Clinical Policy: Obstetrical Home Care Programs

Description
Medical necessity criteria for obstetrical home health programs offered by vendors such as Optum.

Policy/Criteria
I. It is the policy of health plans affiliated with Centene Corporation® that obstetrical home health services are medically necessary for members/enrollees meeting the following criteria:

A. Obstetrical Nurse Assessment ................................................................. 1
B. Metoclopramide or Ondansetron Infusion Therapy ....................................... 1
C. Hydration Therapy – 1 to 4 liters ................................................................ 1
D. Diabetes in Pregnancy Clinical Management Program (case rate) ................... 2
E. Obstetrical Diabetes Management - Daily Insulin Injections or Insulin Pump .......... 2
F. Hypertensive Disorders in Pregnancy Program for Gestational Hypertension .......... 2
G. Hypertensive Disorders in Pregnancy Program for Preeclampsia ...................... 2
H. Preterm Labor Management Program .......................................................... 3
I. Dietary Analysis .......................................................................................... 3
J. Hydroxyprogesterone Caproate (Makena) Administration Nursing Visit ............. 3

A. Obstetrical Nurse Assessment
An obstetrical nurse assessment is considered medically necessary when provided with any of the services listed in B to J.

B. Metoclopramide or Ondansetron Infusion Therapy
See CP.MP.34 Hyperemesis Gravidarum Treatment policy for medical necessity guidelines for metoclopramide or ondansetron therapy.

If meeting criteria per policy, home visits are considered medically necessary for the same period as the infusion therapy is approved, generally up to 7 days of therapy based on clinical information.

C. Hydration Therapy – 1 to 4 liters
Hydration therapy is medically necessary for members/enrollees who could benefit from close surveillance for the onset of dehydration. Examples of diagnoses include:
1. Hyperemesis gravidarum;
2. Malabsorption;
3. Diagnosis, such as flu or GI virus, which impairs the patient’s ability to maintain fluid and/or food in the system.
A course of up to 7 days at a time is considered medically necessary.

D. Diabetes in Pregnancy Clinical Management
   Diabetes in pregnancy clinical management is medically necessary for pregnant members/enrollees with a diagnosis of Type 2 non-insulin dependent diabetes in pregnancy, or non-insulin dependent gestational diabetes.

   One visit is considered medically necessary for diabetes in pregnancy clinical management.

E. Obstetrical Diabetes Management - Daily Insulin Injections or Insulin pump
   Obstetrical diabetes management is medically necessary for pregnant members/enrollees requiring insulin administration.

   An initial course of up to 7 days is considered medically necessary. Additional courses of up to 7-day spans are considered medically necessary until the member/enrollee is able to self-manage blood sugar and insulin administration.

F. Hypertensive Disorders in Pregnancy Management for Gestational Hypertension
   Home visits for management of gestational hypertension are medically necessary for members/enrollees with one of the following:
   1. Elevated or unstable blood pressure;
   2. Member/enrollee who could benefit from education and surveillance for the potential onset of hypertension. Categories of such members/enrollees could include:
      a. Previous episode of hypertension during previous pregnancy;
      b. Chronic hypertension;
      c. Multiple gestation;
      d. Diabetes.

   An initial visit is considered medically necessary.

G. Hypertensive Disorders in Pregnancy Management for Preeclampsia
   Home visits for management of preeclampsia are medically necessary for pregnant members/enrollees who are diagnosed with preeclampsia without severe features, meeting all of the following:
   1. Blood pressure $\geq 140$ mm Hg systolic or $\geq 90$ mm Hg diastolic on two occasions at least 4 hours apart after 20 weeks gestation in a woman with a previously normal blood pressure;
   2. Proteinuria
      a. $\geq 300$ mg per 24-hour urine collection (or this amount extrapolated from a timed collection), or;
      b. Protein/creatinine ratio $\geq 0.3$ mg protein/mg creatinine, or;
      c. Dipstick reading of 2+ (30 mg/dL) (used only if other quantitative methods not available).

   An initial home visit, with additional phone follow up as needed, are considered medically necessary.
H.  **Preterm Labor Management Program**

The preterm labor management program is **medically necessary** for pregnant members/enrollees diagnosed with preterm labor. Early signs and symptoms of preterm labor can include menstrual-like cramping; mild, irregular contractions; low back ache; pressure sensation in the vagina; or vaginal discharge of mucus, which may be clear, pink, or slightly bloody.

An initial home visit, with additional phone follow up as needed, are considered medically necessary for assessment and education. Ongoing visits are considered not medically necessary.

I.  **Dietary Analysis**

A dietary analysis is **medically necessary** for members/enrollees with a diagnosis of obesity or malnutrition.

