Non-Invasive Glucose Monitoring Devices

Wellmark Blue Cross and Blue Shield is an Independent Licensee of the Blue Cross and Blue Shield Association.

Medical Policy #: 01.01.30
Original Effective Date: September 2019
Reviewed: September 2022
Revised: September 2021

NOTICE: This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

Tight glucose control in patients with diabetes has been associated with improved health outcomes. Several devices are available to measure glucose levels automatically and frequently (e.g., every 5-10 minutes). The devices measure glucose in the interstitial fluid and are approved as adjuncts to or replacements for traditional self-monitoring of blood glucose levels. Devices can be used on a long-term (continuous glucose monitoring (CGM)) or short-term glucose monitoring (SGM)/intermittent basis. In addition to CGM and SGM there are other devices which a diabetic may consider adding to their glucose monitoring regimen such as a hypoglycemic wristband alarm or a remote glucose monitoring device.

Hypoglycemic Wristband Alarm

The Sleep Sentry is a device that senses nocturnal hypoglycemia based on sweating and lowered skin temperature and does not measure blood glucose directly. When there is deviation from pre-set levels for skin temperature and/or perspiration, an alarm will sound. The device may be worn on the ankle, forearm, or wrist. One of the

disadvantages of these devices for alerting hypoglycemia is that activities that cause changes in skin temperature and/or perspiration can set off false alarms. An example of this device is the Sleep Sentry. However, the clinical utility of these devices has not been proven.

Remote Glucose Monitoring Device
MySentry (Medtronic) is a remote glucose monitor that can be placed at the bedside of a parent or guardian to allow monitoring of glucose information throughout the night. The system consists of a monitor, power source and radiofrequency operated Outpost that transmits information from a Medtronic MiniMed Paradigm REAL-Time Revel insulin pump. The outpost allows monitoring from 50 feet away or greater. The monitor displays the same information and sounds the same alarms as the pump itself if the alarm silence option is off. The device is not used for making therapy adjustments nor does it control the insulin pump in any way.

Populations
The relevant population of interest is individuals with diabetes. Individuals with diabetes require engagement in a comprehensive self-management and clinical assessment program that includes assessment of blood glucose control.

Interventions
The test being considered is the use of a diabetic device to assess blood glucose levels as part of optimal diabetes management.

Comparators
The following practice is currently being used to measure glucose levels: capillary blood sampling (finger stick) for self-monitoring of blood glucose (SMBG). Standard treatment for patients with type 1 diabetes includes injection of long-acting basal insulin plus multiple daily injections (MDI) of rapid-acting insulin boluses as required for meal intake. Activity level may require patients need to modify the timing and dose of insulin administration. Individuals with type 1 diabetes may also use an insulin pump either for initial treatment or convert to pump use after a period of MDI. Individuals are required to check their blood glucose before making pre-prandial insulin calculations, in response to symptoms of hypoglycemia or related to activity-related insulin adjustments.

Outcomes
The general outcomes of interest are change in hemoglobin A1c (HbA1c) levels, time spent in hypoglycemia and hyperglycemia, time in range (generally glucose of 70-180 mg/dl), the incidence of hypoglycemic events, complications of hypoglycemia, and quality of life (QOL). To assess short-term outcomes such as HbA1c levels, a minimum follow-up of 8 to 12 weeks is appropriate.

Review of Evidence

Hypoglycemic Wristband Alarm

(2015) According to Howsmon, & Bequette the first commercial devices that used skin conductance measurements for nighttime alarms were Erpic's Diabalert and Teledyne's Sleep Sentry. The Diabalert consisted of meter housing the alarm which was attached through a long wire to a skin surface electrode. Pickup tested the Diabalert on 7 patients in a clinical setting and found that 3 patients would have not been able to respond to an alarm while 2 did not show signs of sweating even though their blood glucose levels were 12.6 and 37.8 mg/dL. The original Sleep Sentry resembled a bulky wristwatch and combined skin temperature and skin conductance measurements. Levandoski et al induced hypoglycemia in 17 type 1 diabetic and 10 healthy individuals and observed a sensitivity of 81% for the Sleep Sentry alarms. Hansen and Duck collected data on 24 pediatric patients with type 1 diabetes for a total of 1444 at-home nights, resulting in 42 hypoglycemic events detected by the Sleep Sentry, 4 additional events detected by the patients or their parents without an alarm, and 150 alarms without hypoglycemia. Furthermore, this initial study used a high current density, causing adverse skin reactions in 6 of the 24 patients. Clarke et al revealed failures of the Sleep Sentry to sound in 6 of 18 experiments despite blood glucose readings between 31 and 52 mg/dL. In addition, none of the subjects under study reached the threshold for temperature drop and 80% of nonalarmers self-reported an increase in perspiration. Heger et al studied a myriad of signals on 7 patients and reported that the Sleep Sentry either failed to sound or sounded too late to be of use to the patient in 3 cases Studies by Johansen et al on the use of the Teledyne Sleep Sentry for detection of nocturnal hypoglycemia in 22 patients for a total of 63 nights resulted in 22 alarm sounds with 6 instances of hypoglycemia. Thus, this study concluded with the similar 3:1 ratio of false alarms to true alarms as found by Clarke et al.

