Select Health Medical Policies

Ear, Nose & Throat Policies

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MEDICAL POLICY

AEROSOLIZED ANTI-INFECTIVE TREATMENT FOR SINUSITIS

Policy # 232
Implementation Date: 5/25/04
Review Dates: 6/16/05, 5/5/06, 5/17/07, 4/24/08, 2/18/10, 5/19/11, 2/16/12, 4/25/13, 2/20/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/18/19, 2/17/20, 2/18/21, 1/20/22, 2/16/23, 2/6/24
Revision Dates: 4/23/09

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Aerosolized anti-infective therapy has been proposed as a more effective therapy for the treatment of sinus infections with the potential for fewer systemic side effects than systemic antibiotic therapy. This type of therapy uses compounded medications that are aerosolized to a particle size small enough to disperse within the sinus cavities, yet large enough to be deposited in the sinuses. It can be used to nebulize antibiotics, antifungals, and other medications for the treatment of sinusitis. Use of this device requires purchase of specially compounded formulations of the anti-infective medication. A large volume nebulizer is used to create a vapor of the medicated solution that is inhaled through the nose. PARI Sinus and Sinus Dynamics are examples of nebulized systems used to deliver compounded prescription drugs.

The treatment process is simple: after the unit is connected, a patient simply pours the individual dose of medication into the nebulizer cup, turns on the machine, holds the cup to his/her nose, and breathes in and out naturally through the nose for the duration of the treatment. The treatments last about 10 minutes each. Most medications are given twice daily (morning and evening) for a period of 2–3 weeks.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover aerosolized anti-infective therapy for the treatment of sinusitis. There is inadequate published clinical evidence regarding the effectiveness of aerosolized anti-infectives in the treatment of sinusitis; this meets the plan's definition of experimental/investigational.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit

Select Health

Aerosolized Anti-infective Treatment for Sinusitis, continued

their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information
Clinical evidence supporting the efficacy and safety of aerosolized anti-infective therapy is weak. Two uncontrolled studies have evaluated the safety and efficacy of nebulized anti-infectives for the treatment of sinusitis. SinusPharmacy (Scheinberg, et al.) reported on the results of an uncontrolled study of nebulized antibiotics, totaling 41 patients, with sinusitis reported an “excellent” or “good” outcome in 34 patients (82%) after 3–6 weeks of treatment. Another study (Vaughan and Carvalho), which included 42 patients with acute or chronic sinusitis, offered nebulized antibiotics or “standard” therapy. The experimental treatment group had a longer infection-free period than the standard therapy group, 17 weeks vs. 6 weeks, based on a questionnaire and nasal endoscopy. However, only 3 patients received standard therapy.

A randomized clinical study (Desrosiers, et al.) involving 20 patients with chronic, refractory sinusitis found no clinically significant difference in effectiveness between nebulized tobramycin-saline solution and nebulized saline. These results lead the authors to conclude that the "addition of tobramycin [to saline nebulizer] appears to be of minimal benefit." A small, cross-over study in Europe (Videler, et al.) with 14 patients with chronic staphylococcal sinusitis found no difference in outcomes (symptom reduction, functional status, or economic findings) for patients treated with oral antibiotics and nasal irrigation of bacitracin/colimycin or oral antibiotics and saline irrigation.

In addition, none of the recently published guidelines on sinusitis management from professional medical organizations discuss any role for nebulized antibiotics. Consequently, aerosolized anti-infective therapy is considered experimental and investigational for the treatment of sinusitis, and is therefore, not covered.

Billing/Coding Information
Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

94664	Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB device
99503	Home visit for respiratory therapy care (e.g., bronchodilator, oxygen therapy, respiratory assessment, apnea evaluation)

HCPCS CODES

A7013	Filter, disposable, used with aerosol compressor or ultrasonic generator
A7014	Filter, nondisposable, used with aerosol compressor or ultrasonic generator
A7015	Aerosol mask, used with DME nebulizer
E0572	Aerosol compressor, adjustable pressure, light duty for intermittent use
E0574	Ultrasonic/electronic aerosol generator with small volume nebulizer
E0575	Nebulizer, ultrasonic, large volume
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter
E0585	Nebulizer, with compressor and heater
J7685	Tobramycin, inhalation solution, compounded product, administered through DME, unit dose form, per 300 milligrams

Key References
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Aerosolized Anti-infective Treatment for Sinusitis, continued

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MEDICAL POLICY

ALTERED AUDITORY FEEDBACK (AAF) DEVICES FOR THE TREATMENT OF STUTTERING (SPEECHEASY)

Policy # 255
Implementation Date: 12/14/04
Review Dates: 12/5/05, 12/21/06, 12/20/07, 12/18/08, 10/13/11, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/15/18, 10/14/19, 11/30/20, 10/31/21, 9/15/22, 10/17/23, 10/17/24
Revision Dates: 12/19/09, 10/21/10

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Description

Stuttering is a disturbance in the normal fluency and time patterning of speech that is inappropriate for the person's age. Developmental stuttering is the most common form, with an onset prior to the age of 12, and generally between the ages of 2–5 years. Preschool children normally undergo a transient period of disfluency, and it is estimated that 50%–80% of children with developmental stuttering will recover with or without therapy and generally before puberty. Persistent developmental stuttering is developmental stuttering that has not undergone spontaneous or therapy-related remission. Proposed etiologies include abnormal cerebral dominance with differences in regional brain activation patterns, and a possible hyperdopaminergic origin with an overactive pre-synaptic dopamine system in regions of the brain that modulate verbalization. A genetic component has also been observed. Acquired stuttering in a previously fluent individual is much rarer than developmental stuttering, and may be neurogenic, resulting from brain damage associated with conditions such as traumatic brain injury, Alzheimer's disease, and Parkinson's disease, among others. Psychogenic stuttering is also recognized following emotional trauma.

Altered auditory feedback (AAF) devices use auditory feedback via an earpiece worn in or behind the ear, and utilize, alone or in combination, the following techniques: Delayed auditory feedback (DAF), delaying the user's voice to their ears a fraction of a second (this delay is adjustable); and frequency shifting auditory feedback or frequency altered feedback (FAF), which shifts the pitch of the user's voice in their ears.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover altered auditory feedback devices for the treatment of stuttering. These devices meet the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Select Health

Altered Auditory Feedback (AAF) Devices for the Treatment of Stuttering (Speecheasy®), continued

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Traditional treatments for developmental stuttering have involved various speech therapy techniques. In some cases, pharmacologic therapy has been used. Altered auditory feedback has been investigated as a potential therapy. The rationale for AAF rests in the observation that individuals who stutter tend to become more fluent when speaking in unison with others, the so-called "choral effect." Altered auditory feedback attempts to emulate the choral effect by allowing the user to hear their voice with a slight time delay and/or a pitch shift which is said to create the illusion of another individual speaking at the same time. Such devices include the SpeechEasy and Casa Futura/Jabra Fluency Devices.

However, the published literature on the clinical use and effectiveness of these devices consists of a few reports with extremely small numbers of patients in uncontrolled case series. The results are somewhat mixed but suggest a decrease in stuttering in some individuals performing reading tasks, more so than monologue. There is minimal data on its effect on everyday social fluency. There is little if any data on the long-term use of these devices, and no data to support that fluency would persist following discontinuation of the device. Larger prospective randomized controlled studies would be required to demonstrate the effectiveness of AAF for everyday communication and fluency, compared both to no treatment and to other forms of established therapy.

A December 2009 literature search found a 6-month, Phase I clinical trial looking at the effects of the SpeechEasy device on objective and perceived aspects of stuttering. There were some individual positive responses and self-reports that could suggest some clinical utility for the SpeechEasy. The use of more challenging sampling procedures strengthened external validity and captured more modest altered auditory feedback effects compared with those previously reported in laboratory settings. The device use coincided more so with positive subjective impressions than with measurable fluency improvement, highlighting challenges facing clinicians when implementing principles of evidence-based practice, including client-based preferences.

The degree and pattern of benefit varied greatly across participants. Although a few participants exhibited both a dramatic reduction in stuttering and relative freedom from stuttering in the device conditions, others showed a modest or minimal reduction and continued to exhibit a relatively high level of stuttering.

Little research has been done on the long-term effects and relatively little is known. The current study represents data from the first Phase I Clinical Trial of the SpeechEasy under challenging, relatively naturalist conditions. They concluded there was no statistically significant treatment effect found for any of the three speech tasks used in this study, group results failed to show a significant effect of the SpeechEasy over time compared with baseline, and based on this protocol, Phase II trials are not indicated.

A literature review performed in October 2010 identified a new article by Lincoln et al. They identified a statistically significant difference was found between the NAF conversation condition and the 4 combined altered auditory feedback (AAF) conditions. No statistically significant differences in percentage of syllables stuttered were found in conversation or reading between the control conditions and the FAF/DAF or MAF conditions. The analysis of individual participants' data showed highly individual responsiveness to different conditions.

They concluded that the participants' varying responses to differing AAF settings likely accounted for the failure to find group differences between conditions. These results suggest that studies that use standard DAF and FAF settings for all participants are likely to underestimate any AAF effect. It is not yet possible to predict who will benefit from AAF devices in everyday situations and the extent of those benefits.

A literature review conducted in November 2020 identified a new article by Gallop and Runyan, "Long-term effectiveness of the Speech Easy fluency-enhancement device." Results indicated: "There was no

Altered Auditory Feedback (AAF) Devices for the Treatment of Stuttering (Speecheasy®), continued

significant difference in stuttering frequency when users were wearing versus not wearing the device currently."

Billing/Coding Information

CPT CODES

No specific codes identified

HCPCS CODES

E1399 Durable medical equipment, miscellaneous

Key References

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MEDICAL POLICY

TEMPORAL BONE OSSEOINTEGRATED DEVICES – BONE ANCHORED HEARING IMPLANTS

Policy # 524
Implementation Date: 5/20/13
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Revision Dates: 8/6/15, 1/1/22, 4/14/23

Related Medical Policies:
#302 Cochlear Implantation
#651 Hearing Aids

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Description

Hearing loss occurs when there is loss of sound sensitivity produced by an abnormality anywhere in the auditory system. A wide variety of conditions can cause hearing loss, including otosclerosis, cholesteatoma, noise exposure, genetics, infections, sudden sensorineural hearing loss, post-surgery (especially skull base surgery and tumors of the skull base), ototoxic medications, and others. In some cases, the causes are unknown or idiopathic.

Conductive hearing loss, a subset of general hearing loss, results from lesions involving the external or the middle ear. The most common serious cause of conductive hearing loss is chronic otitis media, which can result from either infected fluid (suppurative otitis) or non-infected fluid (serous otitis) accumulating in the middle ear and impairing conduction of airborne sound, as well as conditions such as cholesteatomas. Some congenital conditions, such as microtia and atresia, result in conductive hearing loss.

Sensorineural hearing loss results from lesions of the cochlea, the auditory division of the acoustic nerve, or both, and results in inability to normally perceive both bone- and air-conducted sound in the ipsilateral ear.

Mixed hearing loss refers to the coexistence of a *conductive* and *sensorineural* hearing loss. In some instances, one specific cause can underlie the presence of a mixed loss (such as otosclerosis that begins to invade the cochlea itself). In other cases, it may reflect different underlying causes, such as the presence of a middle ear infection in a child with a preexisting sensorineural hearing loss. The impact of the mixed loss is to impede transmission of sound via the external/middle ear to an already damaged inner ear.

Most hearing impairments can be helped with a modern hearing aid. Young, middle-aged, and independent elderly individuals who have hearing difficulties that interfere with work and social interactions and who are highly motivated to improve their hearing, make good candidates for hearing amplification.

Cochlear implants, as opposed to hearing aids, are surgically implanted prosthetic devices that use electrical stimulation to provide hearing. The criteria for selecting cochlear implantation include moderate-to-severe unilateral or bilateral sensorineural hearing loss and little or no benefit from hearing aid trial.

Percutaneous and transcutaneous temporal bone osseointegrated devices, sometimes referred to as BAHAs (bone anchored hearing aid), though, this is a name that is specific to a company (Cochlear), allow patients with conductive hearing loss, mixed hearing loss, or unilateral profound sensorineural

hearing loss (single-sided deafness) to achieve improved auditory acuity by transmitting the sound directly through the bone into the inner ears. An osseointegrated hearing device or bone conduction hearing device is not simply a surgical "alternative" to a conventional hearing aid, but a device with a unique set of indications (outlined below). After the implant has become integrated into the temporal bone, a hearing processor is attached, transmitting the sound directly through the bone into the inner ear and bypassing the middle ear.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

For those plans that require coverage of standard hearing aids, such as FEHB or self-funded plans which have added a hearing aid benefit, temporal bone osseointegrated devices are covered based upon specific criteria as coverage of this technology is deemed an extension of the hearing aid benefit using defined criteria.

Nevada Plans

a. Osseointegrated auditory devices (bone anchored hearing aids) are covered for Members who have either of the following:
   i. Craniofacial anomalies whose abnormal or absent ear canals preclude the use of a wearable hearing aid; or
   ii. Hearing loss of sufficient severity that it would not be adequately remedied by a wearable hearing aid.

Idaho Commercial Plans

Idaho Small Employer and Individual Plans

Services for cochlear implants, hearing aids, and osseointegrated auditory (bone conduction) devices are not covered, except when an enrolled Dependent child has a congenital anomaly or acquired hearing loss and the child may develop cognitive or speech development deficits without intervention.

Idaho Large Employer Plans

Services for cochlear implants, hearing aids, and osseointegrated auditory (bone conduction) devices are not covered, except:

a. When a Dependent child has a congenital anomaly or acquired hearing loss and may develop cognitive or speech development deficits without intervention; and
b. Cochlear implants and osseointegrated auditory devices for adult Members in accordance with SelectHealth medical policy. All other hearing aids are not covered for adult Members.

Utah Plans

Temporal bone osseointegrated devices are covered when the following criteria are met:

Coverage Criteria

1. **For Conductive or Mixed Hearing Loss**
   a. **Unilateral or bilateral implantable osseointegrated bone conduction devices** may be considered medically necessary as an alternative to an air-conduction hearing aid in patients 5 years of age and older with **conductive or mixed hearing loss** who also meet at least one of the following medical criteria:

Temporal Bone Osseointegrated Devices - Bone Anchored Hearing Implants, continued

i. Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear refractory to medical therapy limiting the use of an external hearing device;

ii. Chronic external otitis/dermatitis or otitis media that has failed appropriate medical therapy;

iii. Tumors of the external canal and/or tympanic cavity;

iv. Unable to use traditional amplification devices (hearing aids) and persistent conductive/mixed hearing loss after middle ear surgery.

AND

b. Meet the following audiologic criteria:

i. A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of better than or equal to levels established by the FDA for the devices listed below:

Device Name	Decibel Level
Cochlear Americas' BAHA and Osia	≥ 45 dB HL
MED-EL Bonebridge and Samba	≥ 45 dB HL
Ponto 3 and 4	≥ 55 dB HL

For bilateral implantation, patients should meet the above audiologic criteria, and have a symmetrically conductive or mixed hearing loss as defined by a difference between left- and right-side bone conduction threshold of less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies.

2. **For Single-Sided Sensorineural Deafness**

a. Patient has a congenital or acquired severe-to-profound sensorineural hearing loss. The osseointegrated bone conduction device will be implanted in the affected ear.

b. Cochlear implant is not appropriate or indicated.

Bone-anchored hearing aids utilizing a headband will be covered if the member is unable to have an osseointegrated device (because of age, skull bone thickness, etc.), and the criteria outlined above are met.

Temporal bone osseointegrated devices are considered investigational for all other uses not mentioned above, including use in patients with bilateral sensorineural hearing loss, as it meets the plan definition of investigational/experimental.

Select Health does not cover intra oral bone conduction hearing aids, as these are considered experimental/investigational.

Temporal Bone Osseointegrated Devices - Bone Anchored Hearing Implants, continued

Degree of Hearing Loss	Range (dB HL = decibels hearing level)
Normal Hearing	-10 to 15 dB HL
Slight Loss	16 to 25 dB HL
Mild Loss	26 to 40 dB HL
Moderate Loss	41 to 55 dB HL
Moderately Severe Loss	56 to 70 dB HL
Severe Loss	71 to 90 dB HL
Profound Loss	91 dB HL or more

(ASHA, Type, Degree and Configuration of Hearing Loss; Clark, 1981)

SELECT HEALTH MEDICARE

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SELECT HEATH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Five systematic reviews and 27 peer-reviewed journal articles met inclusion criteria for this review. A total of 1,779 patients were examined with an average of 68 participants per study. The majority of the literature was quality of life reports based on the SF-36, Abbreviated Profile of Hearing Aid Benefit tool, and the Single-Sided Deafness Questionnaires. As such, the objectivity of many of the studies is questionable.

