

## Expenditure Analysis

## Spinal Cord Stimulation Trends of Utilization and Expenditures in Fee-For-Service (FFS) Medicare Population from 2009 to 2018

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**Background:** Spinal cord stimulation has been utilized with increasing frequency in managing chronic intractable spinal pain and complex regional pain syndrome (CRPS) in addition to other neuropathic pain states. The literature has shown the effectiveness of spinal cord stimulation in managing chronic pain with improvement in quality of life and cost utility. There have not been any reviews performed in the fee-for-service (FFS) Medicare population in reference to utilization and expenditure patterns of spinal cord stimulators.

**Objectives:** This investigation was undertaken to assess the utilization and expenditures for spinal cord stimulation in the FFS Medicare population from 2009 to 2018.

**Study Design:** The present study was designed to assess the utilization patterns and expenditures in all settings, for all providers in the FFS Medicare population from 2009 to 2018 in the United States.

A standard 5% national sample of the Centers for Medicare and Medicaid Services (CMS) physician outpatient billing claims data. All the expenditures were presented with allowed costs and adjusted to inflation to 2018 US dollars only trials and implants were included.

**Results:** Utilization patterns showed that spinal cord stimulation trials increased from 12,680 in 2009 to 36,280 in 2018, a 186% increase with an annual increase of 12.4%. The rate of trials per 100,000 population increased from 28 in 2009 to 61 in 2018 with a 120% increase, or an annual increase of 9.1%.

The pulse generator implants increased from 7,640 in 2009 to 22,960 in 2018, an increase of 201%, with an annual increase of 13%. In addition, percutaneous placement with pulse generator implants increased from 4,080 in 2009 to 14,316 in 2018, a 252% increase, or 15% annual increase. In contrast, implantation of neurostimulator electrodes with paddle leads with laminectomy and placement of spinal pulse generator increased from 3,560 in 2009 to 8,600 in 2018, a 142% increase or an annual increase of 10.3%.

Analysis of expenditures showed total inflation-adjusted expenditures increased from \$292,153,701 in 2009 to \$1,142,434,137 in 2018, a 291% increase from 2009 to 2018 and 16.4% annual increase. These expenditures were 125% higher than facet joint interventions and 138% higher than epidural interventions in 2018. In contrast, these expenditures were 55% below the expenditures of facet joint interventions and 66% lower than epidural injections in 2009.

Trial to implant ratio improved from 42.5% in 2009 to 63.6% in 2018. An overwhelming majority of trials (90%) were performed by nonsurgical physicians, whereas, 56% of implants were performed by non-surgeons.

**Limitations:** This assessment includes only FFS Medicare population, thus eliminating approximately 30% of the population with Medicare Advantage plans. In addition, this study has not taken into consideration various revisions not included in 3 specific codes.

**Conclusions:** The analysis of spinal cord stimulators in the FFS Medicare population from 2009 to 2018 showed explosive increases of trials, implants and overall costs.

**Key words:** Chronic pain, spinal pain, spinal cord stimulation, spinal cord stimulation trial, pulse generator implant, paddle leads with laminectomy, utilization trends of expenditures

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Chronic pain is a prevalent chronic disease with negative impact on the quality of life and function, with impact not only on individuals, but on families, communities, businesses, and health systems (1-9). The impact of chronic pain, of which spinal pain is the leading cause, is not only enormous, but also disproportionate in growth and expenditures (1-10). This has been reinforced in multiple manuscripts and studies of the economic impact on health care in the United States, showing an estimated spending of \$134.5 billion in 2016, with a 53.5% increase from 2013 of \$87.6 billion spent for managing spinal pain alone. Further, Dieleman et al (6) also showed that low back and neck pain had the highest amount of health care spending among 154 conditions with 57.2% of expenses paid by private insurers, 33.7% paid by public insurance, and 9.2% as out-of-pocket payments (6). National health expenditures (10) are continuing to grow at an average annual rate of 5.4% from 2019 to 2028 and to represent 19.7% of the gross domestic product by the end of the period. Medicare is growing much faster due to the graying of America (1-4,6,10). In addition, health care expenditures have been escalating and the financial impact on the US economy is growing with a perfect storm created by COVID-19, the opioid epidemic and growth in expenditures and utilization patterns often of pain procedures (1-4,11-37). Even though the COVID-19 epidemic resulted in severe access deficits for patients as well as undertreatment and a lack of treatment for elective care in 2020, growth patterns are expected to resume by 2022 (36,37).

Utilization of pharmacological and nonpharmacological modalities including surgical and nonsurgical interventions have been escalating for the treatment of chronic pain, specifically spinal pain including interventional techniques and surgical interventions, despite the decline noted for some interventions (1-4,38-42). Among these, surgical interventions and interventional techniques also have increased with an associated failure rate over the years (1-4,38-42).

Spinal cord stimulation is a neuromodulation tech-

nique utilized in managing chronic intractable pain after failure of other modalities of treatments since its first descriptions by Norman Shealy in 1967 (43). From Shealy's original single monopolar electrode, modern spinal cord stimulation has evolved into a complex multi-independent contact utilizing percutaneous and paddle leads, with the mechanism of action moving beyond the central paradigm derived from gate control theory with new therapies that do not rely on paresthesia (44-46).

Multiple theories have emerged to explain how an electrical pulse applied to the spinal cord could alleviate pain, including activation of specific supraspinal pathways, and segmental modulation of neurological interactions (44-46). Given the apparent effectiveness of the treatment, indications have been expanding associated with increased utilization and expenditures for this modality. In a systematic review of clinical effectiveness and mechanisms of action of spinal cord stimulation for treating chronic low back and lower extremity pain, Vallejo et al (45) performed a review of 11 randomized controlled trials (RCTs) and 7 non-randomized studies, which provided levels of evidence ranging from I to II. Best Practices in Managing Pain, a Department of Health and Human Services (HHS) document, also placed spinal cord stimulation in the management algorithm for chronic pain (29,47). Multiple other reviewers echoed the positive evidence. Positive correlation with cost effectiveness of spinal cord stimulators in improving the quality of life has been described, along with its positive impact (44,46-58). However, this is treatment platform has detractors who cite effectiveness, problematic cost utility, and increasing utilization as issues (59-64). The volume-outcome effect with impact of trial to permanent conversion rates (62), and explantation rates and health care sources of utilization (60), and finally increasing utilization (65) were reported.

Labaran et al (65) in a retrospective review of Medicare and private payer insurance records from 2007 to 2014, showed an overall increase in the annual rate of spinal cord stimulator placements with paddle leads with implantation peaking in 2013. Murphy et al

(62) in a large retrospective analysis using MarketScan database, analyzing adult spinal cord stimulator patients with or without implanted pulse generator implantation from the years 2007 to 2012, showed that high volume providers achieved higher trial to permanent spinal cord stimulator conversion rates than lower volume providers.

There has thus far, to our knowledge, been no analysis of either utilization patterns and expenditure patterns in the fee-for-service (FFS) Medicare population. Consequently, this analysis was undertaken to assess utilization patterns and expenditures in all settings, for all providers in the FFS Medicare population from 2009 to 2018 in the United States.

## **METHODS**

This analysis of expenditures and utilization patterns of spinal cord stimulation in the FFS Medicare population was performed utilizing a retrospective cohort analysis with methodology as described by the Strengthening and Reporting of Observational Studies in Epidemiology (STROBE) (66). The data was obtained from the Centers for Medicare and Medicaid Services' (CMS) physician outpatient billing claims for those enrolled in the FFS Medicare program for 2009 through 2018, consisting of the standard 5% national sample (67). The sample data consisting of 5% from CMS, has been reported to be unbiased and unpredictable to avoid divulging any patient characteristics. However, the data does allow appropriate tracking of patients over time and across databases. As a result of the anonymity, Institutional Review Board (IRB) approval was not required for this study.

### **Study Design**

The estimation of expenditures for spinal cord stimulation in FFS Medicare recipients was designed as a retrospective cohort study calculating the trends of costs and utilization patterns from 2009 to 2018 in the United States (67).

### **Setting**

The standard 5% national sample data was obtained from the CMS services physician outpatient billing claims for those enrolled in the FFS Medicare program from 2009 to 2018. Participants included all Medicare FFS recipients receiving epidural procedures. The current procedural terminology (CPT) codes included in this analysis are listed as follows: CPT 63650, 63655, 63685.

### **Data Sources**

CMS physician outpatient billing claims for those enrolled in the FFS Medicare program from 2009 to 2018 provided the appropriate data, facilitating the analysis.

### **Data Compilation**

Data was compiled utilizing Microsoft 365 Access and Microsoft 365 Excel (Microsoft, Redmond, WA). We removed all spinal cord stimulation interventions services with zero allowed payments. One hundred percent data was obtained by multiplication with 20 to scale up from our 5% sample to the full FFS Medicare population. The data were calculated for overall services for each procedure, and the rate of services, based on utilization per 100,000 FFS Medicare beneficiaries. Expenditures were also calculated for physician and facility, which included allowable charges for physician and facility (ambulatory surgery center [ASC], hospital outpatient department [HOPD], office setting). All the expenditures were presented with allowed costs and were adjusted for inflation to 2018 US dollars. HOPD facility allowed charges were estimated based on National Average rates.

