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A New Spinal Cord Stimulation Option: High-frequency 10 Kilohertz (HF10®)

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Abstract

Spinal cord stimulation is a widely-used modality used to treat pain conditions for individuals who have chronic pain that has not responded to traditional interventions including medication, surgery or physical therapy. Life care planners often include spinal cord stimulation in the life care plans that they prepare for individuals with pain. This article will introduce life care planners to a new type of spinal cord stimulation, high-frequency 10 kilohertz HF10® therapy provided by Nevro Corporation. Efficacy data of HF10® is also included. Guidelines for requisite current procedural terminology (CPT) codes are also provided.

What is Spinal Cord Stimulation?

Chronic pain, defined as pain that persists for three months or longer, affects more than one out of ten American adults (American Pain Society, 2015; Nahin, 2015). Because pain is so restrictive to their everyday lives, individuals with long-term chronic pain often find themselves depressed, withdrawn from friends and family, and reliant on others for even the simplest daily activities. Many individuals living with chronic pain exhaust a variety of treatment options, including physical therapy, lifestyle modifications, medication, steroid injections, and surgery. For some, pain persists through these treatments, or can be made worse by the side effects of those treatments. For these individuals, consideration of a spinal cord stimulator may be recommended.

Spinal cord stimulation (SCS) is commonly used for control of chronic pain secondary to failed back surgery syndrome and complex regional pain syndrome, as well as pain from angina pectoris, peripheral vascular disease, and other causes. Spinal cord stimulation patients report improved quality of life (without the side effects associated with analgesic medications) and improved function, with many returning to work. There is strong evidence for efficacy and cost effectiveness of spinal cord stimulation in the treatment of pain as compared with conservative management alone (Deer et al., 2014).

Spinal cord stimulation is a safe and effective treatment option for chronic pain that has been available in the United States for over 30 years (North, Kidd, Farrokh & Piantadosi, 2005). It is an implanted device sometimes described as a "pacemaker for pain." Spinal cord stimulation works by delivering mild electrical pulses to the spinal cord to mask or interrupt the transmission of abnormal pain signals to the brain. These pulses are delivered by thin wires, called leads, containing small electrodes, which are placed near the spinal cord and connected to a small battery-powered generator implanted under the skin. The Neuromodulation Appropriateness Consensus Committee of the International Neuromodulation Society evaluated evidence regarding the safety and efficacy of neurostimulation to treat chronic pain and validated spinal cord stimulation (Deer et al., 2014). They concluded that neurostimulation is 1) relatively safe because of its minimally invasive and reversible characteristics and 2) that randomized controlled studies support efficacy (Deer et al., 2014).

Spinal cord stimulators consist of an implantable pulse generator, a stimulation lead(s), and an extension cable that connects the lead with the generator. The implantable pulse generator (IPG) delivers electrical stimulation that can be modified by altering the pulse width, frequency, and amplitude to accomplish maximal pain relief. Multiple companies manufacture SCS devices with differentiating features including the method used for controlling electrical energy (i.e., constant current versus constant voltage), the frequency range, tonic versus burst stimulation, rechargeable versus non-rechargeable implantable pulse generator, characteristics of the leads, and magnetic resonance imaging (MRI) compatibility.

Spinal Cord Stimulator Procedures

Spinal cord stimulation consideration typically occurs after the patient has failed conservative treatment options. Patients should be selected for appropriateness for SCS therapy and for comorbidities that may increase the possibility of complications or technical difficulty, including coagulopathy. The evaluation process includes physical exam, psychological evaluation and psychologist and physician approval. Spine imaging studies should be utilized as a differential diagnosis to identify those patients for whom surgery may be a more appropriate treatment than SCS. After being approved by a mental health professional in the psychological evaluation stage, patients move to the implantation stage.

Implantation of a spinal cord stimulator involves a two-phase medical process consisting of phase one (the trial) and phase two (permanent implant). All patients must go through a trial and if the trial is successful, patients proceed to the permanent implant procedure. Both the trial and permanent implant procedures are relatively quick and minimally

invasive.

Stimulator trials typically occur at the physician's office or at an outpatient surgical center. Most percutaneous spinal cord stimulator trials are performed under local anesthesia (LA) with or without sedation and a trial duration of five to seven days. The trial stimulator uses special batteries that do not need to be recharged. The trial stimulator can be placed to the front or side of the body depending on sleeping position. A successful trial is generally defined as achieving 50% or more pain relief from the patient's baseline scores (Deer et al., 2014).

Upon successful trial, the implant surgery takes one to three hours and usually takes place in a hospital or surgery center. There is generally a waiting period of two weeks to two months after trial completion until implantation to make certain there has been no infection. The hospital length of stay will vary depending on doctor's preference and hospital procedures with thoracic/lumbar placement usually performed on an outpatient basis while cervical placement is performed as an inpatient. Spinal cord stimulator implantation may be implemented with general anesthesia, spinal anesthesia, or monitored anesthesia care.

Spinal cord stimulator systems consist of battery-powered implanted pulse generators (IPGs) and leads that are placed either percutaneously or surgically in the epidural space. During the surgical implant, the surgeon initially makes an incision over vertebra and places the leads (medical wires) that deliver the stimulation into the epidural space of the spinal cord. A second incision creates a pocket under the skin that is large enough to hold the neurostimulator or internal pulse generator. The leads are connected to the IPG. Once the leads and neurostimulator are in position, the incisions are closed and the neurostimulator is programmed.

Leads vary by manufacturer; but there are two categories of SCS leads: cylindrical and paddle leads. Cylindrical leads are most commonly used for percutaneous procedures, while paddle leads are placed surgically. HF10® stimulator leads are typically placed with one lead-tip at the top of T8 and the other lead at the top of T9 in order to consistently capture low back and leg pain. Other pain areas, such as upper limb pain, require lead placement in different locations on the spine.

Individuals are advised to be careful not to overstretch during the recovery period, as this could potentially alter the position of the leads and/or the implantable pulse generator. Light lifting and gentle bending and twisting as permitted by the implanting physician are okay.

Although traditional SCS has helped many people, there are also some drawbacks. Spinal cord stimulation has demonstrated relief for chronic pain of the legs, however back pain has historically been difficult to treat. Additionally, some patients who use SCS therapies have reported a tingling or buzzing sensation which many users find unpleasant and can result in barriers to driving and sleeping (Russo & Van Buyten, 2015).

HF10® Spinal Cord Stimulation: A New Option

Traditional spinal cord stimulation (SCS) generators distribute stimulation at frequencies in the 50-Hz range. The FDA (2015) approved Nevro Corp.'s Senza® system, which delivers HF10® therapy at 10,000 Hz, indicated in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain. HF10® uses a proprietary approach to SCS that includes, among other parameters, a much higher stimulation frequency (10,000 Hz). HF10® includes a biphasic stimulator wave form with pulse widths of approximately 30 microseconds at a rate of 10,000 Hz, thus eliminating paresthesia (Russo & Van Buyten, 2015).

In a 24-month SENZA-RCT clinical trial, nearly twice as many trial participants achieved dramatic relief from leg pain and back pain with HF10® than with traditional SCS (Kapural et al., 2016). The study found that the HF10® participants achieved a superior improvement in their ability to accomplish everyday tasks (Kapural et al., 2016). Individuals reported being able to sleep and drive with HF10® remaining on and unlike traditional SCS there are no restrictions on driving while receiving HF10® (Nevro Corp., 2015). There are also no medication restrictions while using HF10® (Nevro Corp., 2015). The Nevro Senza® SCS System received Conformité Européenne (CE) mark in 2010, Therapeutic Goods Administration (TGA) approval in 2011, FDA approval in 2015, and is commercially available in Europe, Australia, and the United States. Conformité Européene marking is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area. Therapeutic Goods Administration is Australia's regulatory authority for therapeutic goods. In 2015, the FDA specified a superiority label, an uncommon designation in the world of medical devices, indicating that HF10® provides more patients more relief of their chronic pain in comparison to traditional SCS for back pain and leg pain. As of February 2018, Nevro statistics show that over 28,000 patients have been treated with HF10®.

HF10® is covered by Medicare and nearly all major private insurance plans in the United States. Medicare National Coverage Determination (Centers for Medicare and Medicaid Studies, 1995) allows for coverage spinal cord stimulation when the following criteria are met:

- The implantation of the stimulator is used only as a late resort for patients with chronic intractable pain;
- With respect to the previous criteria, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated; screening must include psychological, as well as physical evaluation;
- Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to

implantation;
- All the facilities, equipment and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient (including that required to satisfy the previous criteria must be available; and,
- Demonstration of pain relief with a temporarily implanted electrode precede permanent implantation

Life Care Planning Considerations

Considerations for the life care plan include both costing procedures and long-term management of SCS, including special cases where patients undergo other surgical procedures or have unique medical conditions. Like all equipment in the life care plan, the SCS must be replaced over one's life expectancy. Therefore, both the initial costs associated with SCS trial and placement are researched by the life care planner, as well as the subsequent costs associated with equipment replacement and maintenance.

Coding

To determine costs associated with SCS placement, typically CPT codes are necessary. Common CPT codes associated with SCS trial and placement are included below. The CPT codes involved in the trial procedure are outlined below in Table 1.

Table 1. Spinal Cord Stimulator Trial CPT Codes

CPT	DESCRIPTION
63650	Percutaneous implantation of neurostimulator electrode array, epidural
90838	Psychological Exam
99202-99205, 93000	Physical Exam with EKG
85025, 80053, 85610, 85730,	Labs : CBC with Differential, Complete Metabolic Panel; PT/PTT/INR

Upon successful trial, the patient moves to the second phase of implantation of the spinal cord stimulator. Two different sets of CPT codes may be used, depending upon whether the patient receives a system that delivers the therapy via two percutaneous leads (a) or one surgical lead (b). The CPT codes involved in the implantation procedure are outlined below in Table 2.

