
Letter Number 2022-02

Date: January 31, 2022

Fee-for-service [2]

Experience-rated HMO [2]

Community-rated HMO [2]

Subject: Consolidated Pharmacy Benefits Guidance for the FEHB Program

The purpose of this Carrier Letter is to update and reissue the annual Consolidated Pharmacy Benefits Guidance for the FEHB Program. This updated and reissued Consolidated Pharmacy Benefits Carrier Letter supersedes [Carrier Letter 2021-02](#) and includes clarified policies on biosimilars, utilization management, data, PBM arrangements and population health. The following new topics are included under population health:

- Mental health and substance use disorder services and;
- Medical foods.

In the event of a conflict between this letter and a prior FEHB Carrier Letter, this letter supersedes.

The Consolidated Pharmacy Benefits Carrier Letter is updated and reissued periodically, 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.

Overview

OPM expects Carriers to demonstrate effective prescription drug management and to have programs in place to appropriately coordinate with

other health plan operations such as disease management programs and other medical benefit management programs.

Pharmacy costs must be efficiently and effectively managed 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 its enrolled FEHB population. Safe means that the drug's benefits outweigh the risks for the drug's intended use and intended population. Effective 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 its formulary management, P&T committee function, or both.

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 formulary management 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 on or is 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. A non-discriminatory formulary design does not have cost or access barriers imposed by disease or condition.

Requirements:

- Carriers must ensure non-discriminatory access to safe, clinically appropriate drug therapy for members with chronic conditions.
- When several drugs are available in a class to treat a condition, Carriers must not designate specialty conditions or limit drugs for such conditions to higher cost tier(s) of the formulary.
- Formulary design should not result in adverse tiering, wherein higher cost enrollees are steered away in favor of healthier populations.

New-to-Market Drugs

Formulary management is a dynamic process. Some 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 prevent loss of bodily functions or death if used as a treatment as soon as possible.
- While the new-to-market block is in effect, the Formulary Exception Process applies.

Biosimilars (Updated)

The approval of biosimilar products, including interchangeable biosimilars can improve access to care for patients by increasing the number of medication options and potentially lowering costs. An interchangeable biosimilar may be substituted for the reference product at the pharmacy without the intervention of the prescribing health care provider, subject to state pharmacy laws, similar to how generic drugs are substituted.

Biosimilars are expected to foster competition and deliver increased savings from negotiated discounts. Carriers need to review benefits as biosimilar products, including interchangeable biosimilars, enter into the market.

Requirements (Updated):

- Carriers must have a strategy in place to promote the use of biosimilars under the pharmacy and the medical benefit. Carriers should focus on differentiating preferred and non-preferred specialty products in both the pharmacy and the medical benefit as more biosimilars and interchangeable biosimilars come to market.
- Carriers are expected to align reimbursement and formularies to encourage appropriate biosimilar adoption and educate providers and members about biosimilars and interchangeable biosimilars.
- 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. Carriers must also adhere to the requirements of a non-discriminatory formulary design, as outlined above.

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.

Mid-Year Formulary Changes

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.

Requirements:

- Changes to formularies may not become effective until an itemized list is provided to your Contracting Officer.
- FEHB Carriers must notify their Contracting Officer at least 70 days prior to making any restrictive formulary change during the plan year that has member impact. A member is impacted if they are on a prescription at the time of the formulary change.
- FEHB Carriers must provide written notice to members affected by a mid-year restrictive formulary change at least 60 days prior to the date the formulary change becomes effective.
- FEHB Carriers have the option to grandfather members impacted by a restrictive formulary change for coverage and cost-sharing for the remainder of the plan year. In such cases, member notification is not required. However, FEHB Carriers must notify OPMPharmacy@OPM.gov and their Contracting Officer at least 10 days prior to making any restrictive mid-year formulary change that has no member impact.
- Carriers may immediately remove from their formulary drugs deemed unsafe based on new information on a drug's safety or efficacy 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 and OPM as soon as possible.

