WSI
North Dakota Workforce Safety & Insurance

Treatment Policy

Spinal Cord Stimulators for Pain

Effective Date: 05/01/2020 | Revised Date: 09/16/2020

Responsible Department: Utilization Review | Reviewed Date: 09/16/2020

Purpose
Workforce Safety & Insurance (WSI) utilizes ODG by MCG in determining medical necessity for spinal cord stimulators for pain. The following guideline is an excerpt from ODG by MCG's Spinal cord stimulators (SCS) and Psychological evaluations, IDDS & SCS (intracathecal drug delivery systems & spinal cord stimulators) sections accessed on 09/16/2020.

Policy
WSI will enforce the following treatment guidelines for utilization review and claim management processes involving spinal cord stimulators for pain.

Spinal Cord Stimulators (SCS)

Recommendation
Recommended as indicated below on a case-by-case basis as a third-line, last resort treatment for chronic neuropathic pain in post-spinal surgery patients, when ALL criteria are met. Not recommended for radiculopathy or axial back pain in patients who have not undergone spinal surgery, and not recommended to facilitate weaning pain medication. Newer SCS waveforms are considered investigational.

ODG Criteria

Spinal cord stimulators (SCS) are recommended on a case-by-case basis for the following indications:
• Failed back surgery with persistent leg pain that is determined to be related to nerve damage from the initial pathology and/or surgery as confirmed by exam and electrodiagnostic study.

• Neuropathic pain in post-spinal surgery patients in which there is no evidence of a nociceptive component to symptoms.

SCS are not recommended for the following indications:
• Not recommended for radiculopathy in patients who have not undergone spinal surgery.

• Not recommended for axial back pain in patients who have not undergone spinal surgery.

• Not recommended to facilitate weaning of pain medications. There is some suggestion that there is a trend towards lowered drug use with a SCS, but there are no randomized controlled trials with primary outcome of medication use to support this, and no guidance as to what patients would potentially be best treated for this indication. There is no guarantee that substantial pain relief will strongly correlate with lowering or actually stopping opioid use. In addition, higher doses of opioids pre-implant are associated with greater risk of failure and explanation.

• Not recommended to remove a current functional SCS (such as a traditional/tonic model) and replace with a newer waveform technology until there is documentation of a need for battery change or other medical necessity.

• Not recommended as a salvage treatment by replacing a traditional/tonic SCS that has failed with a newer waveform model, such as high frequency or burst.

• Not recommended to perform a repeat trial in patients who have failed a trial of SCS in the past.

• Not recommended for patients who will require future MRI evaluation for existing pathology.

Patient criteria for SCS:

(1) Patients should be informed that as many as 40% of patients may experience a permanent unit not providing pain relief even after a successful trial.

(2) Patients should be informed that the rate of explantation (ie, removal of the unit) is high, generally within 2 to 5 years, and the major reason for explantation is ineffective pain relief.

(3) Patients should be informed that tolerance to the analgesic effect may occur (ie, the unit may lose its effectiveness). This has been documented in a randomized controlled trial at approximately 3 years in CRPS patients, and it has been documented in multiple retrospective studies in patients implanted for failed back surgery syndrome.

(4) Patients should be informed that there are currently no published data using randomized controlled trials longer than 36 months for newer waveform stimulators (eg, high-frequency or burst).

(5) The treatment should not exceed the following parameters: 16 electrodes/contacts, 2 percutaneous leads, or 1 paddle lead for standard spinal cord stimulation.

(6) The pain source addressed with SCS treatment should be neuropathic as confirmed by exam and electrodiagnostic findings (where appropriate).

(7) Conservative therapy has been used and failed or judged unsuitable for at least a 6-month period (eg, pharmacologic, psychologic, physical therapy, less invasive interventional therapy). A summary of this information should be documented with the request.

(8) A complete history and physical should be performed. The findings should be consistent between examiners. The exam should include documentation of all medical conditions (including those that are not work related in workers' compensation patients). The exam should include evidence that peripheral neuropathies (such as those related to metabolic causes, alcohol, and hepatitis), and peripheral vascular disease have been evaluated for. All other causes of pain should be documented by history and exam findings.

