Ablation and Surgical Treatment of Chronic Rhinitis

Medicare Advantage Medical Policy #MA-196
Original Effective Date: 04/01/2026
Current Effective Date: 04/01/2026

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

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 Health Plan considers intranasal ablation (e.g., cryoablation using Clarifix®‡, radiofrequency using RhinAer®‡, or laser ablation) of the posterior nasal nerves and/or sphenopalatine ganglion for the treatment of chronic allergic and non-allergic rhinitis to be **investigational.***

Based on review of available data, the Health Plan considers vidian neurectomy (regardless of approach) in the management of chronic sinusitis, recurrent acute sinusitis, allergic rhinitis, and all other forms of chronic rhinitis to be **investigational.***

Background/Overview

Chronic rhinitis is a common medical condition that encompasses allergic rhinitis, nonallergic rhinitis, and mixed rhinitis and can severely impact quality of life. The initial treatment for chronic rhinitis often involves medical management with pharmacotherapy that may include steroids, anticholinergics, nasal decongestants, and antihistamines. Although medications are the mainstay treatment option, approximately 10% to 22% of the patients with chronic rhinitis still have persistent symptoms despite medical therapy and may require further interventions. For individuals who do not attain improvement in chronic rhinitis symptoms after receiving adequate medical therapy (referred to as refractory chronic rhinitis), invasive surgical options to block posterior nasal nerve may be considered. Historically, vidian neurectomy which targets the vidian nerve was offered for refractory rhinitis. Although vidian neurectomy was shown to be effective in reducing symptoms like rhinorrhea, it is associated with side effects of cheek and palate numbness and dry eyes (in nearly 50% of cases, ranging between 35% to 72%). In an effort to improve on complications of vidian neurectomy such as xerophthalmia, interventions that specifically target the posterior nasal nerve branches of the vidian nerve have been developed. It is thought that such interventions would help to reduce the morbidity associated with vidian neurectomy. These interventions range from surgical ablation of the post-ganglionic posterior nasal nerve to minimally invasive options of cryotherapy, radiofrequency, or laser ablation of the nerve. These minimally invasive procedures can be performed under endoscopy. The efficacy of ablation of posterior nasal nerve is thought to

result from the interruption of efferent parasympathetic stimulation of the nasal mucosa, which leads to reduction in submucosal gland secretions and blood flow.

The nerve of the pterygoid canal, also known as the vidian nerve, supplies parasympathetic fibers to the nasal mucosa, palate, and lacrimal gland through the pterygopalatine ganglion. A vidian neurectomy diminishes autonomic supply to the nasal cavity and reduces nasal secretions. Open approaches to the pterygopalatine fossa, like transantral and transpalatal exposures, were associated with significant morbidity, including ophthalmoplegia, orbital complications, and palatal fistulae. In 1991 Kamel and Zaher introduced endoscopic transnasal vidian neurectomy in cadaveric models. This innovation paved the way for modern surgical techniques, offering a more precise and less morbid approach.

To quantify the severity of chronic rhinitis and to assess treatment response, various outcome measures can be used, including radiologic scores, endoscopic grading, and patient-reported quality of life measures. The primary outcome measures relevant for the treatment of chronic rhinitis are patient-reported symptoms and quality of life. Examiner evaluation of the nasal and sinus appearance and polyp size may provide some information about treatment outcomes, but these evaluations are limited by the lack of universally accepted standards.

Frequently used outcome measures for treatments of chronic rhinitis in adults are shown in Table 1. A consensus on the minimally clinically important difference (MCID) for some of these outcomes has not been established. The U.S. Food and Drug Administration (FDA) guidance on drugs for rhinitis recommends patient-reported total nasal symptom scores as the primary measure of efficacy. The FDA guidance on drugs for rhinitis does not specify a MCID for patient-reported symptom measures, but notes that a MCID should be prespecified in studies and the rationale explained. Adverse events must be assessed immediately (perioperative complications and postoperative pain) and over the longer term.