Table 2. Spinal Cord Stimulator Implant CPT Codes

(a) PERMANENT IMPLANT PROCEDURE (Therapy delivered via 2 percutaneous leads)

CPT	DESCRIPTION
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63685	Insertion of spinal neurostimulator pulse generator or receiver

OR

(b) PERMANENT IMPLANT PROCEDURE (Therapy delivered via 1 surgical lead)

CPT	DESCRIPTION
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685	Insertion of spinal neurostimulator pulse generator or receiver

Nevro's internal pulse generator (IPG), which delivers HF10®, has a minimum battery life of 10 years. Once the IPG has reached its useful life, it will be replaced using the same implant codes minus the lead placement code. Additional codes to be considered for the implant procedure are outlined below in Table 3.

Table 3. Additional Implantation CPT Codes

PRE-OPERATIVE CLEARANCE

CPT	DESCRIPTION
71010	Chest Xray
72100-72120	Lumbar Xray
99202-99205, 93000	Physical Exam with EKG
85025, 80053, 85610, 85730,	Labs : CBC with Differential, Complete Metabolic Panel; PT/PTT/INR

The American Medical Association (AMA) defines simple intraoperative or subsequent programming (95971) as changes to three or fewer parameters described in the programming codes. Complex intraoperative or subsequent programming (95972) includes changes to more than three parameters (AMA, 2017). The CPT codes that are applicable for IPG analysis and programming are outlined below in Table 4.

Table 4. SCS Programming CPT Codes

ANAYLSIS AND PROGRAMMING

CPT	DESCRIPTION
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971	…simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	…complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
99212-99215	Follow- up Examination Implanting Physician: Pain Management Specialist, Orthopedic Spine Surgeon, Neurosurgeon

Facility Coding

The Centers for Medicare and Medicaid Services (CMS) (2016) acknowledged the "substantial clinical improvement" associated with HF10® as compared to traditional SCS and created a new device category (C1822) that is billed with the permanent implant procedure. By definition, C1822 differentiates HF10® from traditional low frequency SCS and is only to be used in conjunction with Nevro's Senza® system. The facility-based CPT codes used in the implantation procedure are outlined below in Table 5.

Table 5. Facility-related SCS Implantation CPT Codes

CPT	Description
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1820	Generator, neurostimulator (implantable), non high-frequency with rechargeable battery and charging system
C1767	Generator, neurostimulator (implantable), non-rechargeable
AND	
DEVICE CODES LEVEL II	
CPT	**Description**
L8680	Implantable neurostimulator electrode, each (leads: 8-contact)
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension (pulse generator)
L8689	External recharging system for battery (internal for use with implantable neurostimulator pulse generator, replacement only (external charger)
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only

Additional Considerations

Other life care planning considerations may include but are not limited to:

(a) Revision of leads may be necessary post-recovery for any number of reasons including lead fracture, though this is rare. Should this occur, the CPT codes outlined in Table 6 below are applicable.

Table 6. SCS Revision CPT Codes

CPT	DESCRIPTION
63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

(b) MRI compatibility: Currently, HF10® permits 1.5T and 3T MRI scanning of head and extremities under certain conditions. Applicable consideration of these limitations may need to be incorporated into the life care plan, including removal if necessary. Removal may also be necessary secondary to infection and intolerance. Should removal of the device become necessary, the CPT codes listed in Table 7 below are applicable.

Table 7. SCS Removal CPT Codes

CPT	DESCRIPTION
63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

Long-Term Management of HF10®

Activity restrictions do apply during the trial and implantation and care considerations should be included. To ensure the leads stay in the right place, individuals are instructed to not lift their arms over shoulders or lift heavy objects and limit physical activity. In general, the device and dressings must remain dry to avoid infection.

Because each patient's pain is different, HF10® can be customized to each individual's need. HF10® follows an evidence-based programming algorithm that is supplemented with the physician's clinical judgement. Multiple advanced programming strategies can also be implemented to further optimize the patient's pain relief, if required. Often, a portion of the programming can also be managed over the phone, similar to common pacemaker protocols that allow telephonic management. This is an advantage to the patient who is recovering from implant surgery by reducing travel to physician offices for some programming steps. Consideration should be made to include physician office visits for programming that cannot be accomplished telephonically.

Each patient's SCS programming and pain status is continuously monitored by Nevro's therapy optimization organization alongside their treating physician. The patient is given a handheld programmer with settings determined by the stimulation that best provides pain relief on the day of implantation. The patient can choose between two or three programmed settings as necessary, and the pain clinician can adjust the choice of settings with assistance of the manufacturing company.

