BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.101 Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

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Related Policies:

2.01.18 - Diagnosis of Obstructive Sleep Apnea Syndrome
2.01.99- Polysomnography for Non-Respiratory Sleep Disorders

Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Description

Description

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. For individuals who have failed conservative therapy, established surgical approaches may be indicated. This evidence review addresses minimally invasive surgical procedures for the treatment of OSA. They include laser-assisted uvuloplasty, tongue base suspension, radiofrequency volumetric reduction of palatal tissues and base of tongue, palatal stiffening procedures, and hypoglossal nerve stimulation (HNS). This evidence review does not address conventional surgical procedures such as uvulopalatopharyngoplasty (UPPP), hyoid suspension, surgical modification of the tongue, maxillofacial surgery, or adenotonsillectomy.

OBJECTIVE

The objective of this evidence review is to determine whether the use of minimally invasive surgical procedures improves the net health outcome for individuals being treated for obstructive sleep apnea.

POLICY STATEMENT

Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharyngoplasty) may be considered **medically necessary** for the treatment of clinically significant obstructive sleep apnea (OSA) syndrome in appropriately select adults who have failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance. Clinically significant OSA is defined as those individuals who have:

- Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of 15 or more events per hour, or
- AHI or RDI of at least 5 events per hour with 1 or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), may be considered **medically necessary** in appropriately selected adults with clinically significant OSA and objective documentation of hypopharyngeal obstruction who have failed an adequate trial of CPAP or failed an adequate trial of an oral appliance. Clinically significant OSA is defined as those individuals who have:

- AHI or RDI of 15 or more events per hour, or
- AHI or RDI of at least 5 events per hour with 1 or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

Adenotonsillectomy may be considered **medically necessary** in pediatric individuals with clinically significant OSA and hypertrophic tonsils. Clinically significant OSA is defined as those pediatric individuals who have:

- AHI or RDI of at least 5 per hour, or
- AHI or RDI of at least 1.5 per hour in anindividual with excessive daytime sleepiness, behavioral problems, or hyperactivity.

Hypoglossal nerve stimulation may be considered **medically necessary** in adults with OSA under the following conditions:

- Age ≥ 22 years; AND
- AHI ≥ 15 with less than 25% central apneas; AND
- CPAP failure (residual AHI ≥ 15 or failure to use CPAP ≥ 4 hr per night for ≥ 5 nights per week) or inability to tolerate CPAP; AND
- Body mass index ≤ 32 kg/m^2; AND
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (see Policy Guidelines).

Hypoglossal nerve stimulation may be considered **medically necessary** in adolescents or young adults with Down syndrome and OSA under the following conditions:

- Age 10 to 21 years; AND
- AHI >10 and <50 with less than 25% central apneas after prior adenotonsillectomy; AND
- Have either tracheotomy or be ineffectively treated with CPAP due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the device; AND
- Body mass index ≤ 95th percentile for age; AND
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (See Policy Guidelines).

Surgical treatment of OSA that does not meet the criteria above would be considered **not medically necessary**.

The following minimally invasive surgical procedures are considered **investigational** for the sole or adjunctive treatment of OSA or upper airway resistance syndrome:

- Laser-assisted palatoplasty or radiofrequency volumetric tissue reduction of the palatal tissues;
- Radiofrequency volumetric tissue reduction of the tongue, with or without radiofrequency reduction of the palatal tissues;

- Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation, injection of a sclerosing agent, and the implantation of palatal implants;
- Tongue base suspension;
- All other minimally invasive surgical procedures not described above.

Implantable hypoglossal nerve stimulators are considered **not medically necessary** for all indications other than listed above.

All interventions, including laser-assisted palatoplasty, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, are considered **not medically necessary** for the treatment of snoring in the absence of documented OSA; snoring alone is not considered a medical condition.

