

# Technology Updates

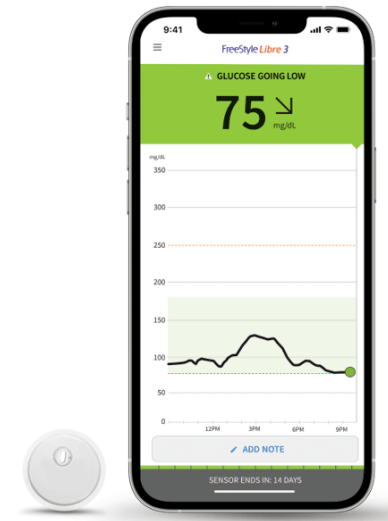
Whitney Beaton, MSN, RN, ACCNS-P, CDCES & Jaclyn Allen, DNP, RN, ACCNS-P

April 19, 2023

# Objectives

- Identify updates and recent new products available for management and monitoring of diabetes
- Explain how school nurses can apply knowledge of new and updated diabetes products to their current practice
- Examine barriers to obtaining updated products and technologies for patients living with diabetes

# Continuous Glucose Monitors



# Dexcom G7



DIVE BRIEF

# Dexcom's G7 glucose monitor wins awaited FDA clearance

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Published Dec. 8, 2022



# The Headlines

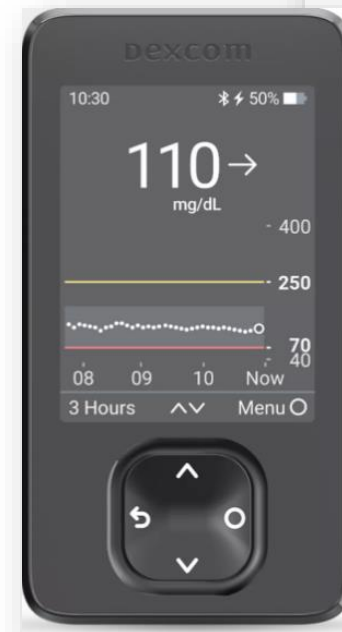
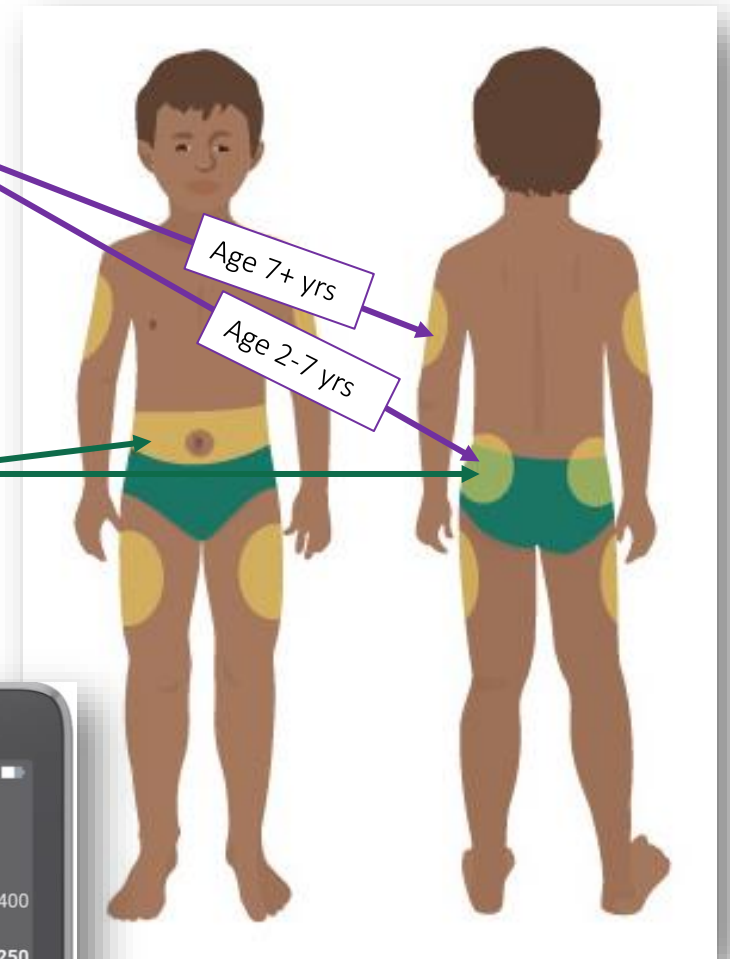
## Dexcom G7 Receives FDA Clearance: The Most Accurate Continuous Glucose Monitoring System Cleared in the U.S.

