Washington State Health Care Authority

June 14, 2024 Meeting Materials
Health Technology Clinical Committee

Previous meeting business

Contents

Washington State Health Care Authority

Health Technology Clinical Committee

Date: May 17, 2024
Time: 8:00 a.m. – 4:00 p.m.
Location: Webinar
Adopted: Pending

Meeting materials and transcript are available on the **HTA website.**

HTCC Minutes

Members present: Clinton Daniels, DC, MS; Janna Friedly, MD, MPH; Chris Hearne, DNP, MPH; Conor Kleweno, MD; Christoph Lee, MD, MS; Laurie Mischley, ND, MPH, PhD; Sheila Rege, MD; Jonathan Sham, MD; Tony Yen, MD
Clinical experts: Joseph Strunk, MD & Judy Chen, MD

HTCC Formal Action

1. **Welcome and Chair remarks:** Dr. Rege, chair, called the meeting to order; members present constituted a quorum.
2. **HTA program updates:** Josh Morse, program director, presented HTCC meeting protocols and guidelines, and an overview of the HTA program.
3. **Previous meeting business:**

   February 16, 2024 meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

   Action: Nine committee members approved the February 16, 2024 meeting minutes.

   Vote on stereotactic body radiation therapy (SBRT) for renal cancer findings and decision:

   Action: Five committee members voted on draft SBRT for renal cancer findings and decision at the February 16, 2024 meeting. Motion made and seconded, then nine members voted to accept the votes from February 16 and confirm the draft SBRT for renal cancer findings and decision.

4. **Spinal cord stimulation (SCS)**

   HTCC discussion and action:

   Discussion

   The committee drafted coverage criteria for use of SCS for the treatment of failed back surgery syndrome (FBSS), nonsurgical refractory back pain (NSRBP), complex regional pain syndrome (CRPS), and painful diabetic neuropathy (PDN). 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 FBSS, NSRBP, CRPS, and PDN. The committee decided that the current

evidence on SCS for FBSS, NSRBP, and PDN is sufficient to determine coverage with conditions. 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 FBSS, NSRBP, and PDN. Separately, the committee voted not to cover SCS for CRPS.

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.

5. Bariatric surgery

Washington State agency utilization and outcomes: Judy Zerzan-Thul, MD, MPH, Chief Medical Officer, Health Care Authority, presented the state agency perspective on Metabolic and Bariatric Surgery: New Populations and Procedures. Find the full presentation published with the May 17, 2024 meeting materials.

Scheduled and open public comments: Chair called for public comments. There were no comments provided.

Vendor report/HTCC questions and answers: Shannon Robalino, MSc presented the evidence review for Metabolic and Bariatric Surgery: New Populations and Procedures. The full presentation is published with the May 17, 2024 meeting materials.

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 adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for adults and adolescents. The committee decided that the current evidence on adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for use in adults and adolescents is sufficient to determine coverage with conditions. 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 adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for use in adults and adolescents. Separately, the committee voted not to cover intragastric balloons for adults or adolescents.

	Not covered	Covered under certain conditions	Covered unconditionally
Adjustable gastric bands,	0	9	0

sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass in adults			
Adjustable gastric bands, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass in adolescents	0	9	0

Discussion

The committee reviewed and discussed the available studies for use of adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for adults and adolescents. Conditions for coverage were discussed, drafted, and voted on. All committee members present supported the conditions of coverage of adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for adults and adolescents. Details of study design, inclusion criteria, outcomes, cost, cost-effectiveness, and other factors affecting study quality were discussed as well as clinical application.

Committee's draft determination

Bariatric surgery is covered with conditions for the following:

- **Approved procedures include:**
    - Adjustable gastric banding
    - Sleeve gastrectomy
    - Endoscopic sleeve gastroplasty
    - Roux-en-Y gastric bypass
    - Biliopancreatic diversion with or without duodenal switch
    - Single-anastomosis duodenal ileostomy with sleeve gastrectomy

  - One-anastomosis gastric bypass
- **Adults**
  - Adults with body mass index (BMI) ≥35 (non-Asian descent) OR BMI ≥32.5 (Asian descent), OR
  - Adults with type 2 diabetes mellitus (T2DM) AND BMI ≥30 (non-Asian descent) OR BMI ≥27.5 (Asian descent)

  AND

  - Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation
- **Adolescents**
  - Adolescents (13+) with bone maturity AND BMI ≥40 OR BMI ≥35 with one obesity-related complication

  AND

  - Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation

Non-covered indicators

- Intragastric balloons are not a covered benefit

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 bariatric surgery:

- Centers for Medicare and Medicaid Services (CMS) National Coverage Determination

  In 2006, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) limiting Medicare coverage to accredited centers[154]; subsequently, by 2010 almost 90% of MBS procedures were performed in accredited centers.[150,153] Although CMS ultimately reversed the facility accreditation requirement in 2013, citing inconsistent outcomes at bariatric centers of excellence and concern regarding access limitations, participation in national accreditation has remained high.[150,153,155-157]

The committee discussed clinical guidelines identified from the following organizations:

- American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (2022)
- Referral of Adults with Obstructive Sleep Apnea for Surgical Consultation: An American Academy of Sleep Medicine Clinical Practice Guideline (2021)
- American Gastroenterological Association (AGA) Clinical Practice Guidelines on Intragastric Balloons in the Management of Obesity (2021)
- VA/DoD Clinical Practice Guideline for the Management of Adult Overweight and Obesity (2020)
- Clinical Practice Guidelines for the Perioperative Nutrition, Metabolic, and Nonsurgical Support of Patients Undergoing Bariatric Procedures - 2019 Update: Cosponsored by American Association of

Clinical Endocrinologists/ American College of Endocrinology, The Obesity Society, American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists (2020)

- 2022 American Society for Metabolic and Bariatric Surgery and International Federation for the Surgery of Obesity and Metabolic Disorders Indications for Metabolic and Bariatric Surgery (2023)
- American Society for Metabolic and Bariatric Surgery Updated Statement on Single-Anastomosis Duodenal Switch (2020)
- American Society for Metabolic and Bariatric Surgery position statement on one-anastomosis gastric bypass (2024)
- Evaluation and Treatment of Obesity and Its Comorbidities: 2022 Update of Clinical Practice Guidelines for Obesity by the Korean Society for the Study of Obesity (2023)
- Metabolic Surgery in Treatment of Obese Japanese Patients with Type 2 Diabetes: A Joint Consensus Statement from the Japanese Society for Treatment of Obesity, the Japan Diabetes Society, and the Japan Society for the Study of Obesity (2022)
- European Guideline on Obesity Care in Patients with Gastrointestinal and Liver Diseases - Joint European Society for Clinical Nutrition and Metabolism / United European Gastroenterology Guideline (2022)
- IFSO Update Position Statement on One Anastomosis Gastric Bypass (OAGB) (2021)
- Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS) IFSO Position Statement-Update 2020 (2021)
- Clinical Practice Guidelines of the European Association for Endoscopic Surgery (EAES) on Bariatric Surgery: Update 2020. Endorsed by IFSO-EC, EASO and ESPCOP
- Clinical Practice Guidelines for Childbearing Female Candidates for Bariatric Surgery, Pregnancy, and Post-partum Management After Bariatric Surgery (2019)
- Obesity Canada and the Canadian Association of Bariatric Physicians and Surgeons Clinical Practice Guidelines: Bariatric Surgery: Surgical Options and Outcomes (2020)
- Remission of Type 2 Diabetes: Diabetes Canada Clinical Practice Guidelines Expert Working Group (2022)
- Ministry of Public Health Qatar National Clinical Guideline: Bariatric & Metabolic Surgery in Adults (2021)
- NICE Guideline: Overweight and Obesity Management: Draft for Consultation (*Expected 2024*)
- NICE Interventional Procedures Guidance: Endoscopic Sleeve Gastroplasty for Obesity (2024)
- European Association for Endoscopic Surgery Rapid Guideline: Systematic Review, Network Meta-Analysis, CINeMA and GRADE assessment, and European Consensus on Bariatric Surgery-Extension 2022

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 bariatric surgery for public comment to be followed by consideration for final approval at the next committee meeting.

