FSIPP

FLORIDA SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS

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REGARDING: FSIPP Position Statement for Spinal Cord Stimulation and Peripheral Nerve Stimulation

Dear CMDs and Medical Affairs Team Members:

Please accept this letter as FSIPP's Official Position Statement regarding Spinal Cord Stimulation (SCS) and Peripheral Nerve Stimulation (PNS). FSIPP has had representation on the (CMS) Carrier Advisory Committee (CAC) for First Coast Service Options (FCSO) in the JN Jurisdiction since 2007. Dr. Deborah Tracy has been our dedicated representative since that time and has already provided a presentation at the August 5th CAC open meeting. The Florida Society of Interventional Pain Physicians (FSIPP) represents ~300 active members and is a sub-chapter of the American Society of Interventional Pain Physicians (ASIPP). FSIPP strongly supports the use of SCS/PNS as a last resort treatment modality for patients with intractable chronic pain. We provide yearly continuing education, with hands-on training workshops and formal didactic lectures on stimulation therapy. Our shared knowledge demonstrates extraordinary results and moreover this treatment as a non-opioid option allows us to reduce the epidemic of opioid addiction.

We would like to note that a National CMS Pain Task Force was established in 2018 to propose best practices that address gaps or inconsistencies for managing chronic and acute pain between jurisdictions across the country. Consequently, we would first like to address the vast differences between the Noridian LCD, A55530, effective date 10/1/2021, and the Proposed Novitas/FCSO, LCD, DL39406. The following is a list of 54 additional covered indications in the Noridian LCD not found in the Novitas/FCSO LCD that should be included.

NORIDIAN LCD, A55530, COVERED INDICATIONS

Zoster encephalitis
Postherpetic trigeminal neuralgia
Postherpetic polyneuropathy
Other postherpetic nervous system involvement
Diabetes mellitus due to underlying condition with diabetic mononeuropathy

Drug or chemical induced diabetes mellitus with neurological complications with diabetic mononeuropathy
Type 1 diabetes mellitus with diabetic mononeuropathy
Type 2 diabetes mellitus with diabetic mononeuropathy
Zoster encephalitis
Postherpetic trigeminal neuralgia
Postherpetic polyneuropathy
Other postherpetic nervous system involvement
Diabetes mellitus due to underlying condition with diabetic mononeuropathy
Drug or chemical induced diabetes mellitus with neurological complications with diabetic mononeuropathy
Type 1 diabetes mellitus with diabetic mononeuropathy
Type 2 diabetes mellitus with diabetic mononeuropathy
Other specified diabetes mellitus with diabetic mononeuropathy
Migraine without aura, intractable, with status migrainosus
Migraine without aura, intractable, without status migrainosus
Migraine with aura, intractable, with status migrainosus
Cyclical vomiting, in migraine, intractable
Ophthalmoplegic migraine, intractable
Periodic headache syndromes in child or adult, intractable
Abdominal migraine, intractable
Other migraine, intractable, with status migrainosus
Other migraine, intractable, without status migrainosus
Chronic cluster headache, intractable
Chronic cluster headache, not intractable
Chronic post-traumatic headache, intractable
Chronic post-traumatic headache, not intractable
Other complicated headache syndrome
Cervicogenic headache
Trigeminal neuralgia
Lumbosacral plexus disorders
Cervical root disorders, not elsewhere classified
Thoracic root disorders, not elsewhere classified
Lumbosacral root disorders, not elsewhere classified
Other nerve root and plexus disorders
Nerve root and plexus disorder, unspecified
Nerve root and plexus compressions in diseases classified elsewhere
Causalgia of right upper limb
Causalgia of left upper limb
Causalgia of bilateral upper limbs
Causalgia of right lower limb
Causalgia of left lower limb
Causalgia of bilateral lower limbs

