

Policy Name:	Medical Policy: Insulin Pumps	Policy #:	MP-45
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Policy Information

Owner Department:	Medical UM & Systems Department
Owner:	Assigned Medical Director

If there is a discrepancy between a medical policy and a patient's policy or plan document/summary plan description, the policy or plan document/summary plan descriptions provisions and limitations will govern the determination of benefits.

Purpose of the Policy

To make utilization decisions, Health Alliance uses written criteria based on sound clinical evidence for appropriately applying the criteria.

Statement of the Policy

To apply objective and evidence-based criteria when determining the medical appropriateness of health care services.

Please refer to plan documents for prior authorization necessity/status.

Interpretations

1. Health Alliance covers external Insulin Pumps for Commercial members when all of the following criteria are met:

- 1.1 There is documentation that the member is on multiple, at least three injections of insulin daily, with frequent documented self and provider adjusted insulin doses for at least six months prior to the request for an insulin pump (this criteria is not required for members less than 14 years of age), AND
- 1.2 The member or supervising parent has completed a comprehensive diabetes education program within the past 12 months, AND
- 1.3 The member has documented glucose self-testing an average of at least 4 times per day or has been using a continuous glucose monitor (CGM) during the two months prior to the request for an insulin pump (this criteria is not required for members less than 14 years of age if using a CGM), AND
- 1.4 Any of the following:
 - 1.4.1 The glycosated hemoglobin level (hbA1c) is greater than 7.0%, or
 - 1.4.2 There is a history of recurring significant hypoglycemia < 70 mg/dl, or
 - 1.4.3 Wide fluctuations in blood glucose before mealtime, or
 - 1.4.4 Dawn phenomenon with increasing fasting sugars usually between 4 a.m. and 8 a.m., frequently exceeding 200 mg/dl.

2. NOTE: Insulin pumps are managed separately from Continuous Glucose Monitors (CGMs), which are covered under the Pharmacy Benefit and all insulin pumps require Prior Authorization using HCPCS E0784 under the Health Alliance Medical Benefit through the Utilization Management department including:

- 2.1 Durable Insulin pumps with insulin delivered via a tube to the adhesive injection site patch are considered Durable Medical Equipment (DME) devices and are serviceable for four to seven years include:
 - 2.1.1 **Tandem Slim T X2** pump with Control-IQ Technology which is compatible with Dexcom 6 CGM
 - 2.1.2 **Medtronic Minimed** series pumps including 770G closed loop compatible with Guardian CGM
 - 2.1.3 **iLet Bionic Pancreas**, hybrid closed loop system, works with the FreeStyle Libre 3 Plus sensor.
- 2.2 **Omnipod patch pumps (non-DME)** infuse insulin without a tube directly through the adhesive patch injection site over a maximum of three days and the patch pump is then disposed and replaced with another adhesive patch pump. These include:
 - 2.2.1 Insulet Omnipod, Omnipod DASH (Omnipod plus a handheld Personal Diabetes Manager (PDM) dispensed free by the manufacturer currently) and Omnipod 5 system (Omnipod plus Dexcom 6 CGM)
- 2.3 Requested Omnipod disposable patch insulin pumps (HCPCS A9274) require Utilization Management (UM) Prior Authorization first under the medical benefit requesting HCPCS E0784 using insulin pump [Criteria 1](#) above and if approved, Utilization Management will notify the Health Alliance Pharmacy Department to authorize the patch pumps (A9274) at the retail pharmacy and if requested the CGM transmitter and receiver/monitor. As all Omnipod patch pumps are disposable they are not considered Durable Medical Equipment (DME) and will not be covered under the DME benefit for Commercial members.
- 3. Pump Replacement: Carefully maintained tube insulin pumps should remain serviceable for four (4) to seven (7) or more years. Pumps that are inoperative (not provide basic functional, safe insulin dose delivery), and unserviceable or repair cost greater than replacement, and no longer under warranty will be considered for replacement. Inoperative pumps subject to misuse, abuse, lost or stolen will not be considered for replacement until the time that the pump warranty would normally expire.**
- 3.1 Requests for DME tube insulin pump upgrades or changes solely on the basis of pump technology advancements or to achieve compatibility with a different CGM device than currently in use will not be covered during the serviceable life of the pump.
- 3.2 Established or members new to Health Alliance currently using a DME tube insulin pump who request initiation of an Omnipod disposable patch pump will not be approved without documentation of significant, medically necessary benefits of Omnipod until their current DME insulin pump is inoperable, unserviceable, and no longer under warranty as in 3.0 above.
- 3.3 For members new to Health Alliance with existing pumps and in need of continuing supplies, 3 months of supplies will be approved in order to obtain medical documentation that the member meets current Health Alliance insulin pump criteria.
- 3.4 V-Go™ Disposable Insulin Delivery Device (Valeritas Inc.) is considered investigational and therefore not covered.
- 4. Medicare Advantage Members - Durable Insulin Pump requests are managed by Utilization Management using CMS criteria: See applicable LCD/LCA in grid below. Medicare Advantage requests for Omnipod insulin patch pumps (A9274) should be submitted directly to the Pharmacy Department for adjudication. See [Criteria 4.2](#) below.**
- 4.1 Medicare Advantage Durable Insulin Pump replacement: Insulin pumps which the member owns or is on a capped rental basis will be replaced in cases of loss or irreparable damage from a specific accident or a natural disaster. Repairs to pumps owned by the member are covered when necessary to make the equipment serviceable as is pump replacement in the case that the repair cost exceeds replacement and the pump is no longer under warranty. "Cases suggesting malicious damage, culpable neglect or wrongful disposition should be investigated." For pumps in continuous use for over 5 years (reasonable useful life) on either a rental or purchase basis, members may elect to obtain a new pump (Medicare Carriers Manual, Transmittal 1815, August 8, 2003).

