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MEDICAL POLICY – 3.03.07

Audio-Visual Neuromodulation for Neuropathic Pain

BCBSA Ref. Policy:	3.03.07	
Effective Date:	Aug. 1, 2026	RELATED MEDICAL POLICIES:
Last Revised:	Jul. 14, 2026	None
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

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Introduction

Neuropathic pain is pain caused by damage or problems in the nerves (neuropathic pain). It can feel like burning, tingling, or sharp shooting pain. This type of pain can be hard to treat and may not respond well to standard medicines. New technologies are being developed with the aim of managing this pain, including audiovisual digital therapeutics. These treatments use light and sound patterns delivered through a device to try to change how the brain processes pain signals. People with neuropathic pain may have ongoing discomfort that affects sleep, mood, and daily activities. Audiovisual digital therapeutics, such as the Sana Device, are designed to be used at home as a non-drug option to reduce symptoms. Audiovisual digital therapeutics for neuropathic pain are considered investigational (unproven). There is not enough evidence to show they are effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Authorized prescription audiovisual digital therapeutics	**The use of US Food and Drug Administration-authorized prescription audiovisual digital therapeutics for neuropathic pain is considered investigational (e.g., Sana Device)**

Coding

HCPCS	
E1399	Durable medical equipment, miscellaneous

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Related Information

N/A

Evidence Review

Description

This policy addresses prescription digital therapeutics (PDTs) that deliver therapeutic benefit through audiovisual (AV) hardware-software systems indicated for the management of neuropathic pain. Unlike software-only PDTs, the products reviewed here require dedicated hardware, a wearable AV stimulation device, through which proprietary software delivers the primary therapeutic intervention. To be within scope, a product must meet the following criteria:

- Be a PDT in which software performs one or more medical purposes as the primary therapeutic component of a hardware-software system, excluding software used solely to store or transmit medical information

- Have received marketing clearance or approval by the US Food and Drug Administration (FDA)
- Be prescribed by a healthcare provider

Background

This policy addresses a specific subset of US Food and Drug Administration (FDA)-authorized prescription digital therapeutics (PDTs) that deliver their primary therapeutic effect through integrated hardware-software systems utilizing visual and/or auditory stimulation. Covered products may have received De Novo classification or 510(k) clearance, depending on the availability of a legally marketed predicate device.

The scope of this policy is restricted to prescription audiovisual therapeutics for management of neuropathic pain that meet the following three criteria:

- Must be a PDT (software that performs one or more medical purposes as the primary therapeutic component of a hardware-software system, excluding software used solely to store or transmit medical information).
- Must have received marketing clearance or approval by the FDA.
- Must be prescribed by a healthcare provider.

BCBSA Evaluation Framework for Digital Health Technologies

FDA-authorized PDTs are subject to the same evaluation standards as other devices; the Blue Cross and Blue Shield Association Technology Evaluation Criterion are as follows:

- The technology must have final approval from the appropriate governmental regulatory bodies.
- The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
- The technology must improve the net health outcome.[a]
- The technology must be as beneficial as any established alternatives.
- The improvement must be attainable outside the investigational settings.[b]

[a] The technology must assure protection of sensitive patient health information as per the requirements of The Health Insurance Portability and Accountability Act of 1996 (HIPAA).

[b] The technology must demonstrate usability in a real-world setting.

Treatment

Neuropathic pain results from a lesion or disease of the somatosensory nervous system and is estimated to affect 7% to 10% of the general population.[2,3] Burning, pressing, tingling, and electrical sensations are common presentations, occurring spontaneously or through hyperalgesia or allodynia. Neuropathic pain is associated with significant impairment in physical function, psychological well-being, and quality of life, and places a substantial economic burden on individuals and the healthcare system.

First-line pharmacological treatment includes gabapentinoids (gabapentin, pregabalin), tricyclic antidepressants (amitriptyline, nortriptyline), and serotonin-norepinephrine reuptake inhibitors (duloxetine). Second-line pharmacological options include topical agents (lidocaine, capsaicin) and opioid-like medications (tramadol, tapentadol).[4] Behavioral and psychological therapies are recommended as adjuncts across the treatment continuum rather than as a specific treatment line. Despite these options, clinical effectiveness of medications is only moderate, and many patients experience persistent symptoms.[5] There is an unmet need for effective, non-pharmacological treatments that can complement existing therapies or provide alternatives for patients with inadequate response to pharmacotherapy.

The purpose of prescribed therapeutic digital applications is to provide a treatment option that is an adjunct or alternative to existing therapies for individuals with neuropathic pain, potentially reducing reliance on pharmacologic interventions and their associated side effects.

