Projected Economic Impact

of Percutaneous Neuromodulation Therapy (PNT)

Among Chronic Low Back Pain Patients

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Background

Low back pain (LBP) is a very common condition, second only to upper respiratory complaints as a leading cause of primary care visits.[1] Despite its widespread prevalence, there remains poor consensus among healthcare providers about how to treat low back pain.[2] Care in the face of poor recovery often involves the use of expensive diagnostic imaging and invasive treatments.

Percutaneous Neuromodulation Therapy (PNT), which has received U.S. Food and Drug Administration clearance, is a minimally invasive, office-based treatment for low back pain. The safety and efficacy of PNT have been demonstrated in clinical trials.[3-9] The purpose of this analysis is to evaluate the potential for PNT to reduce the cost of low back pain-related care.

Methods and Results

From claims data on 1.8 million commercially insured (non-Medicare) individuals, we identified 2,570 patients with chronic, actively treated low back pain having a diagnosis of radiculopathy/spinal stenosis or unremitting low back pain (ULBP). Over a 21-month period, 68% of the radiculopathy/stenosis patients and 37% of the ULBP patients received one or more invasive procedures for low back pain. We classified each patient into one of three groups according to whether the first invasive low back procedure in the study period (the "Starting Event") was a surgery, injection or a specialized diagnostic procedure. We calculated the potential economic impact if all patients had received PNT at the time of referral for the Starting Event procedure during the 21-month period. For the purpose of this study, it was assumed that patients responding to PNT would not require any invasive procedures to treat their low back pain during the 21-month study period.

We estimated "Treatment Pathway Avoidance" rates, representing the fraction of patients who respond to PNT, based upon data from clinical trials of PNT. We then projected changes in healthcare expenditures assuming PNT was prescribed to all patients who would have otherwise received an invasive procedure at the time of the defined Starting Event.

Three components of reduced costs from this model include a reduced number of invasive procedures, complications from such procedures, and pharmaceuticals commonly used with such procedures and their expected complications. Two components of added costs include the cost of PNT for "responders" benefiting from a full trial of PNT (estimated at 10 sessions) and the cost of PNT for "non-responders" who fail to derive benefit after an initial trial of therapy (estimated at 4 sessions). For the purposes of this study, complications are defined as adverse low back pain-related events occurring subsequent to and within the first three months of an invasive procedure.

Based on our estimate that 26% of patients who received PNT would respond to treatment, we estimated an overall reduction of $408 in medical claims per patient receiving PNT (including responders and non-responders) over a 21-month period.

Conclusion

Assuming the cost and efficacy estimates for PNT are borne out in further clinical practice, this technology offers the potential for significant economic benefit to health plans when used as an alternative to more invasive and/or more expensive options for treating chronic low back pain. If PNT were utilized nationwide for all commercially insured patients matching our narrowly defined selection criteria, health plan medical costs would be reduced by an estimated $27 million annually.

PNT represents a potentially important advance in the treatment of one of our society's most pervasive, debilitating, and costly health problems and shows promise as a cost-effective alternative to more invasive and expensive low back pain procedures.

Introduction

Low back pain (LBP) is an extremely common ailment,1 generating nearly 19 million physician visits annually. Among chronic low back pain patients, specialized and often invasive procedures—such as surgery, spinal injections, and MRI scanning—are a major component of health plan costs. Furthermore, patients with chronic pain often receive expensive medications on a routine basis, such as sustained-release opioids and the newer anti-neuropathic drugs. Despite this, it is difficult to predict which, if any, of many possible therapies will be effective.[10, 11] Paradoxically, against a backdrop of extensive clinical research, there remains poor consensus among physicians about how to treat low back pain.[2]

In addition, invasive procedures for the treatment of low back pain may be associated with a significant number of complications, some of which are poorly understood. For example, "failed low back surgery syndrome" describes a poor response to surgery and occurs commonly enough to be labeled as a discrete medical disorder.