POLICY GUIDELINES

Continuous positive airway pressure is the preferred first-line treatment for obstructive sleep apnea for most individuals. A smaller number of individuals may use oral appliances as a first-line treatment (see evidence review 8.01.67). The Apnea/Hypopnea Index is the total number of events (apnea or hypopnea) per hour of recorded sleep. The Respiratory Disturbance Index is the total number of events (apnea or hypopnea) per hour of recording time. An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow compared with baseline and with at least a 4% oxygen desaturation.

The hypoglossal nerve (cranial nerve XII) innervates the genioglossus muscle. Stimulation of the nerve causes anterior movement and stiffening of the tongue and dilation of the pharynx. Hypoglossal nerve stimulation reduces airway collapsibility and alleviates obstruction at both the level of the soft palate and tongue base.

Drug-induced sleep endoscopy (DISE) replicates sleep with an infusion of propofol. DISE will suggest either a flat, anterior-posterior collapse or complete circumferential oropharyngeal collapse. Concentric collapse decreases the success of hypoglossal nerve stimulation and is an exclusion criterion from the U.S. Food and Drug Administration.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Obstructive sleep apnea (OSA) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. The hallmark symptom of OSA is excessive daytime sleepiness, and the typical clinical sign of OSA is snoring, which can abruptly cease and be followed by gasping associated with a brief arousal from sleep. The snoring resumes when the patient falls back to sleep, and the cycle of snoring/apnea/arousal may be repeated as frequently as every minute throughout the night. Sleep fragmentation associated with the repeated arousal during sleep can impair daytime activity. For example, adults with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles (ie, cars, trucks, heavy equipment). OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxia, alveolar hypoventilation, hypercapnia, and acidosis. This, in turn, can cause systemic hypertension, cardiac arrhythmias, and cor pulmonale. Systemic hypertension is common in individuals with OSA. Severe OSA is associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

Terminology and diagnostic criteria for OSA are shown in Table 1

Table 1. Terminology and Definitions for Obstructive Sleep Apnea

Terms	Definitions
Respiratory Event	
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by ≥90% of the pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define apnea as ≥2 missed breaths, regardless of its duration in seconds.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of the pre-event baseline for at least 10 seconds in association with either at least 3% or 4% decrease in arterial oxygen desaturation (depending on the scoring criteria) or arousal. Hypopneas in children are scored by a ≥50% drop in nasal pressure and either a ≥3% decrease in oxygen saturation or associated arousal.
RERA	Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increased respiratory effort, terminating in arousal but not otherwise meeting criteria for apnea or hypopnea
Respiratory event reporting	
AHI	The average number of apneas or hypopneas per hour of sleep
RDI	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.
REI	The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in-home sleep studies when actual sleep time from EEG is not available.
Diagnosis	
OSA	Repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep
Mild OSA	In adults: AHI of 5 to <15. In children: AHI ≥1 to 5
Moderate OSA	AHI of 15 to <30. Children: AHI of > 5 to 10
Severe OSA	Adults: AHI ≥30. Children: AHI of >10
Treatment	
PAP	CPAP, APAP, or Bi-PAP
PAP Failure	Usually defined as an AHI greater than 20 events per hour while using PAP
PAP Intolerance	PAP use for less than 4 h per night for 5 nights or more per week, or refusal to use CPAP. CPAP intolerance may be observed in patients with mild, moderate, or severe OSA

AHI: Apnea/Hypopnea Index; APAP:auto-adjusting positive airway pressure; Bi-PAP: Bi-level positive airway pressure; CPAP: continuous positive airway pressure; EEG: electroencephalogram; OSA: obstructive sleep apnea; PAP: positive airway pressure; RDI: Respiratory Disturbance Index;REI: Respiratory Event Index; RERA: respiratory event-related arousal

The regulatory status of minimally invasive surgical interventions is shown in Table 2.

