# Audio-Visual Neuromodulation for Neuropathic Pain

**Medicare Advantage Medical Policy** #MA-236
Original Effective Date: 11/01/2026
Current Effective Date: 11/01/2026

*Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.*

# When 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 Health Plan 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.

**Evaluation 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]

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 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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|---|---|---|---|---|---|---|
| | | the direction of a healthcare provider. | | | | |

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 federal regulations, other plan medical policies, and accredited national guidelines.

# Supplemental Information

**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 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.

# References

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# Policy History

Original Effective Date: 11/01/2026
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08/18/2026 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 08/2027

# Coding

*The five character codes included in the Health Plan 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.*

*The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

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-G89.89, 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);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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

**NOTICE:** If the Patient's health insurance contract contains language that differs from the Health Plan's 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 Health Plan

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:** All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

**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 Blue Advantage), Blue Advantage 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 Blue Advantage health plan.

**Medicare Advantage Members**
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

**InterQual®**
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening.

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If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.