

A peer reviewer with specialties of neurological surgery and surgery spine on February 7, 2013, at Advanced Medical Reviews (AMR) wrote, after reviewing two studies:

“In summary, multi-level lumbar arthroplasty is not medically necessary due to the paucity of studies revealing safety or efficiency and does not meet criteria for medical necessity.” (BPO 37)

On reconsideration, on May 24, 2013, another reviewer with a specialty in neurological surgery, after a narrative considering studies, wrote:

“Thus, there is insufficient scientific evidence to support the requested treatment and, therefore, it is not medically necessary or the standard of care.” (BPO p. 40)

After further documentation was received on August 9, 2013, another reviewer with a specialty of neurological surgery, wrote:

“There is no indication from the medical charts review that any other surgery was medically necessary including the multiple ADR’s which are considered investigation/experimental by FDA ...” (BPO p. 49)

The Employers’ Trustees ultimately denied the ADR claim, and initially, the fusion claim as well:

“Because the above listed procedures were deemed not medically necessary and/or investigational and experimental, the Employer Trustees determined that these procedures were excluded under the Plan.” (BPO p. 194)

The Claimant submitted numerous further documents with his opening brief. Included was the following declaration under penalty of perjury of Dr. Lanman, the Claimant’s surgeon:

“I am a physician and surgeon. I am Board Certified in Neurosurgery by the American Board of Neurological Surgery. I am also a Fellow of the American College of Surgeons. I specialize in spine surgery and arthroplasty, which is the surgical repair of joints.

I graduated in 1983 from the Northwestern University Medical School. While in medical school, I was inducted into the Alpha Omega Alpha honor society.

Upon graduation from medical school, I completed a one and one half year internship in General Surgery at the University of California, Los Angeles (‘UCLA’) I then completed a five and one half year residency in Neurological Surgery, also at UCLA.

I have conducted many thousands of spinal and other surgeries. I have authored and published over ten peer-reviewed articles and book chapters dealing with neurological surgery, and I have presented over 25 papers at national and regional professional meetings.

I am currently an Assistant Clinical Professor at the UCLA Medical Center. I am also Staff Neurosurgeon at Cedars-Sinai, a member of the Cedars Sinai Institute for Spinal Disorders, Staff of the Neurosurgery department at Saint John’s Health Center, and Staff member at the Neurosurgery Department at Olympia Medical Center. I was also Chief of Neurosurgery, Director of Spine Surgery and a member of the Board of Governors at Century 21st? Doctors Hospital.

There are a number of techniques for treating persons who suffer from back pain due to damaged spinal disks. Initially, unless unusual circumstances are present, a patient should usually go through conservative therapy before looking at surgical options. Conservative therapy usually involves some combination of physical therapy, chiropractic treatment, and pain management. Pain management, in turn, could involve epidural injection or spinal blocks, as well as prescribing a regimen of pain killing drugs. If this conservative care can be used to keep patient working and active, then generally no surgical intervention is warranted.

However, when a patient is suffering from a life altering level of pain that conservative therapy has failed to resolve, then consultation with a surgeon like me is appropriate to see if there are surgical options which could alleviate the patient’s symptoms.

There are a number of surgical techniques for dealing with damaged discs. Some of them are minimally invasive. For example, a decompression or a micro discectomy can be done on an outpatient basis. These techniques involve removal of a portion of the vertebra bone or disc which might be pressing on a nerve and causing pain.

However, in some cases the disc or discs are too damaged for this. The most common technique for dealing with more seriously damaged discs is known as fusion. Fusion generally involves immobilizing the damaged disc by using hardware to fasten together the two vertebrae supported by the disc. There is nothing wrong with fusion in appropriate cases, and in my career as a surgeon I have done many thousands of spinal fusions.

There are, however, a number of downsides to fusion. For one thing, spinal discs are designed to flex, which allows a person to bend and twist. When the vertebrae on both sides of the disc are fastened together this reduces the natural flexibility of the spine. Moreover, when two vertebrae are fastened together, this results in greater stress in those healthy discs adjoining that vertebrae. This greater stress increases the probability that one or both of these discs will fail in the future.

