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Preventing Preterm Birth: Access to Progesterone in Medicaid Managed Care

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The mission of the Institute for Medicaid Innovation is to improve the lives of Medicaid enrollees through the development, implementation, and diffusion of innovative and evidence-based models of care that promote quality, value, equity and the engagement of patients, families, and communities.

Medicaid finances approximately half of all deliveries in the United States.[1] Given that Medicaid managed care provides coverage for most of the Medicaid population, both traditional (i.e., pregnant women, children, aged, blind, and disabled) and newly eligible (i.e., childless adults under 138 percent of the federal poverty level (FPL)), it is likely that pregnant women will increasingly be enrolled in Medicaid managed care organizations (MCOs). In order to improve birth outcomes, address growing costs associated with preterm birth, and reduce complicated hospital stays for newborns,[2] it is important for Medicaid MCOs to utilize cost effective, evidence-based interventions like progesterone to prevent preterm birth.

In 2016, the Institute for Medicaid Innovation conducted a survey on preterm birth and the use of progesterone among Medicaid MCOs. In all, 18 Medicaid MCOs providing coverage in 31 of the 39 Medicaid managed states responded to the survey. The findings suggest that there are barriers to providing all formulations of progesterone to eligible women, including cost, clinician lack of knowledge, and confusion regarding coverage and billing. This may be explained by the gaps in scientific knowledge comparing the effectiveness of branded and compounded forms of progesterone, and in data regarding the optimal gestational age limit for initiating therapy. Scientific evidence is needed to develop evidence-based practice guidelines and inform effective policy-based interventions.

Burden of Preterm Birth

Preterm birth (i.e., delivery prior to 37 weeks of gestation) is a leading cause of infant mortality and disability in the United States.[3] In 2014, 9.6 percent of U.S. births were preterm.[4] Although rates of preterm birth have declined over the past decade, racial, ethnic, and socioeconomic disparities persist.[5] In 2014, preterm birth rates were highest among African American women (13.2 percent) as compared to their White (8.9 percent) and Hispanic (9.0 percent) counterparts.[4] Evidence suggests that lower household income and Medicaid eligibility are associated with preterm delivery.[6]

Infants born preterm are at higher risk for short-term health complications (e.g., respiratory distress, immature brain development) and chronic conditions (e.g., asthma, cognitive development disorders, etc.).[2] Preterm neonates are also more

likely than full-term infants to have longer stays in the Neonatal Intensive Care Unit (NICU) and increased hospital readmissions.[2] As a result, preterm neonates account for half of all annual infant hospitalization costs, and one quarter of subsequent pediatric hospitalization costs.[7] Recent estimates indicate that preterm births account for over $20 billion in United States health care costs.[5]

Preterm Birth and Medicaid

Prior to the Affordable Care Act's (ACA) Medicaid expansion in 2014, the 2010 vital statistics from 33 states and the District of Columbia reported that 44.9 percent of deliveries were paid for by Medicaid.[3] Currently, 32 states and the District of Columbia (DC) have expanded their Medicaid eligibility to include adults with incomes below 133 percent FPL. As more states expand their Medicaid programs, it is likely that the proportion of Medicaid covered deliveries will increase and will continue to provide coverage for a disproportionate number of births complicated by prematurity. In 2009, Medicaid paid for over half of all hospital stays for preterm infants.[8] Furthermore, trends demonstrate that the proportion of complicated newborn stays billed to Medicaid have increased, while the proportion billed to private payers has decreased.[9]

Given the impact of poor birth outcomes, the Centers for Medicare and Medicaid Services (CMS) is continuously developing and supporting new national initiatives to improve care along the pregnancy continuum (i.e., new delivery models, preconception, and interconception care programs*).[10] Additionally, the Health Resources and Services Administration through the Maternal Child Health Bureau launched an ambitious multi-year, national initiative to address infant mortality including strategies that address preterm birth.[11, 12, 13]

Progesterone to Prevent Preterm Birth

The strongest risk factor for preterm birth is history of a previous spontaneous singleton preterm birth.[14] Progesterone has emerged as an evidence-based intervention to prevent recurrent preterm birth in subsequent singleton pregnancies (see Table 1). Findings from a comprehensive systematic review support weekly injections of 17 alpha-hydroxyprogesterone caproate (17P) from 16-36 weeks of gestation for this indication. The review included studies that demonstrated a decrease in the risk of recurrent preterm birth by approximately one-third among women eligible for progesterone.[15, 16] Additionally, the review included prospective studies that demonstrated the effectiveness of 17P, the medication was initiated between 16 and 21 weeks of gestation. While most practice guidelines recommend starting progesterone at 16 weeks, the optimal window for initiation has not been well-studied.[17] Weekly injections may be successfully administered in-office or in the woman's home.[18]

*Interconception care is defined as the medical care provided to a woman for the period of time in between pregnancies.

Table 1. Evidence-based Use of Intramuscular 17P to Prevent Preterm Birth

	Intramuscular 17P
Patient eligible for screening	All patients (at prenatal intake, ideally before 16 weeks of gestation)
Screening modality	Obstetric history taken by clinician
Indication for intervention	History of previous spontaneous preterm singleton preterm birth (less than 37 weeks of gestation)
Regimen	Intramuscular: 250 milligrams weekly
Duration of administration	16 to 36 weeks of gestation
Other considerations	Evidence supports administration both in patient's homes, and in clinical settings

