

Clinical Policy: Pediatric Insulin Pumps

Reference Number: CP.MP.200

Last Review Date: 10/20

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Description An insulin pump is a device that delivers a continuous subcutaneous infusion of a rapid- or short-acting insulin, supplemented by boluses before each meal or snack.¹ This policy describes the medical necessity criteria for approval of pediatric insulin pumps.

Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation® that external insulin pumps for pediatrics are **medically necessary** for when all of the following criteria are met:
 - A. Has a diagnosis of insulin dependent type I diabetes mellitus;
 - B. Completed a comprehensive diabetes education program. (This may include, but is not limited to, leading to demonstrate the ability and commitment to comply with the regimen of pump care, frequent self-monitoring of blood glucose, and careful attention to diet and exercise, and has received appropriate training on pump usage);
 - C. Has been on a program of multiple daily injections of insulin (e.g., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump;
 - D. Has been on an external insulin infusion pump prior and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to enrollment;
 - E. Has an endocrinologist or physician experienced in providing insulin infusion therapy who orders the insulin pump and states that he/she will monitor the members'/enrollees' status while he/she uses the pump;
 - F. Has provider documentation of a history of poor glycemic control on multiple daily injections of insulin, including a persistently elevated glycosylated hemoglobin level (HBA1C>7.0%). Additional history of poor control may be documented in the medical record, including but not limited to:
 1. Widely fluctuating blood glucose levels before bedtime,
 2. History of severe hypoglycemia (<60 mg/dL) or hyperglycemia (>300 mg/dL),
 3. Treatment of secondary diabetic complications requiring more extensive blood glucose control.

Background

Diabetes mellitus is characterized by hyperglycemia due to impaired pancreatic insulin secretion or inefficient use of insulin by the body. Members/enrollees with insulin-dependent (type 1) diabetes require chronic treatment with exogenous insulin. To calculate the insulin dose needed to manage their blood glucose levels, these members/enrollees perform self-monitoring of blood glucose (SMBG) using samples obtained by finger sticks; however, frequent SMBG may not detect all significant deviations in blood glucose, particularly in members/enrollees with rapidly fluctuating glucose levels. As a result, some who perform multiple daily finger sticks may fail to detect blood glucose excursions above or below the desired range, especially when glucose fluctuations occur at night.²

Diabetes cannot be cured, and treatment is focused on self-management education and training that is centered on self-care behaviors such as healthy eating, physical activities, and monitoring blood glucose to improve health outcomes and the patient’s quality of life. Self-management education improves HbA1c levels, and increased contact time with educators enhances the positive effect. It is a collaborative process in which diabetes educators help patients and those who are at risk for diabetes to gain the knowledge, problem-solving, and coping skills that are needed to successfully self-manage the disease and its related conditions.³

Insulin pumps deliver a basal rate of either rapid- or short-acting insulin subcutaneously through a subcutaneously inserted catheter. Benefits of insulin pump therapy include increased flexibility, possible reduction of complications of diabetes later in life and reduction in injections. Although continuous insulin infusion therapy still requires blood glucose monitoring, counting dietary carbohydrates, judging the impact of exercise on insulin requirements, and making the appropriate adjustments to insulin infusion rates, it is preferred by most families.¹

Guidelines published by the American Association of Clinical Endocrinologists (AACE) state that advances in blood glucose monitoring and continuous monitoring of interstitial glucose, along with the introduction of "smart" insulin pumps, provide clinicians and patients with powerful tools to monitor and adjust treatment regimens. The guidelines recommend arranging for continuous glucose monitoring for patients with type 1 diabetes with unstable glucose control and for patients unable to achieve an acceptable HbA1c level; continuous glucose monitoring is particularly valuable in detecting both unrecognized nocturnal hypoglycemia and postprandial hyperglycemia.⁴

Coding Implications

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HCPCS ®* Codes	Description
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
A4230	Infusion set for external insulin pump, non-needle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3 cc
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
E0784	External ambulatory infusion pump, insulin
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date		03/15
Annual review, coding changes only.	03/16	03/16
Annual review, no changes.	03/17	03/17
Annual review, no changes.	02/18	02/18
Annual review, no changes.	02/19	02/19
Annual review, no changes.	03/20	03/20
Replaced all instances of “member” with “member/enrollee.” References reviewed and updated. Changed to Centene template and renumbered to CP.MP.200 from HS-286.	10/20	10/20

References

1. Levitsky LL, Mirsa M. Management of type 1 diabetes mellitus in children and adolescents. UpToDate website. www.uptodate.com. Published September 3, 2020. Accessed October 7, 2020.
2. Diabetes (type 1 and type 2) in children and young people: diagnosis and management. National Institute for Health and Clinical Excellence Web site. <https://www.nice.org.uk/guidance/ng18>. Published August 2015 (updated November 2016). Accessed October 7, 2020.
3. Implantable insulin pumps. Hayes Directory Web site. <http://www.hayesinc.com>. Published June 7, 2011 (archived August 17, 2015). Accessed October 7, 2020.
4. American Association of Clinical Endocrinologists medical guidelines for clinical practice for developing a diabetes mellitus comprehensive plan. American Association of Clinical Endocrinologists Web site. <https://journals.aace.com/doi/pdf/10.4158/EP15672.GLSUPPL>. Published 2011 (updated April 2015). Accessed February 10, 2020.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

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contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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