Prior Authorization Review Panel
MCO Policy Submission

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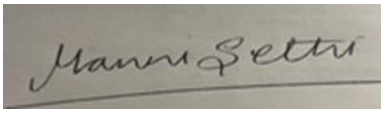
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 7/1/2026
Policy Number: CCP.1558	Effective Date: 7/1/2026 Revision Date:
Policy Name: Tympanostomy tube delivery systems	

Type of Submission:

☒ New Policy	☒ Prior Authorization Policy
☐ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☐ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Tympanostomy tube delivery systems

Clinical Policy ID: CCP.1558

Recent review date: 6/2026

Next review date: 10/2027

Policy contains: Tympanostomy tube delivery systems, automated tympanostomy tube placement, automated tube delivery systems, Tula system, iontophoresis-assisted tympanostomy

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Fully automated tympanostomy tube placement systems, including automated tube delivery systems, iontophoresis-assisted tympanostomy tube delivery systems, the Tula® System (Tusker Medical/Smith & Nephew) are investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Tympanostomy tube delivery systems are technologies intended to facilitate tympanostomy tube placement in an office or other lower-acuity setting. These systems are used in the clinical context of individuals who otherwise meet accepted indications for tympanostomy tube insertion, including recurrent acute otitis media or chronic otitis media with effusion when tube placement is clinically considered. Standard pediatric tube placement has generally been performed in an operating room under general anesthesia, while office-based placement attempts to move selected procedures to a setting that avoids operating room scheduling, preprocedure fasting, anesthetic recovery, and facility or anesthesia charges (Rosenfeld, 2022a; Rosenfeld, 2022b).

Fully automated tympanostomy tube placement systems combine several procedural steps that are traditionally performed separately. The Tula system is the main fully automated platform described in the evidence base. It uses iontophoresis to deliver lidocaine and epinephrine to the tympanic membrane and an automated device that creates a myringotomy and delivers a preloaded tympanostomy tube. For purposes of this policy, fully automated systems include technologies described in relation to Current Procedural Terminology code 0583T. The Tula system received Premarket Approval (PMA P190016) from the Food and Drug Administration on November 25, 2019, following a Breakthrough Device designation received in February 2019; the original PMA holder was Tusker Medical, Inc., which was subsequently acquired by Smith \u0026 Nephew in January 2020. The Breakthrough Device designation reflects FDA's finding that no cleared or approved alternatives were available at the time of review, not that comparative clinical effectiveness was established. The Hummingbird Tympanostomy Tube System (Preceptis Medical) received 510(k) clearance for children 6 to 24 months and subsequently received expanded indication clearance (K221254) in July 2022 for patients 6 months and older. The Solo+ device received expanded indication clearance (K250256) in June 2025 for patients 6 months and older; prior clearance (K232702) had been limited to the 6-to-24-month age range (Waldman, 2023).

Non-fully automated tympanostomy tube delivery devices include single-pass or single-step handheld platforms that consolidate myringotomy and tube placement but retain more direct operator control. Published examples include the Hummingbird Tympanostomy Tube System and the Solo+ device. These platforms may use topical anesthesia, protective stabilization, moderate sedation, or operating room placement depending on the protocol. Manual in-office tube insertion without a proprietary delivery device is a related but distinct approach (Cofer, 2017; Giroux, 2025; McCormick, 2025; Truitt, 2021).

Office-based tube delivery systems are intended to address technical barriers to awake tympanostomy, including tympanic membrane pain, child movement, limited cooperation, and the need for rapid tube placement. The potential advantages depend on appropriate individual selection, adequate visualization, reliable local anesthesia, procedural stabilization when used, and the ability to confirm tube placement and function. The systems vary by anesthesia method, degree of automation, need for restraint or sedation, proprietary tube design, and operator workflow (Rosenfeld, 2022b).

A 2022 American Academy of Otolaryngology-Head and Neck Surgery clinical practice guideline for tympanostomy tubes in children addresses candidacy, perioperative education, management of otorrhea, and postplacement follow-up, but it does not provide device-specific recommendations for automated or non-fully automated tube delivery systems. The American Academy of Otolaryngology-Head and Neck Surgery guideline recommends examination of the ears within three months after tube insertion and routine periodic follow-up until tube extrusion, which is relevant regardless of delivery approach (Rosenfeld, 2022a).

Findings

The evidence base for tympanostomy tube delivery systems is composed primarily of prospective single-arm studies, protocol implementation reports, small regulatory studies, and a systematic review limited by heterogeneous and overlapping observational studies. Randomized trials comparing fully automated or non-fully automated delivery systems with standard operating room tympanostomy were not identified. Evidence is also limited for outcomes that matter after the procedure, including hearing, infection recurrence, quality of life, repeat tube placement, and durability across routine practice environments.

Clinical effectiveness

The clinical evidence has not established whether fully automated or non-fully automated tympanostomy tube delivery systems improve health outcomes compared with conventional tympanostomy tube placement. Most studies evaluated technical success, tolerability, tube retention, patency, and adverse events rather than hearing outcomes, infection frequency, antibiotic use, quality of life, or need for repeat tube placement. The American Academy of Otolaryngology-Head and Neck Surgery guideline supports tube placement for selected children based on standard clinical indications, but it does not endorse a specific delivery platform or office-based technology (Clementi, 2025; Rosenfeld, 2022a; Rosenfeld, 2022b). Separately, a randomized controlled trial in 250 children aged 6 to 35 months with recurrent acute otitis media found that the rate of acute otitis media episodes per child-year over a 2-year period was not significantly lower in the tympanostomy tube group compared with episodic antibiotic management (1.48 vs. 1.56; P\u00a0=\u00a00.66), providing important context about the clinical benefit of tube placement irrespective of delivery method (Hoberman, 2021).

The strongest device-specific durability evidence is for the fully automated Tula system, but the main studies were prospective, single-arm, and industry-supported. Evidence for the Hummingbird single-pass device includes larger office-based pediatric cohorts with short-term procedural outcomes. Evidence for Solo+ is limited by small sample size and use under general anesthesia rather than office-based topical anesthesia. Manual in-office placement studies provide contextual evidence for office feasibility, but they do not evaluate a proprietary delivery system (Giroux, 2025; Lustig, 2020; McCormick, 2025; Truitt, 2021; Waldman, 2023).

Procedural success and feasibility

Across pediatric studies of automated or single-pass systems, the systematic review reported an average procedural success rate of 91%, with study-level rates ranging from 87% to 98%. Escalation to operating room placement occurred in 3.2% of participants in the published literature, although this may underestimate the burden when studies do not fully report outcomes after unsuccessful office placement (Clementi, 2025).

Fully automated office placement with the Tula system achieved placement in all indicated ears in 85.8% of younger children and 89.2% of children aged five to 12 years in the pivotal cohort. The Hummingbird single-pass office study reported completion in 98.7% of children, with three children rescheduled for operating room placement because of anatomy or movement. The earlier single-pass moderate sedation study completed placement without conversion to general anesthesia in 88.3% of children, while all tube placements were ultimately completed. Solo+ placement under general anesthesia was successful in 96.6% of ears, but 22% required additional instrumentation, and the study did not test office placement without general anesthesia (Cofer, 2017; Lustig, 2020; McCormick, 2025; Truitt, 2021).

Safety and adverse events

The systematic review found that intraprocedural complications occurred in 8.2% of participants in the literature. Excessive movement or behavioral intolerance accounted for 56% of reported intraprocedural complications in published studies, while inadequate anesthesia was the leading issue in the Manufacturer and User Facility Device Experience database. These findings are clinically relevant because both fully automated and non-fully automated delivery systems depend on stable visualization and rapid completion in awake or lightly sedated individuals (Clementi, 2025).

Postprocedural complications in the systematic review included short-term and long-term events. Tube occlusion and reluctance to undergo ear examinations were the most frequent short-term events, while otitis media with otorrhea and otitis media were the most frequent longer-term events. The review noted that tube occlusion appeared broadly comparable with historical estimates for conventional tubes, but it also identified procedural distress and reluctance to undergo later ear examination as concerns that may be specific to office-based awake placement, particularly when restraint is used (Clementi, 2025).

In the two-year Tula follow-up, no serious device-, drug-, or procedure-related adverse events were reported. Over a mean follow-up of 14.3 months, otorrhea occurred in 30.3% of ears, tube occlusion in 14.3%, ongoing tympanic membrane perforation at study exit in 1.9%, and medial tube displacement in 0.2%. Waldman and colleagues characterized these rates as generally consistent with traditional tympanostomy tube sequelae, but interpretation is limited by single-arm design, differential follow-up duration across cohorts, and industry sponsorship; no external comparator group was included (Waldman, 2023).

For the Hummingbird single-pass office study, two minor adverse events were reported in one participant, and independent video review judged procedures acceptable in the sampled young children. A later tolerability substudy found concordance among expert video review, staff assessment, and caregiver survey, but the scale used was not validated and the sample included only 30 children. These results address immediate tolerability more than longer-term safety or effectiveness (Cofer, 2024; Truitt, 2021).

Anesthesia considerations

The main rationale for office-based delivery systems is avoidance of general anesthesia and operating room recovery in selected individuals. In December 2016, the Food and Drug Administration issued a drug safety communication warning that repeated or lengthy exposure to general anesthetic and sedation drugs in children younger than three years may negatively affect brain development, and in April 2017, FDA approved label changes across the class to reflect this concern (FDA, 2017). The Rosenfeld 2022b perspective on office tympanostomy noted that this regulatory concern has driven interest in anesthesia-avoidance alternatives, but it also stated that there is no convincing evidence that a single brief general anesthetic exposure for tympanostomy tube insertion causes significant neurotoxicity or developmental sequelae. The potential anesthesia-avoidance rationale is therefore most clinically relevant for individuals with prior multiple or prolonged anesthetic exposures, when office placement is acceptable to the clinician and family (FDA, 2017; Rosenfeld, 2022b).

Anesthesia and stabilization methods differ substantially across technologies. The Tula studies used lidocaine and epinephrine iontophoresis with automated myringotomy and tube delivery, without sedation, anxiolytics, or papoose restraint in the pediatric office cohort. Hummingbird office placement generally used topical phenol and protective restraint, while the earlier single-pass study used oral midazolam, nitrous oxide, topical phenol, and possible conversion to general anesthesia. These differences limit comparisons across systems and make code-level conclusions difficult (Cofer, 2017; Lustig, 2020; Truitt, 2021).

Durability and follow-up outcomes

The most complete durability data are for the Tula system. In the two-year follow-up study, estimated median time to tube extrusion was 15.82 months, 95% confidence interval 15.41 to 19.05, and estimated mean time was 16.79 months, 95% confidence interval 16.16 to 17.42. Tube retention across all cohorts was 99.7% at three

weeks, 91.7% at six months, 67.1% at 12 months, 39.1% at 18 months, and 22.7% at 24 months. These data describe tube performance, not comparative clinical effectiveness (Waldman, 2023).

Evidence for non-fully automated devices is less mature. The Hummingbird studies focused mainly on office completion, short-term procedural tolerability, and early adverse events. The Solo+ study reported 12-month interim tube function and extrusion after placement under general anesthesia, but it did not evaluate the intended office-based topical anesthesia setting. Guideline-based follow-up remains important for all systems because tube obstruction, early extrusion, otorrhea, medialization, perforation, and retained tubes may require detection and management after placement (McCormick, 2025; Rosenfeld, 2022a; Truitt, 2021).

References

On 5/2026 we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were: Automated tympanostomy tube delivery systems We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Waldman EH, Ingram A, Vidrine DM, Gould AR, Zeiders JW, Ow RA, et al. Two-year outcomes after pediatric in-office tympanostomy using lidocaine/epinephrine iontophoresis and an automated tube delivery system. *Otolaryngology-Head and Neck Surgery*. 2023;169(3):692-700. Doi:10.1002/ohn.336.

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Policy updates

Initial review date: 5/2026 and clinical policy effective date: 6/2026

6/2026: Policy created.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1558. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
0583T	Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia