| KAISER PERMANENTE® Mid-Atlantic States | **Continuous Glucose Monitor**<br><br>**Medical Coverage Policy** |
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**Utilization *ALERT***

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please refer to CMS guidelines through Medicare Coverage Database requirements.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

**I. Device: Continuous Glucose Monitor (CGM)**
*Related Medical Coverage Policy: Insulin Pump*

**II. Specialty:** Endocrinology, Adult and Pediatric

**III. Adult and Pediatric Indications for Use**

**A. Clinical Criteria for Adults (1 or 2 or 3, or 4)**

1. Member is 18 years old or older and has *all* the following:
   a. Diagnosis of diabetes;
   b. Using insulin injections at least once daily or on an insulin pump;
   c. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or telehealth visit with the beneficiary to evaluate their diabetes control and determined that the above criteria (section A1a and A1b) are met.

2. Member is 18 years old or older and has a diagnosis of Diabetes AND there is specific documentation of:
   a. History of severe hypoglycemia not responsive to changes in the member's diabetes regimen by the treating provider.
      i. Hypoglycemia requiring assistance and/or glucagon injection or visit to the Emergency Department within the past three months OR hypoglycemia associated seizures within the last 6 months OR
      ii. Nocturnal hypoglycemia (blood glucose < 50 at least three times per week over the past month while asleep, which is refractory to medication dose changes
      iii. Recurrent hypoglycemia seizures (1 or more hypoglycemic seizures in the past year)

3. Individuals of all ages with diabetes mellitus successfully using a continuous glucose meter during the month prior to enrollment with KPMAS. They must meet the medical necessity criteria or have prior insurance authorization for coverage. Proof of prior insurance authorization will be required if

they do not meet the medical necessity criteria.

4. For patients with Type 1 diabetes or Type 2 insulin requiring diabetes diagnoses pre-conception, pre-pregnancy and during pregnancy to reduce the incidence of fetal mortality and anomalies.

B. **Clinical Criteria for Pediatrics (1 or 2 or 3 or 4)**
   1. **Pediatric member is between 2 years and 17 years of age** and has ***all*** the following:
      a. Diagnosis of diabetes;
      b. Using insulin injections at least once daily or is on an insulin pump
      c. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or telehealth visit with the beneficiary to evaluate their diabetes control and determined that criteria (1)-(4) above are met; or
      d. A new diagnosis of type 1 diabetes; and
      e. The device is ordered by a pediatric endocrinologist.

   2. Child meets the above pediatric clinical criteria for a CGM, on an insulin pump or preparing to go on an insulin pump that communicates with a CGM and willing to wear a CGM.

   3. Individuals of all ages with diabetes mellitus successfully using a continuous glucose meter during the month prior to enrollment with KPMAS. They must meet the medical necessity criteria or have prior insurance authorization for coverage. Proof of prior insurance authorization will be required if they do not meet the medical necessity criteria.

**C. Required Clinical Criteria for ongoing use (Adult and Pediatric patients)**
   **1.** Failure to communicate with their diabetes team may result in termination of their CGM supplies
      a. Within 3 months of receiving the system AND
      b. Encounter every 6 months with provider(s) managing diabetes

**D. Exclusion**
   1. Smart devices used to receive glucose readings to are not considered to be DME and are not considered to be medically necessary; and
   2. If a member never uses a DME receiver or insulin infusion pump to display CGM glucose data, the supply allowance is not covered by Kaiser.
   3. Replacement of previously provided CGM devices with a same or similar CGM device, for reasons other than medical necessity of replacement, device failure, device damage, or device obsolescence, is not covered. Replacement for misuse is not covered. Replacement for loss will be evaluated on a case-by-case basis. Clinical documentation must clearly demonstrate the need for the replacement device.

