



Medical Coverage Policy

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Balloon Sinus Ostial Dilation for Chronic Sinusitis and Eustachian Tube Dilation

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Overview

This Coverage Policy addresses balloon sinus ostial dilation, also called balloon sinuplasty, for the treatment of chronic sinusitis and other indications, including recurrent acute rhinosinusitis. The Policy also addresses Eustachian tube dilation for all indications including Eustachian tube dysfunction.

Coverage Policy

Balloon Sinus Ostial Dilation

Balloon sinus ostial dilation (balloon sinuplasty) is considered medically necessary in each of the sinuses being considered for dilation (i.e., frontal, maxillary or sphenoid) for the treatment of chronic sinusitis when ALL of the following criteria are met:

- presence of two or more of the following signs/symptoms for more than three consecutive months:
 - nasal obstruction

- anterior or posterior mucopurulent (foul) drainage
- facial pain, pressure and/or fullness over the affected sinus
- decreased sense of smell
- evidence of chronic rhinosinusitis on computerized tomography (CT) scan in each of the sinuses being considered for treatment including ANY of the following:
 - mucosal thickening >3 millimeters
 - air fluid levels
 - opacification
 - nasal polyposis
- failure, intolerance or contraindication of medical management when ALL the following have been tried, during at least eight (8) consecutive weeks:
 - two different full courses of antibiotics
 - steroid nasal spray
 - antihistamine nasal spray and/or decongestant
 - nasal saline irrigation

Balloon sinus ostial dilation (balloon sinuplasty) is considered experimental, investigational or unproven for all other indications.

Balloon sinus ostial dilation (balloon sinuplasty) when used as an adjunctive procedure during functional endoscopic sinus surgery (FESS) in the same sinus cavity is considered to be an integral part of the primary procedure and not separately reimbursable.

Eustachian Tube Dilation

Unilateral or bilateral Eustachian tube balloon dilation (ETBD) is considered medically necessary once per lifetime for the treatment of chronic obstructive Eustachian tube dysfunction when ALL of the following criteria are met:

- age 18 years or older
- any of the following symptoms continuously for at least six months:
 - aural fullness
 - aural pressure
 - hearing loss
 - autophony
- history of chronic ear disease or intolerance to barometric changes greater than six months
- prior evaluation with nasal endoscopy
- more than one abnormal result of both of the following prior to ETBD:
 - tympanogram (Type B or C)
 - tympanic membrane (i.e., retracted membrane, effusion, perforation) on exam
- failure, intolerance or contraindication to appropriate medical management including at least four weeks of a nasal steroid spray
- if patient has a history of tympanostomy tube placement, symptoms of Eustachian tube obstruction improved while tubes were patent

Eustachian tube balloon dilation (ETBD) is considered experimental, investigational or unproven for all other indications.

General Background

Balloon Sinus Ostial Dilation

Rhinosinusitis, also referred to as sinusitis, is an inflammation of the mucous membrane of the paranasal sinuses and nasal cavity. It affects all age groups and can be caused by infection, airborne allergens (e.g., dust mites, mold, pollen) or autoimmune deficiencies. There are three classifications of rhinosinusitis. Acute

rhinosinusitis (ARS) typically lasts four weeks or less. Subacute sinusitis lasts 4–12 weeks, and chronic rhinosinusitis (CRS) lasts for more than 12 weeks, with or without exacerbation, and can continue for months or years. CRS leads to thickening of the paranasal sinuses due to constant inflammation. The condition can occur with or without nasal polyps. The four cardinal signs/symptoms of CRS are: nasal obstruction; facial congestion, pressure, and or fullness; anterior and/or posterior mucopurulent drainage; and hyposmia (decreased ability to smell). CRS is associated with sinus edema and impaired mucociliary clearance (American Academy of Otolaryngology -Head and Neck Surgery [AAO-HNS], 2015; Parikh, et al., 2014; Ahmed, et al., 2011; Hopkins, et al., 2007).

The diagnosis of CRS is based on presenting signs and symptoms, clinical examination using anterior rhinoscopy, or nasal endoscopy. Radiological evidence of CRS is plain films, computed tomography (CT) scan, and in some cases MRI is a part of the work-up for these patients. CT scan is the standard radiologic examination obtained when endoscopic sinus surgery is being considered. Radiological characteristics of sinusitis include: air fluid levels, mucosal thickening greater than three millimeters, nasal polyposis, opacification, bony remodeling and thickening. CT is also used to determine the Lund-Mackey Score for assessing the severity of rhinosinusitis. This scale grades the right and left sides independently, looking at the maxillary, anterior ethmoids, posterior ethmoids, sphenoid, and frontal sinuses, as well as the ostiomeatal complex. Each sinus is scored a 0 (no abnormality), 1 (partial opacification), or 2 (total opacification), and the ostiomeatal complex is scored either a 0 or 2 (for presence or absence of disease). Each side is divided into six regions, corresponding to the location of specific sinuses. Ethmoid sinuses are divided into two regions, anterior and posterior, and the ostiomeatal complex is evaluated separately. Each sinus is scored as 0, 1, or 2 based on the severity of mucosal inflammation or fluid accumulation. Thus the score can range from 0, complete lucency of all 12 regions, to 24, complete opacity of all regions. Studies have reported an increased complication rate following surgery with increasing Lund-Mackay scores (Brook, 2018; Vartanian, 2016; Ramanan, 2016; Brook, 2015; American Academy of Otolaryngology -Head and Neck Surgery [AAO-HNS], 2015; Parikh, et al., 2014; Noorian and Motaghi, 2012; Rege et al., 2012; Ahmed, et al., 2011; Huang, et al., 2009; Hopkins, et al., 2007).

