Aetna considers Coblation tonsillectomy medical necessary for the treatment of any of the following:

- Peri-tonsillar abscess; or
- Recurrent middle ear infection where tonsillar hypertrophy is believed to be an exacerbating factor; or
- Recurrent or chronic tonsillar infection; or
- Tonsillar hypertrophy leading to respiratory symptoms or airway obstruction.

Aetna considers the following experimental and investigational because their effectiveness has not been established (not an all-inclusive list):

- Cervical Coblation nucleoplasty for the treatment of cervicogenic headache
- Coblation-assisted management of airway stenosis
- Coblation-assisted surgical resection for the treatment of rhinosporidiosis
- Coblation-assisted turbinoplasty and nasal Coblation plasma surgery for the treatment of allergic rhinitis

Policy History

Last Review
07/10/2019
Effective: 04/13/2001
Next Review: 05/08/2020
• Coblation devices (e.g., Topaz Microdebrider) for the treatment of musculoskeletal conditions
• Coblation for soft tissue stenosis of the external auditory canal
• Coblation nasal septal swell body reduction for the treatment of nasal obstruction
• Coblation non-thermal volumetric tissue reduction for dysphagia, laryngo-tracheal papillomatosis, nasopharyngeal angiofibroma, removing soft tissue during arthroscopic surgery, spinal osteoid osteomas, and wound debridement (not an all-inclusive list)
• Coblation of femoral and sciatic nerve for the treatment of stump pain and phantom limb pain
• Cordotomy by Coblation for the treatment of vocal fold immobility
• Endoscopic Coblation cauterization for the treatment of pyriform sinus fistula
• Percutaneous thoracic paravertebral nerve Coblation for the treatment of thoracic neuropathic pain
• Radiofrequency Coblation for the treatment of congenital nasopharyngeal teratoma
• Radiofrequency Coblation for the treatment of glottis cancer
• Radiofrequency Coblation for the treatment of laryngeal cancer
• Radiofrequency to the nasal valve (Vivaer Nasal Airway Remodeling (Aerin Medical)) for the treatment of nasal airway obstruction.

For Coblation non-thermal volumetric tissue reduction for treatment of hypertrophy of nasal turbinates, see CPB 0592 - Radiofrequency Ablation of Hypertrophied Nasal Turbinates (../500_599/0592.html)
For Coblation (Nucleoplasty) for treatment of herniated discs, see CPB 0602 - Thermal Intradiscal Procedures

Background

Standard electro-surgical tools and lasers remove tissue by thermal energy. Other methods of tissue decomposition have evolved to try to address the problems associated with high heat and damage to the surrounding tissue.

Coblation is a new surgical method for removing soft tissue during arthroscopic surgery developed by ArthroCare Corporation (Sunnyvale, CA). Coblation is a method of non-thermal volumetric tissue removal through molecular dissociation, similar to that of excimer lasers. Coblation uses the electrically conductive fluid employed in arthroscopic surgeries in the gap between the electrode and tissue. When electrical current is applied to this fluid, it turns into a charged layer of particles, called a plasma layer. Charged particles accelerate through the plasma and gain sufficient energy to break the molecular bonds within cells. This causes the cells to disintegrate molecule by molecule, so that tissue is volumetrically removed.

Coblation-assisted surgery uses a continuous mode of operation rather than the pulsed mode required for lasers. The purpose of a continuous mode of operation is to allow for coagulation of smaller blood vessels, and when used in sub-ablation mode, the intent is to produce hemostasis in larger vessels as well as shrinkage of collagen. Coblation uses a relatively low-temperature plasma, compared with lasers of high-power density beam of photons with their subsequent heat production. Because Coblation uses a low-temperature, the intent is to decrease the risk for thermal damage to
surrounding tissues. ArthroCare believes Coblation will provide a more precise operative result, reduce surgical time, speed recovery and reduce post-operative pain. However, these claims are not supported by well controlled randomized studies.

Coblation devices such as the Topaz Microdebrider (ArthroCare, Sunnyvale, CA) are also being studied for their use in treating musculoskeletal conditions. In a prospective, non-randomized consecutive case series, Tasto and colleagues (2005) assessed the safety and effectiveness of microtenotomy using a radiofrequency (RF) probe to treat chronic tendinosis of the common extensor tendon origins of the elbow (lateral epicondyle). The average age of the 13 patients was 48.3 +/- 5.5 years. Before receiving the microtenotomy, all patients had tendinosis symptoms for 6 months or longer and had failed conservative treatment. The RF-based microdebridement was performed on the symptomatic tendon using the Topaz Microdebrider device. Patients were followed-up at regular post-operative intervals for 24 months. Pain status was documented using a visual analog scale self-reported measure. Functional outcome was assessed using the upper limb DASH evaluation and grip-strength measures. Quality of life assessment was evaluated using the SF-36 questionnaire. Magnetic resonance imaging was performed at regular intervals over the follow-up period. Patients reported significantly reduced pain from baseline at the 7- to 10-day post-operative examination (p < or = 0.01). Pain reduction was statistically stable from 7 to 10 days through the 24-month post-operative period (p < or = 0.01). Limb-specific functional outcomes and quality of life scores were improved over baseline values. There were no peri-operative or post-operative complications related to the procedure. The authors concluded that the RF-based microtenotomy procedure was safe and effective through at least 2 years. This procedure provides a valuable addition for treating patients with lateral epicondylitis associated with tendinosis who have failed conservative therapy. This was a
small, short-term, non-randomized study; its findings need to be validated by future prospective randomized studies with large sample sizes and longer follow-up. In addition, evidence is needed regarding the effectiveness of this approach compared to established methods of management of these musculoskeletal conditions.

There is insufficient evidence in the medical literature to support the use of Coblation non-thermal volumetric tissue reduction for removing soft tissue during arthroscopic surgery or for treating musculoskeletal conditions.

