

# CMS Coverage of Over-the-Counter Preventive Services (CMS-9891-NC) RFI Comment

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This document is submitted by the Massachusetts Health Data Consortium (MHDC) and its Data Governance Collaborative (DGC) in response to the CMS Coverage of Over-the-Counter Preventive Services RFI (CMS-9891-NC) posted in the Federal Register on October 4, 2023 and found here:

<https://www.federalregister.gov/documents/2023/10/04/2023-21969/request-for-information-coverage-of-over-the-counter-preventive-services>

## About MHDC

Founded in 1978, MHDC, a not-for-profit corporation, convenes the Massachusetts's health information community in advancing multi-stakeholder health data collaborations. MHDC's members include payers, providers, industry associations, state and federal agencies, technology and services companies, and consumers. The Consortium is the oldest organization of its kind in the country.

MHDC provides a variety of services to its members including educational and networking opportunities, analytics services on both the administrative and clinical side (Spotlight), and data governance and standardization efforts for both clinical and administrative data (the Data Governance Collaborative/DGC and the New England Healthcare Exchange Network, respectively).

## About DGC

The DGC is a collaboration between payer and provider organizations convened to discuss, design, and implement data sharing and interoperability among payers, providers, patients/members, and other interested parties who need health data. It is a one stop interoperability resource. The DGC primarily focuses on three areas:

1. Collaboration: Development of common understanding of and specifications for data standards, exchange mechanisms, and what it means to participate in the modern health IT ecosystem
2. Education: helping members understand their regulatory obligations, the data and exchange standards they're expected to use, and modern technology and related processes
3. Innovation: Identification and development of projects and services needed to make modern health data practices and exchange a reality

## General Comments

This section comments on the RFI or comments on items that cross multiple sections of the RFI or that do not have questions.

### Payer Coverage of OTC Items with Prescriptions

Participants in our Data Governance Collaborative were struck by the general assumption in this RFI that payers are currently paying for OTC items if the patient has a prescription for the item. While this was often true perhaps 15-20 years ago, over time this practice has waned and it has become rare for payers to cover OTC items for patients even if they have a prescription. This is true whether the OTC item is a preventive or meant for acute treatment.

This is particularly problematic when a medication, preventive or otherwise, moves from being available only with a prescription to becoming available over the counter. Having a medication move from being covered by a patient's health insurance to not being covered by it can be a huge financial burden on patients for several

reasons:

1. The standard OTC dosing is often lower than the prescription dosing, meaning someone taking the medication as a daily prescription has to buy a significantly higher quantity than someone who is just trying the medication out of interest or to deal with a new short-term issue. In addition, stores may limit purchase amounts to less than the dosage a long term/preventive care patient needs because they assume most people will be using it for acute care. In some cases, this can be solved by getting a prescription for the higher dose – allowing the pharmacist to dispense that dose but paying for it out of pocket because it's not actually covered by insurance. However, in some cases pharmacists may not have the ability to process prescriptions for OTC items and will direct patients to the OTC displays.
2. Medications that have generic equivalents as a prescribed substance often only have brand name versions when they first transfer to over the counter, automatically increasing the cost
3. Medications that previously counted toward out of pocket maximums no longer do so, meaning that the added expense is all extra money the patient has to pay above and beyond their expected maximum healthcare costs for the year

For example, an allergy inhaler moved from prescription only to over the counter in 2022. As a prescription it was sold in 200 dose inhalers and available as a generic via multiple manufacturers. Someone who uses it daily as a preventive drug to prevent acute allergy attacks uses 8 doses per day, meaning each prescription inhaler lasted for approximately 25 days. Because of this, the patient was able to get two inhalers covered every 30 days so long as their prescription was written to dispense two at a time. The patient paid less than \$15/fill for the two inhalers before they hit their out of pocket maximum, after which it was free. When it originally went over the counter, it was sold only under a brand name in 50 dose inhalers which typically cost around \$20 each (the price has since gone down a bit and larger sizes have also been released). That meant the patient went from paying perhaps \$60-75/year (depending on exactly when they hit their out of pocket maximum) to paying over \$100/month every month for the entire year for the same medication. The patient technically still had a prescription for the medication, but it was no longer covered by their insurance as soon as it became available OTC. For this patient, it was the fifth or sixth medication they take that had moved from prescription to over the counter (over a period of years). This is a significant burden.

Further, even in the rare cases where a preventive over the counter medication is covered by insurance, it is rarely covered with no cost sharing for the patient which is the proposal here. It does not seem reasonable to cover over the counter items at a better rate than prescription items.

We respectfully request that any actions taken in this area include over the counter items with a prescription. If coverage of any items – with or without a prescription – winds up including cost sharing, we also ask for a requirement that those costs count toward patient out of pocket maximums.

## Items that Can Be Either Preventive or Used for Acute Care

We note that there are many items that can be used either for preventive or acute care. The example of the inhaler in the previous comment is just one such case. If a rule requiring coverage of OTC preventive care comes to fruition, some mechanism for consistently defining when such items qualify and when they do not is warranted.

## Definition of Preventive Care

In general, we believe any rulemaking in this area should include a very clear, very specific definition of preventive service that can be applied consistently across the entire industry and that makes it clear to both payers and patients (as well as any other interested parties) exactly what should and should not be covered by the payer under the rule.

## Reporting of Patient OTC Usage

Participants in our Data Governance Collaborative believe that payer reporting of OTC medication usage to a patient's providers should be a required part of coverage, preferably via FHIR APIs set up for that purpose. We note that, in theory, this would be included in the data required for the proposed Provider Access API in the

proposed CMS Advancing Interoperability and Improving Prior Authorization processes (CMS-0057-P) rule but that rule does not apply to commercial and certain other payers. Thus, a more expansive rule requiring such data sharing would be needed to ensure the data is available for all patients regardless of their insurance type.

## Use of Credit Cards to Pay for Covered OTC Items

Participants in our Data Governance Collaborative had a lively discussion about using debit or credit cards to pay for covered OTC items. The idea of using a card of some type was almost universally suggested as a good mechanism to simplify coverage, but after discussion we decided it likely would need to be a credit card and not a debit card as is often used for other patient direct pay options. Unlike things like a 125 Cafeteria Plan (flexible spending account), health spending account, or the out-of-pocket payment plan being proposed for Medicare, there likely is not a specific dollar amount available to each individual or family making purchases. Thus, the traditional debit cards currently being used by or proposed for such programs likely will not work. Rather a credit card model that allows the patient to charge the appropriate items to the card without a strict, pre-paid amount available to them seems more appropriate.

However, credit cards are more likely to lead to fraud, and likely have a higher dollar amount impact of fraud when it does occur. We realize this will be a concern. We suggest setting a fairly low credit limit on the card but requiring that the balance be paid off by the payer within 7 or 14 days of a charge and the limit be reset automatically to account for the payments (and not wait for a monthly reset cycle if that is the default card behavior).

We are not certain what the exact credit limit should be as we are not certain how much some of the more expensive OTC preventive devices might cost in general or in high cost of living areas. To prevent a huge gap between the likely highest legitimate costs in lower cost of living areas and the credit limit, we suggest considering setting a general limit but requiring a higher limit in very high cost of living areas like Boston, New York City, and San Francisco. This could be adjusted to incorporate high, average, and low areas if preferred.

The limit should also be high enough to allow someone to purchase at least several months of supply of consumable products at once (preferably a year) to accommodate SDOH issues that make frequent smaller purchases difficult or impossible for some patients.

In addition, some mechanism for repayment or freezing of cards if misused by the individual (as opposed to being stolen or used without the consent of the individual) needs to be in place. There are mechanisms used by 125 plan vendors that could also be used here.

## Interoperable Systems to Check Allowed Coverage

Registers behind the pharmacy counter and sometimes in the rest of a drugstore may include special processing that connects to external sources to determine if certain items are covered by 125 plans, HSA accounts, or other types of accounts typically using debit cards to draw down allotted funds. When these systems are engaged, consumers are prevented from using these cards for disallowed items (transactions containing disallowed items will be rejected).

Unfortunately, it is not always possible to know when those checks are available and in place. We encourage CMS to suggest, recommend, or perhaps even require payers to populate such systems with their coverage levels for OTC items. Patients/consumers should then be encouraged to use credit cards associated with their OTC item coverage at the pharmacy counter to maximize the chances such systems are available and engaged at the point of sale.