**References**

1. Kamath A, Mahalingam A, Brauker J Methods of evaluating the utility of continuous glucose monitor alerts.J Diabetes Sci Technol - Jan 2010; 4(1); 57-66.
2. Klonoff DC, Buckingham B, Christiansen JS, et al. Continuous glucose monitoring: an Endocrine Society Clinical Practice Guideline. Journal of Clinical Endocrinology and Metabolism 2011;96(10).
3. KP Clinical Guidelines Endocrine. Clinical Library. Continuous Glucose Monitors. Accessed May 28, 2014.
4. Lane JE, Shivers JP, Zisser H Continuous glucose monitors: current status and future developments. Curr Opin Endocrinol Diabetes Obes - Apr 2013; 20(2); 106-11.
5. Leinung M, Thompson S, Benefits of continuous glucose monitor use in clinical practice. Nardacci E, - Endocr Pract - May 1, 2010; 16 (3); 371-5.
6. LLC Neithercott,Tracey Using an Insulin Pump and a CGM, American Diabetes Association, January 2013.
7. Meade LT. The use of continuous glucose monitoring in patients with type 2 diabetes. Diabetes Technology and Therapeutics 2012;14(2):190-5.
8. Medicare Coverage Database, search: continuous glucose monitor, diabetes self monitor. Technology Assessments: Intensive Glycemic Control, Sept 2007. Accessed 4/6/2016.
9. Switzer, SM, et al Intensive insulin therapy in patients with type 1 diabetes mellitus. Endocrinol Metab Clin North Am 2012 March: 41(1): 89-104.
10. Szypowska A, Ramotowska A, Dzygalo K, Golicki D. Beneficial effect of real time continuous glucose monitoring on glycemic control in type 1 diabetic patients. Eu J of Endocrinology. 2012;166(4):567-74.
11. U.S. Food and Drug Administration, FDA approves pediatric use of Dexcom's G4 Platinum continuous glucose monitoring system. Feb 3, 2014.
12. Vigersky RA, Fonda SJ, Chellappa M, etal. Shrt and long term effectos of real time continuous glucose lmonitoring in patients with type 2 diabetes. Diabetes Care, 2012; 35(1): 32-8.
13. Walsh, John, Roberts, Ruth et al New Criteria for Assessing the Accuracy of Blood Glucose Monitors. J Diabetes Sci Technology, 2012 March:6:2, 466-474.
14. Mariani, Hanna S.; Layden, Brian T.; Aleppo, Grazia; Continuous Glucose Monitoring: A Perspective on Its Past, Present, and Future Applications for Diabetes Management.(includes abstract) Clinical Diabetes, Winter2017; 35(1): 60-65. 6p. (Article) ISSN: 0891-8929, Database.
15. Van Beers, Cornelis A J; DeVries, J Hans; Kleijer, Susanne J; Smits, Mark M; Geelhoed-Duijvestijn, Petronella H; Kramer, Mark H H; Diamant, Michaela; Snoek, Frank J; Serné, Erik H. Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (IN CONTROL): a randomised, open-label, crossover trial The Lancet Diabetes & Endocrinology. November 2016 4(11):893-902 Language: English. DOI:10,1016/S2213-8587(16)30193-0, Database: ScienceDirect.
16. Toschi, Elena; Wolpert, Howard. Utility of Continuous Glucose Monitoring in Type 1 and Type 2 Diabetes Diabetes, Endocrinology and Metabolism Clinics of North America. December 2016 45(4):895-904 Language: English. DOI: 10.1016/j.ecl.2016.06.003, Database: ScienceDirect
17. Paing, Aye C; Kirk, Alison F; Collier, Andrew; Kubiak, Thomas; Chastin, Sebastien F.M. Are glucose profiles well-controlled within the targets recommended by the International Diabetes Federation in Type 2 Diabetes? A meta-analysis of results from continuous glucose monitoring based studies Diabetes Research and Clinical Practice. December 2018 146:289-299 Language: English DOI: 10.1016/j.diabres.2018.10.010. Database: ScienceDirect.