(9) A complete drug list should be submitted, including for medications that are not work related in workers' compensation patients.

(10) Laboratories should be obtained, including complete blood count, comprehensive metabolic profile, coagulation screening, and urinalysis. Diabetics may require a HgbA1c, and urine culture may be required.

(11) Pre-operative spinal MRI should be performed to search for an organic cause of ongoing pain.

(12) Additional imaging may be required in in the thoracic region to assess for critical stenosis or other anatomical abnormalities prior to implant.

(13) Completion of a neuropathic pain questionnaire is recommended. Examples include the Neuropathic Pain Questionnaire, ID Pain and PainDETECT.

(14) A psychological evaluation should be performed by an independent psychologist with no conflict of interest. A one-on-one evaluation is recommended, with inclusion of psychometric testing (such as the MMPI-2RF or MPI). It is recommended that results of this testing be provided. The procedure is not recommended in patients with major psychiatric disease and/or psychosis. Caution should be used in patients with documented depression, mood disorder, and/or anxiety, as these are considered risk factors for failure. The procedure should not be undertaken in any patient with a diagnosis of somatic symptom disorder, with the knowledge that this can be present in up to 60% of patients who present in specialty pain clinics.

(15) A substance use disorder screen should be part of the psychological evaluation. Patients with evidence of substance-use disorder or frank drug habituation should not be implanted until these conditions are addressed. Presence of ongoing substance use pathology (including that related to prescription drugs) may be a permanent reason to deny this treatment.

(16) Patients who are unable to cognitively participate in an SCS trial, implant and post care should not be implanted.

(17) Any local or systemic infection should be addressed. This may include testing such as urinalysis and culture if indicated.

(18) Compatibility with other implantable devices, such as cardiac pacemakers and defibrillators, should be verified.

(19) After the above criteria have been fulfilled and SCS is considered medically appropriate, a trial is required. This usually occurs from 3-7 days. Pain and function should improve by ≥ 50%, with documentation provided. Documentation should also include whether any changes were made to pain medications.

Evidence Summary

Spinal cord stimulators (SCS) are seen as a therapy for patients suffering primarily from neuropathic pain for which there is no alternative therapy. Conventional (tonic) SCS has been characterized by limited success rates (generally about 50%) and reports of decline in efficacy over time. Newer advances in technology have produced multiple alternatives to the conventional SCS treatment. Both conventional and newer technology is accompanied by lack of scientific understanding of mechanism, including how this therapy modulates physiological

effect and central pain processing. There has been criticism that without a complete understanding of the technology involved in SCS treatment, patients may be subjected to unnecessary health and financial burden. It has also been suggested that industry-sponsored research may create conflicts of interest and influence objectivity. (Duy, 2018) Further unanswered questions include (1) how to best select patient suitable for treatment and (2) how the treatment affects outcomes other than pain (eg, patient preference, function, return to work, and quality-of-life outcomes). Questions about long-term efficacy for all modalities remain a problem (particularly because studies with follow-up longer than 36 months are not available for the new waveforms). There is also suggestion that placebo effect may confound scientific studies to some degree. These problems are all further complicated by the heterogenicity and lack of medical understanding about the two major conditions generally addressed with this treatment: failed back surgery syndrome and CRPS. Due to the limited amount of research to support this technology and the large gaps in our understanding (as noted above), limited approval is recommended. (Lempka, 2018) (Amirdelfan, 2017) (Provenzano, 2017)

Types of SCS

Conventional (tonic):

This treatment involves a low-frequency (40-60 Hz) tonic stimulation to excite the large-diameter sensory afferents in the dorsal columns and create a paresthesia over the painful area. Overall, approximately half of patients do not achieve satisfactory pain control, and for many who do initially, long-term studies suggest that therapy effectiveness can diminish over time. Supraspinal mechanisms (descending inhibition) may also contribute to the effect. Success is largely based on ability to provide coverage over the pain distribution area (limiting coverage of axial back pain) and a patient's willingness to tolerate paresthesia. (Sdrulla, 2018) (Lempka, 2018) (Stauss, 2019)

