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ISSUE BRIEF

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

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The advent of longer-acting injectable antiretroviral therapy (ART) for the prevention and treatment of HIV has created more options for people at risk of and living with HIV. There are several Food and Drug Administration (FDA) approved longer-acting injectable ARTs on the market, and more options in the research pipeline.[1] Unlike an oral medication (typically a pill taken daily), longer-acting injectable ARTs are currently available as an intramuscular or subcutaneous injection administered by a provider every one, two, or six months depending on the product.[2] Because of the different ways they are administered, longer-acting injectable medications are sometimes covered differently than oral medications by public and private payers. The different coverage pathways for these products can impact patient access and affordability as well as the ability of providers to sustainably procure and administer these products. This issue brief will describe the ways that longer-acting injectable ARTs are covered by public and private payers and the impact these coverage pathways have on access, affordability, and HIV clinic sustainability.

COVERAGE PATHWAYS FOR LONGER-ACTING INJECTABLE PRODUCTS

Public and private payers (including Medicaid, Medicare, private insurance, and public health programs) typically cover a defined set of benefits to enrollees when those benefits are deemed medically necessary. Federal laws require a certain level of HIV medication coverage, but requirements vary depending on payer type (see text box on this page). Payers

FOCUS PAYERS AND FEDERAL COVERAGE REQUIREMENTS

PAYER	FEDERAL COVERAGE REQUIREMENT
Medicaid	Medicaid programs must cover every Food and Drug Administration (FDA)-approved medication for manufacturers that participates in the federal Medicaid Drug Rebate program (Medicaid programs can use utilization management and preferred drug lists)
Medicare	Antiretroviral therapies (ARTs) are one of six protected classes that requires Medicare Part D plans to cover all or substantially all drugs in that class. Medicare Part D plans may not apply prior authorization or step therapy to this class. The six protected classes policy does not apply to drugs covered under Medicare Part B.
Commercial insurance	Most commercial insurance plans have wide latitude to choose which ARTs to cover and whether to apply utilization management. Individual and small group plans are also subject to the Affordable Care Act's (ACA's) Essential Health Benefits requirements and must meet a minimum standard for ART coverage.
Ryan White HIV/AIDS Program (RWHAP) AIDS Drug Assistance Program (ADAP) **(full-pay)**	ADAPs providing medications to uninsured clients must cover at least one drug in every ART class.
RWHAP ADAP **(insurance assistance)**	ADAPs providing premium and medication cost-sharing assistance for insured clients must ensure that insurance formularies meet minimum coverage standards and that ADAP insurance assistance programs are cost-effective in the aggregate.

may also deploy utilization management tools, such as prior authorization, to ensure a service or prescription drug is clinically necessary, requiring a provider to demonstrate the necessity of one medication or service over another.

Payers also must decide how to administratively cover these medications. The coverage pathways for longer-acting injectable products administered by a provider are different from how a payer covers oral or self-administered medications. 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).[3] **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.** While medical benefit is newer for HIV medications, it is common across other provider-administered medications. Longer-acting injectable ARTs are generally covered through one of the two pathways described below:[4]

- **Outpatient pharmacy benefit:** the medication is procured by a retail or specialty pharmacy from an authorized distributor or wholesaler. The pharmacy then ships the medication to a provider's office for administration through white bagging or clear bagging, or in some cases, directly to the patient (brown bagging) (see box below for terms).[5] The pharmacy then submits for reimbursement through the patient's public or private insurance payer for the medication. The provider bills the payer for medication administration services.
- **Medical benefit:** the medication is procured by a provider and administered onsite through a process known as buy-and-bill where the provider buys the medication from a wholesaler or authorized distributor and then submits for reimbursement through the patient's public or private insurance payer for the medication, office visit, and administration services. In some cases, if a provider does not have the capacity to buy and bill longer-acting injectable medications, patients may be referred to an alternate site of care (e.g., an infusion center) that procures, bills for, and administers the medication.[6] Alternatively, a retail or specialty pharmacy will sometimes process a medication covered as a medical benefit on behalf of a clinic, procuring and seeking reimbursement from the payer on behalf of the provider. This arrangement, sometimes called an Assignment of Benefits (AOB), varies by payer and is not universally available.

