Health Policy Review

Accountable Interventional Pain Management: A Collaboration Among Practitioners, Patients, Payers, and Government

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Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of interest: Dr. Helm is a clinical investigator with Epimed and receives research support from Cephalon/Teva, AstraZeneca, and Purdue Pharma, LP. He has attended an advisory group meeting for Activas.

Manuscript received: 10-01-2013
Accepted for publication: 11-11-2013

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The prevalence, costs, and disability associated with chronic pain continue to escalate. So too, the numerous modalities of treatments applied in managing these patients continue to increase as well. In the period from 2000 to 2011 interventional techniques increased 228%. In addition, analysis of utilization trends and expenditures for spinal interventional techniques alone from 2000 to 2008 illustrated an increase in Medicare fee-for-service expenditures of 240% in terms of dollars spent in the United States. The Office of Inspector General (OIG) of the Department of Health and Human Services showed an increase in facet joint and transforaminal epidural injections, with a significant proportion of these services did not meet the medical necessity criteria.

The increasing utilization of interventional techniques is also associated with significant variations among specialty groups and regional variations among states. Overall procedures have increased by 173%, with rate of 130% per 100,000 Medicare beneficiaries for epidural injections; 383%, with a rate of 308% for facet joint interventions; and overall 410%, or a rate of 331% for sacroiliac joint interventions. Certain high volume interventions such as lumbar transforaminal epidural injections and lumbar facet joint neurolysis have actually increased a staggering 806% and 662%.

Coverage policies across ambulatory settings and by multiple payers are highly variable. Apart from variability in the development of coverage policies, payments also substantially vary by site of service. In general, amongst the various ambulatory settings the highest payments are made to hospital outpatient departments (HOPDs) the lowest to in-office procedures, and payment to ambulatory surgery centers (ASCs) falling somewhere in the middle.

This manuscript describes the many differences that exist between the various settings, and includes suggestions for accountable interventional pain management with coverage for techniques with evidence, addressing excessive use of specific techniques, and equalizing payments across multiple ambulatory settings.

Key words: Accountable interventional pain management, Medicare, Medicare Evidence Development & Coverage Advisory Committee, epidural injections, facet joint interventions, sacroiliac joint injections, payment policies

Pain Physician 2013; 16:E635-E670

The economic impact and growing prevalence of chronic pain, specifically spinal pain is substantial, not only in the United States, but across the globe (1-14). In 2010, 3 of the five disorders that contributed most years lived with disability were related to chronic pain including low back pain, other musculoskeletal disorders and neck pain. The costs of managing spinal pain are exploding and various interventions range from simple instructions for exercises to complex fusions (15-46). Despite the

increasing costs and modalities, disability continues to rise (15-46). Consequently, spinal interventional techniques are one of the prominent and extensively used interventions even though surgical interventions continue to be the most expensive interventions (41-43,47-49). The focus of this manuscript is interventional techniques.

An assessment of the utilization of interventional techniques in managing chronic pain in the Medicare population in the fee-for-service sector showed an overall increase of 228% and 177% per 100,000 Medicare beneficiaries from 2000 to 2011 (42). The analysis of utilization trends and expenditures for spinal interventional techniques alone (41) from 2000 to 2008 illustrated Medicare fee-for-service expenditures in 2000 were $362,347,025, which increased to $1,231,180,420 in 2008, a 240% increase, in contrast to the increase in prevalence of procedures which increased 228.6%. This analysis showed an increase in per patient cost as well as per procedure cost. Per patient cost increased from $833.17 in 2000 to $1,188.93 in 2008, a 43% increase; whereas the per visit cost increased from $409.91 to $526.12, a 28% increase; however, per procedure increases were minimal with 3% from $300.07 to $310.26. Per patient costs increased the highest in hospital outpatient departments (HOPDs) from $718.81 to $1,354.95, an increase of 88%, whereas, per visit increased 83%, from $369.15 to $675.46, and per procedure increased 63%, from $278.13 to $452.25. In contrast, ambulatory surgery center (ASC) costs decreased per patient by 5% to 25%, and in-office procedures showed decreases per procedure from $236.08 to $194.28, an 18% decrease, while per patient expenditures increased 19%, and per visit expenditures increased 6%.

Similarly, the Office of Inspector General (OIG) of the Department of Health and Human Services (49,50) showed an increase of Medicare payments for facet joint injections from $141 million in 2003 to $307 million in 2006 and for transforaminal epidural injections from $57 million in 2003 to $141 million in 2007.

Interventional pain management is narrowly defined by the National Uniform Claims Committee (NUCC) 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 (51). The Medicare Payment Advisory Commission (MedPAC) defined interventional techniques as being limited to minimally invasive procedures including: percutaneous precision needle placement, with the 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 (52). In addition, interventional pain management also has been designated with a separate practice expense which is different from the primary specialties of anesthesiology, physiatry, neurology, and psychiatry (53), and which highlights rapidly increasing expenses for this emerging and growing specialty (54,55).

In reference to chronic pain, the Institute of Medicine (IOM) (1) , based on a study by Gaskin and Richard (2) reported that more than 100 million Americans are afflicted with pain that persists for weeks to years, with financial costs ranging from $560 billion to $630 billion per year. Among these projected costs, however, approximately $100 billion are attributed to moderate and severe pain, with the remaining expenses attributed to joint pain, arthritis, and functional disability, etc. Martin et al (13,14), in an evaluation of the health care expenditures in the United States in 2005 for treating back and neck problems, found that these expenditures totaled approximately $86 billion, with an increase of 65% between 1997 and 2005 and an increase of 49% in the number of patients seeking spine-related care. Apart from interventional techniques, there continues to be enormous costs and disability associated with chronic pain including reduced functioning, overuse of opioids, and related fatalities (7-15). Not surprisingly, the United States continues to perform more interventions and spends more per capita on health care than any other country (3,56-60).The diagnosis, identification and prevalence of chronic pain continue to increase (3-6). Most importantly, Freburger et al (4), during an evaluation in North Carolina, showed significant increases in low back pain prevalence from 3.9% in 1992 to 10.2% in 2006, a 162% increase over this period.

As it is discussed on a daily basis, not only are U.S. health care costs high, they pose a growing burden on families and businesses and a threat to the fiscal stability of the government (61,62). The Patient Protection and Affordable Care Act (ACA), also known as Obamacare, expands eligibility for Medicaid, creates new subsidies for coverage for large numbers of the uninsured, and changes the terms under which insurance can be sold to persons in the non-group market (61,63,64). Obam-

acare also contains roughly 165 provisions that affect the Medicare program by reducing costs, improving benefits, combatting fraud and abuse, and initiating a major program of research and development to identify alternative provider payment mechanisms, health care delivery systems, and other changes intended to improve the quality of health care and reduce costs (65,66). Much of the federal spending amount of $1.2 trillion through 2012 is offset primarily through reductions in Medicare provider payments (67). However, the trustees of Medicare are skeptical in reference to the ability to achieve productivity improvements at a faster rate than experienced historically (65). Because of a possible failure to transition by the health care sector to a more efficient model of care delivery and achieve productivity increases that are commensurate with economy-wide productivity, the financial outlook for Medicare is uncertain. Some provisions of the current law that are designed to reduce expenditures may in fact be difficult to sustain. Multiple proposals for re-engineering U.S. health care (68) and a bridging of the divide between health and health care delivery (69) go beyond what is included in the ACA. These changes include multiple recommendations by MedPAC (70). However, since Medicare has become a standard and in spite of being larger than any other insurance (provider) is still expanding, all other payers, specifically Medicaid with its expansion, base their decisions on the policies of Medicare. However, Medicaid and other payers also have other options to reduce expenses, which may result in reduced coverage and access beyond the principles applied by Medicare.

Medicare presented its report to Congress (70) to align Medicare payments in ambulatory settings with achievable savings of approximately $4 billion per year. Interventional techniques are a part of the reform recommended by MedPAC.

Multiple measures are applied by insurers and various governmental agencies across the globe to get a handle on exploding health care costs, specifically costs of chronic pain management with a focus on interventional techniques, essentially involving the patients and providers in shared decision-making and value-based interventional pain management (56). As an emerging specialty, interventional pain management encounters multiple problems of disproportionate magnitude compared to established medical specialties and it is difficult to assess for payers and regulators the appropriateness of interventional techniques in managing chronic pain. This review is undertaken to provide a broad overview of accountable, interventional pain management in general, and spinal interventional techniques in particular.

1.0 Interventional Techniques

The increasing utilization of interventional techniques has been criticized as inappropriate, despite significant advances illustrating the clinical and cost effectiveness of interventional techniques when appropriately performed with the establishment of multiple randomized trials, systematic reviews, and guidelines (12,41-43,56,71-100). Furthermore, the available evidence documents a wide range of variations in the definition of the practice of medicine in general and interventional pain management in particular (1-3,56). There is growing evidence of a disproportionate increase in interventional techniques as compared to other interventions. However, specific patterns of increases have been under appreciated (41,43).

Overall, there have been significant variations and increases in procedures with geographic and specialty variations as illustrated in Tables 1 – 4 and Figures 1 and 2.

Further analysis of various spinal interventional techniques shows interesting trends (101-103). The evidence indicates that there has been an overall, the increase in interventions of 177% per 100,000 Medicare fee-for-service population with the highest increases seen for sacroiliac joint injections at 331% (103), facet joint interventions at 308% (102), epidurals at 130% (101). The data also shows how certain specialties have increased their utilization compared to others.

1.1 Epidural Injections

Epidural injections are the most commonly performed procedures in interventional pain management, comprising 46% of all interventional techniques excluding implantables, trigger point injections, intraarticular injections, and vertebral augmentation procedures in 2011.

As shown in Table 5, epidural injections showed an overall increase of 173% or 130% per 100,000 Medicare beneficiaries with an annual increase of 9.5% or 7.5% from 2000 to 2011 (101). The most commonly performed procedures, CPT 62311 lumbosacral interlaminar or caudal epidural injections have increased 25% during this same period, with an annual increase of 2%, increasing from 1,560 per 100,000 Medicare beneficiaries in 2000 to 1,949 in 2011 (101). Cervical and thoracic interlaminar epidural injections also in-

Table 1. *Summary of the frequency of utilization of various categories of interventional procedures in the Medicare population from 2000 to 2011.*

	Epidural and adhesiolysis procedures		Facet joint interventions and SI joint blocks		Disc Procedures (discography & disc decompression)		Other types of nerve blocks		Total*	
	Services	Rate	Services	Rate	Services	Rate	Services	Rate	Services	Rate
2000	860,787 (79%)	*2,172*	424,796 (67%)	*1,072*	14,983 (87%)	*38*	168,929 (42%)	*426*	1,469,495 (72%)	*3,708*
2001	1,013,552 (78%)	*2,531*	543,509 (62%)	*1,357*	17,229 (87%)	*43*	186,166 (38%)	*465*	1,760,456 (69%)	*4,396*
2002	1,199,324 (74%)	*2,961*	708,186 (58%)	*1,748*	20,194 (81%)	*50*	255,348 (30%)	*630*	2,183,052 (64%)	*5,390*
2003	1,370,862 (71%)	*3,333*	884,035 (53%)	*2,150*	24,362 (80%)	*59*	280,064 (27%)	*681*	2,559,323 (60%)	*6,223*
2004	1,637,494 (65%)	*3,924*	1,354,242 (46%)	*3,245*	24,263 (79%)	*58*	319,048 (26%)	*765*	3,335,047 (54%)	*7,992*
2005	1,776,153 (65%)	*4,180*	1,501,222 (47%)	*3,533*	27,950 (78%)	*66*	355,374 (26%)	*836*	3,660,699 (54%)	*8,614*
2006	1,870,440 (63%)	*4,316*	1,896,688 (40%)	*4,376*	27,432 (75%)	*63*	351,564 (26%)	*811*	4,146,124 (49%)	*9,567*
2007	1,940,454 (62%)	*4,384*	1,820,695 (46%)	*4,113*	25,688 (73%)	*58*	324,290 (30%)	*733*	4,111,127 (52%)	*9,288*
2008	2,041,155 (61%)	*4,495*	1,974,999 (46%)	*4,349*	27,735 (70%)	*61*	389,522 (29%)	*858*	4,433,411 (51%)	9,763
2009	2,136,035 (59%)	*4,664*	2,111,700 (46%)	*4,611*	25,929 (69%)	*57*	372,015 (67%)	*812*	4,645,679 (49%)	*10,143*
2010	2,226,486 (57%)	*4,746*	1,937,582 (48%)	*4,130*	22,003 (62%)	*47*	392,906 (34%)	*838*	4,578,977 (52%)	*9,760*
2011	2,309,906 (58%)	*4,923*	2,064,227 (50%)	*4,400*	19,104 (61%)	*41*	422,436 (66%)	*900*	4,815,673 (48%)	*10,264*
Overall Change	168%	*127%*	386%	*310%*	28%	*8%*	150%	*111%*	228%	*177%*
Annaul Change	9.40%	*7.7%*	15.50%	*13.7%*	2.20%	*0.7%*	8.7%	*7.0%*	11.4%	*9.7%*

