MEDICAID HEALTH PLANS OF AMERICA

MHPA

CENTER FOR BEST PRACTICES

Preterm Birth Prevention: Evidence-Based Use of Progesterone Treatment

Issue Brief and Action Steps for Medicaid Health Plans, November 2014

Preterm birth is the leading cause of infant morbidity and mortality, affecting 11.4% of births in the U.S. Preterm birth accounts for 50% of all pregnancy costs, largely due to neonatal admissions. Medicaid pays for approximately 48% of all births in the U.S., and the Medicaid population has twice as many adverse outcomes as non-Medicaid mothers.

The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal and Fetal Medicine (SMFM) issued updated clinical recommendations for prevention of preterm birth in 2012. Based on a review of evidence, ACOG and SMFM now recommend use of vaginal progesterone for pregnant women with no history of spontaneous preterm birth diagnosed with short cervical length mid-pregnancy. ACOG and SMFM continue to recommend that women with a history of spontaneous preterm birth be treated with intramuscular 17 alpha-hydroxyprogesterone caproate (17-OHPC).

Recognizing the importance of preterm birth to Medicaid, in August 2014 Medicaid Health Plans of America (MHPA), a national organization representing Medicaid health plans, convened a Leadership Roundtable to discuss strategies to accelerate adoption of the professional society recommendations. Participants included senior clinical leaders of Medicaid health plans, national experts in obstetrics, and representatives from the March of Dimes, ACOG, and SMFM [See Appendix 3 for participant list].

This Issue Brief offers information and action steps for Medicaid health plans wanting to accelerate evidence-based use of progesterone to prevent preterm birth. Challenges and opportunities are addressed, along with specific strategies for working collaboratively with clinicians and other stakeholders. Key references are also included. The online version of this Issue Brief links to additional resources, including presentations from the Leadership Roundtable and materials to support quality improvement initiatives.

The MHPA Center for Best Practices encourages Medicaid health plans to evaluate the evidence on prevention of preterm birth, assess their clinical infrastructure, and determine how best to support improvements in prenatal care. We encourage Medicaid health plans to move forward expeditiously to drive adoption of evidence-based use of progesterone to prevent preterm birth.

In August 2014, the MHPA Center for Best Practices hosted a Leadership Roundtable to discuss evidence-based use of progesterone to prevent preterm birth. This Issue Brief incorporates ideas from this expert group but does not represent views of any specific individual or organization. Views in this document are those of the MHPA Center for Best Practices. Resource materials linked to the Issue Brief are from multiple sources as noted on the documents, and reflect perspectives of the authors.

The Leadership Roundtable was supported by an unrestricted grant from Cervilenz Inc. to the MHPA Center for Best Practices.

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IMPORTANCE OF PRETERM BIRTH TO MEDICAID

Because of the percentage of pregnancies covered and higher rates of preterm birth, the impact of preterm birth on Medicaid is disproportionate (Smith, 2014).

- One in eight Medicaid-covered babies is born premature. States spend 1.3 times as much on that one premature baby as they do on the remaining seven babies combined.
- Premature or low birthweight babies cost Medicaid 9 times as much as other babies ($13,729 vs. $1,498).
- Each premature or low birthweight baby costs states an additional $12,000, totaling $2.9 billion per year.

There are significant racial disparities in preterm birth and infant mortality. Among African Americans, 16.5% of babies are born preterm, compared to 11.6% for Hispanics and 10.3% for Caucasians (March of Dimes, 2014). African American babies die at more than twice the rate of Caucasian babies (Mathews, 2013). Equitable access to care is a critical strategy for reducing disparities and improving population health for Medicaid health plans.

For most Medicaid health plans, complex neonatal admissions are among the most expensive hospitalizations. Moreover, the morbidities associated with preterm birth significantly impact population health and on-going expenses. Through improvements in evidence-based prenatal care, Medicaid health plans have the opportunity to reduce costs, reduce disparities and importantly, improve long term health outcomes for Medicaid members.

March of Dimes Presentation at the Roundtable by Dr. Ed McCabe

EVIDENCE ON USE OF PROGESTERONE TO PREVENT PRETERM BIRTH

Preterm birth is a complex, multifactorial syndrome, which does not lend itself to a single prevention strategy. Health plans and researchers have developed numerous innovative programs to mitigate social, economic and clinical risk factors. One potential intervention that has been studied extensively is progesterone. Its safety in pregnancy is well established.

