Diabetes Management Devices – Continuous Glucose Monitors

Strong CGM Demand Rolls On

U.S. endocrinology practitioners' 3Q21 CGM starts grew qq and their 2021 forecasts remained strong, as loosening insurance requirements and growing awareness continued to support adoption, especially in the type-2 diabetes market.

BY BETH GILBERT
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- 3Q21 CGM starts up 2%–5% qq, at least met expectations for 20 of 22 sources; increasing in-office visits, rising vaccination rates aiding growth; telemedicine still helpful for CGM starts, follow-ups
- 2021 CGM starts expected up 21%–24% yy (similar to July) aided by expanding CGM awareness; elimination of CMS's SMBG testing requirement, especially helpful to type-2 adoption
- DXCM's CGMs prescribed to 58%–63% type-1, 30%-35% type-2 patients starting a CGM; DXCM gained share qq for 14 of 22 sources, mainly from MDT (similar to July)
- ABT's Libre CGMs prescribed to 33%–38% type-1, 64%-69% type-2 patients starting a CGM; ABT gained share qq for 15 of 22 sources (similar to July), mainly among type-2 patients; lack of pump compatibility still constraining ABT in type-1 market
- MDT lost share qq for 9 of 14 MDT prescribers (similar to July); sources remain concerned about accuracy, lack of Medicare coverage
- Area to Watch: Sources welcome upgraded CGMs from ABT, DXCM, anticipated within 6–12 months, but less enthusiastic about MDT's developmental CGM

KEY DATA

3Q21 and 2021 (estimated) GM Starts
(number of sources)

	3Q21 QQ	2021 YY (EST.)
Up 41%–50%	-	2
Up 31%–40%	-	1
Up 26%–30%	-	1
Up 21%–25%	3	4
Up 16%–20%	-	4
Up 11%–15%	-	4
Up 6%–10%	4	4
Up 1%–5%	4	-
Up	2	1
Flat	8	1
Down 11%–15%	1	-
Weighted average	Up 2%–5%	Up 21%–24%
July weighted average	Up 12%–15%	Up 20%–23%

SOURCES & BACKGROUND

23 U.S. sources, comprising 18 certified diabetes educators (CDEs) and 5 endocrinologists, representing more than 29,600 type-1 and -2 diabetes patients

REPEAT SOURCES 14 from OTR Global's July report

INTERVIEWS Sept. 23 through Oct. 4

AVERAGES Weighted according to the number of type-1 and -2 patients under each source's care

"The CMS changes do not require documentation of the frequency of testing anymore. This was loosened last year because of the pandemic, but now it has been adjusted in the coverage criteria. This will help to get more patients on CGMs, especially type-2 patients who've had a harder time keeping insulin dosing logs."

Endocrinologist

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Q3 CGM Starts Grow QQ

U.S. endocrinology practitioners said their 3Q21 continuous glucose monitor (CGM) starts increased an average 2%–5% qq, despite the pandemic's resurgence and following a 12%–15% qq increase during 2Q21. In addition, 20 of 22 sources said their 3Q21 GM starts met or exceeded their expectations. "We are coming off of a busy spring, and we are still seeing growth this quarter," a CDE said.

CGM starts continued to benefit from increased COVID-19 vaccination rates and patients returning to medical offices. "Many patients are vaccinated and are not afraid to come into the office. All of our staff is vaccinated, too, so we haven't had any issues with the Delta variant or really COVID in general [during 3Q21]," a CDE said. Another said, "We are taking safety precautions and seeing patients in person. We are also doing virtual education classes. Everything is moving forward." In addition, telemedicine remained a helpful tool for CGM starts and follow-up appointments, and also remained more effective for starting CGMs than insulin pumps, which require a more hands-on training approach. (See OTR Global's **Sept. 14** Insulin Pump report). "You can train patients virtually or in person with CGMs, but with insulin pumps it is better to do training in person," a CDE said.