Table 1. Outcome Measures for Chronic Rhinitis Interventions

Outcome	Measures	Description	Minimal Clinically Important Difference	Timing
Symptoms	reflective Total Nasal Symptom Score (rTNSS)	Sum of 4 individual subject-assessed symptom scores for rhinorrhea, nasal congestion, nasal itching, and sneezing, each evaluated using a scale of 0 = none, 1 = mild, 2 = moderate, or 3 = severe. Maximum 12 points.	Not established; 30% change from baseline has been proposed	At least 6 months or longer

	The Chronic Sinusitis Survey (CSS)	Measure of symptoms and medication usage over an 8-week recall period. Includes 3 questions regarding symptoms and 3 regarding medication usage, yielding a total score, symptom subscore, and medication subscore. Ranges from 0 to 100 in which a low CSS score represents greater symptoms and/or medication usage.	Not established	At least 6 months or longer
	Visual Analog Scale (VAS)	Patient-reported.	Not established	At least 6 months or longer
Disease-Specific Quality of Life	Sino-Nasal Outcome Test-20 (SNOT-20)	Patients complete 20 symptom questions on a categorical scale (0 [no bother] to 5 [worst symptoms can be]). Average rankings can be reported over all 20 symptoms, as well as by 4 subclassified symptom domains. The possible range of SNOT-20 scores is 0 to 5, with a higher score indicating a greater rhinosinusitis-related health burden. SNOT-22, a variation of the SNOT-20, includes 2 additional questions (on “nasal obstruction” and “loss of smell and taste”).	SNOT-20: change in score of 0.8 or greater SNOT-22: change in score of 8.9 points	At least 6 months or longer
	Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ)	Measures the functional (physical, emotional, and social) problems associated with rhinitis.	Not established	At least 6 months or longer
	Visual analog scale (VAS)	Patient-reported.	Not established	At least 6 months or longer
Adverse events	Various; patient- and clinician reported	Potential procedure- and device-related adverse events include	Not applicable	Immediately post procedure to

		postoperative pain, epistaxis, and dry eyes.		6 months or longer

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In February 2019, the ClariFix™‡ device (Stryker) was cleared for use in adults with chronic rhinitis by the FDA through the 510(k) process (K190356). Clearance was based on substantial equivalence to the predicate device, ClariFix (K162608). The only modification to the subject device was an update to the indications for use to include adults with chronic rhinitis. As per the FDA 510K summary, the ClariFix device is intended to be used as a cryosurgical tool for the destruction of unwanted tissue during surgical procedures, including in adults with chronic rhinitis.

In December 2019, the RhinAer™‡ stylus (Aerin Medical) was cleared by the FDA through the 510(k) process as a tool to treat chronic rhinitis (K192471). Clearance was based on equivalence in design and intended use of a predicate device, the InSeca ARC Stylus™‡ (K162810). The RhinAer stylus includes modification of the InSeca ARC stylus shaft components and flexibility. As per the FDA 510K summary, the RhinAer is indicated for use in otorhinolaryngology surgery for the destruction of soft tissue in the nasal airway, including in posterior nasal nerve regions in patients with chronic rhinitis.

There are currently no laser ablation devices with FDA clearance for treatment of chronic rhinitis.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

Chronic rhinitis is a common medical condition that encompasses allergic rhinitis, nonallergic rhinitis, and mixed rhinitis and can severely impact quality of life. The initial treatment for chronic rhinitis often involves medical management with pharmacotherapy that may include steroids, anticholinergics, nasal decongestants, and antihistamines. For individuals who do not attain improvement in chronic rhinitis symptoms after receiving adequate medical therapy (referred to as refractory chronic rhinitis), invasive surgical options to block posterior nasal nerve may be considered. Historically, vidian neurectomy which targets the vidian nerve was offered for refractory rhinitis. Although vidian neurectomy was shown to be effective in reducing symptoms like rhinorrhea, it is associated with side effects of cheek and palate numbness and dry eyes (in nearly 50% of cases, ranging between 35 to 72%). In an effort to improve on complications of vidian neurectomy such as xerophthalmia, interventions that specifically target the posterior nasal nerve

branches of the vidian nerve have been developed. These interventions range from surgical ablation of the post-ganglionic posterior nasal nerve to minimally invasive options of cryotherapy, radiofrequency, or laser ablation of the nerve. These minimally invasive procedures can be performed under endoscopy. The efficacy of ablation of posterior nasal nerve is thought to result from the interruption of efferent parasympathetic stimulation of the nasal mucosa, which leads to reduction in submucosal gland secretions and blood flow.