Because CRS is typically not cured, medical management is focused on minimizing mucosal inflammation and edema to prevent obstruction and minimize the incidence of infections and acute exacerbations. Medical treatment is typically tried for at least eight weeks and includes nasal saline irrigation, topical and systemic glucocorticoids, two or more antibiotics, and/or antileukotriene agents. When the patient becomes unresponsive to medical management, surgical intervention to clean and drain the sinuses may be indicated. In cases where obstruction of the nasal passages is present (e.g., polyps, deviated septum) surgery to correct the obstruction may be done (Brook, 2016; Brook, 2015; American Academy of Otolaryngology -Head and Neck Surgery [AAO-HNS], 2015; Parikh, et al., 2014).

Functional endoscopic sinus surgery (FESS), also referred to as endoscopic sinus surgery (ESS), is the standard surgical procedure for CRS that is unresponsive to medical management. The goal of surgery is to improve sinus ventilation and drainage by enlarging the openings of the sinuses, removing any polyps and correcting significant structural problems that may be hindering drainage. FESS involves the insertion of an endoscopy into the nose for direct visual exam of the openings into the sinuses. Special instruments are used along with the endoscope to remove the blockages and improve breathing. Complications that can occur during ESS include: scarring and adhesions, intraoperative bleeding that can obscure surgical visualization, orbital injury, and accidental penetration of the brain (AAO-HNS, 2015; Parikh, et al., 2014; Brown, et al., 2006).

Balloon sinus ostial dilation, also known as balloon sinuplasty and balloon catheter sinusotomy, has become an accepted alternative procedure to functional endoscopic sinus surgery (FESS) for the treatment of CRS in a select subset of patients. Like FESS, balloon sinuplasty is intended to allow access to and ventilation of obstructed sinuses. The procedure is less invasive than FESS and proposed to have minimal bleeding, scarring and less postoperative pain. Risks of balloon sinuplasty include tissue and mucosal trauma, infection or possible optic injury. Basic equipment includes a sinus guidewire, a sinus delivery catheter, a sinus balloon and an inflation device. Guided by X-ray images or by a lighted fiberoptic tip, the catheter is threaded up to the opening of the blocked or poorly draining sinus and the guidewire is passed through the opening of the sinus. The guidewire is passed from the nasal cavity into the specific sinus being addressed and a balloon dilating catheter is passed over the wire to the narrowest part of the sinus drainage pathway. The balloon is then briefly inflated to a high pressure (up to 12 atmospheres). The pressure from the balloon widens the outflow tract of the sinus by

fracturing bone and moving it outward along the mucous membrane without tissue removal. The balloon is then deflated and the catheter is removed (Hayes, 2017, reviewed 2018; Hepworth, 2016; Ahmed, et al., 2011).

When performed alone, balloon sinuplasty is an accepted procedure for a select subset of adult patients, age 18 years and older, with chronic rhinosinusitis (CRS). Appropriate surgical candidates have failed at least eight weeks of consecutive medical therapy including at least two antibiotics, steroid nasal spray, antihistamine nasal spray and/or decongestant and nasal saline washes. Computerized tomography (CT) scan should show air fluid levels, opacification or nasal polyps. When balloon sinuplasty is used as an adjunctive procedure with FESS it is considered an integral part of the procedure.

Balloon sinuplasty has been proposed for the treatment of other conditions including recurrent acute rhinosinusitis (RARS), headaches unrelated to CRS, nasal obstruction and obstructive sleep apnea (AAO-HNS, 2018). There is insufficient evidence in the peer-reviewed literature to support balloon sinuplasty for these other indications.

U.S. Food and Drug Administration (FDA):

Balloon Sinuplasty devices are approved by the FDA 510(k) process as Class I devices. One of the first balloon inflation devices approved was the Relieva Sinus Balloon Inflation Device (Acclarent, Inc., Menlo Park, CA) in 2005. The 2008 approved devices, Relieva Sinus Balloon Catheter and the Relieva Acella Sinus Balloon Catheter, are also Class I devices. These devices are approved to “dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures”. The balloon may be inflated to dilate the frontal recess, frontal sinus ostia and spaces within the frontal sinus cavity. “For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures”. The DSS Balloon Catheter (Intuit Medical Products, LLC., Sugar Hill, GA) is also FDA approved for children aged 17 years and under.

The Dillard Nasal Balloon Catheter (Intuit Medical Products, LLC) was FDA 510(k) approved as a Class I device on January 3, 2020 (K181546). The Dillard Nasal Balloon (DNB) Catheter is “intended to provide increased intranasal space to facilitate access for endonasal and transnasal procedures and/or temporarily address nasal obstruction by displacing the inferior turbinate and lower nasal septum” (FDA 2020).

The Sinusway Dilation System (3NT Medical Ltd., Kfar Saba, Israel) “is intended to access and treat the frontal, maxillary and sphenoid sinuses in sinus procedures in adults using a trans-nasal approach, by dilation and displacement of the anatomic structures along the sinus drainage pathways”. The System was FDA 510(k) approved as a Class I device in 2018.

The Acclarent Airway Balloon Catheter is a catheter with a high pressure balloon on the distal tip. The device is designed with a coaxial lumen for inflation and guidewire access, if required. There are two accessories for the Airway Balloon Catheter: the Inflation Device and the Relieva Vigor Guidewire. The Acclarent Relieva SpinPlus Balloon Sinuplasty System was approved in 2015 to “provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures”. The FDA issued a Class I device 510(k) approval for the RELIEVA ULTIRRA® on Mar 1, 2019. This device is intended to provide the same diagnostic and therapeutic benefits as the previous Acclarent Airway Balloon Catheter. These approved indications also include children aged 17 years and under. As a Class I, the device falls into a generic category and FDA clearance is not required before marketing the device in the US. The manufacturer is required to register their establishment with the FDA.