On the other hand, there is evidence to support the use of Coblation tonsillectomy. In a double-blind, randomized controlled study, Arya et al (2003) compared post-operative pain following Coblation tonsillotomy versus Coblation tonsillectomy. No statistically significant difference in pain was demonstrated in the group of 14 patients studied. Nevertheless, the authors recommended tonsillectomy over tonsillotomy. Furthermore, in a study to measure the benefits of Coblation tonsillectomy (n = 844) against traditional tonsillectomy (n = 743), Belloso et al (2003) concluded that Coblation tonsillectomy was associated with a lesser incidence of delayed hemorrhage, more significantly in the pediatric population. The new technique using tissue Coblation for tonsil dissection offers significant advantages in the post-operative period compared with dissection tonsillectomy with bipolar diathermy hemostasis. Coblation is associated with less post-operative pain and early return to daily activities. Also, there are fewer secondary infections of the tonsillar bed and significantly lower rates of secondary hemorrhage with Coblation.

In a prospective, controlled single-blind study, Stoker et al (2004) compared post-operative recovery after tonsillectomy using Coblation excision (CES, n = 44) or conventional electrosurgery (ES, n = 45). The authors concluded that children who
received CES tonsillectomy appeared to experience a better quality post-operative course, with no detriment to operative benefits of conventional ES.

A review by the National Institute for Clinical Excellence (NICE, 2003) recommended Coblation tonsillectomy for the following indications: (i) recurrent or chronic tonsillar infection, (ii) tonsillar hypertrophy leading to respiratory symptoms or airway obstruction, (iii) peri-tonsillar abscess, and (iv) recurrent middle ear infection where tonsillar hypertrophy is believed to be an exacerbating factor. Subsequent guidance from NICE (2005) concluded that "[c]urrent evidence on the safety and efficacy of electrosurgery (diathermy and coblation) for tonsillectomy appears adequate to support the use of these techniques, provided that normal arrangements are in place for consent, audit, and clinical governance."

A Cochrane evidence review (Burton and Doree, 2007) concluded that, "In terms of postoperative pain and speed and safety of recovery, there is inadequate evidence to determine whether coblation tonsillectomy is better or worse than other methods of tonsillectomy. Evidence from a large prospective audit suggests that it has been associated with a higher level of morbidity, in terms of postoperative bleeding. Large, well-designed randomised controlled trials supplemented by data from large prospective audits are needed to produce information on effectiveness and morbidity respectively."

Freeman and Mehdian (2008) evaluated the evidence for 3 minimally invasive methods in the treatment of discogenic low back pain (LBP) and radicular pain: (i) intra-discal electrothermal therapy (IDET), (ii) percutaneous discectomy, and (iii) Coblation nucleoplasty. An electronic search of the literature carried out using the Cochrane Library database (2007) and Medline (1966 to 2007) identified 77 references relating to IDET, 363 to percutaneous discectomy, and 36 to
Two randomized controlled trials (RCTs) assessed the effectiveness of IDET; 1 demonstrated a positive effect on pain severity only, whereas the other demonstrated no substantial benefit. Other RCTs showed that percutaneous intra-discal RF thermocoagulation is ineffective for the treatment of discogenic LBP. Trials of automated percutaneous discectomy suggested that clinical outcomes after treatment are at best fair and often worse when compared with microdiscectomy. There are no published RCTs assessing Coblation (ArthroCare Spine, Stockholm, Sweden) technology.

In an American Pain Society’s clinical practice guideline on non-surgical interventional therapies for LBP, Chou et al (2009) noted that although use of certain interventional therapies is common or increasing, there is also uncertainty or controversy about their efficacy. These investigators performed electronic database searches on Ovid Medline and the Cochrane databases through July 2008 to identify RCTs and systematic reviews of local injections, botulinum toxin injection, prolotherapy, epidural steroid injection, facet joint injection, therapeutic medial branch block, sacroiliac joint injection, intra-discal steroid injection, chemonucleolysis, RF denervation, IDET, percutaneous intra-discal RF thermocoagulation, Coblation nucleoplasty, and spinal cord stimulation. All relevant studies were methodologically assessed by 2 independent reviewers using criteria developed by the Cochrane Back Review Group (for trials) and by Oxman (for systematic reviews). A qualitative synthesis of results was performed using methods adapted from the U.S. Preventive Services Task Force. For sciatica or prolapsed lumbar disc with radiculopathy, these researchers found good evidence that chemonucleolysis is moderately superior to placebo injection but inferior to surgery, and fair evidence that epidural steroid injection is moderately effective for short-term (but not long-term) symptom relief. They found fair evidence that spinal cord stimulation is moderately effective for failed back
surgery syndrome with persistent radiculopathy, though device-related complications are common. They also found good or fair evidence that prolotherapy, facet joint injection, intra-discal steroid injection, and percutaneous intra-discal RF thermocoagulation are not effective. Insufficient evidence exists to reliably evaluate other interventional therapies. The authors concluded that few non-surgical interventional therapies for LBP have been shown to be effective in RCTs.

