This content has been created to supplement the MCG care guidelines. MCG Health has neither reviewed nor approved the modified material.

SHP Continuous Subcutaneous Insulin Infusion

AUTH: SHP Durable Medical Equipment 11 v4 (AC)

MCG Health
Ambulatory Care
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Link to Codes

Coverage

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See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.

Application to Products

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- Policy is applicable to all products.

Authorization Requirements

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Pre-certification by the Plan is required.

Description of Item or Service

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Continuous subcutaneous insulin infusion is the constant administration of insulin through an external insulin pump, delivered to the individual through a subcutaneous needle.

A 'combination device' is one that both, delivers the continuous insulin infusion and monitors the individual's blood glucose.

Exceptions and Limitations

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- There is insufficient scientific evidence to support the medical necessity of Continuous Subcutaneous Insulin Infusion for uses other than those listed in the clinical indications for procedure section.

Clinical Indications for Procedure

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- Continuous Subcutaneous Insulin Infusion is considered medically necessary for **1 or more** of the following:
    - Individual has an Optima Commercial Plan or Optima Virginia Medicaid Plan and indications for **1 or more** of the following :
        - Initial insulin infusion devices are considered medically necessary for **ALL** of the following
            - Insulin pump requested is FDA approved and is indicated by **1 or more** of the following
                - External insulin pump
                - Hybrid closed-loop threshold-suspend (low-glucose-suspend) external insulin pump
                - Sensor-augmented external insulin pump
                - Threshold-suspend (low-glucose suspend) external insulin pump
            - Diagnosis of diabetes, as indicated by **1 or more** of the following
                - Type 1 diabetes mellitus
                - Type 2 diabetes mellitus and **1 or more** of the following
                    - Daily insulin requirement of 0.7 to 1.8 units per kg
                    - Total daily insulin dose is 220 units or less.
            - Failure of multiple daily injection insulin administration, as indicated by **1 or more** of the following
                - Abnormal early-morning increase in blood glucose ("dawn phenomenon"), unresponsive to management with long-acting insulin analogue (eg, insulin glargine, insulin detemir) regimens
                - Child for whom multiple daily insulin injections are impractical or inappropriate
                - Diabetes complications (eg, neuropathy, nephropathy, retinopathy), and need for more intensive management
                - Extreme insulin sensitivity

- HbA1c greater than 7% (53 mmol/mol), despite intensified multiple daily injection insulin therapy
- Hypoglycemia requiring third-party assistance, including unconsciousness, seizure, glucagon administration, and emergency attendance or admission to hospital
- Individual is pregnant or planning pregnancy
- Wide swings in glycemic control

- Individual or caregiver is motivated, adherent, knowledgeable, and able to monitor blood glucose 3 or more times per day
- Provider team is experienced and expert in management and support of Individual with insulin infusion pump

- Replacement insulin infusion devices are considered medically necessary with **ALL** of the following :
  - The problem(s) which limit the use of the current insulin infusion device is clearly identified (including misuse or abuse of the equipment)
  - There is documentation that the current insulin infusion device is not under warranty, including the date of warranty expiration

- Individual has Optima Medicare Plan and indications for **ALL** of the following
  - Administration of continuous subcutaneous insulin infusion (CSII) (including related drugs/supplies) in home setting are medically necessary with **ALL** of the following
    - FDA approved pump ordered by and follow-up care of individual managed by physician who manages multiple individuals with CSII and who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in use of CSII
    - Individual is diabetic and appropriate for CSII, as indicated by **1 or more** of the following
      - Individual is beta cell autoantibody positive
      - Individual is insulinopenic per updated fasting C-peptide testing requirement, as indicated by **ALL** of the following
        - Fasting C-peptide level obtained concurrently with fasting glucose of ≤ 225 mg/dL
        - Fasting C-peptide level, as indicated by **1 or more** of the following
          - Individual without renal insufficiency: less than or equal to 110% of lower limit of normal of laboratory's measurement method
          - Individual with renal insufficiency and creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine) ≤ 50 ml/minute: ≤ 200% of lower limit of normal of laboratory's measurement method
  - Individual meets criteria for insulin pump therapy, as indicated by **1 or more** of the following
    - Individual is candidate for FDA approved continuous subcutaneous insulin infusion pump, as indicated by **ALL** of the following
      - Individual has completed comprehensive diabetes education program
      - Individual has been on program of multiple daily injections of insulin (ie, at least 3 injections per day), with frequent self-adjustments of insulin doses for at least 6 months prior to initiation of insulin pump
      - Individual has documented frequency of glucose self-testing an average of at least 4 times per day during 2 months prior to initiation of insulin pump
      - Individual is not well-controlled while on multiple daily injection regimen, as indicated by **1 or more** of the following
        - HbAlc > 7.0%
        - History of recurring hypoglycemia
        - Wide fluctuations in blood glucose before mealtime
        - Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
        - History of severe glycemic excursions
    - Individual has been on pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during month prior to Medicare enrollment.

Document History

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- Revised Dates:
  - 2022: July
  - 2021: October
  - 2018: November
  - 2015: February, March, May, October, December
  - 2014: May, August, October
  - 2013: April, May, June, October
  - 2012: June, August
  - 2011: May, September
  - 2010: June
  - 2009: May
  - 2008: June
  - 2007: August, October, December
  - 2006: October
  - 2005: August, December
  - 2004: December
  - 2000: October
  - 1999: February, September, October
  - 1996: May
- Reviewed Dates:
  - 2018: July
  - 2017: November
  - 2016: June
  - 2015: May
  - 2014: May
  - 2010: May

- 2006: May
- 2004: December
- 2003: May, October
- 2002: May
- 2001; June
- 1998: October

- Effective Date: January 1994

Coding Information

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- CPT/HCPCS codes covered if policy criteria is met:
  - HCPCS A4224 – Supplies for maintenance of insulin infusion catheter, per week
  - HCPCS A4225 – Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
  - HCPCS A4226 - Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week
  - HCPCS A4230 – Infusion set for external insulin pump, nonneedle cannula type
  - HCPCS A4231 - Infusion set for external insulin pump, needle type
  - HCPCS A9274 – External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
  - HCPCS E0784 – External ambulatory infusion pump, insulin
  - HCPCS K0552 - Supplies for external drug infusion pump, syringe type cartridge, sterile, each
- CPT/HCPCS codes considered not medically necessary per this Policy:
  - None

References

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References used include but are not limited to the following:

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NCD: Infusion Pumps (280.14). (2004, Dec 17). Retrieved Jul 06, 2022, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=223&ncdver=2&keyword=Subcutaneous%20insulin&keywordType=starts&areaId=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

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FDA authorizes first interoperable insulin pump intended to allow patients to customize treatment through their individual diabetes management devices. (2019, Feb 14). Retrieved Jul 06, 2022, from Food and Drug Administration: https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-interoperable-insulin-pump-intended-allow-patients-customize-treatment-through#:~:text=Insulin%20pumps%20to%20date%20have,%2C%20highest%2Drisk%20devices).

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V-Go Disposable Insulin Delivery Device For The Management Of Type 1 Or Type 2 Diabetes Mellitus. (2021, Jan 20). Retrieved Sep 21, 2021, from Hayes, Inc.: https://evidence.hayesinc.com/report/htb.vgo2634

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Codes

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HCPCS: A4224, A4225, A4226, A4230, A4231, A9274, E0784, K0552

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