-medical-benefit. Published October 1, 2015. Accessed October 2019.

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



The IHI Triple Aim. Institute for Healthcare Improvement website: http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx . Accessed October 2019

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

Harris MI, et al. *Diabetes Care*. 1993 Aug;16(8):1116-23.
American Diabetes Association Standards of Medical Care in Diabetes —2019. *Diabetes Care*. 2019;42(Suppl 1).

Current Benefit Design Schema May Create a Barrier to CGM Access and Uptake

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 22, Number 3, 2020

DOI: 10.1089/dia.2019.0303

DTT

COMMENTARY

Current Eligibility Requirements for Continuous Glucose Monitoring Coverage Are Harmful, Costly, and Unjustified

John E. Anderson, MD,[1] James R. Gavin, III, MD, PhD,[2] and Davida F. Kruger, MSN, APNBC, BCADM[3]

"There is growing and compelling evidence that CGM coverage should be offered to all patients who can benefit from this technology regardless of diabetes type and history of SMBG use."

"The current restrictions, which are based on outdated evidence and questionable assessments, are not supported in the literature."

"[Current restrictions on coverage] ignore the burden frequent SMBG places on individuals."

"Given the growing prevalence of diabetes, the persistent preponderance of individuals with suboptimal glycemic control, and the exorbitant and largely preventable cost of diabetes complications, opinion-based constraints should not continue to supplant evidence-based clinical management."

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

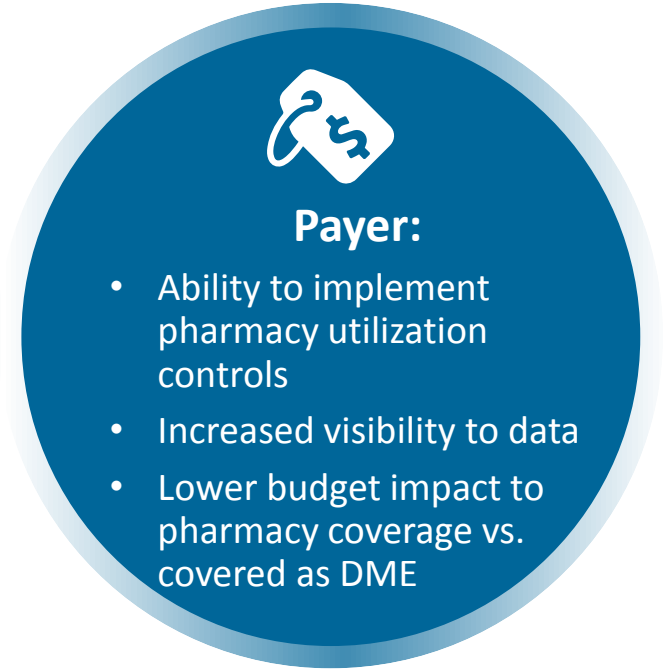
Traditional

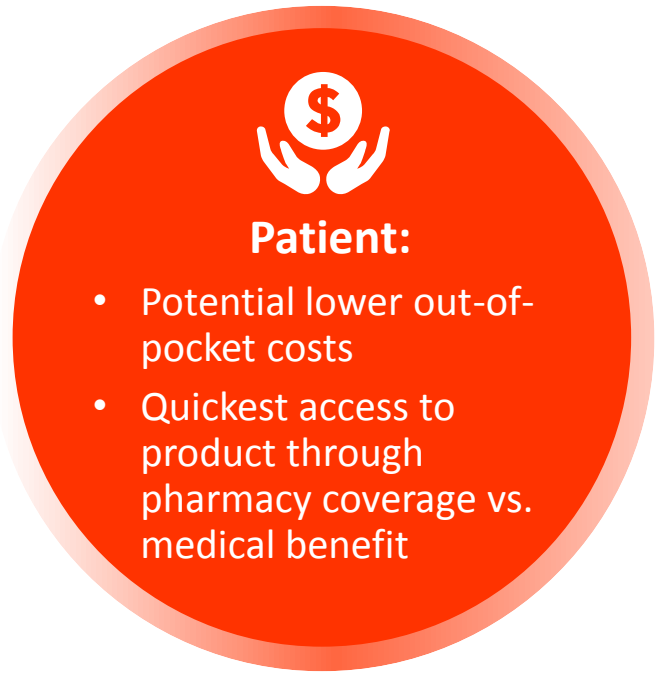
- DME typically covered under the medical benefit
- Supplies such as test strips often covered under the pharmacy benefit

