

STATE OF VERMONT

HUMAN SERVICES BOARD

In re ) Fair Hearing No. 19,661  
 )  
Appeal of )

INTRODUCTION

The petitioner appeals a decision by the Department for Children and Families, Economic Services Division, (DCF) denying the petitioner's request for prior approval for artificial disc replacement through the Vermont Health Access Program (VHAP).

FINDINGS OF FACT

1. The petitioner has suffered from back pain for over ten years due to disc herniations caused by a fall on the ice. He has been treated with pain relieving medications and spinal injections for the last eight years. His treatments have been unsuccessful and his physicians have recommended back surgery for him for relief of pain and restoration of loss function.

2. The petitioner is currently in treatment at a specialty spine clinic at a university-connected hospital. His treating physician is an orthopedic surgeon who specializes in spinal disorders. His surgeon requested prior

authorization to perform a "Charite artificial disc replacement" operation on the petitioner through the VHAP program.

3. In April of 2005, the VHAP Managed Care division denied the petitioner's request for prior authorization, stating in its written decision that the procedure is considered "investigative and experimental."

4. At the hearing held on May 26, 2005, the sole medical witness was the petitioner's treating surgeon, Dr. S., who testified by telephone.

5. Dr. S. is an expert in spinal surgery who has been active in the development of disc replacement surgeries. Dr. S. and his medical group have been treating the petitioner for the better part of ten years using conservative methods. However, the petitioner's pain persists and Dr. S. is now recommending spine surgery.

6. Dr. S. believes that the petitioner is a good candidate for spine stabilization through surgery because he has problems with certain discrete vertebrae. He says that the traditional treatment for such stabilization is fusion of the vertebrae but that this method poses a problem for the adjacent segments of the vertebrae which can be damaged by the fusion due to the need to compensate for the lack of

flexibility in the adjacent vertebrae. He prefers a newer treatment which is replacement of the disc in the back with an artificial disc.

7. Dr. S. is reluctant to perform the old surgery on the petitioner because he considers this one superior and says it is rapidly taking over for the old treatment. He expects the petitioner to be relieved of his pain and recover his functional ability more quickly from the procedure because there is no need to wait for the bones to fuse. He also expects that the disc replacement will not have the grinding effect on the adjacent vertebrae as the old fusion method. He expects that the long term outcome will be equal to and likely better than that of the fusion method. Back surgery is not without its risks but he says that the risk from the disc replacement is comparable to those of disc fusion surgery although they are slightly different. There is an increased risk of vascular damage from the disc replacement surgery and an increased risk of adjacent segment disease from the fusion surgery.

8. The new procedure has been performed in other parts of the world since the 1980's and in the United States since 2000. Dr. S. estimates that the procedure has been performed on 8,000 patients worldwide and about 1,000 in the United

States. He says that the FDA followed up about 200 of the cases in sixteen medical centers for two years before granting its approval. He says he has only done one such procedure himself to date. He has been a peer reviewer of final papers published in two scholarly journals reporting the results of studies on the Charite artificial disc which he submitted at hearing. He described one of the Journals, "The Spine Journal" as the most important journal in the profession and as the most quoted. Dr. S. described the second journal, "The Journal of Neurosurgery: Spine" as a leading respected journal in spine research as well.

9. The article in the "Spine Journal" dated September/October 2004 described randomized studies done by two spine clinics which concluded that the Charite artificial disc was "a viable alternative to fusion for the treatment of single-level symptomatic disc degeneration unresponsive to nonoperative management." It describes the procedure as "an alternative to traditional fusion and its attendant slow recovery process, plus the theoretical advantage of avoiding excessive stresses on the adjacent levels or the 'transition syndrome.'" The article in the "Journal of Neurosurgery" dated March 2004 concluded that the Charite intervertebral disc "is safe and effective for the treatment of mechanical

back pain caused by one-level DDD (degenerative disc disease) at L4-5 or L5-S1. Clinical outcomes at 2 years are equivalent to those resulting from one-level BAK fusion. (Fusion of the vertebrae). Clinical outcomes are equivalent or better than those related to 360 degree or stand-alone interbody fusion reported in the literature; however, there is the added benefit of restoring and maintaining segmental motion two years postoperatively. The incidence of major neurological complications was exceedingly low and equivalent to those demonstrated in control individuals in the BAK fusion group."

10. Following the publication of these findings, the FDA approved the Charite intervertebral disc for the treatment of mechanical back pain in the United States. DCF does not deny that the procedure has been DCF approved but says that the approval requires continued study of the outcomes.

11. Dr. S. was not aware whether a continued study had been required or not but testified that such a continued study would not be unusual for a newly approved FDA procedure and that the focus of any continued study in this case would doubtless be the durability of the artificial disc itself which had only been implanted for some twenty plus years at

this point. It was Dr. S.'s expert opinion that any expressed need for continued study did not mean that the FDA lacked confidence in the safety and effectiveness of the procedure or that it was still seen as investigative and experimental. He strongly disagrees that the procedure is still experimental or investigative, an opinion that he says is more than backed up by the medical journals and DCF approval.

12. The Department had no expert witness present at the hearing to rebut the testimony of Dr. S. The Department was allowed additional time to take a tape recording of Dr. S.'s testimony to its medical consultants for response.

13. After eight weeks, the Department's sole response to the testimony was a hearsay allegation that its medical director had reviewed the tape and the journals and had "determined that there is insufficient evidence to conclude that the medical community in this country has accepted the Charite artificial disc replacement as a proven beneficial option. In light of the fact that the FDA's approval of this device is conditioned upon the performance of long range studies, the Office of Vermont Health Access continues to view it as an experimental, investigative treatment." The Department offered no evidence in support of this assertion,

neither a signed affidavit from a medical expert in this field nor reference to any FDA published information which would support its opinion.

14. Dr. S's testimony is found to be entirely accurate and credible in this matter as it is based upon his expert knowledge of spinal surgery, the conclusions of respected medical journals and his own specific and detailed knowledge of the studies in this area and the course of FDA approval of this surgery. Furthermore, Dr. S.'s testimony was made under oath, was subject to cross-examination, and is uncontradicted in the record by any admissible, detailed or expert evidence in support of the Department's position.

15. Therefore, contrary to the assertions of the Department, the Charite artificial disc is found to be a proven beneficial option for disc surgery and not an experimental or investigative treatment.

ORDER

The decision of the Department denying prior approval because the procedure is investigational or experimental is reversed.

REASONS

The Vermont Health Assistance Program (VHAP) generally covers payment for surgical procedures that are medically necessary. VHAP 4005B(3)(a). The program specifically excludes coverage for "cosmetic surgery or experimental surgery." P4005C(16). The Medicaid program, of which VHAP is a part, has more detailed regulations with regard to the approval of a request for prior authorization for medical services:

Prior Authorization Determination

A request for prior authorization of a covered health service will be approved if the health service:

1. is medically necessary (see M107)
2. is appropriate and effective to the medical needs of the beneficiary;
3. is timely, considering the nature and present state of the beneficiary's medical condition;
4. is the least expensive, appropriate health service available;
5. is FDA approved, if it is FDA regulated;
6. is subject to a manufacturer's rebate, if a drug;
7. is not a preliminary procedure or treatment leading to a service that is not covered;
8. is not the repair of an item uncovered by Medicaid;
9. is not experimental or investigational;

10. is furnished by a provider with appropriate credentials.

M106.3

The sole criterion preventing approval of the petitioner's request is paragraph nine, based on the Department's belief that the procedure is experimental or investigational. The petitioner offered ample expert testimony that the procedure is no longer experimental or investigational, although it is certainly new. DCF offered no evidence whatsoever in support of its position. As such, it must be found that the procedure requested by the petitioner is not investigational or experimental.

As the petitioner has met all of the criteria for prior approval of the requested disc replacement surgery, DCF's denial of the surgery is in violation of its own regulations cited above. The Board is thus bound to reverse the decision of the Department as inconsistent with its own regulations and the petitioner is entitled to payment for the surgery. 3  
V.S.A. § 3091d, Fair Hearing Rule 17.

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