Summary of Evidence: Hypoglycemic Wristband Alarm
The current Sleep Sentry has improved sensor quality and sleeker look are big improvements over the original Sleep Sentry. However, the superior monitoring offered by CGMs has limited the widespread use of the device. The Diabetes Sentry uses noninvasive sensors and is more affordable than alarm systems based on CGMs, but even Diabetes Sentry notes that this product is not an alternative to a CGM. Howsmon and Bequette report that ever-improving CGM technology coupled with the inability to extend the Diabetes Sentry to reliable daytime use will limit the future success of alarm systems based solely on this technology.

Remote Glucose Monitoring Device
(2021) Fremont and Miller reported remote monitoring (RM) may facilitate youth independence by providing a way for them to stay connected to their support system while acquiring developmentally appropriate skills. However, families should have iterative discussions about boundaries to mitigate parental over-involvement.

(2019) Burckhardt et al. detailed five themes related to remote monitoring which emerged: (i) impact on sleep quality for the parents, (ii) peace of mind, (iii) impact on anxiety, (iv) freedom and confidence for the parents and children, and (v) impact on relationships. Furthermore, parents reported on themes related to CGM in general, such

as better understanding of how to manage and control their child's diabetes and experiences related to physical or technical aspects.

(2013) According to Kaiserman et al. the mySentry system met all predefined criteria for acceptability and did not demonstrate safety issues. Alerting parents to abnormal glucose values or trends may attenuate nocturnal hypoglycemia and hyperglycemia by prompting appropriate and timely intervention.

Summary of Evidence: Remote Glucose Monitoring Device
Based on review of the literature regarding remote glucose monitoring devices and hypoglycemic wristband alarms while it appears to provide freedom and confidence to diabetic and diabetic caregiver(s), further clinical trials are needed when comparing these devices to other options for monitoring blood glucose levels. At this time these devices are considered not medically necessary and a convenience item.

Practice Guidelines and Position Statements

The American Diabetes Association (ADA)
(2020) “Standards of Medical Care in Diabetes: Diabetes Technology," included the following statement in the chapter on glycemic targets:

- The American Diabetes Association (ADA) recommends fingerstick self-monitoring of blood glucose (SMBG) as an integral component of diabetes therapy for type 1 diabetics, type 2 diabetics, and gestational diabetes. The ADA stresses the patient/caregiver should receive instructions in, and routine follow-up of, SMBG technique and their capability to use the data to adjust therapy. The ADA reports that clinical trials assessing the impact of glycemic control on diabetes complications have included SMBG as part of multifactorial interventions, suggesting that SMBG is a component of effective therapy. SMBG allows patients to evaluate their individual response to therapy and assess whether glycemic targets are being achieved.

International Diabetes Federation (IDF)
Findings from studies of SMBG (self-monitoring blood glucose) used in non-insulin treated T2DM have been inconsistent due to differences in study designs, populations, and interventions used. However, the data available from randomized controlled trials (RCTs) suggest that SMBG is likely to be an effective self-management tool only when results are reviewed and acted upon by healthcare providers and/or people with diabetes to actively modify behavior and/or adjust treatment.

Although further studies are needed to better assess the benefits, optimal use and cost-effectiveness of SMBG, the following recommendations are proposed to guide individuals with non-insulin-treated diabetes and their healthcare providers in the use of SMBG.

1. SMBG should be used only when individuals with diabetes (and/or their caregivers) and/or their healthcare providers have the knowledge, skills and

willingness to incorporate SMBG monitoring and therapy adjustment into their diabetes care plan in order to attain agreed treatment goals.
2. SMBG should be considered at the time of diagnosis to enhance the understanding of diabetes as part of individuals' education and to facilitate timely treatment initiation and titration optimization.

Regulatory Status
The following are identified devices approved by the U.S. Food and Drug Administration (FDA) but are not limited to the following:

Device	Manufacturer	Approval
mySentry	Medtronic	2012
Diabetes Sentry (the Sleep Sentry Device)	Diabetes Sentry Products	2005

PRIOR APPROVAL

Not applicable.

POLICY

The use of the following glucose monitoring therapies is considered **not medically necessary** and a convenience item due to a lack of evidence supporting they provide an additional benefit over current standard therapies to obtain and monitor blood glucose.

- Remote glucose monitoring device (e.g., mySentry)
- Hypoglycemic wristband alarm (e.g., Diabetes Sentry)

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- A9280 Alert or alarm device, not otherwise classified [(Sleep Sentry)]
- A9999 Miscellaneous dme supply or accessory, not otherwise specified [(Sleep Sentry)]
- S1030 Continuous noninvasive glucose monitoring device, purchase
- S1031 Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor

SELECTED REFERENCES

- Cell Robotics International, Inc. Lasette® plus for clinical use

- Kaiserman K, Buckingham BA, Prakasam G, et al. Acceptability and utility of the mySentry remote glucose monitoring system. J Diabetes Sci Technol. 2013;7(2):356–361. Published 2013 Mar 1. doi:10.1177/193229681300700211
- Yeh H-C, Brown TT, Maruthur N, et al. Comparative effectiveness and safety of methods of insulin delivery and glucose monitoring for diabetes mellitus: a systematic review and meta-analysis. Ann Intern Med. 2012;157(5):336-347. doi:10.7326/0003-4819-157-5-201209040-00508.
- Rodbard D. Continuous Glucose Monitoring: A Review of Recent Studies Demonstrating Improved Glycemic Outcomes. Diabetes Technol Ther. 2017;19(S3):S25-S37. doi:10.1089/dia.2017.0035.
- Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus | Guidance and guidelines NICE.
- Fonseca VA, Grunberger G, Anhalt H, et al. Continuous glucose monitoring: a consensus conference of the American association of clinical endocrinologists and american college of endocrinology. Endocrine Practice. 2016;22(8):1008-1021. doi:10.4158/EP161392.CS.
- American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology. 2016 Outpatient Glucose Monitoring Consensus Statement.
- Society of General Internal Medicine. Choosing Wisely recommendations.
- Kropff, J., Choudhary, P., Neupane, S., Barnard, K., et. al. Accuracy and Longevity of an Implantable Continuous Glucose Sensor in the PRECISE Study: A 180-Day, Prospective, Multicenter, Pivotal Trial. Diabetes Care Jan 2017, 40 (1) 63-68; DOI: 10.2337/dc16-1525.
- Wan W, Skandari MR, Minc A, et al. Cost-effectiveness of continuous glucose monitoring for adults with type 1 diabetes compared with self-monitoring of blood glucose: the DIAMOND randomized trial [published online April 12, 2018]. Diabetes Care. doi: 10.2337/dc17-1821.
- Christiansen MP, Klaff LJ, Bailey TS, Brazg R, Carlson G, Tweden KS. A Prospective Multicenter Evaluation of the Accuracy and Safety of an Implanted Continuous Glucose Sensor: The PRECISION Study. Diabetes Technol Ther. 2019;21(5):231–237. doi:10.1089/dia.2019.0020
- Christiansen MP, Klaff LJ, Brazg R, et al.: A prospective multicenter evaluation of the accuracy of a novel implanted continuous glucose sensor: PRECISE II. Diabetes Technol Ther 2018;20:1–10.
- The JDRF Continuous Glucose Monitoring Study Group: Validation of measures of satisfaction with and impact of continuous and conventional glucose monitoring. Diabetes Technol Ther 2010;12:679–684.
- Lind M, Polonsky W, Hirsch IB, et al.: Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: the GOLD randomized clinical trial. JAMA 2017;317:379–387.
- Cengiz E, Tamborlane WV. A tale of two compartments: interstitial versus blood glucose monitoring. Diabetes Technol Ther. 2009;11 Suppl 1(Suppl 1):S11–S16. doi:10.1089/dia.2009.0002

