A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
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<th>Plan: Aetna Better Health</th>
<th>Submission Date: 11/01/2018</th>
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<tbody>
<tr>
<td>Policy Number: 0592</td>
<td>Effective Date:</td>
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<tr>
<td></td>
<td>Revision Date:</td>
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<tr>
<td>Policy Name: Radiofrequency Ablation of Hypertrophied Nasal Turbinates</td>
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Type of Submission – Check all that apply:

- [X] New Policy*
- [ ] Revised Policy
- [ ] Annual Review – No Revisions

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 0592 Radiofrequency Ablation of Hypertrophied Nasal Turbinates**

Policy is new to Aetna Better Health of Pennsylvania.

Name of Authorized Individual (Please type or print):

Dr. Bernard Lewin, M.D.

Signature of Authorized Individual:

[Signature]
I. Aetna considers radiofrequency volumetric tissue reduction (RFVTR, Somnoplasty) medically necessary for treatment of chronic nasal obstruction due to mucosal hypertrophy of the inferior turbinates.

II. Aetna considers RFVTR of the turbinates for treatment of obstructive sleep apnea experimental and investigational because its safety and effectiveness for this indication has not been established.

III. Aetna considers RFVTR of turbinates for snoring not medically necessary. See CPB 0004 - Obstructive Sleep Apnea in Adults (../1_99/0004.html) .
IV. Aetna considers Coblation non-thermal volumetric tissue reduction for treatment of hypertrophy of nasal turbinates experimental and investigational because of insufficient evidence in the peer-reviewed literature. See also CPB 0475 - Coblation (..400_499/0475.html)

Background

There are many potential causes for nasal obstruction. Some of the most common causes are nasal allergies, deviation of the nasal septum (the partition in the middle of the nose on the inside), or sinus or nasal infection.

The nasal passages can also be obstructed by enlarged turbinates. Enlarged turbinates can impair normal breathing, causing patients to breathe through the mouth. Enlarged turbinates may be treated with intranasal sprays and medications. If turbinate hypertrophy is chronic, surgical interventions may be considered.

The Somnoplasty device (Somnus Medical Technologies, Sunnyvale, CA) employs radiofrequency energy to ablate hypertrophied nasal turbinates. The radiofrequency catheter is inserted into the submucosa of the hypertrophied inferior turbinate. The submucosal tissue around the catheter is heated and the tissue coagulates. As the coagulative lesions heals, the submucosal tissue shrinks.

The advantage of radiofrequency volumetric tissue reduction (RFVTR) over electro-cautery for turbinate hypertrophy is that the former can be performed as an office procedure with local anesthesia, whereas the latter is done in an outpatient surgical center under general anesthesia.

The evidence supporting RFVTR for inferior turbinate reduction consists of prospective case series. However, there are no studies directly comparing RFVTR to electrocautery or cold knife surgery (which are the established alternative
methods of inferior turbinate reduction). In addition, there are no reports of the long-term durability of inferior turbinate reduction with RFVTR. In a review of the literature on radiofrequency ablation for sleep disordered breathing, Massod and Phillips (2001) concluded that "[a]pplication of RFVTR to the tongue and turbinates has not been studied thoroughly enough to assess its efficacy at present."

Recent studies suggest that radiofrequency tissue ablation may be effective in treating chronic nasal obstruction and refractory allergic rhinitis. In a prospective, randomized, double-blind, placebo-controlled clinical pilot study, Powell et al (2001) estimated the treatment effect of temperature-controlled radiofrequency (TCRF) reduction of turbinate hypertrophy in patients with sleep-disordered breathing (SDB) treated with nasal continuous positive airway pressure (CPAP). A total of 22 CPAP-treated patients with SDB with turbinate hypertrophy were randomly assigned to either TCRF turbinate treatment (n = 17) or placebo control (n = 5). Changes in nasal obstruction were assessed between pre-treatment and 4 weeks post-treatment. The primary outcome evaluated changes in the blinded examiners' findings of nasal obstruction on a visual analogue scale (VAS). Secondary outcomes included blinded patients' and unblinded examiner assessments of nasal obstruction VAS, nightly CPAP use, adherence, and tolerance, along with sleepiness and general health status scales. The treatment group findings were subtracted from the changes in the placebo group to yield treatment effect. The authors concluded that TCRF turbinate treatment appears to benefit nasal obstruction and CPAP treatment for SDB. Placebo control and double blinding are critical for establishing the true treatment effect. A future definitive trial is feasible to establish statistical significance of these findings.