J.  **Hydroxyprogesterone Caproate (Makena) Administration Nursing Visit**

The hydroxyprogesterone caproate nurse administration and care management program is **medically necessary** for members/enrollees who meet the criteria for hydroxyprogesterone caproate per CP.PHAR.14 and who require weekly home nursing visit due to any of the following circumstances:

1. High risk of non-compliance based on an identified concern or previous noncompliance;
2. Member/enrollee is on restricted activity and weekly travel to the doctor’s office for injections is potentially harmful;
3. Member/enrollee is physically unable to make weekly trips for injections or does not have adequate access to reliable transportation (either personal or through a transportation benefit).

Hydroxyprogesterone caproate nurse administration in the home is medically necessary for as many weeks as hydroxyprogesterone caproate has been approved.

II. It is the policy of health plans affiliated with Centene Corporation that the following services provided by a home health vendor are considered **not medically necessary**:

A. Betamethasone therapy via multiple repeat courses or intermittent injections;
B. Multiple gestation management (refer to individual program for identified risk factor);
C. Continuous heparin infusion therapy;
D. Patient-administered nonstress test or fetal heart rate monitoring;
E. Gestational diabetes clinical management program for oral medications;
F. Preterm prelabor rupture of membranes (PPROM) management.

**Background**

Optum Women’s Health OB Homecare includes risk assessment and education for identifying pregnant women at risk for complications, case management and homecare services for high-risk
pregnancies. Obstetrical homecare services include providers, diagnostics, devices and timely and actionable information that help women make smarter healthcare decisions.

**Medically Necessary Services:**

**Diabetes in Pregnancy Clinical Management**

Although universal screening criteria for gestational diabetes mellitus (GDM) has not been established, the 100g OGTT has most often been used to diagnose gestational diabetes according to the Carpenter and Coustan or National Diabetes Data Group criteria. In 2008, the landmark Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study established a relationship between pregnancy outcomes and values on a 75g OGTT (HAPO Study Cooperative Research Group, 2008). The World Health Organization, ADA, and the Endocrine Society of the USA endorse the 75g OGTT diagnostic criteria proposed by the IADPSG, which was based on data from the HAPO study.

**Gestational Hypertension Management**

The American College of Obstetricians and Gynecologists (ACOG) recommends that patients with gestational hypertension or preeclampsia without severe features monitor blood pressure twice weekly, self-monitor fetal movement daily, and have platelet counts and liver enzymes assessed weekly, although they do not specifically mention outpatient versus inpatient care (ACOG Hypertension Taskforce, 2013). Few studies have evaluated whether outpatient care is a viable option for preeclamptic patients, although two small studies found positive results. In addition, a systematic review of three studies found no difference in clinical outcomes for mothers or babies receiving care in antenatal day units versus inpatient care. The National Institute for Health and Clinical Excellence recommends outpatient management of preeclampsia and hypertension in pregnancy for mild and moderate hypertension, up to 159/109 mm Hg.

**Preterm Labor Management**

There is little research on the management of women after an episode of preterm labor. One underpowered study found no benefit to hospital care versus discharge home in the proportion of deliveries ≥36 weeks. It is thus recommended that the decision to manage a woman with preterm labor as an inpatient or outpatient should be made on a case by case basis, in conjunction with factors such as cervical dilation, vaginal bleeding, fetal status and travel time to the appropriate level of care.

**Hydroxyprogesterone Caproate (Makena) Administration Nursing Visit**

The American College of Obstetricians and Gynecologists (ACOG) released a statement on 17p Hydroxyprogesterone Caproate (October 25, 2019) noting the following:

“Consideration for offering 17p to women at risk of recurrent preterm birth should take into account the body of evidence for progesterone supplementation, the values and preferences of the pregnant woman, the resources available, and the setting in which the intervention will be implemented. Additional information from planned meta-analysis and secondary analyses will need to be evaluated to assess the impact this intervention has on women at risk of recurrent preterm birth in the United States.

ACOG recognizes that the PROLONG clinical trial evaluating 17p in patients with a history of a prior spontaneous singleton preterm delivery, demonstrated no statistical difference in the co-
primary outcome of preterm birth less than 35 0/7 weeks of gestation and neonatal composite index. Similarly, the rate of preterm birth less than 37 and less than 32 weeks were not different. No other differences in perinatal or maternal outcomes were detected. ACOG also understands that the authors suggest that the study was underpowered to assess treatment efficacy and that due to previous treatment guidelines, there may have been an unintentional selection bias.”

More recently, ACOG released a statement on the FDA proposal to withdraw 17p noting: “The U.S. Food and Drug Administration’s Center for Drug Evaluation and Research (CDER) this week proposed that Makena (hydroxyprogesterone caproate injection [17-OHPC]) and generic equivalents be withdrawn from the market. As of now, Makena and its approved generic equivalents will remain on the market until the manufacturers decide to voluntarily remove the drugs or the FDA commissioner mandates removal.