Treatment options for failed back surgery syndrome may include re-operation, repeated spinal injections, a spinal cord stimulation trial, chronic oral or pump-delivered opioids, and functional restoration programs. All of these care options are expensive, often running into the tens of thousands of dollars, and overall offer only mixed efficacy. In addition, most are invasive and carry significant risks of side effects, complications, or more broadly, the risk of a poor clinical outcome.[12, 13] Low back pain patients—especially those receiving invasive procedures—may also be significant users of opioid pain medications, which are costly and have a potential for increased tolerance (with associated loss of efficacy), physical dependence, and substance abuse.[14]

Percutaneous Neuromodulation Therapy (PNT) is a minimally invasive, FDA-cleared, office-based treatment for low back pain. It has been proposed as a precursor or alternative to more invasive and expensive LBP therapies. The PNT System delivers electrical stimulation via fine-gauge filament electrodes (250 micron diameter) that are housed in unique sharps-safe casings called Safeguides. The Safeguides are used to temporarily insert the electrodes to a depth of three centimeters and enable the delivery of electrical stimulation directly to the deep tissues in order to reach the nerve pathways that lead to the dorsal horn of the spinal column, where pain signals are processed and transmitted to the brain. Researchers believe that the stimulation delivered through PNT modulates the hypersensitivity of the nerve cells that give rise to persistent pain. PNT and other percutaneous electrical therapies have been documented in clinical trials to be effective for the treatment of chronic low back pain patients, including those who have previously failed to respond to more invasive treatments such as back surgery and spinal injections.[3, 4, 6-9, 15]

PNT may achieve notable clinical and economic benefit as a result of reduction in or elimination of more invasive, potentially more harmful, and/or more costly therapies. In our study, we simulated the prescription of PNT for various subgroups of a population with chronic LBP. We projected the economic impact of PNT as the estimated difference between the costs of implementing PNT for patients who would have received an invasive procedure and the savings from avoiding these procedures (among those patients who would have responded to PNT).

Methods

Study Population

We retrospectively examined claims for a population of 1.8 million commercially insured members, supplied by the actuarial firm Reden & Anders, LTD. Patients with a qualifying ICD-9 diagnosis code were grouped according to diagnostic categories based on a clinical algorithm developed for low back pain by the American Academy of Orthopedic Surgeons and the North American Spine Society.[16] Part of this algorithm represents the management of post-acute low back pain patients, and distinguishes between herniated nucleus pulposus, unremitting low back pain, spondylolysis or spondylolisthesis, and spinal stenosis. Within our data set, there were 144,731 patients who had one or more of these, or a closely related qualifying ICD-9 code as a primary or secondary diagnosis during the first 12 months of our study interval.

Within this broad population diagnosed with low back pain, we focused on patients with chronic, actively treated illness. Specifically, the study population included patients who received at least one service (an invasive procedure, physical therapy, acupuncture or TENS, as defined by a CPT code) to treat low back pain (as described by one of the qualifying ICD-9 diagnosis codes) during each of two consecutive three-month periods. Study patients were also required to have 21 months of continuous coverage. Lists of qualifying ICD-9 and CPT codes are provided in Appendix A.

After study criteria were applied to the actuarial claims, only the herniated nucleus pulposus/spinal stenosis (which we have labeled "radiculopathy/stenosis") and unremitting low back pain (ULBP) diagnostic categories produced sample sizes large enough to justify further analysis. The result was a study population of 2,570 patients (924 in radiculopathy/stenosis and 1,646 in ULBP).

Starting Event Classification

Within these two diagnostic categories, patients were classified into three groups according to a Starting Event, defined as the first invasive LBP-related procedure received during the study period. For this study, invasive procedures were defined as surgery, injections, and specialized diagnostic tests, including MRI and CT scans.

When performed without the use of contrast agent, MRI and CT are, strictly speaking, noninvasive. However, for this model, they are classified as invasive procedures because they are typically ordered when invasive treatments are contemplated and after first-line clinical interventions (e.g. physical therapy and medications) have failed. We reasoned that if PNT were to be used in lieu of invasive procedures, the clinician would prescribe PNT prior to ordering an MRI or CT scan. In a fourth group were patients who met the study criteria but who had no invasive procedure(s) during the study period.

In instances where more than one category of invasive procedure occurred on the same day, designation of the Starting Event was based on clinical judgment by the principal author of this paper. In this study, within each diagnostic category, we refer to the Starting Event and subsequent procedures as a "treatment pathway." Distribution of the study population by treatment pathway is shown in Table 1.

