

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13209	Date: May 2, 2025
	Change Request 13843

Transmittal 12987 issued December 05, 2024, is being rescinded and replaced by Transmittal 13209, dated May 2, 2025, to assist MACs in processing claims by updating the following Pub.100-04 business requirements to provide additional clarifying information. A note was added to business requirements 13843-04.2 and 13843-04.2.1, updates business requirement 13843 - 04.4.4 and a new business requirement was added (13843-04.5.2). This correction does not make any revisions to Pub. 100-03. All other information remains the same.

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.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	18/250/Table of Contents
N	18/250/Pre-Exposure Prophylaxis (PreP) for Human Immunodeficiency Virus (HIV) Infection Prevention
N	18/250/1/Policy
N	18/250/2/Healthcare Common Procedural Coding System (HCPCS) Drug Codes and Diagnosis Codes
N	18/250/3/Billing and Payment Requirements
N	18/250/4/Messaging

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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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.

II. GENERAL INFORMATION

A. Background: This CR provides instructions for processing PrEP for HIV Prevention Claims. PrEP involves the use of antiretroviral drugs to decrease the risk of acquiring HIV. Under §1861(ddd)(1) of the Social Security Act (the Act), 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: 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.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	<ul style="list-style-type: none"> • 1 HEPB HCPCS code and LIDOS • NPI (Provider NPI for Outpatient claims and rendering NPI for Part B claims) • ICN/CCN • Claim type 									
13843 - 04.1.2	If a previously covered HIV PrEP claim that populates an HIVP auxiliary file is cancelled or adjusted as denied, CWF shall remove the auxiliary file data that the original claim populated.								X	
13843 - 04.1.3	Contractors shall display next eligible date on the Common Working File (CWF) provider query screen (HUQA) and include the next eligible date for the PrEP HIV services on PRVN screen. NOTE: The next eligible date is based on the earliest posted date of service for the iteration.						X		X	HETS, MBD, NGD
13843 - 04.1.4	The contractor shall create a Multi-Carrier System Desktop Tool (MCSDT) window to display the new HIV PrEP CWF auxiliary file						X			
13843 - 04.1.5	The Fiscal Intermediary Shared System (FISS) shall modify the Direct Data Entry (DDE) screens to include the HIV PrEP auxiliary file information.					X				
13843 - 04.1.6	CWF shall modify the MBD/NGD extract files sent to Medicare Beneficiary Database (MBD) and Next Generation Desktop-Medicare								X	HETS, MBD, NGD

