Musculoskeletal Clinical
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Review and Analysis of CMS's 2006 MEDCAC Panel on Lumbar Fusion for Treatment of DDD

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MEDCAC PANEL: Lumbar Fusion for DDD

Clinicians utilize various types of lumbar spinal surgery in treating their patients' severe chronic low back pain. In lumbar fusion, a surgical procedure that joins two or more vertebrae, clinicians have found that effectively halting motion in one or more segments of a degenerated or otherwise unstable spine alleviates patient-reported pain.[1] In the early and mid 20th Century, fusion techniques were developed which would pave the way for more advanced, and less invasive methods of surgery that currently represent today's standard of medical practice.[2,3,4] As the clinical benefits of treating degenerated intervertebral discs of the lumbar spine (eventually defined as degenerative disc disease – 'DDD'[5]) with fusion became apparent, it eventually became one of the most common reasons for its use.[6]

FUSION FOR MULTI-LEVEL DDD: COVERAGE			
Payor	No Coverage	Coverage	Coverage with Limitations
Medicare (NCD)		✓ (no policy)	
Humana	✓		
Aetna	✓		
BCBS of NC	✓		
Cigna			✓
Blue Cross Idaho		✓ (no policy)	
United Healthcare			✓
First Coast(LCD)			✓

Despite a long-standing evolution in patient care, and widespread use of lumbar fusion techniques for DDD diagnoses, some members of the clinical and payor communities have argued that the base of scientific evidence for the continued use of this treatment option for DDD is insufficient. The Medicare program covers lumbar fusion for treatment of DDD at this time, as the Centers for Medicare and Medicaid Services (CMS) have not issued any National Coverage Determination (NCD) which would limit coverage for such reasonable and necessary medical services. However, since 2008 a number of commercial health insurance plans like BlueCross BlueShield of North Carolina, Aetna, Humana, and even the Medicare Administrative Contractor for Florida, First Coast Service Options, have begun to deny or limit coverage of multi-level lumbar fusion procedures for DDD indications:

In addition to these payors, agencies tasked with assessing medical technologies continue to question this base of evidence for lumbar fusion treatment options. The origin of many current and developing non-coverage or 'coverage-with-limitations' policies on lumbar fusion may be linked back to **November 30, 2006,** when CMS sought recommendations on lumbar fusion for DDD from a panel of experts convened as part of its Medicare Evidence Development & Coverage Advisory Committee (MEDCAC).

In Part One of this White Paper series, MCRA provides an overview of CMS's NCD process, and details the origin and pivotal role of the MEDCAC. Also, MCRA critically analyzes evidence presented at this 2006 meeting, and introduces some of the main issues identified by committee members in reviewing the body of evidence available for lumbar fusion for DDD. This analysis is particularly relevant to today's coverage environment, given the Agency for Healthcare Research and Quality's (AHRQ's) February 2012 solicitation on the issue of "Spinal Fusion for Painful Lumbar Degenerative Disc or Joint Disease." While Part Two of our analysis will provide a more detailed description of the recommendations made by panel members and how the landscape for fusion has changed since 2006, MCRA's analysis in Part One will focus on understanding the MEDCAC process, and the impact of the 2006 panel in shaping the coverage and reimbursement landscape for this treatment option.

