Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

☐ **Commercial (Small & Large Group)** ☐ **ASO** ☐ **Exchange/ACA**
☒ **Medicare Advantage (MAPD)**

Insulin Pump Policy MB2122

Covered Service: Yes

Prior Authorization Required: Yes

Additional Information: Requires prior authorization through Dean Health Plan Utilization Management Department. Applies to MAPD (Medicare Advantage Prescription Drug contracting) and MA only (Medicare Advantage ONLY); Medicare Cost and Select members will not require a Prior Authorization but rather the claims we be evaluated for reimbursement per Medicare LCD.

1.0 DESCRIPTION OF PROCEDURE OR SERVICE

1.1 Infusion pumps are an electrical/battery-operated device used to deliver solutions containing a parenteral drug under pressure at a regulated flow. They are small, portable, and designed to be carried by the member.

1.2 External infusion pumps are considered Durable Medical Equipment.

2.0 POLICY STATEMENT

2.1 Coverage will be provided for external infusion pumps when it is determined to be medically necessary, as outlined in the below guidelines and medical criteria.

3.0 BENEFIT APPLICATION

3.1 Please refer to the member's individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations if the criteria are met

4.0 Coverage decisions will be made in accordance with:

4.1 The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;

4.2 General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and

4.3 Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

4.4 Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

5.0 Dean Health Plan Approval Criteria:

5.1 External Infusion pumps for insulin may be considered medically necessary when the member meets criteria 5.1.1 **OR** 5.1.2 **AND** 5.1.3 **OR** 5.1.4.

5.1.1 C-peptide testing requirement- must meet criterion 5.1.1.1 **OR** 5.1.1.2 **AND** criterion 5.1.1.3:

5.1.1.1 C-peptide (amino acid chain that connects A and B chains of insulin into proinsulin, the precursor of insulin) level that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method, **OR**

5.1.1.2 For patients with renal insufficiency and a creatinine clearance (actual or calculated from age, weight and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200 percent of the lower limit of normal of the laboratory's measurement method; **AND**

5.1.1.3 A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl. **OR**

5.1.2 Beta cell autoantibody test is positive **AND**

5.1.3 The member has completed or is scheduled to complete a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (at least 3 injections per day) with frequent self-adjustments of insulin dosage for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times a day during the 2 months prior to the initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen:

5.1.3.1 Glycosylated hemoglobin level (HbA1c)>7.0 percent;

5.1.3.2 History of recurring hypoglycemia

5.1.3.3 Wide fluctuations in blood glucose before mealtime

5.1.3.4 Fasting blood sugars frequently exceeding 200mg/dl

5.1.3.5 History of severe glycemic excursions - OR

5.1.4 The member with diabetes has been on a pump prior to enrollment in the Plan and has documented frequency of glucose self-testing an average of at least 4 times per day.

****NOTE-HCPCS code E0787 has become an invalid code effective 9/15/2020 and will now need to be filed using E0784 plus E2103 with non-adjunctive continuous glucose sensing or E0784 plus E2102 with integrated adjunctive continuous glucose monitor functionality.. These codes are for an external ambulatory insulin infusion pump, with dose rate adjustment using therapeutic continuous glucose sensing. Coverage for this HCPCS code is only met if the member meets all the coverage criteria for insulin pumps and meets all criteria for a therapeutic Continuous Glucose Monitor (CGM) as outlined in LCD L33822. (See Additional Information about Integrated Pumps under Special Notes Section)

Comment(s):

WHEN COVERAGE WILL NOT BE APPROVED

External infusion pumps and related drugs and supplies will be denied as not medically necessary when the criteria described above are not met. If prior authorization is requested for the external infusion pump and the administration of the drug is started in the physician's office, then the pump is incident to the physician's service and should NOT be approved. Disposable drug delivery systems, including elastomeric (disposable balloon delivery type) infusion pumps are non-covered devices because they do not meet the definition of durable medical equipment.

Special Notes:

For Medicare Gold members: The only Medicare approved integrated pump is the Tandem pump because the CGM used with this pump is the Dexcom CGM and is billed with E0784 and E2102 code. All other CGMs are not billed with a Medicare approved code.

For Medicare Advantage and MA only members: Tandem pump billed medical provider and CGM are approved supplies with a pharmacy provider, Medtronic pumps and supplies MUST be billed by a medical provider.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement. Applicable codes: E0784, E2102.And E2103.

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Omnipod Pump and supplies are not considered a Part B product; need to be billed on Part D only.

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References:

1. Medicare National Coverage Determination for Infusion Pumps (ID #280.14); Effective date, 12/17/2004, accessed via Internet site www.cms.gov/medicare-coverage-database on 12/18/2012, 2/19/20.

2. Medicare Local Coverage Determination for External Infusion Pumps – CGS Administrators (L33794); Effective date 3/29/18, accessed via www.cms.gov/ on 5/20/2020.