North et al. 2005: This was a randomized controlled trial (RCT) with a 6-month crossover design in 60 patients who had undergone one or more lumbosacral spine surgical procedures. The patients presented evidence of surgically remediable nerve root compression and persistent or recurrent radicular pain (with or without low back pain). The authors found that 47% (9/19) of the patients randomized to SCS and 12% randomized to reoperation achieved at least 50% pain relief. The success of the SCS group dropped to 39% if the 3 patients lost to follow-up are included. The authors emphasized that all patients had a specific diagnosis with an anatomic explanation for their pain. They recommended a major psych evaluation and did not recommend the procedure in patients with serious drug-seeking behavior, abnormal illness behavior, or major unresolved issues of secondary financial gain. This study was industry sponsored. (North, 2005)

Kumar et al. 2007: This was an international multicenter RCT with a 6-month follow-up comparing SCS to conventional medical management (CMM). Radicular pain (L4, L5, S1) exceeded back pain, and patients had undergone a minimum of one surgery. CMM was not consistent among centers. At 6 months, 24/50 (48%) in the SCS group and 4/44 (9%) of the CMM group achieved 50% pain relief. There was a trend towards a decrease in analgesic drug intake and non-drug therapy. At 12 months, success rates dropped to 34% in the SCS group and 7% in the CMM group. Six patients had a loss of therapeutic effect (7%). Complications due to the device occurred in 10%, and infection or wound breakdown occurred in 8% (at the 12-month follow-up). This study was industry sponsored. (Kumar, 2007)

Kumar et al. 2008: This was the 24-month follow-up of the study described above. Using an intention-to-treat analysis, 17 SCS patients (37%) versus 1 CMM patient (2%) achieved the primary outcomes. There was a 45% device-related complication rate, which included electrode migration (14%), lead fracture (7%), IPG migration (2%), loss of paresthesia (12%), infection or wound breakdown (10%), pain at IPG site (12%), and IPG pocket fluid collection (5%). Surgical revision was required in 31% (13 patients). This study was industry sponsored. (Kumar, 2008)

HF 10/10 kHz SCS (Senza System):
High-frequency SCS using 10 kHz frequency, referred to as HF 10 therapy or 10 kHz SCS (Nevro Corp; Redwood City, CA) is an alternative frequency waveform therapy that was FDA approved in May 2015. The mechanism of effect is unknown. This therapy does not require anatomic placement of leads, lessening the risk of impact by lead migration. It also does not produce paresthesia. There is therefore no requirement for paresthesia mapping to the painful area. (Kapural, 2017) (Sdrulla, 2018)

Kapural et al., 2015: A multicenter RCT of 198 patients (171 implanted) with heterogeneous diagnoses compared HF 10 therapy to traditional SCS (back and leg pain). At baseline, 56.4% of HF 10 patients and 52.6% of traditional patients had predominant back pain. In the total group of patients, previous back surgery was present in 86.6%, and 88.3% were taking opioids. The response rates, defined as having at least a 50% pain decrease, averaged approximately 80% for back and leg pain in the HF10 group but only 50% in the conventional SCS group at 12 months. Opioid consumption, disability, and satisfaction rates improved at 12 months, but the improvement was more pronounced in the HF10 group. Complication rates were comparable between the two groups. This study was industry sponsored. (Kapural, 2015)

Kapural et al., 2016: This was the 24-month follow-up of the study described above. At 24 months, the back pain responder rate dropped to approximately 70% in the HF 10 group (from 80%) and approximately 40% in the traditional group (from 50%). The leg pain response decreased from approximately 80% in the HF 10 group to 65% and from 50-55% in the traditional group to 46%. Medications were not reported. This study was industry sponsored. (Kapural, 2016)

De Andres et al., 2017: This was a non-industry-sponsored RCT that compared conventional SCS to HF 10 in 60 subjects with FBSS (55 had a permanent implant). Results showed no difference in pain or functional scores between the 2 groups at 12 months. The methodology of this study has been criticized. (De Andres, 2017)

