

Bronchial Thermoplasty (for Pennsylvania Only)

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[Instructions for Use](#)

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Related Policies
None

Application

This Medical Policy only applies to the state of Pennsylvania. Any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis. Refer to [Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101](#).

Coverage Rationale

Bronchial thermoplasty is unproven and not medically necessary for treating asthma due to insufficient evidence of efficacy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

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Description of Services

Asthma is a heterogeneous disease usually characterized by chronic airway inflammation. The symptoms of asthma include wheezing, shortness of breath, chest tightness, and/or cough. These symptoms may vary over time and in intensity, together with expiratory airflow limitation. The treatment for asthma includes a personalized and stepwise approach for symptom control with medications (Global Initiative for Asthma, 2025).

Bronchial thermoplasty (BT) is a minimally invasive procedure intended for treating adults with severe, persistent asthma that is not well controlled with medications. BT uses thermal radiofrequency (RF) energy to reduce airway smooth muscle (ASM) mass and responsiveness. In turn, this may reduce airway constriction and the severity and frequency of asthma symptoms. BT is administered at three outpatient visits about three weeks apart. During the procedure, standard flexible bronchoscope which is introduced through the nose or mouth and into the lungs. A specialized catheter is advanced through the bronchoscope until it contacts the targeted airway wall. Controlled thermal RF energy is then delivered to the ASM while leaving the surrounding tissue undamaged (ECRI, 2020).

Clinical Evidence

Conclusive quality evidence is lacking to support the safety and efficacy of bronchial thermoplasty (BT) in the control of severe asthma. Retrospective studies of BT have shown variable results with less efficacy for individuals older than 65 years of age and higher body mass index (BMI). BT is non-inferior to biologicals in quality of life (QOL) and differences may exist due to the heterogeneity of the cohort populations used in studies. Moreover, there are concerns that some studies involved individuals with less severe asthma and discordant correlation with clinical observations. Thus, the positive outcomes and biased QOL scores observed in these studies may not be applicable to individuals with severe asthma. Further randomized controlled trials (RCTs) are needed to determine the durability of clinical effects, assess long-term adverse events (AEs), and further understand the mechanism of BT on asthma.

Fong et al. (2023) conducted a systematic review and network meta-analysis to examine if BT compares favorably with U.S. Food and Drug Administration (FDA) approved biological therapies for use in severe asthma, and to generate probability-based rankings of safety and efficacy. The review included 29 RCTs and 15,547 individuals. (No RCT included in the network meta-analysis directly compared BT to biologics.) The results of the network meta-analysis revealed that fewer individuals treated with BT experienced greater than one asthma exacerbation compared to control. The annual exacerbation rate ratio of BT versus control was non-significant. Significant improvements in QOL, morning peak expiratory flow (PEF) rate, and oral corticosteroid dose reduction were found. No significant differences between BT and biologics were seen across indirect comparisons of all studies. The authors concluded that despite the lack of head-to-head comparative trials, the network meta-analysis suggests BT is non-inferior to biologics in terms of QOL. BT may also be noninferior for the outcomes of exacerbation rate reduction, lung function improvement, and oral corticosteroid dose reduction. BT is a promising alternative for individuals with severe asthma. Recommendations for future BT clinical trials included biomarkers or direct comparison with biologics to enrich current evidence. Limitations of the network meta-analysis included the absence of individual patient data, difficulty assessing methodological equivalence, and differences in individual selection criteria across studies. (This study is included in the health technology assessment by Hayes, 2022; updated, 2024.)

Hatch et al. (2023) evaluated the safety and efficacy of BT five years post-procedure in a real-world cohort of individuals with severe asthma. The study included 51 individuals enrolled in a registry and treated with BT at two Australian tertiary centers. Five years post-procedure, individuals were evaluated by interview, record review, Asthma Control Questionnaire (ACQ), spirometry, and high-resolution chest computed tomography (CT). The results of the study revealed significant improvements in ACQ from baseline (3.0 ± 1.0) to 60 months later (1.8 ± 1.0) ($p < 0.001$). Seventy-six percent of individuals responded to BT with a fall in ACQ of 0.5 units or greater. Of the 13 individuals in whom the ACQ had not improved by 0.5 units, the ACQ improved by 0.4 units in five individuals. The remaining eight individuals demonstrated no change in ACQ at 60 months. Per annum steroid requiring exacerbation frequency was also reduced from baseline (3.8 ± 3.6) to 60 months later (1.0 ± 1.6) ($p < 0.001$). Forty-four percent of individuals weaned off oral steroids. A greater than 50% reduction in the requirement for reliever medications was also noted. There were no changes in spirometry observed. Minor degrees of localized radiological bronchiectasis were observed on CT for 23/47 individuals. (Four individuals were noted as unavailable to undergo CT). Modified Reiff scores increased from baseline (0.6 ± 2.6) to five years after BT (1.3 ± 2.5) ($p < 0.001$). However, no individuals exhibited features of clinical bronchiectasis. The authors concluded that a sustained clinical benefit from BT at five years was demonstrated in this cohort of individuals with severe asthma. While radiological bronchiectasis was noted on CT, it did not appear to be inducing clinical disease. Limitations of the study included a lack of randomization. (This study is included in the health technology assessment by Hayes, 2022; updated, 2024.)

Nishi et al. (2023) conducted a retrospective case series on individuals with severe asthma who underwent BT at a single institution in Japan. The study included clinical data for 21 individuals recorded at the last visit before BT (baseline assessment) and at 12 months after BT (follow-up assessment). At the follow-up assessment, the study results revealed Asthma Quality of Life Questionnaire (AQLQ) scores ($p = 0.003$), maintenance oral corticosteroids (OCS) ($p = 0.027$), and exacerbation frequency ($p = 0.017$) significantly improved. Prebronchodilator forced expiratory volume in one second (FEV1) (% predicted) did not significantly change ($p = 0.19$). Additionally, when individuals were grouped according to their BMI, AQLQ scores were improved more in individuals with overweight/obesity than those with normal weight ($p =$

0.01). The authors concluded that those with non-controlled severe asthma exhibiting overweight/obesity and low QOL had potential benefits from BT. The study findings are limited by small sample size, the retrospective nature of the review, and lack of a comparison group undergoing a different treatment.

Chupp et al. (2022) conducted a five-year evaluation based on the data collected from the Post-FDA Approval Clinical Trial Evaluating Bronchial Thermoplasty in Severe Persistent Asthma [PAS2] study that evaluated the efficacy and safety for individuals with severe asthma who underwent BT. Inclusion criteria consisted of adults (age 18-65), taking inhaled corticosteroids $\geq 1,000 \mu\text{g/d}$ (beclomethasone or equivalent) and long-acting beta-agonists $\geq 80 \text{ m} = \mu\text{g/d}$ (salmeterol or equivalent). The analysis included 227/284 participants (80%) who completed five years of follow-up. The study results revealed that by year five, the proportion of participants with severe exacerbations, emergency department (ED) visits, and hospitalizations was 42.7%, 7.9%, and 4.8% posttreatment, respectively. This was compared with 77.8%, 29.4%, and 16.1% in the 12 months prior to treatment. Severe exacerbations were defined as a worsening of asthma symptoms requiring the use of systemic corticosteroids; for those already taking OCSs on a daily or alternate-day basis, a severe exacerbation was defined as a worsening of symptoms requiring an increase in the daily dose of systemic corticosteroids. The proportion of participants on maintenance OCS decreased from 19.4% at baseline to 9.7% at five years. Additionally, a subgroup analysis, based on baseline clinical and biomarker characteristics, revealed a statistically significant clinical improvement among all subgroups. The authors concluded, five years after treatment, participants in PAS2 experienced decreases in severe exacerbations, hospitalizations, ED visits, and corticosteroid exposure. All subgroups also demonstrated clinically significant improvement, suggesting that BT improves asthma control in different asthma phenotypes. Limitations of the study included no sham or control group, participants were not followed for the entire five years, which introduced bias, and no comparison was done in response after BT, to responses to biological medications. (This study is included in the health technology assessment by Hayes, 2022; updated, 2024.)