Key findings on the efficacy of progesterone to prevent preterm birth in select high risk populations are summarized in Appendix 1, Table 1. The opportunity to improve outcomes includes:

- For singleton pregnancies with a history of spontaneous preterm birth in a prior singleton pregnancy, appropriate use of 17-OHPC[1] reduces the risk of recurrent preterm birth up to 42% (Meis, 2003).
- Appropriate use of vaginal progesterone reduces the risk of preterm birth up to 50% for women with singleton pregnancies and premature cervical shortening in the second trimester who do not have a history of spontaneous preterm birth (Hassan, 2011).

[1] 17-alpha-hydroxyprogesterone caproate is frequently referred to as 17P. This Issue Brief uses the more clinically specific term, 17-OHPC (Romero, 2013).

- Combined, obstetric history and mid-pregnancy cervical length shortening can identify more than 50% of patients who are at increased risk to deliver before 34 weeks if untreated (Sotiriadis, 2012).
- Pooled data suggest that progesterone for these two high risk populations can reduce composite adverse outcome by 43%, neonatal death by 52%, and neonatal intensive care unit (NICU) admissions by 61% (Sotiriadis, 2012).

Evidence Review Presentation at Roundtable by Dr. Tom Garite

NEW PROFESSIONAL SOCIETY PRACTICE GUIDELINES

ACOG and SMFM published expanded recommendations in 2012 for preterm birth risk screening and evidence based use of progesterone treatment, as outlined below. [Appendix 1, Table 2 provides more detail.]

Progesterone strongly recommended, given strong evidence of efficacy

- 17-OHPC for singleton pregnancies with a prior spontaneous preterm singleton birth, regardless of cervical length – *this treatment has been recommended since 2008*
- Vaginal progesterone for singleton pregnancies diagnosed mid-pregnancy with a short cervical length ≤ 20 mm (2 cm) by transvaginal ultrasound (TVU) and no history of spontaneous preterm singleton birth– *this is a new treatment recommendation*

Progesterone not recommended, given no evidence of efficacy

- Singletons without a prior spontaneous preterm singleton birth with an unknown or normal cervical length
- Multiple gestations, regardless of cervical length
- Symptomatic pregnancies (preterm labor or premature preterm rupture of membranes), regardless of cervical length

The 2012 recommendations potentially add complexity to the prenatal care regimen. While obtaining an obstetric history is routine practice, the addition of cervical length screening is new. It has not previously been included in routine prenatal care because there was not an evidence-based intervention. New protocols are now needed to ensure timely risk screening and appropriate progesterone treatment.

ACOG and SMFM conclude that cervical length screening is a reasonable clinical practice to identify patients eligible for evidence-based progesterone treatment. The professional societies cite a lack of TVU availability in some settings and medical-legal concerns as the rationale for not "mandating" universal cervical length screening. (It should be noted that other routine obstetrics procedures, such as the fetal anatomy scan, are also recommended but not mandatory.)

SMFM, ACOG, and ACNM have issued a call to action in an August 2014 joint letter to Secretary Burwell, U.S. Department of Health and Human Services, which clearly communicates their strong support for universal cervical length screening as part of a much needed, expanded preterm birth prevention strategy.

SMFM Clinical Guideline on Progesterone and Preterm Birth Prevention: Translating Clinical Trials Data into Clinical Practice
ACOG Practice Bulletin No. 130: Prediction and Prevention of Preterm Birth (Used with permission)
ACNM Position Statement Prevention of Preterm Labor and Preterm Birth
Joint Letter to Secretary Burwell on Preterm Birth Prevention

EXPANDING THE PROGESTERONE STRATEGY

Changing clinical practice is always challenging, regardless of compelling evidence and professional society guidelines. Medicaid health plans have a number of opportunities to reduce or eliminate barriers that can slow adoption of evidence-based use of progesterone.

Improve early identification of pregnant members: Early identification of pregnant members is vital to allow expanded risk screening, case management, enhanced services and connections to community services. Many pregnant women in the Medicaid population first seek prenatal care beyond the gestational age indicated for risk screening and progesterone treatment. Another factor in delayed identification is that providers may not submit a timely Notification of Pregnancy (NOP). Successful health plan efforts to improve NOP utilization have focused on building trust and stronger relationships with providers, reporting back to providers on utilization data tied to outcomes, shifting notification tasks at the office level from physicians to nurses, medical assistants or administrative staff, and increasing engagement of patients.

