Commentary

Reducing the Variability of Medicaid Coverage Policies for Pregnant Women

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Article history: Received 12 July 2017; Received in revised form 4 August 2017; Accepted 4 August 2017

In this issue of Women’s Health Issues, Batra, Hernandez Gray, and Moore (2017) find that, in a sample of Medicaid managed care organizations (MCOs), there was variation in several key aspects of coverage design that can affect access to clinically recommended care by Medicaid-covered pregnant women who are asymptomatic but at high risk of a recurrent spontaneous preterm birth. More specifically, the authors found that not all Medicaid MCOs sampled covered progesterone, the professionally recognized course of treatment in this case, and that when they covered progesterone, they provided different levels of coverage and therapy initiation windows for the brand (Makena) and compound versions of the drug. In this sample, the majority of MCOs also required prior authorization for both versions of the drug, but more frequently for the brand than the compound version. The least amount of variation observed pertained to the setting in which the therapy is administered, with very few MCOs imposing limitations on providing the therapy in a home setting. The general findings from the Batra et al. (2017) study are not surprising, but they do augment previous findings from other published studies that show variation in Medicaid coverage of perinatal services, pediatric care, and family planning (Markus & West, 2014; Ranji, Salganicoff, Stewart, Cox, & Doamekpor, 2009a; Ranji, Salganicoff, Stewart, Cox, & Doamekpor, 2009b).

The main problem the Batra et al. (2017) findings highlight is that the level of variation found by the researchers should not exist for two main reasons. First, the evidence-based clinical practice guidelines issued by the American Congress of Obstetricians and Gynecologists (ACOG), the professional association that is recognized as the authority on the matter, are very clear on progesterone as a preventive treatment against recurrent spontaneous preterm birth. The guidelines are also clear on the provision of the therapy in terms of frequency, method, and setting. Clarity of clinical guidelines on these issues is key in minimizing insurers’ discretion to set coverage limitations on a specific service. Second, federal law provides for specific federal coverage standards and mandates applicable to pregnant women and their access to pregnancy-related care. When states participate in the Medicaid program, and all do, then, to receive federal funds, they must comply with a set of minimum federal standards, including standards that govern benefits and coverage rules. In the case of pregnant women, additional federal rules pertaining to the medical necessity standard and cost-sharing apply. Thus, in this case, both evidence-based clinical practice guidelines and federally mandated coverage standards and guidelines pertaining to prenatal care are well-established, so how might one encourage more standardization of coverage at the state and MCO levels, both of which should mirror the federal requirements?

It has been noted that one key reason why this level of variation exists in state Medicaid agency and Medicaid MCO coverage policies is because of the complexity of the federal coverage requirements that apply, which results in different interpretations of those requirements that are then reflected in legally binding documents. In addition, there may be a lack of understanding of the federal standards in the case of pregnant women and how little deviation should occur from those at the state and local levels. The Centers for Medicare and Medicaid Services, the federal agency in charge of overseeing Medicaid, has little enforcement authority to ensure state and MCO compliance. Therefore, one important strategy is to educate and inform those who develop coverage expectations and make coverage decisions for state Medicaid agencies and Medicaid MCOs on the scope of the national mandates and how they should be replicated in the states’ own coverage policies to align with federal requirements. Access to covered care for pregnant women could be further simplified and facilitated if state Medicaid agencies and Medicaid MCOs tied coverage to the national—and oftentimes state—public health priorities of decreasing infant mortality, low birth weight, and prematurity.

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Improving Standardization of Coverage of Prenatal Care Services by Replicating Federal Requirements

Recommended Standard of Care

It is important to start with a clear understanding and a common interpretation of what the standard of care consists of before one can assess whether Medicaid coverage policies are in fact meeting professional recommendations. Using the specific case of progesterone as a preventive measure against a recurrent spontaneous preterm birth, this means reviewing the evidence-based clinical practice guidelines issued by ACOG. As stated and, as can be seen in Table 1, the guidelines are specific in the four key areas—treatment, frequency, method, and setting—that limit an insurer’s ability to use reasonable medical management techniques to determine any coverage limitations (Centers for Medicare and Medicaid Services, N.D.-A).1

Federal Coverage Requirements

Prenatal care services are preventive services that are covered by Medicaid under “pregnancy-related services,” and also fall under the well-woman preventive visit category under the U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA)-supported women’s preventive services guidelines, which further define the content of “other preventive services” under Medicaid. One goal of prenatal care is to prevent complications related to preterm birth, and “progesterone when used properly can help accomplish this goal” (ACOG, 2013); thus, it should be covered under “pregnancy-related services.” Alternatively, progesterone could be covered under “other preventive services,” in which case progesterone—a preventive service recommended by ACOG under prenatal care—is obtained during the well-woman preventive visit. Consequently, there should be very little coverage variation at the state level—whether in state Medicaid agency or Medicaid MCO policies.