Rate - IPM services per 100,000 Medicare Beneficiaries
( )facility percentage
*(Excluding continuous epidurals, intraarticular injections, trigger point and ligament injections, peripheral nerve blocks, vertebral augmentation procedures, and implantables)

creased substantially from 2000 to 2011 by 123% per 100,000 Medicare fee-for-service beneficiaries, with an annual increase rate of 7.6% (101). The startling statistics are related to cervical and thoracic transforaminal epidural injections (CPT 64479 and CPT 64480) with an increase rate of 142%, with an annual increase of 8.4% (101). Major fatalities have been described with transforaminal epidural injections, specifically with cervical and thoracic transforaminal epidural injections, without increased clinical effectiveness (78,79,104-132). Despite the fact that many physicians have ceased providing these procedures and basically no existing evidence either for their diagnostic or therapeutic purposes, the overall number of procedures performed continues to increase. Above all, it is even more striking and disconcerting that lumbosacral transforaminal epidurals (CPT 64483 and CPT 64484) have increased at a rate of 665% (overall 806%), with an annual rate of 22.2% or 20.3%, increasing from 309 to 2,364 from 2000 to 2011, exceeding CPT 62311 with 1,949 per 100,000 Medicare beneficiaries in 2011 (101). Thus, lumbar transforaminals and other explosively increasing procedures, namely lumbar radiofrequency with a rate of 544% or overall 662% increase

Table 2. *Frequency of utilization of interventional pain management techniques from 2000 to 2011, in Medicare recipients.*

Specialty	Interventional Pain Management (interventional pain management, pain medicine, anesthesiology, physiatry, neurology, and psychiatry)		Surgical (neuro & orthopedic)		Radiology (interventional & diagnostic)		Other Physicians		Other Providers (CRNA, NP & PA)		Total	
	Services	Rate	Services	Rate	Services	Rate	Services	Rate	Services	Rate	Services*	Rate
2000	1,176,541 (80.1%)	2,969	84,392 (5.7%)	213	40,491 (2.8%)	102	152,834 (10.4%)	386	15,237 (1.0%)	38	1,469,495	3,708
2001	1,389,569 (78.9%)	3,470	98,037 (5.6%)	245	48,978 (2.8%)	122	203,348 (11.6%)	508	20,524 (1.2%)	51	1,760,456	4,396
2002	1,755,521 (80.4%)	4,334	115,497 (5.3%)	285	62,295 (2.9%)	154	226,776 (10.4%)	560	22,963 (1.1%)	57	2,183,052	5,390
2003	2,098,053 (82.0%)	5,102	126,040 (4.9%)	306	77,160 (3.0%)	188	236,135 (9.2%)	574	21,935 (0.9%)	53	2,559,323	6,223
2004	2,718,622 (81.5%)	6,515	160,035 (4.8%)	384	91,892 (2.8%)	220	338,339 (10.1%)	811	26,519 (0.8%)	64	3,335,047	7,992
2005	2,976,908 (81.3%)	7,005	174,261 (4.8%)	410	101,586 (2.8%)	239	377,014 (10.3%)	887	30,930 (0.8%)	73	3,660,699	8,614
2006	3,196,190 (77.1%)	7,375	192,971 (4.7%)	445	110,472 (2.7%)	255	608,444 (14.7%)	1,404	38,047 (0.9%)	88	4,146,124	9,567
2007	3,405,892 (82.8%)	7,695	205,178 (5.0%)	464	111,423 (2.7%)	252	349,013 (8.5%)	788	39,621 (1.0%)	90	4,111,127	9,288
2008	3,670,828 (82.8%)	8,083	232,405 (5.2%)	512	117,388 (2.6%)	258	369,597 (8.3%)	814	43,193 (1.0%)	95	4,433,411	9,763
2009	3,879,520 (83.5%)	8,470	262,496 (5.7%)	573	123,228 (2.7%)	269	335,669 (7.2%)	733	44,766 (1.0%)	98	4,645,679	10,143
2010	3,917,426 (85.6%)	8,350	213,844 (4.7%)	456	121,127 (2.6%)	258	274,711 (6.0%)	586	51,869 (1.1%)	111	4,578,977	9,760
2011	4,159,585 (86.4%)	8,866	197,624 (4.1%)	421	127,614 (2.6%)	272	268,358 (5.6%)	572	62,492 (1.3%)	133	4,815,673	10,264
Overall Change	254%	199%	134%	98%	215%	166%	76%	48%	310%	246%	228%	177%
Annual change	12.2%	10.5%	8.0%	6.4%	11.0%	9.3%	5.3%	3.6%	13.7%	12.0%	11.4%	9.7%

Rate - IPM services per 100,000 Medicare Beneficiaries
( )percentage of row total
*(Excluding continuous epidurals, intraarticular injections, trigger point and ligament injections, peripheral nerve blocks, vertebral augmentation procedures, and implantables)

(102) and lumbar facet joint injections with 228% (102), have increased and overtaken most commonly performed procedures CPT 62311. Some of the reasons include that transforaminal epidural injections have been promoted as target specific interventions and more effective than caudal or interlaminar epidural injections, despite the lack of proven evidence (12,77-79,81-84).Occasional fatal complications related to

Table 3. *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	Overall Change	Average Change
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%
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%

Table 3 (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	Overall Change	Average Change
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.

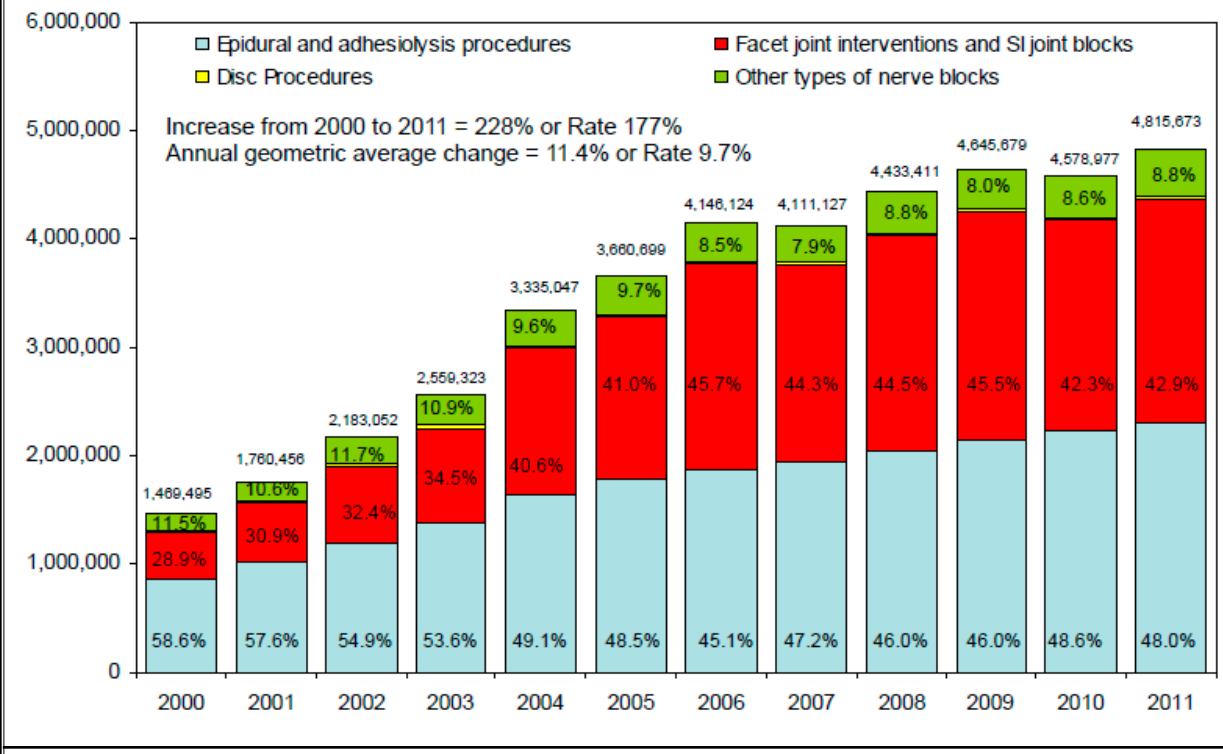


Fig. 1. *Illustration of distribution of procedural characteristics by type of procedures from 2000 to 2011.*

lumbar transforaminal epidural injections have been ignored (12,109-111,113-116,125-128). Despite warnings and recommendations highlighted in the OIG report (50), transforaminal epidural injections continue to increase substantially. Thus, the OIG report (50) did not, have any effect on the utilization patterns, appropriateness of indications and medical necessity for lumbar transforaminal epidural injections.

In addition, these analyses (41,42,56,101) also showed significant variations based on states and specialties as shown in Tables 6 and 7. As shown in Table 6, significant variations were noted with increases of over 5% in Michigan, Arizona, New Hampshire, and the District of Columbia annually from 2008 to 2010. However, while the majority of the states showed small increases, some states including Alabama, Nebraska, Wyoming,

Table 4. *Frequency of utilization of interventional pain management techniques from 2000 to 2011, in Medicare recipients.*

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
01 - Anesthesiology	1,011,773	1,191,891	1,277,160	1,331,136	1,366,464	1,502,779	1,518,295	1,518,326	1,521,678	1,563,161	1,432,130	1,406,632
02 - Interventional Pain Management	-	-	-	89,631	360,217	394,987	500,776	732,563	998,062	1,148,080	1,214,619	1,311,404
03 - Pain Management	-	4,890	197,670	310,634	489,038	534,963	561,862	472,778	388,065	335,436	413,976	533,757
04 - Physical Medicine and Rehabilitation	104,894	123,087	183,630	245,944	374,572	404,111	465,509	523,334	600,757	665,273	690,303	740,661
05 - Neurology	57,476	66,782	91,607	116,056	124,025	135,041	142,995	150,991	155,404	161,273	160,160	160,910
06 - Psychiatry	2,398	2,918	5,454	4,652	4,306	5,027	6,753	7,900	6,862	6,297	6,238	6,221
Interventional Pain Management	**1,176,541**	**1,389,569**	**1,755,521**	**2,098,053**	**2,718,622**	**2,976,908**	**3,196,190**	**3,405,892**	**3,670,828**	**3,879,520**	**3,917,426**	**4,159,585**
Percent	80.1%	78.9%	80.4%	82.0%	81.5%	81.3%	77.1%	82.8%	82.8%	83.5%	85.6%	86.4%
Rate	2,969	3,470	4,334	5,102	6,515	7,005	7,375	7,695	8,083	8,470	8,350	8,866
07 - Neurosurgery	21,539	24,516	32,126	31,421	43,467	48,219	55,752	60,424	78,021	103,286	63,410	46,481
08 - Orthopedic Surgery	62,853	73,521	83,371	94,619	116,568	126,042	137,219	144,754	154,384	159,210	150,434	151,143
Surgery	84,392	98,037	115,497	126,040	160,035	174,261	192,971	205,178	232,405	262,496	213,844	197,624
Percent	5.7%	5.6%	5.3%	4.9%	4.8%	4.8%	4.7%	5.0%	5.2%	5.7%	4.7%	4.1%
Rate	213	245	285	306	384	410	445	464	512	573	456	421
14 - Interventional Radiology	3,590	3,518	4,058	4,948	5,460	6,352	7,721	9,581	12,278	15,571	13,404	11,091
15 - Diagnostic Radiology	36,901	45,460	58,237	72,212	86,432	95,234	102,751	101,842	105,110	107,657	107,723	116,523
Radiology	**40,491**	**48,978**	**62,295**	**77,160**	**91,892**	**101,586**	**110,472**	**111,423**	**117,388**	**123,228**	**121,127**	**127,614**
Percent	2.8%	2.8%	2.9%	3.0%	2.8%	2.8%	2.7%	2.7%	2.6%	2.7%	2.6%	2.6%
Rate	102	122	154	188	220	239	255	252	258	269	258	272
09 - Family Practice	16,619	20,121	28,228	31,950	47,025	53,016	102,912	60,795	56,709	67,142	63,966	67,879
10 - General Practice	18,226	17,555	16,613	21,173	32,690	36,937	149,839	35,848	23,427	22,761	22,198	20,338
11 - Internal Medicine	22,714	25,345	30,112	34,710	64,407	70,244	129,329	69,365	85,723	93,238	68,455	64,445
12 - Rheumatology	29,777	34,473	35,916	33,965	36,739	41,467	42,419	42,779	36,614	27,900	20,935	20,106
13 - Osteopathic Manipulative Therapy	1,865	4,196	5,392	6,271	7,089	8,428	10,612	12,098	9,782	8,024	6,716	5,721
16 - Emergency Medicine	2,812	5,274	5,682	9,777	9,079	10,330	22,516	16,888	11,109	11,415	11,213	11,921
17 - General Surgery	7,734	7,038	7,906	7,125	8,634	9,711	18,609	25,992	14,720	10,940	8,940	9,181
Others	53,087	89,347	96,927	91,164	132,676	146,881	132,208	85,248	131,513	94,249	72,288	68,767
Other Physicians	**152,834**	**203,348**	**226,776**	**236,135**	**338,339**	**377,014**	**608,444**	**349,013**	**369,597**	**335,669**	**274,711**	**268,358**
Percent	10.4%	11.6%	10.4%	9.2%	10.1%	10.3%	14.7%	8.5%	8.3%	7.2%	6.0%	5.6%
Rate	386	508	560	574	811	887	1,404	788	814	733	586	572

Table 4 (cont.). *Frequency of utilization of interventional pain management techniques from 2000 to 2011, in Medicare recipients.*

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
18 - CRNA	14,656	18,667	19,272	16,690	15,953	18,747	19,945	19,348	19,712	20,318	21,936	20,700
19 - NP	362	907	1,765	2,529	5,508	6,257	10,240	10,452	14,585	15,205	18,957	28,117
20 - PA	219	950	1,926	2,716	5,058	5,926	7,862	9,821	8,896	9,243	10,976	13,675
CRNA, NP & PA	**15,237**	**20,524**	**22,963**	**21,935**	**26,519**	**30,930**	**38,047**	**39,621**	**43,193**	**44,766**	**51,869**	**62,492**
Percent	1.0%	1.2%	1.1%	0.9%	0.8%	0.8%	0.9%	1.0%	1.0%	1.0%	1.1%	1.3%
Rate	38	51	57	53	64	73	88	90	95	98	111	133
Total	1,469,495	1,760,456	2,183,052	2,559,323	3,335,047	3,660,699	4,146,124	4,111,127	4,433,411	4,645,679	4,578,977	4,815,673
Rate	3708	4396	5390	6223	7992	8614	9567	9288	9763	10143	9760	10264

Rate - IPM services per 100,000 Medicare beneficiaries
( ) percentage of row total
* (Excluding continuous epidurals, intraarticular injections, trigger point and ligament injections, peripheral nerve blocks, vertebral augmentation procedures, and implantables)
CRNA = certified registered nurse anesthetist
NP = nurse practitioner
PA = physician assistant

and Rhode Island showed significant annual decreases of more than 3% from 2008 to 2010.

