Insurance Denials Due to Experimental Investigational Treatment

These steps will help you win on appeal.

BY LAWRENCE F. KOBAK, DPM, JD

How many times have you received an insurance explanation of benefits that states you are not receiving any payment for the treatment, as it is "experimental or investigational"? How many times has that procedure been a relatively longstanding and accepted one? This may involve any medication, therapy, procedure, vaccine, medical supply, or equipment. The bottom line, however, is that it is the health insurance plan that determines if the treatment is experimental or investigational—if the treatment is deemed experimental or investigational by the insurance plan, it is not paid, due to the contractual exclusion of any "experimental or investigational" procedure or test.

What Constitutes an Experimental or Investigational Treatment?

There is an accepted definition of the terms "experimental or investigational"; a treatment/procedure/therapy that is not FDA-approved and is not recognized by generally accepted medical standards of care. Therapies and tests accepted by Medicare and Medicaid are generally not considered experimental or investigational. Again, the insurance company determines what is and what is not an accepted treatment or therapy. Peer reviewed literature is also considered when making this determination. You can substitute the word "unproven" for investigational or experimental.

Drugs and biologics require FDA approval to be considered both safe and effective. The FDA also approves medical devices and human tissue use. The FDA does not approve surgical techniques. For example, the FDA would not be involved in approving a Lapidus bunionectomy, although they would be involved in approving the type of internal fixation used. In other words, a treatment or therapy cannot be said to be investigational or experimental because the FDA did not approve it, if the FDA had no jurisdiction to approve it. The FDA does not approve companies.

First, establish that the procedure is generally accepted to treat the stated condition or diagnosis. Use at least three peer-reviewed articles, if possible.

Continued on page 36

Insurance Denials (from page 35)

The Process

You have performed a tarsal tunnel release using a new shape of scalpel blade. You have removed an exostosis using a custom-made bone cutter. The surgical procedure fits the CPT description of a tarsal tunnel release, or an exostectomy. Nothing in the CPT code description requires you to use a 15 blade or a particular brand or type of rongeur on the bone. However, the operative report, appearing "different" sets off the alarm of the insurance reviewer. You receive your rejection. What next?

First, establish that the procedure is generally accepted to treat the stated condition or diagnosis. Use at least three peer-reviewed articles, if possible. Establish that Medicare or Medicaid pay for that procedure without regard to the type of blade or rongeur, as in the cases at hand.

If after providing the insurance carrier sufficient information that the procedure or treatment is following a proven therapy, the insurance carrier still refuses to pay for the same reason, they may be acting in bad faith.

What Constitutes Bad Faith by an Insurance Company

1) Delays in response or non-response to your complaints in lack of coverage. Constantly kicking the can down the road is not a legitimate response. Making you, the provider, go in circles, is not a sign of good faith.

2) Refusing to pay the claim prior to an actual investigation. The insurance company, if asked, should provide the factual basis of their denial. Scholarly articles should be cited, CPT codes should be cited, with explanations.

3) Offering to cover a small amount of a legitimate bill to settle the matter, even though your treatment and charge are shown to be reasonable, is not a demonstration of good faith.

4) Stalling the matter by the insurance company opening a new claim is a sign of bad faith. It simply stalls the matter.

An Example or Two

You have performed a Lapidus bunionectomy by using a relatively new measuring system with "new and improved" hardware. You have included this information in your operative report. The insurance company asks for a copy of the operative report. A few weeks later, you receive a denial stating that they will not pay due to its determination that you have performed an investigational or experimental procedure.

If the insurance policy excludes a procedure unless certain criteria are met, that is different than an "investigational or experimental" exclusion. An example of that would be if bunionectomies are only paid for dependent upon various non-surgical treatments being first attempted for a particular length of time, along with certain elevated measured biomechanical angles of the foot. Some companies are even more specific, concerning the need to previously attempt the use of bunion last shoes, cushions, and the like.

Be sure to document all your attempts in resolving a matter that involve an initial denial based on "investigational or experimental" grounds.

Your office manager calls the insurance company and is told that the reason they consider the procedure investigational is based on an ongoing study of this "new" procedure which will not conclude until 2023. They send you a copy of an article describing the ongoing study.