In a prospective, non-randomized study, Black et al (2002) evaluated the effectiveness and morbidity of bipolar radiofrequency thermal ablation of the inferior turbinates in
patients with nasal obstruction caused by turbinate hypertrophy (n = 20). The authors concluded that the bipolar radiofrequency thermal ablation of inferior turbinates is a promising option, for inferior turbinate hypertrophy.

In a prospective, randomized clinical trial, Sapci et al (2003) compared nasal functions of patients with chronic nasal obstruction following treatment by (i) radiofrequency tissue ablation, (ii) laser ablation, and (iii) partial turbinectomy. The study was carried out on 45 adult volunteer patients with symptoms and signs of nasal obstruction and stuffiness related to enlarged turbinates (n = 15 in each group). These investigators found that that radiofrequency tissue ablation to the turbinate was effective in improving nasal obstruction objectively and in preserving nasal mucociliary function. Laser ablation of the turbinate was effective in improving the nasal obstruction; however, it significantly disturbed the mucociliary function. Partial turbinectomy resulted in similar improvements as obtained with radiofrequency tissue ablation. These findings were based on a small sample size and a relatively short follow-up (12 weeks). Thus, further follow-up studies with a larger sample size is needed to evaluate the long-term improvement of symptoms and maintenance of nasal functions.

In a prospective, non-randomized study, Lin et al (2003) assessed the effectiveness of turbinate surgery with radiofrequency for the treatment of allergic rhinitis that is unresponsive to medical therapy (n = 108). These researchers concluded that radiofrequency appears to be an effective and safe tool for treating allergic rhinitis with poor response to medical therapy. If further long-term studies confirm these findings, radiofrequency has the potential to be one of the most popular surgical modalities for the treatment of allergic rhinitis refractory to medical therapy.
An assessment of RFVTR of the turbinates conducted by the National Institute for Clinical Excellence (NICE, 2004) concluded that "[c]urrent evidence on the safety and efficacy of radiofrequency volumetric tissue reduction for turbinate hypertrophy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research .... The Advisory Committee noted that there was insufficient evidence to assess efficacy, given that patient numbers were so small in the studies reviewed".

In a randomized controlled trial (n = 32), Nease and Krempl (2004) assessed the short-term (8 weeks and 6 months) effectiveness of RFVTR in treating nasal obstruction in subjects with inferior turbinate hypertrophy. These investigators concluded that RFVTR is an effective alternative for the treatment of patients with nasal obstruction due to inferior turbinate hypertrophy. However, this is the first randomized study that demonstrates that RFVTR is significantly better than placebo in treating nasal obstruction due to inferior turbinate hypertrophy. Its findings need to be validated by future studies with larger sample size and longer follow-up.

Porter et al (2006) reported the long-term effectiveness of RFVTR and compared this approach with other accepted surgical treatments of inferior turbinate hypertrophy. This study was a prospective, 2-year follow-up of 19 patients originally enrolled in a prospective, randomized, single-blinded, placebo-controlled trial for treatment of inferior turbinate hypertrophy with RFVTR. Patients assessed their severity of obstruction, frequency of obstruction, and overall ability to breathe by way of a 10-cm VAS. Radiofrequency volumetric tissue reduction for inferior turbinate hypertrophy showed continued benefit at 2 years post-treatment, with no indication of increasing symptomatology. The benefit showed in frequency of obstruction, severity of obstruction, and overall ability to breathe (p < 0.05) was maintained at 2 years. No complications occurred. These investigators concluded that
RFVTR is effective in treating inferior turbinate hypertrophy with sustained benefit at 2 years follow-up while resulting in fewer complications than other surgical methods. They noted that RFVTR is a relatively new procedure, and therefore there are few long-term evaluations of its effectiveness; this is the first prospective study to document successful outcomes at 2 years follow-up.