Hayes completed a health technology assessment that focused on the use of BT as an adjunct treatment for severe persistent asthma in adult individuals that remain symptomatic despite medical management with inhaled corticosteroids (ICS) and long-acting beta-2 agonists. The assessment included 18 publications reporting on 15 studies. Hayes concluded that a low-quality body of evidence suggests BT may reduce asthma exacerbations, healthcare utilization, and medication usage in individuals with severe asthma. Improvements in symptom control and asthma-related QOL were also observed, and for the most part, clinically significant. The benefits of BT were generally sustained. BT did not improve pulmonary function measurements. During the BT treatment period, AEs were common. Hayes noted there were individual study limitations, some inconsistency in findings for several outcomes, and limited evidence comparing BT with clinical alternatives. Future studies are needed to determine which individuals with severe asthma are most likely to benefit from BT compared with other add-on treatments. During the most recent annual review for the assessment, Hayes identified five newly published studies. Based on a review of abstracts, Hayes concluded these studies are unlikely to change the conclusion of the assessment. There is a potential, but still unproven benefit for BT as a treatment for severe persistent asthma in adult individuals whose condition is not well controlled with long-acting bronchodilators and glucocorticoids and who accept the short-term risk of increased AEs. Additionally, there remains insufficient evidence for BT as a treatment for mild to moderate asthma in adults (Hayes, 2022; updated, 2024). Akaba et al. 2023, Chaudhuri et al., 2021, and Goorsenberg et al., 2021, which were previously cited in this policy, are included in this Hayes report.

Menzella et al. (2021) conducted a retrospective, observational study to compare those diagnosed with severe refractory asthma who were currently being treated with omalizumab, mepolizumab, benralizumab, or BT and to evaluate the efficacy of these treatments over a 12-month observation period. The study included 199 individuals, older than age 12, from a single-center. The study results revealed a 16.7% reduction in hospitalizations, a 66.6% reduction in exacerbations ($p = 0.0001$), and the greater improvement in FEV1 (+37.4%; $p < 0.0001$) in individuals treated with benralizumab ($n = 32$). There was an 85.7% reduction in hospitalizations ($p = 0.012$) and an 88.8% reduction in exacerbations ($p < 0.0001$) in individuals treated with omalizumab ($n = 54$). There was an 89.5% reduction in hospitalizations ($p = 0.02$) and a 92.1% reduction in exacerbations ($p < 0.0001$) in individuals treated with mepolizumab ($n = 83$). There was a 93.7% reduction in hospitalizations ($p = 0.001$) and a 73.5% reduction in exacerbations ($p < 0.0001$) in individuals treated with BT ($n = 30$). Individuals treated with BT and mepolizumab showed the best OCS sparing effect, - 76% ($p < 0.0001$) and - 90.2% ($p = 0.002$), respectively. The authors concluded that all biologics, to varying degrees, reduced hospitalizations, exacerbations, and usage of OCS. Additionally, despite a starting point for those in the BT group that was worse for hospitalizations, exacerbations, and usage of OCS, BT obtained positive results that were comparable to biologics. The study is limited by lack of randomization to the various treatment groups or comparison to sham procedure. (This study is included in the health technology assessment by Hayes, 2022; updated, 2024.)

