KAISER PERMANENTE®
Mid-Atlantic States

External Insulin Pumps and Supplies
Medical Coverage Policy

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. Coverage Overview

Coverage of external insulin pumps and supplies, for Commercial members, is subject to the terms, conditions, and limitations of the applicable KP benefit plan's DME benefit and schedule of cost shares.

A. Some benefit products/plans may specifically exclude or limit coverage for certain insulin pumps or supplies.

B. Repair and/or replacement of insulin pumps may also be limited under some benefit plans. Please refer to the applicable Kaiser DME benefit plan document to determine benefit availability and the terms, conditions, and limitations of coverage.

C. This MCP does not address coverage of *implanted* insulin pumps.

II. Specialty Management

Primary care physicians should refer members to Endocrinology for initial evaluation and ongoing care of external insulin pump.

A. Initial external insulin pumps, replacement insulin pumps, and supplies are ordered by an endocrinologist.

B. For ongoing use of external insulin pump therapy, Commercial members are evaluated by endocrinologist every 6-12 months, as needed. Long term and stable insulin pump patients may be managed by primary care physicians with endocrine evaluation every year.

C. Primary care physicians may order insulin refills as needed.

III. Coverage Criteria

External insulin pumps (with or without wireless communication capability) are considered medically necessary for individuals with diabetes in any of the following groups: (A, B or C).

Additionally, disposable external insulin pump with wireless communication capability to a hand-held control unit (e.g., OmniPod®) are an acceptable alternative to a standard insulin infusion pump and considered medically necessary when one of the criteria below (A, B, or C) has been

met.

A. Adult individuals with documented diabetes mellitus (Type 1 or Type 2 or gestational) meeting all of the following criteria (1-5):

1. Completed a comprehensive diabetes education program within the past two years; and

2. Follows a program of multiple (3 or more) daily injections of insulin; and

3. Has frequent self-adjustments of insulin doses for the past 6 months; and

4. Has documented frequency of glucose self-testing an average of at least 3 times per day during the past month or monitoring by CGM; and

5. Has documentation of *any* of the following while on a multiple daily injection regimen:

a. Glycosylated hemoglobin level (HbA1c) greater than 7.0 percent; or
b. "Brittle" diabetes mellitus with recurrent episodes of diabetic ketoacidosis, hypoglycemia, or both, resulting in recurrent and/or prolonged hospitalization; or
c. History of recurring hypoglycemia or severe glycemic excursions; or
d. Wide fluctuations in blood glucose before mealtime; or
e. "Dawn phenomenon" with fasting blood sugars frequently exceeding 200 mg/dl; or

B. Preconception or pregnancy to reduce the incidence of fetal mortality or anomaly; or

C. People with diabetes mellitus successfully using continuous insulin pump prior to enrollment with KPMAS; or

D. For children documented with diabetes mellitus (Type I or Type II with insulinopenia) meeting *all* of the following criteria (1-3):

1. Failure of multiple daily injection insulin administration as indicated by **one or more** of the following:
   a. Abnormal early-morning increase in blood glucose ("dawn phenomenon"), unresponsive to management with long-acting insulin analogue (e.g., insulin glargine, insulin detemir) regimens;
   b. Child for whom multiple daily insulin injections are impractical or inappropriate;
   c. Diabetes complications (e.g., neuropathy, nephropathy, retinopathy) and need for more intensive management;
   d. Extreme insulin sensitivity;

e. HbA1c greater than 7.5% (58.5 mmol/mol) despite intensified multiple daily injection insulin therapy;
f. Hypoglycemia requiring third-party assistance, including unconsciousness, seizure, glucagon administration, and emergency attendance or admission to hospital;
g. Patient is pregnant or planning pregnancy; and
h. Wide swings in glycemic control.

2. Patient or caregiver is motivated, adherent, knowledgeable and able to monitor blood glucose 3 or more times per day or using CGM as directed
3. The provider team is experienced in management and support of patients with insulin pumps.

E. Artificial Pancreas

1. A continuous glucose monitors and insulin pump with a low glucose suspend feature (e.g., MiniMed 630G) is an equally acceptable alternative to a standard insulin pump and continuous glucose monitor for medically necessary injections. Criteria for both devices will need to be met.
2. A continuous glucose monitors and insulin pump with closed loop system (programmed to automatically adjust delivery of basal insulin based on continuous glucose monitor sensor glucose values) (e.g., Medtronic MiniMed 670G, Tandem t: slimX2 insulin pump with Basal-IQ Technology) is an equally acceptable alternative to a standard insulin pump and continuous glucose monitor for medically necessary indications. Criteria for both devices will need to be met.

IV. Ongoing Coverage of Supplies and Insulin

A. Refills for disposable external insulin pumps are considered medically necessary.

1. During evaluation of the member's equipment needs, the member's type of pharmacy coverage must be reviewed.
2. If the member does not have KPMAS pharmacy benefits, the physician or UM reviewer must verify that the insulin and/or the refills for the disposable external insulin pumps are covered for the member.