Sean et al (2010) stated that microtenotomy coblation using a RF probe is a minimally invasive procedure for treating chronic tendinopathy. It has been described for conditions including tennis elbow and rotator cuff tendinitis. There have been no studies to show the effectiveness of such a procedure for plantar fasciitis. In this case-series study, a total of 14 patients with plantar fasciitis who had failed conservative treatment underwent TOPAZ RF treatment for their symptoms. The RF-based microdebridement was performed using the TOPAZ Microdebrider device (ArthroCare, Sunnyvale, CA). There were 6 men and 8 women with an average age of 44.0 years (23 to 57). There were 15 feet, with 6 right and 9 left feet. Subjects were followed-up for up to 6 months thereafter. Pre-operative, 3 and 6 months post-operative AOFAS ankle-hindfoot and SF-36 scores were analysed. There was a significant improvement in mean pre-operative, post-operative 3- and 6-month AOFAS hindfoot scores from 34.47 to 69.27 and 71.33 (p = 0.00), respectively. There was a significant decrease in SF-36 for bodily pain, and significant increases in physical and social function scores. Overall, 12 out of 14 (85.7 %) patients reported good to excellent satisfaction results at 6 months, and 12 out of 14 (85.7 %) patients have had their expectations met from the procedure at 6 months follow-up. The authors concluded that TOPAZ RF coblation is a good and effective method for the treatment of recalcitrant plantar fasciitis. They stated that these early results are encouraging, and they will continue to evaluate the patients over a longer follow-up period.
Dasenbrock and colleagues (2012) stated that plasma mediated RF ablation (pmRFA) may allow for the percutaneous treatment of spinal tumors with a decreased risk of thermal injury to neural structures compared with traditional (RF or interstitial laser) ablation. However, usage of pmRFA has not been previously reported for a primary bone tumor, including an osteoid osteoma. In this small study, 3 patients with a spinal osteoid osteoma underwent pmRFA. The procedure was performed under computed tomography guidance using the 11-gauge Coblation SpineWand (ArthroCare). One lesion (at T11) was directly abutting the spinal canal. With an average follow-up of 20.7 (range of 16 to 24) months, the mean visual analog scale score for back pain decreased from 8.67 to 0.67 and no patient experienced tumor recurrence. The authors concluded that pmRFA of spinal osteoid osteomas is feasible, even when the tumor is abutting the spinal canal. Moreover, they stated that larger studies with a longer follow-up are needed to further delineate the safety and effectiveness of this technique.

Pierson et al (2012) presented 2 cases of advanced juvenile nasopharyngeal angiofibroma (JNA) to illustrate the advantages of endoscopic Coblation-assisted resection of intra-nasal extensions of these masses. Both patients (an 11-year old boy and a 14-year old boy) presented with a large, extensive mass (Radkowski stage IIIb and Fisch stage IVb in both cases). After embolization was performed on each patient, his JNA was partially ablated via an endoscopic approach with the Coblator II Surgery System with an EVac Xtra Plasma Wand in conjunction with an image-guided navigation system. Both patients experienced resolution of their nasal obstruction with removal of the intra-nasal extension of the tumor. Coblation allowed for a controlled debulking of the tumors with less blood loss and without the need for multiple instruments. To the best of their knowledge, the authors’ report was one of the first to describe image-guided endoscopic Coblation of advanced JNA tumors. They stated that future studies in adequately sized populations are
needed to determine the safety and effectiveness of Coblation-assisted endoscopic removal of both advanced and lower-stage JNAs.

In a prospective, open-label, non-randomized trial, Di Rienzo Businco 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 enrolment into the study. From June 2007 to June 2008, a total 220 patients with allergic rhinitis (AR) 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: perennial and seasonal. Subjective complaints (nasal obstruction, itching, rhinorrhea, sneezing), clinical rhinoendoscopy and rhinomanometry test 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 nasal provocation test (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 AR. Patients undergoing this surgery had greater reduction of symptoms than patients receiving medical therapy alone, where patients with perennial allergies appeared to benefit most.
Li and colleagues (2013) examined the therapeutic effect of nasal Coblation plasma surgery for the treatment of persistent allergic rhinitis (PAR). A total of 100 patients with mite-sensitized moderate to severe PAR who underwent nasal Coblation plasma surgery (inferior turbinoplasty plus nasal agger ablation) were enrolled in this study. There were 68 males and 32 females patients aged 16 to 62 years (mean of 36.3 years). The visual analog scale (VAS) for global rhinitis symptoms, NPT, anterior rhinomanometry, and T&T olfactometry were used to assess the short-term outcomes, pre-operatively and post-operatively at the end of 3 months after surgical procedure. SPSS19.0 software was applied for statistical analysis. At 3 months after treatment, the total nasal symptom VAS scores significantly decreased from 7.0 ± 2.0 to 2.5 ± 1.5 (X(±) ± s; t = 18.00, p = 0.0001). All patients were allergic to house dust mites with positive NPT before treatment. At 3 months from the Coblation intervention, 88.0% of the patients changed from positive NPT to negative, while 12.0% remained as positive. There was a significant reduction in total nasal resistance, which diminished from 0.772 ± 0.224 to 0.221 ± 0.112 kPa·s·L(-1) after treatment (t = 22.00, p = 0.0001). Pre-operative olfactory tests showed hyposmia in 31.0% of the patients, with 22 cases for slight and 9 cases for moderate disorder. Three months after treatment, 13.0% were diagnosed as hyposmic, with 7 cases for slight and 6 cases for moderate disorder (χ(2) = 10.44, p = 0.005). The authors concluded that nasal Coblation plasma surgery provided favorable short-term outcomes in terms of remarkable improvement in nasal symptoms, hyper-reactivity of nasal mucosa, nasal flow and olfactory function in patients with moderate to severe PAR, but long-term effect needed further observation.

Coblation-Assisted Surgical Resection for the Treatment of Rhinosporidiosis
Khan et al (2014) stated that rhinosporidiosis seeberi causes a chronic granulomatous disease of upper airway, usually involving the nose and nasopharynx, and has a notorious tendency to reoccur. The current line of management is surgical excision of the lesion along with cauterization of the base, which does not prevent reoccurrence of the disease. Coblation EVAC 70 is a novel surgical tool which seems to provide excellent option in management of this notorious disease. These researchers presented an interesting case and the innovative approach in its management, using Coblation system. A 65-year old male resident of rural India reported a history of breathing difficulty and change in voice. Patient is a Hindu priest by profession, who according to their rituals has to take bath in local pond or river. The authors concluded that rhinosporidiosis is a difficult-to-treat pathology due to its tendency to reoccur. To-date the management of the disease is far from satisfactory. They stated that the Coblation system, which has already found its roots in otorhinolaryngology, can be used as a novel tool in surgical resection of recurrent rhinosporidiosis and has added advantage of low temperature dissection along with clear surgical field due to constant suctioning. These preliminary findings need to be validated by well-designed studies.