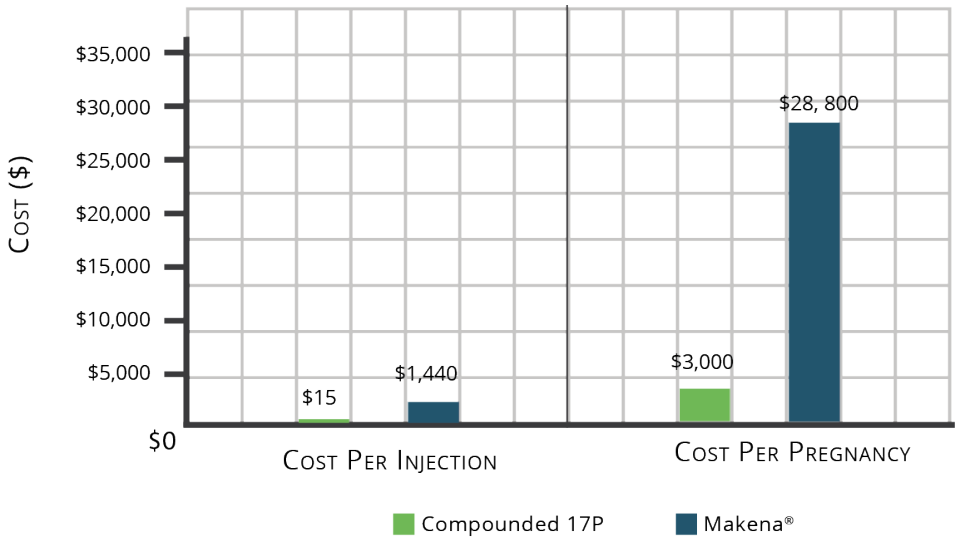
Source: The American College of Obstetricians and Gynecologists. (2012). Practice Bulletin Number 130: Prediction and Prevention of Preterm Birth. Obstetrics and Gynecology. 120(4), 964-73. Retrieved from http://meta.wkhealth.com/pt/pt-core/template-journal/lwwgateway/media/landingpage.htm?issn=0029-7844&volume=120&issue=4&spage=964.

The findings in support of 17P have resulted in strong recommendations from clinical experts, professional organizations, and government agencies to adopt policies that increase access to this medication among women at risk for preterm birth.[16, 19, 20] However, even with strong policy recommendations, if barriers exist for women attempting to enroll in Medicaid, having timely access to progesterone to prevent preterm birth could be challenging.

17P: Branded versus Compounded Formulations

17P currently exists in two forms: a compounded version of the drug, and the branded Makena®. Both drugs contain the same active ingredient with Makena® having two additional preservatives. Currently, the two medications have not been compared directly in any known effectiveness studies. After early studies demonstrated that progesterone was effective in preventing preterm birth, Makena® (developed by KV Pharmaceuticals) was approved by the Food and Drug Administration (FDA). The approval was expedited and Makena® was afforded "orphan drug" status, protecting its patent for seven years.[21] Despite the apparent similarities between the two

Figure 1: Cost of Compounded 17P versus Makena® (2012)



Source: Patel, Y., & Rumore, M. M. (2012). Hydroxyprogesterone Caproate Injection (Makena (R)) One Year Later: To Compound or Not to Compound – That Is the Question. Pharmacy and Therapeutics, 37(7), 405-411.

Due to the cost difference and absence of trials comparing the effectiveness of the two medications, the FDA initially allowed for continued production of compounded 17P after Makena's® introduction into the market. However, subsequent concerns regarding the potency and potential contamination of compounded 17P, led the FDA to restrict the production of the medication exclusively to compounding pharmacies and only for patients who were allergic to or could not tolerate Makena®.[22] The decision regarding compounded 17P by the FDA was based on concerns that were brought to the attention of by KV Pharmaceuticals, the maker of Makena®.[23]

Furthermore, FDA guidance released in June 2012 expressly notes that, pharmacies "compounding large volumes of copies, or what are essentially copies, of any approved commercially available drug... may be subject to enforcement action" under Section 503A of the Food, Drug, and Cosmetic Act (FDCA).[†] Compounded products are not considered to be copies if they include a change from Makena® that was specifically made for an individual patient and "a prescribing practitioner determines that the change produces a significant difference for that patient between the compounded drug product and the commercially available drug product." [‡]

[†]http://www.fda.gov/downloads/NewsEvents/Newsroom/PressAnnouncements/UCM314387.pdfv
[‡]http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm308546.htm

While the price of Makena® has subsequently been reduced since its introduction in 2012 and rebate programs have been initiated, it still remains far more expensive than compounded 17P.[21] In the absence of scientific studies comparing the effectiveness of the two medications, practice guidelines and liability issues continue to favor the use of FDA-approved Makena®. Adherence to FDA-approved therapies is of particular concern to clinicians, who must assume the liability of administering medications in high-risk pregnancies.

In February 2016, AMAG Pharmaceuticals, a specialty pharmaceutical company that now manufactures Makena®, announced the FDA approval of a single-dose, preservative-free Makena®, making the production of preservative-free compounded 17P obsolete.[24] As a result of the production of preservative-free Makena®, compounding pharmacies will no longer be able to produce compounded 17P, securing the market for branded 17 alpha-hydroxyprogesterone caproate.

Vaginal Progesterone to Prevent Preterm Birth

Alternatively, some women may be ideal candidates to receive vaginal progesterone instead of 17P. Vaginally administered progesterone has been shown in prospective studies to reduce the risk of preterm birth among women with no history of a previous preterm birth, and with an asymptomatic shortened cervix (less than 20 mm) demonstrated on transvaginal ultrasound (see Table 2).[25] According to these prospective studies, among a group of 10-19 women with shortened cervix, one preterm birth may be prevented by use of vaginal progesterone treatment.[26] The cost-effectiveness of cervical length screening and vaginal progesterone treatment remains a subject of study.[27-29] Given its potential benefit, vaginal progesterone is currently recommended for women with short cervix diagnosed in the second trimester.[19] To help guide clinical decision-making regarding the use of 17P versus vaginal progesterone, Institute developed a sample decision aid (Appendix A) for clinicians that was informed by current evidence and reviewed by clinical experts and professional organizations.[20, 30]

Table 2. Evidence-based Use of Vaginal Progesterone to Prevent Preterm Birth

	Vaginal Progesterone
Patient eligible for screening	All patients may undergo cervical length screening by transvaginal ultrasound (performed once) at 18-24 weeks of gestation
Screening modality	Transvaginal ultrasound
Indication for intervention	Cervical length less than 20 mm
Regimen	Intravaginal: 200 mg capsule/suppository or 90 mg of progesterone gel daily
Duration of administration	Diagnosis until 36 weeks of gestation
Other considerations	The availability of transvaginal ultrasonography for cervical length screening has been suggested as a limiting factor in identifying all women eligible for vaginal progesterone

Source: The American College of Obstetricians and Gynecologists. (2012). Practice Bulletin Number 130: Prediction and Prevention of Preterm Birth. Obstetrics and Gynecology. 120(4), 964-73. Retrieved from http://meta.wkhealth.com/pt/pt-core/template-journal/lwwgateway/media/landingpage.htm?issn=0029-7844&volume=120&issue=4&spage=964.

