

Retrospective:

100 Years of Diabetes Management Evolution

2023 marks the 100th anniversary of the first commercialization of self-administered insulin for diabetes management, so we thought that it would be interesting to review the past 100 years of innovation for this patient population. Our curiosity started as part of our prescription digital therapeutics study, where we found that separate payment for diabetes management apps is not typically approved by payers. In this article, we will focus on how patient access and payer coverage of glucose monitoring and insulin dosing technology has evolved, with an eye towards incorporating this information into the emerging workflow of provider reimbursement for remote patient monitoring (RPM).

Diabetes Innovation & Coding Timeline

The timeline below highlights key developments in Glucose Monitoring and Insulin Delivery, along with key developments in coding/payment and integration with the physician workflow. Over time, automated insulin delivery based on integration of data from the continuous glucose monitor is drawing diabetes management into a "closed loop" with real-time information to both the patient and the provider.

- Color Key:**
- Glucose Monitoring
 - Insulin Delivery
 - Integrated glucose-insulin
 - Coding Development
 - Other Important Developments

Glucose Monitoring

Insulin Delivery

First commercialized urine glucose test (Benedict's)	1908
	1921
Introduction of the exchange system for diabetes meal planning. The exchange system for diabetes meal planning is a method of meal planning that was developed by the American Dietetic Association and the American Diabetes Association in the 1950s. It was designed to provide people with diabetes with a flexible approach to meal planning that would help them achieve and maintain healthy blood glucose levels.	1923
	1946
	1950s
First portable blood glucose meter (Ames Reflectance Meter)	1962
First blood glucose test strip (Ames Diagnostics' Dextrostix)	1965
First home glucose meter (Ames Pocket Chemist)	1970
	1978

Discovery of insulin (Banting & Best)	1921
First commercial production of self-administered insulin from animal sources	1923
Longer acting insulin (Neutral Protamine Hagedorn)	1946
First disposable insulin syringe	1950s
	1978

First home blood glucose meter with digital display (Dextrometer)	1980
	1982
	1983
	1985
	1986
	1987
	1991
	1995
	1996
	1998
	1999
	2000
	2001
	2002
	2006
First integrated insulin pump and CGM (MiniMed Paradigm REAL-Time Insulin Pump & CGM)	

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Diabetes digital therapeutics can include a number of features, such as glucose monitoring, meal planning, medication reminders, and remote patient monitoring that ports information about the patient into the clinical medical record. Early apps were standalone programs, but today many diabetes Continuous Glucose Monitoring (CGM) and Insulin Pump devices have digital components integrated with the patient's smartphone and the physician's RPM system. To look back on how this technology has evolved to this point, we created this timeline.

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A9276 Subcutaneous disposable sensor for interstitial CGM
A9277 Transmitter, external, interstitial CGM

First smartphone-connected glucose meter (iBGStar, Sanofi)

First meter to automatically send blood glucose results wirelessly via Bluetooth to a mobile app (Tecalre BGM)

Flash Glucose Monitoring System (Freestyle Libre, Abbott)

First hybrid closed-loop insulin delivery system with algorithm (not fully automated) (Medtronic MiniMed 670G)

2007 First multi-dose insulin pen with built-in memory (HumaPen MEMOIR)

2008

2009

A9274 External ambulatory insulin delivery, disposable

2010

2011

The World Health Organization (WHO) proposes a definition for mobile health (mHealth)—a component eHealth—as the “medical and public health practice supported by mobile devices”

2012

2013

First insulin pump “threshold suspend” to prevent hypoglycemia automatically (Enlite Sensor with MiniMed 530G)

2014

2015

First ultra-long-acting insulin (Tresiba)

2016

First CGM with no fingerstick calibrations required (Dexcom G6)
First integration of CGM patient data into the medical record for RPM (Dexcom G5 & Epic)

First implantable CGM (Eversense)

First coverage of RTM codes 99090-1 (with restrictions) by Medicare

First insulin pump to automatically adjust basal dose based on CGM data (Tandem t:slim X2 with Control-IQ hybrid closed-loop with predictive algorithm)

180 day CGM (Eversense XL)

A4238 - Supply allowance for adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
E2102 - Adjunctive, non-implanted continuous glucose monitor or receiver
E2103 Non-adjunctive, non-implanted CGM or receiver

2017

First “smart” insulin pen sends insulin dosing data to smartphone via Bluetooth (Companion Medical InPen)

2018

First “follow-on” rapid-acting insulin analog (Admelog)
First integration of insulin pump data into medical record for RPM (MiniMed 670G CareLink)

2019

2020

First rapid-acting insulin aspart (1-3 minutes) (Semglee)
First integration of personalized algorithm to optimize insulin dosing integrated medical record for RPM (d-Nav)

2021

2022

2023



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Innovation Is Often Ahead of Payer Adoption

