June 16, 2016

BlueCross BlueShield of Tennessee
Medical Policy
1 Cameron Hill Circle
Chattanooga, TN 37402

Re: HF10 Spinal Cord Stimulation Therapy

To whom it may concern:

We are writing on behalf of the American Society of Regional Anesthesia and Pain Medicine (ASRA), one of the largest subspecialty medical societies in anesthesiology, with more than 4,000 members. Recently it has come to our attention, through an April 2016 Highmark and Blue Cross Blue Shield medical policy, that high frequency -10,000 Hz (HF-10) spinal cord stimulation (SCS) therapy will be considered experimental and investigational. We are disappointed in this new labeling and request that Blue Cross Blue Shield remove this labeling in order provide appropriate, optimal medical care for their beneficiaries through access to this evidence-based therapy when deemed medically necessary.

Consider the following:

- The amount of Americans (11.4%) who suffer from chronic pain is larger than those with diabetes (9.3%).[1,2] We know you would not deny an appropriate treatment for diabetes with a demonstrated improved outcome. We are asking for similar consideration for HF-10 for chronic pain.
- Recent advancements in SCS, specifically in electrical parameter adjustments (e.g., high frequencies) and programming, have significantly advanced the efficacy and safety of this treatment modality.
- Use of nonopioid interventions for chronic pain are essential in light of the current opioid crisis in America. Mortality and morbidity associated with opioid use for chronic pain is higher than that of automobile accidents, and, in a recent JAMA paper, long-acting opioids were associated with increased mortality from cardiorespiratory and other causes. The #1 recommendation in the CDC Guideline for Prescribing Opioids for Chronic Pain states that “nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.”
Advancements in SCS
Over the last 30 years, significant advancements have occurred in SCS, specifically in electrical parameter adjustments (e.g., higher frequencies) and programming, which have enhanced the efficacy of the treatment. One recent advancement is the utilization of HF-10. Both preclinical\textsuperscript{5,6} and clinical evidence\textsuperscript{7-11} strongly support the analgesic efficacy and safety of HF-10 therapy to effectively modulate chronic low back and neuropathic pain.

Preclinical work: Schechter et al.\textsuperscript{5}, demonstrated the ability of HF-10 therapy to effectively inhibit mechanical hypersensitivity in a neuropathic pain animal model. Song et al.\textsuperscript{6} established that both conventional SCS (low frequency) and HF-10 were effective in various animal neuropathic pain models.

Clinical evidence: High-quality clinical data demonstrates the therapeutic safety and sustained efficacy of HF-10 therapy.\textsuperscript{7,9-11} HF-10 therapy received European regulatory approval in 2010. Since 2010, more than 2,000 patients have been implanted with HF-10 systems with great success.\textsuperscript{11} In 2013 in an open-label cohort study examining 83 patient with significant back pain, Van Buyten et al.\textsuperscript{8} reported sustained low back pain and leg pain relief in greater than 70% of treated subjects. Not only did patients have significant improvement in pain relief, but they also demonstrated improvements in disability and sleep. In a 24-month, multicenter study, Al-Kaisy et al.\textsuperscript{9}, demonstrated statistically significant, sustained efficacy of HF-10 therapy with mean back pain scores (VAS) going from 8.4 ± 0.1 at baseline to 3.3 ± 0.3 at 24 months. Mean leg pain decreased from 5.4 ± 0.4 to 2.3 ± 0.3.

Kapural et al.,\textsuperscript{7} in a pivotal randomized-controlled trial (RCT), published in the high quality and reputable journal \textit{Anesthesiology}, compared HF-10 therapy to traditional, low-frequency SCS and found HF-10 therapy to be superior to traditional low-frequency SCS in the treatment of chronic back and leg pain. The HF-10 treatment subjects had greater pain relief at 12 months (78.7% reduction for HF-10 vs. 51.3% for traditional SCS). In addition, after HF-10 therapy, 67% of the subjects were considered back and leg pain remitters (defined as pain scores \(\leq 2.5\)) over the 12-month follow-up period. This is a significant clinical improvement and should put in context with pharmacologic management of neuropathic pain, in which less than 50% of patients find significant improvement with any medication.\textsuperscript{12} This study was used in support of the FDA approval for HF-10 therapy and is one of the largest ever conducted RCTs of SCS interventional pain therapy with a long-term follow-up.

In addition to the peer-review process, both the Food and Drug Administration (FDA) and CMS have recognized the high quality of this clinical trial, with the FDA granting the labeling of HF10 as “superior” to traditional SCS based on the study results. Furthermore, the significance of this RCT should be reference to the current literature of SCS therapy. To date, this study is one of four RCTs—with at least 6 months observation—in the SCS literature. In a recent systematic review by Grider et al.,\textsuperscript{13} which performed a methodological assessment of RCTs evaluating SCS in chronic pain, the Kapural et al.\textsuperscript{7} study received the highest quality score.

In addition to its clinical efficacy, HF-10 therapy in a healthcare economic model of SCS demonstrated a favorable incremental cost-effective ratio per quality-adjusted life-years (QALY) gained in comparison to conventional medical management and established dominance compared to traditional SCS.\textsuperscript{14}

We have been informed that Blue Cross Blue Shield, when evaluating HF-10 therapy, has inappropriately included the Perruchoud et al.\textsuperscript{15} study. This study should not be used to evaluate the efficacy of HF-10 therapy. This study was only a two-week trial examining an experimental device modified to examine the efficacy of 5000 Hz SCS in individuals previously successfully treated with traditional SCS therapy. Significant differences exist for the equipment used in this study compared to HF-10 therapy including frequency, waveform, programming, and lead placement. In addition, CMS has specifically defined “high-frequency” SCS as required to deliver a frequency of 10,000 Hz. The device utilized in the
Perruchoud et al.\textsuperscript{15} study delivered half of this frequency, and, therefore, should not be used to evaluate the efficacy of HF-10 therapy.

**The Opioid Epidemic**

With the current opioid epidemic in the United States, any and all nonopioid therapy (e.g., SCS HF-10) should be attempted on patients with chronic pain prior to considering long-term opioid therapy. In fact, the recently published *CDC Guideline for Prescribing Opioids for Chronic Pain*\textsuperscript{4} recommends that alternative treatments be considered prior to prescribing opioids for chronic pain. HF-10 is one such treatment that physicians should be able to consider. Furthermore, by using HF-10 or other similarly valid interventions, physicians are potentially able to help prevent more serious complications. For example, a new study published in *JAMA* found a “significantly increased risk of all-cause mortality,” specifically cardiovascular deaths, in patients receiving long-acting opioids.\textsuperscript{3}

In conclusion, significant preclinical and clinical data demonstrate the safety and efficacy of HF-10 therapy, and this modality is precisely the sort of treatment that the CDC Guideline recommends in light of the opioid crisis in America. It is of critical clinical importance that Blue Cross Blue Shield reverses its decision to classify HF-10 therapy as experimental and investigational. HF-10 therapy has been shown to provide significant pain relief to appropriately selected individuals with chronic pain conditions that are often challenging to treat. In addition, the therapy offers advantages in select individuals to traditional SCS therapy including the ability to deliver paresthesia-free pain control that does not limit activities including driving.

Thank you in advance for your assistance with this matter. Please feel free to contact us with further questions or comments.

Sincerely,

Oscar de Leon Casasola, MD
President, American Society of Regional Anesthesia and Pain Medicine

**References**


