Overview
The purpose of this document is to describe the guidelines Neighborhood Health Plan (NHP) utilizes to determine the medical necessity for insulin pumps. The treating specialist must request prior authorization.

Coverage Guidelines
NHP covers diabetic insulin pumps for individuals when it is recommended by the member’s providers and when the request meets the medical necessity criteria indicated below. The member’s endocrinologist is responsible for providing all necessary clinical information for the determination of benefit coverage including: medical history, diabetes education received, treatment to date, glucose reading logs, pertinent laboratory testing, treatment plan, and medical necessity rational.

NHP does not provide coverage for diabetic durable medical equipment not covered in this coverage criteria; some examples include: pulsatile intravenous insulin therapy or insulin therapy combined with a continuous glucose monitor in a closed loop system that does not require direct patient interaction, e.g. artificial pancreas.

Insulin Pump
NHP covers a medically necessary insulin pump for a member who is already performing meticulous diabetic care and using multiple daily insulin injections, but requires an alternate insulin delivery system to achieve a set goal when the following are met:

Initial Request
All of the following must be met:
1. The member has type 1 diabetes\(^1,2\) (by definitive clinical history and laboratory testing) and has been actively monitored for the past 6 months by an endocrinologist who works closely with a team including nurses, diabetic

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\(^1\) The insulin pump has not been shown to offer advantage over intensive conventional insulin therapy for pregnant women with Type 1 diabetes, and may confer a risk of ketoacidosis. NHP will continue coverage for an insulin pump for a woman who uses one pre-pregnancy and who meets criteria for continued use, and will review requests for new starts on a case-by-case basis.
educators, and dieticians to maximize member education and adherence and who are knowledgeable in the use of continuous subcutaneous insulin infusion;

2. The member demonstrates understanding of and adherence to nutritional recommendations and demonstrates the ability to match insulin to carbohydrates which are documented by a recent nutritionist note; or if a member has been following nutritionist advice for a long time, an endocrinologist note documents the member’s understanding of and adherence to nutritional recommendations and demonstrates adjustments in insulin based on the member’s accurate carbohydrate counting.

3. The member uses multiple daily insulin injections including sliding scale dosing of short/rapidly acting insulin several times a day;

4. The member has been consistently performing at least 4 or more self-monitored blood glucose tests per day with physician guided frequent insulin adjustments based on these readings for at least 6 months;

5. Despite adherence to an endocrinologist-ordered diabetic treatment plan that includes: dietary adherence, continued 4 times a day self-monitoring, and frequent and consistent alterations in an insulin administration regimen, there is:
   
i. Over a six month period, demonstrated inability to continue to improve upon and ultimately achieve (within a 0.5 HbA1C) optimum glycemic control as referenced by the American Diabetes Association Standards of Medical Care in Diabetes (see Definitions).

   Note: This insulin adjustment and adherence must be demonstrated by a downloaded meter read or photocopied log book of the past 60 days with physician-guided insulin instructions and adjustments in clinical notes. The most recent two HgA1c must be submitted;

6. The member is not being simultaneously prescribed a newly starting continuous glucose monitor (i.e. NHP expects a member to be using an insulin pump safely and effectively before also receiving a CGMS);

7. The member is motivated to use the insulin pump, is educated about the device by attending formal insulin pump classes, and is capable of using and maintaining compliance with the insulin pump²;

8. The member understands that they must maintain adherence to dietary recommendations, continue with 4 times a day glucose monitoring, and be closely supervised by the prescribing endocrinologist;

9. There is a defined treatment goal (i.e. defined HbA1C level);

10. The prescribing endocrinologist plans to contact the member via appointment or by phone within one week after receiving the device to guide its use and to insure the member has full understanding and is using the pump appropriately or;

     a. if the device was approved for purchase, returns the pump within the 30 day trial period; or

     b. returns the pump within the rental period for a rental device (see below);

11. Once the member is appropriately using the pump, the results are monitored and interpreted under the supervision of an endocrinologist/office nurse educator at least monthly for three months.

