External Infusion Pumps

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification, as applicable.

External infusion pump and supplies require precertification. Providers may submit precertification on a Medicare DME Information Form (DIF) or Heath Plan referral form.

The Health Plan reserves the right to request additional information as required for review.

Physician face to face is required prior to precertification per Affordable Care Act 6407

National Coverage Determination Policy	CMS Publication 100-3 Medicare National Coverage Determinations Manual, Chapter 1, Section 280.14
Local Coverage Determination Policy	J-B/C
Effective Date	For service performed on or after 05/01/14
Revision/Review Date	Previous review: 01/19, 10/18, 06/01/2018, 01/03/18, 07/01/17, 04/01/17,02/13/17, 01/25/17, 01/01/16, 01/01/15, 05/01/14, 09/16/14
The Health Plan	Plans will follow Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreements, or benefit plan documents. **MHT will follow WV Medicaid for Cuvitru- RDT will almost always be the supplier for Cuvitru vials**

Reimbursement and/or coverage of some codes may be subject to specific contract information.

DESCRIPTION

An external infusion pump is a medical device used to deliver fluids into an individual's body in a controlled manner. There are many different types of infusion pumps, which are used for a variety of purposes and in a variety of environments.

COVERAGE GUIDELINES

An infusion pump described by codes E0779, E0780, E0781, and E0791 is covered for the following indications if the infusion pump is necessary to safely administer a drug parenterally in the home setting versus gravity or bolus.

1. Administration of deferoxamine for the treatment of chronic iron overload.
2. Administration of chemotherapy for the treatment of primary hepatocellular carcinoma or colorectal cancer, where this disease is unresectable or where the member refuses surgical excision of the tumor.
3. Administration of morphine when used in the treatment of intractable pain caused by cancer.
4. Administration of the anticancer chemotherapy drugs cladribine, fluorouracil, cytarabine, bleomycin, floxuridine, doxorubicin (non-liposomal), vincristine (non-liposomal), or vinblastine by continuous infusion over at least eight hours when the regimen is proven or generally accepted to have significant advantages over intermittent administration regimens.
5. Administration of narcotic analgesics (except meperidine) in place of morphine to a member with intractable pain caused by cancer that has not responded to an adequate oral/transdermal therapeutic regimen and/or cannot tolerate oral/transdermal narcotic analgesics.
6. Administration of the following antifungal or antiviral drugs: acyclovir, foscarnet, amphotericin B, and ganciclovir.
7. Administration of parenteral inotropic therapy, using the drugs dobutamine, milrinone, and/or dopamine for members with congestive heart failure and depressed cardiac function if a member meets all of the following criteria: a-h
    a) Dyspnea at rest or with minimal exertion is present despite treatment with maximum or near maximum tolerated doses of digoxin, a loop diuretic, and an angiotensin converting enzyme inhibitor or another vasodilator (e.g., hydralazine or isosorbide dinitrate), used simultaneously (unless allergic or intolerant), **and**
    b) Doses are within the following ranges (lower doses will be covered only if part of a weaning or tapering protocol from higher dose levels):
        i. Dobutamine - 2.5 - 10 mcg/kg/min
        ii. Milrinone - 0.375 - 0.750 mcg/kg/min
        iii. Dopamine - less than or equal to 5 mcg/kg/min, **and**
    c) Cardiac studies by either invasive hemodynamic technique or using thoracic electrical bioimpedance (impedance cardiography), performed within six months prior to the initiation of home inotropic therapy showing a cardiac index (CI) is less than or equal to 2.2 liters/min/meter squared and/or pulmonary capillary wedge pressure (PCWP) is greater than or equal to 20 mm Hg before inotrope infusion on maximum medical management and at least a 20 percent increase in CI and/or at least a 20 percent decrease in PCWP during inotrope infusion at the dose initially prescribed for home infusion, **and**

d) There has been an improvement in the member's well being, (less dyspnea, improved diuresis, improved renal function and/or reduction in weight) with the absence of dyspnea at rest at the time of discharge and the capability of outpatient evaluation by the prescribing physician at least monthly, **and**
e) In the case of continuous infusion, there is documented deterioration in clinical status when the drug(s) is tapered or discontinued under observation in the hospital, or in the case of intermittent infusions, there is documentation of repeated hospitalizations for congestive heart failure despite maximum medical management, **and**
f) Any life threatening arrhythmia is controlled prior to hospital discharge and there is no need for routine electrocardiographic monitoring at home, **and**
g) The member is maintained on the lowest practical dose and efforts to decrease the dose of the drug(s) or the frequency/duration of infusion are documented during the first 3 months of therapy, **and**
h) The member's cardiac symptoms, vital signs, weight, lab values, and response to therapy are routinely assessed and documented in the member's medical record.

8. Gallium nitrate (J1457) is covered for the treatment of symptomatic cancer-related hypercalcemia (E83.52). In general, patients with serum calcium (corrected for albumin) less than 12 mg/dl would not be expected to be symptomatic.

   The recommended usage for gallium nitrate is daily for five consecutive days. Use for more than five days will be denied as not reasonable and necessary.

   More than one course of treatment for the same episode of hypercalcemia will be denied as not reasonable and necessary.