### **Variables**

The analysis of trends of utilization and costs patterns of spinal cord stimulation interventions incorporated multiple variables with analysis and costs for all procedures, utilization based on statewide and Medicare Administrative Contractors (MACs) and location of the service provided, either office-, ASC-, or HOPD-based.

### **Measures**

Allowed services were assessed for each procedure. Rates were calculated based on Medicare beneficiaries for the corresponding year and are reported as procedures per 100,000 Medicare beneficiaries. Data was assessed for the total number of spinal cord stimulation interventions performed.

### **Bias**

Data was purchased from the CMS by the American Society of Interventional Pain Physicians (ASIPP). The study was conducted with the internal resources of the primary author's practice without external funding. The costs were determined without eliciting any bias. Thus, based on the large size of the dataset derived from a government source, there was no information related to patients' individual identification.

**Sample Size**

The size of this retrospective cohort study is robust, providing real-world claims data on Medicare patients with inclusion of all Medicare FFS patients undergoing spinal cord stimulation interventions for chronic pain from 2009 to 2018.

**RESULTS**

**Participants and Characteristics**

In this analysis, the participants were from the Medicare database undergoing spinal cord stimulation interventions from 2009 to 2018.

**Utilization Characteristics**

Table 1 and Fig. 1 show the summary of the frequency of utilization of spinal cord stimulator trials and permanent placements in the Medicare population from 2009 to 2018. As shown in this table, Medicare population increased 3% per year with a total increase of 30%. Spinal cord stimulation trials performed percutaneously increased from 12,420 in 2009 to 35,620

in 2018 with an annual increase of 12.4% and overall increase of 187%. All trials increased from 12,680 in 2009 to 36,280 in 2018, a 186% increase with an annual increase of 12.4%. The rate of trials per 100,000 population was 28 in 2009, increasing to 61 in 2018, with a 120% increase or an annual increase of 9.1%.

Implant of pulse generator interventions increased from 7,640 in 2009 to 22,960 in 2018, a 201% increase, with an annual increase of 13%. Further analysis showed that placement of pulse generator with percutaneous lead placement (CPT 63650 and 63685) increased from 4,080 in 2009 to 14,360 in 2018, a 252% increase or 15% annual increase. In contrast, implantation of neurostimulator electrodes with paddle leads with laminectomy and placement of spinal pulse generator increased (CPT 63655 and 63685), increased from 3,560 in 2009 to 8,600 in 2018, a 142% increase or an annual increase of 10.3%. Overall rate of placement of pulse generators increased from 17 in 2009 to 39 in 2018, a 129% increase or 9.6% annual increase per 100,000 population.

Trial to placement of pulse generator ratio also

Table 1. Summary of the frequency of utilization of spinal cord stimulator trials and permanent pulse generator placements in the Medicare population from 2009 to 2018.

| 100%                         | Y2009  | Y2010  | Y2011  | Y2012  | Y2013  | Y2014  | Y2015  | Y2016  | Y2017  | Y2018  | Change | GM    |
|------------------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|-------|
| SCS Trials                   |        |        |        |        |        |        |        |        |        |        |        |       |
| Medicare                     | 45,801 | 46,914 | 48,300 | 50,300 | 51,900 | 53,500 | 54,900 | 56,500 | 58,000 | 59,600 | 30%    | 3.0%  |
| CPT 63650                    | 12,420 | 19,760 | 22,320 | 23,100 | 23,880 | 21,400 | 21,620 | 27,920 | 33,800 | 35,620 | 187%   | 12.4% |
| CPT 63655                    | 260    | 440    | 400    | 540    | 500    | 380    | 480    | 460    | 540    | 660    | 154%   | 10.9% |
| trials total                 | 12,680 | 20,200 | 22,720 | 23,640 | 24,380 | 21,780 | 22,100 | 28,380 | 34,340 | 36,280 | 186%   | 12.4% |
| Rate                         | 28     | 43     | 47     | 47     | 47     | 41     | 40     | 50     | 59     | 61     | 120%   | 9.1%  |
| PCPY                         |        | 59%    | 12%    | 4%     | 3%     | -11%   | 1%     | 28%    | 21%    | 6%     |        |       |
| Placement of pulse generator |        |        |        |        |        |        |        |        |        |        |        |       |
| 63650 & 63685                | 4,080  | 5,140  | 5,180  | 5,520  | 5,940  | 6,480  | 7,660  | 9,360  | 13,300 | 14,360 | 252%   | 15.0% |
| 63655 & 63685                | 3,560  | 4,440  | 4,760  | 5,820  | 6,500  | 5,080  | 5,000  | 5,900  | 7,320  | 8,600  | 142%   | 10.3% |
| Placement                    | 7,640  | 9,580  | 9,940  | 11,340 | 12,440 | 11,560 | 12,660 | 15,260 | 20,620 | 22,960 | 201%   | 13.0% |
| Rate                         | 17     | 21     | 22     | 23     | 24     | 22     | 24     | 27     | 36     | 39     | 129%   | 9.6%  |
| PCPY                         |        | 27%    | 6%     | 12%    | 8%     | -7%    | 11%    | 19%    | 34%    | 11%    |        |       |
| Placement %                  | 42.5%  | 48.6%  | 45.8%  | 49.3%  | 51.7%  | 53.6%  | 58.6%  | 54.5%  | 60.5%  | 63.6%  |        |       |

63650 - Percutaneous implantation of neurostimulator electrode array, epidural  
 63655 - Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural  
 63685 - Insertion of spinal neurostimulator pulse generator or receiver, direct or inductive coupling  
 Rate - per 100,000 Medicare beneficiaries, GM - Annual average change (geometric)  
 PCPY - Percentage of change from previous year  
 Change - Change 2018 from 2009  
 SCS - spinal cord stimulator

## Expenditures for Spinal Cord Stimulation in Medicare Population

showed significant change from 42.5% in 2009 to 63.6% in 2018. The data which is not shown in the table also showed that duration between trial and placement was less than one month in 43% of the patients, one to 2 months in 37%, 2 to 3 months in 10%, 3 to 6 months in 6%, and above 6 months in 4% of the population with average duration between trial and placement of 7.6 weeks.

Table 2 shows the summary of the frequency of utilization of spinal cord stimulation trials by gender, age, and place of service in the Medicare population by place of service. Rate of trials was 38 to 41 male to female ratio per 100,000 Medicare population, which remained similar with 60% in males and 62 in females in 2018.

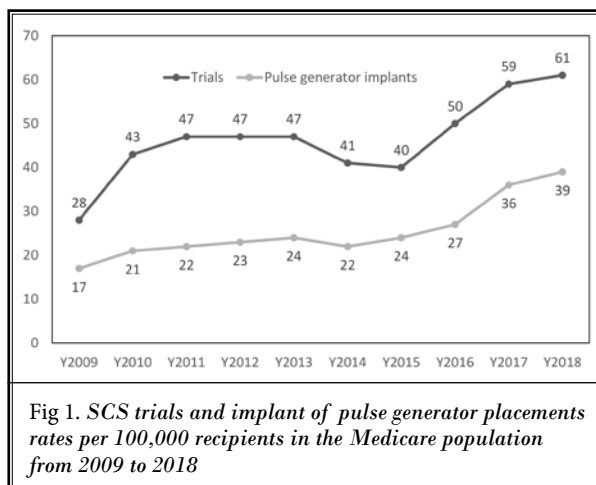


Fig 1. SCS trials and implant of pulse generator placements rates per 100,000 recipients in the Medicare population from 2009 to 2018

Table 2. Summary of the frequency of utilization of spinal cord stimulator TRIALS by gender, age and place of service in the Medicare population by place of service from 2009 to 2018.

| Gender           | F2009  | F2010  | F2011  | F2012  | F2013  | F2014  | F2015  | F2016  | F2017  | F2018  | Change | GM    |
|------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|-------|
| Male             | 5,100  | 7,840  | 8,380  | 9,740  | 10,260 | 8,460  | 9,160  | 12,660 | 15,820 | 15,620 | 206%   | 13.2% |
| Rate             | 25     | 38     | 40     | 44     | 45     | 36     | 38     | 50     | 61     | 60     | 134%   | 9.9%  |
| Female           | 7,580  | 12,360 | 14,340 | 13,900 | 14,120 | 13,320 | 12,940 | 15,720 | 18,520 | 20,660 | 173%   | 11.8% |
| Rate             | 29     | 47     | 53     | 49     | 49     | 45     | 42     | 50     | 57     | 62     | 111%   | 8.6%  |
| Age              | F2009  | F2010  | F2011  | F2012  | F2013  | F2014  | F2015  | F2016  | F2017  | F2018  | Change | GM    |
| <65              | 5,460  | 8,200  | 10,060 | 10,060 | 10,240 | 8,740  | 8,240  | 8,900  | 10,500 | 10,520 | 93%    | 7.6%  |
| Rate             | 72     | 104    | 123    | 119    | 119    | 100    | 94     | 101    | 120    | 122    | 70%    | 6.0%  |
| 65-74            | 3,800  | 6,360  | 6,720  | 7,820  | 8,580  | 7,620  | 8,140  | 11,360 | 13,860 | 14,900 | 292%   | 16.4% |
| Rate             | 19     | 31     | 31     | 34     | 36     | 30     | 31     | 42     | 49     | 51     | 168%   | 11.6% |
| 75-84            | 2,800  | 4,760  | 4,920  | 4,740  | 4,760  | 4,580  | 4,800  | 6,740  | 8,420  | 9,320  | 233%   | 14.3% |
| Rate             | 22     | 38     | 39     | 37     | 37     | 35     | 36     | 49     | 58     | 62     | 176%   | 11.9% |
| >= 84            | 620    | 880    | 1,020  | 1,020  | 800    | 840    | 920    | 1,380  | 1,560  | 1,540  | 148%   | 10.6% |
| Rate             | 11     | 15     | 17     | 16     | 13     | 13     | 14     | 21     | 23     | 23     | 115%   | 8.9%  |
| Race             | F2009  | F2010  | F2011  | F2012  | F2013  | F2014  | F2015  | F2016  | F2017  | F2018  | Change | GM    |
| Caucasian        | 11,400 | 18,060 | 20,340 | 20,840 | 21,940 | 19,120 | 19,900 | 25,240 | 30,520 | 32,380 | 184%   | 12.3% |
| Rate             | 32     | 49     | 54     | 54     | 55     | 47     | 48     | 59     | 70     | 72     | 128%   | 9.6%  |
| African-American | 940    | 1,360  | 1,480  | 1,920  | 1,520  | 1,820  | 1,280  | 1,980  | 2,200  | 2,140  | 128%   | 9.6%  |
| Rate             | 21     | 30     | 31     | 38     | 29     | 33     | 23     | 34     | 37     | 35     | 66%    | 5.8%  |
| Others           | 340    | 780    | 900    | 880    | 920    | 840    | 920    | 1,160  | 1,620  | 1,760  | 418%   | 20.0% |
| Rate             | 6      | 14     | 15     | 14     | 14     | 12     | 12     | 14     | 19     | 20     | 222%   | 13.9% |
| PLACE            | F2009  | F2010  | F2011  | F2012  | F2013  | F2014  | F2015  | F2016  | F2017  | F2018  | Change | GM    |
| ASC              | 2,880  | 4,720  | 5,740  | 4,940  | 4,880  | 6,220  | 7,140  | 10,080 | 13,540 | 14,500 | 403%   | 19.7% |
| Rate             | 6      | 10     | 12     | 10     | 9      | 12     | 13     | 18     | 23     | 24     | 287%   | 16.2% |
| HOPD             | 4,180  | 6,640  | 6,780  | 6,840  | 7,020  | 6,860  | 7,260  | 8,460  | 10,700 | 10,640 | 155%   | 10.9% |
| Rate             | 9      | 14     | 14     | 14     | 14     | 13     | 13     | 15     | 18     | 18     | 96%    | 7.7%  |
| Office           | 5,620  | 8,840  | 10,200 | 11,860 | 12,480 | 8,700  | 7,700  | 9,840  | 10,100 | 11,140 | 98%    | 7.9%  |
| Rate             | 12     | 19     | 21     | 24     | 24     | 16     | 14     | 17     | 17     | 19     | 52%    | 4.8%  |
| Total            | 12,680 | 20,200 | 22,720 | 23,640 | 24,380 | 21,780 | 22,100 | 28,380 | 34,340 | 36,280 | 186%   | 12.4% |
| Rate             | 28     | 43     | 47     | 47     | 47     | 41     | 40     | 50     | 59     | 61     | 120%   | 9.1%  |

Age characteristics showed a rate of 72 per 100,000 Medicare population in 2009 for those below 65, whereas, it was 52 for those 65 or older, with a change in rate to 122 per 100,000 Medicare population in those below 65 and 136 in those 65 or older. While the change was 70% in those below age of 65, it was higher for all other age groups with a 168% increase for an annual increase of 11.6% in those 65 to 74, 176% for an annual increase of 11.9% in those 75 to 84, and 115% for an annual increase of 8.9% in those who were 85 or older.

Racial statistics showed the rate per 100,000 Medicare population of 32 in 2009 compared to 72 in 2018 in those described as Caucasian, with an increase of 128% or 9.6% annually. Comparing this to African American population, the rate was 21 per 100,000 Medicare population in 2009, which increased to 35 in

2018, an overall increase of 66% and annual increase of 5.8%. However, the most increase was in all others, which was 6 per 100,000 Medicare population in 2009 and increased to 20 in 2018, a 222% increase, with an annual increase of 13.9%.

Table 2 also shows site of service for trials. The overall increase in the rate of performance of the trials was 28 in 2009 and 61 per 100,000 Medicare population in 2018, a 120% increase or 9.1% annual increase. Significant increases were seen in ASC settings with rate of 6 in 2009, increasing to 24 in 2018, for an increase of 287%, or 16.2% annual increase. In contrast, rates increased 96% in HOPD settings, and 52% in office settings. Overall, 40% were performed in ASC settings, 29% in HOPD settings, and 31% in office settings in 2018.

Table 3 shows the frequency of utilization of spi-

Table 3. Summary of the frequency of utilization of spinal cord stimulator PLACEMENTS by gender, age and place of service in the Medicare population by place of service from 2009 to 2018.

| Gender           | F2009 | F2010 | F2011 | F2012  | F2013  | F2014  | F2015  | F2016  | F2017  | F2018  | Change | Rate  |
|------------------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|--------|-------|
| Male             | 3,440 | 3,720 | 3,660 | 4,400  | 5,080  | 4,240  | 5,100  | 6,500  | 8,700  | 9,900  | 188%   | 12.5% |
| Rate             | 17    | 18    | 17    | 20     | 22     | 18     | 21     | 26     | 34     | 38     | 120%   | 9.1%  |
| Female           | 4,200 | 5,860 | 6,280 | 6,940  | 7,360  | 7,320  | 7,560  | 8,760  | 11,920 | 13,060 | 211%   | 13.4% |
| Rate             | 16    | 22    | 23    | 25     | 25     | 25     | 25     | 28     | 37     | 39     | 140%   | 10.2% |
| Age              | F2009 | F2010 | F2011 | F2012  | F2013  | F2014  | F2015  | F2016  | F2017  | F2018  | Change | Rate  |
| <65              | 3,180 | 3,480 | 4,560 | 4,780  | 5,140  | 4,620  | 5,040  | 4,840  | 6,140  | 6,660  | 109%   | 8.6%  |
| Rate             | 42    | 44    | 56    | 57     | 60     | 53     | 57     | 55     | 70     | 77     | 84%    | 7.0%  |
| 65-74            | 2,640 | 3,360 | 3,040 | 3,660  | 4,880  | 4,260  | 4,580  | 6,040  | 8,520  | 9,320  | 253%   | 15.0% |
| Rate             | 13    | 16    | 14    | 16     | 20     | 17     | 18     | 22     | 30     | 32     | 141%   | 10.3% |
| 75-84            | 1,620 | 2,380 | 2,000 | 2,400  | 2,080  | 2,220  | 2,560  | 3,820  | 5,060  | 6,000  | 270%   | 15.7% |
| Rate             | 13    | 19    | 16    | 19     | 16     | 17     | 19     | 28     | 35     | 40     | 207%   | 13.3% |
| ≥ 85             | 200   | 360   | 340   | 500    | 340    | 460    | 480    | 560    | 900    | 980    | 390%   | 19.3% |
| Rate             | 3     | 6     | 6     | 8      | 5      | 7      | 7      | 9      | 13     | 15     | 324%   | 17.4% |
| Race             | F2009 | F2010 | F2011 | F2012  | F2013  | F2014  | F2015  | F2016  | F2017  | F2018  | Change | Rate  |
| Caucasian        | 6,880 | 8,660 | 9,180 | 10,060 | 11,160 | 10,340 | 11,680 | 14,080 | 18,460 | 20,840 | 203%   | 13.1% |
| Rate             | 19    | 24    | 24    | 26     | 28     | 25     | 28     | 33     | 42     | 47     | 143%   | 10.4% |
| African-American | 580   | 580   | 520   | 860    | 860    | 880    | 600    | 720    | 1,120  | 1,220  | 110%   | 8.6%  |
| Rate             | 13    | 13    | 11    | 17     | 17     | 16     | 11     | 12     | 19     | 20     | 54%    | 4.9%  |
| Others           | 180   | 340   | 240   | 420    | 420    | 340    | 380    | 460    | 1,040  | 900    | 400%   | 19.6% |
| Rate             | 3     | 6     | 4     | 7      | 6      | 5      | 5      | 6      | 12     | 10     | 211%   | 13.4% |
| Place            | F2009 | F2010 | F2011 | F2012  | F2013  | F2014  | F2015  | F2016  | F2017  | F2018  | Change | Rate  |
| ASC              | 840   | 1,280 | 1,300 | 1,420  | 1,660  | 1,800  | 3,380  | 4,980  | 7,700  | 8,640  | 929%   | 29.6% |
| Rate             | 2     | 3     | 3     | 3      | 3      | 3      | 6      | 9      | 13     | 14     | 690%   | 25.8% |
| HOPD             | 6,800 | 8,300 | 8,640 | 9,920  | 10,780 | 9,760  | 9,280  | 10,280 | 12,920 | 14,320 | 111%   | 8.6%  |
| Rate             | 15    | 18    | 18    | 20     | 21     | 18     | 17     | 18     | 22     | 24     | 62%    | 5.5%  |
| Total            | 7,640 | 9,580 | 9,940 | 11,340 | 12,440 | 11,560 | 12,660 | 15,260 | 20,620 | 22,960 | 201%   | 13.0% |
| Rate             | 17    | 20    | 21    | 23     | 24     | 22     | 23     | 27     | 36     | 39     | 131%   | 9.7%  |



nal neurostimulator pulse generator patterns. Figure 2 illustrates characteristic features of place of service for spinal cord stimulator trials and pulse generator implants with changing utilization patterns as shown in Tables 2 and 3.

Gender variations with male to female ratio remained similar with 17/16 in 2009, changing to 38/39, with overall increase in the rate of 120%/140% with annual rate changes of 9.1%/10.2%.

Age variations also showed similar patterns as in trials with pulse generator placement rate of 42 for those below 65, to 29 for those above 84, changing to 77 for those below 65 to 87 for those 65 and above. The highest change was noted in those 85 or over with a 324% increase, followed by those 75 to 84 with 207%. The least change was in those Medicare recipients less than 65 years of age.

Racial distribution showed Caucasian to African American of 32/21 with others at 6 per 100,000 Medicare population in 2009 changing to 72/35 with others increased to 20 from 6 per 100,000 Medicare population. The highest increase was seen for the others category, non-African-American, and non-Caucasian population; however, the numbers were small. This was followed by a significant increase for the Caucasian population, whereas, increases were less significant for the African American population; however, African American population constitute only 13.4% of Medicare population.

Permanent placements based on the location also changed significantly with extensive increases in the rates of 131% from 17 per 100,000 Medicare population to 39 in 2018, a 131% increase and an annual increase of 9.7%. Dramatic increases were noted in ASC settings with an increase from 2 to 14 per 100,000 Medicare population or 690%; however, in actual numbers HOPD utilizations were

significantly higher with 15 in 2009 to 24 in 2018, for a 62% increase (Tables 1 and 2 and Fig. 3). Hospitals performed 62% of the implants, while 38% were performed in ASC centers (Fig. 3).

Table 4 and Fig. 3 show the utilization patterns of spinal cord stimulation interventions by various specialty groups from 2009 to 2018 with overall interventional groups, including all non-surgical specialties. Interventional pain management specialties performed about 90% of the total trials and 56% of total pulse generator placements with an increased rate of utilization of 189% for trials and 235% for pulse generator placements among these groups. In

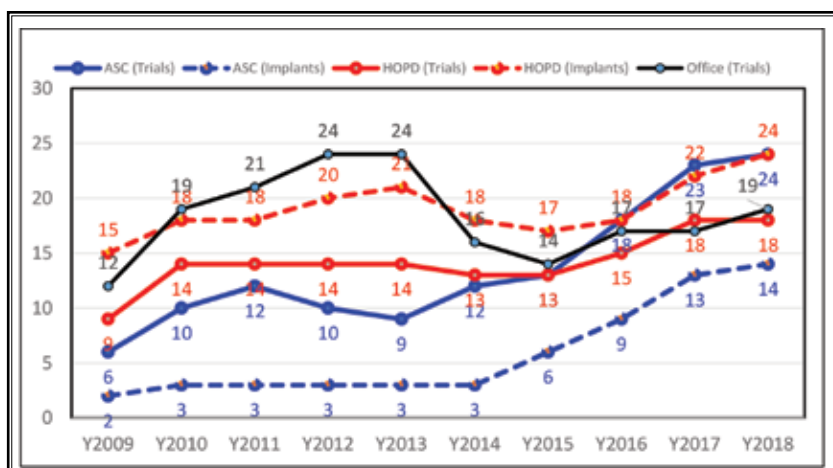


Fig. 2. Characteristics of place of service for spinal cord stimulator trials and pulse generator implants.



Fig. 3. Specialty characteristics of spinal cord stimulator trials and pulse generator implants.

Table 4. Summary of the frequency of utilization of spinal cord stimulation trials and neurostimulator placements in the Medicare population by specialty from 2009 to 2018.

| Specialty (Trials)                    | F2009  | F2010  | F2011  | F2012  | F2013  | F2014  | F2015  | F2016  | F2017  | F2018  | Change | GM    |
|---------------------------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|-------|
| Surgeons Group                        | 840    | 1,360  | 1,160  | 1,820  | 1,620  | 1,240  | 1,240  | 1,620  | 2,620  | 2,380  | 183%   | 12.3% |
| Rate                                  | 2      | 3      | 2      | 4      | 3      | 2      | 2      | 3      | 5      | 4      | 118%   | 9.0%  |
| Interventional Pain Management Groups | 11,340 | 18,000 | 20,780 | 21,120 | 22,140 | 19,580 | 19,760 | 24,740 | 30,320 | 32,820 | 189%   | 12.5% |
| Percentage to Total                   | 90%    | 89%    | 91%    | 89%    | 91%    | 90%    | 89%    | 87%    | 88%    | 90%    |        |       |
| Rate                                  | 25     | 38     | 43     | 42     | 43     | 37     | 36     | 44     | 52     | 55     | 122%   | 9.3%  |
| Others                                | 460    | 840    | 780    | 700    | 620    | 960    | 1,100  | 2,020  | 1,400  | 1,080  | 135%   | 9.9%  |
| Rate                                  | 1      | 2      | 2      | 1      | 1      | 2      | 2      | 4      | 2      | 2      | 80%    | 6.8%  |
| Total                                 | 12,640 | 20,200 | 22,720 | 23,640 | 24,380 | 21,780 | 22,100 | 28,380 | 34,340 | 36,280 | 187%   | 12.4% |
| Rate                                  | 28     | 43     | 47     | 47     | 47     | 41     | 40     | 50     | 59     | 61     | 121%   | 9.2%  |
| Specialty Pulse Generators            | 2009   | 2010   | 2011   | 2012   | 2013   | 2014   | 2015   | 2016   | 2017   | 2018   | change | GM    |
| Surgeon Groups                        | 3,680  | 4,660  | 4,780  | 5,980  | 6,800  | 5,760  | 5,580  | 6,700  | 8,300  | 9,620  | 161%   | 8.4%  |
| % to total                            | 48%    | 49%    | 48%    | 53%    | 55%    | 50%    | 44%    | 44%    | 40%    | 42%    | -13%   | -1.6% |
| Rate                                  | 8      | 10     | 10     | 12     | 13     | 11     | 10     | 12     | 14     | 16     | 101%   | 5.5%  |
| Interventional Pain Management Groups | 3,860  | 4,760  | 4,900  | 5,080  | 5,300  | 5,580  | 6,780  | 8,100  | 11,500 | 12,920 | 235%   | 11.7% |
| % to Total                            | 51%    | 50%    | 49%    | 45%    | 43%    | 48%    | 54%    | 53%    | 56%    | 56%    | 11%    | 1.40% |
| Rate                                  | 8      | 10     | 10     | 10     | 10     | 10     | 12     | 14     | 20     | 22     | 157%   | 8.8%  |
| Others                                | 100    | 160    | 260    | 300    | 340    | 220    | 300    | 460    | 840    | 420    | 320%   | 11.3% |
| Rate                                  | 0      | 0      | 1      | 1      | 1      | 0      | 1      | 1      | 1      | 1      | 223%   | 8.4%  |
| Total                                 | 7,640  | 9,580  | 9,940  | 11,340 | 12,440 | 11,560 | 12,660 | 15,260 | 20,620 | 22,960 | 201%   | 10.2% |
| Rate                                  | 17     | 20     | 21     | 23     | 24     | 22     | 23     | 27     | 36     | 39     | 131%   | 7.3%  |

Surgeons (Neurosurgery & Orthopedic Surgery); Pain Management Groups (Anesthesiology, IPM, Pain Management, PM&R and very few cases from Neurology)

contrast, surgical groups showed a 118% increase in trials and a 161% increase in pulse generator implants from 2009 to 2018.

As shown in Appendix Table 1, the top 5-principal diagnoses for spinal cord stimulation trial implants included chronic pain, post laminectomy syndrome, radiculopathy, low back pain, and others.

State-wide characteristics based on Medicare carrier jurisdictions (Appendix Table 2) showed overall countrywide increase from 28 per 100,000 Medicare population in 2009 to 61 in 2018 for a 120% overall increase and 9% annual increase. The total increases ranged in various MAC jurisdictions from 52% in the old First Coast jurisdiction to a 249% increase in Palmetto, National Government Services (NGS) with an increase of 182%, Noridian with an increase of 119%, Novitas with an increase of 110%, Palmetto with an increase of 164%, and finally WPS with an increase of 159%.