Van Buyten et al., 2013: This was a prospective study of SCS for treatment of chronic back pain (with or without leg pain). After 24 months of HF10 SCS, 60% of patients reported back pain reductions of more than 50% compared to baseline, and 71% of patients reported leg pain reductions of more than 50%. There was a small increase in leg pain at 24 months. Fourteen patients who failed traditional SCS were trialed. Eleven had a successful trial and implant. Fifteen of sixteen patients without previous surgery had a successful trial. The primary diagnosis was degenerative disc disease. (Van Buyten, 2013)
Al-Kaisy et al., 2017: This was a non-controlled, single-center study in the UK that examined 10-kHz SCS in patients with axial low back pain for at least 6 months with no history of surgery. Diagnoses included facet joint arthropathy (25%), lateral recess stenosis (40%), foraminal stenosis (20%), and nerve impingement (15%). Of 98 patients screened, 21 were placed in the

study. There was evidence of disc degeneration in at least one of three levels. At six months, there was an average reduction of VAS of 4.7 and at 12 months, 5.6. One surgical revision was required. The authors recommended the use of 10-kHz SCS instead of surgery in patients with clear and unequivocal correlation between clinical symptoms and radiological findings. (Al-Kaisy, 2017)

Al-Kaisy et al., 2018: This was a 36-month follow-up of a prospective open-label study examining the use of 10-kHz SCS for treatment of low back pain with no history of spinal surgery. Seventeen of the twenty patients reached the 36-month endpoint. The authors indicated that the purpose of the study was not to find an alternative to surgery but to investigate a therapy that can be used when surgery is not appropriate. Further evaluation of the phenotypic characteristics of axial low back pain was suggested to assist in patient selection and help predict successful outcomes. (Al-Kaisy, 2018)

Subthreshold SCS at various kHz frequencies:
Two RCTs evaluated various kHz frequencies in subjects with failed back surgery syndrome. Trials were performed with conventional SCS units and conventional stimulation, and the highest frequency used was 5882 Hz. In a 2013 study, 51% of patients (N=17/33) reported a benefit, whether they received high frequency SCS or sham. (Perruchoud, 2013) Similar results were found in a 2018 prospective RCT (the SCS Frequency Study), with an approximate 3-point VAS change from baseline. The authors of the 2018 study reported that their findings prompted the question of how much of the pain relief was due to sham effect and how much was due to therapeutic effect. (Al-Kaisy, 2018)

Burst SCS:
This SCS treatment was approved in 2016 based on a large, multicenter RCT with a comparison group of conventional SCS (the SUNBURST trial). The treatment consists of intermittent bursts of electrical pulses: five pulses at 500 Hz frequency, delivered at a burst frequency of 40 Hz with a pulse width of 1 ms. This is also a paresthesia-free treatment that is proposed to have better effect for patients with low back pain.

Deer et al., 2018: This is a prospective RCT using the burst waveform. The tested device allows for both tonic and burst stimulation. The primary objective was non-inferiority, and the study was conducted on patients with chronic neuropathic pain of the trunk and/or limbs. Most patients had FBSS (42%) or radiculopathy (40%). Response to burst was found in 60/100 patients and to tonic in 51/100 patients. The authors state that the study was unable to assess the effectiveness of burst stimulation in subjects who failed traditional tonic stimulation and that this is an area of future research. (Deer, 2018)

Use of SCS in workers' compensation populations
Turner et al. evaluated the use of SCS in a workers' compensation population in 2010. There was no difference found in composite primary outcome (≥ 50% improvements in pain, function, and opioid use) among a group receiving SCS, a group with usual care, and a group receiving specialty care in a pain clinic at 12 months and 24 months. At 6 months, the rate of pain relief and function was higher in the SCS group (18% in SCS versus 3% in usual care). Revision surgery was required in 19% and explant occurred in 19% (4 of the 5 patients reported ineffectiveness). (Turner, 2010)

Complications
An overall complication rate of 30% to 40% has been reported. (Eldabe, 2016) Mechanical complications include lead fracture or disconnections (5% to 9%), lead migration (in up to 27%), and implantable pulse generator failure (1.7%). Biological complications include allergic reaction, pain at implant site, implantable pulse generator seroma, epidural fibrosis, epidural hematoma, dural puncture, and neurological injury (rare). Infection is report in 2.5% to 12%. (Verrills, 2016) (Falowski, 2019) Newer types of SCS appear to have similar complications.

