



SmartPA Criteria Proposal

Drug/Drug Class:	Insulin Pumps – Tubeless Clinical Edit
First Implementation Date:	April 1, 2021
Revised Date:	N/A
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" 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® Insulin Management System is a tubeless insulin pump that consists of a Pod, an insulin pump patch with automated cannula insertion, and a personal diabetes manager or PDM, a handheld device used to control and monitor 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 CGM currently covered in the Continuous Glucose Monitors (CGMs) Clinical Edit, MO HealthNet will also cover Omnipod tubeless insulin pumps for select participants diagnosed with Type 1 Diabetes.

Program-Specific Information:	Drug	Cost per package	Cost per year
	OMNIPOD DASH 5 PACK POD	\$249.90 WAC	\$5,997.60 WAC

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

SmartPA Clinical Proposal Form

© 2021 Conduent Business Services, LLC. All rights reserved. Conduent™ and Conduent Design™ are trademarks of Conduent Business Services, LLC in the United States and/or other countries.

Other company trademarks are also acknowledged.

Approval Criteria

- Documentation of compliance to current therapy **OR**
- Documented diagnosis of Type 1 Diabetes in the past 2 years **AND**
- Participant requires insulin administration ≥ 3 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 6 times per day in the past 3 months **AND** documentation of at least one of the following:
 - Participant has a HbA1C $> 7\%$ **OR**
 - Participant has a history of hypoglycemia (defined as blood glucose < 65 mg/dl for participants aged < 8 years and < 55 mg/dl for participants aged ≥ 8 years), including recurrent hypoglycemia or nocturnal hypoglycemia **OR**
 - Participant has a history of glycemic fluctuations as demonstrated by wide fluctuations in blood glucose before mealtime, marked early morning increase in fasting blood sugar (dawn phenomenon = glucose > 200 mg/dl), or other history of severe glycemic fluctuations

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Claim exceeds quantity limitations: 10 pods every 25 days

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

X

Disposition of Edit

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

Default Approval Period

1 year

References

- Omnipod: Insulin Pump Therapy, Simplified. <https://www.omnipod.com/new-to-omnipod>. Accessed March 8, 2021.
- 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>