Langton et al. (2020) conducted a small, prospective case series to evaluate the effects of BT, 12 months post-procedure, on airway volume in participants with severe asthma. The study included 10 consecutive participants that needed to be utilizing inhaled triple therapy, had poorly controlled symptoms, and with frequent exacerbations requiring oral steroids. Baseline data collection included ACQ and high-resolution CT at total lung capacity (TLC) and functional residual capacity

(FRC). CT was repeated 4 weeks after the left lung was treated with BT, but prior to right lung treatment, and then again 12 months after both lungs were treated. Other outcome parameters, including ACQ and oral steroid-requiring exacerbations, were measured at six- and 12-months post-BT. The study results revealed that ACQ improved from 3.4 ± 1.0 to 1.5 ± 0.9 ($p = 0.001$) 12 months post-PT. The frequency of oral steroid-requiring exacerbations also improved ($p = 0.008$). Total airway volume increased 12 months after BT in both the TLC ($p = 0.03$) and the FRC scans ($p = 0.02$). No change was observed in airway volume for the untreated central airways. In the BT-treated distal airways, increases in airway volume of $38.4 \pm 31.8\%$ at TLC ($p = 0.03$) and $30.0 \pm 24.8\%$ at FRC ($p = 0.01$) were observed. The change in distal airway volume was correlated with the improvement in ACQ ($r = -0.71$, $p = 0.02$). The authors concluded that BT induces long-term increases in airway volume, which correlates with symptomatic improvement. This study is limited by a lack of comparison group and small sample size.

ECRI completed a clinical evidence assessment that focused on how well the Alair™ System (Boston Scientific Corp.) worked for treating severe asthma with BT in individuals irresponsive to medications. The assessment included two systematic reviews and one prospective, nonrandomized, comparison study reporting on a total of 1,845 individuals. The results of the assessment revealed that the reported benefits of the Alair are modest and of unclear clinical significance for asthma control, asthma exacerbation, reduced hospitalizations, and QOL up to one year. It was also unclear whether the benefits were clinically significant or sustained beyond one year. The AEs were more common with the Alair than with sham or standard medical therapy. ECRI concluded that the available clinical evidence for the Alair was inconclusive due to study limitations. One systematic review comparing BT to immunotherapy provided only indirect evidence because no head-to-head RCTs were available. The studies in both systematic reviews were at a risk of bias due to small sample size, lack of randomization, lack of blinding, and/or differences in follow-up times. Studies reported between-group differences of unclear significance because the results were imprecise for some outcomes. The findings may also not be generalizable because of differences in patient characteristics across studies. The comparison study is at a high risk of bias due to the small sample size, single-center focus, and lack of randomization. Larger, multicenter RCTs that report longer-term outcomes are needed to validate BT with the Alair (ECRI, 2020). Wu et al., 2011, previously cited in this policy, was included in this ECRI assessment.

Burn et al. (2017) reported results from a retrospective study of BT procedural and short-term safety outcomes for routine United Kingdom (UK) clinical practice individuals. Patient characteristics and safety outcomes were assessed using two independent data sources, the British Thoracic Society UK Difficult Asthma Registry, and the Hospital Episodes Statistics database. A matched cohort of 59 individuals involving 152 procedures at six centers was used to estimate safety outcome event rates compared with clinical trial results. Study results for the matched cohort revealed that procedural complications were reported in 17/152 procedures (11.2%; 13/59 individuals); 18/152 procedures (11.8%; 15/59 individuals) were followed by an emergency readmission within 30 days for respiratory cause; and 13/152 procedures (8.6%; 13/59 individuals) were followed within 30 days by an accident and emergency (A&E) attendance admission for any cause. Overall, 31/152 procedures (20.4%) were associated with at least one safety issue within 30 days. Seventy of 152 procedures (46.1%) were followed by an overnight stay. Compared with published clinical trials, which found lower hospitalization rates, individuals undergoing BT in routine clinical practice were, on average, older, had worse baseline lung function and asthma QOL. The authors concluded that a higher proportion of individuals experienced AEs compared to clinical trials. However, the greater severity of disease in those undergoing BT in routine clinical practice may explain the observed rate of post-procedural stay and readmission. The study findings are limited by lack of randomization. (This study is included in the health technology assessment by Hayes, 2022; updated, 2024.)