The XprESS Multi-Sinus Dilation System (Entellus Medical, Inc., Plymouth, MN) is a Class I device intended to “access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures”. The Dillard Sinuplasty Balloon Catheter (Intuit Medical Products, LLC, Sugar Hill, GA) (DSS Balloon Catheter) is intended “to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 years and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures”. The Sinus Dilation System with

Cannulated Instrument, a modification to ENTrigue Sinus Dilation System, was FDA approved in 2013 for use in surgical procedures to access, examine or treat the nasal and paranasal tissues.

The Nuvent EM Sinus Dilation System (Medtronic XoMed, Inc., Jacksonville FL) is intended for use in conjunction with the Medtronic Computer-Assisted Surgery System during sinus procedures when surgical navigation or image-guided surgery may be necessary. This system combines electromagnetic (EM) “plug and play” tracking capability with the pathway expansion effects of balloon dilation technology and an inflator. Each of the three types of sinus seekers (frontal, maxillary and sphenoid) has a unique shape and angle that allows for entry into the sinus outflow tract. The inflator consists of a plunger, barrel and extension tube (FDA, 2013).

In contrast to the high pressure inflation systems, the Vent-Os™ Sinus Dilation System (SinuSys Corp., Palo Alto, CA), uses low-pressure, self-expanding technology and is proposed to gently and gradually open the maxillary ostia. The device was FDA approved in 2013 to dilate the maxillary sinus in adults for therapeutic and diagnostic procedures. The procedure is performed in the office (FDA, 2013; SinuSys Corp, 2016).

Literature Review – Chronic Rhinosinusitis

Randomized controlled trials have compared FESS to balloon sinuplasty of the frontal, maxillary or sphenoid sinuses for the treatment of CRS. The studies have small patient populations and short-term follow-up. However, outcomes have shown that balloon sinuplasty is noninferior to FESS with shorter operative times, less bleeding and few to no reported complications (Chandra, et al., 2016; Bikhazi, et al., 2014; Marzetti, et al., 2014; Achar, et al., 2012; Plaza, et al., 2011). Balloon sinuplasty has evolved into an accepted alternative procedure for CRS.

Numerous case series have also been conducted to evaluate the safety and efficacy of balloon sinuplasty. Subjects were age 18 years and older with CRS for more than 12 weeks that was unresponsive to medical management (e.g., antibiotic therapy, inhaled and/or systemic corticosteroids, decongestants, saline irrigations). Reported post-operative outcomes included: functional patency in 80.5%–97% of patients; statistically significant improvement in SNOT-20 scores; and CT Lund-Mackey scores and revision rates 3%–7.4%. The studies are limited by the small patient populations (n=37–115) and short-term follow-ups (e.g., 2–12 months) (Sikand, et al., 2015; Gould, et al., 2014; Levine, et al., 2013; Albritton, et al., 2012; Weiss, et al., 2008; Kuhn, et al., 2008). Published studies evaluating the outcomes of balloon sinuplasty in children are lacking (Ramadan, et al., 2010).

Brodner et al. (2013) conducted a prospective case series to evaluate the safety and efficacy of balloon sinuplasty dilation (BSD) (XprESS) in 175 patients and 497 sinuses (279 frontal, 138 sphenoid, 80 maxillary). Patients were age 18 years and older, scheduled for FESS prior to the study, and had a CT scan within 12 months of the surgery. At the one-year follow-up, 44 patients reported significant improvement in sinus symptoms ($p < 0.0001$). At the one-year follow-up, ostial patency was maintained in 91.6% of sinuses and one revision surgery was required.

Karanfilov et al. (2012) conducted a prospective, multicenter, case series to evaluate the safety and efficacy of balloon sinuplasty dilation (BSD) in 203 subjects (552 sinuses). Patients age 18 years and over with CRS had failed the minimum maximal treatment protocol (i.e., more than 3–6 weeks of broad-spectrum or culture-directed antibiotics, intranasal steroid spray and/or oral steroids if polyps or severe inflammation were present; antihistamines and/or decongestants clinically indicated; and routine use of nasal saline irrigation during treatment course). CRS diagnosis was made according to the AAO-HNS CRS definition which includes ≥ 12 weeks of two or more major signs/symptoms and inflammation by purulent mucus/edema, presence of polyps, or radiographic imaging. The technical dilation success was 93.3% for maxillary sinuses, 90.5% for sphenoid and 93.7% for frontal. There was significant improvement in the Sino-Nasal Outcome Test (SNOT-20) and the Lund-Mackay CT scores ($p < 0.0001$, each). Patients (82.3%) considered the procedure tolerable or highly tolerable.

Literature Review – Other Indications

There is insufficient evidence to support balloon sinuplasty for all other indications including the treatment of recurrent acute rhinosinusitis (RARS). Studies are primarily in the form of retrospective reviews or have evaluated balloon ostial dilation for the treatment of chronic sinusitis and included small numbers of patients with RARS (n=9–17) (Costa, et al., 2015; Gould, et al., 2014; Levine, et al., 2013). Data on the clinical effectiveness of balloon sinuplasty for RARS are limited.

Professional Societies/Organizations

American Academy of Allergy, Asthma and Immunology (AAAAI): In the practice parameter on rhinosinusitis, AAAAI defines CRS as persistent symptoms of rhinosinusitis for 12 weeks or longer. Signs and symptoms include purulent rhinorrhea, postnasal drainage, anosmia, nasal congestion, facial pain or pressure, or headache and are associated with objective evidence of inflammation observed on nasal endoscopy and/or CT scan. CRS may occur with or without polyps. Sinus CT scan is the preferred imaging modality and the gold standard to clarify the extent of disease and specific location or locations of obstruction in acute or chronic sinus disease. CT scan is required before surgical intervention or if rhinosinusitis complications are suspected (Dass and Peters, 2016).