Sources also reiterated the pandemic has highlighted the importance of closely managing patients' glucose levels. "CGM data is accessible to clinicians through cloud applications, which helps them monitor patients from a distance, and has been even more important during the pandemic. Once patients get on a CGM and see how well they can do, they are addicted to it," a CDE said.

3Q21 GM Starts vs. Expectations
(number of sources)

Exceeded	**3**
Met	**17**
Fell below	**2**
OTR Comparative Index	**5**
July Index	17

Note: The OTR Comparative Index is a quantitative representation of qualitative responses. The Index is calculated by subtracting the "worse" from the "better" responses, dividing by the total responses and multiplying by 100. An Index below zero indicates a negative trend; above zero indicates a positive trend.

> "We are coming off of a busy spring, and we are still seeing growth this quarter."
>
> *CDE*

2021 Forecast Remains Strong

Endocrinology practitioners expect their 2021 CGM starts to increase an average 21%–24% yy, similar to July, with 2021 forecasts remaining the same or improving qq for 21 of 22 sources. "More diabetes patients are using CGMs because they're seeing how great they are. Physicians are writing more prescriptions for CGMs, and more patients are finding out about them," a CDE said. As in July, sources said CGM technology advances, including improved glycemic control, insulin pump compatibility and ease of use, are still driving 2021 growth estimates. "CGMs have made it easier for us to practice medicine. Data from the patient's CGM can be shared with us through the cloud, and we can now make educated decisions about treatment. Patients are better controlled with CGMs. We have seen huge improvements and continue to offer these options to patients," an endocrinologist said.

In addition, sources said CGM companies' direct-to-consumer marketing (through social media and television) continue to support 2021 growth estimates, especially marketing from **Dexcom Inc.** and **Abbott Laboratories**. "CGM advertisements are blowing up the internet," a CDE said. Another said, "You hear about patients who see CGMs on television, and they know other patients who have a CGM. The word is getting out more. [Patients] hear they don't have to stick to their finger, which really appeals to them."

2021 GM Start YY Forecast During Past 90 Days
(number of sources)

Improved	**5**
Remained the same	**16**
Worsened	**1**

Loosening CMS Criteria Aiding Type-2 Market

Sources were also optimistic about the recent changes to the Centers for Medicare and Medicaid Services' (CMS's) coverage criteria. These changes, which went into effect July 18, eliminate the requirement patients need to perform and document at least four self-monitoring blood glucose (SMBG) tests daily, and builds on CMS's earlier pandemic-related decision to loosen documentation requirements of SMBG testing. Sources expect this latest change to further benefit patients in

the large, relatively untapped type-2 market, who may have not been documenting their testing as regularly or may not be injecting four or more times a day, or both. "The CMS changes do not require documentation of the frequency of testing anymore. This was loosened last year because of the pandemic, but now it has been adjusted in the coverage criteria. This will help to get more patients on CGMs, especially type-2 patients who've had a harder time keeping insulin dosing logs," an endocrinologist said. Another said, "Patients do not have to document four fingersticks per day, which has made it easier to get patients covered on CGMs. Patients no longer have to keep logs, which was an issue because if they missed on log entry, it could throw off coverage."

Sources said positive insurance coverage changes, as well as growing public awareness, have helped CGM trends among type-1 and type-2 diabetes patients. Sources said CGMs are being utilized in an average 18%–21% of their type-2 patients (compared with 20%–23% in July) and 39%–42% of their type-1 patients (compared with 40%–43% in July).

Nevertheless, the process for obtaining insurance coverage from CMS as well as private payers remains time-consuming and cumbersome. "Insurance coverage keeps improving, but it is still a lengthy process. There is documentation that is required, and the right terminology has to be used in order to get it covered, otherwise, the process can get drawn out," an endocrinologist said.