12/08/2022

- Dexcom G7 is now cleared in the U.S. for people with all types of diabetes ages two years and older, giving more people than ever access to a powerfully simple diabetes management solution.
- With an overall MARD of 8.2%, Dexcom G7 is the most accurate CGM cleared by the FDA,<sup>1</sup> building on the trusted performance of Dexcom CGM, which is clinically proven to lower A1C, reduce hyper- and hypoglycemia and increase time in range.<sup>2,3</sup>
- Cleared as an integrated continuous glucose monitoring (ICGM) system, Dexcom G7 will be part of the most connected CGM ecosystem in the world,<sup>1</sup> with real-time connectivity that can drive integrated insulin delivery systems, connect with wearables like the Aacelo Watch and integrate with ocular digital

# The Nitty Gritty

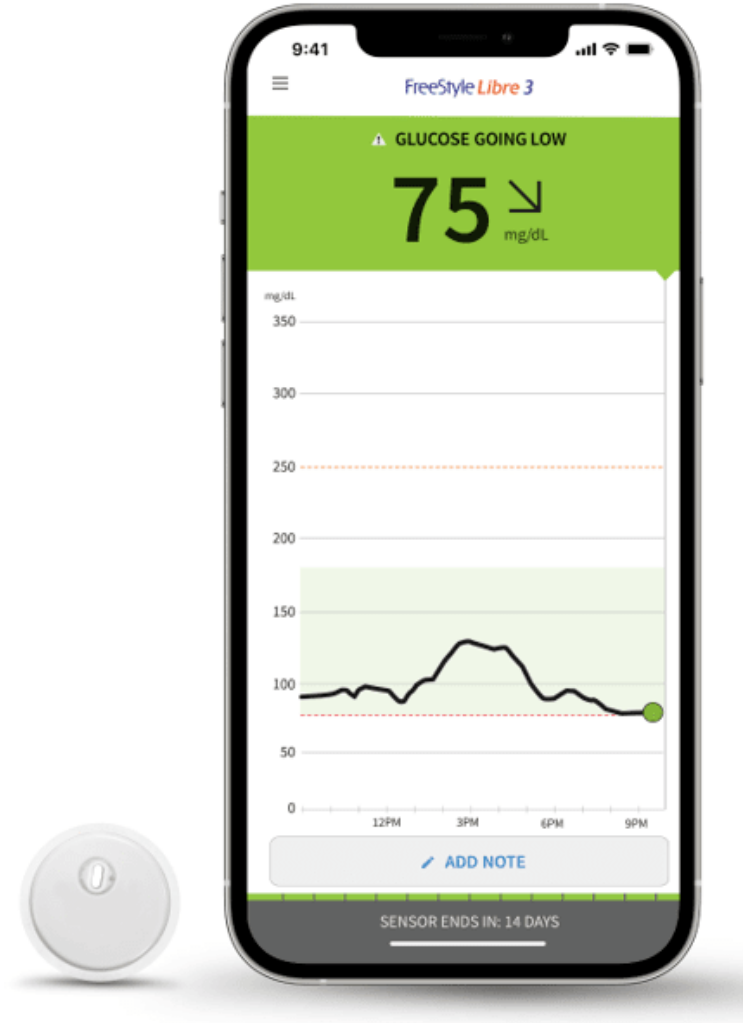
- Smaller size (60% Smaller than G6), Transmitter and sensor all in one
- FDA approved locations
- Improved MARD (8.2%)
- New receiver that holds more days of data
- New App specific to G7 (for cell phone users)
- 30-minute warmup that starts with sensor insertion
- 12-hour grace period to allow easier transition between sessions
- Wear time still 10 days
- Smaller insertion device
- Not currently integrated with insulin pumps



