



*Interim Study*

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**Omnipod Coverage for Medicaid**

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*Senator Carri Hicks*

# Goal

*To provide data-driven insights and policy recommendations to inform the potential integration of Omnipod devices into Medicaid coverage plans.*

## Speakers

### Amber Clour

Lives with Type 1  
Founder of Diabetes  
Daily Grind Podcast

### Christina Foss

Oklahoma Health  
Care Authority  
Chief of Staff

### Ryan Bucalo

Insulet  
Director of National  
Accounts-Medicaid  
Markets

### Trish Winters

Breakthrough T1D  
Market Director

# From Lived Experience: Diabetes Definitions

- + **CGM (Continuous Glucose Monitor)** - Device used for monitoring blood glucose on a continual basis instead of monitoring periodically by drawing a drop of blood from a finger.
- + **A1C** - Blood test that measures a person's average blood glucose over the past three months also known as a glycosylated hemoglobin test (hbA1c).
- + **MDI - Multiple Daily Injections**
- + **TIR (Time In Range)** - Amount of time a person living with diabetes blood sugar is within the recommended range (70 and 180 mg/dL).
- + **Bolus** - Fast Acting Insulin
- + **Basal** - Long Acting Insulin



**Amber Clour**  
Has lived with type 1  
for 40 years  
Patient advocate

# Insulin Pump Therapy Options

*Amber Clour*



**Medtronic  
(tubed)**



**Tandem  
(tubed)**



**Omnipod  
(tubeless)**

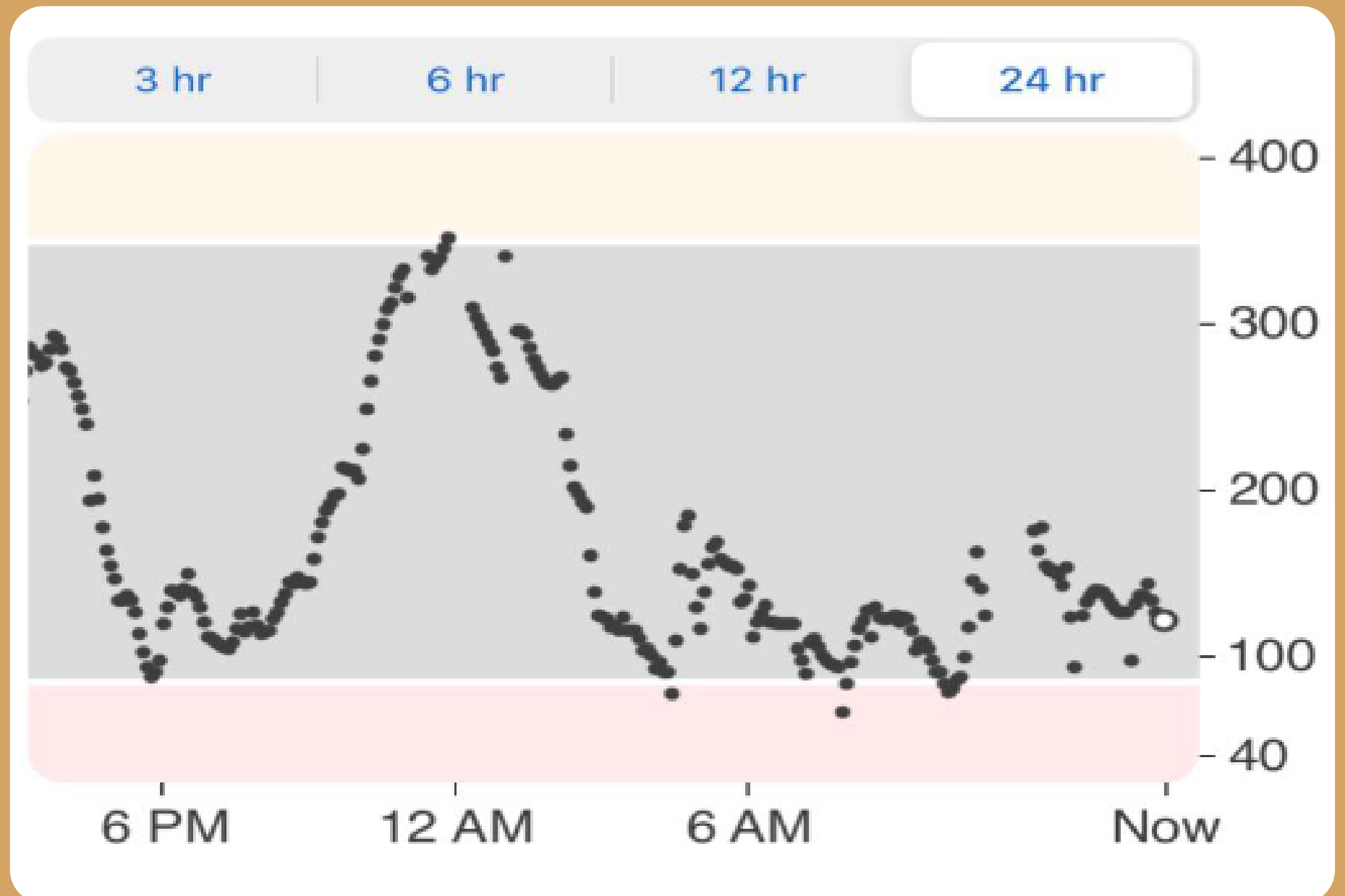
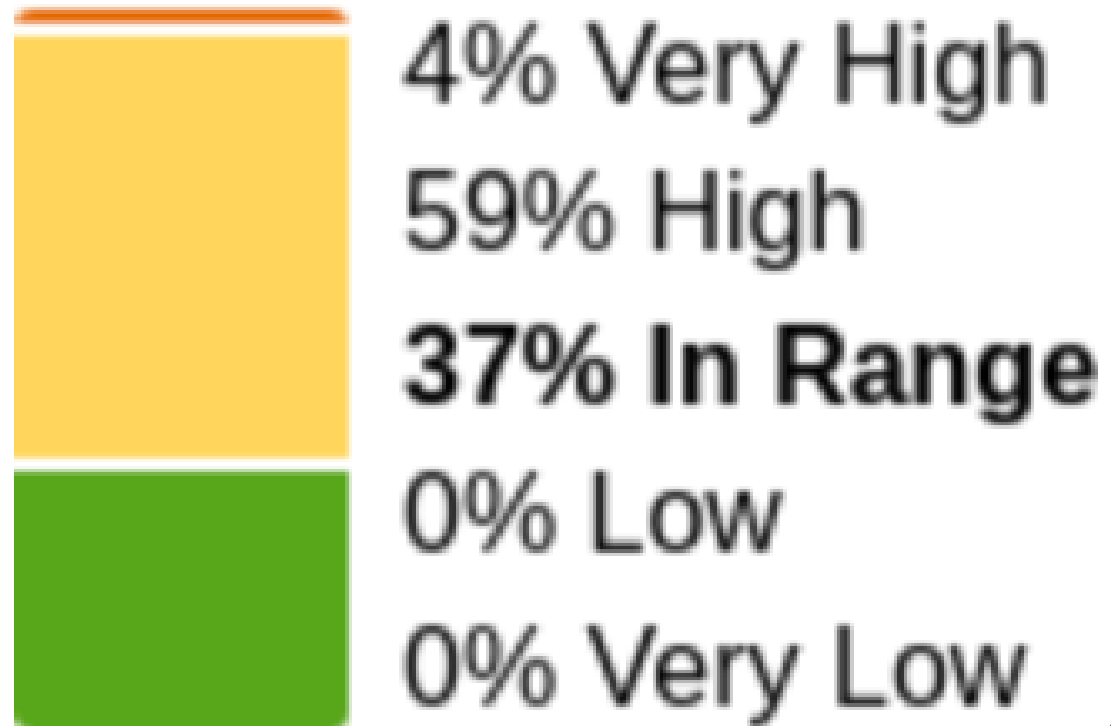
# Time in Range - Multiple Daily Injections