18. Guilmin-Crepon, Sophie; Tubiana-Rufi, Nadia; Carel, Jean-Claude; Dalla-Vale, Fabienne, Stuckens, Chantal; Bony-Trifunovic, Helene; Crosnier, Helene; Kurtz, Francois; Coque, Nathalie; Schroedt, Julien; Alberti, Corinne; Kaguelidou, Florentia; Le Jeeannic, Anais; Durand-Zaleski, Isabelle; Sulmont, Veronique; Salmon, Anne-Sophie; Le Tallec, Claire; Coutant, Regis. Is there an optimal strategy for real-time continuous glucose monitoring in pediatrics? A 12-month French multi-center, prospective, controlled randomized trial (Start-IN!). (includes abstract) Pediatric Diabetes , May 2019, 20(3): 304-313. 10p (Article) ISSN: 1399-543X.
19. Buttomesso, D; Laviola, L; Avogaro, A; Bonora, E. Del Prato, S; Orsi, E; Rabbone, I; Sesti, G; Purrello, F. The use of real time continuous glucose monitoring or flash glucose monitoring in the management of diabetes: A consensus view of Italian diabetes experts using the Delphi Method Nutrition, Metabolism and Cardiovascular Diseases. May 29 29(5): 421-431. Language: English. DOI: 10, 1016/j.numecd.2019.01.018. Database.
20. Lee, Inyoung; Loew, Nova; Tsugawa, Wakako; Ikebukur, Kazunori; Sode, Koji Development of a third-generation glucose sensor-based on the open circuit potential for continuous glucose monitoring. Biosensors and Bioelectronics. 15 January 2019 124-125:216-223 Language: English DOI: 10.1016/j.bios.2018.09.099.
21. Voormolen, Daphne N.; DeVries, J. Hans; Sanson, Rieneke M. E.; Heringa, Martijn P.; de Valk, Harold W.; Kok, Marjolein; van Loon, Aren J.; Hoogenberg, Klaas; Bekedam, Dick J.; Brouwer, Teri C. B.; Porath, Martina; Erdtsieck, Ronald J.; NijBijvank, Bas; Kip, Huib; van der Heijden, Olivier W. H.; Elving, Lammy D.; Hermsen, Brenda B.; Potter van Loon, B. J.; Rijnders, Robert J. P.; Jansen, Henry J. Continuous glucose monitoring during diabetic pregnancy (GlucoMOMS): A multicentre randomized controlled trial. Diabetes, Obesity & Metabolism, Aug2018, Vol. 20 Issue 8, p1894-1902, 9p. Publisher: Wiley-Blackwell.
22. Murphy, Helen R.. Intensive Glycemic Treatment During Type 1 Diabetes Pregnancy: A Story of (Mostly) Sweet Success! Diabetes Care, Aug2018, Vol. 41 Issue 8, p1563-1571, 9p, 3 Charts, 1 Graph. Publisher: American Diabetes Association.,
23. Cappon, G., Vettoretti, M., Sparacino, G., & Facchinetti, A. (2019). Continuous Glucose Monitoring Sensors for Diabetes Management: A Review of Technologies and Applications. Diabetes & metabolism journal, 43(4), 383–397. https://doi.org/10.4093/dmj.2019.0121.
24. Galindo, R. J., Aleppo, G., Klonoff, D. C., Spanakis, E. K., Agarwal, S., Vellanki, P., Olson, D. E., Umpierrez, G. E., Davis, G. M., & Pasquel, F. J. (2020). Implementation of Continuous Glucose Monitoring in the Hospital: Emergent Considerations for Remote Glucose Monitoring During the COVID-19 Pandemic. Journal of diabetes science and technology, 14(4), 822–832. https://doi.org/10.1177/1932296820932903
25. Fabris, C., Ozaslan, B., & Breton, M. D. (2019). Continuous Glucose Monitors and Activity Trackers to Inform Insulin Dosing in Type 1 Diabetes: The University of Virginia Contribution. Sensors (Basel, Switzerland), 19(24), 5386. https://doi.org/10.3390/s19245386.
26. Vettoretti, M., Cappon, G., Facchinetti, A., & Sparacino, G. (2020). Advanced Diabetes Management Using Artificial Intelligence and Continuous Glucose Monitoring Sensors. Sensors (Basel, Switzerland), 20(14), 3870. https://doi.org/10.3390/s20143870
27. Camerlingo, N., Vettoretti, M., Facchinetti, A., Sparacino, G., Mader, J. K., Choudhary, P., & Del Favero, S. (2020). An analytical approach to determine the optimal duration of continuous glucose monitoring data required to reliably estimate time in hypoglycemia. Scientific reports, 10(1), 18180. https://doi.org/10.1038/s41598-020-75079-5
28. Laffel LM, Kanapka LG, Beck RW, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in

Adolescents and Young Adults With Type 1 Diabetes: A Randomized Clinical Trial. *JAMA*. 2020;323(23):2388–2396. doi:10.1001/jama.2020.6940.. https://jamanetwork.com/journals/jama/fullarticle/2767160.

