

## Continuous Glucose Monitor (CGM)

**Policy MP-008**

**Origination Date:** 06/21/2018

**Reviewed/Revised Date:** 07/28/2023

**Next Review Date:** 07/28/2024

**Current Effective Date:** 09/28/2023

### Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. **This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.**

### Description:

The American Diabetes Association (ADA) defines the continuous glucose monitoring system as "a method of continuously following glucose levels in the interstitial fluid as a base for improving metabolic control. This includes increasing time in the target glucose range by reducing hyperglycemia and minimizing the occurrence of low glucose values (including symptomatic hypoglycemia)."

### Policy Statement and Criteria

#### 1. Commercial Plans

**U of U Health Plans may cover non-implantable continuous glucose monitors (CGM) in limited circumstances when coverage standards met.**

#### Coverage Requirements:

##### A. Members with Diabetes mellitus, Type 1

- i. Member at least 2 years old;
- ii. Diabetes members with at least one year of subcutaneous insulin therapy if over age 13;
- iii. Member adheres to a comprehensive diabetes treatment plan supervised by the treating provider and is capable of recognizing and responding to the alarms and alerts of the device.

- iv. Provider attests that the member will receive appropriate ongoing counselling and training for CGM use.
- v. Attestation of diabetes specialist's assessment of ability to train member on appropriate use of continuous glucose monitor;
- vi. Documentation of at least 2 visits with a diabetes specialist during the six months prior to initiation;
- vii. Meets one or more of the following criteria while on a multiple daily injection insulin:
  - a) Glycosylated hemoglobin levels (HbA1c) greater than 8%;
  - b) Recent history (within the last six months) of significant, recurring hypoglycemia (less than 60mg per deciliter or requiring assistance);
  - c) Wide fluctuations (well above and below set glycemic targets) in blood glucose before and after meal times, despite appropriate adjustment of doses;
  - d) At least one documented incidence of hyperglycemic hyperosmotic syndrome or diabetic ketoacidosis within the previous six months;

**B. Members with Diabetes mellitus, Type 2:**

- i. Member adheres to a comprehensive diabetes treatment plan supervised by the treating provider and is capable of recognizing and responding to the alarms and alerts of the device.
- ii. Provider attests that the member will receive appropriate ongoing counselling and training for CGM use.
- iii. Documentation of at least 2 visits with a diabetes specialist during the six months prior to initiation;
- iv. Meets one or more of the following criteria while on a multiple daily injection insulin:
  - a) Glycosylated hemoglobin levels (HbA1c) greater than 8%;
  - b) Recent history (within the last six months) of significant, recurring hypoglycemia (less than 60mg per deciliter or requiring assistance);
  - c) Wide fluctuations (well above and below set glycemic targets) in blood glucose before and after meal times, despite appropriate adjustment of doses;
  - d) At least one documented incidence of hyperglycemic hyperosmotic syndrome or diabetic ketoacidosis within the previous six months.

**C. Gestational Diabetes**

- i. Patients with gestational diabetes or diabetes during pregnancy are exempted from previous management provisions of this policy and are eligible for CGM coverage during the pregnancy.

**D. Covered Preferred Products (on pharmacy benefit only, not covered as medical benefits):**

- i. Dexcom G6
- ii. Freestyle Libre and Libre 2 systems

**E. Covered Nonpreferred Products Covered (only on medical benefit):**

- i. Medtronic Enlite
- ii. Medtronic Guardian

**F. Noncovered Products:**

- i. Dexcom G4
- ii. Dexcom G5
- iii. Eversense implantable CGMS

**G. Renewals:**

- i. Patients must have had at least 2 visits with a diabetes specialist within the previous 12 months;
- ii. Hemoglobin A1c levels must have been checked at least every 6 months within the previous year;
- iii. Documentation must show that the member is adhering to the treatment plan outlined by a diabetes specialist.

**H. Exclusions:**

- i. Member younger than age 2 years;
- ii. Members who require use of chronic acetaminophen.
  - a) Prior use of samples will not be considered in the determination of a member's eligibility for coverage for this medication.