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	has a primary diagnosis code of Z29.81.									
13843 - 04.1.10	The CWF shall populate the Hep B Virus (HBV) screening test codes and LIDOS in the HIV PrEP auxiliary record with the LIDOS of the HCPCS from both institutional or professional claims in the HIV PrEP auxiliary record when a HIV PrEP FROM date is within the 12-month period prior to the HBV Screening code LIDOS and the HBV Screening Test claim has a primary diagnosis code of Z29.81.								X	
13843 - 04.1.11	Contractors shall track up to eight individual counseling visits for PrEP for HIV every 12 months for Hospitals (013x TOB) RHCs (071x TOB), FQHCs (077x TOBs), and CAHs (085x TOB) for dates of service on or after September 30, 2024, for HCPS code G0011 and G0013 as a facility claim for BR13843-04.1.1.					X			X	
13843 - 04.1.12	Contractors shall create a reject for G0011 or G0013 for more than eight separate LIDOS visit encounter claims within a 12-month period (for both professional and institutional claims combined). The new edit will return trailers 08 and 43 on an A/MAC institutional Outpatient claim and trailers 08 and 39 on a B/MAC professional claim. NOTE: For CWF, this edit shall have override capability at the detail level for					X			X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	institutional outpatient claims and for Part B professional claims.									
13843 - 04.1.13	<p>Contractors shall deny the CWF rejected claim and use the following messages:</p> <p>CARC 96 - Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>RARC N640 - Exceeds number/frequency approved/allowed within time period.</p> <p>MSN message: 41.14: This service/item was billed incorrectly. 41.14- Este servicio o artículo fue facturado incorrectamente.</p> <p>Claim Adjustment Group Code - CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item).</p>	X	X							
13843 - 04.1.14	<p>Contractors shall pay for code G0011 on 085X TOB claims submitted with revenue code 96x, 97x, or 98x. NOTE: Payment is based on 115% of the Medicare Physician Fee Schedule.</p>	X				X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13843 - 04.2	<p>Contractors shall accept and pay up to eight HIV screening tests codes:</p> <p>G0475 - HIV antigen/antibody, combination assay, screening</p> <p>G0432 - Infectious agent antibody detection by enzyme immunoassay (EIA) technique, HIV-1 and/or HIV-2, screening,</p> <p>G0433 - Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening,</p> <p>G0435 - Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening, G0475 - Hiv antigen/antibody, combination assay, screening, or</p> <p>80081 – Organ Disease Oriented Panel</p> <p>every 12 months for individuals being assessed for or using PrEP to prevent HIV as identified with primary diagnosis code ICD-10 Z29.81.</p> <p>NOTE: CWF shall create this edit. FISS shall accept the CWF edit and create a corresponding Reason Code.</p>	X	X			X			X	
13843 - 04.2.1	<p>Contractors shall create a reject for ‘G0432 ‘G0433’ G0435’ G0475’ or ‘80081’ for more than eight claims with different LIDOS within a 12-month period. The new edit will return trailers 08 and 43 on an A/MAC institutional</p>					X			X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	<p>Outpatient claim and trailers 08 and 39 on a B/MAC professional claim.</p> <p>NOTE: For CWF, this edit shall have override capability at the detail level for institutional outpatient claims and for Part B professional claims.</p> <p>NOTE: CWF shall create this edit. FISS shall accept the CWF edit and create a corresponding Reason Code.</p>									
13843 - 04.2.2	<p>Contractors shall deny the CWF rejected claim and use the following messages:</p> <p>CARC 96 - Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>RARC N640 - Exceeds number/frequency approved/allowed within time period.</p> <p>MSN message: 41.14: This service/item was billed incorrectly. 41.14- Este servicio o artículo fue facturado incorrectamente.</p> <p>Claim Adjustment Group Code - CO (Contractual Obligation) or PR (Patient Responsibility) dependent</p>	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item).									
13843 - 04.3	Contractors shall accept and pay a single Hep B Virus (HBV) screening test for individuals being assessed for or using PrEP to prevent HIV. This is a once per life-time allowance.	X	X			X			X	
13843 - 04.3.1	<p>Contractors shall create a reject for more than one (HBV screening) claim line of service when HCPCS G0499, 87340, 87341, 86704, or 86706 and the HBV Screening Test claim has a primary diagnosis code of Z29.81. The new edit will return trailers 08 and 43 on an A/MAC institutional Outpatient claim and trailers 08 and 39 on a B/MAC professional claim.</p> <p>NOTE: See specific frequency associated with NCD 210.6, Hepatitis B Screening, still in effect.</p> <p>NOTE: For CWF, this edit shall have override capability at the detail level for institutional outpatient claims and for Part B professional claims.</p>					X			X	
13843 - 04.3.1.1	<p>Contractors shall deny the CWF rejected claim and use the following messages:</p> <p>CARC 96 - Non-covered charge(s). At least one</p>	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	<p>Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>RARC N640 - Exceeds number/frequency approved/allowed within time period.</p> <p>MSN message: 41.14: This service/item was billed incorrectly. 41.14- Este servicio o articulo fue facturado incorrectamente.</p> <p>Claim Adjustment Group Code - CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item).</p>									
13843 - 04.3.1.2	Contractors shall create a reject if an HBV screening is received with primary diagnosis code of Z29.81 and no PrEP HIV service have been submitted, to build the HIVP auxiliary screen. New edit returns trailers 08 and 43 on an A/MAC institutional OP claim and trailers 08 and 39 on a Part B professional claim.					X			X	
13843 - 04.3.1.3	Contractors shall deny the CWF rejected claim and use the following messages: CARC 96 – Non-covered charge(s). At least one	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	<p>Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>RARC – N386 This decision was based on a National Coverage Determination (NCD).</p> <p>MSN message: 15.20 The following policies were used when we made this decision: NCD 210.15</p> <p>Claim Adjustment Group Code - CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item).</p>									
13843 - 04.4	<p>Effective for services on or after September 30, 2024, contractors shall accept and pay for PrEP for HIV claims in individuals at increased risk of HIV acquisition using the following HCPCS:</p> <ul style="list-style-type: none"> J0799 - FDA approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), not otherwise classified, Short Descriptor: Hiv prep, fda approved, noc 	X	X		X	X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	J0799 when there is not a specific code to be utilized. NOTE: HCPCS code G0012 is not payable by DME MACs.									
13843 - 04.4.1	Contractors shall manually contractor Price for HCPCS J0739 J0750, J0751, and J0799 for claims with dates of service September 30, 2024, through December 31. 2024.		X		X					
13843 - 04.4.2	Contractors shall accept the following HCPCS for Pharmacy Supplying Fees effective for claims with dates of service September 30, 2024, through December 31, 2024: <ul style="list-style-type: none"> Q0516- Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 30-days Short Descriptor: Supply fee hiv prep oral 30-days Q0517-Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 60-days, Short Descriptor: Supply fee hiv prep oral 60-days Q0518- Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 90- 	X	X		X	X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	<p>days, Short Descriptor: Supply fee hiv prep oral 90- days</p> <ul style="list-style-type: none"> Q0519- Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 30-days, Short Descriptor: Supply fee hiv prep inj 30 Q0520- Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 60-days, Short Descriptor: Supply fee hiv prep inj 60 <p>Effective for claims with dates of service on and after January 1, 2025, the above HCPCS codes will be replaced with:</p> <ul style="list-style-type: none"> Q0521 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription, Short Descriptor: Supply fee hiv prep fda appr <p>Note: A/B MACs (A) shall allow the above mentioned HCPCS codes on TOBs 71x and 77x only.</p>									
13843 - 04.4.3	Contractors shall accept claims containing one of the following diagnosis codes along with one of the HCPCS	X	X		X	X	X			