States and Medicaid health plans are also making progress developing other tactics and tools to find pregnant members and facilitate risk stratification, such as: patient filing of NOPs, community outreach initiatives, expanding vital records statistics to include gestational age, birth registries and member databases with high risk flags, involving case managers in new ways, improving or creating new intake forms or prenatal checklists, easier and more timely transmission of data to and from providers, mobile apps and online communities used by patients, and retail partnerships for shared data.

Ensure adequate obstetric history: A comprehensive risk profile at the first prenatal visit should include a detailed review of obstetric history with particular attention to whether any prior preterm birth was spontaneous or medically indicated and whether that pregnancy was a singleton or multiple gestation. 17-OHPC is only recommended for singletons with a history of spontaneous preterm singleton birth to prevent recurrent preterm birth. This is an important point for education of providers and patients, with the goal of increasing appropriate use of this medication but also to keep it from being used inappropriately.

Re-educating providers on the importance of identifying this risk factor and following through with 17-OHPC treatment also offers an opportunity to also educate them on NOP utilization and the range of prenatal services offered by Medicaid health plans, including high risk case management.

Improve use of 17-OHPC: Medicaid health plans have covered 17-OHPC for many years.[2] However, under-utilization is still broadly acknowledged. Efforts to improve preterm birth prevention should include a review of potential or known barriers to 17-OHPC. These may include lack of awareness

[2] For the latest guidance on 17-OHPC, visit the Food and Drug Administration website

among providers, patient cost and ease of acquiring the medication. Policy or process updates necessary to minimize any barriers should be considered. Many educational efforts by Medicaid health plans to improve appropriate 17-OHPC treatment have been successful. Tactics that can be helpful are sharing provider level data on NOP and 17-OHPC utilization to motivate improvement, along with other quality improvement strategies discussed in this Issue Brief.

Ensure access to reliable cervical length screening: As noted, cervical length screening is a new addition to clinical practice, and is a necessary precursor to identifying the pregnant patients who can benefit from vaginal progesterone treatment. Medicaid health plans should review the efficacy of screening modalities, determine which to cover, and help providers select and operationalize the method that best meets the needs of their practices and patients.

SMFM and ACOG define TVU as the modality to diagnose short cervix. TVU can be used for screening and diagnosis in one step in some settings with high ultrasound capacity. For example, Maternal-Fetal Medicine practices, ultrasound centers, or OB/GYN practices with full-time sonographers could likely add a TVU cervical length screen routinely at the anatomy scan appointment. However, in settings with limited TVU capacity, adding routine screening may pose scheduling, cost, or other challenges. In some practice or clinics, TVU may not be available at all.

There are also concerns about the availability of trained examiners needed to ensure quality exams with reliable results. ACOG and SMFM recommend a certification program for TVU cervical length from the Perinatal Quality Foundation. Health plans should consider informing providers of the program and, possibly offering incentives to encourage certification.

Medicaid health plans may need to consider policies allowing other cervical length modalities for practices unable to implement TVU screening. A disposable cervicometer device offers an option for screening without ultrasound, reserving TVU as the diagnostic exam (Ross, 2007; Moller, 2011; Pocaro, 2012; Baxter, 2013). SMFM and ACOG note that transabdominal ultrasound (TAU) is not reliable or reproducible for universal cervical length screening. Table 3 in Appendix 1 provides additional information on cervical length screening modalities.

Ensure availability of vaginal progesterone: Vaginal progesterone is available as both a branded and generic Food and Drug Administration (FDA) approved drug, and can also be compounded by a licensed compound pharmacy. While FDA has not approved vaginal progesterone for second trimester use to prevent preterm birth, this does not preclude prescriptions of vaginal progesterone for prematurely short cervix (Combs, 2012). Many drugs in pregnancy are routinely and broadly used without a specific label indication, such as tocolytics for preterm labor and magnesium sulfate for pre-eclampsia.

Many Medicaid health plans may already cover vaginal progesterone for gynecologic use (but not infertility). State approval for coverage of second trimester use during pregnancy may be necessary. Along with coverage, timely treatment is vital. Policies and processes should be in place to simplify prescribing requirements for providers and enable quick and easy prescription filling by patients. Information for providers and patients as well as on-going support from case managers can help improve compliance with the treatment regimen.