6. **Debrief and HTCC scheduling:** The committee discussed recent absences, upcoming meetings, and potential scheduling changes to allow full participation for members.
7. **Meeting adjourned**

Washington State Health Care Authority

Bariatric surgery

Draft findings and decision
Timeline, overview and comments

Timeline

Phase	Date	Public Comment Days
Selected technologies published	July 7, 2023	
Public comments	July 7 to August 7, 2023	**31**
Draft key questions published	October 19, 2023	
Public comments	October 19 to November 1, 2023	**14**
Final key questions published	November 15, 2023	
Draft report published	March 1, 2024	
Public comments	March 1 to April 1, 2024	**31**
Final report published	April 23, 2024	
Public meeting	May 17, 2024	
Draft findings & decision published	May 21, 2024	
Public comments	May 21 to June 3, 2024	**14**

Overview

Category	Comment Period *May 21 to June 3, 2024*	Cited Evidence
Patient, relative, and citizen	0	-
Legislator and public official	0	-
Health care professional	5	Yes
Industry & manufacturer	1	No
Professional society & advocacy organization	0	-
Total	**6**	

Comments

	Respondents	Representing	Cited Evidence
☐ 1.	Mark Eichler, MD	Peace Health Southwest	Yes
☐ 2.	Geri Cramer	Boston Scientific	No
☐ 3.	Travis Piester, MD	Seattle Children's Hospital	No
☐ 4.	Brandon VanderWel, MD	Evia	Yes
☐ 5.	L. Mimi Tan, MD	Evia	No
☐ 6.	Rob Landerholm, MD	Evia	No

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: New bariatric surgery guidelines
Date: Friday, May 31, 2024 11:35:58 AM

External Email

As a bariatric surgeon, I am in agreement with the newer guidelines from the last year or so that have been updated to include BMI 35 or BMI 30 w/ at least 1 weight-related comorbid condition. The other parameters I am in favor for as well.

We should also send letters from the ASMBS of the new guidelines to ALL insurance companies so they can get on board.

Dr. Mark Eichler, MD
Director of Bariatric Surgery
PeaceHealth Southwest
[redacted]

https://asmbs.org/news_releases/after-30-years-new-guidelines-for-weight-loss-surgery/

After 30 Years — New Guidelines For Weight-Loss Surgery

For Immediate Release October 21, 2022 CONTACT: Roger Kissin rkissin@compartnersny.com NEWBERRY, FL – Oct. 21, 2022 – Two of the world's leading authorities on bariatric and metabolic surgery have...

asmbs.org

Mark Eichler

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: 20240517B - Bariatric Surgery
Date: Monday, June 3, 2024 3:05:42 PM
Attachments: image001.png
image002.png
Washington State Supportive Letter Boston Scientific.pdf

External Email

Dear Health Technology Clinical Committee,

Please find attached a letter of support for the draft bariatric surgery policy.

With warm regards,

Geri Cramer, PhD, MBA, BSN
Director, Health Economics and Market
[redacted]
Boston Scientific
Advancing science for life™

Boston Scientific Corporation
[redacted]

June 3, 2024

SUBMITTED ELECTRONICALLY:

Sheila Rege, MD
Chair, Health Technology Clinical Committee
Washington State Health Care Authority
Cherry Street
626 8th Avenue SE
Olympia, WA 98501

Health Technology Clinical Committee DRAFT Findings and Decision: 20240517B - Bariatric Surgery

Dear Chairwoman Rege:

Boston Scientific Corporation appreciates the opportunity to provide comments in response to the Washinton State Health Care Authority's Health Technology Clinical Committee's draft findings and decision on Bariatric Surgery dated May 17, 2024.

As one of the world's largest companies dedicated to developing, manufacturing, and marketing less-invasive therapies, Boston Scientific supplies medical devices and technologies that are used by the following medical specialty areas:

- Cardiac Rhythm Management;
- Electrophysiology;
- Gastroenterology;
- Bariatric and Metabolic Endoscopy;
- Interventional Bronchoscopy;
- Interventional Cardiology;
- Interventional Radiology;
- Oncology;
- Neuromodulation;
- Urology; and
- Peripheral Interventions

Boston Scientific supports the decision to expand coverage of bariatric procedures in the State of Washington, specifically the addition of endoscopic sleeve gastroplasty as an approved procedure in a MBSAQIP accredited center for:

- adults with a body mass index (BMI) ≥35 (≥32.5 if of Asian descent)
- adults with BMI ≥30 (≥27.5 if of Asian descent) with type 2 diabetes mellitus (T2DM)
- adolescents (13+) with bone maturity and BMI ≥40 or BMI ≥35 with one obesity-related complication

Thank you for the opportunity to comment on this draft decision. Please contact me at [redacted] or Ann Roy, Vice President of Health Economics and Market Access, at [redacted] if you have any questions.

Sincerely,

Dr. Brian Dunkin
Chief Medical Officer
Boston Scientific Corporation
Endoscopy

Ann Roy

Ann K. Roy
Vice President
Health Economics & Market Access
Boston Scientific Corporation
Endoscopy

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Letter of support to expand coverage of bariatric procedures
Date: Monday, June 3, 2024 5:21:51 PM
Attachments: image001.png

External Email

Dear Health Technology Clinical Committee,
I am writing to lend my support to the draft policy being considered by the Washington State Health Care Authority to expand coverage of bariatric procedures for individuals in Washington State.

In my specialty treating pediatric patients for obesity and liver disease, I see patients who could benefit from having more options, including Endoscopic Sleeve Gastroplasty, to control their weight and improve their health. The health technology assessment performed by the Center for Evidence-based Policy at Oregon Health and Science University was robust. I am encouraged to see these draft recommendations.

I support finalization of the policy as written.

Thank you!
Travis Piester, MD

Travis L. Piester, MD
Director of Pancreas Program and Director of Endoscopy
Seattle Children's Hospital
Associate Professor – University of Washington School of Medicine
Seattle Children's®

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: Rob Landerholm; Gaia Lukevich; Mimi Tan
Subject: Comments regarding policy changes on bariatric surgery
Date: Monday, June 3, 2024 7:12:47 PM
Attachments: image001.png

External Email

Dear Committee members,

I whole heartedly recommend the proposed changes to bariatric surgery coverage.

It is unfortunate, but true, that obesity is the disease of our time. Bariatric surgery is the most effective therapy to treat obesity. Scientifically speaking it is the most effective, most durable, and most cost-effective therapy. Expanding its access in accordance with ASMBS/IFSO guidelines is critical to treating the epidemic of obesity. We know that the disease of obesity is much easier to reverse at a younger age and reduced lifetime morbidity and improves quality of life. It is also extremely encouraging to see the committee embrace SADI, OAGB and ESG as these therapies have demonstrated benefit in tens of thousands of patients in the published literature.

In my personal practice I have seen huge benefits to patients in all of these proposed criteria.

Obesity robs so many young, working age Washingtonians of health and quality of life.
https://www.axios.com/local/seattle/2023/04/19/washington-state-is-fighting-obesity-like-the-rest-of-the-nation
It is heartbreaking to see a patient struggle with obesity so much and not have access to the best therapy to treat their disease. But it is inspiring to see patients finally break the cycle and succeed against their obesity and comorbidities after they have had a bariatric procedure.

The proposed recommendations are an excellent step in helping Washington healthier and more productive.

Thank you again for your consideration.

Brandon VanderWel, MD
Bariatric/Metabolic Surgeon
Board Certified General Surgeon

eVIVA

[redacted]

[redacted]

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Bariatric Surgery Coverage Proposal
Date: Tuesday, June 4, 2024 9:03:19 AM
Attachments: Outlook-1yjb2ah5.png

External Email

Dear Committee Members,

I enthusiastically support the proposed expansions for coverage on bariatric surgery.

Obesity and overweight is an epidemic that affects the majority of Americans today, and the sequelae of obesity and overweight are far reaching when it comes to physical and mental health. Currently, bariatric surgery is the most effective and durable treatment for not only obesity but the many metabolic diseases that come with it. Unfortunately, access to care continues to be an issue for many individuals hoping to better their health.