9. Ziconotide (J2278) is covered for the management of severe chronic pain in members for whom intrathecal (IT or epidural) therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine.

10. Levodopa-Carbidopa enteral suspension (J7340)) is only covered for treatment of motor fluctuations in members with Parkinson's disease (PD), who meet all of the following criteria.

    a. Evaluated by a neurologist, who prescribes and manages treatment with the drug; **and**,
    b. Idiopathic PD based on the presence of bradykinesia and at least one other cardinal PD features (tremor, rigidity, postural instability); **and,**
    c. L-dopa responsive with clearly defined "On" periods; **and,**
    d. Persistent motor complications with disabling "Off" periods for a minimum of 3 hours/day, despite medical therapy with levodopa-carbidopa, and at least one other class of anti-PD therapy. i.e. COMT inhibitor or MAO-B inhibitor.

It is covered for Medicare members. It will be reviewed on a case -by-case basis for all other lines of business. See below or non-coverage statement

Levodopa-Carbidopa enteral suspension is not covered for patients with any of the following:

1. Atypical Parkinson's syndrome ("Parkinson's Plus" syndrome) or secondary Parkinson's; or,
2. Non-levodopa responsive PD; or,

3. Contraindication to percutaneous endoscopic gastro-jejunal (PEG-J) tube placement or long-term use of a PEG-J.

BUNDLING STATEMENT

Establishment of the transabdominal port with a PEG-J is performed under endoscopic guidance by a gastroenterologist or other healthcare provider experienced in this procedure. The PEG-J is considered a supply provided incident to a physician's service, and claims for this item will not be separately payable as DME. Claims requesting reimbursement for the PEG_J as DME will be denied Levodopa-Carbidopa enteral suspension is delivered through a CADD® –Legacy 1400 portable infusion pump

11. Blinatumomab (J9039)) is only covered per the parameters of this policy for treatment of adults with Philadelphia chromosome negative relapsed/refractory acute lymphoblastic leukemia when treated every 48 hours in the home unsupervised, with drug cassette exchanges that do not require supervision performed in an outpatient or inpatient setting. If the drug is administered in an outpatient or inpatient setting the drug and equipment cannot be billed under the DME benefit.

Submit Name of the drug, Dosage and Strength, amount dispensed.

It is FDA approved for 6 week cycles for a total of 5 cycles.

Maximum utilization is 25 vials per month. Claims for more than 25 vials will be denied as not reasonable and necessary.

Covered for Medicare members- must be reviewed on a case-by-case basis along other lines of business.

INFUSION OF SUBCUTANEOUS IMMUNE GLOBULIN

An E0779 infusion pump is covered for the administration of subcutaneous immune globulin. Administration via another pump will be denied.

Subcutaneous immune globulin (J1559, J1561, J1562, J1569, and J1575) is covered only if criteria 1 and 2 are met:

a) The subcutaneous immune globulin preparation is a pooled plasma derivative which is approved for the treatment of primary immune deficiency disease; and
b) The member has a diagnosis of primary immune deficiency disease.

This policy refers to specifically labeled subcutaneous immune globulin.

An E0781 infusion pump is covered for administration of HyQvia®. It is covered for use in adults who are diagnosed with primary immunodeficiency (PI). Must use pump code E0781- variable infusion pump capable of infusion rates up to 300ml/hr/site. Subcutaneous infusion required. Must be delivered to member in a locked mode that the member cannot adjust.

Information from Jurisdiction B DME MAC listserve Thursday 1/7/2016 3:31 pm

In regards to Cuvitru infusion for WV Medicaid members: The RDT will be the drug supplier/reviewer for West Virginia Medicaid members in most instances, not THP. Therefore requests for pumps and other supplies to be used with Cuvitru will be pended until completion of the RDT review. See Billing Guidelines.

COVERAGE WITH INFUSION PUMP K0455

Administration of epoprostenol (J1325) or treprostinil (J3285) for patients with pulmonary hypertension if they meet the following disease criteria:

a) The pulmonary hypertension is not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc.) or disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.); and
b) The member has primary pulmonary hypertension or pulmonary hypertension which is secondary to one of the following conditions: connective tissue disease, thromboembolic disease of the pulmonary arteries, human immunodeficiency virus (HIV) infection, cirrhosis, diet drugs, congenital left to right shunts, etc. If these conditions are present, the following criteria must be met:
    1. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; **and**
    2. The mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion; **and**
    3. The member has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); **and**
    4. Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out.

Epoprostenol/treprostinil is administered using ambulatory infusion pump K0455. Claims for usage of infusion pumps other than K0455 will be denied as not meeting coverage guidelines.

COVERAGE OF INSULIN INFUSION PUMP E0784

An insulin pump is covered for the administration of continuous subcutaneous insulin for the treatment of diabetes mellitus if criteria A or B is met and criterion C. For those members new to The Health Plan, but already have an insulin pump and are just requesting supplies, criterion D should be met.

A. C-peptide testing requirement – must meet criterion 1 or 2 and criterion 3:
    1. C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method.
    2. For members 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.
    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,
B. Beta cell autoantibody test is positive.

After review, Medicare determined that only islet cell cytoplasmic auto-antibodies (ICA) would be acceptable to meet the beta cell auto-antibody test requirement. The Health Plan will adopt its position

across all lines of business. Other tests would not be acceptable alternatives to justify reimbursement of an external insulin pump.