Predictors of success
Mounting evidence has suggested that increased BMI, smoking, substance abuse, and psychiatric illness (untreated depression and anxiety) tend to correlate with less favorable outcomes. (Simopoulos, 2019) Other risk factors associated with failure include evidence of somatization, substance-use disorder, and lack of social support. (Paroli, 2018) In a retrospective study, chronic pain patients receiving ≥ 90 mg of daily morphine equivalents prior to implant had an increased OR (1.57) of SCS explant. (Sharan, 2018) There is conflicting evidence in terms of success based on time from spinal surgery to implant. (Taylor, 2014)

Use as a salvage treatment
Initiating use of a newer form of SCS after failure of a conventional unit is currently investigational. Current studies on this approach are small and retrospective. Longer-term studies are recommended with appropriate controls to determine the efficacy of these strategies. Salvage therapy has been questioned in patients with advanced disease or changes in pain pattern, but it may be able to address tolerance to paresthesia-induced pain relief. (Simopoulos, 2019)

Use as a treatment to decrease and/or control opioid use
There is no strong evidence to support the effectiveness of neuromodulation in helping to wean patients off of opioids. Some data trend toward a decrease in opioid intake, although the data are limited, and clinical significance requires further study. (Morales, 2019) (Pollard, 2019) Medication use has not been a primary outcome in RCT studies, and changes have not been observed when it was included. North et al. found that patients taking opioid analgesics were more likely to fail treatment. (North, 2005) Kumar et al. initially found a trend toward decreased opioid consumption, but medication use was not discussed in their long-term follow-up. (Kumar, 2007) (Kumar, 2008) In the Kapural et al. 2015 RCT, 35.5% of HF10 patients decreased or eliminated opioids (an 18.8% average decrease) at 12 months versus 26.4% of SCS patients (a 1% average decrease). (Kapural, 2015) Overall, elimination of opioid dependence after SCS has been found to be highly dependent on preimplant dose, with patients on a morphine equivalents dose ≤ 30 mg/day being most likely to wean completely. (Simopoulos, 2019) However, in real-world practice, opioid weaning is a complex psychological and physiological process, and the substantial pain relief after any therapy may not strongly correlate with willingness to reduce or actually stop opioid use. (Pollard, 2019)

Loss of therapeutic effect and tolerance
Loss of therapeutic effect is a common reason for SCS therapy discontinuation. (Hayek, 2015) (Simopoulos, 2019) Reasons given for loss of effect include progression of disease and/or development of new pain conditions. Tolerance has also been proposed. This is a condition that develops when there is a loss of pain control, even when the system is fully functional. The proposed causes of tolerance include neuroplasticity of pain transmission pathways, cellular or

fibrotic changes in the tissues around the electrodes, patients reframing their pain over time, psychiatric affective disorders, and placebo response. (Fishman, 2019) (Aiudi, 2017) (Mann, 2015) There is currently insufficient long-term evidence for newer waveform therapy to determine efficacy over a prolonged period, and loss of effect is noted even in the studies available.

Performing a trial with a different waveform after failure of a previous trial

While it has been suggested that the failure of a trial of one waveform does not preclude success with another, research to support this hypothesis is investigational at this time. Ultimately, devices that can provide multiple waveforms may help to address this issue. (Kriek, 2017) (Berg, 2017) (Haider, 2018)

Trial-to-permanent conversion rate

An overall goal for SCS treatment is improving the selection process to improve the trial-to-permanent conversion rate, which can be as low as 41% according to data from 2000-2009. (Huang, 2015) More recent data show improvement ratios of 63% to 78%. (Hussaini, 2017) (Simopoulos, 2019) (Nissen, 2019) Factors that increase the likelihood of successful conversion include having commercial insurance, younger age, and never having had a previous percutaneous trial attempt. (Huang, 2015) In a 2019 study, there was a greater decrease in pain from initial levels and reduction in opioid analgesia use during the trial compared with final levels (after the permanent stimulator was placed). The authors suggested this difference could be due in part to patients overstating pain relief to obtain the SCS or to obtain more pain medication. (Malige, 2019) The placebo effect has also been suggested.

Revision and explanation

Revision rates for SCS therapy are generally reported to be 23.9% to 37%. The leading cause of revision is hardware and accounts for 24-50% of revisions. (Hayek, 2015) (Bir, 2016) (Dones, 2018) (Nissen, 2019) Explantation rates are highly variable in reported literature (ranging from 0-47%), with major reasons for removal including ineffective pain relief and infection. (Eldabe, 2016) Explant rates appear to increase depending on duration of follow-up (with a greater explant rate noted with longer follow-up), location of care, expertise of the surgeon, and funding of the study. In 2019, Negoita et al. examined 100 patients with SCS treated at Johns Hopkins from 2011 to 2018. Revision surgery was required in 34% and removal in 53%. The median time to the first revision was 16 months, and 56% of patients eventually opted for removal. The median time to removal was 39 months. The authors suggested that > 36 months of follow-up be collected to determine efficacy of the device. They did note that the removal rate was higher than expected and suggested this was due to the setting being a tertiary care referral center. (Negoita, 2019) A 15-year follow-up study at Harvard found an explantation rate of 30%. The rate was attributed in part to the longer follow-up. (Simopoulos, 2019) In a similar study conducted over 17 years at the Allegheny General Hospital in Pittsburgh, PA, the explant rate was similar (27.7%), with the major reason for explantation being inadequate pain control (73%). (Dupré, 2018) (Thomson, 2017) (Han, 2017) (Bir, 2016) (Dones, 2018) (Nissen, 2019)

Last review/update date: May 21, 2020

Psychological Evaluations, IDDS & SCS (Intracathecal drug delivery systems & spinal cord stimulaors)

Recommendation
Recommended prior to a trial for an intrathecal drug delivery system (IDDS) or spinal cord stimulator (SCS) as per the criteria below.

ODG Criteria

Criteria for Psychological evaluations, IDDS and SCS (intrathecal drug delivery systems and spinal cord stimulators):
(1) A one-on-one psychological evaluation is required by an independent unbiased psychologist.

(2) Psychological testing should be included. At least one test should evaluate personality style and coping ability. Examples include the MMPI-2, MMPI-2-RF, and Millon Clinical Multiaxial Inventory. The actual results should be included.

(3) At least one test should contain validity scales.

(4) These procedures are not recommended in patients with major psychiatric disease and/or psychosis.

(5) Caution should be used in patients with documented depression, mood disorder, and/or anxiety, as these comorbids are considered risk factors for failure.

(6) Extreme caution should be used in dealing with patients with personality disorders or untreated posttraumatic stress disorder.

(7) The procedure should not be undertaken in any patient with a diagnosis of somatic symptom disorder, keeping in mind that this condition can be present in up to 60% of patients treated at specialty pain clinics.

(8) A substance use disorder screen should be part of the psychological evaluation. Patients with evidence of substance-use disorder or frank drug habituation should not be implanted until these conditions are addressed. Presence of ongoing substance use pathology (including that related to prescription drugs) may be a permanent reason to deny this treatment.

(9) Personal expectations should be addressed, including clarification that a patient should not expect > 50% reduction in pain. (Fama, 2016)

Recommendations for components of the psychological evaluation:
(1) A clinical interview that allows for measures of personality structure (both before and after the illness), environmental factors that influence pain, and personal strengths and internal resources. The clinical interview should include the following:

(a) Social history including education, psychosocial stress factors, childhood history (including history of abuse), family situation, and work history

(b) Comprehensive history including previous treatment (and response), psychological history

(c) History of substance abuse

(c) Attitudes towards pain and treatment, including painful behavior and moods of the patient

(e) Current emotional state

(f) Mental status exam

(g) Determination of motivation for recovery and return to work

(h) Issues related to implantation therapy

(2) A review of medical records.