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13843 - 04.4.4	<p>Contractors shall deny claims that contain a PrEP HCPCS code listed in 13843-04.4 and a diagnosis code listed in 13843-04.4.3 is not present on the claim and use the following messages:</p> <p>RARC N386 – This decision was based on a National Coverage Determination (NCD).</p> <p>CARC 50 – These are non-covered services because this is not deemed a ‘medical necessity’ by the payer. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>MSN message: 15.20 The following policies were used when we made this decision: NCD 210.15 Group Code CO (Contractual Obligation).</p> <p>Spanish version 15.20 - Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD-210.15.</p> <p>Group Code - CO (Contractual Obligation)</p>	X	X		X	X				
13843 - 04.4.5	This BR has been removed.	X	X			X				
13843 - 04.4.6	Contractors shall accept claims containing one of the following visit HCPCS codes: G0011 or G0013, listed with one of the diagnosis codes in 13843-04.4.3 for PrEP for HIV claims.	X	X			X			X	
13843 - 04.4.7	Contractors shall deny claims	X	X			X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	with the messages listed in 13843-04.4.4 that contain a HCPCS code listed in 13843-04.4.6 and does not have a diagnosis code listed in 13843-04.4.3.									
13843 - 04.5	Contractors shall only allow payment for pharmacy supplying fees HCPCS code listed in 13843-04.4.2 if billed on the same claim as the payable covered drugs for PrEP for HIV HCPCS codes listed in 13843-04.4.	X	X		X	X	X			
13843 - 04.5.1	<p>Contractors shall deny claims that contain a pharmacy supplying fees HCPCS code listed in 13843-04.4.2 and a covered drug for PrEP for HIV HCPCS code listed in 13843-04.4 is not present on the same claim using the following messages:</p> <p>CARC 107: The related or qualifying claim/service was not identified on this claim.</p> <p>MSN 17.11: This item or service cannot be paid as billed.</p> <p>Group Code - CO (Contractual Obligation)</p>	X	X		X					
13843 - 04.5.2	Contractors shall RTP claims that contain a pharmacy supplying fees HCPCS code listed in 13843-04.5 and billed as Patient Responsibility. (Claims are identified when Occurrence Code 32 or the GA modifier is appended to the line item).	X				X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	PrEP HIV services.									
13843 - 04.11	<p>CWF shall send, on the daily file, the following data elements for HIVP PrEP HCPCS for all beneficiaries who have current Part B entitlement and do not have a date of death on file, who have had HIVP claims activity:</p> <ul style="list-style-type: none"> -HCPCS code -Most recent Date of Service -NPI (Provider NPI for Outpatient claims and rendering NPI for Part B claims) <p>CWF shall modify the CABEMBD copybook and expand to include the HIVP occurrence.</p>								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:

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):

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.

ATTACHMENTS: 1

Medicare Claims Processing Manual

Chapter 18 – Preventive and Screening Services

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(Rev. 13209; Issued: 05-02-25)

- 250 - Pre- Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention*
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 - 250.2 - Healthcare Common Procedural Coding System (HCPCS) Drug Codes and Diagnosis Codes*
 - 250.3 - Billing and Payment Requirements*
 - 250.4 - Messaging*

1.2 – Table of Preventive and Screening Services

(Rev. 13209; Issued: 05-02-25; Effective: 09-30-24; Implementation: 04-07-25)

<p><i>Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention</i></p>	<p><i>G0011</i></p>	<p><i>Individual counseling for pre-exposure prophylaxis (PrEP) by physician or QHP to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15-30 minutes</i></p>	<p>B</p>	<p><i>WAIVED</i></p>
	<p><i>G0012</i></p>	<p><i>Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle, Short Descriptor: Inj, prep drug for hiv prev</i></p>		
	<p><i>G0013</i></p>	<p><i>Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence</i></p>		
	<p><i>J0739</i></p>	<p><i>Injection, cabotegravir, 1mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv) Short Descriptor: Injection, cabotegravir, 1 mg</i></p>		
	<p><i>J0750</i></p>	<p><i>Emtricitabine 200mg and tenofovir disoproxil fumarate 300mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), Short Descriptor: Hiv prep, ftc/tdf 200/300mg</i></p>		

	J0751	<i>Emtricitabine 200mg and tenofovir alafenamide 25mg, oral, fda approved prescription, only for use as pre-exposure prophylaxis (not for use as treatment of hiv), Short Descriptor: Hiv prep, ftc/tad 200/25mg</i>		
	J0799	<i>FDA approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), not otherwise classified, Short Descriptor: Hiv prep, fda approved, noc</i>		
	Q0516	<i>Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 30-days, Short Descriptor: Supply fee hiv prep oral 30-days</i>		
	Q0517	<i>Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 60-days, Short Descriptor: Supply fee hiv prep oral 60-days</i>		
	Q0518	<i>Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 90-days, Short Descriptor: Supply fee hiv prep oral 90-days</i>		
	Q0519	<i>Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 30-days, Short Descriptor: Supply fee hiv prep inj 30</i>		
	Q0520	<i>Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 60-days, Short Descriptor: Supply fee hiv prep inj 60</i>		

	<i>Q0521</i>	<i>Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription, Short descriptor: Supply fee hiv prep fda appr</i>		
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250. Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention

250.1 Policy

(Rev. 13209; Issued: 05-02-25; Effective: 09-30-24; Implementation: 04-07-25)

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).