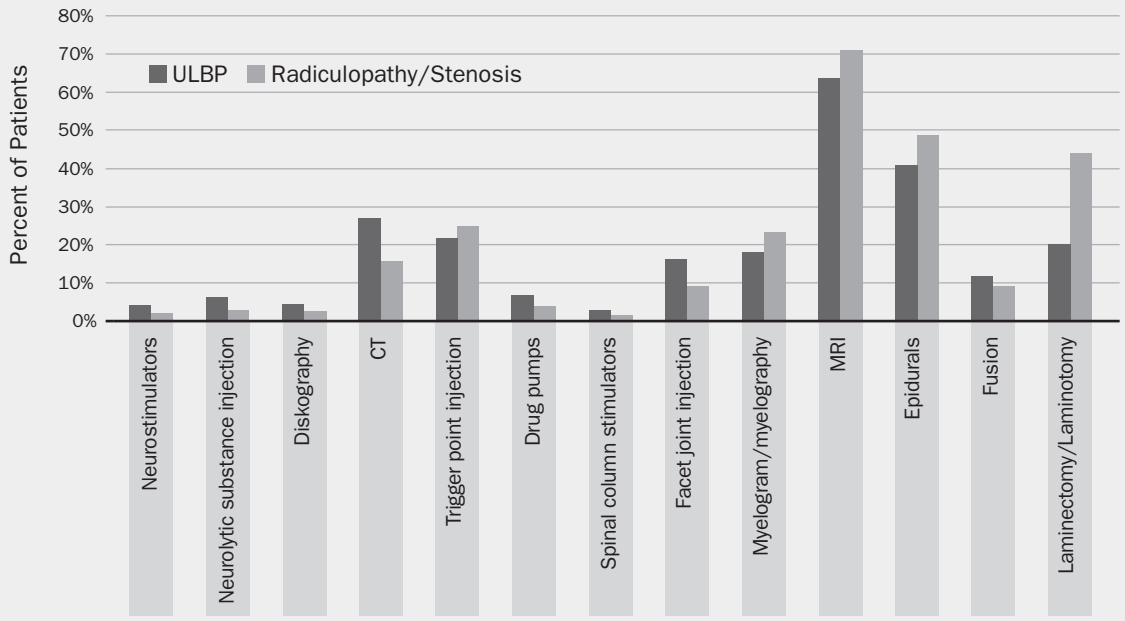
Table 1. Population Distribution by Diagnostic Category and Starting Event

	Radiculopathy		ULBP		TOTAL	
Starting Event	Patients	% of Total	Patients	% of Total	Patients	% of Total
Surgery	38	4%	56	3%	94	4%
Injection	174	19%	200	12%	374	15%
Diagnostic Test	414	45%	360	22%	774	30%
Subtotal: Invasive Proc.	626	68%	616	37%	1242	48%
No Invasive Procedure	298	32%	1030	63%	1328	52%
Total	924	100%	1646	100%	2570	100%

Invasive Procedure Frequency

The percentage of patients having at least one invasive procedure as defined in this study varied by diagnosis—68% of radiculopathy/stenosis patients and 37% of the ULBP patients in the study population had an invasive procedure(s) to treat low back pain. Most patients had more than one kind of invasive procedure. Among patients who had procedures, the average patient had 2.1 to 5.3 different procedures, depending on the treatment pathway. As shown in Figure 1, the most common procedures included MRI, epidurals, laminectomies, and laminotomies. Among all procedures, laminotomies, laminectomies, and fusions were the most costly.

Figure 1. The distribution of invasive procedures within the two diagnostic categories. Totals exceed 100% as many patients had more than one type of procedure.



Frequency and Cost of Complications

Our review of the clinical literature revealed 36 specific diagnoses identified as potential complications of specific invasive procedures to treat low back pain.[17-32] We examined actual claims for our study population to identify occurrences of these codes, and followed a multi-step process to confirm and match the complications with the relevant procedure. We excluded peri-procedure complications and focused exclusively on post-procedure complications, as services to treat a complication occurring during an initial inpatient stay for example, would already be counted in the cost of the procedure itself. We also excluded pre-existing conditions (i.e. any complication whose diagnosis code appeared before the first invasive procedure in the study period).

For the purposes of this study, complications are defined as adverse low back pain-related events occurring subsequent to and within the first three months of an invasive procedure.