Status of Medicaid Managed Care Implementation

State Medicaid programs and Medicaid managed care organizations (MCOs) have moved to cover and provide access to progesterone. In states where the medical and pharmacy benefits are carved into Medicaid managed care contracts ("carve in states"), Medicaid MCOs may have some measure of autonomy when determining coverage of progesterone drugs. However, in states where the pharmacy benefit is carved out managed care contracts ("carve-out states") or when MCOs are required to adhere to state mandated formularies ("unified formulary states"), coverage of progesterone drugs is up to the discretion of the state. Variation in coverage may be a barrier to utilization of progesterone to prevent preterm birth as evidence suggests that when progesterone is covered, access and adherence improves.[18,31] However, the state of Louisiana conducted a study in 2013 reporting that of the total Medicaid beneficiaries that met the clinical guidelines for administration of progesterone to prevent preterm birth, only 7.4 percent received any form of 17P during pregnancy.[32]

Medicaid Managed Care Coverage of Progesterone

Eighteen Medicaid MCOs, providing coverage in 31 of the 39 managed care states completed a questionnaire administered by the Institute for Medicaid Innovation between November 2015 and January 2016.[33] The questionnaire is provided in Appendix B. MCOs provided responses regarding whether coverage was provided in one or multiple states: eight plans (44.4 percent) provided coverage in a single state, and the remaining plans provided coverage across multiple states. The largest responding multistate plan provided coverage in over 19 states. Six of 18 responding MCOs (33.3 percent) reported being structured as non-profit entities; the remaining were for-profit. Among responding MCOs, 37.5 percent of plans covered fewer than 250,000 lives (i.e., Medicaid enrollees), 31.3 percent covered 250,000 to 1,000,000 lives, and 31.2 percent covered more than 1,000,000 lives.

Among all survey respondents, approximately 14 Medicaid MCOs (87.5 percent) covered Makena®, with 13 MCOs (86.7 percent) requiring prior authorization for the administration of the drug. All plans that covered Makena® also provided coverage for home administration. A smaller proportion of Medicaid managed care plans reported providing coverage of the compounded version of 17P (81.3 percent), with 75 percent requiring prior authorization (see Table 3). There was notable variation in the category of benefit in which Makena® and compounded 17P was provided (i.e., medical versus pharmacy benefit), a decision made by the state Medicaid agency (Table 4).

Table 3. Reported Medicaid MCO Coverage of 17P

	Makena® % (n)	Compounded 17P % (n)
Plans providing coverage	87.5 (14)	81.3 (13)
Plans requiring prior authorization	86.7 (13)	75.0 (9)
Plans with gestational age limits for coverage	84.6 (11)	100.0 (8)
Plans covering home administration	100.0 (13)	100.0 (11)
Plans providing coverage as a medical benefit	21.4 (3)	38.5 (5)
Plans providing coverage as a pharmacy benefit	21.4 (3)	15.4 (2)
Plans providing coverage as a combined benefit	42.9 (6)	46.2 (6)

Source: Institute for Medicaid Innovation. (2016). 17P Preterm Birth Questionnaire.

Table 4. Medicaid Managed Care Coverage of Makena® and Compounded 17P by Benefit Type*

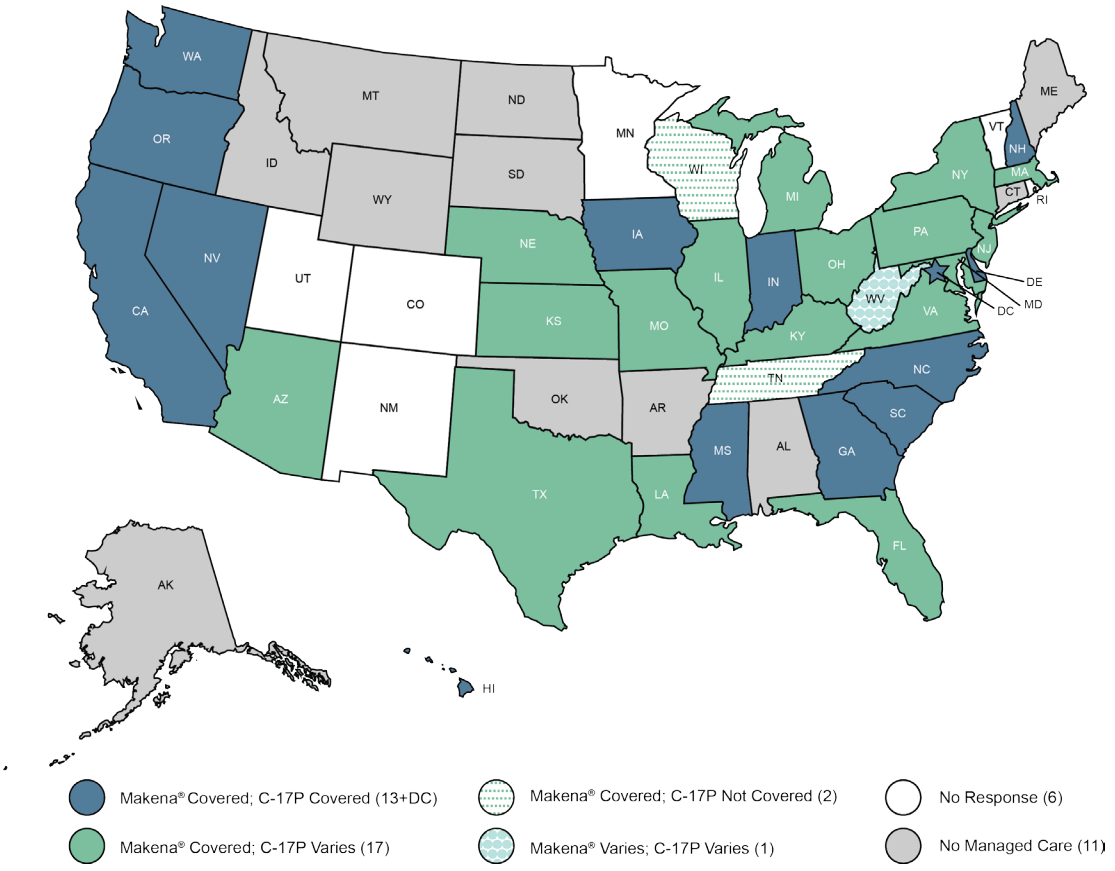
State	Makena®	Compounded 17P
AZ	Medical	Medical
CA	Medical	Medical
CO	Medical	Medical and Pharmacy
DC	Medical	Medical
DE	Medical	Medical
FL*	Medical and Pharmacy	Not covered
GA*	Medical and Pharmacy	Medical and Pharmacy
HI	Medical and Pharmacy	Medical and Pharmacy
IL	Medical	Medical and Pharmacy
IN	Medical and Pharmacy	Medical
IA	^	^
KS	Medical and Pharmacy	Medical
KY	Medical	Medical and Pharmacy
LA	Medical	Medical and Pharmacy
MA	Medical and Pharmacy	Medical
MD	Medical and Pharmacy	Medical and Pharmacy
MI	Medical and Pharmacy	Medical and Pharmacy
MO	^	^
MN	Medical	Medical
MS	Medical	Medical
ND	†	†
NE	^	^
NH	Medical	Medical
NJ	Medical and Pharmacy	Medical and Pharmacy
NM	Medical and Pharmacy	Medical and Pharmacy
NV	Medical and Pharmacy	Medical and Pharmacy
NY	Medical and Pharmacy	Medical and Pharmacy
OH	Medical or Pharmacy	Medical or Pharmacy
OR	Medical or Pharmacy	Medical or Pharmacy
PA	Pharmacy	Medical and Pharmacy
RI	Medical and Pharmacy	Medical and Pharmacy
SC	Medical and Pharmacy	Medical and Pharmacy
TN	Medical	Medical
TX	Medical and Pharmacy	Medical
UT	Medical or Pharmacy	Medical or Pharmacy
VA	Medical and Pharmacy	Medical
WA	Medical and Pharmacy	Medical and Pharmacy
WI	^	^
WV	Medical and Pharmacy	Medical

