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. 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:

A. Diagnosis of diabetes as indicated by Type 1 diabetes mellitus. Type 2 diabetics with insulinopenia or gestational diabetics 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:
   1. HbA1c greater than 7% (0.07), despite intensified multiple daily injection insulin therapy
   2. Abnormal early-morning increase in blood glucose (“dawn phenomenon”), with fasting blood sugars often >200 mg/DL
   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
   6. Patient is pregnant
   7. Wide swings in glycemic control as documented on blood sugar log forms
   8. Child for whom multiple daily insulin injections are impractical or inappropriate

C. Patient or caregiver is motivated, adherent, knowledgeable, and able to monitor blood glucose 3 (three) or more times per day 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.

**CONDITIONS OF COVERAGE**

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

**CPT**
AUTHORIZATION PERIOD

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 (CIIT), 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 (l)(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 charges, 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.

E. REVIEW/REVISION HISTORY
   Date Issued: 06/19/2015
   Date Reviewed: 06/19/2015, 05/17/2016
   Date Revised: 05/17/2016 – Add ‘Child for whom multiple daily insulin injections are impractical or inappropriate’.
F. REFERENCES


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