Name of Policy:
External Ambulatory Insulin Infusion Pump

Policy #: 046       Latest Review Date: April 2014
Category: Durable Medical Equipment       Policy Grade: A

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. 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.
**Description of Procedure or Service:**
External insulin pumps are computerized, battery-powered delivery devices with programming capabilities used as a treatment for persons with insulin dependent diabetes mellitus (IDDM). A reservoir is filled with rapid-acting insulin. The sterile reservoir is connected to the patient by a thin plastic tube called an infusion set. At the end of the infusion set is a small catheter needle, which is generally inserted into the subcutaneous tissue of the abdomen. The infusion set can remain in the subcutaneous tissue for two to three days. The pump is worn continuously day and night. However, there is a disconnect feature on the infusion set which allows the diabetic person to safely disconnect from the pump for short periods of time to exercise, bathe, swim, shop, dress, etc.

The insulin pump delivers insulin continuously in micro-doses of one-tenth of a unit. Basal rates are pre-programmed to deliver subcutaneously at a constant, low level similar to the delivery of insulin from the pancreas in the non-diabetic population. Basal rates can be set to meet the changing background insulin need that differs by individual metabolic rate. Boluses are programmed for actual food consumed and are usually delivered just prior to eating. Because diabetic patients frequently have gastromotility problems, better blood glucose control can be achieved with a bolus that can be spread out over a period of up to eight hours. Furthermore, the pump delivers only short acting insulin in a more physiological way allowing a patient to be under better control despite active daily demands. Meals and snacks can be missed with no adverse effects. With multiple injections and the use of longer-acting insulins, the diabetic patient needs to know significantly in advance what is going to occur during the course of a given day.

External ambulatory insulin infusion pump therapy is also known as continuous subcutaneous insulin infusion (CSII).

**Policy:**
**Effective for dates of service on or after September 26, 2013:**
External ambulatory insulin infusion pumps meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all the following prerequisites are met and are clearly documented in the patient’s medical record.

1. Patient must have had the diagnosis of and been treated for diabetes for six months or greater;
2. Patient/parent of dependent child has demonstrated ability and willingness to monitor blood glucose levels more than four times per day;
3. Patient/parent of dependent child is motivated to achieve and maintain improved glycemic control;
4. Patient/parent of dependent child is capable physically and intellectually to operate pump;
5. Patient demonstrates compliance with dietary and insulin regimen.
In addition to the above prerequisites, the patient must also meet one or more of the following indications:

1. Two glycosylated hemoglobin (HbA1c) greater than 7.0% (where upper range of normal is less that 6.05%; for other assays, 1% over upper range of normal) within a 120-day time span;
2. History of severe glycemic excursions commonly associated with brittle diabetes, such as hypoglycemic unawareness, nocturnal hypoglycemia, extreme insulin sensitivity and/or very low insulin requirements;
3. Wide fluctuations in blood glucose before mealtimes (e.g., preprandial blood glucose level commonly exceeds 140 mg/dL);
4. Dawn phenomenon where fasting blood glucose level often exceeds 200 mg/dL;
5. Day-to-day variations in work schedule, mealtime, and/or activity level, which confound the degree of regimentation required to self-manage glycemia with multiple insulin injections;
6. Preconception or pregnancy with a history of suboptimal glycemic control;
7. Suboptimal glycemic and metabolic control post-renal transplant.

Sensor-augmented insulin pump therapy with the low glucose threshold suspend feature (e.g., MiniMed 530G system with Enlite, Medtronic, Inc) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in children and adults 16 years and older when the criteria for external insulin pumps and continuous glucose monitors has been met.

Sensor augmented insulin pump therapy with the low glucose threshold suspend feature (e.g., MiniMed 530G system with Enlite, Medtronic, Inc) is considered investigational by Blue Cross and Blue Shield of Alabama in children younger than 16 years.

Back up external insulin infusion pumps do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Replacement or upgrade of existing, properly functioning equipment, even if warranty has expired, does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Replacement of a non-functioning external insulin infusion pump with a subsequent pump meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage. If the patient has demonstrated compliance with the current pump, the above medical criteria do not have to be met for the pump to be replaced.