Sources: Institute for Medicaid Innovation. (2016). 17P Preterm Birth Questionnaire; State Medicaid agency websites.
* Medical benefits for prescription drugs typically cover those that are injected or infused by a health care professional in medical facility (e.g., clinic, medical office, hospital out-patient center). Pharmacy benefits typically cover self-administered oral, injectable, and inhaled drugs.
^ Denotes states that either did not have managed care at the time of the survey or carve out the pharmacy benefit from managed care contracts.
† Unable to obtain information about medical or pharmacy benefit coverage of Makena® or compounded 17P.

Progesterone Coverage by State

Makena®, including home administration of the medication, was covered in most states (see Figure 2 and Table 5). Prior authorization for Makena® was required by almost all reporting Medicaid MCOs. In contrast, there was greater variation in whether compounded 17P, or its home administration, was a covered benefit for Medicaid beneficiaries. There was variation in the gestational age limits for initiating both types of progesterone between and within states. In states where progesterone was covered, both Makena® and compounded 17P were variably categorized as either medical or pharmacy benefits.

Figure 2. Medicaid MCO Progesterone Coverage, by State



Source: Institute for Medicaid Innovation. (2016). 17P Preterm Birth Questionnaire.
Note: Information is unavailable for the following states with Medicaid managed care: CO, MN, NM, RI, UT, and VT. Plan responses to 17P Preterm Birth Questionnaire represented 31 of 39 states with Medicaid managed care.

Table 5. Medicaid MCO Progesterone Coverage, by State

State	Prior authorization required		Home administration covered		Gestational age limit for initiating therapy	
	Makena	C-17P	Makena	C-17P	Makena	C-17P
AZ	Y	N	Y	Y	22-37 weeks	28-37 weeks
CA	Y	N	Y	Y	22 weeks	28 weeks
DC	Y	Y	Y	Y	*	*
DE	Y	*	N	N	37 weeks	37 weeks
FL	Y	N	Y	Y	22-37 weeks	28-37 weeks
GA	Y	N	Y	Y	22-37 weeks	28-37 weeks
HI	Y	Y	Y	Y	37 weeks	37 weeks
IL	Y	N	Y	Y	22-37 weeks	28-37 weeks
IN	Y	N	Y	Y	22 weeks	28 weeks
KS	Y	N	Y	Y	22 weeks	28 weeks
KY	Y	Y	Y	Y	37 weeks	37 weeks
LA	N	N	Y	Y	22-37 weeks	22 weeks
MA	Y	N	Y	Y	22 weeks	28 weeks
MD	Y	*	Y	*	37 weeks	*
MI	Y	Y	Y	Y	37 weeks	36-37 weeks
MO	Y	N	Y	N	22-37 weeks	28-37 weeks
MS	Y	N	Y	Y	22 weeks	28 weeks
NE	Y	*	Y	*	37 weeks	*
NH	Y	N	Y	Y	22 weeks	28 weeks
NJ	Y	Y	Y	Y	37 weeks	37 weeks
NV	Y	*	*	*	*	*
NY	Y	Y	Y	Y	37 weeks	37 weeks
OH	Y	N	Y	Y	22-37 weeks	28 weeks
PA	Y	Y	Y	Y	37 weeks	37 weeks
SC	Y	N	Y	Y	22-37 weeks	28-37 weeks
TN	Y	*	*	*	*	*
TX	Y	N	Y	Y	22-37 weeks	28 weeks
VA	Y	*	Y	*	37 weeks	*
WA	Y	N	Y	Y	22 weeks	28 weeks
WI	Y	*	*	*	22-37 weeks	*
WV	Y	*	Y	*	37 weeks	*