A careful look at the article describes a fusion at the first metatarso-cuneiform joint, a resection of the medial eminence with soft tissue correction. That sounds like CPT code 28297. You look at CPT code 28297 and see that the description of the procedure does not depend on any specific type or brand of a measuring device or hardware for internal fixation. Upon further investigation, you find a peer-reviewed article in *Foot and Ankle Orthopaedics* from 2020 using a "cutting guide for controlled saw resection". The study was ongoing. However, the article clearly considers this procedure to be a Lapidus arthrodesis, using improved measuring, cutting, and fixation devices and hardware.

The peer-reviewed *Journal of Bone and Joint Surgery* published on article on the modified Lapidus procedures in 2021. The article traces the Lapidus procedure back to a Dr. Albrecht in 1911! Dr. Lapidus popularized the procedure in 1934. It has become a generally accepted procedure for the treatment of certain types of bunion deformities and has been consistently paid for by Medicare with the appropriate diagnosis.

Armed with these articles and the CPT code definition (this 110-year-old procedure, defined as a first metatarso-cuneiform arthrodesis), you have proved that your surgery was hardly investigational or experimental. It has its own CPT code. It has withstood the test of time in the appropriate patient, albeit with incremental improvements. The fact that a resection of bone today is often performed with power saws, as opposed to bone cutters, does not usually change the name of the procedure being performed. Another example is that a Keller bunionectomy does not assume a different name depending on the type of bone cutter used.

Here is another example; it is a much tougher one. You bill for the treatment of plantar fasciitis via custom made pedal orthotics. Your claim is rejected. As before, see if the insurance plan has an exclusion for such treatment or a requirement for a particular type of heel cup or posting. If denied due to the "investigational or experimental" reason, be prepared to be bombarded with several studies that purport that a custom orthotic does not provide any better relief than an off-the-shelf orthotic. You attempt to distinguish the type of orthotic you are providing with that of the cited studies. You cite the safety of using an orthotic as opposed to a surgical or pharmacological intervention. The insurance company will not budge. The reason is simple: paying for custom made orthotics, except for very specific circumstances, will wind up being a large expense to the insurance company. They

Continued on page 38

Insurance Denials (from page 36)

may feel that a certain percentage of these patients will either go away or opt for injections or over-the-counter remedies. They may feel that a large percentage of these patients will not want the surgical option. In short, a denial will help their bottom line.

How the Provider Responds

Be sure to document all your attempts in resolving a matter that involves an initial denial based on "investigational or experimental" grounds. As illustrated above, provide copies of the peer reviewed article(s) that support your contention that your treatment is a proven treatment and is accepted by your professional community. You can use dermatologic, orthopedic, podiatric, or any other kind of professional peer reviewed journal that is relevant to the treatment provided. Go on the FDA, NIH, or CMS websites for any supporting material. Do not just cite it, provide a copy that is yellow highlighted at the appropriate sections.

If after doing the suggestions provided, you still obtain no relief, consider filing a formal complaint to your State Insurance Department. Please keep in mind that the insurance departments of some states are named differently. An example of this is that the New York State's insurance department is called the Department of Financial Services, not the Department of Insurance!

Conclusion

Each insurance company has its own system of internal appeals. Each state has its own system of external appeals/mediation/arbitration. It is beyond the scope of this article to deal with all the individual specifics. However, in every case, you must prepare your appeal using peer-reviewed studies, FDA approval (if applicable), proof that other insurance carriers or Medicare/Medicaid are covering the treatment, and any other proof that addresses the efficacy and safety of the treatment/procedure. There is no guarantee of success. Try to explain why the treatment was needed on the patient or patients in question. This is often best accomplished with the assistance of a competent health law attorney. **PM**

Dr. Kobak is Senior Counsel in Frier Levitt's Healthcare Department in the Uniondale, New York. Larry has extensive experience representing physicians in connection with licensure issues, as well as successfully defending physicians before Medical Boards, OPMC, OPD investigations, as well as Medicare Fraud, Fraud & Abuse, Hospital Actions, RAC Audits, Medicare Audits, OIG Fraud, Healthcare Fraud, Medical Audits, and Health Plan Billing Audits. As a licensed podiatrist prior to becoming an attorney, he served as the international president of the Academy of Ambulatory Foot and Ankle Surgery.