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Health Policy Review

Value-Based Interventional Pain Management: A Review of Medicare National and Local Coverage Determination Policies

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Major policies, regulations, and practice patterns related to interventional pain management are dependent on Medicare policies which include national coverage policies – national coverage determinations (NCDs), and local coverage policies – local coverage determinations (LCDs).

The NCDs are Medicare coverage policies issued by the Centers for Medicare and Medicaid Services (CMS). The process used by the CMS in deciding what is and what is not medically necessary is lengthy, involving a review of evidence-based literature on the subject, expert opinion, and public comments. In contrast, LCDs are rules and Medicare coverage that are issued by regional contractors and fiscal intermediaries when an NCD has not addressed the policy at issue. The evidence utilized in preparing LCDs includes the highest level of evidence which is based on published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and general acceptance by the medical community (standard of practice), as supported by sound medical evidence.

In addition, the intervention must be safe and effective and appropriate including duration and frequency that is considered appropriate for the item or service in terms of whether it is furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function. In addition, the safe and effective provision includes that service must be furnished in a setting appropriate to the patient's medical needs and condition, ordered and furnished by qualified personnel, the service must meet, but does not exceed, the patient's medical need, and be at least as beneficial as an existing and available medically appropriate alternative. The LCDs are prepared with literature review, state medical societies, and carrier advisory committees (CACs) of which interventional pain management is a member. The LCDs may be appealed by beneficiaries.

The NCDs are prepared by the CMS following a request for a national coverage decision after an appropriate national coverage request along with a draft decision memorandum, and public comments. After the request, the staff review, external technology assessment, Medicare Evidence Development and Coverage Advisory Committee (MedCAC) assessment, public comments, a draft decision memorandum may be posted which will be followed by a final decision and implementation instructions. This decision may be appealed to the department appeals board, but may be difficult to reverse.

This manuscript describes NCDs and LCDs and the process of development, their development, issues related to the development, and finally their relation to interventional pain management.

Key words: Interventional pain management, interventional techniques, national coverage determinations (NCDs), local coverage determinations (LCDs), contractor medical director (CMD), Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services (HHS), guidelines, evidence-based medicine, evidence development with coverage

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Chronic pain is managed by many modalities including interventional pain management (1-6). The National Uniform Claims Committee (NUCC) defined interventional pain management as the discipline of medicine devoted to the diagnosis and treatment of pain-related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatments (7). As the definition illustrates, interventional pain management is predominantly based on interventional techniques. The Medicare Payment Advisory Commission (MedPAC) defined interventional techniques as minimally invasive procedures including percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques for the diagnosis and management of chronic, persistent, or intractable pain such as laser or endoscopic diskectomy, intrathecal infusion pumps, and spinal cord stimulators (8).

As a specialty, interventional pain management has been designated with a separate practice expense which is different from the primary specialties (9). Consequently, the revenues --which have been increasing rapidly--spent on interventional pain management appear as a special item (10,11).

The Institute of Medicine (IOM) report on relieving pain in America (12) noted that not only is the magnitude of pain in the United States astounding, with more than 100 million Americans afflicted with pain that persists for weeks to years, but that it also has estimated financial costs ranging from $560 billion to $630 billion per year with $100 billion spent on moderate and severe pain, with Americans constituting only 4.5% of the global population. There is overwhelming evidence showing an association of chronic pain with significant economic, societal, and health outcomes (1-4,12-45). Further, along with enormous costs and disability associated with reduced functioning, overuse of opioids and related fatalities have been well described (2-4,22,23,34-41). Evidence illustrates that opioid prescriptions have been escalating at a rapid pace, along with related fatalities contributing to 60% of the deaths from appropriate prescriptions for chronic pain compared to 40% due to abuse, with all deaths exceeding the deaths due to motor vehicle injuries (3,4,38,40). Further, a direct correlation has been established with the increase in opioid-related deaths, treatments, and admissions, along with opioid related sales in the United States and across the globe.

Thus, exploding health care costs are a major issue for the United States and the world (1-4,12-45), leading to various measures of health care reform, regulations, and the imposition of guidelines often based on quasi evidence-based medicine. An abundance of criticism and argument have been advanced both for and against proposed reforms (43-73).

As an emerging specialty, interventional pain management encounters multiple problems of a disproportionate magnitude compared to established medical specialties. The increasing utilization of interventional techniques often considered to be inappropriate, even though significant advances have been provided in interventional pain management supported by numerous guidelines (1-4,43-53,74-153), systematic reviews, basic science, randomized trials, and prospective evaluations (43-53,74,75,85-153). However, the available evidence documents a wide degree of variance in the definition of the practice of medicine in general and interventional pain management in particular (1,2,5,6,31,50-53,62-73,75,76,154-163). In the analysis of utilization trends and Medicare expenditures from 2000 to 2008 in relation to the growth of spinal interventional pain management techniques, Manchikanti et al (6) showed that Medicare recipients receiving spinal interventional techniques increased 107.8% from 2000 through 2008 with an annual increase of 9.6%; whereas the number of spinal interventional techniques increased by 186.8%, an annual average increase of 14.1% per 100,000 beneficiaries. Even though this study showed an explosive increase in spinal interventional techniques from 2000 to 2008, there was a slowing of growth observed in later years. In an updated evaluation, Manchikanti et al (5), in an assessment of all interventional techniques, except for implantables, continuous epidurals, intraarticular injections, trigger point and ligament injections, peripheral nerve blocks, and vertebroplasty procedures, showed an overall increase of 228% from 2000 to 2011 for interventional pain management services. They also showed an overall increase of 177% per 100,000 Medicare beneficiaries. Annual increases with geometric average calculations were 11.4%, ranging from a decrease of 1.4% to an increase of 30.3% year-to-year. There were significant variations and increases in procedures and specialties as illustrated in Table 1 and Figs. 1 and 2.

Important aspects related to interventional pain management and various regulations and practice patterns are dependent on Medicare policies which include national coverage policies, national coverage deter-

Table 1. *Characteristics of Medicare beneficiaries and interventional pain management services.*

Year	U.S. Population (,000)	≥ 65 years (,000)	Percent	Medicare Beneficiaries (,000)	% to U.S. population	IPM Services		
						Services*	*% of Change from Previous year*	**Rate per 100,000 Medicare Beneficiaries**
Y2000	282,172	35,077	12.40%	39,632	14.00%	1,469,495	-	3,708
Y2001	285,040	35,332	12.40%	40,045	14.00%	1,760,456	*19.8%*	*4,396*
Y2002	288,369	35,605	12.30%	40,503	14.00%	2,183,052	*24.0%*	*5,390*
Y2003	290,211	35,952	12.40%	41,126	14.20%	2,559,323	*17.2%*	*6,223*
Y2004	292,892	36,302	12.40%	41,729	14.20%	3,335,047	*30.3%*	*7,992*
Y2005	295,561	36,752	12.40%	42,496	14.40%	3,660,699	*9.8%*	*8,614*
Y2006	299,395	37,264	12.40%	43,339	14.50%	4,146,124	*13.3%*	*9,567*
Y2007	301,290	37,942	12.60%	44,263	14.70%	4,111,127	*-0.8%*	*9,288*
Y2008	304,056	38,870	12.80%	45,412	14.90%	4,433,411	*7.8%*	*9,763*
Y2009	307,006	39,570	12.90%	45,801	14.90%	4,645,679	4.8%	10,143
Y2010	308,746	40,268	13.00%	46,914	15.20%	4,578,977	*-1.4%*	*9,760*
Y2011	313,848	41,122	13.10%	46,918	14.90%	4,815,673	*5.2%*	*10,264*
Change	11%	17%	6%	18%	7%	228%		177%
Geometric average annual change	1.00%	1.50%		1.50%	0.6%	11.4%		9.7%

*(Excluding continuous epidurals, intraarticular injections, trigger point and ligament injections, peripheral nerve blocks, vertebral augmentation procedures, and implantables)

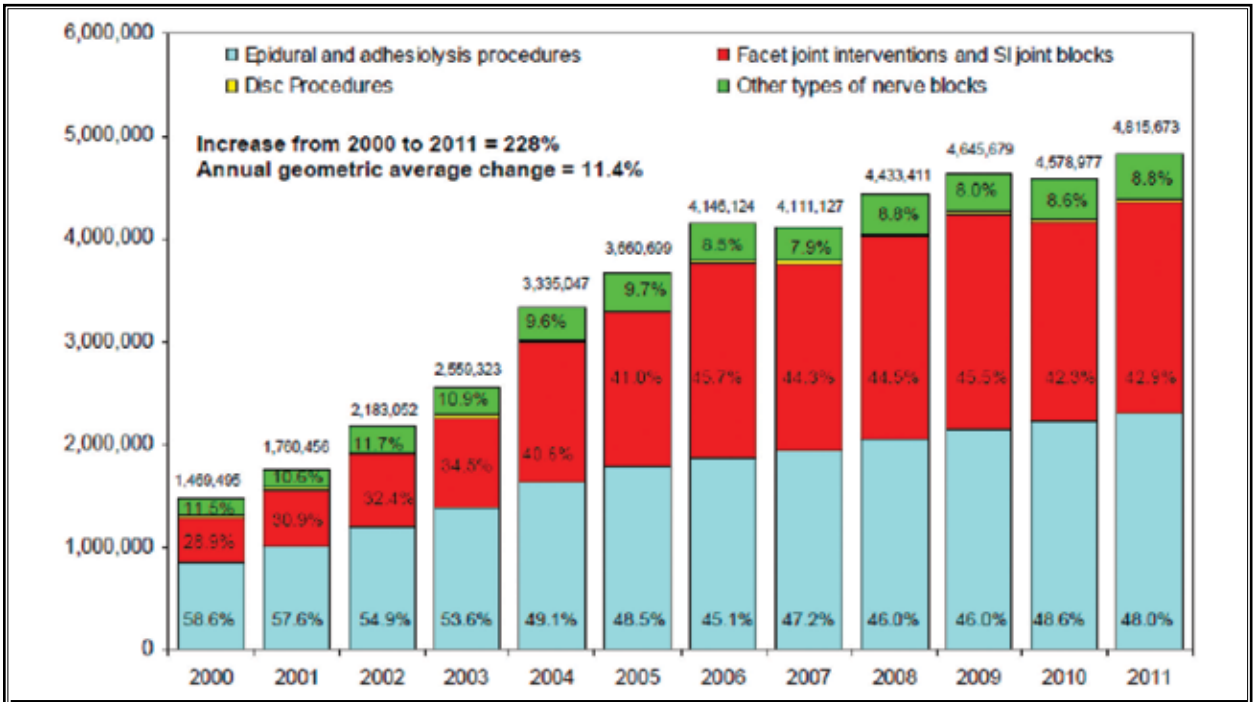
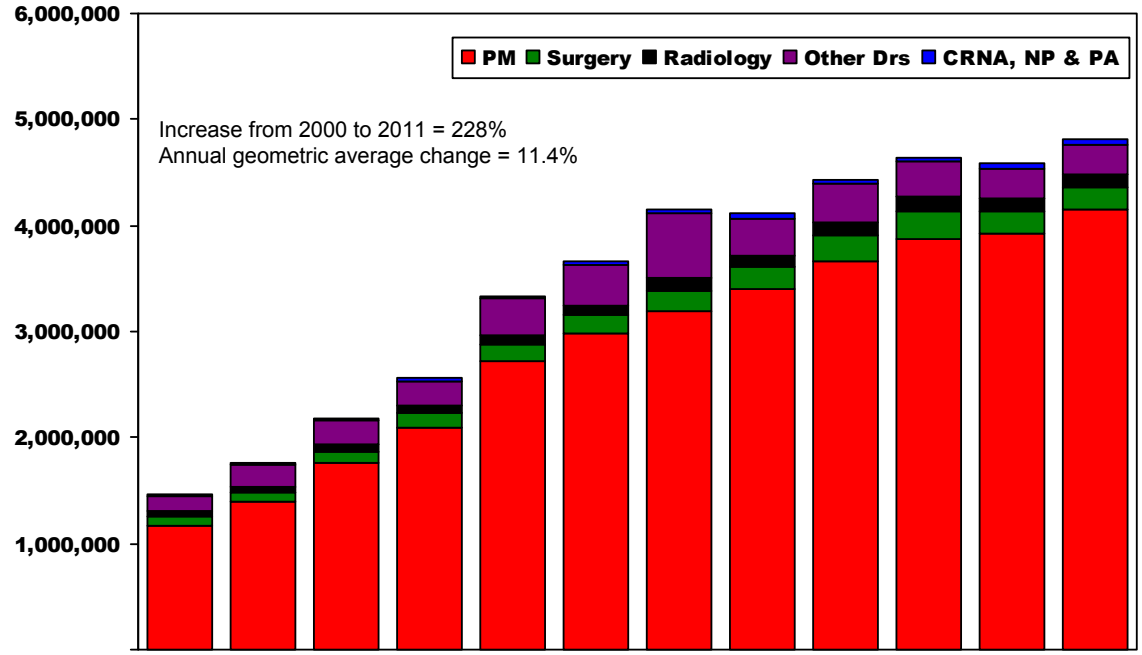


Fig. 1. *Illustration of distribution of procedural characteristics by type of procedures from 2000 to 2011.*
Source: Manchikanti L, et al. Utilization of interventional techniques in managing chronic pain in the Medicare population: Analysis of growth patterns from 2000 to 2011. Pain Physician 2012; 15:E969-E982 (5).