Under federal Medicaid law, state Medicaid agencies must make available medical assistance to eligible pregnant women during their pregnancies. Medical assistance in the case of pregnant women includes prenatal care services and delivery services.2 Both prenatal care and delivery services fall under “pregnancy-related services,” which are defined as “those services that are necessary for the health of the pregnant woman and fetus, or that have become necessary as a result of the woman having been pregnant”3 and “services for other conditions that might complicate the pregnancy including those for diagnoses, illnesses, or medical conditions which might threaten the carrying of the fetus to full term or the safe delivery of the fetus.”4 A state can be more generous in the amount, duration, or scope of care for pregnant women than for other individuals eligible for Medicaid if the services are preventive related to any other condition that may complicate pregnancy5 and if the services are provided in equal amount, duration, and scope to all pregnant women covered under the state plan.6

Medical assistance also specifically includes other preventive services, which are federally defined,7 encompass any clinical preventive services assigned a grade A or B by the U.S. Preventive Services Task Force (USPSTF),8 and in the case of women, should incorporate additional preventive care and screenings not described in USPSTF A or B recommendations but included in the comprehensive guidelines supported by HRSA (HRSA, 2011; U.S. Department of Health and Human Services, 2013). Notably, several specific services that fall under prenatal care, such as hepatitis B and human immunodeficiency virus screening for pregnant women, have received an A or B grading. However, progesterone, which could be considered for grading because it

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**Table 1**

<table>
<thead>
<tr>
<th>Evidence-based Clinical Practice Guidelines: ACOG Recommendations</th>
<th>Prenatal Care and Prevention as Classes of Benefits – Specific Services: Progesterone (17OHPC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommended treatment</strong></td>
<td>As part of its evidence-based clinical practice guidelines, the ACOG recommends the use of 17OHPC, a hormone that plays a key role during pregnancy, including preventing contractions too early in the pregnancy (ACOG, 2012). However, ACOG limits the clinical indication for its use to a subgroup of pregnant women who had a prior preterm birth, are asymptomatic, and currently have a singleton gestation pregnancy (ACOG, 2012). ACOG recommends initiation of the therapy between 16 and 20 weeks, with an extension of the initiation window to 26 weeks, and continuation of the therapy until 36 weeks (ACOG, 2013). The brand Makena is the only FDA-approved version of 17OHPC indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth (ACOG, 2013; Lumara Health, 2014). The FDA directs physicians not to administer the compounded version of 17OHPC unless the physician thinks it is medically necessary for his or her patient (ACOG, 2013). The compounding pharmacy may request physicians opting for the compound to sign a waiver to confirm their knowledge of the existence of a FDA-approved version (ACOG, 2013; Lumara Health, 2014).</td>
</tr>
<tr>
<td><strong>Recommended frequency</strong></td>
<td>Weekly.</td>
</tr>
<tr>
<td><strong>Recommended method</strong></td>
<td>Intramuscular shots in the thigh.</td>
</tr>
<tr>
<td><strong>Recommended setting</strong></td>
<td>Can be administered in the physician’s office or at home through health agency nursing services, if available to the patient. If in-office administration is too difficult and nursing services are not available, a family member can be trained to administer the shots (ACOG, 2013).</td>
</tr>
</tbody>
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5 42 CFR 440.240(p)(1).
6 42 CFR 440.240(p)(2).
7 42 CFR § 440.130(c).
8 42 USC § 1396d(a)(13)(A).
is an injectable drug provided in a clinical setting for the primary purpose of prevention, is not explicitly on that list (Centers for Medicare and Medicaid Services, N.D.-B). Even without making the USPSTF A or B list, progesterone should be covered because of the specific clause requiring coverage of additional women’s preventive services not required by USPSTF but included in the HRSA-supported guidelines. The U.S. Department of Health and Human Services/HRSA guideline for insurance coverage for that particular type of preventive service states that well-woman preventive care visits are used “to obtain the recommended [emphasis added] preventive services that are age and developmentally appropriate, including…many services necessary for prenatal care” (HRSA, 2011). The ACOG guidelines recommend progesterone as a treatment to prevent preterm birth as part of prenatal care (ACOG, 2012).

**Determination of Medical Necessity in Instances of Individual Need**

Whether the services needed by a Medicaid-covered pregnant woman are classified as pregnancy-related care or other preventive care, both are classes of benefits defined in federal law. If specific services that are medically necessary for a pregnant woman fall under either or both categories of benefits, then they should be covered in that instance of need.