I am extremely pleased to see the proposed changes that better reflect current guidelines of major medical societies that will allow many more to benefit from this highly effective treatment. I truly believe this is a major step in improving the health of our communities.

Expansion of coverage to include highly effective procedures such as the SADI, OAGB, and ESG will further allow bariatric surgeons to provide the best possible procedure fitting for our patients.

Thank you for your time.

Sincerely,

L. Mimi Tan, MD

L. Mimi Tan, MD
Bariatric/Metabolic Surgeon
Board Certified General Surgeon

eVIVA

[redacted]

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Comments regarding policy changes on bariatric surgery coverage
Date: Thursday, June 6, 2024 10:14:21 AM
Attachments: image002.png

External Email

Dear Committee members,

Expanding the parameters for bariatric/ metabolic surgery coverage is the right thing to do.

Obesity with its associated comorbidities is a killer. We know diet and exercise, although very good ideas for health, don't work well long term in the vast majority of patients that suffer with the disease of obesity. People can lose weight, but most commonly it comes back plus extra. We also know obesity shortens people's lives by 10 years or more, undermines significantly their quality of life, effects their ability to be active, and even more so their ability to work safely and efficiently.

I have been in medicine for over 40 years. Surgical weight loss is extraordinary in providing the opportunity for patients to truly be healthier, live longer and more vibrant lives.

Thank you for your consideration in this matter.

Rob Landerholm, MD, FACS
President and Medical Director

eVIVA

Washington State Health Care Authority

Health Technology Clinical Committee
DRAFT Findings and Decision

Topic: Bariatric surgery
Meeting date: May 17, 2024
Final adoption: Pending

Number and coverage topic:
20240517B – Bariatric surgery

HTCC coverage determination:
Bariatric surgery is a **covered benefit with conditions.**

HTCC reimbursement determination:
Limitations of coverage:

- **Adults**
  - Adults with body mass index (BMI) ≥35, OR Asian descent ≥32.5,
  - Adults with type 2 diabetes mellitus (T2DM) ≥30, OR Asian descent ≥27.5

  AND
  - Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation
- **Adolescents**
  - Adolescents (13+) with bone maturity AND BMI ≥40, OR ≥35 with one obesity-related complication

  AND
  - Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation
- **Approved procedures include:**
  - Adjustable gastric banding
  - Sleeve gastrectomy
  - Endoscopic sleeve gastroplasty
  - Roux-en-Y gastric bypass
  - Biliopancreatic diversion with or without duodenal switch
  - Single-anastomosis duodenal ileostomy with sleeve gastrectomy (SADI-S)
  - One-anastomosis gastric bypass (OAGB)

Non-covered indicators:

- Intragastric balloons are not a covered benefit

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 adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for adults and adolescents. The committee decided that the current evidence on adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for use in adults and adolescents is sufficient to determine coverage with conditions. 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 adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for use in adults and adolescents. Separately, the committee voted not to cover intragastric balloons for adults or adolescents.

	Not covered	Covered under certain conditions	Covered unconditionally
Adjustable gastric bands, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass in adults	0	9	0
adjustable gastric bands, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single anastomosis duodenal ileostomy with sleeve gastrectomy, and	0	9	0

one-anastomosis gastric bypass in adolescents

Discussion

The committee reviewed and discussed the available studies for use of adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for adults and adolescents. Conditions for coverage were discussed, drafted, and voted on. All committee members present supported the conditions of coverage of adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for adults and adolescents. Details of study design, inclusion criteria, outcomes, cost, cost-effectiveness, and other factors affecting study quality were discussed as well as clinical application.

Decision

Bariatric surgery is covered with conditions for the following:

- **Approved procedures include:**
    - Adjustable gastric banding
    - Sleeve gastrectomy
    - Endoscopic sleeve gastroplasty
    - Roux-en-Y gastric bypass
    - Biliopancreatic diversion with or without duodenal switch
    - Single-anastomosis duodenal ileostomy with sleeve gastrectomy
    - One-anastomosis gastric bypass
- **Adults**
    - Adults with body mass index (BMI) ≥35, OR Asian descent ≥32.5,
    - Adults with type 2 diabetes mellitus (T2DM) ≥30, OR Asian descent ≥27.5

  AND
    - Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation
- **Adolescents**
    - Adolescents (13+) with bone maturity AND BMI ≥40, OR ≥35 with one obesity-related complication

  AND
    - Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation

Bariatric surgery is not a covered benefit for the use of intragastric balloons in adults or adolescents.

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 bariatric surgery:

- **Centers for Medicare and Medicaid Services (CMS) National Coverage Determination**

In 2006, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) limiting Medicare coverage to accredited centers[154]; subsequently, by 2010 almost 90% of MBS procedures were performed in accredited centers.[150,153] Although CMS ultimately reversed the facility accreditation requirement in 2013, citing inconsistent outcomes at bariatric centers of excellence and concern regarding access limitations, participation in national accreditation has remained high.[150,153,155-157]

The committee discussed clinical guidelines identified from the following organizations:

- American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (2022)
- Referral of Adults with Obstructive Sleep Apnea for Surgical Consultation: An American Academy of Sleep Medicine Clinical Practice Guideline (2021)
- American Gastroenterological Association (AGA) Clinical Practice Guidelines on Intragastric Balloons in the Management of Obesity (2021)
- VA/DoD Clinical Practice Guideline for the Management of Adult Overweight and Obesity (2020)
- Clinical Practice Guidelines for the Perioperative Nutrition, Metabolic, and Nonsurgical Support of Patients Undergoing Bariatric Procedures - 2019 Update: Cosponsored by American Association of Clinical Endocrinologists/ American College of Endocrinology, The Obesity Society, American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists (2020)
- 2022 American Society for Metabolic and Bariatric Surgery and International Federation for the Surgery of Obesity and Metabolic Disorders Indications for Metabolic and Bariatric Surgery (2023)
- American Society for Metabolic and Bariatric Surgery Updated Statement on Single-Anastomosis Duodenal Switch (2020)
- American Society for Metabolic and Bariatric Surgery position statement on one-anastomosis gastric bypass (2024)
- Evaluation and Treatment of Obesity and Its Comorbidities: 2022 Update of Clinical Practice Guidelines for Obesity by the Korean Society for the Study of Obesity (2023)
- Metabolic Surgery in Treatment of Obese Japanese Patients with Type 2 Diabetes: A Joint Consensus Statement from the Japanese Society for Treatment of Obesity, the Japan Diabetes Society, and the Japan Society for the Study of Obesity (2022)
- European Guideline on Obesity Care in Patients with Gastrointestinal and Liver Diseases - Joint European Society for Clinical Nutrition and Metabolism / United European Gastroenterology Guideline (2022)
- IFSO Update Position Statement on One Anastomosis Gastric Bypass (OAGB) (2021)
- Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS) IFSO Position Statement-Update 2020 (2021)
- Clinical Practice Guidelines of the European Association for Endoscopic Surgery (EAES) on Bariatric Surgery: Update 2020. Endorsed by IFSO-EC, EASO and ESPCOP

- Clinical Practice Guidelines for Childbearing Female Candidates for Bariatric Surgery, Pregnancy, and Post-partum Management After Bariatric Surgery (2019)
- Obesity Canada and the Canadian Association of Bariatric Physicians and Surgeons Clinical Practice Guidelines: Bariatric Surgery: Surgical Options and Outcomes (2020)
- Remission of Type 2 Diabetes: Diabetes Canada Clinical Practice Guidelines Expert Working Group (2022)
- Ministry of Public Health Qatar National Clinical Guideline: Bariatric & Metabolic Surgery in Adults (2021)
- NICE Guideline: Overweight and Obesity Management: Draft for Consultation (*Expected 2024*)
- NICE Interventional Procedures Guidance: Endoscopic Sleeve Gastroplasty for Obesity (2024)
- European Association for Endoscopic Surgery Rapid Guideline: Systematic Review, Network Meta-Analysis, CINeMA and GRADE assessment, and European Consensus on Bariatric Surgery-Extension 2022

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 bariatric surgery 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.

