
FEHB Program Carrier Letter

All FEHB Carriers

U.S. Office of Personnel Management
Healthcare and Insurance

Letter No. 2019-10

Date: September 6, 2019

Fee-for-service [7]

Experience-rated HMO [7]

Community-rated HMO [10]

Subject: Consolidated Pharmacy Benefits Guidance for the FEHB Program

The purpose of this Carrier Letter is to consolidate and clarify guidance related to the management of pharmacy benefits for the FEHB Program. This letter compiles guidance related to ongoing pharmacy benefit management. In the event of a conflict between this letter and a prior FEHB Carrier Letter, this letter supersedes.

The Consolidated Pharmacy Benefits Carrier Letter will be updated and reissued on a periodic basis, incorporating any changes in pharmacy benefits guidance. Policy issues that are time-sensitive or related to emerging trends in the industry will initially be addressed in separate letters or within the annual Call Letter.

OPM expects Carriers to demonstrate effective prescription drug management and to have programs in place to appropriately coordinate with other health plan functions such as disease management programs and other medical benefit management programs. It is clear that pharmacy costs must be efficiently and effectively managed in order for OPM to meet its strategic objective to improve healthcare quality and affordability in the FEHB Program.

This Carrier Letter discusses the following topics:

- I. Formulary Management
- II. Utilization Management
- III. Pharmacy Network Management
- IV. Specialty Drug Management
- V. Medication Management
- VI. Opioids
- VII. Member Experience and Transparency
- VIII. Cost Containment
- IX. Data
- X. PBM Arrangements
- XI. Population Health
- XII. Clinical Trial Coverage
- XIII. Genetic Testing
- XIV. Fraud, Waste, and Abuse
- XV. Quality Measures

Appendix 1 includes a table of prior Carrier Letters relevant to each topic. For topics that extend beyond the scope of the pharmacy benefit, this letter will refer to the appropriate Carrier Letter.

I. Formulary Management

Carriers must have a safe and clinically effective formulary that includes a range of medications in a broad distribution of therapeutic drug classes to serve the healthcare needs of the FEHB population. Safe means that the drug's benefits outweigh the risks for the drug's intended use and intended population. Effectiveness is the extent to which a drug achieves its intended effect in a clinical setting.

Formulary Decision-Making Process

Established formulary decision-making processes are expected as part of managing the pharmacy benefit. Formulary decisions must be made by an established pharmacy and therapeutics (P&T) or medical policy committee.

Requirements for the committee:

- Free from conflicts of interest;
- Meets at least quarterly;
- Has documented processes in place to ensure the management of clinically appropriate, safe, and cost-effective drugs; and
- Composed of a group of individuals, the majority of which are actively practicing physicians, pharmacists, and nurses and come from clinical specialties that adequately represent the clinical needs of the covered population.

OPM recognizes that Carriers may subcontract the formulary management and/or the P&T committee function.

Requirement: In such cases, OPM (via the Contracting Officer) must receive details of such arrangements, including the contract(s) between the Carrier and its contractor(s) for the formulary management and/or P&T committee functions.

Formulary Exception Process

A formulary exception process sets out the requirements for seeking coverage of a drug that is not covered by or excluded from the current formulary list.

Requirements: Carriers must have a documented formulary exception process that permits reimbursement of non-formulary or excluded drugs when justified by members' medical needs. Descriptions of these processes must include the following timelines for standard and expedited reviews:

- For expedited requests, the Carrier or its PBM must review and respond within 24 hours.

- For other, non-expedited requests, the carrier or its PBM must review and respond within 72 hours.

Non-Discriminatory Formulary Design

Effective formulary design prevents selection bias or discrimination and facilitates appropriate access to affordable prescription drug choices.

Requirement: Carriers must ensure access to safe, clinically appropriate drug therapy for members with chronic conditions.

New-to-Market Drugs

Formulary management is a dynamic process. Some insurance Carriers routinely block new-to-market drugs from the adjudication system so that the P&T or medical committee has a chance to review the drug.

Requirements:

- Carriers must have processes in place to review all new drugs within 120 days of the drug being available for dispensing.
- For new FDA approved drugs with significant clinical impact, OPM expects this timeframe to be significantly accelerated. Significant clinical impact means one that may cause loss of bodily functions or death if not treated as soon as possible.
- While the new-to-market block is in effect, the Formulary Exception Process applies.

Biosimilars

Carriers need to review benefits as biosimilar products enter into the market.

Requirements:

- Focus on differentiating preferred and non-preferred specialty products in both the pharmacy and the medical benefit as more biosimilars come to market.
- Remain vigilant to avoid potential adverse consequences of formulary management strategies with respect to all products, as discussed under “Non-Discriminatory Formulary Design” above.

Exclusions and Off-Label Use

Under the Federal Food, Drug and Cosmetic Act, a drug is considered investigational until the Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) evaluates the new drug application (NDA) and finds that the sponsor has provided “substantial evidence” that the drug was proven safe and effective for its intended use. Once such a finding is made, the FDA approves the drug for marketing and no longer considers it investigational.

Requirements:

- Carriers must accept FDA approval of a drug or biological product through a designated FDA pathway and not deny benefits based upon a separate determination for their plan that the drug is experimental or investigational.
- As with all other covered benefits, prescribed drugs, devices, or biological products must be medically necessary and appropriate for the member's condition in order for the member to receive coverage.

Carriers are not required to cover “experimental or investigational procedures, treatments, drugs or devices.” The FDA recognizes that there may be circumstances under which “good medical practice and the best interests of the patient” prompt prescribers to prescribe a product for “an indication not in the approved labeling.”

Requirement in such cases: Carriers must cover drugs prescribed for off-label use if the medication can be legally prescribed, its use is supported by clinical evidence from established compendia or peer-reviewed literature, and is consistent with generally accepted medical practice.

Coverage of FDA-approved drugs, devices, and biological products goes beyond the scope of the pharmacy benefit. For the full guidance on when to defer to FDA determinations, Carriers should refer to [Carrier Letter 2018-10](#).

Formulary Review

Carriers must regularly review formularies for tier placement of new drugs and ensure that drugs placed in higher (less preferable or more costly) tiers have therapeutically similar drugs in lower (more preferable or less costly) tiers of the formulary, when such drugs are available.

Plans proposing to change formularies or make extensive changes to their existing formularies for the next plan year must provide the following additional information to their Health Insurance Specialist as part of the annual proposal.

Requirements:

- A formulary comparison showing proposed changes;
- A formulary justification for the changes being proposed;
- A member disruption analysis showing the member impact based on prior utilization;
- A cost savings analysis (if applicable); and
- A transition plan including a communication plan for providers, pharmacies and members.

Carriers must have a documented process in place to notify utilizing members of upcoming changes to the formulary.

II. Utilization Management

Trends in prescription drug spending have demonstrated the importance of utilization management both within the FEHB Program and industrywide. Greater utilization of existing drugs and the high cost of new medications contribute significantly to overall FEHB Program costs.

Evidence-based and well-designed utilization management tools ensure that members receive the most appropriate medications while minimizing errors, adverse effects, and unnecessary prescription drug use and cost.

Requirements:

- Carriers must implement, operate, and reinforce drug utilization management strategies that are based on current clinical guidelines and have been shown to be effective in assuring high quality care and clinically appropriate cost savings.
- Carriers must promptly review and respond to requests for prior approval for specific drugs and any other utilization management edits following receipt of all required information. For expedited requests, the carrier must review and respond within 24 hours. For other, non-expedited requests, the carrier must review and respond within 72 hours.

In emergency situations, such as with natural disasters and other public health emergencies, Carriers must remain abreast of the situation. On a case-by-case basis in consultation with the relevant public health authority and OPM, Carriers must be prepared to relax referral or pre-authorization requirements. These situations can extend beyond the scope of the pharmacy benefit. Carriers should refer to the resources in [Carrier Letter 2014-26](#) and subsequent guidance, including the section “Emergency Use” in [Carrier Letter 2018-10](#).