Specialty (%)	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Pain Management	80.1%	78.9%	80.4%	82.0%	81.5%	81.3%	77.1%	82.8%	82.8%	83.5%	85.6%	86.4%
Surgery	5.7%	5.6%	5.3%	4.9%	4.8%	4.8%	4.7%	5.0%	5.2%	5.7%	4.7%	4.1%
Radiology	2.8%	2.8%	2.9%	3.0%	2.8%	2.8%	2.7%	2.7%	2.6%	2.7%	2.6%	2.6%
Other Physicians	10.4%	11.6%	10.4%	9.2%	10.1%	10.3%	14.7%	8.5%	8.3%	7.2%	6.0%	5.6%
CRNA, NP & PA	1.0%	1.2%	1.1%	0.9%	0.8%	0.8%	0.9%	1.0%	1.0%	1.0%	1.1%	1.3%

Fig. 2. *Utilization of interventional pain management techniques by specialty from 2000 to 2011 in Medicare recipients.*
Source: Manchikanti L, et al. Utilization of interventional techniques in managing chronic pain in the Medicare population: Analysis of growth patterns from 2000 to 2011. Pain Physician 2012; 15:E969-E982 (5).

minations (NCDs), and local coverage determinations (LCDs). LCDs are based on the decisions by a Medicare administrative contractor, fiscal intermediary, or carrier whether to cover a particular item or service. The LCDs are formulated based on multiple regulations and instructions from the Centers for Medicare and Medicaid Services (CMS), including the evidence, reasonable and necessary aspect of the service.

1.0 Medicare Coverage

The 1965 Medicare statute prohibited Medicare from interfering with the practice of medicine (164). In other provisions, Congress defined the covered benefit category such as hospital or physician services, placed limitations on some services such as dental or chiropractic care, and excluded some categories such as cosmetic or personal comfort items or services. The law clearly assumed that future questions of coverage might arise, providing that the Medicare program may not "reimburse" for items and services which are not reasonable and necessary for the diagnosis and treatment of an illness or injury (165). In addition, the statute delegated to private contractors the job of processing claims for payment. However, many of the regulations have changed since then with the implementation of the Balanced Budget Act (BBA) (166), Health Insurance Portability and Accountability Act (HIPAA) (167), American Recovery and Reinvestment Act (ARRA) (168), Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (169) and, finally, the Affordable Care Act (ACA), or Obamacare, with the implementation of numerous regulations (43-49,155-157,170,171).

In the early years of the program, interpretation of the reasonable and necessary provision presented few

problems of contractors differing with providers, and any conflicts were resolved informally (172,173). However, as coverage development policy evolved, policies have become evidence-based directives that define specific clinical parameters for appropriate use of services. Consequently, Medicare has become deeply involved in acquisition, development, evaluation, dissemination, and implementation of evidence (172). There are 2 pathways to coverage of Medicare services. These are NCDs and LCDs (174-176). The NCD process is initiated less frequently than the local medical review process. Over the past 30 years, the CMS has made about 300 national coverage decisions. By contrast, Medicare's contractors have made almost 10,000 LCDs during the past decade. Thus, Medicare now has thousands of LCDs and a growing body of NCDs, including for interventional pain management, even though most of the thousands of health care services provided in Medicare are not subject to coverage policies (177).

2.0 National Coverage Determinations

The NCDs are developed by the CMS to describe the circumstances for Medicare coverage nationwide for an item or service. NCDs generally outline the condition for which an item or service is considered to be covered and are usually issued as program instructions. However, once published in the CMS program instruction, an NCD is binding on all Medicare carriers and other related organizations (178). The CMS makes relatively few NCDs (179) because:

- Most decisions to cover services are not controversial
- Most services do not meet the criteria for the CMS to initiate an NCD
- Limited resources may affect the CMS's ability to initiate more NCDs
- Manufacturers and providers of a medical service may be apprehensive about requesting an NCD because they perceive that the decision could result in an all or nothing scenario in terms of their ability to obtain Medicare reimbursement.

Thus, a negative NCD can be especially problematic for providers of a service for which Medicare constitutes a large share of the market. However, NCDs are sometimes written for a specific clinical indication of an item or service and can be modified once new clinical information is available. The NCD process falls into 2 categories with coverage with evidence development and development of an NCD.

2.1 Coverage with Evidence Development

Coverage with Evidence Development (CED) is an evidence-based coverage paradigm that permits the CMS to develop coverage policies for certain items and services that are likely to show health benefits to Medicare beneficiaries but for which the available evidence base is not yet sufficiently developed. The CMS first published guidance on CED on July 12, 2006 which set forth the parameters under which the CMS would apply CED when issuing NCDs (172,179-181). In the 2006 guidance, the CMS described 2 different categories of coverage using either coverage with appropriateness determination or coverage with study participation. Coverage with appropriateness was used when the medical evidence was adequate to conclude that an item or service was reasonable and necessary for certain beneficiaries in certain circumstances, but additional data was required to demonstrate that the item or service was furnished as specified in the NCD. When applying coverage with appropriateness determination, the CMS required the establishment of data registries to which providers must submit clinical data regarding the items or services furnished to Medicare beneficiaries.

Coverage with study participation was used when the medical evidence was not adequate to conclude that an item or service was reasonable and necessary, but coverage would have been provided if the beneficiary was enrolled in a clinical study designed to provide additional medical evidence regarding the health risks and benefits of using the item or services.

Consequently, the CED policies have varied in their data collection requirements with some featuring randomized controlled trials and others relying on patient registries or other data collection strategies.

In November 2011, the CMS announced its intention to withdraw its 2006 guidance on CED and rewrite the policy. Thus, Medicare also convened a Medicare Coverage and Evidence Development Advisory Committee (MedCAC) meeting on the topic in May 2012, which focused mostly on the need for evidentiary standards for triggering a CED policy and whether standards should be different for different technologies. In November 2012 (182), the CMS issued a new draft guidance on CED. The draft was lacking in specifics and was perhaps most notable for affirming the CMS's belief in the CED concept and signaling that the agency envisions the approach as a key part of its future coverage strategy.

The draft guidance confirms the scope of CED for future decisions. In 2006 guidance, the CMS had described 2 types of CED – coverage with appropriateness determination and coverage with study participation. However, in practice, the CMS has seldom used coverage with appropriate determination as part of the CED policy. In the draft guidance, the CMS removed the coverage with the appropriateness determination option, arguing that the principle function of CED is to generate new evidence (i.e., coverage with study participation). The CMS also clarified that it will continue to apply CED under Medicare's authority to pay for "reasonable and necessary" items and services. In addition, the CMS will continue to support CED through the Agency for Healthcare Research and Qualities (AHRQ) legal authority of the act to conduct research with respect to needs and priorities of the Medicare program. The guidance argues that AHRQ has not only the authority but also the experience and resources to complement the CMS's own expertise, and finds out that AHRQ can convene stakeholders to design studies, establish public/private partnerships to financially support CED, and invoke confidentiality protections.

The summary of Medicare CED is as follows:

1. The definition of CED includes study participation, which is more consistent with the conceptualization of CED. Consequently, coverage with appropriateness determination is eliminated.
2. Evidenced criteria for CED has been shortened from the 2006 document. The CMS considers the CED concept as the item or service to be reasonable and necessary only while evidence is being developed pursuant to AHRQ's authority to conduct and support research on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which diseases, disorders, and health conditions can be prevented, diagnosed, treated, and managed clinically.
3. Thirteen standards of scientific integrity and relevance to the Medicare population have been listed.

2.2 Medicare Evidence Development and Coverage Advisory Committee

The MedCAC was established to provide independent guidance and expert advice to the CMS on specific clinical topics. The MedCAC is used to supplement the CMS's internal expertise and to allow an unbiased and current deliberation of state-of-the-art technology and science (183,184). The MedCAC reviews and evaluates medical literature, technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered under Medicare, or that may be eligible for coverage under Medicare (184). The MedCAC judges the strength of available evidence and makes recommendations to the CMS based on that evidence.

In 2007, MedCAC was established to more accurately reflect the committee's role from its original name Medicare Coverage Advisory Committee (MCAC). MCAC was established on December 14, 1998 (183). The MCAC was established to provide independent guidance and expert advice to the CMS on specific clinical topics. MCAC's charter was renewed in November 2002 (185) to terminate in November 2004 (186) and in December 2006, the charter was changed to Medicare Evidence Development and Coverage Advisory Committee (MedCAC) (187).

The MedCAC consists of a panel of 100 experts selected from clinical and administrative medicine, biologic and physical sciences, public health administration, patient advocacy, health care data and information management and analysis, health care economics, and medical ethics. The CMS committee selects no more than 15 members with knowledge specific to the topic in question to serve on the panel for each MedCAC meeting. They also recruit non-MedCAC members who have relevant expertise to provide additional input to panel members and invite experts to make formal presentations to the MedCAC for a particular meeting. The panel meets in a public forum approximately 4 to 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 (183). While multiple representatives assess the evidence of MedCAC including 2 radiology and one radiation oncology representative, there is no interventional pain management representative on MedCAC.

The process for evaluation of effectiveness and committee operations was published in January 2006 (188). The MCAC, now MedCAC, evaluation process consists primarily of 2 steps – first is an assessment of the quality of available evidence to draw conclusions about an intervention's effectiveness, second is an evaluation of what the evidence demonstrates about effectiveness – that is, an evaluation of the magnitude of benefit conferred by the intervention. In addition, at the request of the CMS or at the discretion of the committee, the committee may also provide advice about how to overcome shortcomings in the available evidence. The committee may also discuss the likely con-

sequence of technology dissemination on beneficiaries and Medicare program.

The committee is expected to explore many sources in assembling the body of evidence to be used in their deliberations. The sources of evidence might include peer-reviewed scientific literature, the recommendations of expert committees, and unpublished data used to secure the Food and Drug Administration (FDA) approval.

2.2.1 Outcomes

The committee considers several health outcomes as part of its deliberations. The committee rates how, compared to alternative or standard management approaches for the condition under review, the intervention affects:

- The quality of life morbidity, mortality, diagnostic accuracy for diagnostic interventions, and impact on management
- Other health outcomes as appropriate, such as free hospitalizations.

The MedCAC greatly values information on the effect of treatments on quality of life, functional status, and other relevant aspects of health. While all types of information are utilized, the most valuable data regarding the outcomes are derived from scientific studies such as clinical trials.

2.2.2 Quality of Evidence

The major role of the committee is to determine whether the scientific evidence is of adequate quality to draw conclusions about the effectiveness of the intervention in routine clinical use in the population of Medicare beneficiaries. The committee's definition of adequate evidence includes both validity of the evidence and its general applicability to the population of interest or generalizability.