- Siegmund, T., Heinemann, L., Kolassa, R., & Thomas, A. (2017). Discrepancies Between Blood Glucose and Interstitial Glucose—Technological Artifacts or Physiology: Implications for Selection of the Appropriate Therapeutic Target. Journal of Diabetes Science and Technology, 11(4), 766–772.
- Heinemann, L.., Stuhr, A. Self-Management of blood glucose and continuous glucose monitoring, is there only one future? European Endocrinology, 2018;14(2):24–9 DOI:
- Deiss D, Irace C, Carlson G et al. Real-World Safety of an Implantable Continuous Glucose Sensor over Multiple Cycles of Use: A Post-Market Registry Study.. Diabetes Technol. Ther., 2019 Aug 17. PMID 31418587
- Sanchez P, Ghosh-Dastidar S, Tweden KS et al. Real-World Data from the First U.S. Commercial Users of an Implantable Continuous Glucose Sensor.. Diabetes Technol. Ther., 2019 Aug 7. PMID 31385732
- Aronson R, Abitbol A, Tweden KS. First assessment of the performance of an implantable continuous glucose monitoring system through 180 days in a primarily adolescent population with type 1 diabetes. Diabetes Obes Metab. 2019 Jul;21(7):1689-1694.
- Christiansen, MM, Klaff, LL, Bailey, TT, Brazg, RR, Carlson, GG, Tweden, KK. A Prospective Multicenter Evaluation of the Accuracy and Safety of an Implanted Continuous Glucose Sensor: The PRECISION Study.. Diabetes Technol. Ther., 2019 Mar 30;21(5). PMID 30925083
- Dehennis A, Mortellaro MA, Ioacara S. Multisite Study of an Implanted Continuous Glucose Sensor Over 90 Days in Patients With Diabetes Mellitus. J Diabetes Sci Technol. 2015;9(5):951-956. Published 2015 Jul 29. doi:10.1177/1932296815596760
- American Diabetes Association. 6. Glycemic Targets: Standards of Medical Care in Diabetes-2019. Diabetes Care. 2019 Jan;42(Suppl 1):S61-S70. PMID: 30559232
- Tweden KS, Deiss D, Rastogi R et al. Longitudinal Analysis of Real-World Performance of an Implantable Continuous Glucose Sensor Over Multiple Sensor Insertion and Removal Cycles. Diabetes Technol. Ther., 2019 Nov 8. PMID 31697182
- American Diabetes Association. Standards of Medical Care in Diabetes. 2020. https://professional.diabetes.org/content-page/practice-guidelines-resources.
- Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data: Eversense Continuous Glucose Monitoring System (2019). https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048B.pdf Accessed August 2021
- Peters AL, Ahmann AJ, Battelino T, Evert A, Hirsch IB, Murad MH, Winter WE, Wolpert H. Diabetes Technology-Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2016. Accessed August 2021.
- Cowart K. A Review of the First Long-term Implantable Continuous Glucose Monitoring System Available in the United States. J Diabetes Sci Technol. 2021 Jan;15(1):160-166. doi: 10.1177/1932296819890865. Epub 2019 Dec 13. PMID: 31833388; PMCID: PMC7782996

- Anne L. P., Andrew J. A., Tadej B., et. al, Diabetes Technology—Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 101, Issue 11, 1 November 2016, Pages 3922–3937, https://doi.org/10.1210/jc.2016-2534
- Kaiserman, K., et al. "Acceptability and utility of the mySentry remote glucose monitoring system." Journal of diabetes science and technology vol. 7,2 356-61. 1 Mar. 2013, doi:10.1177/193229681300700211
- Burckhardt, M. A., Fried, L., Bebbington, K., et. al, Use of remote monitoring with continuous glucose monitoring in young children with Type 1 diabetes: the parents' perspective. 2019. Diabetic Medicine https://doi.org/10.1111/dme.14061
- Fremont E.R., Miller V.A., Perspectives on Remote Glucose Monitoring in Youth With Type 1 Diabetes, Journal of Pediatric Psychology, 2021, jsab068, https://doi.org/10.1093/jpepsy/jsab068
- Howsmon, D., & Bequette, B. W. (2015). Hypo- and Hyperglycemic Alarms: Devices and Algorithms. Journal of diabetes science and technology, 9(5), 1126–1137. https://doi.org/10.1177/1932296815583507
- Reddy N, Verma N, Dungan K. Monitoring Technologies-Continuous Glucose Monitoring, Mobile Technology, Biomarkers of Glycemic Control. [Updated 2020 Aug 16]. In: Feingold KR, Anawalt B, Boyce A, et al., editors. https://www.ncbi.nlm.nih.gov/books/NBK279046/

POLICY HISTORY

Date	Reason	Action
September 2022	Annual Review	Policy Renewed
September 2021	Annual Review	Policy Revised
September 2020	Annual Review	Policy Revised
September 2019	New Policy	New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.