C. The member has completed a comprehensive diabetes education program, has been on a program of multiple daily injections of insulin (i.e., at least three injections per day) with frequent self-adjustments of insulin dose for at least six months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least four times per day during the two months prior to initiation of the insulin pump, and meets one or more of the following criteria (1 - 5) while on the multiple injection regimen:
    1. Glycosylated hemoglobin level (HbA1c) greater than seven percent
    2. History of recurring hypoglycemia
    3. Wide fluctuations in blood glucose before mealtime
    4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
    5. History of severe glycemic excursions
D. The member has been on an external insulin infusion pump prior to enrollment, and has documented frequency of glucose self-testing on an average of at least four times per day during the month prior to enrollment. Provider should also submit most recent A1c.

For continued coverage of an external insulin pump and supplies, The Health Plan requires that the member be seen and evaluated by the treating physician at least every three to six months. The external insulin infusion pump must be ordered and follow-up care rendered by a physician who manages multiple patients on continuous subcutaneous insulin infusion therapy and who works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy.

Coverage of insulin via insulin pump will be covered under Part B benefit medical benefit and not the pharmacy (D) benefit for SecureCare HMO members. Please check for method of coverage under other plan designs.

Subcutaneous insulin is administered using ambulatory infusion pump E0784. Claims for usage of infusion pumps other than E0784 will be denied.

NOTE: Criteria A and B are not required for replacement insulin pumps. However, The Health Plan reserves the right to request clinical information as relating to compliance of use of device and current blood sugar readings, hospitalizations, etc.

COVERAGE OF CONTINUOUS GLUCOSE MONITOR

The Health Plan will cover continuous glucose monitoring systems (A9276, A9277, A9278) for Commercial and Self- funded plan members identified with Type I and Type II diabetes, who have had several documented episodes of hypoglycemia(<50mg/dl), when preliminary 72-hour monitoring does not prove diagnostic and other modifications have been attempted in insulin regimen. The member has proven compliant with self-monitoring finger sticks at least four times a day, and agrees to active participation in The Health Plan Diabetes Management Program. Continuous glucose monitoring system must be ordered by an endocrinologist.

Requests for hypoglycemic unawareness require the results from the 72-hour monitor, the member's blood sugar logs and the completed Hypoglycemia Awareness Questionnaire that is attached at the end of this policy, pages 20-21

OR

The patient with diabetes had been using a CGM prior to enrollment with a The Health Plan group and has documented frequency of fingerstick blood glucose testing a minimum of 2 times a day while wearing the CGM in the month prior to enrollment.

Coverage for the Dexcom G5 CGM and Abbott's Libre CGM systems for both Commercial, Medicare, and Medicaid LOB will be as follows:

K0553 - SUPPLY ALLOWANCE FOR THERAPEUTIC CONTINUOUS GLUCOSE MONITOR (CGM), INCLUDES ALL SUPPLIES AND ACCESSORIES,

1 MONTH SUPPLY = 1 UNIT OF SERVICE

• K0554 - RECEIVER (MONITOR), DEDICATED, FOR USE WITH THERAPEUTIC CONTINUOUS GLUCOSE MONITOR SYSTEM

All other devices remain noncovered under the K codes.

See the non-coverage statement below for non-covered device coding for Medicare and Medicaid plans. Criteria as follows:

1. Has diabetes mellitus; and
2. Has been using a home blood glucose monitor (BGM), and performing frequent (four or more times a day) BGM testing, and
3. Is insulin-treated with multiple daily injections (three or more) of insulin or a continuous subcutaneous insulin infusion pump; and requires frequent adjustment, and
4. The insulin regime requires frequent adjustments by the member based on the BGM/CGM test results., and
5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-4) above are met; and,
6. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.

See Glucose Monitor Policy for coding

NONCOVERAGE STATEMENT

Smart devices, such as phones, tablets, & computers, etc... for use with CGM systems or other devices addressed in this policy remain non- covered. The appropriate coding for these devices is A9270 for these devices.

An external infusion pump used for the treatment of thromboembolic disease and/or pulmonary embolism by heparin infusion is not covered in the home setting.

An infusion controller device (E1399) is not medically necessary.

Disposable drug delivery systems, including elastomeric infusion pumps (A4305, A4306, and A9274) are not covered under the DME benefit because they do not meet the Medicare definition of Durable Medical Equipment. Drugs and supplies used with disposable drug delivery systems are also non covered items. May possibly be covered or included as part of a physician service in the office or facility fee but should not pull a durable medical copay and the physician or facility should use the appropriate coding and not the A codes indicated here.

The V-Go insulin delivery system is not covered under the durable medical benefit.

Continuous glucose monitoring systems (A9276, A9277, and A9278) for Medicare and Medicaid plans. See above comments- This coding remains non Covered for Medicare and Medicaid Plans.

Catheter insertion devices for use with external insulin infusion pump infusion cannulas are included in the allowance for code A4224 and are not separately payable.

Since the DME MAC do not process claims for implantable infusion pumps (E0782, E0783, E0785, and E0786) or drugs and supplies used in conjunction with an implantable infusion pump. The Health Plan will not process under DME benefit. Claims for these items must not be submitted as DME.

