Subject: Mid-year Formulary Changes

This guidance provides information on mid-year formulary changes and the extent to which FEHB 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 high quality prescription drug coverage in the FEHB Program.

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 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 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. FEHB Carriers should encourage members to switch to generics as they become available. However, an exception should be made for members who are medically unable to switch.
FEHB Carriers must notify their Contracting Officer at least 90 days prior to making any restrictive formulary change during the plan year. FEHB Carriers must provide written notice to affected members at least 60 days prior to the date the formulary change becomes effective. 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.

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

Sincerely,

Laurie E. Bodenheimer
Acting Director
Healthcare and Insurance