> "I am seeing more patients getting started on Dexcom's G6. More and more patients are getting covered at the pharmacy rather than having to go through DME [durable medical equipment]. This has made the process better and more accessible to patients."
>
> *CDE*

Dexcom Momentum Continues

As in July, sources prescribed Dexcom CGMs most often to their type-1 patients who started a CGM during the past 90 days (58%–63% on average) and second most often to their type-2 patients who started a CGM (30%–35% on average). In addition, 14 of 22 sources said Dexcom gained share within their practices during 3Q21 (mainly from **Medtronic PLC**), similar to OTR Global's findings during the past three years. "Most of my patients using Dexcom's G6 are insulin pump candidates, but I do have some non-pump users, both type-1 and type-2 patients, who are now using the G6. The insurance coverage has improved, and we are seeing more patients opting for the G6," a CDE said. Another said, "I am starting a good number of my type-2 diabetes patients on Dexcom. Nearly all are using insulin. I haven't really started anyone who is not on insulin."

Fifteen of 22 sources also expect Dexcom to gain share during 4Q21 because of increased awareness of the benefits of CGMs, favorable insurance coverage and high satisfaction with the G6. "Patients usually choose Dexcom for the continuous knowledge of blood sugar every five minutes," a CDE said. Another said, "We have been very satisfied with the G6. Patients find it easy to get used to, and it really helps them get better control of the blood sugar levels." In addition, the G6's compatibility with **Tandem Diabetes Care Inc.**'s t:slim X2 insulin pump (as part of the Control-IQ hybrid closed-loop system) continues to drive adoption. "Control-IQ is just a wonderful system. Patients can place the G6 and t:slim anywhere on their body, and parents or caregivers can remotely monitor the patient, too," a CDE said.

Sources said the Dexcom has benefited from the elimination of the SMBG test requirements changes because its CGMs are covered by Medicare, while Medtronic's are not because of a different FDA label. Furthermore, Dexcom's G6 also continues to benefit from commercial insurance categorization through pharmacy benefit. "I am seeing more patients getting started on Dexcom's G6. More and more patients are getting covered at the pharmacy rather than having to go through DME [durable medical equipment]. This has made the process better and more accessible to patients," a CDE said. One source said Dexcom has contracted a third-party company to assist endocrinology practices with the insurance documentation and sorting out whether patients can be covered under

pharmacy benefit. "Basically, I send the company the patient's paperwork, and they determine if it goes through the pharmacy or DME channel, which has made the process so much better. I have even resubmitted some of our patients who wanted a CGM but got lost in the process along the way. It started this summer," the CDE said.

As noted in July, Dexcom's frequent use of free G6 samples as well as direct-to-consumer advertising campaigns continue to help expand Dexcom's presence in the type-2 diabetes market, especially when the insurance coverage process is difficult. "We have samples of the G6. We actually have more samples of the G6 right now than [Abbott's] Libre," a CDE said.

Abbott Still Leading in Type-2 Market

Sources prescribed Abbott's Libre CGMs to an average 64%–69% of their type-2 patients who started a CGM during the past 90 days. Fifteen of 22 sources said Abbott gained share during 3Q21, similar to OTR Global's 2Q21 findings. Sources expect Abbott to continue to gain share during 4Q21, mainly within the growing type-2 CGM market, because of Abbott CGMs' low-cost, easy-to-use arm application and factory calibration, which eliminates the need for fingersticks. "We like Libre because it is simple and easy to use," a CDE said. Another said, "Even if the Libre is not covered by insurance, patients can go to the pharmacy and pay out of pocket for the prescription because it is low cost."

In addition, direct-to-consumer advertising and free samples continue to support Abbott adoption within the type-2 market. "Abbott increased the number of samples a provider can have per year. They are now giving me 160 samples, where they were giving me 100 samples before. It helps to get patients started on the Libre, and most patients fill the prescription when the samples run out," an endocrinologist said. A CDE said, "Abbott has been extremely generous with samples. I slap the Libre on a patient's arm and they can walk out of the office with it. Most patients can get it covered once the samples run out and others actually pay out of pocket for it because they fall in love with it. This is a great device for understanding blood sugar levels."