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Other specified mononeuropathies
Mononeuropathy, unspecified
Mononeuropathy in diseases classified elsewhere
Chronic post-thoracotomy pain
Complex regional pain syndrome I, unspecified
Complex regional pain syndrome I of right upper limb
Complex regional pain syndrome I of left upper limb
Complex regional pain syndrome I of upper limb, bilateral
Complex regional pain syndrome I of right lower limb
Complex regional pain syndrome I of left lower limb
Complex regional pain syndrome I of lower limb, bilateral
Complex regional pain syndrome I of other specified site
Occipital neuralgia

NOVITAS/FCSO LCD, DL39406, COVERED INDICATIONS

Migraine without aura, intractable, without status migrainosus
Migraine with aura, intractable, without status migrainosus
Chronic migraine without aura, intractable, without status migrainosus
Ophthalmoplegic migraine, intractable
Other migraine, intractable, without status migrainosus
Chronic cluster headache, intractable
Chronic post-traumatic headache, intractable
Phantom limb syndrome with pain
Spondylolysis, lumbar region
Spondylolysis, lumbosacral region
Spondylolisthesis, lumbar region
Spondylolisthesis, lumbosacral region
Other spondylosis with radiculopathy, lumbar region
Other spondylosis with radiculopathy, lumbosacral region
Spinal stenosis, lumbar region without neurogenic claudication
Spinal stenosis, lumbar region with neurogenic claudication
Spinal stenosis, lumbosacral region
Intervertebral disc disorders with radiculopathy, lumbar region
Intervertebral disc disorders with radiculopathy, lumbosacral region
Other intervertebral disc degeneration, lumbar region
Other intervertebral disc degeneration, lumbosacral region
Radiculopathy, lumbar region
Radiculopathy, lumbosacral region
Post laminectomy syndrome, not elsewhere classified

The extensive complexity in both the pathophysiology and technical aspects of placing stimulators including (amplitude, frequency, pulse duration and waveforms) primes us to question the data extraction methodology reviewed by the Novitas/FCSO Jurisdiction and

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appears to contradict the intention of the Task Force. We find the Noridian LCD more consistent with concepts that describe and define neuropathic pain. SCS and PNS for refractory pain is considered the standard of care, by pain physicians. We strongly request a reconsideration of the covered indications in the Novitas/FCSO proposed LCD to also include those that are covered in the Noridian LCD.

There has been extensive literature to support SCS for all indications of neuralgia, causalgia, RSD (CRPS) and in fact are covered in the existing LCD. Why it was removed is questioned and we support the inclusion of ALL causes of neuralgia, causalgia, and mononeuropathies. The pathophysiology and mechanism of pain remains the same, but the underlying cause or disease state (direct nerve injury, post herpetic neuralgia, diabetes) is irrelevant, as the resulting pain and pathophysiology that responds to SCS is treated the same way. [39, 41, 42]

The treatment of refractory low back pain due to degenerative disc disease and discogenic pain is supported by published literature for spinal cord stimulation. The proposed mechanisms of neuropathic pain are similar to central and peripheral sensitization of the lumbar disc and vertebral end plates. In addition, patients who have non-surgical refractory low back pain of any cause have also been shown to improve both pain reduction and functional outcomes with spinal cord stimulation when other treatments have failed. [39, 40, 42, 44]

Similarly, cervical and thoracic radiculopathy should be included and not limited to only the lumbosacral area. Patients have cervical and thoracic surgery and injuries and have the same EXACT pathophysiology as if it were in the lumbosacral area. It defies logic to exclude those areas for treatment. Note that most recent studies have shown greater than 80% success in treating pain with SCS and providing greater than 50% pain relief on a long term basis.[39, 42, 43]

