Director of Medical Services, Conduent

Date: March 1, 2022

Drug/Drug Class: Insulin Pumps – Tubeless Clinical Edit

First Implementation Date: April 1, 2021

Revised Date: February 3, 2022

Prepared for: MO HealthNet

Prepared by: MO HealthNet/Conduent

Criteria Status: ☒ Revision of Existing 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 CGM 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:

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<thead>
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<th>Drug Class</th>
<th>Date Range FFS 4-01-2021 to 9-30-2021</th>
<th>Claims</th>
<th>Spend</th>
<th>Avg Spend per Claim</th>
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<tbody>
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Type of Criteria: ☐ Increased risk of ADE ☒ Preferred Drug List

Data Sources: ☒ 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

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th></th>
<th>Progress Notes:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>MedWatch Form:</td>
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<td>Other:</td>
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Disposition of Edit

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

Default Approval Period

1 year

References