Amber Clour

4-8 shots per day

A1c = 6.1

## Time in Range



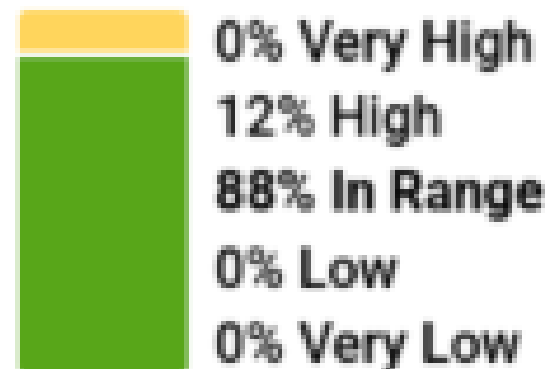
# Time in Range - Omnipod

Amber Clour

## Dexcom Clarity Weekly Summary

Sun Sep 1, 2024 - Sat Sep 7, 2024

### Time in Range



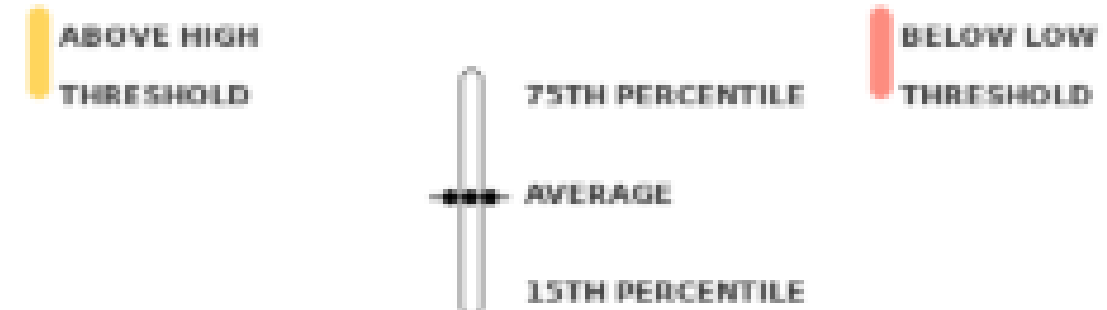
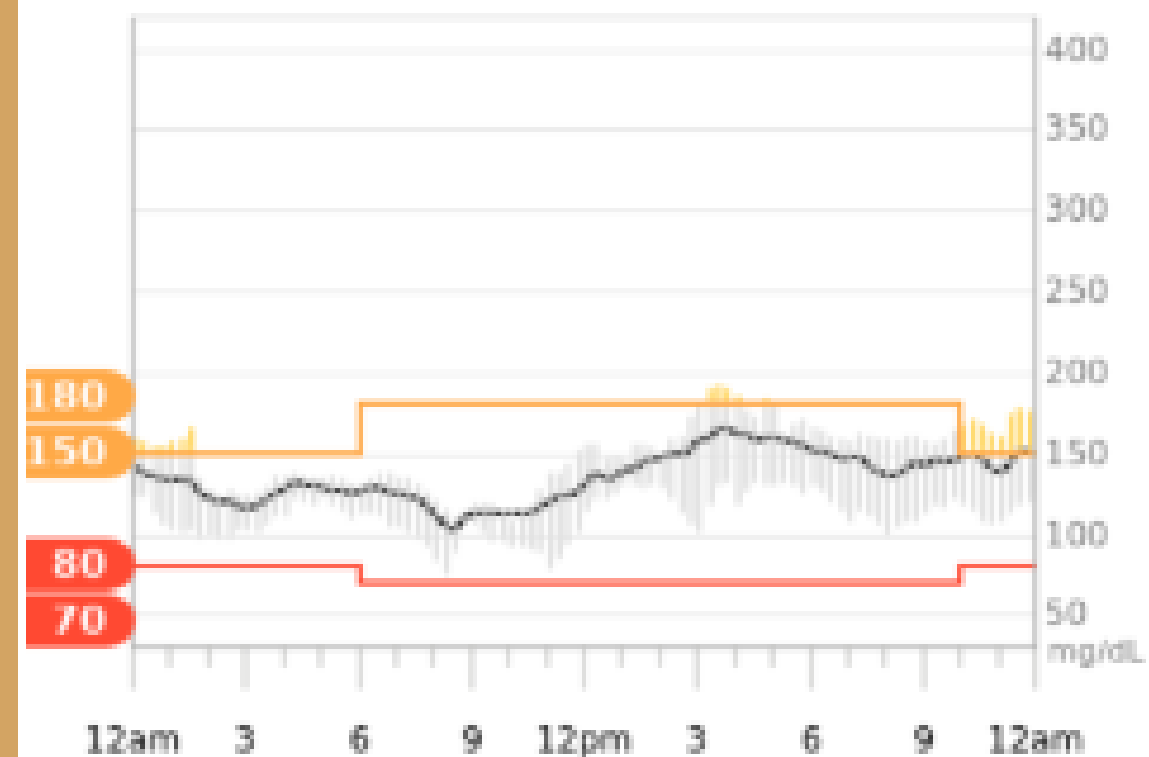
Increase since last week: +8%