Use of an artificial pancreas system does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational. (See Key Points)

Effective for dates of service prior to September 26, 2013:
External ambulatory insulin infusion pumps meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all the following prerequisites are met and are clearly documented in the patient’s medical record.
1. Patient must have had the diagnosis of and been treated for diabetes for six months or greater;
2. Patient/parent of dependent child has demonstrated ability and willingness to monitor blood glucose levels more than four times per day;
3. Patient/parent of dependent child is motivated to achieve and maintain improved glycemic control;
4. Patient/parent of dependent child is capable physically and intellectually to operate pump;
5. Patient demonstrates compliance with dietary and insulin regimen.

In addition to the above prerequisites, the patient must also meet one or more of the following indications:
1. Two glycosylated hemoglobin (HbA1c) greater than 7.0% (where upper range of normal is less that 6.05%; for other assays, 1% over upper range of normal) within a 120-day time span;
2. History of severe glycemic excursions commonly associated with brittle diabetes, such as hypoglycemic unawareness, nocturnal hypoglycemia, extreme insulin sensitivity and/or very low insulin requirements;
3. Wide fluctuations in blood glucose before mealtimes (e.g., preprandial blood glucose level commonly exceeds 140 mg/dL);
4. Dawn phenomenon where fasting blood glucose level often exceeds 200 mg/dL;
5. Day-to-day variations in work schedule, mealtime, and/or activity level, which confound the degree of regimentation required to self-manage glycemia with multiple insulin injections;
6. Preconception or pregnancy with a history of suboptimal glycemic control;
7. Suboptimal glycemic and metabolic control post-renal transplant.

And

**Back up external insulin infusion pumps do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

**Replacement of a functioning external insulin infusion pump with a newer advanced model does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

**Replacement of a non-functioning external insulin infusion pump with a subsequent pump meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage. If the patient has demonstrated compliance with the current pump, the above medical criteria do not have to be met for the pump to be replaced.

**Effective for dates of service prior to June 25, 2008:**
The glucose sensor and transmitter components of a continuous glucose monitor used with a combined continuous subcutaneous insulin infusion and blood glucose monitoring devices do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage. (See also Policy #38 Continuous or Intermittent Monitoring of Glucose in the Interstitial Fluid).
Proprietary Information of Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:
Diabetes mellitus (DM) is a metabolic disorder primarily characterized by elevated blood glucose levels and by microvascular and cardiovascular complications. Type 1 diabetes is characterized by total reliance on exogenous insulin for survival and comprises approximately 10% of all cases of diabetes. Insulin deficiency and/or insulin resistance characterize Type 2 diabetes, the more prevalent form comprising 90% of all people with diabetes. Approximately 16.5 million people in the United States have diabetes, making it one of the most prevalent chronic diseases in the country.

Long-term complications of diabetes include retinopathy with potential loss of vision, nephropathy leading to renal failure, peripheral neuropathy with risk of foot ulcers, amputation, and Charcot joints, and autonomic neuropathy causing gastrointestinal, genitourinary, and cardiovascular symptoms and sexual dysfunction. Patients with diabetes have an increased incidence of atherosclerotic cardiovascular, peripheral vascular, and cerebrovascular disease. Hypertension, abnormalities of lipoprotein metabolism and periodontal disease are often found in people with diabetes. The emotional and social impact of diabetes and the demands of treatment may cause psychosocial dysfunction in patients and their families.