Washington State Health Care Authority

Spinal Cord Stimulation

Draft findings and decision
Timeline, overview and comments

Timeline

Phase	Date	Public Comment Days
Selected technologies published	August 2022	
Public comments	August 11 to September 12, 2022	**32**
Draft key questions published	April 20, 2023	
Public comments	April 20 to May 3, 2023	**14**
Final key questions published	June 15, 2023	
Draft report published	September 1, 2023	
Public comments	September 1 to October 2, 2023	**31**
Final report published	October 23, 2023	
Public meeting	November 17, 2023, February 14, 2024 & May 17, 2024	
Draft findings & decision published	May 21, 2024	
Public comments	May 21 to June 3, 2024	**14**

Overview

Category	Comment Period *May 20 to June 4, 2024*	Cited Evidence
Patient, relative, and citizen	0	-
Legislator and public official	0	-
Health care professional	1	Yes
Industry & manufacturer	1	Yes
Professional society & advocacy organization	1	Yes
Total	**3**	

Comments

	Respondents	Representing	Cited Evidence
☐ 1.	Nilesh Patel, MD	SCS manufacturers group	Yes
☐ 2.	Virtaj Singh, MD	SCS provider workgroup	Yes
☐ 3.	Keri Kramer	Multiple pain societies/associations	Yes
☐ 4.			
☐ 5.			

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Public comment open HTCC Neuromodulation for pain
Date: Monday, June 3, 2024 7:49:00 AM
Attachments: WA HTCC Draft Findings and Decision - SCS Industry Comment Letter_vF.docx

External Email

Dear Members of the Health Technology Clinical Committee, Washington State Health Care Authority,

We thank you for making the determination of Spinal Cord Stimulation (SCS) as a 'covered benefit with conditions' for patients with various pain etiologies. While the draft findings and decision are largely positive, there are a few items worth addressing to ensure optimal access to SCS therapy for appropriate patients. Attached you will find a letter co-signed by various SCS manufacturers in the industry including, Abbott, Biotronik, Boston Scientific, Medtronic, Nevro, and Saluda.

We appreciate the opportunity to provide feedback and look forward to the finalization of this policy, so as to alleviate much suffering and pain that is currently not addressed with conventional therapies.

Nilesh Patel MD, MBA

VIA Electronic Submission to Shtap@hca.wa.gov

June 3, 2024

Re: Health Technology Clinical Committee (HTCC) Draft Findings and Decision on Spinal Cord Stimulation (SCS)

To Members of the Health Technology Clinical Committee,

We appreciate the opportunity to submit comments to the Washington State Health Care Authority's (HCA) Draft Findings and Decision on Spinal Cord Stimulation (SCS). Given the overwhelming volume of peer-reviewed clinical evidence and broad adoption of SCS by private and public payers as a safe and effective therapy for chronic pain, we appreciate the thoughtful and deliberate re-review of the evidence by the HTCC and the draft coverage position for SCS therapies with reasonable, evidence-based coverage criteria. Washington (WA) remains the only State in the US that does not currently cover SCS for any indications. This proposed policy change will provide residents of WA the same level of medical care as in all other states including those with both commercial insurance and Medicare coverage. When clinically appropriate, as determined by their physicians, suffering WA residents deserve access to this demonstrated clinically safe and effective therapy.

The signatories of this letter represent global medical device companies involved in the delivery of high quality and clinically appropriate treatment to patients suffering from debilitating chronic pain. Collectively, the companies have developed and commercialized a number of evidence-based, non-pharmacologic neuromodulation platforms that deliver electrical stimulation for the treatment of chronic intractable pain. These products, approved by the FDA, are indicated for patients suffering from a range of conditions including but not limited to:

- Failed back surgery syndrome;
- Intractable low back pain, leg pain;
- Painful diabetic peripheral neuropathy; and
- Non-surgical refractory back pain[1]

After reviewing the revised draft findings and decision, we commend the HTCC for its proposed coverage of SCS for failed back surgery syndrome (FBSS), non-surgical refractory back pain (NSRBP), and painful diabetic neuropathy (PDN). We thank the Committee for the detailed review and consideration of the clinical evidence and the feedback from stakeholders during the last eighteen months across three different meetings. While we appreciate the revised draft position on coverage for SCS, we have concerns about some language in the draft limitations of coverage and exclusion criteria. Our feedback and recommendations are detailed below.

Conservative Medical Management

The draft findings and coverage state the following criteria for conservative or conventional medical management (CMM):

> *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)*

We support the requirement for failed CMM therapies for a period of time as this criterion is consistent with coverage policies from other payers. However, we have concerns with the level of specificity in the CMM

[1] Specific indication varies by manufacturer.

therapies articulated in the draft policy. If the HTCC can confirm that patients with policies administered by the State specifically can obtain coverage for the aforementioned CMM therapies and can thus ensure that no patient has to pay completely out-of-pocket for the above therapies, then this level of specificity is reasonable and appropriate. In addition, patients may not receive certain CMM therapies if the therapies are deemed to be unsuitable or contraindicated by their physician. ***Thus, we recommend alternative language that broadly specifies "multi-modal failed CMM therapies" without stating which therapies the patients must have tried and failed.***

We have serious concerns as to the length of time – 12 months – required for CMM prior to becoming eligible for SCS. This timeline is inconsistent with existing coverage policies that require failed therapies (a) without specifying a time frame[2][3] or (b) for a minimum of six months.[4] Additionally, the 12 month CMM requirement is in conflict with the inclusion / exclusion criteria of almost all the published studies considered in the WA HCA Final Evidence Report[5]. Nearly all of the listed studies required six months or less of conventional medical management. Chronic pain duration of the patients in these studies is an inappropriate proxy for length of CMM treatments. This position also conflicts with the recommendations articulated by the U.S. Health and Human Services Pain Management Best Practices Task Force which recommends that "CMS and private payers to provide consistent and timely insurance coverage for evidence-informed interventional procedures".[6] Furthermore, requiring 12 months of failed CMM for patients with persistent low-back and neuropathic leg pain may be detrimental to a patient's health and quality of life. It also poses a risk of addiction to opioids for patients for whom physicians prescribe opioids to address their chronic and persistent pain. The Centers for Disease Control & Prevention, in its recent Opioid Prescribing Guidelines, detailed recommendations regarding the risks of initiating opioid therapy and for continuing opioid therapy.

> *If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully evaluate individual benefits and risks when considering increasing dosage, and should avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients (recommendation category: A; evidence type: 3). (Recommendation 4)*[7]

Requiring at least 12 months of failed CMM therapies such as opioid therapy increases the risk of continued usage or escalation of dosage; this risk is outweighed by the benefits of access to clinically proven alternative therapies such as SCS. Not only does SCS serve as an alternative to opioid therapy, there is published evidence from a randomized controlled trial (RCT) that it can lead to a decreased use or complete stoppage of opioid therapy. Specifically, 24-month data from one of the largest RCTs studying NSRBP patients demonstrated that 62% patients using opioids decreased or stopped use of opioids. Access to opioid-sparing therapies such as SCS are vital to patients with chronic intractable pain who have exhausted conservative treatment options."[8] ***In consideration of this evidence, we urge the HTCC to revise its draft coverage position to six months of conservative medical management failing to provide adequate pain control.***

Persistent Low-Back and Neuropathic Leg Pain

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[2] Premera Blue Cross Medical Policy (7.01.546) - Spinal Cord and Dorsal Root Ganglion Stimulation. Last revised January 1, 2024.

[3] Medicare National Coverage Determination (160.7) – Electrical Nerve Stimulators.

[4] Aetna Clinical Policy Bulletin (CPB 0194) – Spinal Cord Stimulation. Last reviewed April 16, 2024.

[5] Spinal Cord Stimulation – Rereview Final Evidence Report, Published October 23, 2023

[6] U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations.

[7] Dowell D, Ragan KR, Jones CM, et al. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022. *MMWR Recomm Rep* 2022;71(No. RR-3):1–95. DOI:http://dx.doi.org/10.15585/mmwr.rr7103a1.

[8] Kapural L, Jameson J, Johnson C, et al. Treatment of nonsurgical refractory back pain with high-frequency spinal cord stimulation at 10 kHz: 12-month results of a pragmatic, multicenter, randomized controlled trial. *J Neurosurg Spine*. 2022 Feb 11;37(2):188-199. doi: 10.3171/2021.12.SPINE211301. Print 2022 Aug 1.

