Clinical Policy: Obstetrical Home Care Programs

Reference Number: CP.MP.91 Revision Log
Last Review Date: 12/19 Coding Implications

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

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

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

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

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

If member meets criteria per policy, home visits are considered **medically necessary** for the same period as the infusion therapy is approved, generally 7 to 14 days of therapy based on clinical information.

C. *Hydration Therapy – 1 to 4 liters*
Hydration therapy is **medically necessary** for members 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.

An initial course of up to 14 days is considered medically necessary. Additional courses of 7 to 14 day spans are considered medically necessary until the member is stable and no longer needs therapy.

D. *Diabetes in Pregnancy Clinical Management Program (case rate with Optum)*
The diabetes in pregnancy clinical management program is **medically necessary** for pregnant members with *one* of the following:

1. Type 2 diabetes in pregnancy with need for diet and exercise control with or without oral glycemic agents and non-insulin dependent; or
2. Gestational diabetes mellitus (GDM) with need for diet and exercise control with or without oral glycemic agents. GDM is diagnosed in pregnant women who have *one* of the following:
   a. Plasma glucose (PG) values that meet or exceed the values listed below in the one-step 75 g Oral Glucose Tolerance Test (OGTT); or
   b. At least two abnormal results during the two-step, 100 gram OGTT with the minimum lab values listed below:

2017 American Diabetes Association (ADA) Guidelines	
One-Step Strategy- per International Association of Diabetes and Pregnancy Study Groups (IADPSG)	**Two-Step Strategy- per Carpenter and Coustan or National Diabetes Data Group**

Step 1: 75-g OGTT with PG measurement fasting and at 1 h and 2 h, at 24-28 weeks in women not previously diagnosed with overt diabetes
 	
• Perform OGTT in the morning after overnight fast (≥8 h)
• GDM diagnosis made if PG values meet or exceed:
  ○ Fasting: 92 mg/dL (5.1 mmol/L)
  ○ 1 h: 180 mg/dL (10.0 mmol/L)
  ○ 2 h: 153 mg/dL (8.5 mmol/L)
	• Step 1: 50-g Glucose Loading Test (nonfasting) with PG measurement at 1 h (Step 1), at 24-28 weeks in women not previously diagnosed with overt diabetes
	  ○ If PG at 1 h after load is ≥140 mg/dL (7.8 mmol/L), proceed to 100-g OGTT (Step 2)
	• Step 2: 100-g OGTT while patient is fasting. GDM diagnosis made when two or more PG levels meet or exceed:
	  ○ Fasting: 95 mg/dL or 105 mg/dL (5.3/5.8 mmol/L)
	  ○ 1 hr: 180 mg/dL or 190 mg/dL (10.0/10.6 mmol/L)
	  ○ 2 hr: 155 mg/dL or 165 mg/dL (8.6/9.2 mmol/L)
	  ○ 3 hr: 140 mg/dL or 145 mg/dL (7.8/8.0 mmol/L)

E. *Obstetrical Diabetes Management - Daily Insulin Injections*
Obstetrical diabetes management with daily insulin injections is **medically necessary** for pregnant members with both:

1. Gestational or pre-gestational diabetes and unable to reach target goals through diet and activity;
2. Daily insulin injections.

An initial course of 14 days is considered medically necessary. Additional courses of 7 to 14 day spans are considered medically necessary until the member is able to self-manage blood sugar and insulin injections.

F. *Obstetrical Diabetes Management – Insulin Pump*
Obstetrical diabetes management with an insulin pump is **medically necessary** for pregnant members who have had a new insulin pump approved based on the appropriate medical necessity criteria.

An initial course of 14 days is considered medically necessary. An additional course of 14 days is considered medically necessary until the member is able to self-manage blood sugar and insulin pumps.

G. *Hypertensive Disorders in Pregnancy Program for Gestational Hypertension*
The gestational hypertension program is **medically necessary** for members with one of the following:

1. Elevated or unstable blood pressure; or
2. Member who could benefit from education and surveillance for the potential onset of hypertension. Categories of such members could include:
   a. Previous episode of hypertension during previous pregnancy;
   b. Chronic hypertension;
   c. Multiple gestation;
   d. Diabetes.

An initial course of 14 days in one month is considered medically necessary (in general, *daily* visits are not necessary). If member remains pregnant, an additional 7 days is considered medically necessary.

