Policy terminated because service is covered under the new NCHC Durable Medical Equipment and Supplies policy.

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1.0 Description of the Procedure, Product, or Service

Measurement of glucose in the interstitial fluid is a technique to automatically measure glucose values throughout the day. These data are able to show trends in glucose measurements, in contrast to isolated glucose readings of traditional blood glucose measurements. The measurement devices rely on the oxidation of glucose by glucose oxidase to produce hydrogen peroxide. Within the sensor, the hydrogen peroxide is further oxidized, which produces electrons and generates a measurable electric current that can be calibrated to the glucose concentration. Continuous glucose monitoring systems may be used intermittently, e.g., time periods of 72 hours, or continuously.

Blood glucose monitors for use by recipients in the home have been available for over 20 years and have revolutionized the management of diabetes. The use of fingersticks allows recipients to monitor their own blood glucose levels to determine the adequacy of their hyperglycemic control and to evaluate hypoglycemic episodes. Tight diabetic control has been proven over the past 10 years to decrease diabetic complications. Tight glucose control is defined as a hemoglobin A1c measurement of less than 7 %.

However, tight glucose control may require multiple measurements of blood glucose each day (i.e., before meals and at bedtime), a commitment that some recipients may be unwilling or unable to meet. The goal of tight glucose control has to be balanced with the associated risk of hypoglycemia. An additional limitation of periodic self-measurements of blood glucose (SMBG) is that glucose values are seen in isolation, and trends in glucose levels are undetected.

The FDA approved the Continuous Glucose Monitoring System (CGMS) (MiniMed) in 1999 and the upgraded version, the Guardian CGMS in 2005. Both use an implanted sensor in the subcutaneous tissue. This is attached to a small plastic disk the size of a dime that is taped to the skin to hold the sensor in place. A thin wire connects the sensor to a pager-sized glucose monitor, which records and stores glucose values in memory. An electrical signal is continuously relayed to the glucose sensor to record glucose levels every 5 minutes. The Guardian CGMS features an audible alarm that sounds when glucose levels become too high or too low per parameters set by the recipient and physician. The alarm is intended to prompt the recipient to perform a fingerstick blood glucose measurement, since a level is not provided with the sounding of the alarm.

According to FDA labeling, the above devices are not intended to be an alternative to traditional self-monitoring of blood glucose levels (SMBG), but rather serve as an adjunct to supply additional information on glucose trends that are not available from self-monitoring. They are intended for occasional rather than everyday use. The data are to be used to guide future management of the recipient based on response to trends noted. Patterns observed may be used to suggest when to take the fingerstick glucose measurements to better manage recipients.

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More recently, several devices have been approved by the FDA to provide real-time glucose monitoring such as the Guardian-RT (Real-Time) CGMS (Medtronic, MiniMed). The DexCom STS Continuous Glucose Monitoring System (Dexcom), which received pre-market approval in March 2006, is indicated for use as an adjunctive device to complement, not replace, information obtained from home glucose monitoring devices. The FreeStyle Navigator Continuous Glucose Monitoring System (Abbott) has sensors that can be worn either on the back of the upper arm or on the abdomen. All are to be used as an adjunct to therapy and any adjustments should be based on the glucose measurements obtained by the use of a home glucose monitor and not on the sensor readings. The Paradigm REAL-Time System consists of an insulin infusion pump, the glucose sensor, and a transmitter.

Continuous glucose monitoring devices display interstitial glucose readings frequently [every one to five (1-5) minutes depending on the device]. The goal of this continuous close monitoring is to provide better management to improve both hemoglobin A1C and to decrease acute glucose fluctuations. Ongoing clinical trials should help assess how this technology impacts health outcomes.

1.1 Medical Term Definitions

Interstitial: pertaining to or situated between parts or in the interspaces of a tissue.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

Note: Most children will be able to get all the services they need under the core (basic) plan of NC Health Choice. A child who qualifies as having special needs may be able to receive additional services not covered by the core plan.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Continuous or intermittent monitoring of glucose in the interstitial fluid may be covered by the NC Health Choice Program when it is determined to be medically necessary because the following medical criteria have been met:

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a. Intermittent monitoring (72 hours) of glucose levels in interstitial fluid may be considered medically necessary in the following situations when the criteria are met:

   1. Recipients with type I diabetes who, despite current use of best practices, have poorly controlled diabetes, including hemoglobin A1c not in acceptable target range for the recipient's clinical situation, unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, or recurrent diabetic ketoacidosis.

   2. Recipients with type I diabetes prior to insulin pump initiation to determine basal insulin levels.

b. Continuous monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique in diabetic monitoring may be considered medically necessary for recipients with type I diabetes who have recurrent unexplained, severe, symptomatic (generally blood glucose levels less than 50 mg/dl) hypoglycemia for whom hypoglycemia puts the recipient or others at risk.

3.3 Policy Guidelines

Best practices in diabetes control are those recipients with type I diabetes who are compliant with a regimen including four (4) or more fingersticks each day and use of an insulin pump. Prior use of an intermittent (72 hour) glucose monitor would be considered a part of best practices for those considering use of a continuous glucose monitor.

Intermittent monitoring is generally conducted in 72-hour periods. It may be repeated at a subsequent time depending on the recipient's level of diabetes control.

The 2008 Standards of Care from the American Diabetes Association (ADA) include a recommendation that "CGMS may be a supplemental tool to self monitoring blood glucose (SMBG) for selected patients with type I diabetes, especially those with hypoglycemia unawareness." This recommendation was based on expert consensus or clinical experience.

The available studies demonstrate that intermittent glucose monitoring provides a different type of data than results from fingerstick glucose levels. This additional information is most likely to benefit those patients with type I diabetes who do not have adequate control, including episodes of hypoglycemia, despite use of current best practices.

Data to support use (that show improved outcomes) of devices that allow wireless connectivity between a continuous monitoring device and insulin pump are still lacking.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

a. the recipient does not meet the eligibility requirements listed in **Section 2.0;**
b. the recipient does not meet the medical necessity criteria listed in **Section 3.0;**
c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
d. the procedure, product, or service is experimental or investigational.

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4.2 Specific Criteria

Continuous monitoring of glucose in the interstitial fluid is not covered in the following situations:

a. For uses other than those in **Subsection 3.2.**

b. Other uses of (including real-time monitoring) as a technique of diabetic monitoring, are considered investigational. The NC Health Choice Program does not cover investigational procedures, products and services.

c. As maternity care and any other pregnancy-related services are non-covered, glucose monitoring for gestational diabetics is not a covered benefit, even if medically necessary.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for glucose monitoring devices.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

a. meet NCHC qualifications for participation;

b. be currently enrolled with NCHC; **AND**

c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

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8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, **Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."**
February 29, 2012	Throughout	Policy Termination

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Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes
95250
95251
99091

HCPCS Codes
A9276
A9277
A9278
S1030
S1031

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Home

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.

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