# What does this mean for care in schools?

- Function will be very similar to G6
- Improved form will be beneficial for kids/families, fewer pieces to buy and keep track of
- 12-hour grace period will mean that kids can be flexible with when they change their sensor
- May see slower uptake until integrated with insulin pump systems
- Dexcom clarity login will be the same; No need to update anything
- Utilizes same Follow App

# Libre 3 & Libre iCGM Designation for Libre 2 and 3







# The Headlines

diaTribe Learn  
MAKING SENSE OF DIABETES

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## FDA Clears Freestyle Libre 2 and 3 for Use With Automated Insulin Delivery

Published 3/16/23 3:45 pm

 43 readers recommend

By Andrew Briskin

*The FDA has cleared Abbott's Freestyle Libre 2 and Libre 3 continuous glucose monitors (CGM) for integration with automated insulin delivery (AID) systems. These devices have also been cleared for younger children, extended wear time, and for use during pregnancy.*

The FDA on March 6 cleared Abbott's Freestyle Libre 2 and Freestyle Libre 3 CGM for use with automated insulin delivery (AID) systems.

AID systems connect a CGM, insulin pump, and smartphone to automatically adjust insulin dosing in real-time in response to changing glucose levels. These systems have been demonstrated to help many people with diabetes improve their time in range and reduce the time spent thinking about managing glucose each day.

With this new clearance from the FDA, Libre 2 and 3 CGMs and the connected smartphone app will soon integrate with insulin pumps to adjust insulin dosing.



Share this article



### FreeStyle Libre 3 SENSORS FOR INTEGRATION WITH



Sensors are cleared for connectivity with automated insulin delivery (AID) systems in the U.S. for people who are pregnant, and for wear time up to 15 days.

The U.S. Food and Drug Administration (FDA) has cleared its FreeStyle Libre 2 and FreeStyle Libre 3 continuous glucose monitors (CGM) for integration with automated insulin delivery (AID) systems. Abbott modified the sensors to enable integration with AID systems.

Abbott's diabetes care business. "The FreeStyle Libre portfolio is already the most prescribed

### [FreeStyle Libre 3 Receives FDA Clearance for Diabetes in Patients 4 Years and Older](#)

Abbott announced the FDA's approval of the FreeStyle Libre 3 CGM system for by people aged 4 years and older in a press release on May 31. Billed as the world's smallest, thinnest, and most accurate 14-day glucose sensor, the FreeStyle Libre 3 system is the size of 2 stacked US pennies and has a Bluetooth integration range of up to 33 feet. According to Abbott, the FreeStyle Libre 3 system is the first continuous glucose monitoring system to demonstrate a sub 8% MARD, with a 7.9% overall MARD.

