

## FAQ 68 Addresses Preventive Care and Mastectomy Coverage

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On October 21, 2024, the Departments of Labor, Health and Human Services, and the Treasury (“the Departments”) issued FAQ Part 68, providing guidance on:

- Pre-Exposure Prophylaxis (“PrEP”) as a preventive care service for persons at high risk of HIV;
- Proper coding and claims management for preventive care services; and
- Coverage requirements under WHCRA for mastectomies.

### ■ Coverage of PrEP

Under the Affordable Care Act (“ACA”), non-grandfathered group health plans and health insurance carriers must provide certain preventive care services without any cost-sharing requirements. The list of preventive care services is based upon recommendations from various agencies and advisory organizations, including the United States Preventive Services Task Force (“USPSTF”). Plans and carriers are allowed to use reasonable medical management techniques should a preventive care service or item requirement fail to include information on frequency, method, treatment or setting to provide the preventive care service.

In 2019, the USPSTF recommended that clinicians offer PrEP with effective antiretroviral therapy as a preventive care service to persons with a high risk of becoming infected with HIV. This guidance was clarified to include U.S. Food and Drug Administration (“FDA”)-approved PrEP antiretroviral medications and specified baseline and monitoring services necessary to the efficacy of PrEP. At that time, the only FDA-approved PrEP formulation was a once-daily oral treatment (TF/FTC, brand name Truvada).

In 2023, two additional FDA-approved PrEP formulations were added:

- Emtricitabine/tenofvir alafenamide (TAF/FTC; brand name Descovy), approved daily oral medication; and

- Cabotegravir (brand name Apretude), a long-acting injectable medication.

FAQ 68 requires that, for plan years beginning on or after August 31, 2024, most health plans must cover without cost-sharing the three FDA approved PrEP formulations. Where necessary, medical management techniques may be used except to direct individuals to use one formulation over another.

## ■ Coding and Claims Management

FAQ 68 also reminds plans and carriers about the importance of properly coding claims for preventive care or services. Items or services that are preventive care in nature should be properly coded and processed without cost-sharing unless there is individualized information to determine that the care or service was not preventive care. Participants, beneficiaries or enrollees (or their authorized representatives) have the right to appeal an adverse benefit determination consistent with ERISA's internal appeal and review requirements.

There are industry-standard coding practices to help differentiate preventive care or services from diagnostic, therapeutic or other non-preventive care purposes. For example, the American Medical Association ("AMA") maintains the Current Procedural Terminology ("CPT<sup>®</sup>") coding system and established "modifier 33" to provide a standard way to communicate that an item or service is recommended preventive care under the ACA. FAQ 68 includes additional examples.

## ■ Mastectomy Related Required Coverages

The Women's Health and Cancer Rights Act ("WHCRA") requires health plans to include coverage for mastectomies and certain services related to consultation with the patient and attending physician. These required coverages include all stages of care on the breast on which the mastectomy was performed, surgery and reconstruction of the other breast for symmetrical appearance, prostheses, and treatment of physical complications related to the mastectomy, such as lymphedema.

FAQ 68 clarifies that WHCRA includes coverage of chest wall reconstruction with aesthetic flat closure if chosen by the patient upon consultation with their attending physician in connection with the mastectomy. Further, plan sponsors and carriers may impose deductibles and coinsurance for WHCRA benefits if such costs are deemed appropriate and consistent with costs for other benefits covered by the health plan.

## ■ Employer Action

Employers should take the following steps concerning this guidance:

- Confirm that the listed PrEP formulations are identified as preventive care services under their group health plans beginning with plan years on or after August 31, 2024;
- Ensure carriers and TPAs have appropriate practices in place to properly identify whether a service or item should be covered as preventive care;
- Examine mastectomy-related services and care under the group health plan for any exceptions or limitations, including cost sharing provisions; and
- Continue to monitor ongoing litigation that could impact preventive care requirements for group health plans.