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
As of February 20, 2017 medical necessity for insulin pumps is determined through McKesson’s InterQual® criteria. To access the criteria, log in to NHP’s provider website at NHP.Net and click the InterQual® Criteria Lookup link under the Resources Menu. 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. In addition, the member’s endocrinologist is responsible for providing all necessary clinical information for the determination of medical necessity including: medical history, diabetes education received, treatment to date, glucose reading logs, pertinent laboratory testing, treatment plan, and medical necessity rational. The treating endocrinologist must sign a prescription for any requested insulin pump/supply at least yearly.

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 - Exclusions
1. Transdermal insulin delivery systems (e.g. V-Go) because it is considered experimental and investigational.
2. 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.
3. Replacement or repair of an insulin pump when:
   a. 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);
   b. The member has a functioning model and a newer or upgraded model is not medically necessary;
4. Pulsatile intravenous insulin therapy also referred to as metabolic activation therapy is not covered because it is considered experimental and investigational;
5. Devices or device features that are to be principally used for convenience and are not medically necessary
6. Devices or device features that are considered experimental and investigational. (e.g. Medtronic My Sentry).
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 sensor, 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 2016:

- Lowering A1C for nonpregnant adults to < or about 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.
Related Policies

- Continuous Glucose Monitors

Effective

February 2017: McKesson’s InterQual® criteria replaced the criteria as indicated in the policy.
July 2016: Annual update
July 2015: Effective date

References