### Expenditure Characteristics

Appendix Table 3 shows Medicare national payment rates. Table 5 shows average allowed charges with inflation-adjusted rates for trials. The total costs of \$77,144,859 in 2009 increasing to \$247,153,988 for a 220.4% increase and an annual increase of 13.8%. The average costs were \$6,084 in 2009 for each trial compared to \$6,812 in 2018, with an annual increase of 1.3% or an overall increase of 12%. Inflation adjusted costs showed an increase of 173.8% compared to 220.4% prior to inflation and an annual increase of 11.8% instead of 13.8% prior to inflation. Average costs per trial also showed a pattern of decline with \$7,118 in 2009 to \$6,812 in 2018 with an overall decrease of 4.3% and an annual decrease of 0.5%.

Major increases in expenditures were seen for ASCs with 773%, whereas, increases were 246% for HOPD settings, followed by a decline of 40% for in-office settings.

Table 6 shows average allowed charges with



Expenditures for Spinal Cord Stimulation in Medicare Population

Table 5. Average allowed charges with inflation-adjusted rates for spinal cord stimulator trials.

| HOPD           | Y2009        | Y2010         | Y2011         | Y2012         | Y2013         | Y2014         | Y2015         | Y2016         | Y2017         | Y2018         | Change | GM     |
|----------------|--------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|--------|--------|
| No. of Trials  | 4,180        | 6,640         | 6,780         | 6,840         | 7,020         | 6,860         | 7,260         | 8,460         | 10,700        | 10,640        | 154.5% | 10.9%  |
| Services       | 6000         | 9200          | 9200          | 9880          | 9400          | 9260          | 9520          | 11000         | 13220         | 13700         | 128.3% | 9.6%   |
| Professional   | \$2,115,784  | \$3,521,579   | \$3,680,797   | \$4,005,979   | \$4,152,926   | \$4,000,812   | \$4,182,739   | \$4,779,693   | \$5,820,782   | \$6,253,744   | 195.6% | 12.8%  |
| Facility       | \$25,910,887 | \$41,760,056  | \$43,595,725  | \$45,601,589  | \$43,129,379  | \$44,139,924  | \$56,327,880  | \$63,059,500  | \$84,231,404  | \$90,676,743  | 250.0% | 14.9%  |
| Total          | \$28,026,671 | \$45,281,634  | \$47,276,521  | \$49,607,568  | \$47,282,305  | \$48,140,736  | \$60,510,619  | \$67,839,194  | \$90,052,186  | \$96,930,487  | 245.9% | 14.8%  |
| Average        | \$6,704.95   | \$6,819.52    | \$6,972.94    | \$7,252.57    | \$6,735.37    | \$7,017.60    | \$8,334.80    | \$8,018.82    | \$8,416.09    | \$9,110.01    | 35.9%  | 3.5%   |
| ASC            | 2009         | 2010          | 2011          | 2012          | 2013          | 2014          | 2015          | 2016          | 2017          | 2018          | 0.4%   | 0.0%   |
| Trials         | 2,880        | 4,720         | 5,740         | 4,940         | 4,880         | 6,220         | 7,140         | 10,080        | 13,540        | 14,500        | 403.5% | 19.7%  |
| Services       | 3840         | 6240          | 8180          | 7620          | 7300          | 8660          | 9800          | 14440         | 17820         | 19940         | 419.3% | 20.1%  |
| Prof           | \$1,349,545  | \$2,293,771   | \$3,122,152   | \$2,868,923   | \$2,964,364   | \$3,447,871   | \$3,900,393   | \$5,798,608   | \$7,449,167   | \$8,265,243   | 512.4% | 22.3%  |
| Facility       | \$13,512,506 | \$25,902,326  | \$34,248,854  | \$28,612,063  | \$29,502,272  | \$35,344,894  | \$44,287,232  | \$71,495,075  | \$107,086,697 | \$121,460,156 | 798.9% | 27.6%  |
| Total          | \$14,862,051 | \$28,196,098  | \$37,371,005  | \$31,480,986  | \$32,466,635  | \$38,792,765  | \$48,187,624  | \$77,293,683  | \$114,535,864 | \$129,725,399 | 772.9% | 27.2%  |
| Average        | \$5,160.43   | \$5,973.75    | \$6,510.63    | \$6,372.67    | \$6,653.00    | \$6,236.78    | \$6,748.97    | \$7,668.02    | \$8,459.07    | \$8,946.58    | 73.4%  | 6.3%   |
| Office Setting | Y2009        | Y2010         | Y2011         | Y2012         | Y2013         | Y2014         | Y2015         | Y2016         | Y2017         | Y2018         |        |        |
| Trials         | 5,620        | 8,840         | 10,200        | 11,860        | 12,480        | 8,700         | 7,700         | 9,840         | 10,100        | 11,140        | 98.2%  | 7.9%   |
| Services       | 8,560        | 13,240        | 15,780        | 18,900        | 19,180        | 12,960        | 10,780        | 13,140        | 13,720        | 14,900        | 74.1%  | 6.4%   |
| Prof           | \$1,228,687  | \$1,893,147   | \$2,311,184   | \$2,695,306   | \$2,909,184   | \$5,025,771   | \$4,371,650   | \$5,428,254   | \$5,602,131   | \$6,665,096   | 442.5% | 20.7%  |
| Over           | \$33,027,450 | \$52,457,136  | \$64,530,057  | \$78,284,495  | \$87,231,905  | \$18,113,172  | \$9,138,630   | \$11,276,861  | \$11,608,828  | \$13,833,006  | -58.1% | -9.2%  |
| Total          | \$34,256,137 | \$54,350,283  | \$66,841,242  | \$80,979,801  | \$90,141,089  | \$23,138,942  | \$13,510,280  | \$16,705,114  | \$17,210,959  | \$20,498,102  | -40.2% | -5.5%  |
| Average        | \$6,095.40   | \$6,148.22    | \$6,553.06    | \$6,827.98    | \$7,222.84    | \$2,659.65    | \$1,754.58    | \$1,697.67    | \$1,704.06    | \$1,840.05    | -69.8% | -12.5% |
| Total Trials   | 12,680       | 20,200        | 22,720        | 23,640        | 24,380        | 21,780        | 22,100        | 28,380        | 34,340        | 36,280        | 186.1% | 12.4%  |
| PCPY           |              | 59%           | 12%           | 4%            | 3%            | -11%          | 1%            | 28%           | 21%           | 6%            |        |        |
| Services       | 18,400       | 28,680        | 33,160        | 36,400        | 35,880        | 30,880        | 30,100        | 38,580        | 44,760        | 48,540        | 163.8% | 11.4%  |
| Professional   | 4,694,016    | 7,708,497     | 9,114,133     | 9,570,208     | 10,026,474    | 12,474,454    | 12,454,782    | 16,006,555    | 18,872,080    | 21,184,083    | 351.3% | 18.2%  |
| Facility       | 72,450,843   | 120,119,518   | 142,374,636   | 152,498,147   | 159,863,556   | 97,597,990    | 109,753,742   | 145,831,436   | 202,926,929   | 225,969,905   | 211.9% | 13.5%  |
| Total          | 77,144,859   | 127,828,015   | 151,488,768   | 162,068,355   | 169,890,029   | 110,072,443   | 122,208,523   | 161,837,991   | 221,799,009   | 247,153,988   | 220.4% | 13.8%  |
| Average        | \$6,084      | \$6,328       | \$6,668       | \$6,856       | \$6,968       | \$5,054       | \$5,530       | \$5,703       | \$6,459       | \$6,812       | 12.0%  | 1.3%   |
| Total*         | \$90,259,485 | \$147,002,217 | \$169,667,420 | \$176,654,507 | \$183,481,231 | \$116,676,790 | \$129,541,034 | \$169,929,890 | \$226,234,990 | \$247,153,988 | 173.8% | 11.8%  |
| PCPY           |              | -263%         | -215%         | -204%         | -204%         | -164%         | -211%         | -231%         | -233%         | -209%         |        |        |
| Average*       | \$7,118      | \$7,277       | \$7,468       | \$7,473       | \$7,526       | \$5,357       | \$5,862       | \$5,988       | \$6,588       | \$6,812       | -4.3%  | -0.5%  |
| PCPY           |              | 2.2%          | 2.6%          | 0.1%          | 0.7%          | -28.8%        | 9.4%          | 2.2%          | 10.0%         | 3.4%          |        |        |

\* inflation adjusted rates

Table 6. Average allowed charges with inflation-adjusted rates for spinal cord stimulator pulse generator implants.

