FEHB Program Carrier Letter All FEHB and PSHB Carriers

U.S. Office of Personnel Management Healthcare and Insurance

Letter Number 2024-18

PSHB ⊠

Fee-for-service [15]

FEHB ⊠

Experience-rated HMO [16]

Community-rated HMO [15]

Date: September 18, 2024

Subject: Coverage for Over-the-Counter Drugs, Products, and Supplies

This Carrier Letter clarifies guidance on coverage for certain drugs, products, and supplies designated by the U.S. Food and Drug Administration (FDA) as over-the-counter (OTC) or nonprescription, and addresses OTC contraceptives, tobacco cessation, opioid rescue agents, and other OTC drugs, products, and supplies. In addition, the Letter provides flexibility for FEHB and PSHB Carriers (hereinafter referred to as "Carriers") to cover other OTC products not described here. Coverage of OTC drugs, products, and supplies with no cost sharing requires a valid prescription from a health care provider.

Background

OPM requires FEHB Carriers to provide coverage for certain OTC drugs, products, and supplies, consistent with section 2713 of the Public Health Service (PHS) Act, as added by section 1001 of the Affordable Care Act. Under PHS Act section 2713 and its implementing regulations, group health plans and health insurance issuers must provide coverage without cost sharing for contraceptives and preventive services recommended with an "A" or "B" rating by the United States Preventive Services Task Force (USPSTF).

Furthermore, in 2019, the Internal Revenue Service (IRS) issued guidance for high-deductible health plans (HDHPs) that allows for some preventive services to be covered without cost sharing before the deductible is met.

Although not required, Carriers are permitted to cover preventive drugs, products, and supplies specified by the IRS without cost sharing.

Contraceptives

Pursuant to previous OPM guidance, including Carrier Letters, 2022-17, 2022-05, and 2022-03, Carriers are responsible for covering without cost sharing, at least one form of contraception in each of the 17 categories listed in the currently applicable Women's Preventive Services Guidelines supported by the Health Resources and Services Administration (HRSA). In addition, Carriers must cover any additional contraceptives approved, cleared, or granted by the FDA.

In <u>Carrier Letter 2024-03</u>, OPM stated that it **strongly encourages** FEHB Carriers to cover **all** FDA-approved contraceptive drugs and drug-led devices without cost sharing, other than those for which there is a covered therapeutic equivalent. OPM's strong encouragement also extends to OTC drugs and drug-led devices given that on <u>July 13, 2023</u>, the FDA announced that it had approved a progestin-only contraceptive as an OTC daily oral contraceptive.

USPSTF

Carriers are responsible for covering, without cost sharing, preventive services recommended with an "A" or "B" rating by the USPSTF. Listed below are those current preventive services recommended with an "A" or "B" rating which include products available OTC:

- <u>Recommendation:</u> Folic acid supplementation during pregnancy to prevent neural tube defects
- <u>Recommendation:</u> Aspirin to prevent preeclampsia and related morbidity and mortality
- <u>Recommendation:</u> Tobacco smoking cessation in adults, including pregnant persons

There may be future updates to USPSTF recommendations. All updates to preventive services guidelines and recommendations must be applied as they occur throughout the year by all Carriers. Carriers should refer to guidance in <u>Carrier Letter 2024-05</u> and <u>Carrier Letter 2021-03</u> for OPM's requirements regarding USPSTF recommendations. USPSTF recommendations are updated frequently, and Carriers are expected to remain aware of new recommendations with an "A" or "B" rating.

Tobacco Cessation

The FEHB Program has been a long-time leader in ensuring coverage for tobacco cessation benefits in the FEHB population. Carrier Letters 2019-01, 2010-06, and 2001-09 communicated the ongoing requirement to provide comprehensive tobacco cessation benefits. This includes coverage for prescription and OTC drugs approved by the FDA to treat tobacco dependence at no cost to the member.

Tobacco smoking cessation has an "A" rating by the USPSTF and may involve prescription medication and/or OTC products to increase the success rate of quit attempts. Nicotine replacement therapy (NRT) replaces tobacco smoking with tapering doses of daily nicotine. NRT is recommended to help tobacco users quit. Many NRT products are available OTC, including nicotine gum, buccal pouches, lozenges, and transdermal patches. Heavy tobacco users often have multiple quit attempts involving behavioral counseling, prescription medication, combination NRT, or some combination of these options. According to the <u>USPSTF recommendation</u> for adults, there is insufficient evidence for the safety and efficacy of smoking cessation pharmacotherapy (e.g., NRT and prescription medications) in pregnant persons. NRT for smoking cessation is not approved for use in children or adolescents.¹

¹ Varenicline is approved for adolescents age 17 and older but requires a prescription and is therefore beyond the scope of this Carrier Letter.

Naloxone

In <u>March 2023</u> and July 2023, the FDA approved the first two OTC naloxone-based opioid rescue products for reversal of opioid overdose.

OPM recognizes opioid rescue agents as preventive care. This policy allows a corresponding cost sharing waiver and removal of any financial barriers that would prevent members from obtaining an opioid rescue agent product. This also allows high deductible health plans (HDHPs) with health savings accounts (HSAs) to provide some opioid rescue agents without applying a deductible under the preventive care safe harbor of Section 223(c)(2)(C) of the Internal Revenue Code.

Carriers may not exclude naloxone from formularies given the new OTC status for some naloxone-based products. OPM requires Carriers to make opioid rescue agents readily accessible and have at least one opioid rescue agent available without cost share.

COVID-19 Diagnostic Testing

The coronavirus disease-2019 (COVID-19) public health emergency (PHE) ended on May 11, 2023. As noted in <u>Carrier Letter 2023-08</u>, Carriers must continue to cover laboratory and OTC COVID-19 diagnostic tests including associated items and services for furnishing those tests. Carriers may impose but are **encouraged** to waive cost sharing and medical management requirements for COVID-19 diagnostic tests and associated items and services furnished.

High Deductible Health Plans and Preventive Care Benefits

Per IRS Notice <u>2019-45</u>, coverage of additional preventive care benefits for certain chronic conditions is permitted before the deductible is met or at a lower deductible than the HDHP statutory minimum. Many preventive care services addressed in IRS Notice <u>2019-45</u> associated with specific chronic conditions include drugs and products which may be available OTC, such as:

Blood pressure monitor

- Peak flow meter
- Insulin
- Glucometer

Summary

The FDA continually reviews new information and approves new OTC products. Carriers should remain abreast of new approvals that may be covered according to the requirements mentioned above or other relevant requirements. Carriers may offer coverage for OTC products beyond what is required in this list to enrich plan benefits for members. However, HDHPs must follow IRS guidance regarding coverage for OTC products.

If you have any questions about this Carrier Letter, please contact OPMPharmacy@opm.gov and copy your Health Insurance Specialist.

Sincerely,

Laurie E. Bodenheimer Associate Director Healthcare and Insurance