Several key issues were routinely assessed in the literature. These were: cost-effectiveness of the technology, patient selection, and adverse events.

Select Health

Temporal Bone Osseointegrated Devices - Bone Anchored Hearing Implants, continued

Cost effectiveness: Cloquitt et al. found the cost-effectiveness analysis of BAHA suggests that BAHAs are unlikely to be a cost-effective option where the benefits (in terms of hearing gain and probability of using of alternative aids) are similar for BAHAs and their comparators. This same group also found in two separate reviews that BAHAs are significantly more costly than conventional bone conduction hearing aids, only if the patient used their device for ≥ 8 hours/day for 10 years.

Conversely, Monksfield et al. found that bone-anchored hearing devices were cost-effective as their ICER per QALY was sufficiently low by NICE standards for patients requiring auditory rehabilitation. This conclusion, however, has limited application in the US Healthcare system as the delivery of care in the UK is substantively different than in the US, and thus, calculated QALY may be markedly different in the US.

Newer osseointegrated bone conduction devices, such as the Bonebridge or Osia, offer advantages over traditional BAHAs. In a study by Amin et al., long-term costs of Bonebridge to healthcare providers are comparable to percutaneous Bahas, whilst offering lower complication rates, comparable audiological benefit and patient satisfaction. Bonebridge or Osia should be considered as a first-line bone conduction option in appropriate cases. In a report by Goldstein et al. the Cochlear Osia 2 System showed significant advantages in auditory osseointegrated implant technology. Osia's digital piezoelectric stimulation delivers high power outputs, improves high frequency gain for optimal speech perception, and maintains safety while providing excellent patient satisfaction.

Patient selection: The papers investigated several etiologies of hearing loss, including conductive, sensorineural, mixed, congenital aural atresia, tinnitus, and otitis media. As noted by the Canadian Agency for Drugs and Technologies in Health (CADTH) and Cloquitt et al., the data could not be reasonably pooled due to the heterogeneity across the studies in outcome measures, and inclusion criteria and inconsistently presented results existed among patient groups. There is some evidence, as presented by Saroul et al., Boleas-Aguirre et al., Cloquitt et al., Pennings et al., Grantham et al., and Kunst et al., that BAHA may be beneficial in patients with conductive hearing loss, but not in sensorineural hearing loss. Cloquitt et al. also reported that BAHA improved hearing thresholds between 0.5 and 4.0 kHz across various etiologies. This finding was echoed by Pai et al. and Ricci et al., who also noted the same range for improvement. This information may guide patient selection criteria in the future.

Adverse events: Cloquitt et al. noted that studies in their systematic review of BAHA in patents with bilateral deafness contained very limited data on adverse events. Five prospective case series reported rates of loss of implants ranging between 6.1% of implants (9–25 months' follow-up) and 19.4% of implants (median six years' follow-up). Most participants experienced zero or minor skin reactions. Siau et al. found that 4.5% of BAHAs were removed because of pain, persistent infection, failure of osseointegration, and trauma. Wallberg et al. had the highest failure rate of all the articles identified for this review, with 27% of BAHAs lost during the follow-up period of nine years. As per the cost analysis of Cloquitt et al. and other similar articles, this high failure rate occurring short of 10 years further decreases the cost-effectiveness of the technology.

In a systematic review by Nadaraja et al. of patients with congenital aural atresia, osseointegrated devices were shown to have consistent and better hearing outcomes than atresiaplasty. A recent systemic review of bone anchored hearing devices demonstrated percutaneous systems provide consistent audiological benefits and improved quality of life for patients. Further, the review demonstrates that the percutaneous systems are safe, with relatively low complication rates. Skin-related complications are the most common complication type and are experienced by approximately one patient out of seven, or in less than one of 20 follow-up visits.

Another recent systematic review of studies reporting experience with the Bonebridge bone conduction hearing implant by Sprinzl and Wolf-Magele summarizes the well-accepted notion that transcutaneous osseointegrated hearing devices offer improved hearing thresholds and speech understanding in conductive hearing loss, mixed hearing loss, and single sided deafness configurations. The experience in children from age 5 and up mirrors that of adults without an increased rate of adverse events.

Non-Implantable Bone Conduction Hearing Aids: Several non-implantable bone conduction hearing aids are FDA approved. They provide an excellent alternative without the costs and potential

Temporal Bone Osseointegrated Devices - Bone Anchored Hearing Implants, continued

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Select Health

MEDICAL POLICY

COCHLEAR IMPLANTATION

Policy # 302

Implementation Date:4/15/06
Review Dates: 5/17/07, 4/24/08, 2/9/09, 2/12/12, 4/25/13, 10/20/16, 10/19/17, 10/9/18, 10/15/19, 11/30/20, 2/11/22, 4/4/23, 6/10/23, 6/20/24
Revision Dates: 1/1/10, 8/6/15, 5/15/18, 8/7/18, 2/19/20, 1/1/22, 4/1/22, 4/14/23, 1/28/25

Related Medical Policies:
#524 Temporal Bone Osseointegrated Devices - Bone Anchored Hearing Implants
#651 Hearing Aids

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

More than 28 million people in the United States have hearing loss. Approximately 600,000 people in the United States (0.22% of the population) have hearing loss and more than half of these are over 65 years of age. Severe-to-profound hearing loss is commonly considered the inability to detect a sound at 70 decibels hearing level or greater (averaged across the frequencies of 500, 1,000, and 2,000 Hertz) in the better ear. Approximately 50% of profoundly deaf adults have prelingual deafness (i.e., deafness occurred before speech developed). Approximately 3 in 1,000 children are born with severe hearing loss. This number almost doubles by school age to approximately 6 in 1,000 children.

There are many important health-related ramifications of hearing loss. In children, hearing loss is associated with impaired speech and language development, learning and literacy, employment opportunities, and psychosocial conditions. In older adults, hearing loss is associated with increased risk of dementia, falls, depression, social isolation, and health care utilization and hospitalization. A 2020 Lancet commission identified hearing loss as the largest modifiable risk factor for Alzheimer's disease dementia.

Hearing loss may result from a mechanical problem in the external ear canal or middle ear that blocks the conduction of sound (conductive hearing loss). More commonly, hearing loss may also result from damage to the sensory structures (hair cells) of the inner ear, auditory nerve, or auditory nerve pathways in the brain (sensorineural hearing loss). These sensory structures may be damaged by congenital malformations, genetic mutations, noise, ototoxic drugs, infections, tumors, following surgery, and trauma/skull injuries. Hearing loss can also be a mixture of a conductive and sensorineural loss.

Amplification of sound with a hearing aid may help people with sensorineural hearing loss, though, it does not restore hearing to normal. A hearing aid should, however, significantly improve a person's ability to communicate and enjoy sounds. All hearing aids have: a microphone to pick up sounds, a battery-powered amplifier to increase their volume, and a means of transmitting the sound to the person. Most hearing aids transmit the sounds through a small speaker placed in the ear canal. Other aural rehabilitation devices such as osseointegrated temporal bone and active middle ear implants require surgical implantation and transmit sounds directly to the bones of the middle ear (ossicles) or the skull instead of through a speaker.

Amplification with a hearing aid or other device does not replace the function of lost cochlear hair cells or other sensorineural functions of the ear and often cannot provide adequate hearing in patients with severe cochlear hair cell loss. If the neural elements that transmit information from the cochlea to the auditory cortex of the brain are intact and functional, it is possible to stimulate auditory nerve impulses with a prosthetic cochlear implantation (CI) device designed to perform the function of cochlear hair cells.

Select Health

Cochlear Implantation, continued

By electrically stimulating the auditory nerve, CI performs the function normally performed by cochlear hair cells, thereby restoring some degree of hearing.

Cochlear implantation is the standard of care for treating individuals with severe-profound hearing loss. It is currently the only way to restore neurologic function of a lost sensory end organ (the cochlea). There are many hearing and non-hearing-related health benefits to cochlear implantation. Several cochlear implantation systems are available, all of which consist of 4 basic components, that: 1) receive external sound information (external receiver); 2) process received information (external speech processor); 3) transmit processed information (external transmitting coil); and 4) receive and use processed information to stimulate auditory nerves (internal receiver/stimulator which includes an intracochlear electrode). The external receiver (a small directional microphone) usually is worn at ear level and captures sounds in the environment as analog signals. The analog information is transmitted by a direct wire connection to the external speech processor, which is powered by batteries and uses coding strategies to convert analog signals to digitalized electronic signals. The coding strategies are considered the "brains" of the cochlear implant device and are where most technological advances for the device occur. The speech processor is worn on the head for adults and most children, while younger children may have a sound processor clipped to their body.

The processed and digitalized information is transmitted by another direct wire connection to the external transmitting coil, which consists of a magnet and a transmitting antenna. The transmitting coil is worn behind the ear and is held in place magnetically by positioning it in close proximity to the implanted portion of the device, the internal receiver/stimulator, which consists of a magnet of opposite polarity to that of the transmitting coil, a receiver/stimulator unit to which the magnet is attached, and a multichannel electrode array or several proximal stiffening (inactive) electrodes and distal stimulating (active) electrodes that is/are connected to the receiver/stimulator unit and placed in the cochlea. The transmitting antenna of the external transmitting coil passes the digital information by electromagnetic induction across the patient's skin to the receiver/stimulator unit, which receives the electromagnetic signals and distributes them to the intracochlear electrodes, thereby stimulating surviving nerve tissue, or spiral ganglion cells for the cochlear nerve.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Cochlear Implants are a limited benefit for many grandfathered plans defined in the certificate of coverage for the specific plan. These criteria are only applied when benefit limitations have not been met for grandfathered plans.

Nevada Based Plans

Cochlear implants are covered in accordance with Select Health medical policy #302 (see criteria outlined below in Utah Based Plans section).

Idaho Commercial Plans

Idaho Small Employer and Individual Plans

Services for cochlear implants, hearing aids, and osseointegrated auditory (bone conduction) devices are not covered, except when an enrolled Dependent child has a congenital anomaly or acquired hearing loss and the child may develop cognitive or speech development deficits without intervention.

Idaho Large Employer Plans

Services for cochlear implants, hearing aids, and osseointegrated auditory (bone conduction) devices are not covered, except:

Select Health

Cochlear Implantation, continued

a. When a Dependent child has a congenital anomaly or acquired hearing loss and may develop cognitive or speech development deficits without intervention; and
b. Cochlear implants and osseointegrated auditory devices for adult Members in accordance with Select Health medical policy. All other hearing aids are not covered for adult Members.

Colorado Based Plans

Cochlear implants are covered in accordance with Select Health medical policy #302 (see criteria outlined below in Utah Based Plans section).

Utah Based Plans

Select Health covers unilateral and bilateral cochlear implantation when ALL the following conditions are met. *These criteria are only used in the context of a member's cochlear implant benefit.*

A. For children, pre- or post-lingual, 9 months of age or older with bilateral sensorineural hearing impairment:
   1. Child has severe-to-profound, bilateral sensorineural hearing loss per the following definitions:

      Profound - Someone with profound hearing loss has a three-frequency pure-tone average (PTA) of 90 dB or greater at 1000*, 2000, and 4000 Hz, **or**
      Severe – Someone with a severe hearing loss has a three-frequency pure-tone average (PTA) of 70 dB or greater at 1000*, 2000, and 4000 Hz**.**

      AND

   2. The child has undertaken a medically appropriate 3-month hearing aid trial to determine benefit from amplification. If limited benefit from hearing aids is identified, a cochlear implant may be indicated. (Exceptions for a hearing aid trial may be necessary when the timing of cochlear implant surgery has significant medical consequences, such as meningitis or sudden hearing loss, or the provider has documented a clinical reason as to why a hearing aid trial is not indicated.)

      a. Limited benefit from appropriately fitted binaural hearing aids is defined as:

      i) For children 5 years of age or younger, limited benefit would be lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in an intensive aural habilitation program. Benefit can be assessed and documented with use of age-appropriate auditory assessments such as the Auditory Skills Checklist (ASC), ages 0- to 36+ months (2005 Cincinnati Children's Hospital), Early Speech Perception Test (ESP) for 2 to 9 years of age and among other similar test instruments. Lack of benefit would be demonstrated by failure to achieve expected auditory skill development after period of amplification.

      ii) For children 6 years and older, 'limited benefit' is defined as: less than 20% correct on open-set sentence discrimination (e.g., Multi-syllabic Lexical Neighborhood Test [MLNT] or Lexical Neighborhood Test [LNT], depending on the child's cognitive ability and linguistic skills).

B. For adults, pre- or post-lingual, aged 18 years and older with bilateral sensorineural hearing impairment:

   1. Member has severe-to-profound, bilateral sensorineural hearing loss per the following definitions:
      Profound - Someone with profound hearing loss has a three-frequency pure-

Cochlear Implantation, continued

tone average (PTA) of 90 dB or greater at 1000*, 2000, and 4000 Hz.,
or
Severe – Someone with a severe hearing loss has a three-frequency pure-tone average (PTA) of 70 dB or greater at 1000*, 2000, and 4000 Hz.
AND

2. Member has limited benefit from appropriately fitted binaural hearing aids. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence cognition.

C. **Select Health considers one-sided cochlear implantation** medically necessary for individuals aged 18 years and older with single-sided deafness (SSD) or asymmetric hearing loss (AHL), who meet the following criteria:

1. For adults 18 years of age or older with SSD or AHL, limited benefit from unilateral amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence cognition. Before implantation with a cochlear implant, individuals with SSD or AHL must have at least 3 months of experience wearing a hearing aid, a CROS hearing aid, or other relevant device, and not show any subjective benefit. (Exceptions for a hearing aid trial may be necessary when the timing of cochlear implant surgery has significant medical consequences, such as meningitis or sudden hearing loss, or the provider has documented a clinical reason as to why a hearing aid trial is not indicated.)

D. **Select Health covers unilateral cochlear implantation** for children with *single-sided deafness* (SSD) when **ALL** the following criteria are met:

1. The member is between 5 and 18 years of age; **and**

2. The member has severe-to-profound sensorineural hearing loss in at least one ear, defined as:
   i. Pure-tone average (PTA) of 70 dB or greater at 1000*, 2000, and 4000 Hz; **or**
   ii. Pure-tone average (PTA) of 90 dB or greater at 1000*, 2000, and 4000 Hz; **and**

3. The member has undertaken a medically appropriate 3-month hearing aid trial with insufficient access to sound. 'Insufficient access to sound' is defined as aided speech perception test scores of 5% or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone. (Exceptions for a hearing aid trial may be necessary when the timing of cochlear implant surgery has significant medical consequences, such as meningitis or sudden hearing loss, or the provider has documented a clinical reason as to why a hearing aid trial is not indicated.)

E. **Select Health covers unilateral cochlear implantation** for children with *asymmetric hearing loss* (AHL) when **ALL** the following criteria are met:

1. The member is between 5 and 18 years of age; **and**

2. The member has severe-to-profound sensorineural hearing loss in at least one ear, defined as:
   i. Pure-tone average (PTA) of 70 dB or greater at 1000*, 2000, and 4000 Hz; **or**
   Pure-tone average (PTA) of 90 dB or greater at 1000*, 2000, and 4000 Hz; **and**

Cochlear Implantation, continued

3. The member has undertaken a medically appropriate 3-month hearing aid trial with insufficient access to sound. 'Insufficient access to sound' is defined as aided speech perception test scores of 5% or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone (Exceptions for a hearing aid trial may be necessary when the timing of cochlear implant surgery has significant medical consequences, such as meningitis or sudden hearing loss, or the provider has documented a clinical reason as to why a hearing aid trial is not indicated.); **and**

4. The member has a difference of at least 15 dB in pure tone averages (PTA) between ears.

(*Note: Particular plans place limits on benefits for speech therapy services. Please consult plan documents for details*.)