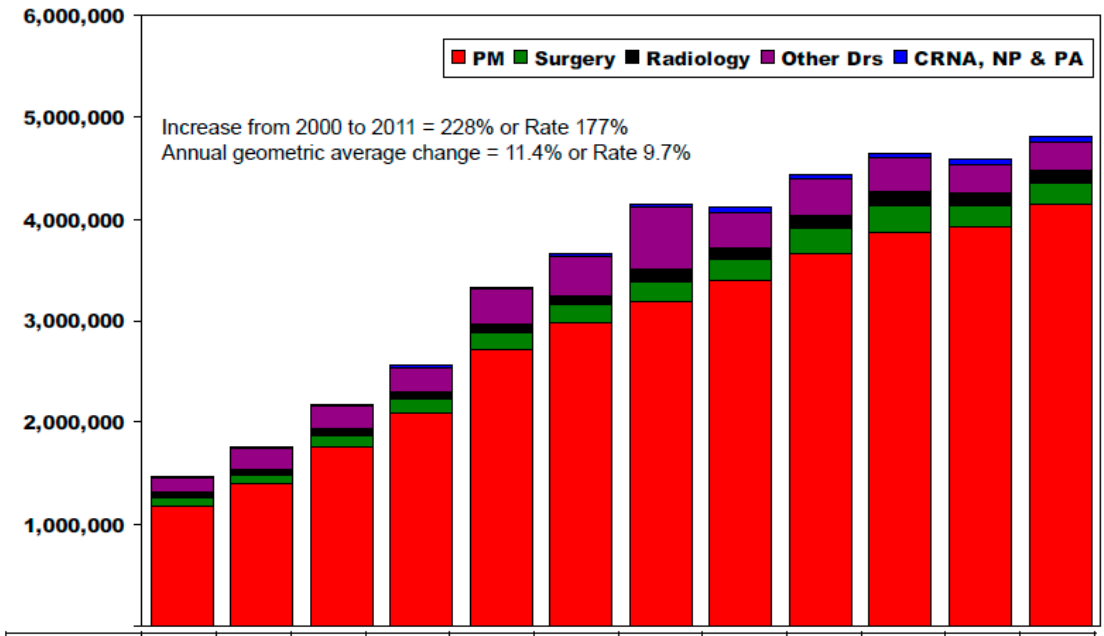
As shown in Table 7 with reference to the frequency of utilization, based on specialties, significant increases were noted, such as 634% from 2000 to 2011 and an annual increase of 19.9% for the physical medicine and rehabilitation specialty, even though many of these physicians have enrolled in interventional pain management and pain medicine. The anesthesiology specialty, however, still continues to dominate with a total proportion of procedures of 31% in 2011, and a total of increase of 13%, again despite the enrollment of physicians practicing pain management in the specialties of interventional pain management and pain medicine. Overall, the radiology specialty also increased their utilization by 284% total and 13% annually from 2000 to 2011; however, their numbers constituted only 3.8% of all the procedures in 2011.

1.2 Facet Joint Interventions

Facet joint interventions as a category are the second most commonly performed procedures constituting 38% of all interventional techniques in 2011, excluding implantables, trigger point injections, intraarticular injections, vertebral augmentation procedures. Variations for facet joint interventions based on utilization patterns, regional, and specialty variations are even more common.

As shown in Table 8, the overall increase in facet joint interventions was 383% at a rate of 308% and an annual increase of 13.6% from 2000 to 2011 per 100,000 Medicare beneficiaries in fee-for-service recipients. All types of facet joint interventions increased at an unsustainable growth rate, starting with lumbosacral facet joint blocks at the minimum of 289%, with an annual increase of 13.1%; followed by cervical and thoracic facet joint blocks with 444%, and an annual rate of 16.6%; leading to lumbosacral facet neurolysis with an explosive increase of 544%, and an annual increase of 18.4% (with a large number of services), and surprisingly an even higher growth rate for cervical/thoracic facet neurolysis with 836% or an annual growth of 22.5% (with a smaller number of services). Lumbosacral facet joint blocks still continue to exceed all other facet joint interventions (55% of total facet joint procedures in 2011). However, lumbosacral facet joint neurolysis procedures that were performed at a rate of 135 in 2000 have increased to 866 in 2011 occupying 22.5% of total procedures in 2011. Cervical/thoracic facet neurolysis increased by 836%, from 22 in 2000 to 208 per 100,000 Medicare beneficiaries in 2011.

There have been substantial variations among the utilization patterns by state and based on specialties. As



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 speciality from 2000 to 2011, in Medicare recipients.*

Table 5. *Utilization of epidural injections in the Medicare population from 2000 to 2011.*

Year	Interlaminar Epidurals				Transforaminal Epidurals								Total Epidural Injections	
					Cervical/Thoracic				Lumbar/Sacral					
	Cervical/Thoracic CPT 62310		Lumbar/Sacral CPT 62311		CPT 64479	CPT 64480	Total		CPT 64483	CPT 64484	Total			
	Services	Rate	Services	Rate	Services	Services	Services	Rate	Services	Services	Services	Rate	Services	Rate
2000	75,741	191	618,362	1,560	13,454	9,434	22,888	58	85,006	37,477	122,483	309	839,474	2,118
2001	84,385	211	702,713	1,755	14,732	8,537	23,269	58	125,534	53,133	178,667	446	989,034	2,470
2002	99117	245	786919	1,943	18583	10835	29,418	73	177679	79115	256,794	634	1,172,248	2,894
2003	109783	267	838858	2,040	21882	15769	37,651	92	242491	114046	356,537	867	1,342,829	3,265
2004	130,649	313	878,174	2,104	25,182	18,094	43,276	104	363,744	196,044	559,788	1,341	1,611,887	3,863
2005	141,652	333	945,350	2,225	27,844	20,525	48,369	114	395,508	216,892	612,400	1,441	1,747,771	4,113
2006	146,748	339	946,961	2,185	29,822	23,073	52,895	122	452,125	245,453	697,578	1,610	1,844,182	4,255
2007	156,415	353	926,029	2,092	29,938	22,266	52,204	118	506,274	274,305	780,579	1,764	1,915,227	4,327
2008	165,636	365	905,419	1,994	32,286	24,003	56,289	124	572,340	317,448	889,788	1,959	2,017,132	4,442
2009	175,503	383	888,166	1,939	37,012	27,487	64,499	141	632,658	351,685	984,343	2,149	2,112,511	4,612
2010	184,750	394	888,421	1,894	40,003	29,888	69,891	149	679,117	383,128	1,062,245	2,264	2,205,307	4,701
2011	200,134	427	914,324	1,949	38,970	26,628	65,598	140	710,638	398,519	1,109,157	2,364	2,289,213	4,879
Overall Change														
	164%	123%	48%	25%	190%	182%	187%	142%	736%	963%	806%	665%	173%	130%
Annual Change														
	9.2%	7.6%	3.6%	2.0%	10.2%	9.9%	10.0%	8.4%	21.3%	24.0%	22.2%	20.3%	9.5%	7.5%

Rate - Per 100,000 Medicare Beneficiaries

Table 6. *Illustration of epidural injections performed (claims data) in each state with claims data from 2008 to 2010, in Medicare recipients, based on utilization patterns, in alphabetical order.*

	Services					Rate per 100,000 Medicare Beneficiaries				
State	2008	2009	2010	Overall Change	Annual Change	2008	2009	2010	Overall Change	Annual Change
Alabama	55,577	53,873	53,297	-4%	-1.4%	6,868	6,510	6,305	-8%	-3%
Alaska	1,648	1,779	1,956	19%	5.9%	2,757	2,837	2,978	8%	3%
Arizona	40,666	44,249	49,704	22%	6.9%	4,676	4,919	5,343	14%	5%
Arkansas	21,476	22,526	22,922	7%	2.2%	4,221	4,329	4,313	2%	1%
California	152,011	158,595	174,349	15%	4.7%	3,384	3,433	3,665	8%	3%
Colorado	23,966	25,162	27,204	14%	4.3%	4,137	4,180	4,354	5%	2%
Connecticut	18,018	18,836	19,544	8%	2.7%	3,284	3,375	3,444	5%	2%
DC	20,014	21,632	24,211	21%	6.6%	26,641	28,206	30,987	16%	5%
Delaware	7,329	7301	8,058	10%	3.2%	5,195	5,033	5,398	4%	1%
Florida	201,171	194,604	195,475	-3%	-1.0%	6,263	5,917	5,793	-8%	-3%
Georgia	68,942	76,431	75,633	10%	3.1%	5,982	6,402	6,121	2%	1%
Hawaii/Guam *	1,561	1,681	2,339	–	–	804	839	1,133	–	–
Idaho	9,439	9,361	9,192	-3%	-0.9%	4,406	4,217	4,000	-9%	-3%
Illinois	78,063	83,272	90,979	17%	5.2%	4,399	4,610	4,946	12%	4%
Indiana	52,135	53,012	54,422	4%	1.4%	5,407	5,381	5,411	0%	0%
Iowa	18,234	18,103	18,198	0%	-0.1%	3,602	3,538	3,517	-2%	-1%
Kansas	27,008	27,058	28,637	6%	2.0%	6,461	6360	6,617	2%	1%
Kentucky	32,697	33,726	36,171	11%	3.4%	4,490	4,537	4,760	6%	2%
Louisiana	34,861	41,842	41,947	9%	2.9%	5,859	6,233	6,108	4%	1%
Maine	8,405	8,665	8,664	3%	1.0%	3,320	3,344	3,271	-1%	0%
Maryland	28,925	31,110	32,696	13%	4.2%	3,885	4,071	4,166	7%	2%
Massachusetts	32,463	34,758	37,148	14%	4.6%	3,187	3,344	3,501	10%	3%
Michigan	76,498	84,431	103,458	35%	10.6%	4,843	5,230	6,266	29%	9%
Minnesota	19,383	20,031	19,851	2%	0.8%	2,588	2,612	2,526	-2%	-1%
Mississippi	25,334	28,065	29,538	17%	5.3%	5,286	5,751	5,941	12%	4%
Missouri	59,547	64,045	66,245	11%	3.6%	6,164	6,500	6,596	7%	2%
Montana	6,448	6,633	6,469	0%	0.1%	4,019	4,029	3,816	-5%	-2%
Nebraska	12,395	12,518	12,236	-1%	-0.4%	4,568	4,542	4,385	-4%	-1%
Nevada	16,447	18,059	19,423	18%	5.7%	4,984	5,265	5,446	9%	3%
New Hampshire	8,838	10,005	11,162	26%	8.1%	4,176	4,603	5,000	20%	6%
New Jersey	51,144	52,646	54,839	7%	2.4%	3,987	4,036	4,133	4%	1%
New Mexico	8,463	8,956	9,738	15%	4.8%	2,876	2,948	3,107	8%	3%
New York	81,344	86,042	89,030	9%	3.1%	2,814	2,930	2,979	6%	2%
North Carolina	70,143	74,156	77,550	11%	3.4%	4,993	5,121	5,205	4%	1%
North Dakota	5,504	5,639	5,537	1%	0.2%	5,160	5,221	5,066	-2%	-1%
Ohio	78,533	83,862	81,001	3%	1.0%	4,266	4,484	4,262	0%	0%
Oklahoma	29,056	31,026	32,236	11%	3.5%	5,023	5,243	5,342	6%	2%
Oregon	11,653	12,370	12,459	7%	2.3%	1,995	2,054	2,006	1%	0%
Pennsylvania	75,599	75,415	82,985	10%	3.2%	3,403	3,349	3,635	7%	2%
Rhode Island	7,059	4,733	5,777	-18%	-6.5%	3,969	2,626	3,157	-20%	-7%
South Carolina	69,074	73,648	76,625	11%	3.5%	9,544	9,837	9,904	4%	1%
South Dakota	5,746	6,456	6,342	10%	3.3%	4,352	4,801	4,644	7%	2%

Table 6 (cont.). *Illustration of epidural injections performed (claims data) in each state with claims data from 2008 to 2010, in Medicare recipients, based on utilization patterns, in alphabetical order.*

	Services					Rate per 100,000 Medicare Beneficiaries				
State	2008	2009	2010	Overall Change	Annual Change	2008	2009	2010	Overall Change	Annual Change
Tennessee	45,312	47,027	44,480	-2%	-0.6%	4,512	4,560	4,205	-7%	-2%
Texas	188,029	204,170	208,216	11%	3.5%	6,711	7,041	6,938	3%	1%
Utah	13,268	14,062	14,888	12%	3.9%	5,024	5,135	5,260	5%	2%
Vermont	2,989	3,157	3,001	0%	0.1%	2,849	2,925	2,691	-6%	-2%
Virginia	37,262	40,357	40,648	9%	2.9%	3,455	3,636	3,564	3%	1%
Washington	28,010	28,688	30,354	8%	2.7%	3,101	3,058	3,122	1%	0%
West Virginia	8,104	8,392	8,635	7%	2.1%	2,173	2,225	2,262	4%	1%
Wisconsin	34,718	34,826	34,089	-2%	-0.6%	3,973	3,905	3,742	-6%	-2%
Wyoming	3,023	2,848	2,943	-3%	-0.9%	3,971	3,641	3,675	-7%	-3%
Medicare Total	2,017,132	2,112,511	2,205,307	9%	3.0%	4,442	4,612	4,700	6%	2%

Rate - Per 100,000 Medicare Beneficiaries

shown in Table 9, there was an overall annual decrease of 2% from 2008 to 2010; however, some states showed over 6% in annual increases, and as high as 12% in Idaho and Wyoming, 10% in Arizona and Alabama, 9% in Nevada, 8% in West Virginia, and 7% in New Hampshire and Massachusetts. Numerous other states have also shown significant decreases, such as Rhode Island which decreased by 13%, 12% in Delaware, 9% in Montana, 8% in South Dakota and Florida, 7% in Michigan and Texas, 6% in Illinois, and 5% in Pennsylvania, Maryland and Alaska.