Table 2. Minimally Invasive Surgical Interventions for Obstructive Sleep Apnea

Interventions	Devices (predicate or prior name)	Manufacturer (previous owner)	Indication	PMA/ 510(k)	Year	FDA Product Code
LAUP	Various					
Radiofrequency ablation	Somnoplasty		Simple snoring and for the base of the tongue for OSA	K982717	1998	GEI
Palatal Implant	Pillar Palatal Implant	Pillar Palatal (Restore Medical/ Medtronic)	Stiffening the soft palate which may reduce the severity of snoring and incidence of airway obstructions in patients with mild-to-moderate OSA	K040417	2004	LRK
Tongue base suspension	AIRvance (Repose)	Medtronic	OSA and/or snoring. The AIRvance TM Bone Screw System is also suitable for the performance of a hyoid suspension	K122391	1999	LRK
Tongue base suspension	Encore™ (PRELUDE III)	Siesta Medical	Treatment of mild or moderate OSA and/or snoring	K111179	2011	ORY
Hypoglossal nerve stimulation	Inspire II Upper Airway Stimulation	Inspire Medical Systems	Patients ≥ 18 years with AHI ≥15 and ≤65 who have failed (AHI >15 despite CPAP usage) or cannot tolerate (<4 h use per night for ≥5 nights per week) CPAP and do not have complete concentric collapse at the soft palate level. Patients between ages 18 and 21 should also be contraindicated for or not effectively treated by adenotonsillectomy.	P130008, S039	2014	MNQ
Hypoglossal nerve stimulation	aura6000	ImThera Medical		IDE	2014	
Hypoglossal nerve stimulation	Genio™	Nyxoa		European CE Mark	2019	
Hypoglossal nerve stimulation	Apnex System	Apnex				

AHI: Apnea/Hypopnea Index; CPAP: continuous positive airway pressure; IDE: investigational device exemption; LAUP: Laser-assisted uvulopalatoplasty; OSA: obstructive sleep apnea.

The expanded indication for hypoglossal nerve stimulation in patients age 18 to 21 was based on patients with Down Syndrome and is contingent on a post-approval study of the Inspire UAS in this age group. The post-approval study will be a multicenter, single-arm, prospective registry with 60 pediatric patients age 18 to 21. Visits will be scheduled at pre-implant, post-implant, 6 months, and yearly thereafter through 5 years.

RATIONALE

Summary of Evidence

For individuals who have obstructive sleep apnea (OSA) who receive laser-assisted uvulopalatoplasty, the evidence includes a single randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The trial indicates reductions in snoring, but limited efficacy on the Apnea/Hypopnea Index (AHI) or symptoms in patients with mild-to-moderate OSA. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive radiofrequency volumetric reduction of palatal tissues and base of tongue, the evidence includes 2 sham-controlled randomized trials and a prospective, single-arm cohort study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Single-stage radiofrequency to palatal tissues did not improve outcomes compared with sham. Multiple sessions of radiofrequency to the palate and base of tongue did not significantly (statistically or clinically) improve AHI, and the improvement in functional outcomes was not clinically significant. The prospective cohort study included 56 patients with mild-to-moderate OSA who received 3 sessions of office-based multilevel radiofrequency ablation (RFA). Results demonstrated improvement in AHI and Oxygen Desaturation Index (ODI) at the 6-month follow up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive palatal stiffening procedures, the evidence includes 2 sham-controlled randomized trials and several case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The 2 RCTs differed in their inclusion criteria, with the study that excluded patients with Friedman tongue position of IV and palate of 3.5 cm or longer reporting greater improvement in AHI (45% success) and snoring (change of -4.7 on a 10-point visual analog scale) than the second trial. Additional studies are needed to corroborate the results of the more successful trial and, if successful, define the appropriate selection criteria. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive tongue base suspension, the evidence includes a feasibility RCT with 17 patients. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT compared tongue suspension plus UPPP with tongue advancement plus uvulopalatopharyngoplasty (UPPP) and showed success rates of 50% to 57% for both procedures. Additional RCTs with a larger number of subjects are needed to determine whether tongue suspension alone or added to UPPP improves the net health outcome. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive hypoglossal nerve stimulation, the evidence includes a systematic reviews, 21RCTs, nonrandomized prospective studies, nonrandomized studies with historical controls, and prospective single-arm studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A double-blind, multicenter RCT of 89 adults with moderate-to-severe OSA who did not tolerate continuous positive airway pressure (CPAP) found significant short-term improvement in AHI, Epworth Sleepiness Score (ESS), and quality of life measures with hypoglossal nerve stimulation (HNS) compared to sham stimulation. The study was limited by a short duration of follow-up and lack of diversity among included participants. Another RCT including 138 patients with moderate-to-severe OSA who did not tolerate CPAP compared outcomes for patients who received HNS therapy at 1 or 4 months after implant for the treatment and control groups, respectively. Results demonstrated significant short-term improvement in AHI and ODI when comparing hypoglossal nerve stimulation (HNS) to no HNS at month 4. However, after 11 months of active therapy, the difference between the treatment and control groups was not statistically significant for AHI, but remained significant for ODI in favor of the treatment group. This trial was also limited by a lack of diverse individuals, as well as a lack of a true control group for long-term outcomes. Hypoglossal nerve stimulation has shown success rates for about two-thirds of a subset of patients who met selection criteria that included AHI, body mass index (BMI), and favorable pattern of palatal collapse across nonrandomized trials. These results were maintained out to 5 years in the pivotal single-arm study. The single prospective comparative study of patients who received HNS versus patients who were denied insurance coverage for the procedure has a high potential for performance bias. For children and adolescents with OSA and Down Syndrome who are unable to tolerate CPAP, the evidence includes a systematic review and a prospective study of 42 individuals. The systematic review investigated HNS in adolescents with Down Syndrome and OSA, and demonstrated significant improvement in AHI and OSA-18 survey scores after HNS. The study of 42 individuals with Down Syndrome and OSA found a success rate of 73.2% with 4 device extrusions corrected with replacement surgery. Limitations of the current evidence base preclude determination of who is most likely to benefit from this invasive procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Sleep Medicine

