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# PRIMARY CARE AND HEALTH SERVICES SECTION

## *Original Research Article*

# Medical Cost Impact of Intrathecal Drug Delivery for Noncancer Pain

**Scott Guillemette, ASA, MAAA,* Susan Witzke, FSA, MAAA,* Jacqueline Leier, ASA,* Jennifer Hinnenthal, MPH,† and Joshua P. Prager, MD, MS‡**

*OptumInsight, Eden Prairie, Minnesota;

†Medtronic, Inc., Minneapolis, Minnesota;

‡Center for the Rehabilitation Pain Syndromes at UCLA Medical Plaza, Los Angeles, California, USA

*Reprint requests to:* Scott Guillemette, ASA, MAAA, OptumInsight, 12125 Technology Drive, Eden Prairie, MN 55344-7302, USA. Tel: 952-942-3225; Fax: 952-942-3201; E-mail: scott.guillemette@optum.com.

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### Abstract

**Introduction. As healthcare budgets continue to contract, there is increased payer scrutiny on the use of implantable intrathecal drug-infusion devices. This study utilizes claims data to evaluate the economic effects of intrathecal drug delivery (IDD) based on health services utilization and costs of care before and after implantation.**

**Methods. We performed a retrospective database study involving 555 noncancer pain patients that received an IDD system implant within a 3-year service period (1/2006–1/2009). IDD patient costs were temporally aligned to implant month and repriced to a standardized, national pricing schedule over a 6-year episode cycle (3 years preimplant, implant month, and 3 years postimplant). Additionally, we made an actuarial projection of postimplant experience, in the absence of IDD intervention, simulating a conventional pain therapy (CPT) protocol by assuming the same slope in costs prior to implantation at standardized, national price levels. Cost projections were produced over a 30-year time horizon at various reimplantation rates.**

**Results. IDD therapy was less costly than the CPT protocol over our baseline implantation cycle. Costs in the month of IDD implantation, and in the year following, are cumulatively $17,317 more than the CPT protocol; however, IDD financial breakeven occurs soon after the second year postimplant. The lifetime analysis indicates that IDD per patient per year savings is $3,111 compared with CPT.**

**Conclusion. The authors found that patients receiving an implantable IDD system may experience reduced cumulative future medical costs relative to anticipated costs in the absence of receiving IDD. This finding complements published literature on the cost-effectiveness of IDD.**

**Key Words. Alternative Therapies; Outcome Assessment; Pain Management; Treatment Outcome; Pain Medicine**

### Introduction/Background

Despite the improvements in the understanding of pain, including diagnosis and treatment, chronic pain continues to be an epidemic. A national survey of 35,000 households in the United States, conducted in 1998, estimated that the prevalence among adults of moderate to severe noncancer chronic pain was 9% [1]. In a 2011 study, the cross-national estimate of chronic pain was 30.7% [2]. Ranked in descending order of prevalence, chronic pain patients commonly suffer low back pain, followed by severe headache or migraine pain, neck pain, and facial ache or pain [3].

Patients with chronic pain may demonstrate pain-related interference with the ability to perform usual activities at home, work, or school; maladaptive or dysfunctional behaviors, social isolation, and poor sleep patterns; and frequent healthcare utilization [4].

The annual healthcare costs incurred by a single chronic pain patient, excluding costs for surgical procedures, may range from $500 to as high as $35,400, with the average being $13,284 [5].

Intrathecal drug delivery (IDD) systems provide targeted drug delivery for chronic, intractable pain. Targeted drug delivery dramatically reduces effective dose and thereby markedly reduces cognitive dysfunction, often a side effect produced by the medications [6]. IDD has therefore become a treatment option for alleviating chronic pain in patients who fail to respond to conventional pain therapies (CPTs) or do not tolerate systemic opioids due to their adverse effects [7–12]. Implantation of an IDD system should follow a successful trial of intraspinal opioid administration by epidural or intrathecal injection, or by epidural or intrathecal infusion using an external pump, evaluating for both efficacy and side effects.

IDD for chronic pain is achieved with an implantable system that consists of an infusion pump and an intraspinal catheter. The pump, which has a fluid reservoir, is placed in a subcutaneous pocket in the anterior abdominal wall. The catheter is inserted into the intrathecal space of the spine, tunneled under the skin, and connected to the pump. The reservoir is refilled by a needle inserted through the skin.

IDD systems offer an alternative for the long-term management of select patients with intractable pain associated with various disease states [13,14]. However, the treatment is not without controversy [15,16]. Perioperative complications have been associated with the procedure, and its cost-effectiveness has been called into question as well [17–19]. Nevertheless, several studies indicate that this therapy improves the patient's quality of life and reduces overall costs [20–23]. This is important given the high cost of chronic pain patients and the expense of the IDD system.

There have been a number of studies on the cost-effectiveness of introducing an implantable system to patients experiencing chronic pain [24–27]. Our study is a cost analysis based on retrospective administrative claims data to determine if IDD treatment is associated with reduced projected medical costs over an extended time period [28].