### **Reauthorization Criteria:**

**For individuals previously using or authorized for CGMS, ongoing authorization will be considered when the following criteria must be met (All):**

- A. Documentation supports active and routine use of device
- B. Documentation supports use of device has resulted in improved diabetic management manifested by any one of the following:
  - i. Hemoglobin A1c within target range
  - ii. Improvement and maintenance of improvement in HgbA1c since onset in use of CGM
  - iii. Reduction in hypoglycemic episodes requiring intervention
  - iv. Reduction in hospitalization or ER usage due to consequences of high or low blood sugars
  - v. Meaningful improvement of time in a normal glycemic range

**U of U Health Plans does NOT cover implantable continuous glucose monitors (CGM) systems (e.g. Eversense® CGM System) as they are considered investigational.**

## **2. Medicaid Plans**

**Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: <https://medicaid.utah.gov/utah-medicaid-official-publications/> or the [Utah Medicaid code Look-Up tool](#)**

**CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.**

## **Clinical Rationale**

A review of literature performed in January 2012 identified 2 systematic reviews and 17 peer-reviewed articles since the last review performed in 2004. After review of the supportive articles, especially the Juvenile Diabetes Research Foundation (JDRF) Continuous Glucose Monitoring Study (Beck et al), the following is a summation of specific patient groups who may benefit from a CGM.

It would seem clinically apparent that glucose measurement every 5 minutes in patients with type 1 diabetes would enhance glucose control and avoid potentially life threatening hypoglycemic events. The evidence in multiple randomized studies demonstrates limited clinical improvement except in adult type 1 patients over the age of 25. This age group demonstrated a decline of A1C by 0.53%. Unfortunately, children and adolescents did not have improvement A1C levels. Hypoglycemia in most of the studies did not show changes in frequency. In the STAR-1 trial severe hypoglycemic rates were higher in the CGM group.

As CGM relates to improvement in hypoglycemic awareness, supporters of CGM report that hypoglycemia with the use of CGM in compliant patients was 11.2 events per 100 patient years over the 12 months of the JDRF CGM study compared with 86 per 100 patient-years in the Diabetic Control and Complication Trial (DCCT). Surprisingly most CGM studies were not powered to demonstrate a lowering of hypoglycemic rates. Most focused on A1C reduction as the target for efficacy. It appears, as illustrated in the article by Battelino et al., that hypoglycemia in type1 diabetic patients with A1C <7.5 may attain enhanced diabetic control without an increase in hypoglycemic events by using a CGM.

The key article which highlights the discrepancy in results from CGM in the medical literature is the sub-analysis of the JDRF study by Beck et al. This article demonstrated that success with CGM in A1C reduction was determined by the duration the CGM was worn. The goal is >6 days /week use. All patients who succeeded in this goal achieved improvement in the A1C.

From Beck et al.'s analysis, 2 factors seemed to determine the frequency of success for the duration of CGM use; 1) the age of the patient and 2) the frequency of SMBG testing prior to initiation of the CGM. In subjects with baseline A1C >7.0% "Daily use after 6 months was strongly associated with age, with 83% of subjects >25 years sustaining CGM use >6 days /week compared with 30% of subjects 15-24 years and 50% of subjects 8-14 years. After adjustment for age, the only other baseline factor associated with successful use after 6 months was the frequency of self-reported pre-study daily blood glucose meter measurements. Subjects in all age groups who performed >6 meter measurements/day were more likely to use the CGM on a near-daily basis than those who were monitoring fewer times per day". The outcome ratio was 1.0 for testing 3-5 times per day, 3.64 for 6-8 times per day and 4.16 for testing >9 times per day.

This Beck et al. article further goes on to summarize the potential gains and risks associated with CGM, noting CGM may be a powerful tool if used consistently. The age of the patient and frequency of pre-monitor SMBG appear predict those patients who have the most to gain from this technology.

With regard to the question of the clinical utility of CGM in patients with type 2 diabetes as discussed in the systematic reviews, A1C reductions may occur in type 2 diabetic patients who use CGM. The articles supporting CGM use have different goals and the types of enrollees are not consistent within the type 2 diabetic studies. Some of the studies include patients who are not on insulin. The studies were also typically of short duration. The American Association of Clinical Endocrinologists (AACE) and the American Diabetes Association (ADA) recommended further studies to predict success and compliance with the device to determine what patients have the most to gain clinically.