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For continued use including during a rental period or for continued pump supplies

All of the following must be met:

1. The member is seen and evaluated every three months or more often as needed, by the prescribing endocrinologist who works closely with a team that includes: nurses, diabetic educators, and dieticians who are knowledgeable in the use of insulin pump therapy;

2. The member demonstrates understanding of and adherence to nutritional recommendations and demonstrates the ability to match insulin to carbohydrates which are documented by a recent nutritionist note; or if a member has been following nutritionist advice for a long time, an endocrinologist note documents the member’s understanding of and adherence to nutritional recommendations and demonstrates adjustments in insulin based on the member’s accurate carbohydrate counting.

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²If the member is a child or adolescent, requests will be reviewed on a case-by-case basis. There is less evidence for the superiority of insulin pump use in lowering hemoglobin A1c compared with multiple daily insulin (MDI) in children and adolescents. There is no clear evidence that insulin pumps reduce hypoglycemia. Compliance in these age groups can be a challenge due to inconvenience of wearing the device, daily calibration required, and intensive monitoring. There must be social and clinical supports in place to assist in maintaining adherence. The burden of day-to-day management also rests with the caregivers, and every effort must be made to ensure that they have realistic expectations and are motivated and clearly committed to insulin pump therapy.
3. The member has been consistently performing at least 4 or more self-monitored blood glucose tests per day with adjustments of the pump;
4. The member has successfully completed and demonstrated compliance with all aspects of the diabetic care and has not had any major adverse reactions or complications from using the pump;
5. The member has had clear benefit from the using the insulin pump (i.e. there is significant improvement in glucose control);
   Note: The insulin adjustments and adherence, and the clinical improvement must be demonstrated by a downloaded meter read or photocopied log book with physician-guided insulin instructions and adjustments in clinical notes. The most recent two HgA1c must be submitted.
6. The member continues to be motivated and capable of maintaining optimal control of his or her diabetes with effective use of the insulin pump;
7. For a replacement pump request, the pump must be greater than 4 years-old or the request for replacement is due to pump failure when the device is out of warranty with proof of warrantee expiration. This pump failure must be documented by a pump investigation during an endocrinologist office visit.

Insulin Pump -Exclusions
1. NHP does not provide coverage for insulin pumps other than listed above;
2. NHP does not provide coverage for insulin pumps when the member enrolled in the 3-month trial either failed or is not motivated and is not likely to benefit from another three-month trial.
3. The member is unable to perform frequent blood glucose monitoring, or is unable to technically operate the insulin pump due to behavioral, psychological, or other reasons;
4. Transdermal insulin delivery systems (e.g. V-Go) because it is considered experimental and investigational.
5. Combined continuous subcutaneous insulin infusion and blood glucose monitoring systems in a closed loop system that does not require direct patient interaction; i.e artificial pancreas, because it is considered experimental/ investigational or unproven
6. Replacement or repair of an insulin pump when:
   a. It is still under manufacture warranty;
   b. It is lost, stolen, or damaged due to improper care, or misuse, or neglect (NHP may require proof of the stolen or damaged item. Proof consists of a police report, pictures, or corroborating statement);
   c. The member has a functioning model and a newer or upgraded model is not medically necessary; or
   d. The pump is less than 4 years old.
7. Pulsatile intravenous insulin therapy also referred to as metabolic activation therapy is not covered because it is considered experimental and investigational;
8. Devices or device features that are to be principally used for convenience and are not medically necessary, or devices or device features that are considered experimental and investigational. (e.g. Medtronic My Sentry Device).

Definitions
Closed loop system of insulin pump and continuous glucose monitor i.e. Artificial pancreas: This system has a continuous glucose monitoring system with a disposable sensor that measures glucose levels in the tissue under the skin for up to 3 days. A transmitter that is connected to the glucose sensor sends data wirelessly to a combination pump and display unit, which can automatically adjust insulin infusion to provide continuous control of glucose levels. The pump will also sound and show alarms when glucose levels are too high or too low.