As in July, sources said Abbott is also helped by favorable insurance categorization, CMS's elimination of SMBG testing requirement and pharmacy availability. "The Libre is on fire; it is really going well. Any patient with Medicare who is on basal and bolus insulin can get it covered. Patients with commercial insurance, if on insulin, can usually get it covered," a CDE said. As in July, several sources said expansion of the type-2 diabetes market is likely to offset any gains the Libre 2 makes against Dexcom.

Abbott's inroads into the type-1 market have been less extensive than in the type-2 market, despite the availability of Abbott's Libre 2 CGM (FDA approved June 2020), which features real-time alarms for hypo- and hyperglycemia, the ability to transmit data every minute and improved accuracy. Sources prescribed Abbott CGMs to an average 33%–38% of their type-1 patients who started a CGM during the past 90 days and reiterated the Libre 2's lack of insulin pump integration is the key hurdle to wider adoption. "We use the Libre among type-1 patients, but they are mainly those who do not want to use a pump. The issue with the Libre is that it is not compatible with any available insulin pumps," a CDE said.

Abbott has cleared a different hurdle, however. In early August, the FDA approved the Libre 2 iOS App for iPhone smartphone compatibility, which had also been hindering adoption, especially in the type-1 market. "Abbott has launched the smartphone application for the iPhone, and the Android application is supposed get approved and launched any time. This was an issue that held patients back from [adopting] the Libre 2," a CDE said.

Medtronic Still Struggling

Medtronic lost share during 3Q21 for nine of 14 sources who use Medtronic's Guardian Sensor 3 CGM (similar to 2Q21) and is expected to continue to lose share during 4Q21. In addition, eight of 22 sources are not recommending the Guardian Sensor 3 to patients at all. Sources said the main challenges remain the lack of factory calibration, problems with accuracy and the lack of Medicare coverage. "I am not prescribing Medtronic's Guardian Sensor 3 as a standalone CGM without being part of the MiniMed system. It is just cumbersome and requires fingerstick calibration," an endocrinologist said. A CDE said, "Most of our patients don't like Medtronic because no one wants to poke their fingers."

As in July, sources said Medtronic continued to lose share despite the recent launch of its MiniMed 770G hybrid closed-loop system and upcoming developmental MiniMed 780G hybrid closed-loop system, which both rely on the Guardian Sensor 3 CGM. "If Medtronic can't improve their CGM, they are going to continue to struggle," an endocrinologist said.

> "If Medtronic can't improve their CGM, they are going to continue to struggle."
>
> *Endocrinologist*

GM Competition Expected to Accelerate

Sources welcome upcoming CGMs from Abbott and Dexcom, which are expected to be approved during the next six to 12 months, but they are not hesitating in prescribing currently available CGMs in the meantime. Sources are optimistic about Dexcom and **Insulet Corp.**'s hybrid closed-loop system, Omnipod 5, which is expected to receive FDA approval during 4Q21 (originally anticipated during 1H21 but delayed because of pandemic-related FDA bottlenecks). "I believe it will help Dexcom because now they will have two hybrid closed-loop systems compatible with their CGM," an endocrinologist said.

In addition, Dexcom is developing its next-generation G7 CGM, which is expected to launch during late 2021 or early 2022 and promises to be smaller than Dexcom's G6 model, lower cost and disposable. "When the G7 is approved, we are going to see an explosion in use. The small size and low cost combined with the improvements in insurance coverage will be a big plus for type-2 patients, which is really a huge market. Fifty percent of type-2 patients at some point in their lives will need insulin, so Dexcom has a big opportunity," an endocrinologist said.

Abbott is also developing a hybrid closed-loop system with Tandem's t:slim insulin pump, but the timing of approval remains unclear. In addition, the company's FreeStyle Libre 3 system (already CE marked in Europe) is awaiting FDA approval, and is expected to be smaller than the Libre 2, allow for 14-day wear as with Libre 2 and offer smartphone compatibility. "Future versions of the Libre, including Libre 3, will be even smaller, easy to use and more accurate. It will be a no-brainer," an endocrinologist said.