B. Documentation of continued effectiveness and safe use of the external insulin infusion pump and supplies may be verified by the UM reviewer prior to approval via chart review of telephone encounters and visits with the primary care physician and a visit with the endocrine team at least once every 12 months.

V. Replacement pumps

A. For pediatric individuals who require a larger insulin reservoir, the medical necessity of replacement external insulin pumps will be considered on a case-by-case basis. The following information is required when submitting requests:

1. Current insulin pump reservoir volume; and
2. Current insulin needs; and
3. Current insulin change-out frequency required to meet individual needs.

B. For adults and children, the replacement of external insulin pumps that are out of warranty, or are malfunctioning and cannot be repaired, is considered medically necessary.

VI. Coverage Exclusions

A. The use of external insulin pumps for any indication other than those listed in section III is not considered medically necessary.

B. Replacement of currently functional and warrantied insulin pumps for the sole purpose of receiving the most recent insulin pump technology (commonly referred to as an “upgrade") is not considered medically necessary as such upgrades have not been shown to make a clinically significant difference.

C. Equipment upgrades or accessories whose sole purpose is to integrate (with wireless communication technology) an insulin pump and interstitial glucose monitor are not considered medically necessary.

VII. Contraindications

Intensive diabetic management in any form, including the use of external insulin infusion pumps, is *CONTRAINDICATED* for individuals (or for children and their caregivers) who ***for any reason*** are unwilling or unable to participate actively in intensive glucose management and to acquire the cognitive and technical skills required for the safe and effective use of the equipment and insulin therapy.

References

1. American Association of Clinical Endocrinologists: Consensus Statement on Insulin Pump Management., Endocr Pract. 2010; 16 (No.5).
2. Castorino K, Paband R, Zisser H, Jovanovic L. Insulin pumps in pregnancy: using technology to achieve normoglycemia in women with diabetes. Current Diabetes Reports 2012;12(1):53-9.
3. Great Britain: Cummins, E., Royle, P.et al, Clinical effectiveness and cost effectiveness of continuous subcutaneous insulin infusion for diabetes: systematic review and economic evaluation. Executive summary of Health Technology Assessment 2010; 14 (11).
4. Grunberger G. Consensus statement by the American Association of Clinical Endocrinologists/American College of Endocrinology Insulin Pump Management Task Force.
5. Mameli C, Scaramuzza AE, Ho J, Cardona-Hernandez R, Suarez-Ortega L, Zuccotti GV: A 7-year follow-up retrospective, international, multicenter study of insulin pump therapy in children and adolescents with type 1 diabetes- Acta Diabetol - Apr 2014; 51(2); 205-10.
6. Maryland Dept. of Health and Mental Hygiene, Medicaid DME/DMS/Oxygen Approved List of Items, July 1, 2015. Accessed July 20, 2015.
7. Medicare Coverage Database, National Coverage Determination (NCD) for Infusion Pumps (280.14). Accessed 6/28/2017.
8. Center for Medicaid and Medicare Services. Medicare Learning Network. An Overview of Medicare Covered Diabetes Supplies and Services MLN Matters Number: SE0738 Revised. Release Date: August 16, 2018. Accessed 4/16/2020 https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE0738.pdf
9. Center for Medicaid and Medicare Services. Medicare Coverage Database. Decision Memo for Insulin Infusion Pump (CAG-00041N). Accessed 4/16/2020. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=40&fromdb=true
10. Pickup JC, Renard E. Long-acting insulin analogs versus insulin pump therapy for the treatment of type 1 and type 2 diabetes. Diabetes Care 2008;31 Suppl 2:S140-5.
11. Virginia Medicaid, Provider Manuals, Chapter IV, Covered Services and Limitations, Durable Medical Equipment, accessed July 20, 2015.
12. Original article: Numerical and clinical precision of continuous glucose monitoring in Colombian patients treated with insulin infusion pump with automated suspension in hypoglycemia Precision numerica y clinica de la monitorizacion continua de glucosa en pacientes colombianos en terapia con bomba de infusion de insulina con suspension automatica en hipoglycemia (Spanis; Castilian). By Gomez, Ana M; Marin Sanchez Alejandro; Munoz, Oscar M.; Colon Pena, Christian Alejandro. In Endocrinologia y nutricion (English Edition). December 2015 62(10): 485-492 Language: English. DOI: 10.1016 (j.endoen 2015.11.04.
13. Insulin Therapy, The Old, the New and the Novel. An Overview by Brady, Veronica J in Glucose Regulation, Nursing Clinics of North America. December 2017 52(4): 539-552 Language: English. DOI: 10.1016/j.cnur.2017.07.004.
14. Real-Life Management and Effectiveness of Insulin Pump with or without Continuous Glucose Monitoring in Adults with Type I Diabetes. by Vinas, Clara; Quiros, Carmen; Gimenez, Marga;

Conget, Ignacio. Diabetes Therapy. June 2019, Vol 10 issue 3, p929-936. 8p. DOI: 10.1007/s 13300-019-0599-1.