#### Target Range:

Day (6:00 AM - 10:00 PM): 70-180 mg/dL

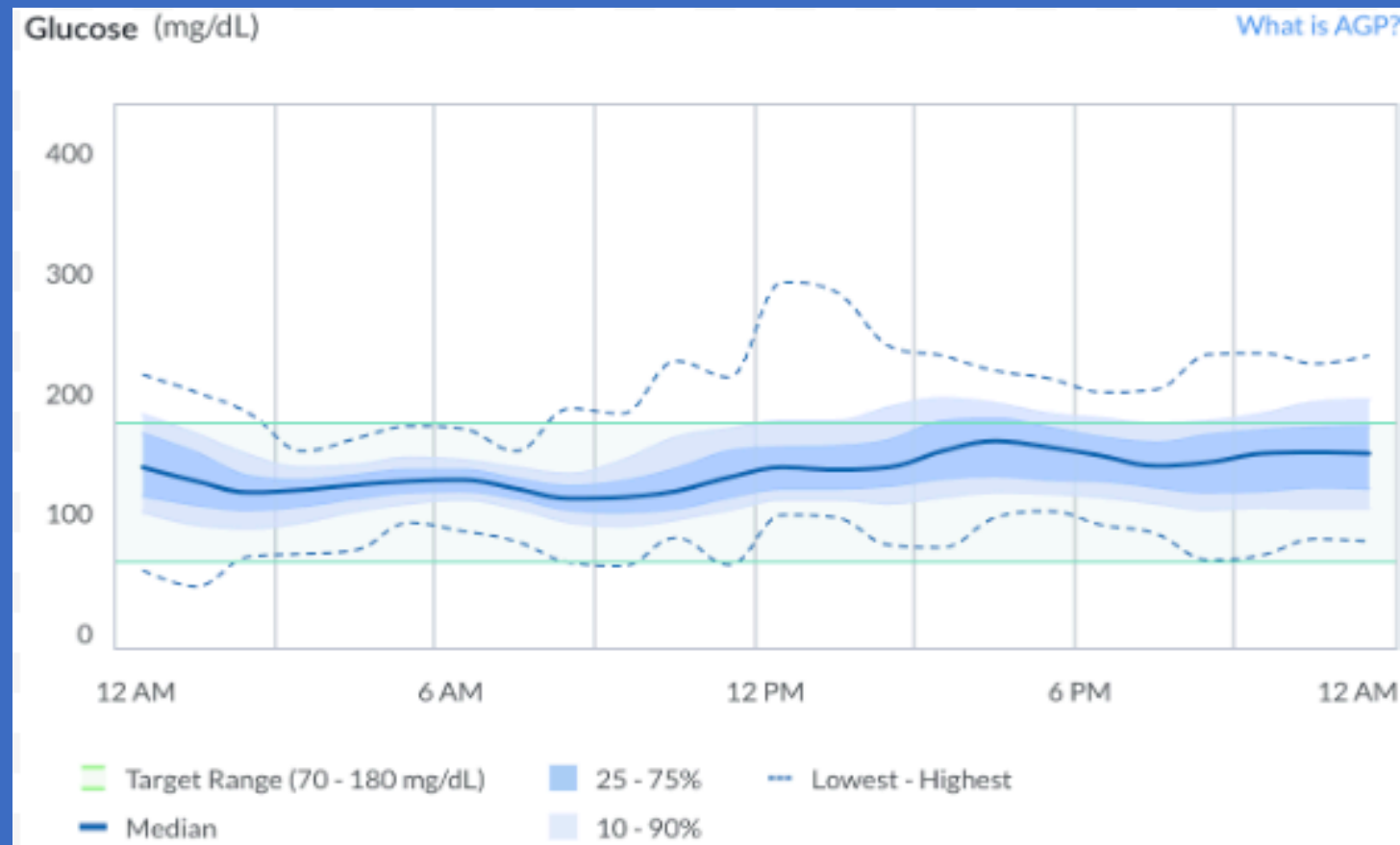
Night (10:00 PM - 6:00 AM): 80-150 mg/dL

### Trends



# Data from Glooko

Amber Clour



## Trends

Comparisons  
Jul 18 - Aug 16 vs  
Aug 17 - Sep 15

Highs Lows In Range **Average**

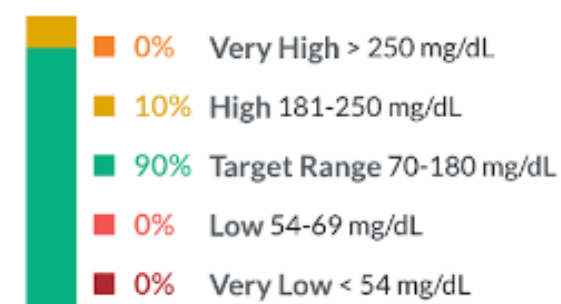


**Your Average**  
Average glucose steady (141 mg/dL vs 148 mg/dL)

glooko



## Glucose (CGM)

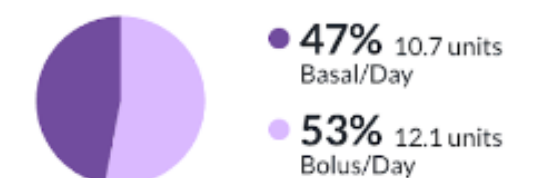


% Time CGM Active 94.7% (28.4 days)

GMI <sup>?</sup>	6.7% (49.6 mmol/mol)
Average	141 mg/dL
SD	29 mg/dL
CV	20.7%
Median	136 mg/dL
Highest	292 mg/dL
Lowest	49 mg/dL

## Insulin - Device <sup>?</sup>

From Insulin Pump



Insulin/Day	22.7 units
Overrides (%)	0% (0 boluses)
# Bolus/Day	3.2

# August 2022 OHCA Hearing



**Jill Geiger - T1D Mom**  
**Amber Clour - T1D (40 years)**

**Trish Winters - T1D Mom of Two**  
**Mark Carter - Person living with T1D**  
**Senator Carri Hicks - T1D Mom**



# Testimony from the OHCA

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+ Current diabetes coverage & efforts

+ Omnipod



**Christina Foss**  
**Oklahoma Health**  
**Care Authority**  
**Chief of Staff**

# Insulet, the maker of Omnipod

- + Insulet is an innovative medical device company improving the lives of people with diabetes and other conditions through its Omnipod delivery system
- + Insulet's corporate headquarters is located in Acton Massachusetts



**Ryan Bucalo**  
Insulet



# A Market Leader in Insulin Delivery



425K

Global Customers

*Insulet*



25

Countries Offering Omnipod

## *Growth*

#1 in 2023 US New Customers Starts



Omnipod 5 Global Expansion (UK, France, Germany, and The Netherlands)

## *Innovation*

FDA Clearance of Omnipod 5 App for iPhone and Type 2 Label Expansion



Launch of Omnipod 5 with Dexcom G7 sensor compatibility



EVOLUTION Next-Gen Algorithm Feasibility Study

## *Evidence*

13 Peer-Reviewed publications across portfolio since 2023



Extension Study Data



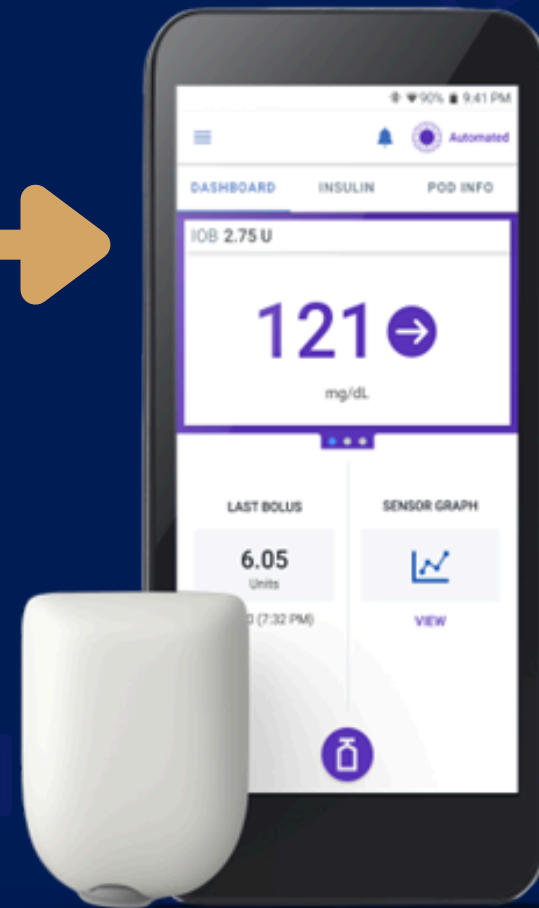
Real-World evidence (cloud data)