H. *Hypertensive Disorders in Pregnancy Program for Preeclampsia*
The preeclampsia program is **medically necessary** for pregnant members who are diagnosed with preeclampsia *without severe features*, meeting all of the following:

1. Blood pressure ≥ 140 mm Hg systolic or ≥ 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. ≥ 300 mg per 24-hour urine collection (or this amount extrapolated from a timed collection); or
   b. Protein/creatinine ratio ≥ 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 course of 7 days is considered medically necessary. If member remains pregnant, an additional 7 days is considered medically necessary.

I. *Preterm Labor Management Program*
The preterm labor management program is **medically necessary** for pregnant members 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 course of 3 visits in 1 week is considered medically necessary for assessment and education. Ongoing visits are considered not medically necessary.

J. *Dietary Analysis*
A dietary analysis is **medically necessary** for members with a diagnosis of obesity or malnutrition.

K. *Hydroxyprogesterone Caproate (Makena) Administration Nursing Visit*
The hydroxyprogesterone caproate nurse administration and care management program is **medically necessary** for members 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 is on restricted activity and weekly travel to the doctor's office for injections is potentially harmful;
3. Member 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 programs include 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 Program
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 (Gupta et al., 2015). 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 (Gupta et al., 2015).

Gestational Hypertension Program
The American College of Obstetricians and Gynecologists (ACOG) Task Force on Hypertension in Pregnancy 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 (Norwitz & Repke, 2015). 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 (Dowswell, Middleton & Weeks, 2009). 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 (AHRQ, 2011).

Preterm Labor Management Program
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 (Caritis & Simhan, 2015). 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 (Caritis & Simhan, 2015).

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."

<u>Not Medically Necessary Services:</u>
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 (ACOG No. 188, p. 5). However, ACOG does not recommend multiple repeated injections as weekly administration is associated with lower birthweight and head circumference (ACOG No. 188, p. 5). 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 et al. 2015). 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 (Crowther et al. 2015).

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 (Dowswell, & Mousa, 2014, p. 11). 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 (Abou El Senoun, Dowswell, & Mousa, 2014, p. 11). 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 (ACOG Practice Bulletin 188, p. 6).

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 2019, 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.

ICD-10-CM Codes	Description
A09	Infectious gastroenteritis and colitis, unspecified
D69.59	Other secondary thrombocytopenia
E86.0	Dehydration
K90.49	Malabsorption due to intolerance, not elsewhere classified
O10.011-O10.019	Pre-existing essential hypertension complicating pregnancy
O10.411-O01.419	Pre-existing secondary hypertension complicating pregnancy
O10.911-O10.919	Unspecified pre-existing hypertension complicating pregnancy
O11.1-O11.9	Pre-existing hypertension with pre-eclampsia
O14.00-O14.03	Mild to moderate pre-eclampsia
O16.1-O16.9	Unspecified maternal hypertension
O21.0-O21.9	Excessive vomiting in pregnancy

O24.410-O24.419	Gestational diabetes mellitus in pregnancy
O25.10-O25.13	Malnutrition in pregnancy
O60.00-O60.03	Preterm labor without delivery
O99.210-O99.213	Obesity complicating pregnancy

HCPCS Codes	Optum specific program codes
S9123	Nursing care, in the home; by registered nurse, per hour
S9140	Diabetic management program, follow up-visit to non-MD provider
S9208	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)
S9211	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)
S9213	Home management of preeclampsia, 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)
S9214	Home management of gestational diabetes, 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)
S9374	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
S9375	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
S9376	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
S9377	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
S9470	Nutritional counseling, dietician visit
S9560	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

Reviews, Revisions, and Approvals	Date	Approval Date
Policy Created Reviewed by Specialist	01/14	01/14
Updated approval timeframes Removed diagnostic criteria in preeclampsia program regarding "in the absence of proteinuria" as these members should be hospitalized	01/15	01/15
Updated template Updated Gestational Diabetes Diagnostic Criteria Removed NST/FHT indications In I.G, changed visits to days Added Betamethasone therapy "via multiple repeated doses" to not medically necessary criteria Added additional background information	01/16	01/16
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.	09/16	09/16
References reviewed and updated, no criteria changes	01/17	01/17
Added units to 2017 American Diabetes Association (ADA) Guidelines for clarity. All references to 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	01/18	01/18
Specified that only preeclampsia without severe features is appropriate for home management, and removed diagnostic criteria which included severe features. Changed "Alere" to "Optum"	01/19	01/19
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.	12/19	12/19

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26. ACOG Statement on 17p Hydroxyprogesterone Caproate October 25, 2019

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.

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.

Note: For Medicare members, 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 for additional information.