FAQ: Insurance Coverage for Pharmacy-Dispensed Medication Abortion

Cat Duffy & Liz McCaman Taylor

The U.S. Food and Drug Administration (FDA) announced new changes to the mifepristone Risk Evaluation and Mitigation Strategy (REMS) in January 2023, opening the door to the expansion of medication abortion access through pharmacist dispensing. While telehealth service delivery models are not a panacea for the abortion access crisis in the U.S., pharmacy-dispensed medication abortion can play a crucial step in reducing travel and cost barriers for patients—but only if it is implemented equitably. Comprehensive insurance coverage is an essential component of equitable abortion access and a series of policy changes are needed to ensure plans will cover this delivery model. This FAQ goes through the key concepts and issues surrounding pharmacist-dispensed medication abortion, including the policy changes that are required to facilitate insurance coverage in both public and private plans.

Medication Abortion Overview

What is medication abortion?

A medication abortion (MAB) typically involves taking two medications, first one dose of mifepristone, which blocks progesterone, a hormone needed to maintain a pregnancy, followed by a dose of misoprostol, which causes the uterus to empty. There is also a misoprostol-only regimen that is commonly used internationally. Medication abortion is extremely safe and common, and its use has increased quickly since the FDA approved mifepristone in 2000.

Does Medicaid cover medication abortion?

The Medicaid Act does not differentiate between medication or procedural abortions and since all states and territories have chosen to participate in the optional prescription drug benefit, state Medicaid programs must cover all outpatient drugs from any manufacturer participating in the Medicaid Drug Rebate Program. Danco Laboratories and GenBioPro, the manufacturers of mifepristone, each have a Medicaid rebate agreement in place, which means all state Medicaid programs must cover mifepristone. States that only comply with the Hyde

Amendment must cover medication abortions that are mailed or delivered under the circumstances of rape, incest, and life endangerment; states that use their own funding to cover abortions must reimburse for all medication abortions that are mailed or delivered.

Does private insurance cover medication abortion?

There is no federal requirement that private insurance cover medication abortion. However, plans can and should do so to meet the needs of their enrollees. Note that some states do the exact opposite and ban abortion coverage in their state-regulated plans. There are also some state laws that require abortion coverage in many private plans; these mandates may or may not specifically require medication abortion coverage depending on the statutory language.

Are there restrictions on the dispensing of medication abortion?

Historically, the REMS for mifepristone included strict restrictions on medication abortion, including requiring mifepristone to be dispensed in-person by certified providers. In January 2023, the FDA announced that it was permanently lifting the in-person dispensing requirement and would also allow mifepristone to be dispensed by certified pharmacies. This opens the door to service delivery models where patients can see a provider via telehealth and have the medication abortion prescription sent to a certified pharmacy, where the medication can either be picked from the pharmacy up in-person or sent directly to the patient.

Medical vs. Pharmacy Benefits

What is the difference between drugs covered as medical and pharmacy benefits?

Drugs can be covered as a medical benefit, a pharmacy benefit, or both. Drugs covered as medical benefits are administered by a health care provider in an inpatient or outpatient setting; this care gets billed directly to an insurance company. Drugs covered as pharmacy benefits are dispensed by a pharmacy and self-administered or self-managed by the patient; generally, insurance companies contract out the responsibility for administering these benefits to a third party called a pharmacy benefits manager (PBM).

What is a pharmacy benefit manager (PBM)?

Pharmacy benefit managers (PBMs) are contractors of insurance companies, and they manage pharmacy benefits on the insurance company's behalf, including establishing a formulary and negotiating rebates with drug manufacturers in exchange for preferred status on the formulary. PBMs also contract directly with pharmacies to dispense drugs, and PBMs pay pharmacies for drug and dispensing fees (which account for pharmacy's administrative costs

from processing claims). The contracting insurance company then reimburses the PBM for the drug and dispensing fees it paid the pharmacy, as well as pays the PBM administrative fees for its services.

What is a formulary?

A formulary is the master list of a plan's covered drugs. The formulary is often not a single document, but multiple lists which all together comprise the formulary. For example, a formulary might include a list of drug names, prior authorization requirements for those drugs, National Drug Code numbers for those drugs, and the therapeutic indications for which the drugs are covered. Importantly, being included in the formulary means the drug is a pharmacy benefit.

Is medication abortion both a medical and pharmacy benefit?

Medication abortion is a two-drug regimen comprising mifepristone and misoprostol. Misoprostol is likely included as a pharmacy benefit in most plans already because it is used to treat ulcers. However, PBMs will need to ensure that misoprostol is covered for the purpose of abortion, as opposed to another medically-accepted indication.

Mifepristone, on the other hand, has been highly restricted through the REMS, and is likely not incorporated into a plan's pharmacy benefit. If it is, it is likely for a treatment indication separate from abortion, such as the treatment of endometriosis or fibroids. We believe at least some plans are aware of this issue and are beginning the process of including all medication abortion drugs as pharmacy benefits.

Should medication abortion be switched to the pharmacy benefit?

No, medication abortion should be **added** as a pharmacy benefit, in addition to remaining a medical benefit. Insurance coverage of medication abortion should provide patients with the flexibility to choose the service delivery model that meets their needs and preferences. Some patients may want to see their provider in-person and receive the medication during that interaction, as a medical benefit. Others might want to see their provider via telehealth and have the medication mailed to them, as a pharmacy benefit. Including medication abortion under both the medical and pharmacy benefits is essential to facilitate patient choice and maximize abortion access.

Additionally, in the medical benefit context, medication abortion may be reimbursed as a bundled payment, where payment for prescribing and dispensing are not separated out from one another. The bundled payment structure, when properly implemented, simplifies the billing process and provides a lump-sum payment that accounts for the comprehensive set of

services associated with medication abortion. However, bundled payments are incompatible with pharmacy dispensing, which generally requires both the prescriber and dispenser to be paid separately. This is another reason why medication abortion must be included on both a plan's medical benefit as well as its pharmacy benefit, in this case to preserve the bundled payment structure where it is working for providers. Sustainable reimbursement for abortion services is crucial to maintaining an adequate provider network.

What are some examples of other products that are both pharmacy and medical benefits?

It is best practice for intrauterine devices (IUDs) to be covered under both the pharmacy and medical benefit, so that providers can write a prescription for the enrollee to fill at a pharmacy **or** the provider can "buy and bill" for the IUD themselves. Additionally, depo-provera, an injectable contraceptive, may be on both pharmacy and medical benefits as it has one form which can be self-administered. California advocates led that change in the state's Medicaid program at the beginning of the COVID-19 pandemic.

Pharmacy Access

What kinds of pharmacies can dispense medication abortion under the updated REMS?

People are likely most familiar with retail pharmacies, which have brick and mortar locations in many regions nationwide. Retail pharmacies could belong to a larger chain, or they could be independently owned and operated. They may also have an online or mail-order component to their pharmacy. Some operate solely on an online and/or mail-order basis. In addition to retail pharmacies, there are specialty pharmacies that serve patients who require more complex treatment therapies, and these pharmacies often develop specialized expertise in managing certain conditions. All of these pharmacy types could become certified pharmacies under the REMS.

Does it matter where patients pick up their abortion medication, for purposes of insurance coverage?

Right now, yes. Historically, the mifepristone REMS has restricted the dispensing of medication abortion to in-person interactions with certified prescribers, and as a result, medication abortion has only been included in an insurance plan's medical benefit.

Patients could theoretically get mifepristone right now from a certified pharmacy, but they can only get insurance coverage for pharmacy-dispensed prescriptions if the medication is on an

insurance plan's pharmacy benefit. We are not aware of any plans that have finalized the changes to include medication abortion in their pharmacy benefit. This means currently, in order for a patient to use their insurance coverage to pay for their medication abortion, they must get their medication directly from the prescriber, as a medical benefit, almost as if the 2023 REMS update did not occur.

Will insurers and PBMs need to verify that pharmacies are complying with the REMS before providing coverage?

Yes, insurers and PBMs will need a system in place to verify REMS compliance. It goes without saying that this should be the least burdensome process possible for patients, providers, and pharmacies, while still ensuring patient safety. These verification processes should already exist, since there are many other medications outside of the reproductive and sexual health context that are subject to REMS. For example, the popular acne medication Accutane is subject to REMS. Insurers and PBMs should apply a similar process they use for other REMS drugs to mifepristone. Additionally, the pharmacy benefit software that pharmacies use may have REMS information integrated, so this data can be sent directly to PBMs as part of the initial pharmacy claim.

If a pharmacy is mailing or otherwise delivering medication abortion to the patient, does insurance have to cover those delivery fees?

There is no legal requirement that delivery fees be included as part of the pharmacy benefit, but it is best practice. Multiple state Medicaid programs do include a modest delivery fee in their pharmacy benefit and have billing guidance to support pharmacies in receiving reimbursement; however, the reimbursement often does not cover the actual delivery costs.

Pharmacies can now dispense medication abortion, but can pharmacists prescribe it?

Not yet. The mifepristone REMS distinguishes between certified pharmacies who dispense medications, and certified prescribers who prescribe medications. Becoming a certified pharmacy does not equate becoming a certified prescriber, and vice versa. There are no existing state laws that would allow pharmacists to independently prescribe medication abortion within their scope of practice, and therefore become certified prescribers under the REMS.

However, assuming a pharmacist could otherwise meet all of the requirements for a certified prescriber under the REMS, state advocates could consider legislative or regulatory action that expands pharmacist scope of practice to prescribe medication abortion, similar to successful efforts to expand scope of

pharmacist practice to prescribe smoking cessation medications, contraception, naloxone, vaccinations, and more. In that situation, it would also behoove advocates to simultaneously consider policy that requires insurance coverage of this expanded care.

Payment & Delivery System Reform

What changes are needed for medication abortion to become both a medical and pharmacy benefit?

Now that pharmacies can dispense medication abortion, insurance companies and PBMs must take steps to add misoprostol and mifepristone to the pharmacy benefit when prescribed for abortion, including adding it the drug formulary and potentially contracting with new pharmacies. Once these changes occur, medication abortion would be covered directly at the pharmacy counter just like any other prescription.

Who needs to make these changes?

PBMs and insurance companies both have a role to play. As the administrator of pharmacy benefits, PBMs will negotiate drug prices and then make the necessary changes to their formulary documents. However, PBMs are acting in this capacity as contractors of the insurance company. Ultimately it is the insurer's responsibility, as the contractee, to ensure PBMs are making these changes.

How will these changes take place in Medicaid?

How these changes will happen in the Medicaid context depends on how the state administers its Medicaid prescription drug benefits. In California, for example, prescription drugs are carved out of managed care and administered by the state through a program called Medi-Cal Rx. In that case, the state itself is acting as the insurer, although it does contract with a PBM. Both the state Medicaid agency and the PBM must ensure medication abortion is included as a pharmacy benefit; specific actions include updating the formulary, provider manual, and potentially issuing billing guidance.

Alternatively, prescription drugs may be part of Medicaid managed care, meaning they are administered by a third-party insurance company which then contracts with a PBM. That means there may be three entities—the Medicaid agency, the private health insurance company, and the insurer's PBM—who each have a role to play. The Medicaid agency should inform health insurers of the REMS changes and their expectations regarding medication

abortion as a pharmacy benefit, although ultimately the insurers and PBMs have a lot of discretion when determining the scope of pharmacy benefits.

How long will these changes take?

PBMs update their prescription drug formularies and national drug code (NDC) lists on a regular basis, likely quarterly. The longest part of this process will be PBM negotiations with the drug manufacturers regarding how much they will pay for mifepristone. PBMs generally prioritize coverage of generic drug products over brand names because they are available at a lower cost, but sometimes brand manufacturers will "sweeten the deal" for PBMs with additional rebates to incentivize coverage of their product.

While these changes are not going to be immediate, they should not take more than a few months, and six months at the longest. A significantly longer time frame would indicate that the insurance company and/or PBM are not pursuing these changes in good faith.

What happens if these changes are not made?

Currently, we are relying on insurers and PBMs to act in good faith and make policy decisions that best reflect patient access. There is no legal requirement that plans include medication abortion on both the medical and pharmacy benefit, even in states that generally require coverage of medication abortion. If a plan includes medication abortion at all, on either benefit, it would likely be considered covered for legal purposes.

In the event that insurers and PBMs do not act in good faith to make changes to the pharmacy benefit, advocates should consider legislative action that mandates coverage in both the medical and pharmacy benefit for state-regulated plans.

Conclusion

The updated REMS presents a unique opportunity to expand medication abortion access, but requires intentional benefit design in order to ensure insurance coverage at the pharmacy counter. This FAQ highlights the barriers to coverage due to the bifurcation of medical and pharmacy benefits, as well as necessary payment and delivery system reforms that can mitigate these barriers. We urge state Medicaid agencies and private payers to prioritize these reforms and make the necessary changes to ensure pharmacy-dispensed medication abortion is accessible to all who need it.