Spinal Cord Stimulation has been accepted as a treatment for neck and back pain for decades. The proposed mechanism of action, in very simplistic terms, is stimulation of specific nerve fibers, inhibition of excitatory nerve fibers, and inhibition of signal transmission.[1, 2] Peripheral nerve stimulation has gained popularity and effectiveness with the increased use of ultrasound and fluoroscopy to target nerves, the development of secure anchors and extraordinary evolution in technology. The first recognized research papers regarding PNS were published in 1974 and 1976.[3,28] Through peripheral mechanisms PNS creates disruption of peripheral afferent nociceptive transmission, excitation failure of A Delta and C fibers, modulating the local biochemical environment by down-regulating local inflammatory mediators, activation of large diameter sensory fibers, and reduction of ectopic discharges to the central nervous system.[4,5,6,7,8] Nerve blocks can help identify that there is mono-neuropathic pain, as in causalgia, to determine if PNS is a treatment option. Trials are critical to assure that patients are responding to neuromodulation.

We agree with the Novitas/FCSO LCD that: "…The use of a SCS and PNS is a <u>late or last resort</u> for pain management, after documented failure to respond to pharmacologic, non-invasive non-pharmacologic management (as tolerated), or targeted interventional pain procedures (e.g., epidural spinal injections)…" We believe that this will decrease the error rate and limit

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untrained physicians. However, we disagree with the Novitas/FCSO LCD Limitations Section specifically, "… The use of SCS or PNS for any conditions other than those listed in indications, including post-herpetic neuralgia…" citing reference #15.[10]

Peripheral nerve pathology or peripheral neuropathy or neuropathic pain can cause a wide variety of pain conditions, many of which may be poorly recognized and therefore misunderstood and under-treated. These painful conditions may cause headaches and face pain (mimicking migraines), neck and arm pain (mimicking cervical radiculopathy and thoracic outlet syndrome), chest pain (mimicking heart attacks), abdominal pain (mimicking irritable bowel syndrome and diverticulitis), pelvic pain (mimicking endometriosis), low back pain and sciatica (mimicking lumbar radiculopathy), and foot pain (mimicking plantar fasciitis) and amputation pain. Patients may develop chronic pain when the pathology goes untreated or when the treatment (such as surgery) worsens the condition.[9,11,39,40]

Post-herpetic neuralgia (PHN) is a neuropathic pain syndrome characterized by pain that persists for months to years after resolution of the herpes zoster (HZ) rash. It stems from damage to peripheral and central neurons that may be a byproduct of the immune/inflammatory response accompanying varicella zoster virus re-activation. The most common location of this condition is following a thoracic dermatome.

The lifetime prevalence of HZ is between 20–30%, rising to 50% by the age of 80 years old.[12] PHN or pain after a shingles attack has been estimated to affect 10% of patients who develop shingles, but appears to be age dependent. Eighteen percent of patients in their 50s have pain for a year or longer after shingles, but that percentage increases to 48% of those patients 70 years old or older. Risk factors include autoimmune conditions (rheumatoid arthritis, systemic lupus erythematosus, and inflammatory bowel disease), chronic obstructive pulmonary disease, depression, diabetes mellitus, asthma, lower socio-economic status, smoking, and non-truncal zoster.[13] The patients experience unbearable pain that is constant or intermittent burning, stabbing, sharp-shooting with hyperalgesia and/or allodynia persisting beyond the healing of herpetic skin lesions. In fact, PHN is one of the most common causes of pain-related suicide in the elderly patient population. [13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23,36]

Other conditions, such as shoulder pain can also benefit from PNS. Current population studies estimate shoulder pain in 18-26% of patients. Shoulder pain disorders account for one-third of musculoskeletal conditions involving the sensory branch of the suprascapular nerve. Approximately half of patients with acute shoulder pain develop chronic shoulder pain and frozen shoulder. Multiple disease states can play a role: rotator cuff disorders, tendinopathies, arthritic conditions, adhesive capsulitis, and instability syndromes.[24,25,26,27] Substantial evidence for a role of Central Sensitization in Chronic Shoulder Pain is prevalent.[24,25] Pain relief can be achieved with PNS to the suprascapular nerve avoiding the use of SCS. (Figure 1)