As in systematic evaluations and guidelines (1-4,52,189-192), the evidence derived from randomized, controlled clinical trials is considered as the most rigorous type of evidence. The ideal randomized clinical trial has appropriate endpoints established before the trial starts, enrolls a representative sample of patients, is conducted in clinical practice in the patient population of interest, and evaluates interventions as typically used in routine clinical practice (1-4,46,47,53,193,194). These issues have been widely discussed in the literature in reference to the type of clinical trials and the expected outcomes (51). However, there continues to be a misunderstanding between a diagnostic intervention study and placebo control and active-control trials, and a misunderstanding of the placebo itself (1-4,46,47,51-53,193-209). Table 2 illustrates the types of clinical studies and expected outcomes (210,211). Figs. 3 and 4 show the pathophysiology of placebo and nocebo intervention and nocebo effects (212,213). Further, specifically for interventional techniques, the role of inactive substances injected into an active structure has been discussed extensively (202-209,214-225). In addition, the flawed design of evidence synthesis is illustrated by consideration of local anesthetic injection and sodium chloride solution injection into closed spaces over the nerves and other active structures as true placebos (212,214-226).

Table 2. *Usefulness of specific control types in various situations.*

Trial Objective	Type of Control						
	Placebo Control	Active Control	Dose Response (D/R)	Placebo + Active	Placebo + D/R	Active + D/R	Placebo + Active + D/R
Measure absolute effect size	Y	N	N	Y	Y	N	Y
Show existence of effect	Y	Y	Y	Y	Y	Y	Y
Show dose-response relationship	N	N	Y	N	Y	Y	Y
Compare therapies	N	Y	N	Y	N	P	Y

Y =Yes, N = No, P = Possible, depending on whether there is historical evidence of sensitivity to drug effects. Adapted and modified from: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guideline. Choice of Control Group and Related Issues in Clinical Trials E10. July 20, 2000 (210).

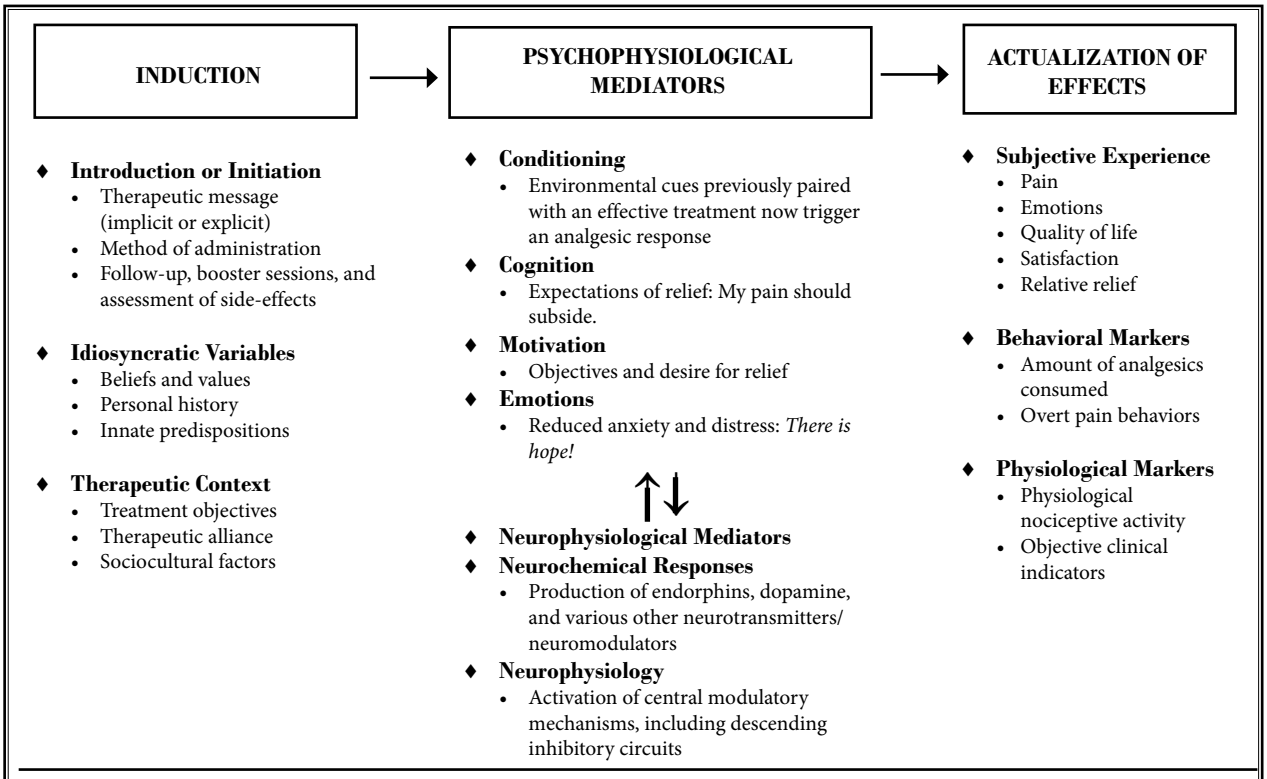


Fig. 3. *General model of placebo effect.*

Reproduced from: Manchikanti L, Giordano J, Fellows B, Hirsch JA. Placebo and nocebo in interventional pain management: A friend or a foe – or simply foes? *Pain Physician* 2011; 14:E157-E175 (212).
Adapted and modified from: Goffaux P et al. Placebo analgesia. In: Beaulieu P, Lussier D, Porreca F, Dickenson AH (eds). Pharmacoloyg of Pain. IASP Press, Seattle, 2010, pp 451-473 (213).

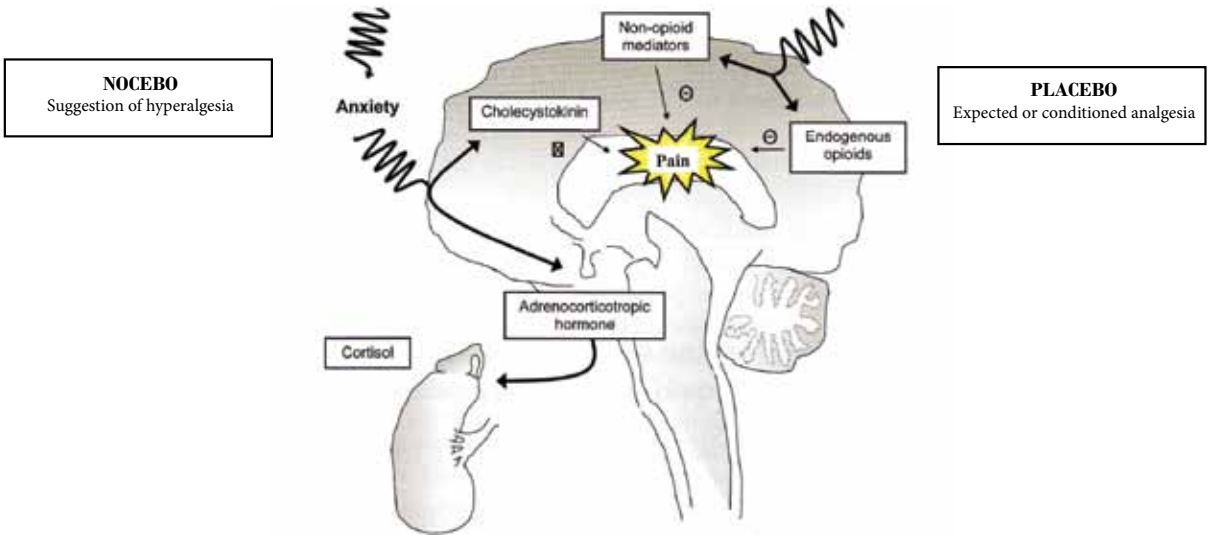


Fig. 4. *Neurophysiological mechanisms associated with placebo analgesia and nocebo hyperalgesia.*

Reproduced from: Manchikanti L, Giordano J, Fellows B, Hirsch JA. Placebo and nocebo in interventional pain management: A friend or a foe – or simply foes? *Pain Physician* 2011; 14:E157-E175 (212). Adapted and modified from: Goffaux P et al. Placebo analgesia. In: Beaulieu P, Lussier D, Porreca F, Dickenson AH (eds). Pharmacoloyg of Pain. IASP Press, Seattle, 2010, pp 451-473 (213).

When several well designed trials yield consistent results, one would expect that there is likely to be a strong consensus that the evidence is sufficient. However, this level of evidence will be unavailable for many of the interventions that MedCAC evaluates and further, there is a substantial difference in evidence synthesis with a constant change in the principles of the assessment of the evidence and interpretation leading to inappropriate conclusions. In addition, there may be randomized trials conducted in populations other than those of over 65 or younger Medicare patients, randomized trials may present with important design flaws – not double blinded, which is considered as a design flaw by MedCAC, or non-randomized studies with concurrent or historic controls. While deciding whether such studies constitute valid, generalizable evidence can be very difficult, appropriate assessment of the literature by clinicians and methodologists is of paramount importance. However, the committee believes that general guidelines for deciding whether the evidence is adequate will serve its purpose better than a rigid set of standards. In considering the evidence from any study, the MedCAC tries to answer 2 main questions which involve proximity of the effects measured in the study to their true value and applicability of the results to Medicare population in the settings in which they receive care.

2.2.3 How Close Are the Effects Measured in the Study to their True Values?

The degree to which the study result differs from the underlying truth is composed of 2 factors: chance and bias. The confidence interval (CI) around the estimated effect is intended to capture the role of the chance; it measures the underlying range of true effects that are compatible with the estimated value. The CI is critical in deciding whether a study has statistically ruled out either a zero (null effect) or, in the case of nonsignificant results, a clinically important effect. The committee also recognizes that it is critical that a statistically significant effect may not be clinically important or meaningful any other way. Conversely, statistically non-significant estimates may not rule out important effects and may collectively provide strong evidence against the null hypothesis.

Other errors of inference are related to fundamental flaws in the study design or analysis, as a result of a bias. An estimate of effectiveness, or any other number that a study is designed to measure, is said to be unbiased if its average or expected value is equal to its true value.

Consequently, randomized trials are viewed as the best approach to avoiding bias because randomization ensures that, on average, measured and unmeasured characteristics are the same for the study subjects assigned to each arm of the trial. Randomization also increases confidence that the expression of uncertainty (i.e., CIs) about the trial's estimates of effect size and other measured outcomes are accurate. The effects of uncertainty due to random variation diminish as sample size increases. Even though there can be random variation in the characteristics of patients assigned to different arms of a randomized trial, any difference in underlying health should not differ systematically.

The committee believes that even though bias can sometimes be minimized or eliminated through analytic means, it is often not correctable. Thus, it is the important task of MedCAC to assess whether the study design is likely to lead to bias, and if so, to consider how large the bias is likely to be. The committee should also consider the magnitude of uncertainty to simple chance variation, drawing conclusions about the range of effect sizes that are consistent with the experimental evidence.

2.2.4 Applicability in the Medicare Population

Applicability in the Medicare population means in the settings they received the care. The studies reviewed by the MedCAC are often conducted in settings that differ from those in which a typical Medicare beneficiary receives care. Many studies of new procedures are conducted in academic medical centers and other institutions that provide a high volume of specialized care and offer a broad set of services. Neither the specific details nor the outcomes that result may become compatible in the diverse institution of community settings in which most Medicare beneficiaries receive care. A key task of MedCAC is to determine whether the results reported in studies are likely to apply to Medicare beneficiaries in the settings in which they receive care.

2.2.5 The Size of Health Effect and Net Health Outcomes

Evidence from well-designed studies must establish how the effectiveness of the new intervention compares to the effectiveness of established services and medical interventions. If the evidence is adequate to draw conclusions about the magnitude of the effect, the next question is the clinical importance of the size of the effect compared with interventions that are widely used, and whether there is a net health benefit (i.e., does the magnitude of beneficial health effect

outweigh the adverse health effects). This judgment should take into account both the size of these effects and other related outcomes.

However, MedCAC does not mandate that the effect size be determined between placebo and intervention groups. Consequently, it is essential to understand the differences between true placebo. However, this necessitates the methodologists to depart from their usual practice and utilize the outcomes between baseline and the trial period (51-53,226,227). In multiple evaluations, the authors have misappropriated the evidence by considering local anesthetic injections given into epidural space, as well as sodium chloride solution injected into the epidural space or intraarticular facet joints, or over the nerves.

As an example, Pinto et al (226) have considered placebo interventions as administration of an inert or innocuous substance either into the epidural space or adjacent spinal tissue. Consequently, they missed the major issue in relation to the placebo that administration of an inert or innocuous substance into an active structure leads to clinical activity along with clinical effectiveness – a different response from the placebo. Moreover, the authors have not considered nocebo experiences in this manuscript.

