

Access to HIV Medication in the Community Versus a Nursing Home for the Medicare Eligible HIV population

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Abstract

Access to appropriate antiretroviral therapy (ART) is key to people living with HIV/AIDS (PLWH) living a near normal life time, which has resulted in increasing numbers of PLWH requiring nursing home care for age-related reasons. However, one study found that 21% of Medicare eligible PLWH in US nursing homes between 2011 and 2013 were not dispensed ART through the nursing home pharmacy. Cost-sharing assistance programs exist to facilitate access to medications for low-income community dwelling older adults, but these programs do not necessarily extend to people admitted to a nursing home, which may cause interruptions in access to ART for PLWH in this setting. Policies may need to be updated to reduce drug-related financial burden to PLWH and nursing homes in order to maintain continued access to ART in the nursing home setting.

Access to appropriate antiretroviral therapy (ART) is key to people living with HIV/AIDS (PLWH) living a near normal life time, which has resulted in increasing numbers of PLWH requiring nursing home care for age-related reasons. However, one study found that 21% of Medicare eligible PLWH in US nursing homes between 2011 and 2013 were not dispensed ART through the nursing home pharmacy.¹ Admission to a nursing home may interrupt already existing coverage for ART and/or present medication-related financial burden to Medicare eligible PLWH or the nursing home to which they are admitted.

This article explores current statistics regarding Medicare eligibility for PLWH – including Medicare Part D drug coverage – followed by a review of assistance programs PLWH may be accessing to help cover out-of-pocket drug costs in the community. A discussion of a lack of similar programs in the nursing home setting highlights that there may be a need for new policies to mitigate cost sharing in the nursing home settings. Finally, suggestions of policies that could augment access to ART in the nursing home setting are presented. It is the aim of this article to inform consumers and nursing home stakeholders of the potential challenges related to ART access and associated financial repercussions that may take place as older, Medicare-eligible PLWH transition from community to nursing home residences.

PLWH on Medicare

Medicare is a federally administered health insurance program, and the largest source of federal money for HIV health care.² There are three ways to become eligible for Medicare: age 65 or older, qualifying for disability status, and having end stage renal disease or Amyotrophic Lateral Sclerosis (ALS). A diagnosis of advanced HIV disease or AIDS is considered a disability. Disability status plus 24 months of Social Security Disability Insurance (SSDI) or Social Security Income (SSI) qualifies people less than 65 years old for Medicare, including PLWH. Currently, more than half of PLWH (56%) are insured by Medicare, of whom approximately

80% are disability-eligible; the rest are either Medicare eligible by age or end stage renal disease/ALS diagnosis.² Furthermore, 69% of Medicare eligible PLWH are dually eligible for Medicaid, a government insurance program for qualified low-income individuals, which is independently administered by each state.^{2,3}

Eligibility for Medicare is evolving for PLWH because longer life expectancy due to advances in treatment means PLWH are transitioning from being strictly disability-eligible for Medicare, to being age-eligible. One study showed that 15% of California's Medicare population of PLWH transitioned from disability to age-eligibility between 2007 and 2010.⁴ It has also been reported that the number of PLWH age-eligible for Medicare doubled between 2000 and 2013; that number is expected to continue to grow as treatment advances and the population of PLWH continues to reach older ages.⁵ Additionally, 17% of incident HIV occurs among people aged 50 or older. Assuming ideal HIV care post diagnosis, this group will most likely age into Medicare eligibility rather than transition through disability eligibility.⁶ The CDC estimates that 70% of PLWH will be over age 50 by 2020.⁶

Prescriptions for PLWH

One of the biggest financial challenges in caring for the Medicare population of PLWH is covering costs for HIV medications vital to survival. Medicare Part D is the primary source of coverage for HIV medications. However, HIV medications often have high cost-sharing and PLWH disproportionately lack financial supports.^{7,8} Cost-sharing relief programs exist for community dwelling older adults, some of which are specifically for PLWH. These programs are of particular interest to long-term survivors (PLWH diagnosed prior to the 1996 introduction of HAART⁹), who have often been exposed to several ART regimens over time, become treatment resistant and are forced to use newer more expensive drugs.¹⁰