We attributed the remaining post-procedure complications to the invasive procedure most recently preceding either an initial complication or the first occurrence of a recurring complication. Where patients had multiple procedures on the same day, we assigned the complication to the procedure in which the greatest frequency of that complication was noted in the clinical literature, and assigned ambiguous cases based on clinical judgment. The cost of services in which more than one complication was treated was allocated evenly among the complications coded in the claim.

As listed in Table 2, we identified 2,253 services rendered for the treatment of post-procedure complications of invasive low back procedures among the 1,242 patients studied receiving an invasive procedure(s). This included 44 inpatient admissions, 339 hospital outpatient treatments, and 1,870 physician services (CPT code lines claimed).

Table 2. Frequency of Services to Treat Identified Complications

	Treatments for Complications Frequency by Claim Type				
Complication Category	IP	OP	MD	Total	Total # Patients
Discogenic syndrome/radiculitis		31	505	536	75
Lumbosacral spondylosis (i.e., arthritis)	9	156	347	512	56
Urinary tract infection	6	10	181	197	44
Discitis	1	13	88	102	22
Other mononeuritis of lower limb (e.g., causalgia)		23	77	100	18
Colitis (e.g., from antibiotic)		6	58	64	18
Constipation	3	9	49	61	16
Reaction to lumbar puncture (including headache)		20	27	47	16
Syncope/vasovagal attack			42	42	13
Postsurgical arthrodesis status (e.g., fusion failure)	2	17	22	41	13
Postlaminectomy syndrome		14	50	64	11
Adverse effect of medicinal substance (e.g., chymopapain)		1	17	18	10
Infection (including into epidural space)	7	9	54	69	9
Liver dysfunction		2	90	92	8
Arachnoiditis/meningitis	2	2	65	69	8
Total	44	339	1,870	2,253	393

Prescription Drug Usage and Cost

Using a list of 28 drugs identified through clinical judgment (refer to Appendix A), we also examined the cost of prescription drugs typically associated with invasive procedures for low back pain. As shown in Table 3, the cost of prescriptions for these selected drugs was nearly ten times higher for patients having invasive procedures than for those not having invasive procedures.

Table 3. Average Cost per Patient of Procedure-Related Pharmaceuticals

Starting Event	Radiculopathy/Stenosis	ULBP	TOTAL
Surgery	$722	$474	$574
Injection	$822	$800	$810
Diagnostic Test	$265	$393	$324
All Patients Having Invasive Procedures	$447	$532	$490
No Invasive Procedure	$55	$49	$50
Total study population	$321	$230	$263

Total Cost of Invasive Procedures and Associated Complications

Invasive procedures for the treatment of low back pain are a major component of medical costs in this population. Invasive procedures for low back pain generated $6.3 million in direct costs during the study period, averaging $5,095 for each patient receiving one or more procedure. ("Direct cost" includes claims for physician, hospital inpatient, and hospital outpatient services involved in the procedures.) In addition, the treatment of post-procedure complications added $694,000 (11%) to the cost of low back procedures in this population.

Estimating the Impact of PNT

We calculated the potential economic impact if all patients had received treatments with PNT at the time of referral for the first invasive procedure for low back pain during the study period. For the purpose of this study, we assumed that patients responding to PNT would not receive the Starting Event or any of the procedures that followed it. Patients failing to respond to PNT would continue on to receive the Starting Event and the mix of subsequent procedures identified in the study data.

Table 4. Clinical Efficacy Assumptions

	Treatment Pathway Avoidance Rates	
Starting Event	Radiculopathy/Stenosis	ULBP
Diagnostic Test	25%	25%
Injection	35%	25%
Surgery	25%	15%

As shown in Table 4, we predicted the potential impact of PNT based on assumed Treatment Pathway Avoidance Rates, estimated from clinical trials of PNT.[3,4] These rates represent the percentage of patients in each treatment pathway (diagnosis/Starting Event group) who will respond to PNT. For example, we assume that 35% of the radiculopathy/stenosis patients whose first invasive procedure was a spinal injection would have responded to prescribed PNT instead of the injection. This 35% would therefore have avoided the injection and all invasive procedures that followed during the remainder of the study period. Note that the 65% of patients in this example who we assume will not respond to PNT continue on to the same mix of procedures as if PNT had not been prescribed. As listed in Table 4 and similar to most LBP treatments, PNT is assumed to be relatively more effective for a population with radiculopathy/stenosis than for a population with localized unremitting low back pain.

