



Louisiana

Vagus Nerve Stimulation

Policy # 00134

Original Effective Date: 06/05/2002

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Meniscal Allografts and Other Meniscal Implants is addressed separately in medical policy 00083.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider vagus nerve stimulation (VNS) as a treatment of medically refractory seizures to be **eligible for coverage.****

Note: Medically refractory seizures are defined as seizures that occur in spite of therapeutic levels of antiepileptic drugs or seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse events of these drugs.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of vagus nerve stimulation (VNS) as a treatment in patients with seizures other than medically refractory seizures to be **investigational.***

Based on review of available data, the Company considers vagus nerve stimulation (VNS) as a treatment for any other condition, including but not limited to depression, heart failure, upper limb

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impairment due to stroke, essential tremor, headaches, fibromyalgia, tinnitus, and traumatic brain injury to be **investigational**.*

Based on review of available data, the Company considers transcutaneous (nonimplantable) vagus nerve stimulation (VNS) devices for all indications to be **investigational**.*

Background/Overview

Vagus nerve stimulation (VNS) was initially investigated as a treatment alternative in patients with medically refractory partial-onset seizures for whom surgery is not recommended or for whom surgery has failed. Over time, the use of VNS has expanded to include generalized seizures, and it has been investigated for a range of other conditions.

While the mechanisms for the therapeutic effects of VNS are not fully understood, the basic premise of VNS in the treatment of various conditions is that vagal visceral afferents have a diffuse central nervous system projection, and activation of these pathways has a widespread effect on neuronal excitability. An electrical stimulus is applied to axons of the vagus nerve, which have their cell bodies in the nodose and junctional ganglia and synapse on the nucleus of the solitary tract in the brainstem. From the solitary tract nucleus, vagal afferent pathways project to multiple areas of the brain. VNS may also stimulate vagal efferent pathways that innervate the heart, vocal cords, and other laryngeal and pharyngeal muscles, and provide parasympathetic innervation to the gastrointestinal tract.

Other types of implantable vagus nerve stimulators that are placed in contact with the trunks of the vagus nerve at the gastroesophageal junction are not addressed in this evidence review.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Table 1 includes updates on the U.S. Food and Drug Administration (FDA) approval and clearance for VNS stimulators devices pertinent to this evidence review.

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Table 1. FDA-Approved or -Cleared Vagus Nerve Stimulators

Device Name	Manufacturer	Approved/Cleared	PMA/510(k)	Product Code(s)	Indications
NeuroCybernetic Prosthesis (NCP [®]) /VNS Therapy [®]	LIvaNov(Cyberonics)	1997	P970003	LYJ, MUZ	Indicated or adjunctive treatment of adults and adolescents >12 y of age with medically refractory partial-onset seizures
		2005	P970003/S50		Expanded indication for adjunctive long-term treatment of chronic or recurrent depression for patients ≥18 y of age

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Device Name	Manufacturer	Approved/Cleared	PMA/510(k)	Product Code(s)	Indications
					experiencing a major depressive episode and have not had an adequate response to ≥ 4 adequate antidepressant treatments
		2017	P970003/S207		Expanded indicated use as adjunctive therapy for seizures in patients ≥ 4 y of age with partial-onset seizures that are refractory to antiepilept

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Device Name	Manufacturer	Approved/Cleared	PMA/510(k)	Product Code(s)	Indications
					ic medications
gammaCore [®]	ElectroCore	2017/2018	DEN150048/K171306/K173442	PKR, QAK	Indicated for acute treatment of pain associated with episodic cluster and migraine headache in adults using noninvasive VNS on the side of the neck

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Device Name	Manufacturer	Approved/Cleared	PMA/510(k)	Product Code(s)	Indications
gammaCore-2 [®] , gammaCore-Sapphire [®]	ElectroCore	2017/2018	K172270/K180538/K182369	PKR	<p>Indicated for:</p> <p>Adjunctive use for the preventive treatment of cluster headache in adult patients.</p> <p>The acute treatment of pain associated with episodic cluster headache in adult patients.</p> <p>The acute treatment of pain associated with</p>

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Device Name	Manufacturer	Approved/Cleared	PMA/510(k)	Product Code(s)	Indications
					migraine headache in adult patients.

FDA: U.S. Food and Drug Administration; PMA: premarket approval; VNS: vagus nerve stimulation.

Rationale/Source

Stimulation of the vagus nerve can be performed using a pulsed electrical stimulator implanted within the carotid artery sheath. This technique has been proposed as a treatment for refractory seizures, depression, and other disorders. There are also devices available that are implanted at different areas of the vagus nerve. This evidence review also addresses devices that stimulate the vagus nerve transcutaneously.