The primary objective of this study was to compare the cost of IDD therapy with that of CPT in patients suffering from noncancer pain. Secondary objectives were to understand the effect of time to pump reimplantation on patient claim costs and to gain insight into the differences in claim costs by service type between the two therapies. Our study hypothesis was patients that receive an IDD implant will experience reduced future medical costs.

## Research Methods and Procedures

### *Study Design*

We performed a retrospective database analysis that leverages the preintervention and postintervention claims to project costs using actuarial methods. This design uses the patient as his/her own control and follows the patient's experience over time. Intervention occurs at the beginning of the post period. In this study the intervention was the month in which the device was implanted. The method used is commonly used in health industry outcomes measurement studies because it is believed by health plans to be impractical or even, in some instances, forbidden by medical ethics or regulation to conduct more stringent randomization studies [29].

The control group in a retrospective database study becomes the time period of the same patients prior to this event. The validity of the design, ceteris paribus, is dependent on the correctness of the assumption that the experience in the "before" period is a good predictor of the experience of the population in the "after" period. If that assumption is true the differences in the results observed in the "after" period compared with the results predicted from the "before" period are valid assessments of the outcomes that can be ascribed to the device.

IDD patient costs were temporally aligned to implant month and repriced to a standardized, national pricing schedule over a 6-year episode cycle (i.e., 3 years preimplant, implant month, and 3 years postimplant). No continuous enrollment requirements were imposed on the identified study cohort to maintain the credibility of cohort claim results. As such, a patient whose implant occurred within the first month of our 3-year data window would be included only in the postimplantation experience portion of the studied episode cycle. Conversely, a patient whose claim costs were nonimplant related until the last month of our 3-year data window would also be included; however, their data would contribute only to the preimplantation experience period. As a result of no continuous enrollment requirements, the aggregate patient claim experience spanned a 6-year time period. The 6-year data window serves as a single, average implantation cycle and is used as the base for modeling patient medical costs over a 30-year time horizon.

### *Patient Selection*

Patient claims utilization and eligibility experience were extracted from OptumInsight nationally consolidated datamart that contains integrated medical and prescription drug claims experience produced by private commercial and Medicaid, fully-insured policyholders. The eligibility and service dates span the time period from January 1, 2006 to December 31, 2008, with claims paid through September 30, 2009. Claim cost unit prices approximately

**Exhibit A** Implant event: ICD-9 CM, UB-92 revenue code and CPT code definitions and logic

| | |
|---|---|
| **ICD-9 procedure codes** | |
| 86.06 AND 03.90 | |
| 86.06 | Insertion of totally implantable infusion pump |
| 03.90 | Insertion of catheter into spinal canal for infusion of therapeutic or palliative substances |
| **CPT-4 procedure codes** | |
| (62350 OR 62351) AND (62361 OR 62362) OR E0783, E0782, E0785 OR E0786 | |
| 62350 | Implantation, revision, or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy |
| 62351 | Implantation, revision, or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy |
| 62361 | Implantation or replacement of device for intrathecal or epidural drug infusion; nonprogrammable pump |
| 62362 | Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming |
| E0783 | Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.) |
| E0782 | Infusion pump system, implantable, nonprogrammable (includes all components, e.g., pump, catheter, connectors, etc.) |
| E0785 | Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement |
| E0786 | Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter) |
| **UB-92 revenue codes** | |
| 270, 278, or 279 | |
| 270 | Medical/surgical supplies and devices, general |
| 278 | Medical/surgical supplies and devices, other implants |
| 279 | Medical/surgical supplies and devices, other supplies/devices |

reflect calendar year average 2007 national commercial reimbursement levels derived from OptumInsight's database. Medicare data were excluded from this analysis due to limited availability of pharmacy data.

Patients with a claim including the procedure for pump or catheter implants were entered into the study. See Exhibit A for the descriptions of codes included. However, we excluded patients with procedure codes that suggested that the patient was receiving a reimplantation rather than an initial implant. To identify these patients we excluded any patient that experienced a procedure code (i.e., CPT-4 procedure code) of 95,990, 95,991, 62,367, or 62,368 in the month before the implant. All procedure code fields in the data were reviewed for inclusion or exclusion. If the patient qualified for inclusion in our study, we extracted his/her entire longitudinal claim and eligibility history. Patients were stratified into one of three mutually exclusive cohorts based on the patient's diagnosis code history. A hierarchical approach was used to identify the noncancer pain patients used in the study. The hierarchy initially identifies cancer pain or spasticity patients, then, by default, the remaining patients are classified as noncancer pain sufferers. Patients diagnosed with neoplasms were assigned to the cancer pain cohort, and patients diagnosed with stroke, traumatic brain injury, multiple sclerosis, cerebral palsy, paralysis, and abnormality of gait were assigned to the spasticity cohort. Exhibit B identifies the diagnostic codes used to identify the cohorts. Patient claim histories were examined using all diagnostic fields in the patient's records to make the classification determination.

*Cost Categories*

Data were organized into the following cost categories: inpatient hospitalization costs for implantations and other types of stays; outpatient facility costs for implantations, medication refills, device analysis and programming, emergency department visits, physiotherapy, ambulatory surgeries, facility-administered prescription drugs, and other facility costs; and professional physician costs in many of the same categories as outpatient facility; however, also including adjunctive therapies (acupuncture, nerve blocks, chiropractic, neurolytic destruction, physical therapy, and massage therapy), office visits, and prescription drugs.