*The exclusion of 500 Hz from pure-tone average calculations appropriately allows members with residual low-frequency acoustic hearing but with severe to profound mid to high frequency hearing loss who do not benefit from traditional amplification to be cochlear implant candidates. As such, preoperative hearing of candidates may range from normal to moderate hearing loss in the low frequencies (thresholds better than 60 dB HL up to and including 500 Hz) but must still meet all the above criteria. For individuals with post-surgical low frequency hearing, the sound processor combines acoustic amplification for the low frequencies with electric stimulation for the high frequencies.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The available literature on cochlear implantation (CI) universally supports use of the device in patients with severe-profound sensorineural hearing loss across the age spectrum. CI's generally improve hearing and communication ability and results in improved quality of life and better educational and occupational opportunities. Variability in these outcomes may occur due to differences in age at diagnosis, level of residual hearing, physical condition of the cochlea, family support, duration of deafness, level of exposure to spoken language before implantation, and the cognitive and psychological characteristics of the patient. However, stringent screening criteria would likely reduce the number of persons inappropriately implanted and improve the likelihood of successful outcomes. Multiple studies have demonstrated the safety, efficacy, and cost-effectiveness of bilateral cochlear implantation.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

69930	Cochlear device implantation, with or without mastoidectomy

Cochlear Implantation, continued

92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming

HCPCS CODES

L8614	Cochlear device, includes all internal and external components
L8615	Headset/headpiece for use with cochlear implant device, replacement
L8616	Microphone for use with cochlear implant device, replacement
L8617	Transmitting coil for use with cochlear implant device, replacement
L8618	Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement
L8619	Cochlear implant external speech processor and controller, integrated system, replacement
L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
L8622	Alkaline battery for use with cochlear implant device, any size,
L8623	Lithium ion battery for use with cochlear implant device speech processor, other than ear level, replacement, each
L8624	Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each
L8627	Cochlear implant, external speech processor, component, replacement
L8628	Cochlear implant, external controller component, replacement
L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement
S2235	Implantation of auditory brain stem implant

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Cochlear Implantation, continued

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Select Health

Cochlear Implantation, continued

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Select Health

Cochlear Implantation, continued

Revision History

Revision Date	Summary of Changes
4/14/23	For Commercial Plan Policy, reformatted overall criteria to show differences in coverage criteria according to plan type/area; removed coverage of Auditory Brainstem Implants to align with exclusion of these devices outlined in plan documents; and modified language in "Limited benefit from amplification …" requirements for adults to align with updated clinical standards adopted by CMS.
1/28/25	For Commercial Plan Policy, added language which clarifies coverage of hearing aids for Colorado Based Plans.

Select Health

Select Health

MEDICAL POLICY

COMMUNICATION DEVICES

Policy # 112
Implementation Date:7/98
Review Dates: 1/4/00, 2/27/01, 8/29/02, 7/8/03, 8/27/03, 6/24/04, 4/14/05, 4/20/06, 7/12/07, 6/19/08, 6/11/09, 6/17/10, 9/15/11, 10/14/14, 12/15/16, 12/21/17, 12/13/18, 1/21/21, 11/16/21, 11/18/22, 12/21/23, 11/29/24
Revision Dates: 8/18/03, 7/24/06, 1/1/10, 10/24/13, 8/24/21, 12/19/24

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description
Communication is an inherent part of the human experience. Communication in some form is necessary for many individuals to make caregivers aware of their basic needs. As such, basic communication may be considered an essential of daily living.

Many devices are currently available which help facilitate, augment, restore, or replace natural communication. Some individuals have congenital problems, which limit their abilities to communicate; others acquire the limitation through illness or injury. Communication devices can be as simple as picture boards that an individual would point to, or advanced computer hardware that are activated through eye movement. Communication devices can be used to enhance the education of individuals who are partially impaired or younger individuals who are continuing to intellectually grow.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers communication devices when used only for activities of daily living (ADL), and when desired results cannot be achieved through using natural communication methods, when the following guidelines are met:

1. The augmentative communication device has been recommended by a speech-language pathologist, who has conducted a thorough assessment, which has included all the following:
   a. A diagnosis, physiological description of the underlying disorder, description of functional impairments, and prognosis for improvement
   b. If complex or high-tech devices (e.g., voice activated systems or computer devices) are requested, rationale why the proposed device is necessary, and a less sophisticated device will not meet the patient's needs
   c. Expected goals of the augmentative communication device (ACD) for the patient
   d. Patient has demonstrated an ability to use the proposed device or a similar device in a home setting for 3 months
   e. The patient is physically able to use the device without assistance
2. The individual using the device has physical limitations, which make this device necessary for the completion of ADLs.
3. The device is not being used primarily for educational purposes.

Select Health

Communication Devices, continued

4. The individual using the device has the cognitive capacity to use the device independently.

Select Health covers speech generating devices applied to the neck or throat area that are necessary to restore spoken language after a patient with previously normal speech function has undergone a surgical procedure due to illness or injury, which eliminated the patient's ability to make any intelligible communication is always covered. These devices are considered restorative and function as prosthesis; the standard DME limitations apply.

Select Health does NOT cover communication devices when used primarily for educational purposes; the use of DME devices for this indication are specifically excluded.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Speech generating devices (SGDs) are speech aids that provide individuals with severe speech impairment the ability to meet their functional speaking needs. Digitized speech sometimes referred to as devices with "whole message" speech output, use words or phrases that have been recorded by an individual other than the SGD user for playback upon command of the SGD user. Synthesized speech, unlike prerecorded messages of digitized speech, is a technology that translates a user's input into device-generated speech using algorithms representing linguistic rules. Users of synthesized speech SGDs are not limited to pre-recorded messages but rather can independently create messages as their communication needs dictate. Some SGDs require message formulation by spelling and access by physical contact with a keyboard, touch screen, or other display containing letters. Speech generating software programs enable a laptop computer, desktop computer or personal digital assistant (PDA) to function as an SGD. Within this policy, the term SGD also describes such speech generating software programs. Speech generating devices may permit multiple methods of message formulation and multiple methods of device access. For purposes of this policy, an SGD with multiple methods of message formulation should include message selection by two or more of the following methods: letters, words, pictures, and symbols. A SGD with multiple methods of access should include the capability to access the device by two or more of the following: direct physical contact with a keyboard or touch screen, indirect selection techniques and a specialized access device such as a joystick, head mouse, optical head pointer, light pointer, infrared pointer, scanning device, or Morse code.

Upgrades of a SGD are subsequent versions of a SGD software program or memory modules that may include enhanced features or other improvements. Mounting switches are devices necessary to place the SGD, switches, and other access devices within the reach of the patient. Accessories for SGDs include, but are not limited to: access devices that enable selection of letters, words, or symbols via direct or indirect selection techniques. Examples of access devices include, but are not limited to: optical head pointers, joysticks, and SGD scanning devices. The assessment of need for an SGD should be performed by a qualified speech-language pathologist (SLP). The SLP should hold a Certificate of Clinical Competence from the American Speech and Hearing Association.

Select Health

Communication Devices, continued

The literature for some communication aids emphasizes their value in expanding vocabulary skills, for use in business and for report preparation, and their ability to be connected to a personal computer. This goes beyond what is considered to be an essential medical device. For similar reasons, Select Health does not cover visual alert systems for the deaf or special controls on cars for people who need them to drive.

Billing/Coding Information

CPT CODES

Covered: For the conditions outlined above

92521	Evaluation of speech fluency (eg, stuttering, cluttering)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	; group, 2 or more individuals
92597	Evaluation for use and/or fitting of voice prosthetic device to supplement oral speech
92609	Therapeutic service for the use of speech generating device, including programming and modification

HCPCS CODES

Covered: For the conditions outlined above

E1902	Communication board, non-electronic augmentative or alternative communication device
E2510	Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access
E2599	Accessory for speech generating device, not otherwise classified

Not covered: Investigational/Experimental/Unproven for this indication

E2500	Speech generating device, digitized speech, using per-recorded messages; less than or equal to 8 minutes recording time
E2502	; greater than 8 minutes but less than or equal to 20 minutes recording time
E2504	: greater than 20 minutes but less than or equal to 40 minutes recording time
E2506	; greater than 40 minutes recording time
E2508	Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device
E2511	Speech generating software program, for personal computer or personal digital assistant
E2512	Accessory for speech generating device, mounting system

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Revision History

Revision Date	Summary of Changes
12/29/24	For Commercial Plan Policy, added the following requirement: "Select Health covers communication devices when used only for activities of daily living (ADL), ***and when desired results cannot be achieved through using natural communication methods***, when the following guidelines are met: …"

Select Health

Select Health

MEDICAL POLICY

EUSTACHIAN TUBE BALLOON CATHETER

Policy # 623
Implementation Date:2/15/18
Review Dates: 1/30/19, 2/17/20, 2/18/21, 1/20/22, 2/16/23, 2/6/24
Revision Dates: 11/8/18, 6/17/20, 2/16/24, 1/6/25

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Eustachian tube dilatory dysfunction (ETDD) is a ubiquitous healthcare problem, affecting children and adults, which can lead to severe consequences, including hearing loss, chronic otitis media, and cholesteatoma. Numerous studies have consistently failed to support the effectiveness of medical management using systemic decongestants or antihistamines and nasal topical decongestants or steroid sprays for the treatment of otitis media with effusion (OME).

BDET, Balloon Dilation of the Eustachian Tube, is a balloon catheter has a shaft consisting of dual lumen tubing with an actuator component to enable careful rotation and advancement of the device, a balled tip catheter to restrict advancement to the isthmus, an endoscopic marker for positioning, and a guide catheter with an angled tip and rigid shaft for access guidance to the ET.

A seven-item scoring questionnaire for eustachian tube dysfunction has been proposed and contains the following seven attributes: ear pressure, ear pain, sensation of clogging, ear symptoms with a cold or sinusitis, popping or crackling sensation, ringing in the ear, and muffled hearing. It had reasonable validity in a small sample (n = 75) to distinguish patients with and without eustachian tube dysfunction, using tympanometry as the gold standard.

A tympanometry procedure measures the movement, or compliance, of the eardrum as air pressure is increased or decreased in the ear canal. Tympanometry is not a test of hearing sensitivity. Results are plotted on a graph called a tympanogram and categorized as either a Type A, B, or C. Type A refers to eardrum movement within normal limits. Type B indicates little or no eardrum movement suggesting fluid in the middle ear space. A child with this type of tympanogram needs medical attention. Type C refers to a middle ear with negative pressure. Such a tympanogram may be caused by retraction of the eardrum or blockage of the Eustachian tube. A child with this type of tympanogram should be monitored and may need medical attention.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers balloon dilation of the Eustachian tube when <u>all</u> the following criteria are met:

1. Patient is 8 years of age or older
2. Tympanogram is Type C or B
3. ETDQ-7* if greater than 2.1 (take the score and divide by 7) after medical management

Select Health

Eustachian Tube Balloon Catheter, continued

4. Failure of medical management, which at a minimum consists of intranasal steroids of at least 8-week duration and decongestants (unless contraindicated)
5. Transnasal endoscopy demonstrates mucosal inflammation
6. An imaging study demonstrates the lack of internal carotid artery dehiscence into the eustachian lumen bilaterally

*The Eustachian Tube Dysfunction Questionnaire–7 Symptom

Over the past 1 month, how much has each of the following been a problem for you?	No Proble			Moderate Problem			Severe Problem
1. Pressure in the ears.	1	2	3	4	5	6	7
2. Pain in the ears?	1	2	3	4	5	6	7
3. A feeling that your ears are clogged or “under water”?	1	2	3	4	5	6	7
4. Ear symptoms when you have a cold or sinusitis?	1	2	3	4	5	6	7
5. Crackling or popping sounds in the ears?	1	2	3	4	5	6	7
6. Ringing in the ears.	1	2	3	4	5	6	7
7. A feeling that your hearing is muffled.	1	2	3	4	5	6	7

Select Health does not cover repeated balloon dilation of the Eustachian tube as it is considered experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Catalano and colleagues (2012) stated that Eustachian tube dysfunction is a common problem, and that trans-nasal endoscopic balloon dilation of the Eustachian tube (ET) is a new surgical technique. These researchers reviewed the evolution of this novel technique and studied the preliminary outcomes. Balloon catheter dilation of the 100 Eustachian tubes in 70 adults was performed at a tertiary medical center from January 2009 to January 2011. A 5-mm sinus balloon catheter was endoscopically placed trans-nasally into the proximal ET to dilate the cartilaginous ET. Cases were reviewed with respect to indications, outcomes, and complications. Of the 100 ETs, ear fullness and pressure were improved in 71% of patients studied for 26.3 weeks (± 3.6). Of 8 patients followed for a minimum of 34 months, 87% reported persistent improvement; 1 complication was reported. The authors concluded that endoscopic trans-nasal ET balloon dilation is a novel approach to treating ET dysfunction. Benefits can be durable up to 3 years. Moreover, they stated that this technique holds much promise and merits further investigation.

Jurkiewicz et al. (2013) noted that the development of minimally invasive procedures such as the balloon dilation Eustachian tuboplasty (BET) is an alternative to the grommet tympanum membrane. BET is applied in cases, where, after elimination of all factors influencing the ET and middle ear functioning, no

Eustachian Tube Balloon Catheter, continued

sufficient improvement is observed. These investigators presented the therapeutic benefits of the BET method in the treatment of ETD caused by disorders in the middle ear ventilation. The BET procedure was offered to 4 patients (3 men and 1 woman) after subjective, physical, otorhino-laryngological, and audiometric examinations, including pure tone audiometry, tympanometry, and pressure-swallow test. As the method was novel, pre-interventional CT angiography of the carotid arteries was performed in all patients. Any complications were noticed during and after the procedure (bleeding or damage of regional mucosa) in any patients. These clinical studies assessed the feasibility and safety of the BET during a short-term period—only a 6-week observation. The authors concluded that although patients revealed a significant improvement of ET score, longer long-term studies are needed to determine whether this method will demonstrate lasting benefits and safety in the treatment of chronic Eustachian tube dysfunction.

Moller et al. (2014) stated that balloon dilation of Eustachian tube is a novel method for managing chronic ventilatory dysfunction in patients with chronic otitis media, as an alternative to classic grommet insertion. Although few retrospective studies have been conducted, the method seems to be rapid, simple, and safe, with promising short-term results. These researchers presented the method and summarized the results of available studies. Optimization of patient selection is needed, and the authors discussed the development of better objective measurement methods as well as the need for randomized prospective studies, which are currently being conducted.

In a retrospective, cohort study, Gurtler et al. (2015) assessed Eustachian tube balloon dilation in the treatment of Eustachian tube dysfunction by objective analysis, especially tubomanometry. Patients undergoing Eustachian tube balloon dilation for treatment of Eustachian tube dysfunction were enrolled in this study. Main outcome measures included subjective improvement, otomicroscopic findings, tympanogram, air-bone gap in pure-tone audiogram, R-value in tubomanometry at 3 pressure measurements (30, 40, and 50 mbar) and the Eustachian Tube Score (ETS). Eustachian tube balloon dilation was performed in 21 patients. The ETS, including the R-values, tympanogram, and air-bone gap, all showed a statistically positive outcome ($p < 0.005$) after Eustachian tube balloon dilation. Subjective improvement was seen in 76%. Normal R-values were achieved in 57%. Retraction processes of the tympanic membrane improved in 18% of patients. Only 1 minor bleeding complication occurred. The authors concluded that Eustachian tube balloon dilation constitutes a safe and very promising treatment option for patients with Eustachian tube dysfunction based on early-outcome analysis; ETS and specifically tubomanometry appeared promising as assessment tools but await validation for use in the diagnostic workup and outcome analysis after ETBD. The pathophysiologic mechanism of Eustachian tube balloon dilation remains unclear. They stated that long-term analysis and stratification of patients are needed to better evaluate the definite value of Eustachian tube balloon dilation.

In a retrospective analysis, Maier et al. (2015) evaluated the role of balloon dilation of the Eustachian tube in a large cohort of children with Eustachian tube dysfunction who did not respond to other treatments and in whom a tumor could be ruled out as the cause. These researchers retrospectively analyzed the medical records of 66 children (mean age of 8.12 years, range of 4 to 14 years) who underwent balloon dilation of the Eustachian tube using the Bielefeld balloon catheter. There were no complications during surgery. Clinical symptoms improved in more than 80% of the patients. No patient reported a deterioration of symptoms. Of the participating parents, over 80% were very satisfied or satisfied with the treatment outcome. The authors concluded that balloon dilation is a rapid, simple, and safe method for treatment of both adults and children with Eustachian tube dysfunction who did not respond to other treatments. Moreover, they stated that further studies, ideally multi-center studies, are needed to optimize the definition of existing and potential new indications for this treatment approach, as well as to establish this treatment in the management of children with refractory chronic Eustachian tube dysfunction.