Vagus Nerve Stimulation

For individuals who have seizures refractory to medical treatment who receive vagus nerve stimulation (VNS), the evidence includes randomized controlled trials (RCTs) and multiple observational studies. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs have reported significant reductions in seizure frequency for patients with partial-onset seizures. The uncontrolled studies have consistently reported large reductions in a broader range of seizure types in both adults and children. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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For individuals who have treatment-resistant depression who receive VNS, the evidence includes an RCT, nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCT only reported short-term results and found no significant improvement in the primary outcome. Other available studies are limited by small sample sizes, potential selection bias, and lack of a control group in the case series. The evidence is insufficient to determine the effects of the technology on health outcomes.

Other Conditions

For individuals who have chronic heart failure who receive VNS, the evidence includes RCTs and case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs evaluating chronic heart failure did not show significant improvements in the primary outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes. For individuals who have upper-limb impairment due to stroke who receive VNS, the evidence includes a single pilot study. Relevant outcomes are symptoms, change in disease status, and functional outcomes. This pilot study has provided preliminary support for improvement in functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have other neurologic conditions (eg, essential tremor, headache, fibromyalgia, tinnitus, autism) who receive VNS, the evidence includes case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Case series are insufficient to draw conclusions regarding efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Transcutaneous Vagus Nerve Stimulation

For individuals with cluster headaches who receive transcutaneous VNS to prevent cluster headaches, the evidence includes 1 RCT. Relevant outcomes are symptoms, change in disease status, quality of life and functional outcomes. One RCT for prevention of cluster headache showed a reduction in headache frequency but did not include a sham treatment group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with cluster headache who receive noninvasive transcutaneous VNS (nVNS) to treat acute cluster headache, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, quality of life and functional outcomes. The Non-invasive Neurostimulation of the

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Vagus Nerve With the GammaCore Device for the Treatment of Cluster Headache (ACT1) and A Randomized, Multicentre, Double-blind, Parallel, Sham-controlled Study of GammaCore[®]‡, a Non-invasive Neurostimulator Device for the Acute Relief of Episodic and Chronic Cluster Headache (ACT2) RCTs compared nVNS to sham for treatment of acute cluster headache in patients including both chronic and episodic cluster headache. In ACT1, there was no statistically significant difference in the overall population in the proportion of patients with pain score of 0 or 1 at 15 minutes into the first attack and no difference in the proportion of patients who were pain-free at 15 minutes in 50% or more of the attacks. In the episodic cluster headache subgroup (n=85) both outcomes were statistically significant favoring nVNS although the interaction p-value was not reported. In ACT2, the proportion of attacks with pain intensity score of 0 or 1 at 30 minutes was higher for nVNS in the overall population (43% vs. 28%, p=0.05) while the proportion of attacks that were pain-free at 15 minutes was similar in the 2 treatment groups in the overall population (14% vs. 12%). However, a statistically significantly higher proportion of attacks in the episodic subgroup (n=27) were pain-free at 15 minutes in the nVNS group compared to sham (48% vs. 6%, p<0.01). These studies suggest that people with episodic and chronic cluster headaches may respond differently to acute treatment with nVNS. Studies designed to focus on episodic cluster headache are needed. quality of life and functional outcomes have not been reported. Treatment periods ranged from only 2 weeks to 1 month with extended open-label follow-up of up to 3 months. There are few adverse events of nVNS and they are mild and transient. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with migraine headache who receive nVNS to treat acute migraine headache, the evidence includes 1 RCT. Relevant outcomes are symptoms, change in disease status, quality of life and functional outcomes. One RCT has evaluated nVNS for acute treatment of migraine with nVNS in 248 patients with episodic migraine with/without aura. There was not a statistically significant difference in the primary outcome of the proportion of participants who were pain-free without using rescue medication at 120 minutes (30% vs. 20%; p = 0.07). However, the nVNS group had a higher proportion of patients with decrease in pain from moderate or severe to mild or no pain at 120 minutes (41% vs. 28%; p=0.03) and a higher proportion of patients who were pain-free at 120 for 50% or more of their attacks (32% vs. 18%; p=0.02). There are few adverse events of nVNS and they are mild and transient. quality of life and functional outcomes were not reported and the double-blind treatment period was 4 weeks with an additional 4 weeks of open-label treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