The patient is consistently provided care by the physician and Nevro team while the device is implanted. The organization is made up of two teams: Therapy Optimization Specialists and Therapy Support Specialists. The Therapy Optimization Specialists at Nevro are therapy specialists who collaborate with internal partners (Nevro), physicians and patients to deliver desired patient outcomes. Their focus is to continue to optimize the algorithm, deliver clinical training and oversee all programming to maintain patient comfort. The Therapy Optimization Specialists are trained Nevro employees with specific neurostimulator program training. The Nevro Therapy Support Specialists team is the core clinical resource for patient support. They are the experts in executing the treatment algorithm remotely and provide a constant resource for the patient both immediately after the procedure and for the long-term, all under the direction of a physician. The patient can contact this team in addition to the treating physician for programming difficulties.

Implanted SCS pulse generators are powered by batteries, which are recharged with external chargers through the patient's skin. HF10® uses more energy and may require more frequent battery charging compared with standard SCS, however the implant was designed to rapidly recharge, requiring about 30-45 minutes of daily charging. The battery life before replacement is 10 years, comparable to other rechargeable systems but much longer than non-rechargeable systems.

The most frequently reported problems following neurostimulator implant surgery include infection, lead movement, lead fracture, pain at the IPG implant site, and that the therapy did not meet the patient's expectations, (Deer et. al, 2014, Hayak et. al, 2015). After taking appropriate time to recover, individuals can return to usual routines. Strenuous activity should be approved prior to performing as this may increase risk for lead fracture. Inclusion of lead replacement surgery in the life care plan is within reason for individuals who are expected to return to a more active lifestyle. Daily battery charging is recommended to optimize battery life.

Additional SCS Considerations

For patients with spinal cord stimulators, MRI compatibility is an important feature. In unique instances, removal may be necessary when clinically indicated MRI scans conflict with device labeling and alternative forms of testing (e.g. CAT scans) cannot be implemented. Apprehensions comprise the potential of hardware damage, lead movement or heating, and reprogramming as a result of radiofrequency (RF) energy. Future surgical considerations include the use of bipolar electrosurgical instruments. Additional perioperative concerns for patients with spinal cord stimulators who undergo surgery include potential complexity with neuraxial anesthesia after SCS.

Spinal cord stimulators are not considered for pregnant patients secondary to the invasive procedure and the required imaging studies. For patients with stimulators who become pregnant, a spinal cord stimulator may affect the options for regional labor analgesia and for regional anesthesia for cesarean delivery. For example, spinal analgesia may be an option for patients with lumbar leads, in whom epidural analgesia may not be safe or appropriate. Prenatal anesthesia consultation should be performed early in pregnancy to plan for labor analgesia and bipolar instrumentation or operative delivery. Specifically, pre-pregnancy imaging should be reviewed to assist with placement of an epidural catheter or spinal anesthesia.

Additional considerations should be given to patients

with SCS who travel, as airports differ in their screening processes. Most SCS patients carry an identification card to show that they have an implanted device. It is advised when going through security, the individual be escorted around the security machine and directed to the appropriate place for a security check. When implanted, the patient is given a handheld programmer with settings determined by the stimulation that best relieves the patient's pain. It is advised that the patient carry handheld programmer and charging device along with medications, rather than packing these items.

Conclusion

The recently approved introduction of HF10® spinal cord stimulation provides individuals diagnosed with chronic pain an additional option in spinal cord stimulation therapy, which has demonstrated superior pain relief and functional improvement, when compared to traditional systems. Life care planners often consider this therapy in life care plans for individuals with chronic pain. Understanding the process for spinal cord stimulation trial and implantation along with coding guidelines and replacement schedules for this device will increase the knowledge base of life care planners and should prove to be valuable.

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Critical Elements of Healthcare Costing

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Abstract

For litigation cases, professionals must determine usual, customary and reasonable healthcare pricing both when evaluating prior healthcare bills and when creating life care plans. To accomplish these tasks, the professional must understand healthcare charge capture data within a geographic location and the use of correct presentation of the bill with diagnosis and procedure codes in their proper context and condition.

Determining fair and reasonable pricing of a healthcare episode is difficult without the knowledge of how fees for healthcare services and products are generated, paid and reconciled (Revenue Cycle). Reasonable pricing analysis may be impacted by contractual or legislated agreements among the healthcare stakeholders. In addition, paid amounts may be materially impacted by monies exchanged long after the service has been rendered, the explanation of benefits (EOB) has been mailed, and the initial provider reimbursement has been paid. This article will demonstrate that the use of an EOB statement often does not reflect an amount paid.

This article highlights the pitfalls that attorneys, courts and other adjudicators face when attempting to use what they believe is the "amount paid" at one point in the continuum of monetary exchanges as a reasonable value for a healthcare episode. Navigating the complex and multi-layered monetary practices among healthcare stakeholders in order to evaluate a reasonable value for projected healthcare services will help life care planners explain pricing data. This article provides an overview of the market problem, how to proceed with a proper costing analysis, and best practices on how to evaluate what is fair and reasonable for a healthcare episode. Finally, this article will review a usual customary and reasonable practice methodology that includes the use of original charge capture data.

