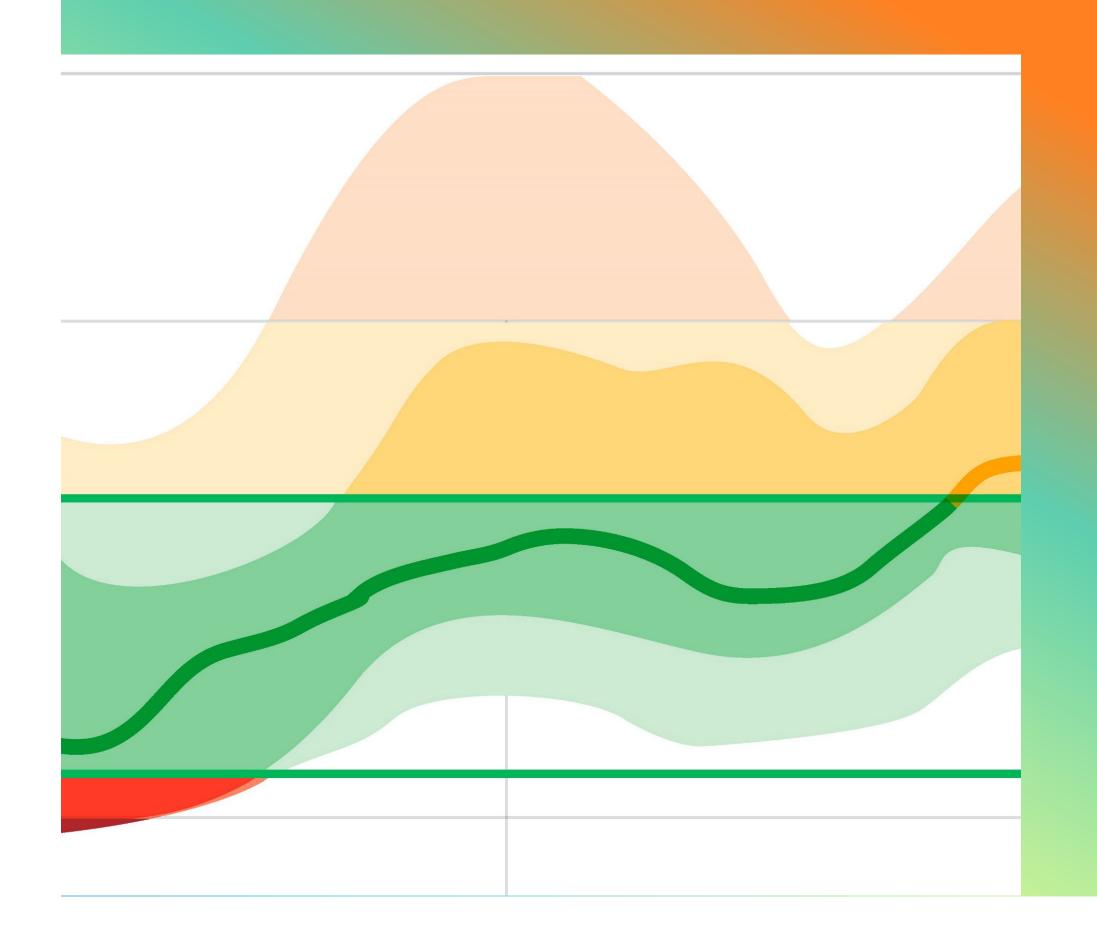
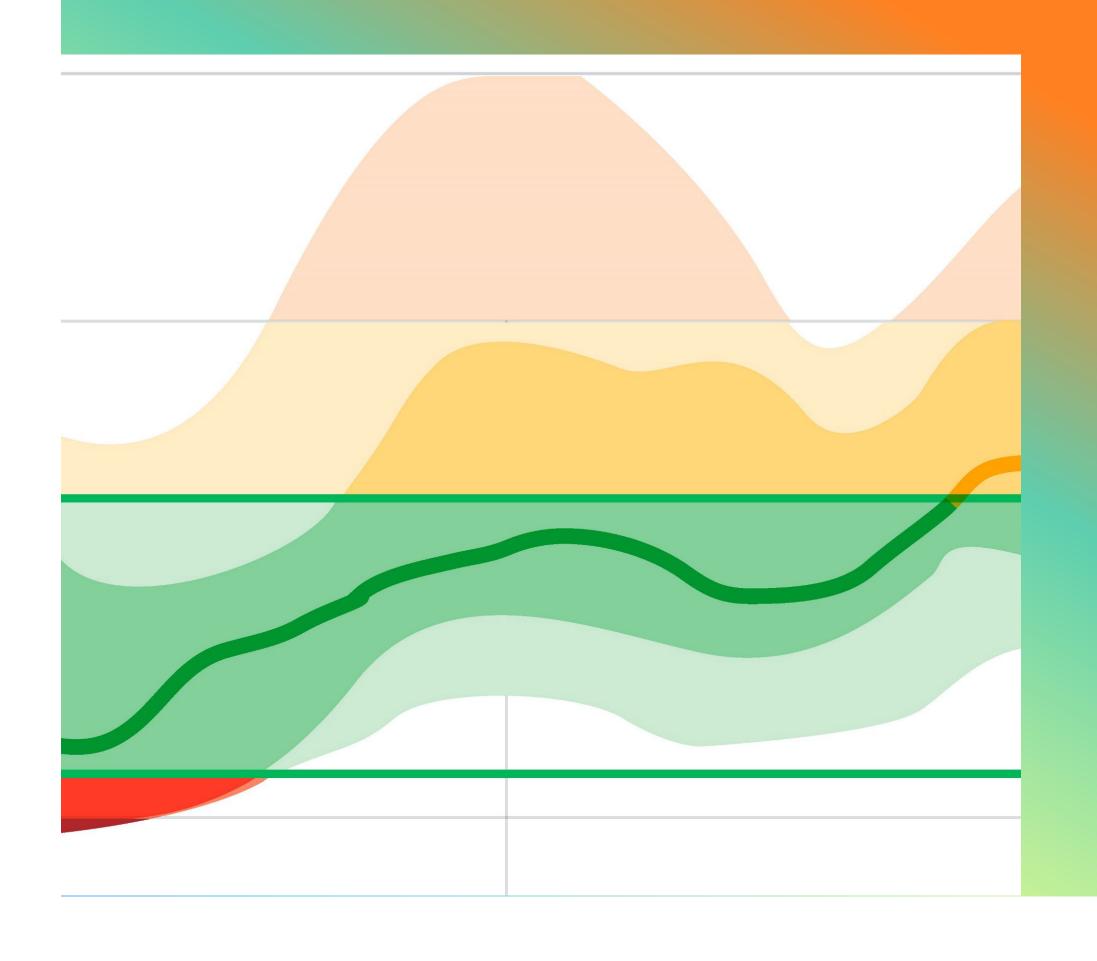
Using **Continuous Glucose** Monitoring and the **Ambulatory Glucose Profile** for Clinical Decision-Making in Primary Care



Using **Continuous Glucose** Monitoring and the **Ambulatory Glucose Profile** for Clinical Decision-Making in Primary Care

Introduction



Shouldn't every patient with diabetes have a CGM?

