Smith+Nephew

# Comprehensive Reimbursement Billing Guide
# Tula Procedure

Tula®
Tympanostomy System

## This guide provides coding and reimbursement information for physicians performing the Tula procedure using the Tula System

This guide provides general coding and billing information for the in-office use of the Tula System. The Tula System enables placement of tympanostomy tubes under local anesthesia and consists of the Tula Iontophoresis System (IPS), the Tube Delivery System (TDS), and TYMBION™ (lidocaine hydrochloride and epinephrine otic iontophoretic drug).[1]

This guide consists of two sections: (1) a coding and billing guide for the Tula System, and (2) frequently asked questions (FAQs). This document is intended to share coding and reimbursement information to help physician practices determine how to appropriately and accurately code and bill for the Tula procedure.

In-office tympanostomy using the Tula System has a designated Category III CPT® code, 0583T — *Tympanostomy (requiring insertion of a ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia.*[2] The shorthand for 0583T, encompassing the Tula System and the physician procedural elements, is the Tula procedure.

## Common Coding Options for the Tula procedure

The Tula procedure has a designated Category III CPT Code, 0583T, *Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia.* Because Category III codes are used for new procedures and do not have standardized payment, it is important to provide enough detail to demonstrate medical necessity and substantiate the charges. This section outlines common coding options for the Tula procedure that may provide that additional detail.

0583T is a unilateral code. If the procedure is performed bilaterally, report 0583T with modifier 50. Do not report 0583T with 69209, 69210, 69420, 69421, 69433, 69436, 69990, 92504, or 97033.[3] These codes represent services that are either bundled or otherwise excluded from separate billing at the same time as the Tula procedure.

**Common ICD-10 Codes[4]**

This table includes common diagnosis codes that may be billed in conjunction with the Tula procedure.

| ICD-10 | Code Description |
|---|---|
| H65.21 | Chronic serous otitis media, right ear |
| H65.22 | Chronic serous otitis media, left ear |
| H65.23 | Chronic serous otitis media, bilateral |
| H65.31 | Chronic mucoid otitis media, right ear |
| H65.32 | Chronic mucoid otitis media, left ear |
| H65.33 | Chronic mucoid otitis media, bilateral |
| H66.04 | Acute suppurative otitis media without spontaneous rupture of ear drum recurrent, right ear |
| H66.05 | Acute suppurative otitis media without spontaneous rupture of ear drum recurrent, left ear |
| H66.006 | Acute suppurative otitis media without spontaneous rupture of ear drum recurrent, bilateral |
| H66.014 | Acute suppurative otitis media with spontaneous rupture of ear drum recurrent, right ear |
| H66.015 | Acute suppurative otitis media with spontaneous rupture of ear drum recurrent, left ear |
| H66.016 | Acute suppurative otitis media with spontaneous rupture of ear drum recurrent, bilateral |

### Modifiers

CPT® Code Modifiers are two-digit numbers, two-character modifiers, or alpha numeric indicators. Modifiers provide additional information to payers to appropriately describe the services rendered.[5] Complete lists of CPT Code Modifiers are available in the AMA/CPT book and online on the Medicare website.

Some examples of modifiers that might be applicable:

| CPT/HCPCS Modifier Options | |
|---|---|
| **Modifier** | **Description** |
| -50 | Bilateral Procedure |
| -59 | Distinct Procedural Service |
| -LT | Left Side. Used to identify procedures performed on the left side of the body |
| -RT | Right Side. Used to identify procedures performed on the right side of the body |

## Crosswalk Coding Options

Crosswalk codes are Category I CPT codes that can be referenced when submitting a claim for a given Category III CPT code. Since Category III CPT codes do not have embedded physician work and practice expense values, representative Category I CPT codes can serve as helpful proxies (i.e., "crosswalks") to characterize the work and practice expense associated with performing the Tula® procedure. Physician work can be quantified in terms of time and intensity.

- **Time**: The time the physician spends with the patient on the day of the procedure before, during, and after the procedure is completed
- **Intensity**: Comprised of three intensity/complexity measures:
  - The mental effort and judgment necessary with respect to the amount of clinical data that needs to be considered, the amount of knowledge required, the range of possible decisions, the number of factors considered in making a decision, and the degree of complexity of the interaction of these factors.
  - The technical skill required with respect to knowledge, training, and actual experience necessary to perform the service and physical effort involved to perform the service.
  - Psychological stress related to pressure involved when the outcome is heavily dependent upon skill and judgment and an adverse outcome has serious consequences.