Meanwhile, sources are less enthusiastic about the upcoming CGM from Medtronic because of problems with Medtronic's current CGM and little information available about the developmental technology, which promises to be compatible with the company's insulin pumps and is expected to reduce or eliminate fingerstick calibrations. (Dexcom and Abbott have already eliminated fingerstick calibrations).

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ON CGM STARTS

"We are seeing dramatic improvements in blood glucose levels with CGMs because patients can see how food affects their levels and can modify their lifestyles. They can check throughout the day without fingersticks." *CDE*

"Doctors know more [about CGMs], and when they see a patient, they're like, 'Oh you don't have a sensor. You should have one!' Everyone is saying 'Hey I got it!' So then you have others who are like, 'can I get one too?'" *CDE*

"Patients are coming in asking for CGMs. They see them on the television or while they are scrolling on social media. We want to provide them because they provide us with a lot of information about patient's blood sugar levels throughout the day and help us to better manage patients with adjustments to medication and other lifestyle changes." *Endocrinologist*

"The number of type-2 patients I am prescribing CGMs to continues to increase because of the easing of insurance coverage requirements. Now patients do not have to document their daily insulin injections, which can be cumbersome and patients are not always good at it." *Endocrinologist*

"Patients are sick of the pandemic and are coming into the office." *CDE*

ON CGM MANUFACTURERS

"For our type-1 patients, we are mostly starting Dexcom because the patient has the option for a pump if they are not already on one." *CDE*

"Dexcom is the patient preference for our pediatric population. Parents need the alarms, and they download the application. They constantly check blood sugar." *CDE*

"Dexcom is our No. 1 CGM. We have samples, and parents feel safe having their children in school with Dexcom. I manage all CGMs, and Dexcom has the best CGM." *CDE*

"Type-2 diabetes patients typically go with the Libre, especially if they aren't meeting the insurance requirements. Abbott is better covered [for type-2 patients] and easier to pay for out of pocket." *CDE*

"The commercials for Libre are out there, and I think it is helping drive the use of Libre." *CDE*

"The Libre 2 received smartphone application approval. They have launched it with the iPhone, but it would help if they got [an] Android application launched." *Endocrinologist*

"We are not starting patients on Medtronic's CGM unless they are using the pump as part of the MiniMed system, but that is really rare anyway." *CDE*

"I have never seen a Medtronic [CGM] used without a Medtronic pump. Poor Medtronic." *CDE*

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1. Approximately how many diabetes patients (type-1 and type-2) do you have under your care?

More than 5,000:	1
3,751-4,000:	1
1,751–2,000:	1
1,251–1,500:	2
1,001-1,250:	1
751–1,000:	1
501–750:	3
251–500:	10
0–250:	2
Total:	**29,659**

2. Approximately what percentage of your patients are type-1 and type-2?

	TYPE-1	TYPE-2
91%–100%:	-	5
81%–90%:	1	4
71%–80%:	3	5
61%–70%:	-	1
51%–60%:	-	2
41%–50%:	1	-
31%–40%:	1	-
26%–30%:	1	-
21%–25%:	2	1
16%–20%:	3	2
11%–15%:	1	-
6%–10%:	3	1
1%–5%:	5	-
No response:	1	1
Weighted average:	**19%–24%**	**76%–81%**

3. What factors are affecting demand for CGMs?

POSITIVE

Improved glycemic control:	20
Compatibility with pump:	13
Advertising:	11
New technology:	11
Patient/provider awareness:	10
Accuracy:	9
Ease of use:	9
Reimbursement:	5
Sampling:	3

NEGATIVE

Cost:	16
Reimbursement:	13
Pandemic:	3
None:	3

Note: Some sources gave more than one answer.

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4. What percentage of your type-1 and type-2 patients are using a CGM?