Another frequent use promoted for CGM is during pregnancy. Continuous glucose monitoring (CGM) personal systems during pregnancy has limited literature to support its use. Articles by Hawkins and Murphy et al., acknowledged CGM was useful in reducing the rates of fetal overgrowth and gestational weight gain. However, determining the optimal frequency and timing of CGM was not established. Professional (office-based or ambulatory) CGM has identified previously unknown hyperglycemia in pregnant women who have both gestational and type 1 diabetes. The AACE recommends that all pregnant women with type 1 diabetes to receive professional CGM. Women with type 2 diabetes are typically able to maintain adequate glucose control if they are adherent to a monitoring schedule requiring 6 SMBG readings per day. For these patients, CGM may facilitate treatment adherence, but its use is not absolutely indicated.

On March 27, 2018 the FDA created a new category of class II integrated CGM (iCGM) devices for 510(k) approval. The G6 CGM has been approved as the first 10-day non-adjunctive factory-calibrated system for ages 2 and older.

In June of 2018, the Eversense Continuous Glucose Monitoring system, a new prescribed CGM system, received FDA approval. This system is indicated for 90 day continuous use for adults (18 and up) and is intended to compliment, not replace finger stick blood glucose monitoring. The sensor is inserted and removed by a physician. The intentions are to provide real-time glucose readings, glucose trend information, and alerts for the detection and prediction of low and high blood glucose.

In summary, the current literature related to the impact CGM is expansive but diffuse. It identifies subpopulations of diabetics such as type 1 diabetics of certain ages which seem to obtain benefit and others who seemingly do not, e.g. gestational diabetes for personal CGM monitors. Many questions remain unanswered.

## **Applicable Coding**

### **CPT Codes**

- 95249** 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
- 95250** Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor
- 95251** Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report

### **Not Covered-Investigational**

- 0446T** Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
- 0447T** Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision
- 0448T** Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation

### **HCPCS Codes**

- A4239** Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
- A9276** Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
- A9277** Transmitter; external, for use with interstitial continuous glucose monitoring system

- A9278** Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
- S1030** Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)
- S1031** Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)
- S1035** Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
- S1036** Transmitter; external, for use with artificial pancreas device system
- S1037** Receiver (monitor); external, for use with artificial pancreas device system