Another major issue is that authors have considered local anesthetic injections, what they defined as short duration of action, as placebo utilized in active treatment and control groups. It has been repeatedly demonstrated that local anesthetics either in the form of a short-acting agent, such as lidocaine, or long-acting agent, such as bupivacaine, provide clinically meaningful effects in multiple randomized trials. The mechanism of action of long-term improvement with local anesthetics has been well described in multiple manuscripts (2,215-219,228-234).

Long-term effectiveness may not be assessed unless procedures are repeated after dissipation of their activity. Failing to do so, would be equivalent to assessing insulin to control blood sugar levels after one year, or for that matter, even after 2 days.

Multiple other investigators also have misinterpreted the evidence without understanding the evidence itself or subsequent consequences of their conclusions. This has happened with methodologists and occasionally with clinicians (51-53,193,194,212,228-234).

2.2.6 Insufficient Evidence

The CMS may ask the MedCAC for advice when the evidence for effectiveness or of safety is ambiguous, scant, or of poor quality. When the MedCaC determines that the evidence is insufficient to draw conclusions about the effectiveness of an intervention, it will not attempt to assess or discuss the health outcomes. Instead, it will explain the reason for its determination and also form a judgment about:

- The possibility of developing better evidence
- The potential consequences of waiting to obtain better information or of permitting dissemination with insufficient knowledge of effects
- Patient and caregiver views

The CMS could deal with the problem of inadequately studied but promising technologies in several ways, either by supporting the research, developing CED, or developing conclusions based upon the best interpretation of the available evidence.

2.3 Development of National Coverage Determinations

The Secretary of the Department of Health and Human Services (HHS) determines whether or not a particular item or service is covered nationally by Medicare. The formal name for this process, which essentially grants, limits, or excludes Medicare coverage, is the national coverage determination, or NCD. NCDs are binding on all Medicare carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations (HMOs), competitive medical plans, and health care prepayment plans.

An NCD generally outlines the conditions for which an item or service is considered to be covered or not covered. When a new NCD is published, the contractor notifies the provider community as soon as possible of the change and corresponding effective date. All authorities including administrative law judges (ALJs) are bound by NCDs. However, NCDs should not be confused with "national coverage requests" or "coverage decision memoranda."

2.3.1 National Coverage Request

Anyone can request an NCD from the CMS; however, "aggrieved" beneficiaries, defined by the CMS as individuals entitled to benefits under Part A, or enrolled under Part B, or both, who are in need of the items or services that are the subject of the coverage determination, are given priority for requesting an NCD. The CMS has outlined a specific process for requesting an NCD, which takes approximately 9 months from the date the complete LCD request is received by the CMS to the

date that coverage changes are implemented (Fig. 5). The information the CMS requires prior to accepting a national coverage request is described in the Federal Register notice entitled: "Revised Process for Making Medicare National Coverage Determinations" (235). If the CMS decides to accept the request, information is posted on the coverage Website. National coverage requests may contain technology assessments. Contractors also may submit national coverage requests to the Coverage and Analysis Group (CAG), Office of Clinical Standards and Quality (OCSQ).

2.3.2 Coverage Decision Memorandum

A coverage decision memorandum is prepared by the CMS, which is a decision memorandum before preparing the national coverage decision. A decision memorandum is posted on the CMS Website that tells interested parties that the CMS has concluded its analysis, describes the clinical position, which the CMS intends to implement, and provides background on how the CMS reached that stance. The coverage decision memos in contrast to NCDs are not binding on contractors or ALJs. However, contractors are instructed to consider coverage decision memos posted on the CMS Website to expend Medicare resource (MR) funds wisely.

2.4 LCD Topics for National Consideration

The evaluation process of LCD topics for NCD consideration are often confused with NCDs. These are distinct not only from NCDs, but also from coverage decision memoranda.

For years, there has been substantial discrepancy and essentially a tug-of-war between Medicare's national and local coverage (176). The Medicare statute entitles all beneficiaries to the same benefit package, which encompasses all reasonable and necessary items and services. However, the Medicare coverage process is highly decentralized. The CMS issues 10 to 12 national coverage

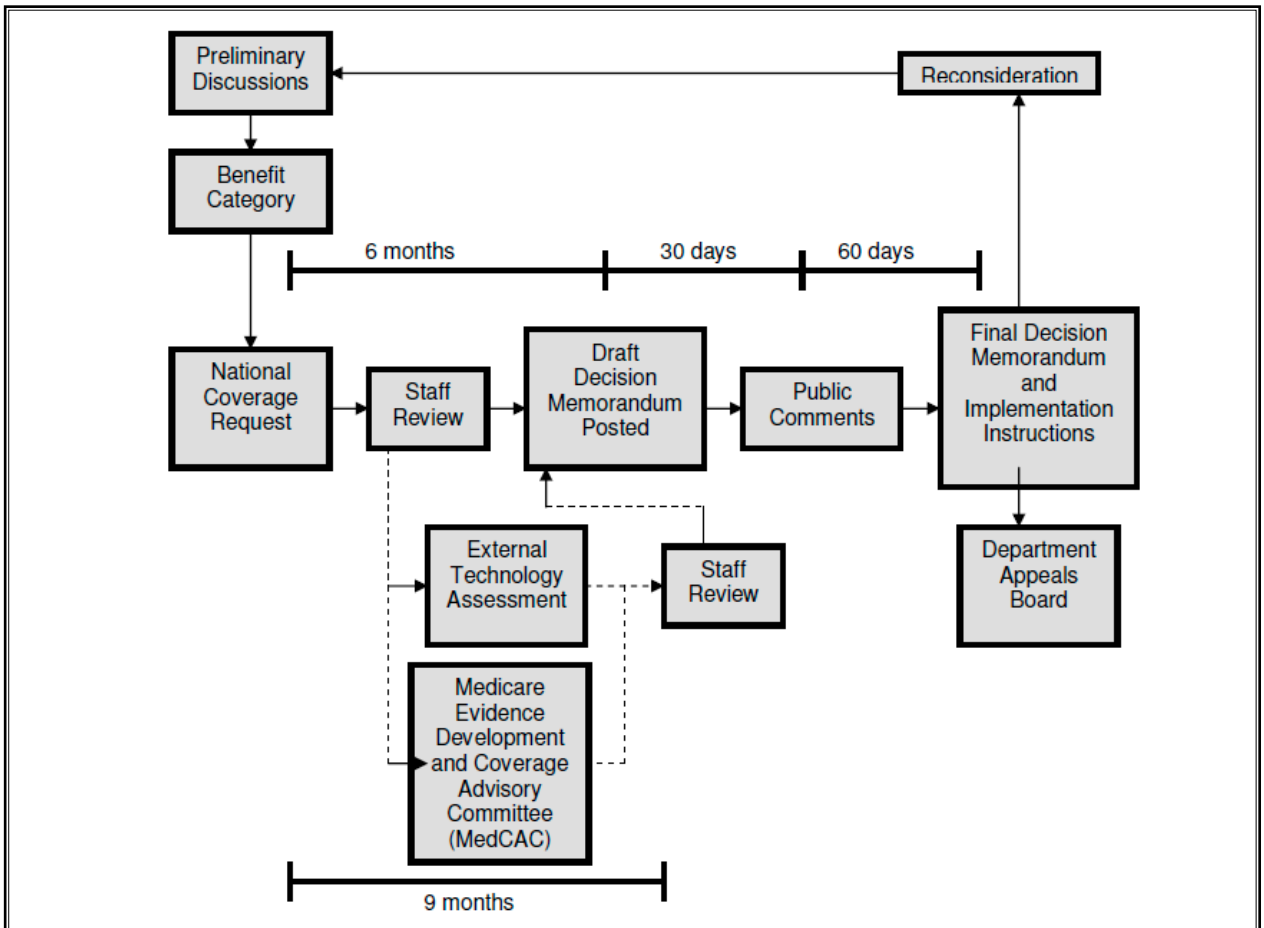


Fig. 5. *Medicare national coverage determination process.*

decisions for each year that apply to all Medicare beneficiaries. More than 10 private contracting organizations develop the vast majority of coverage decisions or LCDs. Thus, it has been criticized that the decentralized local coverage process can lead to different policies in different local areas. In fact, the policy debate about local versus national coverage lead the MedPAC recommending for the elimination of local policies to reduce current complexity, inconsistency, and uncertainty (236). A report from the U.S. Government Accountability Office (GAO) criticized the divided authority and also concluded that Medicare should not develop any new local coverage policies (237). However, the HHS was not persuaded by the GAO report, stating that there was inadequate analytic base to link inequities to the local process or to justify a new, centralized one. However, the Medicare Modernization Act (MMA) called for a plan to determine the need for greater consistency and less duplication among local medicare contractors which essentially lead to formation of LCDs and also application of LCDs nationwide. In an analysis of national and local coverage policies (176), there was a significant difference in the variation of resources allocated, which lead to variations in productivity, finally leading to variation in use of the evidence.

The MMA of 2003 (169) requires the CMS to develop a plan to evaluate new LCDs to decide which local decisions should be adopted nationally. The CMS currently has policies in place that address the MMA requirements to promote greater consistency among LCDs, require Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on LCDs among Medicare contractors. Consequently, this process is distinct from, and should not be confused with, the current NCD request process described (178,235). However, under this process, an advisory group has been established to review LCD topic submissions and determine which LCD topics to forward to the CMS CAG. The CAG will establish standard operating procedures for the contractors to follow regarding how to refer an LCD topic.

In short, when a Medicare contractor begins developing a new LCD and believes the topic may be more appropriate to review as an NCD, the contractor medical director (CMD) should use the LCD evaluation criteria to make a determination as to whether the topic is appropriate to submit to the advisory group for NCD consideration. If the Medicare contractor, after reviewing the LCD evaluation criteria, determines that an LCD topic is appropriate for NCD consideration, the contractor shall submit the LCD topic, a formal evaluation, and appropriate supporting documentation to the Advisory Group. The Advisory Group will review the LCD topic, evaluation, and supporting documentation to determine whether to refer the LCD topic to the CAG for NCD consideration. The Advisory Group will notify the requesting contractor of its decision. The CAG will receive each coverage topic referral and provide feedback to the Advisory Group within 30 working days from the date that the request is deemed complete by the CAG. Final CAG feedback shall include both the decision to accept or reject the LCD topic for a formal NCD review and the rationale for that decision. If the CAG accepts an LCD topic for NCD consideration, the ensuing process, timelines, etc., will follow those outlined (178). The CMS Program Integrity Group in collaboration with the CAG, CMDs, and Medicare contractors, will be responsible for assessing the new process and its impact on the volume of additional NCDs it might generate, as well as the characteristics of LCD topics forwarded for NCD consideration. However, contractors have the discretion to continue development of the LCD throughout this process, regardless of the decision made by the Advisory Group and the CAG.

Contractors should consider multiple criteria when referring an LCD topic to the Advisory Group for NCD consideration. These include:

- Net impact on clinical health outcomes
- Current and projected local utilization patterns outside of perceived and reasonable boundaries
- Current and projected national utilization patterns outside of perceived reasonable and necessary boundaries
- Unit cost
- Collateral costs
- Associated quality and access to care issues including capacity of the health system to use the technology safely
- Medicare payment error rate impact.

Thus, it is essential to understand multiple aspects of NCDs which:

- Approve or disapprove services
- National coverage requests
- Coverage decision memorandum
- Evaluation of LCD topics for NCD consideration.