III. Pharmacy Network Management

Well-designed pharmacy networks can encourage members to use the most appropriate, clinically advantageous and cost-effective pharmacy channels. Member access, availability, quality and safety issues across all pharmacy channels within a pharmacy network must be evaluated and addressed on an ongoing basis.

Requirement: Plans must optimize the use of high-value medication distribution channels by aligning member incentives with the plan’s most cost-effective options.

IV. Specialty Drug Management

New and cutting edge therapies are more frequently specialty medications. While they can be major medical breakthroughs, they are also costly. Coverage of these new specialty medications can be complex and involve the pharmacy and/or medical benefit depending on the drug indication, the route of administration, associated companion diagnostics, and the condition being treated.

Requirements:

- Carriers must have a robust specialty drug program in place that manages drugs under the medical and pharmacy benefit. A robust specialty drug management program ensures appropriate medication use, provides proactive clinical support, and promotes member safety.
- OPM expects Carriers to have a site-of-care program to manage specialty drugs under the medical benefit.
- Specialty management programs, such as utilization and trend management programs, must be applied to drugs managed under the pharmacy and the medical benefit.

V. Medication Management

Chronic physical and mental health conditions continue to be a primary concern in the healthcare market. Carriers cite heart disease, diabetes, breast cancer, cerebrovascular disease, inflammatory conditions, and respiratory conditions as both the most prevalent and costly chronic conditions. Medication management programs work collaboratively with members who have multiple drug regimens and chronic conditions to assess their medication needs, help improve adherence, manage medication costs and avoid adverse safety events to improve health outcomes. Effective medication management programs are critical to achieving optimal member outcomes and keeping premiums affordable.

Requirement: Carriers must have a medication management program to optimize the medication needs of the FEHB population.

VI. Opioids

Reducing and preventing opioid misuse is a critical priority for OPM and the Administration.

Requirements:

- Carriers must promote evidence-based pain management through coverage of and access to non-pharmacological therapies and non-opioid medications or devices used to treat pain.
- Carriers must ensure access to programs to identify members at risk for opioid use disorder (OUD) using tools such as point-of-sale edits, retrospective data review and outreach referral programs.
- Carriers must have provider outreach and education (including network dental providers as applicable) regarding opioid risks, screening of patients for opioid use history, pathways for referral to treatment, as well as recommendations for Prescription Drug Monitoring System use.
- Carriers must provide enrollee outreach and education regarding opioid risks and the availability of other modalities for the treatment of pain.
- OPM expects Carriers to have quantity and prior approval limits on opioid medications, along with safety edits for initial opioid prescription fills and high morphine milligram equivalent doses.

- Carriers must have ongoing efforts in place to promote safe disposal of prescription medications.
- OPM expects Carriers to further improve access to Medication Assisted Treatment (MAT), such as removing prior approval requirements, and adjusting formulary placement.
- Carriers must make naloxone based agents readily accessible and have at least one naloxone preparation on a favorable formulary tier.
- Carriers must have processes in place to detect and remedy concerns about overuse, misuse, or fraud related to opioid prescribing.

OPM recognizes naloxone-based rescue agents as preventive care. This allows a corresponding copay waiver and removal of any financial barriers that would prevent members from obtaining a naloxone-based product. This also allows high deductible health plans (HDHPs) to provide some naloxone-based rescue agents without applying a deductible under the preventive care safe harbor of Section 223(c)(2)(C) of the Internal Revenue Code.

Addressing the opioid epidemic is not limited to strategies implemented within the pharmacy benefit. Carriers should refer to [Carrier Letter 2019-01](#) and related guidance, including the requirements outlined in [Carrier Letter 2018-01](#).