- + Every person with diabetes could benefit from the information offered by real time CGM as well as the data provided by the compiled Ambulatory Glucose Profile (AGP) report, but there are some patients who benefit MORE, and who are likely to have insurance coverage.
 - Patients on insulin, particularly multiple daily injections, or those using an insulin pump
 - ❖ Patients with "problematic" hypoglycemia (On October 6, 2022, The Centers for Medicaid and Medicare Services (CMS) published a proposed local coverage determination (LCD) that modifies the coverage criteria for continuous glucose monitors (CGM) to include people with diabetes who have a history of problematic hypoglycemia.) ICD-10-CM Diagnosis Code E16.2
 - Patients with co-morbid conditions, who struggle with glycemic control

Every year, coverage is expanding as CGM becomes more and more the standard of care for patients with diabetes.

More of your patients qualify under Medicare

- + As of April 16, patients with diabetes qualify for Medicare coverage if...insulin treated or with a history of problematic hypoglycemia with documentation of either
 - •Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
 - •A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

FDA-Approved Personal CGM Devices

	Abbott FreeStyle Libre 14-day/2/3	Dexcom G6 G7 approved by FDA 12/8	Medtronic Guardian Sensor 3 (pump integrated) and Guardian Connect (stand-alone)	Senseonics Eversense
Approved labeling	Replaces fingersticks for treatment decisions; no fingerstick calibration required	Replaces fingersticks for treatment decisions; no fingerstick calibration required	Requires ≥2 fingerstick calibrations/d	Replaces fingersticks for treatment decisions; requires ≥2 fingerstick calibrations/d
Age	≥18 y/≥2 y/≥2 y	≥2 y	≥14y	≥18 y
Medicare coverage	Yes/Yes/Not Yet	Yes	Sensor 3: Yes; Connect: No	Yes
Wear length	14 d/2 & 3 up to 15 ds	10 d/10 d + 12 hr	7 d	90/180 d
Warm-up	1 hr	2 hr/up to 30 min	2 hr	24 hours after implementation
Alarms	No/Yes/Yes	Yes	Yes	Yes
Data Display/ Integration	Reader; Android and iPhone apps; 2 & 3 approved for integration with automatic insulin delivery systems.	Reader; Android and iPhone apps; smartwatches; Tandem t:slim X2 pump, Omnipod 5.	Reader; Android and iPhone apps; 630G, 670G or 770G pump; Guardian Connect	Android and iPhone apps
Form	Disposable transmitter integrated with sensor patch	G6: Transmitter (3-month use) separate from sensor/G7 integrated	Transmitter (rechargeable) separate from sensor	Transmitter (rechargeable) separate from sensor
Accuracy* (lower numbers are more accurate)	11.4%/9.3%/7.9% ¹	9%/8.2% ¹	9.6%/9-11% ¹	8.5%-9.5% ¹
Expense ²	Least expensive	2 nd most expense	2 nd least expensive	Most expensive

^{*}Accuracy measured by MARD (mean absolute relative difference) relative to **YENOUS** glucose. Lower numbers indicate a more accurate device.

¹Accuracy figures provided by manufacturers.

²What is a CGM and how do I choose one? Healthline Diabetes Mine. Updated December 14, 2021. Accessed February 12, 2023. https://www.healthline.com/diabetesmine/ what-is-continuous-glucose-monitor-and-choosing-one

Which CGM is best for the person?

Professional CGM

- Device owned by the healthcare professional and loaned to the patient
- Approved for multiple use when cleaned and used according to labeling (disposable systems also available)
- + Collects real time glucose data (data can be displayed to patient in unblinded mode)
- Worn for varying lengths depending on model, then data can be downloaded for retrospective review

Personal CGM

- + Patient-owned device that can be used on a daily basis
- + Can be stand-alone or linked to other compatible devices
- + Glucose values are visible and actionable
- + Sensor worn for 7, 10, 14 days or 180 days for implanted device

Professional CGM¹

	Abbott FreeStyle Libre PRO	Dexcom G6 Pro (expected G7 in 2023)	Medtronic iPro 2*
Blinded or unblinded	Blinded	Either	Blinded
Wear Time	14 days	10 days	6 days
Calibration?	0	0	3-4 times daily
Care between use	Disposable sensor/transmitter	Disposable sensor/transmitter	Sensor must be cleaned and disinfected
Insertion	Single-step process with auto-inserter	Two-step process which includes inserting sensor and attaching transmitter	Multi-step process which includes inserting and taping both the sensor and transmitter.
Site	Upper Arm	Abdomen	Abdomen
Downloading/ Data Reports	LibreView (download in office)	Blinded: Clarity (download in office) Unblinded: reader/apps	Carelink (download in office)

May be covered by insurance intermittently, multiple times per year, even when personal CGM is not covered.

With professional CGM, there is no need or very limited need for insurance authorization.²

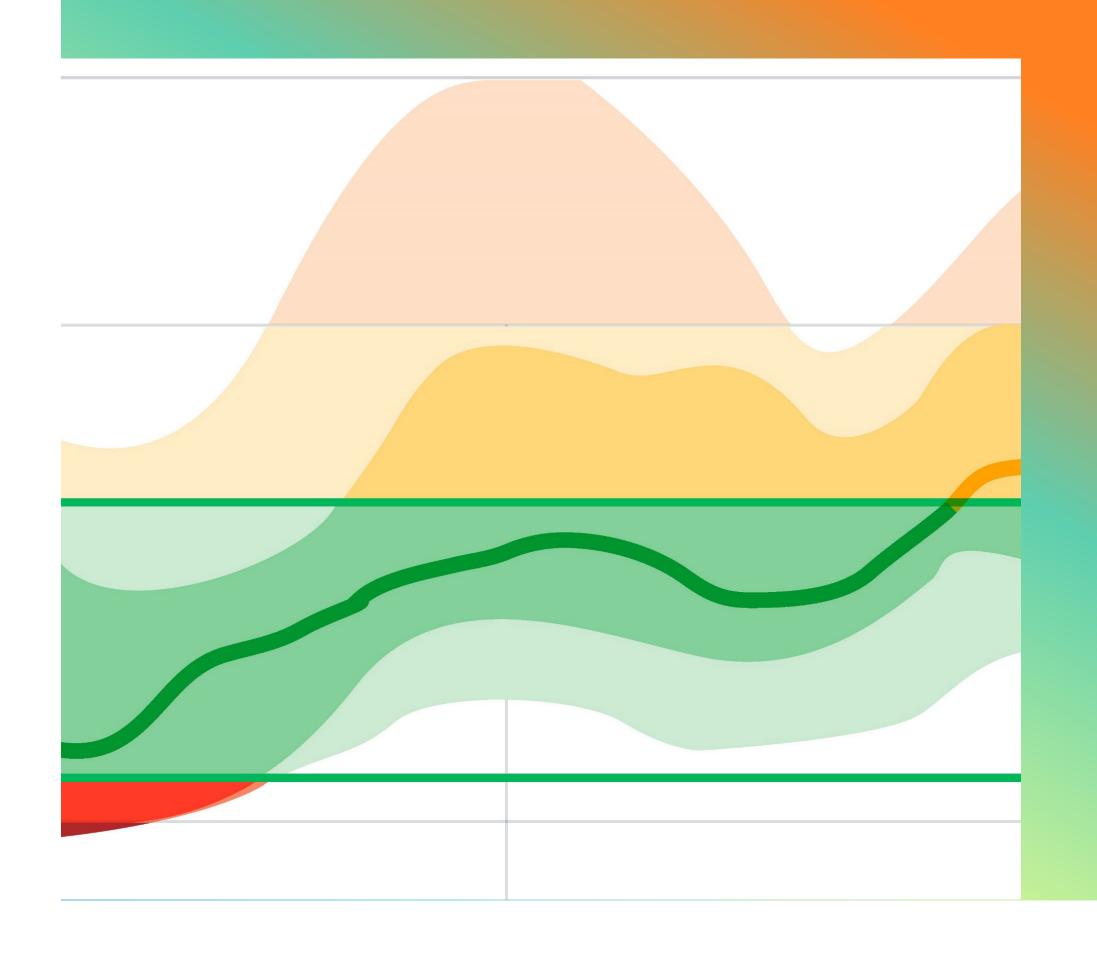
While information on the Medtronic system is still available online, it does not appear to be available for acquisition at this time.

