



# Illinois Department of Insurance

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**TO:** All Health Insurance Issuers Writing Individual or Group Accident and Health Insurance, Health Maintenance Organization Health Care Plans, and Voluntary Health Services Plans

**FROM:** Ann Gillespie, Acting Director *ARG*

**DATE:** December 4, 2024

**RE:** COMPANY BULLETIN 2024-18 - Required Coverage Without Cost-Sharing for HIV Pre-Exposure and Post-Exposure Prophylaxis; Applicability to HDHPs

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This Company Bulletin provides guidance and a reminder that all individual and group policies of accident and health insurance, HMO health care plans, and voluntary health services plans that are amended, delivered, issued, or renewed in Illinois on or after January 1, 2024 shall provide coverage for **all** drugs approved by the United States Food and Drug Administration for HIV Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP). Policies also must cover related follow-up services including, but not limited to, management of side effects, medication self-management or adherence counseling, risk reduction strategies, and mental health counseling. This coverage shall include drugs approved by the United States Food and Drug Administration that are prescribed or ordered for off-label use for the purposes described in 215 ILCS 5/356z.60.

The statute further prohibits a policy from imposing a deductible, coinsurance, copayment, or any other cost-sharing requirement on PrEP, PEP, or the related follow-up services provided in statute. 215 ILCS 5/356z.60(d).

A policy or certificate shall not impose any restrictions or delays on coverage for PrEP, PEP, or the related follow-up services provided in statute. 215 ILCS 5/356z.60(e). As a result, prior authorization, step therapy, waiting periods, and preexisting condition exclusions are prohibited for these items and services.

Section 356z.60 contains a subsection referring to therapeutic equivalent version, but that subsection only applies to abortifacients. *See* 215 ILCS 5/356z.60(c). For PrEP, PEP, and hormonal therapy medication to treat gender dysphoria, all FDA-approved drugs must be included on the formulary for the health insurance coverage, including all therapeutic equivalent versions.

If the FDA approves new drug therapies for PrEP or PEP in the future, those drugs will be subject to the coverage requirements of 215 ILCS 5/356z.60 even if they are not included in the general preventive service mandates under Section 2713 of the Public Health Service Act and 215 ILCS 5/356z.62.

## **I. PrEP and PEP as Preventive Care for Health Savings Account (HSA) Eligibility**

Section 356z.60, which also applies to coverage for abortifacients and for hormonal therapy medication to treat gender dysphoria, contains a generic exception from the cost-sharing prohibition to the extent that such coverage for any of the mandated services under a high-deductible health plan (HDHP) would disqualify the covered individual from eligibility for an HSA pursuant to Section 223 of the federal Internal Revenue Code. *See* 215 ILCS 5/356z.60(d). However, PrEP and related follow-up services are preventive care within the meaning of Section 223 of the Internal Revenue Code, so HDHPs must cover those services without cost-sharing from the first dollar of coverage.

Section 223 contains a safe harbor that prevents ineligibility for an HSA merely because the covered individual's health plan lacks a deductible for "preventive care (within the meaning of section 1861 of the Social Security Act, except as provided by the Secretary [of the Treasury])." 26 U.S.C. § 223(c)(2)(C). As explained in Treasury guidance, the scope of preventive care for Section 223 includes, but is not limited to, the preventive services covered under Section 2713 of the federal Public Health Service Act.<sup>1</sup>

Section 2713 of the PHS Act requires coverage of items and services under a Grade A or B recommendation of the United States Preventive Services Task Force (USPSTF). *See* 42 U.S.C. § 300gg-13(a). *See also* 215 ILCS 5/356z.62(a). The USPSTF published a Grade A recommendation that became a health insurance coverage requirement for plan years beginning on or after June 11, 2020.<sup>2</sup> An update to the recommendation became effective for plan years beginning on or after August 22, 2024.<sup>3</sup> The current USPSTF recommendation for PrEP applies to:

- Oral tenofovir disoproxil fumarate + emtricitabine
- Oral tenofovir alafenamide + emtricitabine
- Injectable cabotegravir, which also may include a 4-week lead-in of oral cabotegravir to assess tolerability per CDC guidelines incorporated by the USPSTF recommendation<sup>4</sup>
- As described in described in joint guidance released by the U.S. Departments of Health and Human Services, Labor, and the Treasury<sup>5,6</sup>, items or services recommended by the USPSTF

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<sup>1</sup> Treasury guidance expressly states, "Under this notice, preventive care for purposes of section 223(c)(2)(C) of the Code is anything that is preventive care under Notice 2004-23 and Notice 2004-50 without regard to whether it would constitute preventive care for purposes of section 2713 of the PHS Act. Preventive care for purposes of section 223(c)(2)(C) also includes services required to be provided as preventive health services by a group health plan or a health insurance issuer offering group or individual health insurance coverage under section 2713 of the PHS Act and regulations and other administrative guidance issued thereunder." *See* "IRS Notice 2013-57". Internal Revenue Service, U.S. Dep't of Treasury. Accessed October 22, 2024. <https://www.irs.gov/pub/irs-drop/n-13-57.pdf>.

<sup>2</sup> "Final Recommendation Statement - Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis - June 11, 2019". United States Preventive Services Task Force. Accessed October 23, 2024. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis-june-2019>.

<sup>3</sup> "Final Recommendation Statement - Prevention of Acquisition of HIV: Preexposure Prophylaxis - August 22, 2023". United States Preventive Services Task Force. Accessed on October 23, 2024. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

<sup>4</sup> "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update: A Clinical Practice Guideline". Centers for Disease Control and Prevention, U.S. Public Health Service. Accessed October 22, 2024. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>.

<sup>5</sup> "FAQs About Affordable Care Act Implementation Part 47". U.S. Dep't of Labor; U.S. Dep't of Health and Human Services; U.S. Dep't of Treasury. Accessed October 22, 2024. <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf>

<sup>6</sup> "FAQs About Affordable Care Act and Women's Health and Cancer Rights Act Implementation Part 68". U.S. Dep't of Labor; U.S. Dep't of Health and Human Services; U.S. Dep't of Treasury. Accessed October 22, 2024. <https://www.cms.gov/files/document/faqs-implementation-part-68.pdf>.

that:

- a covered individual should receive before being prescribed PrEP; or
- serve as ongoing follow-up and monitoring, including medication self-management/adherence counseling, risk reduction strategies, and mental health counseling.

Unlike the Illinois mandate at 215 ILCS 5/356z.60, the USPSTF PrEP recommendation does not also apply to PEP. However, if a PEP encounter results in a covered individual being placed on PrEP, the USPSTF PrEP recommendation will take over for determining preventive status of services that fall within the scope of that recommendation.

Additionally, some of the PEP-related services other than the drugs, themselves, independently are “preventive care” under Treasury guidance implementing 26 U.S.C. § 223(c)(2)(C).

Currently, CDC guidelines identify two PEP regimens<sup>7</sup>:

- Tenofovir disoproxil fumarate + emtricitabine + raltegravir / dolutegravir
- Tenofovir disoproxil fumarate + emtricitabine + darunavir + ritonavir

CDC guidelines<sup>8</sup> recommend other health care services integral to an initial PEP evaluation, such as<sup>9</sup>:

- Screenings for HIV
- Where indicated, screenings for HBV, HCV, other sexually transmitted infections, pregnancy,<sup>10</sup> and chemistries<sup>11</sup>
- Patient education about regimen-specific side effects and adverse events
- Patient counseling about medication adherence
- Prophylaxis for STIs and HBV infection, if indicated
- Patient counseling related to HIV prevention strategies, if indicated

CDC guidelines<sup>12</sup> also recommend follow-up evaluations for persons prescribed PEP, such as:

- HIV and other indicated laboratory testing
- Changes to PEP regimen if indicated by side effects or results of initial testing
- Additional counseling and support for medication adherence and HIV prevention, if indicated

IRS Notice 2004-23 states that screening services are preventive care under Section 223 of the Internal Revenue Code, and it contains a non-exhaustive list of such screening services.<sup>13</sup> All screenings for STIs in the CDC guidelines for PEP appear on the non-exhaustive list in IRS Notice 2004-23.

The CDC guidelines recommend prophylaxis for STIs and Hepatitis B infection for adults and adolescents with exposures by sexual assault. In some instances, such prophylaxis may independently fall under a current USPSTF Grade A or B, HRSA, or ACIP recommendation within the scope of Section

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<sup>7</sup> *Id.*

<sup>8</sup> “Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV - United States, 2016”. Centers for Disease Control and Prevention, U.S. Dep’t of Health and Human Services. Accessed on October 22, 2024. <https://stacks.cdc.gov/view/cdc/38856>.

<sup>9</sup> Omitted here are non-health care services and services rendered once the patient moves off PEP because they test positive.

<sup>10</sup> *Id.* (“Health care providers should be aware that certain medications are contraindicated for use as nPEP among potentially or actually pregnant women as follows...”).

<sup>11</sup> *Id.* (“Laboratory testing is required to...(3) identify any conditions that would affect the nPEP medication regimen, and (4) monitor for safety or toxicities related to the regimen prescribed...”).

<sup>12</sup> *Id.*

<sup>13</sup> “IRS Notice 2004-23”. Internal Revenue Service, U.S. Dep’t of Treasury. Accessed October 22, 2024.

<https://www.irs.gov/pub/irs-drop/n-04-23.pdf>.

2713 of the Public Health Service Act. In those instances, the STI or Hepatitis B prophylaxis must be covered without cost-sharing even though the PEP prescription, itself, does not fall under Section 2713.

Additionally, for some patients who have a PEP encounter, the CDC’s recommended counseling services may independently fall under one of the USPSTF Grade A and B and HRSA recommended preventive services.<sup>14,15,16</sup> In those instances, the counseling must be covered without cost-sharing even though the PEP prescription, itself, does not fall under Section 2713 of the Public Health Service Act.

Therefore, PrEP and related follow-up services, as well as some services arising from a PEP encounter, are preventive care within the meaning of 26 U.S.C. § 223 either directly under Treasury guidance or indirectly under Section 2713 of the Public Health Service Act. Preventive care is not subject to **any** Illinois exemption for HDHPs related to cost-sharing.

For PPO and Point-of-Service plans that provide out-of-network benefits, this further means that the Illinois requirement to “apply any third-party payments, financial assistance, discount, product vouchers, or any other reduction in out-of-pocket expenses made by or on behalf of such insured for prescription drugs toward a covered individual's deductible, copay, or cost-sharing responsibility or out-of-pocket maximum” applies from the first dollar of coverage when PrEP medication is furnished by an out-of-network pharmacy provider, even for HDHPs. *See* 215 ILCS 134/30(d).

This bulletin updates the Department’s comprehensive guidance in [Company Bulletin 2022-06](#) about HDHP-related exemptions.

## **II. Billing and Coding for PrEP, PEP, and Integral Services**

On October 21, 2024, the federal government released updated guidance on coverage for PrEP without cost-sharing under Section 2713 of the Public Health Service Act.<sup>17</sup> This federal guidance applies in Illinois except when Illinois law establishes more stringent coverage requirements. Notwithstanding the federal guidance related to medical management for PrEP, Illinois law prohibits issuers from imposing prior authorization requirements for PrEP, PEP, and related services under 215 ILCS 5/356z.60(e).

Billing and coding practices may help or hinder accurate, timely coverage determinations for claims related to PrEP, PEP, and follow-up services under 215 ILCS 5/356z.60. To prevent the application of cost-sharing to these services or the application of copay accumulators under circumstances not allowed by Illinois law, I encourage issuers to disseminate standardized provider reimbursement guidelines. To the extent that any claims adjudication responsibility is delegated to a third party, including, but not limited to, a pharmacy benefit manager, third party administrator, third party prescription program administrator, or preferred provider program administrator, I encourage issuers to work with these delegates to disseminate standardized provider reimbursement guidelines.

