Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2414270
Decision Date:	12/30/2024	**Hearing Date:**	10/25/2024
Hearing Officer:	Christopher Jones	**Record Open to:**	11/08/2024

Appearances for Appellant:
Pro se
[redacted]

Appearances for WellSense:
Felicia Disciscio – Mgr Mbr App & Grv
Jacqueline Bigbee - Sr Mbr App Specialist
Priya Mehta, Esq. – Asst General Council
Dr. William Keogh – VP, Sr Med Dir for Utilization

APPEAL DECISION

Appeal Decision:	Denied	**Issue:**	Managed Care Organization – Denial of Internal Appeal; Medical Necessity; Experimental / Unproven Procedure
Decision Date:	12/30/2024	**Hearing Date:**	10/25/2024
MCO's Reps.:	Felicia Disciscio; Jacqueline Bigbee; Priya Mehta, Esq.; Dr. William Keogh	**Appellant's Reps.:**	[redacted]
Hearing Location:	Virtual – Teams	**Aid Pending:**	No

Authority

This hearing was conducted pursuant to Massachusetts General Laws Chapter 118E, Chapter 30A, and the rules and regulations promulgated thereunder.

Jurisdiction

Through an internal appeal denial dated June 13, 2024, WellSense Health Plan, an accountable care organization administering Medicaid benefits on MassHealth's behalf, denied the appellant's request for a Sprint Peripheral Nerve Stimulator implant. (Exhibit 1, p. 49.) The appellant filed a timely fair hearing request on September 17, 2024.[1] (Exhibits 1; 3; 130 CMR 610.015(B).) Denial of assistance by a managed care contractor is grounds for appeal. (130 CMR 610.032(B).)

Following the hearing, record was left open until November 8, 2024, for the appellant to submit additional medical evidence supporting the use of peripheral nerve stimulation to treat pain arising from a physical source.

[1] The Board of Hearings dismissed the appellant's initial 64-page appeal submission for not including the internal appeal denial. (Exhibit 2.) This matter was scheduled for hearing after the appellant submitted an 82-page submission on September 26, 2024. (Exhibits 3-4.)

Action Taken by WellSense

WellSense denied the appellant's medical procedure because it considers a peripheral nerve stimulator to be investigational and experimental when it is being used to treat physical pain.

Issue

The appeal issue is whether WellSense was correct, pursuant to 130 CMR 450.204 and 433.404(B), in determining that the appellant's requested procedure was not medically necessary because it is "experimental."

Summary of Evidence

Since March 1, 2023, the appellant's MassHealth benefits have been administered by WellSense Health Plan, an accountable care organization ("ACO").[2] On April 22, 2024, the appellant's physician requested prior authorization for "PNS Implant Procedure, 64555" to treat a diagnosis of "Mononeuropathy, unspecified." (Exhibit 6, p. 21; Exhibit 7, p. 121.) This request was denied on April 25, 2024, and an internal appeal was filed on or around May 16, 2024, by a representative from the implant manufacturer. (Exhibit 7, pp. 87-89, 107.) Also submitted was a doctor's note reflecting the appellant is under the age of [redacted] and she has been receiving steroid injections to alleviate her right shoulder pain with "good but temporary relief … . If she has an inadequate response, can consider posterior GH injection at next visit." The doctor's note goes on to discuss the peripheral nerve stimulator surgery because the appellant "is getting inadequate duration of relief from steroid injections (~4-6 weeks), has completed PT w/ continuation of HEP (>6 weeks in past 3 months) and is too young and active to be a good candidate for [total shoulder arthroplasty]. Her pain limits her function and quality of life." (Exhibit 7, p. 92.) The appellant had been suffering chronic pain for about a year at this time. (Exhibit 7, p. 123.)

This internal appeal was denied on June 13, 2024, because WellSense determined that this procedure is experimental and investigational, given the appellant's condition. (Exhibit 7, pp. 13-15.) The appellant submitted a letter explaining that she suffers from "right shoulder tendon tears, arthritis and joint deterioration [that] has led to severely limited range of motion, rigidity, stiffness and prevalent pain."[3] The appellant is "right hand dominant, [and] every day tasks and activities [are] very difficult and painful i.e. brushing my teeth, putting on makeup, blow drying/styling my hair, getting dressed/undressed, reaching up to a get a plate/glass on a high counter or kitchen shelf, carrying items, opening up a door, jar or container, helping others." The appellant's letter

[2] The appellant's coverage was originally with Tufts Alliance, which has since become WellSense Health Plan. (Exhibit 7, p. 9.)