Practice expense includes general overhead costs and specific expenses incurred in performing the procedure, including:

- Clinical staff time
- Equipment
- Supplies

Note that the costs of the Tula System used for a procedure are not included in the crosswalk codes. All Tula System related expenses will need to be separately identified on the claim.

## Selecting a potential crosswalk code for the Tula® procedure

McDermott+Consulting, LLC ("McDermottPlus"), an experienced consulting firm that specializes in reimbursement and coding for new technologies, conducted detailed interviews with physicians familiar with the Tula procedure. McDermottPlus used the interviews to identify ENT codes with established values that may be used as procedural comparisons to the Tula procedure in terms of procedure time, intensity and other relevant factors.

The Tula procedure (0583T) is a new procedure that has not been formally valued. The codes below have been identified by McDermottPlus as potential crosswalk codes that are familiar to otolaryngologists and can be compared to the Tula procedure in terms of physician work and practice expense. Physicians submitting claims for the Tula procedure should use their judgment in selecting a crosswalk code and may reference codes other than those listed below.

The potential crosswalk code options listed below are intended to provide insurers with an estimate for the cost of 1) the physician effort and 2) the practice expense. The values assigned to the identified codes on their own will not reimburse the full cost of the Tula System because the crosswalk options do not include an appropriate value for the cost of the Tula System. Practices need to include a charge to cover the supply cost for the Tula System used in the procedure and may need to provide appropriate supporting documentation to substantiate the amount.

| Potential Crosswalk Category I CPT®[6] Codes | | RVUs[7] | | Medicare 2020 National Average Payment[8] | |
|---|---|---|---|---|---|
| | | Office | Facility | Office | Facility |
| 30140 | Submucous resection inferior turbinate, partial or complete, any method | 8.08 | 5.11 | $291.60 | $184.42 |
| 31238 | Nasal/sinus endoscopy, surgical; with control of nasal hemorrhage | 7.11 | 4.77 | $256.60 | $172.15 |
| 31254 | Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior) | 11.99 | 6.98 | $432.71 | $251.91 |
| 69610 | Tympanic membrane repair, with or without site preparation of perforation for closure, with or without patch | 10.75 | 8.24 | $387.96 | $297.38 |
| 69801 | Labyrinthotomy, with perfusion of vestibuloactive drug(s), trans canal | 6.05 | 3.55 | $218.34 | $128.12 |

**Important Notes: The Medicare payment amounts listed do not reflect adjustments for deductible, copayments, coinsurance, sequestration or any other reductions. All payment amounts listed are based on national averages and will vary by geographical locations. Practices should review their contracts and negotiated rates for each of their Commercial insurers to determine what their appropriate reimbursement will be.**

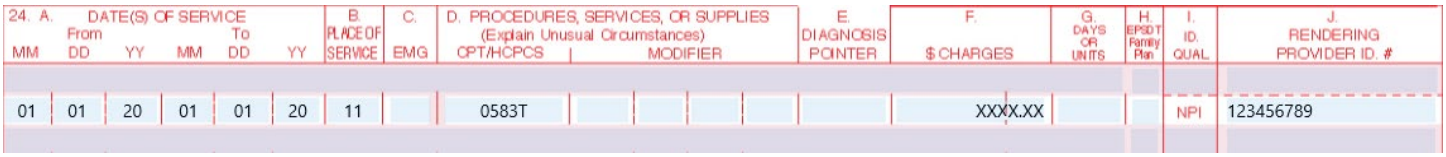
## Billing and Claims Adjudication

### Pre-Service Review

Providers should verify commercial payer requirements regarding benefit investigation, pre-determination, and prior authorization. Some payers may not require pre-determination or prior authorization for codes describing the Tula procedure but may conduct a medical review at the time of claims processing. Providers should be prepared to furnish medical records and other relevant documents that support the medical necessity of the Tula procedure for the patient in question.