# Omnipod 5 - the first & only FDA - cleared tubless AID system

*Intended for the management of Type 1 Diabetes Mellitus in persons 2 years of age and older and Type 2 Diabetes Mellitus in persons 18 years or older*

Pod + Algorithm

Omnipod 5 App



Tubeless, waterproof\* Pod communicates directly with Dexcom G6 and Dexcom G7

Safe to use with U-100 rapid acting insulins:  
**Humalog, NovoLog, Admelog**

200-unit Pod reservoir capacity

Automatic priming and automatic cannula insertion

+ Personalized, adaptive treatment with SmartAdjust technology (algorithm) built into the Pod

+ Omnipod 5 App allows users to control the system from a compatible smartphone

+ Dexcom App on a user's smartphone is required for automated insulin delivery

+ English and Spanish availability

Dexcom G6 and G7 CGM

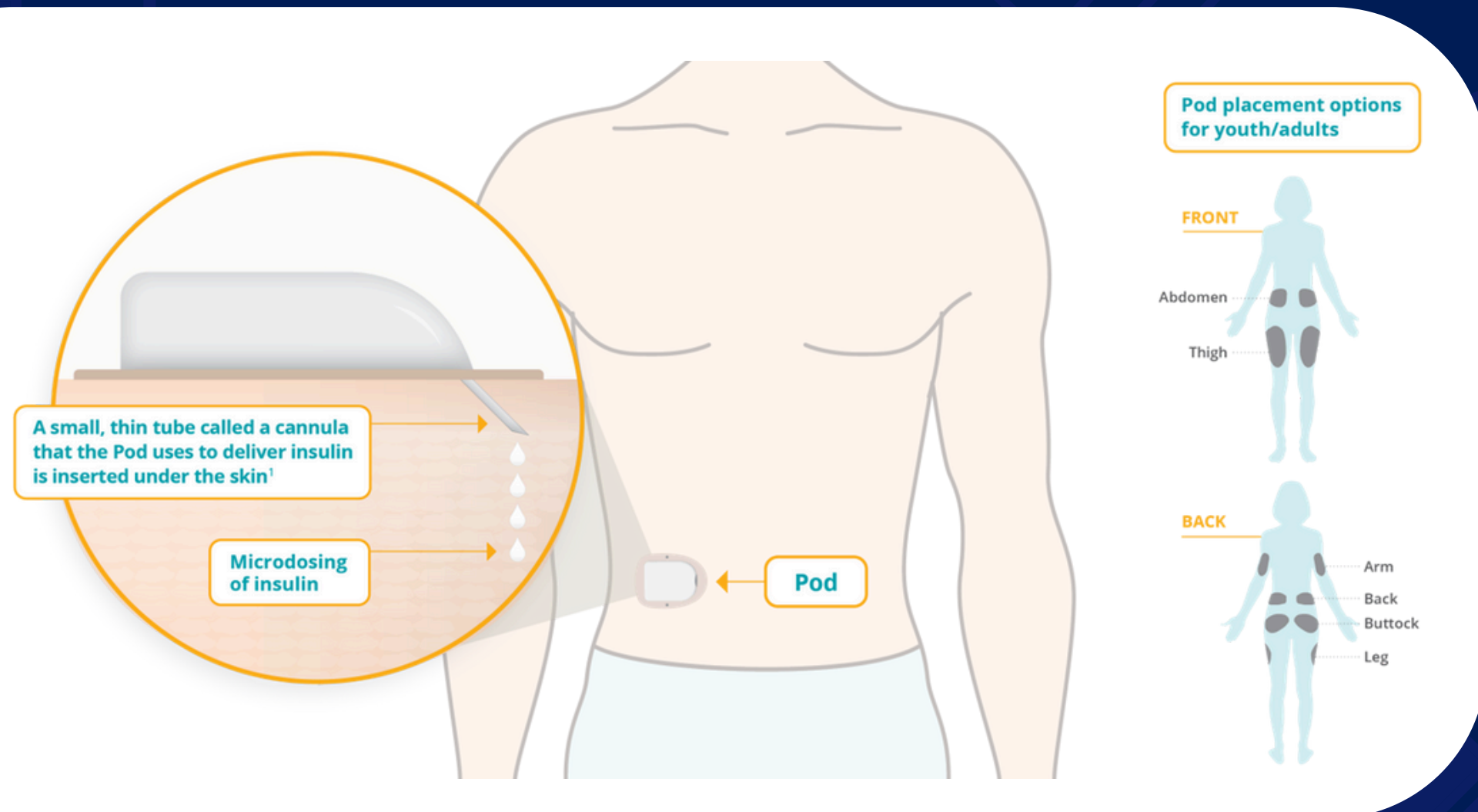
*Insulet*

# Omnipod 5 - How it works

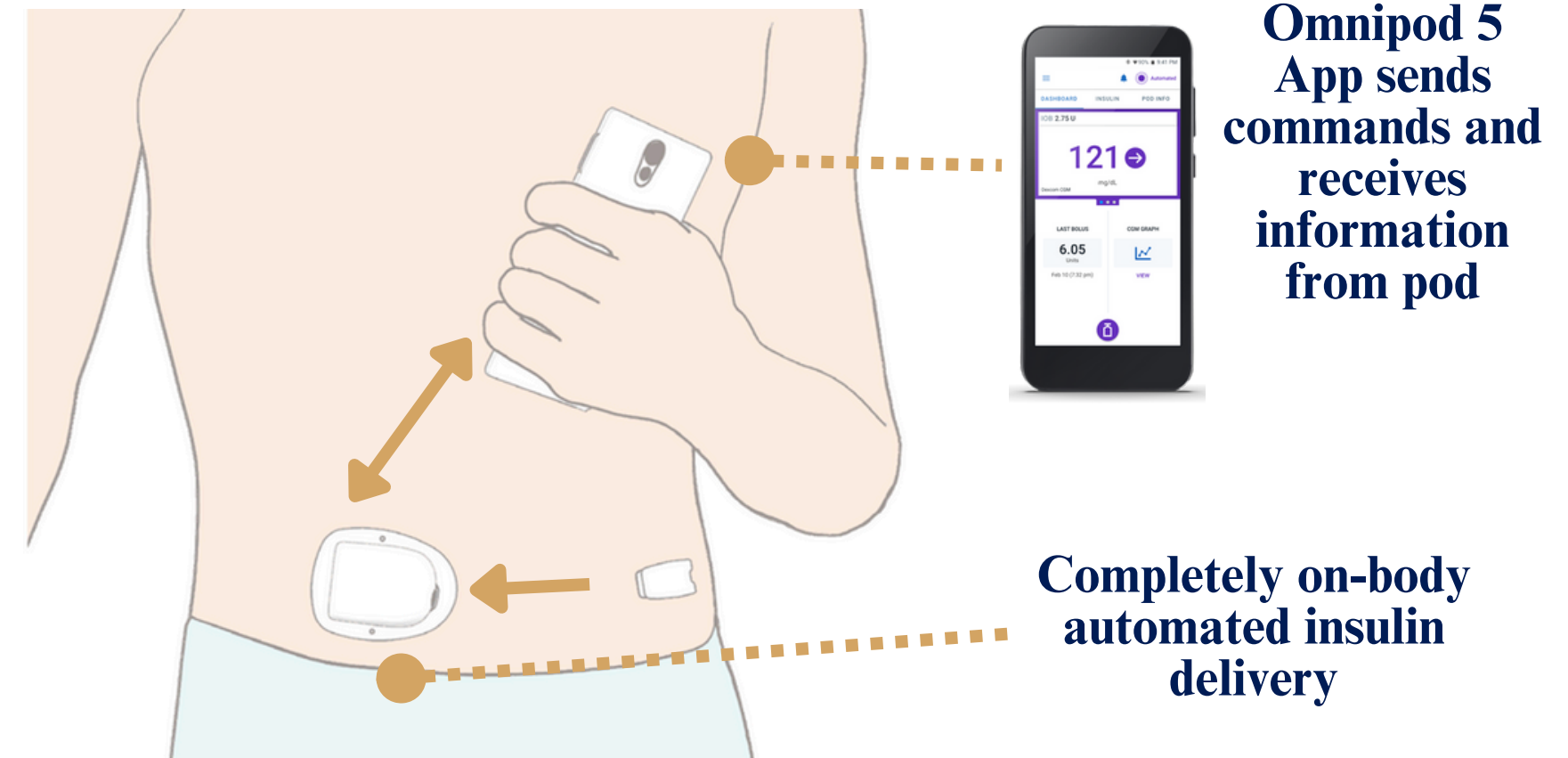
*Insulet*

## Omnipod 5 Automated Insulin Delivery System

### Pod Therapy and Microdosing— Continuous Delivery of Rapid-Acting Insulin



Controlled release of rapid-acting insulin mimics normal function of the pancreas, minimizing peaks and absorption-related variability



### Features

- + SmartAdjust tech: predictive, adaptive algorithm automatically adjusts insulin delivery every 5 minutes **to help protect against highs and lows**