The limitations of coverage for FBSS and NSRBP require that the patient have "persistent low-back and neuropathic leg pain". Our clinical experience is that patients may not exclusively have neuropathic pain but rather may also have "mixed" pain with elements of neuropathic and nociceptive pain. Armstrong and Herr have defined these two types of pain as follows:

> *[N]ociceptive pain arises from tissues damaged by physical or chemical agents such as trauma, surgery, or chemical burns, while neuropathic pain arises from diseases or damage mediated directly to sensory nerves, such as diabetic neuropathy, shingles, or postherpetic neuralgia.*[9]

As SCS is not a first-line therapy but rather a therapy of last resort, patients eligible for SCS therapy often are experiencing both types (or overlapping types) of pain.[10] ***Given this relatively common patient characteristic, we ask that the language limiting the criteria to neuropathic pain be removed or revised to allow for persistent low-back or neuropathic leg pain.***

Spinal Cord Stimulation Trial and Oswestry Disability Index (ODI)

For all three proposed indications, the draft limitations of coverage require the following:

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

While the requirement for a SCS trial is consistent with other public and private payers, we disagree with the specified timeframe for the trial for the following reasons. First, the length of the trial proposed is in conflict with the 2023 guidelines from the American Society of Regional Anesthesia and Pain Medicine (ASRA). These guidelines found that these trials typically last a few days to "allow for the assessment of treatment efficacy and guide decisions for permanent implantation." Furthermore, it recommends against a trial duration of greater than 10 days as "extended duration is associated with higher risk of infection and usually has no clear advantages."[11]

Second, the timeframe stated in this draft coverage policy is inconsistent with other payers such as Aetna, Premera Blue Cross, Blue Cross Blue Shield of Anthem, and United Healthcare which require a trial length of at least three (3) days. Third, many manufacturers have trial leads that have only received approval by the FDA for 10-days of use and as such, requiring a trial for a longer period of time would be in conflict with the device's indications for use. ***As such, we request a revision of the proposed language to state a minimal trial duration (e.g., 3 days) or a shorter time range (e.g., 3 – 7 days).***

We support the proposed language requiring significant pain reduction (>50%) as well as the objective and meaningful degree of functional improvement (without specifying the level of functional improvement against baseline or the specific scale used to measure functioning). To that end, we request that the specific language on Oswestry Disability Index (ODI) in the FBSS and NSRBP be removed as this metric is not common in existing coverage policies and thus may not be widely used in practice. Given the language specific to improvement in the trial, we do not think this language is relevant or necessary in this draft policy.

Painful Diabetic Neuropathy

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[9] Armstrong SA, Herr MJ. Physiology, Nociception. 2023 May 1. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan–. PMID: 31855389.

[10] Matis G, Jain R. Clinical Utilization of Fast-Acting Sub-Perception Therapy (FAST) in SCS-Implanted Patients for Treatment of Mixed Nociceptive and Neuropathic Pain. *Neuromodulation*. 2024; 26(3), S20.

[11] Shanthanna H, Eldabe S, Provenzano DA, et al. Evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation therapy for chronic non-cancer pain. *Regional Anesthesia & Pain Medicine*. 2023;48:273-287.

The limitations of coverage for PDN in the draft document require that a patient have moderate to severe neuropathic pain and objective neurologic impairment which is defined in this document as "objective evidence of … sensory loss determined by monofilament exam or nerve conduction study/EMG in a pattern consistent with diabetic neuropathy." We disagree with this proposed language for two reasons. First, this criterion is inconsistent with the inclusion and exclusion criteria of previously conducted as well as PDN trials underway. Second, we are concerned that requiring confirmation of sensory loss (which is inconsistent with standard practice by pain management practitioners) in addition to pain severity might lead to additional referrals to other specialists (and associated costs). As a result, patients will have additional barriers to access to a therapy that already a therapy of last resort.

In the discussion regarding the SCS trial, it requires a reduction of chronic opioid medications (if applicable) or demonstrated objective and clinically meaningful degree of functional improvement. We disagree with the language specific to chronic opioid medications for painful diabetic neuropathy as it is inconsistent with recommendations from the American Diabetes Association. In their position statement on diabetic neuropathy, the ADA states the following:

> Given the high risks of addiction and other complications, the use of opioids, including tapentadol or tramadol, is not recommended as first- or second-line agents for treating the pain associated with DSPN.[12]

For these reasons, we request that the Committee remove the language specific to documented sensory loss or reduction in chronic opioid medications as it is inconsistent with current practice.

In the draft findings and decision posted on May 24, the exclusion criteria specific to A1c were revised to only apply to PDN. We thank the Committee members for this revision as that criterion is not applicable for the other draft covered indications. ***We ask the Committee to finalize this language as drafted***.

Pending Worker's Compensation Claim

We disagree with the limitations of coverage for patients without a related or pending worker's compensation claim for FBSS or NSRBP. Given that many back-related injuries could be work-related, excluding these patients from access to SCS could eliminate one of the remaining late or last resort therapies.

While not discussed live during public meetings, two studies evaluating SCS for patients with worker's compensation coverage with failed back surgery syndrome (FBSS) was included in the evidence review[13,14]. These were inherently flawed studies given patients were not randomized – patients were instead allowed to choose their own course of treatment resulting in a design that arguably would not meet the GRADE criteria for inclusion in the HTA summary report. Additionally, the SCS treatment arm in this study included *both* patients with only a SCS trial and those progressing to a permanent implant – which is counterfactual to the rationale for a trial procedure. Patients failing a trial procedure are not included in any SCS RCT in the final study intervention cohort for evaluation, since they are not eligible for therapy.

Assuming the same coverage criteria outlined above would be applied to this population, importantly treatment success during a trial procedure, these patients should be afforded equal access to SCS as a treatment option as Medicaid and State Employees. The exclusion of the sub-population of patients with

[12] Pop-Busui R, Boulton AJ, Feldman EL, et al. Diabetic Neuropathy: A Position Statement by the American Diabetes Association. *Diabetes Care*. 2017 Jan;40(1):136-154. doi: 10.2337/dc16-2042.
[13] Turner JA, Hollingworth W, Comstock BA, Deyo RA. Spinal cord stimulation for failed back surgery syndrome: outcomes in a workers' compensation setting. Pain. 2010 Jan;148(1):14-25. doi: 10.1016/j.pain.2009.08.014
[14] Hollingworth W, Turner JA, Welton NJ, Comstock BA, Deyo RA. Costs and cost-effectiveness of spinal cord stimulation (SCS) for failed back surgery syndrome: an observational study in a workers' compensation population. Spine (Phila Pa 1976). 2011 Nov 15;36(24):2076-83.

worker's compensation coverage was not discussed during the public meeting and if finalized, presents a significant health disparity in treating patients under the same health plan differently.

For these reasons, we request that the Committee remove the language specific to related or pending workers compensation claims from the coverage criteria.

Complex Regional Pain Syndrome (CRPS)

Concerning the committee's vote to exclude patients with CRPS from coverage is contrary to coverage policy of all commercial payers in the US, with all payers covering at a minimum FBSS and CRPS indications. These policies generally apply the same coverage conditions to patients with CRPS as those with FBSS. Given there is existing evidence correctly captured in the final evidence report specific to this population, we respectfully request full re-review of that set of evidence.

* * * * *

We thank the HTCC members for their revised draft position that, if finalized, would give patients with FBSS, NSRBP, or PDN with access to this important therapy. We appreciate the opportunity to submit comments and look forward to engaging in the process as you move forward with this review. Should you have any questions, please do not hesitate to contact signatories of this letter at the e-mail addresses noted below. Thank you in advance for your review of our comments.

Sincerely,

Nilesh Patel, MD MBA
Vice President of Medical Affairs
Boston Scientific, Inc.

