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# Summary of Proposed Rules Enhancing Coverage of Preventive Services Under the Affordable Care Act

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## Executive Summary

The Departments of the Treasury, Labor, and Health and Human Services (HHS) (“Departments”) recently issued proposed guidance related to the coverage of preventive services in the Affordable Care Act (ACA) markets.<sup>1</sup> A fact sheet accompanied this.<sup>2</sup>

The document, **CMS-9887-P**, outlines proposed rules to enhance preventive services coverage under the Affordable Care Act (ACA). It details changes to the requirements for health plans, focusing on accessibility, transparency, and equity in coverage for preventive care, including contraceptive services and over-the-counter (OTC) products. The requirements included are proposed to be effective January 1, 2026.

The guidance primarily addresses two topics related to preventive services. The first is about the [Exceptions Process](#) that issuers must implement for medical management techniques to be considered reasonable. This section proposes to clarify and codify guidance related to the process for which an enrollee could access alternative preventive treatments and services without cost-sharing if the treatments and services provided under current medical management techniques are not medically appropriate. It also discusses how the process should be clear and not burdensome to the enrollee or their medical provider.

The second topic is related to coverage for [contraceptives](#). The Departments cited several studies showing the barriers in place for enrollees to access the full range of contraceptive services. The Departments believe guidance to address these barriers would require significant changes to plan and issuer current processes and, therefore, have proposed an incremental approach. These particular proposals primarily discuss OTC contraceptive coverage, including discussions around networks, medical management techniques, exceptions process, and [communication](#).

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<sup>1</sup> <https://www.cms.gov/files/document/cms-9887-p.pdf>

<sup>2</sup> <https://www.cms.gov/newsroom/fact-sheets/enhancing-coverage-preventive-services-under-affordable-care-act-proposed-rules>



## Exceptions Process

The Departments are proposing to codify the requirement that plans and issuers that utilize reasonable medical management techniques regarding preventive services must also provide an *“easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other person acting as the individual’s authorized representative) under which the plan or issuer covers without cost-sharing the recommended preventive service according to the frequency, method, treatment, or setting determined to be medically necessary with respect to the individual, as determined by the individual’s attending provider.”*<sup>3</sup> Thereby, if a plan or issuer is using medical management techniques on preventive services where a service is not considered medically appropriate, an unduly burdensome exceptions process must be in place, where an alternative “medically necessary” service would be covered without cost sharing.

Another way of saying this is, if medical management is used to provide an individual with a particular service with no cost-sharing. Still, their doctor determines this service is not medically appropriate, a process must allow the individual to receive the medically necessary treatment, as determined by their doctor, even if the alternate service is generally not available or not available with no cost-sharing.

The proposed guidance requests guidance on this process but specifically notes that a provider might consider *“severity of side effects, differences in permanence and reversibility of a recommended preventive service, and ability to adhere to the appropriate use of the recommended preventive service, as determined by the attending provider”* as considerations about whether a drug is medically appropriate.

Medical management techniques for preventive services are not considered reasonable without an exception process. However, the Departments noted they have received many complaints regarding violations of this guidance. The Oversight Committee survey found that PBMs denied, on average, 40 percent of exception requests, with one PBM denying more than 80 percent of requests in a year.

Comments are also solicited regarding how an exception process would be *“easily accessible, transparent, and sufficiently expedient.”* Generally, the process should be easily identifiable and understood, not require an appeals process, and have a contact available. It is recommended that a standardized form be considered, and the process should be accessible in writing and electronically.

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<sup>3</sup> II. Overview of the Proposed Rules - A. Coverage of Recommended Preventive Services - 1. Reasonable Medical Management of Recommended Preventive Services: Exceptions Process



## Coverage of Contraceptive Items

The Departments are concerned that women are not able to use their contraceptive of choice and cited many surveys and studies that showed many issuers are failing to provide coverage for a full range of contraceptive services consistent with Department expectations.<sup>4</sup> Therefore, the guidance proposes expanding the coverage scope for contraception using an incremental approach.

The Departments propose requiring that plans and issuers cover contraceptives available over the counter (OTC) without cost-sharing or requiring a prescription. OTC contraceptive products include but are not limited to, contraceptive sponges, spermicides, emergency contraception (levonorgestrel), and daily oral contraceptives, which have FDA approval.<sup>5</sup> Comments were also requested regarding a plan's experience regarding the challenges of covering OTC products without a prescription or how this affects the ability to negotiate the price of OTC products.

Also, for a plan or issuer's medical management techniques to be considered reasonable, a therapeutic approach is required to be applied to contraceptive drugs and drug-led products. Definitions for therapeutic approach and drug-led products were also proposed as:

1. Drug-led combination product “means a combination product, as defined under 21 CFR 3.2(e), that comprises a drug and a device, and for which the drug component provides the primary mode of action.”
2. Therapeutic equivalent has the meaning given the term therapeutic equivalents in 21 CFR 314.3(b), which “are approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.”<sup>6</sup>

The Departments requested comments on whether these proposals should only be included regarding contraceptives or if they should be applied to all preventive services (or a larger subset of preventive services), consistent with the goal of “*minimizing barriers to coverage and expanding the scope of coverage without cost sharing for all recommended preventive services.*” Tobacco cessation was mentioned as a preventive service that could benefit.

The proposed rule does not require preventive services to be provided out-of-network or at no cost-sharing out-of-network unless there are no providers in the network who can provide a recommended preventive service.<sup>7</sup> A discussion regarding pharmacies was included, whereby the rule acknowledges that retail stores that include pharmacies may not be considered in-network. Therefore, if contraceptives were purchased at the retail store, they would be considered out-of-network, and coverage would not be required. However, if purchased at the pharmacy, they would

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<sup>4</sup> II. Overview of the Proposed Rules - A. Coverage of Recommended Preventive Services - 2. Coverage of Contraceptive Items

<sup>5</sup> II. Overview of the Proposed Rules - A. Coverage of Recommended Preventive Services - 2. Coverage of Contraceptive Items - a. Coverage of OTC Contraceptive Items Without Cost Sharing

<sup>6</sup> <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-314/subpart-A/section-314.3>

<sup>7</sup> II. Overview of the Proposed Rules - A. Coverage of Recommended Preventive Services - 2. Coverage of Contraceptive Items - a. Coverage of OTC Contraceptive Items Without Cost Sharing - (1) In-Network and Out-of-Network Coverage of OTC Contraceptive Items



be covered at no cost-sharing. Additionally, contraceptive coverage is expected to be provided consistent with other preventive services.

The Departments also requested comments of various scenarios, including:

1. If a preferred OTC contraceptive is out of stock, should non-preferred be covered without cost-sharing and an exception process? How should this be documented?
2. What standards and guidance are helpful to ensure individuals can maintain access to OTC contraceptives without cost sharing out-of-network if in-network providers are not available?
3. Is additional guidance required for individuals to obtain OTC contraceptives at zero cost sharing outside of the traditional system of network providers without burdensome reimbursement requirements?
4. How can plans and issuers be incentivized to build a broad network allowing the full range of OTC contraceptives to be available in-network?
5. How should exceptions process requirements apply to OTC contraceptives, where no provider is involved?

The Departments are also interested in establishing guidance on reasonable medical management techniques for contraception. Plans and issuers “*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 health service.*”<sup>8</sup> The following would not be considered reasonable or consistent:

1. Coverage limitations that only allow for a 1-month supply of an OTC oral contraception per instance of dispensing.
2. Imposing a prescription requirement for OTC contraception as a form of medical management, including requiring an individual to fail first using a prescription-only contraceptive item before providing coverage of an OTC contraceptive item without cost sharing or to require an individual to fail first with numerous prescription or OTC contraceptive items before the plan or issuer approves coverage for a medically necessary OTC contraceptive item.
3. Age- and gender-based medical management of OTC contraceptive services is reasonable unless the technique relies on a clinical rationale for limiting access to individuals of a certain age or gender and is consistent with FDA approvals of any particular OTC contraceptive product.

Additionally, therapeutic equivalence was proposed as a guardrail against narrow drug formularies regarding contraceptive drugs and drug-led combination products.<sup>9</sup> The guidance proposes “*a therapeutic equivalent drug or drug-led combination product would be designated with a code with*

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<sup>8</sup> II. Overview of the Proposed Rules - A. Coverage of Recommended Preventive Services - 2. Coverage of Contraceptive Items - a. Coverage of OTC Contraceptive Items Without Cost Sharing - (2) Reasonable Medical Management Techniques for OTC Contraceptive Services

<sup>9</sup> II. Overview of the Proposed Rules - A. Coverage of Recommended Preventive Services - 2. Coverage of Contraceptive Items - b. Therapeutic Equivalence Approach to Reasonable Medical Management for Contraceptive Drugs and Drug-Led Combination Products



the first letter “A” in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).”

If the therapeutic equivalent drug is documented, the proposal would allow medical management techniques; however, if there is no therapeutic equivalent or drug-led combination product, plans or issuers would NOT be permitted to use medical management techniques.

The following example was provided, which we believe is helpful in understanding:

*“If the Orange Book does not identify a therapeutic equivalent for either Pill A or Pill B, but identifies the latter four (Pill W, Pill X, Pill Y, and Pill Z) as therapeutic equivalents of each other, then under these proposed rules, the plan would be required to cover without cost sharing Pill A and Pill B, for which there are no therapeutic equivalents. The plan could utilize reasonable medical management techniques that result in it covering only one of Pill W, Pill X, Pill Y, or Pill Z without cost sharing because all four are therapeutically equivalent to each other.”*

However, the Departments recognize in the Orange Book that the FDA does not evaluate therapeutic equivalence for OTC drugs or OTC drug-led combination products, so they are requesting comments on any alternative approaches to determining therapeutic equivalence and what medical management techniques should be considered appropriate.

## Communicating OTC Contraceptive Coverage Requirements

The guidance also discusses how consumers should be notified of coverage of OTC contraceptives, considering OTC is often not covered.<sup>10</sup>

One proposal would require plans and issuers to explain coverage for OTC contraceptives whenever an enrollee requests information about any covered contraceptive drug or service. This would include information such as a phone number or internet link so an enrollee could learn more.

The Departments requested comments on several items:

1. Should the OTC notification include both phone number and internet link, or just one?
2. Whether plans or issuers should be required to include the general names or types of OTC contraceptive items that are covered (for example, “daily oral contraceptive,” “Plan B (levonorgestrel),” or “condoms”).
3. Whether plans or issuers should be required to discuss therapeutic equivalents or the exceptions process on the disclosure and how that impacts cost-sharing.
4. How challenging will it be to implement and maintain disclosure statements, their effectiveness, and other items to consider for other preventive services?
5. Other methods of exposing the public to this information, specifically to vulnerable and underserved communities, including what steps should be taken to access OTC contraceptive items.

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<sup>10</sup> II. Overview of the Proposed Rules - II. Overview of the Proposed Rules - B. Communicating OTC Contraceptive Coverage Requirements