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Agencies Update Guidance on Group Health Plan Contraceptive Coverage Requirements

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The Departments of Labor, Treasury, and Health and Human Services (the "Departments") recently issued guidance for group health plans outlining a "therapeutic equivalence" medical management technique for required preventive services coverage of contraceptives. The guidance, which was issued in the form of FAQs that can be downloaded here, builds on previous FAQs addressing required contraceptive coverage.

How did we get here?

By way of short background, the Affordable Care Act requires non-grandfathered group health plans to cover, without cost-sharing, certain preventive services and items when provided in-network. (For more on the scope of required preventive services coverage, see our prior blog post here).

In the context of contraceptive coverage, the Departments have interpreted the preventive services mandate to require that non-grandfathered group health plans cover, without participant cost-sharing, the following items and services when provided in-network: (1) at least one form of contraception in each of the categories listed in comprehensive guidelines supported by the Health Resources and Services Administration (the "HRSA-supported guidelines") and (2) any FDA-approved, cleared, or granted products and contraceptive services that an individual and attending provider have determined to be medically appropriate for the individual. (The latter requirement applies to the item or service regardless of whether it is listed in the current HRSA-supported guidelines.)

Can group health plans apply medical management techniques to required preventive services coverage of contraceptives?

Generally, yes. However, the technique may be applied (1) only within a specified category of contraceptives described in the HRSA-supported guidelines (or, for contraceptives not described in HRSA-supported guidelines, within the group of substantially similar services or products) and (2) only to the extent that the HRSA-supported guidelines don't specify the frequency, method, treatment, or setting for the item or service. (For a full list of HRSA-supported categories, see here).

As set forth in prior guidance and emphasized by the Departments in the latest round of FAQs, medical management techniques applied to contraceptives within a particular category will not be considered reasonable ***unless*** the health plan maintains an easily accessible and sufficiently expedient exceptions process and the plan covers without cost-sharing any specific contraceptive or device that is medically necessary for the individual, as determined by the individual's attending provider.

That all sounds settled in prior guidance. What is the new guidance about?

The new guidance does not change the underlying preventive services mandate applied to contraceptive coverage. Rather, the new FAQs outline a "therapeutic equivalence" medical management technique that can be used by group health plans (along with an exceptions process) to administer required contraceptive coverage.

How does the "therapeutic equivalence" approach work?

It requires that the group health plan cover, without participant cost-sharing, all FDA-approved drugs and drug-led devices within a specified HRSA-supported guidelines category (or for items and services not included in HRSA-supported guidelines, within a group of substantially similar products or services) ***other*** than those drugs and drug-led devices for which there is a therapeutic equivalent that the plan covers without cost-sharing. Whether a contraceptive drug or drug-led device is considered a therapeutic equivalent is based on the drug's rating in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

If a plan uses the therapeutic equivalence approach, the plan must maintain an exceptions process and cover without cost-sharing any specific contraceptive that is medically necessary for the individual, as determined by the individual's attending provider. The FAQs emphasize that the plan's maintenance of a compliant exceptions process is key, as the Departments continue to receive reports of non-compliant exceptions processes and participants encountering barriers to contraceptive coverage.

Help! I need an example of how this works in practice.

Assume a health plan covers Pill A, Pill B, and Pill C without cost-sharing. Pill W, Pill Y, and Pill Z are covered with cost-sharing. All pills are within the HRSA-supported category of FDA-approved oral contraceptive (combined pill) products. Pill W, Pill Y, and Pill Z are identified in the Orange Book as therapeutic equivalents to Pill C.

The plan's medical management technique with respect to this category would be considered reasonable. Although the plan does not cover Pill W, Pill Y, and Pill Z without cost-sharing, it does cover Pill C without cost-sharing (and Pill C is a therapeutic equivalent to Pill W, Pill Y, and Pill Z). The conclusion that the technique is reasonable in this situation is conditioned on the health plan maintaining an exceptions process and permitting an individual to receive without cost-sharing Pills W, Y, or Z if that particular Pill is determined to be medically necessary with respect to the individual as determined by the individual's attending physician.

Can a plan apply the therapeutic equivalence approach for all forms of contraception required to be covered under the preventive services mandate?

No. The Orange Book does not cover forms of contraception that are not FDA-approved drugs or drug-led devices. This means that the Orange Book does not cover contraceptive methods that are required preventive services, but are not drugs or drug-led devices (*e.g.*, fertility awareness-based methods). As a result, group health plans would not be able to use the therapeutic equivalence approach for those contraceptive items and services.

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Next steps for plan sponsors? Given the emphasis on continued reports of non-compliance in the FAQs, plan sponsors should review their current exceptions processes and confirm their contraceptive coverage complies with the Departments' guidance. For many plan sponsors, this will likely require connecting with their pharmacy benefit manager (PBM) to review the current scope of coverage and assess whether any changes are needed.

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