Use of Scrambler Therapy as an opioid alternative for the treatment of pain

Senate Concurrent Resolution 25 -Louisiana Department of Health's report of findings to the Legislature of Louisiana

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LOUISIANA DEPARTMENT OF HEALTH

Contents

Executive Summary

Purpose: Pursuant to the 2019 Regular Session SENATE CONCURRENT RESOLUTION NO. 25, the Louisiana Department of Health (LDH) was urged to study the use of scrambler therapy as an opioid alternative for the treatment of pain. SCR 25 reported significant increases in opioid-related deaths in Louisiana between 2012 and 2017, including significant increases in deaths in involving fentanyl since 2014. SCR 25 further noted that prescription opioids were significant contributors to these overdoses and deaths.

It was further noted that while many patients with chronic pain are eager to try alternative treatments for relief, health carriers and insurance plans often only cover opioid treatment for pain, even as scrambler therapy has been a widely used alternative for pain treatment in Europe and is being introduced in several markets in the United States.

For these reasons SCR 25 requested that LDH study Scrambler Therapy to determine whether its use is an appropriate alternative treatment for pain in Louisiana, and if so, the feasibility of health insurance coverage of this treatment by government and commercial health plans in Louisiana.

SCR 25 called LDH to consult with the Louisiana Department of Insurance and the Louisiana Association of Health Plans in studying this matter and to provide a report of its findings, including the use of scrambler therapy as an appropriate alternative treatment for pain and the feasibility of health insurance coverage of this treatment to the legislature no later than February 1, 2020.

Overview of Main Themes: A total of 46 publications were identified in the literature through the PubMed search device (https://www.ncbi.nlm.nih.gov/pubmed), spanning from July 2005 until present-day. Most of these publications were case reports, case series, or retrospective case reviews. Few of these publications were randomized controlled trials, comparing Scrambler Therapy to sham (i.e. placebo) treatment.

These case reports and case series generally gave favorable results that were retained during follow-up with patients. These patients often had difficult-to-treat pain disorders such as chemotherapy-induced polyneuropathy or had difficult-to-treat patient populations such as adolescents. The viability of Scrambler Therapy in these difficult-to-treat patients makes it a truly attractive treatment option.

Some of the randomized controlled trials of Scrambler Therapy gave positive results (Loprinzi C et al., 2019), other randomized trials did not show that Scrambler Therapy was any more beneficial than sham treatment (TJ Smith et al., 2019). Therefore, at the very least, it appears that rigorous provider training on the application and employment of Scrambler therapy electrodes appears critical.

Summary and Conclusions: To conclude, the available literature on Scrambler Therapy appears promising, but it does demonstrate deficits in reproducible positive results through randomized controlled trials that would be truly needed to more forcefully support the use of Scrambler Therapy in Louisiana.

Section 1 –Overview and Purpose

Overview and Purpose:

Pursuant to the 2019 Regular Session SENATE CONCURRENT RESOLUTION NO. 25 by Senator Peacock, the Louisiana Department of Health was urged to study the use of scrambler therapy as an opioid alternative for the treatment of pain. SCR 25 cited several compelling opioid-related statistics, which reported opioid related deaths in Louisiana were one hundred fifty times higher in 2017 than they were in 2012; and that deaths in Louisiana involving fentanyl have increased by more than five hundred percent since 2014. SCR 25 further noted that prescription opioids for the treatment of pain were significant contributors to these overdoses and deaths, with Louisiana prescribers writing nearly five million opioid prescriptions per year.

It was further noted that many patients with chronic pain are keenly aware of the risks associated with opioids and eager to try alternative treatments for relief; and although Louisiana has enacted several laws to limit and curtail opioid prescriptions, health carriers and insurance plans often prefer and will only cover opioid treatment for pain; even as scrambler therapy, an experimental, nonnarcotic, noninvasive, pain-free use of electrodes to target specific pain sites, has been a widely used alternative for pain treatment in Europe and is being introduced in several markets in the United States. The SCR 25 author cited a 2018 survey of government and commercial health plans finding that insurance does not cover scrambler therapy for patients in Louisiana, resulting in access being limited to those who can afford to pay cash for the service.

For these reasons, SCR 25 requested that the Louisiana Department of Health study Scrambler Therapy to determine whether its use is an appropriate alternative treatment for pain in Louisiana, and if so, the feasibility of health insurance coverage of this treatment by government and commercial health plans in Louisiana.

SCR 25 called for the Louisiana Department of Health to consult with the Louisiana Department of Insurance and the Louisiana Association of Health Plans in studying this matter and to provide a report of its findings, including the use of scrambler therapy as an appropriate alternative treatment for pain and the feasibility of health insurance coverage of this treatment to the legislature no later than February 1, 2020, requiring that a copy of this Resolution be transmitted to the secretary of the Louisiana Department of Health, the commissioner of the Louisiana Department of Insurance, and the executive director of the Louisiana Association of Health Plans.