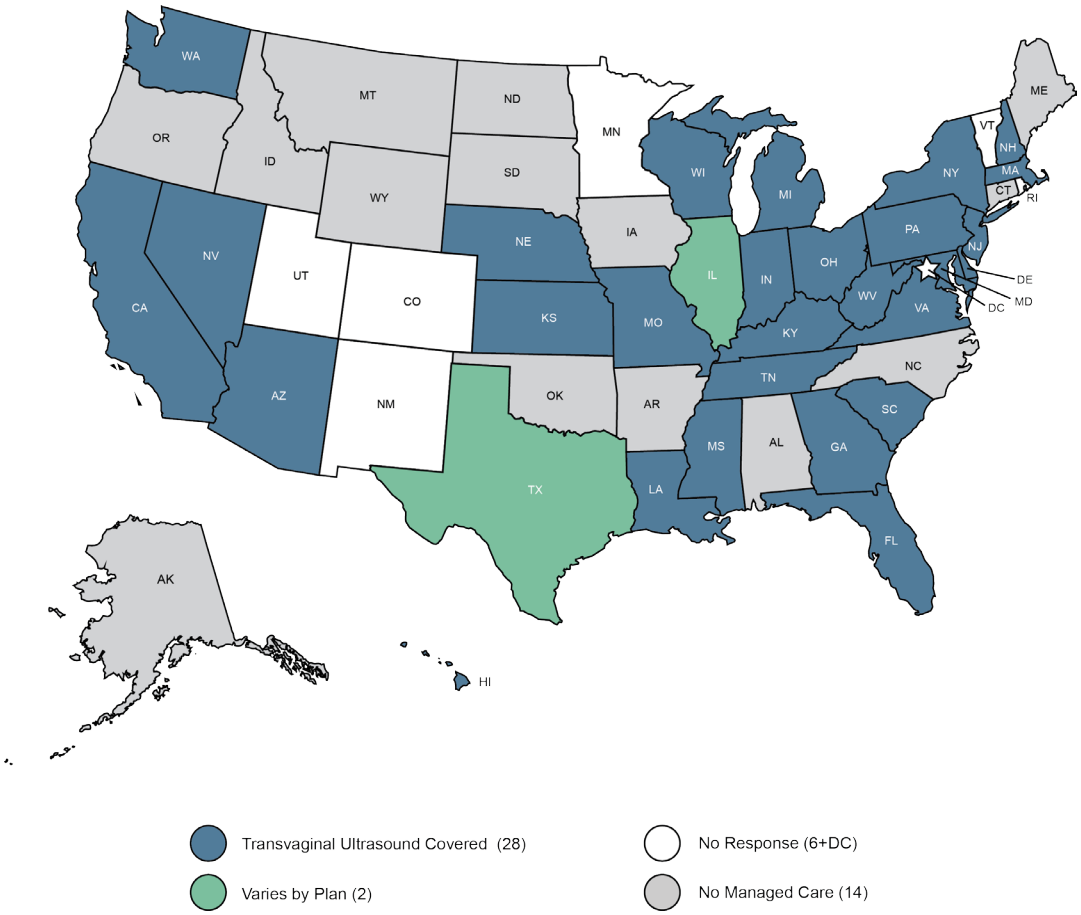
Source: Institute for Medicaid Innovation. (2016). 17P Preterm Birth Questionnaire.
Note: Information is unavailable for the following states with Medicaid managed care: CO, MN, NM, RI, UT, and VT. Plan responses to 17P Preterm Birth Questionnaire represented 31 of 39 states with Medicaid managed care. While states may not require prior authorization for Makena® or compounded 17P, plans may be allowed to require it. In LA, some plans implemented prior authorization requirements for Makena®. Similarly, FL, GA, IL, MO, and SC implemented prior authorization requirements for compounded 17P.

Y = yes; N = no; * = No Response.

Coverage of Transvaginal Ultrasound and Vaginal Progesterone

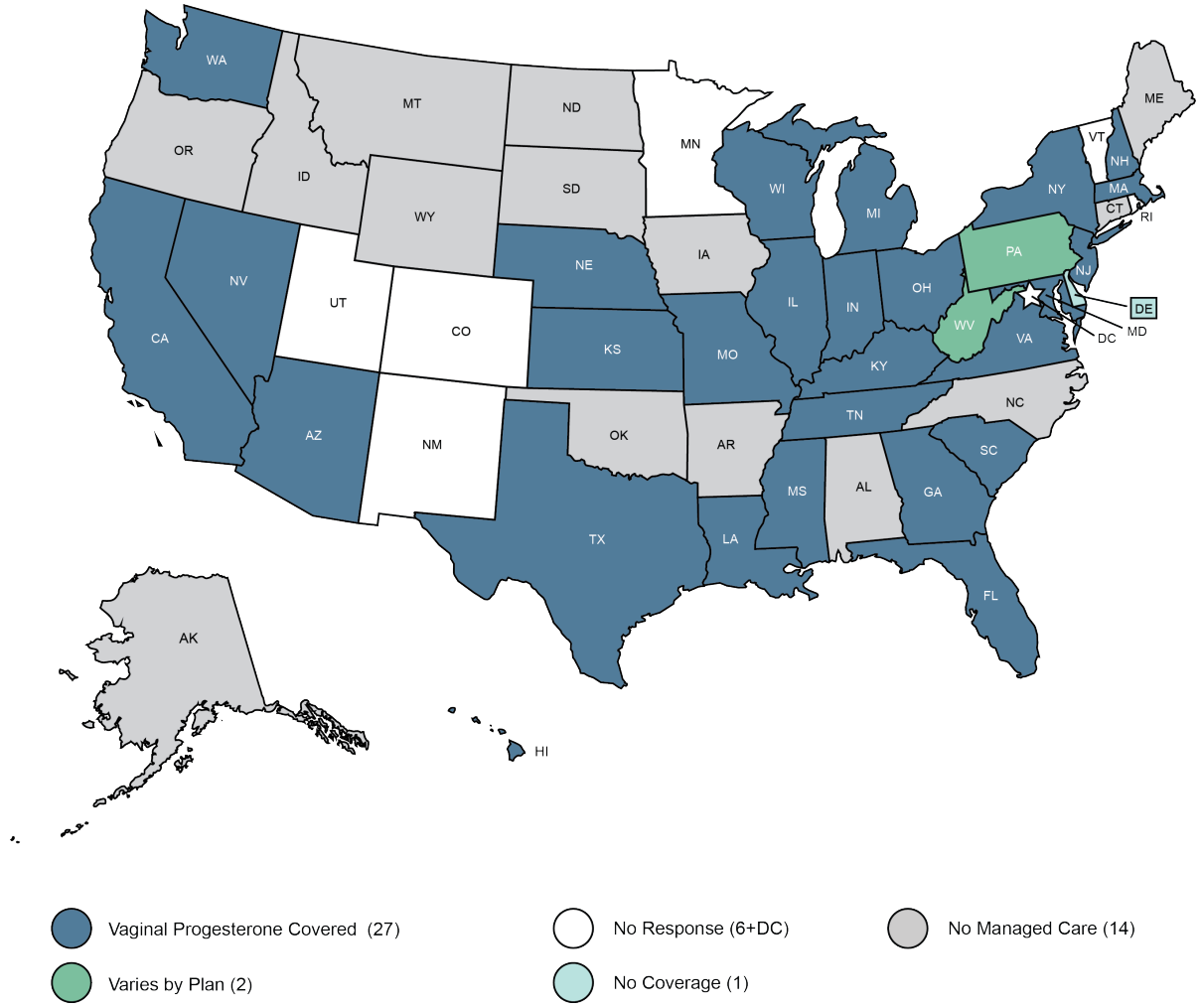
Approximately 87 percent of Medicaid MCOs reported providing coverage for vaginal progesterone and transvaginal ultrasound (necessary to diagnose asymptomatic shortened cervix). The findings are displayed in Figures 3 and 4, below:

