

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal: 12987</b>	<b>Date: December 5, 2024</b>
	<b>Change Request 13843</b>

**SUBJECT: National Coverage Determination (NCD) 210.15 - Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to announce that CMS has determined that Pre-Exposure Prophylaxis (PrEP) using antiretroviral drugs to prevent Human Immunodeficiency Virus (HIV) is covered as an additional preventive service under §1861(ddd)(1) of the Social Security Act (the Act). Specifically, CMS has determined that PrEP using antiretroviral drugs to prevent HIV is reasonable and necessary for the prevention of an illness or disability; is recommended with a grade of A by the United States Preventive Services Task Force (USPSTF); and is appropriate for individuals entitled to Medicare benefits under Part A or enrolled under Part B.

**EFFECTIVE DATE: September 30, 2024**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: April 7, 2025**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)**

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N	Chapter 1/4/Table of Contents
N	1/210/15/Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Business Requirements  
Manual Instruction**

# Attachment - Business Requirements

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## II. GENERAL INFORMATION

**A. Background:** This Change Request (CR) provides the Medicare contractors with instructions for processing *Pre-Exposure*

*Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention Claims.*

Pre-exposure prophylaxis (PrEP) involves the use of antiretroviral drugs to decrease the risk of acquiring human immunodeficiency virus (HIV). Under § 1861(ddd)(1) of the Social Security Act (the Act), the Centers for Medicare & Medicaid Services (CMS) has the authority to add coverage of “additional preventive services” through the Medicare national coverage determination (NCD) process if certain statutory requirements are met: (1) reasonable and necessary for the prevention or early detection of illness or disability, (2) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), and (3) appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

**B. Policy:** The Centers for Medicare & Medicaid Services (CMS) has determined that Pre-Exposure Prophylaxis (PrEP) using antiretroviral drugs to prevent Human Immunodeficiency Virus (HIV) is covered as an additional preventive service under §1861(ddd)(1) of the Social Security Act (the Act). Specifically, CMS has determined that PrEP using antiretroviral drugs to prevent HIV is reasonable and necessary for the prevention of an illness or disability; is recommended with a grade of A by the United States Preventive Services Task Force (USPSTF); and is appropriate for individuals entitled to Medicare benefits under Part A or enrolled under Part B.

Effective for claims with dates of service on or after September 30, 2024, CMS covers 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. The determination of whether an individual is at increased risk for HIV is made by the physician or health care practitioner who assesses the individual’s history. CMS also covers the furnishing of HIV PrEP using antiretroviral drugs, including the supplying or dispensing of these drugs and the administration of injectable PrEP.

For individuals being assessed for or using PrEP to prevent HIV, CMS covers all the following as an additional preventive service:

a) Up to eight individual counseling visits, every 12 months, that include HIV risk assessment (initial or continued assessment of risk), HIV risk reduction, and medication adherence. Counseling must be furnished by a physician or other health care practitioner. Individuals must be competent and alert at the time that counseling is provided.

b) Up to eight HIV screening tests every 12 months.

c) A single screening for hepatitis B virus (HBV).

These screening tests are covered when the appropriate FDA-approved laboratory tests and point of care tests are used consistent with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations.

NOTE: A single (one-time) screening for HBV is available under this NCD. NCD 210.6 Screening for Hepatitis B Virus (HBV) Infection is a separate benefit and continues to apply to eligible beneficiaries.

### III. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13843 - 03.1	<p>Effective for claims with dates of service on or after September 30, 2024, CMS covers 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.</p> <p>Please see Pub. 100-03, chapter 1, section 210.15, of the NCD Manual, and Pub. 100-04, chapter 18, section 250, of the CPM, for further instructions.</p>	X	X		X					

### IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

**Impacted Contractors:** A/B MAC Part A, A/B MAC Part B, DME MAC

## V. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:
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**Section B: All other recommendations and supporting information: N/A**

## VI. CONTACTS

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## VII. FUNDING

### **Section A: For Medicare Administrative Contractors (MACs):**

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**ATTACHMENTS: 0**

# ***Medicare National Coverage Determinations Manual***

## ***Chapter 1 – Part 4 (Sections 200 – 310.1) Coverage Determinations***

***Table of Contents  
(Rev. 12987; Issued:12-05-24)***

***210.15 – Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention***

## **210.15 – Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention**

**(Rev. 12-05-24; Issued: 12-05-24; Effective: 09-30-24; Implementation: 04-07-25)**

### **A. General**

Pre-exposure prophylaxis (PrEP) involves the use of antiretroviral drugs to decrease the risk of acquiring human immunodeficiency virus (HIV). Under § 1861(ddd)(1) of the Social Security Act (the Act), the Centers for Medicare & Medicaid Services (CMS) has the authority to add coverage of “additional preventive services” through the Medicare national coverage determination (NCD) process if certain statutory requirements are met: (1) reasonable and necessary for the prevention or early detection of illness or disability, (2) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), and (3) appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

### **B. Nationally Covered Indications**

Effective for claims with dates of service on or after September 30, 2024, CMS covers 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. The determination of whether an individual is at increased risk for HIV is made by the physician or health care practitioner who assesses the individual’s history. CMS also covers furnishing HIV PrEP using antiretroviral drugs, including the supplying or dispensing of these drugs and the administration of injectable PrEP.

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- b) Up to eight HIV screening tests every 12 months.
- c) A single screening for hepatitis B virus (HBV).

These screening tests are covered when the appropriate FDA-approved laboratory tests and point of care tests are used consistent with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations.

### **C. Nationally Non-Covered Indications**

Preventive services are non-covered by Medicare unless specifically covered in this NCD, any other NCD, in statute, or regulations.

### **D. Other**

Medicare Part B coinsurance and deductible are waived for this preventive service.