The majority of increases were seen in the specialty of interventional pain management, including anesthesiology, interventional pain management, pain management, physical medicine and rehabilitation, neurology, and psychiatry (Table 10). Among these, physical medicine and rehabilitation showed a 781% overall change and an annual change of 21.9%, despite a number of physicians changing their specialty to interventional pain management or pain management. Physiatrists also performed a substantial proportion of procedures with 14.6% in 2011 with many of them enrolled in specialties of pain management and interventional pain management; whereas, in 2000, they performed 8% of procedures without the existence of the specialty of interventional pain management and pain management. Psychiatry also showed a 247% overall increase with an annual increase of 12%, whereas neurology showed an increase of 155%; however, the numbers for psychiatrists were very small with 1,900 per 100,000 Medicare population in 2011 compared to 547 in 2000, constituting 15% of facet joint interventions in 2000 and 10% in 2011. The specialty of anesthesiologists performed 28% of all facet joint interventions in 2011 compared to 66% in 2000, despite a substantial proportion of anesthesiologists changing their designation to either pain management or interventional pain management by 2011. Consequently, it appears that significant growth has been seen among anesthesiologists, physiatrists, and neurologists, along with radiologists and surgeons, whereas all other specialties showed a decrease even though certified registered nurse anesthetists and physicians assistants increased by a whopping 12,460% or 55.2% annually, even though their numbers were small.

Thus, as illustrated in the OIG analysis (49), facet joint interventions continue to grow even though certain specialties have limited their utilization since the OIG study (family practice, internal medicine). Despite this, the growth of facet joint interventions is unsustainable. Consequently, payers and regulators are contemplating how to curb this growth, while at the same time substantially reducing or even eliminating the provision of facet joint interventions.

1.3 Sacroiliac Joint Injections

As shown in Table 11, sacroiliac joint interventions, excluding implantables, trigger point injections, intraarticular injections, and vertebral augmentation procedures, exhibited the highest rates of increases in 2011 even though they constituted only 5% of all interventional techniques (42,101-103). Sacroiliac interventions increased by 331%, or an annual increase of 14.2% (103). The rate of increase of sacroiliac joint neurolysis is undetermined at the present time as these

Table 7. *Frequency of utilization of epidural injections from 2000 to 2011 in Medicare recipients.*

Specialty	F2000	F2001	F2002	F2003	F2004	F2005	F2006	F2007	F2008	F2009	F2010	F2011	Overall Change	Annual Change
Anesthesiology -05	634,408	736,863	779,276	797,243	774,843	842,351	827,898	802,821	779,242	779,019	736,653	715,511	13%	1.1%
Interventional Pain Management -09	-	-	-	39,537	163,369	177,767	225,938	331,475	439,182	505,777	564,807	605,651	-	-
Pain Medicine -72	-	1,827	95,438	160,253	230,325	248,938	257,339	214,129	177,773	157,491	203,125	255,031	-	-
PM&R -25	54,047	65,917	99,301	134,970	198,146	211,230	243,389	272,644	307,888	343,094	371,110	396,892	634%	19.9%
Neurology -13	12,981	15,721	23,551	31,379	28,889	30,971	29,691	29,281	28,510	30,935	32,466	31,300	141%	8.3%
Psychiatry -26	1,295	1,957	3,770	3,239	3,236	3,692	4,309	4,877	3,797	3,552	3,601	3,750	190%	10.1%
Interventional Pain Management	**702731**	**822285**	**1001336**	**1166621**	**1398808**	**1514949**	**1588564**	**165,227**	**1736392**	**1819868**	**1911762**	**2008135**	**186%**	**10.0%**
Percent	83.7%	83.1%	85.4%	86.9%	86.8%	86.7%	86.1%	86.4%	86.1%	86.1%	86.7%	87.7%		
Rate	1,773	2,053	2,472	2,837	3,352	3,565	3,665	3,740	3,824	3,973	4,075	4,280	141%	8.3%
Neurosurgery –14	10,674	11,684	15,166	14,694	22,083	24,029	28,314	29,346	36,235	48,532	36,943	24,034	125%	7.7%
Orthopedic Surgery -20	34,810	39,936	45,872	52,846	61,463	65,507	70,726	76,822	80,930	83,893	85,787	89,192	156%	8.9%
General Surgery -02	1,729	1,738	2,773	2,314	3,000	3,354	4,089	4,403	4,085	3,485	3,389	3,775	118%	7.4%
Surgery	**47,213**	**53,358**	**63,811**	**69,854**	**86,546**	**92,890**	**103,129**	**110,571**	**121,250**	**135,910**	**126,119**	**117,001**	**148%**	**8.6%**
Percent	5.6%	5.4%	5.4%	5.2%	5.4%	5.3%	5.6%	5.8%	6.0%	6.4%	5.7%	5.1%		
Rate	119	133	158	170	207	219	238	250	267	297	269	249	109%	6.9%
Interventional Radiology -94	2,051	2,298	2,530	3,035	3,565	3,993	4,709	5,438	7,079	8,555	7,636	6,507	217%	11.1%
Diagnostic Radiology –30	20,743	27,698	37,687	47,777	60,755	66,022	70,121	71,073	72,816	74,310	76,034	80,940	290%	13.2%
Radiology	**22,794**	**29,996**	**40,217**	**50,812**	**64,320**	**70,015**	**74,830**	**76,511**	**79,895**	**82,865**	**83,670**	**87,447**	**284%**	**13.0%**
Percent	2.7%	3.0%	3.4%	3.8%	4.0%	4.0%	4.1%	4.0%	4.0%	3.9%	3.8%	3.8%		
Rate	58	75	99	124	154	165	173	173	176	181	178	186	224%	11.3%
Family Practice -08	5,336	4,615	6,863	9,683	13,065	14,154	13,492	14,234	15,210	16,239	21,723	20,336	281%	12.9%
General Practice -01	8,597	5,860	5,440	6,142	7,343	8,167	14,236	8,157	7,082	6,906	7,357	3,838	-55%	-7.1%
Internal Medicine -11	7,677	8,247	9,733	9,211	10,520	11,674	13,398	11,625	12,003	14,482	16,851	14,049	83%	5.6%
General Physicians	**21,610**	**18,722**	**22,036**	**25,036**	**30,928**	**33,995**	**41,126**	**34,016**	**34,295**	**37,627**	**45,931**	**38,223**	**77%**	**5.3%**
Percent	2.6%	1.9%	1.9%	1.9%	1.9%	1.9%	2.2%	1.8%	1.7%	1.8%	2.1%	1.7%		
Rate	55	47	54	61	74	80	95	77	76	82	98	81	49%	3.7%
Rheumatology -66	6,895	4,907	4,261	4,119	3,528	3,765	3,910	4,518	4,785	4,657	4,995	3,982	-42%	-4.9%
Osteopathic -12	997	1,318	1,169	1,252	1,052	1,166	1,540	2,383	3,298	3,181	2,949	2,640	165%	9.3%
Emergency Medicine-93	994	3,518	2,989	4,827	4,764	5,430	5,203	6,334	5,244	5,254	4,889	5,257	429%	16.3%
Others	21,933	36,532	17,023	3,315	5,130	6,020	6,276	6,665	13,624	6,377	6,846	8,872	-60%	-7.9%
Other Physicians	**30,819**	**46,275**	**25,442**	**13,513**	**14,474**	**16,381**	**16,929**	**19,900**	**26,951**	**19,469**	**19,679**	**20,751**	**-33%**	**-3.5%**

Table 7 (cont.). *Frequency of utilization of epidural injections from 2000 to 2011 in Medicare recipients.*

Specialty	F2000	F2001	F2002	F2003	F2004	F2005	F2006	F2007	F2008	F2009	F2010	F2011	Overall Change	Annual Change
Percent	**3.7%**	**4.7%**	**2.2%**	**1.0%**	**0.9%**	**0.9%**	**0.9%**	**1.0%**	**1.3%**	**0.9%**	**0.9%**	**0.9%**		
Rate	**78**	**116**	**63**	**33**	**35**	**39**	**39**	**45**	**59**	**43**	**42**	**44**	**-43%**	**-5.0%**
CRNA -43	13,995	17,690	18,244	15,462	14,432	16,717	16,001	15,314	14,516	13,352	14,622	13,131	-6%	-0.6%
NP -50	211	479	768	770	1,479	1,681	2,082	2,276	2,219	1,447	1,311	1,821	763%	21.6%
PA -97	101	229	394	761	900	1,143	1,521	1,412	1,614	1,973	2,213	2,704	2577%	34.8%
CRNA, NP & PA	**14,307**	**18,398**	**19,406**	**16,993**	**16,811**	**19,541**	**19,604**	**19,002**	**18,349**	**16,772**	**18,146**	**17,656**	**23%**	**1.9%**
Percent	**1.7%**	**1.9%**	**1.7%**	**1.3%**	**1.0%**	**1.1%**	**1.1%**	**1.0%**	**0.9%**	**0.8%**	**0.8%**	**0.8%**		
Rate	**36**	**46**	**48**	**41**	**40**	**46**	**45**	**43**	**40**	**37**	**39**	**38**	**4%**	**0.4%**
Total	839474	989034	1172248	1342829	1611887	1747771	1844182	1915227	2017132	2112511	2205307	2289213	173%	9.5%
Rate	2,118	2,470	2,894	3,265	3,863	4,113	4,255	4,327	4,442	4,612	4,701	4,879	130%	7.9%

Rate - Per 100,000 Medicare Beneficiaries; Change - Change from 2000 to 2011; Annual change = geometric change
Interventional Pain Management: Anesthesiology, Pain Management, PM&R, Neurology, Psychiatry,
Surgery: Neurosurgery, Orthopedic Surgery, General Surgery
Radiology: Interventional Radiology, Diagnostic Radiology
General Physicians: Family Practice, General Practice & Internal Medicine

procedures are coded with different CPT codes. Sacroiliac joint injections increased from 2000 to 2001 by 73%, possibly as the result of a payment discrepancy covering the period from 2000 until 2004. During this time a high payment rate for in-office procedures was in effect, without the restriction that fluoroscopy be utilized (133). The procedures increased from 125 in 2000 to 489 in 2006 and then with slower growth through 2011 with 539 per 100,000 Medicare beneficiaries (103).

Regional and specialty variations with utilization and growth patterns persist, and as shown in Tables 12 and 13, are even more prevalent with sacroiliac joint injections than epidural and sacroiliac joint interventions (101-103).

Among regional variations as shown in Table 12, from 2008 to 2010, there was an annual increase of 12% in New Hampshire, 11% in Alabama, 8% in Minnesota, 8% in Vermont, 7% in Oregon, Massachusetts, Kansas, and Maine, and 6% in Utah. The overall annual change was 0.3% from 2008 to 2010, but there were also significant decreases in some states such as as 19% in Hawaii, 13% in New York, 11% in Arkansas, 10% in Maryland, 9% in Louisiana and Oklahoma, 7% in Texas, and 6% in Rhode Island, the District of Columbia, Wyoming, and Delaware.

There were also significant variations based on specialty. The overall rate of increase was 410% of services or 331% per 100,000 Medicare population, with interventional pain management showing an increase of 434% (Table 13). Increases were 1,568% for physical medicine and rehabilitation, 698% for neurology and 85% for anesthesiology, despite the fact that a significant proportion from these specialties are enrolled in pain management and interventional pain management. Overall, general physicians also showed a 779% increase of services, with nurse practitioners, certified registered nurse anesthetists, and physicians assistants combined showing more than a 23,000% increase in performance of services. Anesthesiologists, despite their change of specialty, performed 27% of the total sacroiliac joint injections in 2011 compared to 74% in 2000 prior to the existence of designations of interventional pain management and pain management. In contrast, physiatrists with the ability to enroll in interventional pain management and pain management in 2011 performed 18% of sacroiliac joint injections compared to 5.5% in 2000 prior to the existence of designations of interventional pain management and pain management.

