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Medical Management and Access to Contraception

Updated By: Agata Pelka
Prepared By: Erin Armstrong
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The Affordable Care Act (ACA) requires most health insurance plans to provide coverage for certain preventive health services, including contraception, without cost sharing. Millions of insured individuals have benefitted from new or improved coverage of evidence-based preventive health care through these provisions. While these requirements remove significant barriers associated with cost sharing, accompanying regulations and guidance allow insurers to limit access to these benefits through "reasonable medical management techniques."[1]

According to prevailing medical standards of care, a woman's choice should be the primary factor in determining her contraceptive method.[2] Medical management techniques often result in delays in access to or denials of a chosen method, which deprive women of their reproductive autonomy, increase risk of unintended pregnancy and undermine the intent of the coverage requirement. This issue brief reviews the guidance HHS has provided on the extent insurers may use medical management techniques in their coverage of contraceptives under the ACA.

The ACA contraceptive coverage requirement

The ACA added § 2713 to the Public Health Services Act, requiring most health insurance plans to cover a broad array of evidence-based preventive health services without cost sharing.[3] To meet women's unique preventive health needs, Congress directed the Department of Health and Human Services' Health Resources and Services Administration (HRSA) to develop guidelines to identify the critical women's health benefits that the coverage requirement must include.

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[1] 45 CFR § 147.130(a)(4); U.S. Dep'ts of Labor, Health & Human Serv., & Treasury, *Frequently Asked Questions about Affordable Care Act Implementation Part XII* (February 20, 2013), http://www.dol.gov/ebsa/faqs/faq-aca12.html#5 [hereinafter *February 2013 FAQ*]; U.S. Dep'ts of Labor, Health & Human Serv., & Treasury, *Frequently Asked Questions about Affordable Care Act Implementation Part XXVI* (May 11, 2015), http://www.dol.gov/ebsa/faqs/faq-aca26.html [hereinafter *May 2015 FAQ*]

[2] Standards of care are defined as the practices that are medically necessary and the services that any practitioner under any circumstances should be expected to render. For more information, review NHeLP's report on Health Care Refusals at http://www.healthlaw.org/issues/reproductive-health/health-care-refusals/health-care-refusals-undermining-care-for-women#.VuGj5fkrK71.

[3] 42 U.S.C. § 300gg-13 (ACA § 1001, adding § 2713 of the Public Health Services Act).

To inform these guidelines, HRSA commissioned the Institute of Medicine (IOM) to review existing evidence and make recommendations. In June 2011, the IOM recommended eight women's preventive health benefits, including:

> All Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.[4]

In its accompanying report, the IOM acknowledged that the most appropriate method of contraception varies according to each woman's needs and medical history, and therefore, the full range of contraceptive methods is necessary to ensure that women have "options depending upon their life stage, sexual practices, and health status."[5] HRSA adopted the IOM's eight recommendations, requiring coverage of all FDA-approved contraceptive methods.[6]

Federal regulations implementing the preventive services coverage requirements, however, permit health insurers to use "reasonable medical management techniques" to determine the frequency, method, treatment, or setting for any of the required services to the extent not already specified in the guidelines.[7] The regulations do not define "medical management" or provide clear guidance about when it should or should not be considered reasonable.

The Departments of Labor, Health and Human Services, and the Treasury have addressed the provisions in "Frequently Asked Questions" about the preventive services coverage requirements (FAQ #12 in February 2013 and FAQ #25 in May 2015).[8] Both FAQs reiterate that the use of reasonable medical management is permissible within the bounds of certain limitations (described below).