Endoscopic Coblation Cauterization for the Treatment of Pyriform Sinus Fistula

Zhang and Tian (2016) stated that recurrent neck lesions associated with 3rd or 4th branchial arch fistula are much less common than those of 2nd arch and usually present with acute suppurative thyroiditis or neck abscess. These investigators described clinical features, management and treatment outcomes of 64 cases of congenital pyriform sinus fistula (PSF). Medical record of these 64 patients (33 males, 31 females) treated at the First Affiliated Hospital of Zhengzhou University from 2011 to 2014 were reviewed. The patients comprised 33 males and 31 females, and their ages ranged from 18 months to 47 years (median of 10 years, mean of 12.7
years). Neck abscess and recurrent infection was the mode of presentation in 37 cases (57.8 %), 4 patients (6.3 %) presented with acute supplicative thyroiditis, neck mass was the mode of presentation in 17 cases (26.6 %), 2 patients (3.1 %) presented with neck mass with respiratory distress, and cutaneous discharging fistula was the mode of presentation in 1 cases (1.6 %). The remaining 3 patients (4.7 %) presented with cutaneous discharging fistula with neck infection.

Investigations performed include barium swallow, computed tomography (CT) scan, and ultrasound, which were useful in delineating PSF tract pre-operatively. Barium swallow was taken as the gold standard for diagnosis. Patients were treated by fistulectomy with hemi-thyroidectomy, fistulectomy, fistulectomy with endoscopic electric cauterization, endoscopic electric cauterization or endoscopic Coblation cauterization, respectively. Histopathologic examination of the surgical specimens revealed that they were lined with ciliated epithelium, stratified cuboid epithelium with chronic inflammatory cell infiltration and fibrosis. Voice hoarseness occurred after operation in 7 patients, but disappeared 1 week later. Pyriform sinus fistula recurred in 6 patients, 4 of them were cured by a successful re-excision. One patient was cured by successful endoscopic electric cauterization. The other 1 has remained asymptomatic for 5 months. In this series, mean follow-up period was 13.3 months and median follow-up period was 12.5 months (range of 2 to 40 months). Presence of congenital PSF should be suspected when intrathyroidal abscess formation occurs as the gland is resistant to infection. Strong clinical suspicion, barium swallow study, CT scan and ultrasound are the key to diagnosis. Both fistulectomy with hemi-thyroidectomy and endoscopic treatment have comparable success rate. The authors stated that endoscopic Coblation cauterization may prove a useful and equally effective method of treatment for PSF in future.

Coblation of Femoral and Sciatic Nerve for Stump Pain and Phantom Limb Pain
Zeng and colleagues (2016) noted that there is currently no reliable treatment for stump pain and phantom limb pain. Peripheral factors play a significant role in the pathophysiology of stump pain and phantom limb pain. Coblation technology is a relatively new technology that has shown promise in treating neuropathic pain. In a case report, these researchers described the use of Coblation on femoral and sciatic nerve for stump pain and phantom limb pain. An ultrasound-guided perineural infiltration anesthesia surrounding the neuroma was first performed and achieved approximately 60% stump pain relief that lasted for 2 hours, but no relief of the phantom limb pain. An ultrasound-guided femoral and sciatic nerve block was performed to obtain longer pain relief. The patient reported approximately 80% pain relief in both stump pain and phantom limb pain that lasted for 40 hours. This finding suggested other factors in addition to the ultrasound-detected neuroma in the residual limb generating pain for this patient. Coblation of femoral and sciatic nerves was performed. The stump pain was completely relieved immediately after operation. At 1, 3, and 6 months post-operative review, 80% relief of both stump and phantom limb pain was achieved. Overall activity was improved and there was no need for pain medications. The analgesic effect was stable during the 6-month follow-up period. The authors concluded that their findings suggested that Coblation may be useful in the treatment for stump pain and phantom limb pain; treatments focusing on peripheral nerves may be more effective than those focusing on the neuroma. They stated that additional investigation is needed to confirm these findings.

Radiofrequency Coblation of Congenital Nasopharyngeal Teratoma

Hwang and associates (2015) stated that congenital nasopharyngeal teratomas are rare tumors that pose difficulties in diagnosis and surgical management. These investigators reported the first use of radio-frequency (RF) Coblation in the management of such tumors. They presented
the findings of a premature baby (with a perinatal diagnosis of a large, obstructing nasooropharyngeal mass) who was referred to the ENT service for further investigations and management. The initial biopsy was suggestive of a neuroblastoma, but the tumor demonstrated rapid growth despite appropriate chemotherapy. In a novel use of RF Coblation, the nasooropharyngeal mass was completely excised, with the final histopathology revealing a congenital nasopharyngeal teratoma. The authors reported the first use of RF Coblation to excise a congenital nasopharyngeal teratoma. These preliminary findings need to be validated by additional studies.