Revenue Cycle

To accurately determine the amount paid on a healthcare episode, the life care planner must understand the concept of the revenue cycle. The Healthcare Financial Management Association (HFMA) defines Revenue Cycle as "all administrative services and clinical functions that contribute to the capture, management, and collection of patient service revenue." (Oregon Health & Science University, 2017, para. 1). The provider, patient and payer activities that are typically involved in generating revenue and a final invoice for direct and indirect healthcare services are detailed in Figure 1:

Figure 1. Operational Activities Associated with a Provider's Revenue Cycle

1. Patient admission and registration
2. Pre-authorization with payer and review of any insured contractual obligation
3. Schedule appointment with the patient
4. Rendering of services to the patient
5. Discharge from services (payer, provider, and patient)
6. Medical records documentation and formal diagnostic and procedural coding of services
7. Submission of billing statements (payer, provider and patient)
8. Receipt of bill by payer organization
9. Review of contractual obligations and formal adjudication of the claim by payer
10. Response to claim resulting in payment by payer, denial, or objections (monetary transaction #1)
11. Provider follow up on individual healthcare episodes
12. Provider annual follow-up on contractual reconciliation of payment activities and review contract terms impacting additional financial transactions (monetary transaction #2)
13. Provider annual report submissions (Medicare cost reports/other deliverables) and possible financial disproportionate share payment considerations (monetary transaction #3)
14. Additional payments from supplemental insurance (monetary transaction #4)
15. Additional payments directly from the patient (monetary transaction #5).

Given that a provider may receive additional payments or financial consideration at five different points within the Revenue Cycle (refer to monetary transaction #1 through #5 in Figure 1 above), the amount paid is complex, dynamic and conditional. The basis for determining the usual customary and reasonable (UCR) price goes well beyond a price list for services or documentation of one payment transaction between two parties.

Explanation of Benefits (EOB)

The typical EOB communicates information such as the amount billed, the amount covered, the allowable amount, the amount not covered, the average discounted price (ADP) and the amount approved for payment. The numbers on the EOB are also impacted by year-end reconciliations between providers and payers and the final amount paid over time may change.

The final payments therefore, are opaque to both the patient and the plan sponsor. As a result, EOB data is limited

when evaluating a reasonable fee for a healthcare service.

Figure 2 shows a typical view a patient may receive describing the cash flows for a healthcare episode – an explanation of benefits (EOB). While the "amount billed" may reflect the financial aspect of a complete provider revenue cycle, it does not describe the money the provider will actually receive. Average Discount Price (ADP) reflects the contractual pricing terms negotiated between the provider and the sponsor and provides limited insight to actual financial flows because it is a discount and because it is average. Being a negotiated "discount," the sponsor is not obligated to pay the billed amount, and being "average," it is also only an estimate of what the gap between billed amount and paid amount will actually be – to be resolved only through a year-end reconciliation process. Due to these two contractual features, this illustration does not fully provide the information required to determine the full cash payments for this healthcare episode.

Figure 2 EOB (Large Payer)

Emerg Accid Surgery	03-10-10	1,956.99	1,956.99
Emerg Accid Surgery	03-10-10	1,956.99	1,956.99
Emerg Accid Surgery	03-10-10	1,956.99	1,956.99
Emerg Accid Surgery	03-10-10	1,956.99	1,956.99
Prosthesis	03-10-10	193.14	193.14
Totals		**$11,935.09**	**$11,935.09**

COVERAGE INFORMATION

Totals	**$11,935.09**	**$0.00**	**$11,935.09**
Discount (ADP)			-$8,068.14
Deductions			
Applied to 2010 Health Care Plan Deductible		$62.58	
Total Deductions			-$62.58
Total Benefits Approved			$3,804.37
Amount You May Owe Provider			$62.58

Total Covered Benefits approved for this claim: $3,804.37 to XXXX SURGICENTER on 03-24-10

When utilizing payer data such as EOBs or other financial billing statements, a life care planner cannot assume that an actual cash transaction of the indicated dollar amount occurred. Further, a life care planner cannot assume the dollar amount reported is the entire paid amount representing the value of that particular healthcare episode. The life care planner should review the original price, reconciled against the presenting procedure codes, the diagnosis codes, relevant market practices based on geographic location, and the actual services documented within the medical record. The life care planner should also review medical record documentation to validate the intensity of service in comparison to the price of the service charged. If, at this point in the review, the code and price selected by the provider is not consistent with the intensity of service, then the life care planner will need to choose an alternative source for selecting a price that reflects the level of intensity of services provided.

Patient Responsibility

The other important consumer perspective is the financial language that is frequently buried within a consent form. Terms stating that the patient has the ultimate responsibility for a claim regardless of what a payer pays is a common theme. The presentation of a consent form at the time of admission raises the question of a provider's fiduciary role being commingled with that of providing treatment to the patient. Providers should consider separating consent for treatment from any financial arrangements with the patient. Figure 3 is an example in which the provider appears to be self-serving when it comes to financial arrangements at the time services are about to be rendered.