¹Professional Glucose Monitoring Implementation Handbook. Association of Diabetes Care & Education Specialists and the American Association of Nurse Practitioners (https://www.diabeteseducator.org/practice/practice-tools/app-resources/professional-cgm-play.

²CGM. AAFP website. https://www.aafp.org/family-physician/patient-care/care-resources/continuous-glucose-monitoring.html. Accessed 11/30/2022.

Using Continuous Glucose Monitoring and the **Ambulatory Glucose Profile** for Clinical Decision-Making in Primary Care

Accessing and Reviewing CGM Data



The Ambulatory Glucose Profile (AGP)

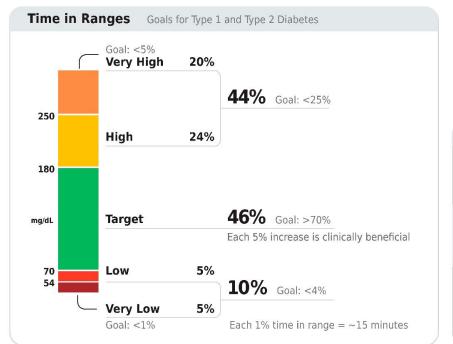
1

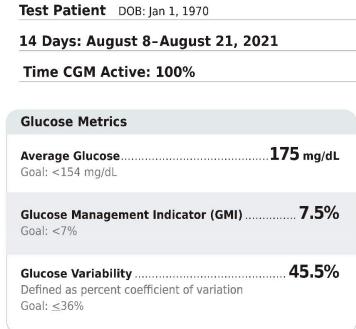
Metrics, Values, Goals
Summary of values to help assess the overall quality of glucose management

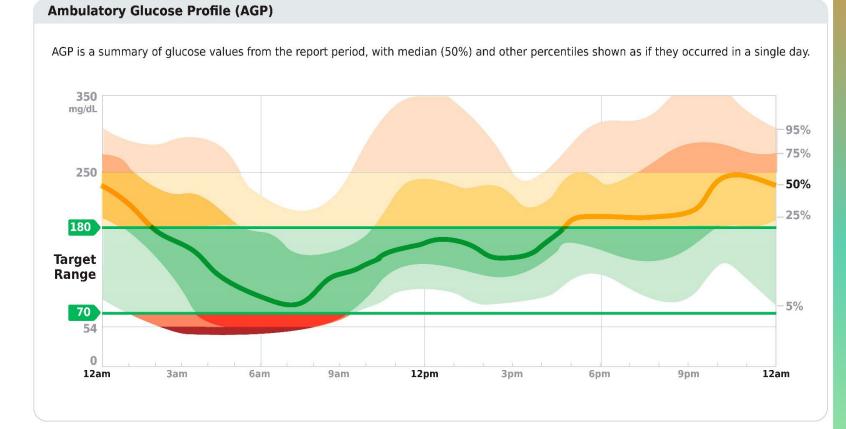
2 AGP Profile
Shows all values as if collected over a single 24-hour period. Shows variability in the mean glucose and patterned areas of highs and lows.

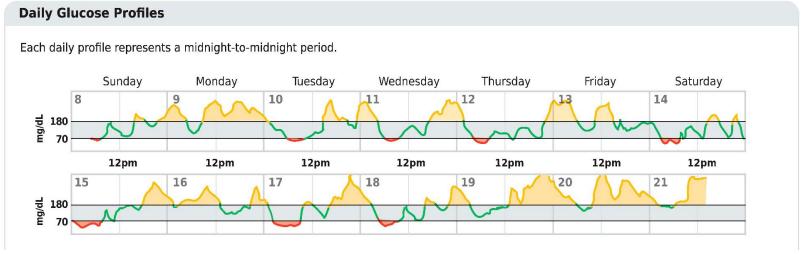
Daily Views
Shows daily values - helpful in determining causes of patterns or exceptions to usual patterns.

Standards of Medical Care in Diabetes - 2023 Abridged for Primary Care Providers. American Diabetes Association website. Figure 6.1, page 9. Reprinted with permission of the American Diabetes Association, Inc. Copyright 2022.









GMI vs A1c

- + The A1c measures the glycated form of hemoglobin to obtain the three-month average of blood sugar.
- + The GMI indicates what your patient's A1c IS LIKELY TO BE IF your patient continues the behavior demonstrated in the AGP for a period of 90 days.

Freestyle Libre 14-day/2/3

+ Libre 14 days (LibreLink) and Libre 2/3 sensor phone-based apps IOS/Android

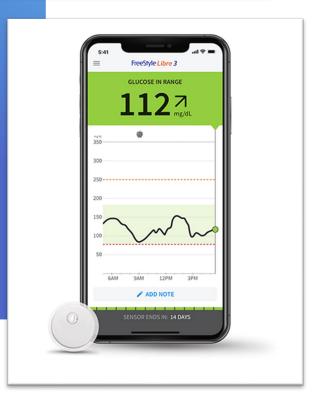


+ *Linkup* for family/friends

- Libre View for download reports Libre 14 day and Libre 2/3



Libre Link Libre LinkUp



The latest Libre View offers the GLUCOSE PATTERN INSIGHTS REPORT (GPI), designed to help you identify and treat trouble spots in the AGP.



Dexcom G6/G7

- + Dexcom iOS and Android apps for data
 - + Share for family/friends
 - + Clarity for download reports











Medtronic Guardian

+ Phone based data apps

+ Guardian System with <u>Connect</u> for family/friends and <u>Carelink</u>

software for downloading reports



Upload to CarelinkTM
Software



Senseonics Eversense

- + Eversense Mobile App iOS and Android
- + Download user data at https://pro.eversensedms.com







