

# ***Medicare Claims Processing Manual***

## ***Chapter 18 – Preventive and Screening Services***

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## 1.2 – Table of Preventive and Screening Services

(Rev. 12987; Issued: 12- 05-24 Effective: 09-30-24; Implementation:04-07-25)

<i>Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention</i>	<i>G0011</i>	<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>	<b>B</b>	<i>WAIVED</i>
	<i>G0012</i>	<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>		
	<i>G0013</i>	<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>		
	<i>J0739</i>	<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>		
	<i>J0750</i>	<i>Emtricitabine 200mg and tenofovir disoproxil</i>		

		<i>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>		
	<i>J0751</i>	<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>		
	<i>J0799</i>	<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>		
	<i>Q0516</i>	<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>		
	<i>Q0517</i>	<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>		
	<i>Q0518</i>	<i>Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug,</i>		

		<i>per 90-days, Short Descriptor: Supply fee hiv prep oral 90-days</i>		
	<i>Q0519</i>	<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>		
	<i>Q0520</i>	<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>		

***250. Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention***  
***(Rev. 12987; Issued: 12- 05-24 Effective: 09-30-24; Implementation:04-07-25)***

***250.1 Policy***  
***(Rev. 12987; Issued: 12- 05-24 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. 12987; Issued: 12- 05-24 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 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*

*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. 12987; Issued: 12- 05-24 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 lessor 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. 12987; Issued: 12- 05-24 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*