*Cost Calculations*

Each implant episode was adjusted so that the midpoint of its implant month was aligned to July 1, 2007. The month of implant was determined as the month the first implant procedure occurred. Procedure codes indicating a pump or catheter implantation occurred were used to identify the time of implant. See Exhibit A for the coding logic and definitions.

If an individual received additional implants or revisions, the month of implant is not reset, and the dollars associated with the additional implants or revisions are included in the respective months subsequent to the initial implant.

Each patient's experience was priced to an allowed charge level based on calendar year 2007 (i.e., January 1,

**Exhibit B** ICD-9 CM code definitions

| | |
|---|---|
| Cancer pain | |
| 140.x(x)–208.xx | Neoplasms |
| 230.x(x)–234.x(x) | |
| 235.x(x)–239.x(x) | |
| Spasticity | |
| 333.6 | Genetic torsion dystonia |
| 333.7x | Acquired torsion dystonia |
| 333.8x | Fragments of torsion dystonia |
| 333.91 | Stiff-man syndrome |
| 723.5 | Torticollis, unspecified |
| 781.7 | Tetany (Carpopedal spasm) |
| 340.xx | Multiple sclerosis |
| 342.1x | Spastic hemiplegia |
| 344.0x | Quadriplegia and quadriparesis |
| 344.1 | Paraplegia |
| 344.2 | Diplegia of upper limbs |
| 344.3x | Monoplegia of lower limb |
| 344.4x | Monoplegia of upper limb |
| 344.5x | Unspecified monoplegia |
| 344.9 | Paralysis, unspecified |
| 334.1 | Hereditary spastic paraplegia |
| 343.xx | Infantile cerebral palsy |
| 344.89 | Other specified paralytic syndrome |
| 342.1x | Spastic hemiplegia |
| 438.2x | Hemiplegia/hemiparesis |
| 438.3x | Monoplegia of upper limb |
| 438.4x | Monoplegia of lower limb |
| 438.5x | Other paralytic syndrome |
| 781 | Abnormal involuntary movements |
| 781.2 | Abnormality of gait |
| Noncancer pain | |
| All other codes | |

2007–December 31, 2007) national average reimbursement information derived from OptumInsight's database. Separate average 2007 discount rates (i.e., discount from billed charges) were calculated for inpatient facility and outpatient facility services using OptumInsight's database and then applied to the billed charge information at a detailed claim level. Physician claims were priced based on a 2007 allowed charge fee schedule that was derived from OptumInsight's database. If a procedure code was supplied on the patient's claim record or if the procedure code was not on the fee schedule, a 39% discount was applied to the billed charge for that claim. Prescription drug claims are priced at the standard 2007 average wholesale ingredient cost of the prescription, including its per prescription dispensing fee.

Finally, we have assumed that a patient's claim would never be reimbursed more than the billed charges in any event; therefore, if the calculated allowed charge payment rate is greater than the billed charge amount for the claim, we assumed that the claim would be paid at the billed charge level.

After all patient claim experience was repriced, annual trend rates were applied to the reimbursement amounts for the periods preimplant and postimplant based on each claim's date of service. Annual trend rates were converted to monthly compound rates to make the trend adjustments. Trend rates were applied to reflect average increases due to medical inflation.

*Actuarial Cost Projections—Initial Implantation Cycle*

In order to understand the potential financial impact of IDD implantation, we make an actuarial cost projection, based on the patient's preimplantation claim experience, to determine expected future patient costs. The actuarial cost projection is intended to simulate a CPT protocol. The actuarial cost projection is compared with the patient's actual postimplant claim experience to determine the difference in outcomes. The projection assumes that no implantation occurs and that the patient's costs will follow historical trend patterns as experienced by the patient during his/her preimplantation period. Projected costs for future years, following the month of implantation, rely on the patient's annual claim cost distribution prior to the implant month as inputs to extrapolate future costs. We assume that future costs will follow the same slope of cost trends as seen prior to implantation. The projection method is commonly used in actuarial pricing exercises.

Incremental differences between the patient's actuarial cost projection and his/her actual postimplant claim experience reflect expected losses (if projected costs are lower than actual costs) or savings (if projected costs are higher than actual costs). Losses or savings represent the expected financial difference in outcomes comparing CPT protocol relative to IDD therapy. Savings are produced from reduced utilization, reduced intensity of medical services, and the reduced need for prescription drug medication. Losses are produced from increased utilization, increased intensity of medical services, and the increased need for prescription drug medication.

*Actuarial Cost Projections—Future Implantation Cycles*

In order to understand the potential financial impact of IDD implantation over a patient's lifetime, we make an actuarial cost projection over a 30-year time horizon. Based on device registration system data on file at Medtronic, we have assumed that the average operating life of an IDD device is 6 years. After approximately 6 years of use, the patient's IDD device must be replaced due to normal battery depletion, and additional medical procedures, including explant and reimplantation, are required. More rarely, the device may need to be replaced due to mechanical failure. Krames et al. [30] reported a 6.3% failure rate at 18 months, while Medtronic, Inc. [31]. reported that the probability of device survival after six years is 96.5% (SynchroMed® II [20 mL]). The process is replicated five times over the 30-year projection period (i.e., reimplantations at years 6, 12, 18, 24, and 30). We

have assumed that future implant episodes, or cycles, will be similar in shape and characteristic to the initial implant cycle demonstrated by the data, but at increased cost levels to reflect inflationary trends.

We assumed that the projected annual net medical trend rates are 10.0% in year 1, 8.8% in year 2, 7.6% in year 3, 6.4% in year 4, 5.2% in year 5, and 4.0% for all subsequent years. The trend rates reflect healthcare industry average expectations.

The results illustrate the present value of costs (i.e., discounted for the time value of money) to the time of the initial implant. A 3% annual discount rate is assumed when performing present value calculations.

*Sensitivity Analysis*

The purpose of a sensitivity analysis is to identify variables that have the greatest influence on the study results. We have modeled sensitivity on three variables that are likely to have a meaningful impact on our results: 1) changes in the IDD system's battery life; 2) altering the preimplant experience period used to establish starting average cost for projection purposes; and 3) altering the medical cost trend assumptions (i.e., both the initial and ultimate trend rates). When we altered the medical cost trend assumptions, we increased or decreased the respective trend rates uniformly. When conducting our sensitivity tests we altered only the variable in question and held all other variables constant (i.e., ceteris paribus). We used the 30-year cost/(savings) result as our output measure to gauge each sensitivity test.

## Results

The final number of participants eligible for analysis was 555. Table 1 includes information on patient characteristics. There were no influential cases (outliers), so no adjustment was made in our final analysis.

Table 1 also identifies the number of patients included in our study at various time intervals from the patient's implantation month (i.e., cohort duration).

Figure 1 graphically illustrates the actuarial cost projection (i.e., red line) as compared with actual implant experience (i.e., blue line). Month 0 represents the patient's month of implantation.

Table 2 summarizes discounted cumulative mean costs per patient receiving CPT as calculated using the actuarial cost projection method described earlier, patients receiving IDD, and the difference in cost outcomes when comparing the two methods. Per patient costs are calculated assuming the same denominator ($N = 555$) across all cost

**Table 1** Noncancer pain patient cohort profile

| | Patient Count | | | | |
|---|---|---|---|---|---|
| Patient Characteristic | Preimplant Only | Postimplant Only | Preimplant and Postimplant | Total | Percent Distribution (%) |
| Number of patients | 18 | 31 | 506 | 555 | 100.0 |
| Gender | | | | | |
| Male | 11 | 18 | 321 | 350 | 63.1 |
| Female | 7 | 13 | 185 | 205 | 36.9 |
| Age (in years) | | | | | |
| Under 20 | — | 1 | 5 | 6 | 1.1 |
| 20–29 | — | 1 | 12 | 13 | 2.3 |
| 30–39 | 1 | 3 | 37 | 41 | 7.4 |
| 40–49 | 6 | 9 | 141 | 156 | 28.1 |
| 50–59 | 7 | 10 | 180 | 197 | 35.5 |
| 60–69 | 4 | 4 | 90 | 98 | 17.7 |
| 70 or above | — | 3 | 41 | 44 | 7.9 |
| Cohort duration (in years) | | | | | |
| –3 years | 16 | — | 23 | 39 | 7.0 |
| –2 years | 7 | — | 151 | 158 | 28.5 |
| –1 year | 2 | — | 377 | 379 | 68.3 |
| 0 (month of implant) | 18 | 31 | 506 | 555 | 100.0 |
| +1 year | — | 22 | 359 | 381 | 68.6 |
| +2 years | — | 15 | 144 | 159 | 28.6 |
| +3 years | — | 8 | 38 | 46 | 8.3 |
| Funding source | | | | | |
| Private commercial | 18 | 31 | 505 | 554 | 99.8 |
| Medicaid | — | — | 1 | 1 | 0.2 |