Anticipated Course of PNT Treatments and Costs

Estimates of the cost of PNT treatments are based on a treatment cycle that varies according to patient response. Experience in clinical trials suggests that patient response to PNT can be predicted fairly accurately within 3-4 treatments. We assumed that patients not responding would cease receiving PNT after an average of four treatments, while those responding to PNT would receive an average of ten treatments. Cost projections are based on an estimated allowed cost of $210 per PNT treatment, as noted in Table 5. Methodology for estimating cost savings associated with PNT on a per-patient basis involved a simple linear model (described mathematically in Appendix B).

Table 5. PNT Treatment Assumptions

Number of treatments for Responders	10
Number of treatments for Non-Responders	4
Allowed Cost Per PNT Session	$210

Results

Financial Impact of PNT

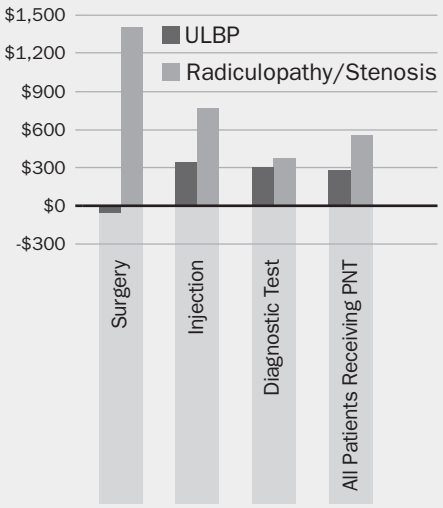
If PNT were used on all patients in the study population who actually received an invasive procedure as defined in this study, we estimate that PNT would reduce the total costs for back-related claims by approximately 25%. As shown in Table 6, the procedure avoidance savings to health plans amount to $1,575 per patient receiving PNT. This includes $1,313 per patient in savings from avoiding the procedures, additional savings of $144 per patient in the cost of treating associated complications, and savings of $118 per patient in procedure-related pharmaceuticals.

Table 6. Impact of PNT on Healthcare Costs in Chronic Low Back Pain Patients

	Procedure Savings	Savings on Complications	Pharmacy Savings	Total Savings
Total Population				
Reduction resulting from PNT use	$1,630,456	$178,534	$146,761	$1,955,751
Percentage Reduction	26%	26%	22%	25%
Cost of PNT Treatments	–$1,449,378			–$1,449,378
Net Savings (Cost Increase)	**$181,078**	**$178,534**	**$146,761**	**$506,373**
Per Patient Using PNT				
Reduction resulting from PNT use	$1,313	$144	$118	$1,575
Percentage Reduction	26%	26%	22%	25%
Reimbursed Cost of PNT	–$1,167			–$1,167
Net Savings	**$146**	**$144**	**$118**	**$408**

The cost of PNT treatments is estimated at $1,167 per patient. This represents 10 treatments at $210 each for the 26% of patients responding to PNT, and 4 treatments at $210 each for non-responders. The reduction in medical costs due to procedure avoidance would exceed the cost of providing PNT treatments, resulting in potential net savings of $408 per patient receiving PNT (including responders and non-responders), or $506,373 for the study population.

Figure 2. Estimated savings per patient receiving PNT, including both responders and non-responders, by diagnostic category and Starting Event



As shown in Figure 2, potential savings by diagnosis and treatment pathway vary from a loss of $32 (diagnosis ULBP, Starting Event surgery) to savings of $1,396 per patient (diagnosis Radiculopathy/ Stenosis, Starting Event surgery). The difference in savings between these two groups—each receiving surgery as their Starting Event procedure—is attributed to the high cost per patient for procedures among the Radiculopathy/Stenosis patients (50% higher than for ULBP) and a lower assumed treatment pathway avoidance rate for the ULBP/Surgery patients (15% vs. 25%).

Study Limitations

The 2,570 patients in this study met requirements for active treatment of chronic LBP defined by a specific mix of diagnostic and procedural codes, as well as continuous eligibility during the study period. We did not assess the frequency and cost of invasive low back procedures in the broader population of 144,371 patients having one or more of the qualifying diagnostic codes.

The study population was limited to patients with commercial health insurance, including managed care and traditional benefit structures. Potential impact on other populations was not assessed.

We classified patients by Starting Event, defined as the first invasive procedure for low back pain within the study period. However, the data revealed that many patients having invasive procedures for low back pain received multiple other such procedures. Therefore, it is reasonable to assume that some of these patients may have had invasive procedures prior to the study period. In other words, for some patients, what we identified as a Starting Event may have actually occurred at a later point in their course of treatment.

Also, our estimation of complications and medications associated with these procedures is subject to clinical judgment and our knowledge of available literature on the topic. Currently, there are no rigorous inclusion and exclusion criteria for apportioning such care to the Starting Event procedures defined within this study. Nor is the set of documented complications restricted to describing procedure-related complications exclusively. In select instances, some percentage of the clinical conditions that were characterized as post-procedural complications, may represent the need for additional interventions due to the failure of the most recent invasive procedure. We recommend further study of invasive procedure-related complications, in particular the added medical resource use and cost associated with these complications.

Conclusions

Assuming that PNT performs as projected in the analysis, this technology is expected to generate savings for health plans by avoiding the cost of more invasive procedures, their complications, and associated pharmaceutical costs. After including the costs for those who do and do not respond to PNT, the average overall projected savings are $408 per patient over a 21-month period.

At a national level, if PNT were prescribed for all commercially insured patients who meet the study criteria, we estimate that costs for back-related claims for this population would be reduced $27 million annually.

PNT represents a potentially important advance in the treatment of one of our society's most pervasive, debilitating, and costly health problems and shows promise as a cost-effective precursor or alternative to more invasive and expensive low back pain procedures.

Appendix A. Coding and Medication Category Assumptions

A-1. Qualifying Diagnosis (ICD-9) Codes

Ankylosing spondylitis	720
Lumbosacral spondylosis w/out myelopathy	721.3
Thoracic or lumbar spondylosis w/myelopathy	721.4
Lumbar region	721.42
Spondylosis of unspec site	721.9
Intervertebral disc disorders	
Displacement of thoracic or lumbar disc	722.1
Lumbar intervertebral disc w/out myelopathy	722.10
Displacement of intervert disc, site unspec	722.2
Degeneration of thoracic or lumbar disc	722.5
Degenerative intervertebral disc, lumbar	722.52
Degeneration of intervert disc, site unspec	722.6
Intervertebral disc disorder w/myelopathy	722.7
Intervertebral disc disorder w/myelopathy, lumbar	722.73
Postlaminectomy syndrome	722.8
Postlaminectomy syndrome, lumbar region	722.83
Other and unspecified disorders of the back	
Spinal stenosis, other than cervical	724.0
Spinal stenosis, unspec	724.00
Spinal stenosis, lumbar	724.02
Lumbago	724.2
Sciatica	724.3
Other and unspecified disorders of the back (cont.)	
Thoracic or lumbosacral neuritis or radiculitis	724.4
Backache, unspecified	724.5
Disorders of sacrum	724.6
Other symptoms referable to back	724.8
Other unspec back disorders	724.9
Other disorders of soft tissues	
Neuralgia, neuritis, and radiculitis, unspec	729.2
Curvature of spine	
Lordosis	737.2
Scoliosis	737.3
Other acquired deformity	
Acquired spondylolisthesis	738.4
Nonallopathic lesions, NOC	
Lumbar region	739.3
Sacral region	739.4
Other congenital musculoskeletal anomalies	
Anomalies of spine	756.1
Sprains/strains	
Sprain or strain of lumbosacral joint/ligament	846
Lumbar strain	847.2
Sacral strain	847.3

A-2. Qualifying Procedure (CPT) Codes

Procedure Categories are defined by CPT Code and aligned by column into Starting Event groups. The fourth group of patients are those having none of the invasive procedures listed below.

INVASIVE PROCEDURES

SURGERY

Fusion (arthrodesis)
22558 22585
22612 22614
22630 22632
22830 22840
22842 22843
22844 22849
22850 22851

Laminectomy/Laminotomy
63005 63011
63012 63017
63030 63035
63042 63044
63047 63048
63056 63057
63267 63268
63272 63273

Spinal column stimulators
63650 63655
63650A 63685
63660 63688
63690 63691
63700-63710

Drug pumps
62350 62351
62355 62360
62361 62362
62365 62319

Neurostimulators
64550 64553
64565 64575
64580 64585
64595 95970
95971 95972
95973