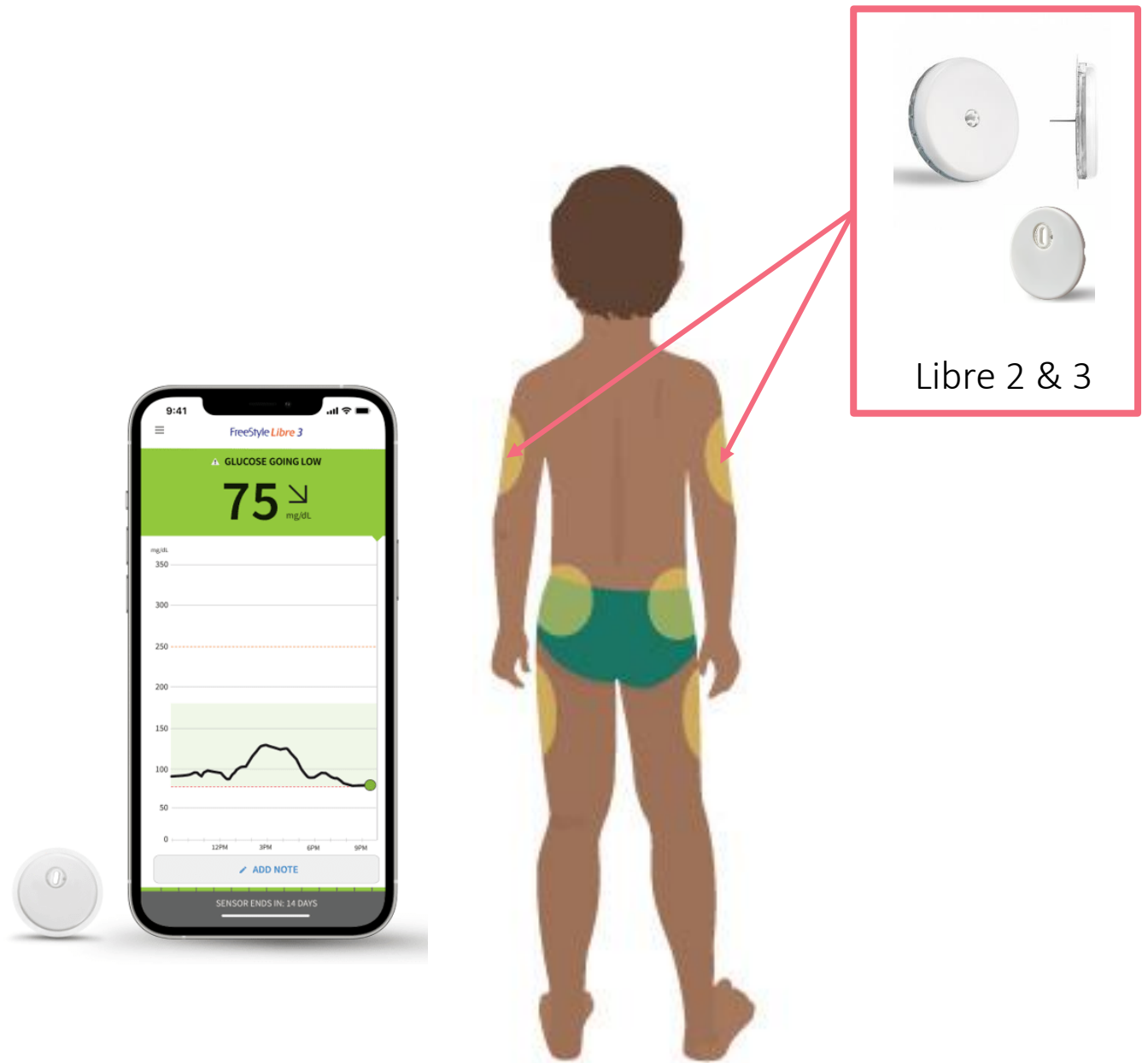
# The Nitty Gritty

- **Freestyle Libre 3 Approved for Kids Age 4 years and Older**

- Smaller size
- True continuous glucose monitoring (no longer must scan to obtain reading)
  - Also means share feature is now real-time, not limited to when scanned as Libre 2 was
- Still 14-day wear with new reading every 1 minute

- **Libre 2 & 3 receive iCGM Designation**

- This means Libre 2 & 3 meet the FDA standards to be integrated with an Insulin pump and used in the algorithms that deliver insulin
- No pumps have this integration yet



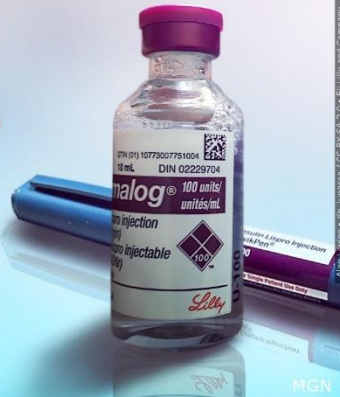
# What does it mean for Care in Schools?