### References:

1. American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards of Medical Care in Diabetes—2022. *Diabetes Care* 1 January 2022; 45 (Supplement\_1): S97–S112. <https://doi.org/10.2337/dc22-S007>
2. Australia and New Zealand Horizon Scanning Network. Continuous Glucose Monitoring Devices. Christ Church, New Zealand: New Zealand Health Technology Assessment, 2006.
3. Bailey TS, Zisser HC, Garg SK. "Reduction in hemoglobin A1C with real-time continuous glucose monitoring: results from a 12-week observational study." *Diabetes Technol Ther* 9.3 (2007): 203-10.
4. Bode B, Gross K, Rikalo N, et al. "Alarms based on real-time sensor glucose values alert patients to hypo- and hyperglycemia: the guardian continuous monitoring system." *Diabetes Technol Ther* 6.2 (2004): 105-13.
5. Bolinder J, Deiss D, Riveline J, et al. Guardian® RT Continuous Glucose Monitoring System with real time glucose values and alarms functions: a new tool for improving glucose control in patients with type 1 diabetes mellitus? Presentation at the 41st EASD Annual Meeting. Athens, Greece; 2005.
6. Boyle JP, Honeycutt AA, Narayan KM, et al. "Projection of diabetes burden through 2050: impact of changing demography and disease prevalence in the U.S." *Diabetes Care* 24.11 (2001): 1936-40.
7. Brauker A, Kamath A, Li Y, et al. Time Lag of a Seven-Day Transcutaneous Glucose Sensor Compared to YSI Blood Glucose Values. Presentation at the 67th Scientific Sessions of the American Diabetes Association. Chicago, IL; 2007.
8. California Technology Assessment Forum. Cryoablation of the prostate for the treatment of primary and recurrent localized prostate cancer/05.
9. Clarke WL, Anderson S, Farhy L, et al. "Evaluating the clinical accuracy of two continuous glucose sensors using continuous glucose-error grid analysis." *Diabetes Care* 28.10 (2005): 2412-7.
10. Deiss D, Phillip M, Battelino T, et al. First experience using the Guardian® RT Continuous Glucose monitoring system with real-time values and alerts in T1 DM patients: results of a pilot study. Presentation at the 65th Annual Scientific Sessions of the American Diabetes Association. San Diego; 2006.
11. DexCom. DexCom™ STS™ Continuous Glucose Monitoring System. 2005. Available: <http://www.dexcom.com/sts.php>. Date Accessed: 4/3 2006.
12. Diabetes Daily. The Guardian RT & Beyond. 2006. Available: <http://www.diabetesdaily.com/content/2005/12/08/the-guardian-rt-beyond.php>. Date Accessed: 4/19/06.
13. Diabetes Technology: Standards of Medical Care in Diabetes—2021. American Diabetes Association. *Diabetes Care* 2021 Jan; 44(Supplement 1): S85-S99. <https://doi.org/10.2337/dc21-S007>
14. Donnelly BJ, Saliken JC, Ernst DS, et al. "Prospective trial of cryosurgical ablation of the prostate: five-year results." *Urology* 60.4 (2002): 645-9.
15. Eisenbarth GS, McCulloch DK. "Pathogenesis of type 1 diabetes mellitus." UpToDate Online [www.utdol.com](http://www.utdol.com) (2006).
16. Ellis SL, Voelml M, Gottlieb PA, Gutin R, Garg SK. Improved Glycemic Control with Real-Time Continuous Glucose Sensors in Patients with Type 1 Diabetes. Presentation at the 67th Scientific Sessions of the American Diabetes Association. Chicago, IL; 2007.
17. Food and Drug Administration (FDA) (2017). Eversense Continuous Glucose Monitoring System; P160048; FDA Approval Letter. Available at: [https://www.accessdata.fda.gov/cdrh\\_docs/pdf16/P160048a.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048a.pdf)
18. Food and Drug Administration (FDA) (2018). Eversense Continuous Glucose Monitoring System; P160049; Available at: <https://www.multivu.com/players/English/8333951-senseonics-continuous-glucose-monitoring-fda-approval/>

