



SmartPA Criteria Proposal

Drug/Drug Class:	Insulin Pumps – Tubeless Clinical Edit
First Implementation Date:	April 1, 2021
Revised Date:	March 30, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of tubeless insulin pumps.

Why Issue Selected: Continuous subcutaneous insulin infusion by an insulin pump has been shown to improve long-term glycemic outcomes and enhance quality of life when compared with multiple daily injections of insulin for patients with Type I Diabetes. Insulin pumps are also increasingly being combined with Continuous Glucose Monitors (CGMs) to create an “artificial pancreas” or “closed loop” system that automates blood sugar monitoring and insulin dosing. The Omnipod DASH® System is a tubeless, wearable insulin pump that holds up to 200 units of insulin and delivers continuous insulin therapy through customizable basal rates and bolus amounts. The system consists of the Pod, which is a waterproof insulin pump worn on-body, and the Omnipod DASH Personal Diabetes Manager (PDM), which is a handheld device used to wirelessly control the Pod. There are several features of this tubeless system, including lack of tubing that can be snagged, fewer components, and lack of seeing or handling a needle, that may help patients overcome barriers and promote treatment adherence. In fact, initial evidence demonstrates that tubeless insulin pump therapy may even further enhance patient quality of life and glycemic outcomes when compared to traditional tubed systems. Along with the Dexcom G6 and G7 CGMs currently covered in the Continuous Glucose Monitors (CGMs) Clinical Edit, MO HealthNet will also cover Omnipod tubeless insulin pumps for select participants who desire to utilize them.

Program-Specific Information:	Date Range FFS 10-01-2021 to 9-30-2022			
	Drug	Claims	Spend	Avg Spend per Claim
	OMNIPOD CLASSIC PODS (GEN 3) 5 PACK	73	\$31,264.31	\$428.28
	OMNIPOD DASH INTRO KIT (GEN 4)	1	\$531.99	\$531.99
	OMNIPOD DASH PODS (GEN 4) 5 PACK	1,940	\$916,777.95	\$472.56
	OMNIPOD 5 G6 INTRO KIT (GEN 5)	287	\$164,184.87	\$572.07
	OMNIPOD 5 G6 PODS (GEN 5) 5 PACK	436	\$217,394.87	\$498.61

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Insulin Pumps - Tubeless
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documentation of compliance to current therapy **OR**
- Participant requires insulin administration multiple times per day **OR** current use of an insulin pump **AND**
- Documentation of current use of a Continuous Glucose Monitor (CGM) **OR**
- Documentation of consistent blood glucose testing at least 4 times per day in the past 3 months

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Claim for any tubed insulin pump in the past 2 years
- Claim exceeds quantity limitations: 10 pods every 25 days

Required Documentation

Laboratory Results:	<input type="checkbox"/>	Progress Notes:	<input type="checkbox"/>
MedWatch Form:	<input type="checkbox"/>	Other:	<input checked="" type="checkbox"/>

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

- Omnipod® Simplify Life™. [Healthcare Providers | Omnipod® HCP Site](#). Accessed March 1, 2023.
- Mehta, S, et al. Improved Glycemic Control Following Transition to Tubeless Insulin Pump Therapy in Adults with Type 1 Diabetes. *Clinical Diabetes* 2021 Jan; 39(1): 72-79. <https://doi.org/10.2337/cd20-0022>
- Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus. *Endocr Pract.* 2021;27(6):505-537. [American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus \(endocrinepractice.org\)](https://doi.org/10.1016/j.eprac.2021.04.008) doi:10.1016/j.eprac.2021.04.008