[3] The appellant stated in letters and in testimony that she has a labrum or tendon tear in her right shoulder. This is not documented in any of the submitted medical records.

goes on to explain that she is a personal trainer, and her shoulder injury prevents her from demonstrating techniques and exercises for clients." In addition to running her own business, the appellant is a caregiver to a teenage child and two aging parents. (Exhibit 7, p. 58.) The appellant has tried physical therapy, acupuncture, shoulder braces, massage, fluid drainage, cortisone and Toradol injections, CBD products of various forms, and "Indian and Chinese herbs and tinctures." (Exhibit 7, p. 59.)

WellSense's representatives testified that the requested Peripheral Nerve Stimulator ("PNS") was denied because it was being requested to treat arthritis in the appellant's right shoulder. WellSense submitted a copy of its Medical Policy regarding Peripheral Nerve Stimulation. This policy documents that prior authorization is not required if it is for "[d]iaphragmatic/phrenic nerve stimulation" related to treating lung conditions. The policy lists "Limitations and Exclusions," including:

> g. Percutaneous electrical nerve stimulation (PENS) with devices such as Moventis PNS, Nalu Neurostimulation System, **SPRINT PNS System**, StimQ Peripheral Nerve Stimulator System, or StimRouter Neuromodulation System **used for the treatment of pain conditions** (e.g., musculoskeletal pain, neck pain, low back pain, neuropathic pain, neurogenic pain, abdominal pain, migraines) or other indications.

(Exhibit 7, p. 137 (emphasis added.)

As of the policy's adoption, WellSense had found no guidelines regarding peripheral nerve stimulation published by the Centers for Medicare and Medicaid ("CMS"). (Exhibit 7, pp. 131-138.) The policy goes on to list CPT Codes and prior authorization descriptions. Regarding CPT Code 64555, the code is listed as a treatment for "Occipital Nerve Stimulation (ONS)," and it is "considered experimental and investigational or NOT medically necessary for ONS." (Exhibit 7, p. 140.)

WellSense also submitted an independent peer review report regarding the appropriateness of the requested treatment. This review notes the appellant's diagnosis described by her prescribing physician as

> a complaint of shoulder pain. An impression is made of component degenerative changes without evidence of osseous abnormality. This does indicate they discussed a peripheral nerve stimulator as an option to improve pain and she would like to pursue this. There is no indication as to what pain they are going to try to address with the stimulator. There is no documentation to support the presence of a nerve injury. A prior authorization form indicates a PNS implant procedure is being requested for the diagnosis of mononeuropathy, unspecified.

(Exhibit 7, p. 83.)

This peer review describes WellSense's coverage policy as allowing "the use of a percutaneous tibial nerve stimulator for urinary conditions, and sacral nerve stimulation when certain criteria are met. The plan indicates that diaphragmatic/phrenic nerve stimulation does not require prior approval." The review also notes that the submitted "documentation does not support the presence of any mononeuropathy with the report indicating a diagnosis of glenohumeral arthritis which responded well but temporarily to corticosteroid injection."[4] (Exhibit 7, p. 83.)

[redacted] explained that the appellant's pain arises from a physical source, her joint inflammation. Nerve stimulators are regularly used to treat refractory pain, such as nerve pain, but they are not proven to be effective in treating physical pain like arthritis. WellSense's representatives argued that their coverage criteria are based on MassHealth's requirements. They acknowledged that individual consideration may allow rare circumstances where the requested Sprint PNS would be approved, but only where it is the only treatment available. [redacted] hypothesized that life-limiting diseases like cancer might make other treatment options impossible, therefore making a PNS implant the only available treatment for osteoarthritic pain. However, [redacted] testified that no such circumstance was apparent here.