Near normal blood glucose levels should be the goal of insulin therapy in patients with insulin dependent diabetes mellitus. This was demonstrated by the results of the Diabetes Control and Complication Trial (DCCT). This large, controlled, multicenter study demonstrated that improvement in glycemic control could reduce by 60% the incidence of microvascular complications in patients with Type 1 diabetes. The United Kingdom Prospective Diabetes Study (UKPDS) studied glycemic control in persons with only Type 2 diabetes. Results of the UKPDS clearly prove that control of blood glucose levels to near-normal delays the onset and significantly slow the progression of microvascular complications in persons with Type 2 diabetes. Also, an epidemiologic analysis of the UKPDS data showed a continuous association between the risk of cardiovascular complications and glycemia: for every percentage point decrease in HbA1c (e.g., from 9% to 8%), there was a 25% reduction in diabetes-related deaths, a 7% reduction in all-cause mortality, and 18% reduction in combined fatal and nonfatal myocardial infarction. As a result of these and other studies, in 1995 the American Diabetes Association (ADA) issued policies stating that “lowering blood glucose levels to or near normal in all patients is mandated” and “CSII is an acceptable alternative to multiple injection therapy in the management of Insulin Dependent Diabetes Melitus (IDDM)”. Multiple studies indicate that strict patient selection is the key to successful CSII therapy.
A search of the literature found minimal published studies related to the use of combined continuous subcutaneous insulin infusion and blood glucose monitoring devices. Wainstein et al (2005) reported on the efficacy of insulin therapy with continuous subcutaneous infusion pump (CSII) vs. multiple daily injections (MDI) in the treatment of 40 poorly controlled obese Type 2 diabetic patients. The results showed treatment with CSII significantly reduced HbAlc levels compared with treatment with MDI.

The American Diabetes Association recently (2004) published a position statement entitled “Continuous Subcutaneous Insulin Infusion”. They stated that the “use of continuous subcutaneous insulin infusion requires care by skilled professionals, careful selection of patients, meticulous patient monitoring and thorough patient education.”

The American Diabetes Association recently (2005) published a statement on the “Care of Children and Adolescents with Type I Diabetes”. They stated that pump use is increasing in the pediatric population, and that adult support is necessary until the child is able to manage the diabetes independently.

Minimal literature has been published related to benefits of clinical use of combined continuous subcutaneous insulin infusion and blood glucose monitoring devices. There are no clinical trials that report clinical outcomes as compared to the use of separate insulin pumps and blood glucose monitoring devices.

**Artificial pancreas device systems (APDS), including low glucose suspend (LGS) technology**

Artificial pancreas systems, as currently in development, consist of a series of devices including a CGM, insulin pump and blood glucose device, controlled by a computer algorithm to automatically monitor glucose levels and adjust insulin doses. In September 2013, the MiniMed® 530G System was approved by the FDA. It is classified by the FDA as an “artificial pancreas device system, threshold suspend.” This system is not approved to directly make therapy adjustments but can be programmed to automatically suspend insulin delivery when the sensor glucose value falls below a predefined threshold value.

A December 2013 TEC Assessment addressed artificial pancreas device systems. The Assessment included the following conclusion:

“The evidence is insufficient to permit conclusions on the impact of the artificial pancreas device system, with low glucose suspend feature, on health outcomes. A single trial has reported the results of its use in a home setting. Although the trial results are generally favorable, the study has limitations and further studies are needed.”

The study referred to in the TEC Assessment was the in-home arm of the Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial, published by Bergenstal et al in 2013. This was an industry-sponsored trial using the Medtronic Paradigm Veo pump. A total of 247 patients were randomly assigned to an experimental group, in which the low glucose suspend feature was used (n=121), or a control group that did not use the LGS feature (n=126). Key eligibility criteria were 16 to 70 years old, Type 1 diabetes, and an HbA1c level between 5.8%
and 10.0%. In addition, patients needed to have at least two nocturnal hypoglycemic events (≤65 mg/dL) lasting more than 20 minutes during a two-week run-in phase. The randomized intervention phase lasted three months. Patients in the low glucose suspend group were required to use the feature at least between 10:00 pm and 8:00 am. The threshold value was initially set at 70 mg/dL and could be adjusted to a value between 70 to 90 mg/dl. The primary efficacy outcome was the area under the curve (AUC) for nocturnal hypoglycemia events during the intervention phase and the primary safety outcome was change in HbA1c. Seven patients withdrew early from the study; all 247 were included in the ITT analysis.