Align clinical and coverage policies: Medicaid health plans can use the new professional society recommendations as an opportunity to review and update clinical and coverage policies. An algorithm defining the eligible patient population, gestational age for screening, screening modalities, and

appropriate treatment will provide important guidance to clinicians. Coverage and coding can be put in place to track appropriate utilization, aligned with the clinical algorithm, and to guard against overuse.

Appropriate utilization of risk screening is a concern, particularly because overuse adds cost and potentially unnecessary treatment for patients. There are already concerns about the overuse of both TAU and TVU ultrasound in obstetrics. Medicaid health plans adopting cervical length screening programs would want to ensure that screening follows published guidelines (such as only one TVU to screen for short cervix in an otherwise uncomplicated pregnancy) and is tightly coupled with appropriate treatment delivery.

Careful consideration should be given to requiring pre-authorization for cervical length screening, regardless of modality, or for either form of progesterone when indicated. Pre-authorization requirements can be a significant barrier for providers and create delays in a clinical situation with a limited time window to initiate treatment. Some plans have adopted CPT modifier codes specifically for use when the cervical length procedure is performed for screening and for which pre-authorization is not required. Importantly, that approach facilitates tracking of screening uptake and, ultimately, measurement of the clinical value and cost effectiveness.

Proactively sharing information about updated or new coverage policies and pharmacy processes will help minimize provider and patient barriers.

Improve member adherence to treatment: Whether a member is prescribed vaginal or injectable progesterone, adherence to the dosage schedule can be a problem. Medicaid health plans can actively involve case managers to help increase attendance at prenatal visits. Education on the importance of consistent, timely treatment can also help.

For 17-OHPC injections, patient compliance may be negatively impacted if the patient has to pick up the medication from the pharmacy as compared to having it shipped to physician offices. Home health services for 17-OHPC injections may also be an option worth considering. Today's technology allows innovative ways to engage patients and provide them with a broad range of prenatal care information. One example is Text4Baby, which is promoted by many Medicaid health plans. As many communication channels as possible should be used to identify and engage pregnant members more fully.

Evaluate cost benefit of new approaches: An extensive review of cost data by the Institute of Medicine (Berhman, 2007) illustrates the potential to reduce short- and long-term costs by preventing preterm birth. Because cervical length screening is a new clinical strategy, Medicaid health plans will likely want to evaluate the cost effectiveness of this strategy coupled with vaginal progesterone treatment. Making the business case is important before embarking on a change in practice and coverage. A cost model would likely compare expected incremental cost of routine cervical length screening and vaginal progesterone to expected cost savings given the impact of improved outcomes on reduced NICU and ongoing medical costs.

Published analyses appear to show favorable cost savings when cervical length screening and vaginal progesterone treatment is modeled. The evidence on vaginal progesterone shows that treating only 11 patients with a short cervix, per ACOG and SMFM recommendations, can prevent one preterm birth before 33 weeks (Hassan, 2011). One NICU admission can be prevented by treating only 14 women (Romero, 2012). An economic analysis concluded that $19.6 million can be saved by screening 100,000 eligible pregnancies and treating short cervix patients with vaginal progesterone, taking into account

pregnancy, neonatal, and longer term societal costs (Werner, 2011). Medicaid health plans can model incremental expense for their own population, as well as potential savings. Some data points to consider include the following:

- Cost of covered screening modalities and drugs
- Projected utilization of screening over time
- Expected numbers of high risk patients identified and treated
- Potential reductions in preterm birth rates
- Estimated reductions in maternal and newborn medical services, especially NICU admissions
- Estimated reductions in long-term medical and other costs on the basis of fewer morbidities

Plan specific data is most helpful for calculating expected costs and improvements, but there are also other data points in the national vital statistics, professional society guidelines, and other clinical literature to use in such models. Over time, tracking and measuring success – both outcomes and costs – will be critical for determining whether this strategy is beneficial for an individual plan and the health of its population.

