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: June 14, 2024

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, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion	0	9	0

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**