29. Kamusheva, M. et al. A Systematic Review of Collective Evidences Investigating the Effect of Diabetes Monitoring Systems and Their Application in Health Care. *Front. Endocrinol*., 16 March 2021 | https://doi.org/10.3389/fendo.2021.636959
30. Vidmar, A. P., Naguib, M., Raymond, J. K., Salvy, S. J., Hegedus, E., Wee, C. P., & Goran, M. I. (2021). Time-Limited Eating and Continuous Glucose Monitoring in Adolescents with Obesity: A Pilot Study. *Nutrients*, *13*(11), 3697. https://doi.org/10.3390/nu13113697
31. Naguib, M. N., Hegedus, E., Raymond, J. K., Goran, M. I., Salvy, S. J., Wee, C. P., Durazo-Arvizu, R., Moss, L., & Vidmar, A. P. (2022). Continuous Glucose Monitoring in Adolescents With Obesity: Monitoring of Glucose Profiles, Glycemic Excursions, and Adherence to Time Restricted Eating Programs. *Frontiers in endocrinology*, *13*, 841838. https://doi.org/10.3389/fendo.2022.841838
32. Villena Gonzales, W., Mobashsher, A. T., & Abbosh, A. (2019). The Progress of Glucose Monitoring-A Review of Invasive to Minimally and Non-Invasive Techniques, Devices and Sensors. *Sensors (Basel, Switzerland)*, *19*(4), 800. https://doi.org/10.3390/s19040800
33. MCG Ambulatory Care 28th edition, Copyright © 2024 MCG Health. ACG: A-0126 (AC). Accessed12/15/23.
34. Addala, A., Ding, V., Zaharieva, D. P., Bishop, F. K., Adams, A. S., King, A. C., Johari, R., Scheinker, D., Hood, K. K., Desai, M., Maahs, D. M., Prahalad, P., & Teamwork, Targets, Technology, and Tight Control (4T) Study Group (2023). Disparities in Hemoglobin A1c Levels in the First Year After Diagnosis Among Youths With Type 1 Diabetes Offered Continuous Glucose Monitoring. *JAMA network open*, *6*(4), e238881. https://doi.org/10.1001/jamanetworkopen.2023.8881
35. Karter, A. J., Parker, M. M., Moffet, H. H., Gilliam, L. K., & Dlott, R. (2021). Association of Real-time Continuous Glucose Monitoring With Glycemic Control and Acute Metabolic Events Among Patients With Insulin-Treated Diabetes. *JAMA*, *325*(22), 2273–2284. https://doi.org/10.1001/jama.2021.6530

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## Approval History

| Date approved by RUMC* | Date filed with the State of Maryland** | Date of Implementation (Ten days after filing) |
|---|---|---|
| 05/23/2013 | 05/24/2013 | 06/03/2013 |
| 06/03/2014 | 06/04/2013 | 06/15/2014 |
| 06/03/2014 | Refiled[1] 07/17/2014 | 07/28/2014 |
| 06/30/2015 | 07/02/2015 | 07/14/2015 |

[1] Refiled with MIA on 7/17/2014 with correction to exclude Medicare members which remain under the coverage uidelines of the Medicare Coverage Database.

## Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

| Date approved by RUMC* | Date of Implementation |
|---|---|
| 06/30/2016 | 06/30/2016 |
| 06/28/2017 | 06/28/2017 |
| 06/15/2018 | 06/15/2018 |
| 06/24/2019 | 06/24/2019 |
| 02/25/2020 | 02/25/2020 |
| 02/17/2021 | 02/17/2021 |
| 02/28/2022 | 02/28/2022 |
| 02/22/2023 | 02/22/2023 |
| 10/03/2023 | 10/03/2023 |
| 03/19/2024 | 03/19/2024 |
| 05/23/2024 | 05/23/2024 |

***The Regional Utilization Management Committee received **delegated authority** to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee in 2011.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Whenever possible, Medical Coverage Policies are evidence-based and may also include expert opinion. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any set of circumstances for an individual member.