If CMS chooses to impose specific coverage requirements, perhaps a single centralized database of covered items could be implemented, with the local price of the item attached at the register. This assumes that these items are covered at their retail price rather than some form of contract/negotiated lower rate exists between the specific payer/plan/PBM/whatever and the retailer. If negotiated prices are allowed/in play then these systems would need to connect to plan-specific data.

## Generic vs Brand

With prescription medication, payers are able to require and enforce the use of generic versions of a

medication, should one exist, unless the patient has shown that it is not effective for them (in which case they may need to go through a prior authorization process or some other formal process to acquire permission to use the brand drug).

If the patient is just pulling the medication off the shelf somewhere, that level of control is much more difficult to require or enforce. In addition, for products that move from prescription to over the counter, they often move from having a generic available back to only being available under a brand name for a time. Thus, the patient may be used to buying the brand version and may not even realize it is the same medication (for the most part) when a generic version becomes available over the counter.

Will CMS require payers to cover all versions of an OTC item? Can a payer require the use of a generic if one is available? If so, how do they handle the case of the generic not being effective for the patient? Will they accept historical data from older prescription versions or will patients have to take a knowingly ineffective generic version to prove that it's ineffective before the payer will cover it? How are those types of exceptions or non-typical needs handled? Can the payer require a prior authorization for an over the counter item?

For that matter, what happens if a pharmacy or other store is out of the generic version and only has a brand version available? Is the patient required to pay for the medication out of pocket because of supply chain or inventory issues? Some patients may not be able to shop around for various reasons (transportation issues, pharmacy desert, time pressures before they run out of a necessary preventive medication, etc).

We strongly urge that any requirements around coverage for over the counter preventive items include both generic and brand versions, if applicable.

## **Payer, Pharmacy, and PBM Burden**

Participants in our Data Governance Collaborative note that a system for making any OTC items without a prescription part of any health insurance plan does not exist right now. We acknowledge that there was a limited example of this with the purchase of Covid-19 rapid tests, but none of our participants were part of dealing with the backend processing of those tests and believe it was mainly done via existing prescription methods. Our experiences as a patient make that seem likely.

From a patient perspective, to get Covid-19 rapid tests covered at no cost to the patient at a pharmacy, the request had to go through a pharmacist who sent a normal request to the payer and the payer had to respond to the request with an approval. The first time one of our staff members tried to purchase tests this way, the request was initially rejected and the pharmacist had to call and get it sorted out with the payer to get coverage. Every set of such tests came with a standard prescription label and associated paperwork but with the prescribing clinician information left blank. There was no mechanism for just purchasing the tests and having them covered by the payer or for purchasing them without going through a pharmacist.

To support widespread coverage of OTC preventative items and services without a prescription, there either needs to be an effort to add those items specifically to an approved formulary (either consistently nationwide or on a payer-by-payer basis) and to either have them go through a prescription process or through some type of credit card processing that checks whether coverage is allowed (or both). In theory, manual/paper refund processing could be required but we strongly urge that CMS encourage this only be allowed as a backup mechanism and not for the primary processing of OTC preventative items.

Any of these avenues comes with additional burdens on the pharmacists (processing more items, needing to answer coverage questions about more items, needing to call about more items when discrepancies occur, etc), on PBMs (needing to add additional items to formularies or interface with national lists of required items to cover, more items to process, etc), payers (more items to potentially negotiate in contracts, potentially more items in some type of utilization management programs, more customer support needs for patients with questions about what is/is not covered or how to get their covered items, potentially manual processing plus – in theory - sending of refund checks, etc).

There would likely also be some potential additional burdens on providers as they navigate making recommendations for OTC items that are covered vs those that may not be and other elements that might impact their interactions with patients. There may also be additional burdens on non-medical pharmacy and staff at other retail locations selling newly covered items, especially if they need to connect to systems they

never had to use before.

The educational component would likely also be a burden to all. Patients would need to be educated about their new rights to coverage, as would staff in the healthcare industry at every stage of the process (providers, pharmacy, PBMs, payers, etc) and likely general retail staff at stores that sell OTC products.

## Response to Specific Questions

This section will list specific questions asked in the RFI and provide our responses to them.

