

ATTACHMENT A
THE PROPOSED DECISION

BEFORE THE
BOARD OF ADMINISTRATION
CALIFORNIA PUBLIC EMPLOYEES' RETIREMENT SYSTEM

In the Matter of the Appeal of the Denial of
Health Benefits Coverage on behalf of
PAMELA WALCHAK, by:

DAVID WALCHAK,

Respondent.

Case No. 2013-0125

OAH No. 2014050385

PROPOSED DECISION

Administrative Law Judge David L. Benjamin, State of California, Office of Administrative Hearings, heard this matter on October 7, 2014, in Oakland, California.

Senior Staff Attorney Jeanlaurie Ainsworth represented complainant Kathy Donneson, Chief, Health Plan Administration Division, California Public Employees' Retirement System.

Respondent David Walchak and his wife, Pamela Walchak, appeared and were not represented by an attorney.

The record closed and the matter was submitted on October 7, 2014.

ISSUE PRESENTED

Respondent and his wife are enrolled in the PERS Choice health plan. Respondent's wife suffers from longstanding back problems that cause her severe pain. Her surgeon has requested authorization to perform a unilateral (left) sacroiliac joint fusion. The issue is whether the procedure is excluded from coverage on the ground that it is "experimental or investigational."

FACTUAL FINDINGS

1. The California Public Employees' Retirement System (CalPERS) is the agency charged with administering the Public Employees' Medical and Hospital Care Act.

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(Gov. Code, § 22750 et seq.) The Act requires CalPERS to provide health benefits for state employees and their dependents. At all times relevant to this proceeding, PERS Choice (health plan) was a preferred provider plan offered by CalPERS under the Act. CalPERS contracts with Anthem Blue Cross to administer PERS Choice medical claims.

2. At all relevant times, respondent David Walchak was enrolled in the health plan, and his wife, Pamela Walchak (claimant), was eligible for benefits under the health plan by virtue of respondent's employment.

3. Claimant is a 56-year-old woman with a history of back problems dating back to 1986. In 1996, claimant had a two-level fusion in her cervical spine. After a motor vehicle accident in 2002, claimant underwent fusion surgery again. She now has a five-level fusion from C5 to T1. Despite these surgeries and extensive conservative treatment, which has included epidural injections, facet blocks, physical therapy and aqua-therapy, claimant continues to suffer from intractable back pain from her neck to her buttocks, and radiating down her legs. Claimant's pain prevents her from sleeping more than an hour or two at a time. Claimant takes narcotic medications for pain, and medications to help her sleep. She is on social security disability and has not worked since 1997.

4. On July 27, 2010, claimant informed her treating physician, orthopedic surgeon Noel D. Goldthwaite, M.D., that although she had neck pain, mid-back pain, and bilateral buttocks pain, with weakness in her legs, most of her pain in the lower body was low in the buttocks. In his July 27, 2010 report, Dr. Goldthwaite reported that claimant's "[s]acroiliac joint exam is positive bilaterally with positive FABER test. Pain over the posterior superior iliac spines and lateral leg lifts." Dr. Goldthwaite's diagnosis was "[b]ilateral sacroiliac joint dysfunction." He referred claimant to Richard Derby, M.D., for bilateral sacroiliac joint blocks under radiographic control.

5. To oversimplify a complex procedure, a bilateral sacroiliac joint block involves the precise injection of anesthetic into the left and right sacroiliac joints. The patient is then asked to perform activities that would normally be painful for her. Dr. Goldthwaite believes, as do some other physicians, that if the patient reports significant pain relief, on the order of 50 to 70 percent improvement, the procedure shows that her pain originates in the sacroiliac joint. Dr. Goldthwaite hoped that the joint blocks would provide therapeutic pain relief for claimant, and confirm his diagnosis of joint dysfunction.

6. Dr. Derby performed bilateral intraarticular sacroiliac injections on September 21, 2010. After the procedures, claimant reported significant relief from pain, stating that she felt 70 percent better. Claimant also reported, however, that her left leg was numb. Dr. Derby felt that this complaint indicated a "probable leak [of anesthetic] outside the [sacroiliac] capsule." The "probable leak" is referred to in later reports as "extravasation."