- You may start to see this product more, especially when approved with pumps
- Has very similar function to Dexcom now that it no longer requires intermittent scanning
- If following a student you should see real-time data as long as they have a wifi or cellular connection

# Medications



*Lilly*  
**INSULIN  
PRICES**



# Teplizumab



# The Headlines

The New York Times

## *F.D.A. Approves a Drug That Can Delay Type 1 Diabetes*

The therapy will cost nearly \$200,000. But it's the first treatment in 100 years to alter the course of the disease, which usually begins in adolescence.

CBS PHILADELPHIA NEWS WEATHER SPORTS VIDEO MORE 46° Live TV

HEALTH

### New Type 1 diabetes drug gives hope to millions of Americans

BY STEPHANIE STAHL  
JANUARY 2, 2023 / 6:08 PM / CBS PHILADELPHIA

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Diabetes

HEALTH

## FDA approves first treatment that delays Type 1 diabetes. Why it could be 'game changing'

Adrianna Rodriguez  
USA TODAY

Published 7:55 a.m. ET Nov. 18, 2022 | Updated 12:01 p.m. ET Nov. 18, 2022

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# The Nitty Gritty

- Monoclonal antibody drug
- FDA approved in November
- Delays the onset of “stage 3 type 1 diabetes”
- Eligibility criteria:
  - 8 years and older
  - “Stage 2 type 1 diabetes”
- \$200,000!!
- 14-consecutive day infusion
- Infusion center or home health
- Side effects:
  - Low white blood cell count
  - Cytokine Release Syndrome
  - Rash
  - Fever
  - Serious Infections

# Stages of Type 1 Diabetes (T1D)

## Stage 1

- Positive for  $\geq 2$  T1D antibodies
- Body has started to attack insulin-making cells
- Blood sugars are still normal

## Stage 2

- **Positive for  $\geq 2$  T1D antibodies**
- **Blood sugar levels are starting to become abnormal**
- **Still no outward symptoms**

## Stage 3

- Positive for  $\geq 2$  T1D antibodies
- Outward signs of diabetes (increased thirst, urination, weight loss, etc.)
- Traditional time of diagnosis for T1D



# What does it mean for Care in Schools?

- This is a delay, not a cure.
- Current students with T1D are not eligible for treatment; siblings may be!
- Psychological impact on siblings with T1D is not well known. Will likely need extra support.
- A lot of unknowns, but still exciting development in T1D care
- More screening will likely happen



novo nordisk®  
**PRICE DROP**



*Lilly*  
**INSULIN PRICES**

Press Release: Sanofi cuts U.S. list price of Lantus®, its most-prescribed insulin, by 78% and caps out-of-pocket Lantus costs at \$35 for all patients with commercial insurance

# Insulin Price Cuts

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HEALTH NEWS

### Novo Nordisk to lower list price of some of its insulin by up to 75% in the U.S.

The change follows a similar move by Eli Lilly and will go into effect in 2024.

### Eli Lilly to cut insulin prices, cap costs at \$35 for many people with diabetes

### Novo Nordisk becomes latest to announce it is cutting insulin prices by up to 75%

# The Headlines


PHARMA

in

Sanofi answers the call, joining Eli Lilly, Novo Nordisk in cutting insulin prices