### **If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, how could plans and issuers ensure that participants, beneficiaries, and enrollees who purchase OTC preventive products do not incur out-of-pocket costs at the point of sale, or are timely and correctly reimbursed, such as through post-purchase reimbursement by the plan or issuer or other mechanisms?**

In our experience it is extremely difficult to get reimbursed by payers for out of pocket costs that should have been covered by the payer. We strongly recommend a model that prioritizes direct payment to the retailer but that permits submission of receipts for later reimbursement if needed.

We believe the best option is to give each patient a credit card that ties into the patient's payer directly (see general comment above). This ensures that the payer is aware of the purchase and it gets funded via normal card processing mechanisms. If available, controls that ensure the cards are only used for allowed items could be put in place (although that assumes that no exceptions to standard policies are ever made).

### **Would utilization rates differ depending on whether the products were covered without cost to the individual at the point of sale or were reimbursed following purchase?**

It is likely that some patients would have difficulty paying up front for some over the counter preventive items, especially some of the more expensive items. In addition, as noted in a previous comment, it can be difficult to get reimbursement from payers for anything. Any efforts to cover these items without requiring patients to pay up front would be greatly preferable.

This is particularly true for items that move from requiring a prescription to being over the counter as this generally greatly increases the cost of those items for patients in multiple ways (more expensive, sold in smaller amounts at once, not counting toward out of pocket maximums, etc – see general comment above). Patients who have difficulty paying for their share of prescription items will almost certainly have even more problems paying for the same items if they change status.

### **Should plans and issuers be required to cover costs associated with shipping and/or taxes for OTC preventive products?**

Participants in our Data Governance Collaborative note that their Medicare Advantage and Medicaid plans that include a prepaid amount toward OTC items do not cover shipping or taxes. The consensus of the group was that shipping, in particular, should be the responsibility of the patient, especially as they are likely making a deliberate choice to use a procurement method that incurs such fees.

We note that charging taxes on any medical item is problematic and we hope that the jurisdictions that do this are limited and decrease over time. While participants in the DGC noted that they do not cover taxes in the programs mentioned above, MHDC is more ambivalent regarding who should be responsible for any taxes that must be paid.

### **If plans and issuers were required to cover OTC preventive products without**

**cost sharing and without requiring a prescription by a health care provider, what types of reasonable medical management techniques related to frequency, method, treatment, or setting would plans and issuers consider implementing with respect to these products, in instances where an applicable recommendation or guideline did not specify the frequency, method, treatment, or setting for the provision of the recommended preventive service?**

Our Data Governance Collaborative feel this is going to be the most problematic area when it comes to payer coverage of OTC items.

We've already noted several examples that will be problematic in various places within this comment, but we will reiterate/collect some situations that may be problematic and frame them specifically around utilization management here:

- When a prescription medication that can be used for either acute or preventive care goes over the counter, the medication is often labelled for acute usage which often has a lower dosage and nearly always requires less total medication than the preventive dose. If utilization management requirements are put in place (such as placing a maximum allowed dosage or a maximum allowed purchase amount per month, quarter, or plan year) it is reasonable to expect they will be based on the standard OTC labeling and not be sufficient for the preventive use case. As this rule is specifically meant to cover preventive use, that is a problem. Are such patients required to get a prior authorization for over the counter items? We strongly believe that is a bad option as it adds to everyone's burden, but at the same time are payers expected to cover an infinite amount of the medication?
- For patients who may have difficulty with transportation or rely on infrequent visiting relatives to do most of their non-food shopping or otherwise may not be able to run out and buy their medications or other OTC items on a whim, any restrictions limiting the purchase amount to what is expected to be a one month or even quarterly supply may be problematic
- For patients who need to take a specific form of a medication that ostensibly comes in multiple "identical" forms, requiring one form over another will be problematic. The most common form of this situation is likely to be generic vs brand name of a particular medication, but it can also happen for certain inhalers (where one delivery mechanism works much better than another for some patients) and likely in other iterations we're not considering right now.

