



A Successful CMS Appeal Case Study: Amniotic Injectables

With proper preparation and documentation, you can win.

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Most podiatrists accept Medicare patients. With increasing frequency, podiatrists are being audited by their MAC, or Medicare Administrative Contractor. The provider often asks what they should do when the audit results arrive with a large recoupment demand. The simple answer would be to contact their experienced health law attorney.

Often, when the podiatrist finally calls their attorney, they have already lost the first two levels of appeal. There are four levels of appeal. If you have not offered an argument or evidence by the second level of appeal, it might be too late for your attorney to advance a new argument or piece of important evidence to the mix. That is why you want to get your attorney involved early in the process. This example uses a recent appeal that involved amniotic injections for the treatment of musculoskeletal lower extremity pathol-

ogy. The podiatrist was represented by experienced health law attorneys from the start. They collected various patient records and documentation as to the efficacy of using amniotic injectables for the treatment of musculoskeletal inflammation and decrease in function. The scholarly

usually unsuccessful. You are asking someone to say that they were wrong. That is like asking a judge to reverse her own decision. This does not occur very often. However, the skilled attorney, like the chess player, is setting the client up for the next move.

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articles were from peer-reviewed, evidence-based journals. The years in question went back from 2020 through 2021.

The first two levels of appeal involve reviews by the MAC, concerning their own prior conclusions. Short of correcting clerical errors by the MAC, the first two levels are

As expected, the first two levels of appeal did not go well in the amniotic injectable matter. CMS, via the MAC, ruled that the use of amniotic injectables was investigational or experimental, there was a lack of medical necessity, and that there lacked sufficient research to

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conclude that the use of amniotic injectables was safe and effective for such use. This decision was despite written expert reports and two dozen peer-reviewed articles. It did not seem to matter that Medicare, at the time, had no local or nation-

pages of emails as well as copies of many of the scholarly articles were missing. There was also an allegation that about 20 chart entries did not have full provider signatures.

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help balance a deficit on the backs of the medical providers.

Questions were drafted and reviewed by the expert. They were modified several times at the expert's suggestion. An expert must have credibility to be effective and believed by the ALJ. There is no jury at an ALJ hearing, just the Administrative Law Judge. The direct examination of the expert is reviewed with the expert several times. There is a need to review possible areas of concern that the ALJ might want to explore with the expert. There is no attorney for CMS that is present, only the ALJ. Occasionally, the MAC will present their own witness to deliver a statement. That did not occur this time. The ALJ may ask questions of the witnesses. They need to be prepared. This is not a deposition or a trial where the witness is prepared to answer with as few words as possible. An administrative hearing is less formal. A rapport can and should be promoted with the ALJ. That rapport begins with the initial interaction

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al determinations concerning the use of amniotic fluid-based injectables for musculoskeletal pathology. When such is the case, coverage depends upon if the injectable is safe, not experimental or investigational, and that research shows it is efficacious as to the intended use.

The first two levels of appeal were filed within the required time period and denied. Now came the third level of appeal, the Administrative Law Judge Hearing. This involved a live conference telephone call, run by an administrative law judge randomly chosen within a pool of CMS ALJ judges. The judge gets to allow what evidence is to be admitted and which witnesses get to participate in the hearing. The attorney can help ensure that they get to present their complete case by doing everything on a timely basis, within the rules of the process. Some of the rules can be detailed and seemingly irrational. They are best handled by an experienced attorney, not a podiatrist or any other healthcare provider.

Let's start with the evidence. You must demand a copy of all the evidence that the ALJ will use. This consists of all the documents that were used in the first two levels of appeal. Some of it comes from the MAC, and you might not have seen the MAC's submissions prior to this level of appeal. Additionally, you might find that some of the evidence you used in the prior appeals is missing. This is exactly what occurred in this amniotic matter. Many

or medical necessity. What occurred was that the copy being used by the MAC had cut off the bottom of some of the medical record entries. Copies that were not cut off had been provided in an exhibit for the second level appeal. Somehow, they were missing from the evidence CD provided by the ALJ's office. We promptly sent the ALJ copies of all the "miss-

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ing signatures". The ALJ graciously accepted this "addition" as part of the evidence to be considered, as well as the "missing" scholarly articles that were provided.

Of great importance is the preparation of your witnesses. In this case, the attorney had an expert concerning injectable amniotic preparations, its efficacy, and its billing. The key to preparing is for the witness and the attorney to work in tandem so that the story is told in a way you need it to be told. If half a story is related, that will not succeed.

It should be noted that CMS, throughout the country, has been attempting to recover millions of dollars for the use of the amniotic injections that they decided years later were improperly billed for and paid. Some might even cynically conclude that the government was trying to

with the appeal papers filed by the law firm. You should not be needlessly adversarial with the ALJ. Do not allow your witnesses to be adversarial in tone with the ALJ.

It was not only the expert that had to be prepared prior to the hearing. The client's testimony would also serve an important purpose. The attorney wanted the ALJ to get a sense of our client, an honest, hard-working podiatrist who really cared about his patients. It had to come out that each dose of amniotic injectable cost him over \$2000. He paid up front for his patients' welfare. Now, after the fact, and without a legitimate reason, they wanted this money back. His attorney wanted to establish that his client was treated with an amniotic injectable by a physician for a skiing injury to his knee. It

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worked very well. This was all prior to his using it on his patients. He would never use experimental or investigational treatments on his patients or himself. He would have to establish that CMS and its local MAC never had any directive, local or national, stating that they would not pay for the use of amniotic injectables for musculoskeletal pathology. He would have to alert the ALJ that not one of his audited patients had any untoward reaction because of the amniotic injectable. He would relate that all the audited patients had various other treatments, prior to considering the use of the amniotic injectable. They did not work satisfactorily. Those treatments consisted of physical therapy, NSAIDs, and in some cases, cortisone injections. Opioids were avoided in all these patients. The operating room was avoided in all the audited patients. This was a good thing, as the time in question for all the amniotic injectable audits was during the middle of the COVID-19 pandemic, and the operating room was not a place where the patient wanted to be. All of this had to be seared into the mind of the ALJ by our client.

The morning of the hearing arrived. As planned, the podiatrist and his expert witness dialed into a phone conference. The ALJ gave a mandated talk about the hearing and various legalities that had to be mentioned. It was then agreed that all the evidence the ALJ had provided, as well as the additional “lost records” the attorney provided, would be in evidence. This simply means that the attorney could use those documents during the hearing to prove his contentions. Then the two witnesses were simultaneously sworn in.

Each ALJ has wide authority in how they wish to conduct a hearing. Most conduct it relatively informally. They allow latitude to the attorney and the witnesses to make their points. Because of that, many of the questions elicit a narrative response from the witness. What results is a less choppy presentation to the ALJ. It should be noted that not all ALJs allow such latitude. The attorney and

witnesses should be prepared for any ALJ “style”.

Sometimes, the ALJ expresses a preference in the order of witnesses. If possible, it is best to follow that preference. At this hearing, no preference was expressed. The client testified first. The ALJ allowed the client to cover all the desired points. He barely interrupted. At the end, and even during the attorney’s questioning, the ALJ was entitled to ask his own questions. None were asked.

It was time for the expert witness to testify. He was going to “go into the weeds” concerning the history of the amniotic injectables, their use,

questions that were factually answered by our expert.

The ALJ asked the attorney if he wanted to deliver a short statement. As the ALJ never interrupted the presentation, the attorney did not rehash a bunch of details that could only bore him. The attorney stated that the provider was a good podiatrist who put the welfare of his patients first. The doctor only used the amniotic treatment after several options failed to provide the desired level of improvement. No patient was injured. All the patients in question demonstrably improved. Medicare had paid for their treatment under the

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and how they had been dealt with by CMS. The expert went into detail about local and national determinations, or the lack thereof. He went into physiology involved with the use of amniotic injectables and why and how they are effective. He referenced a myriad of peer-reviewed articles on this subject, demonstrating that their use was not experimental or investigational. At the end of this section of questioning, the attorney asked if the ALJ had any questions before the attorney proceeded to ask about individual patient treatment. The ALJ only had questions concerning exhibit numbers.

With 25 patients involved, the attorney informed the ALJ they were prepared to go over all 25 patients in detail, but as there was more of a global explanation as to the medical necessity of the use of the amniotic injectable for all patients seen during a number of years, reviewing 5-10 of the patients should suffice. He agreed. The expert witness proceeded to list the diagnoses, prior treatment attempts, the patient history, and when the amniotic injection was given and why. What occurred, or did not occur, and post-treatment were also reviewed for each patient. After six patients were covered, the ALJ stated that “he got it”. He had a few general

policy in place at the time. Medicare was attempting to change the rules after the fact. His colleagues were also paid for these types of treatments at the time in question.

After the brief closing statement was finished, the ALJ asked for copies of any prior favorable decisions that were on point. The attorney had previously stated there were some. It is of the utmost importance to never say you have something you do not have. The ALJ had copies of 3 favorable decisions faxed to him within that hour. Truth be told, there were very few favorable decisions in this area.

Two weeks later, the favorable decision arrived! It pays to prepare, prepare, and then prepare. **PM**



Dr. Kobak is Senior Counsel in Frier Levitt’s Healthcare Department in 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.