Women's Health Issues 27-5 (2017) 513–517

WOMEN'S HEALTH ISSUES
www.whijournal.com

Commentary

Reducing the Variability of Medicaid Coverage Policies for Pregnant Women

Anne Rossier Markus, PhD, MHS, JD *

Department of Health Policy and Management, Milken Institute School of Public Health, The George Washington University, Washington, DC

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 version 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 woman 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.

Funding Statement: None; no conflict of interest.

* Correspondence to: Anne Rossier Markus, PhD, MHS, JD, Associate Professor, Department of Health Policy and Management, Milken Institute School of Public Health, The George Washington University, 950 New Hampshire Avenue, Washington, DC 20052. Phone: +202-994-9139; fax: +202-994-3773.

E-mail address: armarkus@gwu.edu

1049-3867/$ - see front matter
http://dx.doi.org/10.1016/j.whi.2017.08.004

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 includ[ing] 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 pregnancy related or related to any other condition that may complicate pregnancy[5] 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[9] (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

Table 1
Recommended Standard of Care: The Case of the Prevention of Recurrent Spontaneous Preterm Birth in High-risk Women

Evidence-based Clinical Practice Guidelines: ACOG Recommendations	Prenatal Care and Prevention as Classes of Benefits – Specific Services: Progesterone (17OHPC)
Recommended treatment	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 $20^{6/7}$ weeks, with an extension of the initiation window to $26^{6/7}$ weeks, and continuation of the therapy until $36^{6/7}$ 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).
Recommended frequency	Weekly.
Recommended method	Intramuscular shots in the thigh.
Recommended setting	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).

Abbreviations: ACOG, American Congress of Obstetricians and Gynecologists; FDA, U.S. Food and Drug Administration; 17OHPC, 17- α -hydroxyprogesterone caproate.
Sources: ACOG, 2012, 2013; Lumara Health, 2014.

[1] See also 26 CFR 54.9815–2713T(a)(4), 29 CFR 2590.715–2713(a)(4), 45 CFR 147.130(a)(4).

[2] 42 USC §1396a(a)(10)(C)(ii)(II) & 42 USC §1396a(a)(10)(C)(iii).

[3] 42 CFR § 440.210(a)(2)(i).

[4] 42 CFR § 440.210(a)(2)(ii).

[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).

[9] 42 USC § 300gg-13.