MEDICAL POLICY STATEMENT
INDIANA MEDICAID

Original Issue Date	Next Annual Review	Effective Date
07/17/2014	02/01/2020	02/01/2019
Policy Name		**Policy Number**
Continuous Glucose Monitoring Systems (CGMS)		MM-0203
Policy Type		
MEDICAL	Administrative / Pharmacy	Reimbursement

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Contents of Policy

A. SUBJECT

Continuous Glucose Monitoring Systems (CGMS)

B. BACKGROUND

30.3 million or 9.4 percent of the population in the United States are estimated to have diabetes. This does not include the estimated 7.2 million adults aged 18 years or older that are considered undiagnosed. Over 90 percent of cases in the US, Canada and Europe consist of Type II DM; Type I DM accounting for an additional 5 to 10 percent and the remainder due to other causes such as: genetic defects or syndromes, diseases of the exocrine pancreas, endocrinopathies, infections and drug or chemically induced disease. Three-quarters of all cases of type 1 diabetes are diagnosed in individuals <18 years of age.

Patients with diabetes need to be closely monitored. When blood glucose levels are poorly controlled patients are at risk of complications including: heart disease, stroke, peripheral vascular disease, retinal damage, kidney disease, impotence and nerve damage. Patients should also be monitored for comorbidities that may not be present during the early stages of the disease, but develop as the disease progresses, these include: hearing impairment, fatty liver disease, sleep apnea, periodontal disease, depression, anxiety, cognitive impairment and fractures.

Reasonable glycated hemoglobin (A1C) goals for diabetic patients should be customized for the individual patient balancing established benefits with prevention of complications and risk of hypoglycemia. Goals vary depending on age, patients with comorbidities, limited lifetime expectancy and benefits of intensive therapy. Patients with type 1 diabetes and pregnancy may require stricter control.

For patients with type I diabetes, tight glucose control is critical because they require ongoing treatment with exogenous insulin. Self-monitoring of blood glucose (SMBG) is normally accomplished by measuring blood glucose concentration through intermittent capillary blood sampling with a reagent strip, cartridge or cuvette and a drop of capillary blood from a finger puncture. Different testing frequency may be indicated for type 1 and type 2 diabetes. Devices are available for continuous glucose monitoring from interstitial fluid, but SMBG testing must still be used in conjunction with CGM to confirm high and low continuous glucose monitoring values. CGM offers the most benefit in patients or patient's parents that are willing to use them consistently and in patients with hypoglycemic unawareness who are at risk or have a history of severe recurrent hypoglycemia. Recent studies show that continuous glucose monitoring is associated with improved glycemic control in adult patients with type 1 diabetes.

<u>Professional Societies</u>
The following professional society's recommendations are derived from the latest guidelines and scientific based literature available.

<u>American Diabetes Association (ADA)</u>
Continuous glucose monitoring (CGM) is useful for A1C lowering in select adults (aged ≥25 years) with type 1 diabetes who require intensive insulin regimens. CGM may be a useful supplement to SMBG among individuals with hypoglycemia unawareness and/or frequent hypoglycemic episodes. CGM should be considered in children and adolescents with type 1 diabetes, whether using injections or continuous subcutaneous insulin infusion, as an additional tool to help improve glycemic control. Benefits of continuous glucose monitoring correlate with adherence to ongoing use of the device.

National Institute of Health (NIH)
National Institute for Health and Care Excellence
In 2015, the National Institute for Health and Care Excellence released guidelines on diagnosis and management of type 1 diabetes in adults. The guidelines state:

- "Do not offer real-time continuous glucose monitoring routinely to adults with type 1 diabetes"
- "Consider real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimized use of insulin therapy and conventional blood glucose monitoring:
  - More than 1 episode a year of severe hypoglycemia with no obviously preventable precipitating cause.
  - Complete loss of awareness of hypoglycemia.
  - Frequent (more than 2 episodes a week) asymptomatic hypoglycemia that is causing problems with daily activities.
  - Extreme fear of hypoglycemia
  - Hyperglycemia (HbA_{1c} level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. Continue real-time continuous glucose monitoring only if HbA can be sustained at or below.

C. DEFINITIONS

N/A

D. POLICY

I. CareSource will approve the use of CGM and consider it's use medically necessary for the following:
   A. Short-term use (up to 72 hours) as an addition to standard care for blood glucose evaluation to optimize therapy in patients who experience problems controlling blood glucose levels and meet the following criteria (**no prior authorization is required**):
      1. Patient has Type II insulin dependent diabetes
      2. Be a pregnant women with either type 1, type 2 or gestational diabetes
      3. Patient has or is suspected of having hypoglycemia unawareness
      4. Patient has or is suspected of having recurrent hypoglycemia and hyperglycemia
      5. Patient experiences poorly controlled glucose levels although he/she is compliant with current treatment including, self-monitoring at least 4 times per day
      6. Patient requires 3 or more insulin injections per day or an insulin pump to control Glucose

Note: Although short term CGM does not require a prior authorization, CareSource may request documentation to support medical necessity. Appropriate and complete documentation must be presented at the time of review to validate medical necessity.

   B. Long-term use in patients who experience problems controlling blood glucose levels and meet **ALL** of the following criteria (**prior authorization is required**):
      1. Obtains a letter of medical necessity from a board certified endocrinologist.
      2. Has type 1 diabetes
      3. Patient has Type II insulin dependent diabetes
      4. Insulin injections are required 3 or more times per day or an insulin pump is used
      5. Patient experiences poorly controlled levels although he/she is compliant with current treatment including, self-monitoring at least 4 times per day
      6. The patient meets **two or more** of the following :

6.1 HgbA1C ≥7% or that does not meet documented target treatment despite diabetic education and adherence to self-monitoring of glucose levels.
6.2 History of recurrent severe hypoglycemia (<50 mg/dl) with hypoglycemic unawareness requiring assistance of another individual (administering glucagon, oral carbohydrates or other measures) despite appropriate adjustments to a physician ordered and monitored treatment plan based on previous short-term CGMS and/or self-monitoring
6.3 The patient is pregnant with poorly controlled type I or type II diabetes
a. Poorly controlled is defined as unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected post-prandial hyperglycemia, or recurrent diabetic ketoacidosis

7. Documentation that the patient has completed a comprehensive diabetes education program within the last 12 months; and has ongoing oversight by a certified diabetes educator. Remains compliant with the insulin therapy recommended by an endocrinologist as demonstrated by monitoring logs maintained for at least 3 months.

C. Continuation of CGMS use **after one year** or device replacement is considered medically necessary for the following:
1. If for replacement, the device is malfunctioning and out of warranty
2. There is objective documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual patients)
3. There is documented evidence of compliance to CMGS defined as at least 80% use rate of device (must be based on log data of the device)

D. CareSource will **NOT** approve the use of CGMS for the following:
1. Non FDA-approved devices
2. GlucoWatch®
3. Artificial pancreas device systems (APDS)
4. Replacement of an existing CGMS for additional features which are not medically necessary

E. CONDITIONS OF COVERAGE

HCPCS
CPT
AUTHORIZATION PERIOD

F. RELATED POLICIES/RULES

N/A

G. REVIEW/REVISION HISTORY

	DATE	ACTION
Date Issued	0717/2014	New Policy.
Date Revised	10/30/2014 07/15/2015	
	03/06/2018	Removed age criteria, added short-term use criteria
	02/01/2019	Policy coverage expanded to the IN MCD market and added Type II and gestional to short term coverage for approval.
Date Effective	02/01/2019	

H. REFERENCES

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The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 3/2018