Randrup and Ovesen (2015) performed a systematic review and meta-analysis of the evidence on balloon Eustachian tuboplasty (BET) as a treatment modality for Eustachian tube dysfunction (ETD). These investigators followed the PRISMA guideline and registered with PROSPERO No. CRD42014009461. They searched 12 databases, including PubMed and Embase from January 1, 2010, to April 7, 2014, for studies of BET. Main 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. Study quality was assessed using the modified Delphi technique quality appraisal tool for case series studies. Risk of bias was assessed using the Cochrane Collaboration's tool for assessing risk of bias. A total of 9 case-series studies with 443 patients (642 tubes) were included;

Eustachian Tube Balloon Catheter, continued

population size ranged from n = 4 (7 tubes) to n = 210 (320 tubes). All studies were of poor quality and featured a high risk of bias. These researchers found reduction of patient symptoms in ETD questionnaire ($p < 0.001$), post-operative normalization of the tympanic membrane, conversion of type B or type C into type A tympanograms, reduced mucosal inflammation, increased number of positive Valsalva test and Swallowing tests, improvement in Eustachian tube score, reduction in Sino-Nasal Outcome Test (SNOT)-22 score ($p = 0.001$), and increased quality of life ($p = 0.001$). No serious adverse events were found. The authors concluded that the evidence of BET is poor and biased. No firm conclusions can be made to identify patients who will benefit from the procedure or to accurately predict surgical results. They stated that randomized controlled trials or case-control trials are needed.

Hwang et al. (2016) stated that Eustachian tube dysfunction is a disorder for which there are limited medical and surgical treatments. Recently, Eustachian tube balloon dilation has been proposed as a potential solution. These investigators performed a systematic literature review. Abstracts were selected for relevance, and pooled data analysis and qualitative analysis was conducted. A total of 9 prospective studies, describing 713 Eustachian tube balloon dilations in 474 patients (aged 18 to 86 years), were identified. Follow-up duration ranged from 1.5 to 18 months. Ability to perform a Valsalva maneuver improved from 20 to 177 out of 245 ears following Eustachian tube balloon dilation, and where data were reported in terms of patient numbers, from 15 to 189 out of 210 patients. Tympanograms were classified as type A in 7 out of 141 ears pre-operatively and in 86 out of 141 ears post-operatively. The authors concluded that prospective case series can confirm the safety of Eustachian tube balloon dilation. As a potential solution for chronic Eustachian tube dysfunction, further investigations are needed to establish a higher level of evidence of efficacy.

Williams et al. (2016) measured the success of Eustachian tube balloon dilation by comparing pre- and post-operative middle ear pressures using tympanometric testing. A retrospective chart review was performed on all patients who underwent balloon dilation of the Eustachian tube by authors from 2010 to 2014. Pre- and post-operative tympanograms were analyzed and categorized based on type (Type A, Type B, Type C). Success was defined by an improvement in tympanogram type: Type B or C to Type A, or Type B to type C. Pre- and post-operative tympanograms were further analyzed using middle ear pressure values. Follow-up ranged from 3 to 15 months. A total of 25 ears (18 patients) were included in the study. Overall, 36% of ears had improvement in tympanogram type, and 32% had normalization of tympanogram post-operatively. The Jerger tympanogram type improved significantly following the procedure ($p = 0.04$). Patients also had statistically significant improvement in measured middle ear pressure post-operatively ($p = 0.003$). The authors concluded that the natural history of Eustachian tube dysfunction is poorly understood, and evidence for current treatments are limited. Eustachian tube balloon dilation is a safe procedure and produces significant improvement in tympanogram values up to 15 months post-operatively. They stated that further refinement of patient selection and standardization of technique is needed to optimize the effect of this therapy; long-term follow-up data will clarify the persistence of the effect.

A large prospective trial by Poe et al. have demonstrated significant normalization of tympanogram and quality scores on an ETDQ-7(Eustachian Tube Dysfunction Questionnairee-7 Symptom).

Furthermore, an UpToDate review on “Eustachian tube dysfunction” (Poe and Hanna, 2017) states that: “The choice of management strategies for isolated Eustachian tube dysfunction remains controversial as randomized trial data are limited, study outcomes vary widely between studies, and much of what is known about the treatment of Eustachian tube dysfunction comes from animal rather than human studies … Balloon dilation is a novel tuboplasty method to increase the patency of the cartilaginous Eustachian tube. Similar to the concept of balloon sinuplasty for the treatment of chronic sinusitis, a balloon catheter is used to dilate the cartilaginous portion through a minimally invasive transnasal endoscopic approach. Initial cadaveric studies and clinical trials are promising. A 2015 systematic review including 9 case series (443 patients) concluded that balloon tuboplasty is a safe procedure but is still lacking good evidence of benefit.”

Billing/Coding Information

CPT CODES

69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral

Eustachian Tube Balloon Catheter, continued

69706 Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral

69799 Unlisted procedure, middle ear

HCPCS CODES

C9745 Nasal endoscopy, surgical; balloon dilation of eustachian tube

Key References

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2. Gurtler N, Husner A, Flurin H. Balloon dilation of the Eustachian tube: Early outcome analysis. Otol Neurotol. 2015;36(3):437-443.
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4. Jurkiewicz D, Bień D, Szczygielski K, Kantor I. Clinical evaluation of balloon dilation Eustachian tuboplasty in the Eustachian tube dysfunction. Eur Arch Otorhinolaryngol. 2013;270(3):1157-1160.
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7. Poe D, Hanna BMN. Eustachian tube dysfunction. UpToDate Inc., Waltham, MA. Last reviewed May 2017.
8. Poe, D., V. Anand, M. Dean, W. H. Roberts, J. P. Stolovitzky, K. Hoffmann, ... J. P. Leopold (2017). "Balloon dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial." Laryngoscope.
9. Randrup TS, Ovesen T. Balloon eustachian tuboplasty: A systematic review. Otolaryngol Head Neck Surg. 2015;152(3):383-392.
10. Saniasiaya J, Kulasegarah J, Narayanan P. Outcome of Eustachian Tube Balloon Dilation in Children: A Systematic Review. *Ann Otol Rhinol Laryngol.* 2022 Jul;131(7):797-804. doi: 10.1177/00034894211041340.
11. Toivonen J, Kawai K, Gurberg J, Poe D. Balloon Dilation for Obstructive Eustachian Tube Dysfunction in Children. *Otol Neurotol.* 2021 Apr 1;42(4):566-572. doi: 10.1097/MAO.0000000000003009. PMID: 33351568.
12. U.S. Food and Drug Administration. FDA Approval: Acclarent Aera Eustachian Tube Dilation System. December 13, 2023.
13. Williams B, Taylor BA, Clifton N, Bance M. Balloon dilation of the Eustachian tube: A tympanometric outcomes analysis. J Otolaryngol Head Neck Surg. 2016; 45:13.

Revision History

Revision Date	Summary of Changes
2/6/24	For Commercial Plan Policy, changed the minimum age eligible for this treatment in criterion #1 from 18 years to 7 years: "Patient is 7 years of age or older."
1/6/25	For Commercial Policy, changed the minimum age eligible for this treatment in criterion #1 from 7 years to 8 years to align with the FDA approval for these procedures.

Select Health

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MEDICAL POLICY

HEARING AIDS

Policy # 651
Implementation Date:3/18/22
Review Dates: 6/10/23, 7/16/24
Revision Dates: 9/9/22, 10/28/22, 4/14/23, 1/1/24, 1/28/25

Related Medical Policies:
#302 Cochlear Implantation
#524 Temporal Bone Osseointegrated Devices - Bone Anchored Hearing Implants

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Air conduction hearing aids will likely be the most suitable option for most people with hearing loss. They amplify sound by delivering the output of the hearing aid into the ear canal. Different styles can be useful for different levels of hearing loss; they also have varying features. Air conduction hearing aids are used to help with sensorineural hearing loss, and with some conduction hearing loss, too.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Utah Based Plans

Standard hearing aids are not covered, though group exceptions may exist for Large Employer or Self-Funded plans. See the group's Benefit Clarification for benefit exceptions. For groups with hearing aid benefits, benefits are specified on the Member Payment Summary (MPS) or in the group's Benefit Clarification.

Select Health covers air conduction hearing aids for Nevada Small Employer/Individual Plans, Idaho Commercial Plans, and Colorado based plans.

Select Health covers air conduction hearing aids when the following criteria are met:

Nevada Small Employer and Individual Plans

Hearing aids are covered when required for the correction of a hearing impairment. The device, fittings, and testing are covered when prescribed by a provider.

1. Hearing aids, and their fitting and testing, that are prescribed by a Provider are covered when required to correct a hearing impairment (as outlined in #2).

2. Patient has had a recent hearing testing (within last 6 months) performed by a licensed audiologist with test results demonstrating:

   a. Sensorineural or mixed hearing loss with:

Select Health

Hearing Aids, continued

i. Hearing thresholds 40 decibels (dB) or greater at one of the following frequencies: 500, 1000, 2000, 3000, 4000 hertz (Hz); or

ii. Hearing thresholds 26 dB or greater at three of the following frequencies: 500, 1000, 2000, 3000, 4000 Hz; or

iii. Speech recognition less than 94 percent.

See medical policy #302 for Cochlear Implantation and medical policy #524 for Temporal Bone Osseointegrated Devices.

Idaho Commercial Plans

Idaho Small Employer and Individual Plans

Services for cochlear implants, hearing aids, and osseointegrated auditory (bone conduction) devices are not covered, except when an enrolled Dependent child has a congenital anomaly or acquired hearing loss* and the child may develop cognitive or speech development deficits without intervention.

*Sensorineural hearing loss with:
i. Hearing thresholds 40 decibels (dB) or greater at one of the following frequencies: 500, 1000, 2000, 3000, 4000 hertz (Hz); or

ii. Hearing thresholds 26 dB or greater at three of the following frequencies: 500, 1000, 2000, 3000, 4000 Hz; or

iii. Speech recognition less than 94 percent.

See medical policy #302 for Cochlear Implantation and medical policy #524 for Temporal Bone Osseointegrated Devices.

Idaho Large Employer Plans

Services for cochlear implants, hearing aids, and osseointegrated auditory (bone conduction) devices are not covered, except:

a. When a Dependent child has a congenital anomaly or acquired hearing loss** and may develop cognitive or speech development deficits without intervention; and
b. Cochlear implants and osseointegrated auditory devices for adult Members in accordance with SelectHealth medical policy. All other hearing aids are not covered for adult Members.

**Sensorineural hearing loss with:
i. Hearing thresholds 40 decibels (dB) or greater at one of the following frequencies: 500, 1000, 2000, 3000, 4000 hertz (Hz); or

ii. Hearing thresholds 26 dB or greater at three of the following frequencies: 500, 1000, 2000, 3000, 4000 Hz; or

iii. Speech recognition less than 94 percent.

Colorado Based Plans [Effective January 1, 2024]

Hearing aids are covered for members ages 18 and under, in accordance with the following requirements:

a. Hearing loss has been verified by a physician licensed pursuant to article 240 of title 12* and medically appropriate to meet the needs of the child according to accepted professional standards. Coverage must include the purchase of the following:

i) Initial hearing aids and replacement hearing aids not more frequently than every five years;

ii) A new hearing aid when alterations to the existing hearing aid cannot adequately meet the

Hearing Aids, continued

needs of the child;

iii) Services and supplies including, but not limited to, the initial assessment, fitting, adjustments, and auditory training that is provided according to accepted professional standards.

*(Based on Colorado legislative rule: § 10-16-104(19), CRS)

See medical policy #302 for Cochlear Implantation and medical policy #524 for Temporal Bone Osseointegrated Devices.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Billing/Coding Information

HCPCS CODES

V5010	Assessment for hearing aid
V5011	Fitting/orientation/checking of hearing aid
V5014	Repair/modification of a hearing aid
V5020	Conformity evaluation
V5030	Hearing aid, monaural, body worn, air conduction
V5050	Hearing aid, monaural, in the ear
V5060	Hearing aid, monaural, behind the ear
V5070	Glasses, air conduction
V5100	Hearing aid, bilateral, body worn
V5110	Dispensing fee, bilateral
V5120	Binaural, body
V5130	Binaural, in the ear
V5140	Binaural, behind the ear
V5150	Binaural, glasses
V5160	Dispensing fee, binaural
V5241	Dispensing fee, monaural hearing aid, any type
V5242	Hearing aid, analog, monaural, CIC (completely in ear canal)
V5243	Hearing aid, analog, monaural, ITC (in the canal)
V5244	Hearing aid, digitally programmable analog, monaural, CIC
V5245	Hearing aid, digitally programmable, analog, monaural, ITC
V5246	Hearing aid, digitally programmable, analog, monaural, ITE (in the ear)
V5247	Hearing aid, digitally programmable, analog, monaural, BTE (behind the ear)
V5248	Hearing aid, analog, binaural, CIC
V5249	Hearing aid, analog, binaural, ITC
V5250	Hearing aid, digitally programmable analog, binaural, CIC

Select Health

Hearing Aids, continued

V5251	Hearing aid, digitally programmable analog, binaural, ITC
V5252	Hearing aid, digitally programmable, binaural, ITE
V5253	Hearing aid, digitally programmable, binaural, BTE
V5254	Hearing aid, digital, monaural, CIC
V5255	Hearing aid, digital, monaural, ITC
V5256	Hearing aid, digital, monaural, ITE
V5257	Hearing aid, digital, monaural, BTE
V5258	Hearing aid, digital, binaural, CIC
V5259	Hearing aid, digital, binaural, ITC
V5260	Hearing aid, digital, binaural, ITE
V5261	Hearing aid, digital, binaural, BTE
V5262	Hearing aid, disposable, any type, monaural
V5263	Hearing aid, disposable, any type, binaural

ICD-10 CODES

H90.A21	Sensorineural hearing loss, unilateral, right ear, with restricted hearing on the contralateral side
H90.A22	Sensorineural hearing loss, unilateral, left ear, with restricted hearing on the contralateral side
H90.A31	Mixed conductive and sensorineural hearing loss, unilateral, right ear with restricted hearing on the contralateral side
H90.A32	Mixed conductive and sensorineural hearing loss, unilateral, left ear with restricted hearing on the contralateral side

Key References

1. https://thehearinghouse.com/blog/what-is-an-air-conduction-hearing-aid

Revision History

Revision Date	Summary of Changes
4/14/23	For Commercial Plan Policy, reformatted overall criteria to show differences in coverage criteria according to plan type/area.
1/1/24	For Commercial Plan Policy, added coverage criteria for Colorado Based Plans.
1/28/25	For Commercial Plan Policy, added language which clarifies both non-coverage and coverage of hearing aids for Utah Based Plans.

Select Health

Select Health

MEDICAL POLICY

LATERA

Policy # 633
Implementation Date: 6/24/19
Review Dates: 7/31/20, 8/19/21, 7/21/22, 8/22/23, 7/30/24
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

The Latera implant is designed to support the lateral nasal cartilage. It is used to treat nasal valve collapse, which leads to nasal obstruction and difficulty breathing. It is endoscopically placed inside the nasal wall in a minimally invasive procedure by otolaryngologists or plastic surgeons using the manufacturer provided accessory delivery device.

The implant is intended to support the nasal cartilage and potentially reduce the symptoms of airway obstruction. It is composed of poly (l-lactic acid) (PLLA) and poly (dlactic acid) (PDLA) copolymer materials and is designed to be absorbed by the body within approximately 18 months after implantation. The implant and the delivery apparatus are both intended for single-patient use.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does not cover the Latera Absorbable Nasal Implant as there is insufficient published evidence to assess the safety and/or impact of the Latera Absorbable Nasal Implant on health outcomes or patient management. This device meets the plan's definition of experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Latera, continued

Summary of Medical Information
Two additional relevant studies have recently been published. In the first, the Latera implant was compared to a sham group in a prospective single-blinded, randomized controlled trial. Three-month outcomes showed significant improvement in nasal airway obstruction, as measured by the NOSE scale, in patients treated with the Latera implant, compared to those in the sham group. However, while 82% of those in the Latera group responded to the intervention, 54% in the sham group also responded. This study also only followed outcomes for 3 months, so long-term data on this resorbable implant is not provided in this study.

In the second publication, a prospective, nonrandomized study evaluated outcomes 12 months after placement of the Latera implant. This study included 166 patients who underwent placement of the Latera implant alone or placement of the Latera implant with inferior turbinate reduction. Patients demonstrated significant reduction in NOSE scores in both groups at 12 months after the procedure. Thirty-one patients reported a total of 41 procedure- or implant-related adverse events. 17 of 319 implants (5.3%) were retrieved, and 6.5% reported a cosmetic change that was worse than baseline. Overall, these findings suggested an adequate safety profile for the implant.

In conclusion, two studies in the past year provide additional evidence to the safety profile and potential short- to medium-term benefit of the Latera implant. The greatest advantage for the implant would be the ability to place the implant in appropriate patients in the office setting, thereby avoiding the risks and expenses of the operating room. However, long-term efficacy (> 2 years) has not been established for this resorbable implant.

