External Insulin Pump

Policy # 00232
Original Effective Date: 12/17/2008
Current Effective Date: 07/13/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of external insulin infusion pumps - continuous subcutaneous insulin infusion (CSII) - to be **eligible for coverage**** for the treatment of patients with diagnosis of insulin dependent diabetes who meet the following criteria:

Patient Selection Criteria

Coverage eligibility for use of external insulin pump will be considered when all of the following criteria are met:

Note: Insulin pump must be prescribed by an endocrinologist or physician with similar skill and training in the management of external insulin pumps.

- Supporting clinical documentation from either the patient's primary physician or a consulting endocrinologist must be submitted for review when requesting the insulin pump; AND
- The patient/family has completed a comprehensive diabetes education program; AND
- A complete assessment that provides documented evidence of patient/family commitment to self-management of the insulin pump including documentation of very good compliance with the current self-management program; AND
- Must be on a program of multiple daily insulin injections (3 or more per day) with frequent self-adjustments of insulin for at least 6 months prior to the initiation of insulin pump therapy; AND
- Must have the ability to self-monitor blood glucose levels at least four times/day as documented on a certificate of medical necessity form; AND

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- The member must also meet one or more of the following criteria while on multiple daily insulin injections:
  - Hgb A1c is > 7%; or
  - History of recurrent hypoglycemia; OR
  - Wide fluctuations in blood sugar levels before meals (pre-prandial blood glucose levels frequently exceeding 140 mg/dl); OR
  - Presence of Dawn Phenomenon with fasting blood sugar values frequently exceeding 200 mg/dl; OR
  - History of severe glycemic excursions (usually associated with brittle diabetes, hypoglycemic unawareness, nocturnal hypoglycemia, extreme insulin sensitivity and/or very low insulin requirements.

Note: Members who have been on insulin pump therapy prior to enrollment with BCBSLA must have documentation of glucose self-monitoring at least four times/day during the month prior to enrollment.

External Infusion Pump Replacement:

Based on review of available data, the Company may consider replacement of an insulin pump to be **eligible for coverage**** when following criteria are met and clearly documented in medical records:

- The device is out of warranty; AND
- The device is malfunctioning; AND
- The device cannot be refurbished.

When Services Are Considered Investigational
Note: Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers external insulin pump use when the patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers the use of a nonprogrammable disposable transdermal insulin delivery device (e.g., V-Go™‡) to be **investigational.***

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Background/Overview

External insulin pumps are designed to provide CSII in patients with diabetes mellitus. The external insulin pump is a programmable battery-powered mechanical syringe/reservoir regulated by a miniature computer. Typically, the syringe has a 2-day insulin capacity and is connected to an infusion set attached to a small needle or Teflon cannula. The patient inserts the needle or cannula into subcutaneous tissue. The syringe is activated by a battery-operated pump programmed to deliver a steady "basal" amount of insulin and release a bolus dose at meals or smaller amounts at programmed times. Frequent monitoring of the blood glucose is essential to ensure appropriate delivery of insulin dosage. An insulin pump is considered durable medical equipment.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration (FDA) approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies and accredited national guidelines.

A newer type of mechanical disposable insulin delivery device (V-Go) has been proposed as an alternative to standard pump therapy. At this time, there is no clinical trial data comparing this type of device to a standard battery operated pump devices. The safety and efficacy has not been sufficiently evaluated to demonstrate equivalent clinical outcomes.

Based upon our criteria and review of the peer-reviewed literature, nonprogrammable disposable insulin delivery systems (e.g., V-Go disposable insulin delivery device) are considered investigational.

References

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Policy History

Original Effective Date: 12/17/2008
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12/03/2008	Medical Director Review
12/17/2008	Medical Policy Committee approval. New policy.
12/04/2009	Medical Director Review
12/16/2009	Medical Policy Committee approval. No change to coverage.
06/03/2010	Medical Policy Committee review. Policy revised; Type I removed from coverage eligibility statement. This change means policy no longer excludes Type II insulin dependent diabetes mellitus.
06/16/2010	Medical Policy Implementation Committee review

08/04/2011	Medical Policy Committee review.
08/17/2011	Medical Policy Implementation Committee approval. No change to coverage.
03/01/2012	Medical Policy Committee review.
03/21/2012	Medical Policy Implementation Committee approval. Bullet stating that you must have demonstrated an effort to comply with an intensive insulin regimen for a minimum of two months as documented in physician notes and daily logs was removed from the policy.
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/02/2015	Medical Policy Committee review
04/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
04/06/2017	Medical Policy Committee review
04/19/2017	Medical Policy Implementation Committee approval. Added the V-Go transdermal insulin delivery system as investigational.
05/03/2018	Medical Policy Committee review
05/16/2018	Medical Policy Implementation Committee approval. No change to coverage.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Adoption of additional eligible criteria with bullets for supporting clinical documentation from either the patient's primary physician or a consulting endocrinologist which must be submitted for review when requesting the insulin pump; and patient/family completion of a comprehensive diabetes education program; and requirement for a complete assessment that provides documented evidence of patient/family commitment to self-management of the insulin pump including documentation of

	very good compliance with the current self-management program. Revision of external infusion pump replacement criteria.
03/13/2020	Coding update
04/23/2020	Coding update
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 06/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code

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CPT	No codes
HCPCS	A4224, A4225, A4230, A9274, E0784, J1817, S1034, S1035, S1036, S1037, S9145 Codes added eff 1/1/2020: A4226, E0787
ICD-10 Diagnosis	E08.0-E13.9

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.