

**DURABLE MEDICAL EQUIPMENT MANUAL**

COVERAGE AND LIMITATION CRITERIA AND POLICY

EFFECTIVE: June 2011

REVISED: November 2023

**Indications and limitations of coverage and medical appropriateness:**

Members ages 0-20 only, coverage allowed if ordered by an endocrinologist or a physician/practitioner with expertise in caring and managing diabetic members that includes insulin pump management and **all** criteria are demonstrated and documented in the clinical and DMEPOS providers records:

- Type 1 insulin dependent diabetic or pancreatic failure requiring ongoing insulin therapy (e.g., pancreatectomy, pancreatitis, pancreatic fibrosis, pancreatic damage from hemochromatosis, etc.) this is not an all-inclusive list; **and**
- Member/caregiver has completed a comprehensive diabetes education program; **and**
- Device meets FDA age limit.

Members ages 21 and older, coverage allowed if ordered by an endocrinologist or a physician/practitioner with expertise in caring and managing diabetic members that includes insulin pump management and **all** criteria are demonstrated and documented in the clinical and DMEPOS providers records:

- Type 1 insulin dependent diabetes **not** less than 6 months duration; **and**
- Has completed a comprehensive diabetes education program; **and**
- Has demonstrated the ability to maintain a close relationship with appropriate providers (i.e., physician, nurse practitioner, diabetes educator, etc.) and participation in ongoing medical supervision. This should include regular glycosylated hemoglobin determinations and ophthalmological evaluations; **and**
- Is motivated and mentally capable of proper operation of the pump; **and**
- Has been on a program of multiple daily injections of insulin (≥3 injections per day), with frequent self-adjustments of insulin dose; **and**
- Has documented frequency of glucose self-testing an average of 4 times per day during the 2 months prior to initiation of the insulin pump or has been prescribed and is appropriately using a continuous glucose monitor; **and**



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## EXTERNAL INSULIN INFUSION PUMP

Service Authorization Required: Yes – pump only.

CMN Required: No

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- Meets at least **two** or more of the following:
  - Elevated glycosylated hemoglobin (HbA1c)  $\geq 7\%$ ; **or**
  - Wide fluctuations in blood glucose before mealtime (e.g., pre-prandial blood glucose levels commonly exceed 140 mg/dL); **or**
  - Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; **or**
  - History of severe glycemic excursions commonly associated with brittle diabetes, such as hypoglycemic unawareness, nocturnal hypoglycemia, extreme insulin sensitivity and/or very low insulin requirements; **or**
  - Day-to-day variations in work schedule, mealtimes, and activity level, which confound the degree of regimentation required to self-manage glycemia with multiple insulin injections; **or**
  - Preconception or pregnancy with a history of suboptimal glycemic control; **or**
  - Suboptimal glycemic and metabolic control post-renal transplant.

#### Billing Guidelines:

Effective January 1, 2023, HCPCS Code **A4224** and **A4225** - will only be allowed when Medicare is the primary payer and has made a payment on the claim. No service authorization required per HB1115.

- Code A4224 includes dressings for the catheter site and flush solutions not directly related to drug infusion. The catheter site may be a peripheral intravenous line, a peripherally inserted central catheter (PICC), a centrally inserted intravenous line with either an external or a subcutaneous port, or an epidural catheter. Code A4224 also includes all cannulas, needles, dressings, and infusion supplies (excluding the insulin reservoir) related to continuous subcutaneous insulin infusion via external insulin infusion pump (E0784).
- Code A4225 describes a syringe-type reservoir that is used with the external insulin infusion pump (E0784). The reservoir may be either glass or plastic and includes the needle for drawing up the drug. This code does not include the drug for use in the reservoir.

Effective January 1, 2023, HCPCS Code **A4230**, **A4231**, and **A4232** for Medicaid primary claims as well as claims where Medicaid is secondary to a commercial health plan the following codes should be utilized based on the product dispensed.



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No service authorization is required. All required supporting documentation is needed in member file for possible audit purposes.

- A4230 - *Infusion set for external insulin pump, non-needle cannula type. Limit of 1 per day.*
- A4231 - *Infusion set for external insulin pump, needle type. Limit of 1 per day.*
- A4232 - *Syringe with needle for external insulin pump, sterile, 3 cc. Limit of 1 per day.*

A 90-day supply will be allowed if ordered. The from and through dates on the claim must reflect the date dispensed.

#### Continued coverage:

- External insulin pump and supplies requires documents from treating practitioner at least every 6 months for a total of 2 practitioner visits documentation since last service authorization request.

#### Replacement:

- A member with Type 1 diabetes mellitus successfully using a continuous insulin infusion pump prior to becoming Medicaid eligible with documented frequency of glucose self-testing on average of at least 4 times per day meets the definition of medical necessity.
- For requests for a non-functioning or malfunctioning external insulin infusion pump, an expired warranty must be verified and include a manufacturer statement why the existing pump is unrepairable/refurbish.

#### Non-covered:

- Back up external insulin infusion pumps.
- Replacement or repair of an external insulin infusion pump that is damaged/destroyed by a member's carelessness, misuse, or abuse.
- Replacement of a functioning external insulin infusion pump with a newer advanced model.
- Insulin pump is under warranty.
- Supplies/equipment billed by a supplier for a member who does not meet the above stated criteria.



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#### Documentation Requirements:

- A prescription from a physician/practitioner who manages members with insulin pumps and who works closely with a team including nurses, diabetes educators, and dietitians.
- Physician/practitioner exam within 90 days of the service authorization start date.
- Certification of Diabetic Education Class with first initial request.
- Qualifying lab results per coverage criteria.

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Date Revised	Revisions
January 2017	A4221 deleted and A4224 replaced. K0552 deleted and A4225 replaced. Changed CMN number to SFN 96 as new form created specific to insulin pumps and supplies. Reviewed and reformatted.
August 1 <sup>st</sup> , 2021	<ol style="list-style-type: none"> <li>1. Reformatted and reviewed</li> <li>2. Deleted CMN required SFN 96.</li> <li>3. <u>Indications and limitations of coverage and medical appropriateness section:</u> <p>Members ages <u>0-20 only</u>, coverage allowed if ordered by an endocrinologist or a physician/practitioner with expertise in caring and managing diabetic members that includes insulin pump management and <b>all</b> criteria are demonstrated and documented in the clinical and DMEPOS providers records:</p> <ul style="list-style-type: none"> <li>• Type 1 insulin dependent diabetic or pancreatic failure requiring ongoing insulin therapy (e.g., pancreatectomy, pancreatitis, pancreatic fibrosis, pancreatic damage from hemochromatosis, etc.) this is not an all-inclusive list; <b>and</b></li> <li>• Member/caregiver has completed a comprehensive diabetes education program; <b>and</b></li> <li>• Device meets FDA age limit</li> </ul> <p>Members ages <u>21 and older</u>, coverage allowed if ordered by an endocrinologist or a physician/practitioner with expertise in caring and managing diabetic members that includes insulin pump management and <b>all</b> criteria are demonstrated and documented in the clinical and DMEPOS providers records:</p> <ul style="list-style-type: none"> <li>• Type 1 insulin dependent diabetes <b>not</b> less than 6 months duration; <b>and</b></li> <li>• Has completed a comprehensive diabetes education program; <b>and</b></li> <li>• Has demonstrated the ability to maintain a close relationship with appropriate providers (i.e., physician, nurse practitioner, diabetes educator, etc.) and participation in ongoing medical supervision. This should include regular glycosylated hemoglobin determinations and ophthalmological evaluations; <b>and</b></li> <li>• Is motivated and mentally capable of proper operation of the pump; <b>and</b></li> </ul> </li> </ol>

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- Has documented frequency of glucose self-testing an average of 4 times per day during the 2 months prior to initiation of the insulin pump or has been prescribed and is appropriately using a continuous glucose monitor; **and**

4. “Insulin Pump Supplies Section: Renamed section to “Billing Guidelines”.
5. Replacement Section: Deleted “Replacement of a non-functioning or malfunctioning external insulin infusion pump and cannot be refurbished.” Non-covered Section: third bullet deleted “does not meet North Dakota Medicaid’s medical coverage criteria. Bullet four deleted “drugs and related”.

November 23, 2022

Reformatted and reviewed. Documentation Equipment’s section bullet 2 replaced “60” with “90”. Header logo updated with new logo.

January 17, 2023

Deleted from Billing Guide:

1. Code A4224 includes dressings for the catheter site and flush solutions not directly related to drug infusion. The catheter site may be a peripheral intravenous line, a peripherally inserted central catheter (PICC), a centrally inserted intravenous line with either an external or a subcutaneous port, or an epidural catheter. Code A4224 also includes all cannulas, needles, dressings, and infusion supplies (excluding the insulin reservoir) related to continuous subcutaneous insulin infusion via external insulin infusion pump (E0784).
2. Billing for more than 1 unit of service per week is incorrect use of the code and will be denied accordingly.
3. Code A4225 describes a syringe-type reservoir that is used with the external insulin infusion pump (E0784). The reservoir may be either glass or plastic and includes the needle for drawing up the drug. This code does not include the drug for use in the reservoir.
4. All supplies (including dressings) used in conjunction with an external insulin infusion pump (E0784) are billed with A4224 and A4225. Other codes should not be used for the separate billing of these supplies as they are included in the A4224.



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Added to Deleted from Billing Guide:

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Continued Coverage section replaced 3 months every for a total of 4 with 6 months for a total of 2.

November 29, 2023

Reviewed and reformatted. No changes made.