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For individuals with chronic migraine headache who receive nVNS to prevent migraine headache, the evidence includes 2 RCTs. Relevant outcomes are symptoms, change in disease status, quality of life and functional outcomes. The Non-Invasive Neurostimulation of the Vagus Nerve With the GammaCore Device for the Prevention of Chronic Migraine; nVNS: noninvasive transcutaneous vagus nerve stimulation (EVENT) RCT was a feasibility study of prevention of migraine that was not powered to detect differences in efficacy outcomes. It does not demonstrate the efficacy of nVNS for prevention of migraine. The Randomized, Multicentre, Double-blind, Parallel, Sham-controlled Study of gammaCore, a Non-invasive Vagal Nerve Stimulator (nVNS), for Prevention of Episodic Migraine (PREMIUM) RCT was a phase 3, multicenter, sham-controlled RCT including 341 randomized participants with a 12-week double-blind treatment period. The results of PREMIUM demonstrated that nVNS was not statistically significantly superior to sham. with respect to the outcomes of reduction of at least 50% in migraine days from baseline to the last 4 weeks, reduction in number of migraine days from baseline to the last 4 weeks or acute medication days. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have other neurologic, psychiatric, or metabolic disorders (eg, epilepsy, depression, schizophrenia, noncluster headache, impaired glucose tolerance) who receive transcutaneous VNS, the evidence includes RCTs and case series for some of the conditions. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs are all small and have various methodologic problems. None showed definitive efficacy of transcutaneous VNS in improving patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes

Supplemental Information

Practice Guidelines and Position Statements

American Academy of Neurology

In 1999, the American Academy of Neurology released a consensus statement on the use of vagus nerve stimulation (VNS) in adults, which stated: “VNS is indicated for adults and adolescents over 12 years of age with medically intractable partial seizures who are not candidates for potentially curative surgical resections, such as lesionectomies or mesial temporal lobectomies.” The Academy updated these guidelines in 2013, stating: “VNS may be considered for seizures in children, for LGS

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[Lennox-Gastaut syndrome]-associated seizures, and for improving mood in adults with epilepsy (Level C). VNS may be considered to have improved efficacy over time (Level C).”

American Psychiatric Association

Updated in 2010, the American Psychiatric Association guidelines for the treatment of major depressive disorder in adults included the following statement on the use of VNS: “Vagus nerve stimulation (VNS) may be an additional option for individuals who have not responded to at least four adequate trials of antidepressant treatment, including ECT [electroconvulsive therapy],” with a level of evidence III (may be recommended on the basis of individual circumstances).

National Institute for Health and Care Excellence

In 2016, the National Institute for Health and Care Excellence (NICE) issued guidance on use of transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine (IPG552). The guidance states: “Current evidence on the safety of transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine raises no major concerns. The evidence on efficacy is limited in quantity and quality.” The guidance also comments that further research is needed to clarify whether the procedure is used for treatment or prevention, for cluster headache or migraine, appropriate patient selection, and treatment regimen and suggests that outcome measures should include changes in the number and severity of cluster headache or migraine episodes, medication use, quality of life in the short and long term, side effects, acceptability, and device durability.

In 2018, the NICE also published a Medtech innovation briefing on nVNS for cluster headache (MIB162). The briefing states that the 'intended place in therapy would be as well as standard care, most likely where standard treatments for cluster headache are ineffective, not tolerated or contraindicated' and that key uncertainties around the evidence are that 'people with episodic and chronic cluster headaches respond differently to treatment with gammaCore. The optimal use of gammaCore in the different populations is unclear. The NICE published a Medical technologies guidance [MTG46] on gammaCore for cluster headache in December 2019. The recommendations state that evidence supports using gammaCore to treat cluster headache and that gammaCore is not effective in everyone with cluster headache.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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Medicare National Coverage

Medicare has a national coverage determination for VNS. Medicare coverage policy notes that “Clinical evidence has shown that vagus nerve stimulation is safe and effective treatment for patients with medically refractory partial onset seizures, for whom surgery is not recommended or for whom surgery has failed. Vagus nerve stimulation is not covered for patients with other types of seizure disorders that are medically refractory and for whom surgery is not recommended or for whom surgery has failed.” Effective May 2007, VNS is not reasonable and necessary for resistant depression.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03062514 ^a	Vagus Nerve Stimulation for Pediatric Intractable Epilepsy (VNS-PIE)	84	Dec 2019
NCT03380156	Effect of Transcutaneous Vagal Stimulation (TVS) on Endothelial Function and Arterial Stiffness in Patients With Heart Failure With Reduced Ejection Fraction	25	May 2018
NCT01281293 ^a	A Post Market, Long Term, Observational, Multi-site Outcome Study to Follow the Clinical Course and Seizure Reduction of Patients With Refractory Seizures Who Are Being Treated With Adjunctive VNS Therapy	124	Dec 2018
NCT03327649	Neuromodulation of Inflammation to Treat Heart Failure With Preserved Ejection Fraction	72	Dec 2019