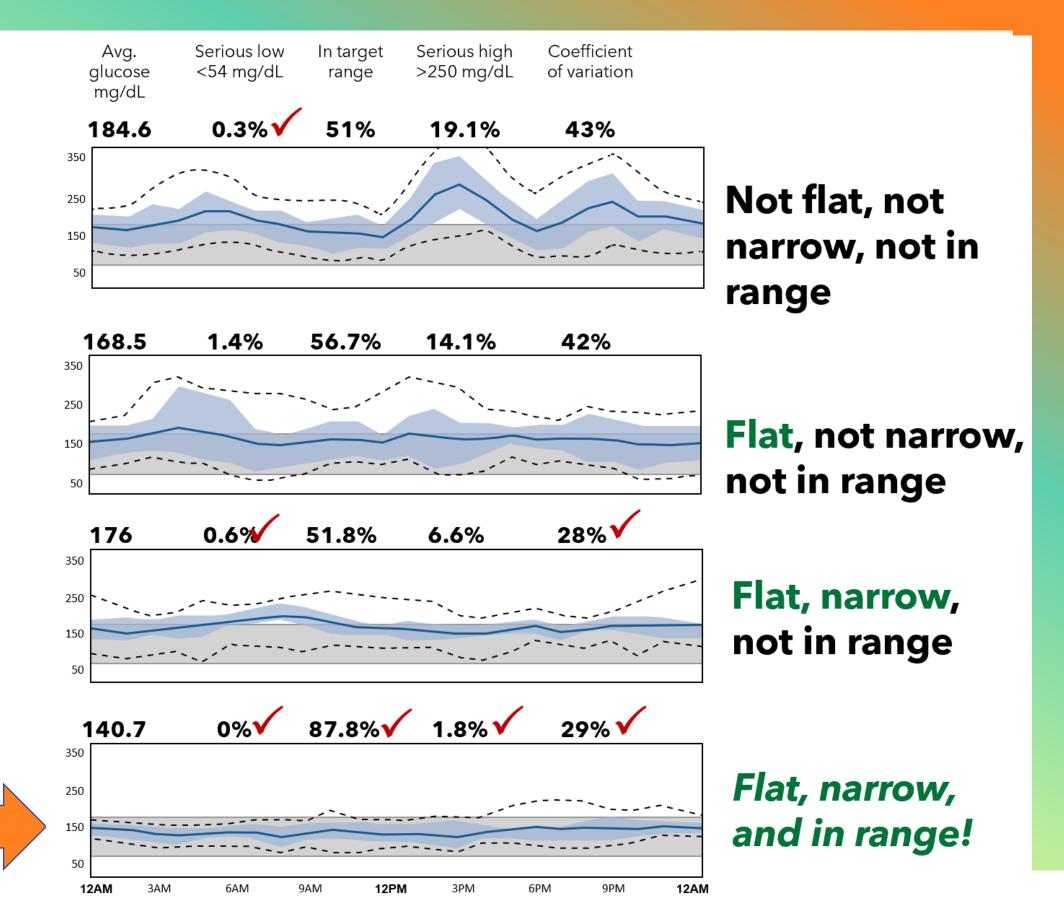


The Ideal Ambulatory Glucose Profile

Desired Targets*¹

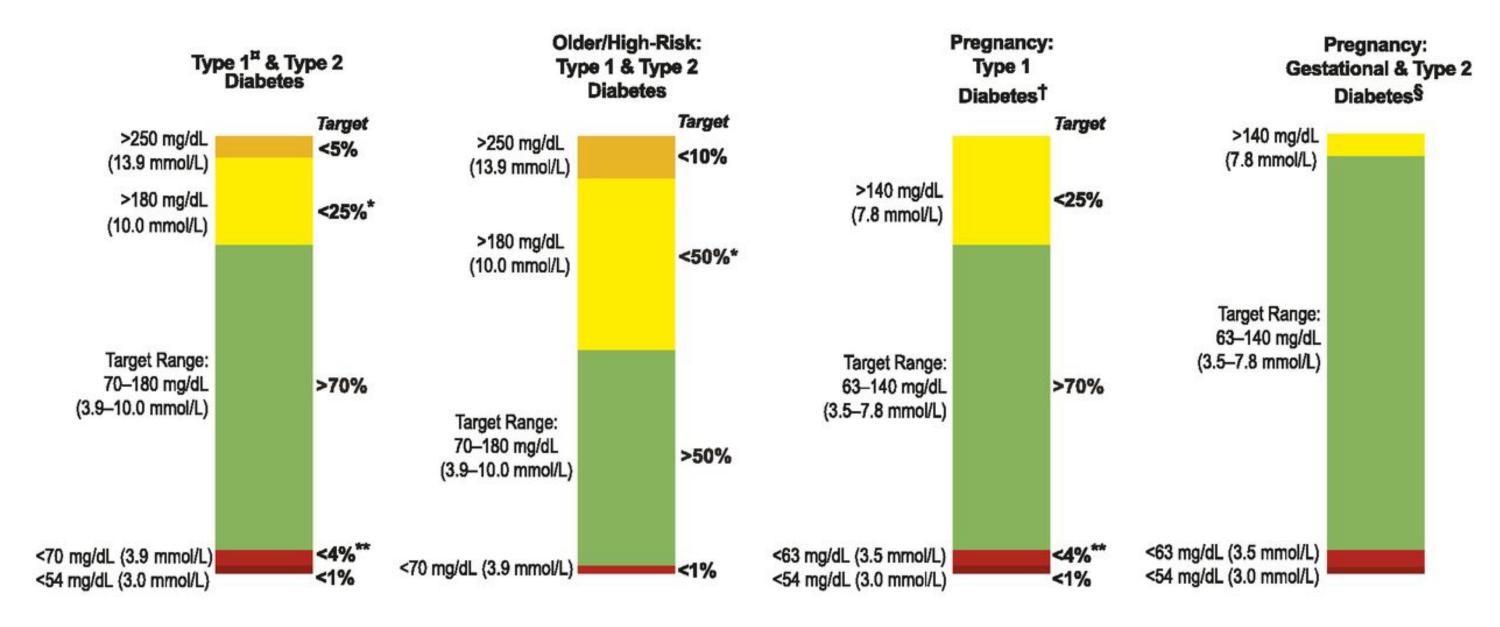
- + Time in range (TIR) (70-180 mg/dL): >70%
- + Time below range (TBR):
 - <70 mg/dL: <4%
 - <54 mg/dL: <1%
- + Time above range (TAR):
 - >180 mg/dL: <25%
 - >250 mg/dL: <5%
- + Coefficient of variation (glucose variability): <36%

*For most adults with T1DM or T2DM and age 25-65 y



- 1. Battelino T, et al. *Diabetes Care*. 2019;42:1593-1603.
- 2. With permission of Richard Bergenstal, MD, International Diabetes Center

Not all patients have the same TIR goals



[¤] For age <25 yr., if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See Clinical Applications of Time in Ranges section in the text for additional information regarding target goal setting in pediatric management.)

[†] Percentages of time in ranges are based on limited evidence. More research is needed.

[§] Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see *Pregnancy* section in text for more considerations on targets for these groups.

^{*} Includes percentage of values >250 mg/dL (13.9 mmol/L).

^{**} Includes percentage of values <54 mg/dL (3.0 mmol/L).

Steps to Interpret the AGP

- Check for adequate data.
 Mark up the AGP, noting factors affecting management.
 Ask the patient "What do you see?" Listen.
 - Look for patterns of low blood glucose levels.
 - Look for patterns of high blood glucose levels.
 - Look for areas of wide glucose variability.
 - Compare to past AGP and reinforce successful strategies.
 - Agree on an action plan with the patient.

The Ambulatory Glucose Profile (AGP)



- Mark up the AGP, noting factors affecting management.
- Ask the patient "What do you see?" Listen.
- Look for patterns of low blood glucose levels.
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- Look for areas of wide glucose variability.
- Compare to past AGP and reinforce successful strategies.
- Agree on an action plan with the patient.

Used with permission of Richard Bergenstal, MD, International Diabetes Center

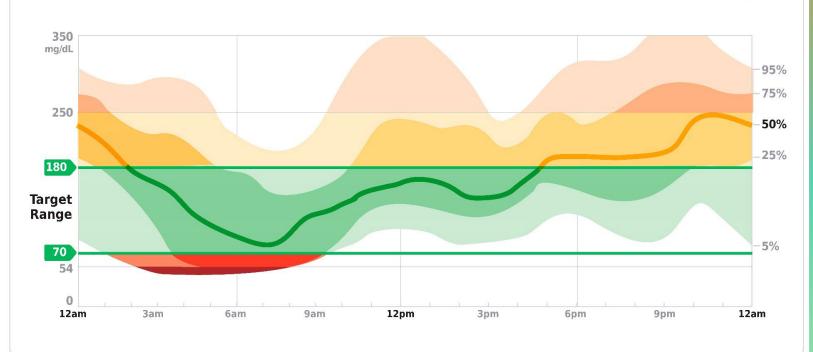
Standards of Medical Care in Diabetes - 2023 Abridged for Primary Care Providers. American Diabetes Association website. Figure 6.1, page 9. Reprinted with permission of the American Diabetes Association, Inc. Copyright 2022.