Replacement batteries (K0601 - K0605) are not separately payable when billed with a rented infusion pump.

Only one pump (K0455) for administering epoprostenol and treprostinil will be reimbursable. The provider of the pump is responsible for ensuring that there is an appropriate and acceptable contingency plan to address any emergency situations or mechanical failures of the equipment. A second pump provided as a backup is not separately payable.

An IV pole (E0776) is not covered with ambulatory infusion pumps (E0779, E0780, E0781, E0784, or K0455).

Yondelis (trabectedin) is not eligible for inclusion in this policy. Please consult with The Health Plan's Pharmacy Department. See Jurisdiction B DME MAC list serve information email Thursday 1/7/2016 3:31 PM

An External Infusion Pump is not covered for use with compounded drugs

CODING INFORMATION

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS

EY	NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE
GA	WAIVER OF LIABILITY STATEMENT ISSUED, AS REQUIRED BY PAYOR POLICY, INDIVIDUAL CASE

GY	ITEM OR SERVICE STATUTORILY EXCLUDED OR DOES NOT MEET THE DEFINITION OF ANY MEDICARE BENEFIT
GZ	ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE AND NECESSARY
JB	ADMINISTERED SUBCUTANEOUSLY
JW	DRUG AMOUNT DISCARDED/NOT ADMINISTERED BY PATIENT
KX	REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET

HCPCS CODES EQUIPMENT

E0776	IV POLE
E0779	AMBULATORY INFUSION PUMP, MECHANICAL, REUSABLE, FOR INFUSION 8 HOURS OR GREATER
E0780	AMBULATORY INFUSION PUMP, MECHANICAL, REUSABLE, FOR INFUSION LESS THAN 8 HOURS
E0781	AMBULATORY INFUSION PUMP, SINGLE OR MULTIPLE CHANNELS, ELECTRIC OR BATTERY OPERATED, WITH ADMINISTRATIVE EQUIPMENT, WORN BY PATIENT
E0784	EXTERNAL AMBULATORY INFUSION PUMP, INSULIN
E0791	PARENTERAL INFUSION PUMP, STATIONARY, SINGLE OR MULTI-CHANNEL
E1399	DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS
K0455	INFUSION PUMP USED FOR UNINTERRUPTED PARENTERAL ADMINISTRATION OF MEDICATION, (E.G., EPOPROSTENOL OR TREPROSTINOL)

HCPCS CODES SUPPLIES

A4221	SUPPLIES FOR MAINTENANCE OF NON-INSULIN DRUG INFUSION CATHETER, PER WEEK (LIST DRUGS SEPARATELY)
A4222	INFUSION SUPPLIES FOR EXTERNAL DRUG INFUSION PUMP, PER CASSETTE OR BAG (LIST DRUGS SEPARATELY)
A4223	INFUSION SUPPLIES NOT USED WITH EXTERNAL INFUSION PUMP, PER CASSETTE OR BAG (LIST DRUGS SEPARATELY)
A4224	SUPPLIES FOR MAINTENANCE OF INSULIN INFUSION CATHETER, PER WEEK
A4225	SUPPLIES FOR EXTERNAL INSULIN INFUSION PUMP, SYRINGE TYPE CARTRIDGE,STERILE,EACH
A4230	INFUSION SET FOR EXTERNAL INSULIN PUMP, NON-NEEDLE CANNULA TYPE (invalid for Medicare submission)

A4231	INFUSION SET FOR EXTERNAL INSULIN PUMP, NEEDLE TYPE (invalid for Medicare submission)
A4232	SYRINGE W/ NEEDLE EXTERNAL INSULIN PUMP (invalid for Medicare Submission)
A4305	DISPOSABLE DRUG DELIVERY SYSTEM, FLOW RATE OF 50 ML OR GREATER PER HOUR
A4306	DISPOSABLE DRUG DELIVERY SYSTEM, FLOW RATE OF LESS THAN 50 ML PER HOUR
A9270	NONCOVERED ITEM OR SERVICE
A9274	EXTERNAL AMBULATORY INSULIN DELIVERY SYSTEM, DISPOSABLE, EACH, INCLUDES ALL SUPPLIES AND ACCESSORIES
A9276	SENSOR; INVASIVE (E.G. , SUBCUTANEOUS), DISPOSABLE, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM, 1 UNIT = 1 DAY SUPPLY
A9277	TRANSMITTER; EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM
K0552	SUPPLIES FOR EXTERNAL NON-INSULIN DRUG INFUSION PUMP,SYRINGE TYPE CARTRIDGE, STERILE EACH
K0601	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, SILVER OXIDE, 1.5 VOLT, EACH
K0602	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, SILVER OXIDE, 3 VOLT, EACH
K0603	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, ALKALINE, 1.5 VOLT, EACH
K0604	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, LITHIUM, 3.6 VOLT, EACH
K0605	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, LITHIUM, 4.5 VOLT, EACH