Figure 3 Consent for Treatment

Request and Consent to Perform Nuclear Medicine Study/Procedure/Treatment and Release of Authorization and Payment Contract

I request Dr. John Doe to perform the following Nuclear Medicine Study/Procedure/Treatment: Whole Body Bone Scan & Digital & Spect studies. Please read carefully: I understand and agree to be responsible for full and complete payment of the charges incurred for the above-posted Nuclear Medicine study(ies), including any and all legal and court costs, and any and all discovery matters and deposition, should it become necessary to file a collection action, appear at an arbitration hearing, appear at an adjudication hearing, or file an appeal, or appeal answer/defense in an appellate court. This extension or credit with full and complete payment is due 30 days from the Date of Service. I understand and agree to the submission, by myself and/or XXXXX Nuclear Medicine Clinic, of a valid, fully executed claim to any and all insurance carriers providing coverage. I understand and agree to pay 1-1/2 percent per month as compound interest on my outstanding balance if I did not pay my bill in 30 days from the Date of Service. Insurance and/or Medicare assignment is not accepted as payment. In Personal Injury cases, in all other types of injury cases, and in Workmen's Compensation cases, neither payment contingent upon the outcome of the case nor a Physician's Lien is accepted as payment. I authorize release of my Nuclear Medicine Consultation Report to any healthcare practitioner(s) who may need it for evaluation and/or treatment purposes, as well as to the person(s)/insurance company(ies)/employer(s)/government agency(ies) responsible for payment of my bill. By signing this, I acknowledge that I have received a copy of this Financial Policy of XXXXXXX Nuclear Medicine and agree with its contents.

Signed_____ Date_____

EXHIBIT 11.3 Sample Contract

The consumer perspective is further complicated by a trend in which providers ignore health sponsored plans that an individual patient may have. The provider sometimes refuses patient requests to submit claims to their benefit plan. The trend has been noted with patients across the full spectrum of benefit plans - Medicare, Medicaid, private and public employer-based benefit plans. During the course of litigation, if a provider refuses to submit a healthcare benefit claim to the patient's plan, the patient may ultimately lose the

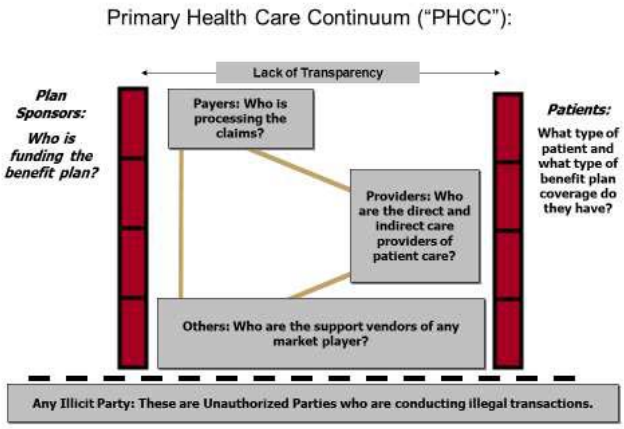
opportunity to benefit from their contracted plans. Patients will lose the opportunity to receive benefits if the bill is not submitted within one year, whereas most litigation goes beyond one year. If the patient loses their case in court, no funds exist to pay the healthcare bills and the patient may be exposed to unreasonable requests for payment in full by the provider. If the patient does receive a monetary award, the patient may be exposed to providers who request payment of unusually high bills that are not usual, customary and reasonable (UCR).

This market trend of fiduciary contractual obligations being signed between the patient and the provider do not have a direct impact on the costing of a life care plan, but the life care planner should nevertheless be aware of these practices. The knowledge of these practices may support the life care planner during expert testimony in responding to questions as to why certain methods are not acceptable. The inverse is just as important. The ability to determine when it is appropriate to rely on billing and payment activity requires the life care planner to understand provider-billing methodologies. Regardless, life care planners should support their opinions on costing data by documenting the basis for their determinations (Johnson, 2015). When relying on prior bills, regardless of any contractual language signed between the parties, the life care planner should continue a process that properly evaluates the projected services. This analysis uses medical billing audit professional judgment to determine if current provider pricing is reasonable as a basis in the preparation of a life care plan. For example, if a current provider is not following proper coding procedures and is up-coding services, the life care planner should utilize an alternative source for the basis of the costing portion of the life care plan. If the provider is utilizing correct procedure codes and the prices are excessive (or outliers in the market), the life care planner should consider an alternative source for the costing portion of the life care plan.

Healthcare Stakeholders

A review of healthcare stakeholders involved with one episode of care further delineates the complexity in understanding the term "amount paid." The relationships between healthcare stakeholders start with the patients and their direct relationship with the plan sponsor. This relationship is the type of insurance coverage they carry (or lack). The patients have an additional relationship with the provider. This relationship is a signed consent form. Within the consent form is typical language stating that the patient is obligated to pay for services regardless of any third party determinations (such as insurance). The provider has a direct independent relationship with an additional stakeholder - the payer. The payer has a direct relationship with a plan sponsor (e.g. Medicare, Medicaid, or Employer), completing the loop back to the patient. Finally, as Figure 4 (the Primary Health Care Continuum, or PHCC) shows, all stakeholders have additional multi-layered direct and indirect relationships with third parties categorized as "Others." These stakeholders may include case managers, pharmacies, and other support vendors - even unauthorized stakeholders, including those involved in illegal or ethically challenged behaviors.

Figure 4 Primary Healthcare Continuum (PHCC)



In the United States, when a patient seeks services from a provider, the provider is clinically responsible to provide treatment according to the terms of consent agreed upon directly with the patient. However, it is also responsible to treat the patient in accordance with its contractually based financial commitments with payers. The payer, in turn, has its own fiscal responsibilities based upon two separate contracts. The first responsibility to the plan sponsor, as supported by the plan documents. The second responsibility is to the independent contract that they have with a provider. The payer is hired to adjudicate the claims according to the plan documents. In addition, at times, the payer is involved with pre-certification activities of services based on the benefit plan prior to a provider delivering those services. The illustration of two brick walls in Figure 5 depicts the lack of transparency that occurs in the middle triangle. Neither the plan sponsor nor the patient is aware of all the transactions that occur inside the triangle. The patient does not have access to transactions that occur in steps 2,5,6,7,8,9, and 10. The plan sponsor does not have access to transactions the that occur in steps 5,6,7,8, and 9. This explanation sets the stage to follow the money among the parties. One episode of care can trigger up to ten financial transactions. These transactions are illustrated in Figure 5.

Figure 5 Healthcare Stakeholders Monetary Transactions

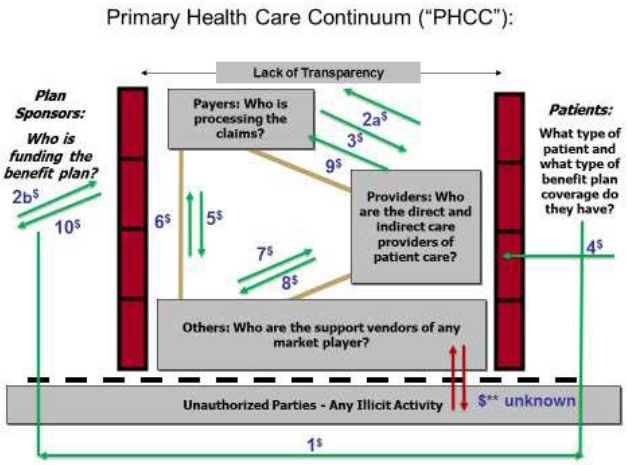


Figure 5 illustrates an "Amount Paid" activity among stakeholders once a healthcare transaction is initiated and fulfilled. The numbered transactions shown in Figure 5 are described below:

1: Amount paid by the patient as premium and collected by the plan sponsor

2a: Original amount charged to the patient and submitted to the payer

2b: Amount provided to the Payer (Third Party Administrator or insurance company) to pay claims in response to 2a

3: Amount paid to a provider after the claim has been reconciled against a contract directly between the payer the provider (this is hard for a life care planner to identify)

4: Amount paid by the patient to the provider based on the Explanation of Benefits (EOB) that is driven by the plan sponsor benefit plan. This transaction is independent of any attributes of the transaction described under 3$

5: Amount paid by a stakeholder to a support vendor (this is typically not transparent to the life care planner)

6: Amount paid by a support vendor in the form of rebates (this is not always transparent)

7: Amount paid to providers in the form of rebates/supplements

8: Amount paid to support vendors in support of services to the patient

9: Amount paid back to the payer after year end contractual reconciliations

10: Amount paid back to benefit plan after year end reconciliations.

The activities associated with the referenced unauthorized parties in Figure 5 illustrate that illicit transactions do occur and that they impact the costs associated with the delivery of a healthcare episode. In addition, they also may occur at any point among the stakeholders. Therefore, defining the amount paid becomes a question of which stakeholder and at what point in time is the service being evaluated. Reasonable value cannot be reached by the review of one paid amount transaction. The paid amount in this discussion is limited to cash transaction between two parties. Thus, the paid amount alone cannot be relied upon for the basis of what is UCR for an episode of care. This leads us back to relying on sources that collect original charge data.

Special care should be taken to ensure that direct and indirect healthcare support services are included in supporting a healthcare episode (Figure 5, Flows 5 and 8). For example, if a patient has surgery, the category of "others" illustrated in Figure 4 may include an independent pathologist for evaluating any surgical specimens. Even in these cases where the service provider has not directly interacted with the patient, the life care planner can verify that codes are correctly utilized to support the level of intensity of provider services – necessary information for accurate pricing data. The projected service is then supported by diagnostic codes. In working with catastrophic patients, the life care planner should consider other indirect support providers such as case managers. Typically, a life care planner does not perform a contractual analysis among the stakeholders as illustrated in Figure 5 when estimating costs.