Part D for PLWH

Medicare Part D was introduced in 2006 and is part of Medicare. This means that, unlike Medicaid, the requirements for the program are the same regardless of an individual's state of residence. Medicare beneficiaries must sign up for a Part D plan administered by a third party insurer, prove they have equivalent drug coverage and are eligible to decline Part D, or face penalties for late enrollment in the event they do not sign up during open enrollment. Part D plans differ in what drugs are covered and how much of the cost of that medication is covered making, it imperative that PLWH choose a Part D plan carefully to minimize out-of-pocket costs. Dual eligible individuals – eligible for Medicare and Medicaid – are automatically enrolled in baseline low-cost Part D plans, but can change their Part D plan during open enrollment.

Part D is mandated to cover at least 2 drugs in each of 6 protected drug classes, including antiretrovirals and HIV related pharmacotherapies. The amount of coverage for each antiretroviral can vary by Part D provider. In turn, medications may be covered, but as tier 3 or 4 or specialty drugs with high cost-sharing. It is also possible that certain drugs have restricted access through utilization management processes. Utilization management is a way of limiting access to certain medications to control costs and may include, but is not limited to, step therapy and prior authorization. Though HIV medications are not currently subject to prior authorization, there is legislation proposed in the Bipartisan Budget Act of 2018 to give Part D insurers more ability in fiscal year 2019 to implement such processes for drugs in protected classes, including antiretrovirals.¹¹

Clearly there are several variables governing the cost assumed by PLWH related to their HIV medications: the regimen prescribed, insurance coverage, or eligibility for cost-sharing assistance programs, to name a few. Increases in out-of-pocket costs may be a barrier to accessing ART. However, when out-of-pocket ART costs increased with the introduction of Part D in 2006, HIV medication adherence among Medicare eligible PLWH did not seem to be impacted.³ One likely explanation is that PLWH were taking advantage of medication cost-sharing assistance programs. Assistance programs ensure continued access to ART despite cost-sharing that PLWH may not otherwise be able to afford.

Examples of prescription cost-sharing and coverage assistance

Medicaid and Extra Help drug coverage

Where Medicare is the source of the greatest federal funding for PLWH, Medicaid – the joint state and federal low-income insurance – is the largest source of health coverage for PLWH. All states voluntarily offer Medicaid outpatient drug coverage.¹² Drug coverage is provided through Medicare Part D and pricing determined by each state's unique Medicaid formulary.¹³ Regardless of state of residence, Medicaid eligible people are automatically qualified for an additional federal program, Extra Help, also known as the Part D Low-income Subsidy. This program can provide full or partial cost-sharing assistance, depending on income.

Extra Help offers alternative copayments (full program) and/or a 15% coinsurance (partial program). In addition to reducing prescription costs, this program can also pay for Part D premiums up to an amount determined by each state (\$29.98 in Delaware) and remove Part D late enrollment penalties.¹⁴ Extra Help enrollees are still responsible for prescription copayments, however will pay the lower of the two copayments/coinsurance between Extra Help or Part D, until they reach the Part D coverage gap. Once in the coverage gap, individuals are responsible for full drug costs according to Part D coverage. Once the out-of-pocket maximum has been reached, full Extra Help coverage eliminates drug costs, and partial coverage reduces copayments to equal those offered to full Extra Help enrollees prior to the coverage gap.¹⁵

If a person does not qualify for Medicaid based on income, but has healthcare costs including prescriptions which deplete their monthly income to the point where they would otherwise qualify, there exist Medicaid Medically Needy Programs in select states. Delaware does not have a Medically Needy Program.¹⁶ Many of the people in this program are living in nursing homes, and by depleting assets through cost of medical care become eligible for Medicaid and subsequently Extra Help.¹⁶ Other programs, including Programs of All-Inclusive Care for the Elderly (PACE), Medicare Advantage Special Needs Plans, and Medicare Savings Plans provide varying degrees of healthcare cost-sharing assistance, specifically for Medicare Part A and B premiums. However, all rely on Part D and Extra Help eligibility to determine drug coverage and copayment amounts as outlined above. Qualifying for Extra Help in 2019 requires an individual's income to be at or below 114% of the federal poverty level, or \$14,390 annually.¹⁷ Additionally, enrollment in either Extra Help or Medicaid requires annual re-application.