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

Pharmacy Access Benefits All Stakeholders





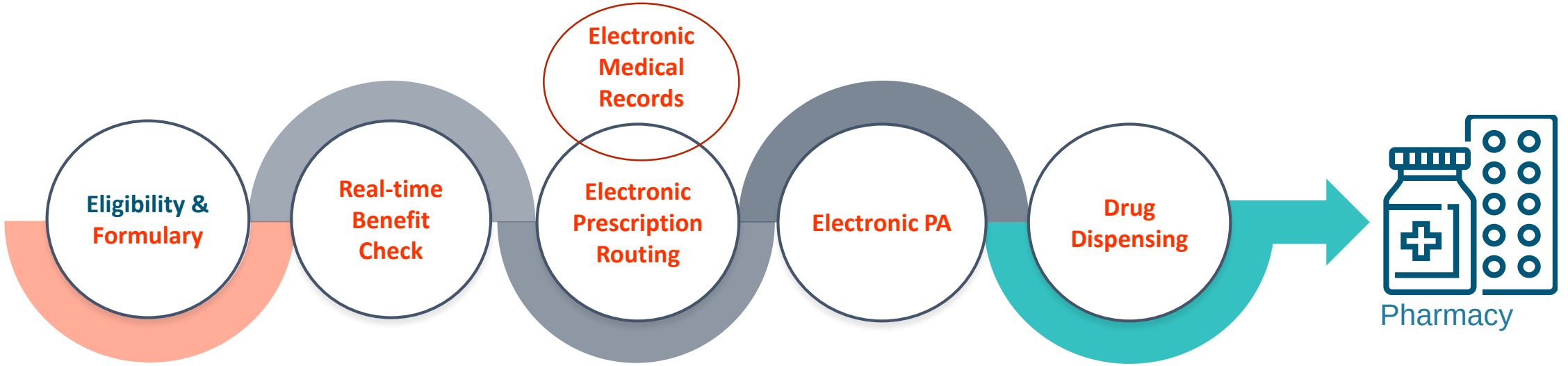
Providing convenient and cost-effective access through the pharmacy channel will lead to quicker access to the product.

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

Mehrabian N. Reinventing Utilization Management (UM) to Bring Value to the Point of Care. *Healthcare IT News*. https://www.healthcareitnews.com/news/reinventing-utilization-management-um-bring-value-point-care. Published September 18, 2017.

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)

1. Manufacturer receives patient info and Rx
2. Manufacturer identifies payer to determine channel
3. Manufacturer processes order (if in-network) or transfers to distribution partner
4. Manufacturer or distributor conducts benefits check with insurance company
5. Manufacturer or distributor collects necessary information
6. Prior authorization to health plan (if required)
7. Manufacturer or distributor collects out-of-pocket cost and ships product
8. Claims generated and submitted to insurance

Pharmacy Channel (1-2 Days)

1. HCP gives Rx to patient or pharmacy
2. Patient goes to pharmacy, which determines out-of-pocket cost
3. Patient pays out-of-pocket cost
4. Pharmacy distributes product immediately or orders it

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

As a result of CMS ruling inferring causality from correlation of available data…

Nearly 60% 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.