HCPCS CODES DRUGS

J0133	INJECTION, ACYCLOVIR, 5 MG
J0285	INJECTION, AMPHOTERICIN B, 50 MG
J0287	INJECTION, AMPHOTERICIN B LIPID COMPLEX, 10 MG
J0288	INJECTION, AMPHOTERICIN B CHOLESTERYL SULFATE COMPLEX, 10 MG
J0289	INJECTION, AMPHOTERICIN B LIPOSOME, 10 MG
J0895	INJECTION, DEFEROXAMINE MESYLATE, 500 MG
J1170	INJECTION, HYDROMORPHONE, UP TO 4 MG

J1250	INJECTION, DOBUTAMINE HYDROCHLORIDE, PER 250 MG
J1265	INJECTION, DOPAMINE HCL, 40 MG
J1325	INJECTION, EPOPROSTENOL, 0.5 MG
J1455	INJECTION, FOSCARNET SODIUM, PER 1000 MG
J1457	INJECTION, GALLIUM NITRATE, 1 MG
J1555	INJECTION, IMMUNE GLOBULIN (CUVITRU), 100 MG
J1559	INJECTION, IMMUNE GLOBULIN(HIZENTRA),100 MG
J1561	INJECTION, IMMUNE GLOBULIN(GAMUNEX), INTRAVENOUS, NONLYOPHILIZED (E.G. LIQUID), 500 MG
J1562	INJECTION, IMMUNE GLOBULIN (VIVAGLOBIN), 100 MG
J1570	INJECTION, GANCICLOVIR SODIUM, 500 MG
J1575	INJECTION, IMMUNE GLOBULIN/HYALRONIDASE, (hyqvia),100 MG IMMUNOGLOBULIN
J1817	INSULIN FOR ADMINISTRATION THROUGH DME (I.E., INSULIN PUMP) PER 50 UNITS
J2175	INJECTION, MEPERIDINE HYDROCHLORIDE, PER 100 MG
J2260	INJECTION, MILRINONE LACTATE, 5 MG
J2270	INJECTION, MORPHINE SULFATE, UP TO 10 MG
J2274	INJECTION, MORPHINE SULFATE, PRESERVATIVE- FREE FOR EPIDURAL OR INTRATHECAL USE, 10 MG
J2278	INJECTION, ZICONOTIDE, 1 MICROGRAM
J3010	INJECTION, FENTANYL CITRATE, 0.1 MG
J3285	INJECTION, TREPROSTINIL, 1 MG
J7340	CARBIDOPA 5 MG/LEVODOPA 20 MG ENTERAL SUSPENSION, 100 ML
J7799	NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME
J9000	INJECTION, DOXORUBICIN HYDROCHLORIDE, 10 MG
J9039	INJECTION, BLINATUMOMAB, 1 MICROGRAM
J9040	INJECTION, BLEOMYCIN SULFATE, 15 UNITS
J9065	INJECTION, CLADRIBINE, PER 1 MG
J9100	INJECTION, CYTARABINE, 100 MG
J9190	INJECTION, FLUOROURACIL, 500 MG
J9200	INJECTION, FLOXURIDINE, 500 MG

J9360	INJECTION, VINBLASTINE SULFATE, 1 MG
J9370	VINCRISTINE SULFATE, 1 MG

The presence of an ICD-10 code listed in the section below is not sufficient by itself to assure coverage. Refer to coverage guidelines and documentation requirement sections for further coverage information.

ICD-10 CODES for E0784 and J1817

See https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794&ContrID=140

ICD-10 CODES for J1457, J1559, J1561, J1562, 1569

See https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794&ContrID=140

Please refer to coverage guidelines for information for covered diagnosis and HCPCS codes.

DOCUMENTATION REQUIREMENTS

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other health care professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
    a. Member's name
    b. Date
    c. Description of item. The medical record must contain the information that supports the request for each item and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required
    d. Order must include diagnosis code
    e. Physician signature with date. Date stamps are not appropriate
    f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used

    The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier's records to support the medical necessity of that item. This information must be available upon request, usually with precertification per The Health Plan policy.

For parenteral inotropic therapy, there should be the information regarding the member's history (e.g., dates of past hospitalization for heart failure, prior use of parenteral inotropic and the results, etc.). If invasive hemodynamic studies or impedance cardiography were not performed, the referral should be accompanied by a letter from the attending physician explaining the rationale for not performing the tests and accompanied by any other documentation deemed appropriate to explain this exception.

If additional information on epoprostenol or treprostinil is requested, the supplier should submit signed and dated information from the treating physician stating the member's diagnosis, the member's current symptoms caused by pulmonary hypertension, and date and results of the pulmonary artery pressure. There must be a statement that the pulmonary hypertension is not secondary to pulmonary venous hypertension or a disorder of the respiratory system. There must be a statement of whether oral calcium channel blocking agents were tried and if so, the results, and if not, why a trial was not conducted.

3. Proof of delivery to be kept on file by the provider of the item.

Note: If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

Precertification is required when supplies used are greater than the usual maximum quantity listed in above. There must be adequate, clear documentation in the medical record corroborating the medical necessity of this amount. This documentation is to be submitted with precertification.

Providers may use a DME DIF which has been completed, signed, and dated by the supplier, must be kept on file by the supplier. The DIF for external infusion pumps is CMS form 10125. It must be submitted with precertification.