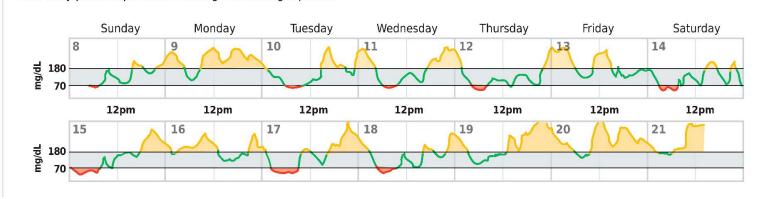
Ambulatory Glucose Profile (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if they occurred in a single day



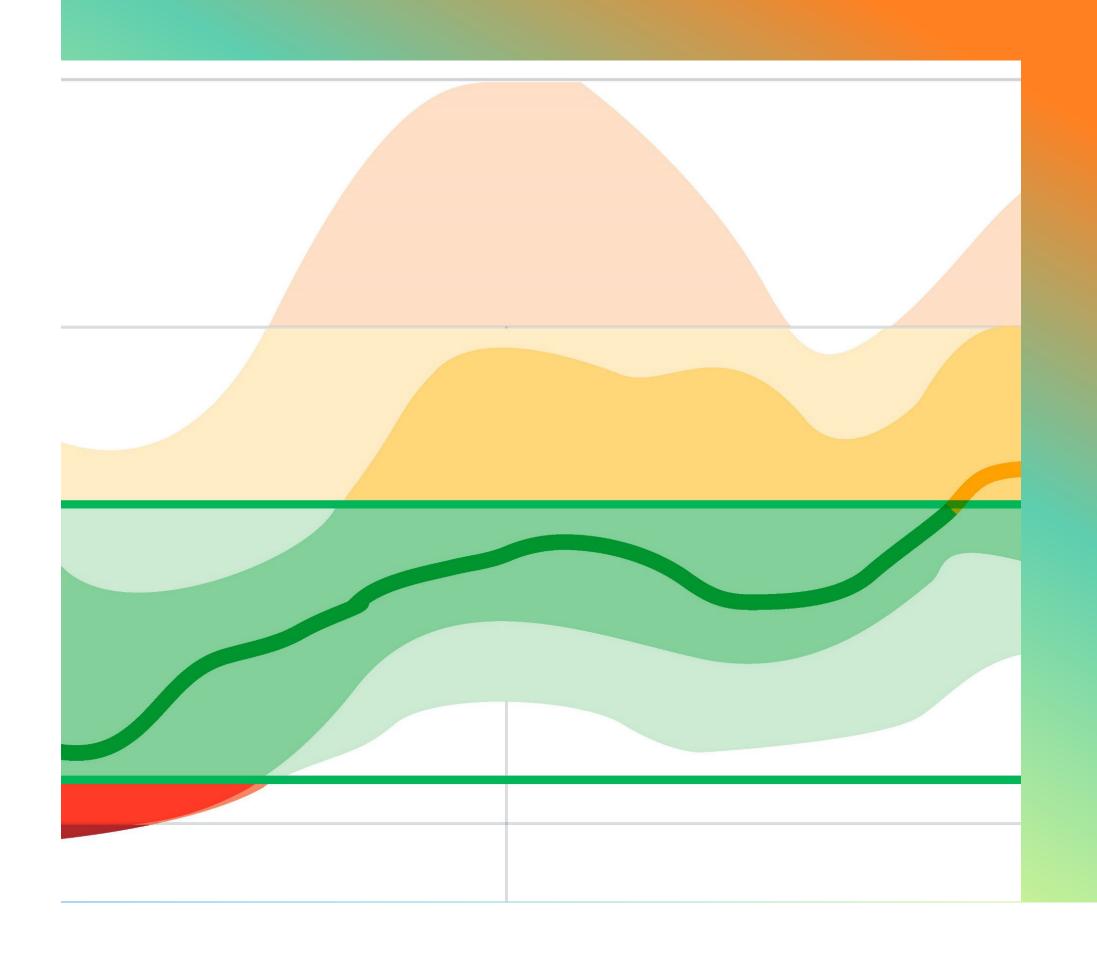


Each daily profile represents a midnight-to-midnight period.



Using Continuous Glucose Monitoring and the **Ambulatory Glucose Profile** for Clinical Decision-Making in Primary Care

The AGP in Clinical Decision-Making



Case Study One

Patient Current Medical History

- + No insurance coverage for CGM
- + 62 year old white woman
- + Type 2 diabetes 22 years
- + Hypertension, Elevated lipids, CKD
- + Fingerstick Data: Reports FBS 140-160 range, Bed Bg 180 range, no data brought to clinic, no meter to upload, not sure what is happening before meals to guide insulin
- + Hypoglycemia: denies
- + A1c: 8.4 %

Current Medications (with comments)

- + Basal Insulin 42 units 9 PM
- + Meal time insulin:
 Prescribed based on BG
 and Carbohydrate intake,
 (unsure if being taken)
- + SGLT-2 inhibitor
- + Metformin XR 1000 M daily
- + Does not tolerate GLP1 RA

Case Study One (cont)

 Professional CGM (covered)

What do we see?

AGP Report

November 29, 2022 - December 13, 2022 (15 Days)

GLUCOSE STATISTICS AND TARGETS

November 29, 2022 - December 13, 2022 15 Days % Time CGM is Active 100%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 70-180 mg/dL	Targets % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)
Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

Average Glucose

Glucose Management Indicator (GMI)

Glucose Variability

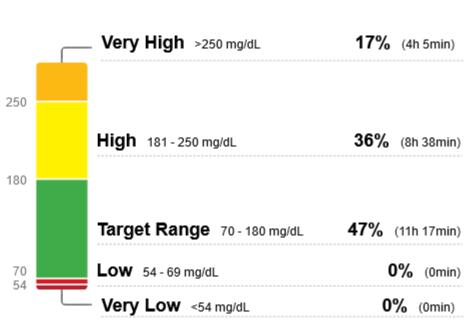
Defined as percent coefficient of variation (%CV)

191 mg/dL

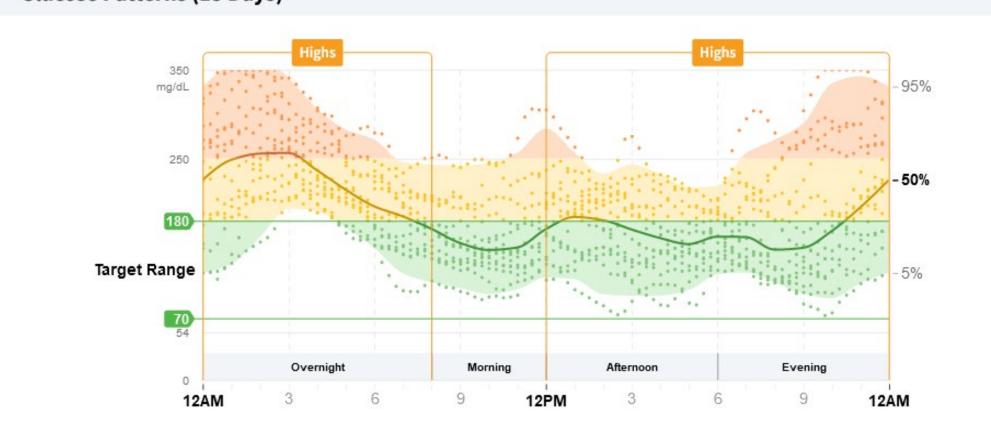
7.9%

31.8%

TIME IN RANGES



Glucose Patterns (15 Days)