“At this time, ACOG recommendations remain unchanged, as outlined in the Oct 2019 Practice advisory and ACOG’s standing clinical guidance, “Prediction and Prevention of Preterm Birth”. Current guidelines in the United States recommend the use of progesterone supplementation in women with prior spontaneous preterm birth. Consideration for offering 17-OHPC to women at risk of recurrent preterm birth should continue to take into account the body of evidence for progesterone supplementation, the values and preferences of the pregnant woman and the resources available.”

Not Medically Necessary Services:
Betamethasone therapy via intermittent injections
ACOG recommends a single course of corticosteroids for women with preterm prelabor rupture of membranes (PROM) between 24 and 34 weeks, as it reduces the risk of neonatal mortality, respiratory distress syndrome, intraventricular hemorrhage and necrotizing enterocolitis. However, ACOG does not recommend multiple repeated injections as weekly administration is associated with lower birthweight and head circumference. A Cochrane meta-review of repeat doses of antenatal corticosteroids states that there was lower incidence of respiratory distress and serious infant health problems in the first few weeks after birth, but no evidence of harm or benefit in early childhood. Furthermore, repeat doses of corticosteroids were associated with lower birthweight and head circumference, as ACOG noted, although these reductions were small. Crowther and colleagues conclude by recommending further research on the long term benefits and risks of repeat doses of antenatal corticosteroids for the woman and infant.

Preterm Prelabor Rupture of Membranes Management
A Cochrane systematic review of two small studies concludes that the majority of women should be managed in the hospital after PPROM. Although the two studies suggest that outcomes are similar between women and babies managed at home or inpatient, the evidence is not sufficient to make a recommendation regarding the safety of home care for PPROM. ACOG sites the same studies and also notes that the evidence is insufficient, adding that the increased risk of sudden infection and umbilical cord compression with PPROM make hospital surveillance the appropriate management.

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted
2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<table>
<thead>
<tr>
<th>ICD 10 CM Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>A09</td>
<td>Infectious gastroenteritis and colitis, unspecified</td>
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<tr>
<td>D69.59</td>
<td>Other secondary thrombocytopenia</td>
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<tr>
<td>E86.0</td>
<td>Dehydration</td>
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<tr>
<td>K90.49</td>
<td>Malabsorption due to intolerance, not elsewhere classified</td>
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<tr>
<td>O10.011-O10.019</td>
<td>Pre-existing essential hypertension complicating pregnancy</td>
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<tr>
<td>O10.411-O10.0149</td>
<td>Pre-existing secondary hypertension complicating pregnancy</td>
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<tr>
<td>O10.911-O10.919</td>
<td>Unspecified pre-existing hypertension complicating pregnancy</td>
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<tr>
<td>O11.1-O11.9</td>
<td>Pre-existing hypertension with pre-eclampsia</td>
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<tr>
<td>O14.00-O14.03</td>
<td>Mild to moderate pre-eclampsia</td>
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<tr>
<td>O16.1-O16.9</td>
<td>Unspecified maternal hypertension</td>
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<tr>
<td>O21.0-O21.9</td>
<td>Excessive vomiting in pregnancy</td>
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<tr>
<td>O24.410-O24.419</td>
<td>Gestational diabetes mellitus in pregnancy</td>
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<tr>
<td>O25.10-O25.13</td>
<td>Malnutrition in pregnancy</td>
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<td>O60.00-O60.03</td>
<td>Preterm labor without delivery</td>
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<tr>
<td>O99.210-O99.213</td>
<td>Obesity complicating pregnancy</td>
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<tr>
<th>HCPCS Codes</th>
<th>Optum specific program codes</th>
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<tr>
<td>S9123</td>
<td>Nursing care, in the home; by registered nurse, per hour (use for general nursing care only, not to be used when CPT codes 99500-99602 can be used)</td>
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<tr>
<td>S9140</td>
<td>Diabetic management program, follow up-visit to non-MD provider</td>
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<tr>
<td>S9208</td>
<td>Home management of preterm labor, includes administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (do not use this code with any home infusion per diem code)</td>
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<tr>
<td>S9211</td>
<td>Home management of gestational hypertension, includes administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (do not use this code with any home infusion per diem code)</td>
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<tr>
<td>S9213</td>
<td>Home management of pre-eclampsia, includes administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (do not use this code with any home infusion per diem code)</td>
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<tr>
<td>S9214</td>
<td>Home management of gestational diabetes, includes administrative services, professional pharmacy services, care coordination, and all necessary supplies</td>
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<tr>
<td>HCPCS Codes</td>
<td>Optum specific program codes</td>
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<tr>
<td>S9374</td>
<td>Home infusion therapy, hydration therapy; one liter per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
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<tr>
<td>S9375</td>
<td>Home infusion therapy, hydration therapy; more than one liter but no more than two liters per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
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<tr>
<td>S9376</td>
<td>Home infusion therapy, hydration therapy; more than two liters but no more than three liters per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
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<tr>
<td>S9377</td>
<td>Home infusion therapy, hydration therapy; more than three liters per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
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<td>S9470</td>
<td>Nutritional counseling, dietician visit</td>
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<td>S9560</td>
<td>Home injectable therapy; hormonal therapy (e.g., leuprolide, goserelin), including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
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**Reviews, Revisions, and Approvals**