Figure 3. Medicaid MCO Coverage of Transvaginal Ultrasound, by State



Source: Institute for Medicaid Innovation. (2016). 17P Preterm Birth Questionnaire.
Note: Information is unavailable for the following states with Medicaid managed care: CO, MN, NM, RI, UT, and VT. Plan responses to 17P Preterm Birth Questionnaire represented 31 of 39 states with Medicaid managed care.

Figure 4. Medicaid MCO Coverage of Vaginal Progesterone, by State

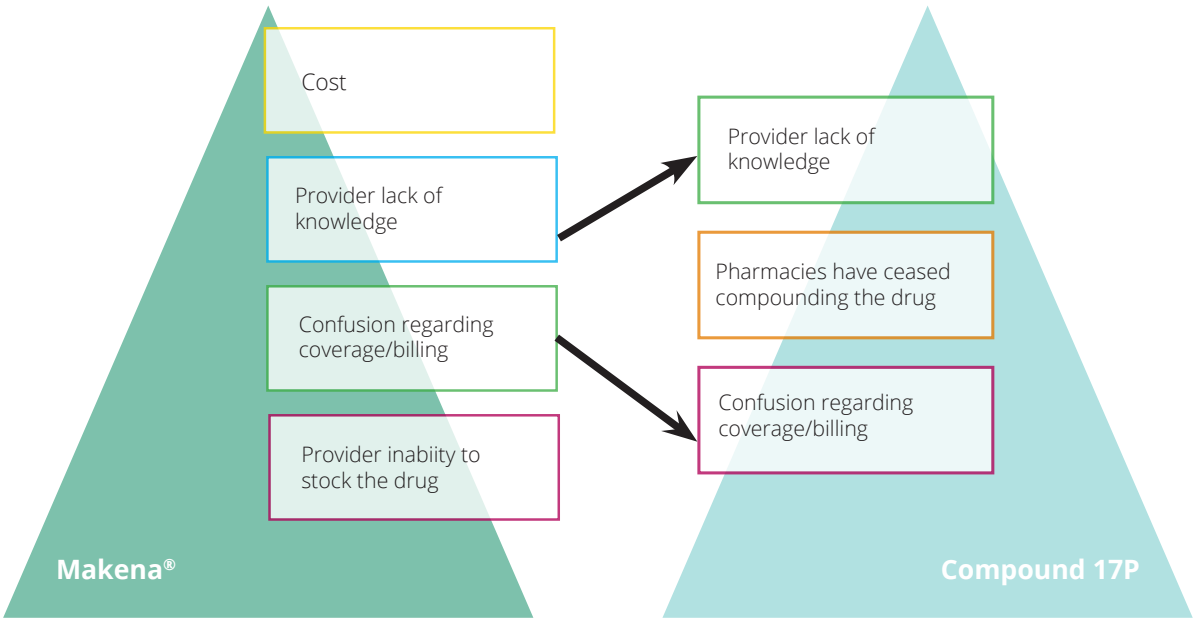


Source: Institute for Medicaid Innovation. (2016). 17P Preterm Birth Questionnaire.
Note: Information is unavailable for the following states with Medicaid managed care: CO, MN, NM, RI, UT, and VT. Plan responses to 17P Preterm Birth Questionnaire represented 31 of 39 states with Medicaid managed care.

Barriers to Providing Progesterone

The majority of Medicaid MCOs identified "clinician lack of knowledge" regarding progesterone, and "confusion regarding coverage/billing" as barriers to providing both Makena® and compounded 17P. Even several years after the FDA's approval of Makena® to prevent recurrent preterm birth, the literature has confirmed that clinician knowledge regarding the indications for and the effectiveness of 17P varies.[34-36] In the case of Makena®, the most commonly cited barrier to providing the drug was its cost. The responses suggest that clinician education – both regarding indications for progesterone and administrative processes for providing it – may be important areas of focus for improving the implementation of this treatment. Continuing efforts to address the high price of Makena® must also continue. Figure 5 identifies the common barriers that the MCOs identified in rank order.

Figure 5. Barriers in Providing Makena® and Compounded 17P (Rank Order)



Source: Institute for Medicaid Innovation. (2016). 17P Preterm Birth Questionnaire.
Note: Information is unavailable for the following states with Medicaid managed care: CO, MN, NM, RI, UT, and VT. Plan responses to 17P Preterm Birth Questionnaire represented 31 of 39 states with Medicaid managed care.