Cervical Coblation Nucleoplasty for the Treatment of Cervicogenic Headache

He and associates (2016) stated that a degenerative cervical disc is a pain generator for headaches, and headaches can benefit from cervical prolapse surgery. However, as an alternative intervention for open cervical surgery, no study has reported whether headaches can benefit from cervical nucleoplasty. In a prospective cohort study, these researchers evaluated the effectiveness of cervical Coblation nucleoplasty in the treatment of cervicogenic headaches (CEHs). A total of 20 patients with CEHs undergoing cervical nucleoplasty for shoulder-arm pain were recruited into group C, and 20 patients with CEHs undergoing lumbar nucleoplasty for LBP, matched for age and sex, were recruited into group L. Cervicogenic pain was diagnosed according to the International Headache Society criteria. During the 24-month follow-up, pain VAS scores were collected as the primary outcomes, and significant pain relief rate, Neck Disability Index (NDI) headache scores, and Patients Satisfaction Index (PSI) scores were recorded as secondary outcomes to evaluate headache severity and physical function post-operatively. During the 24-month follow-up, a significant decrease in headache VAS scores was observed in group C, but not in group L; NDI and PSI scores in group C were better than those in group L. In comparison with
the final follow-up, no significant differences in the NDI and PSI scores were found in all observations after surgery. In comparison to group L, greater than or equal to 50% pain relief was significantly better in group C. No serious complications were observed except for less than or equal to 20% of ecchymoma at the needle insertion site. The authors concluded that the findings of this study indicated that CEHs may benefit from cervical Coblation nucleoplasty.

The authors noted that this study had 2 major drawbacks: (i) it ignored the notion that the upper cervical discs C2 to C3/C3 to C4 were also potential sources of the headaches. This was related to the study design. According to the inclusion criteria, all subjects with CEHs were recruited from a group of patients who had undergone nucleoplasty for discogenic or radicular pain in the neck, shoulder, or arm, which mostly originated from lower degenerative cervical discs, and (ii) the outcomes derived from this study did not indicate that CEH without discogenic or radicular pain can benefit from cervical nucleoplasty. This needs to be investigated in additional studies. However, compared with discogenic or radicular pain, there are no gold standard diagnostic criteria of CEH for nucleoplasty, which results in difficulties in enrolling subjects.

Coblation-Assisted Management of Airway Stenosis

In a retrospective, case-series study, Fastenberg and colleagues (2016) evaluated the use of bipolar RF plasma ablation (Coblation) in the treatment of pediatric airway stenosis. The medical records of 6 pediatric patients at Cohen Children's Medical Center from July 2009 to December 2015 were reviewed. All cases involved the use of RF plasma ablation to address airway stenosis. Patient presentation, surgical intervention(s), post-operative course and complications were analyzed. All 6 cases involved pediatric airway stenosis, including glottic stenosis (n = 2), bilateral
vocal fold immobility (n = 2), and intra-tracheal lesions (n = 2). Coblation was used to perform a range of different procedures, including removal of scar/granulation tissue, partial arytenoidectomy, and posterior cordectomy. All patients experienced good results without major complications, peri-operative, or post-operative sequelae. The authors concluded that the findings of this study suggest that RF plasma ablation may be an effective endoscopic tool for the treatment of pediatric airway stenosis. Moreover, they stated that further study and more patients are needed as this technique becomes increasingly applied.

Coblation Nasal Septal Swell Body Reduction for the Treatment of Nasal Obstruction

In a retrospective, case-series study, Kim and associates (2016) presented the results of Coblation nasal septal swell body (NSB) reduction for the treatment of nasal obstruction in patients with abnormally thickened NSB. The study was conducted at a single tertiary medical center; 8 patients underwent Coblation NSB reduction. Pre-operative and post-operative nasal functions were evaluated by acoustic rhinometry and subjective symptom scales. These researchers also analyzed pre-operative CT scan images and nasal endoscopic findings. The mean maximal NSB width was 16.4 ± 2.2 mm on pre-operative coronal CT scan images. The mean VAS score for nasal obstruction was decreased from pre-operative 7.63 ± 0.99 points to 3.88 ± 0.92 points (post-operative 3 months), 4.16 ± 0.78 points (post-operative 6 months), and 4.63 ± 0.69 points (post-operative 1 year); 6 of the 8 patients were satisfied with the clinical outcome at 1 year after the procedure. The authors stated that, to the best of their knowledge, Coblation NSB reduction has not yet been reported in the medical literature; these findings showed that it can be an effective treatment modality for nasal valve narrowing in patients with abnormally thickened NSB. However, these preliminary findings need to be validated by well-designed studies.
Percutaneous Thoracic Paravertebral Nerve Coblation for the Treatment of Thoracic Neuropathic Pain

Yang and colleagues (2017) noted that patients with thoracic neuropathic pain often do not respond to medication and physical therapy. Coblation technology has been demonstrated to have potential for pain management. A total of 15 patients underwent CT-guided percutaneous Coblation to ablate the thoracic paravertebral nerve for their medication-resistant thoracic neuropathic pain. The pain intensity was assessed by VAS 1 day before surgery and 1 week and 1, 3, and 6 months after surgery, and the difference between pre-operative and post-operative VAS values was determined to evaluate the pain relief effectiveness. Patients who achieved greater than 50% pain relief were defined as responders and the ratio in all patients was calculated. The number of patients who reported mild pain (VAS less than or equal to 3) was recorded and the ratio in all responders was calculated. In addition, adverse events (AEs) were also recorded to examine the security of procedure; 12 (80%) responders achieved greater than 50% pain relief. The VAS score of responders significantly decreased from 7.42 ± 1.38 before surgery to 2.17 ± 1.11 (p = 0.000), 1.92 ± 1.16 (p = 0.000), 1.75 ± 0.97 (p = 0.000), and 1.58 ± 1.08 (p = 0.000) at 1 week, 1 month, 3 months, and 6 months after surgery, respectively. The number of responders with mild pain was 10 (83.3%), 11 (91.7%), 12 (100%), and 12 (100%) at 1 week, 1 month, 3 months, and 6 months after surgery, respectively. All responders and 1 non-responder reported slight numbness after the surgery. The authors concluded that CT-guided percutaneous thoracic paravertebral nerve Coblation is a potential method for the treatment of thoracic neuropathic pain. These preliminary findings need to be validated by well-designed studies.