QUALITY IMPROVEMENT STRATEGIES FOR HEALTH PLANS

Medicaid health plans can directly impact changes in clinical practice through quality improvement initiatives, and can apply this strategy to preterm birth prevention. Initiatives should include efforts to expand risk screening and increase use of both 17-OHPC and vaginal progesterone as recommended by the professional societies. The focus of efforts to improve practices that prevent preterm birth may be:

- Integrating improved risk screening and progesterone therapy into existing comprehensive medical management and prenatal care programs before, during, and after pregnancy
- Improving consistency of physician screening and prescribing practices
- Addressing formulary gaps impacting the cost of and access to both formulations of progesterone
- More effectively identifying and engaging all pregnant members

Action steps to consider when planning and executing quality improvement in evidence-based use of progesterone to prevent preterm birth may include:

Secure executive buy-in

- Present the clinical case to medical executives; emphasize the importance of aligning medical and coverage policies with current professional society guidelines on evidence-based practice
- Present the business case to financial executives; leverage published economic analyses and baseline data to project cost savings

Identify a project manager and engage a cross-functional team

- Assign responsibility for planning and coordinating execution of the initiative
- Create a culture of shared responsibility for outcomes; include medical executives, perinatal program directors, case managers, provider relations, and member relations
- Partner more actively with providers and all office staff to improve prenatal care for all patients

Develop a clinical algorithm

- Review ACOG and SMFM algorithms and other clinical literature to determine medical policies
- Define and illustrate a comprehensive progesterone strategy to improve uptake and consistency of patient management
- Include risk screening to enable utilization of both 17-OHPC and vaginal progesterone, with detailed recommendations on indications for each treatment
- Engage practitioners to participate in the review and development process

Review and update policies, processes, and provider information

- A comprehensive review will inform updates necessary to support adoption of the clinical algorithm
- Ensure coverage for risk screening, and easy coding for claims and tracking
- Address any formulary gaps in progesterone coverage; consult with CMS if necessary to secure State coverage or approval
- Simplify prescribing processes and eliminate barriers to timely treatment
- Consider incentives or pay for performance measures
- Summarize key information in fact sheets for medical and administrative staff

Establish metrics to track uptake and evaluate impact on outcomes and cost

- Collect and share robust data to motivate change and celebrate success
- Consider piloting the initiative in high volume practices with providers most likely to be early adopters; assess and re-tool for phased roll-out to all providers
- Integrate into the quality system to drive on-going provider compliance and accountability
- Monitor metrics and feedback from providers to inform continuous improvement

Educate clinicians and build momentum for change

- Use multiple communication channels to reach providers, including calls and visits to offices, eNewsletters, and website postings; repeat communication will be necessary
- Enlist Chief Medical Officers, Medical Directors, or local Maternal-Fetal Medicine (MFM) specialists to lead educational forums
- Identify and deploy early adopters for peer-to-peer training
- Support offices with in-services and repeat visits; protocols need to become systematic for medical and administrative staff while being seamless for patients (e.g. scheduling, patient flow, flagging charts, setting up exam rooms, and charting results)
- Engage the cross-functional team in this provider outreach
- Collaborate with local partners, such as the March of Dimes or Perinatal Quality Collaboratives, to extend the reach and connect this initiative to others also focused on improving birth outcomes (e.g., reducing unnecessary c-sections, reducing early elective deliveries, smoking cessation and substance abuse programs, Centering Pregnancy)

Empower patients

- Integrate education on preterm birth risk screening and progesterone treatment into existing prenatal outreach and education programs
- Leverage technology to communicate in visible, meaningful ways, such as smart phones, texting, apps, and social media
- Connect patients with other Medicaid services, such as WIC, help paying utility bills, community programs, and other organizations that offer support and education

- Collaborate with community outreach organizations and other local partners to connect more pregnant women with prenatal care earlier

Maximize case management utilization and effectiveness

- Review referral procedures; update if necessary, and educate providers
- Involve case managers in new ways to help identify pregnant members and stratify risk to increase appropriate referrals
- Create stronger, more frequent connections between case managers, patients, and providers
- Integrate information from case management with other relevant data points (e.g., NOP, risk screening procedures, pharmacy, specialty health care services, behavioral care)
- Extend the reach of case managers to post-partum and inter-conception care for education on steps toward healthier future pregnancies; NICU case management, post discharge, is also critical

Promote greater awareness of evidence-based recommendations:

- Reach out to State Medicaid agencies to discuss professional society recommendations and availability of progesterone for appropriate utilization
- Collaborate with States or the Health Resources and Services Administration (HRSA) to develop pilot programs for increasing evidence-based use of progesterone to reduce preterm birth
- Communicate with the Centers for Medicare and Medicaid (CMS) as appropriate about effective programs and track State and Federal guidance regarding indications for progesterone
- Collaborate with State and local initiatives to reduce infant mortality and/or to improve prenatal care. Preventing infant mortality has mobilized many constituencies and can be a lever for adoption of professional society recommendations on preterm birth prevention
- Collaborate with national partners on education such as CDC, the March of Dimes, or the National Healthy Babies Healthy Mothers Coalition

The resources below provide more detailed information on critical success factors and tactics to consider for Medicaid health plans that choose to initiate quality improvement programs.