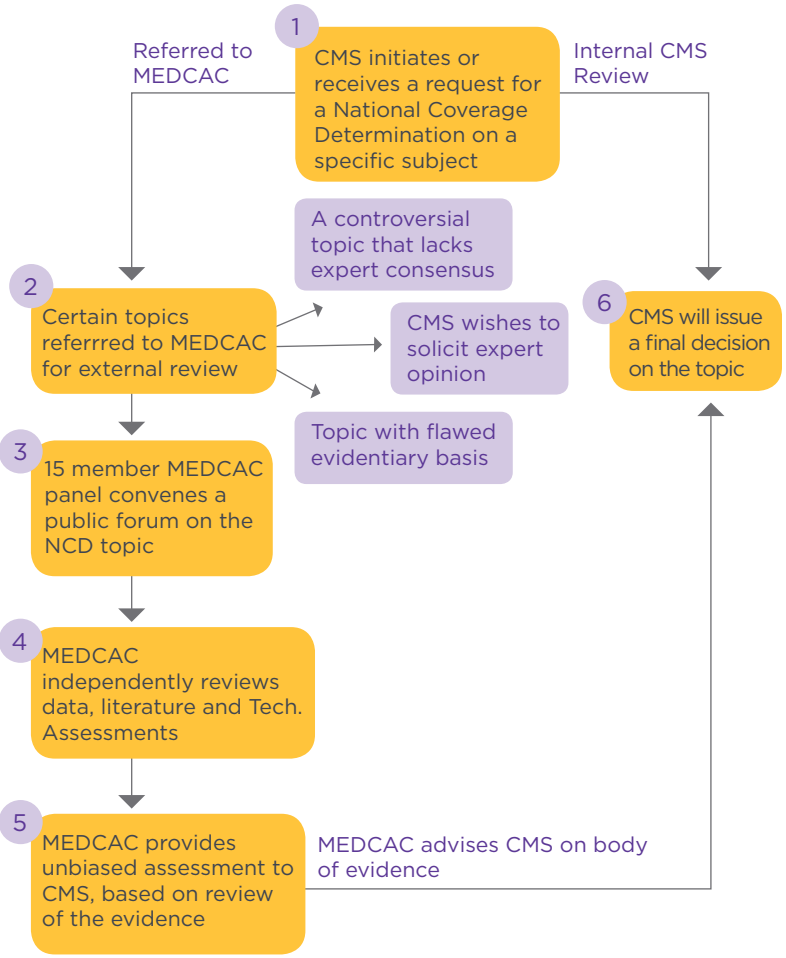
WHAT IS MEDCAC?

In 1989, CMS published a proposed regulation stating that for purposes of coverage, a technology would have to be accepted by the medical community as "safe, effective, non-investigational, and appropriate."[7] Ten years later, the Medicare Coverage Advisory Committee (MCAC) was established to help define for the agency what constituted "reasonable and necessary" medical care, in light of emerging technologies.[7]

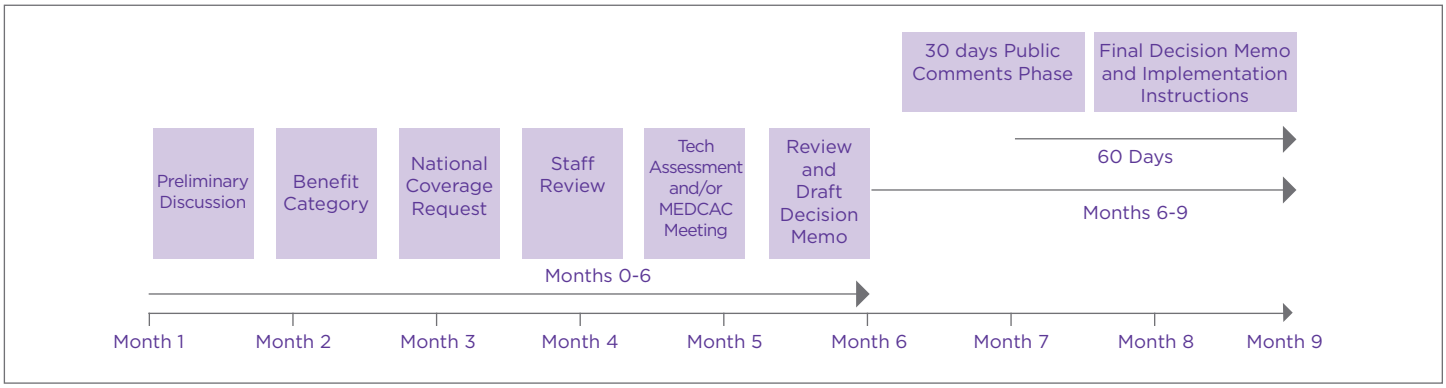
CMS ESTABLISHED THE MEDCAC TO SUPPLEMENT ITS INTERNAL EXPERTISE AND ALLOW AN UNBIASED ASSESSMENT OF "STATE OF THE ART" TECHNOLOGY AND MEDICAL TREATMENT OPTIONS.