### Billing and Coverage

Payers may not have established reimbursement rates for the Tula® procedure. A Category III CPT® code should be reported using the standard CMS-1500 form. The total billed charges should be entered in Item **24F** of the form.



| 24. A. DATE(S) OF SERVICE From MM | DD | YY | To MM | DD | YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. # |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 01 | 01 | 20 | 01 | 01 | 20 | 11 | | 0583T | | | XXXX.XX | | | NPI | 123456789 |

Figure 1. Sample CMS-1500 form[9]

To support the charges listed, a cover letter should be attached to the form. For a complete sample cover letter, see **page 7**.

Attach the operative note and office notes. Submitting medical documentation with claims along with invoices for the cost of supplies (including the Tula System) may help support the medical necessity determination for the service and substantiates the level of work and expenses necessary to complete the procedure.

### Global Periods and Post-Operative Follow-up Visits

Category III CPT codes (e.g., 0583T) do not have associated post-procedure global periods, so any subsequent follow-up visits or services may be billed independently from the initial procedure.[10] Examples of CPT codes that may be used to bill for post-operative follow-up visits may include the following options:

### Possible Codes for the Tula Procedure Follow-up Visits

| CPT Code[11] | Description |
|---|---|
| 99212 | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family. |
| 99213 | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family. |
| 99214 | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family. |
| 99215 | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family. |

# Frequently Asked Questions

## 1. What code should I use for the Tula® procedure and how should I properly bill for the procedure?

The Tula procedure has a designated Category III CPT® code, 0583T. Because Category III codes are used for new procedures and do not have standardized payment, it is important to provide enough detail to demonstrate medical necessity and substantiate the charges. In addition to the standard claim information, practices submitting a claim for 0583T should include a cover letter or detailed special report/claim letter explaining the medical necessity, the reason for using the Tula procedure, invoices for the costs of supplies, including the Tula System, and an explanation of the billed charges, as well as relevant documentation such as, operative notes, office notes, test results, and any other relevant documentation of the procedure. A sample cover letter can be seen on page 7.

## 2. What is a category III code and how do payers reimburse physicians for these codes?

Category III CPT codes are temporary codes that represent new and emerging technologies, procedures, and services. The AMA/CPT Editorial Panel has established the Category III code process to aid in data collection and the potential future valuation of new Category I procedures.

Typically, there is no fee schedule amount associated with Category III codes. Payers may determine payment amounts for Category III CPT codes on a claim-by-claim basis based on the description of the procedure, documentation of the time and complexity of the work, crosswalk codes provided by the physician, relevant practice expenses such as devices and disposable supplies and equipment required for the procedure, the provider's billed charges, and the provider's contract with the payer.

## 3. Why isn't an existing Category I code appropriate for use?

Category I tympanostomy codes, 69433 (under local anesthesia) and 69436 (under general anesthesia), do not adequately describe the procedural elements associated with the Tula procedure. The Tula procedure involves different procedural time, intensity, and procedural steps. CPT I 69433 (Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia)[12] involves different procedural elements and has significantly lower practice expenses than the Tula procedure. CPT I 69436 (Tympanostomy (requiring insertion of ventilating tube), general anesthesia)[13] does not describe the Tula System's local anesthesia approach and that code cannot be billed when the procedure is performed in an office setting. CPT codes 69433 and 69436 do not have appropriate Relative Value Units (RVUs) assigned to incorporate the cost of all elements of the Tula procedure.

## 4. How should a practice bill appropriately for the Tula procedure?

A practice will need to determine a single charge that includes all elements, such as the physician component, practice expenses, malpractice insurance, and the Tula System costs.

Physicians should propose a crosswalk to a Category I CPT code that is consistent with the Tula procedure in physician work and practice expense (not including the cost of the Tula System). Identifying a reference procedure may provide the payer with a eference amount for the Tula procedure.

Documentation to support the relationship between the Tula procedure and the proposed crosswalk code is critical and should include at a minimum:

- A cover letter that details the relationship between a crosswalk code and the Tula procedure to determine the fee charged.
- An operative report to provide a description of the procedure, and other relevant clinical documentation of illness, tests, and treatment to support medical necessity.

It is important to point out that comparator Category I CPT codes will not include the practice expense cost of the Tula System. Physicians and their billers will need to address the Tula System cost on their claim and provide documentation to support the associated charges.

## 5. How do I identity a Category I CPT® code similar to the Tula® procedure Category III CPT code (0583T)?

The "Potential Crosswalk Category I CPT Codes" table on page 3 references Category I CPT codes that may have physician work and practice expense similarities to the Tula procedure, billed using Category III CPT 0583T. When cross-walking to a CPT code, it is important to explain how the procedures are similar or different. In choosing an appropriate crosswalk code, practices should consider the following:

- **Work**: the amount of time it takes to perform the service, and three intensity measures: the technical skill and physical effort, mental effort and judgment, and stress and risk of the procedure.
- **Practice expense**: non-physician clinical labor, supplies, and equipment directly involved with furnishing the procedure, plus general overhead expenses allocated based upon the specialties that perform the service.
- **Tula System costs**: To get appropriate reimbursement for 0583T, it is critical to include the appropriate charges for the Tula System components used in the procedure.

## 6. How will commercial insurance reimburse the Tula procedure?

Payment is likely to vary from payer to payer and claim by claim. Because Category III CPT codes do not have assigned values, these claims will be adjudicated and assessed individually. Commercial payers use a variety of reimbursement methodologies and guidelines to reimburse physician services. Possible methods include but are not limited to payment based on established fee schedules, such as the Medicare Physician Fee Schedule (MPFS), or payment based on charges, such as a set percentage of the billed charges.

Payment methodologies vary from payer to payer, and the above are only a few examples of how payment may be determined for a claim. Providers should contact the specific payer in question with any payment-related inquiries.

## 7. What can practices do to support patient access to the Tula procedure?

Practices should make sure that patients meet the criteria for medical necessity, provide a cover letter with the claim, and include all relevant documentation.

## 8. How will contracts between practices and insurers affect reimbursement for the Tula procedure?

Commercial payers and physician practices negotiate contracts to set procedure payment. Contracts may contain language for specific procedures or CPT codes. Contracts may also have language addressing payment for Category III CPT codes. For example, a contract may state that the provider agrees to accept a specific percentage of billed charges for a Category III CPT code or that the payer will accept the physician's reasonable and customary charges for a code. Commercial payers typically have a specific provider relations contact assigned to a physician's office or the surgical facility, who can discuss the provider's specific contract in detail if there are questions about what the contract does and does not cover, or specific payment terms involved. We recommend that you connect with the Health Plan's provider relations contact with any questions about your contract with that specific Health Plan.

## 9. What is best practice for receiving appropriate reimbursement for the Tula procedure?

We recommend that practices set charge amounts that adequately reflect the work, complexity, resources required to provide the service, and associated costs for the Tula System and any other supplies used during the Tula procedure. Providers should contact their patients' commercial insurers to understand a payer's policy on in-office tympanostomy procedures and any special instruction for claims submission. Specific network contract terms may dictate reimbursement amounts; therefore, we recommend discussing **any existing contracts** with the payer's provider relations contact before submitting any claims.

# Sample Cover Letter to Support Tula® Claims Submission

The following sample cover letter may be used to create the "crosswalk" code validation. All providers should modify the sample and include case specific language and description of actual procedures performed. The sample cover letter shows one example of how to construct a clear and concise explanation of the procedure performed and include the necessary details to illustrate how to document the complexities and skill set needed to perform the procedure.

**[cover letter: site letterhead]**

**[date]**

**[name of insurance company]**

RE: **[patient name]**
**[insurance policy number]**
**[date of service]**

Dear:

On **[date of service]**, I performed a tympanostomy (requiring insertion of a ventilating tube), using the Tula Iontophoresis System (IPS), TYMBION™ (lidocaine hydrochloride and epinephrine otic iontophoretic drug), and the automated Tula Tube Delivery System (TDS). This procedure has a Category III CPT® code, 0583T.

The patient **[patient name, first and last]** was diagnosed with **[insert primary diagnosis, include ICD-10 and description]** and has been experiencing the following symptoms: **[include the patient's symptoms that support the basis for the treatment]**.

**[Describe the patient's medical history, current and previous medications taken, if any, and labs or tests done that support the use of the Tula procedure]**.

This procedure can be compared to Category I CPT code **[insert crosswalked Category I CPT code number and description]** in terms of physician work and practice expense.

The Tula procedure, in my professional opinion, **[detail here time and intensity elements that make the Tula procedure more or less or the same physician work than the crosswalked Category I CPT code. Express any differences in time and intensity as percentages compared to the crosswalked code]**.

I estimate that the fee for 0583T should be **[insert percentage higher or lower or the same]** as compared to **[insert crosswalked Category I CPT code number]** for the above reasons. There are also additional supply expenses of **[$_____]** for the Tula System, including the Tula Iontophoresis System (IPS), TYMBION (lidocaine hydrochloride and epinephrine otic iontophoretic drug), and the automated Tula Tube Delivery System (TDS).

My fee for **[insert crosswalked Category I CPT code number]** is **[$_____]**. Using the Category I cross walked fee, the difference in work (if any), and the Tula System supply costs, my fee for 0583T is **[$_____]**.

The patient's outcome was **[insert the specific details to explain the patient's outcome from the Tula procedure]**.

Please find attached copies of the operative report, other supporting documentation, and a claim for this patient.

Sincerely,

**[physician's name]**
**[practice name]**

## Tula® Claim Packet Checklist

To support the claim and procedure performed, we recommend that you consider including the following:

- ☐ Cover Letter or Detailed Special Report/Claim Letter used to outline the medical necessity of the procedure and create the "crosswalk" code validation
- ☐ Complete HCFA-1500 form, ensuring all pertinent fields are populated
- ☐ Medical history, prior treatment and outcomes, labs, testing, including supporting chart notes and other relevant documentation
- ☐ Attributable symptoms and/or patient characteristics that supports medical necessity for the procedure
- ☐ Operative note
- ☐ Procedural success and patient's outcome post-procedure
- ☐ Copy of manufacturer's invoice, or supply costs, to support total billed charges

## Claim Denial Appeal Process

When a third-party health plan denies a procedure per their medical policy guidelines or covers the procedure at a level that is less than the practice believes is appropriate, there is a process available within the health plan to appeal that decision. Insurance carriers are required to allow providers and patients the right to appeal the decision rendered by their health plan.[14] Each health plan will have its own appeals process and it can vary depending on the specific plan and applicable laws; however, there are necessary steps that can assist the provider in appealing the initial denial.

To present an effective appeal, follow these steps:

1. Carefully review the denial reason and understand the specific health plan's policy.
2. Write an appeal letter clearly addressing the specific denial reason.
3. Provide supporting information including medical and clinical documents and FDA approval letter; and
4. Submit the appeal on time

## Writing an Appeal Letter

When appealing a denial, the first step is often composing a letter to the health plan that initially reviewed the case. This letter is submitted by the provider on behalf of the patient, with the patient's approval, and should outline the reasons the denial should be overturned.

First, collect all the information required to support the appeal:

- ☐ Denial letter
- ☐ Health plan contracts and provider agreements
- ☐ Applicable medical policy guidelines from the health plan (note: insurance website(s) can be a good resource for general policy)
- ☐ Literature supporting the technology
- ☐ FDA approval letter
- ☐ Patient medical records (e.g., chart notes, labs, operative notes)

**In drafting an appeal letter, consider the following:**

- ☐ Did the reviewer miss information about the procedure?
- ☐ Did the reviewer overlook a case-specific detail?
- ☐ Does the health plan clearly understand the procedure?
- ☐ Was the information provided about the case correctly submitted?
- ☐ Review the plan's official policy online for more detailed understanding of the denial reason

**Be mindful of details, including:**

- ☐ Patient's name
- ☐ Subscriber's name
- ☐ Policy number
- ☐ Description of exact service denied
- ☐ Date denied

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. Contraindications include certain abnormal ear anatomy, sensitivity/allergy to lidocaine or other local anesthetics, and reliance on electrically sensitive medical implants such as a pacemaker. Risks may include, but are not limited to, inadequate local anesthesia, dizziness, and common tympanostomy procedure risks. For full prescribing information, see the Tula IFU and TYMBION Drug Package Insert at **www.tulatubes.com/IFU**. Rx only.

**Disclaimer**

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**References**

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