Summary of Evidence

For individuals with chronic rhinitis who receive cryoablation, the evidence includes a randomized controlled trial (RCT) and nonrandomized studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. One RCT that compared cryoablation using the ClariFix device with a sham procedure showed a statistical significant difference in response rate in favor of cryoablation group compared to the sham group. However, it is unclear if the trial enrolled individuals with chronic rhinitis who were refractory to medical management. This limitation precludes meaningful interpretation of these results as the intended use of ClariFix device is for individuals with chronic rhinitis who are refractory to medical management. Three single-arm prospective studies evaluated efficacy and safety of cryoablation for patients with chronic rhinitis. Out of the 3, 2 studies enrolled individuals who were refractory to medical management. The definition of refractory varied from symptoms not adequately controlled with a minimum of 4 weeks of topical nasal steroid treatment or failure of medical therapy for a duration of at least 3 months. Although all 3 single arm studies reported improvement in symptom control, the major limitation is lack of a comparator group and open-label nature of the study design, which likely introduces biases. Additionally, loss to follow-up was high. Randomized controlled trials with a clearly defined refractory patient population directly comparing cryoablation with sham surgery or other surgical interventions are needed to confirm the efficacy of cryoablation for treatment of chronic rhinitis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with chronic rhinitis refractory to medical management who receive radiofrequency ablation, the evidence includes an RCT and nonrandomized studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. One RCT that compared radiofrequency using the RhinAer device with a sham procedure showed a statistical significant difference in response rate in favor of radiofrequency ablation group compared to the sham group. However, it is unclear if the trial enrolled individuals with chronic rhinitis who were refractory to medical management. This limitation precludes meaningful interpretation of these results as the intended use of RhinAer device is for individuals with chronic rhinitis who are refractory to medical management. Two single-arm prospective studies evaluated efficacy and safety of radiofrequency ablation for patients with chronic rhinitis. Out of the 2, 1 study enrolled individuals who were refractory to medical management. Although both single arm studies reported improvement in symptom control, the major limitation is lack of a comparator group and open-label nature of the study design, which likely introduces biases. Randomized controlled trials with a clearly defined refractory patient population directly comparing radiofrequency with sham surgery

or other surgical interventions are needed to confirm the efficacy of radiofrequency ablation for treatment of chronic rhinitis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with allergic or nonallergic chronic rhinitis who receive laser ablation, the evidence includes one nonrandomized study. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Although the single-arm prospective study reported improvement in symptom control, the major limitation is lack of a comparator group and open-label nature of the study design, which likely introduces biases. In addition, the authors did not define how study participants were classified as refractory to medical management. Randomized controlled trials with a clearly defined refractory patient population directly comparing laser ablation with sham surgery or other surgical interventions are needed to confirm the efficacy of radiofrequency ablation for treatment of chronic rhinitis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with allergic or nonallergic chronic rhinitis who receive vidian nerve resection (vidian neurectomy) the evidence is limited to case series. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Clinical studies have reported improved nasal symptom outcomes with vidian neurectomy compared to medical management or alternative surgical procedures like turbinoplasty or septoplasty. It has also been reported that endoscopic vidian neurectomy is more likely to cause dry eyes and palatal numbness. Despite the growing interest in vidian neurectomy, there remains limited evidence concerning its long-term results and potential complications. Further research is needed to comprehensively understand the procedure's efficacy and safety in the context of long-term outcomes. 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 Allergy, Asthma, and Immunology

The 2023 International Consensus Statement on Allergy and Rhinology stated the following for cryotherapy/radiofrequency ablation of posterior nasal nerve.

- Aggregate grade of evidence: C (Level 3: 2 studies, level 4: 4 studies, level 5: 5 studies)
- Benefit: Improvement in rhinorrhea.
- Harm: Risk of complications (e.g., epistaxis, temporary facial pain and swelling, headaches), limited long-term results.
- Cost: Surgical/procedural costs, cost of device, potential time off from work.