Billing/Coding Information

Not covered: Experimental/investigational/Unproven for this indication

CPT Codes

30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)
30469	Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling

HCPSC CODES

C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)

Key References

1. Bikhazi, N., Ow, R. A., O'Malley, E. M., et al. Long-Term Follow-up from the Treatment and Crossover Arms of a Randomized Controlled Trial of an Absorbable Nasal Implant for Dynamic Nasal Valve Collapse. *Facial Plast Surg*. 2022 Oct;38(5):495-503.
2. Hayes, Inc. (2018 March 16). Latera Absorbable Nasal Implant (Spirox) for Nasal Vestibular Lateral Wall Stenosis. doi: 10.1055/s-0037-1598655
3. Kim, D. H., Hyun, H. L., Kim, S.H., & Hwang, S.H. Effectiveness of using a bioabsorbable implant (Latera) to treat nasal valve collapse in patients with nasal obstruction: systemic review and meta-analysis. *Int Forum Allergy Rhinol*. 2020 Jun;10(6):719-725.
4. Sidle DM, Stolovitzky P, Ow RA, et al. Twelve-month outcomes of a bioabsorbable implant for in-office treatment of dynamic nasal valve collapse. *Laryngoscope*. 2020 May; 130(5): 1132-1137.
5. Stolovitzky P, Senior B, Ow RA, et al. Assessment of bioabsorbable implant treatment for nasal valve collapse compared to a sham group: a randomized control trial. *Int Forum Allergy Rhinol*. 2019 Aug; 9(8): 850-856.

Latera, continued

refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

Select Health

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MEDICAL POLICY

LOW-PRESSURE PULSATILE THERAPY IN THE MANAGEMENT OF MÉNIÈRE'S DISEASE

Policy # 437
Implementation Date: 3/22/10
Review Dates: 8/16/11, 8/16/12, 7/18/13, 8/28/14, 8/20/15, 8/25/16, 8/17/17, 7/25/18, 6/13/19, 6/18/20, 6/17/21, 5/19/22, 6/10/23. 7/16/24
Revision Dates:

Disclaimer:
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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Ménière's disease is a syndrome manifesting episodic vertigo, tinnitus, and hearing loss with no known cause. It is a condition thought to arise from abnormal fluid and ion changes in the inner ear. It is unclear why excess fluid builds up in the endolymphatic spaces of the inner ear. Several theories have been proposed, but all remain unproven.

The course of Ménière's disease varies among individuals. As the etiology is not clearly defined, the goals of treatment are to reduce the frequency and severity of vertigo attacks, reduce or eliminate hearing loss and tinnitus associated with attacks, alleviate chronic symptoms (tinnitus and balance issues), minimize disability and prevent disease progression (particularly hearing loss and imbalance). However, determining the optimal treatment for Ménière's disease is limited by the lack of randomized, controlled trials, and drug therapy has been associated with a significant placebo effect. Additionally, the relapsing remitting nature of the disorder has made evaluation of various treatments difficult.

Therapies can be divided into non-interventional and interventional therapies. Non-interventional therapies are further divided into lifestyle adjustments, medical management with antihistamines, benzodiazepines and antiemetics, and vestibular rehabilitation. Interventional therapies are divided into destructive and nondestructive procedures. Interventional procedures include surgical labyrinthectomy, vestibular nerve resection, and more commonly Endolymphatic sac procedures and sacculotomy

Additionally, pressure chamber therapy has been applied with some success for acute attacks of vertigo associated with Meniere's disease, but it was cumbersome, expensive, and not widely available. From this experience, two devices have been developed, the Meniett (Medtronic ENT Inc, Jacksonville, FL) device and the P100-Meniere device (Enttex GmbH, Hanover, Germany).

The Meniett device delivers a computer-controlled, complex algorithm of low-pressure pulses that are transmitted to the middle ear space and act on the round window membrane. Whereas, the P100-Ménière is a handheld manual device about the size of a cell phone. A specially designed valve prevents the user from producing excessive pressure so that a safe pressure level is always applied. A ventilation tube (or grommet) is usually recommended to obtain the correct and effective treatment with both devices. Neither device improves hearing; the P100 is not currently available in the US.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health

Low-Pressure Pulsatile Therapy in the Management of Ménière's Disease, continued

Select Health covers low-pressure pulsatile therapy in the management of Ménière's disease using the Meniett device in *limited circumstances*. Current evidence is supportive of the safety and efficacy for this device.

Criteria for coverage:

- The device has been recommended by a board-certified otolaryngologist
- Despite maximal medical therapy, the member continues to experience debilitating vertigo

***Member must successfully complete a 2-month trial of therapy before Select Health will approve purchase of the device.*

Select Health does NOT cover low-pressure pulsatile therapy in the management of Ménière's disease using ANY other device. This meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A 2010 Medical Technology Assessment of the published literature identified 2 health technology assessments related to the use of low-pressure pulse generators for the treatment of Ménière's disease. Both systematic reviews are dated having been completed in 2005 and 2006. Though dated, both assessments were supportive of the technology, with the Hayes review providing a 'C' rating due to the assessment that larger well-designed studies needed to be completed to support the findings available at the time, and the Australian technology assessment similarly recommended broader studies as the current evidence was supportive of the technology.

Since 2006, several additional studies have been completed, though, for the most part these studies suffer methodological flaws in that they are not randomized, are single arm case series, or retrospective analyses. The size of the studies also remains an issue as the largest of the studies since 2008 involved only 53 patients and was also a retrospective analysis. Of interest, some studies have attempted to address the durability of the therapy related to its effect on vertigo. Though an unblinded follow-up study by Gates et al. (2006) followed 61 patients for 2 years, and noted vertigo levels gradually improved for most, but not all participants, with 67% (Intention to Treat analysis) of patients continuing with therapy, they either greatly improved or remitted their symptoms over the 2 years, though 24% of patients dropped out due to lack of efficacy. Huang et al. identified similar findings in their case series of 18 patients followed over 28 months.

In summary, current evidence is supportive of the safety and efficacy of low-pressure pulse generators in the treatment of Ménière's disease. However, the data lacks the appropriate methodology and size to draw any definitive conclusions regarding this manner of treatment. Studies are too limited, as related to the P-100 device, to draw any conclusions regarding its effectiveness or safety.

Select Health

Low-Pressure Pulsatile Therapy in the Management of Ménière's Disease, continued

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

No specific codes identified

HCPCS CODES

E2120 Pulse generator system for tympanic treatment of inner ear endolymphatic fluid

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Select Health

Low-Pressure Pulsatile Therapy in the Management of Ménière's Disease, continued

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MEDICAL POLICY

MICROTIA REPAIR

Policy # 657
Implementation Date: 1/11/23
Review Dates: 12/21/23, 12/19/24
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Microtia is the congenital malformation spectrum of the ear, ranging from smaller than the other side to completely absent. Classification of grade is based on the amount of missing external ear components. Hearing restoration is dependent on an external ear to funnel sound, auditory canal, and internal ear components including the bones and vestibular parts.

Hearing loss in microtia is ~15% sensorineural and ~85% conductive. There can also be mixed (sensorineural and conductive). It is associated with:

- Ossicles: disrupted or absent
- External Auditory Canal: stenosis (linked to mixed hearing loss and risk of cholesteatoma) or atresia (linked to a conductive hearing loss) 5
- Loss of tympanic cavity

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Idaho Plans:

Services to correct congenital anomalies in a dependent child are covered. This is not dependent of restoring function if the member is a dependent. If the member is on their own Idaho Individual plan, a functional component is also necessary.

Utah/Nevada Plans:

SelectHealth covers microtia repair when the following criteria are met:

1) A functional hearing impairment is required.
   a. Patient has had a recent hearing testing (within last 6 months) performed by a licensed audiologist with test results demonstrating:

      i. Sensorineural or mixed hearing loss with:
      ii. Hearing thresholds 40 decibels (dB) or greater at one of the following frequencies: 500, 1000, 2000, 3000, 4000 hertz (Hz); **or**

Select Health

Microtia Repair, continued

iii. Hearing thresholds 26 dB or greater at three of the following frequencies: 500, 1000, 2000, 3000, 4000 Hz; **or**

iv. Speech recognition less than 94 percent; and

2) A CT scan or MRI of the temporal bone is required to determine a Jahrsdoerfer score; must have a Jahrsdoerfer score of ≥ 7; and

3) Must be Microtia Grade 2−4** (supported by pictures); and

4) A recommendation from an otologist for both microtia and functional repair.

*Jahrsdoerfer Scale

Parameter	Points
Stapes present	2
Oval window open	1
Middle ear space	1
Facial nerve normal	1
Malleus-incus complex present	1
Mastoid well pneumatized	1
Incus-stapes connection	1
Round window normal	1
Appearance of external ear	1
Total available points	**10**

Rating	Type of candidate
10	Excellent
9	Very Good
8	Good
7	Fair
6	Poor
≤ 5	Very Poor

**Microtia Grades

Grade 1: The ear is smaller than normal, but the key features of the normal ear are present, though they may have minor alterations in shape or form.

Grade 2: Some of the features of the ear are missing, though usually much of the lower two-thirds of the ear is still present. Grade 2 microtia is sometimes called “conchal type microtia.” The ear canal may be present, but frequently is very narrow (canal stenosis).

Grade 3: This is the most common type of microtia, in which the only feature remaining is a small peanut-shaped remnant ear lobe. Grade 3 microtia is sometimes called “lobular type microtia.” The ear canal is usually completely absent (aural atresia).

Grade 4: Complete absence of the external ear without any remnant. This is called “anotia” and is rarely seen.

(Note: The grade of microtia applies only to the external ear and not the internal structures.)

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Select Health

Microtia Repair, continued

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Billing/Coding Information

Covered for the indications listed above when criteria are met

CPT CODES

14060	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10 sq cm or less
20912	Cartilage graft; costochondral
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21230	Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft)
21235	Graft; ear cartilage, autogenous, to nose or ear (includes obtaining graft)
69320	Reconstruction external auditory canal for congenital atresia, single stage

Not Covered for the indications listed above

69300	Otoplasty, protruding ear, with or without size reduction

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Select Health

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MEDICAL POLICY

PALATAL IMPLANTS (PILLAR) FOR OBSTRUCTIVE SLEEP APNEA

Policy # 378

Implementation Date:8/8/07

Review Dates: 6/19/08, 8/13/09, 8/19/10, 9/15/11, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/15/18, 10/15/19, 10/15/20, 11/18/21, 1/17/23, 10/4/23, 9/27/24

Revision Dates:

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Obstructive sleep apnea (OSA) is a common medical condition that is under-recognized and undiagnosed in many adults. It is estimated that 26% of adults are at high risk of OSA. Snoring and daytime sleepiness are common manifestations of OSA.

Numerous measures that may benefit and should be recommended to all patients with OSA include weight control, avoidance of alcohol, and safety awareness. Treatments available for OSA include continuous positive airway pressure (CPAP), bi-level positive airway pressure (BiPAP), as well as surgical techniques including uvulopalatopharyngoplasty (UPPP), genioglossus advancement, hypoglossal resuspension, maxillary-mandibular advancement, and radiofrequency ablation (RFA).

CPAP/BiPAP is recommended as first-line therapy for most patients with OSA as its efficacy has been proven to be superior to any other therapy. However, studies have demonstrated non-compliance rates of 20%−40% with this therapy for various reasons. An alternative non-surgical therapy is the use of molded oral appliances inserted into the mouth at night to keep the jaw forward and improve upper airway patency during sleep in patients with OSA. Some of these devices protrude the mandible forward and others hold the tongue in a more anterior position, away from the posterior pharyngeal wall.

When more conservative therapies fail or are not tolerated, surgery is sometimes performed even in the absence of a strictly defined anatomic lesion. Uvulopalatopharyngoplasty (UPPP) is one of the most performed surgical procedures; it involves resection of the uvula as well as redundant retrolingual soft tissue (and palatine tonsillar tissue when present). Other surgical techniques include genioglossus advancement, hypoglossal resuspension, maxillary-mandibular advancement, and radiofrequency ablation (RFA), alone, or in combination. Radiofrequency ablation is the least invasive surgical technique available for OSA.

The Pillar Procedure (Restore Medical Inc.) is a new minimally invasive procedure for treating mild-to-moderate OSA. The system consists of an implant and a delivery tool. The implants are designed to stiffen the tissue of the soft palate, reducing the dynamic flutter which causes snoring. Rather than surgically removing tissue, the Pillar Procedure is designed to stiffen the soft palate. Once in place, the implants add structural support in the muscular layer of the soft palate and induce a natural tissue response that secures them within the palate. Once inserted, fibrosis created around the implants creates additional stiffening and structural support of the soft palate.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover palatal implants (Pillar) for snoring or obstructive sleep apnea. This therapy meets the plan's definition of experimental/investigational.

Select Health

Palatal Implants (Pillar®) for Obstructive Sleep Apnea, continued

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Current literature suggests some potential benefit of palatal implant therapy as noted by Mundy et al. in their 2007 Systematic Review. However, as is noted in that review: "There are currently no cost-effectiveness data available on the use of the Pillar palatal implant system for the treatment of patients with obstructive sleep apnea."

The number of studies available to answer questions of the effectiveness, durability of effect, and complications related to the therapy on treating obstructive sleep apnea are limited, with only 6 studies being deemed of adequate methodological quality to be considered. Of these studies, none employed a prospective randomized method, nor were any blinded or employed sham comparison, though, several used a prospective nonrandomized methodology. Additionally, in Friedman et al. inclusion criteria required failure of a previous UPPP. Though it might be argued that this minimizes the potential for impact of palatal implantation on OSA, the fact that this therapy would typically be employed prior to UPPP surgery as it is less invasive, and likely less expensive, does not allow key questions as to its effectiveness prior to UPPP to be answered. This study showed an objective cure rate of 21.7%, which is far below the published success rates for CPAP therapy.

Except for the retrospective review completed by Friedman.et al., which looked at 125 patients, and Walker et al., which looked at 53 patients in a prospective nonrandomized, non-blinded study, none of the other studies contained more than 25 patients. This too, limits any conclusions drawn from the studies.

There is a definite lack of studies evaluating the long-term effectiveness of this therapy in the treatment of this chronic condition. Nordgard et al. looked at the impact on AHI and the Epworth Sleepiness Score and concluded a statistically significant improvement was achieved out to 1 year. None of the others exceed a duration of 90 days. Notable in the Norgard study, however, is the small size (n = 25), < 50% of patients achieved an AHI <10 with even fewer achieving levels < 5 and only non-obese (BMI ≤ 30) were evaluated. Given that OSA occurs most frequently in the obese population and this study failed to include patients with AHIs > 30, this further limits this study's conclusions.

Further investigation is required to establish which patients (mild or moderate obstructive sleep apnea) would benefit the most from this procedure, and whether greater success would be achieved in conjunction with more invasive surgical procedures. In addition, long-term follow-up of obstructive sleep apnea patients may indicate whether the observed reductions in AHI delivered a clinical benefit to these patients.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

42299	Unlisted procedure, palate, uvula

Select Health

Palatal Implants (Pillar®) for Obstructive Sleep Apnea, continued

HCPCS CODES

C9727 Insertion of implants into the soft palate; minimum of three implants

Key References

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Select Health

Palatal Implants (Pillar®) for Obstructive Sleep Apnea, continued

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MEDICAL POLICY

PHRENIC NERVE STIMULATION (PNS)

Policy # 653
Implementation Date:6/1/22
Review Dates: 10/4/23, 9/27/24
Revision Dates:12/2/24

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Phrenic nerve stimulation (PNS), also known as diaphragm pacing, is the electrical stimulation of the phrenic nerve using a surgically implanted device. This device contracts the diaphragm rhythmically, improving breathing function in patients with central sleep apnea. The Remedē System (Respicardia Inc.) is a fully implanted neurostimulator intended for treatment of moderate-to-severe CSA in adults (FDA, 2017a). The system delivers unilateral transvenous PNS to cause diaphragmatic contraction that mimics a normal breathing pattern. The contraction of the diaphragm creates a negative intrathoracic pressure like that generated by normal breathing, resulting in a decrease in central apnea during sleep. The system includes a battery-powered pulse generator that is implanted under the skin in the upper chest and thin wire leads that are threaded through veins near the phrenic nerve (FDA, 2017b). The system is programmed using an external system programmer and programming wand.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health considers phrenic nerve stimulation (e.g., the Remede System) medically necessary for the treatment of adults who meet both of the following criteria:

1. Moderate-to-severe central sleep apnea*; must be diagnosed from an overnight study in a lab
2. Failed adaptive support ventilation (ASV) (e.g., BiPAP or CPAP), or it is not medically appropriate

***Apnea Hypopnea Index (AHI)**
The AHI is the number of apneas or hypopneas recorded during the study per hour of sleep. It is generally expressed as the number of events per hour. Based on the AHI, the severity of central sleep apnea is classified as follows:

- None/Minimal: AHI < 5 per hour
- Mild: AHI ≥ 5, but < 15 per hour
- Moderate: AHI ≥ 15, but < 30 per hour
- Severe: AHI ≥ 30 per hour

Select Health

Phrenic Nerve Stimulation (PNS), continued

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The implantation procedure is comparable with that of a conventional cardiac pacemaker; it is generally performed under local anesthesia (FDA, 2017b). An introducer sheath is inserted into the subclavian vein, and a catheter is advanced to the pericardiophrenic vein or the right brachiocephalic vein; the neurostimulation lead is advanced to 1 of these locations. The neurostimulation lead is designed so that the stimulation electrodes rest directly against the vessel wall to maximize the stimulation current applied to the adjacent phrenic nerve. A sensing lead that detects the patient's respirations is placed in a thoracic vein such as the azygos vein. Both leads are attached to the battery-operated pulse generator, which is implanted in a subcutaneous pocket in the pectoral region (preferably on the right side of the chest to accommodate present or future cardiac device placement).