There are 2 main drawbacks of this study: (i) the 19 patients represented a long-term follow-up rate of 68% (19/28), which may have introduced bias; and (ii) there was no other treatment arm included in this study. These results need to be verified in future large, prospective, randomized, controlled trials comparing RFVTR with submucosal resection of the inferior turbinate.

Coblation:

In a prospective, open-label, non-randomized trial, Di Rienzo Businco and colleagues (2010) evaluated the effectiveness of adding Coblation-assisted inferior turbinoplasty to a medical treatment regimen for symptoms associated with hypertrophic inferior turbinates. Patients were assigned to treatment groups in order of enrollment into the study. From June 2007 to June 2008, 220 patients with allergic rhinitis and hypertrophic inferior turbinates were enrolled and assigned into 2 groups: (i) the surgical group who received radiofrequency thermal ablation inferior turbinoplasty and medical therapy, and (ii) the medical group who received medical therapy only. Groups were further divided into 2 allergen types based on antigen sensitivity: (i) perennial and (ii) seasonal. Subjective complaints (itching, nasal obstruction, rhinorrhea, sneezing), clinical rhinoendoscopy and rhinomanometry tests results were recorded at the start of the study and 2 months post-treatment. Effect sizes for the mean improvements after treatment were tabulated for all groups. All study outcomes improved within all groups. Comparison between medical and surgical groups showed higher
improvement in both perennial and seasonal, respectively, in nasal obstruction, sneezing, rhinomanometry, and rhinomanometry after NPT. Itching improved only in perennial allergen type. Rhinoendoscopy clinical score showed improvement in surgical group over medical group in both allergen types. The authors concluded that Coblation-assisted turbinate reduction is a promising adjunct to medical therapy in patients with persistent symptoms associated with allergic rhinitis. Patients undergoing this surgery had greater reduction of symptoms than patients receiving medical therapy alone, where patients with perennial allergies appeared to benefit most.

In a prospective study, Simeon et al (2010) evaluated the effectiveness of Coblation turbinate reduction in children presenting with obstructive allergic rhinitis after failure of medical management (n = 9). Coblation was performed after assessment of rhinitis. Obstruction was assessed on rhinomanometry and VAS; other rhinologic functional signs were assessed on interview, and functional impact was assessed on the PRQLQ quality of life questionnaire. After the procedure, all 9 children showed reduced nasal obstruction and improved rhinologic function signs, confirmed by the favorable evolution of PRQLQ scores. The authors concluded that these findings demonstrated the interest of Coblation in controlling nasal obstruction in children with allergic rhinitis refractory to medical treatment, with conserved nasal function. They stated that larger-scale studies with longer follow-up are needed to confirm these results.

Leong and associates (2010) evaluated the evidence for inferior turbinate surgery in children suffering with chronic nasal congestion. A structured review of the PubMed, EMBASE and the Cochrane Collaboration databases (Cochrane Central Register of Controlled Trials, Cochrane Database of Systemic Reviews) was undertaken, using the MeSH terms: nasal obstruction, turbinates, surgery and children. Only articles focusing on turbinate surgery with an
exclusively paediatric cohort were included. A total of 11 studies fulfilled the inclusion criteria. The ages of the children ranged from 1 to 17 years at the time of surgery and were followed-up for a period of 3 months to 14 years. Surgical indication for all studies was chronic nasal congestion, resistant to a trial of medical treatment for 2 to 3 months preceding surgery. Of the 730 cases reviewed, 79.1% had turbinate surgery as the standalone procedure. The remaining 21.9% had other concurrent procedures performed, the most common being adeno-tonsillectomy. Although all studies generally supported the effectiveness of turbinate reduction surgery for inferior turbinate hypertrophy, the outcome measures used were varied and did not allow comparison across studies. The authors concluded that there is currently little evidence to support turbinate reduction surgery in children. The role of surgery, if any, has not been properly examined. Furthermore, the long-term effects on nasal airflow dynamics, nasal physiology and long-term complications remain to be studied.

The evidence supporting the use of Coblation in the treatment of hypertrophied nasal turbinates consists of small scale studies, the largest of which had a sample size of 60 patients, of whom 30 underwent Coblation. The overall analysis of the current literature illustrated conflicting results regarding the efficacy of Coblation relative to other currently available treatment options.