VII. Member Experience and Transparency

Member Transparency Tools

Transparent benefit information assists members in understanding their benefits and costs. Beginning in 2006, OPM focused on fostering pharmacy price transparency. Current and prospective enrollees have convenient access to information about the formulary tier, member cost-share and utilization management requirements for covered prescription drugs. Carriers have made significant strides in improving transparency tools, from formulary lists to drug cost calculators.

General requirements:

- Current formulary lists must be available online.
- Carriers must continue to seek improvements to the member experience, by applying innovative solutions, new technologies, and enhanced transparency to ensure members understand their benefits structure and cost sharing requirements.
- OPM expects Carriers to continue to improve the interactive functionality of existing transparency tools, including drug cost calculators, and add enhancements that will further increase transparency and foster member engagement.

Requirements for drug cost calculators: Drug cost calculators must be accurate, intuitive, easy to navigate, understandable, and member-friendly. Carriers' drug cost calculators must offer, at a minimum, the following features:

- Ease of navigation that provides the ability to move within screens without being redirected back to the beginning of the menu;

- User-friendly capabilities and explanations of basic pharmacy benefit concepts in an easy to understand manner;
- Pricing information, including information about any utilization management edits applied and any accumulators such as, deductibles and out-of-pocket maximums;
- Pricing for brand and generic alternatives;
- Explanations of benefit plan factors that impact drug pricing such as day supply limits;
- A list of formulary alternative medications including biosimilars; and
- Pricing across variety of pharmacy networks.

Provider Transparency Tools

Technology continues to improve the efficiency of provider and pharmacy electronic workflows. Enhanced provider tools such as electronic prior authorizations allow the provider to exchange clinical information in real time, which results in quicker coverage determination turnaround times, reduced prescription abandonment rates and increased member satisfaction.

Requirements:

- Carriers must adopt technologies that streamline the pharmaceutical coverage determination process and enhance the member experience.
- Carriers must promote the use of provider tools, when available, such as electronic prior authorization and benefit check tools that display drug formulary and pricing information at the time of prescribing.

VIII. Cost Containment

The prescription drug benefit is a significant portion of overall FEHB Program costs. Most Carriers also report an increase in drug costs per member per year.

Requirements:

- Carriers must continuously review plan design, network, and benefit management initiatives to address the rising cost of health care.
- Carriers must also review healthcare expenditures to ensure correlation with high quality and efficiency in the delivery of services to members.
- Carriers must ensure that members are charged the lesser of the prescription price or applicable cost share amount for prescription medications. OPM considers the prescription price to be the drug's negotiated price plus dispensing fee or the cash price at the point of sale.
- Carriers must ensure that pharmacies with which they contract directly or through a PBM are not restricted from disclosing prescription prices. This is consistent with the Patient Right to Know Drug Prices Act signed into law in 2018.

The availability of generic drugs in the United States has significantly lowered the cost of prescription drugs. Pharmaceutical manufacturer copayment coupons or copay cards have been offered to reduce member out-of-pocket expenses on brand drugs. Copay cards have

been linked to an increase in brand drug sales. Though this reduces out-of-pocket costs for members, it can bypass plan design and lower the Generic Dispensing Rate (GDR).

Requirement: Carriers must have policies and programs in place to encourage the use of generic drugs.

IX. Data

OPM supports the use of accurate and useful data to better serve the needs of the FEHB Program and its members.

Requirement: Carriers must use internal data to determine their strategies, programs, and innovations. For example, pharmacy claims data can help identify non-adherent patients and the Carrier can intervene to ensure high-value medication use.

X. PBM Arrangements

Standards for PBM arrangements are set out in the FEHB contracts for fee-for-service and experience-rated plans. In an update of these standards, OPM identified the following transparency principles:

- Pass-through transparent pricing is an arrangement based on the PBM's cost for drugs in which the carrier receives the value of the PBM's negotiated discounts, rebates, or other credits.
- The PBM's profit under the contract comes from clearly identifiable sources.
- The PBM's administrative fees, such as dispensing fees, are clearly identified to retail claims, mail claims, and clinical programs, if applicable.
- All contracts and other documentation that support amounts charged to the carrier contract are fully disclosed to and auditable by the carrier, or its agent, and the OPM OIG.