While some payers choose only one coverage pathway for a particular medication, others cover the medication under either pathway, leaving it up to the provider to make a choice about how to process and/or bill for the medication.

PAYER DECISIONS ON COVERAGE PATHWAY

The coverage pathway for a longer-acting injectable product has implications for access, affordability, and clinic sustainability. For example, the coverage pathway may impact patient cost-sharing obligations and clinic revenue capture opportunities. Payers are ultimately responsible for choosing whether a medication is covered as a pharmacy or medical

MEDICATION PROCUREMENT AND REIMBURSEMENT TERMINOLOGY

Buy-and-bill: Provider or clinic purchases medication from wholesaler or distributor and maintains an inventory of the drug for use on an as-needed basis. Following administration of the medication, the provider submits a reimbursement claim for both the medication and administration services to the patient's public or private payer.

Brown bagging: A pharmacy ships a medication prescribed by a health care practitioner directly to the patient, who then brings the medication to the provider's office for administration. The pharmacy bills the payer for the medication, the provider bills for any administration costs.

White bagging: Providers submit a prescription to a payer's network pharmacy, which processes the claim and ships the product to the provider. The pharmacy procures and bills the public or private payer for the medication and the provider bills for any administration costs.

Clear bagging: A hospital or health system's in-house pharmacy maintains inventory of the medication and processes the claim when a prescription is received from a health system provider, and then delivers the medication for the patient's drug administration appointment. The in-house pharmacy procures and bills a public or private payer for the medication and the provider bills for any administration costs.

Alternate sites of care: Sites such as outpatient infusion centers, physician offices, or home infusion services that handle the purchasing, dispensing, and administration of injections.

benefit, taking into account any differences in net price of the medication (inclusive of negotiated rebates) as well as access considerations for each pathway. But manufacturers can also exert influence over this decision through negotiation of discounts and rebates, taking into account patient reach as well as favorable pricing dynamics.[7]

For patients and providers, it can sometimes be difficult to tell under which coverage pathway a medication is provided and if a certain medication is covered at all.[8] While payers typically publish a list of medications covered under the pharmacy benefit on the plan's formulary, there may not be the same publicly available list of medications covered under a plan's medical benefit, making it impossible for an individual to make an informed plan choice.

COVERAGE LANDSCAPE FOR LONGER-ACTING HIV MEDICATIONS

There are three FDA-approved longer-acting injectable medications for HIV treatment and prevention currently on the market (see text box below) and several more products in the research pipeline.[9]

IMPACT OF COVERAGE PATHWAY ON ACCESS, AFFORDABILITY, AND SUSTAINABILITY

The way that a longer-acting injectable ART is covered can result in pros and cons across payers, patients, and providers.[10] These dynamics in turn impact access (whether a patient can receive the drug), affordability (whether a patient can afford the drug), and system sustainability (whether HIV providers and programs can efficiently provide the drug). The following section describes the different considerations for each coverage pathway from the perspective of the payer, the patient, and the provider.

Payer pricing considerations

Some public and private payers may prefer coverage of longer-acting injectable ARTs as a pharmacy benefit because they can more easily negotiate for pricing concessions from a manufacturer (discounts or rebates) as well as formulary placement and utilization management via a pharmacy benefits manager (PBM).[11] PBMs are entities contracted with payers to manage the plan's pharmacy benefit. Even within the pharmacy benefit, payers often direct patients to certain pharmacies with which the payer has either a contractual or ownership interest as a way to control costs. For example, a number of payers have policies in place that not only require coverage of longer-acting injectable ARTs through the pharmacy benefit, but mandate white bagging through a payer's preferred pharmacy network.[12] Medications covered under a medical benefit are typically not negotiated by a PBM.