By Kevin Dunleavy • Mar 17, 2023 10:45am

Sanofi insulin Diabetes Novo Nordisk



### A Major Victory in the Battle for Affordable Insulin: Eli Lilly & Co. Slash Prices

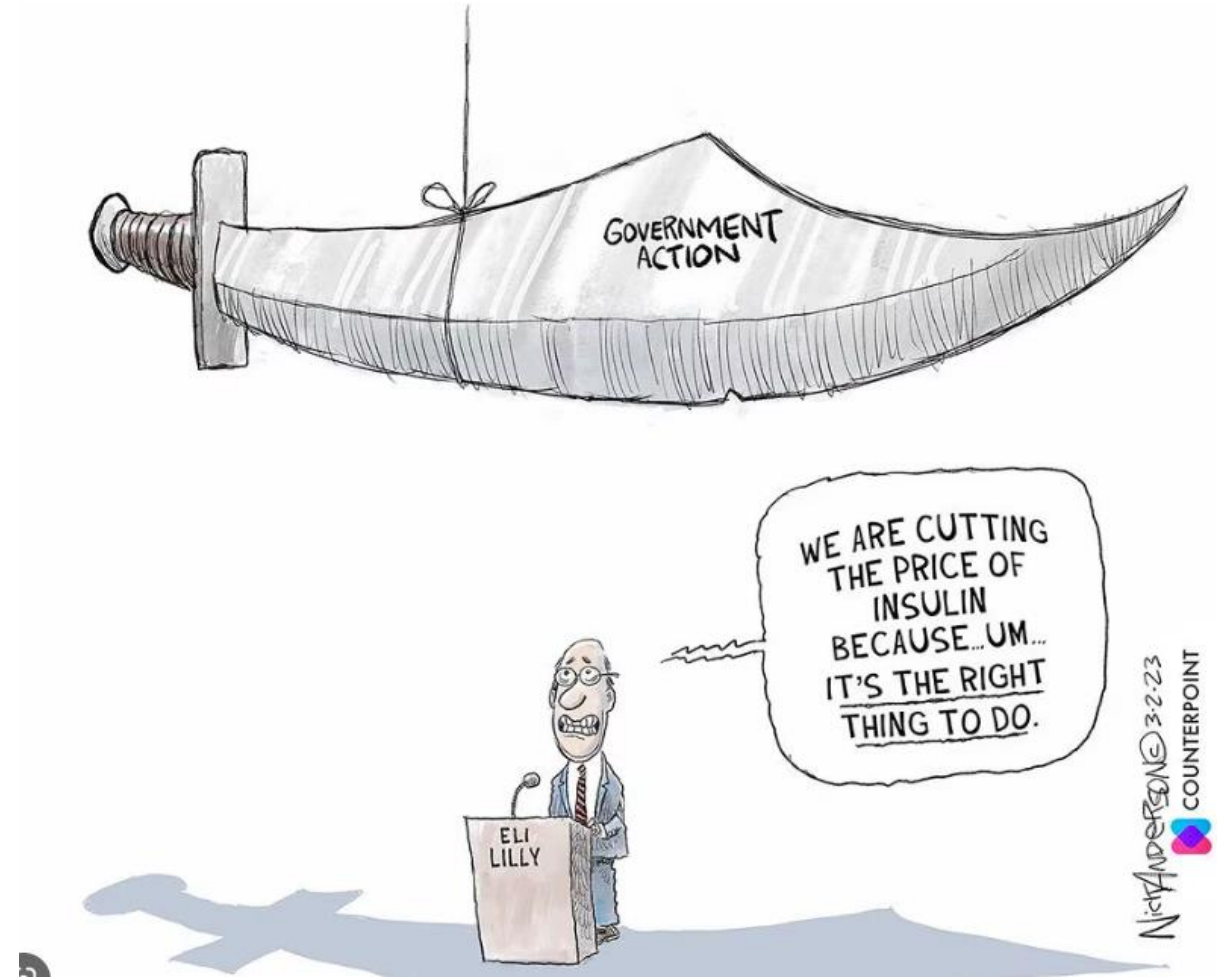
Christopher Shanks 9 days ago

The cost of insulin, a life-saving drug used by millions of Americans, just got a lot cheaper.