Chupp et al. (2017) published a comparison of three-year follow-up results from two prospective, multicenter studies of BT for subjects with severe asthma. The study compared the first 190 participants enrolled in the post-marketing PAS2 trial with the 190 participants treated with BT in the Asthma Intervention 2 (AIR2) RCT. The study results revealed that the percentage of participants enrolled in PAS2 with severe exacerbations, ED visits, and hospitalizations at year three after BT, significantly decreased by 45%, 55% and 40%, respectively. The PAS2 results echoed the AIR2 results. Participants enrolled in PAS2 and AIR2 were both able to significantly reduce their mean ICS daily dose. The percentage of participants enrolled in PAS2 who were taking daily OCS to improve asthma control was reduced from 18.9% at baseline to 10.2% in the third year after BT. However, this decrease was not apparent in the AIR2 trial, where a lower percentage of the participants who received BT were on maintenance OCS medication at baseline. Prebronchodilator FEV1 remained unchanged from baseline throughout the three-year follow-up period. Postbronchodilator FEV1 remained higher than prebronchodilator values at all times. The authors concluded that PAS2 demonstrated similar improvements in asthma control after BT compared with the AIR2 trial despite enrolling participants who may have had poorer asthma control. BT was safe, participants had durable and markedly lower rates of steroid exacerbations, ED visits, and hospitalizations three years after BT. Limitations of the study include lack of comparison with a contemporary control group undergoing a different therapy.

Zhou et al. (2016) performed a systematic review and meta-analysis to evaluate the long-term efficacy and safety of BT in the treatment of participants with moderate to severe persistent asthma. The review included 249 participants treated with BT who had one-year follow-up data and 216 participants who had a five-year follow-up data from three RCTs and three extension studies. Outcomes assessed after BT included spirometric data, respiratory AEs, ED visits, and hospitalization for respiratory illness at a one-year and five-year follow-up. The study results revealed no evidence of significant decline in prebronchodilator FEV1 or in postbronchodilator FEV1 between one year and five years. The frequency of respiratory AEs was reduced significantly during the follow-up. The number of ED visits for respiratory AEs remained unchanged after BT treatment. There was no statistically significant increase in the incidence of hospitalization for respiratory AEs. The authors concluded that BT showed reasonable long-term safety and efficacy for participants with moderate to severe persistent asthma. However, a large-scale clinical study should be performed to confirm the finding. There are several limitations in this study. Almost all studies included in this meta-analysis did not have a control group (sham group) for the five-year follow-up. The authors stated that findings from current studies are based merely on clinical manifestations and outcomes. Histological assessment after BT could provide more evidence to support the findings. (This study is included in the health technology assessment by Hayes, 2022; updated, 2024 and the clinical evidence assessment by ECRI, 2020.)

A Cochrane systematic review by Torrego et al. (2014) concluded, based on a review of the Asthma Intervention Research (AIR), AIR2, and Research in Severe Asthma (RISA) RCTs (429 participants), that BT for individuals with moderate to severe asthma provides a modest clinical benefit in QOL and lower rates of asthma exacerbation, but no significant difference in asthma control scores. The QOL findings were at risk of bias, as the main benefits were seen in the two studies that did not include a sham treatment arm. This procedure increases the risk of AEs during treatment, but has a reasonable safety profile after completion of the bronchoscopies. The overall quality of evidence regarding this procedure is moderate. Further research should provide a better understanding of the mechanisms of action of BT, as well as its effect on different asthma phenotypes or in participants with worse lung function. (This study is included in the health technology assessment by Hayes, 2022; updated, 2024 and the assessment by ECRI, 2020.)

Clinical Practice Guidelines

American College of Chest Physicians (CHEST)

CHEST published a coverage and payment position statement that concluded, based on the strength of the clinical evidence, BT offers an important treatment option for adult patients with severe asthma who continue to be symptomatic despite maximal medical treatment (CHEST, 2014).