For ADAP, pricing is a key consideration in coverage determinations. As with oral drug products, formulary inclusion of longer-acting injectable products is largely dictated by the availability of statutorily mandated 340B discounts as well as supplemental discounts and rebates that ADAPs negotiate with HIV manufacturers. The prices ADAPs are able to negotiate for longer-acting products do not vary by whether the ADAP utilizes a buy-and-bill arrangement (where contracted RWHAP or other providers procure the product themselves and then bills ADAP) or procures and dispenses the medication through a pharmacy network. However, the ADAP's ability to capture those rebates in practice depends heavily on which coverage pathway is used. ADAPs are generally more easily able to capture rebates through pharmacy benefit channels (see below for additional discussion of ADAP sustainability considerations).

FDA-APPROVED LONGER-ACTING ANTIRETROVIRAL MEDICATIONS (as of September 2026)

LONGER-ACTING INJECTABLE PRODUCTS CURRENTLY ON THE MARKET	INDICATION	ORAL LEAD IN	LIMITED DISTRIBUTION NETWORKS
CAB	HIV prevention (intramuscular injection every 2 mos)	Optional (provided by manufacturer)	The manufacturer of each longer-acting injectable medication typically approves a limited number of specialty pharmacies approved to dispense the medication and/or a limited list of distributors approved to buy, store, and ship the medication
CAB/RPV	HIV treatment (intramuscular injection every 1 or 2 mos)	Optional (provided by manufacturer)	
LEN	HIV prevention/treatment (subcutaneous injection every 6 mos)	Required (billed through pharmacy benefit)	

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.
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.	

The way that a longer-acting injectable ART is covered can result in pros and cons across payers, patients, and providers. These dynamics in turn impact access (whether a patient can receive the drug), affordability (whether a patient can afford the drug), and system sustainability (whether HIV providers and programs can efficiently provide the drug).

Patient access and affordability considerations

Patient cost sharing varies by medication indication (use, i.e., whether for treatment or prevention), payer, and plan design and, with some exceptions, there may not be clear patient affordability benefit to a pharmacy or medical benefit coverage pathway. An exception here may be for Medicare, where for HIV treatment there is a clear benefit for coverage as a pharmacy benefit because drugs covered under Medicare Part D and Medicare Advantage drug benefits are now subject to a $2,100 annual out-of-pocket maximum.[13] HIV medications used for treatment covered as a medical benefit under Medicare B are not subject to an out-of-pocket maximum, meaning that individuals (and ADAPs providing insurance assistance support) could face high cost sharing for drugs covered by Medicare Part B. All HIV prevention medications (oral and longer-acting injectable) are covered as a medical benefit under Medicare Part B with no cost sharing.[14] Commercial insurers are also required to cover HIV prevention medications without cost sharing (regardless of coverage pathway), though there have been widespread compliance issues with this requirement.[15]

Access also may differ depending on whether the medication is covered as a pharmacy or a medical benefit. For example, in the pharmacy benefit scenario, because the medication needs to be prescribed to a specific patient, there can sometimes be a delay between when a medication is prescribed and when the medication can be delivered to the provider's office for administration via white or clear bagging mechanisms. Additionally, many health care systems are unable or unwilling to accept white-bagged medications from an outside pharmacy. These health care systems may have blanket prohibitions on acceptance of medications shipped from specialty pharmacies, requiring use of the health care system's own pharmacy or requiring a buy-and-bill pathway instead. These prohibitions on white-bagged medications may hinder access if a payer is unable to accept claims from providers or if the health care system's in-house pharmacy is not in the payer's limited network.