Continuous Glucose Monitors: Minimally invasive or noninvasive devices that measure glucose levels in the interstitial fluid surrounding skin cells over a short-term period of several days or for long-term use to provide continuous information about glucose fluctuations that is not otherwise captured by intermittent testing. The continuous glucose monitoring systems measure blood glucose with minimal invasiveness through continuous measurement of interstitial fluid (ISF) with a subcutaneously implanted senor, or with the noninvasive method of applying an electric current (i.e., reverse iontophoresis) through the skin to blood vessels in the body. The readings from the CGMS are intended to supplement, not replace, information obtained from standard home glucose monitoring devices. Several CGMS have been approved by the FDA. In addition to stand-alone continuous glucose monitors, several insulin pump systems have
included a built-in continuous glucose monitor. Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower hemoglobin A1C levels in highly selected patients.

**Glycated hemoglobin** : also known as HbA1c, is a form of hemoglobin. (Hemoglobin is the iron rich protein in red blood cells that gives blood its red color.) In the normal 120-day life span of a red blood cell, glucose molecules react with hemoglobin forming glycated hemoglobin. Individuals with diabetes have higher quantities of glucose in their capillary blood and as a result they also have increased numbers of glycated hemoglobin molecules. The 2010 American Diabetes Association Standards of Medical Care include an HbA1c level $\geq 6.5\%$ as one of the criteria for diagnosing diabetes. Once a hemoglobin molecule is glycated, it remains that way. A build-up of glycated hemoglobin within the red blood cells therefore reflects the average level of glucose to which the cell has been exposed during its life cycle. Measuring glycated hemoglobin assesses the effectiveness of therapy for the treatment of diabetes.

**Hypoglycemia** : The definition of hypoglycemia has been the subject of controversy; activation of glucose counterregulatory systems occurs when blood glucose levels reach the 65–70 mg/dL range; symptoms of hypoglycemia present at the 50–55 mg/dL range, and cognitive dysfunction occurs when blood glucose levels are in the 45–50 mg/dL range.

**External insulin pump** : An external insulin pump is a computerized, battery-powered device with programming capabilities that delivers insulin subcutaneously. The insulin is delivered in a programmed and controlled manner and eliminates the need for the patient to self-inject insulin. The main goal in using an insulin pump is to achieve near-normal blood glucose levels in order to prevent both acute and chronic complications of diabetes.

**Pulsatile intravenous insulin therapy**: Also known as hepatic activation therapy, metabolic activation therapy, pulse insulin therapy and pulsatile intravenous insulin therapy. This type of therapy is usually performed as a weekly procedure in conjunction with daily intensive subcutaneous insulin therapy. Treatment session entails a 6 hour period in an outpatient or inpatient setting. During the treatment session the patient receives interment pulses of insulin through an intravenous catheter in a peripheral vein in the hand or arm. The interment pulses are controlled by a computerized program which produces the desired geometric wave forms and the doses are adjusted based on frequent monitoring of the glucose levels, respiratory quotient response, and the timing of a glucose load ingested by the patient.

**Optimum Glycemic Control per ADA 2015**:
- Lowering A1C for nonpregnant adults to $< 7\%$ to reduce microvascular and neuropathic complications of diabetes and, possibly, macrovascular disease.
- Lowering A1C for a selected individual adult to $< 6.5\%$ without causing significant hypoglycemia or other adverse effects of treatment.
- Less stringent A1C goals (e.g. $< 8\%$) may be appropriate for an adult patient with a history of: severe hypoglycemia, limited life expectancies, advanced microvascular or macrovascular complications, extensive comorbid conditions, or those with longstanding diabetes in whom the general goal is difficult to obtain despite education, monitoring, and appropriate medications.
- Lowering A1C for children to $< 7.5\%$ with special consideration for the unique risks of hypoglycemia in very young children.

**Relevant Regulation**

**Related Policies**
- Continuous Glucose Monitors

**Effective**
July 2015: Effective date.

**References**


Standards of Medical Care in Diabetes—2015. ADA. Diabetes Care. January 2015 Volume 38, Supplement 1