Radiofrequency Coblation for the Treatment of Glottis Cancer
Liu and colleagues (2016) evaluated the feasibility, complications, and effectiveness of low-temperature (40 to 70°C) RF Coblation as a treatment modality for the early-stage glottic cancer. These investigators presented the data obtained from a 1-year study of T1 glottic cancer patients treated at their department. A total of 6 early-stage glottic cancer (T1a = 5; T1b = 1) patients (male; mean age of 60.1 years) were enrolled in this study. Study outcomes were analyzed (noted and/or photographed). All patients were able to eat on the next day after the surgery. No gastric tube or tracheotomy was required. No post-operative cough, discomfort or difficult breathing was noted. No complications, such as recurrence or cervical lymph node metastasis, occurred over the 6 to 12 months follow-up. All patients regained satisfactory voice 2 months after the surgery. The authors concluded that due to the small number of patients included in this study, these findings need to be taken only as the preliminary data that need to be further validated by large-cohort multi-center studies. Furthermore, RFA surgery has a few disadvantages as well. For instance, due to the scalpel tip design, this technique may not be applicable for certain sites such as subglottic and anterior commissure tumors without compromising safe margins. Nonetheless, with the modified tip types, such as the ones with more angles available or smaller sizes, doing more accurate surgery will be possible. This study was also limited by a short post-operative follow-up period (up to 12 months).

Coblation for Wounds Debridement / Management

Trial et al (2012) noted that debridement is needed to prepare the wound bed, essentially in removing undesired tissues observed both in acute wound after burns or trauma and in chronic wounds (e.g., diabetic foot ulcers, leg ulcers, and pressure ulcers). Surgical debridement has been described as one of the most effective methods but can be contraindicated in the elderly, arteriopathic context, or patients under effective anti-coagulation. Recently described debridement
technologies are based on application of important mechanical severing forces over the wound surface using high-power hydrojets. High water flux acts as a vector for separating necrotic and sloughy tissues from the wound bed and aspirates them out of the wound immediately. Electrical powered techniques and lasers were also scarcely described. The Coblation debridement technology presented here was based on the local induction of a focused plasma field chemically deleting undesired tissues. This technique is a modification of conventional electro-surgical devices, developed in 1928 where tissue excision and coagulation of tissues were observed. Principles of plasma-mediated debridement were based on a bipolar radiofrequency energizing the molecules, thus creating a plasma field. This glow discharge plasma produces chemically active radical species from dissociation of water, breaking molecular bonds, and causing tissue dissolution. The thermal effects are a by-product, which can be modulated by modifying the electrode construction, limiting the local temperature to less than 50°C in order not to induce wound bed re-necrosis. The authors described the principle, the first technical adaptation for wound debridement, and the potential clinical interest of the Coblation technology. Well-designed studies are needed to develop clinical evidence of Coblation technology for surgical wound debridement.

Bekara and colleagues (2018) noted that debridement is a crucial component of wound management. Recent technologies such as hydrosurgery (Versajet), ultrasound therapy (the MIST therapy device), or plasma-mediated bipolar RFA therapy (Coblation) appeared to represent interesting alternatives for wound debridement. These investigators evaluated and compared these 3 recently developed methods for the management of chronic wounds. In January 2016, an electronic database search was conducted of Medline, PubMed Central, and Embase for articles concerning these 3 innovative methods for the management of chronic wounds. A total of 389 references were identified by the search strategy,
and 15 articles were included. These researchers extracted data regarding the number and age of patients, indications, operating time, number of procedures, costs, wound healing time, decrease in exudation, peri-operative blood loss, bacterial load, and the occurrence of complications. The 15 articles included studies that involved a total of 563 patients who underwent hydrosurgery (7 studies), ultrasound therapy (6 studies), or Coblation (2 studies); 6 RCTs were included that compared the use of a scalpel or curette to hydrosurgery (2 studies) or ultrasound therapy (6 studies). Hydrosurgery, in addition to being a very precise and selective tool, allowed significantly faster debridement. Ultrasound therapy provided a significant reduction of exudation, and improved the wound healing time. No comparative study dedicated to Coblation was identified. The authors concluded that the review of the current literature revealed a lack of prospective randomized studies comparing these devices with each other or with standard techniques, particularly for Coblation and hydrosurgery.

Coblation of Soft Tissue Stenosis of the External Auditory Canal

Gu and Bauman (2017) noted that soft tissue occlusion of the external auditory canal (EAC) can cause intense pruritis, recurrent foul smelling otorrhea, recurrent otitis externa, and conductive hearing loss. Occlusion of the EAC can be challenging to treat as the area is prone to circumferential scarring. These researchers described the novel use of serial bipolar RFA (Coblation) to treat 3 children with complete EAC occlusion from congenital and acquired conditions including lymphedema (n = 1), microcystic lymphatic malformation (n = 1), and venolymphatic malformation (n = 1). Patients underwent a mean of 3 procedures with post-operative EAC stenting (7 days) and antibiotic and steroid aural preparations (10 days). Otologic symptoms resolved in all patients, and their EACs remained patent 14 months after last procedure (range of 4 to 32 months); 1 patient experienced a pinpoint
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Tympanic membrane perforation that healed spontaneously 2 weeks later. The authors concluded that Coblation of soft tissue stenosis of the EAC can be an effective treatment for this problematic condition. These preliminary findings need to be validated by well-designed studies.

