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Pending Medicare National Coverage Determination (NCD) for HIV PrEP: What It Could Mean for PrEP Access

Under federal law, the Centers for Medicare and Medicaid Services (CMS), the agency that oversees the Medicare program, can ensure coverage of preventive services under Medicare Part A and Part B through a process called a National Coverage Determination (NCD). CMS has started this process for HIV Pre-Exposure Prophylaxis (PrEP), with a few unexpected twists and turns along the way. Read on to learn more about what NCD is, what an NCD would mean for PrEP availability in Medicare, why the NCD process for PrEP has been particularly complex, and what to expect going forward.

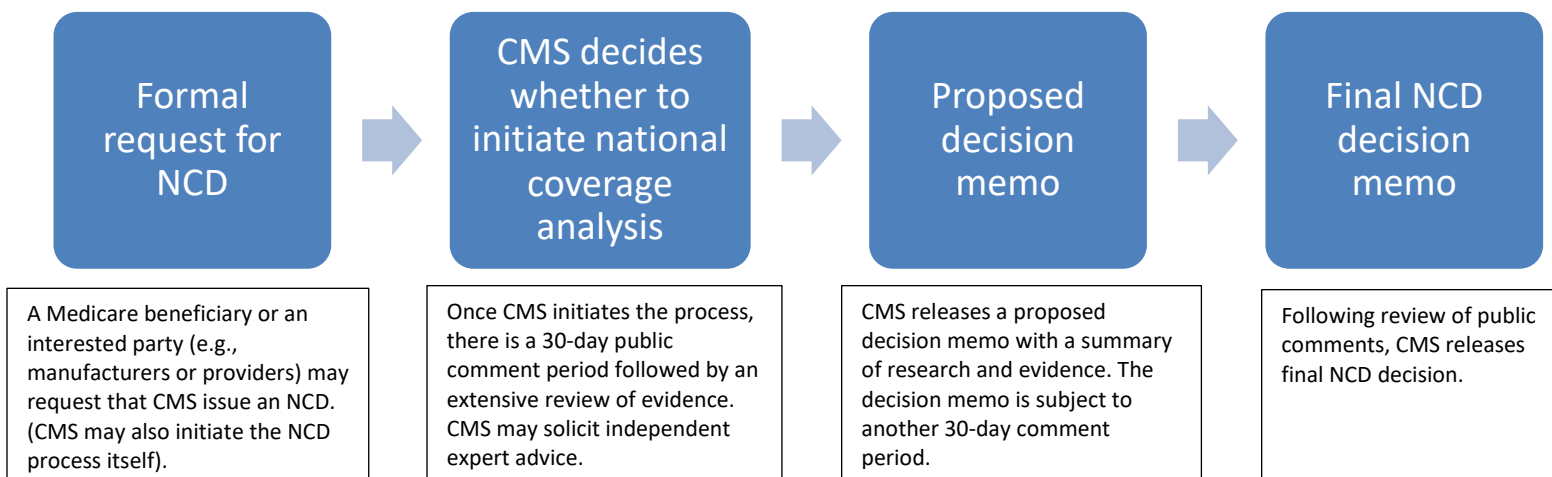
What's a Medicare NCD and How Does It Work?

Medicare covers services and items that are “reasonable and necessary” for care. For services covered by Medicare Part A (which covers hospital and inpatient services) and Part B (which covers outpatient services and provider-administered drugs), CMS uses the NCD process to determine which services are reasonable and necessary and must be covered by Medicare nationwide. This process includes an extensive review of evidence and multiple public comment periods.

For Medicare coverage of preventive services, there is another twist. CMS may use the NCD process to decide to cover a preventive service in Medicare Part A or Part B, but if the service has a grade A or B from the U.S. Preventive Services Task Force, CMS may use the NCD to require coverage of the preventive service under Medicare Part B without cost sharing. To make this determination, CMS must determine that the service is “reasonable and necessary for the prevention or early detection of an illness or disability” and appropriate for the population that Medicare serves.

The graphic below shows the process that CMS follows in undertaking an NCD.

Medicare National Coverage Determination Process



Services may be covered by Medicare even without an NCD at the discretion of local entities charged with making regional decisions about Medicare Part A and B coverage, but the NCD is necessary to create a federal mandate for coverage for every Medicare enrollee. The NCD process is only for Medicare Part A and Part B services and is not used to develop coverage requirements for prescription drugs covered under Medicare Part D. NCDs apply to Medicare Part A and B services that are available through traditional Medicare or through Medicare Advantage plans.

The PrEP NCD Process and Proposed Decision Memo

PrEP, a highly effective method of preventing HIV transmission through medications and services for uninfected individuals, has a [grade A from the USPSTF](#). PrEP medications can be in the form of a daily oral pill or a long-acting injection. In February 2022, ViiV Healthcare, the drug manufacturer that makes the only long-acting injectable PrEP product currently available, submitted [a formal NCD request to CMS](#). ViiV asked the agency to develop an NCD for long-acting injectable PrEP administered by a provider. ViiV sought a decision requiring Medicare Part B to cover

How Does Medicare Currently Cover Oral and Injectable Forms of PrEP?

- Oral medications are typically covered under the Medicare Part D benefit, which is provided through private plans in which Medicare beneficiaries can enroll.
- For most drugs, Part D plans determine which ones to cover on their formularies. However, HIV antiretroviral medications (whether used for prevention or treatment) are a “protected class,” meaning that all Part D plans must cover these drugs and cannot use prior authorization or step therapy. Part D plans can (and do) use high cost sharing for oral HIV medications.
- Provider-administered drugs, including long-acting injectable medications to prevent HIV, are typically covered under the Medicare Part B benefit. Part B covered drugs ordinarily come with a 20% coinsurance.
- Although CMS can issue an NCD to cover PrEP in Medicare Part B, there is no mechanism for CMS to require Part D plans to cover PrEP without cost sharing.

long-acting injectable PrEP, and the ancillary services that go with the medication, without cost sharing. CMS formally accepted ViiV's NCD request in January 2023 and initiated its evidence review process.

In July 2023, CMS issued a [proposed coverage decision memo](#). In the memo, CMS proposed to do the following—which included a few surprises:

- Long-acting injectable medications for PrEP would be covered without cost sharing.
- Coverage of oral medications for PrEP, which are currently covered under the Medicare Part D benefit, would be moved to Medicare Part B. This means that oral PrEP medications would also be covered without cost sharing. Oral medications used for HIV treatment would not be affected and would continue to be covered under Medicare Part D. (While unusual, coverage of oral medications in Medicare Part B is [not unprecedented](#).)
- Medicare Part B would cover seven individual counseling visits every 12 months without cost sharing. Services would include HIV risk assessment, HIV risk reduction and medication adherence services.
- Medicare Part B would cover HIV screening for those initiating and taking PrEP antiretroviral medications up to seven times annually and a single screening for hepatitis B virus (HBV) without cost sharing.
- CMS did not include all services recommended to be provided in coordination with PrEP medications, as described in [CDC guidelines](#) and in [guidance](#) issued by the Departments of Health and Human Services, Treasury, and Labor that govern private insurance coverage of PrEP. These include tests for other sexually transmitted infections (STIs) that are recommended as part of the PrEP intervention.

CHLPI, along with 31 other members of the HIV Health Care Access Working Group, the HIV Prevention Action Coalition, and the Federal AIDS Policy Partnership, [submitted comments](#) in response to the proposed decision memo. The comments applauded the move to make PrEP more affordable for Medicare members but highlighted concerns, particularly around coverage of ancillary services.

How Did PrEP Advocates, Providers, and Industry Representatives Respond to the Proposed Decision Memo?

The response to the decision was somewhat mixed. While commenters expressed support for any administrative change that would make PrEP more accessible and affordable, they noted other concerns with the way CMS is proposing to implement these protections.

First, commenters noted that moving oral PrEP medications from the Medicare Part D benefit to Medicare Part B may cause administrative challenges for pharmacies and clinics and, by extension, access concerns for Medicare enrollees. They pointed out that not every pharmacy that currently provides PrEP is certified to bill Medicare Part B. This may be particularly true of community clinics with in-house pharmacies or smaller independent pharmacies. The process for becoming a Medicare Part B pharmacy is arduous and may not be worthwhile for pharmacies with a relatively low volume of Medicare beneficiaries on PrEP.

This challenge may not be insurmountable, but commenters implored CMS to develop a more specific implementation plan, which should include technical assistance for pharmacies and solutions to overcome the administrative barriers to becoming eligible to bill Part B. Adding to the billing complexity is the fact that under

Part B, there is sometimes a lag between when a pharmacy dispenses a drug and when it gets reimbursed from Medicare, an issue that may present financial and administrative challenges for some pharmacies.

Second, commenters were concerned that moving oral medications used for PrEP from Part D to Part B would mean these drugs would no longer be protected by provisions that prohibit Medicare Part D plans from subjecting HIV drugs to prior authorization or step therapy. Inappropriate prior authorization requirements – such as requiring providers to go through a burdensome prior authorization process to verify that a plan member is at high risk for HIV and eligible for PrEP – remains a barrier to even generic PrEP. This issue would be important primarily for enrollees in Medicare Advantage plans, as standard Medicare Part B doesn't require prior authorization for most items and services.

And third, commenters raised concerns that the ancillary services that must be covered in addition to PrEP medications under the proposed decision were inadequate and not aligned with CDC guidelines for PrEP. The failure to include STI services – a mainstay of PrEP clinical care – was noted as a particularly egregious omission. This issue was raised by almost all of the comments submitted.

What's Next?

CMS had indicated that the final coverage determination was imminent last fall, but the final NCD has yet to materialize. It is possible that CMS did not anticipate the concerns raised in public comments around moving oral HIV medications from the Medicare Part D benefit to the Part B benefit and is taking more time to consider the best way forward. Many NCDs are issued with an immediate effective date, but with something so complex as the pharmacy changes proposed, there may be lead time needed for a PrEP NCD. In the meantime, long-acting injectable coverage is not guaranteed for Medicare enrollees, and enrollees continue to incur cost sharing for all forms of PrEP.

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