Coblation is a non-heat driven process which ablates hypertrophied tissues through use of radiofrequency energy in a conductive medium such as saline. Lee et al (2006) compared the long-term effectiveness of coblation- and microdebrider-assisted partial turbinoplasty. Thirty patients were treated with microdebrider and 30 with Coblation. Patients were followed for 12 months post-operatively. Nasal obstruction was improved significantly in both groups after 12 months, but symptom improvement was statistically significant only in the microdebrider group. Lee et al (2006) concluded
that “microdebrider-assisted partial turbinoplasty is more effective and satisfactory in long-term relief of nasal obstruction and reduction in mucosal volume of anterior head of inferior turbinate.”

Gindros et al (2010) aimed to evaluate the effectiveness and safety of ultrasound treatment of the hypertrophied inferior turbinates in comparison to radiofrequency cold Coblation turbinate reduction and traditional submucosal monopolar inferior turbinate cauterization. They prospectively studied 60 patients with chronic hypertrophic rhinitis of nonallergic etiology. Thirty patients received inferior turbinate volume reduction using ultrasound procedure on the left side and monopolar diathermy on the right and the remaining 30 patients received radiofrequency Coblation on the left side and ultrasound turbinate reduction on the right. Patients were followed post-operatively for six months. Gindros et al (2010) found the best results in terms of decreasing subjective symptoms and nasal obstruction were obtained with the ultrasound procedure, and second with the radiofrequency technique. A limitation of this study in the evaluation of Coblation is that only 30 patients received Coblation, and those patients received Coblation only on one side.

Leong et al (2010) followed a cohort of 18 patients who had undergone Coblation inferior turbinate reduction surgery (CITR), of whom 13 patients were available for follow-up at 32 months. The mean baseline nasal conductance improved significantly (p = 0.033), but the mean VAS scores, although improved, did not achieve statistical significance. This study was a pilot study of the long-term outcomes of CITR, and the sample size adversely affects the strength of the findings.

Roje et al (2011) performed Coblation in 52 patients with inferior turbinate hypertrophy who were refractory to medical therapy. Nasal breathing was significantly improved in all patients, with total nasal resistance decreased from 0.44 Pa +/- 0.50 to 0.24 Pa +/- 0.11 (p < 0.001). Improvement was
statistically significant for hyposmia (p = 0.005), nasal draining (p = 0.003), and post-nasal drip (p < 0.001). However, it should also be noted that there was no comparison group in this study.

In a prospective, single-blinded study, Shah et al (2015) compared intramural bipolar electro-cautery and RF coblation in the treatment of inferior turbinate hypertrophy with regards to objective and subjective improvement in nasal obstruction, rate and type of complications, experience during the procedure, and rate of recovery. A total of 41 adult patients with inferior turbinate hypertrophy refractory to medical management were treated with RF coblation in 1 nostril and intramural bipolar cautery in the other. Subjective and objective data, including use of a VAS for subjective outcomes, acoustic rhinometry, and nasal endoscopy, were then obtained from each patient comparing the 2 techniques. Radiofrequency coblation was significantly less painful than intramural bipolar cautery during the procedure (p = 0.03) and during the early post-operative period (p < 0.02) and produced less crusting at 3 weeks (p = 0.009). Both interventions were similar in subjective and objective improvements in nasal obstruction as measured by acoustic rhinometry and subjective VAS outcomes. The authors concluded that RF coblation appeared to offer an equivalent alternative to bipolar electro-cautery for the treatment of inferior turbinate hypertrophy with less discomfort during the procedure and early post-operative period.

Ye and Zhou (2015) noted that there are numerous surgical managements of hypertrophied inferior turbinate. Controversy still exists involving the optimal surgical technique for hypertrophic inferior turbinate. These investigators discussed the most commonly used techniques for turbinate surgery and highlighted their recently published clinical outcomes. Microdebrider-assisted turbinoplasty, along with total removal of inferior turbinate mucosa, turned out to have no negative impact on healing time and no adverse post-operative events.
The majority of recently published studies were focused on surgical outcomes of RFA. It appeared that RFA could improve nasal resistance, sense of smell, and nasal mucociliary function. A 1470-nm diode laser was found superior to a conventional 940-nm diode laser in reducing scar formation. Ultrasonic bone aspirator was used to manage hypertrophic inferior turbinate caused by bone enlargement. Few recent literatures reported turbinectomy. The authors concluded that inferior turbinate surgery offered benefit and improved nasal obstruction in patients with hypertrophic inferior turbinate refractory to medical treatment. Moreover, they stated that rigorously designed study including subjective and objective measurements, control or comparison group, and long-term follow-up should be carried out in the future.