The appellant's representative, another representative from the device manufacturer, argued that this device is on the MassHealth fee schedule, and it has been approved in Massachusetts by both MassHealth and WellSense. They cited statistics developed by the manufacturer alleging that over 90% of these devices were approved by MassHealth MCOs in 2023. WellSense's representatives objected that it was inappropriate to discuss other patients' cases in the present appeal due to privacy concerns. The appellant's representative asked if the appellant's request could be approved if they documented that the other approvals occurred in non-life-limiting circumstances. [redacted] was concerned by how readily the manufacturer appeared to be to divulge other patients' clinical information, and further testified that the Sprint PNS shares a code with devices that can be approved in various circumstances. For physical pain, WellSense considers the requested device and procedure to be experimental and investigatory, therefore it is not covered.

The appellant's representatives argued that this device has been used to treat arthritis and it has effectively alleviated pain for up to 2 years. They submitted various studies and a Medicare National Coverage Determination ("NCD") that they claim supported their position. WellSense's representative argued that Medicare NCDs are not binding on Medicaid.

The appellant testified that her condition is life-limiting, in that it is limiting her ability to live her life and perform her job. The appellant testified that the only other treatment left is a total shoulder replacement. The appellant's orthopedist had recommended her for a total shoulder

[4] Mononeuropathy is a form of nerve damage that may be effectively treated by nerve stimulation. (See Exhibit 6, pp. 31-52.) Like the appellant's assertion of a tendon tear, the prescribing physician's diagnosis of "mononeuropathy" is not supported in the clinical record.

replacement, but she is too busy at this time to have her shoulder immobilized for 9 months to a year. The appellant testified that her mother was recently diagnosed with Leukemia, and she expects to be physically relied upon in caring for her mother for the next year or two. She understands that this implant could last up to 2 years, and she was hoping to link together treatments to put off the shoulder surgery for 10 more years.

The submitted NCD does not include coverage criteria, simply stating that "[p]ayment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators." There is a cross-reference to a related NCD that reviews the coverage criteria for Percutaneous Electrical Nerve Stimulators ("PENS") and Transcutaneous Electrical Nerve Stimulators ("TENS"), but no additional reference is made to PNS. [redacted] testified that he was familiar with the NCD, and it addresses electrical stimulators in general. [redacted] felt that this NCD was not applicable to the specific requested service, and the appellant's representatives were unable to identify how it was relevant.

The appellant also submitted a publication review from the Journal of Pain Research, "Evidence-Based Clinical Guidelines from the American Society of Pain and Neuroscience for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain." (Exhibit 6, pp. 31-52.) This article reviews published "studies that described peripheral nerve stimulation in patients in terms of clinical outcomes for various pain conditions, physiological mechanism of action, surgical technique, technique of placement, and adverse events." For upper extremities, the article reviews two random control trials that involved stroke survivors suffering chronic shoulder pain after the stroke. The review also notes a small observational study of 26 patients "afflicted with refractory neuropathic pain in the upper extremity including 16 patients with [complex regional pain syndrome] … ."[5] This study noted 20 patients were still reporting some degree of pain relief over two years after their PNS treatment. The review gives a B grade[6] to the association of PNS with: "modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain" following a stroke, and modest to moderate pain relief "for mononeuropathies of the upper extremity … following a positive diagnostic ultrasound-guided nerve block of the targeted nerve … ." The article notes there is an ongoing randomized study to evaluate the role of PNS in reducing postoperative opioid use, and it "may provide reproducible and effective targets for stimulation in certain upper extremity … pain conditions."

[redacted] testified that refractory pain could mean different things. Normally, refractory pain means that it does not respond to treatment, and refractory pain generally refers to pain generated by the nerves misfiring, not pain with a physical source.

[5] CRPS is a condition resulting from nerve pain. (Exhibit 6, pp. 39-40.)

[6] "Recommendable (at least moderate evidence that the measure if effective and that benefits exceed harms)." P. 35

The appellant testified that her doctor had told her that he has used the device in the past to diminish pain in patients for up to two years. The appellant acknowledged that this PNS device is not an alternative to the shoulder surgery, but rather a way to delay surgery. Because the study review submitted by the appellant only found PNS devices were effective at treating nerve pain, the appellant requested that the record be left open for her doctor to submit a letter addressing the question of the use of the Sprint PNS to treat pain not arising from nerve issues.

