Clinical Policy: Continuous Glucose Monitoring System (CGMS)
Reference Number: OH.PHAR.PPA.20
Effective Date: 08/19
Last Review Date: 10/20
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Continuous glucose monitoring (CGM) systems consist of several components which can vary depending on the brand and model of CGM. Such components may include a monitor, transmitter, handheld reader and a sensor worn on a designated area of the body.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan that a Continuous Glucose Monitoring System (CGMS) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Type 1 Diabetes Mellitus or Type II Diabetes Mellitus (must meet all):
      1. Diagnosis of Type 1 Diabetes Mellitus; Type II Diabetes Mellitus
      2. Member has completed a diabetes education program within the preceding 12 months.
      3. Member has been on a maintenance program for at least 6 months involving at least THREE injections of insulin per day and frequent self-adjustments of insulin dosage.
      4. Member (or someone assisting member) has performed glucose self-testing at least FOUR times per day on average during the preceding month.
      5. Member is at high risk for preventable complications of diabetes.
      6. Member (or someone assisting member) is capable of managing the device and that the desired improvement in metabolic control can be achieved.
      7. Member has one or more of the following symptoms or conditions (note all that apply):
         a. HbA1c greater than 7%
         b. History of recurring hypoglycemia
         c. Wide fluctuations in blood glucose before mealtime
         d. A marked early morning increase in fasting blood sugar (Dawn Phenomenon – glucose level exceeds 200mg/dl)
         e. History of severe glycemic excursions

   Approval duration: 12 months (1 CGM system - approve the corresponding transmitter or sensor for one year).

B. Other diagnoses/indications
   1. Refer to CP.PMN.53 if diagnosis is NOT Type 1 Diabetes Mellitus or Type II Diabetes Mellitus.
II. Continued Therapy
   A. Type 1 Diabetes Mellitus and Type II Diabetes Mellitus (must meet all):
      1. Currently receiving device via Buckeye benefit or member has previously met initial
         approval criteria;
      2. Member (or someone assisting member) is capable of managing the device and that
         the desired improvement in metabolic control can be achieved.
      3. There is documented evidence of improvement in control of diabetes (specific to
         baseline status of disease for individual members).

      Approval duration: 12 months (approve the corresponding transmitter or sensor for one
      year).

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via Buckeye benefit and documentation supports
         positive response to therapy.
      2. Refer to CP.PMN.53 if diagnosis is NOT Type 1 Diabetes Mellitus or Type II
         Diabetes Mellitus.

III. Product Availability
   CGM System Continuous Glucose Monitor Models (this is not an exhaustive list):
   - Freestyle Libre 10 day **Pharmacy benefit**
   - Freestyle Libre 14 day **Pharmacy benefit**
   - Dexcom G4 **DME – medical benefit**
   - Dexcom G5 **DME – medical benefit**
   - Dexcom G6 **DME – medical benefit**
   - Medtronic MiniMed Guardian Connect **DME – medical benefit**

IV. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created.</td>
<td>06/19</td>
<td>07/19</td>
</tr>
<tr>
<td>Annual Review – no changes deemed necessary</td>
<td>10/20</td>
<td>10/20</td>
</tr>
</tbody>
</table>

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care
professionals based on a review and consideration of currently available generally accepted
standards of medical practice; peer-reviewed medical literature; government agency/program
approval status; evidence-based guidelines and positions of leading national health professional
organizations; views of physicians practicing in relevant clinical areas affected by this clinical
policy; and other available clinical information. The Health Plan makes no representations and
accepts no liability with respect to the content of any external information used or relied upon in
developing this clinical policy. This clinical policy is consistent with standards of medical
practice current at the time that this clinical policy was approved. “Health Plan” means a health
plan that has adopted this clinical policy and that is operated or administered, in whole or in part,
by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.
The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

©2017 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.