Mean HbA1c changed from 7.26 to 7.24 in the low glucose suspend group and from 7.21 to 7.14 in the control group. Change was minimal and there was not a statistically significant difference between groups. The AUC for nocturnal events was 980 (SD=1200) in the low glucose suspend group and 1568 (SD=1995) in the control group. The difference between groups was statistically significant, p<0.001, favoring the intervention group. As cited in the TEC Assessment, among secondary outcomes, the LGS group also experienced fewer hypoglycemic episodes, one per week than the control group (3.3 ± 2.0 vs 4.7 ± 2.7; p<0.001), and the percentage of two sensor glucose values at or below 50 mg/dL was 57.1% lower in the LGS Group (0.9% vs 1.9%, respectively; p<0.01). For patients in the LGS group, the mean number of times the feature was triggered per patient was 2.08 per day, for a median of 1.42 minutes (mean, 25.5 minutes), and 0.77 times per night. Insulin infusion was suspended for the whole two hours in only 19.6% of episodes.

The TEC Assessment had the following comments on potential limitations of the Bergenstal et al study:

1. The authors reported that 43.1% of low glucose suspend events lasted less than five minutes, and 19.4% of the low suspend episodes were 120 minutes. Thus, most of the events were very short, for reasons that are not discussed. Also, the study did not track whether or not subjects who underwent low glucose suspend for two hours ate or drank food or glucose during that time or in the two hours afterward. Therefore, it is not clear whether changes in hemoglobin levels were due to the suspension of insulin infusion or to the subject’s response. The latter might produce overestimates of the impact of the low glucose suspend feature by attributing all improvements to it.

2. It was not reported whether subgroup results, grouped by age, HbA1c at randomization, and duration of diabetes, were prespecified.

3. There was one equipment malfunction (prolonged pump suspension in one patient with no adverse events), which might have had serious effects. Also, there were three adverse events in which the infusion-set malfunctioned resulting in severe hypoglycemia (>300 mg/dL). All were in the low glucose suspend group; none were in the control group.”

One published study has used a CGM device integrated with Paradigm® VEO™ insulin pump and evaluated a feature to suspend insulin delivery when glucose levels fall below a pre-specified threshold, known as a “low glucose suspend (LGS)” feature. The study, called the Automation to Simulate Pancreatic Insulin Response (ASPIRE) was published in 2012 by Garg and colleagues. It was a randomized, crossover trial that included 50 patients with Type 1 diabetes who had at
least three months’ experience with an insulin pump system. After a two-week run-in period to verify and optimize basal rates, patients underwent two in-clinic exercise sessions to induce hypoglycemia. The LGS feature on the insulin pump was turned on in one session and off in the other session, in random order. When on, the LGS feature was set to suspend insulin delivery for two hours when levels reached 70 mg/dL or less. The goal of the study was to evaluate whether the severity and duration of hypoglycemia was reduced when the LGS feature was used. The study protocol called for patients to start exercise with a glucose level of 100-140 mg/dL, and to use a treadmill or stationary bicycle until their plasma glucose level was 85 mg/dL or less. The study outcome, duration of hypoglycemia, was defined as the period of time glucose values were lower than 70 mg/dL and above 50 mg/dL, and hypoglycemia severity was defined as the lowest observed glucose value. A successful session was defined as an observation period of three to four hours and with glucose levels above 50 mg/dL. Patients who did not attain success could repeat the experiment up to three times.

The 50 patients attempted 134 exercise sessions; 98 of these were successful. Duration of hypoglycemia was significantly less during the LGS-on sessions (mean: 138.5 minutes, standard deviation (SD): 68 minutes) than the LGS-off sessions (mean: 170.7 minutes, SD: 91): p=0.006. Hypoglycemia severity was significantly lower in the LGS-on group. The mean lowest glucose level was 59.5 mg/dL (SD: 72) in the LGS-on group and 57.6 mg/dL (SD: 5.7) in the LGS-off group, p=0.015. The Garg study evaluated the LGS feature in a research setting and over a short time period. Another arm of the ASPIRE study evaluating the LGS feature in the outpatient setting over five months is underway (see section below on ongoing clinical trials).