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<sup>14</sup> *E.g.*, “Final Recommendation Statement - Sexually Transmitted Infections: Behavioral Counseling - August 18, 2020”. United States Preventive Services Task Force. Accessed October 23, 2024.

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/sexually-transmitted-infections-behavioral-counseling>.

<sup>15</sup> *E.g.*, “Final Recommendation Statement - Unhealthy Alcohol Use in Adolescents and Adults: Screening and Behavioral Counseling Interventions -November 13, 2018”. United States Preventive Services Task Force. Accessed October 24, 2024.

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/unhealthy-alcohol-use-in-adolescents-and-adults-screening-and-behavioral-counseling-interventions>.

<sup>16</sup> *E.g.*, “Women’s Preventive Service Guidelines”. Health Resources and Services Administration. Accessed October 24, 2024. <https://www.hrsa.gov/womens-guidelines>.

<sup>17</sup> *See* Footnote 6, *supra*.

As mentioned in the October 21, 2024 federal guidance on PrEP, “the recently added ICD-10-CM code Z29.81 [*Encounter for HIV pre-exposure prophylaxis*]...can be used both to denote that an item or service that was billed as part of a recommended preventive item or service and to identify the furnishing of the recommended preventive item or service itself.”<sup>18</sup>

Additionally, the CPT coding system “established modifier 33 in 2010 to provide a standardized means to communicate that an item or service was furnished as a recommended preventive item or service under PHS Act section 2713(a).” The modifier “should be used when the primary purpose of the service is the delivery of an evidence-based service in accordance with the guidelines provided by one of the ACA-designated organizations...[or] to communicate that an item or service was integral to the furnishing of a recommended preventive item or service.”<sup>19</sup>

Any standardized reimbursement guidelines should provide that PrEP encounters and integral services must be billed with ICD-10 diagnosis code Z29.81 in the primary position.<sup>20</sup> Issuers may also incorporate CPT modifier 33 consistent with ICD-10-CM coding guidelines. PrEP reimbursement policies should not require any other diagnosis codes, including but not limited to, Z20.6, Z72.51, Z72.52, or Z72.53.

Similarly, for PEP encounters and integral services, ICD-10-CM contains diagnosis code Z20.6 [*Contact with and (suspected) exposure to human immunodeficiency virus [HIV]*]. The ICD-10-CM distinguishes this code from Z21 [*Asymptomatic human immunodeficiency virus [HIV]*] and B20 [*Human immunodeficiency virus [HIV] disease*]. This distinction between A) actual or suspected exposure to HIV versus B) asymptomatic or other confirmed HIV aligns with the CDC recommendation that PEP be provided when there is actual or suspected exposure but no positive HIV test result.

Any standardized reimbursement guidelines should provide that PEP encounters and integral services must be billed to include diagnosis code Z20.6 but not Z21 or B20. The Department declines to make specific recommendations at this time about other diagnosis codes, but I encourage issuers to consult guidance from authoritative specialized sources, such as the National Association of State and Territorial AIDS Directors. Because PEP is not an ACA preventive service, CPT modifier 33 should not be used for PEP-related encounters unless they also fall under a USPSTF Grade A or B, HRSA, or ACIP recommendation. For PEP (or PrEP) encounters that split a session between preventive and non-preventive services, such as a counseling appointment when some time is spent on HIV or STI prevention and other time is spent only on treating the underlying condition, please consult authoritative guidance.

For questions regarding this Company Bulletin, please direct inquiries to [DOI.InfoDesk@Illinois.gov](mailto:DOI.InfoDesk@Illinois.gov).

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<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> For fuller discussion of this recommendation: “Pre-Exposure Prophylaxis (PrEP), Post-Exposure Prophylaxis (PEP), and Other HIV Prevention Strategies: Billing and Coding Guide”. October 2023. National Alliance of State and Territorial AIDS Directors. Accessed on October 23, 2024. <https://nastad.org/sites/default/files/2023-10/PDF-HIV-Prevention-BillingAndCoding-101223.pdf>.