Cordotomy by Coblation for the Treatment of Vocal Fold Immobility

Benninger and associates (2018) stated that bilateral vocal fold immobility (BVFI) can result in considerable voice and airway impairment. Although the CO2 laser is commonly used in transverse cordotomy, the Coblator, a minimally invasive, low-thermal technology, has been increasingly used in otolaryngology. In a retrospective, case-series study, these investigators examined outcomes associated with Coblation to treat BVFI. This trial included 19 patients with BVFI who underwent cordotomy by Coblation in a single tertiary-care institution. Clinical, operative, and health status data for all patients were reviewed. Quality of life (QOL) was measured by the EuroQol 5-Dimensions (EQ-5D), and the Voice Handicap Index (VHI) was used to measure vocal cord function. A total of 19 patients were eligible for inclusion, 15 of which underwent cordotomy by Coblation for BVFI without stenosis. Mean age was 57 years with 13 (68%) women. The etiology of BVFI included thyroidectomy in 8 (42%) patients and prolonged intubation in 7 (37%). Mean length of surgery for BVFI without stenosis was 17 minutes; mean operating room (OR) time was 63 minutes compared with 88 scheduled OR minutes (effect size, 25 minutes; 95% confidence interval [CI]: 9 to 40 minutes). During follow-up, 4 (27%) of these patients developed granulation tissue post-operatively.

Following surgery, patient-reported shortness of breath significantly improved, with 10 of 14 (71%; 95% CI: 45% to 88%) patients with some level of pre-operative breathing difficulty experiencing improvement in their breathing. Stridor also significantly improved, with 10 of 12 (83%; 95% CI: 55% to 95%) patients with some level of pre-operative stridor.
improved after surgery. The EQ-5D results trended toward improvement post-operatively (0.67 to 0.80; effect size, 0.13; 95% CI: -0.10 to 0.34). The functional (22 to 12; effect size, -10; 95% CI: -19 to -2), emotional (23 to 11; effect size, -12; 95% CI: -23 to -3), and total VHI all significantly improved (68 to 39; effect size, -29; 95% CI: -49 to -8). The authors concluded that initial outcomes of cordotomy by Coblation revealed that this technique was a safe and efficient approach to treating BVFI; Coblation was associated with significant reduction in OR time compared with scheduled time, and patients experienced significant improvement in shortness of breath, stridor, and vocal cord function. These preliminary findings from a small (n = 15), retrospective study need to be validated by well-designed studies.

Laryngeal Papillomatosis

In a retrospective case-series study, Carney et al (2010) examined the effectiveness of RF cold ablation (Coblation) for the treatment of laryngo-tracheal recurrent respiratory papillomatosis, by comparing treatment intervals for coblation and carbon dioxide (CO2) laser vaporization. A total of 6 adult patients with advanced laryngo-tracheal recurrent respiratory papillomatosis were treated for at least 2 years by CO2 laser vaporization with or without intra-lesional cidofovir. All 6 subsequently underwent treatment with RF Coblation with or without intra-lesional cidofovir. Coblation resulted in longer periods between interventions, compared with CO2 laser (p = 0.03). The authors concluded that RF Coblation appeared to be an attractive alternative technique to CO2 laser for the surgical treatment of advanced laryngo-tracheal papillomata. The findings of this small study need to be validated by well-designed studies.

Awad and colleagues (2019) stated that recurrent respiratory papillomatosis is a disease caused by the human papilloma virus (HPV), which is frequently localized in the larynx. The disease tends to recur and frequent intervention is often
needed. Management modules include surgical intervention using micro-debride or laser ablation as well as adjuvant treatments that aim mainly at maintaining an adequate airway and secondly to manage dysphonia caused by the growth on the vocal folds. In a pilot study, another surgical modality is tried using plasma-mediated RF ablation (Coblation). These researchers examined management of 15 adult patients diagnosed with recurrent laryngeal papillomatosis and surgically treated using RF Coblation; 1 patient needed multiple procedures. Pre-operative assessment in voice clinic evaluating voice quality and its impact on patients' life-quality using voice parameters and self-assessment questionnaires. Follow-up post-operatively using the same parameters from 4 to 6 weeks after surgery until up to 2 years later to check recurrence rate. No other adjuvant treatment was used and all patients received post-operative voice therapy. A total of 78.6 % of patients did not show evidence of recurrence during the study period. Improvement in voice handicap following 1st intervention was reported and recurrence rate in the rest of the sample reported. The authors concluded that the findings of this small sample (n = 15) appeared to support the previous small studies' findings that RF Coblation is a good excisional technique to use for removal of laryngeal papillomatosis; recurrence rates appeared to be slightly lower than rates reported in the literature for the other surgical modalities. Level of evidence = IV.

Radiofrequency Coblation for the Treatment of Laryngeal Cancer

Gong and colleagues (2019) examined the safety, efficacy and prognosis of low-temperature plasma RF Coblation for early-stage laryngeal cancer(Tis, T1 and T2). These researchers carried out a retrospective analysis of 202 patients with early-stage laryngeal cancer who underwent the low-temperature RF Coblation surgery, including 34 cases of Tis (16.83 %), 49 cases of stage T1aN0M0 (24.26 %), 50 cases of stage T1bN0M0 (24.75 %) and 69 cases of stage T2N0M0 (34.16 %).
Surgical patients were followed-up closely for 6 to 60 months, with a median follow-up of 29 months. Of the 202 patients, 165 (81.68%) had no recurrence and achieved good surgical results. None of them suffered severe complications such as post-operative hemorrhage and asphyxia; 37 cases (18.32%) had recurrence, including 1 case (0.50%) in stage Tis, 7 cases (3.47%) in stage T1a, 7 cases (3.47%) in stage T1b, and 22 cases (10.89%) in stage T2; 13 patients who had recurrence underwent total laryngectomy (5 of which had a recurrence of T3 and 8 of which progressed to T4), including 1 in the stage T1a, 2 in the stage T1b, and 10 in the stage T2. Vertical hemi-laryngectomy were performed in 4 cases, 3 cases of stage T1a and 1 case of stage T2; 5 cases underwent plasma RF Coblation again, including 3 cases of stage T1b and 2 cases of stage T2, no recurrence was found in all the patients; 1 patient had no obvious recurrence in the larynx but had cervical lymph node metastasis, radical neck dissection was performed; 1 patient with stage T2 recurrence was treated with a tracheotomy to relieve laryngeal obstruction without further treatment; 3 cases showed improvement by radiotherapy and chemotherapy treatment after recurrence; 9 death cases, 5 patients died after radiotherapy and chemotherapy, and 4 patients stopped getting treatment after recurrence. The authors concluded that low-temperature RF Coblation surgery for patients with early-stage laryngeal cancer has great advantages in the preservation of laryngeal function and reduction of surgical trauma after surgery compared with traditional surgical method, and could obtain satisfactory results, but the selection of surgical indications for some patients with clinical stage T2 still needs to be carefully considered.