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): The AAO-HNS (2018) developed a clinical consensus statement on balloon dilation of the paranasal sinuses. The target population included adults \geq age 18 years with chronic or recurrent rhinosinusitis (with or without nasal polyps, with or without prior sinus surgery) for whom sinus ostial dilation (SOD) was being recommended. SOD was defined as endoscopic use of a balloon device to enlarge or open the outflow tracts of the maxillary, frontal, or sphenoid sinuses, as a standalone procedure or with endoscopic surgery. The use of serial dilations over time in the same patient was not considered. According to AAO-HNS, there has been an increasing rate of utilization of SOD without a reduction in the number of traditional functional endoscopic sinus surgeries being performed. Due to limited evidence to support a guideline, the topic of SOD was selected for clinical consensus statement (CCS) development. Based on a systematic review of the literature and expert consensus, the Society's statements included the following:

- Balloon dilation is not appropriate for patients who are without both sinonasal symptoms and positive findings on CT.
- Balloon dilation is not appropriate for the management of headache in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis.
- Balloon dilation is not appropriate for the management of sleep apnea in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis.
- CT scanning of the sinuses is a requirement before balloon dilation can be performed.
- Balloon dilation is not appropriate for patients with sinonasal symptoms and a CT that does not show evidence of sinonasal disease.
- Balloon dilation can be appropriate as an adjunct procedure to FESS in patients with chronic sinusitis without nasal polyps.
- There can be a role for balloon dilation in patients with persistent sinus disease who have had previous sinus surgery.
- There is a role for balloon sinus dilation in managing patients with recurrent acute sinusitis as defined in the AAO-HNSF guideline based on symptoms and the CT evidence of ostial occlusion and mucosal thickening.
- Balloon dilation can improve short-term quality-of-life outcomes in patients with limited CRS without polyposis.
- Balloon dilation can be effective in frontal sinusitis.

In a 2017 position statement on dilation of the sinuses, AAO-HNS stated that sinus ostial dilation (e.g. balloon ostial dilation) is an appropriate therapeutic option for selected patients with chronic rhinosinusitis (CRS) and acute rhinosinusitis (RARS) who have failed medical therapy. Clinical diagnosis of CRS and RARS should be based on symptoms of sinusitis and supported by nasal endoscopy documenting sinonasal abnormality or mucosal thickening on computed tomography of the paranasal sinuses. The Society noted that sinus ostial dilation can be used alone or in conjunction with other instruments. The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon.

The AAO-HNS (2015) clinical practice guideline on adult sinusitis defines chronic rhinosinusitis as twelve weeks or longer of two or more of the following signs and symptoms:

- mucopurulent drainage (anterior, posterior, or both),
- nasal obstruction (congestion),
- facial pain/pressure/fullness, or

- decreased sense of smell
- AND inflammation as documented by one or more of the following:
- purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region,
 - polyps in nasal cavity or the middle meatus, and/or
 - radiographic imaging showing inflammation of the paranasal sinuses

The Society recommends that the clinician confirm the diagnosis of CRS with objective documentation of sinonasal inflammation using anterior rhinoscopy, nasal endoscopy, or computed tomography. The diagnosis CRS cannot be made based on signs and symptoms alone. CT of the paranasal sinuses should be obtained when endoscopic sinus surgery is considered or planned for patients with CRS.

American Rhinologic Society (ARS): In a position paper (2017), ARS stated that sinus ostial dilation is an appropriate therapeutic option for selected patients with chronic rhinosinusitis (CRS) and recurrent acute rhinosinusitis (RARS) who have failed appropriate medical therapy. Clinical diagnosis of CRS and RARS should be based on symptoms of sinusitis and supported by nasal endoscopy documenting sinonasal abnormality or mucosal thickening on computed tomography of the paranasal sinuses. This procedure may be used alone to dilate a sinus ostium (frontal, maxillary, or sphenoid) or in conjunction with other instruments (e. g., microdebrider, forceps). The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon.

Use Outside of the US

Acclarent Inc. received Conformité Européene (CE) marking approval of their first-generation balloon sinuplasty devices in February 2006. The XprESS multi-Sinus Dilation System received CE Marking in October 2010 (Hayes, 2016).

The National Institute for Health and Care Excellence (United Kingdom) (2008) guidance on balloon catheter dilation stated that the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis was supported by the evidence and raised no major safety concerns. The conclusion was based on case series, nonrandomized controlled trials and data registry (n=1036).

Eustachian Tube Balloon Dilation

Eustachian tube dysfunction (ETD), or eustachian tube dilatatory dysfunction (ETDD), occurs in about 1% of the adult population. There is a lack of consensus on the definition of ETD. ETD ranges from obstructive dysfunction, in which there is failure of the Eustachian tube (ET) to open and provide adequate ventilation to the middle ear, to patulous ETD in which there is failure of the ET to close. Patients may move back and forth on this spectrum, creating difficulties in diagnosis and appropriate treatment. Clinical signs include: sensations of pressure; full or heavy ear; fluctuating hearing loss; popping/snapping/buzzing sounds; and in severe cases vertigo. Untreated ETD may lead to hearing loss, chronic otitis media or cholesteatoma. Endoscopic assessment of the pharyngeal opening of the tube mainly provides anatomic information, and functional correlations are not well established for obstructive Eustachian tube dysfunction. The choice of management strategies for isolated Eustachian tube dysfunction remains controversial due to the lack of evidence. The treatment of ETD should be directed at the underlying etiology, if known. The usual treatments for obstructive Eustachian tube dysfunction include decongestants, oral and nasal steroids, antihistamines, pressure equalization methods, nasal douching, and antibiotics. Treatment primarily treats the symptoms and not the underlying cause of ETD (Poe, et al., 2018; Poe and Hanna, 2018; Schmitt, et al., 2018; Hayes, 2017; Tisch, et al., 2017).