Section 2 –Methods

To fulfill intent of SCR 25, the Louisiana Department of Health convened a workgroup consisting of the following members and clinical subject matter experts to review scientific literature, survey other states' Medicaid, Medicare, and commercial insurance coverage, as well as conduct an evidence review for scrambler therapy:

- Marcus Bachhuber, MD, MS, FACP, Board Certified Internal Medicine and Addiction Medicine – Chief Medical Officer, Bureau of Health Services Financing (Medicaid), Louisiana Department of Health,
- Cheryll Bowers-Stephens, MD, MBA, Board-Certified Child-Adolescent Psychiatrist and Provider Performance Medical Director for Healthy Blue
- James E. Hussey, MD, Medical Director, Louisiana Office of Behavioral Health, Board Certified Psychiatrist, Chairman of Louisiana Heroin and Opioid Prevention and Education Advisory Council to the Governor's Drug Policy Board, and SCR 25 workgroup lead for LDH
- Frank Opelka, JD -Deputy Commissioner of Health, Life and Annuity, Louisiana Department of Insurance
- Mordecai N. Potash, MD -Associate Professor of Clinical Psychiatry, Tulane School of Medicine, Board Certified Pain Medicine and Palliative Care specialist
- Randolph L Roig, MD –Clinical Associate Professor of Medicine, Neurology, and Anesthesiology, LSU School of Medicine, Department of Medicine, New Orleans, LA, Certified Pain Medicine Specialist

Between October 7, 2019 and January 10, 2020, the workgroup convened three times, researched and reviewed numerous documents, including, but not limited to the following:

- Louisiana Senate Concurrent Resolution No. 25, Senator Peacock, 2019 Regular Session
- SCR 25-Scrambler Therapy for opioid pain management, Benefit Decision Brief, November 2019
- Scrambler Therapy MC-5 Treatment Dossier, a document summarizing Scrambler Therapy technology, FDA status, indications and diagnoses for use, contraindications, features and benefits, payments and costs, etc.
- Scrambler Therapy User Manual, Model MC-5A, May 2015 Version, Delta International Service & Logistic
- Loprinzi, Le-Rademacher, et al. Scrambler therapy for chemotherapy neuropathy: a randomized phase II pilot trial., *Support Cancer Care, 2019 Jun 17*,
- Thomas J. Smith, MD and Giuseppe Marineo, ScD Treatment of Postherpetic Pain With Scrambler Therapy, a Patient-Specific Neurocutaneous Electrical Stimulation Device, , *American Journal of Hospice & Palliative Medicine, 2018, Vol. 35(5) 812-813*
- So Young Joo, Yoon Soo Cho, et al. Effects of pain Scrambler therapy for management of burn scar pruritus: A pilot study, *Journal of the International Society of Burn Injuries, September 2016*
- Giuseppe Marineo Inside the Scrambler Therapy, a Noninvasive Treatment of Chronic Neuropathic and Cancer Pain: From the Gate Control Theory to the Active Principle of Information, *Integrative Cancer Therapies, Volume 18:1-17, October 2018*
- Thomas J. Smith, MD, A. Rab Razzak, MD, et al. A Pilot Randomized Sham-Controlled Trial of MC5-A Scrambler Therapy in the Treatment of Chronic Chemotherapy-Induced Peripheral Neuropathy (CIPN), *Journal of Palliative Cre, 2019, Vol. XX9X) 1-6*

- Marianna Ricci, MD, Laura Fabbri, MD,, et al. Scrambler therapy: what's new after 15 years? The results from 219 patients treated for chronic pain, *Medicine, Observational Study*
- Caterina Tomasello, Rita Maria Pinto, et al. *Scrambler therapy efficacy and safety for neuropathic pain correlated with chemotherapy-induced peripheral neuropathy in adolescents: A preliminary study, Pediatric Blood and Cancer, May 2017*
- *Scrambler Therapy FDA 510(k) Clearance letter to Delta International Service and Logistics, May 22, 2015,* Felepe Aguel for Carlos Pena, PhD, MS, Office of Device Evaluation, Center for Devices and Radiological Health
- Neil Majithia, Thomas J. Smith, et al. *Scrambler Therapy for the management of chronic pain*, Support Care Cancer 2016, June: 24(6): 2807-2814

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To conclude, the available literature on Scrambler Therapy appears promising, but it does demonstrate deficits in reproducible positive results through randomized controlled trials that would be truly needed to more forcefully support the use of Scrambler Therapy.

Section 3 –Summary of Findings and Recommendations

- Studies using Scrambler therapy are promising and consistent in their findings thus far; however such studies are still in their early stages and must be expanded.
- Scrambler therapy may represent a safe alternative to pain management with a very rare possibility of adverse events.
- The costs associated with Scrambler therapy range from $200 to $500 per session with a minimum of 10 sessions recommended.
- There is minimal evidence evaluating the effectiveness of Scrambler therapy; even more limited evidence on evaluating the comparative effectiveness of Scrambler therapy with placebo or opioid treatment.

For the above-stated reasons, the Louisiana Department of Health and those participating in the SCR 25 workgroup have determined that there is minimal evidence evaluating the effectiveness of Scrambler therapy; even more limited evidence on evaluating the comparative effectiveness of Scrambler therapy with placebo or opioid treatment. The studies uncovered during research were small and most details were reported in abstract form. Overall, it appears there is low strength of evidence for the listed outcomes of scrambler therapy, and further study and FDA review and approval is required prior to recommending health insurance coverage in Louisiana at this time.

Bibliography

- Louisiana Senate Concurrent Resolution No. 25, Senator Peacock, 2019 Regular Session
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