15. Obesity Management for the Treatment of Type 2 Diabetes: Standards of Medical Care in Diabetes—2020. *American Diabetes Association Diabetes Care* 2020 Jan; 43 (Supplement 1): S89-S97. Accessed 4/16/2020. https://doi.org/10.2337/dc20-S008
16. Introduction: Standards of Medical Care in Diabetes—2021. *Diabetes Care 2021*. Jan; 44 (Supplement 1): S1-2. Accessed 03/12/2021 https://doi.org/10.2337/dc21-Sint https://care.diabetesjournals.org/content/44/Supplement_1
17. Auzanneau, M., Karges, B., Neu, A., Kapellen, T., Wudy, S. A., Grasemann, C., Krauch, G., Gerstl, E. M., Däublin, G., & Holl, R. W. (2021). Use of insulin pump therapy is associated with reduced hospital-days in the long-term: a real-world study of 48,756 pediatric patients with type 1 diabetes. *European journal of pediatrics*, *180*(2), 597–606. https://doi.org/10.1007/s00431-020-03883-2
18. Marks, B. E., Williams, K. M., Sherwood, J. S., & Putman, M. S. (2021). Practical aspects of diabetes technology use: Continuous glucose monitors, insulin pumps, and automated insulin delivery systems. *Journal of clinical & translational endocrinology*, *27*, 100282. https://doi.org/10.1016/j.jcte.2021.100282
19. Dirnena-Fusini, I., Åm, M. K., Fougner, A. L., Carlsen, S. M., & Christiansen, S. C. (2021). Physiological effects of intraperitoneal versus subcutaneous insulin infusion in patients with diabetes mellitus type 1: A systematic review and meta-analysis. *PloS one*, *16*(4), e0249611. https://doi.org/10.1371/journal.pone.0249611
20. Nuha A. ElSayed, Grazia Aleppo, Vanita R. Aroda, Raveendhara R. Bannuru, Florence M. Brown, Dennis Bruemmer, Billy S. Collins, Marisa E. Hilliard, Diana Isaacs, Eric L. Johnson, Scott Kahan, Kamlesh Khunti, Jose Leon, Sarah K. Lyons, Mary Lou Perry, Priya Prahalad, Richard E. Pratley, Jane Jeffrie Seley, Robert C. Stanton, Robert A. Gabbay; on behalf of the American Diabetes Association, *2023*. New Practice Clinical Guidelines. Standards of Care in Diabetes. *Diabetes Care* 1 January 2023; 46 (Supplement_1): S111–S127. Accessed: 05/15/2023. https://doi.org/10.2337/dc23-in01
21. Nathalie Jeandidier, Sylvie Boullu, Marie-Sophie Busch-Brafin, Gerard Chabrier, Rémy Sapin, Françoise Gasser, Michel Pinget; Comparison of Antigenicity of Hoechst 21PH Insulin Using Either Implantable Intraperitoneal Pump or Subcutaneous External Pump Infusion in Type 1 Diabetic Patients . *Diabetes Care* 1 January 2002; 25 (1): 84–88. https://doi.org/10.2337/diacare.25.1.84
22. Center for Medicaid and Medicare Services. LCD. External Infusion Pump (L33794). Accessed: 05/15/23. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33794
23. Center for Medicaid and Medicare Services. Local Coverage Article. External Infusion Pumps. Policy Article. A52507. Accessed: 05/15/23 https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52507
24. MCG 28th edition. Copyright © 2024 MCG Health, LLC. ACG: A-0339 (AC) Insulin Infusion Pump. Accessed 12/20/2023
25. Anthony L McCall, David C Lieb, Roma Gianchandani, Heidemarie MacMaster, Gregory A

Maynard, M Hassan Murad, Elizabeth Seaquist, Joseph I Wolfsdorf, Robin Fein Wright, Wojtek Wiercioch, Management of Individuals With Diabetes at High Risk for Hypoglycemia: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 108, Issue 3, March 2023, Pages 529–562, https://doi.org/10.1210/clinem/dgac596

26. Korytkowski, M. T., Muniyappa, R., Antinori-Lent, K., Donihi, A. C., Drincic, A. T., Hirsch, I. B., Luger, A., McDonnell, M. E., Murad, M. H., Nielsen, C., Pegg, C., Rushakoff, R. J., Santesso, N., & Umpierrez, G. E. (2022). Management of Hyperglycemia in Hospitalized Adult Patients in Non-Critical Care Settings: An Endocrine Society Clinical Practice Guideline. *The Journal of clinical endocrinology and metabolism*, *107*(8), 2101–2128. https://doi.org/10.1210/clinem/dgac278

Approval History

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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
07/26/2016	07/26/2016
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*The Regional Utilization Management Committee received delegated authority in 2011 t o review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

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. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.