DRAFT Medical Coverage Policy | Audio Visual Neuromodulation for Neuropathic Pain

EFFECTIVE DATE: 12|01|2026
POLICY LAST REVIEWED: 08|19|2026

OVERVIEW

This evidence review 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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

The use of U.S. Food and Drug Administration-authorized prescription audiovisual digital therapeutics for neuropathic pain is considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

The use of U.S. Food and Drug Administration-authorized prescription audiovisual digital therapeutics for neuropathic pain is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

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. Products 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.

FDA-authorized PDTs are subject to the same evaluation standards as other devices; the evaluation criteria is as follows:

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 (HIPPA).

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

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.

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

CODING

Medicare Advantage Plans and Commercial Products

There is not a specific code(s) for this service. Claims must be filed with the following unlisted code(s):

E1399 Durable medical equipment, miscellaneous

RELATED POLICIES

Unlisted Procedures

PUBLISHED

Provider Update, October 2026

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