FEHB Program Carrier Letter All FEHB Carriers

U.S. Office of Personnel Management Healthcare and Insurance

Letter No. 2020-18		Date: November 23, 2020	
Fee-for-Service [15]	Experience-rated HMO [15]	Community-rated [16]	

Subject: Update on Mid-year Formulary Changes

This letter supersedes guidance issued in Carrier Letter 2020-06 on mid-year formulary changes. In response to feedback from FEHB Carriers, this updated guidance expands the extent to which Carriers can make formulary changes during the plan year.

FEHB members select plans partly based on the formulary that is marketed during the annual Open Season and, therefore, have a reasonable expectation that they will have access to coverage of the prescription drugs they are using throughout the plan year. Prescription drug therapies are constantly evolving; new drug availability, medical knowledge, and opportunities for improving safety and quality in prescription drug use occur over the course of the year. These developments may require formulary changes during the year in order to maintain affordable, high quality prescription drug coverage in the FEHB Program. However, processes should be in place to minimize member disruption including member education, member notification, grandfathering policies and an exception process.

Mid-year changes can enhance formularies by adding drugs or removing or relaxing utilization management (UM) requirements for drugs. On the other hand, some mid-year changes can restrict formularies by removing drugs, moving drugs to higher tiers, or tightening UM requirements for drugs, which, in turn, may result in disruption of benefits to members.

FEHB Carriers may add drugs to their formularies, reduce copays or cost-sharing by placing a drug on a lower cost-sharing tier, or delete UM requirements anytime during the plan year. As previously stated in Carrier Letter 2020-01, FEHB Carriers should make every effort to promote the use of biosimilars as they come to market. No changes to formularies may become effective until an itemized list is provided to <u>OPMPharmacy@OPM.gov</u> and a copy to your Contracting Officer.

Restrictive or adverse changes to the prescription drug formulary that occur in the middle of a plan year may disrupt FEHB members' access to certain prescription drugs or make members responsible for new or unexpected costs. Carriers may not make negative mid-year formulary changes that result in disruption to member access to drugs except in the circumstances below.

• New information on a drug's safety or efficacy, such as FDA boxed warnings or new clinical guidelines, drug recalls such as FDA market withdrawal notices, or cases of

long-term drug shortages. When long-term drug shortages result in disruption to the formulary, FEHB Carriers must review their formularies and ensure that alternative drug(s) are available at the same tier or at a lower tier.

- When a new A-rated generic drug or multi-source brand-name equivalent comes to market and is placed in a lower cost tier, the equivalent brand-name drug can be placed in a less preferred tier or excluded, if applicable. FEHB Carriers should encourage members to switch to generics as they become available. However, an exception must be made for members who are medically unable to switch.
- Negative or restrictive formulary changes for reasons other than listed above may occasionally come up due to changes in drug costs or contracts such as hyperinflationary drug cost changes or new/revised manufacturer drug rebate contracts. Current utilizers must be notified, and an exception must be made for members who are medically unable to switch. Carriers have the option to grandfather impacted members for coverage and cost-sharing for the remainder of the plan year. Member notification is not required in cases where a member is grandfathered as a result of a mid-year formulary change.

FEHB Carriers must notify their Contracting Officer at least 70 days prior to making any restrictive formulary change during the plan year. A sample template for the OPM notification of mid-year formulary change is provided as Attachment A. FEHB Carriers must provide written notice to affected members at least 60 days prior to the date the formulary change becomes effective. Written notice includes U.S. mail, secure e-mail or text message (if approved by the member).

Carriers may immediately remove from their formulary drugs deemed unsafe by the FDA or removed from the market by their manufacturer without meeting the advance notice requirement specified above. In such cases, FEHB Carriers must provide retrospective notice of any such formulary changes to affected enrollees as soon as possible.

OPM applauds FEHB Carriers for having several processes in place to minimize member disruption due to mid-year formulary changes. The notification requirements outlined in this letter that are not currently in place should be put into effect for Contract Year 2021. FEHB Carriers unable to meet the member notification requirement by Contract Year 2021 due to contractual reasons may contact their Contracting Officer for a temporary exception.

For questions about this carrier letter or other aspects of pharmacy operations for the FEHB Program, please write <u>OPMPharmacy@opm.gov</u> and copy your Health Insurance Specialist.

Sincerely,

Laurie E. Bodenheimer Acting Director Healthcare and Insurance