For the full guidance on when mid-year formulary changes may occur, Carriers should refer to [Carrier Letter 2020-18](#).

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 (Updated):

- 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 situations where the Carrier does not have sufficient information to make a determination, there should be at least one outreach attempt to the member and the provider for additional information within a reasonable timeframe.
- FEHB Carriers must have in place a process to review all expiring prior authorizations (PAs) and must notify members a minimum of 45 days before the expiration of a PA for a maintenance medication. FEHB Carriers are encouraged to consider putting in place an automatic renewal for prescription PAs if the member has a chronic condition, has been filling the medication regularly and the PA is not put in place for safety reasons. Carriers should refer to [Carrier Letter 2021-03](#).
- 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](#) and the section "Rapid Coverage of Preventive Services and Vaccines for Novel Coronavirus" in [Carrier Letter 2020-08](#).

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 often costly. Decisions on when and whether to cover these new specialty medications can be complex and involve the pharmacy or medical benefit or both depending on the drug indication, the route of administration, associated companion diagnostics, and the condition being treated.

Requirements:

- Carriers must have in place a robust specialty drug program 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 chronic conditions and multiple drug regimens 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 their enrolled FEHB population. The program must address transitions of care, polypharmacy, complex medication management, including medication appropriateness, effectiveness and safety.

VI. Opioids

Reducing and preventing opioid misuse is a critical Administration priority.

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.

- Carriers must, when supported by clinical evidence and safety standards, 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.
- Carriers must, when supported by clinical evidence and safety standards, 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 and should be a multi-pronged approach as described in [Carrier Letter 2021-03](#), [Carrier Letter 2020-01](#) and related guidance.

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.
- Carriers must 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 should adopt technologies that streamline the pharmaceutical coverage determination process and enhance the member experience.
- Carriers should 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.
- Carriers must adopt one or more real time benefit- check tools (RTBT) that can integrate with at least one prescriber's e-prescribing system or electronic health record.

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.

Generic Drugs

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.

Coinsurance

As the cost of prescription drugs continues to rise, there is concern that some FEHB members may not be able to afford their medication costs and that the amount of their cost share is less transparent. Some Carriers have moved away from drug copayments to coinsurance.

Requirement: Carriers must make every effort to place a maximum dollar limit on the cost of drugs that are subject to coinsurance (e.g., 20% up to a maximum of \$150) for non-HDHP or CDHP plans to reduce the financial burden on members while keeping premiums neutral.

IX. Data

OPM supports the use of accurate and useful data to better serve the needs of the FEHB Program and its members. OPM is also required by statute to study the operation and administration of the FEHB Program. As such,

Carriers are expected to furnish reasonable reports that OPM determines to be necessary to carry out its functions.

Requirements (Updated):

- 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.
- Carriers must submit aggregate pharmacy claims and utilization data to OPM on an annual basis. Carriers should refer to the additional guidance, submission instructions, and format in [Carrier Letter 2020-17](#).

X. PBM Arrangements (Updated)

Standards for PBM arrangements are set out in the FEHB contracts. In an update of standards for fee-for-service and experience-rated plans, 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 (Updated)

Mental Health and Substance Use Disorder Benefits (New Section)

OPM requires FEHB Carriers to comply with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 ([MHPAEA](#)). The Consolidated Appropriations Act, 2021 (CAA) [amended MHPAEA](#) to provide important new protections related to non-quantitative treatment limitations (NQTLs) on mental health or substance use disorder (MH/SUD) benefits. The Departments of Labor, Health and Human Services, and the Treasury (collectively, "the Departments") prepared Frequently Asked Questions ([FAQs](#)) which can be used as a compliance resource. FEHB Carriers that impose NQTLs on MH/SUD benefits must perform and document their comparative analyses of the design and application of NQTLs. FEHB Carriers must make their comparative analyses available upon OPM's direction. MH/SUD services go beyond the scope of the pharmacy benefit. Carriers should refer to Carrier Letter 2021-16.