Case Study One (cont)

The Plan

- + Encourage patient to take all insulin as prescribed
- + Increase basal insulin to 46 units, consider a longer acting basal insulin
- + Mealtime insulin: Patient not doing BG before meals and typically omitting insulin. Provide a set dose of insulin for each meal
- + Continue: SGLT2 inhibitor, Metformin XR 1000 M daily
- + Discuss GLP-1 and consider again with more education and nutrition counseling

Case Study Two

Patient Current Medical History

- + 56-year-old black male
- + Type 2 diabetes 14 years
- History of hypertension,
 elevated lipids both well
 controlled
- + Returns for 3 month follow up
- + Weight: BMI 29
- + A1c 7.6 % (goal < 7% with >70% TIR and < 5% low BG)

Present Medications

- + Daily GLP-1 at max dose tolerated
- + Metformin 1000mg daily (max tolerated)
- + SGLT-2 Inhibitor

Case Study Two (cont)

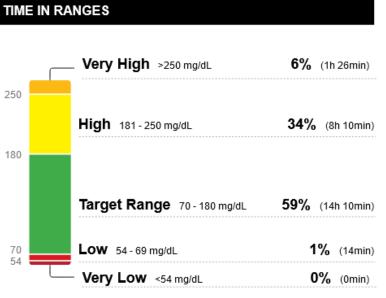
What do we see and what do we try to fix first?

AGP Report

January 31, 2023 - February 13, 2023 (14 Days)

GLUCOSE STATISTICS AND TARGETS

January 31, 2023 - February 13, 2023 14 Days 89% % Time CGM is Active Type 1 or Type 2 Diabetes Ranges And Targets For Glucose Ranges **Targets** Target Range 70-180 mg/dL % of Readings (Time/Day) Greater than 70% (16h 48min) Less than 4% (58min) Above 180 mg/dL Less than 25% (6h) Above 250 mg/dL Less than 5% (1h 12min) Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial. 166 mg/dL Average Glucose



AMBULATORY GLUCOSE PROFILE (AGP)

Glucose Management Indicator (GMI)

Defined as percent coefficient of variation (%CV)

Glucose Variability

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.

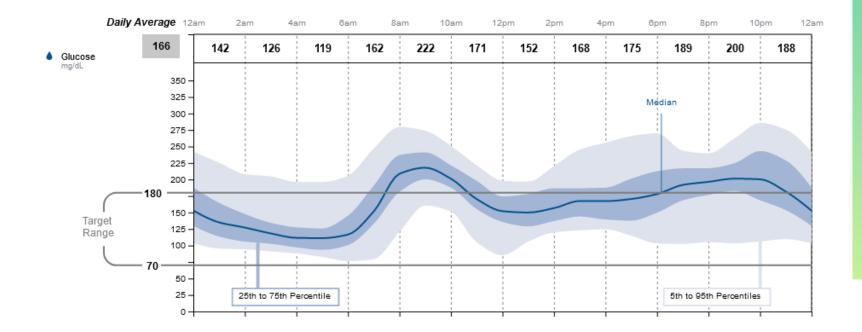
7.3%

30.2%

Daily Patterns

LibreView

January 31, 2023 - February 13, 2023 (14 Days)



Case Study Two (cont)

The Plan

- + A1c goal <7% with >70% TIR and <5% low BG
- + Switch to a once weekly GLP-1
- + Refer for Medical Nutritional Therapy and Diabetes Education
- + Continue 1000mg Metformin
- + Continue SGLT-2 inhibitor
- + Advise patient that while we are connected in the cloud I will not look at CGM data unless asked
- + Patient asks me to look at data 2-4 weeks after change in GLP1
- + May need basal insulin, decide after once weekly GLP-1 titrated
- + Return 3 months

Case Study Three

Patient Current Medical History

- + 60-year-old female
- + Breast Cancer
- + Hypertension
- + Hyperlipidemia
- + BMI 40.3, 265# 68"
- + A1c 10.7%
- + Insulin Degludec 45 units in AM
- Dapagliflozin 10 mg QD
- + Metformin 1000 mg BID
- + Patient works nights at care home and has some stress at work

In Office...

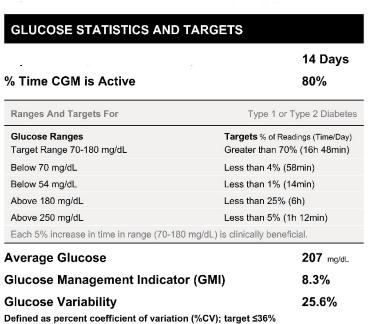
- + Applied continuous glucose monitor
- Patient was to be mindful of the effects of food on glucose and make notes of these times
- + Advised patient to titrate insulin initially to AM glucose of less than 200 mg/dl
- + Addition of .75 Dulaglutide sub Q weekly
- She will return in 2 weeks for first review of AGP (Ambulatory Glucose Profile)

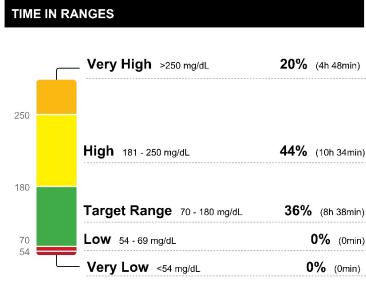
Case Study Three (cont.)

1st AGP Report (2 wk. follow-up)

- + First FU appt after CGM application
- + Patient reports learning the effects of food on glucose levels
- + She has been slowly increasing the insulin one unit ever 3 days and is up to 49 units
- Her AM glucose is still above target range
- + She has noticed her glucoses falling much more now after meals

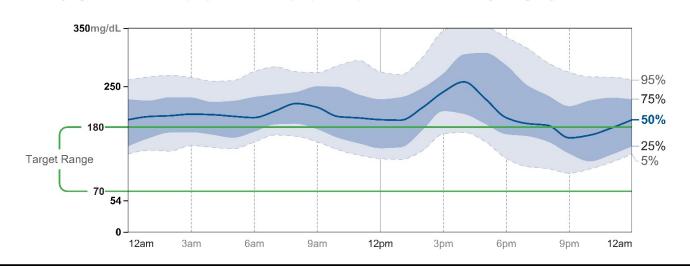
AGP Report





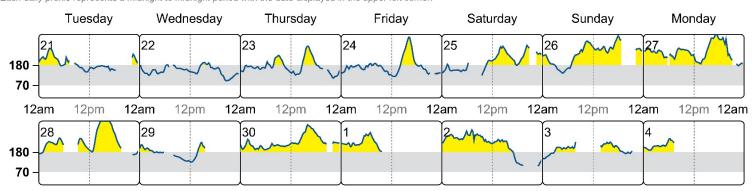
AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day



DAILY GLUCOSE PROFILES

Each daily profile represents a midnight to midnight period with the date displayed in the upper left corner.



Case Study Three (cont.)