7. Claimant went straight from Dr. Derby's office to an appointment with Dr. Goldthwaite. Her husband had to assist her because, according to claimant, her left leg collapsed. At that appointment, Dr. Goldthwaite raised the possibility of fusing claimant's

sacroiliac joint. Dr. Goldthwaite told claimant when her leg wakes from the local anesthetic, she “should perform most of the activities which normally flare her buttocks and leg pain to see how difficult it is to flare it. [¶] This will be the measure she can expect in the way of relief from fixing the SI [sacroiliac] joints.”

8. Claimant returned to Dr. Goldthwaite’s office on November 9, 2010. She told him that, after the September 21 procedure, she had several days of “excellent relief” after which she returned to baseline. Dr. Goldthwaite concluded that “[o]wing to the major disruption of the left joint, I do not believe it is necessary to repeat the injection to offer the patient a transarticular screw fixation and fusion of both SI joints.”

9. On December 7, 2010, Dr. Goldthwaite requested authorization from Anthem to perform a bilateral sacroiliac joint fusion. On December 15, 2010, Marappa Gopinath, M.D., a medical reviewer for Anthem, denied the request. Dr. Gopinath advised claimant that the health plan considers sacroiliac joint fusion for the treatment of low back pain to be “investigational.” The Evidence of Coverage for the health plan, which sets forth the plan’s obligations, excludes coverage for experimental or investigational procedures.

10. Claimant appealed the decision. Anthem assembled a three-person panel, which included a board certified orthopedic surgeon, to review claimant’s records. The panel denied claimant’s appeal. In a letter dated January 12, 2011, Lynn Cooman, M.D., a medical director for Anthem, informed claimant that “[y]our request to fuse two bones in your pelvis (sacroiliac joint) cannot be approved as this treatment is considered investigational. There are not enough studies showing improved long-term results for fusion compared to other available treatments.”

11. Claimant asked Anthem to reconsider its decision. Anthem assembled another three-person panel, which again included a board certified orthopedic surgeon. Anthem denied claimant’s request for reconsideration. In a letter dated March 17, 2011, Maureen Prowse, M.D., a Medical Director in the Grievance and Appeals Department of Anthem, informed claimant that

your records do not include findings on your examination that clearly document a disease in your SI joint other than tenderness over the joints, left more than right. There were no x-rays documenting any significant SI joint disease in the records provided. The medical literature reviewed fail to document the safety and effectiveness of SI joint fusions. A procedure is or technology is considered investigational because available medical studies do not show that this service improves health outcomes, is as good as or better than standard alternatives, or shows improvement outside the research setting. As a result, the denial is upheld as investigational.

Claimant asked Anthem to reconsider its decision.

12. As she pursued her administrative appeals with Anthem, claimant continued treatment with Dr. Goldthwaite, who requested a second opinion from orthopedic surgeon Bruce McCormack, M.D. Dr. McCormack reviewed claimant's medical records and wrote a report dated January 22, 2011. In his report, Dr. McCormack writes that "the SI block . . . was non-diagnostic on the left, due to extravasation of the local, and on the right was diagnostic." Dr. McCormack concludes that claimant is a patient "with chronic pain with positive response to SI joint injections this past fall and in the past. She meets criteria for SI joint fusion. Bilateral procedure has been entertained. It would seem to me, doing one at a time would also be prudent." Dr. McCormack's report does not state whether he believes the initial fusion should be on the right side, where he found the procedure diagnostic, or on the left, where he found it non-diagnostic. The report does not state what Dr. McCormack means by the criteria for fusion.

13. On February 14, 2011, Dr. Derby repeated the bilateral sacroiliac blocks he had performed five months earlier. In his Procedure Note dated February 14, Dr. Derby writes that it was "difficult to tell if there was a leak on the left side." He states that, following the procedure, "there was some leg weakness, again confirming a leak through the left SI joint capsule. Overall, she was better. It is difficult to tell with [claimant] because of her chronic pain symptoms. She will, however, note the relief for the rest of the day, to see whether there is any significant decrease in symptoms over the next two weeks."

14. These events led Dr. Goldthwaite to modify the request for authorization he had submitted to Anthem. After Dr. McCormack's examination, Dr. Goldthwaite requested authorization for a unilateral sacroiliac joint fusion on the left side, instead of the bilateral procedure he had proposed earlier.

15. A three-member review panel assembled by Anthem addressed claimant's request for reconsideration, and Dr. Goldthwaite's revised authorization request. On May 18, 2011, Anthem denied claimant's request for a unilateral joint fusion on the same grounds that it had denied her request for a bilateral fusion.

16. Claimant, supported by Spine Care Alliance, a patient advocacy group, asked Anthem to review its decision. In a letter dated September 20, 2011, Dr. Goldthwaite also urged Anthem to approve the fusion procedure:

[Claimant] suffers from persistent bilateral gluteal pain with only transient relief resulting from the SI Block in the right joint. Although she will eventually need the fusion in both SI joints it is imperative at this time to proceed with the previously requested arthrodesis of her left sacroiliac joint. As far as her left SI joint is concerned she is no longer a candidate for conservative treatments as the joint is essentially "blown out" and will not hold any of the medication that can be injected for relief. Exhausting all of her non-operative alternatives surgical intervention is the only option available to her. Prolonging the

issue further will only serve to exacerbate [claimant's] increasingly deteriorating condition.

17. On October 13, 2011, Anthem again denied Dr. Goldthwaite's request for authorization on the ground that it considers a unilateral sacroiliac joint fusion to be investigational. The letter advised claimant that she had exhausted her appeal rights with Anthem.

18. In a letter dated November 18, 2011, Dr. Goldthwaite urged Anthem to revisit its decision. He wrote:

Your reviewer objected that there were no radiographic changes in the SI joint. [¶] There rarely are. The "Gold Standard" of making the diagnosis is radiographically controlled intra-articular injection. . . . [¶] Repeat bilateral SI joint injections were performed by Dr. Derby on 14 February 2011 with the same result: leakage from the left joint with leg numbness and relief on the right side without numbness. Again, short lived. [¶] Physical therapy, including aqua therapy, was performed 9 March through 9 May 2011 with no benefit to the SI joint symptoms. [¶] The fact that the left joint leaked fluid during injection allowing local anesthetic to spill onto the nerves of the lumbo-sacral plexus producing numbness and weakness in the leg is evidence of very severe disruption of the joint capsule. It is hopeless to treat such a situation conservatively. [¶] The excellent relief during anesthetic phase of the injection confidently makes the diagnosis. The short duration of the steroid phase of the injection indicates the futility of conservative treatment. Arthrodesis can be expected to give permanent relief equivalent to that of the maximum relief seen in the anesthetic phase of the injection.

Dr. Goldthwaite informed Anthem that, in his experience, sacroiliac joint fusion is routinely approved in similar circumstances by Blue Cross, other private carriers, all workers' compensation carriers, Medicare and Medi-Cal.

19. Although the administrative record is not clear on the point, it appears that Anthem took no further action on claimant's appeal after October 13, 2011, and claimant then directed her appeal to CalPERS. CalPERS contracts with MAXIMUS Federal Services, Inc., to independently review requests for authorization that have been denied on the ground that the procedures are investigational or experimental. An independent review involves a review of the patient's chart by three specialists in the field who report their conclusions anonymously. Claimant requested an independent review, and CalPERS granted her request. MAXIMUS referred the matter to three physicians, board certified in orthopedic surgery and currently in practice, to reviewed claimant's request for authorization.

Reviewer #1 questioned whether the sacroiliac joint is the source of claimant's pain. He/she noted that Dr. McCormack found the left sacroiliac joint injection to be non-diagnostic, and that claimant's MRI examination revealed only mild, stable degenerative change of the left sacroiliac joint, as opposed to diffuse thoracic degenerative disc disease, and significant lumbar spondylosis at L3-4, L4-5 and L5-S1. Reviewer #1 concluded that even if claimant's pain originates with the left sacroiliac joint, "there is insufficient evidence to support the long-term efficacy and safety of sacroiliac joint fusion for the treatment of low back pain, or to establish its effectiveness compared to more conservative approaches."

Reviewer #2 acknowledged that the sacroiliac joint can be a source of pain and radiation into the lower extremities, but found "no definite historical, physical or radiological features to provide a definite diagnosis." Reviewer #2 thought that the "accuracy of maneuvers and injections of the joint is limited, the validity of anesthetic injections is unproven, and there is a lack of published prospective data to document the efficacy of arthrodesis of the sacroiliac joints."

Reviewer #3 felt that it was "questionable" to focus on the sacroiliac joint as the source of claimant's pain "in light of [claimant's] documented multiple pain generators." Reviewer #3 noted that patients can have serious conditions of the sacroiliac joint without any symptoms. He/she believes that the primary use of fusion is in cases of fracture and instability, which claimant does not have.¹

In a letter to claimant dated November 15, 2011, MAXIMUS informed her of its conclusion that unilateral sacroiliac joint fusion "is not likely to be more beneficial for treatment of your medical condition than any available standard therapy. Therefore, MAXIMUS has decided that PERS Choice's denial of the requested procedure should be Upheld."

20. Claimant asked CalPERS to reject the recommendation of MAXIMUS. CalPERS referred the matter to its medical consultant, Richard Sun, M.D., M.P.H., for review. Dr. Sun earned his medical degree from the University of California, San Francisco, and his master's degree in public health from the University of California, Berkeley. He is board certified in preventive medicine. Dr. Sun and his team review requests for authorization to insure that they are consistent with the terms of the plan: PERS Choice is self-funded from premiums paid by employers and members, and therefore requests for authorization are reviewed carefully to insure that the plan remains solvent.

Dr. Sun reviewed all of the documents submitted by claimant over the past four years, and reviewed the medical literature pertaining to the proposed fusion procedure. He prepared a written decision on claimant's appeal dated November 28, 2011, which sets forth

¹ It is unquestioned that sacroiliac fusion is an appropriate procedure in cases of severe pelvic fracture, and infections or cancers of the bone. Claimant, however, does not have these conditions. In this case, fusion is proposed to treat claimant's complaints of low back pain.

his findings and attaches copies of the articles cited in his report. The decision denied claimant's appeal, and upheld Anthem's conclusion that the proposed fusion is experimental or investigational.

Dr. Sun identified several reasons for his conclusion, but the fundamental reason is that he found the medical literature to be inconclusive on the efficacy of sacroiliac fusion to treat low back pain.

In Dr. Goldthwaite's opinion, the sacroiliac joint blocks performed by Dr. Derby establish the sacroiliac joint as the source of claimant's pain. Dr. Sun found, however, that joint blocks have not been proven to reliably diagnose the source of low back pain, with or without radiculopathy. Dr. Derby, who performed the joint blocks on claimant, was one of the authors of a study that found "fair to poor evidence for sacroiliac joint blocks to diagnose sacroiliac joint pain." And in this particular case, after the February 2011 joint blocks, Dr. Derby questioned whether the procedure was diagnostic of sacroiliac dysfunction, in light of claimant's chronic pain complaints.

Dr. Goldthwaite believes that the extravasation of anesthetic from claimant's left side, accompanied by temporary pain relief, confirms the diagnosis of sacroiliac joint dysfunction and supports his plan for joint fusion. Dr. Sun found that the medical literature failed to demonstrate that extravasation is an indication for fusion. Dr. Sun cites a 2005 study that found that ". . . SI joint block can be one of the most challenging spinal injection procedures. Extravasation of LA [local anesthetic] to surrounding pain-generating structures such as muscles, ligaments, and lumbosacral nerve roots can lead to false-positive blocks." Another study found extravasation of anesthetic in 90 percent of asymptomatic subjects.

Dr. Goldthwaite maintains that sacroiliac fusion is an effective treatment of low back pain. Dr. Sun, however, notes that there have been no controlled studies to support that assertion, and five case studies have failed to establish the effectiveness of sacroiliac fusion to treat low back pain. Dr. Sun cites a 2011 article from the North American Spine Society ("Physicians debate role of surgery for sacroiliac joint pain") that states, "The jury is still out on the efficacy of SI joint surgery and fusions, as the evidence that currently exists is scarce and based on case studies, thus necessitating additional controlled studies on the this topic." Dr. Sun found that this conclusion accurately reflects the state of the medical literature.

Dr. Goldthwaite believes that the pain relief claimant experienced with the joint blocks is the relief she can expect to experience with fusion. Dr. Sun found that this proposition is not supported by the medical literature. He cites a 2007 study ("The ability of diagnostic spinal injections to predict surgical outcomes"), which concluded that "a review of the disparate outcomes of the literature does not support the conclusion that patient selection based on SI joint blocks will improve the results of SI joint fusion."

In addition to reviewing the medical literature, Dr. Sun surveyed the commercial health plan policies available on the internet and found that all of them classify sacroiliac joint fusion as experimental and/or investigational. Dr. Sun also identified other state,

national, and international organizations that have classified sacroiliac fusion for the treatment of low back pain as investigational or “not recommended.”

Dr. Sun testified at hearing. His review of the medical literature was thorough, and his summary of the findings set forth in the medical literature was credible.

21. Claimant filed a timely appeal from CalPERS’s decision, and this hearing followed.

Respondent’s evidence

22. Claimant feels that she is “out of options” to address her extreme, debilitating pain. She has had two spine surgeries resulting in a five-level fusion in her cervical spine, and the insertion of a titanium plate, but these procedures did not provide lasting relief. She has tried numerous conservative therapies including epidurals, aqua-therapy and physical therapy, but feels that these treatments only made her pain worse. Claimant has great faith in her orthopedic surgeon, whom she describes as world renowned, and she is convinced that the sacroiliac fusion will bring her the relief she hopes for.

23. Dr. Goldthwaite performed over 150 sacroiliac joint fusions between February 2006 and May 2013. These procedures were paid for primarily by Medicare, workers’ compensation, and Blue Cross. The evidence did not establish whether these patients had the same condition as claimant, or whether the procedures were effective. The coverage obligations and exclusions of Medicare, workers’ compensation, and Blue Cross were not addressed or established.

LEGAL CONCLUSIONS

1. The CalPERS Choice plan excludes from coverage “[e]xperimental or investigational practices or procedures.” The terms “experimental or investigational” are defined by the Evidence of Coverage as “any treatment . . . [or] procedure . . . which [is] not recognized in accordance with generally accepted professional medical standards as being safe and effective for use in the treatment of [a] condition at issue.” The party asserting that a claim is excluded from coverage has the burden of proof. (*Garvey v. State Farm Fire & Casualty Co.* (1989) 48 Cal.3d 395, 406.) As no statute provides otherwise, the standard of proof to be applied is preponderance of the evidence. (Evid. Code, § 115.)

2. Complainant has met its burden. The medical literature demonstrates that sacroiliac joint fusion is not recognized, in accordance with generally accepted professional medical standards, as being effective for use in the treatment of low back pain. Dr. Goldthwaite’s belief in the effectiveness of the procedure, supported by his experience with his own patients, does not establish that the procedure has been recognized as effective in accordance with generally accepted professional medical standards. Evidence that Medicare, workers’ compensation, and Blue Cross have paid for sacroiliac fusions performed by Dr.

Goldthwaite is given little weight, as the patients' conditions, the effectiveness of the procedure, and the terms of coverage of those plans are unknown. And while some insurers may pay for the procedure under some circumstances, other insurers and government agencies have classified the procedure as investigational. It is difficult to deny coverage for a procedure in which claimant has placed so much faith and hope. The evidence establishes, however, that the proposed unilateral sacroiliac joint fusion is experimental or investigational for the treatment of claimant's low back pain, and therefore is not covered by the PERS Choice plan.

ORDER

The appeal of respondent David Walchak is denied.

DATED: November 5, 2014



DAVID L. BENJAMIN
Administrative Law Judge
Office of Administrative Hearings