Per the Medicaid statute and regulations, the definition of pregnancy-related services includes a “built-in” medical necessity standard in that pregnancy-related services are those services that are necessary for the health of the pregnant woman and fetus, or that have become necessary as a result of the woman having been pregnant.10 Because the standard stresses the health of the pregnant woman and fetus, it in essence gives access to a wide array of services by overriding any other coverage limitations that might be in place.

**Determination of Cost-sharing Rules**

Whether the services are categorized as pregnancy-related care or other preventive care, both classes of benefits are exempt from any cost-sharing requirements. State Medicaid agencies may not impose cost-sharing on pregnancy-related services.11 Federal Medicaid rules provide that all services provided to pregnant women will be considered as pregnancy-related, except those services specifically identified in the state plan as not being related to the pregnancy, during the pregnancy and through the postpartum period which begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends.12 States may choose to exempt all services provided to pregnant women from cost-sharing, including prescription drugs, such as Makena (U.S. Department of Health and Human Services, 2013).

Similarly, state Medicaid agencies may not impose cost-sharing on preventive services.13 Medicaid law further specifies that covered clinical preventive services assigned a grade of A or B and, in the case of women, additional services included in the HRSA-supported guidelines should be provided free of charge.

Table 2 provides a side-by-side summary of the federal coverage requirements.

**Facilitating Access to Federally Required Prenatal Care Services Because Improving Birth Outcomes Is a Public Health Priority**

**Medicaid and Preterm Birth**

The Medicaid program pays for close to one-half of all births in the United States, (Markus, Andres, West, Garro, & Pellegrini, 2013). It also pays for a disproportionate number of preterm births, defined as a live birth occurring before 37 completed weeks of gestation, compared with private insurance (Markus, Krohe, Garro, Gerstein, & Pellegrini, 2017). Deliveries are generally among the most expensive claims faced by insurers, whether private or public, and preterm deliveries, although less common, are very expensive as individual claims, on average, about $50,000 in medical care for the first year of life (March of Dimes, 2013). Preventing preterm births from reoccurring to reduce even one unanticipated high claim that taxes a state’s budget should seemingly be, and often is, a key concern for state Medicaid agencies.

**Tying Medicaid Coverage to a National or a State Public Health Priority**

Birth outcomes are typically looked to as a way to measure a health system’s performance against other health systems’ performance. Improving birth outcomes (specifically infant mortality, low birth weight, and prematurity) then becomes a shared goal by many health systems around the world. The United States has some of the worst birth outcomes in the world particularly when compared with similarly situated countries, and reducing infant mortality and preterm birth continues to be a top public health priority nationally. Both are leading health indicators in Healthy People 2020 and, as such, signal that they are high-priority health issues at the national level (Office of Disease Prevention and Health Promotion, N.D.). At the state level, 26 state Maternal and Child Health agencies have made reducing infant mortality, preterm birth, or both a priority for the state (Maternal and Child Health Bureau, N.D.).

One strategy to encourage coverage of appropriate pregnancy-related care is to tie coverage of specific services, such as progesterone, to the state plan to reduce infant mortality and/or reduce prematurity. For example, all of the Medicaid MCOs serving Ohio agreed to eliminate prior authorization requirements for progesterone in early 2016 (Iams et al., 2017). Molina Healthcare of Ohio Medicaid adopted this strategy for the brand Makena and for the skilled home health nursing visits needed to administer the intramuscular injection, stating that “these changes are part of Molina Healthcare’s commitment to the state of Ohio’s initiative to reduce the infant mortality rate” (Molina Healthcare, 2016). More Medicaid MCOs and state Medicaid agencies could follow suit. Batra et al. (2017) recommend specific steps MCOs can take to standardize Medicaid MCO coverage policies to increase pregnant women’s access to progesterone and other measures to prevent preterm birth.

**Recommendation**

Reducing the variability of Medicaid coverage policies for pregnant women is not only possible, it is also necessary to comply with federal law and to ensure that pregnant women...
Medical necessity standard

[“T]hose services that are necessary for the health of the pregnant woman and fetus, or that have become necessary as a result of the woman having been pregnant.”]  *Medical assistance also includes “other preventive services” defined as:

- Services recommended by a physician or other licensed practitioner of the healing arts acting within the scope of authorized practice under State law to—(1) Prevent disease, disability, and other health conditions or their progression; (2) Prolong life; and (3) Promote physical and mental health and efficiency.”

Cost-sharing rules

State Medicaid agencies may not impose cost-sharing on pregnancy-related services. Federal Medicaid rules provide that “all services provided to pregnant women will be considered as pregnancy-related, except those services specifically identified in the state plan as not being related to the pregnancy, during the pregnancy and through the postpartum period which begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends.”