- Benefits-harm assessment: Potential benefit must be balanced with low risk of harm, especially considering limited long-term results.
- Value judgments: Patients may experience an improvement in symptoms.
- Policy level: Option.
- Intervention: Cryoablation and radiofrequency ablation of the posterior nasal nerve may be considered in allergic rhinitis patients that have failed medical management, particularly for rhinorrhea.

Grade of evidence "C" implies that body of evidence consisted of observational studies (case control and cohort design). Policy level "Option" implies "either that the evidence quality that exists is suspect or that well-designed, well conducted studies have demonstrated little clear advantage to one approach versus another. Options offer clinicians flexibility in their decision-making regarding appropriate practice, although they may set boundaries on alternatives. Patient preference should have a substantial role in influencing clinical decision-making, particularly when policies are expressed as options." As per the consensus statement, "because the current evidence is primarily based on industry-sponsored studies with limited long-term data, these office-based interventions remain an option for properly selected patients".

American Academy of Otolaryngology
In January 2023, the American Academy of Otolaryngology issued a position statement on peripheral nerve ablation for the treatment of chronic rhinitis. The position statement was not based on a systematic review or strength of evidence rating. According to the position statement, " Based on these safety and efficacy data, the American Academy of Otolaryngology endorses the use of posterior nasal nerve ablation for the treatment of medically-refractory chronic rhinitis. We do not consider these treatments to be experimental."

American Rhinologic Society
In January 2022, the American Rhinologic Society issued a position paper on posterior nasal nerve ablation. The position statement was not based on a systematic review or strength of evidence rating. According to the position statement, "The American Rhinologic Society supports the use of posterior nasal nerve ablation for the treatment of chronic rhinitis, including both allergic and non-allergic subtypes. This procedure should not be considered experimental, but should be considered as an effective option in treating chronic rhinitis and improving patient quality of life in those suffering from rhinorrhea and nasal congestion based on the following data."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and 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
Ongoing			
NCT04154605[a]	ClariFix Rhinitis Randomized Controlled Trial	133	Jul 2022 (unknown status)
NCT04533438[a]	The RhinAer Procedure for Treatment of CHronic RhInitis - A Prospective, MulticeNter Randomized ConTrolled TRial Comparing RhinAer to Sham Control (RHINTRAC)	116	Apr 2025
NCT04154605[a]	ClariFix Rhinitis Randomized Controlled Trial	133	Jul 2022 (unknown status)
Unpublished			
NCT05648565	Effects of Radiofrequency Ablation of Posterior Nasal Nerves on Inflammatory Cytokines, Peak Nasal Inspiratory Flow, and Nasal Blood Flow in Patients with Chronic Rhinitis	17	Feb 2024

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Settipane RA, Charnock DR. Epidemiology of rhinitis: allergic and nonallergic. Clin Allergy Immunol. 2007; 19: 23-34. PMID 17153005
2. Lieberman P, Kaliner MA, Wheeler WJ. Open-label evaluation of azelastine nasal spray in patients with seasonal allergic rhinitis and nonallergic vasomotor rhinitis. Curr Med Res Opin. Apr 2005; 21(4): 611-8. PMID 15899111
3. Halderman A, Sindwani R. Surgical management of vasomotor rhinitis: a systematic review. Am J Rhinol Allergy. 2015; 29(2): 128-34. PMID 25785754
4. Marshak T, Yun WK, Hazout C, et al. A systematic review of the evidence base for vidian neurectomy in managing rhinitis. J Laryngol Otol. Jul 2016; 130 Suppl 4: S7-S28. PMID 27488341