Defining medical management

Although the preventive services regulations and FAQs do not define "medical management," the term is broadly understood to encompass insurer practices that aim "to control costs and promote efficient delivery of care."[9] Insurers routinely use medical management techniques to govern the availability of benefits, steer patients away from costly or unnecessary services, and dictate courses of treatment for particular medical

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[4] Inst. Of Med. ("IOM"), *Clinical Preventive Services For Women: Closing The Gaps* at168 (Prepublication Ed.) (2011).
[5] *Id.* at 104-105.
[6] U.S. Dep't Of Health & Human Services, *Women's Preventive Services: Required Health Plan Coverage Guidelines*, http://www.hrsa.gov/womensguidelines/.
[7] 45 CFR § 147.130(a)(4).
[8] U.S. Dep'ts of Labor, Health & Human Serv., & Treasury, *Frequently Asked Questions about Affordable Care Act Implementation Part XII* (February 20, 2013), http://www.dol.gov/ebsa/faqs/faq-aca12.html#5 [hereinafter *February 2013 FAQ*]; U.S. Dep'ts of Labor, Health & Human Serv., & Treasury, *Frequently Asked Questions about Affordable Care Act Implementation Part XXVI* (May 11, 2015), http://www.dol.gov/ebsa/faqs/faq-aca26.html [hereinafter *May 2015 FAQ*].
[9] *See February 2013 FAQ*, *supra* note 1, Q14.

conditions. For example, prior authorization is a medical management technique that requires a provider to obtain a determination from the insurer that a recommended drug or service is necessary for an enrollee before it can be provided. This allows insurers to override providers' clinical judgments and make individualized determinations about who may receive particular benefits. Similarly, step therapy refers to insurer policies that require enrollees to try less expensive treatments and experience failure or contraindications before the insurer will grant access to more expensive options, even when those options are recommended by a provider and/or preferred by the enrollee.

Other common medical management techniques include limits on the number of covered visits or prescriptions available per year and requirements that an enrollee try a generic form of a drug unless a medical reason indicates she must have the brand name version.

When medical management practices align with standards of care, they can improve efficiency without sacrificing quality of care or patient wellbeing. For example, if a patient complains of mild headaches, it may be reasonable for an insurance company to deny coverage of narcotic pain medication as a first-line treatment absent some showing of medical necessity. But when medical management techniques ignore or override standards of care and are driven solely by insurers' desire to control costs, they can prevent or delay access to necessary treatments and services that are preferred or recommended for particular enrollees.

Medical management techniques in the context of contraceptive care

Standards of care require that women have access to a wide range of contraceptive brands, formulations, and delivery systems. For women with certain medical conditions or risk factors—such as hypertension, migraine headaches, or obesity—some contraceptives may be contraindicated, and "variations in hormonal content and delivery methods may affect women with certain conditions differently."[10] For some, side effects associated with particular methods are not well tolerated and may lead to dissatisfaction and discontinued use.[11] When insurers adopt policies or make coverage decisions that limit a woman's contraceptive options, some women are left without meaningful access to a suitable method.

According to the American College of Obstetricians and Gynecologists, "in the absence of contraindications, patient choice should be the principal factor in prescribing one method of contraception over another."[12] Choosing the most appropriate method is a complex and individualized process that cannot be determined by an insurer apart from a woman's preferences, concerns, reproductive goals, and interpersonal relationships.

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[10] American College of Obstetricians and Gynecologists, *Use of Hormonal Contraception in Women With Coexisting Medical Conditions, ACOG Practice Bulletin Number 73* (2006).
[11] Kimberly Daniels et al., U.S. Dept. of Health & Human Services, Centers for Disease Control and Prevention, *Contraceptive Methods Women Have Ever Used: United States, 1982-2010*, 62 National Health Statistics Reports 8 (2013).
[12] American College of Obstetricians and Gynecologists, *Guidelines for Women's Health Care: A Resource Manual* 183 (3rd ed. 2007).

To adequately address women's contraceptive needs, a prescribed method must reflect women's sexual, emotional, and social lifestyles.[13] Research also shows that when women are able to access their method of choice, they are more likely to use contraception effectively.[14] Medical management techniques that limit or delay a woman's access to her preferred method contribute to lapsed or inconsistent contraceptive use and increased risk of unintended pregnancy.