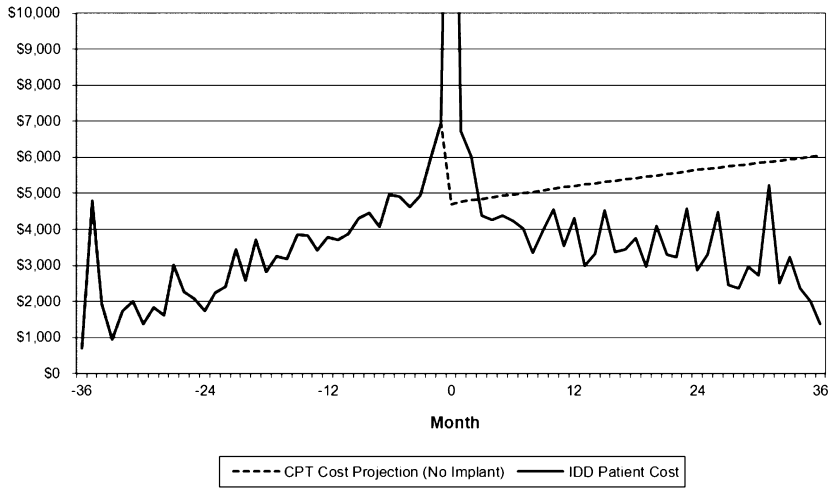


**Figure 1** Actuarial cost projection—initial implantation cycle.

categories. In essence, the costs represent the average distribution of patient expenses by category and can be added to produce a total for the average patient. The actuarial cost projection is a function of the noncancer pain cohort's preimplantation trend experience and reflects the slope in costs present in the 3-year period prior to implantation. The costs underlying the IDD figures in this table are based on actual postimplant experience adjusted for annual medical trend rates and discount rates. Discounted cumulative mean costs are calculated for three time intervals: the month of implantation, 1 year after implantation, and 3 years after implantation.

Cost categories in Table 2 that include positive figures indicate that IDD therapy was more expensive than CPT therapy for the respective time period. Costs in the month of IDD implantation, and in the year following, are cumulatively $17,317 more than the CPT protocol; however, IDD financial break-even occurs soon after the second year postimplant (i.e., 27 months). After 3 years of cumulative experience, it appears that the financial benefits of IDD therapy are derived from lower inpatient facility costs, fewer emergency department visits, fewer ambulatory surgeries, fewer office visits, fewer adjunctive therapies, and reduced prescription drug costs. Conversely, IDD therapy surgical implantation costs (i.e., both facility and professional) plus device costs partially offset the financial benefits of the therapy.

Table 3 illustrates the cost and prevalence of complications and revisions by year after implant. During the year postimplant, 32 patients (5.8%) experienced at least one complication, and 81 patients received revisions (14.6%). After the first year postimplant, the prevalence of complications and revisions decreased to approximately 1%.

Table 4 supplies a comparison of CPT and IDD therapies at specific time intervals from implantation. CPT costs were calculated using the actuarial projection techniques described earlier. Both therapies include medical inflation and discounting for the time value of money. Discounted cumulative costs, per patient costs/(savings), and per patient per year costs/(savings) are illustrated. We note that per patient per year results fluctuate over the 30-year time period, largely due to the assumed implantation cycle length and the associated reimplantation costs. Recall, the IDD device must be replaced, on average, every 6 years due to battery life among other reasons. Inflections in durational savings can be seen 6 years from initial implantation and every 6 years thereafter; however, the level of savings is greater than the periodic additional costs to reimplant the device.

Figure 2 graphically illustrates the actuarial cost projection (i.e., red line) as compared with actual implant experience (i.e., blue line). Month 0 represents the patient's initial month of implantation.

*Sensitivity Analysis*

The first sensitivity test performed was for various implantation cycle lengths. An alternative cycle length assumes that future technological advances will occur that increase the life expectancy of the pump. Increasing pump life expectancy will reduce the number of replacement pumps and associated implantation costs. For example, increasing the pump's life expectancy 50%, from 6 years to 9 years, will increase per patient per year savings by 311%. Note, when assuming a 3-year pump replacement cycle, IDD will cost more than CPT over the 30-year time horizon.

The second test performed altered the preimplant experience period used to establish the starting average cost for projection purposes. The purpose for this test is to determine whether cost/(savings) projections are influenced when using shorter durations of preimplant experience to develop model assumptions. While it is customary in actuarial analysis to use longer time frames (i.e., 12 months or longer) to produce reliable results, we found that the shorter the experience period, the greater the savings. One explanation for this phenomenon may be due to seasonal cycles present in the underlying claim