Medical benefit coverage with buy-and-bill may provide a more direct access point because providers generally keep a certain amount of medication in stock for immediate use. Because of the upfront costs of purchasing high-cost medications upfront (and at times slow reimbursement process) discussed in more detail, however, not all HIV providers are able to implement buy-and-bill, which may limit access points, especially when a payer only covers a medication as a medical benefit. An HIV clinic that does not have the capacity to implement buy-and-bill for a longer-acting HIV injectable product may refer the patient to an alternative site of care, typically an infusion center, which procures, seeks reimbursement for, and administers the drug. While this can be a good workaround for HIV clinics that do not have the capacity to administer ARTs covered as a medical benefit, it can add an extra referral and set of steps for the patient and require the clinic to forgo 340B program income.

CLINIC SUSTAINABILITY CONSIDERATIONS

HIV clinics and pharmacies are also impacted by payer coverage decisions. A drug covered under a medical benefit that requires a provider to buy-and-bill means that a provider must have enough capital on hand to purchase the medication upfront and wait to seek reimbursement from a payer. Not only is there a delay in reimbursement, but there is also a chance the payer will deny coverage for a particular patient based on application of prior authorization or medical necessity criteria.[16] This can be an untenable position for smaller providers with less capital and thinner operating margins. Critically, there is no guarantee that a payer's reimbursement rate for a provider-administered drug will exceed the provider's acquisition cost: commercial payers without established fee schedules for newer products may default to reimbursement formulas that fall short of actual purchase prices, which can be below what non-340B providers pay if the acquisition costs exceed those benchmarks.

For larger providers with more capacity and who are also 340B covered entities, the upside of buy-and-bill is that the 340B revenue generation opportunities may be greater because 340B providers are often able to negotiate a higher reimbursement for provider-administered medication than a pharmacy.[17] In other words, the 340B provider is able to seek reimbursement from payers at a price much higher than heavily discounted acquisition cost (this is not true for an ADAP using a medical benefit coverage model, where providers are only reimbursed acquisition cost plus administration costs).

An additional buy-and-bill risk specific to longer-acting injectables is wastage. Some longer-acting injectable ARTs require refrigeration and have strict time limits for use after removing from refrigeration (e.g., longer-

CLINIC SUSTAINABILITY ACROSS PHARMACY AND MEDICAL BENEFITS		
PAYER	PHARMACY BENEFIT	MEDICAL BENEFIT
Commercial insurance, Medicare, Medicaid	Clinics and providers that are 340B covered entities may see less 340B generated revenue on claims covered as a pharmacy benefit. The trade-off, however, may be that even if 340B revenue is lower, reimbursement occurs in a more timely and predictable manner.	Clinics and providers that are 340B covered entities may see more 340B generated revenue on claims covered as a medical benefit. However, a buy-and-bill model requires an outlay of upfront funding to purchase medications and can be risky if a payer ends up denying coverage.
ADAP full pay (uninsured)	ADAP does not provide any clinic/provider revenue generation opportunities because of when a clinic buys-and-bills, ADAP should only reimburse at acquisition cost, plus reimbursement to the clinic/provider for administration of the drug. This is different from public/private payers, where the reimbursement amount often exceeds acquisition cost, resulting in revenue generation.	

acting cabotegravir products must be used within six hours of removal from refrigeration). This means that if a patient misses a scheduled injection appointment after the medication has been pulled from inventory, the vial may have to be discarded, and under buy-and-bill, the provider bears that financial loss. Clinics managing modest patient volumes on a tight margin may find this exposure difficult to absorb.

Because many HIV providers simply cannot sustainably implement a buy-and-bill model, pharmacy benefit coverage offers a somewhat more reliable pathway to ensure patients can access longer-acting injectable medications. However, pharmacy benefit administration can also bring its own sustainability headaches. When medications are covered as a pharmacy benefit, 340B revenue generation opportunities can be smaller because some revenue is siphoned to middlemen in the drug procurement and distribution channels.[18] For HIV safety net providers, for whom 340B revenue generation is a core funding component for basic service delivery, differences in revenue generation opportunities are important fiscal considerations.[19] In addition, payer policies mandating white bagging can mean that clinics lose out on 340B revenue if the payer requires use of a pharmacy that is not one of the clinic's 340B contract pharmacies.[20] In response to a payer's mandatory white bagging policies, some clinics (particularly large academic institutions) have instituted their own prohibitions on use of white bagging altogether, meaning providers cannot dispense injectable medications shipped from pharmacies not contractually affiliated with the academic institution. These types of provider/payer disputes can put the patient in the middle, with more limited access options.