Carriers should refer to [Carrier Letter 2010-04](#) and their contracts for the current requirements for PBM arrangements.

XI. Population Health

Tobacco Cessation: The FEHB Program has been a long-time leader in ensuring coverage for tobacco cessation benefits and successful in reducing tobacco use in the FEHB population. [Carrier Letter 2001-09](#) and [Carrier Letter 2010-06](#) communicated the ongoing requirement for all plans to provide comprehensive smoking cessation benefits. This includes coverage for appropriate prescription and over-the-counter drugs approved by the FDA to treat tobacco dependence, without copayments and not subject to annual deductibles or annual or lifetime dollar limits. Tobacco cessation goes beyond the scope of the pharmacy benefit. Carriers should refer to [Carrier Letter 2019-01](#) and related guidance.

Gender Dysphoria: Effective January 1, 2016, no carrier participating in the FEHB Program may have a general exclusion of services, drugs or supplies related to gender transition. Treatment of gender dysphoria goes beyond the scope of the pharmacy benefit. Carriers should refer to [Carrier Letter 2015-12](#).

Preventive Services: Consistent with the Affordable Care Act, Carriers are responsible for covering preventive services recommended with an “A” or “B” rating by the United States Preventive Services Task Force (USPSTF), as well as immunizations recommended by the Advisory Committee on Immunization Practices (ACIP), women’s health services specified in guidelines issued by the Health Resources and Services Administration (HRSA), and contraceptive coverage mandated by section 726 of the Consolidated Appropriations Act, 2018 (P.L. 115-141) or later renewals. Preventive care goes beyond the scope of the pharmacy benefit. Carriers should refer to the guidance in [Carrier Letter 2019-01](#) and [Carrier Letter 2015-14](#).

Weight Loss Medications: Weight loss medications must not be excluded on the basis that obesity is a lifestyle condition, and Carriers may offer coverage as long as there are appropriate safeguards implemented concurrently to ensure safe and effective use. Weight loss coverage goes beyond the scope of the pharmacy benefit. Carriers should refer to [Carrier Letter 2014-04](#) and related guidance.

XII. Clinical Trial Coverage

Section 2709 of the Public Health Service Act, as amended by the Affordable Care Act, requires group health plans to provide coverage for approved clinical trials. FEHB plans are expected to comply with these coverage requirements for clinical trials, regardless of grandfathered status. Coverage of clinical trials goes beyond the scope of the pharmacy benefit. Carriers should refer to [Carrier Letter 2012-09](#) and subsequent guidance.

XIII. Genetic Testing

Genetic tests are increasingly available to refine the clinical management of many conditions. Applications of these tests range from pre-conception counseling for prospective parents, to evaluation of metabolic disorders, to precision cancer diagnosis and treatment. Defining covered benefits in this area is challenging, but OPM recognizes that effective genetic benefits management can speed time to diagnosis, optimize treatment, improve health outcomes, and avoid costs associated with adverse drug effects. Defining a genetic testing benefit goes beyond the scope of the pharmacy benefit. Carriers should refer to [Carrier Letter 2018-01](#)

XIV. Fraud, Waste, and Abuse

Carriers must, at minimum, perform activities to prevent, detect, investigate, and report fraud, waste, and abuse. Carriers must implement processes that monitor pharmacy claims in order to identify outliers that may be evidence of fraud, waste, and abuse. Fraud, waste, and abuse goes beyond the scope of the pharmacy benefit. Carriers should refer to [Carrier Letter 2017-13](#) and [Carrier Letter 2019-01](#) for guidance on fraud, waste, and abuse generally and with respect to pharmacy claims.