**Table 2** Mean medical resource use per patient (US$) discounted cumulative claim costs*

| | Patients Receiving CPT (Actuarial Cost Projection) | | | Patients Receiving IDD Therapy | | | Difference: IDD Therapy Less CPT | | |
|---|---|---|---|---|---|---|---|---|---|
| Cost Category | Month of Implantation | 1 Year Postimplant | 3 Years Postimplant | Month of Implantation | 1 Year Postimplant | 3 Years Postimplant | Month of Implantation | 1 Year Postimplant | 3 Years Postimplant |
| Number of patients | 555 | 381 | 46 | 555 | 381 | 46 | 555 | 381 | 46 |
| Inpatient facility | | | | | | | | | |
| Implantation | — | — | — | 7,138 | 8,910 | 9,034 | 7,138 | 8,910 | 9,034 |
| Other | 1,023 | 13,849 | 41,638 | 893 | 11,888 | 28,463 | (130) | (1,961) | (13,175) |
| Outpatient facility | | | | | | | | | |
| Implantation | — | — | — | 13,757 | 15,330 | 16,103 | 13,757 | 15,330 | 16,103 |
| Refill and programming | — | — | — | — | 37 | 98 | — | 37 | 98 |
| Emergency room | 163 | 2,205 | 6,629 | 115 | 1,223 | 3,034 | (48) | (982) | (3,595) |
| Physiotherapy | 16 | 212 | 637 | 9 | 104 | 212 | (7) | (108) | (425) |
| Surgery/ASC | 620 | 8,386 | 25,214 | 1,422 | 4,860 | 13,149 | 802 | (3,526) | (12,065) |
| Pharmacy | 14 | 191 | 574 | 1 | 55 | 110 | (13) | (136) | (464) |
| Other | 390 | 5,280 | 15,876 | 304 | 3,822 | 10,316 | (86) | (1,458) | (5,560) |
| Professional physician | | | | | | | | | |
| Implantation | — | — | — | 2,665 | 3,404 | 3,667 | 2,665 | 3,404 | 3,667 |
| Refill and programming | — | — | — | 69 | 2,696 | 7,260 | 69 | 2,696 | 7,260 |
| Accup/Blocks/Chiro | 55 | 749 | 2,252 | 16 | 257 | 708 | (39) | (492) | (1,544) |
| Emergency room | 38 | 513 | 1,544 | 48 | 352 | 819 | 10 | (161) | (725) |
| Injections | 34 | 458 | 1,378 | 72 | 183 | 315 | 38 | (275) | (1,063) |
| Physiotherapy | 18 | 248 | 746 | 3 | 78 | 478 | (15) | (170) | (268) |
| Office visits | 138 | 1,861 | 5,596 | 139 | 1,315 | 3,497 | 1 | (546) | (2,099) |
| Other | 552 | 7,464 | 22,442 | 647 | 5,413 | 13,899 | 95 | (2,051) | (8,543) |
| Prescription drugs | 372 | 5,038 | 15,147 | 405 | 3,844 | 10,521 | 33 | (1,194) | (4,626) |
| Subtotal | 3,433 | 46,454 | 139,673 | 27,703 | 63,771 | 121,683 | 24,270 | 17,317 | (17,990) |
| Standard error | 3,898 | 60,281 | 213,672 | 17,478 | 56,771 | 74,224 | 17,102 | 75,337 | 213,651 |

* Assumes an annual discount rate of 3%. Assumes annual medical trend rates of 10.0%, 8.5%, 7.0%, 5.5%, and 4.0% for years 1, 2, 3, 4, and 5+, respectively.
CPT = conventional pain therapy; IDD = intrathecal drug delivery; ASC = ambulatory surgery center; Accup = acupuncture; Blocks = nerve blocks; Chiro = chiropractic.

**Table 3** Patients with complication or revisions

| | Number of Patients | Number of Patients in the Study | Cost/(Savings) per Patient by Year* |
|---|---|---|---|
| Within 1 year after implant | | | |
| Troubles/complications | 32 | 555 | 3,036 |
| Reimplant | 81 | 555 | 18,571 |
| Explant | 43 | 555 | 15,285 |
| 1–2 years after implant | | | |
| Troubles/complications | 4 | 381 | 1,368 |
| Reimplant | 7 | 381 | 30,415 |
| Explant | 3 | 381 | 32,147 |
| 2–3 years after implant | | | |
| Troubles/complications | 2 | 159 | 5,694 |
| Reimplant | 2 | 159 | 147,145 |
| Explant | 1 | 159 | 21,394 |

* Assumes an annual discount rate of 3%. Assumes annual medical trend rates of 10.0%, 8.5%, 7.0%, 5.5%, and 4.0% for years 1, 2, 3, 4, and 5+, respectively.

experience (i.e., data that experience regular and predictable changes within a 1-year period). Another reason may be due to statistical credibility of the data. We did not investigate the reasons for the phenomenon; rather, we chose to err on the conservative side and decided to use the full preimplant experience period as our baseline for analysis. Recall that our actuarial cost projection (i.e., the dotted line in Figure 1) is simply the average preimplant cost estimate trended to a future period using the assumed medical cost trend rates.

The third test performed altered the medical cost trend assumption (i.e., both the initial and ultimate trend rates). In essence the test indicates that the higher the medical cost trend assumption, the greater the savings. Fundamentally, the postimplant claim experience exhibits an implied slope, or cost trend, that remains constant throughout the projection period. The slope produced by the assumed medical cost trend rates affects the actuarial projection of the preimplant average cost experience. Visually, in Figure 1, the postimplant slope is flatter than

**Table 4** Cost comparison: conventional pain therapy (CPT) versus intrathecal drug delivery (IDD) therapy (US$)

| | Discounted Cumulative Cost* | | | |
|---|---|---|---|---|
| Time from Implantation | CPT (Actuarial Cost Projection) | IDD Therapy | Cost/(Savings) per Patient Cumulative | Cost/(Savings) per Patient per Year |
| Month of implant | 3,432 | 27,704 | 24,271 | 24,271 |
| 1 year postimplant | 46,454 | 63,771 | 17,317 | 17,317 |
| 2 year postimplant | 92,037 | 93,408 | 1,371 | 686 |
| 3 years postimplant | 139,672 | 121,684 | (17,988) | (5,996) |
| 4 years postimplant | 188,759 | 157,069 | (31,690) | (7,922) |
| 5 years postimplant | 238,627 | 208,303 | (30,324) | (6,065) |
| 6 years postimplant | 288,959 | 287,431 | (1,528) | (255) |
| 7 years postimplant | 339,759 | 331,347 | (8,412) | (1,202) |
| 8 years postimplant | 391,032 | 365,814 | (25,218) | (3,152) |
| 9 years postimplant | 442,781 | 402,874 | (39,907) | (4,434) |
| 10 years postimplant | 495,012 | 440,526 | (54,486) | (5,449) |
| 15 years postimplant | 763,545 | 700,372 | (63,173) | (4,212) |
| 20 years postimplant | 1,044,800 | 973,447 | (71,352) | (3,568) |
| 30 years postimplant | 1,647,919 | 1,554,595 | (93,324) | (3,111) |

* Assumes an annual discount rate of 3%. Assumes annual medical trend rates of 10.0%, 8.5%, 7.0%, 5.5%, and 4.0% for years 1, 2, 3, 4, and 5+, respectively.

