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National Coverage Determination 210.15: Pre-Exposure Prophylaxis (PrEP) for HIV Prevention

Related CR Release Date: December 5, 2024	**MLN Matters Number:** MM13843
Effective Date: September 30, 2024	**Related Change Request (CR) Number:** CR 13843
Implementation Date: April 7, 2025	**Related CR Transmittal Number:** R12987CP & R12987NCD
Related CR Title: National Coverage Determination (NCD) 210.15 - Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention	

Affected Providers

- Physicians
- DMEPOS suppliers
- Part B pharmacy suppliers
- Other providers billing Medicare Administrative Contractors (MACs) for HIV preventive services they provide to Medicare patients

Action Needed

Make sure your billing staff knows about:

- National coverage of Pre-exposure prophylaxis (PrEP) using FDA-approved antiretroviral drugs to prevent HIV
- HCPCS and diagnosis codes
- Billing and payment requirements

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Background

Starting September 30, 2024, CMS covers these services as an additional preventive service under Section 1861(ddd)(1) of the Social Security Act:

- PrEP using FDA-approved antiretroviral drugs to prevent HIV in patients at increased risk of acquiring HIV
- Supplying or dispensing the PrEP drugs
- Administration of injectable PrEP

The physician or health care practitioner who assesses the patient's history determines whether an individual is at increased risk for HIV.

For patients you're assessing for or who are currently using PrEP to prevent HIV, we also cover these additional preventive services under National Coverage Determination (NCD) 210.15:

- Up to 8 individual counseling visits every 12 months, including:
  - HIV risk assessment (initial or continued assessment of risk)
  - HIV risk reduction
  - Medication adherence
- Up to 8 HIV screening tests every 12 months
- 1 screening for hepatitis B virus (HBV)

A physician or other health care practitioner must provide counseling, and patients must be competent and alert at the time of counseling.

We cover these screening tests when a health care practitioner uses appropriate FDA-approved laboratory and point of care tests, consistent with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations.

Note: We cover a one-time HBV screening test under this NCD. NCD 210.6, Screening for HBV Infection, is a separate benefit and continues to apply to eligible patients.

Rural Health Clinics (RHCs) & Federally Qualified Health Centers (FQHCs)

- RHC and FQHC practitioners can bill for individual counseling when they perform these services in RHCs and FQHCs. Use PrEP for HIV Counseling HCPCS code G0011 for a counseling visit. We cover 8 counseling visits every 12 months for RHCs and FQHCs.
  - RHCs bill G0011 with a CG modifier and payment is at the all-inclusive rate (AIR).
  - FQHCs 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.
- RHCs and FQHCs don't need to enroll as a Medicare Part B or DMEPOS pharmacy supplier to bill for PrEP for HIV drugs.

HCPCS & Diagnosis Codes

Section 250 of the Medicare Claims Processing Manual, Chapter 18 includes the approved HCPCS and diagnosis codes for PrEP for HIV prevention.

Drug HCPCS codes:

- G0012: Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle
- J0739: Injection, cabotegravir, 1 mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv)
- J0750: Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)
- J0751: Emtricitabine 200 mg and tenofovir alafenamide 25 mg, oral, fda approved prescription, only for use for hiv pre-exposure prophylaxis (not for use as treatment of hiv)
- J0799: Fda approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), not otherwise classified

Counseling HCPCS Codes:

- G0011: Individual counseling for pre-exposure prophylaxis (prep) by physician or qualified health care professional (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

Pharmacy Supplying Fee HCPCS Codes:

Use the following codes through December 31, 2024:

- Q0516: Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 30-days
- Q0517: Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 60-days
- Q0518: Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 90-days
- Q0519: Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 30-days
- Q0520: Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 60-days

Starting January 1, 2025, Q0521 (Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription) will replace the above HCPCS codes for pharmacy supplying fee.