2nd AGP Report (3 mo. follow-up)

- Insulin Degludec up to 52 units
- Weight loss 10 #
- BMI 38.6
- A1c is 7.6%
- Tolerating 1.5 Dulaglutide weekly
- Learning foods effect on glucose
- Note GMI 7.4%
- Some dawn phenomenon
- AM scan around 150 mg/dl
- Still some data gaps and scanning needed.
- She indicates this sometimes can be hard when at work
- Advised to further increase Dulaglutide to 3mg weekly
- Continue target long acting try for less then 140 or near 120
- FU appt in 3 mos

AGP Report

GLUCOSE STATISTICS AND TARGETS	
% Time CGM is Active	14 Days 54%
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 70-180 mg/dL	Targets % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)
Each 5% increase in time in range (70-180 mg/dl	L) is clinically beneficial.
Average Glucose	170 mg/dL

TIME IN RA	ANGES	
250	_ Very High >250 mg/dL	2% (29min)
180	High 181 - 250 mg/dL	35% (8h 24min)
	Target Range 70 - 180 mg/dL	63% (15h 7min)
70 54	Low 54 - 69 mg/dL Very Low <54 mg/dL	0% (0min)

Glucose Variability

Glucose Management Indicator (GMI)

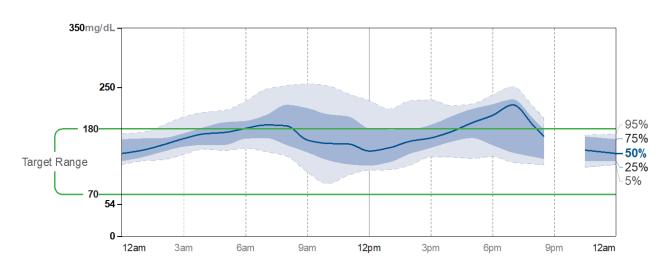
Defined as percent coefficient of variation (%CV)

AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day

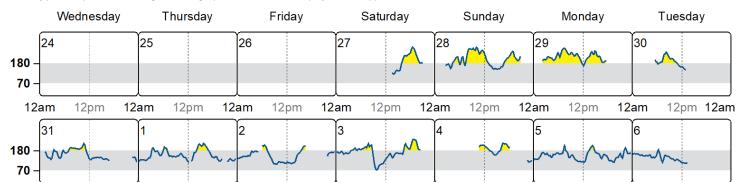
7.4%

22.0%





Each daily profile represents a midnight to midnight period with the date displayed in the upper left corner



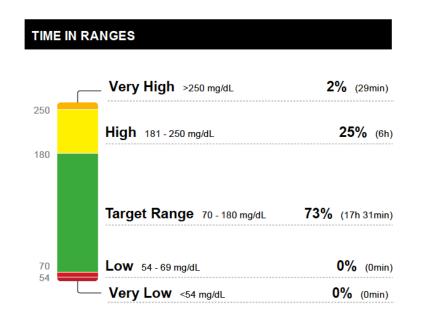
Case Study Three (cont.)

3rd AGP Report (5 mo. follow-up)

- + Current a1c 6.9% GMI is 7.0%
- Insulin Degludec at 52 units
- Dulaglutide increase prior to follow up is now at 4.5mg weekly as she called and noticed post meal glucoses over 200
- + BMI 37.2
- Additional 4# weight loss
- + Total weight loss 14#
- Watching her food and trying to lose additional weight
- Additional engagement and scanning needed
- Discussion switching to another device by the same manufacturer for streaming capability

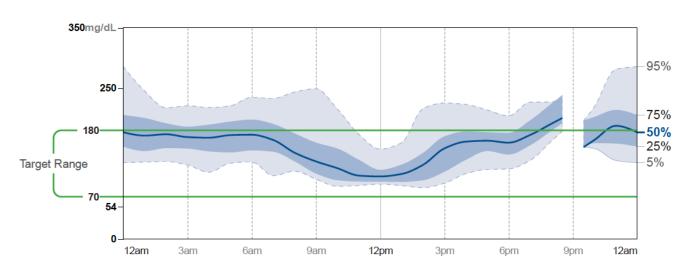
AGP Report

% Time CGM is Active	14 Days 69%	
Ranges And Targets For	Type 1 or Type 2 Diabet	
Glucose Ranges Target Range 70-180 mg/dL	Targets % of Readings (Time/Day) Greater than 70% (16h 48min)	
Below 70 mg/dL	Less than 4% (58min)	
Below 54 mg/dL	Less than 1% (14min)	
Above 180 mg/dL	Less than 25% (6h)	
Above 250 mg/dL	Less than 5% (1h 12min)	
Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.	
Average Glucose	155 mg/dL	
Glucose Management Indicator (GMI)	7.0%	



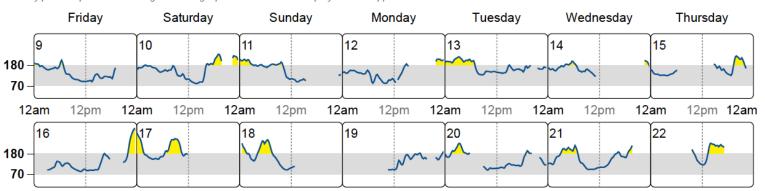
AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day



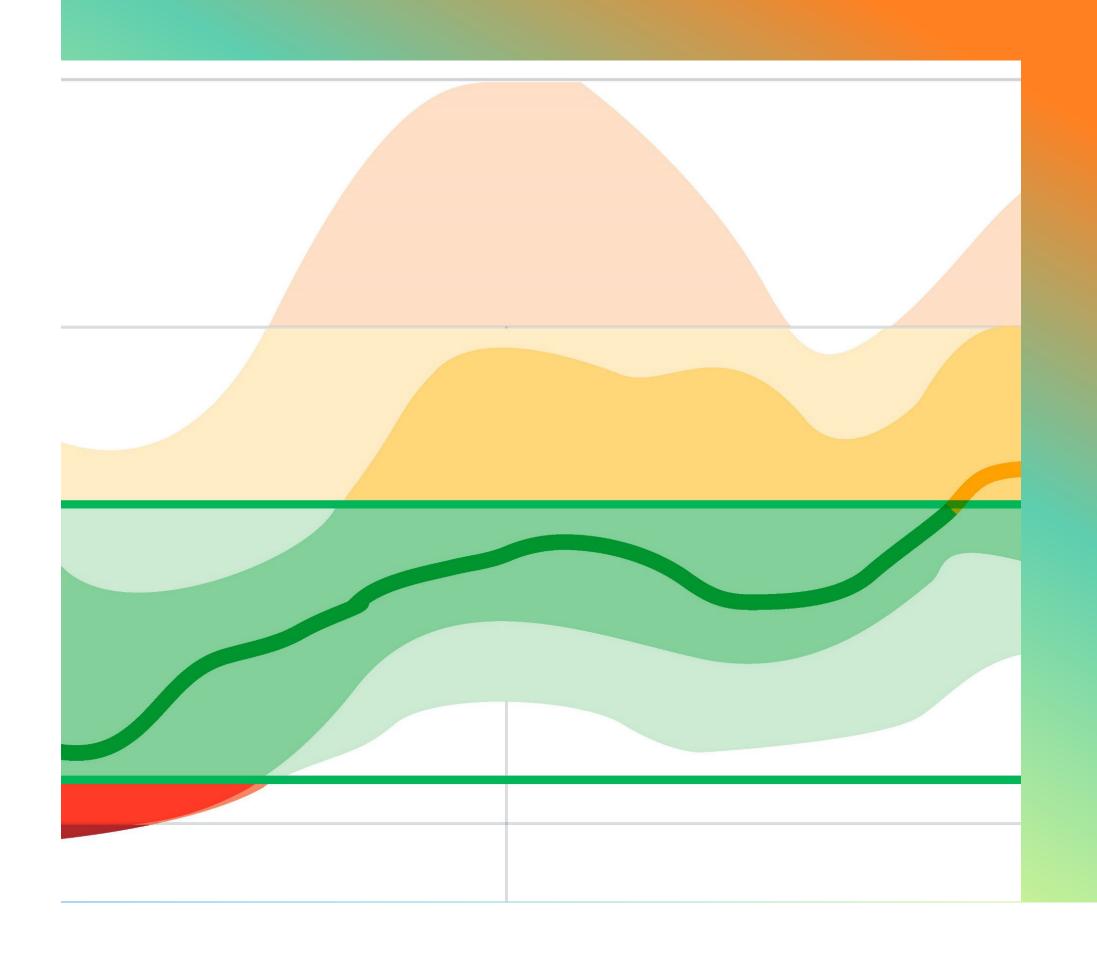
DAILY GLUCOSE PROFILES

each daily profile represents a midnight to midnight period with the date displayed in the upper left corne