Balloon dilation of the Eustachian tube, or balloon Eustachian tuboplasty (BET) is a novel, minimally invasive method proposed for the treatment of chronic obstructive Eustachian tube dysfunction. A Eustachian tube balloon dilation system is a device that includes a flexible catheter attached to an inflatable balloon. The system is intended for use in dilating the cartilaginous portion of the Eustachian tube to improve ET function (Luukkainen, et al., 2018; Poe, et al., 2018; Poe and Hanna, 2018; Schmitt, et al., 2017; Tisch, et al., 2017).

Unilateral or bilateral Eustachian tube balloon dilation (ETBD) is a treatment option for a patient who is age 18 years or older and has a diagnosis of chronic obstructive ETD. Patients with obstructive ETD experience aural

fullness (clogged ear sensation), aural pressure, otalgia (earache), hearing loss or autophony continuously, rather than episodic, for greater than three months. Evaluation for ETD may include clinical history, physical exam, tympanometry, audiometry, otoscopy, otomicroscopy, nasal endoscopy or nasopharyngoscopy. Potential candidates for ETBD should have either a Type B (a flat or unidentifiable peak suggesting middle ear effusion) or Type C (a negative pressure or peak below 100 max pressure [daPa] suggesting ETD) tympanogram result on tympanometry, or have an abnormal tympanic membrane found on exam. ETD and any co-occurring conditions such as allergic rhinitis, rhinosinusitis, middle ear effusion and laryngopharyngeal reflux are typically treated prior to undergoing ETBD. Medical management may include systemic decongestants, antihistamines, nasal topical decongestants, or corticosteroid sprays. Tympanostomy tubes create a route for ventilation of the middle ear to help alleviate obstructive ETD symptoms, but does not address the root problem and could result in infection, otorrhea, persistent perforation, and tympanosclerosis. If the patient has a history of tympanostomy tube placement, symptoms of ETD should have improved while the tubes were patent (Hayes, 2021; Tucci, et al., 2019).

ETBD has been proposed for the treatment of other conditions including: craniofacial syndromes; neoplasms causing obstruction of the Eustachian tube; systemic mucosal or autoimmune inflammatory disease affecting the mucosa of the nasopharynx and patulous Eustachian tube dysfunction (Hayes, 2021; Tucci, et al., 2019). There is insufficient evidence in the published peer-reviewed literature to support ETBD for these other conditions.

US Food and Drug Administration (FDA): The Acclarent® Aera™ Eustachian Tube Balloon Dilation System (Acclarent, Inc., Irvine CA) is FDA approved as a De Novo Class II device. The Food and Drug Administration Modernization Act of 1997 (FDAMA) added the De Novo classification option, also known as Evaluation of Automatic Class III Designation, to provide an alternate pathway to classify novel devices of low to moderate risk that are not substantially equivalent to an existing FDA approved device (predicate device). Devices that are classified through the De Novo process may be marketed and used as predicates for future 510(k) submissions and are typically Class II devices. The Acclarent System is FDA approved to “dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in adults ages 22 years and older. January 2018 the Acclarent System was FDA approved (K171761) as a 510(k) Class II device intended to “dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in patients ages 18 and older” (FDA, 2018).

The Acclarent System includes the Eustachian Tube Balloon Catheter (ETBC) and the Eustachian Tube Guide Catheter (ETGC). The system also includes the Acclarent SE Inflation Device (or Acclarent Balloon Inflation Device) and Relieva Extension Tubing. The Acclarent SE Inflation Device (or Acclarent Balloon Inflation Device) is used to inflate the ETBC. The Acclarent SE Inflation Device and Acclarent Balloon Inflation Device are FDA cleared devices (K150172 and K052198, respectively). The Relieva Extension Tubing may be used to connect the Balloon Catheters and the Inflation Device when additional tubing length is required. The Relieva Extension Tubing is a Class I exempt device (FDA, 2016). In addition, the Acclarent SE Inflation Device and the Relieva Sinus Balloon Inflation Device are used to inflate the ETBC (Hayes, 2017).

XprESS ENT Dilation System (Entellus Medical, Inc., Plymouth, MN) was approved by the FDA 510(k) process as a Class II device on April 4, 2017. This system is an expansion of the XprESS Multi-Sinus Dilation System “to dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in patients 18 years and older using a transnasal approach” (FDA, 2017).

Literature Review: Overall, the evidence in the published peer-reviewed literature supports the safety and efficacy of Eustachian tube dilation. Randomized controlled trials have compared ETBD to medical management alone (i.e., nasal topical steroids, autoinflation) and/or tympanoplasty alone for the treatment of obstructive ETD. Reported outcomes have shown that ETBD is noninferior to medical management and tympanoplasty with few to no reported complications (Si, et al., 2019; Poe, et al., 2018; Meyer, et al., 2018; Liang, et al., 2016). Studies have primarily been in the form of case series and retrospective reviews with small, heterogeneous patient populations (Huisman, et al., 2018; Luukkhainen, et al., 2018; Schröder, et al., 2015; Silvola, et al., 2014; McCoul and Anand, 2012). Follow-up times vary, but are typically 12 months or more.

Froehlich et al. (2020) conducted a systematic review and meta-analysis to examine the efficacy of Eustachian tube balloon dilation for Eustachian tube dysfunction. Twelve studies (n=448; 545 ears) including three randomized control trials, five prospective studies, and four case series met inclusion criteria. The inclusion

criteria were adults diagnosed with ETD and one of the following outcome measures: ETDQ7 scores, tympanometry, otoscopy findings, ability to perform Valsalva maneuver. From baseline to six weeks, ETDQ7 scores decreased by 2.13, 53.0% had improvement in tympanograms, and normal otoscopy exams increased by 30%. Baseline to long-term results (3-12 months) included 50.5% improved tympanograms, normal otoscopy exams increased by 55.4% and 67.8% increase in patients able to perform Valsalva maneuver. Author noted limitations included: possible theoretical publication bias due to only positive outcomes published in the individual studies; variations in surgical techniques including three different balloon dilation devices with different dilated diameters; some studies include patient populations with previous tympanostomy tubes or perforation at the time of balloon dilation.

