Washington State Health Care Authority

Health Technology Clinical Committee
DRAFT Findings and Decision

Topic: Spinal cord stimulation (SCS)
Meeting date: May 17, 2024
Final adoption: Pending

Number and coverage topic:
20240517A – Spinal cord stimulation

HTCC coverage determination:
SCS is a **covered benefit with conditions** for treatment of failed back surgery syndrome, non-surgical refractory back pain, and painful diabetic neuropathy.

SCS is **not a covered benefit** for treatment of complex regional pain syndrome.

HTCC reimbursement determination:
Limitations of coverage:

- **Failed back surgery syndrome (FBSS) when each of the following are met**:
  - At least 12 months post-surgery, persistent low-back and neuropathic leg pain
  - Moderate to severe [≥5 on the visual analog scale (VAS) pain scale] **neuropathic pain and objective neurologic impairment** with documented pathology related to pain complaint (i.e., abnormal MRI). Neurologic impairment is defined as objective evidence of one or more of the following:
    - Markedly abnormal reflexes
    - Segmental muscle weakness
    - Segmental sensory loss
    - Electromyography (EMG) or nerve conduction study (NCS) evidence of nerve root impingement
  - Functional disability assessed using the Oswestry Disability Index (ODI); **ODI score ≥21%**, AND
  - **Psychological evaluation** and appropriate treatment for substantial mental health disorders, AND
  - 12 months of **conservative medical management in total**, comprised of regular attendance, participation and compliance with a multidisciplinary approach including:
    - Full course of physical therapy, AND
    - Cognitive behavioral therapy, AND
    - Another modality of conservative management (e.g., acupuncture, chiropractic)
  - Must meet above criteria prior to percutaneous trial
  - **7 to 14 day trial** of percutaneous spinal cord stimulation, AND
    - Experienced significant pain reduction (50% or more) AND, either:
      - Reduction of chronic opioid medications (if applicable), OR
      - Objective and clinically meaningful degree of functional improvement

- **Nonsurgical refractory back pain (NSRBP) when each of the following are met:**
  - Persistent low-back and neuropathic leg pain

- Moderate to severe [≥5 on the visual analog scale (VAS) pain scale] **neuropathic pain and objective neurologic impairment** with documented pathology related to pain complaint (i.e., abnormal MRI). Neurologic impairment is defined as objective evidence of one or more of the following:
  - Markedly abnormal reflexes
  - Segmental muscle weakness
  - Segmental sensory loss
  - Electromyography (EMG) or nerve conduction study (NCS) evidence of nerve root impingement
- Functional disability assessed using the Oswestry Disability Index (ODI); **ODI score ≥21%**, AND
- **Psychological evaluation** and appropriate treatment for substantial mental health disorders, AND
- 12 months of **conservative medical management in total**, comprised of regular attendance, participation and compliance with a multidisciplinary approach including:
  - Full course of physical therapy, AND
  - Cognitive behavioral therapy AND
  - Another modality of conservative management (e.g., acupuncture, chiropractic)
- Must meet above criteria prior to percutaneous trial
- **7 to 14 day trial** of percutaneous spinal cord stimulation, AND
  - Experienced significant pain reduction (50% or more) AND, either:
    - Reduction of chronic opioid medications (if applicable), OR
    - Objective and clinically meaningful degree of functional improvement

- **Painful diabetic neuropathy (PDN) when each of the following are met:**
  - Diagnosis of diabetes for 12 months or greater.
  - Moderate to severe [≥5 on the visual analog scale (VAS) pain scale] **neuropathic pain and objective neurologic impairment** with documented pathology related to pain complaint. Neurologic impairment is defined as objective evidence of one or more of the following:
    - Sensory loss determined by monofilament exam or nerve conduction study/electromyography (EMG) in a pattern consistent with diabetic neuropathy
  - **Psychological evaluation** and appropriate treatment for substantial mental health disorders, AND
    - 12 months of **conservative medical management in total**, comprised of compliance with a comprehensive trial of drug therapy for PDN (e.g., gabapentin)
  - Meets above criteria prior to percutaneous trial
  - **7 to 14 day trial** of percutaneous spinal cord stimulation, AND
    - Experienced significant pain reduction (50% or more) AND, either:
      - Reduction of chronic opioid medications (if applicable), OR
      - Objective and clinically meaningful degree of functional improvement

Non-covered indicators:

Coverage is excluded when any of the following are present:

- Life expectancy less than one (1) year
- Hemoglobin A1C (HbA1C) >10 (for PDN)
- Body mass index (BMI) >45

- Maximum daily morphine milligram equivalent (MME) ≥120
- Concurrent, untreated, substance use disorder (including alcohol, prescription or illicit drugs) per American Society of Addiction Medicine (ASAM) guidelines
- Active, substantial chronic pain in other regions that have required treatment in the past year
- Related or pending worker's compensation claim (for FBSS and NSRBP)
- Pending or existing litigation for the condition being treated with SCS

Related documents:

- Final key questions
- Final evidence report
- Meeting materials and transcript

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public and School Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee discussed and voted separately on the evidence for the use of SCS for failed back surgery syndrome, nonsurgical refractory back pain, painful diabetic neuropathy, and complex regional pain syndrome. The committee decided that the current evidence on SCS for included conditions is sufficient to determine coverage. The committee considered the evidence, public comment and expert input, and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover with conditions SCS for failed back surgery syndrome, non-surgical refractory back pain, and painful diabetic neuropathy. The committee voted not to cover SCS for complex regional pain syndrome.

Note on final decision: The committee received comment, reviewed evidence and drafted coverage criteria over the course of 3 meetings with a final vote on the draft coverage determination on May 17, 2024.