Todd Langevin
President
Biotronik Neuro

Allen W. Burton, MD
Divisional Vice President
Chief Medical Officer
Abbott Neuromodulation

Ashwini D. Sharan, MD, MSQHS
Chief Medical Officer
Medtronic Neuromodulation

David Caraway, MD, PhD
Chief Medical Officer
Nevro Corporation

Dan Brounstein
Chief Strategy Officer
Saluda Medical

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: SCS response letter
Date: Monday, June 3, 2024 12:31:12 PM
Attachments: HTCC draft guidelines response.pdf

External Email

All,

Here is our public response letter to be forwarded to the HTCC.

Thank you,
Virtaj

June 3, 2024

RE: Health Technology Clinical Committee Draft Guidelines and Decision on SCS

To Whom It May Concern:

The Washington State Spinal Cord Stimulator Work Group applauds the Health Technology Clinical Committee (HTCC) for their thorough analysis of the available evidence and work in producing the recent coverage decision. Although we do not agree with every decision made (see our concerns below), we believe this was a 'good faith' effort on the part of the committee to be guided by the best available evidence. Our work group of concerned pain management physicians very much appreciate that we were afforded the opportunity to present the best evidence to the committee and feel the presented material was taken into account.

We will present our suggested revisions and rationale for such in consistent tabular form so that it is more easily understood by the HTCC and hopefully actionable.

Failed back surgery syndrome (FBSS) when each of the following are met:		
Original Draft Text	**Suggested revisions**	**Rational**
At least 12 months post-surgery, persistent low-back and neuropathic leg pain.	None	
Moderate to severe (≥5 on the visual analog scale (VAS) neuropathic pain and objective neurologic impairment with documented pathology related to pain complaint (ie 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	Moderate to severe (≥5 mm on the visual analog scale (VAS) or ≥5 numeric pain scale (NRS). Pain should be neuropathic and may show signs of objective neurologic impairment.	We disagree with the proposed criteria that includes segmental muscle weakness or segmental sensory loss or electrodiagnostic evidence of nerve impairment is required. Objective neurologic signs including electrodiagnostic testing were not inclusion criteria in the reviewed studies or other data discussed during the committee proceedings. Sensory radiculopathy may not have any overt neurological signs, but sill result in severe functionally limiting pain. *Kapural L, et al. Treatment of nonsurgical refractory back pain with high-frequency spinal cord stimulation at 10 kHz: 12-month results of a pragmatic, multicenter, randomized controlled trial. J Neurosurg Spine. 2022;37(2):188-199.*

Functional disability assessed using the Oswestry Disability Index; ODI score ≥21	Functional disability assessed using a validated functional measure.	We strongly agree with the requirement to assess function in addition to pain relief. In clinical practice, there are many functional measures in routine use, and there is no broad consensus on the best measure. The ODI is only validated in the measurement of back pain and does not address neuropathic leg pain. Moreover, the ODI is insufficiently sensitive and would not be the most reliable metric. Other functional measurement tools include PROMIS-29, SF-36, Roland Morris Disability Index, WHODAS, EQ-5D, amongst others. Within the studies reviewed by the HTCC, multiple different functional measurements were in use. There is precedent in Washington State from both the Department of Labor and Industries as well as the Bree Collaborative to allow for "a validated functional measure" to satisfy this kind of requirement. *Finkelstein JA, et al. Patient-reported outcomes in spine surgery: past, current and future directions. J Neurosurgery Spine. 2019; 31: 155.164.*
AND Psychological evaluation and appropriate treatment for substantial mental health disorders	AND Psychological pre-procedural screening evaluation and appropriate treatment for substantial mental health disorders.	Minor clarification of psychological evaluation
AND 12 months of conservative medical management in	AND 12 months of conservative medical management in	As the committee members noted, the studies reviewed showed a high level of variability regarding

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 (eg acupuncture, chiropractic)	total, comprised of documented attendance, participation, and compliance with a multidisciplinary approach as tolerated based on individual clinical circumstance. This includes: - 8 sessions of physical therapy OR documentation from physical therapist that patient unable to participate in treatment. AND - Psychological therapy if indicated by Psychological Prescreen. AND - Another modality of conservative management (e.g. medication management, acupuncture, chiropractic, or other similar treatment).	definitions of conservative medical management (CMM). While there is not broad agreement regarding CMM, we believe there are some key foundational elements. While therapeutic exercise is essential, there may be circumstances where patients cannot tolerate physical therapy. At a minimum they must be evaluated by a physical therapist and make a good faith effort to engage in care. We agree that psychological therapies (e.g. cognitive behavioral therapy, mindfulness-based stress reduction, and trauma-based therapies) are an important part of a comprehensive treatment program for many patients suffering from chronic pain conditions. The data reviewed by the HTCC did not stipulate CBT nor did it mandate CBT in any of the relevant studies. Moreover, psychological therapies in routine use include multiple different approaches, one of which is CBT. Psychological therapies may be beneficial but should be tailored to the clinical condition at hand, which is best determined by the treating physician. *Driscoll MA, et al. Psychological Interventions for the treatment of chronic pain in adults. Psychological Science in the Public Interest. 2021; 22(2): 52-95.* Each clinical circumstance is unique as pointed out by multiple committee members during the hearing, the physician caring for the patient needs to be permitted to use clinical training and

		judgement to render appropriate care to the patient.
Must meet above criteria prior to percutaneous trial	Must meet above criteria prior to percutaneous trial	Agree
7-14 day trial of percutaneous spinal cord stimulation AND Experienced significant pain reduction (50% or more) AND, either Reduction of chronic opioid medicines (if applicable) OR Objective and clinically meaningful degree of functional improvement	5–14-day trial of percutaneous spinal cord stimulation. AND Experienced significant pain reduction (50% or more) AND, either- Reduction of chronic opioid medicines (if applicable and being used for treatment of index symptom), OR Objective and clinically meaningful degree of functional improvement**.**	Several pivotal studies including those discussed during the HTCC proceeding had SCS trial duration as short as 5 days.

Nonsurgical refractory back pain when each of the following are met:		
Original Draft Text	**Suggested revisions**	**Rational**
Persistent low-back and neuropathic leg pain.	At least 12 months of persistent low-back and neuropathic leg pain. AND Mandatory spine surgical consultation that deems the patient not fit for surgery or not a candidate for surgical correction.	Requiring surgical consultation is an important guardrail to help limit overutilization and consistent with the studies reviewed.
Moderate to severe (≥5 on the visual analog scale (VAS) neuropathic pain and objective neurologic impairment with documented pathology related to pain complaint (ie abnormal MRI). Neurologic impairment is defined as objective evidence of one or more of the following:	Moderate to severe (≥5 mm on the visual analog scale (VAS) or ≥5 numeric pain scale (NRS). Pain should be neuropathic and may show signs of objective neurologic impairment.	We disagree with the HTCC proposed criteria that includes segmental muscle weakness or segmental sensory loss or electrodiagnostic evidence of nerve impairment is required. Objective neurologic signs including electrodiagnostic testing were not inclusion criteria in the reviewed studies or other data discussed during the committee

- Markedly abnormal reflexes - Segmental muscle weakness - Segmental sensory loss - Electromyography (EMG) or nerve conduction study (NCS) evidence of nerve root impingement		proceedings. Sensory radiculopathy may not have any overt neurological signs, but sill results in severe functionally limiting pain. *Kapural L, et al. Treatment of nonsurgical refractory back pain with high-frequency spinal cord stimulation at 10 kHz: 12-month results of a pragmatic, multicenter, randomized controlled trial. J Neurosurg Spine. 2022;37(2):188-199.*
Functional disability assessed using the Oswestry Disability Index; ODI score ≥21	Functional disability assessed using a validated functional measure.	We strongly agree with the requirement to assess function in addition to pain relief. In clinical practice, there are many functional measures in routine use, and there is no broad consensus on the best measure. The ODI is only validated in the measurement of back pain and does not address neuropathic leg pain. Moreover, the ODI is insufficiently sensitive and would not be the most reliable metric. Other functional measurement tools include PROMIS-29, SF-36, Roland Morris Disability Index, WHODAS, EQ-5D, and others. Within the studies reviewed by the HTCC, multiple different functional measurements were used. There is precedent in Washington State from both the Department of Labor and Industries as well as the Bree Collaborative to allow for "a validated functional measure" to satisfy this kind of requirement. *Finkelstein JA, et al. Patient-reported outcomes in spine surgery: past, current and future directions. J Neurosurgery Spine. 2019; 31: 155.164.*
AND	AND	Minor clarification of psychological evaluation