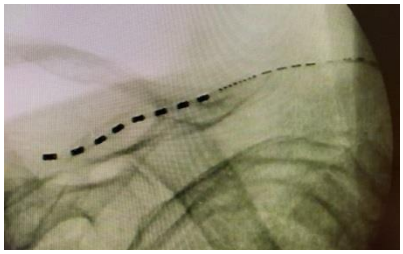

Figure 1. ASIPP 7/2022
PNS supra scapular Nerve

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PNS stimulation is often indicated when SCS systems cannot be placed, due to systemic coagulopathy, inability to access the epidural space (prior surgery, patient refusal, pacemaker, etc.) or patient preference. Additionally this modality is less invasive than SCS.

Rates of chronic pain @ 1 year after total hip replacement (THR) are 38%.[29] The surgical destruction of peripheral nerves and scar overgrowth into nerves leads to permanent nerve damage, neuropathic pain. PNS has been an effective treatment for this condition as well as similar pre-operative and post-operative conditions for total knee replacement (TKR) or chronic knee pain. [29] (Figure 2)

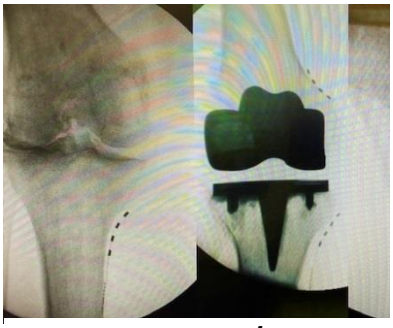

Figure 2. ASIPP 7/2022 PNS TKR

Meralgia paresthetica, a condition involving innervation of the lateral femoral cutaneous nerve to the anterolateral portion of the thigh, as a result of obesity, pregnancy, pelvic masses, external compression by belts or iatrogenic after laparoscopic surgeries, orthopedic procedures involving the pelvis have an incidence: 32.6 per 100,000 person-years. Success has been reported with PNS.[30,31,32]

Complex regional pain syndrome (CRPS) is, as the name describes, a complex and poorly understood collection of symptoms related to neuropathic pain. There are 2 types, Type I (where there is no known nerve injury) and Type II (where there is a defined nerve injury), though clinically there is little difference in the treatment or outcomes. CRPS usually affects an extremity, the edema, hypersensitivity (allodynia), shocking pains (paresthesias), vasomotor instability, and pain with movement causes significant morbidity. The associated wide variety of symptoms, often results in underdiagnoses by primary care physicians, leading to delay in diagnosis and treatment. CRPS makes up approximately 10% of the overall diagnoses of chronic neuropathic pain. [37,38]

Incidence of brachial plexopathy and upper limb nerve pathologies from upper extremity injuries occur in 3.7% of the population per year. The Incidence of direct nerve injury are more uncommon 0.14/1000 per year, but brachial plexopathies account for 14% of upper extremity nerve lesions due to: trauma, such as seat belt injury after motor vehicle accident, thoracic outlet syndrome, radiation, and CRPS.[33,34,35]

We advise that centrally mediated tracts in the spinal cord and/or peripheral nerves in the human body can suffer from neuropathic pathoanatomy, leading to unbearable pain in the target area that does not respond to multiple modalities of treatment. The peripheral nerves affected include, but are not limited to: ulnar, radial, medial, axillary, suprascapular, superior and middle cluneal, iIlioinguinal, iliohypogastric, occipital nerves, cervical sympathetics, intercostal, brachial plexus, sciatic, pudendal, tibia, sural, saphenous, femoral, superior and inferior genicular, common/deep peroneal.[33]

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We agree with the Noridian coverage decision to not support:

- fibromyalgia, diffuse polyneuropathy.

In summary FSIPP requests that the Novitas/FCSO re-evaluate its coverage indications and limitations to allow more alignment with the Noridian LCD, expanding the coverage indications and allow greater patient access to these life-saving neuromodulation treatments.

Sincerely,
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