The Sana Device (Sana Health) is a prescription wearable audio-visual stimulation (AVS) mask that delivers personalized pulses of light and sound over the eyes and ears to modulate neural activity. The device operates through a 16-minute session protocol (per the NCT04280562 pivotal trial registration) run by proprietary software that personalizes stimulus delivery using heart rate variability biofeedback. The therapeutic mechanism is sensory neuromodulation targeting central mechanisms of neuropathic pain. The Sana Device received FDA De Novo authorization (DEN250005) in January 2026, establishing a new device class for AVS neuromodulation, and is intended for home or clinic use under the direction of a healthcare provider.

Summary of Evidence

For individuals with neuropathic pain who receive the Sana Device, the evidence includes a single pivotal, double-blind, sham-controlled randomized controlled trial (RCT; N=75). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The Sana Device received FDA De Novo authorization in January 2026. The pre-specified primary endpoint for the pivotal trial was the between-group comparison of neuropathic pain symptom severity at week 14 (off-treatment follow-up); this endpoint was met (mean difference, 8.75; 95% CI, 1.30 to 16.20, calculated from reported standard errors; p=.021). Both active (Sana Device) and sham groups improved significantly within-group at week 10 (end of treatment) with no significant between-group difference. Only the active group maintained improvement at week 14; the sham group returned toward baseline. Active participants also showed significant reductions in use of multiple pain medication classes compared to sham. A responder analysis based on an anchor-derived clinically important difference threshold showed a significantly higher response rate in the active arm (67%) versus sham (32%; NNT=2.89; χ^2=4.44; p=.035). No significant between-group differences were observed for secondary outcomes assessing mood, anxiety, sleep quality, or quality of life. The evidence base is limited to a single trial with no independent replication, an externally validated minimum clinically important difference (MCID; threshold and the result claiming success drawn from the same trial data), and baseline imbalance across key prognostic variables (age, sex, pain severity, and pain duration) not controlled for in the primary model. It is unknown whether neuroplastic changes observed at week 14 are sustained, whether repeated treatment cycles are needed to maintain benefit, and what retreatment intervals if any would be appropriate. The evidentiary standard for moving from investigational to a determination of improved net health outcome would require, at minimum: independent replication with prognostic variables controlled as covariates; a prospectively established MCID derived from an external cohort independent of the pivotal trial; and controlled follow-up of at least 6 to 12 months to establish durability of effect. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06655844[a]	Extended Home-use Trial of a Novel Device to Reduce Chronic Pain	30	Mar 2026
NCT06885554	Adjustment Disorders in the US Military: Disease Trajectories and ADNM-20-Mil Validation	60	Jan 2028

NCT: national clinical trial. [a] Denotes an industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No relevant clinical practice guidelines specifically addressing the Sana Device were identified.

Medicare National Coverage

There is no National Coverage Determination (NCD) for prescription digital therapeutics in the pain management category.

No HCPCS code or Medicare reimbursement framework has been established for the Sana Device as of March 2026. The Sana Device received FDA De Novo authorization in January 2026 and is not currently covered under any Medicare national reimbursement pathway.

Regulatory Status

In January 2026, the US Food and Drug Administration (FDA) granted De Novo marketing authorization (DEN250005) for the Sana Device (Sana Health, Inc.) for the adjunctive treatment of neuropathic pain, as summarized in **Table 2.**[1]

The Sana Device is currently the only FDA-authorized prescription audiovisual therapeutic indicated for neuropathic pain management in the United States.

Table 2. Prescription of Audiovisual Therapeutics for Neuropathic Pain

Application	Manufacturer	FDA Cleared Indication	Description	FDA Product Codes	Clearance	Date
Neuropathic Pain						
Sana Device	Sana Health	The Sana Device is indicated as an adjunctive treatment for the temporary relief of neuropathic pain in patients 18 years of age and older. The device is intended for use at home or in the clinic, under the direction of a healthcare provider.	The Sana Device is a prescription wearable AVS mask that delivers personalized pulses of light and sound to modulate neural activity. The device is worn over the eyes and ears and provides treatment sessions intended to reduce neuropathic pain through sensory neuromodulation.	QYN	DEN250005 (De Novo)	2026

AVS: audiovisual stimulation; CBT: cognitive behavioral therapy

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History

Date	Comments
08/01/26	New policy, approved July 14, 2026. Policy created with literature review through March 31, 2026. The use of US Food and Drug Administration-authorized prescription audiovisual digital therapeutics for neuropathic pain is considered investigational.

and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.