Table 8. *Utilization rates (per 100,000 Medicare recipients) of various facet joint interventions in the Medicare population from 2000 to 2011.*

Year	Facet Joint Blocks								Facet Neurolysis								All Facet Joint Interventions	
	Cervical/Thoracic				Lumbar/Sacral				Cervical/Thoracic				Lumbar/Sacral					
	64470	64472	Total	Rate	64475	64476	Total	Rate	64626	64627	Total	Rate	64622	64623	Total	Rate	Services	Rate
F2000	24751	33573	58324	147	101539	153252	254791	643	2750	6054	8804	22	15117	38206	53323	135	375242	947
F2001	34500	47684	82184	205	121234	175854	297088	742	3815	8334	12149	30	18792	47632	66424	166	457845	1143
F2002	41935	61981	103916	257	155620	240243	395863	977	5190	12202	17392	43	25744	63522	89266	220	606437	1497
F2003	49958	75489	125447	305	189263	299802	489065	1189	6877	15301	22178	54	35315	83166	118481	288	755171	1836
F2004	77620	126145	203765	488	286394	467823	754217	1807	10691	23461	34152	82	57053	132351	189404	454	1181538	2831
F2005	86541	141999	228540	538	316158	519689	835847	1967	12015	26298	38313	90	63228	146688	209916	494	1312616	3089
F2006	121312	204178	325490	751	370809	636673	1007482	2325	14207	31993	46200	107	79289	226299	305588	705	1684760	3887
F2007	108103	179279	287382	649	365372	599568	964940	2180	17689	39710	57399	130	88069	209416	297485	672	1607206	3631
F2008	114497	201857	316354	697	385491	634775	1020266	2247	20729	48089	68818	152	100606	240268	340874	751	1746312	3845
F2009	126730	214802	341532	746	418036	663690	1081726	2362	25510	57973	83483	182	112627	263386	376013	821	1882754	4111
F2010	114753	175887	290640	620	386897	557572	944469	2013	26588	59219	85807	183	116959	261802	378761	807	1699677	3623
F2011	124431	192789	317220	676	402507	587942	990449	2111	29904	67622	97526	208	125630	280748	406378	866	1811573	3861
Overall Change																		
	403%	474%	444%	359%	296%	284%	289%	228%	987%	1017%	1008%	836%	731%	635%	662%	544%	383%	308%
Annual Change																		
	15.8%	17.2%	16.6%	14.9%	13.3%	13.0%	13.1%	11.4%	24.2%	24.5%	24.4%	22.5%	21.2%	19.9%	20.3%	18.4%	15.4%	13.6%

Table 9. *Frequency of claims of utilization of facet joint interventions performed (claims data) in each state with claims data from 2008 to 2010 in Medicare recipients, in alphabetical order.*

State	F2008	F2009	F2010	Overall Change	Annual Change	R2008	R2009	R2010	Overall Change	Annual Change
Alabama	27,412	34,681	37,764	38%	11%	3,388	4,191	4,468	32%	10%
Alaska	1,528	1,279	1,432	-6%	-2%	2,556	2,040	2,180	-15%	-5%
Arizona	36,124	48,359	51,232	42%	12%	4,154	5,376	5,508	33%	10%
Arkansas	38,483	36,987	35,111	-9%	-3%	7,564	7,108	6,607	-13%	-4%
California	137,088	154,921	133,684	-2%	-1%	3,052	3,354	2,810	-8%	-3%
Colorado	10,733	12,258	12,839	20%	6%	1,853	2,036	2,055	11%	4%
Connecticut	11,810	11,554	12,167	3%	1%	2,152	2,070	2,144	0%	0%
DC	11,540	12,641	12,004	4%	1%	15,361	16,482	15,363	0%	0%
Delaware	5,616	4,536	4,022	-28%	-11%	3,981	3,127	2,694	-32%	-12%
Florida	264,406	259,799	212,902	-19%	-7%	8,232	7,899	6,309	-23%	-8%
Georgia	60,718	76,481	65,230	7%	2%	5,268	6,406	5,279	0%	0%
Hawaii	841	815	930	11%	3%	433	407	450	4%	1%
Idaho	3,448	4,933	5,145	49%	14%	1,609	2,222	2,239	39%	12%
Illinois	57,328	67,939	49,567	-14%	-5%	3,231	3,761	2,695	-17%	-6%
Indiana	38,750	39,868	41,891	8%	3%	4,019	4,047	4,165	4%	1%
Iowa	9,123	8,850	9,007	-1%	0%	1,802	1,730	1,741	-3%	-1%
Kansas	10,242	11,933	11,112	8%	3%	2,450	2,805	2,568	5%	2%
Kentucky	31,612	33,580	31,077	-2%	-1%	4,341	4,517	4,089	-6%	-2%
Louisiana	26,301	24,152	24,953	-5%	-2%	4,007	3,598	3,634	-9%	-3%
Maine	4,708	5,256	5,385	14%	5%	1,859	2,029	2,033	9%	3%
Maryland	30,821	30,310	27,498	-11%	-4%	4,139	3,967	3,504	-15%	-5%

Table 9 (cont.). *Frequency of claims of utilization of facet joint interventions performed (claims data) in each state with claims data from 2008 to 2010 in Medicare recipients, in alphabetical order.*

State	F2008	F2009	F2010	Overall Change	Annual Change	R2008	R2009	R2010	Overall Change	Annual Change
Massachusetts	28,026	32,249	35,597	27%	8%	2,751	3,103	3,355	22%	7%
Michigan	109,510	118,627	92,593	-15%	-5%	6,933	7,348	5,608	-19%	-7%
Minnesota	13,394	14,896	13,869	4%	1%	1,788	1,943	1,765	-1%	0%
Mississippi	19,786	26,739	22,420	13%	4%	4,129	5,480	4,510	9%	3%
Missouri	35,584	38,174	37,224	5%	2%	3,683	3,874	3,706	1%	0%
Montana	4,515	4,663	3,587	-21%	-7%	2,814	2,832	2,116	-25%	-9%
Nebraska	4,322	5,421	4,685	8%	3%	1,593	1,967	1,679	5%	2%
Nevada	12,229	14,438	17,294	41%	12%	3,706	4,209	4,849	31%	9%
New Hampshire	7,382	8,175	9,612	30%	9%	3,488	3,761	4,305	23%	7%
New Jersey	29,557	29,375	30,735	4%	1%	2,304	2,252	2,316	1%	0%
New Mexico	7,705	7,964	8,248	7%	2%	2,618	2,621	2,632	1%	0%
New York	62,844	55,294	57,025	-9%	-3%	2,174	1,883	1,908	-12%	-4%
North Carolina	51,826	55,887	49,289	-5%	-2%	3,689	3,860	3,308	-10%	-4%
North Dakota	1,560	2,044	1,803	16%	5%	1,463	1,893	1,649	13%	4%
Ohio	57,542	65,808	67,447	17%	5%	3,126	3,519	3,549	14%	4%
Oklahoma	14,567	18,698	18,187	25%	8%	2,518	3,160	3,014	20%	6%
Oregon	8,656	10,055	10,631	23%	7%	1,482	1,670	1,712	16%	5%
Pennsylvania	61,486	56,582	54,218	-12%	-4%	2,768	2,513	2,375	-14%	-5%
Rhode Island	10,879	8,945	7,259	-33%	-13%	6,116	4,963	3,967	-35%	-13%
South Carolina	44,696	50,727	47,945	7%	2%	6,176	6,776	6,197	0%	0%
South Dakota	6,666	7,264	5,295	-21%	-7%	5,048	5,402	3,877	-23%	-8%
Tennessee	53,527	55,494	57,376	7%	2%	5,330	5,381	5,424	2%	1%
Texas	189,830	210,162	161,265	-15%	-5%	6,775	7,247	5,374	-21%	-7%
Utah	10,546	12,136	12,755	21%	7%	3,993	4,431	4,507	13%	4%
Vermont	2,259	2,615	2,653	17%	6%	2,153	2,422	2,379	10%	3%
Virginia	24,677	27,730	24,753	0%	0%	2,288	2,498	2,170	-5%	-2%
Washington	17,750	22,060	19,815	12%	4%	1,965	2,351	2,038	4%	1%
West Virginia	10,492	12,397	13,422	28%	9%	2,813	3,286	3,516	25%	8%
Wisconsin	24,306	24,961	25,427	5%	2%	2,782	2,799	2,791	0%	0%
Wyoming	1,561	2,036	2,288	47%	14%	2,051	2,603	2,857	39%	12%

2.0 Payment Policies for Interventional Techniques

Interventional techniques are covered by Medicare, Medicaid, and private insurers. Medicare, however, has well defined policies whereas the others do not. Medicare promulgates its coverage policies in the form of local coverage determinations (LCDs) and national coverage determinations (NCDs) (56). The decision to cover a particular item or service is made by a Medicare administrative contractor, fiscal intermediary, or carrier, and is the basis for determining the LCD.

2.1 Medicare Coverage Policies

All other insurers including Medicaid and other governmental agencies have developed their own policies and procedures in developing payment policies for interventional techniques, some derived from Medicare. Large insurers such as Blue Cross Blue Shield and others also have their own technology assessment divisions or outsource to various commercially available agencies.

2.1.1 Coverage Determinations

The LCDs are formulated based on multiple regula-

Table 10. *Frequency of utilization of facet joint interventions by specialty from 2000 to 2011, in Medicare recipients.*

Specialty	F2000	F2001	F2002	F2003	F2004	F2005	F2006	F2007	F2008	F2009	F2010	F2011	Overall Change	Annual Change
Anesthesiology -05	247,282	294,402	337,191	369,024	430,372	480,429	513,444	539,743	559,342	600,380	512,925	507,531	105%	6.8%
Interventional Pain Management -09	**0**	**0**	**0**	**37,882**	**155,989**	**172,078**	**218,021**	**325,813**	**459,996**	**535,496**	**532,584**	**578,317**	-	-
Pain Management -72	0	2,383	77,284	114,290	204,118	225,969	246,039	213,972	173,536	146,861	170,084	224,075	-	-
PM&R -25	29,984	33,772	49,416	71,278	126,738	138,649	162,075	186,232	220,863	248,619	241,261	264,274	781%	21.9%
Neurology -13	15,560	17,260	22,660	30,687	40,182	44,228	48,532	53,192	55,599	57,422	47,281	39,693	155%	8.9%
Psychiatry -26	547	544	1,073	814	627	769	1,858	2,347	2,445	2,190	2,087	1,900	247%	12.0%
Interventional Pain Management	**293,373**	**348,361**	**487,624**	**623,975**	**958,026**	**1,062,122**	**1,189,969**	**1,321,299**	**1,471,781**	**1,590,968**	**1,506,222**	**1,615,790**	**451%**	**16.8%**
Percent	78.2%	76.1%	80.4%	82.6%	81.1%	80.9%	70.6%	82.2%	84.3%	84.5%	88.6%	89.2%	-	-
Rate	740	870	1,204	1,517	2,296	2,499	2,746	2,985	3,241	3,474	3,211	3,444	365%	15.0%
Neurosurgery -14	7,983	9,281	12,577	12,129	17,632	19,938	22,886	26,636	36,428	48,305	21,905	18,388	130%	7.9%
Orthopedic Surgery -20	18,549	23,107	26,144	29,177	41,367	45,169	51,827	53,211	57,856	60,293	50,284	48,023	159%	9.0%
General Surgery -02	2,960	2,404	1,752	1,627	2,551	2,755	10,743	17,821	6,654	4,533	3,074	2,696	-9%	-0.8%
Surgery	**29,492**	**34,792**	**40,473**	**42,933**	**61,550**	**67,862**	**85,456**	**97,668**	**100,938**	**113,131**	**75,263**	**69,107**	**134%**	**8.0%**
Percent	7.9%	7.6%	6.7%	5.7%	5.2%	5.2%	5.1%	6.1%	5.8%	6.0%	4.4%	3.8%	-	-
Rate	74	87	100	104	147	160	197	221	222	247	160	147	98%	6.4%
Interventional Radiology -94	694	496	821	1,082	942	1,199	1,885	2,484	3,265	4,911	3,891	2,932	322%	14.0%
Diagnostic Radiology -30	9,447	11,113	13,323	15,700	16,453	18,504	22,196	20,889	21,772	22,958	21,799	25,258	167%	9.4%
Radiology	**10,141**	**11,609**	**14,144**	**16,782**	**17,395**	**19,703**	**24,081**	**23,373**	**25,037**	**27,869**	**25,690**	**28,190**	**178%**	**9.7%**
Percent	2.7%	2.5%	2.3%	2.2%	1.5%	1.5%	1.4%	1.5%	1.4%	1.5%	1.5%	1.6%	-	-
Rate	26	29	35	41	42	46	56	53	55	61	55	60	135%	8.1%
Family Practice -08	4,382	6,572	7,928	11,237	22,011	25,463	73,265	30,776	26,914	35,041	20,328	22,897	423%	16.2%
General Practice -01	6,108	6,846	7,738	11,547	20,532	23,331	126,883	22,850	12,436	11,608	6,060	5,721	-6%	-0.6%
Internal Medicine -11	6,753	6,503	8,874	14,782	42,534	45,312	102,060	43,134	57,399	62,839	33,660	32,772	385%	15.4%
General Physicians	**17,243**	**19,921**	**24,540**	**37,566**	**85,077**	**94,106**	**302,208**	**96,760**	**96,749**	**109,488**	**60,048**	**61,390**	**256%**	**12.2%**
Percent	4.6%	4.4%	4.0%	5.0%	7.2%	7.2%	17.9%	6.0%	5.5%	5.8%	3.5%	3.4%	-	-
Rate	44	50	61	91	204	221	697	219	213	239	128	131	201%	10.5%
Rheumatology -66	13,724	18,862	20,794	20,666	23,289	27,086	25,814	24,433	17,683	11,755	3,453	4,367	-68%	-9.9%
Osteopathic Manipulative Therapy -12	563	2,505	3,810	4,433	5,284	6,410	8,145	8,402	4,486	2,730	1,308	973	73%	5.1%
Emergency Medicine -93	982	691	1,315	2,829	2,290	2,539	14,325	6,731	1,312	2,081	2,365	2,467	151%	8.7%
Others	9,581	20,436	12,126	3,452	23,839	27,292	26,652	17,959	13,949	8,637	6,848	8,026	-16%	-1.6%