AIDS Drug Assistance Program (ADAP)

Specific to PLWH, the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 has several parts that, combined, provide access to HIV/AIDS related primary medical care and support services across the United States and related territories. Part B of the Ryan White

CARE Act includes funding for the AIDS Drug Assistance Program (ADAP), which is provided to all states and territories based on a calculation weighted by reported cases of PLWH/AIDS in the designated area.¹⁸ Though ADAP funds can be used to purchase health insurance and provide services for improved access and adherence to HIV medications, it is most known for acting as a payer of last resort, helping to provide FDA approved HIV medications to low-income PLWH lacking adequate drug coverage. Each ADAP is independently operated by the state or territory. More than 500,000 PLWH are served by ADAPs and the majority have some insurance, but need ADAP funds to off-set out-of-pocket costs such as copayments.¹⁹ Specific eligibility criteria are determined by each state or territory and must be only for those that prove, every 6 months, both residency in the designated catchment area and financial and medical need. Financial need is often defined as a percent of the Federal Poverty Level and medical need is based on the presence of a HIV diagnosis. Each ADAP covers at least one drug from each category of HIV medications and independently governs distribution of the covered medications to community dwelling PLWH.²⁰

340B Drug Pricing Program

One of the reasons ADAPs are able to provide low cost medications is due to their eligibility for the 340B Drug Pricing Program.¹⁹ This program was initiated in 1992 to bolster hospitals and clinics serving low income clients. Pharmaceutical manufacturers that participate in Medicaid must offer 340B eligible clinical sites prescription drugs at a cost lower than the Medicaid reimbursement rate. Cost of acquiring medications for the facility is thus much lower than it would be if the facility was not 340B eligible. The money that the clinical sites save was meant to be returned to the healthcare system in order to alleviate some of the debt incurred by serving low-income clients that otherwise could not afford healthcare. The discounted medications are reserved for outpatients that are regular clients of the eligible facility.^{19,21} Notably, ADAPs only provide medications and not healthcare, but are exempt from this requirement. Unfortunately, the unintended consequence of 340B drug pricing is that the money the facility saves on the cost of acquiring drugs does not always translate into reduced copayments for people seeking care at a 340B clinical site.²¹

Manufacturer cost-sharing and patient assistance programs

Many drug manufacturers offer cost-sharing assistance or patient assistance programs to underinsured or uninsured individuals for their HIV medications. Cost-sharing assistance programs offer financial assistance with copayments, coinsurance, and deductibles. Eligible individuals have commercial insurance, but are unable to cover the cost-sharing for HIV medications. These programs are not available to anyone receiving medication coverage through government programs such as Part D, which would often serve the population aged 65 and older. Each cost-sharing assistance program is unique to the company and provides cost-sharing assistance up to specified monthly or annual amounts.^{22,23}

Patient assistance programs are also offered through drug manufacturers and are targeted at helping the uninsured, people who do not qualify for insurance such as Medicaid, Medicare, or ADAP or are eligible, but on an ADAP waiting list. There is a universal application for these types of drug cost assistance programs that can be submitted to each individual program of interest. There are also several resources available to navigate the wide variety of patient assistant programs, such as RxAssist²² or HarborPath, which specifically operates the ADAP

waitlist patient assistance program.²³ Like cost-sharing assistance programs, patient assistance programs are unique to the companies offering them and may not apply to people with Part D drug coverage.^{22,24}

Prescriptions in the nursing home setting

Between 2011 and 2013 there were approximately 7,500 Medicare eligible PLWH residing in nearly half of US nursing homes, 93% of whom were dually eligible for Medicaid.¹ During the first 90 days of a nursing home stay after a qualified hospital stay, healthcare, including prescriptions, are covered by Medicare Part A. When the Part A covered care is for a person with an AIDS diagnosis, facilities are eligible for an AIDS adjustment, a 128% add-on to their usual reimbursement, to better cover the costs associated with caring for a PLWH.²⁵ After the 90 days expire, prescription coverage for most Medicare eligible PLWH in US nursing homes is through Medicare Part D or equivalent coverage (e.g. Retiree Drug Subsidy related plan, henceforth collectively referred to as Part D), and depends on the nursing home pharmacy contracting with the residents' specific Part D plan. If the pharmacy does not contract with the Part D provider, the individual has the opportunity to change Part D providers. Changing Part D providers is allowable upon admission to the nursing home, once a month while in residence, and once within two months after discharge from the nursing home. Copayments, deductibles and premiums remain the responsibility of the nursing home resident unless they are also eligible for Medicaid (dual eligibility).

Cost-sharing for Part D covered drugs for qualified dual eligible individuals residing in a nursing home for 30 or more days should be fully subsidized. For other medications, the Extra Help program still applies while residing in a nursing home, however other cost-sharing assistance programs do not.²⁶ The manufacturer cost-sharing assistance and patient assistance programs are only available for community dwelling individuals and Ryan White legislation views residence in a nursing home as inpatient status. Inpatient status precludes use of ADAP funds. If the Part D provider does not cover a drug or the out-of-pocket for the drug is beyond the ability of an individual to pay, there is also an exceptions process where individuals can petition the Part D plan to cover or lower the cost of the drug needed. During this process a Part D plan is required to provide an emergency 31 day supply of the medication.²⁷ In the event that a nursing home resident can not get drugs covered by their plan provider, nursing homes should still provide the needed medication, but are allowed to bill residents separately for dispensing the prescription.²⁶ In each of these instances the patient becomes responsible for higher out-of-pocket costs than they would have incurred outside the nursing home due to a lack of available cost-sharing assistance programs.

PLWH are often mitigating out-of-pocket drug costs through programs like those mentioned above. This ensures their continued access to ART and viral suppression. In the event of admission to a nursing home, there is potential for interrupted access to these necessary medications due to reduced availability of assistance programs. For example, if a person relies on ADAP for access to ART medications and is then admitted to a nursing home, they must find new means by which to cover HIV medications. Additionally, CMS has acknowledged and attempted to address the issue of dual eligible individuals admitted to a nursing home incorrectly being billed with copays that they otherwise would not have to pay in the community setting.²⁸ If PLWH are accessing assistance programs to cover out-of-pocket costs related to HIV

medications prior to admission to a nursing home, there is no reason to believe the financial need would change upon admission.

With less cost-sharing assistance available to nursing home inpatients, nursing homes may be at risk for incurring debt related to unpaid medication costs. In the event that nursing homes provide HIV medications in a timely manner after someone is admitted, avoiding gaps in medication, they may dispense the drug before checking if the drug is covered by a residents' Part D coverage. If PLWH are unable to afford the subsequent bills, the facility must absorb the costs related to the medications. Evidence suggests there may also be instances of Part D plans do not cover an emergency drug supply and placing a cost burden on the nursing home. One report mentioned this type of debt represents one percent of a long-term care pharmacy's revenue.²⁹ This is particularly a problem given the high cost of acquiring and dispensing HIV drugs.²⁹ The risk of high cost burden related to HIV medication dispensing may incentivize nursing homes to refuse admission to PLWH. A relative dearth of information regarding costs incurred by nursing homes related to unpaid HIV medication cost-sharing by residents presents an opportunity for future research.