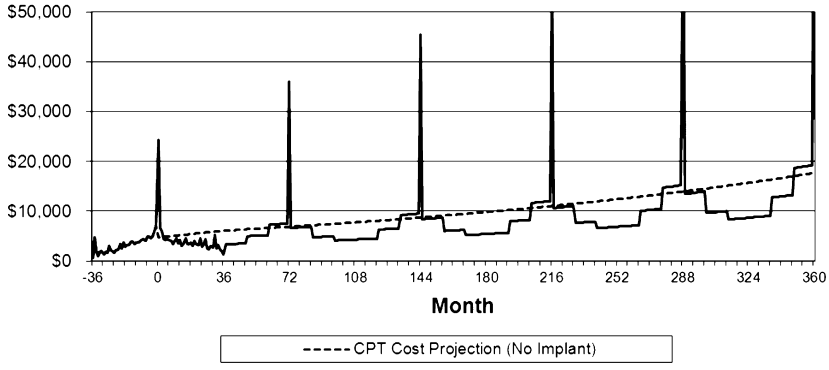


**Figure 2** Actuarial cost projection—30-year projection period.

the projection slope. As such, the higher the assumed medical cost trend rates, the steeper the projection slope relative to the postimplant slope, thereby creating more savings. The opposite will also be true.

Table 5 illustrates per patient per year 30-year cost/(savings) for the three tested variables.

## Discussion

In the advent of healthcare reform, it has become evident that cost-effectiveness studies are a critical prerequisite to treatment planning [32]. The studies will enable organizations to reduce cost by illustrating the benefits of one therapy compared with another. The IDD implantation has higher initial costs but given time may be more cost-effective than CPT. Our cost analysis showed that the financial break-even point occurs soon after the second year postimplant derived from fewer ambulatory surgeries, inpatient facility costs, and prescription drug costs. The lifetime analysis shows an annual per patient savings of $3,111 compared with CPT.

Due to the limited battery life of the IDD implant, a reimplant is needed, on average, every 6 years. The amount of savings decreases each time a reimplant occurs; however, the overall cost is likely to still be less than the cost of CPT. As the savings has a cyclical pattern, a lifetime analysis was performed projecting the 30-year cost savings. The lifetime analysis showed an annual per patient savings of $3,111 compared with CPT. Based on the results from the sensitivity tests performed, the length of the reimplant is an important variable in the study. Increasing the pump life expectancy will significantly increase the amount of

**Table 5** Sensitivity test results discounted cost/(savings) per patient per year*

| | Patients | Claim Months | Cost/(Savings) per Patient per Year ($) | Relative Factor to Baseline |
|---|---|---|---|---|
| Sensitivity test of preimplant experience period (for projection) | | | | |
| Baseline (36-month period) | 555 | 7,395 | (3,111) | 1.00 |
| 12-month period | 555 | 5,052 | (3,350) | 1.08 |
| 6-month period | 555 | 3,227 | (4,953) | 1.59 |
| Sensitivity test of implantation cycle length | | | | |
| Baseline | 555 | 14,352 | (3,111) | 1.00 |
| 3-year cycle | | | 7,679 | (2.47) |
| 4-year cycle | | | (2,325) | 0.75 |
| 5-year cycle | | | (761) | 0.24 |
| 6-year cycle | | | (3,111) | 1.00 |
| 7-year cycle | | | (6,723) | 2.16 |
| 8-year cycle | | | (9,497) | 3.05 |
| 9-year cycle | | | (9,671) | 3.11 |
| Sensitivity test of medical cost trend rate assumptions | | | | |
| Baseline (10.0% initial; 4.0% ultimate) | 555 | 14,352 | (3,111) | 1.00 |
| Initial trend 8.0%; Ultimate trend 2.0% | | | (2,408) | 0.77 |
| Initial trend 12.0%; Ultimate trend 6.0% | | | (3,994) | 1.28 |

* Assumes an annual discount rate of 3%. Assumes annual medical trend rates of 10.0%, 8.5%, 7.0%, 5.5%, and 4.0% for years 1, 2, 3, 4, and 5+, respectively.

savings. Conversely, using a reimplant cycle of 3 years or less may result in costs that are higher than the cost of CPT. Adjusting the future medical cost trend assumptions and length of preimplant experience did not have a significant effect on the results.

