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ACA-Required Coverage of Contraceptive Care Remains Agency Focus

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Once again, the U.S. Departments of Labor, Health and Human Services, and the Treasury have issued guidance on the Affordable Care Act's (ACA) required coverage of contraception without cost sharing, clarifying the permitted use of reasonable medical management techniques to set coverage limitations on contraceptive care.

Quick Hits

- Despite repeated clarification regarding what the U.S. Departments of Labor, Health and Human Services, and the Treasury consider to be reasonable medical management techniques, the departments continue to identify plans that are out of compliance, creating barriers to contraceptive coverage.
- Medical management techniques within a specific contraceptive category will be considered reasonable if the plan covers, without cost sharing, all FDA-approved contraceptive drugs and drug-led devices, other than those for which there is at least one therapeutic equivalent drug or drug-led device that is covered without cost sharing.
- When a therapeutic equivalent treatment is covered, the departments expect health plans to have a reasonable exceptions process available.
- The guidance reinforces that contraceptive coverage is a compliance priority for the departments.

Background

The ACA requires non-grandfathered group health plans to cover, without cost sharing, preventive care and screenings for women, as described in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). When the HRSA guidelines do not specify the frequency, method, treatment, or setting for a recommended preventive service, plans are allowed to use "reasonable medical management techniques" to determine coverage limitations.

The HRSA guidelines recommend that women have access to the full range of contraceptives and contraceptive care, to prevent unintended pregnancies and improve birth outcomes. This includes the

full range of U.S. Food and Drug Administration (FDA) approved, granted, or cleared contraceptives, effective family planning practices, and sterilization procedures.

On January 10, 2022, the departments issued guidance in the form of answers to frequently asked questions (FAQs) that summarized prior guidance on the required coverage of contraceptive care. Then, on July 28, 2022, the departments released FAQs that require plans and issuers to: (1) cover without cost-sharing at least one form of contraception in each of the categories listed in the HRSA-supported guidelines, and (2) cover without cost-sharing any contraceptive services and FDA-approved products that an individual's attending provider has determined to be medically appropriate.

Unreasonable Medical Management Techniques

Despite the 2022 guidance, the departments have continued to see a number of "unreasonable medical management techniques" and "problematic practices" by plans and insurers, including:

- using step-therapy ("fail-first") protocols before approving medically necessary contraceptive coverage "as determined by the individual's attending health care provider";
- imposing age-related restrictions for a contraceptive service or product that is medically necessary "as determined by the individual's attending health care provider";
- "[i]mpos[ing] unduly burdensome administrative requirements as part of an exceptions process"; and
- "[r]equiring cost sharing for services that are integral" to preventive contraceptive care, "such as anesthesia [and] pregnancy tests needed before the provision of certain forms of contraceptives."

2024 FAQs

Because the departments are concerned about continued barriers and difficulty accessing contraceptive coverage without cost sharing, they released another round of ACA-related FAQs on January 22, 2024, which contain the following additional guidance regarding the application of "reasonable" medical management techniques:

- If a plan applies medical management techniques within a category of contraceptives, the departments will generally consider them to be reasonable if the plan covers all FDA-approved contraceptive drugs and drug-led devices in that category (for example, implantable forms of contraceptive devices) without cost sharing, "other than those for which there is a therapeutic equivalent that is covered without cost sharing." (Drugs will be considered therapeutically equivalent if they are identified as therapeutic equivalents in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the "Orange Book.")
- Even when a therapeutic equivalent treatment is covered, plans must maintain an exceptions process so that individuals can access coverage without cost sharing for a contraceptive service or FDA-approved contraceptive product that is medically necessary, "as determined by the individual's attending provider." This exception process must be reasonable and not unduly burdensome on the individual or the individual's provider.
- Plans "must cover, without cost sharing, items and services that are integral to the furnishing of a recommended preventive service, regardless of whether the item or service is billed separately."

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