Table 10 (cont.). *Frequency of utilization of facet joint interventions by specialty from 2000 to 2011, in Medicare recipients.*

Specialty	F2000	F2001	F2002	F2003	F2004	F2005	F2006	F2007	F2008	F2009	F2010	F2011	Overall Change	Annual Change
Other Specialties	24,850	42,494	38,045	31,380	54,702	63,327	74,936	57,525	37,430	25,203	13,974	15,833	-36%	-4.0%
Percent	6.6%	9.3%	6.3%	4.2%	4.6%	4.8%	4.4%	3.6%	2.1%	1.3%	0.8%	0.9%	-	-
Rate	63	106	94	76	131	149	173	130	82	55	30	34	-46%	-5.5%
CRNA -43	101	189	358	529	442	618	696	821	1,921	3,039	2,112	2,124	2003%	31.9%
NP -50	0	111	276	1,068	1,957	2,191	3,713	4,103	8,168	9,276	11,997	14,346	-	-
PA -97	42	368	977	938	2,389	2,687	3,701	5,657	4,288	3,780	4,371	4,793	11,312%	53.8%
CRNA, NP & PA	143	668	1,611	2,535	4,788	5,496	8,110	10,581	14,377	16,095	18,480	21,263	14,769%	57.6%
Percent	0.04%	0.1%	0.3%	0.3%	0.4%	0.4%	0.5%	0.7%	0.8%	0.9%	1.1%	1.2%	-	-
Rate	0.4	2	4	6	11	13	19	24	32	35	39	45	12,460%	55.2%
Total	**375,242**	**457,845**	**606,437**	**755,171**	**1,181,538**	**1,312,616**	**1,684,760**	**1,607,206**	**1,746,312**	**1,882,754**	**1,699,677**	**1,811,573**	**383%**	**15.4%**
Rate	947	1,143	1,497	1,836	2,831	3,089	3,887	3,631	3,845	4,111	3,623	3,861	308%	13.6%

Rate - Per 100,000 Medicare Beneficiaries; Change - Change from 2000 to 2011; GM- Geometric average annual change

tions and instructions from the Centers for Medicare and Medicaid Services (CMS), including evidence as well as reasonable and necessary aspects of the service (134). In contrast, 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. Once published in the CMS program instruction manual, an NCD is binding on all Medicare carriers and other related organizations. NCDs are made infrequently. However, a negative NCD can be especially problematic for providers of a service for which Medicare covers a large proportion of the market and the patients who receive those services.

The Medicare Integrity Manual (135) outlines the process of developing LCDs.

- 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.
- Contractors have the option to develop LCDs when a validated widespread problem in one or all states covering all states, occurs, to assure beneficiary access to care, and when frequent denials are issued or anticipated.

2.1.2 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 (135).

2.1.3 Reasonable and Necessary Provisions in LCDs

An item or service may be covered by an LCD (135) if it is reasonable and necessary (only reasonable and necessary provisions are considered part of the LCD). Further, a service is reasonable and necessary if 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.

Table 11. *Characteristics of Medicare beneficiaries and sacroiliac joint injections.*

	U.S. Population (,000)			Medicare Beneficiaries (,000)						SI Joint Injections		
Year	All Ages	≥ 65 Years	Percent	< 65 Years	Percent	≥ 65 Years	Percent	Total Medicare Beneficiaries	% to U.S.	Services	% of change from Previous Year	Rate per 100,000 Medicare Beneficiaries
Y2000	**282,172**	35,077	12.4%	5,370	13.5%	34,262	86.5%	**39,632**	14.0%	49,554 (59%)		**125**
Y2001	**285,040**	35,332	12.4%	5,567	13.9%	34,478	86.1%	**40,045**	14.0%	85,664 (51%)	72.90%	**214**
Y2002	**288,369**	35,605	12.3%	5,805	14.3%	34,698	85.7%	**40,503**	14.0%	101,749 (48%)	18.80%	**251**
Y2003	**290,211**	35,952	12.4%	6,078	14.8%	35,050	85.2%	**41,126**	14.2%	128,864 (42%)	26.60%	**313**
Y2004	**292,892**	36,302	12.4%	6,402	15.3%	35,328	84.7%	**41,729**	14.2%	172,704 (41%)	34.00%	**414**
Y2005	**295,561**	36,752	12.4%	6,723	15.8%	35,777	84.2%	**42,496**	14.4%	188,606 (42%)	9.20%	**444**
Y2006	**299,395**	37,264	12.4%	7,022	16.2%	36,317	83.8%	**43,339**	14.5%	211,928 (40%)	12.40%	**489**
Y2007	**301,290**	37,942	12.6%	7,297	16.5%	36,966	83.5%	**44,263**	14.7%	213,489 (41%)	0.70%	**482**
Y2008	**304,056**	38,870	12.8%	7,516	16.6%	37,896	83.4%	**45,412**	14.9%	228,687 (42%)	7.10%	**504**
Y2009	**307,006**	39,570	12.9%	7,624	16.6%	38,177	83.3%	**45,801**	14.9%	228,946 (42%)	0.10%	**500**
Y2010	**308,746**	40,268	13.0%	7,923	16.9%	38,991	83.1%	**46,914**	15.2%	237,905 (42%)	3.90%	**507**
Y2011	**313,848**	41,122	13.1%	7,786	16.6%	39,132	83.4%	**46,918**	14.9%	252,654 (43%)	6.20%	**539**
Overall Change	**11%**	17%		45%		14%		**18%**		410%		**331%**
Annual Change	**1.0%**	1.5%		3.4%		1.2%		**1.5%**		16.0%		**14.2%**

( ) shows percentage of procedures utilized in facility settings (HOPD and ASC)

Table 12. *Utilization of sacroiliac joint injections performed (claims data) in each state with claims data from 2008 to 2010, in Medicare recipients, in alphabetical order.*

State	F2008	F2008	F2009	Overall Change	Annual Change	R2008	R2009	R2010	Overall Change	Annual Change
Alabama	4,914	5,108	7,069	44%	13%	607	617	836	38%	11%
Alaska	85	87	89	5%	2%	142	139	135	-5%	-2%
Arizona	3,276	3,671	4,102	25%	8%	377	408	441	17%	5%
Arkansas	3,384	2,827	2,490	-26%	-10%	665	543	469	-30%	-11%
California	12,122	13,186	14,236	17%	6%	270	285	299	11%	4%
Colorado	1,908	2,027	2,198	15%	5%	329	337	352	7%	2%
Connecticut	1,684	1,617	1,627	-3%	-1%	307	290	287	-7%	-2%
DC	1,493	1,280	1,281	-14%	-5%	1,987	1,669	1,639	-18%	-6%
Delaware	497	431	432	-13%	-5%	352	297	289	-18%	-6%
Florida	28,436	28,531	26,725	-6%	-2%	885	867	792	-11%	-4%
Georgia	8,389	8,544	8,267	-1%	0%	728	716	669	-8%	-3%
Hawaii	135	108	75	-44%	-18%	70	54	36	-48%	-19%
Idaho	847	918	898	6%	2%	395	414	391	-1%	0%
Illinois	7,691	6,980	7,395	-4%	-1%	433	386	402	-7%	-2%
Indiana	6,061	6,069	7,107	17%	5%	629	616	707	12%	4%
Iowa	1,995	2,015	2,229	12%	4%	394	394	431	9%	3%
Kansas	2,238	2,341	2,817	26%	8%	535	550	651	22%	7%
Kentucky	6,025	5,818	6,573	9%	3%	827	783	865	5%	1%
Louisiana	2,464	2,033	1,931	-22%	-8%	375	303	281	-25%	-9%
Maine	706	777	893	26%	8%	279	300	337	21%	7%

Table 12 (cont.). Utilization of sacroiliac joint injections performed (claims data) in each state with claims data from 2008 to 2010, in Medicare recipients, in alphabetical order.

State	F2008	F2008	F2009	Overall Change	Annual Change	R2008	R2009	R2010	Overall Change	Annual Change
Maryland	3,965	3,085	3,036	-23%	-9%	533	404	387	-27%	-10%
Massachusetts	3,332	3,668	4,251	28%	8%	327	353	401	22%	7%
Michigan	13,611	13,501	16,928	24%	8%	862	836	1025	19%	6%
Minnesota	1,901	2,118	2,543	34%	10%	254	276	324	28%	8%
Mississippi	2,530	2,887	2,749	9%	3%	528	592	553	5%	2%
Missouri	8,035	8,527	8,538	6%	2%	832	865	850	2%	1%
Montana	435	564	447	3%	1%	271	343	264	-3%	-1%
Nebraska	1,313	1,552	1,614	23%	7%	484	563	578	20%	6%
Nevada	1,167	1,339	1,429	22%	7%	354	390	401	13%	4%
New Hampshire	990	1,384	1,460	47%	14%	468	637	654	40%	12%
New Jersey	4,956	4,500	4,629	-7%	-2%	386	345	349	-10%	-3%
New Mexico	875	923	913	4%	1%	297	304	291	-2%	-1%
New York	8,978	7,348	6,169	-31%	-12%	311	250	206	-34%	-13%
North Carolina	8,686	8,883	9,212	6%	2%	618	613	618	0%	0%
North Dakota	574	512	598	4%	1%	538	474	547	2%	1%
Ohio	10,192	10,420	10,177	0%	0%	554	557	535	-3%	-1%
Oklahoma	2,401	2,020	1,886	-21%	-8%	415	341	313	-25%	-9%
Oregon	1,150	1,295	1,484	29%	9%	197	215	239	21%	7%
Pennsylvania	6,812	6,649	7,211	6%	2%	307	295	316	3%	1%
Rhode Island	2,935	2,444	2,518	-14%	-5%	1,650	1,356	1,376	-17%	-6%
South Carolina	7,327	7,663	8,585	17%	5%	1,012	1,024	1,110	10%	3%
South Dakota	1,201	1,346	1,362	13%	4%	910	1,001	997	10%	3%
Tennessee	8,465	9,229	9,525	13%	4%	843	895	900	7%	2%
Texas	17,465	16,413	15,163	-13%	-5%	623	566	505	-19%	-7%
Utah	1,445	1,610	1,868	29%	9%	547	588	660	21%	6%
Vermont	323	364	429	33%	10%	308	337	385	25%	8%
Virginia	5,990	6,253	6,656	11%	4%	555	563	584	5%	2%
Washington	1,849	2,110	2,109	14%	4%	205	225	217	6%	2%
West Virginia	1,667	1,853	1,636	-2%	-1%	447	491	429	-4%	-1%
Wisconsin	3,525	3,910	4,132	17%	5%	403	438	454	12%	4%
Wyoming	242	208	210	-13%	-5%	318	266	262	-18%	-6%
Total	228,687	228,946	237,905	4%	1%	504	500	507	1%	0.3%

However, as described by Neumann and Chambers (136) 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.

Furthermore, 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 the multiple difficulties and various issues involved, Fox (137) 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.

Table 13. *Frequency of utilization of sacroiliac joint injections from 2000 to 2011, in Medicare recipients, based on speciality.*

Specialty	F2000	F2001	F2002	F2003	F2004	F2005	F2006	F2007	F2008	F2009	F2010	F2011	Overall Change	Average Change
Anesthesiology -05	36,811	62,183	64,851	71,969	72,475	79,597	82,373	80,455	78,847	75,418	70,652	68,103	85%	5.8%
Interventional Pain Management -09	-	-	-	5,329	20,889	22,613	29,470	41,041	53,194	56,882	61,836	67,653	-	-
Pain Management -72	-	426	10,424	16,236	29,112	31,695	31,356	22,935	17,928	15,325	21,038	28,344	-	-
PM&R -25	2,754	6,245	9,887	14,990	21,978	23,735	28,294	33,591	37,908	40,564	42,659	45,936	1568%	29.2%
Neurology -13	614	1,354	2,239	4,248	2,836	3,073	4,423	4,652	6,334	5,895	5,934	4,900	698%	20.8%
Psychiatry -26	95	94	139	161	105	137	225	286	226	242	267	271	185%	10.0%
Interventional Pain Management	**40,274**	**70,302**	**87,540**	**112,933**	**147,395**	**160,850**	**176,141**	**182,960**	**194,437**	**194,326**	**202,386**	**215,207**	**434%**	**16.5%**
Percent	81.3%	82.1%	86.0%	87.6%	85.3%	85.3%	83.1%	85.7%	85.0%	84.9%	85.1%	85.2%		
Rate	81	82	86	88	85	85	83	86	85	85	85	85	5%	0.4%
Neurosurgery -14	196	704	1,369	1,454	1,497	1,627	1,691	1,438	2,589	3,573	1,959	1,575	704%	20.9%
Orthopedic Surgery -20	2,525	3,558	3,577	4,250	5,562	6,074	6,683	7,315	7,539	7,377	6,795	6,532	159%	9.0%
General Surgery -02	57	54	155	221	448	514	622	711	620	602	719	898	1,475%	28.5%
Surgery	**2,778**	**4,316**	**5,101**	**5,925**	**7,507**	**8,215**	**8,996**	**9,464**	**10,748**	**11,552**	**9,473**	**9,005**	**224%**	**11.3%**
Percent	5.6%	5.0%	5.0%	4.6%	4.3%	4.4%	4.2%	4.4%	4.7%	5.0%	4.0%	3.6%		
Rate	6	5	5	5	4	4	4	4	5	5	4	4	-36%	-4.0%
Interventional Radiology -94	147	160	200	224	389	463	549	886	1,135	1,342	1,121	1,184	705%	20.9%
Diagnostic Radiology -30	2,024	1,446	2,010	2,796	3,766	4,103	4,331	4,696	5,052	5,221	5,449	6,104	202%	10.6%
Radiology	2,171	1,606	2,210	3,020	4,155	4,566	4,880	5,582	6,187	6,563	6,570	7,288	236%	11.6%
Percent	4.4%	1.9%	2.2%	2.3%	2.4%	2.4%	2.3%	2.6%	2.7%	2.9%	2.8%	2.9%		
Rate	4	2	2	2	2	2	2	3	3	3	3	3	-34%	-3.7%
Family Practice -08	447	872	1,176	1,963	3,316	3,560	5,932	3,949	5,137	5,143	5,954	6,226	1,293%	27.1%
General Practice -01	258	490	509	589	1,599	1,701	5,202	1,152	1,177	1,345	1,165	1,048	306%	13.6%
Internal Medicine -11	555	1,301	1,265	2,229	4,132	4,556	4,998	4,526	3,863	3,535	4,241	3,805	586%	19.1%
General Physicians	**1,260**	**2,663**	**2,950**	**4,781**	**9,047**	**9,817**	**16,132**	**9,627**	**10,177**	**10,023**	**11,360**	**11,079**	**779%**	**21.8%**
Percent	2.5%	3.1%	2.9%	3.7%	5.2%	5.2%	7.6%	4.5%	4.5%	4.4%	4.8%	4.4%		
Rate	3	3	3	4	5	5	8	5	4	4	5	4	72%	5.1%
Other Physicians	**3,050**	**6,606**	**3,589**	**1,584**	**2,951**	**3,296**	**3,152**	**3,251**	**4,508**	**3,609**	**4,584**	**5,122**	**68%**	**4.8%**
Percent	6.2%	7.7%	3.5%	1.2%	1.7%	1.7%	1.5%	1.5%	2.0%	1.6%	1.9%	2.0%		
Rate	6	8	4	1	2	2	1	2	2	2	2	2	-67%	-9.6%