# The Nitty Gritty

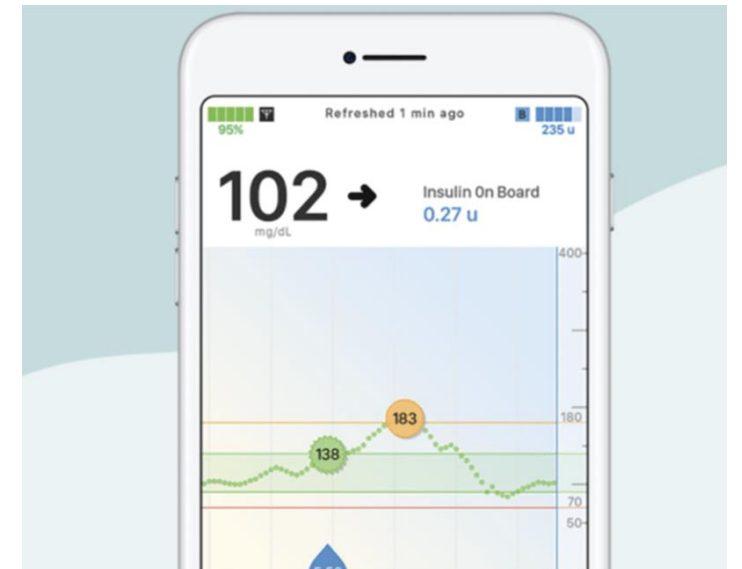
- All major insulin manufacturers in the US recently announced plans to reduce the price of insulin
- Out of pocket maximum generally ~ \$35 *per insulin*. For patient on 2 types of insulin this would still be about \$70/month max.
- Not all programs are effective immediately



# What does it mean for Care in Schools?

- Ease some of the financial burden of diabetes for our students
- Share the news!
- Keep the pressure on!

# Insulin Pump Innovations



# Tandem Mobile Bolus



## FDA clears first app for iPhone and Android phones to deliver insulin doses for diabetics



**Brett Molina**

USA TODAY

Published 10:02 a.m. ET Feb. 18, 2022 | Updated 4:07 p.m. ET Feb. 18, 2022

People with Diabetes, Brett.

# The Headlines



# The Nitty Gritty

- Users can request insulin delivery or cancel insulin bolus directly from their compatible personal cell phone
- Insulin pump can still function independently from app
- Users can still view data and access pump features via the pump directly
- Requires user to upgrade to latest pump software



# What does it mean for Care in Schools?

- Student may choose to bolus through phone instead of accessing the pump
- Not all pump features can be activated through mobile bolus

# Omnipod 5



## Omnipod 5 Cleared by the FDA

Updated: 8/22/22 4:16 pm

Published: 1/28/22

♥ 88 readers recommend

**Katie Mahoney**

...ry system has been cleared by the  
...system, which includes a tubeless  
...glucose monitor, and a smartphone

...et's Omnipod 5 automated insulin  
...new AID system was initially cleared

BREAKING NEWS

### Insulet's Omnipod 5 OK'ed for Kids Aged Two to Five

Diabetes Care published study showed Omnipod 5 "significantly improved" time in range.



### FDA Approved the Use of Omnipod 5 for Children Over 2

Recently, the FDA approved the use of Omnipod 5 for children over 2 with type 1 diabetes, expanding on its previous approval, which only allowed for use in people over 6 years old.



CLINICAL ROLE: Retail | Hospital | Oncology | Pharmacy Technician | Student

### FDA Clears Omnipod 5 Automated Insulin Delivery System for Type 1 Diabetes Patients 2 Years of Age and Older

Aug 22, 2022

PT Staff



Omnipod 5 is an automated, tubeless insulin dispensing system that allows for continuous infusion and bolus dosing as needed.

The FDA has granted clearance to the Omnipod 5 Automated Insulin Delivery System (Insulet

