Medical Coverage Policy

Effective Date.....7/15/2024
Next Review Date.....7/15/2025
Coverage Policy Number..... 0570

Tympanostomy with iontophoresis local anesthesia

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Related Coverage Resources

Balloon Sinus Ostial Dilation for Chronic Sinusitis and Eustachian Tube Dilation

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses CPT® Code 0583T (tympanostomy with iontophoresis local anesthesia), also known as Tula® Tympanostomy System (Tubes Under Local Anesthesia = TULA).

This policy does NOT address CPT® Code 69433 (tympanostomy with local or topical anesthesia), or CPT® Code 69436 (tympanostomy with general anesthesia).

Coverage Policy

Tympanostomy tube insertion using the Tula® System (CPT® 0583T) is considered medically necessary for an individual six months of age or older when ANY of the following criteria are met:

- chronic (at least three months) otitis media with effusion (OME) in the ear considered for tube insertion, AND documented hearing difficulties
- chronic unilateral or bilateral OME AND symptoms that are likely attributable, all or in part, to OME that include, but are not limited to, ear pain, ear fullness, balance (vestibular) problems, poor school performance, behavioral problems, or reduced quality of life
- recurrent acute otitis media (AOM) AND unilateral or bilateral middle ear effusion (MEE) at the time of assessment for tube candidacy
- children at risk for developmental delays or disorders* AND unilateral or bilateral OME that is likely to persist as reflected by a type B (flat) tympanogram or a documented effusion for three months or longer

  *Sensory, physical, cognitive, or behavioral factors that place children with otitis media with effusion at increased risk for developmental difficulties (delay or disorder) may include:
  - Permanent hearing loss independent of otitis media with effusion
  - Suspected or confirmed speech and language delay or disorder
  - Autism spectrum disorder
  - Syndromes (e.g., Down) or craniofacial disorders that include cognitive, speech, or language delays
  - Blindness or uncorrectable visual impairment
  - Cleft palate, with or without associated syndrome
  - Developmental delay
  - Intellectual disability, learning disorder, or attention-deficit/ hyperactivity disorder

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

U.S. Food and Drug Administration (FDA)
Initial approval occurred April 1, 2011 (K103595) for the Acciarent Tympanostomy Tube and Tympanostomy Tube Delivery System (Acclarent, Inc., USA, now Tusker Medical Inc.). Several related approvals occurred since then including but not limited to:

- June 16 2011 (K110636 Tula™ Iontophoresis System , Acclarent, Inc., USA)
- May 20, 2015 (K150453, Tula Iontophoresis System with Earset, Acclarent, Inc., USA)
- June 28, 2017 (K171239, TULA Tube Delivery System, Tusker Medical, USA)

On November 25, 2019, Tula® System (Tusker Medical Inc., USA) received PMA approval (P190016):

- Device Description: The Tula® System is a combination product that consists of an Iontophoresis System (IPS), a Tube Delivery System (TDS), and a lidocaine hydrochloride 2% and epinephrine 1:100,000 (0.01 mg/mL) otic iontophoretic drug solution (TYMBION) to be used with the IPS.
- Indications for Use:
  - Tula System: The Tula® System is intended to create a myringotomy and insert a tympanostomy tube using the Tula Tube Delivery System in pediatric (aged 6 months and older) and adult patients indicated to receive tympanostomy tubes. The Tula System is used to deliver a tympanostomy tube under local anesthesia induced using the Tula Iontophoresis System and TYMBION™, a combination of an amide local anesthetic and an alpha- and beta-adrenergic agonist.
  - TYMBION: TYMBION™, a combination of an amide local anesthetic and an alpha- and betaadrenergic agonist, is indicated for the induction of local anesthesia of the tympanic membrane via iontophoresis using the Tula® Iontophoresis System in pediatric (aged 6 months and older) and adult patients undergoing tympanostomy tube placement using the Tula Tube Delivery System.

Feb 1, 2024: The FDA approved modifications to the design of the Iontophoresis System (IPS) Earset and Tube Delivery System (TDS) components of the Tula System, collectively described as the next generation (Tula Gen 2).

The use of the Tula® System is CONTRAINDICATED in the following patients:

- Cases in which the tympanic membrane is significantly atrophic, significantly retracted in the target location for tube delivery, or completely atelectatic.
- Patients presenting with tympanic membrane (TM) perforation(s). It is recommended that otoscopy and tympanometry be used in the assessment of the TM.
- Active or recent conditions of the tympanic membrane (e.g., prior myringotomy with incomplete wound healing or re-epithelialization)
- Hemotympanum or other suspicion of aberrant vasculature (e.g., carotid artery; high riding jugular bulb, vascular tumors) impacting the tympanic membrane or middle ear.
- Patients presenting with lacerations/abrasions to the external auditory canal.
- Patients presenting with dimeric or monomeric tympanic membrane.