Table 13 (cont.). Frequency of utilization of sacroiliac joint injections from 2000 to 2011, in Medicare recipients, based on speciality.

Specialty	F2000	F2001	F2002	F2003	F2004	F2005	F2006	F2007	F2008	F2009	F2010	F2011	Overall Change	Average Change
CRNA -43	-	23	41	70	63	89	106	181	221	248	315	519		
NP -50	-	111	177	177	727	787	947	773	875	1,221	1,489	2,296		
PA -97	21	37	141	374	859	986	1,574	1,651	1,534	1,404	1,728	2,138	10,081%	52.2%
CRNA, NP & PA	**21**	**171**	**359**	**621**	**1,649**	**1,862**	**2,627**	**2,605**	**2,630**	**2,873**	**3,532**	**4,953**	**23,486%**	**64.3%**
Percent	0.04%	0.2%	0.4%	0.5%	1.0%	1.0%	1.2%	1.2%	1.2%	1.3%	1.5%	2.0%		
Rate	0.04	0.2	0.4	0.5	1.0	1.0	1.2	1.2	1.2	1.3	1.5	2.0	4,526%	41.7%
Total SI Joint Injections	49,554	85,664	101,749	128,864	172,704	188,606	211,928	213,489	228,687	228,946	237,905	252,654	410%	16.0%
Rate	125	214	251	313	414	444	489	482	504	500	507	539	331%	14.2%

2.1.4 Cost Effectiveness Considerations

The cost effectiveness considerations by Medicare have also been a subject of debate. The U.S. Panel on Cost Effectiveness in Health and Medicine, composed of physicians, health economists, ethicists, and other health policy experts, recommended in 1996 that cost effectiveness analysis should use quality-adjusted life years (QALY) as a standard metric for identifying and assigning value to health outcomes (138,139). In contrast, the 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 (56,57,140). While the ACA specifically forbids the use of cost per QALY as a threshold, multiple organizations and clinical guidelines support this concept of using as a threshold. Even then, it is generally believed that Medicare does have an implicit cost-effectiveness threshold. In assessing whether or not an implicit cost effectiveness threshold exists and to determine if economic evidence has been considered in previous NCDs (141), 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. Of the 64 coverage decisions determined by the authors 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. Furthermore, 14 of the sampled 64 decision memos cited or discussed cost effectiveness information.

2.1.5 Alternate Treatments

The Medicare Integrity Manual (135) 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, effective, or appropriate for a given condition without exceeding the patient's medical needs. Prerequisites shall be based solely on medical appropriateness, not on cost effectiveness.

2.1.6 Evidence Supporting LCDs

The Medicare Program Integrity Manual (135) instructs that LCDs shall be based on the strongest evidence available. Furthermore, the extent and quality of supporting evidence is vital to defending challenges to LCDs. 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

Table 14. *Illustration of various 2013 payment groups per procedure in APC 203, 204, and 207.*

HCPCS	Descriptor	APC	Facility Payment Rates ($)			Physician Payment Rate ($)
			HOPD	ASC	Office overhead	
62263	Epidural lysis mult sessions	0203	856.68	480.71	365.41	357.24
62264	Epidural lysis on single day	0203	856.68	480.71	199.03	241.22
62281	Treat spinal cord lesion	0203	856.68	480.71	88.80	161.27
62282	Treat spinal canal lesion	0203	856.68	480.71	148.00	146.30
62319	Inject spine w/cath lmb/scrl	0203	856.68	480.71	76.56	96.97
62355	Remove spinal canal catheter	0203	856.68	480.71	0	267.76
63746	Removal of spinal shunt	0203	856.68	480.71	0	612.75
64600	Injection treatment of nerve	0203	856.68	480.71	182.36	219.45
64620	Injection treatment of nerve	0203	856.68	480.71	34.36	177.26
64635	Destroy lumb/sac facet jnt	0203	856.68	480.71	189.85	218.77
64680	Injection treatment of nerve	0203	856.68	480.71	154.80	171.14
64681	Injection treatment of nerve	0203	856.68	480.71	168.07	198.35
20526	Ther injection carp tunnel	0204	182.61	29.25	20.07	56.48
20550	Inj tendon sheath/ligament	0204	182.61	22.25	17.35	41.17
20551	Inj tendon origin/insertion	0204	182.61	23.75	18.03	42.53
20600	Drain/inject joint/bursa	0204	182.61	16.50	12.25	35.04
20605	Drain/inject joint/bursa	0204	182.61	20.75	12.93	52.74
20610	Drain/inject joint/bursa	0204	182.61	21.50	14.29	45.93
64400	N block inj trigeminal	0204	182.61	60.25	56.14	69.75
64402	N block inj facial	0204	182.61	55.75	47.97	76.55
64408	N block inj vagus	0204	182.61	34.00	26.54	73.15
64410	N block inj phrenic	0204	182.61	102.47	53.76	75.19
64491	Inj paravert f jnt c/t 2 lev	0204	182.61	102.47	36.40	61.24
64492	Inj paravert f jnt c/t 3 lev	0204	182.61	102.47	36.06	61.92
64494	Inj paravert f jnt l/s 2 lev	0204	182.61	102.47	37.43	52.06
64495	Inj paravert f jnt l/s 3 lev	0204	182.61	102.47	36.74	53.08
64505	N block spenopalatine gangl	0204	182.61	40.75	18.37	86.76
64634	Destroy c/th facet jnt addl	0204	182.61	102.47	121.80	66.69
64650	Chemodenerv eccrine glands	0204	182.61	73.50	86.42	41.17
64653	Chemodenerv eccrine glands	0204	182.61	85.00	100.37	53.42
G0260	Inj for sacroiliac jt anesth	0207	565.75	317.46	84.38	85.74
62268	Drain spinal cord cyst	0207	565.75	317.46	0.00	263.68
62273	Inject epidural patch	0207	565.75	317.46	62.94	114.66
62280	Treat spinal cord lesion	0207	565.75	317.46	167.73	177.26
62292	Injection into disk lesion	0207	565.75	317.46	0.00	601.19
62310	Inject spine cerv/thoracic	0207	565.75	317.46	141.54	110.23
62311	Inject spine lumbar/sacral	0207	565.75	317.46	122.14	89.82
62318	Inject spine w/cath crv/thrc	0207	565.75	317.46	140.17	100.03
64416	N block cont infuse b plex	0207	565.75	317.46	0.00	77.57
64421	N block inj intercost mlt	0207	565.75	317.46	62.94	95.60
64430	N block inj pudendal	0207	565.75	317.46	57.84	82.00

Table 14 (cont.). *Illustration of various 2013 payment groups per procedure in APC 203, 204, and 207.*

HCPCS	Descriptor	APC	Facility Payment Rates ($)			Physician Payment Rate ($)
			HOPD	ASC	Office overhead	
64445	N block inj sciatic sng	0207	565.75	60.50	66.34	71.79
64446	N blk inj sciatic cont inf	0207	565.75	317.46	0.00	77.57
64449	N block inj lumbar plexus	0207	565.75	317.46	0.00	81.66
64479	Inj foramen epidural c/t	0207	565.75	317.46	111.94	136.43
64483	Inj foramen epidural l/s	0207	565.75	317.46	117.38	115.00
64490	Inj paravert f jnt c/t 1 lev	0207	565.75	317.46	91.86	110.23
64493	Inj paravert f jnt l/s 1 lev	0207	565.75	317.46	89.48	93.22
64510	N block stellate ganglion	0207	565.75	317.46	57.50	74.51
64517	N block inj hypogas plxs	0207	565.75	317.46	60.56	123.50
64520	N block lumbar/thoracic	0207	565.75	317.46	112.28	81.32
64530	N block inj celiac pelus	0207	565.75	317.46	105.81	94.92
64630	Injection treatment of nerve	0207	565.75	317.46	33.68	181.34
64633	Destroy cerv/thor facet jnt	0207	565.75	317.46	194.27	221.83
64636	Destroy l/s facet jnt addl	0207	565.75	317.46	111.26	58.52
64640	Injection treatment of nerve	0207	565.75	68.00	42.19	95.94

- 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.

2.1.7 LCD Advisory Process

The LCD advisory process consists of external evidence gathering along with the Carrier Advisory Committee (CAC) process. Each state should have its own CAC (135). 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 (135).

While the CAC is not a forum for peer review, the CAC reviews all draft LCDs. The final implementation decision about LCDs, however, rests with the contractor medical director (CMD). Membership on a CAC is to be composed of physicians, a beneficiary representative, and representatives of 34 medical organizations (142). Interventional pain management was provided with mandatory membership on February 1, 2005 (143). Members of anesthesiology, physical medicine and rehabilitation, neurology, psychiatry, orthopedia surgery, neurosurgery, and radiology represent their respective specialties. Members are recommended by the state specialty societies.

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 medical review policies.

2.1.8 Effectiveness of Coverage Policies

There is controversy in reference to the evidence of the effectiveness of coverage policies to change utilization patterns. Some argue that policies have had little impact on utilization (12,41,42,144-147). Wennberg (146) found significant and persistent variations in utilization patterns in Medicare, even adjusting regionally for age and severity of illness differences. His findings showed important differences in the ways in which medicine is practiced and services are used across the country, suggesting that the misuse, underuse, and overuse of services are widespread. While NCDs without coverage lead to non-performance of procedures, when they are covered they do not appear to have changed any utilization patterns (145). In reference to drug-coated stents, Kaul and Diamond (148) 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 (149). Thus, with utilization that is contrary to clinical evidence potentially causing 2160 fatalities each year, the more than one million Americans receiving stents, according to K and D are costing billions of dollars (148,149). A study from the University of Minnesota evaluating the impact of coverage policies on utilization in Medicare (150) found that in 7 of the 8 cases, there were no measurable changes in use, suggesting 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 those with 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 3 (41,42,56). The assessment of statewide utilization illustrates no significant variations in the utilization of interventional techniques irrespective of the type of LCD, its presence or absence.

2.2 Coverage Policies by Medicaid

Medicaid coverage policies are based on evidence synthesis by the provider, outsourcing to other companies, or following Medicaid policies (151-155). Similar to private insurers, however, private contractors utilize their own policies for Medicaid management.(156-167). These policies describe background information, medical necessity limitation, exclusions, and also provide references.

2.3 Coverage Policies by Other Payers

Other payers, while occasionally using Medicare policies, utilize their own methodology. In describing their policies they include background, indications, medical necessity, exclusions, investigational and experimental, as well as references. These policies are developed by individual carriers using their own internal resources either using technology assessment or by outsourcing to various commercial agencies (156,157,162-169).

3.0 Accountable Interventional Pain Management

Traditionally, Medicare payment rates vary for the same ambulatory services provided to similar patients in different settings, such as physicians' offices, HOPDs, and ASCs (170-191). The MedPAC is concerned that payment variations across settings may encourage arrangements among providers that result in care being provided primarily in high paid settings, thereby increasing total Medicare spending and beneficiary cost sharing (70). Furthermore, the MedPAC also believes that Medicare should base payment rates on the resources needed to treat patients in the most efficient setting, adjusting for differences in patient severity, to the extent the severity differences affect costs. However, other payers share a different philosophy on a per diem payment rate to the hospitals favoring the hospital payment system.