Wang et al. (2018) conducted a meta-analysis to examine balloon dilatation and laser tuboplasty for treatment of Eustachian tube dysfunction. Primary outcome measures for included studies were improvement of Eustachian tube score (ETS) and tympanometry and Valsalva maneuver results. Included were the results of two retrospective and eleven prospective studies which included both balloon tuboplasty and laser tuboplasty (n=13 studies; n=1063 patients; n=942 balloon tuboplasty; n=121 laser tuboplasty). Author concludes that balloon tuboplasty showed a statistically significant improvement of ETS overall (p=0.009). When compared with laser tuboplasty, balloon tuboplasty also showed a statistically significant improvement in tympanometry (p=0.001). Valsalva maneuver rate did not show a statistically significant difference between the procedures (p=0.472). Author noted limitations included heterogeneous outcome protocol between studies, sensitivity analysis indicated ETS results could have been overly influenced by two studies and no balloon tuboplasty studies reported ETS data which prevented comparison of two procedures.

Huisman et al. (2018) conducted a systematic review to evaluate effects of balloon dilation of the Eustachian tube in adult patients with Eustachian tube dysfunction. Inclusion criteria were balloon dilation of Eustachian tube (BDET) in adults with tube dysfunction. Eleven retrospective reviews and four case series (n=1155) met inclusion criteria. Outcome parameters included: relief of symptoms, otoscopy, Valsalva maneuver or Toynbee test, audiometry, tympanometry, Eustachian tube dysfunction classification, and Eustachian tube score. Patient populations were less than 70 with the exception of two studies (n=271; 622). Follow-ups primarily ranged from one week to 15 months. Several studies used BDET as an adjunct to other sinonasal and/or otologic procedures. All studies reported short-term improvement of original symptoms and some showed further improvement over time. Meta-analysis was conducted on four subgroups: Valsalva maneuver, otoscopy, tympanometry, and Eustachian tube score. The Valsalva analysis (n=5 studies; 153 procedures) showed a significant decline of inability to perform the Valsalva maneuver after BDET (p=0.0002). A significant difference was seen in a decline in the inability to dilute the Eustachian tubes (p=0.0002) (n=9 studies; 255 procedures) and in the mean improvement in the ET score (p<0.00001). Six studies (n=166 procedures) showed a decline of otoscopic abnormal tympanic membranes after BDET, but the difference was not significant (p=0.26). Relatively mild and self-limiting complications were described in 36 patients. Most common events were a diffuse crush injury or local bleeding of the mucosa at the site of the Eustachian tube. The limitations of the study include the retrospective study design, small heterogenic patient populations, short-term follow-ups, heterogeneity of outcome measures, and high risk of bias.

A systematic review was conducted by Luukkainen et al. (2018) to identify studies reporting 12 months follow-up post BET. Five studies met the inclusion criterion (two prospective studies and three retrospective reviews). In the five individual studies, inclusion criteria varied and no two studies used the same outcome measures. No single outcome measure was used in all of the studies. Following BET, Valsalva maneuver improved in 80%–98% of patients, overall subjective symptoms improved in 73%–98%, and otoscopic findings improved in 90% of the patients. Tympanometry and tubomanometry improved less, in 24%–54% and 28%–43% patients, respectively. Due to the limited number of studies, five additional studies with a 6–11 months follow-up were included and reported similar outcomes.

Poe et al. (2018) conducted a 2:1 ratio, randomized controlled trial (n=323 patients; 462 ears) to assess the safety and efficacy of balloon dilation of the Eustachian (BDET) using a custom-designed ET balloon catheter (ETBC) (Acclarent, Inc., Irvine, CA) in conjunction with medical management (MM) compared to MM alone in adult patients with drug-refractory Eustachian tube dilatatory dysfunction (ETDD). Inclusion criteria were: 1) age ≥ 22 years; 2) persistent ETDD (defined by patient-reported symptoms and at least one of the protocol defined confirmatory indicators for 12 weeks or more prior to enrollment); 3) a positive diagnosis of persistent ETDD was

confirmed with both abnormal tympanometry and symptomatic dysfunction per Eustachian Tube Dysfunction Questionnaire-7 Symptom (ETDQ-7) mean item score 2.1 after failed MM; 4) transnasal endoscopy of the ET was performed and the degree of mucosal inflammation scored with a validated scale, 5) absence of internal carotid artery (ICA) dehiscence on both sides per computed tomography (CT) scan, and 6) failed MM (i.e., four weeks intranasal steroid spray or minimum of one completed course of an oral steroid within 90 days prior to study enrollment). The primary outcome measure was normalization of tympanometry at the six-week follow-up. Secondary outcome was improvement in ETDQ-7, tympanograms and mucosal inflammation. Follow-ups occurred at 2, 6, 12, and 24 weeks. At six weeks follow-up, failed controlled group patients had the option of crossing over to BDET. A statistically significant improvement in tympanogram normalization at the 6-week follow-up was reported in 51.8% (72/139) of the study group compared to 13.9% (10/72) of control group ($p < 0.0001$). At 24 weeks, tympanogram normalization was seen in 62.2% of BDET patients. Normalization of the ETDQ-7 scores at six weeks was observed in 56.2% (77/137) of the study group versus 8.5% (6/71) of controls ($p < 0.001$). However, this difference was not maintained at the 12- and 24-week follow-ups. Significantly more normal levels of mucosal inflammation were seen in the study groups versus the control group at the six-week follow-up ($p < 0.001$). The percentage of patients that could perform a positive modified Valsalva maneuver at 6-weeks was significantly higher in the study group ($p < 0.001$). Limitations of the study include: the short-term follow-up (6 weeks for the two randomized groups); 59 control group patients (82%) crossed over to BDET at the six-week follow-up period; and randomization was 2:1. According to the authors this is the first RCT investigating the safety and efficacy of BDET for ETDD compared to MM and they noted that MM has not been successful in treating ETDD. Anand et al. (2019) completed a follow up of this study focusing on a twelve month outcomes of the Poe study. This was a prospective cohort from the previous multicenter randomized controlled trial. This study extends the follow up to fifty two weeks measuring ETDQ-7. The enrolled subjects ($n=323$) were randomized to BDET ($n=149$) and medical management ($n=80$) treatment groups. Primary endpoints and adverse events were described in original study. Results noted the subjects randomized to BDET and medical management remained comparable to those reported at six versus fifty two week followup: 73 of 143 (51.0%) versus 71 of 128 (55.5%); ETDQ-7, 79 of 142 (55.6%) versus 71 of 124 (57.3%). The overall number of ears with normalized tympanograms also remained comparable, with 117 of 204 (57%) versus 119 of 187 (63.6%).

