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Guidance Issued on Contraception Coverage Mandate

On January 22, 2024, the Departments of Labor, Health and Human Services, and the Treasury (collectively, "the Departments") answered a new round of FAQs, providing additional guidance on the Affordable Care Act ("ACA")'s requirement for non-grandfathered medical plans to cover certain preventive services including contraceptives, without cost-sharing. These FAQs answer questions from stakeholders to help people understand the contraceptive coverage mandate and promote compliance by providing an alternate method of compliance. It should be noted that religious employers, certain non-profit religious organizations, and closely held for-profit entities can exclude contraception.

Background

Plans and issuers must cover at least one form of contraception in each of the following categories:

1. Sterilization surgery for women
2. Implantable rods
3. Copper intrauterine devices
4. Intrauterine devices with progestin (all durations and doses)
5. Injectable contraceptives
6. Oral contraceptives (combined pill)
7. Oral contraceptives (progestin only)
8. Oral contraceptives (extended or continuous use)
9. Contraceptive patch
10. Vaginal contraceptive rings
11. Diaphragms
12. Contraceptive sponges
13. Cervical caps
14. Condoms
15. Spermicides
16. Emergency contraception (levonorgestrel)
17. Emergency contraception (ulipristal acetage)

Plans must also cover any additional contraceptives approved, cleared, or granted by the FDA (including newer contraceptive products) so long as the individual's attending provider determines such care as medically appropriate and necessary. Plans may apply reasonable medical management techniques for newer products and procedures only if there exists at least one other substantially similar product or service available and medically appropriate, and that similar product or service is covered without cost sharing.

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, then the plan or issuer may use reasonable medical management techniques to determine any such coverage limitations. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive item or service.

The Departments are aware of reports that plans and issuers continue to apply unreasonable medical management techniques and exclusions that present barriers to access contraceptive care without cost sharing. Examples of potentially unreasonable medical management techniques and other problematic practices include actions by plans that:

- require individuals to satisfy step therapy protocols (a medical management technique also known as "fail first") using numerous other services or FDA-approved, -cleared, or - granted contraceptive products within the same category of contraception before the plan or issuer will approve coverage for the contraceptive service or FDA-approved, -cleared, or -granted contraceptive product that is medically necessary for the individual, as determined by the individual's attending health care provider;

- apply age-related restrictions for a contraceptive service or product that is medically necessary for the individual, as determined by the individual's attending health care provider;

- impose unduly burdensome administrative requirements as part of an exceptions process, such as onerous documentation requirements or multiple levels of processes (such as one to cover an excluded drug that is medically necessary and another to remove cost-sharing requirements), that result in denials of coverage or imposition of a cost-sharing requirement for contraceptive services or products that are medically necessary for the individual, as determined by the individual's attending health care provider; and

- require cost sharing for services provided that are integral to the preventive service provided (regardless of whether the items and services are billed separately), such as anesthesia, pregnancy tests needed before the provision of certain forms of contraceptives, or other pre and post-operative items and services integral to the furnishing of sterilization surgeries including tubal ligation.

In response to such reports, the Departments are clarifying how plans and issuers can remain compliant while applying medical management techniques, as summarized below.

Therapeutic Equivalence

As an alternative to complying with prior guidance, a plan may provide coverage consistent with the therapeutic equivalence approach outlined in these FAQs. Specifically, with respect to FDA-approved contraceptive drugs and drug-led devices, if a plan utilizes medical management techniques within a specified category described in the HRSA-supported Guidelines (or group of substantially similar products that are not included in a specified category), the Departments will generally consider such medical management techniques to be reasonable if the plan covers all FDA-approved contraceptive drugs and drug-led devices in that category (or group of substantially similar products) without cost sharing, other than those for which there is at least one therapeutic equivalent drug or drug-led device that the plan or issuer covers without cost sharing.

The Departments will determine whether a drug or procedure is therapeutically equivalent using the FDA's "Orange Book." Forms of contraception that are not FDA-approved drugs or drug-led devices are not listed in the Orange Book. Therefore, the therapeutic equivalence approach described above does not apply to such other forms of contraception.

Exceptions Process

Regardless of approach, and even if a plan covers a substantially similar product or service in a given category, the plan must also have in place an exceptions process that would allow the individual to access the medically necessary product or service without cost sharing; the individual's provider determines medical necessity.

Example: Within the category of "oral contraceptives (combined pill)," a plan covers all FDA-approved oral contraceptives (combined pill) products without cost sharing, other than those for which there is a therapeutic equivalent that is covered without cost sharing. Specifically, the plan covers Pill A, Pill B, and generic Pill D without cost sharing. Neither Pill A nor Pill B has a therapeutic equivalent product according to the Orange Book. Pill W, Pill X, and Pill Y, as well as Pill Z (which is a more expensive brand name product) are all classified in the Orange Book as therapeutic equivalents to Pill D and are not covered by the plan without cost sharing. However, the plan provides an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on an individual or their provider (or other individual acting as the individual's authorized representative). The plan's exceptions process allows an individual to receive coverage without cost sharing for a therapeutic equivalent to Pill D (i.e., Pill W, Pill X, Pill Y, or Pill Z) if the therapeutic equivalent product is determined to be medically necessary with respect to the individual, as determined by the individual's attending provider.

Conclusion: The plan's medical management techniques with respect to the category of "oral contraceptives (combined pill)" are generally reasonable. However, the plan's medical management techniques could be considered unreasonable if the plan imposes additional medical management techniques that are problematic, such as those highlighted earlier in this article.

Reporting Noncompliance

The FAQ provides contact information at relevant state and federal agencies that individuals with concerns about their plan's compliance with the contraceptive coverage requirements should contact.

Employer Action

It is important for plan sponsors to understand that the Departments do not view this set of FAQs as adding any additional requirements to health plans and plan designs that were compliant before the publication of this guidance remain compliant. Groups that have a fully insured plan can defer to the insurance carrier to deploy reasonable medical management techniques and designs. For groups that are self-insured, it is recommended to review the plan design and any medical management techniques with their third-party administrators in order to ensure compliance with the ACA's contraceptive care requirements.