Furthermore, National Comprehensive Cancer Network's clinical practice guideline on "Head and neck cancers" (Version 1.2019) does not mention radiofrequency Coblation as a therapeutic option.
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 "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CPT codes not covered for indications listed in the CPB:</td>
</tr>
<tr>
<td></td>
<td>Coblation non-thermal volumetric tissue reduction or radio frequency coblation, cervical coblation nucleoplasty, coblation-assisted management of airway stenosis, coblation nasal septal swell body reduction, Coblation for soft tissue stenosis of the external auditory canal, cordotomy by Coblation of vocal fold - no specific code</td>
</tr>
<tr>
<td>30465</td>
<td>Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction) [not covered for Vivaer Nasal Airway Remodeling]</td>
</tr>
</tbody>
</table>

Other CPT codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>29800</td>
<td>Endoscopy/arthroscopy</td>
</tr>
<tr>
<td>29999</td>
<td></td>
</tr>
<tr>
<td>31254</td>
<td>Nasal/sinus endoscopy, surgical; ethmoid, maxillary, frontal, or sphenoid</td>
</tr>
<tr>
<td>31288</td>
<td></td>
</tr>
<tr>
<td>42820</td>
<td>Tonsillectomy</td>
</tr>
<tr>
<td>42826</td>
<td></td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J03.00</td>
<td>Acute tonsillitis</td>
</tr>
<tr>
<td>J03.91</td>
<td></td>
</tr>
<tr>
<td>J35.01</td>
<td>Chronic tonsillitis</td>
</tr>
<tr>
<td>J35.1</td>
<td>Hypertrophy of tonsils</td>
</tr>
<tr>
<td>J36</td>
<td>Peritonsillar abscess</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>----------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>B48.1</td>
<td>Rhinosporidiosis</td>
</tr>
<tr>
<td>C32.0 -</td>
<td></td>
</tr>
<tr>
<td>C32.9</td>
<td>Malignant neoplasm of larynx</td>
</tr>
<tr>
<td>D10.6</td>
<td>Benign neoplasm of nasopharynx</td>
</tr>
<tr>
<td>D14.1</td>
<td>Benign neoplasm of larynx [papillomatosis of larynx]</td>
</tr>
<tr>
<td>D14.2</td>
<td>Benign neoplasm of trachea [papillomatosis of trachea]</td>
</tr>
<tr>
<td>D16.6</td>
<td>Benign neoplasm of vertebral column [spinal osteoid osteomas]</td>
</tr>
<tr>
<td>D37.05</td>
<td>Neoplasm of uncertain behavior of pharynx [congenital nasopharyngeal teratoma]</td>
</tr>
<tr>
<td>G44.81</td>
<td>Hypnic headache</td>
</tr>
<tr>
<td>G44.84</td>
<td>Primary exertional headache</td>
</tr>
<tr>
<td>G54.6</td>
<td>Phantom limb syndrome with pain</td>
</tr>
<tr>
<td>H61.301 -</td>
<td></td>
</tr>
<tr>
<td>H61.399</td>
<td>Acquired stenosis of external ear canal.</td>
</tr>
<tr>
<td>J34.3</td>
<td>Hypertrophy of nasal turbinates</td>
</tr>
<tr>
<td>J34.89</td>
<td>Other specified disorders of nose and nasal sinuses [nasal obstruction]</td>
</tr>
<tr>
<td>J38.00 -</td>
<td></td>
</tr>
<tr>
<td>J38.02</td>
<td>Paralysis of vocal cords and larynx [vocal fold immobility]</td>
</tr>
<tr>
<td>J39.8</td>
<td>Other specified diseases of upper respiratory tract [airway stenosis]</td>
</tr>
<tr>
<td>L89.000 -</td>
<td></td>
</tr>
<tr>
<td>L89.95</td>
<td>Pressure ulcer of skin</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>M00.00 - M99.9</td>
<td>Diseases of the musculoskeletal system and connective tissue</td>
</tr>
<tr>
<td>Q16.1</td>
<td>Congenital absence, atresia and stricture of auditory canal (external)</td>
</tr>
<tr>
<td>R13.10 - R13.19</td>
<td>Dysphagia</td>
</tr>
<tr>
<td>Too Numerous to List</td>
<td>Open wound of head, neck, trunk and limbs</td>
</tr>
<tr>
<td>T20.00x+ - T32.99</td>
<td>Burns</td>
</tr>
<tr>
<td>T87.9</td>
<td>Unspecified complications of amputation stump [stump pain]</td>
</tr>
</tbody>
</table>

Nasal coblation plasma surgery:
No specific code

CPT codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>30801 - 30802</td>
<td>Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (eg, electrocautery, radiofrequency ablation, or tissue volume reduction)</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB (not all inclusive):

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J30.1 - J30.9</td>
<td>Allergic rhinitis</td>
</tr>
</tbody>
</table>

Paravertebral nerve Coblation:
CPT codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>64633</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>+64634</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB (not all inclusive):

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M79.2</td>
<td>Neuralgia and neuritis, unspecified</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0475 Coblation

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania