Pharmacy Benefit vs. Medical Benefit: Deciphering Coverage Pathways for HIV Medications

The advent of longer-acting injectable antiretroviral therapy (ART) has expanded options for the prevention and treatment of HIV, but because these products are administered by a provider rather than taken as an oral pill, they are often covered differently than oral medications by public and private payers. This brief describes how longer-acting injectable ARTs are covered and the impact those coverage pathways have on access, affordability, and HIV clinic sustainability.

COVERAGE PATHWAYS FOR LONGER-ACTING INJECTABLE PRODUCTS

Longer-acting injectable ARTs are one subset of a much broader category of provider-administered drugs, meaning medications a clinician injects or infuses in a clinical setting rather than ones a patient takes home and self-administers (a category that also includes many oncology and rheumatology biologics). It is this broader category of provider-administered drugs, not anything specific to HIV or to longer-acting formulations more generally, that drives the pharmacy-benefit-versus-medical-benefit distinction. Some payers use only one pathway, while others cover the medication under either and leave the choice to the provider. This shapes access to the drug and what patients pay, and whether they can get the drug, or whether clinics can afford to provide it.

PAYER DECISIONS ON THE COVERAGE PATHWAY

The coverage pathway a payer selects has real implications for patient cost-sharing, clinic revenue capture, access, and affordability, and payers ultimately weigh the medication's net price. Payers, not patients or providers, usually decide whether a drug runs through the pharmacy or medical benefit, mostly based on price after rebates. Medical benefit coverage is often not public, so patients and providers cannot always tell what is covered. For AIDS Drug Assistance Programs (ADAPs), the ability to capture rebates, in practice, depends on which coverage pathway is used.

IMPACT OF COVERAGE PATHWAY ON ACCESS, AFFORDABILITY, AND SUSTAINABILITY

How a drug is covered creates trade-offs for payers, patients, and providers. It shapes access (whether a patient can get the drug), affordability (whether they can pay for it), and sustainability (whether clinics and programs can keep providing it). Cost-sharing and access both shift depending on the pathway.

CLINIC SUSTAINABILITY CONSIDERATIONS

HIV clinics and pharmacies are also impacted by payer coverage decisions. Coverage decisions hit clinics financially. Buy-and-bill forces providers to pay for the drug upfront and risk slow or denied reimbursement, which is hard for small clinics. The pharmacy benefit is steadier but can shrink 340B revenue. Wasted refrigerated doses and complex billing add further strain, especially for smaller providers.

ADAP SUSTAINABILITY CONSIDERATIONS

The pathway affects whether ADAPs can capture the 340B rebates that fund their programs. Rebates are easier to collect through the pharmacy benefit for uninsured clients. Covering drugs as a medical benefit forces ADAPs to handle buy-and-bill and cost-sharing they usually are not set up for, putting rebate revenue at risk.

CONCLUSION AND POLICY CONSIDERATIONS

The coverage landscape for longer-acting injectable ARTs is complex, compounded by a lack of payer transparency about whether a drug is covered as a pharmacy benefit, a medical benefit, or both. While there might be no one-size-fits-all policy, considerations should include allowing pharmacy-benefit coverage options so small providers are not disadvantaged, requiring public listing of medications covered as a medical benefit, providing federal capacity-building support for ADAPs, and encourage good-faith payer-manufacturer pricing negotiations. Above all, affordability must remain paramount. The coverage pathway is largely meaningless if the medication remains unaffordable to the patient at the point of sale.

PATIENT AFFORDABILITY AND ACCESS ACROSS PHARMACY AND MEDICAL BENEFIT

PAYER	PHARMACY BENEFIT	MEDICAL BENEFIT
Commercial insurance	**Affordability:** Patient costs vary based on plan design, including deductible, coinsurance/ copayments, and out-of-pocket maximum. Medications used for HIV prevention should be covered without cost sharing.	**Affordability:** Patient costs vary based on plan design, including deductible, coinsurance/ copayments, and out-of-pocket maximum. Medications used for HIV prevention should be covered without cost sharing.
	Access: White and clear bagging policies allow the pharmacy to ship medication directly to provider, but sometimes there may be delays in patient access to allow time for pharmacy coordination. Additionally, some providers will not accept white-bagged medications.	**Access:** The patient can access the medication at the clinic, where stock is kept onsite. A clinic also may refer a patient to an alternate site of care for administration, which can sometimes delay access or fragment care.

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PATIENT AFFORDABILITY AND ACCESS ACROSS PHARMACY AND MEDICAL BENEFIT		
PAYER	**PHARMACY BENEFIT**	**MEDICAL BENEFIT**
Medicare	**Affordability:** Medications used for HIV treatment are subject to $2,100 Medicare Part D and Medicare Advantage prescription drug benefit out-of-pocket maximum (Medicare Part B covered medications, including all ARTs covered for prevention, are not subject to an annual out-of-pocket maximum).	**Affordability:** For medications used for HIV treatment, there is no out-of-pocket maximum for Medicare Part B drug costs and typically 20% coinsurance. There is no out-of-pocket maximum, but some beneficiaries may receive support from a Medicare Savings Program. Medications for HIV prevention must be covered under Medicare Part B with no cost sharing.
	Access: White and clear bagging policies allow pharmacy to ship medication directly to provider, but there may sometimes be delays in patient access to allow time for pharmacy coordination. Additionally, some providers will not accept white-bagged medications.	**Access:** In addition to provider buy-and-bill arrangements, pharmacies are able to bill Medicare Part B for longer-acting injectable products covered as a medical benefit, however not all pharmacies are registered with Part B, which can limit patient access.
Medicaid	**Affordability:** Medications used for HIV prevention should be covered without cost sharing for individuals in the Medicaid expansion group; other medications may be subject to nominal cost sharing.	**Affordability:** Medications used for HIV prevention should be covered without cost sharing for individuals in the Medicaid expansion group; other medications may be subject to nominal cost sharing.
	Access: White and clear bagging policies allow pharmacy to ship medication directly to provider, but there may sometimes be delays in patient access to allow time for pharmacy coordination. Additionally, some providers will not accept white-bagged medications.	**Access:** The patient can access the medication at the clinic, where stock is kept onsite. A clinic may also refer a patient to an alternate site of care for administration, which can sometimes delay access or fragment care.
ADAP full pay (uninsured)	**Affordability:** No cost sharing	**Affordability:** No cost sharing
	Access: White and clear bagging policies allow ADAP-designated pharmacies to ship medication directly to provider, but there may sometimes be delays in patient access to allow time for pharmacy coordination. Additionally, some providers will not accept white-bagged medications.	**Access:** When ADAP is able to process a buy-and-bill medical benefit claim, the patient accesses the medication at the clinic, where stock is kept onsite. However, many ADAPs are unable to receive and process buy-and-bill claims as a medical benefit, which can pose access challenges, especially when clinics refuse to accept white-bagged medications from ADAP network pharmacies.
ADAP insurance assistance (insured)	ADAP also provides assistance to insured clients, covering client premiums and medication cost sharing. ADAPs can often more easily cover cost sharing for clients when the medication is covered as a pharmacy benefit, because ADAPs are able to use their usual PBM facilitated process. When the medication is covered as a medication benefit, paying the medication cost sharing may be more difficult and require building new infrastructure to track claims payment and capture rebates.	

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MAKING AIDS HISTORY

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