| HOPD             | 2009          | 2010          | 2011          | 2012          | 2013          | 2014          | 2015          | 2016          | 2017          | 2018          | Change | GM    |
|------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|--------|-------|
| Placements       | 6800          | 8300          | 8640          | 9920          | 10780         | 9760          | 9280          | 10280         | 12920         | 14320         | 111%   | 8.6%  |
| 63650            | 5,320         | 6,440         | 6,400         | 7,000         | 7,260         | 7,180         | 7,160         | 7,400         | 9,240         | 10,000        | 88%    | 7.3%  |
| 63655            | 3,620         | 4,380         | 4,400         | 5,780         | 6,400         | 5,000         | 4,360         | 5,040         | 5,720         | 6,800         | 88%    | 7.3%  |
| 63685            | 6,800         | 8,140         | 8,080         | 9,960         | 10,940        | 9,720         | 9,260         | 10,340        | 12,380        | 14,320        | 111%   | 8.6%  |
| Prof.            | \$5,881,289   | \$7,697,025   | \$7,991,367   | \$9,192,718   | \$10,195,827  | \$9,034,023   | \$8,434,750   | \$9,327,707   | \$11,678,505  | \$12,890,579  | 119%   | 9.1%  |
| Facility         | \$148,131,620 | \$167,660,297 | \$176,052,795 | \$218,742,671 | \$255,354,166 | \$238,349,880 | \$355,130,554 | \$403,087,750 | \$490,084,527 | \$585,459,008 | 295%   | 16.5% |
| Total            | \$154,012,909 | \$175,357,322 | \$184,044,162 | \$227,935,389 | \$265,549,993 | \$247,383,903 | \$363,565,304 | \$412,415,457 | \$501,763,032 | \$598,349,587 | 289%   | 16.3% |
| Average          | \$22,649      | \$21,127      | \$21,301      | \$22,977      | \$24,634      | \$23,347      | \$39,177      | \$40,118      | \$38,836      | \$41,784      | 84%    | 7.0%  |
| ASC              | 2009          | 2010          | 2011          | 2012          | 2013          | 2014          | 2015          | 2016          | 2017          | 2018          | 0%     | 0.0%  |
| Placements       | 840           | 1280          | 1300          | 1420          | 1660          | 1800          | 3380          | 4980          | 7700          | 8640          | 929%   | 29.6% |
| 63650            | 1320          | 2100          | 1900          | 2140          | 2100          | 2480          | 4220          | 6280          | 9060          | 9760          | 639%   | 24.9% |
|                  |               | 20            | 100           | 140           | 280           | 140           | 620           | 820           | 1220          | 1660          |        |       |
| 63685            | 840           | 1080          | 1180          | 1280          | 1480          | 1560          | 3060          | 4660          | 6800          | 8280          | 886%   | 28.9% |
| Prof.            | \$630,637     | \$931,597     | \$1,060,264   | \$1,150,537   | \$1,346,469   | \$1,394,933   | \$2,737,271   | \$4,077,199   | \$6,108,309   | \$7,199,072   | 1042%  | 31.1% |
| Facility         | \$17,915,613  | \$27,013,473  | \$26,220,750  | \$30,339,994  | \$34,582,954  | \$40,083,414  | \$98,087,052  | \$137,649,365 | \$222,981,439 | \$289,731,490 | 1517%  | 36.2% |
| Total            | \$18,546,250  | \$27,945,070  | \$27,281,014  | \$31,490,531  | \$35,929,423  | \$41,478,347  | \$100,824,323 | \$141,726,564 | \$229,089,747 | \$296,930,562 | 1501%  | 36.1% |
| Average          | \$22,079      | \$21,832      | \$20,985      | \$22,176      | \$21,644      | \$23,044      | \$29,830      | \$28,459      | \$29,752      | \$34,367      | 56%    | 5.0%  |
| Total Placements | 7,640         | 9,580         | 9,940         | 11,340        | 12,440        | 11,560        | 12,660        | 15,260        | 20,620        | 22,960        | 201%   | 13.0% |
| Prof.            | \$6,511,926   | \$8,628,621   | \$9,051,631   | \$10,343,255  | \$11,542,296  | \$10,428,955  | \$11,172,021  | \$13,404,907  | \$17,786,814  | \$20,089,651  | 209%   | 13.3% |
| PCPY             |               | 33%           | 5%            | 14%           | 12%           | -10%          | 7%            | 20%           | 33%           | 13%           |        |       |
| Overhead         | \$166,047,233 | \$194,673,770 | \$202,273,545 | \$249,082,665 | \$289,937,120 | \$278,433,294 | \$453,217,606 | \$540,737,115 | \$713,065,966 | \$875,190,498 | 427%   | 20.3% |
|                  |               | 17%           | 4%            | 23%           | 16%           | -4%           | 63%           | 19%           | 32%           | 23%           |        |       |
| Total            | \$172,559,159 | \$203,302,391 | \$211,325,176 | \$259,425,920 | \$301,479,416 | \$288,862,249 | \$464,389,627 | \$554,142,022 | \$730,852,780 | \$895,280,149 | 419%   | 20.1% |
| PCPY             |               | 18%           | 4%            | 23%           | 16%           | -4%           | 61%           | 19%           | 32%           | 22%           |        |       |
| Total*           | \$201,894,216 | \$233,797,750 | \$236,684,197 | \$282,774,253 | \$325,597,769 | \$306,193,984 | \$492,253,005 | \$581,849,123 | \$745,469,835 | \$895,280,149 | 343%   | 18.0% |
| PCPY             |               | 16%           | 1%            | 19%           | 15%           | -6%           | 61%           | 18%           | 28%           | 20%           |        |       |
| Average          | \$22,586      | \$21,222      | \$21,260      | \$22,877      | \$24,235      | \$24,988      | \$36,682      | \$36,313      | \$35,444      | \$38,993      | 73%    | 6.3%  |
| Average*         | \$26,426      | \$24,405      | \$23,811      | \$24,936      | \$26,173      | \$26,487      | \$38,883      | \$38,129      | \$36,153      | \$38,993      | 48%    | 4.4%  |

inflation-adjusted rates for neurostimulator implants. Total expenditures for neurostimulator implants were \$172,559,159 to \$895,280,149 in 2009 and in 2018, for a 419% increase or an annual increase of 20.1%. The inflation-adjusted costs also showed significant increases with a 343% increase overall and an 18% increase per year.

Figure 4 shows increasing expenditures with inflation-adjusted rates in a graphic display of spinal cord stimulator trials and pulse generator implants from 2009 to 2018, showing total costs increasing from \$292,153,701 to \$1,142,434,137, with an increase of 291% or 16.4% annual increase.

Average cost per procedure increased from \$22,586 in 2009 to \$38,993 in 2018, for a 73% overall increase or annual increase of 6.3%. However, inflation-adjusted costs showed increases of 48% with an annual increase of 4.4%. Similar to trials, dramatic increases in utilization and expenditures were seen in ASC settings with an increase of 1,501% overall and 36.1% annually, with an average procedure increase of 56% and 5% annually compared to HOPD increases of 289%, or 16.3% annually with an average procedural increase of 84% total or 7% per year.

Comparative expenditures with facet joint interventions and epidural procedures, based on our previous evaluations (3,4) were assessed. Table 7 and Fig. 5 show total comparative expenditures of facet joint interventions, epidural injections, and spinal cord stimulation trials and placements combined, including number of patients receiving these services. Based on this assessment, it appears that

expenditures for spinal cord stimulation for a small number of patients have rapidly exceeded the total costs for either facet joint interventions or epidural procedures, with 125% higher expenditures than facet joint interventions and 138% higher than for epidural interventions in 2018. In 2009, spinal cord stimulator expenditures were 55% below the expenditures of facet joint interventions and 66% lower than epidural injections.

## DISCUSSION

The estimated costs and utilization patterns of spinal cord stimulation interventions from 2009 to 2018 in the Medicare FFS population shows significant increases in utilization patterns per 100,000 Medicare popula-

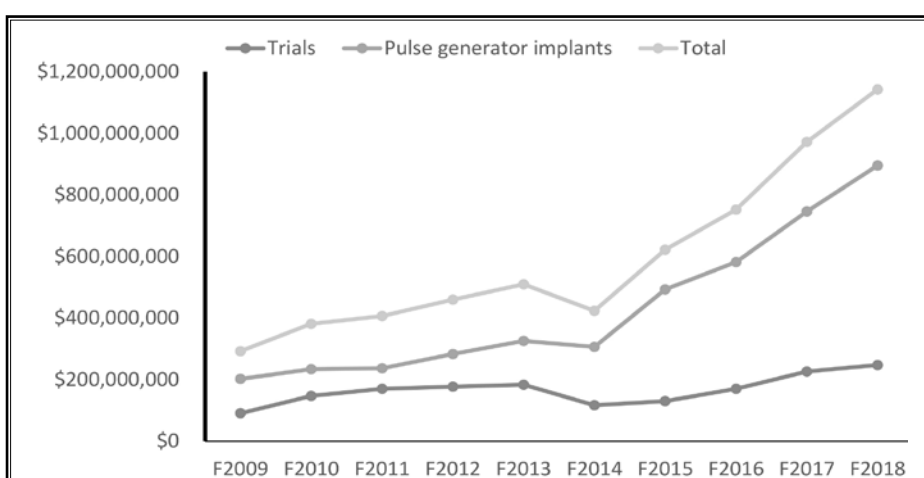


Fig. 4. Increasing expenditures of spinal cord stimulator trials and pulse generator implants.