Resources:

Sample Clinical Algorithm (Buckeye Community Health Plan)
Discussion Guide: Clinical Algorithm
Discussion Guide: Policy Review
Discussion Guide: Metrics
Coding Information for Cervical Length Procedures

CAPITALIZING ON THE OPPORTUNITY

Infant mortality is a public health crisis in the U.S. and can be a mobilizing force to focus on delivering evidence-based prenatal care. Reducing preterm birth offers a valuable opportunity to also improve population health and reduce cost. New recommendations from the obstetrics professional societies outline a clear pathway to preterm birth prevention. These recommendations serve as a call to action that must be addressed by many stakeholders: elected officials, State Medicaid agencies, Federal agencies, the March of Dimes, other advocacy organizations, and parent groups. Medicaid health plans are well positioned to play a leading role in education and support for providers and patients. Moreover, Medicaid health plans can use their levers of payment policies and quality measures to

accelerate adoption. Medicaid health plans have responsibilities to States and their members to deliver high quality, cost-effective, evidence-based care. Reducing preterm birth is an opportunity to improve cost, quality and outcomes.

APPENDIX 1: Tables

Table 1: The Efficacy of Progesterone: Key Data

Progestogen	**17 alpha-hydroxyprogesterone caproate (17-OHPC): synthetic; intramuscular injection**	**Vaginal Progesterone: natural, micronized; gel, suppository, or dissolving capsule**
High Risk Group	Singleton pregnancies with a prior spontaneous preterm singleton birth; asymptomatic	Singleton pregnancies with a mid-pregnancy short cervical length; no history of spontaneous preterm singleton birth; asymptomatic
Background	• Recurrent preterm accounts for 15% of all preterm birth • Relative risk is 2x (Iams and Berghella, 2010)	• Cervical shortening mid-pregnancy is a powerful predictor of preterm birth • Relative risk is 10x (Iams, 1996)
Reduced Risk	17-OHPC: 250 mg IM weekly • 34% reduction in PTB risk < 37 weeks • 33% reduction in PTB risk < 35 weeks • 42% reduction in PTB risk < 32 weeks (Meis, 2003)	Vaginal: 90 mg gel, daily • 38% reduction in PTB risk < 35 weeks • 45% reduction in PTB risk < 33 weeks • 50% reduction in PTB risk < 28 weeks (Hassan, 2011)
Improved Outcomes	Significantly lower rates of: • Birthweight less than 2,500 g • Necrotizing enterocolitis • Need for supplemental oxygen • IVH of any grade (Meis, 2003)	• 43% reduction in any neonatal morbidity or mortality event • 53% reduction birthweight less than 1,500 g • 61% reduction in respiratory distress syndrome (Hassan, 2011)

Table 2: SMFM and ACOG Recommendations for Preterm Birth Prevention

Preterm birth risk screening	**1st prenatal visit:** **Comprehensive review of obstetric history** – with particular attention to any prior preterm birth, noting whether spontaneous or medically indicated and whether singleton or multiple pregnancy *This risk assessment is routine.*	**18-24 weeks gestation:** **Universal cervical length screening** – one cervical length measurement to identify premature shortening *This is a new recommendation.*
Patients eligible for screening	All pregnancies	Singleton pregnancies without a prior spontaneous preterm singleton birth
Patients eligible for intervention	Singleton pregnancy with one or more prior spontaneous preterm singleton birth (20 to 37 weeks)	Cervical length ≤ 20 mm diagnosed by transvaginal ultrasound (TVU)
Progesterone treatment	**17-OHPC:** 250 mg IM weekly, from 16-20 weeks to 36 weeks *Recommended since 2008.*	**Vaginal progesterone:** 90 mg gel or 200 mg suppository daily, from diagnosis to 36 weeks *This is a new recommendation.*
Cervical length surveillance	Serial TVU measurements from 16 to 24 weeks, every two weeks If cervical length shortening < 25 mm is diagnosed by TVU, cerclage may be considered; and, 17-OHPC should be continued *While TVU surveillance is common, this recommendation for cerclage is new.*	Not recommended
Additional information in the guidelines	**Regarding 17-OHPC:** • The best efficacy is for treatment initiation before 21 weeks; however, starting up to 28 weeks has also been reported beneficial • Treatment should not be stopped early, as this is associated with an increased incidence of preterm birth • The evidence for efficacy of 17-OHPC is stronger for this high risk group than for other progesterone preparations; • There is no evidence of benefit for adding vaginal progesterone to or switching from 17-OHPC to vaginal progesterone if there is cervical shortening	**Regarding cervical length screening:** • Universal screening for mid-pregnancy short cervix is supported as a reasonable clinical practice to enable intervention, for which there is Level 1 evidence • Meets World Health Organization for an effective screening test • Economic analyses show cost savings • TVU is a safe, accurate, reproducible test; however quality control and monitoring are essential; the Perinatal Quality Foundation offers online CME and certification for TVU cervical length, the CLEAR program • A lack of TVU availability in some settings precludes mandating universal screening