Effective 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.

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.

Further information, including coverage guidelines can be found in Publication 100-03, Section 210.15.

250.2 Healthcare Common Procedural Coding System (HCPCS) Drug Codes and Diagnosis Codes

(Rev. 13209; Issued: 05-02-25; Effective: 09-30-24; Implementation: 04-07-25)

CMS has approved the following HCPCS and diagnosis codes for PrEP for HIV infection prevention.

A. Drug HCPCS Codes

J0799 - FDA approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), not otherwise classified, Short Descriptor: Hiv prep, fda approved, noc

J0750 - Emtricitabine 200mg and tenofovir disoproxil fumarate 300mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), Short Descriptor: Hiv prep, ftc/tdf 200/300mg

J0751 - Emtricitabine 200mg and tenofovir alafenamide 25mg, oral, fda approved prescription, only for use as pre-exposure prophylaxis (not for use as treatment of hiv), Short Descriptor: Hiv prep, ftc/tad 200/25mg

J0739 - Injection, cabotegravir, 1mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv) Short Descriptor: Injection, cabotegravir, 1 mg

G0012 - Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle, Short Descriptor: Inj, prep drug for hiv prev

B. Counseling HCPCS Codes

G0011 - Individual counseling for pre-exposure prophylaxis (PrEP) by physician or QHP to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15-30 minutes

G0013 - Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence

C. Pharmacy Supplying Fees HCPCS Codes

a. Prior to 01/01/2025

Q0516 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 30-days, Short Descriptor: Supply fee hiv prep oral 30-days

Q0517 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 60-days, Short Descriptor: Supply fee hiv prep oral 60-days

Q0518 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 90-days, Short Descriptor: Supply fee hiv prep oral 90-days

Q0519 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 30-days, Short Descriptor: Supply fee hiv prep inj 30

Q0520 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 60-days, Short Descriptor: Supply fee hiv prep inj 60

b. On or after 1/1/2025

Q0521 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription, Short descriptor: Supply fee hiv prep fda appr

D. Diagnosis Codes:

A51.31 Condyloma latum

A51.32 Syphilitic alopecia

A51.39 Other secondary syphilis of skin

A51.41 Secondary syphilitic meningitis

A51.42 Secondary syphilitic female pelvic disease

A51.43 Secondary syphilitic ophthalmopathy

A51.44 Secondary syphilitic nephritis

A51.45 Secondary syphilitic hepatitis

A51.46 Secondary syphilitic osteopathy

A51.49 Other secondary syphilitic conditions

A52.01 Syphilitic aneurysm of aorta

A52.02 Syphilitic aortitis

A52.03 Syphilitic endocarditis

A52.04 Syphilitic cerebral arteritis

A52.05 Other cerebrovascular syphilis

A52.06 Other syphilitic heart involvement

A52.09 Other cardiovascular syphilis

A52.11 Tabes dorsalis

A52.12 Other cerebrospinal syphilis

A52.13 Late syphilitic meningitis

A52.14 Late syphilitic encephalitis

A52.15 Late syphilitic neuropathy

A52.16 Charcot's arthropathy (tabetic)

A52.17 General paresis

A52.19 Other symptomatic neurosyphilis

A52.2 Asymptomatic neurosyphilis

A52.71 Late syphilitic ophthalmopathy

A52.72 Syphilis of lung and bronchus

A52.73 Symptomatic late syphilis of other respiratory organs

A52.74 Syphilis of liver and other viscera

A52.75 Syphilis of kidney and ureter

A52.76 Other genitourinary symptomatic late syphilis

A52.77 Syphilis of bone and joint

A52.78 Syphilis of other musculoskeletal tissue

A52.79 Other symptomatic late syphilis

A53.0 Latent syphilis, unspecified as early or late

A54.00 Gonococcal infection of lower genitourinary tract, unspecified

A54.01 Gonococcal cystitis and urethritis, unspecified

A54.02 Gonococcal vulvovaginitis, unspecified

A54.03 Gonococcal cervicitis, unspecified

A54.09 Other gonococcal infection of lower genitourinary tract

A54.1 Gonococcal infection of lower genitourinary tract with periurethral and accessory gland abscess

A54.21 Gonococcal infection of kidney and ureter

A54.22 Gonococcal prostatitis

A54.23 Gonococcal infection of other male genital organs

A54.24 Gonococcal female pelvic inflammatory disease

A54.29 Other gonococcal genitourinary infections

A54.31 Gonococcal conjunctivitis

A54.32 Gonococcal iridocyclitis

A54.33 Gonococcal keratitis

A54.39 Other gonococcal eye infection

A54.41 Gonococcal spondylopathy

A54.42 Gonococcal arthritis

A54.43 Gonococcal osteomyelitis

A54.49 Gonococcal infection of other musculoskeletal tissue

A54.5 Gonococcal pharyngitis

A54.6 Gonococcal infection of anus and rectum

A54.81 Gonococcal meningitis

A54.82 Gonococcal brain abscess

A54.83 Gonococcal heart infection

A54.84 Gonococcal pneumonia

A54.85 Gonococcal peritonitis

A54.86 Gonococcal sepsis

A54.89 Other gonococcal infections

A56.01 Chlamydial cystitis and urethritis

A56.02 Chlamydial vulvovaginitis

A56.09 Other chlamydial infection of lower genitourinary tract

A63.8 Other specified predominantly sexually transmitted diseases

A64 Unspecified sexually transmitted disease

F11.10 Opioid abuse, uncomplicated

F11.20 Opioid dependence, uncomplicated

F11.21 Opioid dependence, in remission

F11.90 Opioid use, unspecified, uncomplicated

Z11.3 Encounter for screening for infections with a predominantly sexual mode of transmission

