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INSIGHT: Viscosupplement Enforcement—Provider Pain Points

By Lisa Noller and Torrey Young

Introduction

In recent years the Department of Justice (DOJ) has increased enforcement activity for orthopedists, physician therapists, and anesthesiologists whose practices include pain management through the provision of joint injections to ease pain. These joint injection medications for osteoarthritis, also known as viscosupplements, have been the subject of False Claims Act (FCA) enforcement activity in two types of cases: 1) when providers allegedly purchase viscosupplements manufactured or distributed outside of the United States, in violation of regulations prohibiting such purchases; and, 2) when providers allegedly administer nonmedically necessary injections, in violation of billing and coding guidelines.

The government contends the reimportation into the United States from other countries renders the viscosupplements (while often chemically identical) not approved by the Food and Drug Administration (FDA) and consequently not eligible for Medicare coverage. Reimportation refers to the practice of bringing back in to the United States items that were originally manufactured here but then exported to another country for sale. Importation would assume the items were never manufactured in the United States. FDA approval is required for Medicare coverage, so FCA liability potentially exists with unapproved drugs, including foreign-made versions of U.S. approved drugs and devices (importation issue) as well as U.S.-made drugs that were manufactured for international sale, do not contain FDA-approved labeling, and are then brought back into the United States (reimportation issue).

For the medical necessity cases, viscosupplements are largely reimbursable by Medicare for knee treatment if patients do not respond to conservative nonpharmacologic therapy and simple analgesics, and there is radiological evidence to support the diagnosis of osteoarthritis. As providers submit claims to Medicare but expand the use of viscosupplements to other joints, or do not document the requisite information for coverage, they risk FCA enforcement activity, including for off-label uses. The claims submitted by providers for the viscosupplements and the ancillary service relating to the provision of the viscosupplements, such as ultrasound guidance for the injection, are therefore allegedly false claims under the FCA.

Legal Background

The FCA (31 U.S.C. § § 3729-33) is the one of the fastest growing areas of federal litigation, with settlements and judgments totaling billions of dollars each year. The statute imposes civil liability on any person or entity who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval. This includes submission of false statements or records material to a false claim and the knowing retention of an overpayment. ''Knowingly'' is defined to include actual knowledge of the information, deliberate ignorance of the truth or falsity of the information, or reckless disregard of the truth or falsity of the information. FCA cases may be premised on underlying violations of regulations or statutes; the claim for payment is deemed ''false'' if the underlying service violated another legal requirement.

Viscosupplements, such as Synvisc, Orthovisc, Hyalgan, and Euflexxa, are injections approved by the FDA for the treatment of osteoarthritis joint pain. When these drugs are manufactured, marketed, and sold in the United States, the marketing and labeling for specific indications is approved by the FDA on a case-by-case basis. Final FDA marketing approval typically is

required for drug administration and purchase to be billed to Medicare. Typically, drugs that do not have FDA approval will be denied by Medicare, unless a provider is well-informed and elects (on his own, without pressure from the manufacturer or distributor) to prescribe the drugs for uses other than those approved by the FDA (i.e., off-label). *See United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012). There are instances when unapproved drugs may be reimbursable by Medicare if ''reasonable and necessary,'' but in these viscosupplement cases the DOJ has taken the position that it is not reasonable and necessary to use unapproved drugs if FDA approved drugs are available. *See* Medicare Benefit Policy Manual, Chapter 15, Section 50.4. Reimported viscosupplements often will be marketed with the same name brand and be included on the FDA approval list, but they may include labeling in foreign languages and labeling for additional uses that may not be approved by the FDA. And of course, the FDA requires any drugs sold in the United States to first be approved by the agency. *See* 21 U.S.C. § 301 *et seq*. The FDA claims this caution is due to reimported products lacking the same manufacturer assurances regarding storage and lack of tampering.

Viscosupplements are reimbursed by Medicare, Medicaid, and other federal health-care programs at a set rate based on the average wholesale price (AWP) of the products sold in the United States. *See* 42 CFR § 405.517. The government's theory in FCA cases has been that providers knowingly purchase viscosupplements reimported from foreign countries that are then billed to state and federal health-care programs, which leads to false claims to the government because such reimported non-FDA-approved viscosupplements are not reimbursable by federal health-care programs. Because reimported viscosupplements tend to be sold at deeply discounted prices significantly less than AWP, the government is harmed.

