

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>EXTERNAL INFUSION PUMPS FOR INSULIN DELIVERY</b>
<b>POLICY NUMBER</b>	<b>MP-6.007</b>

<b>Original Issue Date (Created):</b>	<b>7/1/2002</b>
<b>Most Recent Review Date (Revised):</b>	<b>3/27/2020</b>
<b>Effective Date:</b>	<b>6/1/2020</b>

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**I. POLICY**

**Insulin infusion pumps** for treatment of diabetes mellitus may be considered **medically necessary** in patients who meet all of the following set of criteria\*:

- Supporting clinical documentation from either the patient’s primary physician or a consulting endocrinologist must be submitted for review when requesting the insulin pump; and
- The patient/family has completed a comprehensive diabetes education program; and
- A complete assessment that provides documented evidence of patient/family commitment to self-management of the insulin pump. including documentation of very good compliance with the current self-management program and demonstrated mastery of carbohydrate counting; and
- The patient has been on a program of multiple daily injections of insulin (i.e., two [2] to three [3] injections per day); and
- The patient/family has had frequent self-adjustments of insulin dose for at least six (6) months prior to initiation of the insulin pump; and
- The patient/family has documented glucose self-testing at least four (4) times per day during the two (2) months prior to initiation of the insulin pump; and
- Meets one or more of the following criteria while on the multiple daily injection regimen:
  - Glycosylated hemoglobin level (HbA1c) greater than 7.0 percent;
  - History of recurring hypoglycemia;
  - Wide fluctuations in blood glucose before mealtime;
  - Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl; or
  - History of severe glycemic excursions.

**Note: Individual consideration is provided for diabetic women who are pregnant.**

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In addition, a patient with Type 2 diabetes may be considered for an insulin pump if he/she meets the above criteria as well as the following:

- Has been on a combination of at least two oral agents used concomitantly, prior to beginning insulin therapy (either alone or while continuing oral therapy).

\* To demonstrate that medical necessity criteria have been met, please submit the following:

- Certificate of Medical Necessity
- Chart Notes supporting the Certificate of Medical Necessity
- Blood glucose logs documenting sugars and any interventions (such as sliding scale insulin dose etc.).

*Note: Glucose logs of less than 30 days will be considered on a case by case basis should the provider feel there is a danger to the member's health; please provide an explanation.*

Note: A programmable disposable external insulin infusion pump (e.g., OmniPod® Insulin Management System) is an acceptable alternative to a standard insulin infusion pump for persons who meet medical necessity criteria for external insulin infusion pumps.

**External Infusion Pump Replacement:**

Requests for replacement of an insulin pump that is out of warranty must include one of the following;

- Clear and conclusive documentation from either the treating physician's office notes or the device supplier's customer service notes, that the pump is non-operational; or
- Documentation that the patient has reverted to use of multiple daily injections of insulin or a loaner pump because the pump is non-operational.

Replacement of insulin pumps for reasons other than those stated above is considered **not medically necessary**.

***Cross-reference:***

**MP-1.058** Implantable Infusion Pumps for Pain and Spasticity

**MP-6.004** Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid and Artificial Pancreas Device

**II. PRODUCT VARIATIONS**

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

*Note\** - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

**FEP PPO - Note\*** - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

**III. DESCRIPTION/BACKGROUND**

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External Infusion Pump (EIP) is a portable battery operated device intended to provide continuous ambulatory drug infusion therapy over an extended time period. The EIP is also known as an external pump, ambulatory pump, or a mini-infuser. Proposed drug delivery routes using the EIP include the intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural, intrathecal, and intraventricular routes. A heparinized saline solution may be used during an interruption of drug therapy to maintain catheter patency. A catheter from the pump is attached to the desired access route for drug delivery. The drug reservoir refilling is non-invasive.

Some external insulin infusion pumps (e.g., Paradigm Real-Time Insulin Pump and Continuous Glucose Monitoring System) are able to take results of the blood glucose reading, calculate the appropriate insulin infusion rate, wirelessly transmit the results from the blood glucose monitor to the pump, and automatically adjust the insulin infusion rate, saving the member some extra steps. These insulin pump features, when present, are considered integral to the external insulin infusion pump and blood glucose monitor.

There are over 600 different models of pumps, most of which have received clearance for marketing by the Food and Drug Administration (FDA) through a pre-notification application (510 (K)).

**IV. RATIONALE**

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NA

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### V. DEFINITIONS

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NA

### VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

### VII. DISCLAIMER

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*Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

### VIII. CODING INFORMATION

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

#### Covered when medically necessary:

<b>HCPCS Code</b>	<b>Description</b>
A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each

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A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week
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
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing.

*\*Specific ICD-10-CM Codes do not apply; must meet policy criteria above.*

**IX. REFERENCES**

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1. Eugster EA, Francis G, Lawson-Wilkins Drug and Therapeutics Committee. Position statement: continuous subcutaneous insulin infusion in very young children with Type I diabetes. *Pediatrics* 2006; 118: 1244-1249. [Website]:<http://pediatrics.aappublications.org>. Accessed March 27, 2020.
2. Levitsky L, Misra M, Management of type 1 diabetes mellitus in children and adolescents. In: *UpToDate Online Journal [serial online]*. Waltham, MA: UpToDate; updated October 24, 2019. [Website]: [www.uptodate.com](http://www.uptodate.com) . Accessed March 27, 2020.
3. Weinstock R. Management of blood glucose in adults with type 1 diabetes mellitus In: *UpToDate Online Journal [serial online]*. Waltham, MA: UpToDate; updated November 18, 2019. [Website]: [www.uptodate.com](http://www.uptodate.com) . Accessed March 27, 2020.
4. Wexler D. Insulin therapy in type 2 diabetes mellitus. In: *UpToDate Online Journal [serial online]*. Waltham, MA: updated November 26, 2019. [Website]: [www.uptodate.com](http://www.uptodate.com) . Accessed March 27, 2020..
5. Greene M. Pregestational (preexisting) diabetes mellitus: Glycemic control during pregnancy. In: *UpToDate Online Journal [serial online]*. Waltham, MA: updated January 3, 2020. [Website]: [www.uptodate.com](http://www.uptodate.com). Accessed March 27, 2020.

**X. POLICY HISTORY**

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<b>MP 6.007</b>	<b>CAC 7/29/03</b>
	<b>CAC 11/30/04</b>
	<b>CAC 10/25/05</b>
	<b>CAC 11/28/06</b>
	<b>CAC 1/30/07 Milliman Criteria</b>

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	<b>CAC 5/27/08</b>
	<b>CAC 5/26/09</b>
	<b>CAC 5/25/10</b> Consensus
	<b>CAC 7/26/11</b> Minor Revision. Deleted information related to combination pump (Paradigm). Added statement “individual consideration is provided for diabetic women who are pregnant”. Deleted statement indicating requests for pump replacements will be reviewed on an individual consideration basis. Deleted statement “An external infusion pump out of warranty does not constitute a reason for a new pump.” List of criteria for insulin pump replacement remains unchanged.
	<b>10/13/11</b> FEP variation changed to refer to refer to FEP medical policy.
	<b>CAC 10/30/12</b> Consensus review. References updated; no changes to the policy statements.
	<b>CAC 11/26/13</b> Consensus. No change to policy statement. References updated. Deleted FEP reference to policy manual – this FEP policy was retired. Added standard FEP variation.
	<b>CAC 11/25/14.</b> Consensus review. References updated. No changes to the policy statements. Codes reviewed, no changes.
	<b>CAC 11/24/15</b> Consensus review. No change to policy statements. References updated. Coding updated. Changed LCD number from L5044 to L33794 due to NHIC update to ICD-10.
	<b>07/15/16</b> Administrative posting. LCD revised to reflect Noridian LCD L33794.
	<b>Admin update 1/1/17:</b> Product variation section reformatted. New code A4224 added; effective 1/1/17.
	<b>CAC 11/29/16</b> Minor review. Added note addressing the Omnipod device. Changed the FEP variation -- For insulin pumps refer to the FEP Service Benefit Plan brochure found at <a href="http://www.fepblue.org">www.fepblue.org</a> . Added list of documentation that is needed to demonstrate that medical necessity criteria have been met for an insulin infusion pump. Variations reformatted. References updated. Coding reviewed/updated.
	<b>12/19/17</b> Consensus review. No changes to the policy statements. References updated. Coding reviewed.
	<b>3/23/18</b> Minor review. Removed information on external infusion pumps used for drugs other than insulin. Changed title to External Infusion Pumps for Insulin Delivery. Formerly External Infusion Pumps. Coding Reviewed.
	<b>3/5/19</b> Consensus review. No change to policy statements.
	<b>1/1/20</b> Coding update. New 2020 codes added to policy, A4226 and E0787.
	<b>3/27/20</b> Consensus review. No change to policy statement or coding. Referenced updated.

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