The American Academy of Sleep Medicine (AASM, 2021) published practice guidelines on when to refer patients for surgical modifications of the upper airway for OSA.[43,] These guidelines replaced the 2010 practice parameters for surgical modifications.[44,] The AASM guidelines note that positive airway pressure (PAP) is the most efficacious treatment for OSA, but effectiveness can be compromised when patients are unable to adhere to therapy or obtain an adequate benefit, which is when surgical management may be indicated. The AASM guideline recommendations are based on a systematic review and meta-analysis of 274 studies of surgical interventions, including procedures such as uvulopalatopharyngoplasty (UPPP), modified UPPP, MMA, tongue base suspension, and hypoglossal nerve stimulation.[45,] The systematic review deemed most included data of low quality, consisting of mostly observational data. The AASM strongly recommends that clinicians discuss referral to a sleep surgeon with adults with OSA and body mass index (BMI) <40 kg/m2 who are intolerant or unaccepting of PAP. Clinically meaningful and beneficial differences in nearly all critical outcomes, including a decrease in excessive sleepiness, improved quality of life (QOL), improved Apnea/Hypopnea Index (AHI) or respiratory disturbance index (RDI), and sleep quality, were demonstrated with surgical management in patients who are intolerant or unaccepting of PAP. The AASM makes a conditional recommendation that clinicians discuss referral to a sleep surgeon with adults with OSA, BMI <40 kg/m2, and persistent inadequate PAP adherence due to pressure-related side effects, as available data (very low-quality), suggests that upper airway surgery has a moderate effect in reducing minimum therapeutic PAP level and increasing PAP adherence. In adults with OSA and obesity (class II/III, BMI >35) who are intolerant or unaccepting of PAP, the AASM strongly recommends discussion of referral to a bariatric surgeon, along with other weight-loss strategies.

American Academy of Pediatrics

The American Academy of Pediatrics (2012) published a clinical practice guideline on the diagnosis and management of childhood OSA.[46,] The Academy indicated that if a child has OSA, a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery, the clinician should recommend adenotonsillectomy as first-line treatment. The Academy recommended that patients should be referred for CPAP management if symptoms/signs or objective evidence of OSA persist after adenotonsillectomy or if adenotonsillectomy is not performed. Weight loss was recommended in addition to other therapy if a child or adolescent with OSA is overweight or obese.