Tobacco Cessation

The FEHB Program has been a long-time leader in ensuring coverage for tobacco cessation benefits 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 dysphoria. Treatment of gender dysphoria goes beyond the scope of the pharmacy benefit. Carriers should refer to [Carrier Letter 2015-12](#).

Preventive Services

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.

USPSTF recommendations with a "D" rating indicate that the USPSTF recommends against the service because there is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits and should not be covered *as a preventive service*. Carriers should refer to guidance in [Carrier Letter 2021-03](#).

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](#).

Rapid Coverage of Preventive Services and Vaccines for Novel Coronavirus (Updated):

As evidence-based preventive services or vaccines become available, Carriers must cover them, without any cost-sharing, as soon as possible after approval, clearance, or authorization by the FDA.

OPM's policy supplements the rapid coverage requirements under section 3203 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). That statute directs Carriers to provide coverage, without cost-sharing, no later than 15 business days after a preventive service or vaccine has been recommended with an "A" or "B" rating by the United States Preventive Services Task Force (USPSTF) or by the Advisory Committee on Immunization Practices (ACIP). The CARES Act provision accelerates the traditional timeline for providing coverage of preventive services and vaccines. But given the public health emergency related to the novel

coronavirus, OPM is directing FEHB Carriers to make coverage available even sooner than CARES Act's already accelerated timeline.

Carriers should refer to the guidance in [Carrier Letter 2020-02](#), [Carrier Letter 2020-08](#), [Carrier Letter 2020-19](#), and [Carrier Letter 2022-01](#), including related guidance on testing and therapeutics.

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.

Benefits for Certain Medical Foods (New Section)

A medical food as defined in the Orphan Drug Act (21 USC § 360ee (b)(3)), is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." These diseases are typically classified as Inborn Errors of Metabolism (IEM), and medical foods help maintain neurological and physical function throughout the lifespan. They may also prevent birth defects in the unaffected children of pregnant mothers affected by phenylketonuria (PKU). OPM encourages FEHB Carriers to offer coverage for medical food regardless of age of those affected by IEM. Carriers should refer to guidance in [Carrier Letter 2017-04a](#) and [Carrier Letter 2021-03](#).

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.

Requirements:

- Carriers must implement processes that monitor pharmacy claims in order to identify outliers that may be evidence of fraud, waste, and abuse.
- The PBM must establish fraud, waste and abuse detection processes and procedures.
- Other entities that provide services or supplies to the PBM related to the administration of payments or benefits must certify to the PBM the establishment of fraud, waste and abuse detection processes and procedures.

Fraud, waste, and abuse goes beyond the scope of the pharmacy benefit. Carriers should refer to [Carrier Letter 2017-13](#), [Carrier Letter 2019-01](#), and their contracts 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 2021-19](#), 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 Bodenheimer
Associate Director
Healthcare and Insurance

Appendix 1: Table of Carrier Letters

Topic	Carrier Letters
Formulary Management	Carrier Letter 2020-01 , Carrier Letter 2020-06 , Carrier Letter 2020-18 , 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 2021-03 , Carrier Letter 2020-08 , 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 2021-03 , Carrier Letter 2020-01 , 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 2020-17 , 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

FEHB Program Carrier Letter 2022-02

Topic	Carrier Letters
Population Health	Carrier Letter 2022-01 , Carrier Letter 2021-16 , Carrier Letter 2021-03 , Carrier Letter 2020-02 , Carrier Letter 2020-08 , Carrier Letter 2020-19 , Carrier Letter 2019-01 , Carrier Letter 2018-01 , Carrier Letter 2017-04a , Carrier Letter 2015-12 , Carrier Letter 2015-14 , Carrier Letter 2014-04 , Carrier Letter 2010-06 , Carrier Letter 2001-09 , Carrier Letter 2008-17
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 2021-19 , Carrier Letter 2020-20 , 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