Table 3: Cervical Length Screening Modalities

TVU	• Designed to image the reproductive organs • Certification program available for TVU cervical length from the Perinatal Quality Foundation • Technique recommends imaging and recording at least three measurements with and without fundal pressure (or maternal valsalva) and using the "shortest best" measurement • SMFM and ACOG define TVU as the diagnostic for prescription of short cervix • TVU can be used for screening and diagnosis in one step • Settings with high ultrasound capacity can likely add TVU at the anatomy scan, such as MFM practices, ultrasound centers, ob/gyn offices/clinics with full-time sonographers • Standard protocol for the facility or a standing order from select referring physicians • Schedule appointments in advance to accommodate both exams
TAU	• Designed to image the baby • Full bladder required often distorts or elongates the cervix • SMFM and ACOG note that TAU is not reliable or reproducible for cervical length measurements • ACOG notes that if TAU suggests the cervix may be short or have some other abnormality, a subsequent TVU is recommended • One study reported that TAU measurements fails to identify 57% of patients with a short TVU cervical length at a cut off of 30 mm (Hernandez-Andrade, 2012) • Another study reported that achieving high sensitivity with TAU screening would require a cut off of 35 mm and approximately 60% of patients to have a TVU exam (Friedman, 2013) • Patient logistics may be difficult if a large percentage of patients need an unscheduled TVU at the anatomy scan appointment
Cervicometer	• Disposable device that directly measures vaginal cervical length while visualizing the cervix during a speculum exam • Procedure during a regular prenatal by a physician, midwife or nurse • May be an option where TVU screening is not feasible or easily accessible • Research shows efficacy of the cervicometer to rule out a short cervix by TVU with high sensitivity (84-100%) and high negative predictive value (98-100%), with either a 25 mm or 30 mm cut off (Ross, 1997; Moller, 2011; Pocaro, 2013; Baxter, 2013) • Patients with a short cervicometer measurement are referred for a diagnostic TVU cervical length, which can be scheduled in advance as an add-on at the anatomy scan appointment.

APPENDIX 2: References

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APPENDIX 3: Roundtable Participants

Specialty Organizations

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March of Dimes

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March of Dimes

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Dan O'Keeffe, MD
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Tom Garite, MD
Editor Emeritus, Am Journal of Obstetrics & Gynecology
E.J. Quilligan Professor Emeritus of Obstetrics and Gynecology, University of California Irvine
Director of Research and Education for Obstetrics, Pediatrix Medical Group

Medicaid Health Plans

Judith Chamberlain, MD
National Senior Medical Director for Care Management
Aetna Medicaid

Mark R. Fracasso, MD, MBA
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The AmeriHealth Caritas Family of Companies

Stephen Friedhoff, MD
Chief Medical Officer
Wellpoint Government Business Division

Andrea Gelzer, MD, MS, FACP
Senior Vice President /Corporate Chief Medical Officer
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Medical Director
WellCare Health Plans, Inc.

Brad Lucas, MD, MBA, FACOG
Chief Medical Officer
Buckeye Community Health Plan (Centene)

Mary V. Mason, M.D. *(by phone)*
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Centene Corporation, Medical Affairs

Rhonda Medows, MD
Chief Medical Officer and Executive Vice President
Optum / UnitedHealthcare

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