Z11.4 Encounter for screening for human immunodeficiency virus [HIV]

Z11.59 Encounter for screening for other viral diseases

Z13.29 Encounter for screening for other suspected endocrine disorder

Z20.2 Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission

Z20.5 Contact with and (suspected) exposure to viral hepatitis

Z20.6 Contact with and (suspected) exposure to human immunodeficiency virus [HIV]

Z20.828 Contact with and (suspected) exposure to other viral communicable diseases

Z20.89 Contact with and (suspected) exposure to other communicable diseases

Z20.9 Contact with and (suspected) exposure to unspecified communicable disease

Z29.81 Encounter for HIV pre-exposure prophylaxis

Z32.00 Encounter for pregnancy test, result unknown

Z32.01 Encounter for pregnancy test, result positive

Z32.02 Encounter for pregnancy test, result negative

Z72.51 High risk heterosexual behavior

Z72.52 High risk homosexual behavior

Z72.53 High risk bisexual behavior

Z72.89 Other problems related to lifestyle

Z79.899 Other long term (current) drug therapy

Z86.59 Personal history of other mental and behavioral disorders

Z87.898 Personal history of other specified conditions

250.3- Billing and Payment Requirements

(Rev. 13209; Issued: 05-02-25; Effective: 09-30-24; Implementation: 04-07-25)

Effective for claims with dates of service on or after September 30, 2024:

- A. *Contractors shall accept and pay for PrEP for HIV claims using antiretroviral drugs (HCPCS J0739, J0799, J0750, or J0751) approved by the US Food and Drug Administration (FDA) to prevent HIV infection in individuals at increased risk of HIV acquisition using one of the diagnosis codes listed in 250.2(D).*

Contractors shall accept and pay for up to (8) counseling sessions related to PrEP for HIV medications every 12 months using HCPCS G0011 or G0013.

Contractors shall not apply the deductible or co-insurance for PrEP claims for HIV prevention medications or related services, including counseling, HIV and HBV screening.

- B. *Contractors shall pay for code G0011 on 085X TOB claims submitted with revenue code 96x, 97x, or 98x.*

NOTE: Payment is based on 115% of the Medicare Physician Fee Schedule.

- C. *Contractors shall pay code G0011 on Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) claims. RHCs shall bill G0011 with a -CG Modifier and payment is at the all-inclusive rate (AIR). FQHCs shall bill G0011 along with the appropriate FQHC specific payment code (G0466 or G0467). Payment is at the lesser of charges or the FQHC PPS rate. PrEP for HIV Counseling HCPCS Code G0011 is considered a visit for RHCs and FQHCs when furnished by an RHC or FQHC Practitioner.*
- D. *Contractors shall accept and pay up to eight HIV screening tests (codes G0432 - Infectious agent antibody detection by enzyme immunoassay (EIA) technique, HIV-1 and/or HIV-2, screening; G0433 - Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening; G0435 - Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening; G0475 - Hiv antigen/antibody, combination assay, screening; or 80081 – Organ Disease Oriented Panel) every 12 months when providing individual counseling for PrEP for HIV.*

E. Contractors shall accept and pay a single Hep B Virus (HBV) screening test (codes G0499, 87340, 87341, 86704, 86706) for individuals being assessed for or using PrEP to prevent HIV. This is a once per life-time allowance.

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

F. Contractors shall only allow payment for supplying fees if billed on the same claim as the payable covered drug. RHCs and FQHCs do not need to enroll as a Medicare Part B pharmacy supplier or a DMEPOS pharmacy supplier to bill for PrEP for HIV drugs.

G. Deductible and coinsurance do not apply.

250.4 Messaging

(Rev. 13209; Issued: 05-02-25; Effective: 09-30-24; Implementation: 04-07-25)

Contractors shall deny the CWF rejected claims for G0011 or G0013 for more than eight separate LIDOS visit encounter claims within a 12-month period (for both professional and institutional claims combined) and use the following messages:

CARC 96 - Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N640 - Exceeds number/frequency approved/allowed within time period.

Claim Adjustment Group Code - CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item).

MSN message: 41.14: This service/item was billed incorrectly. 41.14- Este servicio o artículo fue facturado incorrectamente.

Contractors shall deny the CWF rejected claim for G0432 'G0433' G0435' G0475' or '80081' for more than eight claims with different LIDOS within a 12-month period and use the following messages:

CARC 96 - Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N640 - Exceeds number/frequency approved/allowed within time period.

Claim Adjustment Group Code - CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item).

MSN message: 41.14: This service/item was billed incorrectly. 41.14- Este servicio o artículo fue facturado incorrectamente.

