

## **NOTICE**

TO: All Disability Insurers Providing Health Insurance Coverage in

California

FROM: Insurance Commissioner Ricardo Lara

DATE: February 7, 2024

RE: Health Insurer HIV Preexposure Prophylaxis (PrEP) and Integral

Services Reimbursement Guidelines

This Notice sets forth best practices for health insurers' reimbursement policies for billing and coding of claims for HIV preexposure prophylaxis (PrEP) and associated integral services by participating providers. State and federal preventive care law under the federal Affordable Care Act prohibits cost sharing, including deductible, copayment, and coinsurance, for recommended preventive services, including PrEP. This cost sharing prohibition extends not just to recommended preventive services, but also to items and services that are integral to providing recommended preventive services.

A recent report<sup>1</sup> shared with the National Association of Insurance Commissioners by its consumer representatives found that payer guidance on preventive services billing and coding was inconsistently available and rarely provided complete information that providers would need to appropriately bill and code preventive services to ensure accurate adjudication of claims as preventive care not subject to cost sharing. Of particular concern to me was the report's finding that despite the law, consumers are receiving surprise bills for integral services for PrEP.

To prevent the application of cost sharing to integral services for PrEP, I encourage health insurers to issue guidelines, as detailed in Section II below, to participating providers with uniform billing and coding policies for integral services. Health insurers that do not issue standardized reimbursement guidelines risk being found to violate preventive care law if cost sharing is required for PrEP integral services claims.

<sup>&</sup>lt;sup>1</sup> Consumer Representatives to the National Association of Insurance Commissioners, <u>Preventive Services Coverage and Cost-Sharing Protections Are Inconsistently and Inequitably Implemented: Considerations for Regulators</u> (Aug. 2023).

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## I. Background

Pursuant to California Insurance Code section 10112.2 and federal Public Health Service (PHS) Act section 2713 (42 USC section 300gg-13)<sup>2</sup>, non-grandfathered group and individual health insurance policies, including student health insurance policies, must cover certain preventive health services without cost sharing. This requirement includes "A" and "B" grade recommendations of the U.S. Preventive Services Task Force (USPSTF), for plan years that begin on or after the date that is one year after the date the recommendation was issued. The USPSTF has recommended since June of 2019, with an "A" grade, that providers prescribe effective antiretroviral therapy to adults and adolescents who are at increased risk of HIV acquisition.<sup>3</sup> Effective antiretroviral therapy for preventing HIV currently includes both daily oral PrEP and long-acting injectable cabotegravir.<sup>4</sup> Health insurers must cover all FDA-approved PrEP medications without cost sharing or medical management restrictions.

On June 10, 2020, I issued a Notice<sup>5</sup> to disability insurers providing health insurance coverage in California, clarifying the services that must be covered without cost sharing pursuant to the USPSTF recommendation for PrEP. The Notice clarified that in addition to the antiretroviral drug itself, services necessary for PrEP initiation and ongoing follow-up and monitoring, as specified in the Centers for Disease Control and Prevention's (CDC's) most recently updated clinical guidance and determined by a patient's attending health care provider, must also be covered without cost sharing.

Subsequently, on December 29, 2021, I issued Bulletin 2021-10.<sup>6</sup> The Bulletin advised that under Insurance Code sections 10112.2 and 10123.1933, health insurers must cover longacting injectable cabotegravir for PrEP, drug administration, and other integral services that are necessary to initiate therapy and provide ongoing follow-up without cost sharing. Coverage of integral services for daily oral PrEP and cabotegravir must be provided consistent with the 2021 update to the CDC's PrEP guideline. The Bulletin also advised that section 10123.1933 prohibits health insurers from imposing prior authorization or step therapy on PrEP drugs for which a therapeutic equivalent is unavailable, which currently includes combination emtricitabine/tenofovir alafenamide and cabotegravir.

Similarly, federal guidance provides that issuers of health insurance subject to PHS Act section 2713 must cover, without cost sharing, items and services that are integral to the furnishing of a recommended preventive service, regardless of whether the item or service is billed separately. Affordable Care Act Implementation FAQs Part 47 specified integral services that are recommended by the CDC for daily oral PrEP, including HIV and hepatitis B and C testing, creatinine testing, pregnancy testing, sexually transmitted infection screening and counseling,

<sup>&</sup>lt;sup>2</sup> See also, 45 CFR § 147.130.

<sup>&</sup>lt;sup>3</sup> USPSTF, <u>Prevention of Acquisition of HIV: Preexposure Prophylaxis</u> (Aug. 22, 2023). The first recommendation statement, which is consistent with the August 2023 recommendation statement, was issued on June 19, 2019.

<sup>&</sup>lt;sup>4</sup> Should the FDA approve other antiretroviral drug therapies for preventing HIV in the future, those drugs would also be required preventive care benefits under Insurance Code sections 10112.2 and 10123.1933. <sup>5</sup> Insurance Commissioner Ricardo Lara, *Notice Re: Preventive Health Services Coverage for HIV Preexposure Prophylaxis (PrEP)* (June 10, 2020).

<sup>&</sup>lt;sup>6</sup> Insurance Commissioner Ricardo Lara, <u>Bulletin 2021-10: Preventive Services Coverage for HIV</u>

<u>Preexposure Prophylaxis (PrEP) with Provider-Administered Antiretroviral Drug Therapy</u> (Dec. 29, 2021).

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and adherence counseling.<sup>7</sup> FAQs Part 59 reiterated that all items and services that are integral to furnishing a recommended preventive service must be covered without cost sharing.<sup>8</sup> However, unlike federal law permitting reasonable medical management, state law prohibits medical management of antiretroviral drugs for PrEP.<sup>9</sup>

#### II. Uniform Billing and Coding Guidelines for PrEP Integral Services

The charts below set forth integral services that are recommended by the CDC in its 2021 clinical practice guideline<sup>10</sup> for both daily oral PrEP (Chart 1) and cabotegravir (Chart 2). With respect to each form of PrEP, the listed integral services must all be covered as preventive care without cost sharing. Each chart includes the CDC-recommended frequency for each integral service. If an insurer imposes frequency limits on any integral services for PrEP, the frequency limits must not be more restrictive than those set forth in the CDC's guideline.<sup>11</sup>

The charts also include examples of billing codes for integral services, which were sourced from a recent publication on billing and coding for PrEP that was published by the National Alliance of State and Territorial AIDS Directors (NASTAD). The billing codes included in the charts are not intended to be a complete list of qualifying codes. As noted by NASTAD, there is a new ICD-10 diagnosis code, Z29.81 (encounter for HIV preexposure prophylaxis), for PrEP encounters. PrEP reimbursement policies should not require any other diagnosis codes, including but not limited to, Z20.6, Z72.51, Z72.52, or Z72.53.

To prevent the application of cost sharing to integral services for PrEP, I encourage insurers to issue provider reimbursement guidelines providing that PrEP encounters and integral services must be billed with ICD-10 diagnosis code Z29.81 in the primary position. Reimbursement guidelines should standardize billing and coding for PrEP integral services to prevent consumers from being held responsible for cost sharing.

<sup>&</sup>lt;sup>7</sup> Departments of Labor, Health and Human Services, and the Treasury, <u>FAQs About Affordable Care Act Implementation Part 47</u> (July 19, 2021).

<sup>&</sup>lt;sup>8</sup> Departments of Labor, Health and Human Services, and the Treasury, <u>FAQs About Affordable Care Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 59</u> (April 13, 2023).

<sup>9</sup> Cal. Ins. Code § 10123.1933.

<sup>&</sup>lt;sup>10</sup> Centers for Disease Control and Prevention: U.S. Public Health Service, <u>Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update – A Clinical Practice Guideline</u> (CDC guideline).

<sup>&</sup>lt;sup>11</sup> *Ibid.* note 7 at Q2.

<sup>&</sup>lt;sup>12</sup> National Alliance of State and Territorial AIDS Directors (NASTAD), <u>Pre-Exposure Prophylaxis (PrEP)</u>, <u>Post-Exposure Prophylaxis (PEP)</u>, <u>and Other HIV Prevention Strategies: Billing and Coding Guide</u> (Oct. 12, 2023). Note that the list of billing codes in the charts may be underinclusive.

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## Chart 1, Daily oral PrEP with:

- 200 mg emtricitabine/300 mg tenofovir disoproxil fumarate (F/TDF)
- 200 mg emtricitabine/25 mg tenofovir alafenamide (F/TAF)

Primary ICD-10 Diagnosis Code: Z29.81 – Encounter for HIV preexposure prophylaxis				
CDC-Recommended Integral Services	Frequency	CPT Code Examples		
Encounter for prescribing (up to 90-day supply), adherence and behavioral risk reduction counseling, medication management <sup>13</sup>	At baseline and at least every 3 months	Preventive medicine counseling: 99401-99404, 99411, 99412 Preventive medicine services: 99384-99387, 99394-99397		
HIV screening test <sup>14</sup>	At baseline and at least every 3 months	86689, 86701, 86702, 86703, 87389, 87390, 87391, 87534, 87535, 87536, 87806		
Hepatitis B virus screening	At baseline	86704-86706, 87340, 87341, 87467		
Hepatitis B virus vaccination	At baseline	90743, 90746 <sup>15</sup> Administration: 90471, 90472		
Hepatitis C virus screening	At baseline and every 12 months	86803, 86804		
Renal function testing (estimated creatinine clearance)	At baseline and at least every 6 <sup>16</sup> or 12 <sup>17</sup> months	82565, 82570, 82575		
Gonorrhea, chlamydia, and syphilis screening <sup>18</sup> for men and transgender women who have sex with men	At baseline and at least every 3 months	Gonorrhea: 87590, 87591, 87592, 87850 Chlamydia: 86631, 86632, 87110, 87270, 87320, 87490, 87491, 87810 Syphilis: 86592, 86593, 86780		
Gonorrhea and syphilis screening for heterosexually active women and men	At baseline and at least every 6 months	Gonorrhea: 87590, 87591, 87592, 87850 Syphilis: 86592, 86593, 86780		

<sup>&</sup>lt;sup>13</sup> Per the CDC guideline, includes Tele-PrEP, *i.e.*, with telehealth Place of Service (POS) codes 02 (telehealth provided other than in patient's home) and 10 (telehealth provided in patient's home).

<sup>14</sup> HIV Ag/Ab plasma test (including home specimen collection kits), rapid point-of-care Ag/Ab blood test,

and quantitative or qualitative HIV-1 RNA assay. *Ibid.* note 10 at pages 29-31, 40.

<sup>&</sup>lt;sup>15</sup> Source: American Medical Association, <u>Coding Guidelines for Vaccine-Preventable Hepatitis</u>.

<sup>&</sup>lt;sup>16</sup> Patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation.

<sup>&</sup>lt;sup>17</sup> All patients

<sup>&</sup>lt;sup>18</sup> Gonorrhea and syphilis screening of pharyngeal, rectal, and urine specimens (3-site testing) using NAAT tests preferred. *Ibid.* note 10 at page 32.

Primary ICD-10 Diagnosis Code: Z29.81 – Encounter for HIV preexposure prophylaxis				
CDC-Recommended Integral Services	Frequency	CPT Code Examples		
Chlamydia screening for	At baseline and at least	86631, 86632, 87110,		
heterosexually active women	every 12 months	87270, 87320, 87490,		
and men		87491, 87810		
If on F/TAF, triglyceride and	At baseline and at least	80061		
cholesterol level monitoring	every 12 months			
Pregnancy testing	At baseline and as performed	81025, 84702, 84703		

Chart 1

# Chart 2, Long-acting injectable PrEP with:

• 600 mg cabotegravir<sup>19</sup>

Primary ICD-10 Diagnosis Code: Z29.81 – Encounter for HIV preexposure prophylaxis				
CDC-Recommended Integral Services	Frequency	CPT Code Examples		
Encounter for injection, adherence and behavioral risk reduction counseling, medication management	At baseline, 4 weeks later, and every 8 weeks thereafter (months 0, 1, 3, 5, 7, etc.)	Preventive medicine counseling: 99401-99404, 99411, 99412 Preventive medicine services: 99384-99387, 99394-99397		
cabotegravir	At baseline, 4 weeks later, and every 8 weeks thereafter	HCPCS Code J0739 Injection: 96372		
HIV screening test <sup>20</sup>	At baseline, 4 weeks later, and every 8 weeks thereafter	86689, 86701, 86702, 86703, 87389, 87390, 87391, 87534, 87535, 87536, 87806		
Hepatitis C virus screening	At baseline and every 12 months	86803, 86804		
Gonorrhea, chlamydia, and syphilis screening <sup>21</sup> for men and transgender women who have sex with men	At baseline and at least every 4 months	Gonorrhea: 87590, 87591, 87592, 87850 Chlamydia: 86631, 86632, 87110, 87270, 87320, 87490, 87491, 87810 Syphilis: 86592, 86593, 86780		

<sup>&</sup>lt;sup>19</sup> Optional 4-week lead-in prior to injection with 30 mg daily oral cabotegravir.

<sup>&</sup>lt;sup>20</sup> Quantitative or qualitative HIV-1 RNA assay; however, can use rapid point-of-care Ag/Ab blood test for same-day PrEP administration. *Ibid.* note 10 at pages 48-49.

<sup>&</sup>lt;sup>21</sup> Gonorrhea and syphilis screening of pharyngeal, rectal, and urine specimens (3-site testing) using NAAT tests preferred. *Ibid.* note 10 at page 32.

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Primary ICD-10 Diagnosis Code: Z29.81 – Encounter for HIV preexposure prophylaxis			
CDC-Recommended Integral Services	Frequency	CPT Code Examples	
Gonorrhea and syphilis screening for heterosexually active women and men	At baseline and at least every 6 months	Gonorrhea: 87590, 87591, 87592, 87850 Syphilis: 86592, 86593, 86780	
Chlamydia screening for heterosexually active women and men	At baseline and at least every 12 months	86631, 86632, 87110, 87270, 87320, 87490, 87491, 87810	
Pregnancy testing	At baseline and as performed	81025, 84702, 84703	

Chart 2

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