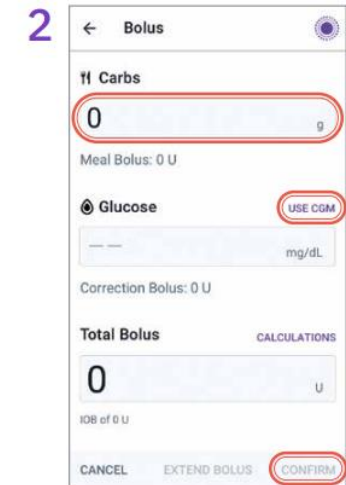
# The Headlines

# The Nitty Gritty

- All 3 major Insulin Pump Companies in the US now have an Automated Insulin Delivery System in the Market!
- First tubeless AID system in US
- Pairs with Dexcom G6 CGM to adjust basal insulin delivery every 5 minutes
  - First pod starts in a limited mode based on Total Daily Dose of Insulin
  - System “learns” the user’s response and incorporates that information into future dosing decisions
  - Food and Correction boluses are based on programmed settings, but the user still must command them



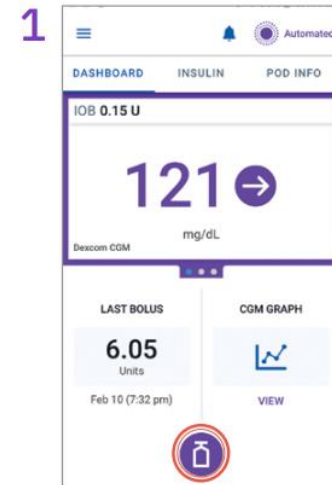
- Tap the Bolus button on the Home screen



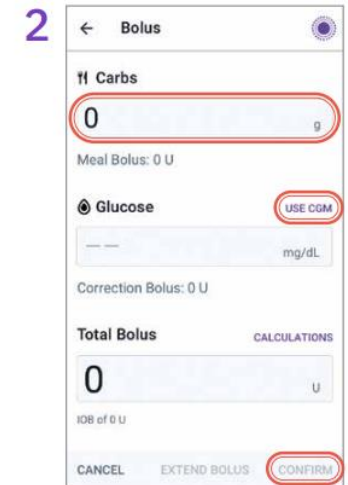
- Tap on the Carbs field to manually enter carbs
- Tap **USE CGM** to use CGM value and trend or add blood glucose reading by tapping the Glucose field
- Tap **CONFIRM**

# The Nitty Gritty

- Pod and CGM connect via Bluetooth and can continue to adjust insulin delivery even when the controller is not in range
- Controller (compatible cell phone OR receiver) required to deliver meal doses or adjust other settings
- If User utilizes the SmartBolus Calculator (see image) the system will consider both CGM value and trend when making dosing decision
- User can define their blood sugar target (110-150 mg/dL), and can use different targets at different times of day
- Activity mode raises target to 150 mg/dL to reduce hypoglycemia risk
- Available through the pharmacy



- Tap the Bolus button on the Home screen



- Tap on the Carbs field to manually enter carbs
- Tap **USE CGM** to use CGM value and trend or add blood glucose reading by tapping the Glucose field
- Tap **CONFIRM**

# What does it mean for Care in Schools?

- The system will adjust basal rates up or down with goal of reducing time spent in hypo- and hyperglycemia/Increasing Time in Range
- The pump is “smart” but still needs oversight by a person and requires glucose and carb entries when eating to deliver boluses
- If CGM isn’t on or isn’t connected to pump the pump will function but would be in a “limited mode” or operate as a traditional pump

*Note: Omnipod is not an insulin pump covered by WI Medicaid, even with appeals. Children on Badgercare are not able to access this technology.*

# References

## Insulin Price Cuts:

[Lilly Insulin value Program](#)

[Sanofi Patient Assistance Application](#)

[Novo Nordisk Patient Assistance Program](#)

[Getinsulin.org](#)



# Resources

[Diabetes technology for healthcare professionals | Danatech \(diabeteseducator.org\)](#)

[Omnipod-5 Quick-Start-Guide.pdf](#)

Article that provides overview of OP5 and compares with other AID systems: [Clinical Implementation of the Omnipod 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People With Diabetes | Clinical Diabetes | American Diabetes Association \(diabetesjournals.org\)](#)

Tzield Website: <https://www.tzield.com/>

Screening Information: [T1Detect: Learn why you should be screened](#) and [Home | TRIALNET Type 1 Diabetes TrialNet](#)