FEHB Program Carrier Letter
All FEHB Carriers

U.S. Office of Personnel Management
Healthcare and Insurance

Letter Number 2024-03

Date: January 30, 2024

Fee-for-service [X] Experience-rated HMO [X] Community-rated HMO [X]

Subject: Contraceptive Drugs and Drug-Led Devices; Member and Provider Education

OPM **strongly encourages** FEHB Carriers to cover all U.S. Food and Drug Administration (FDA)-approved contraceptive drugs and drug-led devices[1] without cost sharing, other than those for which there is a covered therapeutic equivalent, consistent with the approach outlined in the Frequently Asked Questions (FAQs) about Affordable Care Act Implementation Part 64 that were issued on January 22, 2024, by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the "Departments").

OPM also directs Carriers to offer multi-faceted educational initiatives to members and providers on how to access their contraception benefits.

Access to affordable contraception is a Biden-Harris Administration priority, and FEHB Carriers should continue their focus on this important initiative. OPM intends to further address contraceptive coverage requirements, including the therapeutic equivalence approach, in the future and will continue to monitor access to contraceptive services closely.

Background

On June 23, 2023, President Biden issued Executive Order 14101, "Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services." Under section 4(a) of E.O. 14101, the OPM Director shall

[1] For purposes of this Carrier Letter, a drug-led device refers to a combination product, as defined under 21 CFR 3.2(e), that is comprised of a drug and a device, and for which the drug component provides the primary mode of action. The primary mode of action of a combination product is the single mode of action (that is, the action provided by the drug, device, or biological product) that provides the most important therapeutic action of the combination product. *See* 21 U.S.C. § 353(g)(1)(C) and 21 CFR 3.2(m).

consider additional actions that, among other things, "ensure, where appropriate, robust coverage of contraception" and educate members "on how to access affordable, high-quality contraception." This Carrier Letter is in furtherance of E.O. 14101 and builds on existing requirements.

As noted in previous guidance, including Carrier Letter 2022-17, FEHB plans must:

1. Cover, without cost sharing, at least one form of contraception in each of the 17 categories listed in the Women's Preventive Services Guidelines supported by the Health Resources and Services Administration (HRSA-supported Guidelines), inclusive of sterilization surgery for women.
2. Cover, without cost sharing, any contraceptive services and FDA-approved, -cleared, or -granted products that a member and their attending provider have determined to be medically appropriate for the member, whether or not those services or products are specifically identified in the categories listed in the HRSA-supported Guidelines.
3. Make available an easily accessible, transparent, and sufficiently expeditious exceptions process that is not unduly burdensome so the member or their provider (or other individual acting as the member's authorized representative) can obtain coverage for the medically necessary service or product without cost sharing. OPM expects Carriers to respond to contraception exception requests within 24 hours of receipt of sufficient information to make a determination.

In addition to noting these FEHB plan responsibilities, Carrier Letter 2022-17 allows FEHB plans to use reasonable medical management techniques, consistent with the Departments' prior FAQs Part 54 (Question 8).

OPM Guidance Based on FAQs Part 64

As noted in the Departments' FAQs Part 64, there are reports of continued barriers to contraceptive coverage, which make it difficult for individuals to access the coverage without cost sharing.[2] Therefore, in light of such reports, FEHB plans are strongly encouraged to adopt the therapeutic equivalence approach outlined in the Departments' FAQs Part 64 (in combination with maintaining an easily accessible, transparent, and sufficiently expeditious exceptions process that is not unduly burdensome). Specifically:

[2] See, for example, report by the U.S. House of Representatives Committee on Oversight and Reform, "Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance" (October 25, 2022).

1. FEHB plans must continue to cover the full-range of FDA-approved, -cleared, and -granted contraceptives without cost sharing. To meet this requirement, an FEHB plan may continue to follow the guidance set forth in Carrier Letter 2022-17 and explained above. Further, consistent with Question 1 of FAQs Part 64, FEHB plans are **strongly encouraged** to follow the therapeutic equivalence approach defined in the FAQs with respect to FDA-approved contraceptive drugs and drug-led devices.

   Under this therapeutic equivalence approach, with respect to FDA-approved contraceptive drugs and drug-led devices, OPM will generally consider an FEHB plan's medical management techniques to be reasonable if the FEHB plan covers **all** FDA-approved contraceptive drugs and drug-led devices without cost sharing, other than those for which there is at least one therapeutic equivalent drug or drug-led device that is covered without cost sharing. An FEHB plan following this approach still must provide an exceptions process for therapeutic equivalents, which would allow access, without cost sharing, to the specific contraceptive drug or drug-led device that is medically necessary with respect to a member, as determined by the member's attending provider. The contraception exception process must be clearly spelled out in Section 5f of the brochure.

2. Consistent with Question 2 of FAQs Part 64, OPM will consider a drug or drug-led device to be therapeutically equivalent to another drug or drug-led device if the drug products or drug-led devices are identified as therapeutic equivalents (that is, designated with a code with the first letter "A") in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

Carriers are also strongly encouraged to recognize the 'Dispense as Written' (DAW) function that is currently available on a prescription as the prescriber's expression of medical necessity for contraceptive drugs and drug-led devices.

Member and Provider Education

Through member and provider education initiatives, FEHB plans must amplify the availability of contraceptive care and provide information about how to access contraceptive coverage. These initiatives should raise awareness of:

- Contraceptive coverage available at no cost to members;
- Where members can find contraceptive coverage in the plan brochure;

- The availability of information on contraceptive coverage and the contraceptive exceptions process on the plan website and where to find such information on the website;
- Where FEHB members and their providers can easily access the necessary documents for the expedited contraception exceptions process;
- The steps FEHB members can take to contact OPM if they have difficulty accessing contraceptive coverage or other reproductive healthcare, to include contacting OPM at contraception@opm.gov; and
- OPM's web page about contraception.

Further, OPM encourages FEHB plans to keep FEHB members informed of their reproductive rights by sharing this link to HHS's web page about reproductive healthcare on plan websites and other member focused communications.

FEHB plans must provide information on their member and provider education initiatives to their Health Insurance Specialist within 60 days of receipt of this Carrier Letter.

If you have any questions, please contact your Health Insurance Specialist.

Sincerely,

Laurie Bodenheimer
Associate Director
Healthcare and Insurance