British Thoracic Society (BTS)/National Institute for Health and Care Excellence (NICE)/Scottish Intercollegiate Guidelines Network (SIGN)

BTS/NICE/SIGN guidelines for the diagnosis, monitoring, and management of chronic asthma in adults, young people, and children do not mention BT as a potential treatment nor address managing severe asthma (NICE, 2024).

European Respiratory Society/American Thoracic Society (ERS/ATS)

ERS/ATS guidelines for the treatment of severe asthma recommend BT for adults only in the context of an independent systematic registry or a clinical study with institutional review board (IRB) approval (strong recommendation, very low-quality evidence). The guidelines note, "This is a strong recommendation, because of the very low confidence in the currently available estimates of effects of bronchial thermoplasty in patients with severe asthma. Both potential benefits and harm may be large and the long-term consequences of this new approach to asthma therapy utilizing an invasive physical intervention are unknown. Specifically designed studies are needed to define its effects on relevant objective primary outcomes such as exacerbation rates, and long-term effects on lung function. Studies are also needed to better understand the phenotypes of responding patients, its effects in patients with severe obstructive asthma (FEV1 < 60% of predicted value) or in whom systemic corticosteroids are used, and its long-term benefits and safety. Further research is likely to have an important impact on this recommendation" (Chung et al., 2014).

Global Initiative for Asthma (GINA)

GINA guidelines for asthma management and prevention state that BT is a potential treatment option for select adult patients with uncontrolled asthma despite optimized therapeutic regimens and referral to an asthma specialty center. However, BT should only be performed as part of an independent IRB-approved systematic registry or clinical research study. BT is associated with an increase in asthma exacerbations during the three-month treatment period followed by a subsequent decrease in frequency. BT has shown no beneficial effect on lung function or asthma symptoms when compared with sham control. Though, during extended follow-up, some patients treated with BT reported a sustained reduction in exacerbations. The number of BT clinical studies is small. Patients with chronic sinus disease, frequent chest infections, or FEV1 < 60% predicted were excluded from the pivotal sham-controlled study. Patients were also not on

optimized asthma treatment prior to treatment with BT. There is a need for larger sham-controlled studies with a longer-term follow-up period, comparing both effectiveness and safety, including lung function (GINA, 2025).

National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC)/National Heart, Lung, and Blood Institute (NHLBI)

NAEPPCC/NHLBI asthma management guidelines state, "Most individuals ages 18 years and older with uncontrolled, moderate-to-severe, persistent asthma should not undergo BT to treat asthma because the benefits are small, the risks are moderate, and the long-term outcomes are uncertain. Some individuals with moderate-to-severe persistent asthma who have troublesome symptoms may be willing to accept the risks of BT and, therefore, might choose this intervention after shared decision-making with their health care provider. Clinicians should offer the procedure in the setting of a clinical trial or a registry study to enable the collection of long-term data on the use of BT for asthma." These guidelines are based on the AIR, AIR2, and RISA RCTs. Limitations of these three trials include funding by the company that markets the BT device, a lack of long-term follow-up, and an insufficient number of patients to fully assess clinical benefits and harms. Additional research that includes RCTs and long-term registry outcomes would be beneficial (NAEPPCC/NHLBI, 2020).

National Institute for Health and Care Excellence (NICE)

NICE interventional procedures guidance on BT for severe asthma states that the current safety and efficacy evidence is adequate to support the use of this procedure, provided that standard arrangements are in place for clinical governance, consent, and audit. However, BT should only be used for severe asthma that is uncontrolled despite optimal drug treatment. BT should only be performed by a multidisciplinary team in specialist centers with on-site access to intensive care. Additionally, BT should only be performed by clinicians with training in the procedure and experience managing severe asthma. There is uncertainty about which patients may benefit from BT. Future research should report the details of BT patient selection and long-term safety and efficacy outcomes (NICE, 2018).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

For information on BT systems, refer to the following website (use product code O0Y):
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>. (Accessed June 10, 2025)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2025	Supporting Information <ul style="list-style-type: none">Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current informationArchived previous policy version CS014PA.N

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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