Using Continuous Glucose Monitoring and the **Ambulatory Glucose Profile** for Clinical Decision-Making in Primary Care

Practical Implementation at the Practice



How do you get your practice ready?

Make a clinic decision for CGM utilization

Create Team Diabetes-CGM

Identify a Diabetes Champion

Determine which systems to integrate

Gain additional initiation support through online resources or representatives

Create a workflow that works for you and your staff

Preparing your colleagues/staff

The Front Office

- Reminder calls with encouragement to collect additional data (food/exercise/stress/meds)
- Collect devices
- Get staff started on data access (can be before appointment or when patient shows up with devices)

The Back Office

- Familiar with all CGM systems used
- Have set up a clinic log-in profile
- Able to access the AGP for all systems
- Download data and upload to chart at or prior to appointment

Prepare for billing

Who owns the equipment?

Patient or Provider: Unique codes for each

Service occurs > 1 day

Minimum of 72 hours of wear

Download of receiver occurs in office, cloud based printed out, or electronic transfer

Service can be charged at the day of download or time of analysis

Interpretation of data

Minimum of 72 hours of wear time

Face to face is not required, CPT stand alone or with E&M Code

Limitations of who can bill: Physician, NP, PA (those who can prescribe)

CODES & DESCRIPTIONS

95249:

Personal CGM - Startup/Training: Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training and printout of recording. (Do not report more than once while patient owns device.)

95250:

Professional CGM - Ambulatory continuous glucose monitoring of interstitial fluid via a subcutaneous sensor for a minimum of 72 hours; clinician-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording. (Do not report more than once per month.)

95251:

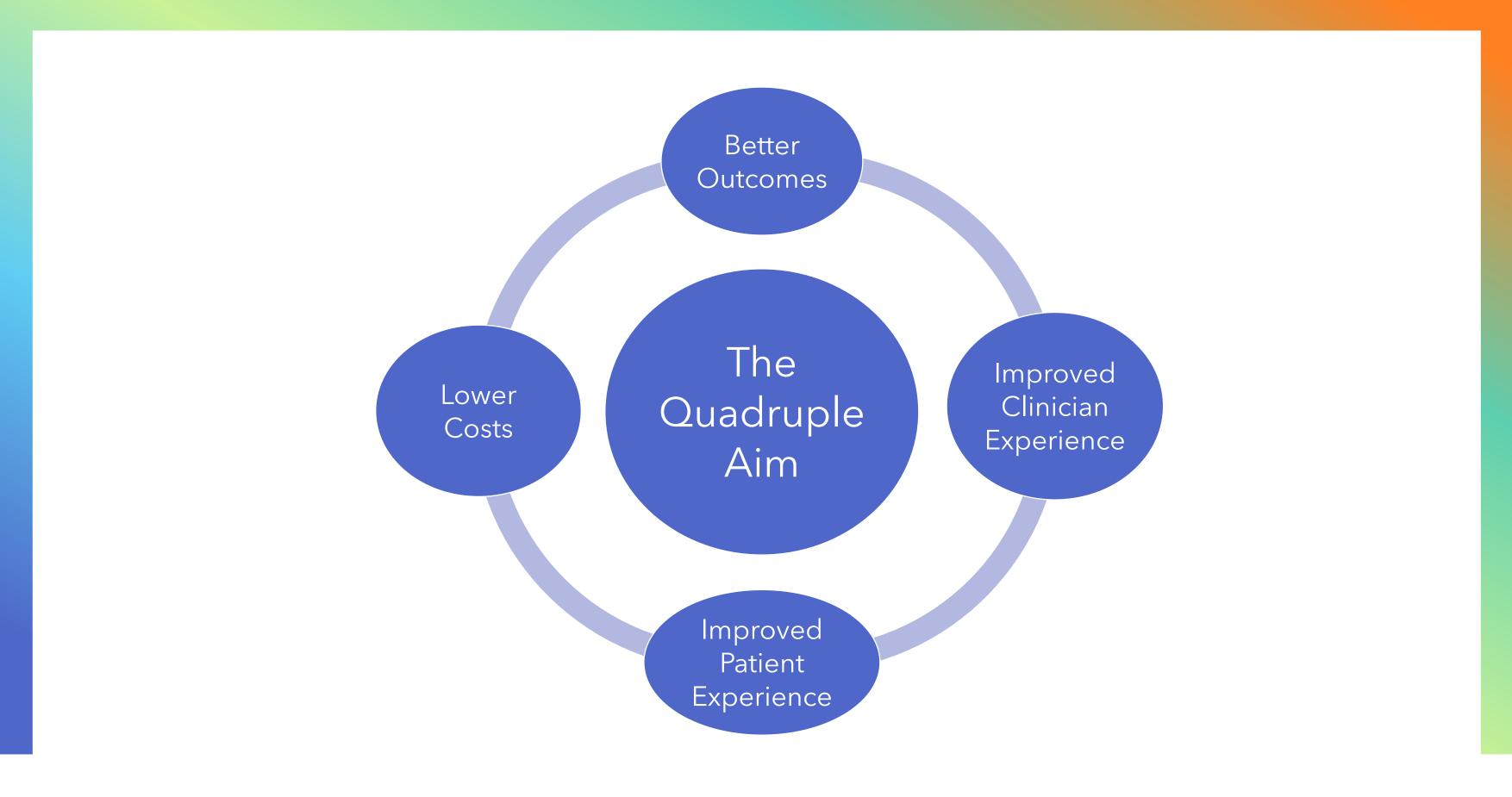
Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report. (Do not report more than once per month.)

Evaluation and Management (E/M) Codes 99212-99215

Established Patient Visit or G0463 (Medicare Outpatient Clinic Visits)

Eversense Only Codes:

0446T (creation of subcutaneous pocket with insertion of implantable sensor, including system activation and patient education), 0447T (removal of implantable sensor from subcutaneous pocket via incision), 0448T (removal of sensor with creation of new pocket for new sensor at a different location, including system activation).



Bodenheimer T, Sinsky C. From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider. Ann Fam Med, Nov 2014;12(6):573-576. DOI: 10.1370/afm.1713.

RESOURCE TOOLKIT



https://www.pcmg-us.org/toolkit/cgm

Links to pages devoted to the individual devices, both professional and personal, including insertion videos

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Links to download the deck and review the presentation (share with colleagues who can also earn additional CME credit)

Extensive cost and use data

A list of helpful resources from the ADA, diaTribe, AAFP, the Association of Diabetes Care & Education Specialists, and more

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END