Obstructive Sleep Apnea:

An UpToDate review on “Management of obstructive sleep apnea in adults” (Kryger and Malhotra, 2015) states that “A systematic review reported that most of the evidence related to surgical treatments for OSA is from case series. Meta-analyses of data extracted from these series suggest that UPPP, laser-assisted uvulopalatoplasty, radiofrequency ablation, and maxillo-mandibular advancement (MMA) decrease the AHI. MMA is most consistently associated with a decreased AHI, although the morbidity of MMA has not been determined. These meta-analyses were limited by a serious risk for bias and inconsistency among the series …. Radiofrequency ablation -- RFA targeted to the turbinates, soft palate or tongue can be considered as a treatment option in patients with mild to moderate OSA who cannot tolerate or adhere to positive airway pressure, or in whom oral devices have been considered and found to be ineffective or undesirable. The data supporting this technique are very limited, however, and the procedure is seldom used”.

Snoring:
Casale et al (2014) noted that simple snoring represents a social problem, not only because it could affect the patient's married life, but it often goes along with sleep-disordered breathing. Chronic nasal obstruction has many sequel including snoring and the inferior turbinate hypertrophy (ITH) is its most common cause. In a prospective study, these researchers evaluated the effectiveness of video-assisted endoscopic RFVTR to reduce snoring in patients affected by chronic nasal obstruction due to ITH. This study was conducted over 48 habitual snoring persons with persistent nasal obstruction due to bilateral ITH refractory to medical management; they received one time RFVTR. Nasal symptoms were assessed both subjectively, by VAS and NOSE Scale, and objectively by video-rhinohygrometer.

Snoring was measured by Snoring severity rated by the bed partner, in a longitudinal fashion, using VAS. All patients were evaluated pre-operatively, and after 45th day (range of 35 to 50 days) post-operatively. A total of 32 subjects completed study. All patients had significant symptomatic improvement in nasal breathing (5.53 ± 2.88 versus 1.87 ± 1.75; p < 0.05), confirmed by video-rhinohygrometer values (p < 0.05). All patients had significant improvement of snoring (5.62 ± 2.80 versus 1.86 ± 1.43, p < 0.001) with a mean snoring VAS improvement of 77.4 %. The authors concluded that based on the findings of this study and literature review, it seems that RFVTR represents a safe, minimally invasive, easily performed, and time- and cost-effective surgery, which may decrease symptoms of snoring in patients with ITH, at least, in short-term follow-up. This was a small study (n = 32) with short-term follow-up (mean of 45 days); these findings need to be validated by well-designed studies with larger sample size and longer follow-up.

CPT Codes / HCPCS Codes / ICD-10 Codes

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*
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<th>Code</th>
<th>Code Description</th>
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<td><strong>ICD-10 codes will become effective as of October 1, 2015:</strong></td>
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<tr>
<td>CPT codes covered if selection criteria are met:</td>
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<td>30801</td>
<td>Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (eg, electrocautery, radiofrequency ablation, or tissue volume reduction); superficial [RFVTR or somnoplasty]</td>
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<td>30802</td>
<td>intramural [RFVTR or somnoplasty]</td>
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<td>C1886</td>
<td>Catheter, extravascular tissue ablation, any modality (insertable)</td>
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<td>Other specified disorders of nose and nasal sinuses [chronic nasal obstruction]</td>
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<tr>
<td>R06.83</td>
<td>Snoring</td>
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</tbody>
</table>

The above policy is based on the following references:


Available


38. Pelen A, Tekin M, Ozbilen Acar G, Ozdamar OI. Comparison of the effects of radiofrequency ablation and microdebrider reduction on nasal physiology in patients...

AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0592 Radiofrequency Ablation
of Hypertrophied Nasal Turbinates

There are no amendments for Medicaid.