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NCT03716505	A Randomized, Multicenter, Double-blind, Parallel, Sham-controlled Study of Non-invasive Vagus Nerve Stimulation for the Prevention of Migraines. (Premium II)	500	Dec 2020
NCT03320304 ^a	A Global Prospective, Multi-center, Observational Post-market Study to Assess short, Mid and Long-term Effectiveness and Efficiency of VNS Therapy [®] as Adjunctive Therapy in real-world patients With difficult to Treat Depression	500	Dec 2025
<i>Unpublished</i>			
NCT03163030 ^a	Autonomic Neural Regulation Therapy to Enhance Myocardial Function in Heart Failure With Preserved Ejection Fraction (ANTHEM-HFpEF) Study	50	Dec 2018 (unknown)
NCT02562703	Transcutaneous Vagus Nerve Stimulation for Treating Major Depressive Disorder: a Phase II, Randomized, Double-blind Clinical Trial	40	Jul 2016 (unknown)
NCT02089243	Prospective Randomized Controlled Study of Vagus Nerve Stimulation Therapy in the Patients With Medically Refractory Medial Temporal Lobe Epilepsy; Controlled Randomized Vagus Nerve Stimulation Versus Resection (CoRaVNStiR)	40	Jul 2017 (unknown)
NCT02378792 ^a	The Clinical Research on TsingHua Vagus Nerve Stimulator for Treatment of Refractory Epilepsy Enrollment	300	Dec 2017 (unknown)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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03/21/2002 Medical Policy Committee review
06/05/2002 Managed Care Advisory Council approval
05/07/2004 Medical Director review
05/18/2004 Medical Policy Committee review. Format revision. No substance change to policy.
06/28/2004 Managed Care Advisory Council approval
06/07/2005 Medical Director review
06/21/2005 Medical Policy Committee review. Clinical criteria revised to add
investigational statement for VNS treatment for essential tremor
07/15/2005 Managed Care Advisory Council Approval
06/07/2006 Medical Director review
06/21/2006 Medical Policy Committee approval. Format revision, including addition of FDA and
or other governmental regulatory approval and rationale/source. Coverage eligibility
unchanged
08/04/2006 Medical Director Review
08/09/2006 Medical Policy Committee approval
11/07/2007 Medical Director Review
11/15/2007 Medical Policy Committee approval. Added headaches to the investigational policy
statement.
11/05/2008 Medical Director Review
11/18/2008 Medical Policy Committee approval. No change to coverage eligibility.
11/12/2009 Medical Policy Committee approval
11/18/2009 Medical Policy Implementation Committee approval. Deleted “partial-onset” verbiage
from “medically refractory seizures” in the coverage section. Added the treatment of
obesity as an investigational indication.
11/04/2011 Medical Policy Committee review

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11/16/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/31/2010	Coding updated.
11/03/2011	Medical Policy Committee review
11/16/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. Added heart failure and fibromyalgia to the list of investigational indications.
01/23/2013	Coding updated
11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. No change to coverage.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. Policy statement updated to include the addition of tinnitus and traumatic brain injury to the list of investigational conditions. "Based on review of available data, the Company considers non implantable vagus nerve stimulation (VNS) devices for all indications to be investigational" was added to the investigational section.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. No change to coverage.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. No change to coverage.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. No change to coverage. FDA updated.
01/01/2019	Coding update
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/07/2020	Medical Policy Committee review
05/13/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/11/2020	Coding update

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Code Type	Code
CPT	0312T, 0313T, 0314T, 0315T, 0316T, 0317T, 61885, 61886, 61888, 64553, 64568, 64569, 64570, 95976, 95977
HCPCS	C1767, C1778, C1787, C1816, C1820, C1822, C1883, L8679, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689, L8695
ICD-10 Diagnosis	G40.101-G40.119, G40.501-G40.509, G40.801-G40.814, G40.822-G40.89, G40.901-G40.919, G40.B01-G40.B19, G43.109, G35.369

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H35.361-, H93.11-G93.19, N39.3, O90.6, O99.315, O99.345, R27.0-R27.9, R33.9, R34, R35.0, R39.15, R39.19, S09.10XA, S09.11XA, S09.19XA, S09.8XXA, S09.90XA Added codes eff 10/1/2020: O99.891-O99.893

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services

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at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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