May 17, 2024 Vote

	Not covered	Covered under certain conditions	Covered unconditionally
SCS for failed back surgery syndrome	4	5	0
SCS for non-surgical refractory back pain	4	5	0
SCS for painful diabetic neuropathy	3	6	0
SCS for complex regional pain syndrome	7	2	0

Discussion

The committee reviewed and discussed the available studies for use of SCS for failed back surgery syndrome, non-surgical refractory back pain, painful diabetic neuropathy, and complex regional pain syndrome. Conditions for coverage were discussed and a draft was started, but not completed by the time the November 17, 2023 meeting was adjourned. On February 16, 2024, the committee began their review and discussion of available studies for use of SCS. Committee deliberation included straw poll voting on the evidence using the Decision Aid. The committee began to review potential coverage criteria on SCS for failed back surgery syndrome, painful diabetic neuropathy, and nonsurgical refractory back pain. A formal vote and draft coverage criteria were not completed by the time the meeting was adjourned. On May 17, 2024 members drafted coverage criteria for failed back surgery syndrome, nonsurgical refractory back pain, painful diabetic neuropathy, and complex regional pain syndrome and voted on a draft findings and decision exclusive to SCS for complex regional pain syndrome. Details of study design, inclusion criteria, outcomes, cost, cost-effectiveness, and other factors affecting study quality were discussed as well as clinical application.

Decision

SCS is covered with conditions for the following:

HTCC determination SCS
Adults (18 and over)
Proposed Criteria FBSS or NSRCBP:

- FBSS- at least 12 months post-surgery, persistent low-back and neuropathic leg pain
- Nonsurgical refractory chronic back pain- persistent low-back and neuropathic leg pain
- The patient has moderate to severe (>5 on the VAS pain scale) **neuropathic pain and objective neurologic impairment** with documented pathology related to pain complaint (i.e., abnormal MRI). Neurologic impairment is defined as objective evidence of one or more of the following:
  - Markedly abnormal reflexes
  - Segmental muscle weakness
  - Segmental sensory loss
  - EMG or NCV evidence of nerve root impingement
- Member's functional disability assessed using the Oswestry Disability Index (ODI); member has received an **ODI score greater than or equal to 21%**, AND
- **Psychological evaluation** and appropriate treatment for substantial mental health disorders, AND
- 12 months of **conservative medical management in total**, comprised of regular attendance, participation and compliance with a multidisciplinary approach including:
  - Full course of physical therapy, AND
  - Cognitive behavioral therapy AND
  - Another modality of conservative management (acupuncture, chiropractic)
- Patient meets above criteria prior to percutaneous trial.
- Patient underwent a **7 to 14 day trial** of percutaneous spinal cord stimulation, and
  - Experienced significant pain reduction (50% or more) AND, either:
  - Reduction of chronic opioid medications (if applicable) OR
  - Showed objective and clinically meaningful degree of functional improvement

Exclusion criteria

- Life expectancy < 1 year
- MED >=120
- Concurrent, untreated, substance use disorder (including alcohol, prescription or illicit drugs) per ASAM guidelines
- Related pending or existing worker's compensation claim
- Active, substantial chronic pain in other regions that have required treatment in the past year

Pending or existing litigation for the condition being treated with SCS

Proposed Criteria PDN:

- PDN- Diagnosis of diabetes for 12 months or greater.
- The patient has moderate to severe (>=5 on the VAS pain scale) **neuropathic pain and objective neurologic impairment** with documented pathology related to pain complaint. Neurologic impairment is defined as objective evidence of one or more of the following:

  - Sensory loss determined by monofilament exam or nerve conduction study/EMG in a pattern consistent with diabetic neuropathy

- **Psychological evaluation** and appropriate treatment for substantial mental health disorders, AND
  - 12 months of **conservative medical management in total**, comprised of compliance with a comprehensive trial of drug therapy for PDN (e.g., gabapentin)
- Patient meets above criteria prior to percutaneous trial.
- Patient underwent a **7 to 14 day trial** of percutaneous spinal cord stimulation, and
  - Experienced significant pain reduction (50% or more) AND, either:
  - Reduction of chronic opioid medications (if applicable) OR
  - Showed objective and clinically meaningful degree of functional improvement

Exclusion criteria

- Life expectancy < 1 year
- Hba1c>10
- BMI>45
- MED >=120
- Concurrent, untreated, substance use disorder (including alcohol, prescription or illicit drugs) per ASAM guidelines
- Active, substantial chronic pain in other regions that have required treatment in the past year
- Pending or existing litigation for the condition being treated with SCS

SCS is not a covered benefit for treatment of complex regional pain syndrome.

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Based on the information provided in the systematic review, there is an NCD for electrical nerve stimulators:

- NCD – Electrical Nerve Stimulators (160.7) - There are two types of implantations covered by this instruction: Dorsal Column (Spinal Cord) Neurostimulation - The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered. Depth Brain Neurostimulation - The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

The committee discussed clinical guidelines identified from the following organizations:

- American Society of Regional Anesthesia and Pain Medicine, *2023*
- Dutch Quality of Healthcare Institute, 2022
- European Academy of Neurology, *2016*
- Dutch Orthopedic Association and the Dutch Neurosurgical Society, *2015*
- American Society of Interventional Pain Physicians, *2013*

- Neuropathic Pain Special Interest Group, *2013*
- Canadian Pain Society, *2012*
- Neuromodulation Access Therapy Coalition, *2008*
- National Institute for Health and Care Excellence, *2014 Technology appraisal guidance [TA159]*

The recommendations of the guidelines vary. The committee's determination is consistent with the noted guidelines.

HTA staff will prepare a findings and decision document on use of spinal cord stimulation for the treatment of selected conditions for public comment to be followed by consideration for final approval at the next committee meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company that takes public input at all stages.

Pursuant to RCW 70.14.110, a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.