2.5 NCDs for Chronic Pain Management

Multiple treatment modalities in chronic pain management have been considered an issue with NCDs, with coverage, noncoverage, or coverage with limitations. Table 3 illustrates current published NCDs. Mul-

Table 3. *Illustration of current published NCDs.*

10	Anesthesia and Pain Management	Covered	Non-covered
10.2	Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain	√	
10.3	Inpatient Hospital Pain Rehabilitation Programs	√	
10.4	Outpatient Hospital Pain Rehabilitation Programs	√	
10.5	Autogenous Epidural Blood Graft	√*	
30	**Complementary and Alterative Medicine**		
30.3	Acupuncture		
30.3.1	Acupuncture for Fibromyalgia		√
30.3.2	Acupuncture for Osteoarthritis		√
70	**Evaluation and Management of Patients - Office/hospital/home**		
70.1	Consultations With a Beneficiary's Family and Associates	√	
70.3	Physician's Office Within an Institution - Coverage of Services and Supplies Incident to a Physician's Services	√	
130	**Mental Health**		
130.5	Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic	√	
130.6	Treatment of Drug Abuse (Chemical Dependency)	√	
130.7	Withdrawal Treatments for Narcotic Addictions	√	
150	**Musculoskeletal System**		
150.3	Bone (Mineral) Density Studies (Effective January 1, 2007)	√	
150.5	Diathermy Treatment	√	
150.6	Vitamin B12 Injections to Strengthen Tendons, Ligaments, etc., of the Foot		√
150.7	Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents		√
150.8	Fluidized Therapy Dry Heat for Certain Musculoskeletal Disorders	√	
150.9	Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee (Effective June 11, 2004)		√
150.10	Lumbar Artificial Disc Replacement (LADR) (Effective August 14, 2007)	√**	
150.11	Thermal Intradiscal Procedures (Effective September 29, 2008)		√
160	**Nervous System**		
160.2	Treatment of Motor Function Disorders with Electric Nerve Stimulation	√	
160.4	Steroetactic Cingulotomy as a Means of Psychosurgery	√	
160.24	Deep Brain Stimulation for Essential Tremor and Parkinson's Disease		√
160.27	Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)	CED	
190	**Pathology and Laboratory**		
190.6	Hair Analysis		√
200	**Pharmacotherapy**		
210.4	Smoking and Tobacco-Use Cessation Counseling (Effective March 22, 2005)	√	
210.4.1	Counseling to Prevent Tobacco Use (Effective August 25, 2010)	√	
210.9	Screening for Depression in Adults (Effective October 14, 2011)	√	
220	**Radiology**		
220.1	Computed Tomography	√	
220.2	Magnetic Resonance Imaging (MRI) (Various Effective Dates Below)	√	
220.2.1	Magnetic Resonance Spectroscopy		√
220.5	Ultrasound Diagnostic Procedures (Effective May 22, 2007)	√	
230	**Renal and Genitourinary System - ESRD Services**		
230.18	Sacral Nerve Stimulation for Urinary Incontinence	√	

* with limitations
**< 60 yrs. of age
CED = Coverage with Evidence Development

tiple other interventions have been considered in the NCD analysis. These included all procedures with application of heat into either the nucleus or annulus of the disc including nucleoplasty and biacuplasty, intradiscal electrothermal therapy (IDET), vertebral augmentation techniques, and fusion techniques.

2.6 Practical Implications

Neumann et al (238) assessed Medicare national coverage decisions for technologies from 1999 to 2007. This analysis of Medicare national coverage decisions showed that the CMS considers the available evidence as no better than fair for most of the technologies considered. Still, the CMS issued favorable decisions in 60% of the cases it took on, although almost always with conditions placed on coverage. Since the enactment of the 2003 Medicare Modernization Act (MMA) which legislated maximum review times for NCDs, the CMS has eliminated long duration "decisions" entailing more than one year and has issued several CED decisions, which promote flexibility, but also carried implementation challenges.

A review of Medicare's NCDs in diagnostic radiology (239) showed that 22 of 152 (15%) NCDs pertained to diagnostic imaging technologies. The supporting evidence was judged to be good, fair, and poor in 5, 6, and 11 cases, respectively. Consequently, the decisions were made to cover 11 technologies (50%) with conditions, 4 (18%) deferred the coverage decision to the local level, and 2 (9%) were completely not covered. In 5 instances there was no change to the prior coverage status. Of the 11 decisions resulting in positive coverage, 8 (73%) restricted use to specific population subgroups, 5 (46%) applied restrictions related to treatment, 4 were covered with evidence development, and 2 were restricted to care in specific settings. However, it has also been stated that there have been variations between clinical trial participants and Medicare beneficiaries in evidence used for Medicare NCDs (240). Based on some of the requests, at present, epidural and transforaminal injections and spinal cord stimulation with deep brain stimulation are on the potential list of NCDs; however, no formal application has been made and no formal notice has been issued.

2.7 Appeals Process for National Coverage Determinations

Medicare beneficiaries whose requests for services or claims for payment have been denied as a result of a current NCD can seek consideration of their individual coverage denial through the coverage and payment appeals process and challenge the validity of the NCD as it applies to all similarly situated Medicare beneficiaries. Since the CMS utilizes an extensive and lengthy process, which is considered an evidence-based process, for determining Medicare coverage under NCDs, NCDs are often difficult to challenge and overturn. Stages of an NCD appeal include a Medicare beneficiary either seeking treatment or with a documented need for the treatment within 6 months of the date of the beneficiary's treating physicians' written statement in support of Medicare coverage or parties seeking payment for medical services already received within 120 days of the initial denial notice. Once the complaint is filed with the Departmental Appeals Board (DAB), within 30 days of receiving the DAB docketing letter, upon review of the NCD received from Medicare, the Medicare beneficiary may file a statement with the DAB and Medicare that explains why the NCD is invalid. At this point, Medicare may submit a statement as to why the beneficiary is incorrect and the NCD is valid. Subsequently, upon review of the statements and the evidence the ALJ makes a determination of the validity of the NCD. At this stage the DAB applies the reasonableness standard to determine whether the NCD record is complete and adequate to support the validity of the NCD. Subsequently, the DAB conducts a review of the NCD review and statement submitted by Medicare and the Medicare beneficiary. Within 90 days of closing the NCD review record to new evidence, the DAB must issue written notification of a decision or the approximate date a decision will issue. Under the reasonableness standard, the DAB must uphold a challenged NCD as valid if the findings of fact, interpretations of the law, and applications of fact of law as determined by Medicare in creating the NCD were reasonable based upon the NCD record.

If the DAB determines that the NCD is valid, it must issue this decision to the Medicare beneficiary along with information on how the beneficiary may file a federal judicial appeal. If DAB determines that the NCD is not valid, the DAB instructs Medicare to reevaluate the beneficiary's claim for services or payment without relying on the invalid NCD provision. Additionally, Medicare must implement the DAB's decision as Medicare policy and determine subsequent similar claims within 30 days.

3.0 Local Coverage Determinations

LCDs are developed at the local level. The rules are structured. The Benefits Improvement and Protection Act (BIPA) (241) created the LCDs. An LCD is a decision by a Medicare administrative contractor (MAC), fiscal intermediary, or carrier whether to cover a particular item or service on a MAC-wide, intermediary wide, or carrier-wide basis (178).

Evolution of local coverage policy dates back to compromise over protracted and bitter political battles leading up to the passage of Medicare in 1965, to resolve the fears that a government health program would interfere with the practice of medicine that allowed private insurers to act as fiscal intermediaries and carriers, serving as a "buffer" between the federal government and the providers (175,242-244).

In the early years, evaluation of items and services occurred when local contractors processed individual claims (245). For the most part, the national office of coverage policy was rarely involved with coverage decisions, relying on contractors and local doctors to mediate disputes (173). However, the Health Care Financing Administration (HCFA), now CMS, developed some informal guidelines establishing general criteria for claims review (246). Further, in 1981 the HCFA issued a directive restating its expectations that contractors refer coverage issues of national interest to the central office (175). This also led to the creation of the Coverage/Payment Technology Advisory Group (TAG), comprised of contractors and agency staff, to discuss coverage and payment issues (175). Subsequently, since 1989, local coverage policies have emerged (175). This proposed rule making included a list of criteria necessary to Medicare coverage, including limited cost-effectiveness requirements for certain types of technologies. However, this effort was abandoned in 1992 (173). Nonetheless, the HCFA continued efforts to improve the local process. The new authority for local contractors arrived with little fanfare in early 1990s (175). The first reference to the term local medical review policy (LMRP) appeared in the intermediary manual in 1994 (247). Over time, the HCFA enhanced the structure and capability of contractors to develop policies, including a Carrier Medical Director (CMD) in each contract, national and regional conferences for medical directors, work groups to collaborate on technology evaluation, and carrier advisory councils of physicians. The HCFA also imposed more requirements for LMRP development (248). The HCFA promulgated each state to have a CMD in 1987, and Carrier Advisory Committee (CAC) in 1992.

The LMRPs have been transformed to LCDs. BIPA published the final rule establishing LCDs on November 11, 2003 (241). Beginning December 7, 2003, local policies were referred to as LCDs with the understanding of the relative standing of both LCDs and LMRPs (178). Since then LCDs have been issued instead of LMRPs and all LMRPs have been converted to LCDs. The LCDs specify under what clinical circumstances an item or service is considered to be reasonable and necessary. Their administrative and educational tools assist providers in submitting correct claims for payment. Contractors publish LCDs to provide guidance to the public and medical community within their jurisdictions. Contractors develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community (178).

3.1 When to Develop/New Revised LCDs

LCDs help avoid situations in which claims are paid or denied without a provider having a full understanding of the basis of payment and denial. The Medicare Integrity Manual (178) provides the process to develop LCDs.

1. Contractors shall develop LCDs when they have identified an item or service that is never covered under certain circumstances and wish to establish automated review in the absence of an NCD or coverage provision in an interpretative manual that supports automated review.
2. Contractors have the option to develop LCDs when any of the following occur:

- A validated widespread problem demonstrating a significant risk to the Medicare trust funds (identified or potentially high dollar and/or high volume items or services). Multi-state contractors are provided with the ability to develop uniform LCDs across all its jurisdictions even if data analysis indicates that the problem exists only in one state.
- An LCD is needed to assure beneficiary access to care.
- A contractor has assumed the LCD development workload of another contractor and is undertaking an initiative to create uniform LCDs across its multiple jurisdictions; or is a multi-state contractor undertaking an initiative to create uniform LCDs across its jurisdiction; or
- Frequent denials are issued (following routine or complex review) or frequent denials are anticipated.

3. Contractors shall review and appropriately revise affected LCDs within 90 days of the publication of the program instructions. Further, to ensure that all

LCDs remain accurate and up-to-date at all times, at least annually, contractors shall review and appropriately revise LCDs based upon CMS NCD, coverage provisions in interpretative manuals, national payment policies, and national coding policies.

3.2 Content of an LCD

The CMS instructs that an LCD shall be clear, concise, properly formatted, and not restrict or conflict with NCDs or coverage provisions in interpretative manuals (178).

3.3 Reasonable and Necessary Provisions in LCDs

An item or service may be covered by an LCD (178) if:

- It is reasonable and necessary. Only reasonable and necessary provisions are considered part of the LCD. Consequently, to meet the criteria of reasonable and necessary, contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary. Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:
- Safe and effective; and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service in terms of whether it is:
- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
- Furnished in a setting appropriate to the patient's medical needs and condition
- Ordered and furnished by qualified personnel
- One that meets, but does not exceed, the patient's medical need
- At least as beneficial as an existing and available medically appropriate alternative.

However, there are several exceptions to the requirement that an item or service be reasonable and necessary for diagnosis or treatment of illness or injury. These exceptions include multiple vaccinations, hospice care in terminal illness, screening mammography, screening pap smears, prostate cancer screening test, colorectal cancer, and eyeglasses furnished subsequent to cataract surgery.

Even though since its inception in 1965, Medicare policy has been guided by legislation mandating that the program not pay for items and services that are not reasonable and necessary, over the years, amid escalating costs and the medical communities embrace of evidence-based medicine, the CMS has struggled to interpret and apply the reasonable and medical necessary criteria (249). Neumann and Chambers (249) described that defining reasonable and necessary has proven to be an enduring challenge. Consequently, determinations of what is necessary care generally turn on the strength of the medical evidence, as encapsulated, for example, in clinical guidelines. Such determinations, however, are rarely straightforward, given the complexity of individual cases. In addition, the influence of various interest groups has challenged Medicare's attempts to stick closely to the data. Consequently, Medicare has to reverse multiple decisions (249).

Further, determining reasonableness implies moderation, suggesting that the resources expended should not be excessive. Thus, the issue is not simply whether care is essential, but whether it is advisable given a delicate balance of benefits, risks, and costs. Due to multiple difficulties and various issues involved, legal scholar Jacqueline Fox argued that amending the original statute so that it prohibits payment "for any expenses which are unreasonable and which are incurred for items and services" would provide the CMS authority and legitimacy to consider costs openly (250).

