



Guidance on Preventive Care Services and PrEP Coverage

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The Departments of Labor (“DOL”), Health and Human Services (“HHS”), and the Treasury (collectively, “the Departments”) have jointly released a new FAQ regarding preventive care services and coverage for pre-exposure prophylaxis (“PrEP”).

As background, non-grandfathered group health plans must cover certain preventive care items and services without cost-sharing. On June 11, 2019, the USPSTF released a recommendation with an “A” rating that clinicians offer PrEP with “effective antiretroviral therapy to persons who are at high risk of human immunodeficiency virus (“HIV”) acquisition.” Non-grandfathered group health plans must cover PrEP consistent with the USPSTF recommendations and without cost-sharing effective for plan years beginning on or after June 30, 2020.

This FAQ 47 clarifies:

- Plans must cover, without cost-sharing, items and services that USPSTF recommends should be received prior to being prescribed PrEP as part of the determination of whether such medication is appropriate for the individual and for ongoing follow-up and monitoring. The Q/A-1 provides additional detail of baseline and monitoring services.
- Plans are also required to cover, without cost-sharing, office visits associated with each recommended preventive service for the individual when:
 - the service is not billed separately (or is not tracked as individual encounter data separately) from an office visit, and
 - the primary purpose of the office visit is the delivery of the recommended preventive service.
- Plans may not use reasonable medical management techniques to restrict the frequency of benefits for services specified in the USPSTF recommendation for PrEP, such as HIV and STI screening.
 - When PrEP is medically appropriate for an individual specified in the USPSTF recommendation, as determined by the individual’s health care provider, it would not be reasonable to restrict the number of times the individual may start PrEP.
- Reasonable medical management techniques with respect to coverage of PrEP may be used to encourage individuals prescribed PrEP to use specific items and services, to the extent the frequency, method, treatment, or setting is not specified in the USPSTF recommendation.

- For example, since the branded version of PrEP is not specified in the USPSTF recommendation, plans may cover a generic version of PrEP without cost-sharing and impose cost-sharing on an equivalent branded version (subject to an accommodation when the generic is not medically appropriate for a particular individual).
- As described in earlier guidance, plans utilizing reasonable medical management techniques must have an easily accessible, transparent, and sufficiently expedient exceptions process.
 - For example, one that allows prescribing and accessing PrEP medications on the same day that an individual receives a negative HIV test or decides to start taking PrEP. Such process cannot be unduly burdensome on the individual or provider.

As plans may not have understood that the regulatory coverage requirements apply to all support services of the USPSTF's recommendation for PrEP, the Departments will not take enforcement action against a plan for failing to provide coverage of such services until September 17, 2021 (the period ending 60 days after publication of these FAQs), and encourage states to take a similar enforcement approach.