The complexity of medical benefit billing can also present a meaningful operational challenge to HIV providers. Medical benefit claims for longer-acting injectable ARTs require very specific billing codes. Errors on any of the many required billing fields routinely trigger claim denials, adding administrative burden for clinics that are new to provider-administered billing.

The combination of these challenges mean that smaller providers, many of whom have significant ties to specific communities, cannot sustainably provide access to longer-acting injectable ARTs. This may exacerbate existing health disparities.[21]

ADAP SUSTAINABILITY CONSIDERATIONS

There are ADAP sustainability issues related to the coverage pathway of longer-acting injectable ARTs both when ADAP is the primary payer for uninsured ADAP clients and when ADAP provides assistance for insured clients. This is primarily because of the impact the coverage pathway has on the ability of the ADAP to claim a rebate on an HIV medication. ADAPs are entitled to 340B discounts from manufacturers, often provided in the form of a rebate, and negotiate sub-340B discounts as well. ADAPs are unique in that they receive rebates for medications that they purchase for uninsured clients as well as rebates generated off of medication cost-sharing payments for insured clients.

For uninsured clients, ADAPs that direct dispensing through pharmacy networks (white-bagging through a contracted specialty pharmacy) can generally process rebate claims through established PBM channels. Covering longer-acting injectables as a medical benefit, by contrast, requires ADAPs to process buy-and-bill claims and client cost-sharing payments directly from clinical providers, functions that fall outside the standard scope of contracted PBMs and that most ADAPs have not yet built. Programs without that infrastructure may be unable to effectively cover medical benefit pathway clients or capture rebates on claims processed through that channel.

For ADAP-funded insurance program clients, it can be more difficult for the ADAP to cover client cost sharing when the longer-acting injectable ART is covered by a public or private payer as a medical benefit because ADAP infrastructure is typically built around a pharmacy claims. If another party covers cost-sharing instead of

the ADAP, rebate eligibility for that cost-sharing claim is lost, which can be a financial challenge for ADAPs that invest rebate revenue back into the program.

CONCLUSION AND POLICY CONSIDERATIONS

The coverage landscape for longer-acting injectable ARTs is complex. And the complexity is compounded by a lack of transparency from payers on when a drug is covered as a pharmacy benefit, medical benefit, or both. Because the coverage pathway has different implications across payers, patients, and providers, it is difficult to identify a one-size-fits-all policy approach that mitigates the complexity and administrative burden for access to these products. However, there are some considerations policymakers may take into account when developing broader systemic reforms:

Medical benefit may be a disproportionate challenge for small providers: Requiring a medication to be covered as a medical benefit without an option for pharmacy benefit coverage can be challenging, particularly for smaller providers. Allowing medications to be covered as a pharmacy benefit and shipped to a provider for administration via white or clear bagging may open up access points for longer-acting injectable products.

Publicly listing drugs covered as a medical benefit may help patients and providers understand coverage and access: Transparency requirements for formulary data should also include a requirement that any medications covered as a medical benefit also be publicly listed. While formularies must include medications covered under a plan's pharmacy benefit, medications covered as a medical benefit are often omitted, leaving providers and patients to guess at what is covered, how it is covered, and any limitations placed on coverage.

Federal capacity building support is needed for ADAPs: ADAPs should receive additional federal capacity building assistance to enable nimble responses to longer-acting injectable ART coverage that allow for both medical benefit and pharmacy benefit options for uninsured clients. This includes additional guidance to ensure appropriate 340B coordination across ADAPs and other covered entities.

