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**DATE:** October 1, 2024

**TO:** All Medicare Advantage Organizations, Part D Plan Sponsors, 1876 Cost Plans and Programs of All-Inclusive Care for the Elderly (PACE)

**SUBJECT:** Significant Cost Determination for Medicare Coverage of Pre-exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention

On September 30, 2024, CMS issued the “Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention” National Coverage Determination (NCD 210.15). This NCD outlines Medicare coverage for PrEP using antiretroviral drugs approved by the U.S. Food and Drug Administration (FDA) to prevent HIV in individuals at increased risk of HIV acquisition.

If CMS determines that an NCD meets the criteria for “significant cost” under § 422.109 of Title 42 of the Code of Federal Regulations, MA organizations are not required to assume risk for the costs of that service or benefit until the contract year for which MA payments are appropriately adjusted in the rate book to account for the cost of the NCD. If CMS determines that an NCD does not meet the “significant cost” criteria, MA organizations are required to provide coverage for the NCD and assume risk for the costs of that service as of the effective date stated in the NCD.

CMS has determined that the cost of coverage under NCD 210.15 does not meet the significant cost threshold. Therefore, MA plans are required to assume the costs and cover PrEP drugs for HIV under NCD 210.15 beginning on September 30, 2024.

For more information on the NCD and related information see:

- <https://www.cms.gov/medicare/coverage/prep>
- <https://www.cms.gov/medicare-coverage-database/view/ncacal-tracking-sheet.aspx?NCAId=310>

A link to the previously issued memo encouraging MA organizations and Part D sponsors to work with pharmacies and other interested parties to prepare for this transition in coverage for PrEP from Part D to Part B may be found here: [August 1, 2024 HPMS memo](#).