4.2 **Omnipod Exception Note:** Omnipod insulin patch pumps are not considered a Durable Medical Equipment item as they are disposable and **Omnipod patch pumps (A9274) are not covered by Traditional Medicare.** For Medicare Advantage Members, Omnipod is considered a Part D Formulary pharmacy benefit.

- All requests for Medicare Advantage coverage of Omnipod requires prior authorization submitted to the Health Alliance Pharmacy Department through the Guiding Care portal and should NOT be submitted to Utilization Management. Omnipod approval requires that the member meets current Medicare criteria under LCD L33794 for external infusion pumps as well as medical necessity for need of a tubeless Omnipod pump.
 - Enter the Regional LCD/LCA ID in the Medicare website/link below for criteria details. [MCD Search](#)

Regional Medicare Admin Contractor (MAC) (DME) – Member’s state	Regional LCD/LCA Identifier	Applicable Criteria
CGS (IL, IN, OH, NC)	L33794/A52507	Applicable CGS LCD/LCA
Noridian (WA & IA)	L33794/A52507	Applicable Noridian LCD/LCA

CPT Codes	
A4224	Supplies for maintenance of insulin infusion catheter, per week
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, 3cc
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories – OmniPod
E0784	External ambulatory infusion pump, insulin
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensor
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver
S1034	Artificial pancreas device system (e.g., low glucose suspend (LGS) feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S0135	Sensor, invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
S1036	Transmitter; external, for use with artificial pancreas device system
S0137	Receiver (monitor); external, for use with artificial pancreas device system
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)

Providers are required to indicate the diagnosis and procedure codes when requesting review of coverage.

References

1. "V-Go™ Disposable Insulin Delivery Device (Valeritas Inc.)". Hayes Search & Summary, July 1, 2013.
2. Reznik Y, Cohen). (2013 Aug) "Insulin pump for type 2 diabetes: use and misuse of continuous subcutaneous insulin infusion in type 2 diabetes". *Diabetes Care*; 36(Suppl 2): pp. S219 – S225.

3. Leinung MC, Thompson S, et al. (2013 Jan-Feb) "Use of insulin pump therapy in patients with type 2 diabetes after failure of multiple daily injections". *Endocr Pract*; 19(1): pp. 9-13.
4. Golden SH, Brown T, et al. (2012 Jul) "Methods for insulin delivery and glucose monitoring: comparative effectiveness [internet]". Agency for Healthcare Research and Quality (US); Report No. 12-EHC036-EF.
5. Aetna, Clinical Policy Bulletin, No. 0161, Infusion Pumps, August 23, 2005
6. Dr. Kathryn Wilson, Head Division of Endocrinology, CCA, 7/94, & 5/98
7. Hayes Medical Technology Directory. Insulin Pumps, external. May 1, 1997, April 22, 2002.
Drs. Kathryn and Paul Wilson, Division of Endocrinology, CCA, 2002
8. Hayes Executive Summary February 2003
9. "Insulin Pump Therapy for Type 2 Diabetes" Susan Kirk, MD
10. Current Diabetes Reports, 2003; 3:373-377
11. Hayes, Inc. Hayes Health Technology Assessment. Subcutaneous Insulin Infusion with OmniPod Insulin Management System (Insulet Corporation) for Management of Diabetes Mellitus. Lansdale, PA; Hayes, Inc.: Jan. 23, 2020.

History			
Created Date:	07/08/92		
Effective Date:	07/08/92		
Next Review Date:	12/10/2026		
Revision Date:	10/14/92	01/10/95	07/28/98
	08/24/99	04/11/01	06/12/02
	06/11/03	11/12/03	09/08/04 – MDC
	11/11/05 – MDC	12/13/06 – MDC	11/07/08 – MDC
	12/09/09 – MDC	09/08/10 – MDC	11/09/11 – MDC
	08/15/12 – MDC	10/09/13	08/11/14
	03/03/15		
	07/30/15 – MDC-Revision added language in 1.6 to define inoperative, unserviceable pumps and pump upgrades.		
	08/08/16 – MDC-Revision 1.6 adding insulin pump coverage criteria for pregnant members.		
	12/08/17 – MDC-Revision to adjudicate using InterQual DME criteria.		
	08/21/18 – MDC-Approved InterQual 2018 revisions.		
	09/17/19 – MDC-Annual review, no changes.		
	08/26/20 & 10/26/20 – MDC-Annual review, finalized updates to be added to go into effect on 01/01/21 in conjunction with Pharmacy.		
	12/21/21 – MDC-Annual review, no changes, HCPCS codes added.		
	12/20/22 – MDC-Annual review, delete references to InterQual and change to internal policy criteria.		
	12/08/23 – MDC-Annual review, removal of use of InterQual for MA pump adjudication, clarification of operational issues.		

	01/22/24 – Minor language revision for clarity for Medicare Advantage adjudication.
	12/17/24 – MDC-Annual review, Commercial: revision to enable pediatric members with new onset diabetes quicker access to insulin pumps. Utilization Management will continue to manage commercial requests for Omnipod and all requests for DME pumps and Medicare Advantage: revision for prior authorization requests for Omnipod disposable pumps to be managed by pharmacy department.
	12/08/25 – MDC-Annual review, Commercial: no changes and Medicare Advantage: no changes.