(3) Psychological testing. This testing supplements information provided in the clinical interview and, at minimum, should evaluate personality style and coping ability. At least one test should contain validity scales, with the Minnesota Multiphasic Personality Inventory-2 (MMPI-2), a test for personality and psychopathology profile, commonly recommended. The Minnesota Multiphasic Personality Inventory-2-RF (MMPI-2-RF) has also been studied, particularly using the scales of emotional dysfunction (particularly Demoralization and Dysfunctional Negative Emotions), somatic/cognitive dysfunction, and interpersonal functioning. (Block, 2017) (Marek, 2020) Other tests in this category include the Millon Clinical Multiaxial Inventor (MILLON-IV) and the Life Orientation Test-Revised (LOT-R). Other testing can include those for pain assessment and beliefs, quality of life and disability, anxiety and depression, and coping.

(4) An interview with a significant other (if approved by the patient) to confirm findings, alert for other significant information, and allow for assessment of social support.

Evidence Summary
Existing behavioral literature provides considerable support for use of psychological assessments and treatments for patients undergoing spinal cord stimulators or implanted medication pumps, although there is no consensus in terms of specific psychological screening. Formal psychometric testing is recommended as a component of psychological screening in order to generate a clear and justifiable prognosis and potential treatment plan. Screening should be performed by a neutral independent psychologist or psychiatrist unaffiliated with the treating physician or spine surgeon to avoid bias. (Blackburn, 2016) (Van Dorsten, 2006) (De Andrés, 2020) (Celestin, 2009) (Sparkes, 2010) (Wolter, 2013) (Campbell, 2013)

Three general categories of patients can be identified based on psychological evaluation.

Group 1 includes patients with no contraindications for implantation.

Group 2 includes patients who may require brief cognitive and/or behavioral intervention prior to the trial. These have also been referred to as "yellow flag" patients. There is no good research regarding who falls into this group, but the following are factors that have been found to increase the risk for a poor outcome: (a) mild to moderate depression or anxiety; (b) somatization disorder in the presence of medically explained pain; (c) hypochondriasis if the focus is on something other than pain; (d) mild to moderate impulsive or affective disorder; (e) family distress/dysfunctional behavior; (f) social distress/dysfunctional behavior; and (g) job distress/dysfunctional behavior. Treatment duration has been suggested according to severity of symptoms, with a general suggestion of approximately 6 sessions. Williams has suggested that this therapeutic intervention should include: a) education; b) skills training (training for a variety of cognitive and behavioral pain coping skills including relaxation training, activity pacing, pleasant activity scheduling, problem solving, and sleep hygiene); and c) an application phase to apply the above learned skills. (Williams, 2003) (Fama, 2016)

Group 3 includes patients who have a high likelihood of failure. Falling into this category does not mean that an implantable device should not be used but that contraindications should be treated prior to the intervention. Suggested exclusionary criteria for the use of an implantable pain treatment include the following: (a) active psychosis; (b) active suicidal ideation; (c) active homicidal ideation; (d) somatization disorder or other somatoform disorder involving multiple bodily complaints that are unexplained or exceed what could be explained by the physical exam; (e) alcohol or drug dependence (including drug-seeking behavior and/or uncontrolled escalated use); (f) lack of appropriate social support; and (g) neurobehavioral cognitive deficits that compromise reasoning, judgment, and memory. (Nelson, 1996) Untreated or poorly treated major depression, major mood disturbance, or anxiety may also fall into this category. Other "red flags" include a) unusual pain ratings (for example, the pain rating never changes from 9-10); b) unstable personality and interpersonal function; c) non-physiological signs reported on physical exam; or d) unresolved compensation and litigation issues. (Celestin, 2009)

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