American Academy of Otolaryngology - Head and Neck Surgery

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS; 2021) has a position statement on surgical management of OSA.[47,] Procedures AAO-HNS supported as effective and not considered investigational when part of a comprehensive approach in the medical and surgical management of adults with OSA include:

- tracheostomy,
- nasal and pharyngeal airway surgery,
- tonsillectomy and adenoidectomy,
- palatal advancement,
- UPPP,
- genioglossal advancement,
- hyoid myotomy,
- midline glossectomy,
- tongue suspension,
- maxillary and mandibular advancement.

In a 2021 position statement, AAO-HNS supported hypoglossal nerve stimulation as an effective second-line treatment of moderate-to-severe OSA.[48,]

American Society for Metabolic and Bariatric Surgery

The American Society for Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA.[49,] The guideline indicated that OSA is strongly associated with obesity, with the incidence of OSA in the morbidly obese population reported as between 38% and 88%. The Society recommended bariatric surgery as the initial treatment of choice for OSA in this population, besides CPAP, as opposed to surgical procedures directed at the mandible or tissues of the palate. The updated 2017 guidelines reaffirmed these recommendations.[50,]

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) 2017 guidance concluded that evidence on the safety and efficacy of hypoglossal nerve stimulation is limited in quantity and quality, and the procedure should only be used in the context of a clinical trial.[51,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services (CMS; 2001) published a decision memorandum that addressed how to define moderate-to-severe OSA as a guide for a coverage policy on CPAP.[52,] Because surgical approaches are considered when CPAP fails, CMS policy was adapted to this evidence review on the surgical management of OSA. The CMS review of the literature suggested there is a risk of hypertension with an AHI or RDI of at least 15 events per hour, and thus treatment is warranted for patients without any additional signs and symptoms. For patients with an AHI or RDI between 5 and 14 and associated symptoms, CMS concluded that the data from randomized controlled trials have demonstrated improved daytime somnolence and functioning in those treated with CPAP.

There is no national coverage determination for hypoglossal nerve stimulation. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
September 2014	Replace policy	Policy updated with literature search, adding references 13, 14, 29, 30, 35-38, and 40. New FDA approved device, Hypoglossal Nerve Stimulator has been added to policy. Policy statement has been updated to indicate it is not medically necessary
September 2015	Replace policy	Policy updated with literature review; reference 31 added; policy statements unchanged.
December 2016	Replace policy	Policy updated with literature review, adding references 17-20. Medically necessary policy statement revised to include variants of palatopharyngoplasty.
December 2017	Replace policy	Policy updated with literature review through July 20, 2017; reference 26 added; reference 27 updated. Policy statements unchanged except Hypoglossal Nerve Stimulator policy statement corrected from investigational (as noted in Dec. 2016 version) back to not medically necessary per 2014 OPM guidance regarding devices with Premarket Approval
March 2018	Replace policy	Policy updated with literature review through October 29, 2018; Clinical input added for hypoglossal nerve stimulation. References added and some references removed. Hypoglossal nerve stimulation is considered medically necessary under specified conditions. (FDA cleared 510k) minimally invasive surgical procedures are considered investigational for the sole or adjunctive treatment of OSA or upper airway resistance syndrome.
September 2019	Replace policy	Policy updated with literature review through April 22, 2019; references added. The indication for hypoglossal nerve stimulation changed to apnea/hypopnea index of € 15 for alignment with the Food and Drug Administration-approved indication. Edits were also made to the Policy section regarding signs and symptoms in mild OSA to align with BCBSA policy #2.01.18. Policy statements otherwise unchanged.
September 2020	Replace policy	Policy updated with literature review through May 11, 2020; references added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through April 26, 2021; references added. Policy statements unchanged.
September 2022	Replace policy	Policy updated with literature review through May 8, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Policy statements unchanged.

Date	Action	Description
September 2023	Replace policy	Policy updated with literature review through April 26, 2023; references added. Policy statements unchanged.