Options for reducing HIV drug costs to nursing homes and residents

If it is, in fact, the case that nursing homes are at undue risk for HIV medication related debt, one solution may be to extend the 340B Drug Pricing Program to include nursing homes and their respective pharmacies. Currently nursing homes do not qualify for this program, despite their disproportionately low-income patient population, for two reasons: (1) nursing home residents are considered inpatients and (2) the majority of nursing homes are for-profit institutions.³⁰ Exceptions to the rule have been made in the past, such as allowing ADAPs to acquire drugs through 340B, despite the fact that they do not provide healthcare services.

ADAPs assist in drug coverage by design and nursing homes do not. Nursing homes dispense drugs by design and their for-profit status makes them averse to financial risk, including that related to acquiring and dispensing drugs. To that end, one hesitation to expand the 340B program to include nursing homes may stem from their often for-profit status: money saved on medications may be perceived as revenue rather than as a means for low-cost or fully subsidized ART dispensing in this setting. Another concern may be that expanding 340B eligibility could encourage drug manufacturers to increase drug prices more quickly, in an effort to save profits, particularly in the case of HIV medications which are generally high cost and rising.^{10,21} Monitoring how 340B savings are returned to the healthcare system could quell some of these concerns, but there are currently no agencies responsible for monitoring what 340B eligible facilities do with saved money.²¹ Nursing homes are unique in that there already exists a mandated system of reporting nursing home quality to the government. Including 340B revenue assessments in the existing quality evaluation structure may be one option to address the lack of oversight and assuage anxieties related to expanding the legislation to such for-profit institutions.

Another option to diffuse medication-related costs incurred by a nursing home is to expand ADAP. Allowing similar coverage of copayments and cost-sharing for individuals residing in nursing homes as are offered to outpatients would minimize potential interruptions in care for the more than half a million individuals that currently rely on ADAPs for HIV medications.

Considerations for Delaware

As of 2015, Delaware has a population of 944,076, of which 3,230 are living with HIV and 18.1% are aged 65 or older.^{31,32} As of 2013, Delaware contains less than 7% of the population of PLWH residing in nursing homes, but still has more PLWH in nursing homes than 19 states and the District of Columbia.¹ Most PLWH reside in the south, the census region in which Delaware is included.³³ Southern nursing homes care for more PLWH than nursing homes in any other census region, making it particularly imperative for southern states to assess policies related to ART access in nursing homes.¹

PLWH in Delaware currently utilize many of those cost-sharing assistance programs described above, as well as the Delaware Prescription Assistance Program (DPAP).³⁴ Specifically, DPAP is funded by a tobacco settlement and reduces copays to \$5 or 25% of a drug's cost for people ineligible for Medicaid or lacking health insurance. Also, Delaware received \$6.1 million dollars in Ryan White funds in fiscal year 2016.³¹ The primary payer for nursing home care, Medicaid, is called Diamond State Health Plan in the state of Delaware. It paid for 61.2% of nursing home care in 2017 and an individual's income can be no more than \$1,927.50 per month in order to qualify.³⁵ Furthermore, it can be inferred that if 84.9% of admissions to any nursing home in Delaware in 2017 were 65 years or older and Medicaid paid for more than half of nursing home care, many people in Delaware nursing homes were dual eligible for Medicare and Medicaid.³⁶ Medicaid eligibility is an automatic qualifier for the federal Extra Help program, which, along with ADAP and pharmaceutical company cost assistance programs, can help PLWH access ART. However, as described earlier, many of these programs no longer apply once admitted to one of the 46 Delaware nursing homes that were at nearly 90% occupancy in 2017.³⁶

Conclusion

Cost-sharing assistance programs exist to facilitate access to medications for low-income community dwelling older adults, some of which are specific to PLWH. However, these programs do not extend to people admitted to a nursing home, which may cause interruptions in access to ART for PLWH in this setting. Utilizing existing infrastructure to expand or amend drug cost reduction programs might provide one solution to this issue. Otherwise, current policies may be incentivizing nursing homes to refuse PLWH admission on the grounds of high drug-related financial risk. It is an ideal time, while the population of PLWH in nursing homes is still relatively small, to proactively consider how we maintain seamless access to ART without undue financial burden to PLWH or nursing homes.

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