If a member begins using an infusion pump for one drug and subsequently the drug is changed or another drug is added, the provider is to notify The Health Plan, a revised DIF may be submitted for use of the pump with the new or additional drug. In the case of an additional drug, all drugs for which the pump is used should be included on the revised DIF, if the provider is using the DIF with precertification.

Medical necessity provided on any form used for precertification of parenteral inotropic therapy must be completed by the physician. It cannot be completed by the supplier or anyone with a financial relationship with the supplier.

EXTERNAL INFUSION PUMPS PROVIDED WHILE IN A PART A FACILITY

Reimbursement for an external infusion pump provided to a member while in a covered part A (acute hospital, skilled inpatient, or rehabilitation unit) admission, will be based on specific contract language with the individual facility.

BILLING GUIDELINES

CMS has added 2 new codes for 2017 for insulin pump infusions. They are A4224 and A4225 listed above. It should be noted that A4224 is a weekly supply code.

Code A4224 describes all necessary supplies (excluding the insulin reservoir – see code A4225) used with an external infusion pump (E0784) for the administration of continuous subcutaneous insulin and includes, but is not limited to, all cannulas, needles, dressings and infusion supplies.

Drugs and ongoing supplies are covered with external infusion pumps under part B benefit for Medicare members as long as the criteria has been met for the pump. Coverage for the medications for other lines of business is based on the individual plan design.

An IV pole (E0776) is covered only when a stationary infusion pump (E0791) is covered.

Supplies for the maintenance of a parenteral drug infusion catheter (A4221) are covered for up to 4 weeks in between during use of an infusion pump.

Allowance for supplies is based on the number of cassettes or bags (A4222) prepared or syringes (K0552) used. For intermittent infusions, no more than one cassette or bag is covered for each dose of drug. For continuous infusion, the concentration of the drug and the size of the cassette, bag, or syringe should be maximized to result in the fewest cassettes, bags, or syringes in keeping with good pharmacologic and medical practice.

Suppliers are expected to anticipate changing needs for drugs (e.g., planned hospital admissions, drug level testing with possible dosage change, etc.) in their drug and supply preparation and delivery schedule and formulate and deliver accordingly. In situations where wastage occurred due to unforeseen circumstances (e.g., emergency admission to hospital, drug toxicity, etc.), and the drug was authorized by the medical management or pharmacy department, wastage would be covered. In these situations, no more than 7 or 8 days wastage would be covered. Please use modifier JW for wastage as indicated below.

Charges for drugs administered by an external infusion pump are to be billed by the entity that actually dispenses the drug to the member. The provider of the drug must meet all The Health Plan, federal, state, Medicare, Medicaid regulations.

Injectable drugs administered in a physician's office, whether with or without a pump, must be billed to The Health Plan as a physician service. Drugs put into an infusion pump in the physician's office for use in the member's home will be reviewed for benefit category. See disposable pumps.

All supplies (including dressings) used in conjunction with a durable infusion pump (E0779, E0780, E0781, E0784, E0791, K0455) are billed with (1) codes A4221 and A4222 or (2) codes A4221 and K0552 Other codes should not be used for the separate billing of these supplies. Codes A4230 (infusion set for external insulin pump, non-needle cannula type) and A4231 (infusion set for external insulin pump, needle type) are subject to contract determination.

Note: D/T individual contracts, providers may need to use applicable "S" codes per infusion fee schedule for certain services, rather than "A" codes listed in this policy.

Requests for Levodopa-Carbidopa Enteral Suspension require Name of Drug, Dosage strength, amount dispensed, administration instructions. Refer to NHIC, Corp. - DME MAC JA Medicare nhic-dmemacwebmaster@nhic.ccsend.com Thursday 1/7/16

Levodopa-Carbidopa enteral suspension is supplied as a single-use cassette. Each cassette contains 20 mg levodopa and 4.63 mg carbidopa (as 5 mg of the monohydrate) and per mL of enteral suspension. Each cassette contains approximately 100 mL of suspension. One (1) unit of service (UOS) is one cassette.

Blinatumomab One unit of service (UOS) equals one (1) vial, and each UOS must be prepared using the combination of vials that result in the least amount of wastage for the dosage amount being administered. Reconstituted blinatumomab is stored in a bag coated with an IV Solution Stabilizer, which can be subsequently refrigerated (2°C to 8°C) for up to eight-days. Five vials should be used to reconstitute three bags, each containing 56 mcg of blinatumomab, which can be refrigerated and used within six-days, leading to the least amount of wastage.

CUVITRU™ (Shire): is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults. It is approved by for use in pump code E0779. The member must meet guidelines for subcutaneous immune globin as described in this policy.

DISPENSING SUPPLIES

The Health Plan is following Medicare's guidelines for supplies provided on a reoccurring basis.

Suppliers are not to automatically dispense supplies according to allowable limits. Suppliers are required to reorder supplies based on actual usage of each member. There must be a specific request for the supplies from the member or caregiver prior to dispensing the supplies. Supplies should not be shipped/delivered no sooner than 10 days prior to end of usage. Please refer to CMS Program Integrity Manual for more information. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

The DME supplier is responsible to monitor utilization of covered, rented, and frequently purchased supplies for member-owned equipment that they would be requesting reimbursement from The Health Plan.

Utilization above the current allowable quantities will not be reimbursed unless corroborated by the medical record of the medical necessity of the quantity of supplies being used.