Physician payments are generally based on the physician fee schedule (PFS) (170-179,188,189), HOPD services in the outpatient prospective payment system (OPPS) (180-187), and payment rates for ASC services in the ASC payment system (180-187,192). Consequently, Medicare makes 2 payments that involve physicians' professional fees under the PFS and a facility fee for the HOPD or ASC under the OPPS or ASC payment system. In addition, while subject to a multitude of regulations, an outpatient facility that has provider-based status is considered part of the hospital. Provider-based status is available for hospital-owned entities that meet criteria rules such as being located on the hospital campus, or off campus but within 3 or 5 miles of the hospital campus. In general, the non-facility rate provided to physicians in their offices is higher than the facility rate because physicians' practice costs are higher due to direct costs. In many cases, however, this may be lower than the differential paid for ASCs and even substantially lower than what would be paid in hospital outpatient surgery departments and ASCs owned by hospitals. These differences in payment systems have resulted in disturbing trends such as hospitals acquiring physician practices leading to the end of individual practices in the foreseeable future. The payment differences span from 50% to 300% across various settings. The MedPAC has described equalizing payment systems for evaluation and management services, as well as other outpatient procedures, including interventional techniques. Table 14 shows various payment groups per procedures in the Ambulatory Payment Classification (APC), which may be transformed for equalization among various settings, specifically between ASCs and HOPDs. As one can see, there are significant differences between payments in various groups.

MedPAC also recommended equalizing payments for evaluation and management (E/M) office visits pertaining to interventional techniques. As shown in Table 15, if an established patient office visit (CPT 99213) is provided in a freestanding physician's office,

the program pays the physician 80% of the non-facility payment rate from the PFS, with the beneficiary being responsible for the remaining 20% (70). Based on this philosophy, in 2013, the PFS non-facility rate for CPT 99213, including an E/M office visit with approximately 15-minute time utilization is $72.50. In contrast, when the same service is provided in an HOPD, the total payment rate is $123.38 – 70% more than in-office service. Ironically, when hospitals purchase a physician's practice, the practice continues to stay in the same location as long as it is within 5 miles and treats the same patients (193-195). However, by converting a practice to an outpatient department and billing under the OPPS, hospitals are able to generate higher revenues for the same service, while Medicare beneficiaries and others pay more for the exact same services. It is believed that these conditions are what is fueling the hospital purchase of practices and dominating the market.

In responding to the proposal for equalizing payments, hospitals continue to make the arguments that there are legitimate factors supporting the differences between payments. However, the MedPAC has developed a procedure for equalizing payments: same amounts have been paid for outpatient therapy services, mammography tests, dialysis services, and clinical lab tests regardless of the setting, without an interruption in access to these services. MedPAC has admitted (70) that for certain services there may be a higher level of payments required for outpatient departments due to emergency patients who may need to be transferred, the increased complexity of patients and services, licensing and accreditation requirements, and the fact that hospitals tend to combine ancillary services and supplies into a single payment. Consequently, it has been proposed that CMS may equalize payments for interventional techniques based on the ASC payment system as both facilities require accreditation licensing and other regulatory policies (192).

For accountable interventional pain management, the authors propose that coverage be based on evidence, that the excessive use of certain techniques must be addressed, and finally, that payments be equalized across ambulatory settings.

3.1 Coverage for Techniques with Evidence

The evidence for Medicare coverage policies is derived from the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), the IOM, Agency for Healthcare Research and Quality (AHRQ), and various other sources including effective health care programs (EHCs).

The MEDCAC was previously the Medicare Coverage Advisory Committee (MCAC), which was established to provide independent guidance and expert advice to the CMS on specific clinical topics (196). 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 signs (196,197). 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 (197). The MEDCAC judges the strength of available evidence and makes recommendations to the CMS based on the evidence. The MEDCAC considers several health outcomes as part of the deliberations. The committee rates how when compared to alternative or standard manage-

Table 15. *Medicare and beneficiaries pay more for a 15-minute evaluation and management office visit provided in an outpatient department than in a free-standing physician's office, 2013.*

	Service provided in freestanding physician practice*	Service provided in OPD		
		Physician facility rate*	OPPS rate	Total, OPD rate
Program payment	$58.00	$39.76	$58.94	$98.70
Beneficiary cost sharing	14.50	9.94	14.74	24.68
Total payment	72.50	49.70	73.68	123.38

Note: E&M (evaluation and management), OPD (hospital outpatient department), OPPS (outpatient prospective payment system). The Current Procedural Terminology code for this visit is 99213.
*Paid under the Medicare physician fee schedule.

Source(s): MedPAC analysis of payment rates in the 2013 physician fee schedule and OPPS and Medicare Payment Advisory Commission. Report to the Congress. Medicare and the Health Care Delivery System. Washington, DC: MedPAC. June 2013. www.medpac.gov/documents/Jun13_EntireReport.pdf

ment 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.

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

As with per many of the systematic evaluations, guidelines, and the MEDCAC, the definition of adequate evidence includes both the validity of the evidence and its general applicability or generalizability to the population of interest. The evidence derived from randomized-controlled trials is considered as the most rigorous type of evidence (12,45,61-64,198-201). The ideal randomized clinical trial is conducted in clinical practice in the patient population of interest, and evaluates interventions as typically used in routine clinical practice (12,57,140,202,203). However, there continues to be misunderstanding between a diagnostic intervention study and placebo-control and active-control trials, and a misunderstanding of the placebo itself (12,45,57,63,140,202-218). Overall, this lack of understanding and ignoring the evidence with methodological assessment alone leads to inappropriate conclusions which may be incorporated into various policies (12,70,77,219-235).

Further, the Medicare Integrity Manual (134) also provided the process to develop LCDs with the inclusion of reasonable and necessary provisions 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). Further, the conclusions and opinions must be supported by sound medical evidence based scientific data or research studies published in peer-reviewed medical journals. Thus, this evidence takes the precedence over consensus of expert medical opinion or medical opinions derived from consultations with medical associations or other health care experts. In general, Medicaid and all other carriers also utilize the same philosophy; however, most of these guidelines are developed by commercial organizations with a focus on reducing the expenditures with minimal consideration to access to care.

Development of policies based on these principles will reduce significant utilizations, specifically those with limited evidence which should be performed under only restricted conditions.

Even though there is significant debate on the effectiveness of various interventional techniques and no single guideline, systematic review or organization accepted by all, a collaborative evidence development must be based on the synthesis of evidence. . The American Society of Interventional Pain Physicians (ASIPP) interventional techniques guidelines, based on IOM principles (12), provided recommendations for various interventional techniques. They concluded that the evidence was fair to good for only 62% of the diagnostic interventions and 52% of the therapeutic interventions assessed. These guidelines were developed by a multidisciplinary panel of 51 experts with broad representation of academic and nonacademic clinical practitioners, a variety of practices and geographic areas, all with interest and expertise in interventional techniques and chronic pain management. They provided positive as well as negative evidence. Of the 8 diagnostic techniques assessed, good evidence was available for only 4 or 50% of the diagnostic interventions, with fair evidence for one intervention and limited evidence for the remaining 3 interventions. Similarly, of the 42 therapeutic interventions assessed, good evidence was available for only 5 or 12% of interventions, fair evidence was available for 17 or 40% of interventions, and/or poor evidence was available for the remaining 20 interventions. Consequently, good to fair evidence is available for only half of the therapeutic interventions and slightly less than two-thirds of the diagnostic interventions assessed. These evidence-based guidelines provide an appropriate approach to coverage policies describing the frequency of interventions.

3.2 Addressing Excessive Use of Specific Techniques

As shown earlier in this manuscript, some interventional techniques are escalating at a rapidly increasing rate (i.e., lumbar transforaminal epidural injections 806% and lumbar radiofrequency neurotomy 662%). In addition, certain areas have utilized techniques more than other areas. On the same token, there have been substantial specialty variations.

Any policy should address these issues and isolate the reasons for excessive use. The OIG investigations

into transforaminal epidural injections and facet joint injections (49,50) have shown significant issues with specialties and certain areas.

Changes in the proposed rates (190,191) in the payment schedule eliminating payments for subsequent procedures in facility settings may reduce some of these overuses. However, a significant proportion of procedures are also performed in office settings. Despite 2 separate specialty designations of interventional pain management in 2002 and pain management in 2001, the MedPAC definition of interventional techniques, and representation of interventional pain management as a specialty on the CAC, multiple primary specialties leading to specialization in interventional pain management or pain medicine, including anesthesiology, physical medicine and rehabilitation, neurology and psychiatry, have dominated the utilization of interventional techniques, along with various other specialties including surgical specialties, radiology specialties, medical specialties, and other providers. Only 29% of procedures were performed in 2011 by those designated for interventional pain management, whereas 9% were performed by the physicians designated for pain management during 2011, which included all interventional techniques except implantables, vertebral augmentation procedures, continuous epidurals, intraauricular injections, trigger point or ligament injections, and peripheral nerve blocks. Consequently, the majority (62%) of procedures are performed by various other specialties and defined as interventional techniques by the MedPAC.

Thus, the appropriate training of physicians is an important facet which may be reinforced with board certification or fellowship training, specifically by those boards which assess a person's ability to perform interventional techniques safely and effectively.

Specialty variations are also significantly important. While their primary specialty is anesthesiology, many well trained anesthesiologists and physiatrists continue to perform a majority of the procedures; however, other specialties, with no training in interventional pain management, also continue to perform these procedures.

3.3 Equalizing Payments across Ambulatory Settings

Utilizing payments for E/M services is one of the components of controlling costs of interventional pain management techniques. The second component relates to equalizing payments for interventional techniques. The MedPAC looked at HOPD and ASC procedures for equalizing payment rates, comparing the procedures that are performed in ASCs to hospital outpatient surgery rather than an office settings. Payments in ASC and HOPD settings are based on relative weights, even though the ASC system uses a lower conversion factor. In contrast to ASC and HOPD payments, in-office payments are calculated with a different practice expense component rather than a facility component. Consequently, payment rates for all procedures are much higher in the OPPS for 2013, with Medicare rates for most services being 80% higher in HOPDs than in ASCs as shown in Table 14. However, the differences are even more dramatic in the proposed 2014 schedule, with most services being 87% higher in HOPDs than ASCs (191). Similarly, payment rates are higher in ASCs compared to physician offices. Consequently, we propose that payments be equalized between ASCs and HOPDs since the complexity of these patients and other overhead factors such as licensing and regulations are similar in both settings. Manchikanti et al (42), in their analysis of the growth of spinal interventional pain management techniques and expenditures from 2000 to 2008, showed significant differences between various settings, with hospitals being the most expensive settings. As the MedPAC proposed, 3 criteria may be utilized to select services for which payment rates could be equalized between outpatient departments and ASCs.

- Safe and appropriate services
- Infrequently provided with an emergency department visit when furnished in an HOPD.
- Similar payment severity, i.e., difference in payment rate between the systems.

The MedPAC defined 12 APCs that met the 3 criteria for making payment rates equal between HOPDs and ASCs (70). These APCs included 3 nerve injection groups, namely APC 203, 204, and 207 as shown in Table 15. The MedPAC estimated that equalizing payment rates between HOPDs and ASCs for these 12 APCs would reduce program spending and beneficiary cost sharing by a total of about $590 million in one year. Equalizing payments for level IV nerve injections with APC 203 describing percutaneous adhesiolysis and neurolytic procedures will reduce payments by $13.2 million, whereas Level III nerve injections with APC 207 describing epidural injections, facet joint injections, and sacroiliac joint injections will reduce payments by

$147.5 million with a total savings from both APCs of $160.7 million. The MedPAC also projected that APC 204 with Level I nerve injections including trigger point injections and peripheral nerve blocks, there would be a savings of $46.7 million with a total savings of $207.4 million per year from Medicare payments. The MedPAC also estimated that equalizing payment rates between settings for these multiple APCs would reduce the overall Medicare revenue by 0.4% for hospitals and HOPD revenue by 1.7%. The MedPAC also described and illustrated the stop loss model in the context of revising payment rates for APCs and equalizing payment rates between various settings.

As described earlier, the changes for physical therapy and mammography testing have not produced any significant access issues. Consequently, Medicare, Medicaid, and all other providers may apply the same philosophy and curb expenses while maintaining access for a large proportion of patients when coverage is provided based on the evidence, and when excessive use of specific techniques are addressed.

Conclusion

We recommend providing coverage for techniques with evidence, addressing excessive use of specific techniques, and equalizing payments across multiple ambulatory settings.

This manuscript describes various suggestions for providing accountable interventional pain management. However, this is only achievable through collaboration between practitioners, patients, payers, and government. For evaluation and management services at present, Medicare pays approximately 70% more in a HOPD setting than in office service. For interventional techniques, total Medicare payments vary from $211.96 in an office setting to $407.28 in an ASC setting, and $655.62 in a HOPD for procedures such as epidural injections.

Consequently, we assert that a prudent purchaser should not pay more for that service in one setting than in another. At the same time, a patient should not have to undergo either an unnecessary procedure or omit a procedure based on insurance coverage and misappropriation of revenues based on inappropriate evidence. Thus, accountable interventional pain management also provides uniformity among payments, avoiding total health care expenses by moving the services to more expensive settings.

In summary, we have identified multiple interventional techniques with escalating growth and variations with payment discrepancies in different settings. We propose that coverage for interventional techniques be linked with evidence, they the excessive use of specific techniques is addressed, and that payments are equalized across various ambulatory settings.

Acknowledgments

The authors wish to thank Vidyasagar Pampati, MSc, for statistical assistance; Alvaro F. Gómez, MA, and Laurie Swick, BS, for manuscript review; and Tonie M. Hatton and Diane E. Neihoff, transcriptionists, for their assistance in preparation of this manuscript. We would like to thank the editorial board of *Pain Physician* for review and criticism in improving the manuscript.

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