Psychological evaluation and appropriate treatment for substantial mental health disorders	Psychological pre-procedural screening 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 (eg acupuncture, chiropractic)	AND 12 months of conservative medical management in total, comprised of documented attendance, participation, and compliance with a multidisciplinary approach as tolerated based on individual clinical circumstance. This includes: - 8 sessions of physical therapy OR documentation from physical therapist that patient unable to participate in treatment. AND - Psychological therapy if indicated by Psychological Prescreen. AND - Another modality of conservative management (e.g. medication management, acupuncture, chiropractic, or other similar treatment).	As the committee members noted, the studies reviewed showed a high level of variability regarding definitions of conservative medical management (CMM). While there is not broad agreement regarding CMM, we believe there are some key foundational elements. While therapeutic exercise is essential, there may be circumstances where patients cannot tolerate physical therapy. At a minimum they must be evaluated by a physical therapist and make a good faith effort to engage in care. We agree that psychological therapies (e.g. cognitive behavioral therapy, mindfulness-based stress reduction, and trauma-based therapies) are an important part of a comprehensive treatment program for many patients suffering from chronic pain conditions. The data reviewed by the HTCC did not stipulate CBT nor did it mandate CBT in any of the relevant studies. Moreover, psychological therapies in routine use include multiple different approaches, one of which is CBT. Psychological therapies may be beneficial but should be tailored to the clinical condition at hand, which is best determined by the treating physician. *Driscoll MA, et al. Psychological Interventions for the treatment of chronic pain in adults.*

		Psychological Science in the Public Interest. 2021; 22(2): 52-95. Each clinical circumstance is unique as pointed out by multiple committee members during the hearing, the physician caring for the patient needs to be permitted to use clinical training and judgement to render appropriate care to the patient.
Must meet above criteria prior to percutaneous trial	Must meet above criteria prior to percutaneous trial	Agree
7-14 day trial of percutaneous spinal cord stimulation AND Experienced significant pain reduction (50% or more) AND, either Reduction of chronic opioid medicines (if applicable) OR Objective and clinically meaningful degree of functional improvement	5–14-day trial of percutaneous spinal cord stimulation. AND Experienced significant pain reduction (50% or more) AND, either- Reduction of chronic opioid medicines (if applicable and being used for treatment of index symptom), OR Objective and clinically meaningful degree of functional improvement**.**	Several pivotal studies including those discussed during the HTCC proceeding had SCS trial duration as short as 5 days.

Painful diabetic neuropathy (PDN) when each of the following are met:		
Original Draft Text	**Suggested revisions**	**Rational**
Diagnosis of diabetes for 12 months or greater	none	agree
Moderate to severe (≥5 on the visual analog scale (VAS) neuropathic pain and objective neurologic impairment. Neurologic impairment is defined as objective evidence of one or more of the following: - Sensory loss determined by monofilament exam or	Moderate to severe (≥5 mm on the visual analog scale (VAS) or ≥5 numeric pain scale (NRS) neuropathic pain demonstrating a combination of symptoms and signs of distal sensory motor polyneuropathy with any **two or more** of the following:	Diabetic peripheral polyneuropathy is a diagnosis defined by sensory symptoms. The examination in diabetic peripheral polyneuropathy is often devoid of objective neurologic findings. The proposed changes are concordant with accepted

nerve conduction study/electromyography (EMG) in a pattern consistent with diabetic neuropathy	- neuropathic symptoms - decreased distal sensation - unequivocally decreased or absent ankle reflexes.	clinical and research definitions in the literature. *Dyck PJ, et al. Diabetic polyneuropathies: update on research definition, diagnostic criteria and estimation of severity. Diabetic neuropathy; 2011; 27(7): 620-628.*
AND Psychological evaluation and appropriate treatment for substantial mental health disorders	AND Psychological pre-procedural screening evaluation and appropriate treatment for substantial mental health disorders.	Minor clarification of psychological evaluation
AND 12 months of conservative medical management in total, comprised of compliance with a comprehensive trial of drug therapy for PDN (e.g. gabapentin)	AND 12 months of conservative medical management in total, comprised of compliance with a comprehensive trial of drug therapy for PDN (eg, pregabalin/gabapentin + one other class of analgesic including duloxetine, or other pain agents)	This is concordant with the studies reviewed by the HTCC. *Peterson EA, et al. Effect of high frequency (10-kHz) spinal cord stimulation in patients with painful diabetic neuropathy: a randomized clinical trial. JAMA Neurol. 2021; 78(6): 687-698.*
Must meet above criteria prior to percutaneous trial	Must meet above criteria prior to percutaneous trial	Agree
7-14 day trial of percutaneous spinal cord stimulation AND Experienced significant pain reduction (50% or more) AND, either Reduction of chronic opioid medicines (if applicable) OR Objective and clinically meaningful degree of functional improvement	5–14-day trial of percutaneous spinal cord stimulation. AND Experienced significant pain reduction (50% or more) AND, either- Reduction of chronic opioid medicines (if applicable and being used for treatment of index symptom), OR	Several pivotal studies including those discussed during the HTCC proceeding had SCS trial duration as short as 5 days.

	Objective and clinically meaningful degree of functional improvement.	

Our biggest concern is the decision for non-coverage of Complex Regional Pain Syndrome (CRPS). While this is a rare condition, it has significant functional impacts on patients suffering from this condition. In an effort to wrap up a very broad discussion spanning an unprecedented 6 months, the committee reversed their initial favorable coverage impression given in an initial straw poll. We are concerned that insufficient, focused attention was given to the data regarding CRPS, and an important treatment option is now excluded for a marginalized group of highly vulnerable patients. The disease is difficult to study given the small numbers of patients affected and limited understanding of the disease process itself. This makes interpretation of the literature difficult. None-the-less, we must rely on the best available evidence to render treatment for these patients at high risk for suicidality and chronic disability (*Lee, D et al. Risk factors for suicidal ideation among patients with CRPS. Psychiatry Investig. 2014; 11(1): 32-38.*). We respectfully request the committee undertake a focused discussion on this topic alone as we believe the review of this evidence was obscured by the broad nature of the discussion.

Please do not hesitate to contact us if we can provide any further information, thoughts, or guidance as you go forward.

Thank you for your consideration,

Washington State Spinal Cord Stimulator Work Group

James Babington, MD

Paul Dreyfuss, MD

Jennifer Lee, MD

Virtaj Singh, MD

Brett Stacey, MD

Steven Stanos, MD

FangFang Xing, MD

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Response to public comment period on draft guidelines for SCS
Date: Monday, June 3, 2024 3:11:10 PM
Attachments: Washington State Draft SCS Guidelines.pdf

External Email

Dear Washington State HTCC,

On behalf of the societies who have signed the attached letter, we commend the HTCC for its dedication and circumspection in evaluating coverage for spinal cord stimulation. We appreciate the opportunity to provide our commentary on the guidelines proposed during this open period and invite the HTCC to reach out if any additional information or clarification is needed.

Sincerely,
American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American Society of Neuroradiology
American Society of Regional Anesthesia and Pain Medicine
Congress of Neurological Surgeons
International Pain and Spine Intervention Society
North American Neuromodulation Society
North American Spine Society
Society for Interventional Radiology

KERI KRAMER | **CEO**

NORTH AMERICAN NEUROMODULATION SOCIETY

[redacted]

NEUROMODULATION.ORG

June 3, 2024

Sue Birch, MBA, BSN, RN
Director, Washington State Health Care Authority
Cherry Street Plaza 626 8th Avenue SE
Olympia, Washington 98501
Via e-mail: shtap@hca.wa.gov

Dear Ms. Birch:

We applaud the recent proposed coverage policy changes regarding spinal cord stimulation (SCS) for the indications of failed back surgery syndrome, peripheral diabetic neuropathy (PDN) and nonsurgical refractory back pain (NSRBP). This extends a widely successful therapeutic modality to patients suffering from these conditions in Washington State who were previously denied access to a pain treatment that has been proven across dozens of clinical trials to be safe, effective, and cost-effective in the long term. However, we were very concerned to learn that the draft findings proposed by the HTA Committee contain several elements that are poorly aligned with standard of care for SCS therapy for the proposed covered conditions, and wish to provide guidance for consideration by the Committee.