- Presence of otitis externa.
- Patients with electrically sensitive medical support systems (e.g., pacemakers, defibrillators, cochlear implants).
- Patients with a history of sensitivity or allergic reaction to lidocaine hydrochloride (HCl), tetracaine, epinephrine, or any hypersensitivity to local anesthetics of the amide type, or any component of the anesthetic drug formulation.
- Patients with a familial history of insensitivity to lidocaine or other local anesthetics.
- Anatomical or visualization reasons preventing tympanostomy tube placement in the anterior half of the tympanic membrane.

Literature Review
FDA approval was primarily based upon the Tusker Medical 'OTTER' clinical trial (in-Office Tympanostomy Tube placEment in childRen; NCT03323736; Lustig, et al., 2020). The study established a reasonable assurance of safety and effectiveness of the Tula® System for the placement of tympanostomy tubes in unsedated and unrestrained children in a physician office setting. The OTTER study was a prospective, single-arm, multi-center, non-randomized study in pediatric subjects undergoing tympanostomy tube placement. There were 18 investigational sites.

Each investigator was required to treat a minimum of two 'OR Lead-In' subjects under general anesthesia using the tube delivery system (TDS) alone without iontophoresis. Following completion of the OR procedures, each investigator was required to treat a minimum of two 'Office Lead-In' subjects undergoing tympanostomy tube placement under local anesthesia using the tube delivery system (TDS) and iontophoresis system (IPS) with TYMBION™. Upon completion of the OR and Office subjects, investigators were permitted to begin treating subjects to obtain study findings (the Pivotal Cohort). Exclusion criteria included behavioral intolerance.

The studied 'Pivotal' cohort included 222 pediatric individuals (N=120 < age 5 years, N=102 age 5-12 years).

Technology explanation: An iontophoresis system (IPS) together with an iontophoretic otic anesthesia solution were used to provide local anesthesia to the tympanic membrane (TM), and a tube delivery system (TDS) was used to rapidly create the myringotomy and deliver the tube.

The TM was anesthetized using the IPS and an iontophoretic otic solution (TYMBION™) consisting of 2% lidocaine HCl and 1:100,000 epinephrine (Tusker Medical, Menlo Park, CA), henceforth referred to collectively as IPS. The IPS accelerates tissue uptake of the local anesthetic using a submilliamp electrical current that mobilizes ions of lidocaine and epinephrine achieving local anesthesia of the TM in approximately 10 minutes (unilateral or simultaneous bilateral). The IPS system includes specialized earplugs that maintain the otic solution in the ear canal during the iontophoresis process.

Once the TM was anesthetized, the lidocaine and epinephrine solution was drained from the ear canal by gravity or wicking, and TTs were placed using the TDS (Tusker Medical). The TDS automates myringotomy and tube placement. Upon device actuation, an incision is created, and the tube is placed in <500 milliseconds. The myringotomy blade is recessed within the device except for a brief exposure during myringotomy creation.

Results: Twelve patients treated in-office were determined to have inadequate anesthesia for tube placement in one or both ears following iontophoresis. Tubes were successfully placed in all indicated ears in 85.8% (103/120) of children <5 and 89.2% (91/102) of children 5 to 12 years old. Patients 5 to 12 years old self-reported tube placement pain using the Faces Pain Scale–Revised (FPS-R) instrument, which ranges from 0 (no pain) to 10 (very much pain). Mean FPS-R score was 3.30 (mild range) (standard deviation [SD] = 3.39) for tube placement and 1.69 (SD =

2.43) at 5 minutes post-procedure. There were no serious AEs in any study cohorts that were associated with the study devices, drug, or procedure. Nonserious adverse events occurred at rates similar to standard tympanostomy procedures. Study limitations included only 3 week post-procedure follow-up and exclusion criteria of 'behavioral intolerance' (Lustig, et al., 2020).

Waldman et al. (2023) reported results on the above (Lustig, et al., 2020) patient cohort (mean follow-up was 14.3 months). Patients were followed for 2 years or until tube extrusion, whichever occurred first. Patient compliance with protocol-required follow-up visits was 94.5% (189/200) in the OR Lead-In and 92.3% (930/1008) in the In-Office cohorts.