The appellant's representative responded during the record open period to argue that WellSense misclassified

> the Sprint PNS Device as a PENS, which falls under a different CPT code (CPT 64999). We are not requesting a PENS bu [*sic*] rather a PNS which is (CPT 64555), and it's important to note that PNS is distinct from PENS. Therefore, this policy does not apply to the service we are requesting.
>
> • This policy pertains specifically to PENS, PNT, PSFS, etc., and does not cover the service we requested.
>
> • The policy correctly identifies the proper coding for those other technologies as CPT 64999.
>
> The doctor has requested authorization for the implantation of peripheral nerve stimulator lead(s) (CPT code 64555). The policy goes on to only list our code 64555 as excluded when considered for occipital nerve PNS placement. This shows that they acknowledge 64555 is a PNS code - further evidence that they have us misclassified this treatment [*sic*]

(Exhibit 8, p. 3.)

The appellant's physician also submitted a letter stating that the appellant

> has severe osteoarthritis of the shoulder and has exhausted all other conservative treatment options including physical therapy, medications and injections. … [I]t has been strongly recommended by her referring shoulder surgeon to delay shoulder replacement surgery as long as possible. … While [the appellant's] pain is not primarily due to a nerve issue, all pain signals are transmitted through the nervous system. This is why stimulating the nerve is an effective way to treat pain, even when the issue is due to osteoarthritis.

(Exhibit 9.)

Findings of Fact

Based on a preponderance of the evidence, I find the following:

1) The appellant is enrolled in WellSense Health Plan ACO, which administers her MassHealth benefits. (Exhibit 7, p. 9.)

2) The appellant is under the age of [redacted] physically fit and active. She runs her own personal training business. The appellant has a right shoulder osteoarthritis that has been causing chronic pain for over a year. Because the appellant is right-hand dominant, this severely restricts her activities of daily living as well as her quality of life. (Testimony by the appellant; Exhibit 7, pp. 59, 92, and 123.)

3) On April 22, 2024, the appellant's physician requested prior authorization for "PNS Implant Procedure, 64555" to treat a diagnosis of "Mononeuropathy, unspecified." (Exhibit 7, p. 121.)

4) This request was denied on April 25, 2024, and an internal appeal was filed on or around May 16, 2024, by a representative from the implant manufacturer. (Exhibit 7, pp. 87-89, 107.)

5) The internal appeal was denied on June 13, 2024, because the procedure is considered by WellSense to be experimental and investigational, given the appellant's diagnosis of osteoarthritis. (Exhibit 7, pp. 13-15.)

6) The appellant's medical care team has informed her that the long-term treatment for her condition would be a total shoulder replacement. This treatment would make her right shoulder effectively unusable for 9 months to a year. (Testimony by the appellant.)

7) The doctor requesting the PNS device believes that the appellant is too young and active to be a good candidate for a total shoulder replacement. (Exhibit 7, p. 92; see also Exhibit 9.)

8) WellSense has developed a policy regarding when it covers peripheral nerve stimulation. The "SPRINT PNS System" is specifically excluded from coverage when it is "used for the treatment of pain conditions … ." (Exhibit 7, p. 137.)

9) There is evidence to support PNS devices being used to treat nerve pain, such as misfiring nerves causing pain following a stroke, and for mononeuropathies of the upper extremities. (Testimony by [redacted]; Exhibit 6, pp. 31-52.)

10) There are ongoing studies regarding the effectiveness of PNS devices in treating post-surgical pain and, presumably, other forms of physical pain in upper extremities. (Exhibit 6, pp. 31-52.)

11) No diagnostics support that mononeuropathy is the source of the appellant's pain rather than osteoarthritis. (See Exhibit 7, pp. 83, 128; Exhibit 9.)

Analysis and Conclusions of Law

MassHealth members under the age of 65 must generally enroll in a MassHealth managed care provider. (130 CMR 508.001(A).) Managed care organizations provide "management of medical care, including primary care, behavioral health services, and other medical services" for enrolled members. (130 CMR 450.117(B).) Members enrolled in a managed care provider are entitled to a fair hearing under 130 CMR 610.000 to address adverse determinations by an Accountable Care Organization ("ACO") if the member has exhausted all remedies available through the contractor's internal appeal process. (130 CMR 508.010.)