These downsides to fusion are increased where the spinal injury involves two or more adjacent damaged discs. If there are two damaged discs that need to be immobilized, then the loss of spinal flexibility is that much greater. Moreover, where multiple discs are manually mobilized it results in much greater stress on the healthy adjacent discs, which increases the risk that they will fail.

This increased possibility of disc failure leads to another factor to consider in deciding to perform a fusion, which is the age of the patient. Most fusions are performed on people in their 50s and 60s, where the expectation is that the fusion will last out their natural lifespan without causing an additional disc failure. However, for a younger person, in his 20s or 30s, the expectation is that the increased stress fusion puts on the adjacent healthy disc will cause that disc to fail at some point in the person's lifetime. At that point, with present technology, the only option for a surgeon is to increase the scope of the fused vertebrae to include the newly damaged disc. This, of course, reduces the mobility of the spine still further and increases the risk of additional disc failure.

A viable option to fusion in certain cases is 'Artificial Disc Replacement' or 'ADR.' This involves removing the damaged disc

and replacing it with an artificial construct which is shaped like a spinal disc and designed to function as one. For example the ProDisc, one of the most commonly used artificial discs, is manufactured by DePuy Synthes. It consists of two chrome alloy end plates and a polyethylene inlay. It has the shape of a spinal disc and, when correctly inserted will function as one.

When properly done in an appropriate case, ADR will allow much greater spine flexibility than fusion. Further, because the vertebrae on both sides of the artificial disc are not fused together, the problem of additional stress on the adjacent healthy discs is eliminated.

ADR has been in development and use for over 25 years. Currently it is in wide use among surgeons, who perform the process at the nation's top hospitals. There are a number of artificial discs which have been approved by the Food and Drug Administration ('FDA'), these include the ProDisc and the Charite for the lumbar spine and the Prestige. Bryan, Mobi-C secure-C and PCM for the cervical spine.

I have a great deal of experience with ADR. I first became involved with ADR approximately 12 years ago, when I participated as a surgeon in the FDA clinical trials for the Prestige system made by Medtronic. These clinical trials led to the FDA approval of the Prestige artificial disc.

As noted above, fusion is particularly troublesome where there is more than one damaged adjacent disc. It is in cases like this where ADR is more likely to be a superior treatment option, and for this reason multi-level ADR is in common use among surgeons.

Over the course of my career I have done thousands of artificial disc placements. Many of these surgeries involved implantation of two or more artificial discs. For the most part these surgeries have had excellent outcomes, clearly better than would have been the case had fusion been utilized.

ADR has been widely studied. I am aware of numerous published and peer reviewed studies that demonstrate single level and multi-level ADR is a safe and effective treatment for serious cases of degenerative disc disease. Some of these studies have compared single-level and multi-level ADR to fusion. These studies show that ADR has generally better results than fusion in terms of recovery time and outcome. Other studies have compared

singlelevel ADR to multi-level ADR and have shown that multi-level ADR is as safe and effective a treatment as single-level ADR.

Because of its utility as a treatment option, ADR is widely used. I doubt there is a major hospital in Southern California in which this treatment would not be available. As noted above, I perform the procedure at a number of area hospitals, including Cedars-Sinai, Saint John's Health Center, Olympia Medical Center, and Century City Doctors Hospital. I am aware of dozens of other spinal surgeons who have single and multi-level ADR as one of their treatment options. All of them believe that in appropriate cases it is safe and effective and is often the best treatment option for a patient.

There is another reason why I believe that in many cases multi-level ADR is the best treatment option. Several years ago I myself suffered from degenerative disc disease in three adjacent discs. When presented with treatment options I chose multi-level ADR. In my case, the surgery was a complete success. My symptoms of severe back, pain were almost completely resolved and I was able to resume a full work schedule and an active lifestyle. While surgical outcomes do vary from patient to patient, my own experience allows me to recommend this treatment in appropriate cases with even more confidence.

With respect to [the Claimant], he was referred to me in April of 2012. At that time he was suffering from severe low back pain across the low lumbar area. He also had severe radiculopathy in the right buttock and right leg down to his calf. He described his pain as constant, seven out of ten in his back and four out of ten in his leg.

Radiculopathy is what occurs where a nerve is impinged upon by a portion of the spine. It can result in pain running along the nerve, or numbness or tingling. In F's case, the nerve impingement caused pain as well as tingling and numbness.

I believe that severe radiculopathy like F's suffered from is serious, and not just due to the symptoms of pain. If the spine is impinging on the nerve it can cause permanent nerve damage. That is why surgical intervention is usually appropriate in cases of severe radiculopathy.

In F's case, I was aware from talking to F and reviewing his medical records that he had initially been injured in 2009. He had undergone three years of conservative therapy, which included

physical therapy, epidural injections, and chiropractic treatments. While F did get some relief, by April of 2012, it was clear to me that conservative therapy had failed. At that time F was essentially disabled and incapacitated due to his back pain and the associated radiculopathy.

When I saw F in April of 2012, I had available a recent CT scan and an MRI of Frank's lumbar spine. These, coupled with the symptoms that Frank reported, indicated that F's serious disc problems at numerous adjacent discs in his lumbar spine.

Specifically, he had: A massive disc herniation at L5-S1, with S1 right radiculopathy; At L4-5 the disc appeared relatively healthy, but it also had a bulging protrusion; At L3-4 there was a large disc herniation which encroached into the spinal canal; There was also disc herniation at L2-3 which included marked narrowing around the nerve root; In short, my review showed that F had four adjacent damaged discs in his lumbar spine.

Given that there are only five discs in a person's lumbar spine, F had only one single normal disc in his lumbar spine, at L1-2.

I sent F out for a CAT scan of his lumbar spine. This CAT scan showed that F had a fracture in his right pars interarticularis (or 'pars' for short) at L5. The pars is a small bone segment that joins the facet joints. The fracture in the right pars at L5 meant that Frank needed urgent spinal surgery with fusion at that level.

The problem presented is what type of spinal surgery would best suit F, given his age and condition. Fusion was a possible option, but F had four damaged adjacent discs. While L4-5 was not badly damaged, given that there were seriously injured discs on both sides of it, it could not be skipped over.

There are only five discs in F's lumbar spine, and immobilizing four of them together through fusion would have seriously limited his mobility. With this large a fusion he would have no chance at a normal, active lifestyle.

More significantly, at the time I saw F in April of 2012, he was only 24 years old. As I stated earlier, a fusion results in added stress on the healthy discs that are adjacent to the fusion. This stress increases as the scope of the fusion increases, and increases the risk that, over time, the healthy disc will fail.

As such, I do not think it would be advisable to perform a four-level fusion on a 24-year-old man. Given F's age it would be a virtual certainty that the fusion would fail during his lifetime. As noted above, at that point a surgeon would have no option but to increase the scope of the fusion, which would further limit F's mobility, and further increase the chance of additional failures. Putting it bluntly, I believe using fusion on F would likely doom him to a lifetime of back pain and disability.

Because of this, in my opinion F's only reasonable treatment option was multi-level ADR. This was the only treatment option that could successfully resolve F's back pain and radiculopathy while allowing him some hope of a normal lifestyle going forward. I explained all of this to F, and he agreed with me as to the plan for the surgery. Basically, what we planned was a three-level ADR at L2-3, L3-4, and L4-5. We would use the ProDisc L (the 'L' meaning it was designed for use in the lumbar spine). Further, I would do a fusion at L5-S1. Fusion, rather than ADR, was the best option there because of the existence of the pars fracture.

I performed the surgery at Cedars-Sinai on May 23, 2012, with Dr. Pazmino and Dr. Wagner assisting. As planned, we removed the damaged discs at L2-3, L3-4 and L4-5, replacing them with ProDisc L artificial discs. In addition, I performed a fusion at L5-S1 disc. The surgery was a complete success, and post-surgery imaging showed the artificial discs and the fusion hardware all properly placed and firmly attached.

The surgery resolved F's radiculopathy. However, he continued to experience some back pain. Eventually, F was scheduled for an outpatient procedure with me on August 6, 2012. During the procedure I determined that there was a bone spur in the right mesial facet at L5-S1 which was protruding into the nerve root. I shaved off the spur.

After this second procedure F recovered normally from the surgery. Eventually he was weaned off his narcotic pain medication and, on November 9, 2012, I was able to release F back to work. The only limitation on his return to work was that he not lift more than 35 pounds.

I understand that reviewing physicians hired by F's medical plan have determined that the fusion at L5-S1 which performed was not medically necessary. This, frankly, is ridiculous. F had a pars fracture. This could not be left untreated, and fusion of the effected discs was the best treatment for this condition.

I also understand that the plan's medical reviewers have opined that the use of multi-level ADR was not medically necessary and experimental. This is also wrong. Multi-level ADR is widely accepted by the medical community as safe and effective in treating certain types of spinal injuries. It is commonly done in major hospitals and routinely prescribed in appropriate cases.

Moreover, for reasons I describe above, it is not only the most appropriate treatment for F, but really the only possible treatment that would afford him a reasonable chance at a productive and active lifestyle.

Finally, in determining whether I was right in performing this surgery, it should be considered that the surgery was a complete success in resolving F's serious medical problem. When I performed the surgery on F in May of 2012, he was a virtual invalid. Due to the pain caused by his serious back injury he wasn't capable of working or doing much else, and he was living on narcotic pain medication. In less than six months we had him back working, free of the need for narcotics, and almost fully functional. As such, and given that there were no other reasonable treatment options, I don't see how anyone can question that this treatment was medically necessary to treat F." (Claimant pps. 1003-1010)

The matter was then remanded to the Trustees, and a final AMR peer review occurred from a physician with a specialty in neurological surgery and surgery spine. He wrote, on October 14, 2014, that the Claimant's L5-S1 fusion, which had theretofore been denied, was medically necessary. With respect to the ADR, which had been performed at the same time, he provided similar rationale for his answers to the following three questions:

“ 2) Were the L2-3, L3-4 and L4-5 artificial disc replacements done on 5-23-12 medically necessary? **No**

The current medical literature does not support the performance of artificial disc replacements at L2-3 through L4-5 as medically necessary or standard of care. There is very limited evidence from the current clinical literature establishing the post-operative

outcomes from hybrid lumbar fusion and artificial disc replacement procedures at multiple levels as compared to the standard alternative of multi-level lumbar fusion. There are no current lumbar artificial disc replacement systems currently approved by the Food and Drug Administration (FDA) for use at multiple levels. The use of artificial disc replacements at these levels was off-label and outside of the FDA indications for use of these symptoms. As such, the use of artificial disc replacements at levels L2-3 through L4-5 on 05/23/12 was not medically necessary as they were not standard of care. The use of multiple artificial disc replacements would be considered unproven per the current clinical recommendations for this technology.

3) Were the L2-3, L3-4 and L4-5 artificial disc replacements done on 5-23-12 standard of care? **No**

The current clinical literature would not have supported the performance of artificial disc replacements at L2-3 through L4-5 as standard of care and would have been considered unproven in nature. There is very limited evidence from the current clinical literature establishing the post-operative outcomes from hybrid lumbar fusion and artificial disc replacement procedures at multiple levels as compared to the standard alternative of multi-level lumbar fusion. There are no current lumbar artificial disc replacement systems currently approved by the FDA for use at multiple levels. The use of artificial disc replacements at these levels was off-label and outside of the FDA indications for use of these symptoms. As such, the use of multiple artificial disc replacements would be considered unproven per the current clinical recommendations for this technology.

4) Were the L2-3, L3-4 and L4-5 artificial disc replacements done on 5-23-12 experimental and investigational? **Yes**

The current clinical literature would not have supported the performance of artificial disc replacements at L2-3 through L4-5 as standard of care and would have been considered experimental and investigational in nature. There is very limited evidence from the current clinical literature establishing the post-operative outcomes from hybrid lumbar fusion and artificial disc replacement procedures at multiple levels as compared to the standard alternative of multi-level lumbar fusion. There are no current lumbar artificial disc replacement systems currently approved by the FDA for use at multiple levels. The use of artificial disc replacements at these levels was off-label and outside of the FDA indications for use of these symptoms. The use of multiple

artificial disc replacements would be considered experimental and investigational per the current clinical recommendations for this technology.” (Tosdal Dec’1 Ex. G. bold type in original)

The Trustees agreed that the fusion was medically necessary and allowed that claim. As to the ADR, the Employers’ Trustees denied the claim, and the Union’s allowed it, leading to the deadlock here.

PLAN PROVISIONS:

“General Exclusions

The following general exclusions are in addition to limitations and exclusions listed elsewhere in this booklet for Basic, Major medical, Medicare Supplemental and Additional Benefits.

- Services which are not medically necessary to treat an illness or injury, ...
- Services performed in or outside the United States which are experimental in nature or do not meet established treatment protocols in the United States. ...” (Summary Plan Description, p. 56, BPO p. 175)

POSITION OF THE PARTIES:

Position of the Individual Claimant:

That with four adjacent badly damaged spinal discs, and that a four-level fusion would not be optimal given the Claimant’s young age, ADR was considered advantageous and was completely successful; that since neither “medical necessity” nor “experimental treatments” are defined in the Welfare Plan, and court decision definitions which include that medically necessary treatments are those which are effective and useful for treating a patient’s injuries should be accepted; that a denial on the basis of a

treatment being “investigational” is not a recognized exclusion under the Plan; that a reasonable definition of experimental treatment is one that is used only in an investigational setting or is below the standard of care of professionals in the relevant specialty; that the burden is on the Plan to prove the claim is excluded from coverage as well established in ERISA cases; that multi-level ADR is safe, effective, widely used and available in every major hospital in southern California; that numerous peer-reviewed studies have shown multi-level ADR to be an effective treatment for degenerative disc disease and, in appropriate cases, as this one, is superior to fusion; that a court has held that multi-level ADR is not experimental; that there was no contradiction to the evidence that ADR was the only viable treatment for the Claimant; that “off-label” usages have been recognized as a common and necessary part of medical practice; that court decisions on the burden of proof are applicable in arbitration; that reference by the Employers’ Trustees to the Milliman Guidelines are nowhere mentioned in the Plan as decisive of medical necessity determinations; that in any event there was no inquiry of nor reference to such Guidelines with respect to the ADR in issue here; that studies claimed to support the AMR experts were not identified, and those cited in the record highly support ADR and multi-level ADR as an alternative to fusion.

Position of the Union Trustees:

That the FDA has not yet expressly approved multi-level ADR does not render the procedure medically improper or inappropriate given its very efficacy as in this case, it having approved the artificial disc used and one level of ADR; that this is so given the support of medical studies that find no difference in the effectiveness of treatment

between one-level versus multiple levels as well as the experience of surgeons as Cedars-Sinai and other leading hospitals.

Position of the Employers' Trustees:

That four medical experts determined the ADR procedure to not be medically necessary and that clinical studies were inadequate to show the efficacy of the procedure; that the Trustees, as fiduciaries, cannot pay claims that are not covered by the Plan or construe it to conflict with its plain language; that the Claimant bears the burden of proof to show his claim is covered under the Plan, and the cases cited by the Claimant to the contrary are not applicable; that the Trustees are entitled to consult with independent health care professionals to make medical judgments given that they are not medical experts; that the Trustees bent over backwards to be fair by its four submissions to neurological experts; that the medical experts relied on the standards of the Milliman Guidelines in making medically necessary determinations; that courts' definitions of "medical necessity" or "experimental" under different plans are not relevant; that while Trustees are to consider a treating physician's opinion during the full and fair review process, the Trustees are not bound by that opinion since that physician is not independent and has interests in being paid and assisting his patient; that the treating physician should be given less deference since his opinion was not provided contemporaneously with the procedure in question; that the efficacy of the procedure for the time being is not relevant since the long-term effects are unclear and unknown so the procedure is not currently considered the appropriate standard of care; that the Plan's experts all reviewed the studies cited by the Claimant in reaching their conclusion.

DISCUSSION:

The denial of the claim for ADR rests, ultimately, on the Trustees' reliance on the final AMR medical review, for it was that reviewer who had, for the first time, the declaration under penalty of perjury of Dr. Lanman. When the reviewer's conclusions are compared to that declaration, what is apparent is that the reviewer did not directly address the specifics of the circumstances of the Claimant's ADR, but gave general, abstract answers relative to the questions posed and did not provide the definitions he was using for the terms "medically necessary" and "standard of care."

Whatever the merits of those answers may be, they failed to come to grips with three or four important issues raised by Dr. Lanman's declaration as to those specifics. First, whether, as a matter of medical necessity, a total fusion, as opposed to multi-level ADR, would be appropriate for a 24-year-old patient, given the indication that such a fusion would immobilize him for a substantial portion of his life, and not relieve his back pain, while endangering his one good disc? This was, apparently, the crucial decision to be made as to whether fusion or ADR would be the appropriate surgical treatment, and the final reviewer did not address that issue.

Second, whether ADR was within the standard of care? The reviewer opined that it was not, but, as noted, failed to define what "standard of care" he was applying. Dr. Lanman addressed the standard of care in leading hospitals in southern California and the reviewer, in not addressing that that was an appropriate standard to use, provided no information to the Trustees on that issue. If ADR was the appropriate standard of care in that area, and there is no evidence to the contrary, then Dr. Lanman, or another similarly

situated surgeon, would not be offering the proper level of care to his patient, as he would be required to do.

The third unanswered question concerning experimentation was that while there was no FDA approval for multi-level ADR, as opposed to single-level ADR; whether a multi-level ADR in the circumstances of the Claimant's case met established treatment protocols in the United States. Again, Dr. Lanham pointed to the consistent use of multi-level ADR in southern California in appropriate cases. The reviewer's finding did not dispel the conclusion that there is no major experiment in that area going on involving multiple hospitals and multiple surgeons with respect to that procedure, but that it is acceptable there as a non-experimental treatment protocol for a young patient with multiple damaged discs as was the Claimant. In addition, although studies purporting to support the procedure were cited in Claimant's opening brief, they were not in the studies the final reviewer listed as his references.

Finally, as shown, the procedure is neither quackery nor an outlier being pushed by a single or very few physicians, given the declaration, and its success, as noted.

As made clear in past Coast decisions, the resolution of claims requires that the Trustees address the specific facts of a given case. Properly, as here, they have sought expert guidance to do so when they do not have such expertise. As their contract with their expert reviewer agency shows, the reviewer is required to deal with the specific case, including the ability of a physician reviewer to "contact the physician or medical services provider for the claim under review to fully understand the received treatment prior to making a determination." That apparently was not done here. (ICM Contract

App. A-3, Bohl dec'1, Ex. 2) In addition, while the contract provides that determination is made "in accordance with Milliman Care Guidelines," none were cited in the final review, even assuming any would be applicable.

As the Employers' Trustees point out, a treating physician's declaration can be viewed as biased, since, at the least, it defends what the physician did, and, secondly, it can be flavored to support a claim for ultimate payment. But while those may be inferences that can be drawn, the assertions in such declarations have to be investigated and conclusions reached as to their veracity, not, as here, by generalized conclusions, but by directly meeting those assertions and rejecting them based on the investigation and direct, detailed rejection of their specifics, if required, as here, in a given case. Since that did not occur here, there is no basis to disregard them as to the southern California practice. Unlike other cases from that area involving other physicians and providers, there are no allegations that the procedure in question did not occur as stated.

Accordingly, the conclusion reached from this record is that the report of the final expert reviewer, who, among all reviewers, had the most exposure to the records and declaration here, is that that report was inadequate to dispel the conclusions of Dr. Lanham as to the appropriateness, standard of care, medical necessity and acceptance of the procedure in F's case.

This conclusion is independent of legal issues raised by the Claimant, including burden of proof, and the appropriateness of applying Milliman guidelines, if they were applied, when those guidelines are not mentioned in the Summary Plan Description and other issues.

DECISION:

The claim for ADR is allowed. Payment in full shall be made forthwith.



Coast Arbitrator