Market Transparency

Market participants in every industry are reluctant to share information about costs and prices, which they deem proprietary. Healthcare, however, is unique in its need to determine usual customary prices and to forecast such costs well into the future. The life care planner, then, struggles to evaluate healthcare bills because all paid amounts are not transparent. Additionally, terms of payment in a contract between a patient and a provider (consent form), for example, may contradict the terms of payment specified in that provider's contract with that patient's payer and plan sponsor. Various stakeholders have self-serving interests and may not necessarily act in the patient's best interests. For example, language may be found in consent forms that allows the provider to choose filing a lien against a pending lawsuit versus filing an insurance claim based on other contractual arrangements. Another example is that payers in the private sector may have undisclosed differences in their terms with different providers. These subtle but important realities are often not available to either the patient or the medical billing specialist who may be evaluating the final bill presented for services rendered. In the midst of all this is the life care planner retrieving pricing data to select a price for a healthcare service that is usual, customary, and reasonable, which is not easy.

Bill Evaluation

Evaluating a healthcare bill for being fair and reasonable

should begin with the review of the original amount charged to the patient. The medical audit definition of UCR value of a healthcare bill is:

- "Usual" if it is a professional charge for an in-scope practice service/procedure by an appropriately licensed and credentialed professional, or if it is a facility (e.g. hospital, outpatient, nursing home, rehabilitation, long-term care) for a defined facility-based licensed scope of services/procedure
- "Customary" if it is within the range of fees, quantity, volume, and or coding that most professionals (CMS-1500) or facilities (UB-04, CMS 1450) in the geographic area charge for a given procedure; if it is a facility within a ranges of fees, quantity, volume, and or coding (UB-04, CMS 1450), in scope facility license
- "Reasonable" if it is usual and customary and or if it is clinically relevant, with informed consent, and clinically justified. Any special condition (e.g. a difficult procedure) will be articulated based on current practice standards (Busch, 2017, p. 9).

A five-step medical audit process may be utilized for UCR opinions and as a costing methodology for pricing of services presented in a life care plan. These steps are outlined below:

Five-Step Medical Audit Process

Step 1: Define the scope of the life care plan review and document the description of the nature of health condition that is the subject of the litigation.

Step 2: Define the data necessary for evaluation to support the life care plan review.

Step 3: Define parties to be interviewed that would facilitate an understanding of the subject's condition and what the condition requires for treatment and management.

Step 4: Conduct an analysis and prepare the life care plan. In itemizing services within a life care plan, delineating services by procedure codes (when applicable) is helpful towards isolating pricing data for similar in-kind services.

Step 5: Define market comparisons, analysis, and generate life care plan report.

When preparing a life care plan, a review of prior billing data is useful in understanding current pricing that is being experienced by the patient. However, proper vetting of that data should be considered. If the life care planner finds that existing bills are not an appropriate source, other options should be vetted. A life care planner has several options for selecting pricing data including prior experience with billing of services, published data, and/or through purchased subscriptions services of vendors with claims data including original charge capture data. In all three scenarios, the life care planner needs to understand the source of the data, be able to evaluate if the data source is unbiased, and determine if the data source is sufficiently comprehensive. The life care planner should evaluate if the data source is broken down by procedure code, and if the data is broken down by intensity of services and by procedure code types. Ultimately, the life care planner will utilize professional judgment on the reasonableness of the price by reviewing the service in its context and condition.

When giving expert testimony, the life care planner should have a general understanding of healthcare industry billing and reimbursement. Experts may vary in their educational and work experience in understanding healthcare coding systems. Educational support may come in the form of ongoing education from certified coursework, formal academic education, and professional certifications. The following are a sample listing of questions to test an expert's understanding of healthcare industry billing practices:

- How does a provider generate a bill?
- What is the proper way to present a bill? The healthcare industry operates on coding systems. The two central categories are procedure codes, which communicates what you did to the patient. The second category is diagnosis codes, which are provider attestations on why a procedure was performed on a patient.
- Do they understand the rules of coding on a bill? Understanding payment basics under www.medpac.gov is for an advanced medical billing expert. This site is helpful to stay current on ongoing updates on formulas being used to pay healthcare bills.
- Do they have sufficient medical terminology experience and training to read about the services within the medical records? This is important to understand the context and conditions of the services provided to the patient.

Conclusion

Life care costing methodology cannot solely rely on the amount paid without fully defining the stakeholders involved in the paid transaction and the respective service. Likewise, the life care planner cannot assume the billed amount by a provider is usual customary and reasonable for costing items in a life care plan. The life care planner should be consistent in identifying and extracting the critical data elements involved in understanding the service being provided. Healthcare has long utilized coding systems to bring healthcare experiences to par by defining them in diagnostic and procedural coding language. The coding language in and of itself provides consistent requirements in order to represent the level of intensity of service. Therefore, starting the costing process by defining projected services in appropriate coding language will increase the life care planner's success in arriving at an appropriate estimation of price for the service.

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