19. Food and Drug Administration. "Summary of safety and effectiveness data." (2005).
20. Food and Drug Administration. 510(k) Approval. Available: <http://www.fda.gov/cdrh/pdf7/K070850.pdf> . Accessed 3/21/08.
21. Food and Drug Administration. Summary of Safety and Effectiveness. 2007. Available: <http://www.fda.gov/cdrh/pdf5/p050012s001b.pdf> . Date Accessed: September 26, 2007.
22. Galderisi, Alfonso, Elise Schlissel, and Eda Cengiz. "Keeping up with the diabetes technology: 2016 endocrine society guidelines of insulin pump therapy and continuous glucose monitor management of diabetes." *Current Diabetes Reports* 17.11 (2017): 111.
23. Garg S, Jovanovic L. "Relationship of Fasting and Hourly Blood Glucose Levels to HbA1c Values: Safety, accuracy, and improvements in glucose profiles obtained using a 7-day continuous glucose sensor." *Diabetes Care* 29.12 (2006): 2644-2649.
24. Garg S, Zisser H, Schwartz S, et al. "Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial." *Diabetes Care* 29.1 (2006): 44-50.
25. Garg SK, Schwartz S, Edelman SV. "Improved glucose excursions using an implantable real-time continuous glucose sensor in adults with type 1 diabetes." *Diabetes Care* 27.3 (2004): 734-8.
26. Garg, S. K. and H. K. Akturk (2018). "A New Era in Continuous Glucose Monitoring: Food and Drug Administration Creates a New Category of Factory-Calibrated Nonadjunctive, Interoperable Class II Medical Devices." *Diabetes Technol Ther* 20(6): 391-394. Available at: <http://doi.org/10.1089/dia.2018.0142>
27. Geiger MC, Ferreira JV, Hafiz MM, et al. "Evaluation of metabolic control using a continuous subcutaneous glucose monitoring system in patients with type 1 diabetes mellitus who achieved insulin independence after islet cell transplantation." *Cell Transplant* 14.2-3 (2005): 77-84.
28. Gross TM, Bode BW, Einhorn D, et al. "Performance evaluation of the MiniMed continuous glucose monitoring system during patient home use." *Diabetes Technology & Therapeutics* 2.1 (2000): 49-56.
29. Han KR, Cohen JK, Miller RJ, et al. "Treatment of organ confined prostate cancer with third generation cryosurgery: preliminary multicenter experience." *J Urol* 170.4 Pt 1 (2003): 1126-30.
30. Hawkins, J. S. (2010). "Glucose monitoring during pregnancy." *Curr Diab Rep* 10(3): 229-234.
31. Hay LC, Wilmschurst EG, Fulcher G. "Unrecognized hypo- and hyperglycemia in well-controlled patients with type 2 diabetes mellitus: the results of continuous glucose monitoring." *Diabetes Technology & Therapeutics* 5.1 (2003): 19-26.
32. Hayes Directory. Continuous glucose monitoring systems: Winifred S. Hayes, Inc. /03.
33. Hayes Outlook. Freestyle® Navigator for continuous glucose monitoring: Winifred S. Hayes, Inc. /05.
34. Hayter PG, Sharma M, Dunka L, et al. "Performance Standards for Continuous Glucose Monitors." *Diabetes Technology & Therapeutics* 7.5 (2005): 721-726.
35. Høj-Hansen T, Pedersen-Bjergaard U, Thorsteinnsson B. "Reproducibility and reliability of hypoglycemic episodes recorded with Continuous Glucose Monitoring System (CGMS) in daily life." *Diabetic Medicine: A Journal of the British Diabetic Association* 22.7 (2005): 858-862. [https://store1.dexcom.com/shop/OA\\_HTML/ibeCZzpHome.jsp?a=b](https://store1.dexcom.com/shop/OA_HTML/ibeCZzpHome.jsp?a=b)
36. Jovanovic L, Zisser H, Schwartz S, Bailey T, Kaplan R. A randomized controlled study of a transcutaneous, real-time continuous glucose sensor demonstrates improvement in glycemic control. Presentation at the 65th Scientific Sessions of the American Diabetes Association. San Diego; 2005.
37. Jovanovic L, Zisser H, Schwartz S. Results from a real-time unblinded study of a short-term continuous glucose sensor in subjects with type 1 diabetes. Presentation at the 65th Scientific Sessions of the American Diabetes Association. San Diego; 2005.
38. Jovanovic LG, Zisser H, Bailey T, Kaplan R, Garg S. A Prospective, 21-Day Trial of a Transcutaneous, Real-Time Continuous Glucose Sensor Demonstrates Improvement in Glycemic Excursions. Presentation at the American Association of Clinical Endocrinologists 15th Annual Meeting & Clinical Congress. Chicago, IL; 2006.
39. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study, G, Beck, R (2010). "Effectiveness of continuous glucose monitoring in a clinical care environment: evidence from the Juvenile Diabetes Research Foundation continuous glucose monitoring (JDRF-CGM) trial." *Diabetes Care* 33(1): 17-22.
40. Kaufman FR, Gibson LC, Halvorson M, Carpenter S, Fisher LK, Pitukcheewanont P. "A pilot study of the continuous glucose monitoring system: clinical decisions and glycemic control after its use in pediatric type 1 diabetic subjects." *Diabetes Care* 24.12 (Print) (2001): 2030-2034.
41. Kaufman FR. "Type 1 Diabetes Mellitus." *Pediatrics in Review* 24.9 (2003): 291-300.
42. Kerssen A, de Valk HW, Visser GHA. "The Continuous Glucose Monitoring System during pregnancy of women with type 1 diabetes mellitus: accuracy assessment." *Diabetes Technology & Therapeutics* 6.5 (Print) (2004): 645-651.
43. Klonoff DC. "A Review of Continuous Glucose Monitoring Technology." *Diabetes Technology & Therapeutics* 7.5 (2005): 770-775.
44. Kovatchev BP, Gonder-Frederick LA, Cox DJ, Clarke WL. "Evaluating the accuracy of continuous glucose-monitoring sensors: continuous glucose-error grid analysis illustrated by TheraSense Freestyle Navigator data." *Diabetes Care* 27.8 (2004):1922-8.