In recognition of these facts, the February 2013 FAQ reiterated that plans subject to the preventive services coverage requirements must ensure that women have access to the full range of FDA-approved contraceptive methods.[15] The May 2015 FAQ clarified further that plans must provide coverage without cost sharing for at least one form of contraception in each of the FDA-approved contraceptive method categories.[16] For example, a plan must cover both the copper IUD (Paraguard) and at least one progestin-based IUD (Mirena, Skyla, or Lilleta) as the FDA classifies them as distinct methods.

Plans are only allowed to utilize reasonable medical management techniques within the distinct method categories as defined by the FDA, not between categories. As an example of a permissible medical management technique, the May 2015 FAQ explains that a plan could encourage the use of a generic progestin IUD over a brand name progestin IUD by imposing cost sharing. However, if a woman's provider recommends a particular item or service based on a determination of medical necessity, the plan must defer to the provider's recommendation and cover that item or service without cost sharing even if the plan could otherwise impose reasonable medical management parameters. The plan must provide a waiver process to facilitate coverage in such a situation. The exceptions process must be "easily accessible, transparent, and sufficiently expedient" so that it is not "unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative)." For example, if a generic substitution is determined to be medically inappropriate by a woman's provider, the plan must cover the branded version at no cost to the woman.[17] The May 2015 FAQ outlines several considerations that may lead a provider to recommend a particular item or service due to medical necessity, such as severity of

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[13] Caroline Moreau et al., *Social, Demographic and Situational Characteristics Associated with Inconsistent Use of Oral Contraceptives: Evidence from France*, 38(4) Perspectives on Sexual and Reproductive Health 190 (2006).
[14] *Id.*; Noone J., *Finding the Best Fit: A Grounded Theory of Contraceptive Decision Making in Women*, 39(4) Nursing Forum 13 (2004).
[15] *February 2013 FAQ*, *supra* note 1, Q14-Q17.
[16] The FDA currently classifies contraceptives into 18 distinct methods: (1) sterilization surgery for women; (2) surgical sterilization implant for women; (3) implantable rod; (4) IUD copper; (5) IUD with progestin; (6) shot/injection; (7) oral contraceptives (combined pill); (8) oral contraceptives (progestin only); (9) oral contraceptives extended/continuous use; (10) patch; (11) vaginal contraceptive ring; (12) diaphragm; (13) sponge; (14) cervical cap; (15) female condom; (16) spermicide; (17) emergency contraception (Plan B/Plan B One Step/Next Choice) and (18) emergency contraception (Ella) .

side effects, differences in permanence and reversibility of methods, and ability to adhere to the appropriate use of the item or service. In March 2016, HHS emphasized that this exceptions process is unique from others required by the ACA, and plans must set up a waiver system to specifically address contraceptive services.[18]

Additionally, plans may continue to impose cost sharing for services and contraceptives provided by out-of-network providers and pharmacies. But plans must cover out-of-network services without cost sharing if there is no provider in-network who can perform the service.

Recommendations

While HHS has made it explicitly clear that medical management techniques may only be applied in limited circumstances (within categories of FDA-approved methods), these insurer practices interfere patient decision-making and conflict with the ACA's intent to eliminate barriers to all FDA-approved methods of contraception. The May 2015 FAQ's articulation that plans must cover all 18 contraceptive methods still leaves gaps and barriers for women. For example, the three available progestin IUDs (Mirena, Skyla, and Lilleta) are distinct and different, yet plans only have to cover one without cost sharing. Further, Mirena is indicated to be replaced every five years, while Lilletta and Skyla are indicated to be replaced every three years. Skyla is smaller than Mirena, and may be recommended for younger or smaller women.

Moreover, even though medical management techniques must be waived due to a medical necessity determination by a provider, the process for implementing the exceptions provision is not sufficiently detailed laid out. HHS should develop and implement a standard form that triggers the exceptions provision to ensure that the process is expedient and does not require multiple provider visits.

On the state level, advocates should encourage policymakers and insurance regulators in their states to use their enforcement authority to ensure that medical management is not used to create or perpetuate barriers in the context of contraceptive care.

[18] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017; Final Rule, 81 Fed. Reg. 12,204, 12,296 (Mar. 8, 2016).