Community Pharmacy Chains are Streamlining Medicare Part B Pharmacy Access for CGM Interventions

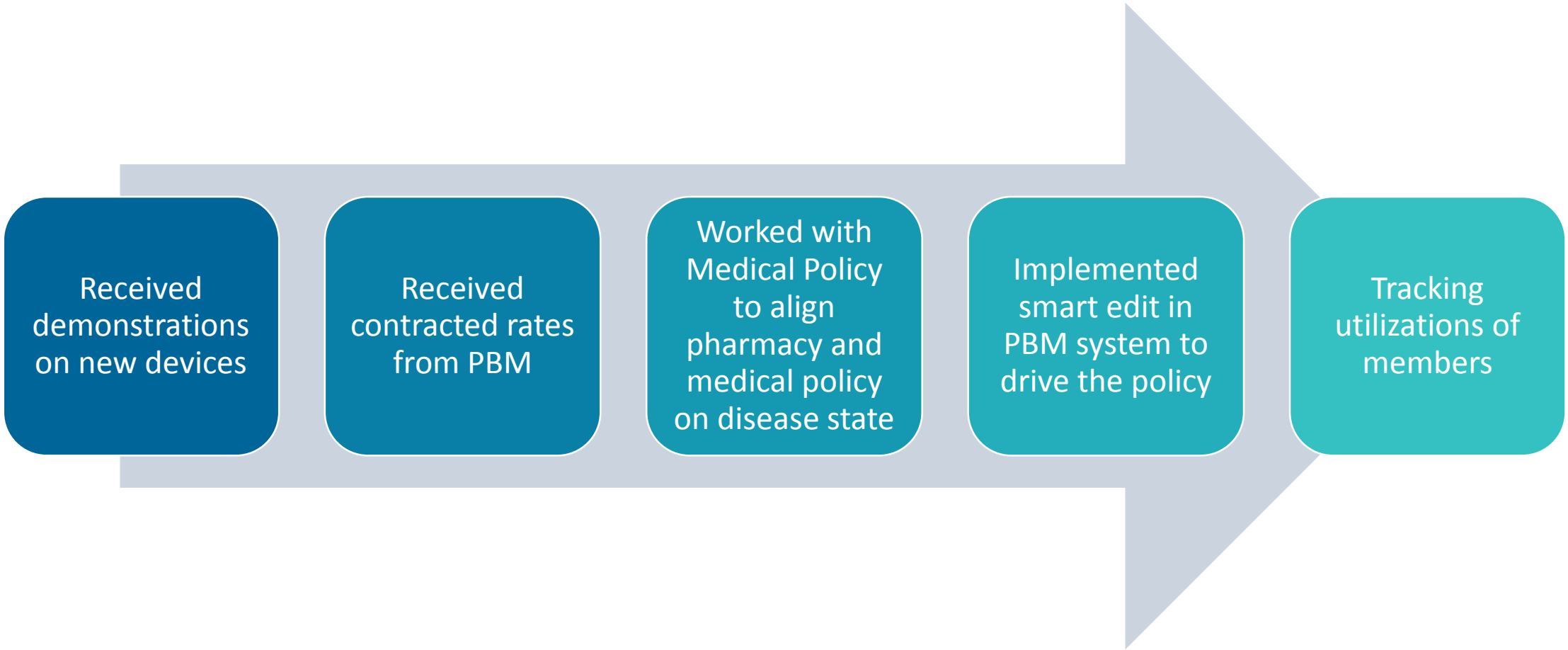
Previously, prescriptions for CGM devices covered by Medicare Part B could only be filled through DME manufacturers or limited pharmacies, leading to additional costs and delays

Walgreens‘ Find Care platform has been updated to include several manufacturers' connected medical devices and digital solutions for patients with chronic conditions

This new billing solution allows Medicare patients using rtCGM devices to fill their prescription at any of the 9,200 Walgreens pharmacies across the country

Salazar D. *Drug Store News*. November 4, 2019. https://drugstorenews.com/walgreens-debuts-medicare-billing-solution-enable-cgm-access.

Health Plan Experience: Moving CGM to the Pharmacy Benefit



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

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

Jointly provided by

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MEDICAL EDUCATION RESOURCES

This activity is supported by an independent educational grant from Dexcom.