45. Lee SW, Freitas M, Petrofsky J, et al. Glucose excursions detected by the continuous glucose monitoring system and missed and type 2 diabetes requiring insulin of the American Diabetes Association. Orlando, Florida; 2004.
46. Mastrototaro J, Rother C, Comerio M, Shah R, Leon RD, Hong P. Alarms based on real-time sensor glucose values alert patients to hypo- and hyperglycemia and reduce glycemic excursions: results of a randomized multicenter study. Presentation at the 64th Scientific Sessions of the American Diabetes Association. Orlando, Florida; 2004.
47. Mastrototaro JJ, Cooper KW, Soundararajan G, Sanders JB, Shah RV. "Clinical experience with an integrated continuous glucose sensor/insulin pump platform: a feasibility study." *Adv Ther* 23.5 (2006): 725-32.
48. Mazze RS. "Making sense of glucose monitoring technologies: from SMBG to CGM." *Diabetes Technol Ther* 7.5 (2005): 784-7.
49. McCulloch DK. "Blood glucose monitoring in management of diabetes mellitus." UpToDate Online [www.utdol.com](http://www.utdol.com) (2006).
50. McCulloch DK. "Classification of diabetes mellitus and genetic diabetic syndromes." UpToDate Online [www.utdol.com](http://www.utdol.com) (2006).
51. McCulloch DK. "Definition of diabetes mellitus." UpToDate Online [www.utdol.com](http://www.utdol.com) (2006).
52. Medtronic I. MiniMed Paradigm REAL-Time Insulin Pump and Continuous Glucose Monitoring System. 2006. Available: <http://www.minimed.com/products/insulinpumps/realtime>. Date Accessed: 4/14 2006.
53. Medtronic. Guardian RT. 2006. Available: <http://www.minimed.com/professionals/guardianrt/>. Date Accessed: 3/13/06.
54. Mlcák P, Fialová J, Trnková K, Chlup R. "A Continuous Glucose Monitoring System (CGMS) - a promising approach for improving metabolic control in persons with type 1 Diabetes mellitus treated by insulin pumps." *Biomedical Papers Of The Medical Faculty Of The University Palacký Olomouc, Czechoslovakia* 148.1 (Print) (2004): 33-38.
55. Murphy, H. R., et al. (2008). "Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomized clinical trial." *BMJ* 337: a1680.
56. Nyback-Nakell A, von Heijne M, Adamson U, Lins PE, Landstedt-Hallin L. "Accuracy of continuous nocturnal glucose screening after 48 and 72 hours in type 2 diabetes patients on combined oral and insulin therapy." *Diabetes Metab* 30.6 (2004): 517-21.
57. Petrie, J. R., et al. (2017). "Improving the Clinical Value and Utility of CGM Systems: Issues and Recommendations: A Joint Statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group." *Diabetes Care* 40(12): 1614-1621.
58. Pfützner J, Forst T, Butzer R, et al. Performance of the Continuous Glucose Monitoring System CGMS® during development of ketosis in patients on insulin pump therapy. Presentation at the 65th Annual Scientific Sessions of the American Diabetes Association. San Diego; 2006.
59. Saliken JC, Donnelly BJ, Brasher P, Ali-Ridha N, Ernst S, Robinson J. "Outcome and safety of transrectal US-guided percutaneous cryotherapy for localized prostate cancer." *J Vasc Interv Radiol* 10.2 Pt 1 (1999): 199-208.
60. Saliken JC, Donnelly BJ, Ernst S, Rewcastle J, Wiseman D. "Prostate cryotherapy: practicalities and applications from the Calgary experience." *Can Assoc Radiol J* 52.3 (2001): 165-73.
61. Skyler JS. "The economic burden of diabetes and the benefits of improved glycemic control: the potential role of a continuous glucose monitoring system." *Diabetes Technol Ther* 2 Suppl 1 (2000): S7-12.
62. Standards of medical care in diabetes--2007. *Diabetes Care* 30 Suppl 1 (2007): S4-S41.18.
63. Stout P, Pokela K, Mullins-Hirte D, et al. "Site-to-Site Variation of Glucose in Interstitial Fluid Samples and Correlation to Venous Plasma Glucose." *Clin Chem* 45.9 (1999): 1674-1675.
64. Tanenberg R, Bode B, Lane W, et al. "Use of the Continuous Glucose Monitoring System to guide therapy in patients with insulin-treated diabetes: a randomized controlled trial." *Mayo Clin Proc* 79.12 (2004): 1521-6.
65. Tavis DR, Shoaibi A. "The public health impact of the MiniMed Continuous Glucose Monitoring System (CGMS)-an assessment of the literature." *Diabetes Technol Ther* 6.4 (2004): 518-22.
66. Tice J. Continuous glucose monitoring devices in diabetes mellitus. San Francisco, CA: California Technology Assessment Forum/03.
67. University Health System Consortium. Medtronic MiniMed Paradigm REAL-Time Insulin Pump and Continuous Glucose Monitoring System, 2006.
68. Wang L. An engineering analysis of guardian continuous glucose monitoring system alerts. Presentation at the 65th Annual Scientific Sessions of the American Diabetes Association. San Diego; 2005.
69. Warren J, Sabicer S. Medtronic Receives FDA Approval for World's First Insulin Pump with Real-Time Continuous Glucose Monitoring. 2006. Available: [http://wwwp.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1123700847661&lang=en\\_US](http://wwwp.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1123700847661&lang=en_US). Date Accessed: 4/14 2006.
70. Wilson DM, Block J. "Real-Time Continuous Glucose Monitor Use and Patient Selection: What Have We Learned and Where Are We Going?" *Diabetes Technology & Therapeutics* 7.5 (2005): 788-791.
71. Wong LJ, Buckingham BA, Kunselman B, Istoc E, Leach J, Purvis R. "Extended use of a new continuous glucose monitoring system with wireless data transmission in children with type 1 diabetes mellitus." *Diabetes Technology & Therapeutics* 8.2 (Print) (2006): 139-145.