*Contractors shall deny the CWF rejected claim if an HBV screening is received with primary diagnosis code of Z29.81 and no PrEP HIV service have been submitted.
and use the following messages:*

CARC 96 – Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC – N386 This decision was based on a National Coverage Determination (NCD).

Claim Adjustment Group Code - CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item).

MSN message: 15.20 The following policies were used when we made this decision: NCD 210.15

Contractors shall deny the CWF rejected claim when the primary diagnosis code of Z29.81 is present on the Part B or Outpatient claim and claim has service for HIV or HBV that should apply to PrEP HIV services and use the following messages:

CARC 96 - Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC – N386 This decision was based on a National Coverage Determination (NCD).

Claim Adjustment Group Code - CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item).

MSN message: 15.20 The following policies were used when we made this decision: NCD 210.15

Contractors shall deny claims that contain a pharmacy supplying fees HCPCS code listed in Section 250.2 and a covered drug for PrEP for HIV HCPCS code listed in Section 250.2 is not present on the same claim using the following messages:

CARC 107: The related or qualifying claim/service was not identified on this claim.

MSN 17.11: This item or service cannot be paid as billed.

Group Code - CO (Contractual Obligation)

Contractors shall deny the claim if there is an acquisition HCPCS listed in Section 250.2 without a diagnosis code listed in Section 250.2 and use the following messages:

RARC N386 – This decision was based on a National Coverage Determination (NCD).

CARC 50 – These are non-covered services because this is not deemed a ‘medical necessity’ by the payer. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

Claim Adjustment Group Code - CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item).

MSN message: 15.20 The following policies were used when we made this decision: NCD 210.15. Spanish version 15.20 - Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD-210.15.

Contractors shall deny claims that contain a visit HCPCS (G0011 or G0013) listed without one of the diagnosis codes in Section 250.2 for PreP for HIV claims and use the following messages:

RARC N386 – This decision was based on a National Coverage Determination (NCD).

CARC 50 – These are non-covered services because this is not deemed a ‘medical necessity’ by the payer. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

Claim Adjustment Group Code - CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability. (Use PR when Occurrence Code 32 (Institutional claim) or the GA modifier (Professional claim) is appended to the line item).

MSN message: 15.20 The following policies were used when we made this decision: NCD 210.15

NCD: 210.15										
NCD Title: Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention (CR13843)										
IOM:										
MCD: https://www.cms.gov/medicare-coverage-database/view/hccal-decision-memo.aspx?proposed=N&NCAId=310										
Part A	Rule Description Part A	Proposed HCPCS/CPT Part A	Frequency Limitations	TOB (Part A)	Revenue Code Part A	Modifier Part A	Provider Specialty	Proposed MSN Message Part A	Proposed CARC Message Part A	Proposed RARC Message Part A
Part A	Effective for claims with dates of service (DOS) on or after 9/30/24, contractors shall accept and pay for up to 8 individual counseling visits for PrEP for HIV every 12 months using the specified HCPCS codes. NOTE: This edit shall have override capability at the claim detail line.	G0011 G0013	8 x 12 months					41.14	96	N640
Part A	Contractors shall pay for codes G0011 on 085X TOB claims submitted with revenue code 96x, 97x, or 98x. NOTE: Payment is based on 115% of the Medicare Physician Fee Schedule.	G0011		085X	96x, 97x, 98x					
Part A	Contractors shall accept and pay up to 8 HIV screening tests. Contractors shall deny claims for HIV tests (codes G0432, G0433, G0435, G0475, or 80081) that exceed the allowed frequency. NOTE: This edit shall have override capability at the claim detail line.	G0432 G0433 G0435 G0475 80081	8 x 12 months					41.14	96	N640
Part A	Contractors shall accept and pay a single HBV screening test (codes G0499, 87340, 87341, or 86706) when codes G0432, G0433, G0435, G0475 or 80081 are in history within a 12-month period, when providing individual counseling for PrEP for HIV. Contractors shall deny claims for HBV tests (codes G0499, 87340, 87341, or 86706) that exceed the allowed frequency NOTE: See specific frequency associated with NCD 210.6, Hepatitis B Screening, still in effect. NOTE: This edit shall have override capability at the claim detail line.	G0499 87340 87341 86704 86706						41.14	96	N640
Part A	As per Medicare Claims Processing Manual Chapter 32 section 412.2, Contractors shall deny claims that do not contain one of the HCPCS codes for PrEP for HIV along with one of the diagnosis codes listed.							15.20	50	N386
Part A	and pay for PrEP for HIV claims in individuals at increased risk of HIV acquisition using the following HCPCS and specified dx codes. Contractors shall deny claims that do not contain a HCPCS drug code listed AND a code from the dx list. NOTE: Contractors shall only accept and pay for NOC code J0799 when there is not a specific code to be utilized. NOTE: HCPCS code G0012 is not payable by DME MACs. Contractors shall complete the PARM PRMMNOPR that applies payer only modifier @3 to HCPCS J0739, J0750, J0751, J0799, G0011, G0012, and G0013. NOTE: Once this CR is implemented, deductible and coinsurance do not apply to the above listed HCPCS codes.	G0012 J0739 J0750 J0751 J0799						15.20	50	N386