Programming of the device is performed with use of an external programmer, which provides readouts of monitoring and allows for programming of patient-specific stimulation therapy (FDA, 2017b). The system automatically delivers PNS during the scheduled time at night only when the patient is at rest and in a sleeping position, which is detected by a position and motion sensor within the device. Respiration is sensed by thoracic impedance and is used both for patient monitoring and for automatic titration of therapy at night based on changes in the respiratory pattern. Therapy is initiated approximately 1 month after implantation to allow for lead healing. Stimulation levels are set at the time of therapy initiation and can be modified with the use of a proprietary algorithm.

Billing/Coding Information

Covered for the indications outlined above when criteria are met

CPT CODES

0424T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)
0425T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; sensing lead only
0426T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; stimulation lead only
0427T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; pulse generator only
0428T	Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only

Select Health

Phrenic Nerve Stimulation (PNS), continued

0429T	Removal of neurostimulator system for treatment of central sleep apnea; sensing lead only
0430T	Removal of neurostimulator system for treatment of central sleep apnea; stimulation lead only
0431T	Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only
0432T	Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only
0433T	Repositioning of neurostimulator system for treatment of central sleep apnea; sensing lead only
0434T	Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea
0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session
0436T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; during sleep study
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed
33277	Insertion of phrenic nerve stimulator transvenous sensing lead (List separately in addition to code for primary procedure)
33278	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)
33279	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only
33280	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only
33281	Repositioning of phrenic nerve stimulator transvenous lead(s)
33287	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator
33288	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s)

Key References

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Select Health

Phrenic Nerve Stimulation (PNS), continued

Revision History

Revision Date	Summary of Changes
12/2/24	For Commercial Plan Policy, modified criterion #1 as follows: "Moderate-to-severe central sleep apnea; ***must be diagnosed from an overnight study in a lab***"; and included table for scoring central sleep apnea.

Select Health

Select Health

MEDICAL POLICY

PROPEL AND SINUVA IMPLANTS FOR THE TREATMENT OF CHRONIC RHINOSINUSITIS

Policy # 545

Implementation Date: 1/6/14

Review Dates: 10/20/16, 10/19/17, 10/9/18, 10/8/19, 9/29/20, 11/24/21, 9/15/22, 10/17/23, 10/17/24

Revision Dates: 7/28/15, 2/28/20

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Sinusitis is an inflammation of the nasal cavity and paranasal sinuses that is estimated to affect 13% to 15% of adults in the United States, resulting in more than 30 million annual diagnoses. The American Academy of Otolaryngology−Head and Neck Surgery defines chronic rhinosinusitis (CRS) as persistent for > 12 weeks, with or without acute exacerbations.

Endoscopic sinus surgery (ESS) is the standard of care for CRS that is refractory to medical management. The goal of the procedure is to expand the openings of the sinuses, and remove diseased tissue and bone, while preserving the mucosa. However, ESS is not without issues, including postoperative inflammation, polyposis, adhesions, and displacement of the medial turbinate from the medial position that may require additional intervention. In addition, revision surgery is estimated to occur in approximately 4% of patients after 1 year, 12% after 3 years, and 20% within 5 years. Steroid therapy is considered a mainstay for control of inflammation. However, topical steroid treatments have limited systemic absorption. They also have variable penetrance of the sinus recess, do not reach the frontal sinus very well, and have relatively short duration of up to a few hours. Furthermore, long-term use of systemic oral steroids is associated with avascular necrosis of the femoral head, osteoporosis, adrenal suppression, hyperglycemia, dyslipidemia, psychiatric disturbances, cardiovascular disease, and immunosuppression.

The Propel sinus device is a self-expanding bioabsorbable stent formed of a synthetic polymer (L-lactide-co-glycolide) in a lattice pattern. Mometasone furoate (MF) is a topical synthetic corticosteroid with activity against nasal symptoms. The Propel stent is coated with 370 micrograms (µg) of MF that is released locally to the mucosa over a 30-day period. The Propel device can be placed immediately post-ESS or within 1 week of ESS for the treatment of CRS in patients undergoing ethmoidectomy or frontal sinusotomy.

The Sinuva Sinus Implant (Intersect ENT, Inc.) is composed of bioresorbable polymers that soften over time. The Sinuva implant contains 1350 micrograms (µg) of mometasone furoate (MF), an anti-inflammatory corticosteroid. The implant is loaded into a proprietary delivery system and placed in the ethmoid sinus under endoscopic visualization by an otolaryngologist. The implant expands in the sinus where it remains for the elution of MF over 90 days. The Sinuva implant may be removed on day 90, or sooner, at the physician's discretion.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health

Propel and Sinuva Implants for the Treatment of Chronic Rhinosinusitis, continued

Select Health may cover either the Propel implant during the surgical treatment of chronic rhinosinusitis or the Sinuva implant post-surgery once per rolling 12 months (see the below criteria).

A. For members who meet ALL the following criteria (1–6):

1. Age ≥ 18 years;
2. Chronic rhinosinusitis with severe polyposis (bilateral polyposis with multiple polyps in each nasal vault);
3. Previous history of sinus surgery;
4. No sensitivity to mometasone furoate;
5. Failed 3 months of maximal medical therapy (topical and oral steroids);
6. Propel will be used ethmoid, maxillary, or frontal intraoperatively, and Sinuva will be used outpatient for ethmoid or frontal.

For aspirin sensitivity, patients with aspirin sensitivity (Samter's Triad: nasal polyps, aspirin sensitivity, and asthma) desensitization for asthma is the preferred treatment for nasal polyposis. When medical therapy has failed, these steroid stents may be utilized with or without surgery.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

In a prospective, multi-center, single-cohort trial (Advance Trial), Forwith et al. (2011), evaluated the safety and effectiveness of a bioabsorbable, steroid-eluting implant (the Propel device) used following ESS in patients with CRS (n = 50). The study allowed bilateral or unilateral steroid-eluting implant placement. Oral and topical steroids were withheld for 60 days post-operatively. Endoscopic follow-up was performed to 60 days. Patient-reported outcomes (SNOT-22 Questionnaire, Rhinosinusitis Disability Index) were collected to 6 months. Efficacy was assessed by grading inflammation, polyp formation, adhesions, and middle turbinate position. Safety assessment included ocular examinations at baseline and 30 days. Implants were successfully placed in all 90 sinuses. Mean inflammation scores were minimal at all time-points. At 1-month, the prevalence of polypoid edema was 10.0%, significant adhesions 1.1%, and middle turbinate lateralization 4.4%. Changes from baseline in patient-reported outcomes were statistically significant ($p < 0.0001$). No clinically significant changes from baseline in intra-ocular pressure (IOP) occurred. The authors concluded that this consecutive case-series study provided clinical evidence of the safety, effectiveness, and clinical utility of a bioabsorbable steroid-eluting implant for use in CRS patients. The implant was associated with favorable rates of sinus patency. At 1-month, minimal degrees of inflammation and adhesions were observed, suggesting a positive clinical impact of local steroid delivery without evidence of ocular risks.

Propel and Sinuva Implants for the Treatment of Chronic Rhinosinusitis, continued

In a prospective, multi-center, randomized, controlled, double-blind trial (Advance II Trial), Marple et al. (2012) examined the safety and effectiveness of controlled delivery of mometasone furoate to the sinus mucosa via the Propel sinus implant deployed at the time of ESS. This study enrolled 105 patients with CRS undergoing bilateral ethmoidectomy to compare the effect of drug-releasing to non-drug-releasing implants using an intra-patient control design. Post-operative interventions, polyposis, and adhesions were assessed post-operatively. Efficacy was determined through independent analysis of randomized video-endoscopies by 3 blinded sinus surgeons. Safety assessments included ocular examinations. Implants were successfully deployed in all 210 ethmoid sinuses. Compared with control sinuses with non-drug-releasing implants, the drug-releasing implant provided a 29% relative reduction in post-operative interventions ($p = 0.028$) and a 52% ($p = 0.005$) decrease in lysis of adhesions. The relative reduction in frank polyposis was 44.9% ($p = 0.002$). Similar reductions were observed in real-time grading performed by the clinical investigators. No clinically significant changes from baseline in IOP or cataracts were observed. The authors concluded that this study provided evidence that use of the Propel sinus implant that applies a sustained release of corticosteroid improves surgical outcomes by reducing synechiae formation, polyposis, and the need for post-operative interventions, with no observable ocular safety risk.

While the results of the two Advance Trials are promising, they were limited to small, heterogeneous populations with short-term follow-up. Furthermore, the trials were performed in a setting where both sinuses had implants, one with steroids, and the other without. The two trials discussed above did not compare the post-operative outcomes using this device with outcomes following standard ESS without an ostial implant but with topical steroid sprays, saline irrigation, debridement, and conventional post-operative packing. The available evidence is insufficient to determine whether sinus spacers and stents improve outcomes when used post-operatively following ESS. Further randomized controlled trials (RCTs) are needed to compare the Propel device to optimal post-operative care without the device to determine whether it can improve post-operative outcomes for patients undergoing ESS.

In a randomized, double-blind, placebo-controlled trial, Rudmik et al. (2012) evaluated a dexamethasone Sinu-Foam spacer following ESS for CRS without nasal polyposis (CRSsNP). Patients with CRSsNP ($n = 36$) were enrolled into a double-blind, placebo-controlled trial and randomized into either a treatment arm (dexamethasone Sinu-Foam mixture; $n = 18$) or placebo arm (Sinu-Foam alone; $n = 18$). Therapeutic outcomes were evaluated at 1 week, 4 weeks, and 3 months using sino-nasal endoscopy and graded using the Lund-Kennedy scoring system. Post-operative care included nasal saline irrigations and a short course of systemic steroids. All patients completed the study follow-up period. Both study arms experienced significant improvement in endoscopic grading over the study duration ($p < 0.001$). There was no difference in average endoscopic scores between the treatment and placebo groups at 1 week, 4 weeks, and 3 months (all $p > 0.489$). The authors concluded that the findings of this study demonstrated that an off-label drug-eluting MM spacer of dexamethasone and Sinu-Foam does not improve endoscopic outcomes in the early post-operative period following ESS when combined with post-operative saline irrigations and a short course of systemic steroids.

Weitzel and Wormald (2008) performed a literature review to identify all forms of scientifically evaluated absorbable packing for ESS. Only English studies identifiable within the PubMed database were included. Studies were categorized by level of evidence and evaluated for methodological errors. A total of 38 studies met the inclusion criteria. There was a diverse range of article evidence and quality. The most effective hemostatic agent currently available is FloSeal; however, this product causes an increase in adhesion formation. For the purpose of preventing adhesions, resorbable packs appear to have no benefit over either non-resorbables or no packing. If the middle turbinate is unstable at the conclusion of surgery, suturing it to the septum may reduce adhesions. Although mitomycin C, hyaluronic acid, and retinoic acid all have shown potential in these roles, to date, none has shown to be useful in post-ESS CRS patients.

In a systematic review and meta-analysis, Lee and Grewal (2012) examined if MM spacers reduce the risk of synechiae following ESS. The Preferred Reporting of Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines was used for reporting this review of RCT evaluating the effectiveness of MM spacers compared to no spacers in patients undergoing ESS. Where appropriate, a meta-analysis on outcome data using a random effects model was performed. A total of 8 RCTs were included in this systematic review. A pooled analysis on relevant trials found a non-significant trend favoring MM spacers compared to no spacers for the prevention of synechiae following ESS (relative risk [RR], 0.40;

Propel and Sinuva Implants for the Treatment of Chronic Rhinosinusitis, continued

95% confidence interval [CI]: 0.14 to 1.12). Sub-group analysis suggested that non-absorbable spacers (NAS) may be more effective than absorbable spacers (AS) for reducing the risk of synechiae compared to no spacers. The authors concluded that MM spacers may be more effective than no spacers for the prevention of synechiae following ESS, especially when employing the use of an NAS. However, the authors noted that significant heterogeneity was observed among included trials and future studies are needed to further validate these findings.

A variety of implants/spacers (e.g., the Propel sinus implant, the Relieva Stratus MicroFlow spacer, and the Sinu-Foam spacer) have been employed to maintain patency of the sinuses and deliver local steroids with varying success in the reported literature. However, the available studies have significant heterogeneity in this outcome. There remains a continued debate on whether these devices improve the health outcomes following ESS.

In an updated review completed in July 2015, one new systematic review and 4 new primary literature studies were identified for review.

Though 2 of the studies were level 1 evidence-randomized controlled trials, methodological issues limit the conclusiveness of their findings as neither involved a truly active comparator consistent with the current standard of care but instead used an inert nasal stent which is infrequently used in clinical practice and excluded post-operative topical or systemic steroid use which is not uncommonly used. These studies were also sponsored by the manufacturer of the device which creates the potential for hidden bias.

The study by Rudmik, L. et al., related to cost-effectiveness, is also limited by its conclusions being based on a mathematical model with specific assumptions and not based on clinical evidence.

In conclusion, no conclusive statement can be made regarding the efficacy of Propel, with regards to standard treatment options after ethmoid sinus surgery, as adequate head-to-head trials have not been conducted.

Billing/Coding Information

CPT CODES

31299 Unlisted procedure, accessory sinuses

HCPCS CODES

No specific codes identified

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Select Health

Propel and Sinuva Implants for the Treatment of Chronic Rhinosinusitis, continued

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Select Health

Propel and Sinuva Implants for the Treatment of Chronic Rhinosinusitis, continued

Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call SelectHealth Provider Relations at (801) 442-3692.

Select Health

MEDICAL POLICY

RADIOFREQUENCY ABLATION FOR BENIGN THYROID NODULES

Policy # 646
Implementation Date:4/17/21
Review Dates: 3/15/22, 4/3/23, 4/17/24
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Thyroid nodules are common and occur in up to 50% of individuals. Most are benign (non-cancerous) and only require monitoring. However, sometimes even benign nodules become large enough to either cause pressure symptoms in the neck or be otherwise bothersome to the patient. Surgery is then an option, but leaves a scar, and, depending upon the extent of surgery needed, can result in hypothyroidism and rarely problems with the parathyroid glands that control calcium in the blood.

When nodules are cystic, ethanol infusion can be used to decrease the size. However, with solid nodules, other methods, such as radiofrequency ablation (RFA) and laser ablation (LA), have been used.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers radiofrequency ablation of thyroid nodules for symptomatic benign thyroid nodules.

Select Health does not cover radiofrequency ablation of thyroid nodules for cosmetic purposes or as a primary cancer treatment.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Radiofrequency Ablation for Benign Thyroid Nodules, continued

Summary of Medical Information

Both RFA and LA have been shown to be effective in many studies including a recent meta-analysis with volume reduction rates at 6 months, 1 year, and 2 years were 68%, 75%, and 87% for RFA and 48%, 52%, and 45% for LA. However, the two techniques have not been compared head-to-head.

This study was done to directly compare RFA and LA in their ability to decrease the size and symptoms of benign, solid thyroid nodules.