Meyer et al. (2018) conducted a randomized controlled trial ($n=60$) to compare the safety and efficacy of Eustachian tube balloon dilation ($n=31$) versus continued medical therapy ($n=29$) (control) for treating persistent Eustachian tube dysfunction (ETD). Patients were included in the study if they were age ≥ 18 years, had a diagnosis of ETD for 12 months or longer with ≥ 3 ETD symptoms (ear pain, ear pressure, tinnitus, cracking or popping in ears, muffled hearing, feeling that ears were clogged) and had failed medical therapy. Failed medical therapy was defined as a minimum of either four weeks of daily intranasal steroid spray or one completed course of an oral steroid within 12 months before study enrollment. Patients were required to have an overall Eustachian Tube Dysfunction Questionnaire (ETDQ-7) score of ≥ 3 (moderate to severe symptoms). The primary outcome measures were the comparison between randomization arms for the mean change in overall ETDQ-7 scores from baseline to six weeks and complications related to the device or procedure. Secondary outcomes included technical success, procedural details, and differences between treatment arms for changes from baseline in tympanic membrane position, Valsalva maneuver, and tympanogram type. All planned in-office procedures were completed in the office with dilation durations of 2 minutes per Eustachian tube and were performed under topical and local anesthetics. At the six-week follow-up the ETDQ-7 score was significantly more improved than the control group ($p < 0.0001$). All dilation attempts were successful (91/91). For the patient with retracted tympanic membrane position measured at baseline ($n=15$), 66.7% of those undergoing ETD showed an improvement at six weeks ($p=0.002$) compared to no control patients ($n=12$). The comparison between the groups was significantly different in favor of the ETD group ($p < 0.001$). Among the ears with type B or C tympanograms at baseline ($n=14$ ETD; $n=10$ control) there was a statistically significant improvement in favor of the ETD groups ($p=0.006$). There was no significant difference between the groups for those patients who had a negative Valsalva maneuver at baseline. At the six-week follow-up 23 patients crossed over to ETD and 49 patients completed the one-year follow-up. The mean overall ETDQ-7 score was significantly reduced from 4.6 at baseline to 2.1 ($p < 0.0001$) 6 weeks following ETD maintained through the 12-month follow-up ($p < 0.0001$). At 12 months, patients with normal tympanic membrane position, type A tympanograms, and ability to clear the ears with Valsalva maneuver was significantly improved compared to baseline. No complications were reported. During the study, two participants underwent additional ear surgeries for continuing or recurring symptoms. Five patients were lost to the six-week follow-up. Limitations of the study include the small patient population; short-term follow-up; inability to blind the patients to their treatment; secondary outcome data was not available on all

patients; five patients were lost to the six-week follow-up; and 23 patients crossed over to ETD after six weeks. Cutler et al. (2019) completed a follow up of the Meyer study focusing on outcomes greater than 12-months (mean 29.4 months; range 18-42 months). This was a prospective cohort from the previous multicenter randomized controlled trial. Participants of the extension study had to have undergone balloon dilation and completed the 12-month follow-up from the original study. Forty-seven participants were enrolled and evaluated at six-month intervals with the ETDQ-7 and middle ear functional assessments. Results noted that 93.6% of the subjects reported a reduction of one or more of their overall ETDQ-7 score with a mean score of 4.5 at baseline to 2.0 at last follow-up; tympanic membrane position improved from 46.8% within normal limits at baseline to 85.1% at last follow-up; Valsalva maneuver improved from 28.3% to 73.9%; and type A tympanograms improved from 70% to 86.3% at the last follow-up.

Randrup and Ovesen (2015) conducted a systematic review and meta-analysis of the literature to review the evidence of Eustachian tuboplasty (BET) for the treatment of ETD. Studies that included patients eligible for balloon Eustachian tuboplasty with a clinical diagnosis of Eustachian tube dysfunction were included. Outcome measures included: change in symptoms, middle ear pathology, eardrum status, Eustachian tube function tests, hearing, adverse events, complications, and health-related quality of life. Eight case series and one retrospective review with 8–210 patients (total n=443 patients; 642 tubes) met inclusion criteria. Follow-ups primarily ranged from 8–30 weeks. A significant reduction of patient symptoms in ETD questionnaire ($p<0.001$), reduction in Sino-Nasal Outcome Test (SNOT)-22 score ($p=0.001$), and increased quality of life ($p=0.001$) were reported. Postoperative normalization of the tympanic membrane, reduced mucosal inflammation, increased number of positive Valsalva test and swallowing tests, and improvement in ET score were also reported. Adverse events included mucosal tear, bleeding from turbinectomy site, tinnitus, and epistaxis. Comparison of results across the studies could not be made due to the heterogeneity of the inclusion criteria. Diagnostics and outcome measures varied. No study reported pre- and post-surgery results of pure-tone or speech audiometry. According to the authors, the evidence of BET was poor and featured a high risk of bias. No firm conclusions could be made to identify patients who would benefit from the procedure or to accurately predict BET outcomes.