72. Yates K, Hasnat Milton A, Dear K, Ambler G. "Continuous glucose monitoring-guided insulin adjustment in children and adolescents on near-physiological insulin regimens: a randomized controlled trial." *Diabetes Care* 29.7 (Print) (2006): 1512-1517.
73. Zisser H, Shwartz S, Ratner R, Wise J, Bailey T. Accuracy of a Seven-Day Continuous Glucose Sensor Compared to YSI Blood Glucose Values. Presentation at the 67th Scientific Sessions of the American Diabetes Association. Chicago, IL; 2007.
74. Zisser HC, BAILEY t, Jovanovic L., Diabetes Self-Management Guided Continuous Glucose Monitoring: Results of a Pilot Study. Presentation at the 66th Scientific Sessions of the American Diabetes Association. Las Vegas, NV; 2006

**Disclaimer:**

This document is for informational purposes only and should not be relied on in the diagnosis and care of individual patients. Medical and Coding/Reimbursement policies do not constitute medical advice, plan preauthorization, certification, an explanation of benefits, or a contract. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the member's individual benefit plan that is in effect at the time services are rendered.

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

U of U Health Plans makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. U of U Health Plans updates its Coverage Policies regularly, and reserves the right to amend these policies and give notice in accordance with State and Federal requirements.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from U of U Health Plans.

"University of Utah Health Plans" and its accompanying logo, and its accompanying marks are protected and registered trademarks of the provider of this Service and or University of Utah Health. Also, the content of this Service is proprietary and is protected by copyright. You may access the copyrighted content of this Service only for purposes set forth in these Conditions of Use.

© CPT Only – American Medical Association