A precertification is required for requests above the allowable amounts.

No more than one month's equipment or supplies are allowed for one month's prospective billing. Claims submitted retroactively, however, may include multiple months. Providers are reminded that timely filing will apply.

JB MODIFIER

The JB modifier should be used for all subcutaneous administration of immune globulin (J1559, J1561, and J1562, J1569) and associated pump (E0779). No modifier should be added for other methods.

JW MODIFIER

Effective for claims with dates of service on or after January 1, 2017, the JW modifier must be used when billing for discarded drugs and biologicals.

Multi-use vials are not subject to payment for discarded amounts of drug or biologicals.

The use of the JW modifier should be rare and The Health Plan reserves the right to review these submissions.

KX, GA, and GZ MODIFIERS

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier, if they have not obtained a valid ABN.

ADVANCED BENEFICIARY NOTICE

The Health Plan expects providers to follow the Medicare policy on the ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN's are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Please refer to the PDAC website for product classification list. Suppliers should contact the PDAC contractor for guidance on the correct coding of these items. dmepdac.com/

MEDICARE DEFINITIONS AND DESCRIPTION

An ambulatory infusion pump (E0781) is an electrical or battery operated device, which is used to deliver solutions containing a parenteral drug under pressure at a regulated flow rate. It is small and portable and is designed to be carried by the patient.

A stationary infusion pump (E0791) is an electrical device, which serves the same purpose as an ambulatory pump, but is larger and typically mounted on a pole.

A disposable drug delivery system (A4305, A4306, and A9274) is a device used to deliver solutions containing injectable drugs that are not reusable (i.e., it is used by a single patient for a limited time and then discarded).

An infusion controller (E1399) is an electrical device, which regulates the flow of parenteral solutions under gravity pressure.

A reusable mechanical infusion pump (E0779) is a device used to deliver solutions containing parenteral drugs under pressure at a constant flow rate determined by the tubing with which it is used. It is small,

portable, and designed to be carried by the patient. It must be capable of a single infusion cycle of at least eight hours.

Code E0780 describes a mechanical infusion pump which is similar to an E0779 pump, but which is only capable of a single infusion cycle of less than eight hours.

Code K0455 describes an ambulatory electrical infusion pump, which is used for the administration of epoprostenol.

Code A4221 includes dressings for the catheter site and flush solutions not directly related to drug infusion. The catheter site may be a peripheral intravenous line, a peripherally inserted central catheter (PICC), a centrally inserted intravenous line with either an external or a subcutaneous port, or an epidural catheter.

Code A4221 also includes all cannulas, needles, dressings, and infusion supplies (excluding the insulin reservoir) related to continuous subcutaneous insulin infusion via external insulin infusion pump (E0784) and the infusion sets and dressings related to subcutaneous immune globulin administration. Billing for more than one unit of service per week is incorrect use of the code and will be denied accordingly.

Code A4222 includes the cassette or bag, diluting solutions, tubing and other administration supplies, port cap changes, compounding charges, and preparation charges. This code is not used for a syringe-type reservoir.

Code K0552 describes a syringe-type reservoir that is used with the external insulin infusion pump (E0784), or with a K0455 pump when it is used to administer epoprostenol/treprostinil, or with an E0779 pump used to administer subcutaneous immune globulin. The reservoir may be either glass or plastic and includes the needle for drawing up the drug. This code does not include the drug for use in the reservoir.

Code A4232 is subject to contract determination.

Use A4223 for infusion supplies not used with a covered external infusion pump.

Drugs used in a durable external infusion pump must be coded using the appropriate HCPCS codes. If the drug does not have a distinct code, then use the unclassified drug code J7799. Do not use code J9999 - this code is not valid for claims billed to the DME MAC/The Health Plan.

An infusion drug not administered using a durable infusion pump must be billed using the appropriate HCPCS code plus the GY modifier. If the drug does not have a unique code, use the unclassified drug code, J3490.

Use code J2274, only for morphine sulfate that is labeled "preservative free.” Morphine sulfate that is not labeled "preservative free," must be coded J2270

Use code J1817 for insulin administered through an external insulin pump (E0784).

Pump code E0779 is the associated infusion pump for use with IV immune globulin code J1569 - injection immune globulin (GAMMAGARD LIQUID), intravenous nonlyophilized, (e.g., LIQUID), 500 mg. If a different pump is used, it will be denied as not reasonable and necessary.

AMA CPT/ COPYRIGHT STATEMENT

MEDICARE CERTIFICATE OF MEDICAL NECESSITY:

DME Information Form - External Infu

INTERNET LINKS AND SOURCES

Coding and Coverage –Therapeutic Glucose Monitors (CGM). A Joint MAC Article. Posted March 23 2017. Last accessed 10/26/18. Retrieved from: http://cgsmedicare.com/jb/pubs/news/2017/03/cope2581.html

Noridian HealthCare Solutions. DME Jurisdiction D. Coding and Coverage-Therapeutic Continuous Glucose Monitors (CGM). Joint DME MAC Article. Posted March 23, 2017. Last accessed 10/26/18. Retrieved from: https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/coding-and-coverage-therapeutic-continuous-glucose-monitors