3.3.1 Cost Effectiveness Considerations

The cost effectiveness considerations by Medicare also have been a subject of controversy. The U.S. Panel on Cost Effectiveness in Health and Medicine, composed of physicians, health economists, ethicists, and other health policy experts, recommended that cost effectiveness analysis should use quality adjusted life years (QALY) as a standard metric for identifying and assigning value to health outcomes in 1996 (251,252). Further, the recently enacted Patient Protection and Affordable Care Act (ACA) created a Patient-Centered Outcomes Research Institute (PCORI) to conduct comparative effectiveness research (CER), and, in contrast, prohibited this institute from developing or using cost per QALY thresholds (40,46,47). While the ACA specifically forbids the use of cost per QALY as a threshold, multiple organizations and clinical guidelines support this concept. Even then, it is generally believed that Medicare does have an implicit cost-effectiveness threshold. In assessment of whether an implicit cost effectiveness threshold exists and to determine if economic evidence has been considered in previous NCDs (253), it was shown

that the CMS is covering a number of interventions that do not appear to be cost effective, suggesting that resources could be allocated more efficiently. Authors identified 64 coverage decisions determined to have a corresponding cost effectiveness estimate, 49 were associated with a positive covered decision, and 15 with a noncoverage decision. Of the positive decisions, 20 were associated with an economic evaluation that estimated the intervention to be dominant (cost less and was more effective than the alternative), 12 with an incremental cost effectiveness ratio (ICER) of less than $50,000, 8 with an ICER greater than $50,000 but less than $100,000, and 9 with an ICER greater than $100,000. Further, 14 of the sampled 64 decision memos cited or discussed cost effectiveness information.

3.4 Use of Absolute Words in LCDs

The CMS (178) instructs that contractors should use phrases such as "rarely medically necessary" or "not usually medically necessary" in proposed LCDs to describe situations where an item or service is considered to be, in almost all instances, not reasonable and necessary. However, contractors may also develop LCDs that contain absolute words such as "is never covered" or "is only covered for" when strong clinical justification exists.

3.5 Alternate Treatments

The Medicare Integrity Manual (178) directs that contractors should incorporate into LCDs the concept that the use of an alternative item or service precedes the use of another item or service. This approach is termed a prerequisite. Contractors shall base any requirement on evidence that a particular alternative is safe, as effective, or appropriate for a given condition without exceeding the patient's medical needs. Prerequisites shall be based on only medical appropriateness, not on cost effectiveness.

3.6 Evidence Supporting LCDs

The Medicare Program Integrity Manual (178) instructs that LCDs shall be based on the strongest evidence available. Further, the extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
- Scientific data or research studies published in peer-reviewed medical journals
- Consensus of expert medical opinion (i.e., recognized authorities in the field)
- Medical opinion derived from consultations with medical associations or other health care experts.

3.7 LCD Advisory Process

The LCD advisory process consists of external evidence gathering along with the CAC process. Each state should have its own CAC (178). The purpose of a CAC is to provide a formal mechanism for physicians in the state to be informed of and participate in the development of an LCD in an advisory capacity; a mechanism to discuss and improve administrative policies that are within carrier discretion; and a forum for information exchange between carriers and physicians (178).

While the CAC is not a forum for peer review, discussion of individual cases, or individual providers, the CAC reviews all draft LCDs, the final implementation decision about LCDs, however, rests with the CMD. Membership on a CAC is to be composed of physicians, a beneficiary representative, and representatives of 34 medical organizations (254). Interventional pain management was provided with mandatory membership on February 1, 2005 (255). The clinical specialties included are listed in Table 4.

Medicare defines physicians as:

- Doctors of medicine
- Doctors of osteopathy
- Doctors of dental surgery or dental medicine
- Chiropractors
- Doctors of podiatry or surgical chiropody
- Doctors of optometry.

Carriers select committee representatives from names recommended by state medical societies and specialty societies. If the CMD is concerned because of identified utilization/ MR problems with an individual who has been recommended as a committee representative, the CMD should discuss the recommendation with the nominating body. They must maintain confidentiality of the specifics of the situation in any discussion.

If there is no organized specialty society for a particular specialty, the CMD should work with the state medical society to determine how the specialty is to be represented. Encourage each state medical society and

specialty society to nominate representatives to the CAC.

If there are multiple specialty societies representing a specialty, select only one representative. Encourage specialty societies to work together to determine how a representative is selected and how that representative communicates with each society.

Members of a CAC include physician representatives from each of the following groups (255):

Table 4. *Clinical specialties and subspecialties included in CAC.*

1.	Allergy
2.	Anesthesia
3.	Cardiology
4.	Cardiovascular/Thoracic Surgery
5.	Dermatology
6.	Emergency Medicine
7.	Family Practice
8.	Gastroenterology
9.	Gerontology
10.	General Surgery
11.	Hematology
12.	Internal Medicine
13.	Infectious Disease
14.	**Interventional Pain Management**
15.	Medical Oncology
16.	Nephrology
17.	Neurology
18.	Neurosurgery
19.	Nuclear Medicine
20.	Obstetrics/Gynecology
21.	Ophthalmology
22.	Orthopedic Surgery
23.	Otolaryngology
24.	Pathology
25.	Pediatrics
26.	Peripheral Vascular Surgery
27.	Physical Medicine and Rehabilitation
28.	Plastic and Reconstructive Surgery
29.	Psychiatry
30.	Pulmonary Medicine
31.	Radiation Oncology
32.	Radiology
33.	Rheumatology
34.	Urology

- State medical and osteopathic societies (president or designee)
- National Medical Association (representative of either the local or state chapter or its equivalent, if one exists)
- Medicare Advantage organizations. In order to enhance the consistency of decision-making between Medicare Advantage plans and traditional fee-for-service Medicare, Medicare Advantage organizations shall also have representation on the CAC. The number of Medicare Advantage representatives on the CAC should be based on the Medicare penetration (enrollment) rates for that state; one representative for those states with penetration rates of less than 5 percent and 2 representatives for those states with penetration rates of 5 percent or higher. The state HMO association should periodically submit nominees for membership on the CAC.
- Physician representatives for each of the following: 1) Chiropractic; 2) Maxillofacial/Oral surgery; 3) Optometry; and 4) Podiatry.

Based on the directive (255), the CMD must work with the societies to ensure that committee members are representative of the entire service area and represent a variety of practice settings.

In addition to the representatives for physician clinical specialties, include an individual to represent clinical laboratories. This individual may also be a physician. Recommendations from national and local organizations that represent independent clinical laboratories must be considered in making this selection.

In addition, 2 representatives of the beneficiary community are included:

- One based on recommendations made by an association(s) representing issues of the elderly (e.g., coalitions for the elderly, senior citizen centers)
- One based on recommendations made by an association(s) representing the disabled.

One role of the beneficiary representatives is to communicate with other beneficiary groups that have an interest in LMRP.

Carriers invite the following to be members:

- A representative from the State Hospital Association
- QIO medical director
- Intermediary medical director
- Medicaid medical director (or designee)
- A representative of an association representing ad-

ministrative practices, such as the American Group Practice Association or the Medical Group Management Association.

CAC members serve to improve the relations and communications between Medicare and the physician community. Specifically, they:

- Disseminate proposed LCDs to colleagues in their respective state and specialty societies to solicit comments
- Disseminate information about the Medicare program obtained at CAC meetings to their respective state and specialty societies
- Discuss inconsistent or conflicting MR policies.

3.8 Appeals Process for Local Coverage Determinations

Similar to NCDs, LCDs may be challenged by Medicare beneficiaries whose requests for services or claims for payment have been denied as a result of a current LCD. They can seek reconsideration of their individual coverage denials through the coverage and payment appeals process, and challenge the validity of the LCD as it applies to all similarly situated Medicare beneficiaries. Because individual regional contractors issue LCDs, a Medicare beneficiary with a particular illness may receive Medicare covered treatment under one contractors LCD in a particular state, but find that he or she cannot receive the same treatment in a different state because the LCD does not apply. When beneficiaries believe that scientific and medical data support the medical need for the treatment at issue, then they start an LCD appeal.

Step one of the appeals process involves filing the LCD complaint by a Medicare beneficiary either seeking medical treatment or who sought the treatment or seeking payment for Medicare services already received with the DAB. Following the filing of the complaint, the next step (step 2) involves the Medicare contractor sending the beneficiary a copy of the LCD record. As described above, the LCD contains multiple items in reference to the LCD rule being challenged, medical evidence considered on or before the date the LCD was issued, and comments that were made in response to early drafts of the rule.

Upon review of the record, the Medicare beneficiary may file a statement with the ALJ indicating why the LCD is incorrect under the Medicare reasonable and necessary standard. The contractor may also submit a statement as to why the beneficiary is incorrect. Following this, the ALJ makes a determination after review of the statements and the evidence.

Step 3 involves the review by the ALJ. If the ALJ determines that the LCD is valid, the beneficiary may appeal this decision to the DAB. If the ALJ determines that LCD is not valid and the Medicare contractor fails to appeal, the contractor must reevaluate the beneficiary's claim for services or payment without relying on the invalid provision.

Further, within 30 days, the contractor must implement the ALJ's decision as policy in determining subsequent claims. If the Medicare contractor chooses to appeal the ALJ's determination, the LCD remains in force and the individual claim reevaluation is stayed until the DAB issues a final decision.

Step 4 involves review by the DAB which is based upon a Medicare beneficiary's appeal that at the ALJ level was unsuccessful. The appeal must be filed within 30 days of the ALJ issuing its decision.

As a final step, the DAB reviews the LCD record and the arguments submitted by the parties to determine whether the ALJ made a material error in reaching its decision. The DAB may allow oral argument if it believes that it would be helpful in deciding the matter. The DAB then issues a written decision upholding, modifying, or revising the ALJ decision. However, if the DAB decision remains adverse to the beneficiary's interests, the beneficiary may file a complaint for judicial review.

3.9 Effectiveness of Coverage Policies

There is an argument in reference to the evidence of effectiveness of coverage policies to change utilization patterns. Some argue that policies have had little impact on utilization (1,2,5,6,172,256,257). Wennberg (256) found significant and persistent variations in utilization patterns in Medicare, even adjusting for age and severity of illness differences regionally. His findings showed important differences in the ways in which medicine is practiced and services are used across the country, which suggest that misuse, underuse, and overuse of services are widespread. While NCDs without coverage do change the behavior, when they are covered they do not appear to have changed any utilization patterns (172). In reference to drug coated stents, Kaul and Diamond (258) found that only about 20% of drug coated stents are inserted in patients with a clinical condition supported by clinical trial data that lead to the initial federal approval of the stents (259). Thus, it has been postulated that with more than one million Americans receiving stents each year, utilization that is contrary to clinical evidence costs billions of dollars and, according to Kaul and Diamond, potentially

causes 2,160 deaths (258,259). In a study from the University of Minnesota evaluating the impact of coverage policies on utilization in Medicare (260), in 7 of the 8 cases, there were no measurable changes in use, which suggests that providers continue to behave as they had prior to the policy's enactment.

In interventional pain management, review of the data from various regions in reference to LCDs and without LCDs either based on evidence or not based on evidence, there were no significant differences noted in utilization patterns as shown in Table 5 (5,6). The assessment of statewide utilization illustrates no significant variations in the utilization of interventional techniques irrespective of the type of LCD or its presence or absence.

3.10 LCD Topics for National Consideration

As described in section 2.4, LCD topics for national consideration is a confusing issue as they are also called NCDs. However, these are distinct not only from NCDs, but also from coverage decision memoranda and very similar to LCDs. Based on the MMA of 2003 (169), the CMS developed a plan to evaluate new LCDs to decide which local decisions should be adopted nationally. These LCDs also considered as NCDs, provide an avenue for uniform coverage across the nation. In this process, when contractors believe that LCD topics are appropriate for NCD consideration they submit the LCD topic, a formal evaluation and appropriate supporting documentation to the advisory group.

4.0 Value Based Care in Interventional Pain Management

In a value based health care economy, the preferred goal for health care delivery is superior patient value. Using interventions providing the most value to the patients is essential to achieve the high standards of patient care avoiding over utilization, abuse, fraud, and without curtailing patient access. The cost utility of an intervention may be used to identify interventions that provide the most benefit to patients while incurring the least expense. Prior to assessing the cost utility it is essential to assess the available evidence of effectiveness, evidence-based recommendations, or utilization in various aspects. The comprehensive evidence-based guidelines for spinal interventional techniques based on comprehensive review of the literature with numerous systematic reviews (1,2,85-103,105-115,126,127) illustrated various levels of evidence for technologies utilized in interventional pain management in managing spinal pain. No such assessments are available for other chronic pain conditions.