Several small trials conducted outside the U.S. have evaluated a non-FDA-approved device, the MD-Logic artificial pancreas. This device is a closed-loop system that provides safety alerts before hypoglycemia and hypoglycemia events. The study included 56 Type 1 diabetic patients who were attending a diabetes camp, were 10 to 18 years old, and had used an insulin pump for at least three months. The study was done over two consecutive nights, during which each patient received an artificial pancreas one night and a continuous glucose monitor the other night, in random order. The primary endpoints were the number of hypoglycemic episodes (defined as glucose <63 mg/dL for at least 10 minutes), the total time that glucose levels were <60 mg/dL, and the mean overnight glucose levels.

There were fewer episodes of hypoglycemia recorded in the artificial pancreas group compared to the CGM group (7 versus 22, p=0.003). The median time that patients had a glucose level <60 was 0 minutes in both groups, but the time was significantly less in the artificial pancreas group (p=0.02). There was no significant difference in the mean glucose level in the artificial pancreas group compared to the CGM group (126.4 mg/dL versus 140.4 mg/dL).

Also in 2013, Nimri et al published a randomized crossover trial that included twelve patients at least ten years-old who had type 1 diabetes and had used an insulin pump for at least three months. The study was conducted in the inpatient setting over two consecutive nights. The artificial pancreas was used one night and an insulin pump was used the other night, in random order. The primary end point, number of hypoglycemic episodes defined as glucose <63 mg/dL for at least 10 minutes, did not differ significantly between groups, p=0.18. There were no events in the artificial pancreas group and three in the insulin pump group. A secondary outcome was
the percentage of time spent in the target range (i.e., a glucose level between 80 and 120 mg/dL). Time in the target range was significantly higher when the artificial pancreas device was used than when the insulin pump alone was used, p=0.002. The percentage of time in the target range was 94% (95% CI, 86 to 100) when the artificial pancreas device was used and 74% when it was not used (95% CI, 42 to 96).

There are two small RCTs that report that use of an artificial pancreas device reduces hypoglycemic episodes. The only artificial pancreas device to receive FDA-approval is the MiniMed 530G system. While this new pump is marketed as having artificial pancreas technology, it is not considered an artificial pancreas by Blue Cross and Blue Shield of Alabama since it does not mimic the glucose regulating function of a healthy pancreas.

**Key Words:**

**Approved by Governing Bodies:**
There are several FDA approved combined continuous subcutaneous insulin infusion and blood glucose monitoring (BGM) systems. Three of these models require the use of computer software and access to an interactive web based diabetes management program to fully utilize the coordinated CSII and BGM features. The OmniPod device is a fully integrated, all-in-one device that does not require separate computer software.

- iXL-II Diabetes Management System with Blood Glucose Measurement (Insulet Corporation, Boston, MA) Marketed as OmniPod™ Insulin Management System FDA-approved on January 3, 2005
- Animas Model IR 1250 Insulin Infusion Pump (Amimas Corporation, West Chester, PA) used in conjunction with Animas ezManager Plus. FDA-approved on December 10, 2005 and June 5, 2003
- The Paradigm® REAL-Time System (Medtronic, MiniMed) was approved by FDA in 2006. This system integrates a CGM with a Paradigm insulin pump. The second generation integrated system is called the MiniMed Paradigm Revel System.
- The OmniPod® Insulin Management System (Insulet Corporation), integrating the Freestyle Navigator CGM system with the Pod insulin pump, was approved in December 2011.
• The MiniMed 530G system with Enlite (Medtronic, MiniMed) was FDA approved September 2013. This system is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required.

On April 13, 2006, Medtronic, Inc. announced FDA approval of the MiniMed Paradigm Real-Time Insulin Pump and Continuous Glucose Monitoring System. This system consists of two parts, an insulin pump and a glucose sensor, that makes continuous glucose measurements. The insulin pump therapy may be used with or without continuous glucose monitoring. There is not a feedback mechanism between the two components, i.e., changes in monitored glucose levels do not result in pump driven changes in insulin infusion. Any changes in insulin infusion rates or boluses are patient driven. The insulin pumps are the MiniMed Paradigm 522 insulin pump and the MiniMed Paradigm 722 insulin pump.