- + Customizable target glucose from 110-150 mg/dL, adjustable by **time of day in increments of 10 mg/dL**
- + Activity feature **for times of reduced insulin needs**, such as exercise
- + SmartBolus Calculator informed by **sensor value and trend**

# Omnipod App Features

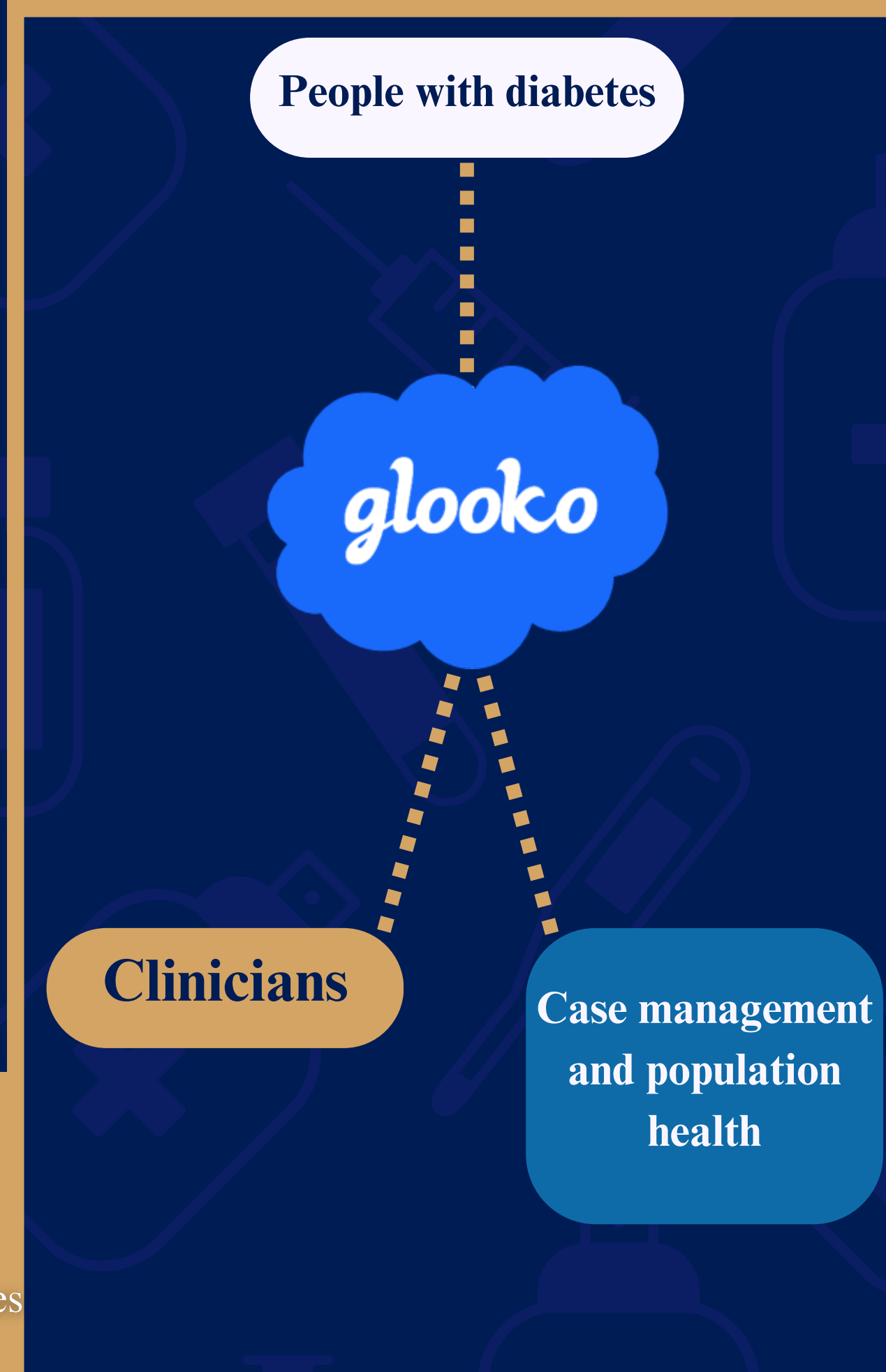
Activity Features - useful for times of heightened sensitivity when less insulin is needed

- + Adjusts glucose target to 150 mg/dL, regardless of the user's target glucose setting
- + Reduces automated insulin delivery
- + Useful for when less insulin is needed (exercise, increased activity)
- + Available in Automated Mode
- + Duration—1-24 hours in 1-hour increments

	CGM mg/dL	Insulin Amount U
11:35 am		Switched to Manual Mode
11:33 am	124	0.15
11:28 am	127	0.05
11:23 am	138	0.05
11:18 am	--	0
11:13 am	139	0
11:08 am	151	0
11:03 am	169	0.1
10:50 am		Switched to Automated Mode

Cloud-based features of Omnipod 5 enable remote management and virtual patient care coordination with data

- + Data is automatically uploaded to the Glooko cloud with cellular or WiFi connection
- + Simple CGM and insulin data report integration
- + Digital glucose readings provide actionable and valid data for HCPs vs patient-reported outcomes