- Tube retention: At the 3-week visit, 99.7% of tubes were present across the TM, with 91.7% at 6 months, 67.1% at 12 months, 39.1% at 18 months, and 22.7% at 24 months for all subjects. In a small number of patients, a tube was removed by the physician. Six patients (9 ears) had tubes removed due to a history of infection or tube occlusion, and 5 patients (5 ears) had a tube removed and replaced during a subsequent tube placement procedure for the contralateral ear.
- Time to Extrusion: The estimated median and mean times to tube extrusion for the combined OR and In-Office cohorts were 15.82 and 16.79 months, respectively. When removed tubes were included in the analysis, the estimated median and mean times to tube extrusion or removal were 15.77 and 16.72 months, respectively.
- Sequelae included ongoing perforation for 1.9% of ears (11/580) and medial tube displacement for 0.2% (1/580) observed at 18 months. Over a mean follow-up of 14.3 months, 30.3% (176/580) of ears had otorrhea and 14.3% (83/580) had occluded tubes.

The authors concluded that in-office placement of tubes using the Tula System results in rates of tube retention and patency within the ranges described for similar short term tympanostomy tubes. Complications were of a type and rate consistent with expectations for tube placement via traditional methods in the OR (Waldman, et al., 2023).

Cohen 2022 reported a sub-analysis from the above (Lustig, et al., 2020) patient cohort. Behavioral strategies were used to minimize procedural distress. Anxiolytics, sedation, or papoose board were not used. Face, legs, activity, cry, consolability (FLACC) behavior observational rating scale to quantify children's distress. Mean tube placement FLACC score was 4.0 (out of a maximum score of 10) for children ages 6 months to 4 years and was 0.4 for children age 5–12 years. Mean FLACC score 3-min post-tube placement was 1.3 for children ages 6 months to 4 years and was 0.2 for children age 5 12 years. FLACC scores were inversely correlated with age, with older children displaying lower distress.

Professional Societies/Organizations
The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) has published several recent related articles:

- Position Statement: In-office Placement of Tubes in Pediatric Patients While Awake (2019) The statement says "The position of the AAO-HNS is that tympanostomy tubes are safe and effective for managing otitis media in children who meet current guidelines for tube insertion [Rosenfeld, 2013]. Although insertion of tympanostomy tubes in children is generally accomplished in the operating room under general anesthesia, insertion in the clinic in appropriately selected patients using shared decision making between clinicians and families can be appropriate" (Adopted 7/09/2019).

- Clinical Practice Guideline: Tympanostomy Tubes in Children (Update) (Rosenfeld 2022a) This update does not include any recommendations regarding office insertion of tubes in children without general anesthesia.

The group consensus was that the quality and breadth of published research (November 2020) was insufficient to facilitate evidence-based recommendations on in-office tube insertion.
Readers are referred to a 'Companion Article' that is a 'State of the Art' Review.

- State of the Art Review: The existing literature is too sparse to make recommendations about procedure setting and optimal technique or assess long-term outcomes. The role of automated devices is uncertain, given the increased equipment cost and limited information on characteristics of the proprietary preloaded tubes, including intubation duration and rates of otorrhea, obstruction, medialization, granulation tissue, and persistent perforation (Rosenfeld 2022b).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No Determination found.	
LCD		No Determination found.	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

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

CPT®* Codes	Description
0583T	Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia

References

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11. Waldman EH, Ingram A, Vidrine DM, Gould AR, Zeiders JW, et al. Two-Year Outcomes After Pediatric In-Office Tympanostomy Using Lidocaine/Epinephrine Iontophoresis and an Automated Tube Delivery System. Otolaryngol Head Neck Surg. 2023 Apr 1. doi: 10.1002/ohn.336. Epub ahead of print.

12. Yen DM, Murray MT, Puchalski R, Gould AR, Ansley J, et al. In-Office Tympanostomy Tube Placement Using Iontophoresis and Automated Tube Delivery Systems. OTO Open. 2020 Feb 24;4(1):2473974X20903125.

13. Zeiders JW, Syms CA, Mitskavich MT, Yen DM, Harfe DT, et al. Tympanostomy tube placement in awake, unrestrained pediatric patients: A prospective, multicenter study. Int J Pediatr Otorhinolaryngol. 2015 Dec;79(12):2416-23.

Revision Details

Type of Revision	Summary of Changes	Date

Annual Review	• No clinical policy statement changes.	7/15/2024