

FAQs (Part 68) Address Coverage of PrEP and Reconstructive Breast Surgery and Provide Guidance on Preventive Services Coding

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FAQs About Affordable Care Act and Women's Health and Cancer Rights Act Implementation Part 68 (Oct. 21, 2024)

Available at <https://www.cms.gov/files/document/faqs-implementation-part-68.pdf>

HHS, the DOL, and the IRS have jointly issued FAQs addressing coverage of pre-exposure prophylaxis (PrEP) to reduce the risk of HIV infection, issues relating to medical coding for preventive services, and required coverage under the Women's Health and Cancer Rights Act (WHCRA). As background, the Affordable Care Act (ACA) requires non-grandfathered group health plans and insurers to cover certain preventive services without cost-sharing, including certain evidence-based items and services recommended by the United States Preventive Services Task Force (USPSTF). WHCRA sets forth coverage requirements for reconstructive surgery following a mastectomy. (As noted in a related [news release](#), the agencies also released proposed preventive services regulations.) Here are highlights of the FAQs:

- **PrEP Coverage.** An FAQ explains that in 2023, the USPSTF updated its recommendations to include additional approved formulations of PrEP and clarify the group of individuals covered by its PrEP recommendations. Coverage of PrEP, including applicable PrEP formulations and specified baseline and monitoring services, must be provided in accordance with these expanded recommendations as of the first plan or policy year beginning on or after August 31, 2024. The FAQ advises that plans and insurers must cover the approved formulations without cost-sharing and are not permitted to apply medical management techniques to direct the use of one formulation over another. [EBIA Comment: While challenges to the PrEP coverage requirements and USPSTF recommendations in general are making their way through the courts, the preventive service requirements continue to apply except with respect to the challengers.]
- **Medical Service Coding.** According to the agencies, individuals have reported difficulty obtaining coverage without cost-sharing for recommended preventive items and services due to coding issues. The FAQs explain that plans and insurers must cover items or services coded as preventive without cost-sharing unless the plan or insurer has individualized information to establish that the item or service is not preventive. If the plan or insurer does have such individualized information, it is not required to cover the item without cost-sharing. (The agencies note that participants and beneficiaries have the right to pursue an appeal and external review of an adverse benefit determination such as this.) If the plan or insurer has information that merely suggests, but does not establish, that the item or service is not preventive, the plan or insurer should communicate with the individual to obtain any additional information needed. The FAQs note that ERISA and ACA rules for claims and appeals require such communication so as to

facilitate full and fair review and provide a reasonable claims procedure. The agencies indicate that plans and insurers should review their coding guidelines, claims processing systems, and other protocols to ensure proper treatment of preventive services. Examples are provided to illustrate the coding guidance.

- *Coverage of Breast Reconstruction.* An FAQ reiterates that plans and insurers that provide medical and surgical services for mastectomy and are subject to WHCRA are required to provide coverage for all stages of breast reconstruction (if the patient elects reconstruction). This includes coverage for chest wall reconstruction with aesthetic flat closure if chosen by the patient in consultation with the patient's physician. The agencies note that cost-sharing may be imposed if deemed appropriate and if consistent with cost-sharing for other plan benefits.

EBIA Comment: Health plan administrators and insurers should review plan terms and procedures for compliance with the updated coverage requirements and should provide clear coding instructions to network providers so that recommended preventive items and services are covered without cost-sharing. For more information, see EBIA's Group Health Plan Mandates manual at Sections XIV.C ("Required Preventive Health Services Coverage") and XI.F ("Required Benefits Following Mastectomy"). See also EBIA's Health Care Reform manual at Section XII.C.3 ("United States Preventive Services Task Force (USPSTF) Recommendations") and EBIA's Self-Insured Health Plans manual at Section XIII.C ("Federally Mandated Benefits").

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