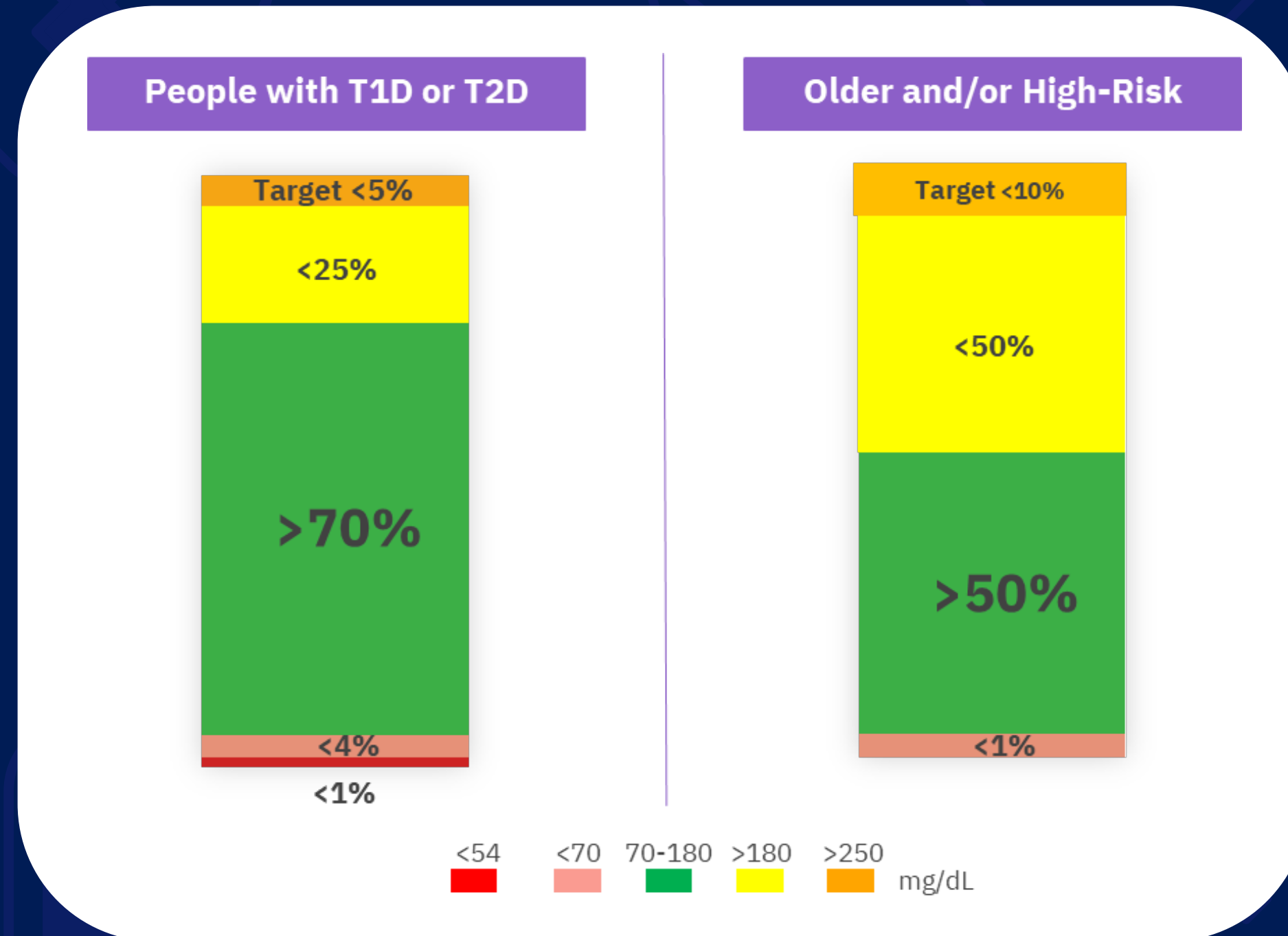


# Omnipod 5 - Type 1 Diabetes Clinical Results

*Insulet*

## What about pediatric management?

- + For people aged 25 and younger with an A1C goal of 7.5%, a 60% TIR target is recommended
- + This may be appropriate in the following situations:
  - inability to articulate hypoglycemia symptoms,
  - hypoglycemia unawareness, history of severe hypoglycemia

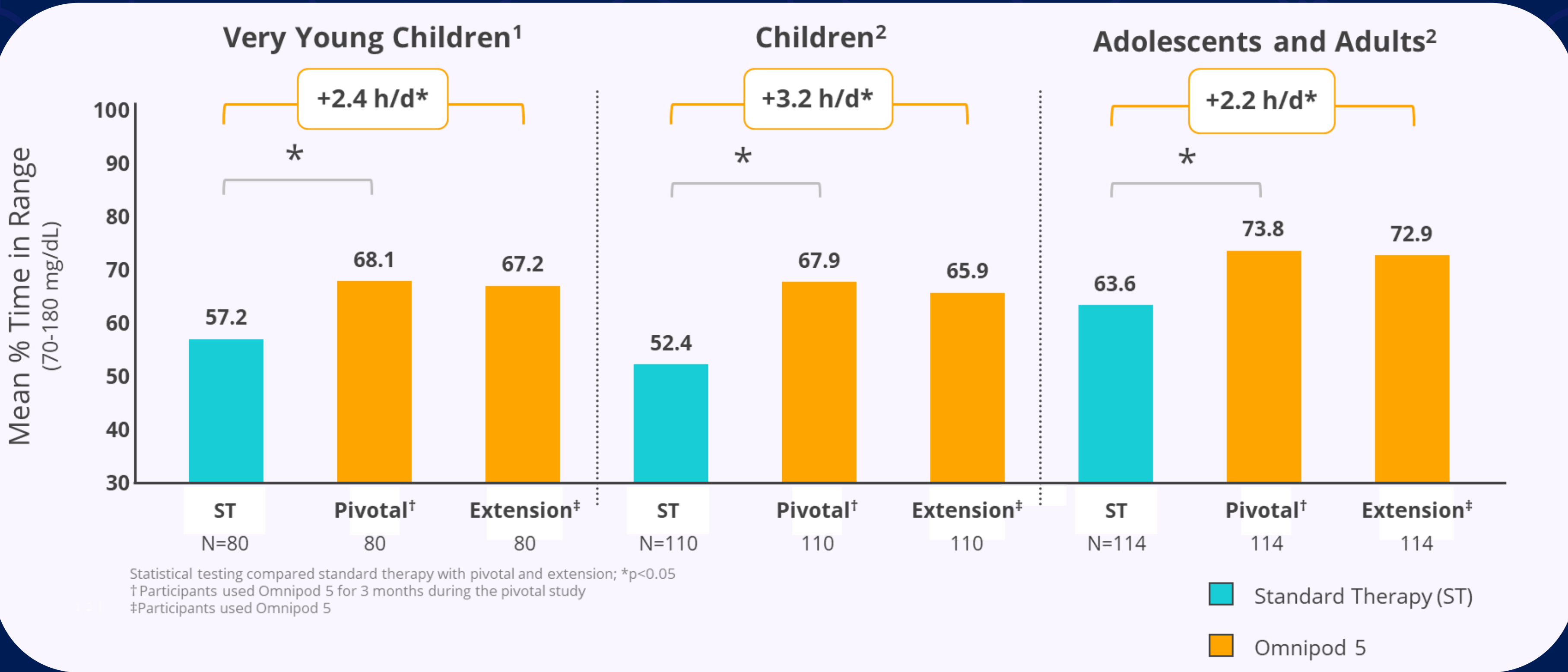


## What are the considerations for Older and/or High-Risk?

- Age +
- Duration of Diabetes +
- Duration on Insulin Therapy +
- Hypoglycemia Unawareness +
- High Risk of Complications +
- Co-morbid Conditions (e.g. cognitive impairment, osteoporosis + renal, joint and cardiovascular disease)
- Require Assisted Car +