States may choose to exempt all services provided to pregnant women from cost-sharing, including prescription drugs, such as Makena (U.S. Department of Health and Human Services, 2013).

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Covered preventive services include any clinical preventive services assigned a grade of A or B by the USPSTF. Several specific services that fall under prenatal care have received an A or B grading. For example: Hepatitis B screening for pregnant women; human immunodeficiency virus screening for pregnant women.

In addition, in the case of women, preventive services should include additional preventive care and screenings not described in USPSTF A or B recommendations, but included in the comprehensive women’s preventive guidelines supported by the HRSA of the HHS. The well-woman preventive visit is a category of preventive services under the HRSA-supported guidelines. The HHS guideline for insurance coverage for that particular type of preventive service states that these visits are used “to obtain the recommended [emphasis added] preventive services that are age and developmentally appropriate, including... many services necessary for prenatal care” (HRSA, 2011). One goal of prenatal care is to prevent the neonatal complications from preterm birth, and progesterone when used properly can help to accomplish this goal (ACOG, 2013). The ACOG guidelines recommend progesterone as a treatment to prevent preterm birth, and provide the frequency, method, and setting for its provision and, therefore, insurers are limited in their ability to use reasonable medical management techniques to determine any coverage limitations (ACOG, 2012; CMS, n.d. (a)).” The well-woman preventive visit is used to obtain the recommended progesterone at specific intervals, by injection, in a physician’s office or home setting, when indicated for an asymptomatic pregnant woman who is at high risk of a recurrent preterm birth. “[T]hose services that are necessary for the health of the pregnant woman and fetus, or that have become necessary as a result of the woman having been pregnant.”

State Medicaid agencies may not impose cost-sharing on preventive services. Preventive services with an A or B rating should be provided free of any cost-sharing requirements and, in the case of women, should include—also free of charge—additional preventive care and screenings not described in USPSTF A or B recommendations but included in the HHS/HRSA-supported women’s preventive services guidelines."

### Abbreviations:
- **HRSA**, Health Resources and Services Administration; **USPSTF**, Services as in United States Preventive Services Task Force.
- **42 USC** 1396a(a)(10)(C)(II) & 42 USC 1396d(a)(10)(C)(iii).
- **42 CFR**: 440.130(c).
- **42 USC**: 1396d(a)(13)(A).
- **42 USC**: 300gg-13.
- **42 CFR**: 447.56(a)(2)(iv).
- **42 CFR**: 447.56.
- **42 CFR**: 447.56(a)(2)(iii).

**Sources:** HRSA, 2011; ACOG, 2012, 2013; CMS, N.D.-A; United States Code (USC) and Code of Federal Regulations (CFR), including the above references.
have access to the full array of recommended care and ultimately enjoy a healthy pregnancy.

State Medicaid agency and Medicaid MCO medical directors, who make medical necessity determinations, and state Medicaid agency managed care directors and procurement officers, who oversee MCOs and their contracts, should first have a clear understanding of the recommended standard of care, in this case the ACOG evidence-based clinical practice guidelines that govern prenatal care services, and adopt a common interpretation of these guidelines to align Medicaid coverage requirements with the recommended standard of care. In addition, if the guidelines are clear on treatment, frequency, method, and setting, coverage policies should be devoid of coverage limitations that hinder compliance with those guidelines. Second, coverage policies should replicate federal coverage requirements when in fact they set a national floor. Furthermore, they should explicitly state that, in the case of prenatal care, the “pregnancy-related” medical necessity standard that emphasizes the health of the pregnant woman and the fetus applies. Although state Medicaid agencies and MCOs have the ability to establish an ongoing process of review of medical necessity, the burden imposed by that process should be minimized as much as possible for pregnant women, as was done in Ohio. State Medicaid agencies also need to update their coverage policies to ensure access to FDA-approved therapies. When updating their coverage policies, they should also make similar updates to their contracts with MCOs in the next round of contractual negotiations and, in the meantime, communicate the changes to MCOs and network providers through their traditional provider communication bulletins.

Facilitating access to federally required pregnancy-related services is also an integral part of improving birth outcomes, which is a public health priority in the United States and in many states and a main indicator of health system performance against which all countries in the world measure themselves. A complex health system such as the U.S. health system and a constantly evolving environment should not deter state Medicaid agencies and MCOs from keeping this priority in mind. Explicitly tying their coverage policies to state priorities focused on infant mortality and prematurity reduction, and implementing coverage policies that act as facilitators, not barriers, toward access to recommended pregnancy-related care present opportunities that should not be ignored.

Acknowledgments

The author thanks Liz Borkowski, MPH, Senior Research Scientist at GWU and Managing Editor of Women’s Health Issues, for her helpful guidance in shaping up this commentary.

References


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