CareSource

MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
06/19/2015	06/19/2016	06/19/2015

Policy Name	Policy Number
Insulin Infusion Pump Therapy for Diabetes	**MM-0032**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Insulin Infusion Pump Therapy for Diabetes

B. BACKGROUND

Insulin infusion pump therapy for diabetes mellitus delivers continuous short-acting or rapid-acting insulin at a slow basal rate via a subcutaneous small bore cannula 24 hours a day. At mealtimes, patient-activated bolus insulin may also be delivered.[1-3] The cannula should be changed every 2-3 days to a new anatomical location to avoid infection and lipohypertrophy. An insulin pump is typically a small battery-operated pump about the size of a personal pager or cell phone, and is filled with short-acting or rapid-acting insulin.

C. DEFINITIONS

- **CGM** – Continuous glucose monitoring
- **DME**- Durable medical equipment

D. POLICY

I. For selected patients an insulin pump provides glucose control that may be difficult to achieve by intermittent insulin injections. Fewer highs and lows in blood sugars may help prevent or delay serious complications of diabetes such as retinopathy, nephropathy, and neuropathy. Disadvantages of insulin pumps include the time and learning it takes to program and use the device. The management of a subcutaneous catheter may be complicated by catheter kinking, occlusion, or catheter migration and the person may not receive insulin. Carrying a pump and its delivery system can be bothersome. Skin sites for catheter entry can become infected.

Some members are at high risk for preventable complications of diabetes. Early signs of diabetic complications include micro-albuminuria demonstrating persistent difficulty in achieving optimal control of blood sugar levels despite good compliance with an intensive, intermittent, multiple-injection insulin regimen.

II. A physician's order given to the durable medical equipment (DME) provider is a requirement for an insulin pump to be medically necessary.

III. Pumps, Supplies, and Prior Authorizations
The point of service (POS) for insulin pumps includes out-patient/home. Requests for ancillary supplies totaling less than $750 do not require a prior authorization.

IV. Clinical Indications for Procedure
Continuous subcutaneous insulin infusion using insulin infusion pump may be indicated when **ALL** of the following are present:[4,5]

A. Diagnosis of diabetes as indicated by Type 1 diabetes mellitus.[1-3,6] Type 2 diabetics with insulinopenia[7] or gestational diabetics [8,9] will be considered on a case-by-case evaluation.

B. Failure of multiple daily injection insulin administration, as indicated by **1 (one) or more** of the following: [10,11]
   1. HbA1c greater than 7% (0,07), despite intensified multiple daily injection insulin therapy[12]
   2. Abnormal early-morning increase in blood glucose ("dawn phenomenon"), with fasting blood sugars often >200 mg/DL [13,14]
   3. Diabetes complication (e.g., neuropathy, nephropathy, retinopathy), and need for more intensive management
   4. Extreme insulin sensitivity
   5. Recurring hypoglycemia which may require third-party assistance, including unconsciousness, seizure, glucagon administration, and emergency attendance or admission to hospital[1,2,15]
   6. Patient is pregnant[1,2,8,16,17]
   7. Wide swings in glycemic control as documented on blood sugar log forms

C. Patient or caregiver is motivated, adherent, knowledgeable, and able to monitor blood glucose **3 (three) or more** times per day[18-21] as indicated by **1 (one)** of the following:
   1. This is an initial insulin pump for a patient where **ALL** of the following are met:
      1.1 Member administers 3 (three) or more daily insulin injections to self for at least 6 (six) months
      1.2 Member must self-test glucose levels at least 4 (four) times daily for at least 2 (two) months as documented by glucose logs
      1.3 Documentation of diabetes education must be on file
   2. This is a replacement insulin pump for an existing pump greater than or equal to 5 (five) years old, or the current pump is unrepairable

D. Provider team is experienced and expert in management and support of patient with insulin infusion pumps.[8,10,19]

For Medicare Plan members, reference the Applicable National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Compliance with NCDs and LCDs is required where applicable.

CONDITIONS OF COVERAGE

HCPCS A4230, A4231, A4232, C1772, C1891, C2626, E0779, E0780, E0781, E0782, E0783, E0784, E0786, E0791

CPT

AUTHORIZATION PERIOD

E. RELATED POLICIES/RULES

A. For MyCare Ohio coverage determinations (CMS LCD ID L27215, LCD Title "External Infusion Pumps"):

1. Utilize code E0784 (Rental and Purchase) External Ambulatory Infusion Pump
2. Requests from both participating and non-participating providers require a prior authorization
3. There is no J code submitted with a prior authorization as medications are processed as a pharmacy benefit
4. A Beta Cell autoantibody test must be positive
5. A physician's order and/or new Certificate of Medical Necessity (CMN), when required, is needed to reaffirm the medical necessity of the item for replacement of an item
6. An Omnipod (A9274) insulin pump is not payable according to CMS
7. On a single prior authorization, an insulin pump may be approved for up to 13 months rental purchase (rolling 12 months, not yearly calendar 12 months) or purchases (with CCS/DEGC)

B. For Medicaid Ohio coverage determinations (OAC 5160-10-29):

1. C-Peptide = < 0.5 (for Adults)
2. Insulin pumps are covered under Ohio Medicaid as a purchase only (with *CCS/DEGC*) – 80% approximately. Rentals on a rolling 10 months interval are obtainable on a selective case by case review through other vendors
3. An Omnipod and a Personal Diabetic Manager (A9274) can be considered and must be specifically requested for review
4. A Non-coverage exclusion is present if:
   - 4.1 Consumer is unable, because of behavioral, psychological problems or functional ability, to technically operate the pump and perform frequent blood glucose monitoring; or
   - 4.2 Consumer is being prescribed pump therapy to be used for convenience purposes
   - 4.3 The department will not cover jet pressure or surgically implanted infusion devices or systems, chronic intermittent intravenous insulin therapy (CIIIT), or pulsatile IV insulin therapy (PIVIT)
   - 4.4 Insulin pumps may not be requested for members who are in renal failure
5. Prior authorization

   The following documentation must be submitted for prior authorization (PA) before reimbursement for a standard portable external insulin infusion pump will be considered:
   - 5.1 A fully completed form JFS 07136 (rev. 2/2006 3/2008) "Certificate of Medical Necessity/Prescription External Infusion Pump" (CMN) (appendix to this rule) that is signed and dated no more than thirty days before the first date of service
   - 5.2 Prior authorization for a standard portable external insulin infusion pump must include a three-month trial rental period conducted in which the consumer has undergone a successful trial period with a pump that demonstrates that the consumer is capable of managing the pump and that the desired improvement in metabolic control can be achieved. If a prescriber certification is submitted to the department at the conclusion of a successful trial rental period, the device will be considered for purchase by the

department in accordance with paragraph (I)(4) of rule 5101:3-10-05 of the Administrative Code

6. Reimbursement
   - 6.1 Portable external infusion insulin pumps are reimbursed according to the department fee schedule contained in appendix DD to rule 5101:3-1-60 of the Administrative Code or the providers' usual and customary charge s , whichever is less
   - 6.2 Previously utilized or loaner portable external infusion insulin pumps are not eligible for purchase by the department

C. For Health Insurance Exchange coverage determinations:

1. Insulin pumps are eligible for purchase only, and not rentals.

F. REVIEW/REVISION HISTORY

Date Issued: 06/19/2015
Date Reviewed: 06/19/2015
Date Revised:

This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

G. REFERENCES

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