	TYPE-1	TYPE-2
91%–100%:	2	1
81%–90%:	2	-
71%–80%:	7	-
61%–70%:	2	-
41%–50%:	2	4
31%–40%:	3	-
21%–25%:	-	5
11%–15%:	-	4
6%–10%:	2	4
1%–5%:	-	1
Don't know:	2	3
Weighted average:	**39%–42%**	**18%–21%**
July average:	**40%–43%**	**20%–23%**

5. Did the pandemic have a positive, negative or no impact on your 3Q21 CGM starts?

Positive impact:	-
No impact:	19
Minor negative impact:	2
Moderate negative impact:	1

6. Has insurance coverage/reimbursement for CGMs improved remained the same or worsened during the past 90 days?

Improved:	5
Remained the same:	17
Worsened:	-

7. Did the number of patients starting a CGM during 3Q21 increase, remain the same or decrease qq?

Up 21%–25%:	3
Up 6%–10%:	4
Up 1%–5%:	4
Up:	2
Flat:	8
Down 11%–15%:	1
Weighted average:	**Up 2%–5%**
2Q21 average:	**Up 12%–15%**

8. Did your 3Q21 GM starts exceed, meet or fall below your expectations?

Exceeded:	3
Met:	17
Fell below:	2
OTR Comparative Index:	**5**
July Index:	**17**

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9a. Do you expect your 2021 GM starts to increase, remain the same or decrease yy?

Up 41%–50%:	2
Up 31%–40%:	1
Up 26%–30%:	1
Up 21%–25%:	4
Up 16%–20%:	4
Up 11%–15%:	4
Up 6%–10%:	4
Up:	1
Flat:	1
Down:	-
Weighted average:	**Up 21%–24%**
July average:	**Up 20%–23%**

9b. Has your 2021 forecast improved, remained the same or worsened during the past 90 days?

Improved:	5
Remained the same:	16
Worsened:	1

10. Which vendors' CGMs is your practice prescribing/recommending to patients?

Abbott:	22
Dexcom:	21
Medtronic:	14

Note: Some sources gave more than one answer.

11. What are the most important factors when prescribing or recommending a particular CGM to your patients?

Calibration:	15
Compatibility with pump:	15
Ease of use:	13
Insurance coverage/reimbursement:	10
Cost:	8
Accuracy:	7
Glycemic control:	7
Remote monitoring:	7
Alarms:	5
Patient preference:	4
Brand recognition/advertising:	2
Comfort:	2
Sales representation:	2
Other:	3

Note: Some sources gave more than one answer.

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12a. What percentage of your type-1 diabetes who started a CGM during the past 90 days were prescribed Dexcom, Medtronic and Abbott?

	DEXCOM	MEDTRONIC	ABBOTT
91%–100%:	1	-	1
81%–90%:	1	-	-
71%–80%:	4	-	-
61%–70%:	2	-	-
51%–60%:	4	1	-
41%–50%:	6	1	6
31%–40%:	1	-	4
26%–30%:	-	-	1
21%–25%:	-	1	3
16%–20%:	1	-	2
6%–10%:	-	2	2
1%–5%:	-	2	2
0%:	1	14	-
Don't know:	1	1	1
Weighted average:	**58%–63%**	**1%–6%**	**33%–38%**

12b. What percentage of your type-2 diabetes starting a CGM during the past 90 days were prescribed Dexcom, Medtronic and Abbott?

91%–100%:	-	-	3
81%–90%:	1	-	2
71%–80%:	-	-	5
61%–70%:	1	-	4
51%–60%:	-	-	2
41%–50%:	5	-	4
31%–40%:	3	-	-
26%–30%:	2	-	-
21%–25%:	4	1	-
16%–20%:	1	-	-
11%-15%:	1	-	-
6%–10%:	1	-	1
1%–5%:	1	2	1
0%:	2	19	-
Weighted average:	**30%–35%**	**0%–3%**	**64%–69%**

13. Which CGM vendors gained or lost share within in your practice during 3Q21?

	GAINED	LOST
Abbott:	15	1
Dexcom:	14	2
Medtronic:	2	9
None:	5	11

Note: Some sources gave more than one answer.

14. Which CGM vendors do you expect to gain or lose share within in your practice during 4Q21?

	GAIN	LOSE
Abbott:	15	1
Dexcom:	15	1
Medtronic:	2	9
None:	4	11
Don't know:	1	1

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Additional information available upon request.