4.1 Cost Effectiveness in Value Based Interventional Pain Management

Due to escalating health care costs and questionable effectiveness of multiple interventions, cost utility analysis has become a cornerstone of evidence-based medicine, clinical practice, and health care policy making (76,261-263). Multiple cost effectiveness analysis studies have been performed in managing spinal pain (18,76,261-271). Kepler et al (262), in a systematic review of cost utility analysis in spine care including 33 studies in the assessment, showed that approximately 45% of the studies reported cost utility assessments with less than $100,000 for QALY gain, and 23% were greater than $100,000 QALY gain. Indrakanti et al (263) assessed cost utility analysis of value-based care in the management of spinal disorders after selecting 27 studies for inclusion. They concluded that studies of non-operative treatments demonstrated greater value for

Table 5. *Spinal interventional techniques* per 100,000 Medicare recipients by state from 2000 to 2010.*

State	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	Change	Ave
Alabama	5,348	7,163	8,379	9,685	10,823	13,947	11,537	10,869	11,194	11,642	11,921	123%	8%
Alaska	1,618	2,328	2,359	3,477	5,884	5,396	7,731	6,373	5,460	5,022	5,299	227%	13%
Arizona	3,157	3,501	3,644	4,942	6,486	7,211	7,032	7,581	9,242	10,734	11,309	258%	14%
Arkansas	3,692	4,155	4,546	4,878	6,839	8,324	9,446	11,569	12,463	11,998	11,408	209%	12%
California	2,409	2,679	3,809	3,891	4,793	5,271	5,717	6,284	6,787	7,167	6,872	185%	11%
Colorado	2,777	3,402	4,040	4,223	5,031	6,528	6,983	7,366	6,322	6,556	6,765	144%	9%
Connecticut	1,176	1,437	2,176	2,550	3,626	4,016	5,041	5,705	5,765	5,756	5,884	400%	17%
DC	1,859	1,285	2,454	2,466	4,183	3,301	3,786	4,670	44,518	46,822	48,544	2512%	39%
Delaware	2,444	2,896	4,054	4,962	7,147	7,264	9,239	9,442	9,528	8,458	8,381	243%	13%
Florida	5,398	6,533	8,019	10,056	12,206	16,002	24,742	16,897	15,480	14,767	12,966	140%	9%
Georgia	3,764	4,731	6,292	6,371	8,311	10,002	8,965	10,784	11,992	13,559	12,080	221%	12%

Table 5 (cont.). *Spinal interventional techniques* per 100,000 Medicare recipients by state from 2000 to 2010.*

State	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	Change	Ave
Hawaii	581	1,058	1,238	1,512	1,778	1,592	1,730	1,373	1,309	1,302	1,621	179%	11%
Idaho	3,297	4,485	5,498	5,234	7,477	7,473	6,687	5,751	6,412	6,860	6,635	101%	7%
Illinois	2,822	3,987	4,607	5,176	6,190	7,309	7,202	8,098	8,102	8,793	8,080	186%	11%
Indiana	3,706	4,768	5,904	6,795	7,957	8,197	8,799	8,756	10,070	10,060	10,295	178%	11%
Iowa	3,843	5,242	5,482	4,756	5,860	6,365	6,932	6,535	5,802	5,665	5,690	48%	4%
Kansas	3,781	4,899	5,347	7,372	7,895	9,291	9,511	8,896	9,480	9,765	9,864	161%	10%
Kentucky	3,593	4,840	5,120	6,468	7,640	8,082	8,594	8,796	9,715	9,907	9,786	172%	11%
Louisiana	2,091	3,158	4,429	5,224	7,285	8,838	9,286	8,913	10,282	10,162	10,046	380%	17%
Maine	2,310	3,201	3,424	4,155	4,596	4,699	5,387	5,443	5,481	5,690	5,651	145%	9%
Maryland	2,336	3,578	4,380	5,228	6,420	7,703	8,087	8,613	8,582	8,454	8,067	245%	13%
Massachusetts	1,799	2,407	2,933	3,501	4,174	5,302	5,924	6,467	6,304	6,816	7,268	304%	15%
Michigan	4,381	5,533	7,600	7,975	9,892	12,656	12,851	13,228	12,725	13,489	12,971	196%	11%
Minnesota	1,947	2,371	3,078	3,564	4,221	4,653	4,876	4,943	4,633	4,834	4,615	137%	9%
Mississippi	3,670	4,695	6,217	6,201	8,144	9,584	9,358	10,797	9,978	11,843	11,015	200%	12%
Missouri	3,816	4,557	6,142	6,275	7,017	7,893	9,762	9,359	10,693	11,250	11,164	193%	11%
Montana	3,935	5,034	5,618	6,290	6,911	7,527	8,027	7,627	7,109	7,208	6,204	58%	5%
Nebraska	3,462	4,060	4,330	5,032	5,069	6,543	6,695	6,891	6,660	7,081	6,647	92%	7%
Nevada	2,352	2,930	4,453	5,122	5,908	6,476	6,004	8,523	9,079	9,879	10,701	355%	16%
New Hampshire	2,952	4,007	4,695	5,146	6,054	6,982	7,795	7,596	8,145	9,010	9,971	238%	13%
New Jersey	3,260	3,730	4,284	4,418	4,853	5,827	6,172	5,999	6,724	6,675	6,844	110%	8%
New Mexico	2,031	2,986	2,946	4,590	5,430	6,292	5,968	6,872	5,819	5,885	6,035	197%	12%
New York	1,853	2,464	3,199	3,755	4,846	5,479	5,417	5,654	5,329	5,105	5,133	177%	11%
North Carolina	2,684	3,794	4,840	5,674	6,526	7,965	8,496	8,970	9,321	9,613	9,147	241%	13%
North Dakota	2,268	3,200	4,728	5,464	5,621	5,420	6,126	5,773	7,163	7,596	7,262	220%	12%
Ohio	2,970	3,244	4,292	4,774	5,566	6,662	8,254	8,827	7,990	8,602	8,377	182%	11%
Oklahoma	3,749	4,199	5,221	4,654	5,798	6,846	7,298	7,457	7,982	8,782	8,697	132%	9%
Oregon	1,042	1,287	1,619	2,350	2,456	3,529	3,093	3,344	3,682	3,943	3,960	280%	14%
Pennsylvania	2,953	3,876	4,457	4,915	5,696	6,552	6,806	6,958	6,483	6,164	6,335	115%	8%
Rhode Island	1,445	1,897	2,371	2,725	2,880	3,670	4,631	5,302	7,081	6,716	7,281	404%	18%
South Carolina	3,892	5,918	5,286	7,029	8,355	9,966	10,843	10,666	16,824	17,669	17,232	343%	16%
South Dakota	3,332	3,166	3,926	3,433	5,122	6,276	7,705	7,775	10,321	11,214	9,526	186%	11%
Tennessee	3,442	4,362	5,292	5,482	6,611	7,667	8,238	8,666	10,693	10,854	10,539	206%	12%
Texas	3,803	5,549	6,772	7,401	8,822	10,584	12,239	12,714	14,287	15,011	12,931	240%	13%
Utah	3,358	4,468	5,771	5,885	7,965	9,046	9,628	9,801	9,579	10,159	10,429	211%	12%
Vermont	2,673	2,421	2,495	4,379	5,638	5,712	6,040	5,079	5,330	5,692	5,463	104%	7%
Virginia	2,694	3,798	4,527	4,812	5,373	5,827	6,757	6,925	6,312	6,708	6,331	135%	9%
Washington	1,802	2,319	3,304	3,343	4,068	4,673	4,509	4,626	5,278	5,642	5,382	199%	12%
West Virginia	2,451	2,866	2,983	3,868	5,038	5,549	6,432	5,929	5,459	6,025	6,214	154%	10%
Wisconsin	3,487	4,242	5,820	5,729	6,117	6,635	7,028	6,417	7,170	7,154	6,999	101%	7%
Wyoming	3,301	4,606	5,582	5,803	5,853	8,075	7,984	7,286	6,342	6,516	6,797	106%	7%
Total	3,047	3,884	4,678	5,391	6,510	7,629	8,721	8,489	8,844	9,354	9,170	201%	12%

* Spinal interventional techniques included Epidural procedures, Percutaneous adhesiolysis, Facet joint interventions and Sacroiliac joint interventions. From 2000 to 2007 based on 5% data and 2008 – 2010 based on 100% data.

graded activity over physical therapy and pain management; spinal manipulation over exercise; behavioral therapy and physiotherapy over advice; and acupuncture and exercise over usual practitioner care. In another systematic review and meta-analysis of efficacy, cost effectiveness, and safety of selected complementary and alternative medicines for neck and low back pain, Furlan et al (76) showed that complementary and alternative therapies did not significantly reduce disability compared to sham. However, complementary and alternative medicine treatments were significantly more efficacious than no treatment, placebo, physical therapy, or usual care in reducing pain immediately or short-term after improvement. In an assessment of the role of cost utility evaluations, Dagenais et al (18) showed that most studies were published in the United Kingdom in the past 3 years prior to the publication in 2009, and with data converted to US dollars, cost per QALY ranged from $304 to $579,527, with a median of $13,015. Among recent assessments evaluating surgical interventions over conservative treatment, Tosteson et al (269,270) showed that over a period of 2 years, surgery was more costly than nonoperative care. However, the costs for QALY gained from surgery relative to nonoperative care in lumbar disc herniation using general adult surgery costs was $69,403 and using Medicare population surgery costs was $34,355. In surgical treatment of spinal stenosis with and without degenerative spondylolisthesis, they showed that stenosis surgery improved health to a greater extent than nonoperative care at a cost of $77,600 per QALY gained, whereas degenerative spondylolisthesis surgery gained a QALY with a cost of $115,600. In another study, Parker et al (271) showed that in lumbar stenosis associated with radiculopathy, multilevel hemilaminectomy was associated with a mean 2 year cost per quality gained of $33,700 per QALY. Taylor et al (265) showed the incremental cost effectiveness of spinal cord stimulation compared with conventional medical management with £5,624 per QALY. However, Hollingworth et al (267) in an analysis of the cost effectiveness of spinal cord stimulation for failed back surgery syndrome in a workers' compensation population showed mean medical cost per spinal cord stimulation patient over 24 months of $52,091 which was $17,291 higher than the pain clinic group and $28,128 higher than the usual care group.

However, cost effectiveness evaluations in interventional pain management involving basic interventional techniques have been rare. In an evaluation of epidural injections by Whynes et al (268) assessing 39 patients over a period of 13 weeks, the results showed mean QALY gains per patient for 2 injections amounted to £8,975 per QALY gained. Thus there has been significant variation in cost effectiveness or cost utility analysis and their findings in spine interventions, specifically interventional techniques. In a recent manuscript, Manchikanti et al (261), assessing the data from 4 randomized controlled trials of low back pain with 480 patients with a 2 year follow-up with actual reimbursement data, showed cost utility for one year of QALY of $2,206 for disc herniation, $2,136 for axial or discogenic pain without disc herniation, $2,155 for central spinal stenosis, and $2,191 for post surgery syndrome. The average cost utility analysis per year was $2,172.50 for all patients and $1,966.03 for patients who were judged to be successful with at least 3 weeks of improvement noted with the first 2 epidural injections. There was no significant difference whether steroids were utilized or not.

4.2 Evidence Synthesis in Value Based Interventional Pain Management

An update of comprehensive evidence-based guidelines for interventional techniques of chronic spinal pain (1,2) provided recommendations in managing low back pain, cervical pain, and thoracic pain based on the comprehensive review of the literature.

The American Society of Interventional Pain Physicians (ASIPP) guideline committee provides a broad representation of academic and non-academic clinical practitioners, representing a variety of practices and geographic areas, all with interest and expertise in interventional techniques and chronic pain management. The committee formulized the elements of the guideline preparation process, including literature searches, literature synthesis, consensus evaluation, open forum presentations, and peer review. However, there were no patients, patient advocates, or patient/consumer organizations represented in the guideline development process, which may be considered as a deficiency. The evidence synthesis and analysis resulted in multiple conclusions and recommendations based on evidence with overwhelming majority consent.