Open dialogue and good-faith negotiations are needed between payers and manufacturers: Negotiations that balance access, value, and pricing are critical to enabling unfettered access to highly effective medications for the treatment and prevention of HIV. Patients are often left in the middle of these tense, zero-sum pricing negotiations. Fair prices for emerging, safe, and effective HIV medications that offer adherence benefits for some communities over oral regimens will eliminate much of the friction in the drug procurement and administration channels described above.

Patient affordability must remain paramount: The coverage pathway is fairly meaningless if the medication is still unaffordable for the patient at point-of-sale. While the ACA ensures access to HIV prevention medications at zero cost to the consumer, compliance gaps mean that despite this promise, affordability is still a barrier to access, especially in the commercial market. HIV treatment has few affordability protections, putting pressure on ADAP and RWHAP programs to cover cost sharing for low-income people with HIV. Any policies aimed at smoothing out coverage for longer-acting injectable ARTs should address cost head on (which is necessarily in tandem with fair pricing described above).

ENDNOTES

1 National Institutes of Health, Long-Acting HIV Medicine, available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/long-acting-hiv-medicine

2 Some available longer-acting injectable ARTs require an oral lead-in dose, meaning that the individual must take an oral form of the medication before or when first receiving an injection.

3 Medications dispensed to hospital inpatients are covered separately and are outside the scope of this brief.

4 NASTAD, Long-Acting Injectable PrEP is Here: Frequently Asked Questions (FAQs) for Implementation, 2023, available at https://nastad.org/sites/default/files/2023-04/LAI-FAQ-Formatted-Updated4.17.23.pdf ; HIVMA and NASTAD, Preparing for Long-Acting Antiretroviral Treatment, https://www.hivma.org/news/news_and_publications/hivma_news_releases/2019/preparing-for-long-acting-antiretroviral-treatment/

5 Brown bagging is generally not appropriate for HIV medications as it can raise safety concerns by removing the medication from the medical system chain of custody. Some longer-acting injectable medications require cold storage, which also makes brown bagging risky.

6 Michael Einodshofer and Lars Duren, Cost Management through Care Management, Part 2: The Importance of Managing Specialty Drug Utilization in the Medical Benefit. Am Health Drug Benefits. 2012 Sep;5(6):359-64. PMID: 24991333; PMCID: PMC4031694.

7 Inmaculada Hernandez and Anna Hung, A Primer on Brand-Name Prescription Drug Reimbursement in the United States. J Manag Care Spec Pharm. 2024 Jan;30(1):99-106. doi: 10.18553/jmcp.2024.30.1.99. PMID: 38153864.

8 National Council of Prescription Drug Plans, Specialty Pharmacy Benefit Coverage Identification White Paper 2020, available at https://www.ncpdp.org/NCPDP/media/pdf/WhitePaper/NCPDP-Specialty-Pharmacy-Benefit-Coverage-Identification-White-Paper.pdf?ext=.pdf

9 AVAC, Long-acting HIV Treatment Pipeline, May 2026, available at https://avac.org/resource/infographic/long-acting-hiv-treatment-pipeline/

10 Josh Havens, University of Nebraska Medical Center, Annoying But Necessary: Navigating the Operational Challenges of Long-Acting Treatment and Prevention Strategies, IAS-US 2023, https://www.iasusa.org/wp-content/uploads/hiv/2023/long-acting/esyllabus/2023-long-acting-havens-handouts.pdf

11 A number of studies in other therapeutic areas have shown that provider-administered drugs covered as a pharmacy benefit instead of a medical benefit can be cheaper for the payer. See, e.g., Aliaksandr Budovich, Maria Claudio-Saez, and Jason Hershberger, Savings on High-Cost Drugs Such as Atypical Long-Acting Injectable Antipsychotics: Switching to Billing Under the Pharmacy Benefit in Outpatient Settings. P T. 2019 Aug;44(8):474-496. PMID: 31447535; Chris Carlson, Steven Armstrong, Dhwayne Henry, Oliver Wyman (on behalf of AHIP), Pricing of Specialty Drugs, Analysis of the Impact on Premiums of Provider Markups on Specialty Drugs, March 2024, available at https://ahiporg-production.s3.amazonaws.com/documents/Pricing-of-Specialty-Drugs.pdf.