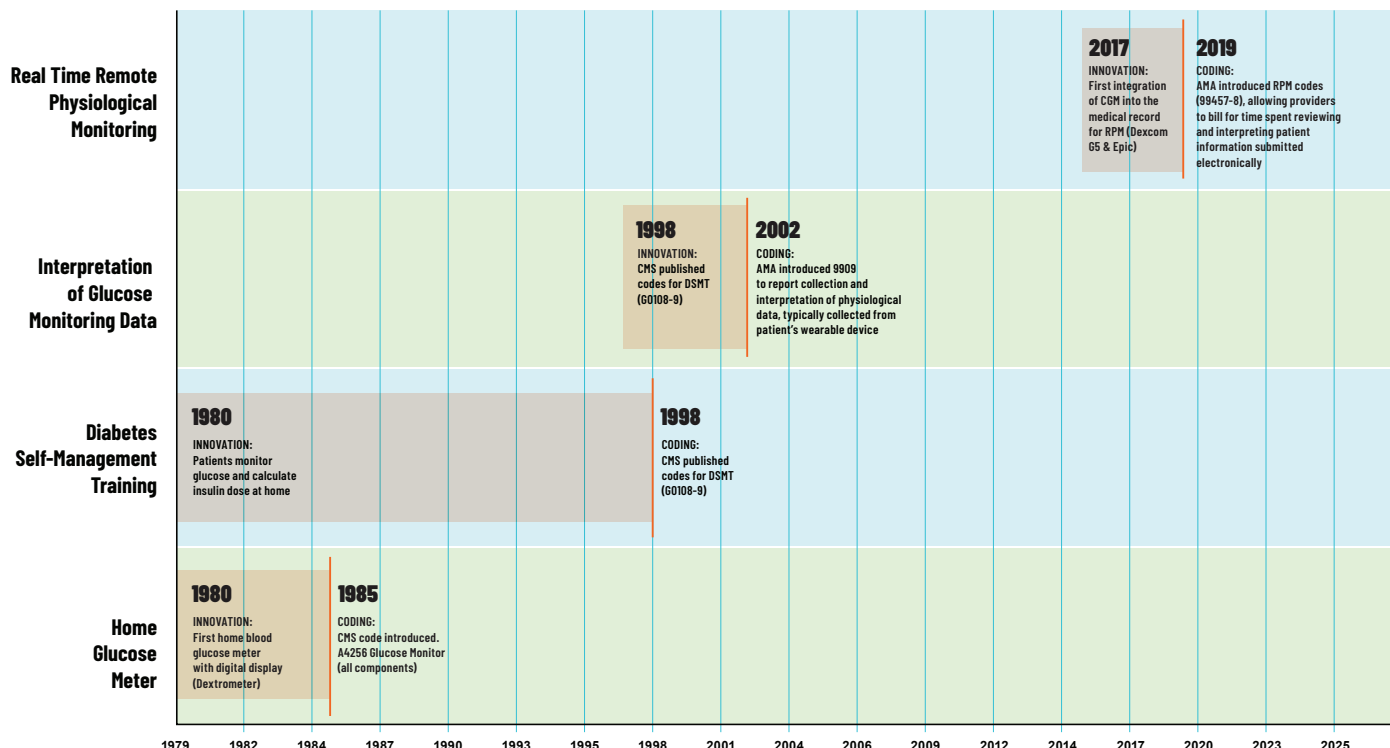
Across many specialties and types of technology, scientific innovation and payer coverage typically have an associated lag time. This is easy to see when we look at the diabetes technology and treatment guideline. To illustrate this more clearly, the coding developments chart highlights the time between a few key innovations in the 100-year timeline, then the publication of applicable procedure codes and subsequent payment by CMS and commercial payers. Note that this is not an exhaustive list of innovations, and does not track when codes were replaced or retired.

We see from this examination that by the 1980s, technology that allowed a patient to monitor their own glucose levels and calculate their insulin doses at home had become quite common. Yet, the diabetes self-management training codes to allow providers to bill for teaching patients to use their equipment were not published by CMS until 1998 (G0108-9) - a lag of over a decade.

Similarly, the first wearable CGM with data that the physician could download and review was commercialized in 1999, and it was three years before there was even a code (99091) to allow for the physician

to include the collection and interpretation of a claim. CMS finally “unbundled” 99091 for the first time in 2018, allowing physicians to receive separate reimbursement for this service - a lag of nearly two decades! Presently, commercial payers also seem to still be behind. A study we completed in 2022 found only 11% of sampled payers (among top 25 commercial, top 10 managed Medicaid, and all state Medicaid fee for service payers) had policy language to address remote patient monitoring of diabetes generally, and only 30 of 68 of those policies mentioned the code 99091.

One final (and newer) example is that the first real-time remote physiological monitoring data that integrated directly into the medical record started in 2017 (with Dexcom G5 and Epic). Again, billable codes did not emerge for RPM until 2019 (99457-8) to allow providers to bill for time spent reviewing and interpreting this data. Note that these codes are about remote monitoring generally, not specific to diabetes. This time, CMS tracked closely with the code creation, publishing physician rates for those codes the same year. The 2019 national unadjusted non-facility rate was \$51.54 (\$32.44 facility), and those rates are \$48.89 and \$31.16 respectively in 2023. Here we see a narrowing of the gap to two years for Medicare, but commercial payers are still not caught up. In our 2022 study, only 37 of the 68 RPM for diabetes policies mentioned code 99457.





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