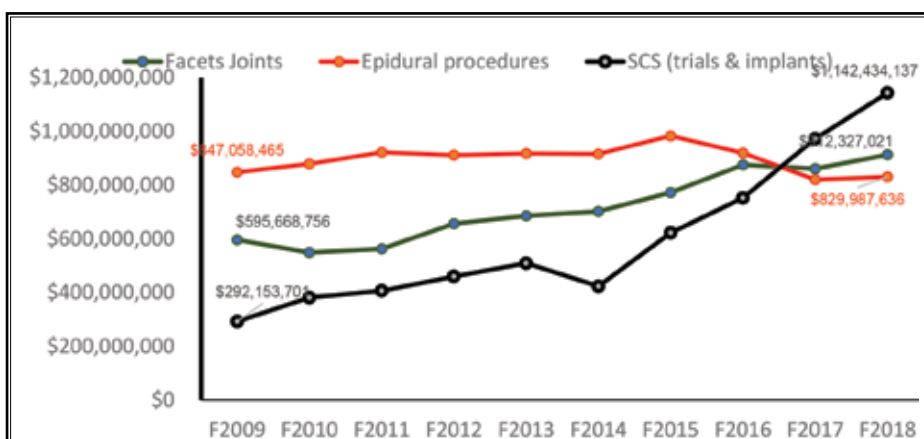


Fig 5. Total cost for facet joints interventions, epidural services, spinal cord stimulators.

Table 7. Total cost for facet joints interventions, epidural services, spinal cord stimulators.

|                          | F2009         | F2010         | F2011         | F2012         | F2013         | F2014         | F2015         | F2016         | F2017         | F2018           |
|--------------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|-----------------|
| <b>Epidural Services</b> |               |               |               |               |               |               |               |               |               |                 |
| Patients                 | 856,540       | 891,640       | 936,500       | 967,080       | 959,520       | 971,280       | 993,960       | 1,027,120     | 1,001,700     | 1,013,080       |
| Total Cost*              | \$847,058,465 | \$878,749,582 | \$921,450,280 | \$911,390,471 | \$917,400,419 | \$914,992,157 | \$982,528,003 | \$918,611,597 | \$819,768,949 | \$829,987,636   |
| Per Patient              | \$989         | \$986         | \$984         | \$942         | \$956         | \$942         | \$988         | \$894         | \$818         | \$819           |
| <b>Facets Joints</b>     |               |               |               |               |               |               |               |               |               |                 |
| Patients                 | 309,440       | 312,940       | 330,660       | 356,220       | 366,860       | 396,040       | 433,520       | 463,900       | 489,320       | 511,020         |
| Total cost*              | \$595,668,756 | \$548,183,220 | \$562,602,189 | \$655,649,594 | \$685,356,524 | \$701,726,706 | \$771,820,485 | \$875,301,195 | \$860,710,496 | \$912,327,021   |
| Per Patient              | \$1,925       | \$1,752       | \$1,701       | \$1,841       | \$1,868       | \$1,772       | \$1,780       | \$1,887       | \$1,759       | \$1,785         |
| <b>SCS</b>               |               |               |               |               |               |               |               |               |               |                 |
| Total cost*              | \$292,153,701 | \$380,799,967 | \$406,351,617 | \$459,428,760 | \$509,079,000 | \$422,870,774 | \$621,794,039 | \$751,779,013 | \$971,704,825 | \$1,142,434,137 |
| Patients                 | 12440         | 19300         | 21800         | 22720         | 23620         | 20520         | 20980         | 26420         | 32720         | 35240           |
| Per Patient              | \$34,032      | \$31,522      | \$30,942      | \$32,322      | \$33,899      | \$32,219      | \$44,996      | \$44,511      | \$43,601      | \$46,384        |

\* inflation-adjusted  
SCS – spinal cord stimulator

tion, along with inflation-adjusted costs. The number of patients receiving spinal cord stimulation interventions per 100,000 Medicare population increased from 12,680 in 2009 at a rate of 28 per 100,000 population to 36,280 in 2018 at a rate of 61, a 99% increase, with an annual increase of 9.1% based on 100,000 Medicare population (Table 2). At the same time, the Medicare beneficiaries increased 30.1% or 3% annually. Thus, there is a net increase of spinal cord stimulation interventions based on population increases or per 100,000 Medicare population. The proportion of the patients receiving spinal cord stimulation interventions in the age group of less than 65 years of age on Medicare (disabled population) increased 70% at an annual rate of 6.6%.

As shown in Table 5, average allowed charges per spinal cord stimulator trial increased from \$6,084 in 2009 to \$6,812, for a 12% increase of 1.3% annually. Inflation-adjusted cost of trials decreased 4.3% or annually 0.5%.

Spinal cord stimulator pulse generator implant costs (Table 6) showed an increase of 73% overall per implant, increasing from \$22,586 to \$38,993, with an annual increase of 6.3%; however, inflation-adjusted costs showed lower increases of 48% overall and 4.4% annually. Overall, costs of implants increased from \$172,559,159 in 2009 to \$895,280,149, for a 419% increase or 20.1% increase on an annual basis. The inflation adjusted costs increased 343% with an annual increase of 18%. Table 6 and Fig. 4 show increasing expenditures per year of spinal cord stimulator trials and pulse generator implants from \$292,153,701 in 2009 to \$1,142,434,137 in 2018, a 291% increase from 2009 to 2018 and 16.4% annual increase.

In this assessment we also compared trends in expenditures in the Medicare population with facet joint interventions and epidural interventions during the same periods (3,4), which showed higher expenditures for spinal cord stimulator trials and implants combined of more than 125% above facet joint interventions and 138% above epidural procedures in 2018, whereas in 2009, it was only 34% above facet joint interventions and 29% above epidural procedures.

The results of this investigation indicate significant increases in utilization patterns, as well as expenditures of spinal cord stimulation trials and implants. In contrast to epidural injections, which showed declines, and facet joint interventions, which showed minor increases, spinal cord stimulation showed consistent increases in utilization and expenditures; however, the number of patients receiving spinal cord stimulation, in comparison, is low. The number of patients receiving epidural injections is over a million/year or 1,700 per 100,000 Medicare population and over 511,000 or at a rate of 857 for facet joint interventions,

whereas over 36,000, or at a rate of 61 per 100,000 Medicare population for spinal cord stimulator interventions in 2018. Further, of the number of patients receiving spinal cord stimulation procedures, only 64% received permanent implants in 2018.

Medicare is concerned with utilization patterns and increasing expenditure overall for services provided, specifically of low back and neck pain and those of interventional techniques and spinal cord stimulation, along with surgical interventions. Epidural procedures have been shown to be in decline, whereas facet joint interventions showed very mild increases but with flattening. While the proportion of patients receiving these services is very small, the proportion of expenditures is high being 38% above epidural interventions and 25% over facet joint interventions in 2018. This is in contrast to the proportion of expenditures in 2009, which were 51% below the expenditures of facet joint interventions or 66% below that of epidural injections.

CMS continues to update Local Coverage Determinations (LCDs) by calling for multijurisdictional Contractor Advisory Committee (CAC) assessment of present LCDs for facet joint interventions, epidural interventions, and is performing enhanced audits, and investigations (67-70). The philosophy and emphasis continues towards reducing utilization and expenditures by not only reducing fraud and abuse, but also by enforcing the appropriate indications and medical necessity criteria. This is reinforced by initiation of pre-certification requirements for spinal cord stimulation in hospital settings (71).

## CONCLUSION

The estimations of expenditures of spinal cord stimulation interventions in the Medicare FFS population from 2009 to 2018 showed significant increases in the costs from \$292,153,701 in 2009 to \$1,142,434,137 in 2018, a 291% increase from 2009 to 2018 and a 16.4% annual increase.

From 2009 to 2018, spinal cord stimulation trials increased 186% with an annual increase of 12.5%. Pulse generator implants increased 201% with an annual increase of 13%. Total inflation-adjusted expenditures for spinal cord stimulation, including trials and implants, increased from \$292,153,701 in 2009 to \$1,142,434,137 with an overall increase of 291% and an annual increase of 16.4%.

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## Author Contributions

The study was designed by LM, VP, BV, and JAH. Data collection and analysis was performed by VP. All authors contributed to the preparation of the manuscript, review, and approval of the content with final version.

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Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/ Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services

Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID-19. Final rule and interim final rule. December 28, 2020.

