Medical Policy:

gammaCore Sapphire CV for Coronavirus Disease 2019 (COVID-19)

FDA Emergency Use Authorization for the Duration of the COVID-19 Emergency Declaration

POLICY NUMBER	LAST REVIEW
MG.MM.DM.19C2	September 9, 2022

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Background

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.

Definition

The gammaCore Sapphire CV (non-invasive Vagus Nerve Stimulator) is a portable device that provides a mild electrical stimulation to the vagus nerve, which runs through the neck and carries information to the central nervous system. Each stimulation with the gammaCore Sapphire CV lasts 2 minutes. The patient controls the intensity level. The gammaCore Sapphire CV delivers up to 30 stimulations in a 24-hour period, starting when the device is turned on and the intensity level is increased above 3. Once the maximum daily number of stimulations

has been reached, the device will not deliver any more stimulations until the following 24- hour period. The number of remaining stimulations available in a 24-hour period is indicated on the display. gammaCore Sapphire CV is rechargeable and includes a charging case to charge the device. The use of more than 24 stimulations per day has not been evaluated in controlled clinical trials.

The gammaCore Sapphire CV may help patients with reduced airflow and dyspnea due to exacerbation of asthma from COVID-19 by potentially inhibiting airway constriction, resulting in smooth muscle relaxation and reducing the potential for the virus to induce such symptoms. Each treatment should consist of two consecutive 2-minute stimulations at the onset of respiratory distress or shortness of breath. Stimulations may be applied to either side of the neck.

Guideline

The gammaCore Sapphire is considered medically necessary for acute use at home or in a healthcare setting to treat adults with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, by using non-invasive Vagus nerve Stimulation (nVNS) on either side of the patient's neck during the COVID-19 pandemic.

Limitations and Exclusions

The gammaCore Sapphire CV is contraindicated for:

1. Patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
2. Patients with a metallic device, such as a stent, bone plate, or bone screw, implanted at or near their neck
3. Patients with an open wound, rash, infection, swelling, cut, sore, drug patch, or surgical scar(s) on their neck at the treatment location

Procedure Codes

E1399	Durable medical equipment, miscellaneous

ICD-10 Diagnoses

Primary

U07.1	COVID-19

Associated with:

U07.1	COVID-19

References

electroCore™. gammaCore Sapphire™. Instructions for Use for gammaCore Sapphire™. https://www.fda.gov/media/139970/download. Accessed September 16, 2022.

U.S. Food & drug Administration. Letter of Authorization. https://www.fda.gov/media/139967/download. Accessed September 16, 2022.

U.S. Food & drug Administration. Fact Sheet for Healthcare Providers. https://www.fda.gov/media/139968/download. Accessed September 16, 2022.

Revision History

Aug. 14, 2020	New Policy