Looking Ahead: Improving Access to Progesterone

Medicaid MCOs expressed a need for further scientific research on progesterone and preterm birth prevention. Many respondents called for comparative effectiveness research evaluating the compounded versus the branded version of progesterone. Additionally, more research regarding a gestational age beyond which intramuscular progesterone may no longer be beneficial is needed. It is notable that the greatest variation in practice and guidelines between plans was seen in areas where a need for further study was identified. Findings from such research could guide plan policies regarding coverage and potentially allow states the opportunity to invest savings from prevented preterm births in their Medicaid programs.[37]

From a policy perspective, guidance from clinician organizations and payers is needed to clarify policies on the appropriate use of compounded 17P, which is not currently FDA-approved. These policies are urgently needed, given the marked cost differential between Makena® and compounded 17P and the length of time that the Makena® patent has been protected. Furthermore, given the disproportionate share of preterm births among Medicaid-eligible women, state Medicaid agency policies encouraging the expedited enrollment of pregnant women into managed care plans may lead to better outcomes as their risk for preterm birth may be identified and addressed in a more timely manner.

Clinical Priorities

Clinician education

Barriers to providing 17P may be reduced by improving clinician education on the use of progesterone, coverage of the drug in medical and pharmacy benefits, and the proper procedures for billing.

Research Priorities

Comparative effectiveness research

Studies comparing the effectiveness of Makena® versus compounded 17P for the prevention of preterm birth would be valuable in guiding the development of state Medicaid formularies and Medicaid MCO coverage policies.

Optimal window for treatment

Studies defining the gestational age beyond which the benefits of progesterone administration decreases could aid in the development of evidence-based pharmacy benefits and policies that expedite the enrollment of pregnant women in Medicaid MCOs.

Policy and Advocacy Priorities

Expediting and standardizing prior authorization processes

Prior authorization was part of the process of providing 17P in almost all health plans surveyed. Given its near universality in Medicaid managed care plans, this process could be expedited and standardized to decrease delays and the administrative burden faced by both health plans, clinicians, and beneficiaries.

More specific evidence-based policies from CMS

As new data emerge and further refine eligibility criteria and indications for progesterone, clear policies from CMS could provide guidance to states as they develop their formularies.

Adoption of presumptive eligibility for pregnant women

In order to get Medicaid-eligible pregnant women at risk for preterm birth the access to progesterone when it is most effective, eligibility pathways that expedite enrollment in Medicaid should be adopted, including presumptive eligibility[§] for pregnant women.

Eliminate fee-for-service transition period

Along with presumptive eligibility, eliminating fee-for-service (FFS) transition periods once Medicaid eligibility is confirmed will allow Medicaid MCOs to enroll, screen, and treat newly eligible pregnant woman as quickly as possible. In doing so, pregnant women at risk for preterm birth will more quickly be able to access progesterone.

[§]Presumptive eligibility allows states to authorize specific types of "qualified entities," such as federally qualified health centers (FQHCs) and hospitals, to screen income-based eligibility and immediately enroll eligible children, pregnant women, or both in Medicaid or the Children's Health Insurance Program (CHIP).

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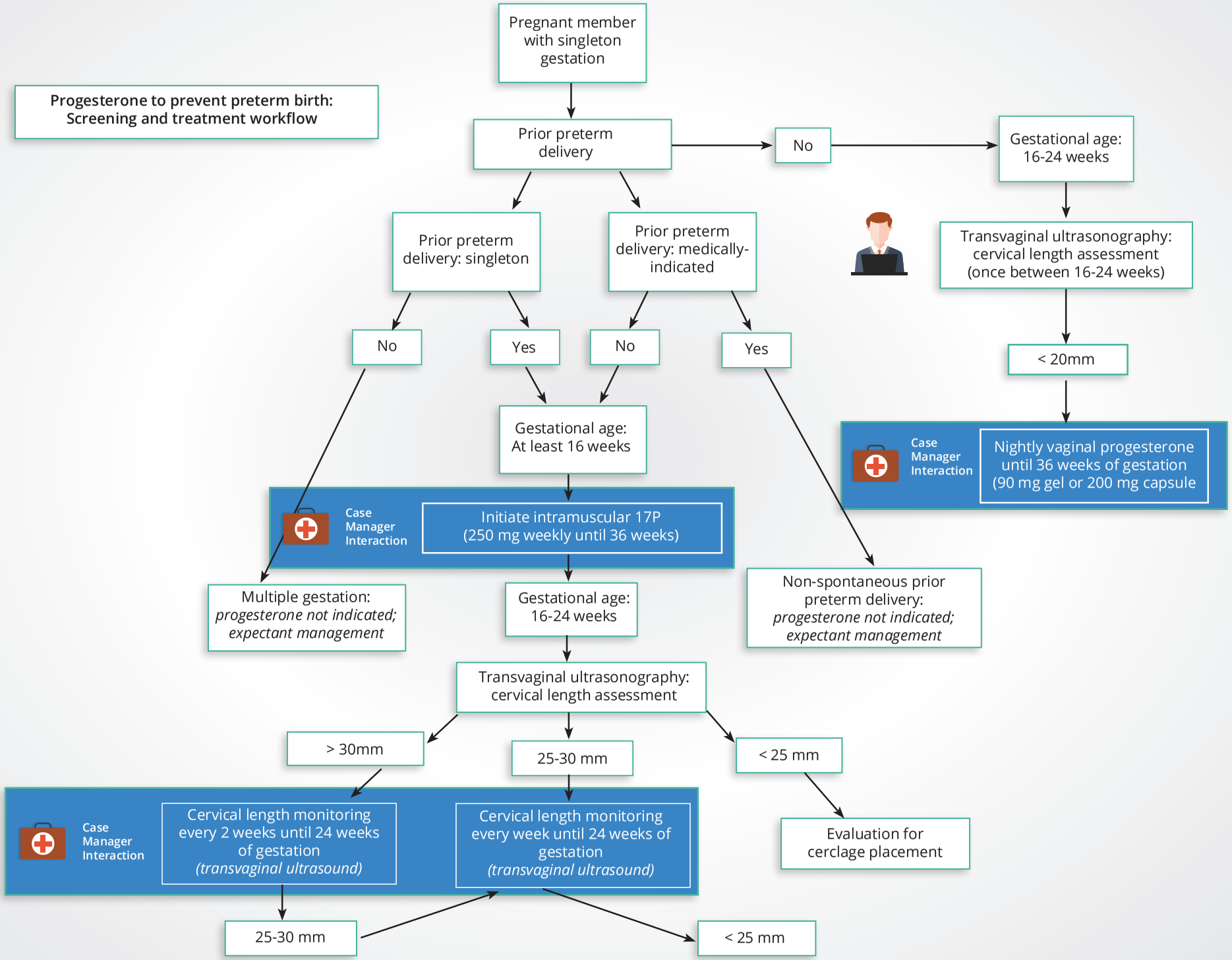
Appendix A: Clinical Decision Aid for Use of Progesterone to Prevent Preterm Birth