Typically, MassHealth and MCOs must cover any service that is deemed "medically necessary." The regulatory definition of "Medical Necessity" is:

> (1) it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity; and
>
> (2) there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency. Services that are less costly to the MassHealth agency include, but are not limited to, health care reasonably known by the provider, or identified by the MassHealth agency pursuant to a prior-authorization request, to be available to the member through sources described in 130 CMR 450.317(C), 503.007: *Potential Sources of Health Care*, or 517.007: *Utilization of Potential Benefits*.

(130 CMR 450.204(A).)

MassHealth's regulations further identify that "[a]dditional requirements about the medical necessity of MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines. (130 CMR 450.204(D).) One such requirement is that MassHealth "does not pay a physician for performing, administering, or dispensing any experimental, unproven, cosmetic, or otherwise medically unnecessary procedure or treatment." (130 CMR 433.404(B).) WellSense's Member Handbook echoes this restriction. (See Exhibit 7, pp. 136-138.)

This appeal comes down to the question of what qualifies as an "experimental" medical procedure. The Board of Hearings has a highly circumscribed jurisdiction. (See 130 CMR 610.032.) A fair hearing decision must be "based upon evidence, testimony, materials, and legal rules, presented at the hearing, including the MassHealth agency's interpretation of its rules, policies, and regulations." (130 CMR 610.082(A); see also 610.065(A)(7).) Furthermore, a fair hearing decision is limited to "the parties to that case and cannot be disputed again between them in any other administrative proceeding nor used as binding precedent by other parties in other proceedings." (130 CMR 610.085(A)(2).)[7]

There is no clearly defined standard of review in the regulations for deciding when medical care is "experimental." The structure of the Board of Hearings indicates that hearing officers are not intended to set policy that would be widely applicable to MassHealth members. Further, in contracting with managed care organization to administer benefits, MassHealth essentially delegates to an ACO its authority to determine clinical criteria above and beyond the minimal guidance set forth in the regulatory definition of "Medical Necessity." [8] (See 130 CMR 508.001(B)(2)(b).) WellSense's clinical criteria specifically defines the SPRINT PNS device to be experimental and investigational when used to treat pain conditions.[9] (Exhibit 7, p. 137.) The appellant does not argue that this policy directly contradicts a MassHealth regulation, therefore, it is effectively the agency's policy interpretation of what services are covered. For this reason, this appeal is DENIED.

Further, even if this appeal were decided upon a direct application of the medical necessity regulation, the appellant has failed to establish that the requested treatment is most conservative and the least costly treatment available to treat her osteoarthritis pain. There is some evidence that peripheral electrical nerve stimulation is an effective treatment for pain induced by nerve conditions. However, the submitted evidence reflects only anecdotal evidence from the appellant's prescribing physician that he has successfully treated osteoarthritis for up to 2 years with peripheral nervous stimulation. It is certainly possible that the requested treatment would help the appellant's pain, but it is also possible, given the available evidence, that it might not. Therefore, the state of evidence at this time is that the requested treatment is experimental for the treatment of physical pain. This appeal would be DENIED even if there were not a duly published policy excluding its coverage.

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[7] For this reason, MassHealth or WellSense approvals of PNS devices in the past would not be dispositive here.

[8] There is no published guidance by MassHealth governing the Sprint PNS procedure, specifically, or PENS or TENS more generally.

[9] This explains why the CPT Code 64555 does not exist in WellSense's claims listings for the requested device to be used in the treatment of pain.

Order for WellSense

None.

Notification of Your Right to Appeal to Court

If you disagree with this decision, you have the right to appeal to Court in accordance with Chapter 30A of the Massachusetts General Laws. To appeal, you must file a complaint with the Superior Court for the county where you reside, or Suffolk County Superior Court, within 30 days of your receipt of this decision.

Christopher Jones
Hearing Officer
Board of Hearings

cc: [redacted]

MassHealth Representative: BMC Wellsense, Member Appeals & Grievances, Attn: Felicia DiSciscio, 529 Main Street, Ste. 500, Charlestown, MA 02129