

Audio-Visual Neuromodulation for Neuropathic Pain

Policy # 00977

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of U.S. Food and Drug Administration-authorized prescription audiovisual digital therapeutics for neuropathic pain, e.g., the Sana Device, to be **investigational**.*

Background/Overview

Scope of Review

This review addresses a specific subset of U.S. 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 review is restricted to prescription audiovisual therapeutics for management of neuropathic pain that meet the following 3 criteria:

1. 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).
2. Must have received marketing clearance or approval by the FDA.
3. Must be prescribed by a healthcare provider.

Framework for Digital Health Technologies

FDA-authorized PDTs are subject to the same evaluation standards as other devices:

1. The technology must have final approval from the appropriate governmental regulatory bodies.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
3. The technology must improve the net health outcome.^a

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- 4. The technology must be as beneficial as any established alternatives.
- 5. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In January 2026, the U.S. 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 1.

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

Table 1. Prescription 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	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

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		healthcare provider.				
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AVS: audiovisual stimulation; CBT: cognitive behavioral therapy

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Description

This medical 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: 1) 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; 2) have received marketing clearance or approval by the U.S. Food and Drug Administration (FDA); and 3) be prescribed by 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; $\chi^2=4.44$; 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

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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.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. 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 ADN-20-Mil Validation	60	Jan 2028

NCT: national clinical trial.

^a Denotes an industry-sponsored or cosponsored trial.

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08/06/2026 Medical Policy Committee review

08/12/2026 Medical Policy Implementation Committee review

08/20/2026 Medical Quality Management Committee approval. New policy.

Next Scheduled Review Date: 08/2027

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Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	E1399
ICD-10 Diagnosis	G89.21-G89.29, G89.3-G89.4, M79.2

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);

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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.