# Omnipod Statistics

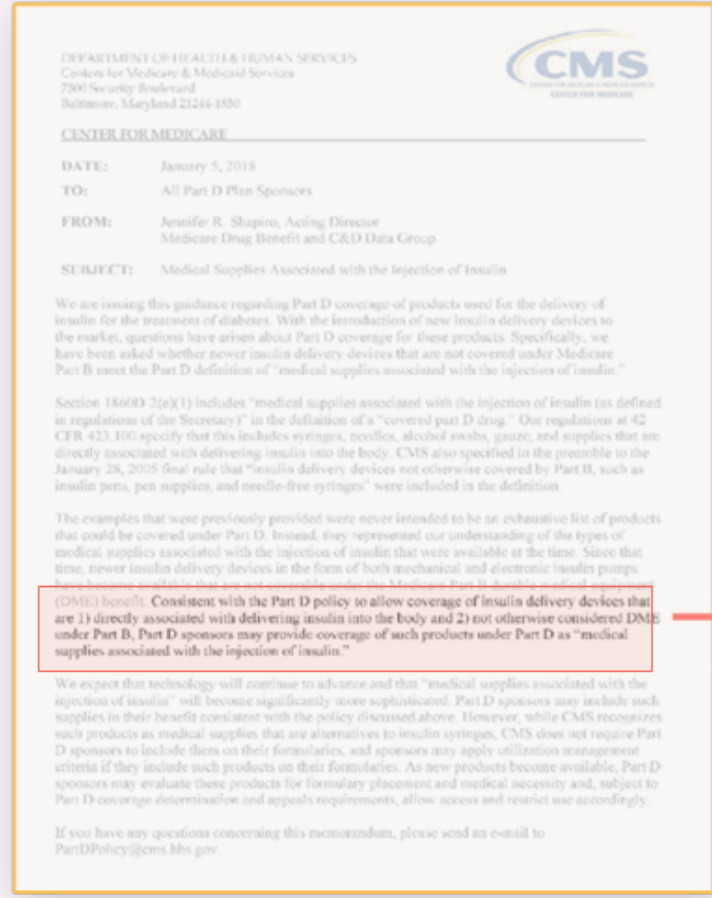
*Omnipod 5 demonstrated a sustained improvement in overall percentage time in range across all age groups*





# Disposable Insulin Delivery Systems Shifting to Pharmacy Channel

In 2018, CMS issued guidance clarifying that the Omnipod® Insulin Management System **fit Medicare Part D benefit criteria and must be covered as such**<sup>1</sup>



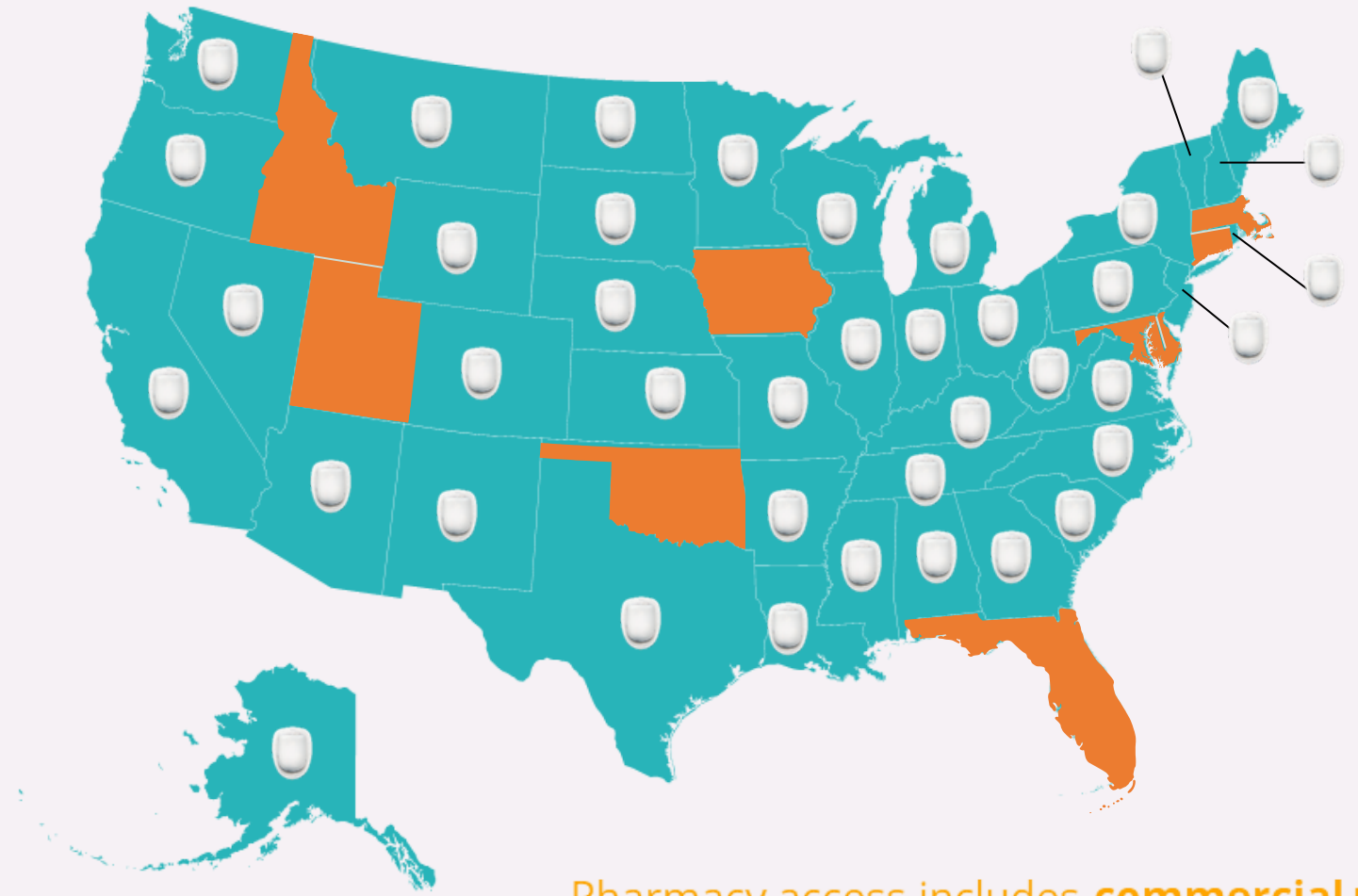
Consistent with the Part D policy to allow coverage of insulin delivery devices that are