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Revision Date</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>Policy Created</td>
<td>01/14</td>
<td>01/14</td>
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<tr>
<td>Reviewed by Specialist</td>
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<tr>
<td>Updated approval timeframes</td>
<td>01/15</td>
<td>01/15</td>
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<tr>
<td>Removed diagnostic criteria in preeclampsia program regarding “in the absence of proteinuria” as these members/enrollees should be hospitalized</td>
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<td>Updated template</td>
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<tr>
<td>Updated Gestational Diabetes Diagnostic Criteria</td>
<td>01/16</td>
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<tr>
<td>Removed NST/FHT indications</td>
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<td>In I.G, changed visits to days</td>
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<tr>
<td>Added Betamethasone therapy “via multiple repeated doses” to not medically necessary criteria</td>
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<td>Added additional background information</td>
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<tr>
<td>Added criteria for hydroxyprogesterone caproate (Makena) administration in the home. Added H.3. as alternative criteria for preeclampsia, per 2013 ACOG Hypertension in Pregnancy Task Force Report.</td>
<td>09/16</td>
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<tr>
<td>References reviewed and updated, no criteria changes</td>
<td>01/17</td>
<td>01/17</td>
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<td>Revision Date</td>
<td>Approval Date</td>
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<tr>
<td>Added units to 2017 American Diabetes Association (ADA) Guidelines for clarity. All references to</td>
<td>01/18</td>
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<tr>
<td>premature rupture of membranes is changed to prelabor rupture of membranes, per ACOG “revitalize obstetric data” definitions. Added units to H.2.b and H.2.c for clarification. Replaced Makena with hydroxyprogesterone caproate in all instances.</td>
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<tr>
<td>Specified that only preeclampsia without severe features is appropriate for home management, and removed diagnostic criteria which included severe features. Changed “Alere” to “Optum”</td>
<td>01/19</td>
<td>01/19</td>
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<tr>
<td>Updated description to include OptionCare. Noted in D. Diabetes Clinical Management program that the case rate is with Optum. Pre-eclampsia program: I.H changed dipstick reading from 1+ to 2+. Updated background with ACOG’s statement on administration of Hydroxyprogesterone Caproate. Specialist review.</td>
<td>12/19</td>
<td>12/19</td>
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<tr>
<td>Removed reference to OptionCare in description. In C. Hydration therapy, changed initial course and additional course of up to 14 visits to up to 7 visits at a time. In D. Diabetes in pregnancy, removed the word “program” form the title and criteria; deleted all criteria except the requirement for diagnosis of type 2 DM, or gestational diabetes, and specified that both are non-insulin dependent; deleted reference to case rate, and added that 1 visit is medically necessary. Combined criteria in E. for insulin injections and F. for insulin pump into E; removed criteria except for being pregnant and requiring insulin administration; changed number of medically necessary visits from 14 to up to 7 days for the initial and additional courses. For hypertensive disorders in pregnancy, replaced “program” in the title with “management;” changed number of medically necessary visits from up to 14 days with an additional 7 if needed to one visit. For preeclampsia in pregnancy, replaced “program” with “visits for management;” changed the number of initial and additional medically necessary visits from up to 7 to an additional home visit with phone follow up as needed. For preterm labor management, changed number of medically necessary visits from 3 in one week to 1 home visit in a week, with additional phone follow up as needed. Replaced all instances of “member” with “member/enrollee.” Reviewed by specialist. References reviewed and updated.</td>
<td>11/20</td>
<td>12/20</td>
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<tr>
<td>Annual review. Updated table of contents. Corrected A. to state that it is medically necessary with services in A-J, not A-K. References reviewed and updated. Specialist review. Changed &quot;Last Review Date&quot; in the header to &quot;Date of Last Review&quot; and &quot;Date&quot; in revision log to &quot;Revision Date&quot;. Added info in Background regarding ACOG’s Statement on FDA Proposal to Withdraw 17p Hydroxyprogesterone Caproate. Note added to HCPCS S9123 regarding CPT usage.</td>
<td>12/21</td>
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References


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/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees 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/enrollees 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/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

**Note: For Medicaid members/enrollees**, 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.

**Note: For Medicare members/enrollees**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at [http://www.cms.gov](http://www.cms.gov) for additional information.

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