ICD-10 Codes:

- Z29.81: Encounter for HIV pre-exposure prophylaxis
- Z11.4: Encounter for screening for human immunodeficiency virus [HIV]
- Increased risk factors reported:

  A51.31, A51.32, A51.39, A51.41, A51.42, A51.43, A51.44, A51.45, A51.46, A51.49, A52.01, A52.02, A52.03, A52.04, A52.05, A52.06, A52.09, A52.11, A52.12, A52.13, A52.14, A52.15, A52.16, A52.17, A52.19, A52.2, A52.71, A52.72, A52.73, A52.74, A52.75, A52.76, A52.77, A52.78, A52.79, A53.0, A54.00, A54.01, A54.02, A54.03, A54.09, A54.1, A54.21, A54.22, A54.23, A54.24, A54.29, A54.31, A54.32, A54.33, A54.39, A54.41, A54.42, A54.43, A54.49, A54.5, A54.6, A54.81, A54.82, A54.83, A54.84, A54.85, A54.86, A54.89, A56.01, A56.02, A56.09, A63.8, A64, F11.10, F11.20, F11.21, F11.90, Z11.3, Z11.59, Z13.29, Z20.2, Z20.5, Z20.6, Z20.828, Z20.89, Z20.9, Z29.81, Z32.00, Z32.01, Z32.02, Z72.51, Z72.52, Z72.53, Z72.89, Z79.899, Z86.59, and Z87.898

Billing & Payment Requirements for Claims with Dates of Service on or after September 30, 2024

Section 250 of the Medicare Claims Processing Manual, Chapter 18 includes the billing and payment requirements for PrEP for HIV prevention.

Deductibles and coinsurance don't apply to PrEP claims for HIV prevention medications or related services, including counseling and HIV or HBV screening.

Submit claims for G0011 on type of bill 085X with revenue code 96x, 97x, or 98x. We base payment on 115% of the Medicare Physician Fee Schedule.

We'll pay for:

- Up to 8 individual counseling visits (codes G0011 or G0013) every 12 months.
- Up to 8 HIV screening tests (codes G0432, G0433, G0435, G0475, or 80081) every 12 months for patients being assessed for or using PrEP to prevent HIV with a primary diagnosis code of Z29.81.
- 1 HBV screening test (codes G0499, 87340, 87341, 86704, or 86706) for patients being assessed for or using PrEP to prevent HIV. This is a once per life-time allowance.

We'll deny claims that exceed the allowed frequency and use these 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.
- MSN message 41.14 – This service/item was billed incorrectly.
- 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).

We'll deny claims for an HBV screening test with primary diagnosis code Z29.81 if a PrEP for HIV service hasn't also been submitted and use these 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).
- MSN message 15.20 – The following policies were used when we made this decision: NCD 210.15.
- 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).

We'll pay for PrEP for HIV claims using antiretroviral drugs (G0012, J0739, J0799, J0750, or J0751) to prevent HIV infection in patients at increased risk of acquiring HIV using 1 of the diagnosis codes listed in Section 250.2 of the Medicare Claims Processing Manual, Chapter 18. We'll deny claims that don't contain 1 of the HCPCS codes for PrEP for HIV, along with one of the diagnosis codes and use these messages:

- 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.
- RARC N386 – This decision was based on a National Coverage Determination (NCD).
- MSN message 15.20 – The following policies were used when we made this decision: NCD 210.15.
- Group Code – CO (Contractual Obligation).

We'll pay for pharmacy supplying fees if billed on the same claim as the payable covered drug. We'll deny claims if you don't bill the supply fees on the same claim as the payable covered drug using these 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)

Your MAC won't adjust previously processed claims unless you bring those claims to their attention.

More Information

We issued CR 13843 to your MAC as official instruction for this change. The CR is in these 2 transmittals:

- Transmittal R12987CP adds billing instructions in Section 250 of the Medicare Claims Processing Manual, Chapter 18
- Transmittal R12987NCD adds Section 210.15 to the Medicare NCD Manual, Chapter 1, Part 4

For more information, find your MAC's website.

Document History

Date of Change	Description
December 12, 2024	Initial article released.