Billing/Coding Information

CPT CODES

60660	Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency
60661	Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, including imaging guidance, radiofrequency (List separately in addition to code for primary procedure)

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Select Health

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MEDICAL POLICY

SPEECH THERAPY GUIDELINES

Policy # 178

Implementation Date:7/98
Review Dates: 2/27/01, 6/17/02, 10/23/03, 10/23/08, 10/22/09, 5/19/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 12/21/17, 12/18/18, 12/18/19, 12/14/20, 10/28/21, 11/17/22, 12/17/23, 12/9/24
Revision Dates: 11/18/04, 9/20/06, 10/18/07, 4/16/14, 1/12/17, 12/21/17, 4/8/19, 8/10/20, 11/17/21, 11/21/23, 1/3/24, 10/18/24

Related Medical Policies:

#518 Physical Therapy (PT) Occupational Therapy (OT)

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Speech, language, cognitive-communication, voice, fluency, swallowing problems, and other disorders affect an individual's ability to talk, understand, read, write, and swallow safely. Such disorders have different causes and may range from a few speech/sound errors, or repetitions of sounds or words, to a total loss of the ability to use speech to communicate effectively. Swallowing problems affect nutrition and the ability to eat and swallow safely.

The clinical methods used to treat speech, language, swallowing, and related disorders vary depending on the nature and severity of the problem, the age of the individual, and the individual's awareness of the problem. Thus, speech therapy may have a variety of different aims:

- Help individuals with articulation disorders to learn proper production of speech sounds.
- Assist individuals with voice disorders to develop proper control of the vocal and respiratory systems for correct voice production.
- Assist individuals who stutter to increase the amount of fluent speech.
- Help children with difficulty understanding and using language to improve language comprehension and production (e.g., grammar, vocabulary, and conversation and story-telling skills).
- Assist individuals with aphasia to improve comprehension of speech and reading and production of spoken and written language.
- Assist individuals with severe communication disorders with the use of augmentative and alternative communication (AAC) systems, including speech-generating devices (SGDs).
- Counsel individuals with speech and language disorders and their communication partners to help them understand the disorders and to achieve more effective communication in educational, social, and vocational settings.

Assist individuals with swallowing and feeding problems or disorders to avoid serious lung infections and help others avoid tube feedings (e.g., swallowing problems that result from treatment for head and neck cancer, stroke, or head injury).

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers speech therapy when the plan determines that services can be expected to significantly improve the member's condition, as defined by the following. (*This coverage is defined by a pre-specified benefit limit specific to the member's benefit plan.*)

Select Health

Speech Therapy Guidelines, continued

1) Documentation of a written plan of care that is sufficient to determine the medical necessity of treatment. The written plan of care should include all the following:
   a. The diagnosis along with the date of onset or exacerbation of the disorder/diagnosis; and
   b. A reasonable estimate of when the goals will be reached; and
   c. Long-term and short-term goals that are specific, quantitative, and objective; and
   d. Speech therapy evaluation; and
   e. The frequency and duration of treatment; and
   f. The specific treatment techniques and/or exercises to be used in treatment; and
   g. If the treatment is in a home setting, explanation of why it cannot be done in the office setting needs to be included.

   Continuation of Therapy:

2) Select Health covers continuation of speech therapy with objective documentation showing improvement and progress towards pre-established speech therapy goals; improvement is evidenced by successive objective measurements.

3) Covered conditions include, but are not limited to, the following:

   a. Stroke or other traumatic brain injuries
   b. Laryngectomy
   c. Medical conditions such as vocal nodules
   d. Cleft palate and other acquired or congenital oral facial anomalies
   e. Mutism, or severely impaired speech in a child under the age of 18; severely impaired speech is defined as either:
   f. Equal to or greater than 1.5 standard deviations below the mean, as measured by an age-appropriate standardized test for articulation, phonology, fluency, or language. A standard score of 78 is equivalent to 1.5 standard deviations below the mean; or
   g. A percentile score below the 7th percentile.
   h. Dysphagia, regardless of the presence of a communication disorder; when the member is motivated, can cooperate with therapy, and has some degree of deglutition/swallowing functions.
   i. Chronic or recurrent otitis media, when all the following criteria are met:
      I. Evidence of chronic or recurrent otitis media, defined as:
      II. Otitis media with effusion lasting three months or more or;
      III. More than one episode of otitis media;
      IV. Another episode of otitis media after placement of myringotomy tubes or;
      V. Otitis media with effusion in a child over the age of four.
   j. Documented significant hearing loss measured through formal pure tone audiometry testing. Significant hearing loss is defined as hearing loss of 30 or more decibels at one or more of the frequencies of 500, 1,000, 2,000, and 4,000 Hz.
   k. Myofunctional therapy to correct oral muscular forces is covered when provided in conjunction with speech therapy, and the condition is resulting from a functional deficiency (e.g., poor swallowing habits, allergies, tongue-tied).

Select Health

Speech Therapy Guidelines, continued

4) Limitations/Exclusions

a. Speech therapy that does not require the direct supervision or expertise of a licensed speech language pathologist is not covered.

b. Speech therapy services provided to improve a member's condition beyond normal variations in individual development and aging (e.g., voice training for a singer) are not covered.

c. Habilitative speech therapy services are covered; except for members on plans which specifically exclude habilitative services.

d. Speech therapy services for children under age 2 are not covered unless there is a specific medical diagnosis for which early speech therapy intervention is efficacious and medically necessary.

e. Speech therapy for idiopathic delays in speech development for infants and children younger than 18 months of age is considered experimental/investigational because idiopathic delays in speech development cannot be reliably diagnosed or treated in the prelingual developmental stage.

Notes:

Speech or language therapy not medically indicated for school-age children can usually be obtained through the school system. State Education Codes allow for speech therapy services for children ages 3 and older who demonstrate significant speech/language deficits interfering with the child's education potential.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A review by Enderby et al. in 1996 made several conclusions about speech therapy:

"Speech and language therapy is often viewed as a group of prescribed and precise activities. Indeed, it is often referred to as a single entity, similar to a drug, as if it were made up of chemicals required in a certain dose. One of the challenges we in the profession face is to describe in detail the components of therapy in order to evaluate the most active and desirable features and to eliminate the aspects that have no effect or are possibly harmful. Even such descriptions, by themselves, maybe inadequate as it becomes increasingly evident that different approaches by individual therapists may be more, or less, effective with different clients with similar speech and language problems but differing personal and psychosocial needs. The box gives an indication of some of the key strategies in speech and language therapy, but each of these can be approached in a different way.

'Research into speech and language therapy has mostly used outcome measures related to improving speech or language itself, but the goals of therapy are usually broader--for example, providing alternative

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Speech Therapy Guidelines, continued

methods to communicate, improving interaction strategies, and advising patients and relatives. Thus, evaluations of the real impact of intervention have often ignored aspects that may be of value. Outcome measures that target these broader domains of speech and language therapy have only recently been developed.

'Research in speech and language therapy, as in other professions, shows a considerable disparity in volume across the specialist areas. Researching the efficacy of treatment for dysphasia attracts relatively more investment, whereas work-evaluating therapy for those with learning difficulties and developmental speech and language disorders has only recently attracted interest and, even now, the amount of research and the methods used are inadequate for the task.

'This disparity may be related to the different clinical domains of these disorders. Disorders more closely allied to medical and surgical disciplines were exposed earlier to the philosophy of objective investigation, and much of the early work in speech and language therapy was fostered by, or associated with, medical research programs, often using the related resources and methods. Difficulties more traditionally associated with education, or social science, have attracted studies that have concentrated more on the philosophy of treatments and the generation of hypotheses.

'The challenge to researchers to address the effectiveness of speech and language therapies becomes ever greater as we become more aware of the underlying deficits associated with many communication disorders; as multimodal treatments develop; as we harness physiological, psychological, and social strands; and as we broaden our therapeutic objectives. Research done as recently as a decade ago may look simplistic and inappropriate. A broad range of methods, including well designed qualitative and quantitative studies, will help us in ensuring that effective help for those with communication disorders is available."

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

92521	Evaluation of speech fluency (eg, stuttering, cluttering)
92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria);
92523	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)
92524	Behavioral and qualitative analysis of voice and resonance
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder (includes aural rehabilitation); group, two or more individuals
92610	Evaluation of oral and pharyngeal swallowing function
92611	Motion fluoroscopic evaluation of swallowing function by cine or video recording

HCPCS CODES

G0153	Services of a speech and language pathologist in home health setting, each 15 minutes
G0161	Services performed by a qualified speech-language pathologist, in the home health setting, in the establishment or delivery of a safe effective therapy maintenance program, each 15 minutes
S9128	Speech therapy, in the home, per diem
S9152	Speech therapy, re-evaluation

Speech Therapy Guidelines, continued

Key References
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Revision History

Revision Date	Summary of Changes
11/21/23	For Commercial Plan Policy, clarified for criteria #5, meeting either criterion #a ***or*** criterion #b fulfills that requirement.
1/3/24	For Commercial Plan Policy, added new criteria #1 which requires a written plan of care be submitted by the provider; aligning with similar requirements to qualify for Select Health coverage of physical therapy/occupational therapy.
10/18/24	For Commercial Plan Policy, added the following exclusion: "Speech therapy for idiopathic delays in speech development for infants and children younger than 18 months of age is considered experimental/investigational because idiopathic delays in speech development cannot be reliably diagnosed or treated in the prelingual developmental stage."

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MEDICAL POLICY

STEREOTACTIC ENDOSCOPIC SINUS SURGERY (IMAGE-GUIDED SINUS SURGERY)

Policy # 228

Implementation Date: 5/15/04

Review Dates: 4/14/05, 5/5/06, 5/17/07, 4/24/08, 4/23/09, 2/18/10, 4/21/11, 4/25/13, 2/20/14, 2/11/16, 2/16/17, 2/15/18, 2/18/19, 2/17/20, 2/18/21, 1/11/22, 2/16/23, 2/6/24

Revision Dates: 2/16/12

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Description

Nasal and sinus complaints are among the most common reasons for visits to primary care clinicians, otolaryngologists, and allergists. The cornerstone of accurate diagnosis and treatment of chronic sinusitis is a thorough history and a complete physical examination, including nasal endoscopy. Surgery should not be considered unless the evaluation clearly identifies chronic sinusitis as the cause of the patient's constellation of symptoms. The history should elucidate the frequency of infections, the type and the duration of symptoms, and the response to medical therapy.

Although functional endoscopic sinus surgery is the primary approach used today for the surgical treatment of chronic sinusitis, the time-honored external approaches still play a role. Therefore, familiarity with endoscopic and external approaches, in conjunction with a precise understanding of the anatomy, ensures optimal patient care and outcome.

Computer-augmented endoscopic sinus surgery (CAESS), also known as: stereotactic sinus surgery; image-guided endoscopic ENT or sinus surgery; computer-guided, or -aided, or -assisted (sinus) surgery, computed-assisted navigation systems; intraoperative -image guidance or -navigation systems; and other terms, is a stereotactic technology that provides a direct interactive link with the patient's preoperative CT images. With superimposed positioning of the endoscope as a localizing probe intraoperatively, various 2D and 3D on-screen displays of the reconstructed images incorporates a marker by which surgical location is identified and immediate three-dimensional appreciation of the anatomy surrounding the surgical field outside direct endoscopic visualization is gained.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers stereotactic endoscopic sinus surgery; relevant medical literature has shown use of this technology improves the health outcomes of patients.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Sterotactic Endoscopic Sinus Surgery (Image-guided Sinus Surgery), continued

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Current evidence is scant and based predominantly on (uncontrolled) case series, with a handful of non-randomized studies using historical cases as controls (i.e., cohort). The bulk of available studies address technical performance (e.g., spatial accuracy of the system, comparison of different devices/systems). There is currently no high-quality, randomized, controlled trials which thoroughly evaluate the benefit of this technology for patients undergoing endoscopic sinus surgery when compared to standard endoscopic sinus surgery techniques.

It is clear that use of stereotactic image-guidance during sinus surgery requires more operating room (OR) time (about 15 minutes for experienced operators/OR teams), provides intra-operative localization of surgical instruments relative to anatomical landmarks to an accuracy of about 1–2 mm, and leads to increased confidence among surgeons about surgical decisions.

However, multiple studies have suggested improved efficacy and reduced complications for patients undergoing endoscopic sinus surgery with the use of this technology. Fried et al., comparing endoscopic sinus surgery, with and without image guidance, concluded that the use of an IGS for endoscopic sinus surgery may reduce the complications associated with the procedure and allow for a more thorough operation. However, operative time and EBL were increased in this study. Tabaee et al., who reviewed the 5-year outcomes of computer-assisted sinus surgery, also, concluded that CAS helps in avoiding trauma to the orbit and anterior skull base, and has a low incidence of major complications. Similar conclusions were drawn by Eliashar et al. in December 2003.

In a study looking at the costs related to the use of this technology compared with standard sinus surgery, published in 2001, Gibbons et al. found no statistically significant difference between the two groups in terms of surgery duration, extent of surgery, percent of complementary procedures, percent of supplementary procedures, complexity of surgery, and percent revision surgery. Computer-assisted surgery (CAS) was 6.7% more expensive than sinus surgery without computerized surgical navigation ($p = 0.01$). However, they also felt the intangible benefits of CAS may outweigh the added expense.

The American Academy of Otolaryngology Head and Neck Surgery also endorses the intraoperative use of computer-aided surgery in appropriately select cases to assist the surgeon in providing localization of anatomic structures and to reduce the risk of complications. They specifically identify this technology appropriate for use with: revision sinus surgery; distorted sinus anatomy of development; postoperative or traumatic origin; extensive sino-nasal polyposis; pathology involving the frontal, posterior ethmoid, and sphenoid sinuses; disease abutting the skull base, orbit, optic nerve, or carotid artery; CSF rhinorrhea, or conditions where there is a skull base defect and benign, and malignant sino-nasal neoplasms.

Billing/Coding Information

CPT CODES

61781	Stereotactic computer-assisted (navigational) procedure; cranial, intradural (List separately in addition to code for primary procedure)
61782	; cranial, extradural (List separately in addition to code for primary procedure)

HCPCS CODES

No specific codes identified

Select Health

Sterotactic Endoscopic Sinus Surgery (Image-guided Sinus Surgery), continued

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Select Health

Sterotactic Endoscopic Sinus Surgery (Image-guided Sinus Surgery), continued

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MEDICAL POLICY

TONSILLECTOMY AND ADENOIDECTOMY

Policy # 621
Implementation Date: 1/1/18
Review Dates: 2/18/19, 3/17/20, 2/18/21, 1/20/22, 2/16/23, 2/6/24
Revision Dates: 1/12/18, 1/18/18, 2/26/18, 3/1/18, 12/5/18, 3/25/20, 11/6/23, 2/23/24

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Tonsils and adenoids are lymphatic tissue located in the oral cavity and posterior to the nasal cavity respectively. Typically, the tissues are removed if obstruction is present which could be the cause of obstructive sleep apnea or causing dysphagia. Recurrent infections typically caused by group A beta – hemolytic Streptococcus is another significant cause of tonsillectomies.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers tonsillectomy and adenoidectomy if the following criteria are met:

1. **Tonsillectomy or Adenotonsillectomy (Either A or B or C):**

   A. Sleep disordered breathing with tonsillar hypertrophy, **AND** (must have one of the following: i, ii, or iii):

      i. OSA (Obstructive Sleep Apnea) has been confirmed by sleep study in adults or children.

      ii. Children must have at least 2 of the following:

         1. Snoring in children ≥ 3 nights/week; labored breathing, gasping, or choking during sleep.
         2. Witnessed apneic episodes during sleep.
         3. Restless sleep and/or difficulty waking in the morning.
         4. Excessive daytime sleepiness.

      iii. Children having referral to sleep specialist, or sleep study or weight management or other contributing disorders have been excluded, **AND** (must have at least 2 of the following) for **> 3 months:**

         1. Intermittent snoring.
         2. Witnessed apneic episodes during sleep.
         3. Restless sleep and/or difficulty waking in the morning.
         4. Excessive daytime sleepiness.

   B. Infection (must have **ONE** of the following: i, ii, or iii):

      i. Recurrent acute tonsillitis by documentation with **ANY** of the following:

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1. ≥ 3 episodes per year x 3 years.
2. ≥ 5 episodes per year x 2 years.
3. ≥ 7 episodes per year for 1 year.
4. Periodic fevers in children with aphthous stomatitis, pharyngitis, and adenitis (PFAPA) and who may have **ANY** of the following indications: (if surgery is performed, either tonsillectomy or adenotonsillectomy is recommended)
    a. Failed steroid therapy and alternative diagnoses ruled out
    b. Contraindication to steroid therapy
    c. Events < 1 month apart requiring steroid therapy
    d. If shared decision-making has occurred, and the tonsillectomy has been recommended by the PCP or non-surgical specialist

ii. Peritonsillar abscess with **ANY** of the following:
1. Acute Airway Obstruction.
2. Needle aspiration or incision and drainage (I and D) unsuccessful or not feasible.
3. Recurrent peritonsillar abscess.
4. History of peritonsillar abscess and recurrent or chronic tonsillitis.

iii. Chronic Tonsillitis
1. Sore throat ≥ 12 weeks with continued symptoms after antibiotics ≥ 10 days with **ANY** of the following:
    a. Tender cervical lymph nodes.
    b. Tonsillar erythema or exudate.
    c. Enlarged tonsils.