XV. Quality Measures

Plan Performance Assessment evaluates carrier performance and provides more transparency for enrollees. Some measures used in Plan Performance Assessment will cover pharmacy topics, but this goes beyond the scope of the pharmacy benefit. Carriers should refer to the annually published Plan Performance Assessment Manual, most recently [Carrier Letter 2018-15](#), and other related guidance.

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

Sincerely,

Laurie E. Bodenheimer
Acting Director
Healthcare and Insurance

Appendix 1: Table of Carrier Letters

Topic	Carrier Letters
Formulary Management	Carrier Letter 2019-01 , Carrier Letter 2018-01 , Carrier Letter 2018-05 , Carrier Letter 2018-10 , Carrier Letter 2017-01 , Carrier Letter 2017-04 , Carrier Letter 2016-03 , Carrier Letter 2016-04 , Carrier Letter 2016-07 , Carrier Letter 2014-03 , Carrier Letter 2012-09
Utilization Management	Carrier Letter 2019-01 , Carrier Letter 2018-01 , Carrier Letter 2018-05 , Carrier Letter 2016-03 , Carrier Letter 2016-04 , Carrier Letter 2016-07 , Carrier Letter 2014-03 , Carrier Letter 2012-09
Pharmacy Network Management	Carrier Letter 2018-05 , Carrier Letter 2014-03
Specialty Drug Management	Carrier Letter 2019-01 , Carrier Letter 2017-01 , Carrier Letter 2017-04 , Carrier Letter 2014-03 , Carrier Letter 2012-09
Medication Management	Carrier Letter 2019-01 , Carrier Letter 2018-01 , Carrier Letter 2018-05 , Carrier Letter 2016-04 , Carrier Letter 2016-07
Opioids	Carrier Letter 2019-01 , Carrier Letter 2019-05 , Carrier Letter 2018-01 , Carrier Letter 2018-05 , Carrier Letter 2017-01 , Carrier Letter 2016-03
Member Experience and Transparency	Carrier Letter 2019-01 , Carrier Letter 2017-01 , Carrier Letter 2017-04 , Carrier Letter 2016-03 , Carrier Letter 2016-07
Cost Containment	Carrier Letter 2019-01 , Carrier Letter 2018-01 , Carrier Letter 2016-03 , Carrier Letter 2016-07 , Carrier Letter 2014-12 , Carrier Letter 2012-09 , Carrier Letter 2011-05 , Carrier Letter 2011-10 , Carrier Letter 2006-09 , Carrier Letter 2003-15 , Carrier Letter 2002-14
Data	Carrier Letter 2019-01 , Carrier Letter 2016-03 , Carrier Letter 2016-07
PBM Arrangements	Carrier Letter 2010-04 , Carrier Letter 2009-15 , Carrier Letter 2006-09 , Carrier Letter 2004-04

Topic	Carrier Letters
Population Health	Carrier Letter 2019-01 , Carrier Letter 2018-01 , Carrier Letter 2015-12 , Carrier Letter 2015-14 , Carrier Letter 2014-04 , Carrier Letter 2010-06 , Carrier Letter 2001-09
Clinical Trial Coverage	Carrier Letter 2018-01 , Carrier Letter 2018-10
Genetic Testing	Carrier Letter 2019-01 , Carrier Letter 2018-01 , Carrier Letter 2018-10
Fraud, Waste, and Abuse	Carrier Letter 2019-01 , Carrier Letter 2017-13 , Carrier Letter 2014-29 , Carrier Letter 2011-13 , Carrier Letter 2007-12 , Carrier Letter 2003-02 , Carrier Letter 2003-23 , Carrier Letter 2003-25 , Carrier Letter 2002-01
Quality Measures	Carrier Letter 2018-15 , Carrier Letter 2017-02 , Carrier Letter 2017-12 , Carrier Letter 2017-15 , Carrier Letter 2016-02 , Carrier Letter 2016-11 , Carrier Letter 2016-14 , Carrier Letter 2015-10 , Carrier Letter 2015-15 , Carrier Letter 2015-19 , Carrier Letter 2014-19 , Carrier Letter 2014-28