On March 11, 2007, the FDA approved a pediatric model of a continuous glucose monitoring (CGM) system (REAL-Time; Medtronic, Inc) for use with a pediatric version of the company's insulin pump (MiniMed Paradigm) or as a stand-alone device (Guardian) in diabetic patients aged 7 to 17 years.

The system consists of a subcutaneously placed wire-like disposable sensor that continuously measures interstitial fluid glucose levels, transmitting the readings via radiofrequency transmitter to a pager-size monitor every five minutes for real-time display.

In November 2011, Tandem Diabetes Care (San Diego CA), Inc announced FDA approval for the t:slim™ Insulin Delivery System. According to Tandem’s press release, in addition to being the smallest insulin pump system available, the t:slim is the first pump with a color touch screen.

Currently under development is what is known as an artificial pancreas or artificial pancreas device system (APDS). The proposed artificial pancreas is a series of devices e.g., a CGM, blood glucose device and an insulin pump, plus a computer algorithm that communicates with all of the devices. The goal of the APDS is to automatically monitor glucose levels and adjust insulin levels. These systems are also called closed-loop systems or autonomous systems for glucose control. One technology associated with artificial pancreas development is a “low glucose suspend (LGS)” feature included with an insulin pump.

The MiniMed 530G System (Medtronic) integrating an insulin pump and glucose meter, and including a low glucose suspend feature, was cleared for marketing in September 2013. The threshold suspend tool temporarily suspends insulin delivery when the sensor glucose level is equal to or lower than a preset threshold within the 60 mg/dL to 90 mg/dL range. When the glucose value reaches this threshold, an alarm sounds. If patients respond to the alarm, they can choose to continue or cancel the insulin suspend feature. If patients fail to respond to the alarm, the pump automatically suspends action for two hours, and then insulin therapy resumes. The device is approved only for use in patients 16 years and older.
**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan.

**Coding:**
HCPCS code:
- **A9274** External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
- **E0784** External ambulatory infusion pump, insulin
- **S1034** Artificial Pancreas Device System (e.g., Low Glucose Suspend [LGS] Feature) Including Continuous Glucose Monitor, Blood Glucose Device, Insulin Pump And Computer Algorithm That Communicates With All Of The Devices (Effective 7/1/2014)

**References:**

**Policy History:**
TEC, 1996
Medical Policy Group, 1996
Medical Policy Group, April 1999
Medical Policy Group, May 2002
Medical Policy Administration Committee, June 2002
Available for comment July 9-August 22, 2002
Medical Policy Group, April 2003 (2)
Medical Policy Group, May 2003
Available for comment May 23-July7, 2003
Medical Policy Group, September 2004 (2)
Medical Policy Administration Committee, September 2004
Available for comment October 5-November 18, 2004
Medical Policy Group, May 2006 (2)
Medical Policy Administration Committee, June 2006
Available for comment July 7-August 21, 2006
Medical Policy Group, March 2007 (2)
Medical Policy Group, April 2007 (2)
Medical Policy Administration Committee, April 2007
Available for comment July 3-August 29, 2007
Medical Policy Group, May 2008 (2)
Medical Review Committee, June 2008
Medical Policy Administration Committee, July 2008
Medical Policy Group, December 2008 (2)
Medical Policy Group, April 2014 (5): Policy statement added for coverage of sensor-augmented insulin pump therapy with the low glucose threshold suspend feature; Sensor-augmented insulin pump therapy with the low glucose threshold suspend feature is considered investigational in children younger than 16 years; Replacement or upgrade of properly functioning equipment, even if warranty has expired, does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage; Artificial pancreases systems are considered investigational. Description, Key Points, Key Words, and References updated to support Policy Statements.
Medical Policy Administration Committee, April 2014
Available for comment April 4 through May 19, 2014

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.