C. Structural/Other (must have **ONE** of the following: i, ii, iii, or iv):
i. Tonsillolithiasis with both:
1. Chronic tonsilloliths ≥ 12 weeks **AND**
2. Continued symptoms or findings after oral hygiene.

ii. Tonsillar hemorrhage.

iii. Children only - symptomatic tonsillar hypertrophy with **ANY** of the following:
1. Hyponasal speech ≥ 12 weeks.
2. Snoring or mouth-breathing ≥ 12 weeks.
3. Dysphagia ≥ 12 weeks.

iv. Malignancy or autoimmune with **ANY** of the following:
1. Suspected by unilateral tonsillar enlargement or abnormal appearance.
2. Confirmed by FNA or Biopsy.

2. <u>Adenoidectomy Alone (Either A or B or C):</u>

A. Obstructive Sleep Apnea (OSA)
i. *(For Adults)* Confirmed by sleep study with a tonsillectomy planned or previously done.
ii. *(For Pediatrics)* OSA with adenoid hypertrophy by either **(1 or 2):**
1. Confirmed by sleep study; **or**
2. Snoring ≥ 3 nights/week with **ANY** of the following:

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a. Labored breathing or gasping or choking during sleep.
b. Witnessed apneic episodes during sleep.
c. Sleep enuresis.
d. Excessive daytime sleepiness.
e. Documented behavioral problems or learning problems.

B. Infection (must have **ONE** of the following: i, ii, iii, or iv)
   i. Chronic adenoiditis in pediatrics with continued findings after oral antibiotics ≥ 3 weeks with **ANY** of the following:
      1. Purulent nasal drainage ≥ 12 weeks.
      2. Postnasal drip ≥ 12 weeks.
      3. Cough ≥ 12 weeks.
      4. Nasal obstruction ≥ 12 weeks.
   ii. Chronic rhinosinusitis that failed oral antibiotics ≥ 3 weeks, intranasal corticosteroid ≥ 3 weeks (if not contraindicated) and evaluated for environmental allergies and treated if indicated. With **ANY** of the following:
      1. Purulent nasal drainage ≥ 12 weeks.
      2. Postnasal drip ≥ 12 weeks.
      3. Cough ≥ 12 weeks.
      4. Nasal obstruction ≥ 12 weeks.
   iii. Recurrent acute otitis media with tympanostomy tube placement by history and to be performed with myringotomy with or without tubes.
   iv. Otitis media with effusion when ≥ 4 years old and to be performed with or without tubes.

C. Structural/Other (must have **EITHER** of the following: i or ii)
   i. Symptomatic adenoid hypertrophy confirmed by exam with **ANY** of the following:
      1. Hyponasal speech ≥ 12 weeks.
      2. Snoring or mouth breathing ≥ 12 weeks.
      3. Dental or craniofacial abnormalities such as “adenoid facies.”
   ii. Adenoid Tumor

Select Health does NOT cover tonsillectomy or adenoidectomy for any other indication as it is considered not medically necessary.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

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SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information
The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) has a clinical practice guideline addressing the use of tonsillectomy in children (Mitchell, 2019). This guideline updates the 2011 Guideline (Baugh, 2011) In this guideline, they recommend the following:

1. Clinicians may recommend tonsillectomy for recurrent throat infection with a frequency of at least 7 episodes in the past year or at least 5 episodes per year for 2 years or at least 3 episodes per year for 3 years with documentation in the medical record for each episode of sore throat and one or more of the following: temperature > 38.3°C, cervical adenopathy, tonsillar exudate, or positive test for Group A Beta-Hemolytic Streptococci (GABHS).
2. Clinicians should assess the child with recurrent throat infection who does not meet criteria in Statement 2 for modifying factors that may nonetheless favor tonsillectomy, which may include but are not limited to multiple antibiotic allergy/intolerance, Periodic Fevers in children with Aphthous stomatitis, Pharyngitis, and Adenitis (PFAPA), or history of peritonsillar abscess.
3. Clinicians should ask caregivers of children with Sleep-Disordered Breathing (SDB) and tonsil hypertrophy about comorbid conditions that might improve after tonsillectomy, including growth retardation, poor school performance, enuresis, and behavioral problems.

It should be noted that the AAO-HNS guideline states the following:

The guideline does not apply to tonsillotomy, intracapsular surgery, or other partial removal techniques of the tonsil because of the relatively sparse high-quality published evidence on these techniques and limited long-term follow-up. Similarly, the guideline does not apply to populations of children excluded from most tonsillectomy research studies, including those with diabetes mellitus, cardiopulmonary disease, craniofacial disorders, congenital anomalies of the head and neck region, sickle cell disease, and other coagulopathies or immunodeficiency disorders.

The most frequent indication for tonsillectomy is recurrent throat infection. According to the AAO-HNS, a throat infection is defined as sore throat caused by viral or bacterial infection of the pharynx, palatine tonsils, or both, which may, or may not be, culture positive for group A streptococcus. This includes strep throat infection and acute tonsillitis, pharyngitis, adenotonsillitis, or tonsillopharyngitis. The symptoms of a throat infection vary due to the root cause but may include a scratchy sensation in the throat; dry throat; white patches, or pus on the tonsils; redness and inflammation of the larynx, pharynx, or tonsils; swollen or sore glands of the neck and jaw; and pain when swallowing or speaking. The treatment methods used to address throat infections will depend upon the cause of the infection, but medications such as antibiotics and anti-inflammatory drugs to treat infection and alleviate symptoms are common. When an individual has frequent throat infections despite optimal treatment, the use of surgical interventions such as tonsillectomy may be warranted.

SDB is the second most common indication for tonsillectomy in children and is characterized by disturbances in breathing pattern or efficacy during sleep. Unfortunately, there is no widely accepted standard for the diagnosis of SDB. However, it is recognized that SDB may involve snoring, mouth breathing, and pauses in breathing (apnea). However, the use of snoring as a criterion for the diagnosis of SDB should be used carefully, as the AAO-HNS states: "The presence or absence of snoring neither includes nor excludes SDB, as not all children who snore have SDB, and caregivers may not observe intermittent snoring that occurs during the night." (Baugh, 2011). Daytime symptoms associated with SDB may include excessive sleepiness, inattention, poor concentration, aggression, depression, hyperactivity, and wetting the bed. A wide array of obstructive disorders may result in SDB, ranging in severity from simple snoring to obstructive sleep apnea. The most common cause of SDB in children is tonsillar hypertrophy, which is an abnormal enlargement of the tonsils. This may be due to chronic infection or

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excess tissue growth. Diagnosis of SDB may be based on an individual's medical history, physical examination, audio/video taping, pulse oximetry, or limited or all-night polysomnogram, also known as a sleep test. History and physical examination are the most common initial methods for diagnosis. Treatment may involve antibiotics to address underlying infection, but if such treatment fails or is not indicated, tonsillectomy may be warranted.

In children under 3 years of age, behavioral issues related to SDB may be more difficult to identify (for example, they may not yet be continent and, as such, enuresis would not necessarily be a sign of SDB). In addition, access to diagnostic polysomnography may be difficult and the results may be less reliable. Based on additional clinical input from specialists in the field, it would be appropriate to consider tonsillectomy when a parent or caregiver reports regular episodes of nocturnal choking, gasping, apnea, or breath holding which have persisted for several months in the setting of documented tonsillar hypertrophy.

Obstructive Sleep Apnea (OSA) is a major subset of SDB. Individuals with OSA suffer from redundant soft tissue in the pharynx, including the adenoids and tonsils, which block the upper airway leading to periodic cessation of breathing. Individuals with OSA must change sleep position or increase their respiratory effort to overcome the blockage, disrupting sleeping patterns. Symptoms of OSA may include nocturnal gasping, cyanosis, excessive daytime sleepiness, pulmonary hypertension, and snoring, to name just a few. The diagnosis of OSA in children has not been standardized, although there is some consensus that a threshold of greater than one on the Apnea-Hypopnea Index (AHI) is an indication of OSA (Au, 2009; Chan, 2004; Spruyt, 2012). Both the American Academy of Pediatrics (AAP; Burns, 2017; Marcus, 2012) and AAO-HNS (Baugh, 2011) regard tonsillectomy as a reasonable option for any child with documented OSA.

In 2013, Marcus et al. published a single-blind randomized controlled trial (RCT) involving 464 children, 5 to 9 years of age, with OSA, 400 of whom completed the trial (86%). Subjects were randomized to either watchful-waiting (n=203), or early adenotonsillectomy (n=194), and followed for 7 months after randomization. The primary outcome, the attention and executive function score on the Developmental Neuropsychological Assessment, did not differ significantly at follow-up (p=0.16). However, the authors reported that there were significantly greater improvements in behavioral, quality-of-life, and polysomnographic findings and significantly greater reduction in symptoms in the early-adenotonsillectomy group vs. the watchful-waiting group. Furthermore, normalization of polysomnographic findings was observed in a larger proportion of subjects in the early-adenotonsillectomy group than in the watchful-waiting group (79% vs. 46%). They concluded that their findings provide evidence of beneficial effects of early adenotonsillectomy.

In 2017, the Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness review, here is what they found. Tonsillectomy can produce short-term improvement in sleep outcomes and reduction in throat infections compared with no surgery in children with Obstructive Sleep-Disordered Breathing (OSDB) or recurrent throat infections. Relative to no intervention, most studies reported better sleep-related outcomes in children with OSDB who had a tonsillectomy, but longer-term data on durability of outcomes are limited. Children undergoing tonsillectomy to improve number of throat infections, associated health care utilization (clinician visits), and work/school absences had improvements in these outcomes in the first postsurgical year compared with children not receiving surgery. These benefits did not persist over time, and data on longer-term results are lacking. This short-term improvement must be weighed against a roughly 4 percent frequency of Post-Tonsillectomy Hemorrhage (PTH).

The use of adenoidectomy for the treatment of Otitis Media (OM), either Acute (AOM) or with Effusion (OME), has been a focus of investigation for many years. One area of concern is the use of this procedure, with or without the use of tympanostomy tubes, in the treatment of OM in children under 4 years of age. Several large, well-designed Randomized Controlled Trials (RCTs) have published a mix between no benefit and only small benefits reported. Of the studies reporting no benefit, the use of tympanostomy tubes was included in the study protocol (Casselbrant, 2009; Hammaren, 2005; Koivunen, 2004; Mattila, 2003). The studies that did report some benefit, tympanostomy tubes were used in two (Kujala, 2012; MRC, 2012), but not in a third (Paradise, 1999).

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) updated their guideline for treatment of otitis media with effusion in 2016 (Rosenfeld, 2016). This update specifically recommends against the use of adenoidectomy for the treatment of OME in children younger than 4 years of age, "…

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unless there is distinct indication (e.g. nasal obstruction, chronic adenoiditis) exists other than OME." AAO-HNS had previously recognized some indications for adenoidectomy to treat OME in younger children. The change is based on recent systematic review data (Boonacker, 2014; Mikals, 2014) showing no difference in the rate of repeat tympanostomy tube insertion between children younger than 4 years old treated with primary adenoidectomy compared to tympanostomy tube insertion alone as the primary procedure.

The new AAO-HNS guideline also changed their position on the use of adenoidectomy only as a second line treatment after failure of an initial trial of tympanostomy tubes. The updated recommendation suggests that adenoidectomy should be considered a first-line therapy along with, or as an option to tympanostomy tube insertion. As with the previously mentioned change, this recommendation is based on recent systematic review data (Boonacker, 2014; Mikals, 2014; Wallace, 2014). However, the data supporting this change are weak. Most notably, the Boonacker study does not address adenoidectomy as a primary procedure. The only support for primary adenoidectomy comes from the Mikals study which states:

> *When studies were limited to level 1b quality data, only 5 studies met inclusion criteria. In these studies, the pooled estimate of the rate of repeat T Tubes for children undergoing a primary adenoidectomy was 20.4% (95% CI, 9l.2% to 31.6%) vs 34.1% (95% CI, 13.2% to 54.9%) for children undergoing primary T Tube only.*

These results are not provided with p-value data, and with such significant overlap of confidence intervals, the value of primary adenoidectomy is questionable.

The American Academy of Pediatrics (AAP) guideline for the diagnosis and management of acute otitis media (Lieberthal, 2013) states: "Adenoidectomy alone should not be used for prevention of AOM but may have benefit when performed with placement of tympanostomy tubes or in children with previous tympanostomy tube placement in OME." Note that this statement is equivocal, in that they say it "may" be of benefit for AOM. However, the available data from RCTs does not support this statement at this time.

Thus, currently the evidence is not supportive of the use of adenoidectomy with or without tympanostomy tubes, in children under the age of 4 years of age who have chronic OM with effusion or recurrent acute otitis media.

The use of adenoidectomy is widely accepted to be an effective treatment for suspected adenoid tumor. While there is little clinical trial evidence to support this procedure, the removal of malignant tissue is the standard of care in most head and neck cancers (NCCN, 2013).

Sleep disordered breathing (SDB) is a frequent indication for adenoidectomy in children and is characterized by disturbances in breathing pattern or efficacy during sleep. Unfortunately, there is no widely accepted standard for the diagnosis of SDB. However, common definitions of SDB may involve snoring, mouth breathing, and pauses in breathing (apnea). The AAO-HNS advise care in the use of snoring to diagnose SDB: "The presence or absence of snoring neither includes nor excludes SDB, as not all children who snore have SDB, and caregivers may not observe intermittent snoring that occurs during the night" (Baugh, 2011). Daytime symptoms associated with SDB may include excessive sleepiness, inattention, poor concentration, aggression, depression, hyperactivity, and wetting the bed. A wide array of obstructive disorders may result in SDB, ranging in severity from simple snoring to obstructive sleep apnea. The most common cause of SDB in children is tonsillar hypertrophy, which is an abnormal enlargement of the tonsils, including the adenoids. This may be due to chronic infection or excess tissue growth. Physicians may diagnose SDB based on an individual's medical history, physical examination, audio/video taping, pulse oximetry, or limited or all-night polysomnogram, also known as a sleep test. History and physical examination are the most common initial methods for diagnosis. Treatment may involve antibiotics to address underlying infection, but if such treatment fails or is not indicated, tonsillectomy may be warranted.

In children less than 3 years of age, behavioral issues related to SDB may be more difficult to identify (for example, they may not yet be continent and, as such, enuresis would not necessarily be a sign of SDB). In addition, access to diagnostic polysomnography may be difficult and the results may be less reliable. Based on additional clinical input from specialists in the field, it would be appropriate to consider adenoidectomy when a parent or caregiver reports regular episodes of nocturnal choking, gasping,

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apnea, or breath holding which have persisted for several months in the setting of documented adenoid hypertrophy.

Obstructive sleep apnea (OSA) is a major subset of SDB. Individuals with OSA suffer from redundant soft tissue in the pharynx, including the adenoids and tonsils, which blocks the upper airway leading to periodic cessation of breathing. Individuals with OSA must change sleep position or increase their respiratory effort to overcome the blockage, disrupting sleeping patterns. Symptoms of OSA may include nocturnal gasping, cyanosis, excessive daytime sleepiness, pulmonary hypertension, and snoring, to name just a few. The diagnosis of OSA in children has not been standardized, although there is some consensus that a threshold of greater than one on the AHI is an indication of OSA (Au, 2009; Chan, 2004; Spruyt, 2012). The AAP regards adenoidectomy as a reasonable option for any child with documented OSA and adenoid hypertrophy (2012; Marcus, 2012).

Billing/Coding Information

CPT CODES

42820	Tonsillectomy and adenoidectomy; younger than age 12
42821	; age 12 or over
42825	Tonsillectomy, primary or secondary; younger than age 12
42826	; age 12 or over
42830	Adenoidectomy, primary; younger than age 12
42831	; age 12 or over
42835	Adenoidectomy, secondary; younger than age 12
42836	; age 12 or over
42870	Excision or destruction lingual tonsil, any method (separate procedure)

HCPCS CODES

No specific codes identified

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Tonsillectomy and Adenoidectomy, continued

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