5. Senanayake P, Wong E, McBride K, et al. Efficacy of Vidian Neurectomy and Posterior Nasal Neurectomy in the Management of Nonallergic Rhinitis: A Systematic Review. Am J Rhinol Allergy. Nov 2022; 36(6): 849-871. PMID 35695191
6. Zubair A, Lasrado S. Vidian Neurectomy. [Updated 2024 Feb 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK563142/]
7. Food & Drug Administration. Clarifix 510(k) Premarket Notification. 2019 (K190356). https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190356.pdf.
8. Food & Drug Administration. RhinAer (RHIN1 Stylus) 510(k) Premarket Notification. 2019 (K192471).
9. Del Signore AG, Greene JB, Russell JL, et al. Cryotherapy for treatment of chronic rhinitis: 3-month outcomes of a randomized, sham-controlled trial. Int Forum Allergy Rhinol. Jan 2022; 12(1): 51-61. PMID 34355872
10. Hwang PH, Lin B, Weiss R, et al. Cryosurgical posterior nasal tissue ablation for the treatment of rhinitis. Int Forum Allergy Rhinol. Oct 2017; 7(10): 952-956. PMID 28799727
11. Chang MT, Song S, Hwang PH. Cryosurgical ablation for treatment of rhinitis: A prospective multicenter study. Laryngoscope. Aug 2020; 130(8): 1877-1884. PMID 31566744
12. Ow RA, O'Malley EM, Han JK, et al. Cryosurgical Ablation for Treatment of Rhinitis: Two-Year Results of a Prospective Multicenter Study. Laryngoscope. Sep 2021; 131(9): 1952-1957. PMID 33616224
13. Gerka Stuyt JA, Luk L, Keschner D, et al. Evaluation of In-Office Cryoablation of Posterior Nasal Nerves for the Treatment of Rhinitis. Allergy Rhinol (Providence). 2021; 12: 2152656720988565. PMID 33598336
14. Stolovitzky JP, Ow RA, Silvers SL, et al. Effect of Radiofrequency Neurolysis on the Symptoms of Chronic Rhinitis: A Randomized Controlled Trial. OTO Open. 2021; 5(3): 2473974X211041124. PMID 34527852
15. Takashima M, Stolovitzky JP, Ow RA, et al. Temperature-controlled radiofrequency neurolysis for treatment of chronic rhinitis: 12-month outcomes after treatment in a randomized controlled trial. Int Forum Allergy Rhinol. Feb 2023; 13(2): 107-115. PMID 35714267
16. Takashima M, Stolovitzky JP, Ow RA, et al. Temperature-controlled radiofrequency ablation for the treatment of chronic rhinitis: Two-year outcomes from a prospective multicenter trial. Int Forum Allergy Rhinol. Jul 2024; 14(7): 1182-1194. PMID 38266636
17. Lee JT, Abbas GM, Charous DD, et al. Clinical and Quality of Life Outcomes Following Temperature-Controlled Radiofrequency Neurolysis of the Posterior Nasal Nerve (RhinAer) for Treatment of Chronic Rhinitis. Am J Rhinol Allergy. Nov 2022; 36(6): 747-754. PMID 35818709
18. Ehmer D, McDuffie CM, Scurry WC, et al. Temperature-Controlled Radiofrequency Neurolysis for the Treatment of Rhinitis. Am J Rhinol Allergy. Jan 2022; 36(1): 149-156. PMID 34382444
19. Ehmer D, McDuffie CM, McIntyre JB, et al. Long-term Outcomes Following Temperature-Controlled Radiofrequency Neurolysis for the Treatment of Chronic Rhinitis. Allergy Rhinol (Providence). 2022; 13: 21526575221096045. PMID 35663498

20. Krespi YP, Wilson KA, Kizhner V. Laser ablation of posterior nasal nerves for rhinitis. Am J Otolaryngol. 2020; 41(3): 102396. PMID 31948695
21. Wise SK, Damask C, Roland LT, et al. International consensus statement on allergy and rhinology: Allergic rhinitis - 2023. Int Forum Allergy Rhinol. Apr 2023; 13(4): 293-859. PMID 36878860
22. American Academy of Otolaryngology. Position Statement: PNN ablation for the treatment of chronic rhinitis. January 2023.
23. American Rhinologic Society. Posterior Nasal Nerve Ablation ARS Position Statement. January 2022.
24. Xun Niu MM, Yuzhang Chen MB, Tao Zhou MD, et al. Endoscopic vidian and vidian-branch neurectomy for refractory allergic rhinitis: A systematic Review. Int Forum Allergy Rhinol. Mar 2024; 14(3):679-694. First published: 16 September 2023 https://doi.org/10.1002/alr.23259.

Policy History

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Current Effective Date: 04/01/2026
01/20/2026 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 01/2027

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	30117, 30999, 31242, 31243, 31299, 64771
HCPCS	No Codes
ICD-10 Diagnosis	All Related Diagnoses

*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 technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

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 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.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.