In general, we believe the following should be considered:

- Payers should be required to cover OTC items with a prescription, full stop. We believe this is a higher priority than covering OTC items without a prescription.
- A patient should not be required to get a prior authorization for any OTC item, and definitely not for one that is typically purchased without a prescription
- A patient should be able to get up to a full year's worth of a consumable OTC item as a single purchase if they wish
- A payer can limit the purchase amount of a consumable OTC item to one year's worth of the item at the dose that's appropriate for the patient even if it's more than the on label amount (perhaps proof of former dosage if the medication was previously taken with a prescription could suffice for this, or requiring a one time prescription for an item that is then carried over throughout the rest of the relationship with the patient whether that spans one plan year or multiple plan years, or perhaps there are other reasonable mechanisms for establishing a patient's expected dose)
- There should be some mechanism to deal with periodic mistakes such as dropping a bottle of pills or having some items go prematurely bad or having a purse with medication in it stolen that would allow for extra coverage of items beyond a one-year supply, with documentation of the reason (like a pharmacist's override for prescription items)

- Should any OTC items be covered in a way that does include cost sharing, those patient costs should count toward out of pocket maximums for the plan year

### **If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, what guardrails would plans and issuers consider implementing to mitigate fraud, waste, and abuse?**

We recognize that fraud, waste, and abuse is a legitimate issue and that ballooning coverage costs come with their own issues such as increased premiums for patients and their employers and increased expenses for payers. At the same time, most of the existing controls are difficult to manage without a system of prescriptions, prior authorizations, overrides, and the like that have been built up between payers, pharmacies, PBMs, and providers.

We believe that limiting consumable items to a one year supply as outlined above will prevent practices such as purchasing items to resell as much as possible (it is likely not possible to prevent this entirely; but even if someone buys a one year supply of a medication they do not actually need to take this likely will not be a sufficient quantity to make reselling worthwhile for them).

If you are not going to require a prescription then there cannot reasonably be limitations on the number or type of medications someone takes; we know several people who take 40-50 medications daily if you include both prescription and over the counter medications and any system must be able to accommodate any patient's normal needs.

### **What other strategies could the Departments implement to increase utilization of OTC preventive products, other than, or in addition to, requiring plans and issuers to cover such products without cost sharing and without a prescription by a health care provider?**

As noted previously, at the current time many payers have significantly limited or ceased coverage for OTC items with a prescription. We believe that just requiring such coverage – even with cost sharing – would be a major step forward for patients so long as any cost sharing counted toward out of pocket maximums. We believe this should be required for both preventive and acute products, but coverage for preventive items would still be helpful.

### **Do workplace wellness programs provide access to OTC preventive products?**

We have encountered workplace wellness programs that provide blood pressure monitors to participants and some of our Data Governance Collaborative participants note that they've been involved in wellness programs that provided FitBit or other similar personal data collection devices. However, this is not universal and others have been part of wellness programs that provided no such items.

### **Under current standards and requirements, do certain populations face additional or disproportionately burdensome challenges to accessing OTC preventive products?**

With the advent of telehealth, some of the additional burdens on populations like disabled individuals or single working parents have been reduced, but any reduction in the need for healthcare appointments can only be a good thing for patients as a whole as well as for providers who are struggling to keep up with appointment demands. Many patients who are only making an appointment to get a prescription refill would no longer need to do so, freeing up the patient to do other things and providers to care for patients with real diagnostic or treatment needs. In addition, the need for an appointment, even a telehealth appointment, could greatly delay access to necessary OTC items as many providers are scheduling months in advance.

### **To what degree would any potential increases in costs or premiums associated with a requirement for plans and issuers to cover OTC preventive products**

## **without cost sharing and without a prescription by a health care provider be offset by greater access to OTC preventive products?**

Participants in our Data Governance Collaborative note that it's extremely difficult to make direct correlations between specific costs and resulting later savings because issues are prevented, caught early, or otherwise ameliorated by use of OTC preventive items.

One case that was particularly called out was the use of smoking cessation products. They almost certainly decreasing smoking which almost certainly lowers costs, but again no one was able to produce quantitative data or even approximate numbers as to the degree this was true or the amounts potentially saved.

Participants also noted that offering something that is known to improve outcomes doesn't automatically lead to improved outcomes. Some of our payer members brought up health club benefits as an example. Many payers offer a health club subsidy as part of their plans and many patients may use that benefit who do not actually use the health club regularly (or even at all). Thus, they do not see any potential health benefits from increased exercise because they did not actually increase their level of exercise.