NCD: 210.15											
NCD Title: Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention (CR13843)											
IOM:											
MCD: https://www.cms.gov/medicare-coverage-database/view/hcaccid-decision-memo.aspx?proposed=N&NCAId=310											
Part A	Contractors shall not apply deductible or coinsurance for claim lines billed with the above listed HCPCS codes including drugs, counseling sessions, and pharmacy dispensing or supplying fees. Contractors shall remove the PARM PRMMNOPR that applies payer only modifier @3 to HCPCS J0739, J0750, J0751, J0799, G0011, G0012, and G0013. NOTE: Once this CR is implemented, deductible and coinsurance do not apply to the above listed HCPCS codes.	G0012 J0750 J0751 J0799									
Part A	Contractors shall not search for PrEP claims but may adjust claims that are brought to their attention.										
Part A	Contractors shall accept the following HCPCS for Pharmacy Supplying Fees. Contractors shall only allow payment for supplying fees if billed on the same claim as the payable covered drug. Contractors shall deny claims if the supplying fees are not billed on the same claim as the payable covered drug. Contractors shall deny supplying fee HCPCS listed if the claim does not contain G0012, J0739, J0750, J0751 or J0799 AND a code from the dx list.	9/30/24-12/31/24: Q0516 Q0517 Q0518 Q0519 Q0520 1/1/25: Q0521						17.11	107		
Part B	Rule Description Part B	Proposed HCPCS/CPT Part B	Frequency Limitations	POS Part B	Revenue Code	Modifier Part B	Provider Specialty	Proposed MSN Message Part B	Proposed CARC Message Part B	Proposed RARC Message Part B	Part B
Part B	Effective for claims with DOS on or after 9/30/24, contractors shall accept and pay for up to 8 individual counseling visits for PrEP for HIV every 12 months using the specified HCPCS codes. NOTE: This edit shall have override capability at the claim detail line.	G0011 G0013	8 x 12 months					41.14	96	N640	
Part B	Contractors shall accept and pay up to 8 HIV screening tests. Contractors shall deny claims for HIV tests (codes G0432, G0433, G0435, G0475, or 80081) that exceed the allowed frequency. NOTE: This edit shall have override capability at the claim detail line.	G0432 G0433 G0435 G0475 80081	8 x 12 months					41.14	96	N640	
Part B	Contractors shall accept and pay a single HBV screening test (codes G0499, 87340, 87341, or 86706) when codes G0432, G0433, G0435, G0475 or 80081 are in history within a 12-month period, when providing individual counseling for PrEP for HIV. Contractors shall deny claims for HBV tests (codes G0499, 87340, 87341, or 86706) that exceed the allowed frequency NOTE: See specific frequency associated with NCD 210.6, Hepatitis B Screening, still in effect. NOTE: This edit shall have override capability at the claim detail line	G0499 87340 87341 86704 86706						41.14	96	N640	
Part B	As per Medicare Claims Processing Manual Chapter 32 section 412.2, contractors shall deny claims that do not contain one of the HCPCS codes for PrEP for HIV along with one of the dx codes listed.							15.2	50	N386	

NCD: 210.15										
NCD Title: Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention (CR13843)										
IOM:										
MCD: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=310										
Part B	Effective for DOS on or after 9/30/24, contractors shall accept and pay for PrEP for HIV claims in individuals at increased risk of HIV acquisition using the following HCPCS and specified dx codes. Contractors shall deny claims that do not contain a HCPCS drug code listed AND a code from the dx list. NOTE: Contractors shall only accept and pay for NOC code J0799 when there is not a specific code to be utilized. NOTE: HCPCS code G0012 is not payable by DME MACs. Contractors shall manually contractor price for HCPCS J0739 J0750, J0751, and J0799. NOTE: Once this CR is implemented, deductible and coinsurance do not apply to the above listed HCPCS codes.	G0012 J0739 J0750 J0751 J0799						15.2	50	N386
Part B	Contractors shall accept the following HCPCS for Pharmacy Supplying Fees. Contractors shall only allow payment for supplying fees if billed on the same claim as the payable covered drug. Contractors shall deny claims if the supplying fees are not billed on the same claim as the payable covered drug. Contractors shall deny supplying fee HCPCS listed if the claim does not contain G0012, J0739, J0750, J0751 or J0799 AND a code from the dx list.	9/30/24-12/31/24: Q0516 Q0517 Q0518 Q0519 Q0520 1/1/25: Q0521						17.11	107	
Part B	Contractors shall not apply deductible or coinsurance for claim lines billed with the above listed HCPCS codes including drugs, counseling sessions, and pharmacy dispensing or supplying fees. NOTE: Once this CR is implemented, deductible and coinsurance do not apply to the above listed HCPCS codes. Contractors shall not search for PrEP claims but may adjust claims that are brought to their attention.	G0012 J0750 J0751 J0799								
Revision History										
<p>CR13483: 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. For individuals being assessed for or using PrEP to prevent HIV, CMS covers all the following as an additional preventive service:</p> <p>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.</p> <p>b) Up to eight HIV screening tests every 12 months.</p> <p>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.</p> <p>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.</p>										