Glucose Monitors LCD and Related Policy Article – Revised. Joint DME MAC Article. Posted on May 18, 2017 https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/glucose-monitors-lcd-and-related-policy-article-revised

National Government Services Local Coverage Determination Policy. External Infusion Pumps LCD L27215 and Article A47226. Last accessed 10/26/18. Retrieved from https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/entry/!ut/p/a1/04_Sj9CPykssy0xPLMnMz0vMAfGjzOJNHD1dDQ2dDbzdvTxNDBxNXAKDHH1DDS2MjYEKIoEKDHAARwNC-sP1o1CV-Bv7WwCVuDm5uAQGGLs7GUEV4LHCSz8qPSc_CejccCf9KFWD4IikqkCQyxzzkowt0vWjilLTUotSi_Qy8otL9CPKy8v10vPz03NS9ZLzc_ULciMMskyzwwFmLqV3/dl5/d5/L2dBISEvZ0FBIS9nQSEh/

The DME MAC Jurisdiction C Insider Spring 2010.Last accessed 10/26/18. Retrieved from: https://www.cgsmedicare.com/jc/pubs/insider/2010_insider_Ed. 11. Spring.pdf

CGS A Celerian Group Company Local Coverage Determination Policy. External Infusion Pumps LCD L33794 and ArticleA52507. Last accessed 10/26/18. Retrieved from https://www.cgsmedicare.com/jc/coverage/lcdinfo.html

The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11

The Pricing, Data Analysis, and Coding Contractor. Noridian. Internet website. Last accessed 10/26/18. Retrieved from https://www.dmepdac.com/dmecsapp/

West Virginia Medicaid Internet Provider Manual. Chapter 506. Covered Services, Limitations, and Exclusions for DME Medical Supplies. Last accessed 10/26/18. Retrieved from dhhr.wv.gov/bms/Pages/default.aspx

Hayes Health Technology Assessment and Consulting Inc. Continuous Glucose Monitoring Systems. Dec. 1/2010. Last accessed 10/26/18. Retrieved from hayesinc.com/hayes

Highmark Medical Policy Bulletin. Continuous Glucose Monitors. Issued Date: October 20, 2008. Revised 7/5/10. Last accessed 10/26/18. Retrieved from secure.highmark.com/ldap/medicalpolicy/wpa-highmark/E-42-009.html

The Pricing, Data Analysis, and Coding Contractor. Noridian. Internet website. Last accessed 10/26/18. Retrieved from https://www.dmepdac.com/dmecsapp/

Physician's Desk Reference, or the U.S. Pharmacopeia Drug Information

See below for the Hypoglycemic Questionnaire.

AWARENESS OF HYPOGLYCEMIA

Survey items used to assess reduced awareness of hypoglycemia.

Four or more "R" responses = reduced awareness
Two or fewer "R" responses = aware

1. Check the category that best describes you: (check one only)
   - ☐ I always have symptoms when my blood sugar is low (A)
   - ☐ I sometimes have symptoms when my blood sugar is low (R)
   - ☐ I no longer have symptoms when my blood sugar is low (R)

2. Have you lost some of the symptoms that used to occur when your blood sugar was low?
   - ☐ Yes (R)
   - ☐ No (A)

3. In the past six months, how often have you had moderate hypoglycemia episodes? (Episodes where you might feel confused, disoriented, or lethargic and were unable to treat yourself.)
   - ☐ Never (A)
   - ☐ Once or twice (R)
   - ☐ Every other month (R)
   - ☐ Once a month (R)
   - ☐ More than once a month (R)

4. In the past year, how often have you had severe hypoglycemic episodes? (Episodes where you were unconscious or had a seizure and needed glucagon or intravenous glucose.)
   - ☐ Never (A)
   - ☐ 1 time (R)
   - ☐ 2 times (R)

- ☐ 3 times (R)
- ☐ 5 times (R)
- ☐ 6 times (R)
- ☐ 7 times (R)
- ☐ 8 times (R)
- ☐ 9 times (R)
- ☐ 10 times (R)
- ☐ 11 times (R)
- ☐ 12 or more times (U)

5. In the last month, how often have you had readings <70 mg/dl with symptoms?
   - ☐ Never
   - ☐ 1 to 3 times
   - ☐ 1 time/week
   - ☐ 2 to 3 times/week
   - ☐ 4 to 5 times/week
   - ☐ Almost daily

6. In the last month, how often have you had readings <70 mg/dl without any symptoms?
   - ☐ Never
   - ☐ 1 to 3 times
   - ☐ 1 time/week
   - ☐ 2 to 3 times/week
   - ☐ 4 to 5 times/week
   - ☐ Almost daily

(for questions 5 and 6: R = answer to 5 < answer to 6, A = answer to 6 > answer to 5)

7. How low does your blood sugar need to go before you feel symptoms?
   - ☐ 60-69 mg/dl (A)
   - ☐ 50-59 mg/dl (A)
   - ☐ 40-49 mg/dl (R)
   - ☐ < 40 mg/dl (R)

8. To what extent can you tell by your symptoms that your blood sugar is low?
   - ☐ Never (R)
   - ☐ Rarely (R)
   - ☐ Sometimes (R)
   - ☐ Often (A)
   - ☐ Always (A)

Adapted from William L. Clarke, MD