INJECTIONS
(code 76005-26, fluoroscopic guidance, can be used in conjunction with any of the following)

Epidurals
62311 64483
64484

Facet joint
64475 64476

Sacroiliac joint
27096

Neurolytic substance
62282 64622
64623

Trigger point
20550

DIAGNOSTIC TESTS

MRI
72148 72149
72158

CT
72131 72132
72133

Myelogram/myelography
62284 72265

Diskography
62290 72295-26

Epidurography
72275-26

SI joint arthrography
73542

NONINVASIVE PROCEDURES

PHYSICAL MEDICINE

Physical Therapy
97001 97002
97003 97004
97110 97112
97140

Acupuncture/TENS
97780 97781
97014 97032

A-3. Prescription Drugs Related to Low Back Pain Procedures

Acetaminophen W/Codeine
Aspirin W/Codeine
Butalbital W/ Acetaminophen/Aspirin
Chloral Hydrate
Chlordiazepoxide
Clonazepam
Clorazepate
Codeine
Diazepam
Fentanyl
Flurazepam
Hydrocodone W/Acetaminophen/Aspirin
Hydromorphone
Levorphanol
Meperidine
Meprobamate
Methadone
Morphine
Oxazepam
Oxycodone
Oxycodone W/Acetaminophen
Oxycodone W/Aspirin
Pentobarbital
Phenobarbital
Propoxyphene
Propoxyphene W/Acetaminophen
Secobarbital
Triazolam

Appendix B. Methodology for Estimating the Financial Impact of PNT

Our methodology for estimating cost savings associated with Vertis PNT on a per-patient basis involved a simple linear model, described as follows:

$$C' = P_{RESP} \times PAR + (C + P_{NON}) (1 - PAR)$$

Definitions:
C = Actual cost data from the data set, without the use of PNT
C' = Calculated cost, with the use of PNT
PAR = Procedure Avoidance Rate
P_{NON} = Session Cost of PNT x No. of Sessions tried (if not responding)
P_{RESP} = Session Cost of PNT x No. of Sessions given (if responding)

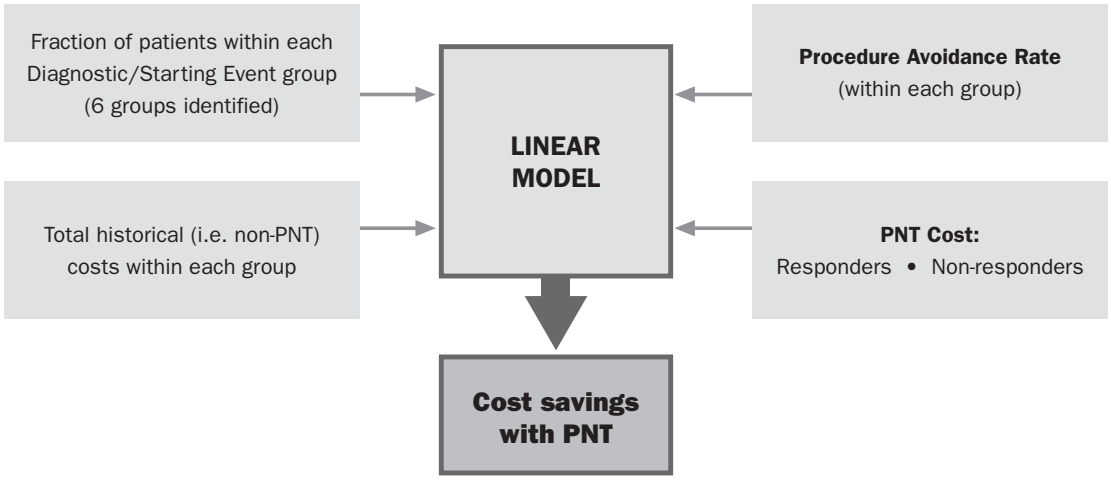
Define Cost savings with PNT as DC = C – C'

Solve for DC:

$$DC = PAR \times (C - P_{RESP}) - (1 - PAR) * P_{NON}$$

In other words, this states that PNT cost savings are equal to the fraction of responders to PNT times the net savings of PNT for the responders, minus the fraction of non-responders to PNT times the net cost of PNT for the non-responders.

Note that the reimbursement model is a linear model, with a fairly straightforward formula. Conceptually, it can be diagrammed as follows:



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