Appendix Table 1. *Top 5 principal diagnosis for spinal cord stimulator trial patients*

|   | F2009  | F2010  | F2011  | F2012  | F2013  | F2014  | F2015  | F2016  | F2017  | F2018  |
|---|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Chronic pain (G89.21, G89.28, G89.29, G89.4)    | 2,420  | 4,720  | 6,480  | 8,640  | 8,620  | 7,540  | 8,040  | 10,780 | 12,320 | 13,780 |
| Percent   | 19%    | 23%    | 29%    | 37%    | 35%    | 35%    | 36%    | 38%    | 36%    | 38%    |
| Post laminectomy syndrome (M96.1)               | 3,720  | 5,080  | 5,140  | 5,140  | 4,660  | 4,740  | 4,240  | 5,160  | 7,380  | 8,400  |
| Percent   | 29%    | 25%    | 23%    | 22%    | 19%    | 22%    | 19%    | 18%    | 21%    | 23%    |
| Radiculopathy, lumbar region (M54.16 or M54.17) | 2,440  | 3,280  | 4,220  | 4,040  | 4,100  | 3,280  | 3,500  | 4,800  | 6,500  | 6,160  |
| Percent   | 19%    | 16%    | 19%    | 17%    | 17%    | 15%    | 16%    | 17%    | 19%    | 17%    |
| Low back pain (M54.5)                           | 740    | 1,300  | 1,480  | 1,060  | 1,140  | 1,200  | 860    | 1,280  | 840    | 780    |
| Percent   | 6%     | 6%     | 7%     | 4%     | 5%     | 6%     | 4%     | 5%     | 2%     | 2%     |
| Others  | 3,330  | 2,640  | 2,360  | 1,720  | 3,120  | 1,980  | 2,020  | 1,500  | 2,320  | 2,380  |
| Percent   | 27%    | 13%    | 10%    | 7%     | 13%    | 9%     | 9%     | 5%     | 7%     | 7%     |
| Total   | 12,680 | 20,200 | 22,720 | 23,640 | 24,380 | 21,780 | 22,100 | 28,380 | 34,340 | 36,280 |

Appendix Table 2. *Summary of the frequency of utilization of spinal cord stimulator trials in the Medicare population by state and 2016 Medicare carrier from 2009 to 2018.*

| State Name  | F2009  | F2010  | F2011  | F2012  | F2013  | F2014  | F2015  | F2016  | F2017  | F2018  | Change | GM  |
|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|-----|
| Cahaba      | 1,120  | 1,360  | 1,820  | 1,700  | 1,520  | 1,380  | 1,200  | 2,440  | 2,260  | 2,740  | 145%   | 10% |
| Rate        | 37     | 43     | 56     | 51     | 44     | 39     | 33     | 66     | 58     | 68     | 85%    | 7%  |
| PCPY        | 18%    | 30%    | -9%    | -14%   | -12%   | -15%   | 99%    | -12%   | 18%    |        |        |     |
| CGS         | 880    | 1,440  | 1,780  | 1,720  | 1,620  | 1,160  | 1,500  | 1,260  | 1,640  | 2,180  | 148%   | 11% |
| Rate        | 34     | 54     | 66     | 62     | 58     | 40     | 51     | 42     | 52     | 68     | 102%   | 8%  |
| PCPY        |        | 61%    | 21%    | -5%    | -7%    | -30%   | 27%    | -18%   | 25%    | 30%    |        |     |
| First Coast | 1,080  | 1,520  | 1,740  | 2,260  | 2,180  | 1,620  | 1,740  | 1,900  | 2,460  | 2,200  | 104%   | 8%  |
| Rate        | 33     | 45     | 50     | 64     | 59     | 42     | 44     | 47     | 57     | 50     | 52%    | 5%  |
| PCPY        |        | 37%    | 11%    | 28%    | -8%    | -28%   | 4%     | 7%     | 21%    | -13%   |        |     |
| NGS         | 1,320  | 1,660  | 2,400  | 2,140  | 2,760  | 2,460  | 3,080  | 2,740  | 4,260  | 4,600  | 248%   | 15% |
| Rate        | 15     | 19     | 26     | 23     | 30     | 26     | 32     | 27     | 40     | 42     | 182%   | 12% |
| PCPY        |        | 23%    | 42%    | -12%   | 30%    | -13%   | 23%    | -15%   | 49%    | 5%     |        |     |
| Noridian    | 2,340  | 3,380  | 3,680  | 3,700  | 2,320  | 3,640  | 2,020  | 5,680  | 3,280  | 6,980  | 198%   | 13% |
| Rate        | 28     | 39     | 41     | 41     | 25     | 38     | 21     | 55     | 30     | 61     | 119%   | 9%  |
| PCPY        |        | 40%    | 6%     | -1%    | -38%   | 51%    | -46%   | 167%   | -46%   | 106%   |        |     |
| Novitas     | 3,420  | 5,780  | 6,060  | 6,640  | 8,260  | 6,060  | 7,620  | 7,740  | 12,300 | 9,240  | 170%   | 12% |
| Rate        | 32     | 53     | 54     | 58     | 72     | 51     | 63     | 61     | 92     | 68     | 110%   | 9%  |
| PCPY        |        | 65%    | 2%     | 7%     | 23%    | -29%   | 23%    | -3%    | 52%    | -27%   |        |     |
| Palmetto    | 1,020  | 2,100  | 2,320  | 2,180  | 2,480  | 2,200  | 2,040  | 2,780  | 3,380  | 3,560  | 249%   | 15% |
| Rate        | 28     | 55     | 60     | 55     | 60     | 52     | 47     | 62     | 71     | 73     | 164%   | 11% |
| PCPY        |        | 100%   | 7%     | -8%    | 10%    | -14%   | -10%   | 33%    | 15%    | 2%     |        |     |
| WPS         | 1,480  | 2,900  | 2,800  | 3,220  | 3,180  | 3,200  | 2,880  | 3,800  | 4,620  | 4,740  | 220%   | 14% |
| Rate        | 31     | 59     | 56     | 63     | 61     | 60     | 53     | 68     | 80     | 80     | 159%   | 11% |
| PCPY        |        | 92%    | -5%    | 13%    | -4%    | -2%    | -12%   | 30%    | 16%    | 0%     |        |     |
| US Total    | 12,680 | 20,200 | 22,720 | 23,640 | 24,380 | 21,780 | 22,100 | 28,380 | 34,340 | 36,280 | 186%   | 12% |
| Rate        | 28     | 43     | 47     | 47     | 47     | 41     | 40     | 50     | 59     | 61     | 120%   | 9%  |
| PCPY        |        | 56%    | 9%     | 0%     | 0%     | -13%   | -1%    | 25%    | 18%    | 3%     |        |     |

Appendix Table 3. Medicare national payment rates.

| Professional Rates |             |             |             |             |             |             |             |             |             |             |
|--------------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| CPT                | 2009        | 2010        | 2011        | 2012        | 2013        | 2014        | 2015        | 2016        | 2017        | 2018        |
| 63650              | \$379.06    | \$393.68    | \$414.85    | \$427.17    | \$437.20    | \$427.37    | \$425.45    | \$429.93    | \$424.20    | \$425.88    |
| 63655              | \$773.63    | \$802.85    | \$855.53    | \$832.90    | \$841.73    | \$847.21    | \$857.37    | \$859.87    | \$864.56    | \$866.51    |
| 63685              | \$370.40    | \$373.48    | \$396.50    | \$363.18    | \$370.17    | \$373.27    | \$378.74    | \$381.21    | \$378.27    | \$376.92    |
| HOPD Rate          |             |             |             |             |             |             |             |             |             |             |
| CPT                | 2009        | 2010        | 2011        | 2012        | 2013        | 2014        | 2015        | 2016        | 2017        | 2018        |
| 63650              | \$4,206.45  | \$4,429.21  | \$4,553.02  | \$4,437.12  | \$4,399.77  | \$4,626.50  | \$5,288.58  | \$5,244.37  | \$5,742.69  | \$6,055.19  |
| 63655              | \$5,476.61  | \$5,831.77  | \$6,201.79  | \$6,203.77  | \$6,792.04  | \$7,424.49  | \$17,099.35 | \$17,359.37 | \$17,795.86 | \$18,367.62 |
| 63685              | \$15,566.65 | \$13,892.45 | \$14,743.58 | \$15,188.78 | \$16,394.73 | \$17,232.90 | \$26,152.16 | \$26,728.39 | \$27,035.69 | \$27,889.86 |
| ASC Rates          |             |             |             |             |             |             |             |             |             |             |
| CPT                | 2009        | 2010        | 2011        | 2012        | 2013        | 2014        | 2015        | 2016        | 2017        | 2018        |
| 63650              | \$3,495.96  | \$3,495.96  | \$3,707.45  | \$3,593.57  | \$3,550.55  | \$3,691.78  | \$3,836.95  | \$3,993.90  | \$4,421.66  | \$4,594.66  |
| 63655              | \$4,969.87  | \$4,969.87  | \$5,223.67  | \$5,264.08  | \$5,860.83  | \$6,295.98  | \$15,854.21 | \$14,797.32 | \$14,674.55 | \$15,005.88 |
| 63685              | \$12,877.21 | \$12,877.21 | \$13,816.04 | \$14,283.97 | \$15,431.30 | \$16,172.35 | \$20,806.60 | \$21,258.56 | \$23,148.41 | \$22,891.80 |
| Office Overhead    |             |             |             |             |             |             |             |             |             |             |
| CPT                | 2009        | 2010        | 2011        | 2012        | 2013        | 2014        | 2015        | 2016        | 2017        | 2018        |
| 63650              |             |             |             |             |             | \$922.07    | \$929.24    | \$940.49    | \$912.30    | \$927.35    |
| 63655              |             |             |             |             |             |             |             |             |             |             |
| 63685              |             |             |             |             |             |             |             |             |             |             |

From 2009 to 2014 – L0860 payments were separate