Technology Assessment: Hayes (2017) conducted a Technology Brief on the Acclarent Eustachian Tube Balloon Dilation System for the treatment of chronic eustachian tube dysfunction in adults. The review identified five studies ($n=22-109$ patients; $n=35-171$ ears) that evaluated Eustachian tube balloon dilation (ETBD) using the Aera ETBD System or other sinus balloon systems manufactured by Acclarent Inc. Overall, the studies were of “very-low-quality” and did not allow for definitive conclusions regarding the efficacy, effectiveness, or safety of the Acclarent systems. Study interventions were heterogeneous, with a majority of studies including concurrent sinonasal and/or otologic procedures which limited the conclusions that could be drawn regarding the effectiveness of ETBD for chronic ETD. Overall, Follow-ups were short-term (3 months to 4.2 years). Definitive patient selection criteria could not be determined.

Professional Societies/Organizations

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): The AAO-HNS (2019) developed a clinical consensus statement on balloon dilation of the Eustachian tube (ET). The target population included adults \geq age 18 years with obstructive Eustachian tube dysfunction (ETD) in one or both ears for greater than three months affecting quality of life or functional health status for whom balloon dilation of the Eustachian tube was being recommended. Patients with patulous ETD, extrinsic obstruction of the ET, or active primary inflammatory disorders were excluded. Eustachian tube balloon dilation was defined as “inserting a catheter with a balloon temporarily into the cartilaginous portion of the ET and then inflating the balloon to alleviate obstructive ETD.” Due to the knowledge gap regarding the role of balloon dilation of the Eustachian tube (BDET) in managing obstructive ETD and an increasing rate of utilization, but limited evidence to support a clinical practice guideline, the topic of BDET was selected for clinical consensus statement development. Based on a systematic review of the literature and expert consensus, the Society’s statements included the following:

- “A comprehensive history and physical exam, including otoscopy, are essential parts of the diagnostic evaluation of a candidate for BDET
- Nasal endoscopy is an essential part of the diagnostic evaluation prior to BDET.
- BDET is contraindicated for patients diagnosed as having a patulous ETD.
- Nasal endoscopy in patients who are candidates for BDET is necessary for assessing the ET lumen and assessing the feasibility of transnasal access to the nasopharynx.

- A diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and/or aural fullness.
- The benefit of repeat BDET after a prior ineffective BDET has not been determined.
- Symptoms of obstructive ETD can include aural fullness, aural pressure, hearing loss, and otalgia.
- Tympanometry is an essential part of the diagnostic evaluation prior to BDET.
- Establishing a diagnosis of obstructive ETD requires ruling out other causes of aural fullness such as patulous ETD, temporomandibular joint disorders, extrinsic obstruction of the ET, superior semicircular canal dehiscence, and endolymphatic hydrops.
- Patient-reported symptom scores alone are insufficient to establish a diagnosis of obstructive ETD.
- Nasal endoscopy is necessary to rule out extrinsic causes of ETD.
- Comprehensive audiometry is an essential part of the diagnostic evaluation prior to BDET.
- BDET is appropriate in patients with obstructive ETD who have failed medical therapy for identified treatable causes.
- Common causes of obstructive ETD that benefit from identification and management are allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux.
- Medical management of known pathology that could affect nasal or ET function is appropriate to perform prior to BDET.
- Patients with a history of recurrent barochallenge, defined as uncomfortable pressure in the ear upon exposure to ambient pressure changes that cannot be easily relieved, may improve following BDET.
- There is no scientifically proven or standard medical therapy for ETD.
- Pneumatic otoscopy can identify negative pressure in the middle ear space and can differentiate between adhesive and nonadhesive retractions of the tympanic membrane.
- Patients undergoing BDET concurrent with sinus ostial dilation should meet the same diagnostic criteria for BDET as those undergoing BDET alone.
- Potential risks of BDET that are relevant to patient counseling include bleeding, scarring, infection, development of patulous ETD, and/or the need for additional procedures.
- Myringotomy with or without tympanostomy tube placement is not a mandatory prerequisite to BDET.
- A dehiscent carotid artery identified on imaging is a contraindication to use of a device without a depth marker that demarcates insertion into the cartilaginous eustachian tube.
- Patients with a middle ear effusion at the time of BDET may benefit from concurrent myringotomy with or without tympanostomy tube placement.
- BDET is an alternative to tympanostomy tube placement for obstructive ETD.
- Failure to relieve symptoms despite a functioning myringotomy or tympanostomy tube suggests a diagnosis other than obstructive ETD.
- Patient-reported symptom scores are useful in assessing baseline ETD symptoms and treatment outcomes.
- The ability to perform a modified Valsalva maneuver is appropriate for assessing outcome after BDET.
- Change in patient-reported symptom scores is appropriate for assessing outcome following BDET.”

Use Outside of the US

The National Institute for Health and Care Excellence (United Kingdom) (2019) interventional procedures guidance on balloon dilation for chronic Eustachian tube dysfunction stated that the current evidence on the efficacy and safety of balloon dilatation of the Eustachian tube is adequate to support the use of this procedure.

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Balloon Sinus Ostial Dilation

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
31295	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal sinus ostium
31297	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); sphenoid sinus ostium
31298	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal and sphenoid sinus ostia

Eustachian Tube Dilation

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral

HCPCS Codes	Description
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube (code deleted 12/31/2020)

***Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.**

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