NCD:	210.15
NCD Title:	Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention (CR13843)
IOM:	
MCD:	NCA - Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection (CAG-00464N) - Decision Memo (cms.gov)
	CMS reserves the right to add or remove codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.
ICD-10 CM	ICD-10 DX Description
A51.31	Condyloma latum
A51.32	Syphilitic alopecia
A51.39	Other secondary syphilis of skin
A51.41	Secondary syphilitic meningitis
A51.42	Secondary syphilitic female pelvic disease
A51.43	Secondary syphilitic oculopathy
A51.44	Secondary syphilitic nephritis
A51.45	Secondary syphilitic hepatitis
A51.46	Secondary syphilitic osteopathy
A51.49	Other secondary syphilitic conditions
A52.01	Syphilitic aneurysm of aorta
A52.02	Syphilitic aortitis
A52.03	Syphilitic endocarditis
A52.04	Syphilitic cerebral arteritis
A52.05	Other cerebrovascular syphilis
A52.06	Other syphilitic heart involvement
A52.09	Other cardiovascular syphilis
A52.11	Tabes dorsalis
A52.12	Other cerebrospinal syphilis
A52.13	Late syphilitic meningitis
A52.14	Late syphilitic encephalitis
A52.15	Late syphilitic neuropathy
A52.16	Charcot's arthropathy (tabetic)
A52.17	General paresis
A52.19	Other symptomatic neurosyphilis
A52.2	Asymptomatic neurosyphilis
A52.71	Late syphilitic oculopathy
A52.72	Syphilis of lung and bronchus
A52.73	Symptomatic late syphilis of other respiratory organs
A52.74	Syphilis of liver and other viscera
A52.75	Syphilis of kidney and ureter
A52.76	Other genitourinary symptomatic late syphilis
A52.77	Syphilis of bone and joint
A52.78	Syphilis of other musculoskeletal tissue
A52.79	Other symptomatic late syphilis
A53.0	Latent syphilis, unspecified as early or late
A54.00	Gonococcal infection of lower genitourinary tract, unspecified
A54.01	Gonococcal cystitis and urethritis, unspecified
A54.02	Gonococcal vulvovaginitis, unspecified
A54.03	Gonococcal cervicitis, unspecified
A54.09	Other gonococcal infection of lower genitourinary tract
A54.1	Gonococcal infection of lower genitourinary tract with periurethral and accessory gland abscess
A54.21	Gonococcal infection of kidney and ureter
A54.22	Gonococcal prostatitis
A54.23	Gonococcal infection of other male genital organs

	CMS reserves the right to add or remove codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.
A54.24	Gonococcal female pelvic inflammatory disease
A54.29	Other gonococcal genitourinary infections
A54.31	Gonococcal conjunctivitis
A54.32	Gonococcal iridocyclitis
A54.33	Gonococcal keratitis
A54.39	Other gonococcal eye infection
A54.41	Gonococcal spondylopathy
A54.42	Gonococcal arthritis
A54.43	Gonococcal osteomyelitis
A54.49	Gonococcal infection of other musculoskeletal tissue
A54.5	Gonococcal pharyngitis
A54.6	Gonococcal infection of anus and rectum
A54.81	Gonococcal meningitis
A54.82	Gonococcal brain abscess
A54.83	Gonococcal heart infection
A54.84	Gonococcal pneumonia
A54.85	Gonococcal peritonitis
A54.86	Gonococcal sepsis
A54.89	Other gonococcal infections
A56.01	Chlamydial cystitis and urethritis
A56.02	Chlamydial vulvovaginitis
A56.09	Other chlamydial infection of lower genitourinary tract
A63.8	Other specified predominantly sexually transmitted diseases
A64	Unspecified sexually transmitted disease
F11.10	Opioid abuse, uncomplicated
F11.20	Opioid dependence, uncomplicated
F11.21	Opioid dependence, in remission
F11.90	Opioid use, unspecified, uncomplicated
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z11.4	Encounter for screening for human immunodeficiency virus [HIV]
Z11.59	Encounter for screening for other viral diseases
Z13.29	Encounter for screening for other suspected endocrine disorder
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Z20.5	Contact with and (suspected) exposure to viral hepatitis
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
Z20.89	Contact with and (suspected) exposure to other communicable diseases
Z20.9	Contact with and (suspected) exposure to unspecified communicable disease
Z29.81	Encounter for HIV pre-exposure prophylaxis
Z32.00	Encounter for pregnancy test, result unknown
Z32.01	Encounter for pregnancy test, result positive
Z32.02	Encounter for pregnancy test, result negative
Z72.51	High risk heterosexual behavior
Z72.52	High risk homosexual behavior
Z72.53	High risk bisexual behavior
Z72.89	Other problems related to lifestyle
Z79.899	Other long term (current) drug therapy
Z86.59	Personal history of other mental and behavioral disorders
Z87.898	Personal history of other specified conditions

NCD:	210.15
NCD Title:	Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention (CR13843)
IOM:	
MCD:	NCA - Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection (CAG-00464N) - Decision Memo (cms.gov) CMS reserves the right to add or remove codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.
ICD-10 PCS	ICD-10 PCS Description
N/A	N/A