FEHB Program Carrier Letter
All Carriers

U.S. Office of Personnel Management
Office of Insurance Programs

Letter No. 2001-27 **Date:** August 27, 2001

Fee-for-service [22] Experience-rated HMO [25] Community-rated HMO [25]

Subject: Coverage for FDA-Approved Drugs, Devices, and Biological Products

Because carriers have not been consistent in applying the experimental/investigational brochure exclusion, we are again clarifying the definition of "investigational" to assure consistent application of contractual exclusions for experimental/investigational treatments and therapies across the Federal Employees Health Benefits (FEHB) Program.

As we explained in FEHB Carrier Letter 1998-015, under the Federal Food, Drug, and Cosmetic Act, a drug is considered "investigational" until the FDA finds that the sponsor has provided "substantial evidence" that the drug has been proven safe and effective for its intended use. Once such a finding has been made, FDA approves the drug, device, or product for marketing and no longer considers it to be investigational. We expect all FEHB carriers to accept FDA's determination, and not deny benefits for such items based upon a separate determination by the Plan that the drug, device, or biological product is considered "investigational."

When the FDA has approved a drug, device, or biological product, all FEHB plans must provide coverage when the product is used for its intended purposes and labeled indications, as approved by FDA, if those purposes and indications would otherwise be eligible for benefits under the plan's benefit structure. This includes coverage for related injection, infusion, surgery, or other services necessary for administration or utilization of the drug, device, or biological product in the manner for which it was approved. However, as with all other covered benefits, the services must be medically necessary and appropriate for the patient's condition.

All FEHB plans must also cover drugs, devices, and biological products which are intended for the treatment of serious or life-threatening conditions, that have received FDA approval through the FDA's Accelerated Approval or "Fast Track" process. Such approvals are based on FDA's determination that, based on an assessment of preliminary studies, the product provides meaningful therapeutic benefits to patients over existing treatments. FDA may approve such products subject to a requirement that the sponsor conduct further studies or clinical trials (generally Phase IV trials) post-approval to validate or confirm the effect on clinical outcomes. The existence of such postmarketing approval trials may not be used as justification for denying benefits on the basis that the services are experimental or investigational.

Similarly, we expect all FEHB plans to cover medical devices classified by the FDA as "Category B Non-experimental/Investigational," in a manner similar to the coverage made available under the Medicare Program for such products. Since November 1, 1995, the Medicare Program has provided coverage for certain medical devices that are being studied in FDA-approved clinical trials. These devices are generally those for which scientific evidence that the safety and effectiveness of the device type is already known. The device is either an incremental evolution (newer generation) of a previously approved device, or another manufacturer has

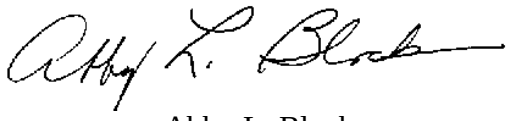
already received approval to market a similar device. In either case, the primary risk being investigated is incremental, or to establish evidence related to the particular specific device.

Coverage for Category B Non-experimental/Investigative medical devices applies only to devices classified as such by FDA. FEHB plans may not substitute their own classifications or criteria. Coverage may be restricted to those clinical trials and trial sites approved by the FDA, and benefits payable may be limited to the lesser of the manufacturer's cost (FDA permits manufacturers to charge for such devices on a cost recovery basis only during such trials) or the amount the plan would otherwise have paid for a comparable FDA-approved device.

We are not requiring plans whose benefit structure does not currently include coverage for medical devices, equipment, and products as described above to add such coverage in order to comply with the requirements of this letter. Rather, our intent is to assure consistency of application of existing coverage by requiring that services as described above that would otherwise be eligible for coverage not be denied on the basis that the plan considers them experimental or investigational. Plans should not substitute their judgement for that of FDA concerning the appropriateness of use of FDA-approved products when they are used for FDA-approved intended purposes.

If you have any questions, please contact your contract specialist.

Sincerely,



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