1) directly associated with delivering insulin into the body

and

2) not otherwise considered DME under Part B, Part D sponsors may provide coverage of such products under Part D as "medical supplies associated with the injection of insulin."<sup>1</sup>

Over 300M lives covered with Omnipod 5® including over 40 State Medicaid Plans



Pharmacy access includes **commercial plans, all major PBMs, Medicare Part D plans, and state and Managed Medicaid plans\***

# Insulet to continue Pay-As-You-Go Model for Omnipod 5

- + Health plans and users avoid the high up-front costs and 4-year warranty of traditional pump payment model<sup>1</sup>
- + Reduced financial risk due to user attrition and health plan turnover compared with traditional payment model
- + Monthly billing provides simple, predictable budgeting for health plans<sup>2</sup>



Omnipod 5 is available through retail and mail-order pharmacies, including CVS and Walgreens<sup>3</sup>

Distribution agreements exist with all major wholesalers, including McKesson, Cardinal Health, and AmerisourceBergen<sup>3</sup>

# Insulet

## Cost Comparison New Pump Start

### New Insulin Pump Start Cumulative Payer Cost

These results compare the cumulative payer cost at different timepoints to start one (1) new beneficiary in your plan on Omnipod through the pharmacy benefit vs. a Tubed Pump through the DME Benefit. It is assumed that a DME pump warranty is four years and therefore the payor will bear the cost of a new DME pump at month 49.

	12 Months	24 Months	36 Months	48 Months	49 Months
Omnipod Rx	\$4,596	\$9,192	\$13,788	\$18,384	\$18,767
DME Tubed Pump	\$7,244	\$9,003	\$10,763	\$12,522	\$18,153
Omnipod Rx Difference	(\$2,648)	\$189	\$3,025	\$5,862	\$614
The above results are based on the following inputs:					
Average Pods/Month	10				
Omnipod Rx WAC	\$580				
Omnipod Rx Rebate	34%				
DME Tubed Pump Cost	\$5,485				
DME Monthly Supply Cost	\$147				

## Attrition-Induced Cost Comparison

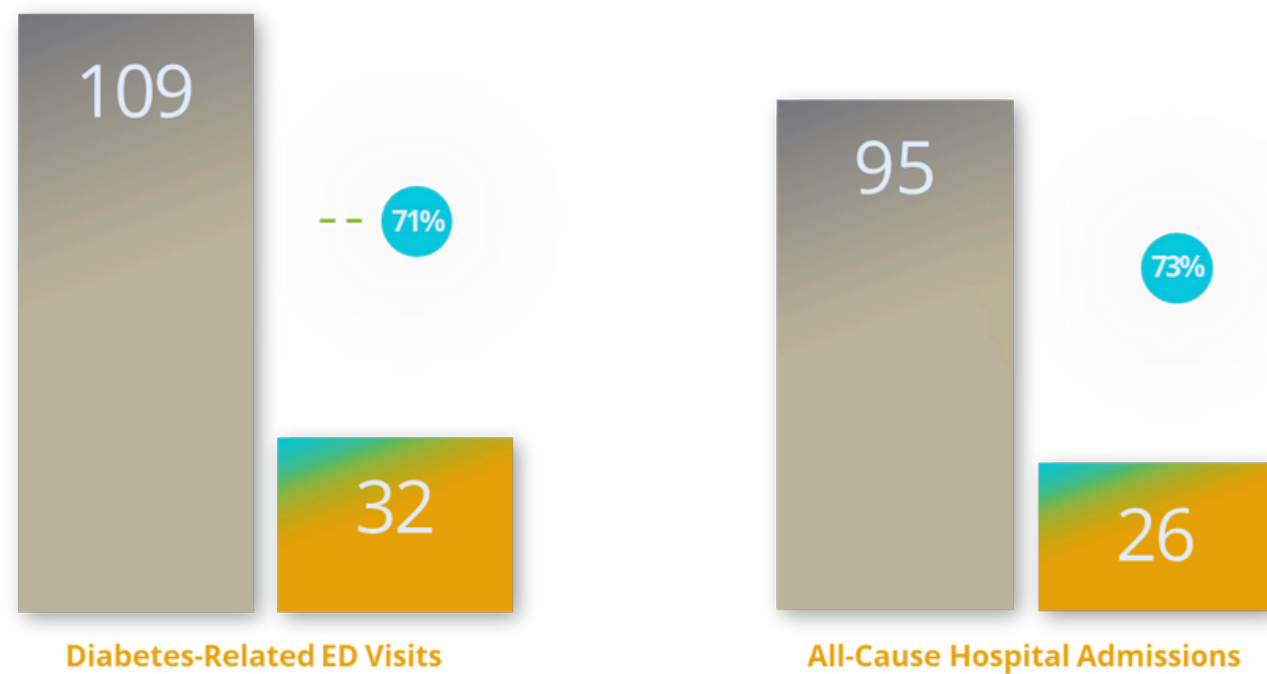
### Attrition-Induced Average Monthly Payment

These results compare the average monthly cost to your plan at varying attrition timelines for Omnipod through the pharmacy benefit vs. a Tubed Pump through the DME Benefit. For example, if a patient were to attrite at 12 months, this model takes your cumulative payer cost over that 12 month duration and divides it by 12 to arrive at an attrition-induced average monthly payment.

	12 Months	24 Months	36 Months	48 Months	49 Months
Omnipod Rx	\$383	\$383	\$383	\$383	\$313
DME Tubed Pump	\$604	\$375	\$299	\$261	\$303
Omnipod Rx Difference	(\$221)	\$8	\$84	\$122	\$10
The above results are based on the following inputs:					
Average Pods/Month	10				
Omnipod Rx WAC	\$580				
Omnipod Rx Rebate	34%				
DME Tubed Pump Cost	\$5,485				
DME Monthly Supply Cost	\$147				

## Omnipod System Users Experienced >70% Decrease in Costly Hospitalizations and ED Visits

Claims data analysis demonstrates potential cost reductions for health plans when members use the Omnipod® System\*



Pre-Omnipod System Use
  Post-Omnipod System Use

Based on an observational analysis of real-world data collected from a large United States insurance claims database over a 12-month period.

A statistical analysis comparing the change in ED visits and hospital admissions pre- and post-Omnipod System use was not conducted.

### SSDC Members

State	PDL Lives	Omnipod Coverage
Delaware	280,751	FFS and MCO
Iowa	694,011	MCO
Kentucky	1,652,917	FFS and MCO
Maine	360,563	FFS and MCO
Mississippi	846,264	FFS and MCO
North Dakota	121,503	FFS and MCO
Ohio	3,542,000	FFS and MCO
<b>Oklahoma</b>	<b>1,470,000</b>	<b>No Medicaid Coverage</b>
Oregon	1,465,100	MCO
Pennsylvania	3,588,000	FFS and MCO
South Dakota	132,000	FFS and MCO
Utah	482,000	FFS and MCO
Vermont	186,233	FFS and MCO
West Virginia	633,397	FFS and MCO
Wyoming	73,909	MCO

# Testimony from Trish Winters

+ Mother of two with Type 1 Diabetes



**Trish Winters**  
**Breakthrough T1D**  
**Market Director**

# Questions from Members

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## Retirement & Insurance

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*Chaired by Senator Dewayne Pemberton*