CMS established the MCAC to provide external assistance in judging whether evidence existed to establish the safety, efficacy, and clinical benefit of a medical service or product for national coverage decisions.

Today, the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) provides independent guidance and expert advice to CMS on specific clinical topics.[8] The MEDCAC supplements CMS's internal expertise and allows an unbiased assessment of "state of the art" technology and medical treatment options. Convened panels meet in a public forum approximately 4-8 times a year, to review medical evidence for the topic under deliberation, listen to public testimony, and provide advice about the quality of the evidence.



Medicare Coverage Timeline



The MEDCAC reviews topics on new or emerging technology, or on issues which have significant controversy among experts, as in the case of lumbar fusion for DDD. As well, topics are chosen where the evidentiary base may be flawed by the design of studies underpinning it; or where CMS wishes to solicit expert opinion on external technology assessments; or where the public's input is specifically desired. Once a coverage issue is referred to the MEDCAC, a public meeting is scheduled to discuss the matter. Notice of the meeting is issued in the Federal Register, as are instructions for public comment opportunities outside the formalized process for the panel's posed questions to be answered.

CMS MAY REFER A TOPIC TO THE MEDCAC WHICH HAS CONTROVERSY AMONG EXPERTS, AS IN THE CASE OF LUMBAR FUSION FOR DDD.

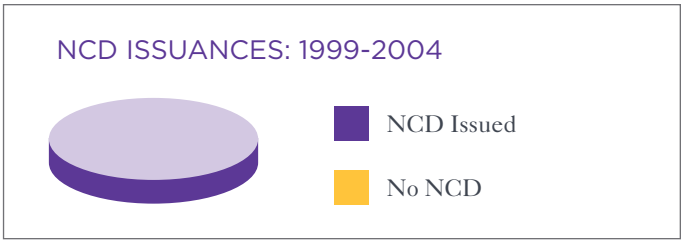
For a more complete discussion of the history, structure, criteria and process of the MEDCAC, please refer to Guidance for the Public, Industry, and CMS Staff: Factors CMS Considers in Referring Topics to the Medicare Evidence Development & Coverage Advisory Committee.[9]

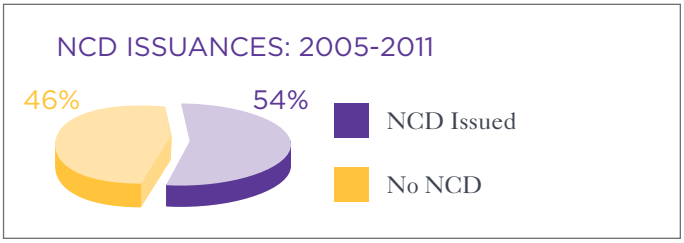
OVERVIEW OF CMS'S COVERAGE PROCESS

The MEDCAC process ultimately impacts Medicare's National Coverage Process. In 2003, the process was most recently amended pursuant to an Act of Congress, which states CMS must issue a proposed decision regarding a particular NCD request, either within six months of receiving a recommendation from MEDCAC, or nine months of receiving the completed request.[10] Please see the Medicare Coverage Timeline above.

60 days of the close of this comment period. Though CMS attempted to promote process transparency through publishing these procedures, explicit criteria for judging evidence have never been published. Furthermore, it does not appear that this process or these timelines are strictly adhered-to any longer.

In order to determine the consistency of this process, MCRA's public policy analysts conducted a thorough review of the topics for which MEDCAC has convened a meeting since 1999, finding strict adherence to the above procedures through 2004. However, beginning in 2005, this process became more sporadic and was less frequently adhered-to. In fact, while all 17 topics reviewed from the initial 5-year period 1999 through 2004 resulted in NCDs, only 13 of the 24 topics reviewed from 2005 through 2011 (54%) resulted in an NCD issuance. The side-by-side comparison below reveals the discrepant processes utilized during these two time periods:





CMS has not issued any formal statements as to the reason for such disparate treatment of MEDCAC topics between the two time periods. Nevertheless, there has been a clear shift in policy and standard of review for MEDCAC-referred topics, which does not appear to distinguish between the fields of medicine for which NCDs were issued versus those where no NCD was issued, nor could any distinction be drawn between treatments that were life-saving versus those that were merely life-enhancing. In fact, MCRA was unable to identify a precise document authorizing or explaining this change. Some suggest that CMS's more recent inaction is a reflection of their current emphasis on the oncology healthcare landscape,[11] though this theory remains largely speculative. Regardless, MEDCAC's silence with regard to the November 2006 meeting is unsettling because its ultimate impact on the future coverage of lumbar fusion for DDD is not yet known. The lack of either a Decision Memo or a draft NCD following this 2006 meeting leaves the status of CMS's coverage of lumbar fusion for DDD uncertain. Additionally, AHRQ's February 2012 solicitation of comments makes clear that lumbar fusion for DDD is again on the radar of health policy decision-makers for the government.

NOVEMBER 2006 MEDCAC PANEL: SPINAL FUSION FOR DDD

A convened MEDCAC panel's voting process involves both an analysis of the sufficiency and quality of the evidence presented, as well as an evaluation of whether this evidence sufficiently demonstrates clinical effectiveness when compared with the current standard of care. Where the evidence regarding a technology or intervention is not sufficient, MEDCAC will not determine net health outcomes of effectiveness, but will instead focus on building the body of evidence in the future. However, where the panel is satisfied with the sufficiency of the evidence, each member will answer the "Key Questions" that are drafted by CMS staff and by MEDCAC's chair and vice-chair.[12]

The questions posed to the 2006 panel remain key questions relating to reviews of lumbar spinal fusion for DDD today, performed by health technology assessment organizations, AHRQ, and many commercial health insurance companies. The following 6 key questions were posed to the panel convened in November 2006, to judge the evidence for lumbar fusion for DDD:

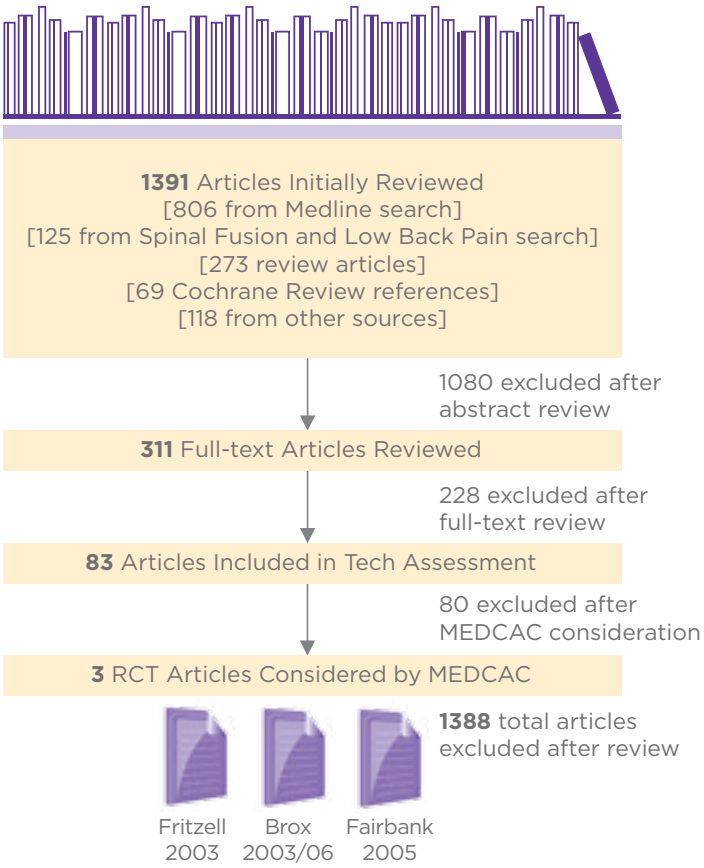
Question	Subject	Discussion
1	Does the evidence address outcomes needed to determine the effectiveness of lumbar spinal fusion for low back pain due to lumbar DDD?	• Relief of pain as best primary outcome -or restoration of function, return to work measures
2	Does the evidence characterize the short- and long-term complications, adverse events and other harms from lumbar spinal fusion for DDD?	• Variability in surgical risk
3	Does lumbar spinal fusion for lumbar DDD improve short- and long-term clinical outcome as compared to conservative treatment?	• The causes of low back pain • Patient selection importance • Long term benefit • The best clinical trial to study this topic
4	Based on the evidence presented, how likely is it that the various fusion procedures improve health outcomes for lumbar DDD?	• Patient selection importance, relative to procedure type • Specific fusion types; fusion with vs. without instrumentation; short- vs. long term)
5	Does evidence show that radiographic interpretations are correlated with clinical outcomes for lumbar spinal fusion due to lumbar DDD?	• (None)
6	Can the results generalize to the Medicare population for (a) relief of pain and (b) complications, adverse events and other harms?	• Medicare-specific population study to strengthen the conclusions as to age/comorbidity

*(Emphasis added.)

INTRODUCTION TO NOVEMBER 2006 PANEL FINDINGS

The MEDCAC Chair began the November 30, 2006 panel meeting on lumbar fusion for DDD with the statement, **"We are not doing a national coverage determination on spinal fusion."** Rather, the stated purpose of the meeting was to discuss spinal fusion for the treatment of low back pain secondary to lumbar DDD and to evaluate the body of evidence demonstrating clinical effectiveness. Following the presentation of the Technology Assessment and additional public comments and presentations, panelists were permitted to ask follow-up questions and engaged in a discussion of topics related to the evidence.

The panel noted the confounding of concurrent diagnoses to DDD, which further confuses the issue. One overarching theme repeated throughout the meeting by panel members and presenters alike was the difficulty in diagnosing DDD. As Sohail Mirza, MD, stated to the panel, surgeons largely disagree on when exactly to offer fusion; there is an even greater divide as to when to diagnose DDD, and if it is ever an appropriate diagnosis.



These theoretical differences are exacerbated in the elderly population, who often have multiple and confounding diseases of the spine, making it difficult to pinpoint the cause of lower back pain. As former President of NASS, Richard Guyer, MD, pointed out, less than 1% of Medicare beneficiaries are fused for DDD alone.

> SURGEONS LARGELY DISAGREE ON WHEN EXACTLY TO OFFER FUSION; THERE IS AN EVEN GREATER DIVIDE AS TO WHEN TO DIAGNOSE DDD, AND IF IT IS EVER AN APPROPRIATE DIAGNOSIS.

Finally, panel members raised the issue of coding and how coding nuances and coding for various comorbid conditions can often hinder one's ability to isolate DDD. In many ways, the elusiveness of DDD as a diagnosis has obstructed the medical community's ability to conduct high-quality studies focused exclusively on the disease.

The panel was also extremely focused on the lack of randomized controlled trials (RCTs) conducted within the United States. Notably, MEDCAC only reviewed and assessed RCTs; no other type of clinical literature was considered. None of the evidence reviewed during the meeting had been published in the United States.

> ULTIMATELY, THE MEDCAC PANEL LACKED CONFIDENCE IN THE AMOUNT OF EVIDENCE OF EFFICACY AND SAFETY OF LUMBAR FUSION FOR DDD, AND FOUND THE ISSUE OF DIAGNOSIS AND PATIENT SELECTION TO BE UNCLEAR.

Panelists had deep concerns about the ability to generalize these European study findings to U.S. populations, due to differences in regulatory processes, societal influences and clinical study protocol. Ultimately, the MEDCAC panel "lacked confidence" in the available published evidence documenting efficacy and safety of the treatment, and found the issue of diagnosis and patient selection to be unclear. Furthermore, the identified studies (all RCTs) had inconsistent findings regarding efficacy when compared to conservative care, as well as design and execution limitations.

THE IDEAL CLINICAL STUDY FOR DDD

Given the significance placed on the value of RCTs, as well as the paucity of relevant RCTs available for review by MEDCAC, a large portion of this meeting was devoted to discussing the

likelihood of conducting a relevant RCT within the U.S., and outlining the parameters of a meaningful lumbar fusion RCT. Though alternative study designs were briefly discussed, all MEDCAC members seemed to agree that the RCT design was necessary to glean the most powerful and impactful data. The panel members of the 2006 MEDCAC provided a robust discussion on how the ideal investigation for the efficacy and safety of lumbar fusion for DDD in the Medicare population would be structured. The volume of time MEDCAC spent describing this ideal clinical trial truly highlights the value the committee, and by extension CMS, places on this high-quality study design.

MCRA's reimbursement and regulatory analysts reviewed transcripts of the MEDCAC's ongoing discussion of the ideal RCT, in order to precisely identify the variables, criteria and measures valued most by this influential branch of CMS. This information will be particularly relevant in Part Two of MCRA's White Paper, where the post-2006 published literature will be analyzed and compared against MEDCAC's ideal study, permitting a more thorough evaluation of the future for lumbar fusion for DDD. The following is a depiction of the critical elements of this ideal RCT, as identified by MEDCAC:

Design Element	Description
Study Type	Multi-center prospective, randomized, controlled trial
Follow-up	4-8 years
Subjects	250-400
Age	40-80 years old
Inclusion	• DDD in one vertebral level from L3 to S1 • Back and/or leg pain • Radiographic confirmation of any 1 of the following: instability, decreased disc height, scarring, thickening of annulus fibrosis, herniated nucleus pulposis, vacuum phenomenon
Exclusion	• More than 2 levels requiring intervention • Prior fusion surgery at any level • Radiographically compromised vertebral bodies at any lumbar levels • Degenerative spondylolisthesis • Scoliosis • Active infection • Systemic disease • Morbid obesity • Active malignancy • Back or leg pain of unknown etiology
Treatment Arms	• Consistent conservative care across control group • Lumbar fusion (alternate type(s))
Randomization	1:1
Primary Outcomes	ODI
Secondary Outcomes	SF-36 VAS Radiographic Adverse events Intraoperative data

Key elements of the panel's review and analysis of the 'ideal' RCT of lumbar fusion for DDD included the following:

Study Design

The ideal study which would provide sufficient evidence supporting lumbar fusion for DDD must be in the form of a prospective, multi-center, randomized, controlled clinical trial (RCT) comparing fusion to conservative (non-operative) care. This RCT should have a follow-up length of at least 4 to 8 years in order to capture the long-term outcomes data valued so highly be CMS. The U.S.-based patient population should be large enough to provide sufficient power to detect differences between treatment groups. The outcome measures included quality of life assessment, disability, pain, and adverse events measures. While not an explicit requirement of the MEDCAC, the age range of subjects should breach 65 years, if outcomes are to be generalizable to the Medicare population.

Patient Selection

Careful patient screening was determined to be extremely important for any future study of lumbar fusion for DDD. In order to isolate the effects of treatment, patients selected for the study should have low back pain attributed solely to DDD, avoiding as much as possible any comorbid conditions. Additionally, patients with an ongoing workers compensation claim should be excluded from the study.

Consistency Among Treatment Modalities

The most significant attribute of this ideal study was the consistency of treatment arms. In order to compare the treatment effects of surgery and conservative care, identical treatments must be performed for each cohort, respectively. This was determined to be much more straightforward to ensure for the surgical arm, since conservative care has historically varied based upon practitioner preference. Specific algorithms of conservative therapy would need to be agreed-upon by all investigators, rooted in professional treatment guidelines or peer-reviewed literature, and be strictly adhered-to – a difficult feat for most physicians, and most study sites. The precise type of non-operative care prescribed (be it physical therapy or lumbar injections) was not found to be as important as consistency across all patients randomized into the control group. Thus, all patients randomized to the control group should receive the same type of conservative treatment. Ideally, the fusion group should be either with instrumentation, or without, or large enough so that it is possible to detect differences between the instrumented and non-instrumented groups.

Ethical Dilemmas And Issues

MEDCAC's discussion of this ideal study also identified practical limitations and potential obstacles. Given the difficulty of blinding randomized patients to a surgical treatment (at least, pre-operatively), the viability of enrolling patients into a conservative control arm is even more limited. This is due to the fact that indications for surgery typically include a lengthy period of conservative care, so that patients would likely be unwilling to undergo treatment in the control arm, which is essentially an already failed treatment. For many surgeons, randomly subjecting surgery-ready patients to continue a course of further conservative therapy also poses an ethical dilemma. Additionally, physicians with their individual preferences for conservative treatment would have to reach a consensus as to what precisely constitutes "conservative care" for the purposes of the control arm consistency. These limitations highlight the real-world difficulties of successfully conducting an RCT for lumbar fusion for DDD, and should be kept in mind when critically reviewing the actual clinical literature that has been published since the 2006 MEDCAC meeting.

PART ONE CONCLUSION; INTRODUCTION TO PART TWO

Lumbar fusion for DDD has been under attack over the past decade. Restrictive commercial policies, local Medicare contractor coverage determinations, and convened (yet still unresolved) MEDCAC meetings have all contributed to an industry-wide concern that we now operate under a figurative sword of Damocles, on the precipice of a Medicare NCD on this topic which would domino into universal non-coverage for a majority of lumbar fusion cases. AHRQ's recent solicitation for comments on spinal fusion for DDD in February 2012, and the mere fact that they have reopened this issue, only adds to the unease and seemingly implies that the evidence is still relatively thin.

PART ONE KEY FINDINGS

- In 2006, a MEDCAC panel found insufficient evidence on lumbar fusion for DDD. Issues such as a lack of high-quality published clinical studies, and confounding factors in diagnosis and treatment of the disease contributed to this finding.

- Inconsistent decision-making by CMS following the MEDCAC panel on lumbar fusion has created concerns about the future of insurance coverage for this treatment option.

- Since 2008, payors have begun to limit coverage of lumbar fusion for DDD indications, and health technology assessment groups have indicated a growing concern for this treatment option's current use for U.S. patients.

- Analysis of the panel's recommendations on the ideal clinical trial to study fusion for DDD reveals certain ethical dilemmas and issues which would affect enrollment of such a study.

The difficulty in predicting with any degree of certainty what the future holds for coverage of lumbar fusion cases for DDD by private payors and Medicare is amplified by the fact that CMS has never published criteria for how coverage is determined. MEDCAC's silence following the November 2006 meeting further clouds the issue. Part Two of MCRA's White Paper on this topic will involve a more comprehensive analysis of the pre- and post-2006 clinical literature, while keeping in mind the MEDCAC's notion of the "ideal" RCT. Further, MCRA will more closely examine precise issues identified by the committee as being problematic to the evidence base, and will compare the more recently published literature in order to evaluate whether the future for lumbar fusion for DDD remains viable, and whether coverage for this treatment option can be saved.

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