The IOM Committee concluded that systematic reviews should be used to inform health care decision-makers about what is known and not known about the effectiveness of health interventions (1-4,189-194). However, the evidence that informs current health care decisions often is incomplete and may be

biased, and there are no standards in place to ensure that systematic reviews of the evidence are objective, transparent, and scientifically valid (1-4,51-53,189-194,226). Thus, the IOM committee concluded that better quality systematic reviews have the potential to improve the decisions made by clinicians, to better inform patient choice, and to provide a more trustworthy basis for decisions by payers and policy-makers (1-4,189-191,264).

Evidence assessment for systematic reviews was based on methodological quality assessment criteria recommended for randomized trials, observational studies, and diagnostic studies (192,227,272-291). The quality of each individual article used in this comprehensive assessment was assessed by Cochrane review criteria has been shown in Table 4 in Part I of the guidelines (1,192) for randomized trials, Newcastle-Ottawa Scale for observational studies as shown in Tables 5 and 6 in Part I of the guidelines (1,272), and Quality Appraisal of Reliability Studies (QAREL) checklist for diagnostic accuracy studies (273-278) as shown in Table 7 in Part I of the guidelines (1). The systematic reviews for guideline preparation have utilized robust outcome measures. The analysis of evidence was based on the United States Preventive Services Task Force (USPSTF) criteria as illustrated in Table 8 in Part I of the guidelines (1,291), which has been utilized by multiple authors (52,85-103). The analysis was conducted using 3 levels of evidence, ranging from good, fair, and limited or poor, in all systematic reviews (85-103). The summary of evidence derived from the systematic reviews and comprehensive review of the literature in preparation of the guidelines (1,2) is shown below. The guidelines (1,2), some of the systematic reviews (85-103), multiple other systematic reviews, and other sources of information with extensive literature synthesis is found in the guidelines, as well as in the systematic reviews.

Management of Low Back Pain

1. Diagnostic Selective Nerve Root Blocks

- The evidence for accuracy of diagnostic selective nerve root blocks is limited in the lumbar spine in patients with an equivocal diagnosis and involvement of multiple levels.
- Diagnostic selective nerve root blocks are recommended in the lumbar spine in select patients with an equivocal diagnosis and involvement of multiple levels.

2. Lumbar Discography

- The evidence for diagnostic accuracy for lumbar provocation discography is fair and the evidence for lumbar functional anesthetic discography is limited.
- Lumbar provocation discography is recommended with appropriate indications in patients with low back pain to prove a diagnostic hypothesis of discogenic pain specifically after exclusion of other sources of lumbar pain.

3. Diagnostic Lumbar Facet Joint Nerve Blocks

- The evidence for diagnostic lumbar facet joint nerve blocks is good with 75% to 100% pain relief as the criterion standard with controlled local anesthetic or placebo blocks.
- Diagnostic lumbar facet joint nerve blocks are recommended in patients with suspected facet joint pain.

4. Diagnostic Sacroiliac Joint Blocks

- The evidence for diagnostic intraarticular sacroiliac joint injections is good with 75% to 100% pain relief as the criterion standard with controlled local anesthetic or placebo blocks, and fair due to the limitation of the number of studies with 50% to 74% relief with a dual block.
- Controlled sacroiliac joint blocks with placebo or controlled comparative local anesthetic blocks are recommended when indications are satisfied with suspicion of sacroiliac joint pain

5. Therapeutic Epidural Injections

- The evidence for caudal epidural, interlaminar epidural, and transforaminal epidural injections is good in managing disc herniation or radiculitis; fair for axial or discogenic pain without disc herniation, radiculitis or facet joint pain with caudal and lumbar interlaminar epidural injections, and limited with transforaminal epidural injections; fair for spinal stenosis with caudal, interlaminar, and transforaminal epidural injections; and fair for post surgery syndrome with caudal epidural injections and limited with transforaminal epidural injections.
- The recommendation for epidural injections for disc herniation is that one of the 3 approaches may be used for spinal stenosis any of the 3 approaches are recommended whereas for axial or discogenic pain, either lumbar interlaminar or caudal epidural injections are recommended. However for trans-

foraminal epidural injections, the evidence is limited for axial or discogenic pain and post surgery syndrome.

6. Therapeutic Lumbar Facet Joint Interventions

- The evidence for lumbar conventional radiofrequency neurotomy is good, limited for pulsed radiofrequency neurotomy, fair to good for lumbar facet joint nerve blocks, and limited for intraarticular injections.
- Among the therapeutic facet joint interventions either conventional radiofrequency neurotomy or therapeutic facet joint nerve blocks are recommended after the appropriate diagnosis with controlled diagnostic lumbar facet joint blocks.

7. Therapeutic Sacroiliac Joint Interventions

- The evidence for sacroiliac cooled radiofrequency neurotomy is fair, limited for intraarticular steroid injections, limited for periarticular injections with steroids or botulinum toxin, and limited for both pulsed radiofrequency and conventional radiofrequency neurotomy.
- Due to emerging evidence for intraarticular injections, they are recommended in select cases with or without periarticular injections. Cooled radiofrequency neurotomy is recommended after appropriate diagnosis confirmed by diagnostic sacroiliac joint injections.

8. Percutaneous Adhesiolysis

- The evidence for lumbar epidural adhesiolysis in managing chronic low back and leg pain secondary to post lumbar surgery syndrome is fair to good and for spinal stenosis is fair.
- Percutaneous adhesiolysis is recommended after failure of conservative management and fluoroscopically directed epidural injections.

9. Thermal Annular Procedures

- The evidence for IDET and biaculoplasty is limited to fair and is limited for discTRODE.
- IDET and biaculoplasty may be performed in a select group of patients with discogenic pain nonresponsive to conservative modalities including epidural injections.

10. Percutaneous Disc Decompression

- The evidence for various modes of percutaneous disc decompression is limited to fair for nucleoplasty, and limited for APLD, percutaneous lumbar disc decompression, and decompressor.

The CMS has issued a noncoverage decision for nucleoplasty as a part of the thermal intradiscal procedures noncoverage determination.

- APLD and percutaneous lumbar disc decompression and nucleoplasty are recommended in select cases.

Management of Neck Pain

1. Cervical Provocation Discography

- The evidence for the diagnostic accuracy of cervical discography is limited.
- Cervical discography is indicated to test the diagnostic hypothesis of discogenic pain of the cervical spine in individuals who have been properly selected and screened to eliminate other sources of cervical pain.

2. Diagnostic Cervical Facet Joint Nerve Blocks

- The evidence for diagnostic cervical facet joint nerve blocks is good with a criterion standard of 75% or greater relief with placebo or local anesthetic controlled diagnostic blocks.
- Diagnostic cervical facet joint nerve blocks are recommended for the diagnosis of cervical facet joint pain.

3. Therapeutic Cervical Interlaminar Epidural Injections

- The evidence is good for cervical disc herniation or radiculitis; whereas, it is fair for axial or discogenic pain, pain of spinal stenosis, and pain of post cervical surgery syndrome.
- Cervical interlaminar epidural injections are recommended for patients with chronic neck and upper extremity pain secondary to disc herniation, spinal stenosis, and post cervical surgery syndrome.

4. Therapeutic Cervical Facet Joint Interventions

- The evidence is fair for cervical radiofrequency neurotomy and cervical medial branch blocks, and limited for cervical intraarticular injections.
- Conventional radiofrequency neurotomy or therapeutic facet joint nerve blocks are recommended in managing chronic neck pain after the appropriate diagnosis from controlled diagnostic blocks.

Management of Thoracic Pain

1. Thoracic Provocation Discography

- The evidence for thoracic discography is limited.
- Thoracic discography is recommended to decide if an intervertebral disc is painful or not in rare circumstances.

2. Diagnostic Thoracic Facet or Zygapophysial Joint Nerve Blocks

- The evidence for diagnostic accuracy of thoracic facet joint nerve blocks is good with a criterion standard of at least 75% pain relief with placebo or local anesthetic controlled diagnostic blocks.
- The diagnostic thoracic facet or zygapophysial joint nerve blocks are recommended in the diagnosis of chronic thoracic pain.

3. Thoracic Epidural Injections

- The evidence for thoracic epidural injection in treating chronic thoracic pain is fair.
- Thoracic epidural injections are recommended for thoracic discogenic, disc-related, post surgery syndrome, or spinal stenosis pain.

4. Therapeutic Thoracic Facet or Zygapophysial Joint Nerve Blocks

- The evidence is fair for therapeutic thoracic facet or zygapophysial joint nerve blocks, limited for radiofrequency neurotomy, and none for thoracic intraarticular injections.
- Therapeutic thoracic facet or zygapophysial joint nerve blocks are recommended.
- However, radiofrequency neurotomy and conventional radiofrequency neurotomy may be performed based on emerging evidence.

Implantables

1. Spinal Cord Stimulation

- The evidence for SCS is fair in managing patients with FBBS.
- Spinal cord stimulation is indicated in chronic low back pain with lower extremity pain secondary to FBBS, after exhausting multiple conservative and interventional modalities.

2. Implantable Intrathecal Drug Administration Systems

- The evidence for intrathecal infusion systems is limited in managing chronic noncancer pain.
- The recommendations for intrathecal infusion pumps include recalcitrant chronic noncancer pain.

5.0 Summary

As an evolving specialty, interventional pain management has been increasing substantially over the years. Today it has its own separate specialty designation, practice expense allocation, and membership on Carrier Advisory Committees. Exploding health care costs are a major issue for the United States and the world, and are especially so for interventional pain management in the United States. The increasing utilization of interventional techniques is often considered to be inappropriate, despite the significant advances in interventional pain management research, and the evidence base. Even though increases in all health care segments have been demonstrated, the focus on interventional pain management may be even higher than other specialties.

Since the inception of Medicare in 1965, a simple fee-for-service program has evolved into a complex entity with the evolution of multiple regulations over the years. As coverage development policies evolved, they have become evidence-based directives that define specific clinical parameters for appropriate use of services. There are 2 pathways to coverage of Medicare services. They include National Coverage Determinations and Local Coverage Determinations. Over the past 30 years, the CMS has made about 300 NCDs, and over 10,000 LCDs.

NCDs are developed by CMS to describe the circumstances for Medicare coverage nationwide for an item or service. NCDs outline the condition for which an item or service is considered to be covered and are usually issued as program instructions. NCDs are binding on all Medicare Carriers and other related organizations. Thus, a negative NCD means no coverage. In the development process of NCDs, a Medicare evidence development and coverage advisory committee was established to provide independent guidance and expert advice to the CMS on specific clinical topics. The MedCAC is used to supplement the CMSs internal expertise and to allow an unbiased and current deliberation of state-of-the art technology and science. Local coverage determinations are developed at the local level under the Benefits Improvement and Protection Act (BIPA). An LCD is a decision by a Medicare Administrative Contractor (MAC) fiscal intermediary or carrier whether to cover a particular item or a service on a MAC-wide, intermediary-wide, or

carrier-wide basis. An item or service may be covered by an LCD if it is reasonable and necessary; safe and effective; and appropriate, including the duration and frequency that is considered appropriate for the item or service in terms of which it is furnished with accepted standards of medical practice, in a setting appropriate to the patient's medical needs and condition, and at least as beneficial as an existing and available medically appropriate alternative.

Evidence needed for supporting LCDs is rigorous and includes published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and general acceptance by the medical community as supported by sound medical evidence. The LCD advisory committee process consists of external evidence gathering along with advice from carrier advisory committees and discussions. There is also a provision under the MMA of 2003 (169) which requires the CMS to develop a plan to evaluate new LCDs to decide which local decisions should be adopted nationally.

The overall NCDs are very effective as the services are eliminated if they are not covered under an NCD; however, the effectiveness of LCDs has been questioned.

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Conflict of Interest:

Dr. Falco is a consultant for St. Jude Medical Inc. and Joimax Inc.

Dr. Benyamin is a consultant with Bioness and Nevro; serves on the advisory boards of Vertos Medical and Nuvo Pharma; teaches/lectures for Vertos Medical, Boston Scientific, Neurotherm, and Bioness; and receives research/grants from Alfred Mann Foundation, Teknon Foundation, Spinal Restoration, Inc., Bioness, Boston Scientific, Vertos Medical, Medtronic, Kimberly Clarke, Epimed, BioDelivery Sciences International, Inc., Theravance, Mundipharma Research, Cephalon/Teva, AstraZeneca, and Purdue Pharma, LP.

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