We have several concerns with the language surrounding coverage for all three covered indications:

Failed back surgery syndrome (FBSS): The requirement of a minimum of 12 months of failed conservative medical management (CMM) is twice that of most policies that require a minimum of 6 months. Mandating that patients suffer from severe, intractable pain for such an extended period of time will lead to detrimental impacts on mood, function and quality of life for patients. The use of language limiting to neuropathic pain only for patients with FBSS is unnecessary and inappropriate, given that many patients experience mixed nociceptive and neuropathic elements of chronic pain in this condition. The language should be revised to specify that patients should be experiencing neuropathic pain, but not *exclusively* neuropathic pain. The 2019 Health and Human Services Pain Management Task Force urges payors to extend "consistent and timely insurance coverage" for evidence-based interventions including neuromodulation.[1] Given the updated CDC guidelines regarding opioid prescribing, every reasonable attempt should be made to prevent unnecessary escalation of opioid medication for patients with chronic non-cancer pain, which is far more likely with such a lengthy period of time required for patients experiencing severe FBSS.[2] The requirement of a 7-to-14-day trial is inconsistent with the most recently published guidelines suggesting a maximum 10-day trial in order to not unnecessarily expose patients to a higher infection risk, and points out that most studies report a trial duration of 5-7 days. [1] By requiring a minimum of 7 days for an SCS trial, patients on chronic anticoagulation who must hold their anticoagulation therapy starting 24 hours prior to trial lead insertion may be exposed to greater risk of a thrombotic event when 5 days may be adequate to assess a trial response. Other policies (specifically Aetna and Premara) require a minimum trial of 3 days. Most manufacturer leads are not approved for more than 10 days use during an SCS trial. We recommend that the Committee consider imposing a minimum trial duration of a shorter period of time (3-5 days), and not necessarily impose a maximum trial duration. Finally, the highly specific requirements regarding baseline function is not consistent with other policies, which do not typically use a specific scale or require a specific degree of improvement, if they are required at all. Most policies require a 50% improvement in pain and either a nonspecific degree of functional improvement OR require functional improvement only if the 50% threshold for pain is not met. Also, in accordance with recently published guidelines regarding SCS trials,[3] assessment of functional improvement should be individualized based

on a patient's unique characteristics and lifestyle, and may include ability to participate in activities specific to an individual patient. The requirement of baseline ≥21% ODI is not evidence-based, nor aligned with clinical guidelines or the industry standard.

Language appearing in the corrected version of the draft findings and recommendations inappropriately denies coverage patients with FBSS or NSRBP if they have an open or pending worker's compensation claim. As we noted in our initial letter to HCA on October 2, 2023, we are concerned about the weight given to the thirteen-year-old Hollingworth, et al. study of Washington Workers' Compensation patients, with its low 5% response rate for SCS, which is truly an outlier versus other published SCS studies.

Nonsurgical Refractory Back Pain (NSRBP): We support the committee's decision to cover this condition. However, our positions as stated above regarding the requirements for minimum of 12 months (as opposed to 6 months) of failed CMM, baseline ODI score ≥ 21%, and consideration of removing the requirement that pain be exclusively neuropathic also apply to the condition of NSRBP. We also object to denial of coverage to those with a worker's compensation claim as noted above.

Painful Diabetic Neuropathy (PDN): While support the committee's decision to cover this condition, we disagree for the reasons outlined above that patients should be required to fail 12 months of CMM. This places an undue burden of pain and suffering upon patients. Additionally, the requirement of documented sensory loss is inconsistent with the inclusion and exclusion criteria of published clinical trials demonstrating the efficacy of SCS for PDN.[4] We also object to the requirement of greater than 50% pain reduction in addition to reduction of chronic opioid medications or objective and clinically meaningful degree of functional improvement. Traditional opioid medications are not recommended for the treatment of PDN and should not be considered in the criteria for coverage for SCS for this condition.[5,6] As described above, what is considered objectively and clinically meaningful in terms of functional improvement can vary considerably from patient to patient, and this requirement is typically only considered if patients experience *less than* 50% pain improvement during their trial.

In short, we agree with the Committee's consideration to extend coverage of SCS for the treatment of FBSS, NSRBP, and PDN, but wish to point out inconsistencies between the considered determination policies and the standard of care according to published clinical trials, guidelines, and the practices of other insurance companies including United Healthcare, Aetna, Premera Blue Cross, and BCBS Anthem.

- Patients may be expected to fail 6 months of CMM, but 12 months is unnecessarily long and imposes undue suffering on patients.
- Limiting SCS therapy to patients experiencing *exclusively* neuropathic pain is inappropriate given that most patients may experience more than one source of pain, including nociceptive pain.
- Trial length is typically 5-7 days and imposing a 7–14-day trial requirement is inconsistent with nationally published guidelines and other standard practice.
- The requirement of a baseline ODI score ≥21% is not evidence-based, nor an accepted or recommended way to assess a patient's candidacy for SCS trial or therapy. Functional improvement *during* an SCS trial may be considered in patients who have equivocal pain improvement (less than 50%), but should not be considered in a patient's candidacy for therapy.
- For PDN, objective and documented sensory loss should not be a requirement to proceed with SCS trial, as this is inconsistent with published studies regarding SCS for PDN.

We do hope that, in the future, the Washington State Health Care Authority may reconsider its position on denial of SCS for complex regional pain syndrome (CRPS). Spinal cord stimulation has been

demonstrated to be an excellent treatment for patients with CRPS who have failed CMM with improved pain, function and quality of life with reduced opioid utilization.[7] Spinal cord stimulation has also been found to be cost effective in the treatment of CRPS compared to CMM alone.[8] All major commercial payors and guidelines recommend the use of SCS for CRPS, and such access should not be denied to patients in Washington State.

Thank you for considering our concerns regarding the recently announced draft policies. We believe we are ideologically aligned in pursuing the best evidence-based care for patients suffering with chronic pain, to improve function, quality of life, and reduce unnecessary use of medications. We offer our suggestions in support of the efforts being made the HTA Committee to improve access to therapies that can substantially improve the lives of patients living with chronic pain.

Respectfully submitted on behalf of the 40,000+ members our undersigned societies represent,

American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American Society of Neuroradiology
American Society of Regional Anesthesia and Pain Medicine
Congress of Neurological Surgeons
International Pain and Spine Intervention Society
North American Neuromodulation Society
North American Spine Society
Society for Interventional Radiology

References

1. U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html
2. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1
3. Shanthanna H, Eldabe S, Provenzano DA, et al. Evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation therapy for chronic non-cancer pain. Reg Anesth Pain Med. Jun 2023;48(6):273-287. doi:10.1136/rapm-2022-104097
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5. Waldfogel JM, Nesbit SA, Dy SM, et al. Pharmacotherapy for diabetic peripheral neuropathy pain and quality of life: A systematic review. Neurology. May 16 2017;88(20):1958-1967. doi:10.1212/wnl.0000000000003882
6. Pop-Busui R, Boulton AJ, Feldman EL, et al. Diabetic Neuropathy: A Position Statement by the American Diabetes Association. Diabetes Care. Jan 2017;40(1):136-154. doi:10.2337/dc16-2042
7. Oliveira MJ, Matis GK. Spinal cord stimulation as a treatment option for complex regional pain syndrome: a narrative review. Br J Neurosurg. Dec 22 2022:1-5. doi:10.1080/02688697.2022.2159930
8. Zhou X, Zhou Y, Zhang X, Jiang F. Economic evaluation of management strategies for complex regional pain syndrome (CRPS). Front Pharmacol. 2024;15:1297927. doi:10.3389/fphar.2024.1297927

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.

Washington State Health Care Authority

HTCC final approval of coverage decision

Next step: proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination

Following review of the proposed findings and decision document and public comments:

Final vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome chair will lead discussion to determine next steps.