GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
The purpose of the insulin pump is to provide an accurate, continuous, controlled delivery of insulin, which can be regulated by the user to achieve intensive glucose control objectives and to prevent the metabolic complications of hypoglycemia, hyperglycemia and diabetic ketoacidosis.

A standard portable external insulin infusion pump is a small battery-operated pump about the size of a personal pager that is filled with insulin, and is connected to thin tubing ending in a needle. The needle is inserted into the skin around the abdomen and supplies a regulated dose of insulin to the user for a day or more at a time. The pump may be carried in a pocket, or in a case worn attached to a belt fastened around a consumer's waist.

The OmniPod™ Insulin Management System (Insulet Corporation, Boston, MA) has two separate components, a disposable "Pod" affixed to the skin that acts as the insulin pump and reservoir, and a hand-held control unit referred to as a "Personal Diabetes Manager" (PDM). The pod is filled with insulin by the patient and replaced every 72 hours. The PDM also incorporates a free-style blood glucose monitor (not continuous). Disposable external insulin pumps are considered equivalent to standard insulin pumps.

POLICY
Standard portable external insulin pumps and disposable external insulin pumps (A9274) with wireless communication capability to a hand-held control unit (e.g., OmniPod) do not require prior authorization. (See terms of coverage below.)

Transdermal insulin delivery system (e.g., V-Go™ Disposable Insulin Delivery Device) and micro-delivery technology insulin pump (e.g., t:slim® insulin pump) are non-covered.

HMO, PPO, Individual Marketplace, Elite, Advantage Coverage Determination
Standard portable external insulin infusion pumps and disposable external insulin pumps (A9274) with wireless communication capability to a hand-held control unit (e.g., OmniPod) are medically necessary for members with type 1 diabetes mellitus documented by a C-peptide level less than 0.5 and when all of the following medical necessity criteria are met:

1. The member has completed a diabetes education program within the last twenty four months of being prescribed an insulin infusion pump.
2. The member has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin dose, for at least 6 months before initiation of the insulin infusion pump.
3. The member had documented frequency that is kept in the member's medical record of glucose self-testing an average of at least 4 times per day during the 2 months before initiation of the insulin infusion pump.
4. The member is at high risk for preventable complications of diabetes. Early signs of diabetic complications include micro-albuminuria and/or documented in the member's medical record persistent difficulty in achieving optimal control of blood sugar levels despite good compliance with an intensive multiple injection regimens.
5. The member needs to meet at least one of the following criteria in order to be eligible for a standard portable external insulin infusion pump:
   - Glycated hemoglobin level (HbA1c) > 7.0%
   - History of recurring hypoglycemia
• Wide fluctuations in blood glucose before mealtime
• Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
• History of severe glycemic excursions

Non-Coverage Determination
Standard portable external insulin infusion pumps and disposable external insulin pumps (A9274) with wireless communication capability to a hand-held control unit (e.g., OmniPod) are non-covered if any of the following contraindications exist:

1. Member has non-insulin dependent (NIDDM or IR-NIDDM, Type II) diabetes, even if insulin is taken
2. Member has end-stage complications such as renal failure
3. Member is unable, because of behavioral, psychological problems or functional ability, to technically operate the pump and perform frequent blood glucose monitoring
4. Member is being prescribed pump therapy to be used for convenience purposes

Paramount does not cover EITHER of the following because each is considered experimental, investigational or unproven:
• transdermal insulin delivery system (e.g., V-Go™ Disposable Insulin Delivery Device)
• micro-delivery technology insulin pump (e.g., t:slim® insulin pump)

Dispensing
The following components are considered "inclusive" with any external (portable) continuous insulin infusion pump rental or purchase payment made by the department on behalf of a member and cannot be submitted to the department for separate reimbursement:

1. Any supporting wires, power supply, cables, attachment kits, or disposable items associated with the operation of the pump
2. Pump education, training, monitoring, or counseling in support of the member's ordered treatment
3. Maintenance, repair, or cleaning charges in association with the three-month trial rental period
4. Delivery, set-up, or pick-up charges

The provider of the standard portable external insulin infusion pump must assure that the member utilizing the device is properly instructed on how to use the device in support of his or her ordered treatment and is aware of and understands any emergency procedures regarding the use of the pump. The provider must maintain written documentation regarding the member's instruction on the use of the pump in the provider's records.

The prescriber of the standard portable external insulin infusion pump must assure and document in the member's medical record that the continued use of the device is resulting in the clinical improvement of the member utilizing the device. The use of the device must be discontinued immediately and an alternative treatment method considered if the member demonstrates no progressive clinical improvement during the rental period of the device.

When purchasing a standard portable external insulin infusion pump is appropriate, the member must be provided with a product warranty that covers any required maintenance or repairs for duration of at least one year and commences on the date the infusion pump was authorized for purchase.

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4230</td>
<td>Infusion set for external infusion pump non-needle cannula type</td>
</tr>
<tr>
<td>A4231</td>
<td>Infusion set for external infusion pump needle type</td>
</tr>
<tr>
<td>A4232</td>
<td>Syringe with needle for external pump</td>
</tr>
<tr>
<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</td>
</tr>
<tr>
<td>E0784</td>
<td>External ambulatory infusion pump, insulin</td>
</tr>
<tr>
<td>K0552</td>
<td>Supplies for external drug infusion pump, syringe type cartridge, each</td>
</tr>
<tr>
<td>K0601</td>
<td>Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each</td>
</tr>
<tr>
<td>K0602</td>
<td>Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each</td>
</tr>
<tr>
<td>K0603</td>
<td>Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each</td>
</tr>
<tr>
<td>K0604</td>
<td>Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each</td>
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</tbody>
</table>
**TAWG REVIEW DATES:** 07/11/2012

**REVISION HISTORY EXPLANATION**
06/15/09: Clarification of verbiage
09/24/11: Replacement clarification
07/11/12: Added Exception for OmniPod coverage per TAWG approval.
09/09/14: Disposable external insulin pumps (A9274) with wireless communication capability to a hand-held control unit (e.g., OmniPod) is covered without prior authorization for all product lines. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.

**REFERENCES/RESOURCES**
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid [http://jfs.ohio.gov/](http://jfs.ohio.gov/)
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.