Viscosupplements also have been the subject of FCA investigations on the basis of medical necessity and off-label use. For example, the government has alleged that providers have routinely and knowingly billed for certain injections in the absence of medical necessity. *See e.g.*, U.S. Attorney's Office Middle District of Florida, United States Settles False Claims Act Allegations Against Orthopedic Surgery Practice for $4,488,000. The Centers for Medicare & Medicaid Services (CMS) has provided some guidance for when medications are not reasonable and necessary. For example, the agency will not cover claims for the prescription of medication for a purpose other than the treatment of a particular condition, illness, or injury. And, CMS does not cover payment for claims where the injection method is not indicated, or when the medications administered exceed the frequency or duration of injections indicated by accepted standards of medical practice. *See* Medicare Benefit Policy Manual, Chapter 15, Section 50.4.3.

For off-label use cases, an unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA-approved drugs used for indications other than indications on the official, approved label may be covered under Medicare if the Medicare contractor determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature, and/or accepted standards of medical practice. *See* Medicare Benefit Policy Manual, Chapter 15, Section 50.4.2. However, DOJ's view is that claims for reimbursement for off-label injections are rendered false by virtue of their nonconformance with FDA labeling requirements.

Recent Enforcement Activity

FCA viscosupplement investigations have appeared across the country, including but not limited to in Georgia, Tennessee, Virginia, and California. While enforcement activity extends to many states, there also are clusters of cases within certain geographic areas, likely because different U.S. Attorney's Offices gain access to information through one case that makes it easier for them to pursue additional, similar cases. For example, if through a whistleblower complaint the government learns of a particular distributor selling reimported viscosupplements, it is not difficult for it to learn through the course of its investigation of other providers reimporting the same drugs. These investigations therefore can be relatively low-hanging fruit for government attorneys who can trace the thread of reimported products.

In reimportation cases, the government often argues the ''knowing element'' of the FCA is met because providers are put on notice of whether the drugs are reimported simply by looking at the viscosupplement labeling—often in foreign languages. The reimported products allegedly also may include additional uses not approved in the United States, which demonstrates to a knowledgeable provider that the product was reimported. Likewise, the government has pointed to shipment addresses from distributors, and significant discounts in pricing, as key indicators to providers that their viscosupplements may be reimported.

Medical necessity cases are more difficult for the government to prove, as they require more in-depth analysis of medical records and an evaluation of medical opinions and medical necessity. Additionally, courts have not found in the government's favor recently for some medical necessity FCA cases because the difference in medical opinions may not equate to falsity under the FCA. While in a different context (hospice care), the District Court in *AseraCare* ruled the government failed to prove objective evidence of falsity and held, ''contradiction based on clinical judgment or opinion . . . alone cannot constitute falsity under the FCA as a matter of law.'' *United States ex rel. Paradies v. AseraCare, Inc.*, 176 F.Supp.3d 1282 (N.D. Ala. 2016).

In addition to civil FCA enforcement activity, there also has been enforcement activity against wholesale distributors and providers under the Federal Food, Drug, and Cosmetic Act (FDCA) for misbranded drugs and devices associated with reimportation. *See e.g.*, U.S. Attorney's Office for the Eastern District of New York, Americourcebergen Specialty Group Pleads Guilty to Distributing Misbranded Drugs and is Sentenced to Pay $260 Million to Resolve Criminal Liability; *see also*, *United States v. Amerisourcebergen Specialty Group, LLC*, 17 CR 507 (NG), Plea Agreement. The FDCA requires domestic and foreign businesses that manufacture prescription drugs sold the United States to register with the FDA. According to the FDA, a drug may be considered misbranded even if it is identical in composition to an FDA-approved drug made by the same manufacturer in the same facility if it is reimported. A prescription drug is ''misbranded'' if it is not registered with the FDA for commercial distribution

within the United States or inadequately provides directions for use. Misbranding is a strict liability offense under the FDCA, such that a violation can lead to a conviction even absent intent. *See* 21 U.S.C. § 352. For example, an oncologist who ordered prescription cancer drugs from Canada pleaded guilty to charges of causing the introduction of misbranded drugs into interstate commerce in violation of the FDCA. He was sentenced to three years of probation and was ordered to pay $1,298,543 in restitution and forfeit an additional $750,000. *See* U.S. Attorney's Office District of New Mexico, Deming Oncologist Pleads Guilty to Introducing ''Misbranded'' Drugs into Interstate Commerce.

Lastly, drug reimportation continues to be a health reform topic of discussion. Those in support of drug reimportation say it will drive pharmaceutical costs down, by increasing price and quality competition from overseas manufacturers and distributors. Opponents argue it will limit the FDA's ability to monitor safety. While the issue is being debated, providers must continue to be wary of their drug sources so as to avoid potential enforcement actions. Additionally, providers should continue to be cautious of off-label use and documentation of medical necessity at the risk of FCA liability.

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