We are evaluating whether to find data for a control group with similar pain issues to the nonmalignant patients who received implants. Other improvements include additional sensitivity tests of other variables, such as the cost of the pump and the cost of complications associated with surgery for IDD therapy.

*Cost-Effectiveness Studies*

Other published articles addressing the value of IDD pumps are summarized below.

De Lissovoy et al. studied the long-term cost-effectiveness of IDD pump therapy [24]. They published a decision analytic study estimating the direct cost of IDD pump therapy relative to medical management. The study modeled 1,000 patients with failed back surgery syndrome (FBSS) over a 60-month course of treatment, and included short- and long-term complications of the therapy, which include normal battery replacement and mechanical device failure. The study also took into account that many patients continue to receive supplemental analgesics, such as oral opioids and nerve blocking agents. Average monthly cost, over 60 months, is $1,382 (base case), but could range from $891 (best case) to $2,085 (worst case). De Lissovoy et al. determined that the IDD pump is cost-effective compared with medical management when the duration of the therapy exceeds 22 months (base case) or 12 months (best case). However, in a worst-case scenario, comprising highest cost and highest adverse event rate estimates, IDD remains more costly than medical management. These results are similar to the results of our sensitivity tests where we varied the length of pump reimplantation.

Kumar et al. compared IDD therapy with CPT [25]. Their study included 67 patients with FBSS. In comparing the IDD pump patients ($N = 23$) with the CPT patients ($N = 44$), the calculated costs for the IDD therapy was $29,410 compared with $38,000 for conventional treatment over 5 years. Despite the complications in the worst-case scenario, IDD therapy remains cost-effective when compared with conventional therapy, which differs from our analysis. Expenses included initial evaluation and subsequent expenses for physician visits; procedures such as computerized topography scanning, magnetic resonance imagery, and myelography; adjunctive therapies; and medications and hospital stays. For the IDD therapy group costs included the implanted pump and accessories, hospital and surgical fees, complications, maintenance, and the drugs used in the pump.

The article *Cost Effectiveness of Intrathecal Therapy for Pain*, Mueller-Schwefe et al. review studies showing the cost-effectiveness of IDD over oral opioid therapy [26]. The studies show that initial costs of IDD are high, but as the duration of patient survival increases, the intensity of these costs decrease. The cost-effectiveness of the implant occurs after 3–6 months of treatment for patients who have a life expectancy of 3 months or longer and require pain management for chronic pain. This observation coincides with our analysis shown by the costs/(savings) by year after implant.

A recent study in the United Kingdom by Biggs, et al. found that IDD was cost-effective relative to conventional treatment both with and without consideration of the costs incurred during the waiting period between the time of a successful trial and the time of implant [27]. This finding was similar to ours, but also included a cost per quality-adjusted life-year analysis.

Time to cost neutrality for IDD, also known as the break-even period, was determined in two separate analyses to be 22 [24] and 28 [30] months, respectively.

*Study Limitations*

Patient selection was based on the occurrence of an implantation. We did not consider patients with similar conditions that did not have an implantation. Our study does not address patient behavior on outcome variance due to adherence to their physician's instructions. Patient comorbidity may affect claim levels and the slope of a patient's claim experience, thereby affecting our actuarial projections. The patient's perception of quality of care or life was not measured nor reflected in this study. We did not control for benefit plan design influences that may affect a patient's utilization patterns.

Our pre-post design has its strengths and weaknesses. One of the strengths is a 3-year inclusion period by which a credible number of claimants receiving an implant can be identified. Cohort credibility will decrease the effects of claim variability and allow us to create reliable actuarial assumptions for use in making actuarial claim cost projections. The structured administrative claims database provides access to detailed diagnostic and procedural patient treatment information that were incurred by the patient during the study time frame. The detailed claim information helps us satisfy secondary study objectives. A general weakness of a pre-post study design is that there is no mutually exclusive control group that can be observed relative to the intervention group. Arguably, the fact that patient medical costs, specific to the treatment of noncancer pain conditions, could not be separated from the patient's medical claim costs for other conditions presents a dichotomy, of sorts, in perceived strength or weakness. Painful conditions are so intertwined with psychological conditions, such as depression, that trying to separate what is and is not pain related may actually be more challenging than to capture the patient's entire healthcare experience, as we have done in this study. All claims for an included claimant were included in the medical costs for this study, including those that could pertain to other illnesses. Due to Health Insurance

Portability and Accountability Act privacy laws, we had minimal information on patient characteristics.

*Comparative Literature Limitations*

The low number of cost-effectiveness reviews on IDD therapy for noncancer pain patients limits our ability to compare and validate our results against other independent studies. Few randomized trials are available. The recently passed Patient Protection and Affordable Care Act will likely increase the core body of evidence-based medicine as federal funding will be put forth to conduct pain management research [33].

## Conclusion

In our study we have shown that noncancer pain patients that receive an IDD implant may experience reduced future medical costs relative to anticipated costs under conventional therapeutic methods. The level of savings is sensitive to the duration of the implantation cycle. The longer the cycle, the greater the savings as implantation costs are amortized over the cycle period and reductions in patient utilization begin to accumulate. Implant financial break-even point is likely to occur soon after the second year for noncancer pain patients.

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