Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP104

Section: Medical Benefit Policy

Subject: Continuous Subcutaneous Insulin Infusion Pump (CSII)

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Continuous Subcutaneous Insulin Infusion Pump (CSII)

II. Purpose/Objective:

To provide a policy of coverage regarding Continuous Subcutaneous Insulin Infusion Pump (CSII)

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

Continuous Subcutaneous Insulin Infusion (CSII) pump: external device designed to deliver subcutaneous insulin in a continuous fashion.

ALL Durable Medical Equipment provided for home use requires advanced determination of coverage. Devices furnished at inpatient or outpatient centers are **NOT SEPARATELY REIMBURSABLE.**

DESCRIPTION: CSII pump requests are pre-certified through the Plan's Medical Management department prior to delivery. CSII pumps are utilized for the glycemic management of member with Type 1 and Type 2 diabetes mellitus and gestational diabetes. Coverage will be in accordance with Act 98 for commercial lines of business. CSII pumps are supplied through a contracted vendor.

COVERAGE STATEMENT:
Equipment and supplies, including but not limited to, insulin infusion pumps and related supplies, for the treatment of Type1 diabetes mellitus, Type 2 diabetes mellitus with insulin requirement, and gestational diabetes mellitus with insulin requirement will be covered when prescribed by a health care professional legally authorized to prescribe such items. Equipment and supplies must be provided by a participating provider and are limited to those which are preferred by the Plan, unless other equipment or supplies have been authorized as an exception, based on, and supported by, medical justification from the ordering provider.

CRITERA FOR COVERAGE:
REQUIRES PRIOR MEDICAL DIRECTOR OR DESIGNEE AUTHORIZATION

Insulin infusion pumps will be considered to be medically necessary in Type I and Type 2 diabetics when the following criteria are met:
Physician provided documentation of:
- The member is treated with multiple daily injections of insulin (i.e. at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump,
- Documented frequency in the medical record of glucose self-testing an average of at least 4 times per day prior to initiation of the insulin pump,
- and meets one or more of the following criteria while on the multiple daily injection regimen:
    - Glycosylated hemoglobin level(HbA1c) > 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

Sensor-augmented insulin pump therapy with the low glucose threshold suspend

Sensor-augmented insulin pump therapy with the low glucose threshold suspend will be considered for coverage for coverage in members 2 years and older with Type 1 diabetes when the current criteria for both external insulin pumps **and** the additional criteria for continuous glucose monitors listed below have been met:

1. Documentation of three (3) months active participation in either the Plan Diabetes Management program or an American Diabetes Association recognized program with continuing diabetes education; **AND**
2. Documentation by either a certified diabetic educator (CDE) or Plan Case Manager of compliance with self-monitoring testing, diet or other recommendations to improve glycemic control; AND
3. Documentation of insulin injections three or more times a day, or use of an insulin pump; and

- Documented episodes of recurrent severe hypoglycemia (less than 50 mg/dL) or physician documented evidence of severe ketosis, suspected postprandial hyperglycemia, or hypoglycemic unawareness including symptoms, consequences, frequency, and patterns identified; and
- Documentation of insulin regimen modification and compliance with frequent finger-stick self-monitoring (at least four times per day)

EXCLUSIONS:

Replacement of a currently functioning Continuous Subcutaneous Insulin Infusion pumps for the sole purpose of expired warranty, upgrade in model or use with a non-covered monitoring device **is not** considered **medically necessary**. Replacement due to slight damage to the pump without causing the pump to malfunction is also considered **not medically necessary**.

Equipment failure requires detailed documentation and must include the pump serial number. The vendor must provide the member's equipment serial number with request for repair or replacement.

Equipment upgrades or accessories whose sole purpose is to integrate (with wireless communication technology) an insulin pump and interstitial glucose monitor are considered **not medically necessary.**

Additional software or hardware required for downloading data to a personal computer to aid in self-management of diabetes mellitus is considered a convenience item and **not medically necessary**.

Use of an artificial pancreas system is considered investigational, experimental or unproven and **NOT COVERED**

Disposable external insulin pump with no wireless communication capability (e.g., V-Go™ Disposable Insulin Delivery Device) is considered **experimental, investigational or unproven** and is **NOT COVERED. (Commercial Business Segment only).** For **Medicare Business Segment,** disposable insulin delivery devices are covered under the Medicare Part D pharmacy benefit.

*For information regarding devices that combine external insulin infusion pumps with a continuous glucose monitor, please refer to MP 71 for a description of coverage in regards to Continuous Subcutaneous Glucose Monitors.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

CODING ASSOCIATED WITH: External Insulin Infusion Pump

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

E0784 External ambulatory infusion pump, insulin
E0787 EXTERNAL AMBULATORY INFUSION PUMP, INSULIN, DOSAGE RATE ADJUSTMENT USING THERAPEUTIC CONTINUOUS GLUCOSE SENSING
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
A4231 Infusion set for external insulin pump, needle type
A4232 Syringe with needle for external insulin pump, sterile, 3cc
A6257 Transparent film, 16 sq. in. or less, each dressing (GOLD only)
A9274 External ambulatory insulin delivery system, disposable, each; includes all supplies and accessories
S1034
S1035
S1036
S1037

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

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Rosenfeld CR, Bohannon NJ, et al. TheV-Go insulin delivery device used in clinical practice: patient perception and retrospective analysis of glycemic control. Endocr Pract. 2012 Sep-Oct;18(5):660-7

Kapitza C, Fein S, et al. Basal-prandial insulin delivery in type 2 diabetes mellitus via the V-Go: a novel continuous subcutaneous infusion device. J Diabetes Sci Technol. 2008 Jan;2(1):40-6.

Hayes WS. Hayes Search & Summary. V-Go™ Disposable Insulin Delivery Device (Valeritas Inc.). January 7, 2016

U.S Food and Drug Administration. Summary of safety and effectiveness data for the MiniMed 670G system. September 28, 2016.

Tauschmann M, Allen JM, Wilinska ME, et al. Day-and-night hybrid closed-loop insulin delivery in adolescents with Type 1 diabetes: a free-living, randomized clinical trial. Diabetes Care. 2016a; 39(7):1168-1174.

Tauschmann M, Allen JM, Wilinska ME, et al. Home use of day-and-night hybrid closed-loop insulin delivery in suboptimally controlled adolescents with Type 1 diabetes: a 3-week, free-living, randomized crossover trial. Diabetes Care. 2016b; 39(11):2019-2025.

Tauschmann M, Allen JM, Wilinska ME, et al. Sensor life and overnight closed loop: a randomized clinical trial. J Diabetes Sci Technol. 2016c; pii: 1932296816678631

This policy will be revised as necessary and reviewed no less than annually.

Devised: 4/03

Revised: 4/04 (Lab value designation change); 9/04; 4/05 grammatical change; 10/10 (exclusion) 11/11 (added coverage criteria), 8/14 (criteria, exclusion), 8/16 (gender language), 7/17 (age restriction change); 9/18 (criteria revision for fingerstick requirement timeframe), 9/19 (Updated Exclusion Language); 9/20 (revised age limitation for sensor augmented pump)

Reviewed: 4/06; 4/07, 4/08, 4/09, 10/12, 10/13, 8/15, 9/21, 9/22