



December 1, 2023

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Julie Su
Acting Secretary of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

The Honorable Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220

Submitted electronically via regulations.gov

Re: Request for Information; Coverage of Over-the-Counter Preventive Services [RIN 1210-ZA31]

Dear Secretaries Becerra, Su, and Yellen:

The Academy of Managed Care Pharmacy (AMCP) thanks the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury (collectively, the Departments) for the opportunity to provide comments in response to the request for information titled “Coverage of Over-the-Counter Preventive Services” published in the Federal Register on October 4, 2023.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP’s nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

Coverage of Over-the-Counter Preventive Services

AMCP supports the use of over the counter (OTC) preventive products when medically appropriate, safe, and effective but opposes broad coverage requirements when there is no prescription for the medication. AMCP does not believe the government should mandate coverage of specific pharmaceuticals, especially without direction from a healthcare professional. Benefit design, including coverage determination, must be the responsibility of

managed care organizations so they may ensure the provision of appropriate services for their members. Coverage determination when used in conjunction with other managed care pharmacy tools, such as formularies, drug utilization review and medical treatment guidelines promote quality and optimal outcomes. As part of developing a sound formulary system, managed care plans use a variety of tools and strategies with input from practicing health care professionals and Pharmacy and Therapeutic Committees. To ensure the provision of appropriate services for their members, managed care organizations must have authority to determine when to cover medication, and in making these determinations, should be able to consider medical appropriateness, fiscal responsibility, and principles of compassionate use. If the Departments determine that coverage of OTC preventive products is to be required, the Departments should ensure that sufficient guardrails are in place. For example, the Departments should allow payers to use appropriate medical management strategies and apply reasonable quantity limits.

Even with such guardrails in place, adding coverage requirements without cost sharing will be expensive for payers. This will likely lead to higher premiums as payers try to find ways to cover these new expenses. The Departments should also consider other possible unintended consequences, such as the potential for drug companies to see an opportunity to increase the price of these products knowing that payers must cover them. This could further raise costs across the healthcare system while leaving uninsured individuals with access to fewer preventive medications as pricing moves out of reach. The Departments should also ensure guardrails against the possibility of fraud, waste, and abuse. Requiring a prescription allows the plan to monitor for FWA and to ensure the appropriate covered drugs are being dispensed to the plan's covered members.

Operational Challenges

AMCP's members are concerned about the operational challenges that coverage of OTC preventive services could require.

Submitting the claim is the initial hurdle, which could generally be accomplished by having the patient take the product to the pharmacy counter for the pharmacist to process it on the patient's insurance. AMCP's members are concerned about whether plans would be able to use their existing pharmacy network for these types of claims. If there is a requirement to allow any pharmacy to process the claims, it could increase costs by adding markups to the OTC.

It is also important to consider the variety of other possible locations where patients might obtain OTC preventive products and how that might impact claims. In addition to brick-and-mortar retail pharmacies, OTC preventive products may be available through mail order pharmacies and at retail locations that lack pharmacies such as online retailers, grocery stores, convenience stores, and/or gas stations. Scenarios that do not involve a pharmacy would likely require the patient to purchase the product and then submit a claim for post-payment reimbursement. If patients can purchase OTC preventive products at these types of locations, there are fewer cost controls in place, further increasing the potential for increasing costs. Post-purchase reimbursement is also likely to be burdensome for patients and insurers, even on a limited basis, which is a lesson learned from COVID. Store receipts often do not have sufficient detail to process the claim. Other lessons learned from COVID tests include over-testing and products that never get used and then expire.

AMCP believes that utilization management strategies should be available to help control costs. For example, step therapy could be used if a prescription generic contraceptive is cheaper than the OTC version for both the plan and member. An additional avenue for controlling costs is to prevent waste, such as with appropriate quantity limits. These utilization management strategies are an important tool for managing costs and should be made available if coverage of OTC preventive services is to be required.

Another possible approach that the Departments should consider is the use of an OTC card. Such a card could be used to purchase preventive products as part of the plan's benefit design. An OTC card would function much like a debit or credit card, allowing the patient to purchase a covered item at a participating retailer and deducting the price from the OTC card balance.

Fraud, Waste, and Abuse

AMCP encourages the Departments to include guardrails against fraud, waste, and abuse. Requiring a prescription is an important guardrail. AMCP is concerned that, without a prescription, there is limited ability to ensure that the insured individual is the one using the product (e.g., OTC products can be used by family, friends, etc.). Additionally, without a prescription, online telehealth providers could improperly process OTC products at pharmacies they own to make a profit. Other valuable guardrails include appropriate quantity limits, in-network only coverage, and requiring point-of-sale claims. The Departments should also consider additional penalties for engaging in fraud, waste, and abuse.

Strategies to Increase Use of OTC Preventive Products

AMCP believes that standardized communications about coverage of OTC preventive products and education by all stakeholders are critical. These educational efforts should be available in accessible formats and multiple language and should inform Americans about healthy behavioral and lifestyle changes, behavioral approaches to preventive care, personal accountability, and responsibility. The OTC product should not be a first solution in many clinical cases.

Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Director of Regulatory Affairs, Geni Tunstall, at etunstall@amcp.org or (703) 705-9358.

Sincerely,



Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer