

STATE OF VERMONT

HUMAN SERVICES BOARD

In re) Fair Hearing No. 13,753

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Appeal of)

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INTRODUCTION

The petitioner appeals the decision by the Department of Social Welfare denying him medicaid coverage for pedicle screw spinal implant surgery. The issue is whether this is a covered service within the meaning of the pertinent regulations.

This matter was initially considered by the Board in a decision dated November 13, 1995.⁽¹⁾ In that decision the Board remanded the matter to the Department to make a determination specific to the petitioner whether the surgery in question is "justified". Upon remand the Department resubmitted the matter to its private contractor for reviewing health care services under Medicaid, and then reiterated and provided further documentation for its determination that the surgery sought by the petitioner is not approved by the federal Food and Drug Administration (FDA) due to an unacceptable (to the FDA) statistical risk of serious failure and complications.

FINDINGS OF FACT

In lieu of an oral hearing the parties have submitted written arguments. The petitioner suffers from chronic severe lower back pain. His physician has recommended that he undergo surgery to insert an internal spinal fixation device known as a pedicle screw. The petitioner concedes that pedicle screws have not been approved by the FDA for use in the spinal area where his doctor has recommended it be inserted. Although there appears to be considerable controversy in the national medical community about this procedure, the Department does not appear to dispute that despite the lack of FDA approval pedicle screw surgery is performed on tens of thousands of patients annually in the United States. It also appears that the petitioner's physician is experienced and has a successful track record in performing this surgery. There is no question that the petitioner's physician does not consider the surgery to be "experimental", and that he strenuously disagrees with the Department's decision of non-coverage. The Department does not dispute that spinal fusion surgery (not involving a pedicle screw implant) is "medically necessary" for the petitioner. The basis of the Department's decision is that any procedure not approved by the FDA due to substantial statistical risk of serious failure and complications will not be approved for coverage under medicaid.

ORDER

The Department's decision is affirmed.

REASONS

Under the medicaid regulations all surgical procedures fall under the category of "Physician Services". M.M. §§ M610 et seq.⁽²⁾ These regulations require medicaid coverage for all physician services that are "medically necessary". § M610. The preliminary issue in this case is whether the service in question falls under § M618, "Procedures Requiring Prior Authorization", which provides as follows:

Routine payment will not be made for procedures falling into one or more of the following four categories. Written justification will have to be made by the physician and approved by the Medicaid Division before service is rendered.

1. New procedures of unproven value; or
2. Established procedures of questionable current usefulness; or
3. Procedures which tend to be redundant when performed in combination with other procedures; or
4. Diagnostic procedures which are unlikely to provide a physician with additional information when they are repeated.

Identification of such procedures is made through the Medical Necessity Program begun by Blue Shield with the assistance of the American College of Physicians, American College of Radiology and American College of Surgeons. Also participating, is the American Academy of Family Practice, Council of Medical Specialties, American Hospital Association and American Associations of Medical Colleges.

The Board concluded in its Order of Remand (and the petitioner did not dispute) that any procedure not approved by the FDA is sufficient under the above regulation to establish that it is a "new procedure of unproven value" that requires prior authorization.

As the Board noted in its prior Order, however, the fact that prior authorization is required does not mean that such a procedure is automatically excluded from coverage under the regulations. Under § M618, the Department is required to make a determination whether there is "written justification" for that procedure--despite the fact that the procedure is "new" or "unproven". Moreover, as noted above, the regulations require that such a determination be specific to the petitioner and based on "medical necessity". Although it may be arguable the degree to which the Department in this case specifically addressed and countered the opinion of the petitioner's doctor that pedicle screw surgery for him is necessary, cost effective, and safe,⁽³⁾ the majority of the Board concludes that in cases such as this, where the FDA has withheld approval of a particular surgical procedure due to clearly documented statistical evidence of serious risk and complications, the Department is within its authority and discretion under § M618 to deny a request for approval of Medicaid coverage. In such cases, even

though the opinion of the patient's own doctor may not be specifically refuted, it is held that lack of FDA approval provides sufficient basis for the Department to conclude under § M618 (supra) that the procedure is not "justified" and, therefore, not "medically necessary".

Inasmuch as the Department's decision in this matter is found to be in accord with its regulation governing prior approval, it is affirmed. 3 V.S.A. § 3091(d) and Fair Hearing Rule No. 17.

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1. The Board's original decision in this matter was part of a consolidated case involving two petitioners with nearly identical circumstances. The cases have since been severed because the medical circumstances of the petitioner in Fair Hearing No. 13,752 have changed since the Board's initial decision (see infra).
2. In its prior Order of Remand the Board rejected the petitioner's alternative argument that pedicle screw surgery is covered under the medicaid regulations as a "prosthetic device" under Medicaid Manual (M.M.) § M844.
3. Three members of the majority would have held that the Department sufficiently addressed and countered the petitioner's evidence in this regard.