Appendix B: Survey Instrument

Data for this issue brief were collected through a questionnaire administered to Medicaid MCOs. The survey contained items inquiring about coverage of progesterone and associated interventions to prevent preterm birth. Participation was offered to members of Medicaid Health Plans of America (MHPA) – a nonprofit trade association representing Medicaid health plans. The survey was offered to health plans in hard copy form on November 11, 2015 (at an MHPA conference). A web-based version was also offered to these plans for completion via the Qualtrics® secure online survey platform. Responses that were provided between November 11, 2015 and January 15, 2016 were accepted.

Hydroxyprogesterone caproate is administered as a weekly intramuscular injection from 16 to 36 weeks of gestation in women with history of a previous singleton, spontaneous preterm birth. The branded drug is called Makena ®; a compounded version may also be available.

1. Name of Health Plan: _____

Your health plan will not be identified in any document or report.
All responses will be de-identified, and results will be reported in aggregate only.

2. Please complete the following grid. If your plan offers coverage in more than five states, please use additional forms.

State(s) in which your plan provides coverage	State 1:_____(e.g., MI)	State 2:_____	State 3:_____	State 4:_____	State 5:_____
Type of plan	□ For-profit □ Non-profit	□ For-profit □ Non-profit	□ For-profit □Non-profit	□ For-profit □Non-profit	□ For-profit □Non-profit
How many lives are covered?					
For each state, is Makena® a covered benefit?	□ Yes □ No □ Unknown	□ Yes □ No □ Unknown	□ Yes □ No □ Unknown	□ Yes □ No □ Unknown	□ Yes □ No □ Unknown

State(s) in which your plan provides coverage	State 1:_____(e.g., MI)	State 2:_____	State 3:_____	State 4:_____	State 5:_____
If Makena® is covered…					
What is the benefit?	☐ Medical Benefit ☐ Pharmacy Benefit ☐ Med & Pharm ☐ Unknown	☐ Medical Benefit ☐ Pharmacy Benefit ☐ Med & Pharm ☐ Unknown	☐ Medical Benefit ☐ Pharmacy Benefit ☐ Med & Pharm ☐ Unknown	☐ Medical Benefit ☐ Pharmacy Benefit ☐ Med & Pharm ☐ Unknown	☐ Medical Benefit ☐ Pharmacy Benefit ☐ Med & Pharm ☐ Unknown
Is prior authorization required?	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown
Is there an upper gestational age limit (in weeks)?	☐ Yes, Age:_____ ☐ No ☐ Unknown	☐ Yes, Age:_____ ☐ No ☐ Unknown	☐ Yes, Age:_____ ☐ No ☐ Unknown	☐ Yes, Age:_____ ☐ No ☐ Unknown	☐ Yes, Age:_____ ☐ No ☐ Unknown
Is administration at home a covered benefit?	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown
For each state, is compounded hydroxyprogesterone caproate a covered benefit?	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown
If the compounded version is covered…					
What is the benefit?	☐ Medical Benefit ☐ Pharmacy Benefit ☐ Med & Pharm ☐ Unknown	☐ Medical Benefit ☐ Pharmacy Benefit ☐ Med & Pharm ☐ Unknown	☐ Medical Benefit ☐ Pharmacy Benefit ☐ Med & Pharm ☐ Unknown	☐ Medical Benefit ☐ Pharmacy Benefit ☐ Med & Pharm ☐ Unknown	☐ Medical Benefit ☐ Pharmacy Benefit ☐ Med & Pharm ☐ Unknown
Is prior authorization required?	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown
Is there an upper gestational age limit?	☐ Yes, Age:_____ ☐ No ☐ Unknown	☐ Yes, Age:_____ ☐ No ☐ Unknown	☐ Yes, Age:_____ ☐ No ☐ Unknown	☐ Yes, Age:_____ ☐ No ☐ Unknown	☐ Yes, Age:_____ ☐ No ☐ Unknown
Is administration at home a covered benefit?	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown

What are common and/or significant barriers to providing Makena® to Medicaid beneficiaries? (Select all that apply.)

☐ Cost
☐ Clinician inability to stock the drug
☐ Confusion regarding coverage
☐ Confusion regarding billing
☐ Clinician lack of knowledge
☐ Other (specify below):

What are common and/or significant barriers to providing compounded hydroxyprogesterone caproate to Medicaid beneficiaries? (Select all that apply.)

☐ Pharmacies have ceased compounding the drug
☐ Confusion regarding coverage
☐ Confusion regarding billing
☐ Clinician lack of knowledge
☐ Other (specify below):

What resources would benefit your health plan on this topic?
(Select all that apply.)

☐ Fact sheet
Quick overview of topic with key issues.
☐ Issue brief
In-depth analysis and overview highlighting different models.
☐ Position statement
☐ Convening meeting of key stakeholders to identify strategies
☐ Toolkit
Specify toolkit focus:
_____

☐ Research
Specify type of research:
_____

☐ Other (specify below):

_____

Please identify recommendations that you want us to provide to the Centers for Medicare and Medicaid Services (CMS) that would help overcome issues that your health plan is experiencing.

In other words, what are the solutions that CMS can implement to help you? We will collect all of the responses and schedule a meeting with CMS to share your ideas with them. Please share in the space below.

Did we miss anything important? Please share in the space below.

Reviewers

Prior to publication of the final issue brief, the Institute for Medicaid Innovation sought input from independent clinical, scientific, and policy experts as peer reviewers who do not have conflicts of interest.
However, the conclusions and synthesis of information presented in this issue brief does not necessarily represent the views of individual peer reviewers or their organizational affiliation(s).

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