12 Caroline Pearson, Lindsey Schapiro, and Steven Pearson, White bagging, Brown Bagging and Site of Service Policies: Best Practices in Addressing Provider Markup in the Commercial Insurance Market. J Comp Eff Res. 2023 Oct;12(10):e230128. doi: 10.57264/cer-2023-0128. Epub 2023 Sep 19. PMID: 37724721.

13 Jalpa Doshi, Pengchiang Li, Matthew Klebanoff, and John Lin, Inflation Reduction Act Provisions and Medicare Part D Out-of-Pocket Costs for Specialty Drugs. JAMA Health Forum. 2025 May 2;6(5):e251387. doi: 10.1001/jamahealthforum.2025.1387. PMID: 40377932; PMCID: PMC12084838

14 Centers for Medicare and Medicaid Services, Fact Sheet: Medicare Part B Coverage of Pre-exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention, February 2026, available at https://www.cms.gov/files/document/fact-sheet-potential-medicare-part-b-coverage-preexposure-prophylaxis-prep-using-antiretroviral.pdf. During the transition of HIV medications previously covered under the Medicare Part D pharmacy benefit to the Medicare Part B medical benefit, pharmacies expressed concern about the administrative complexity of enrolling with the Medicare Part B program and processing ART claims through Part B instead of Part D. This experience highlights the difficult trade-offs at play as policymakers balance access, affordability, and provider sustainability. Medicare serves a relatively small share of the population of people needing HIV prevention medications when compared to other payers, but this policy change highlighted the need for consumer advocates, providers, and other HIV community stakeholders to grapple with the administrative complexity that different coverage pathways can present.

15 The AIDS Institute, Pre-exposure Prophylaxis: Coverage, Compliance, Ending the HIV Epidemic 2026 Policy Report, April 2026, available at https://theaidsinstitute.org/media/documents/04-20-2026-16-47-34-2026%20PrEP%20Report%20Final%20v2.pdf

16 McKesson, The Pros And Cons of The "Buy And Bill" Model of Pharmaceutical Distribution: What's Appropriate for Your Practice? January 2022, available at https://mms.mckesson.com/content/insights/the-pros-cons-of-the-buy-and-bill-model-of-pharmaceutical-distribution-whats-appropriate-for-your-practice/

17 See, e.g., Altus Biologics, Demystifying the Buy-and-Bill Model, 2026, available at https://altusbiologics.com/demystifying-the-buy-and-bill-model-what-specialty-practices-need-to-know-in-2026/.

18 See Aliaksandr Budovich, et al., supra note 9

19 Valerie B. Kirby, Emma Wilde Botta, Wayne T. Steward, California HIV/AIDS Policy Research Centers, The Role of the 340B Drug Pricing Program in HIV-Related Services in California, 2018, available at https://www.californiaaidsresearch.org/files/340B-HIV-Rapid-Response-Report-FINAL.pdf

20 Deborah Abrams Kaplan, Managed Healthcare Executive, How 'White Bagging' Affects Patients, Physicians and 340B Funding, February 18, 2021, available at https://www.managedhealthcareexecutive.com/view/how-white-bagging-affects-patients-physicians-and-340b-funding

21 See, e.g., Jose Figueroa, Rebekah Stein, Jessica Phelan, et al., Long-Acting Injectable Antiretroviral Therapy in Medicare-Enrolled Adults With HIV, JAMA Network Open. 2026;9(6):e2618029. doi:10.1001/jamanetworkopen.2026.18029.

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