Description

Myringotomy and tympanostomy are related terms that are sometimes used interchangeably to describe an opening in the tympanic membrane. In this policy, the term myringotomy will be used to describe a temporary opening in the tympanic membrane without insertion of a pressure-equalizing tube (PET), while tympanostomy will be used to describe an opening in the tympanic membrane in conjunction with insertion of a PET. This categorization is consistent with the CPT coding of these 2 procedures.

Insertion of a PET is indicated for continuous middle ear aeration in patients with chronic otitis media with effusion (OME). It is estimated that some 27 million cases of otitis media occur each year, and that 1 million children undergo PET insertion each year, making this procedure the most frequently performed pediatric surgery requiring anesthesia. Nevertheless, since conventional PET requires general anesthesia, it is typically not considered unless multiple courses of antibiotics fail to clear the infection and resolve the effusion. Myringotomy alone is less frequently performed. Since a conventional incision typically closes up within 1 or 2 days it cannot be used for prolonged ventilation of the middle ear. Myringotomies can be used to acutely decompress the ear and thus relieve pain. In addition, aspiration of fluid can be used for diagnostic purposes to determine whether the fluid is sterile and, if not, to assess antibiotic sensitivities.

Recently, laser-assisted procedures have become available, not only to perform myringotomies, but also to perform tympanostomies with PET insertion. Laser-assisted procedures can be performed in the pediatrician’s office using only local anesthesia. For example, the tympanic membrane may be anesthetized using topical tetracaine. A video monitor is used to pinpoint the exact location for the hole, and the precise size of the hole is programmed into the computer. A
CO2 flash scanner laser requires one-tenth of a second to create a bloodless opening in the tympanic membrane. A PET tube may be inserted, if desired, under microscopic control. OtoLam® is a laser device approved by the U.S. Food and Drug Administration (FDA) that is intended to be used as a technique for performing myringotomies and tympanostomies. In addition, devices used for laser-assisted palatoplasty may be adapted for this use.

As a surgical tool, the laser-assisted approach is an alternative to conventional myringotomy and tympanostomy. However, the opening created by a laser-assisted myringotomy may remain patent for a longer period of time (3–4 weeks) compared to conventional myringotomies (several days). Thus a laser-assisted myringotomy, which may be referred to as laser-assisted tympanic membrane fenestration (LTMF), could be potentially considered an alternative to a conventional tympanostomy with PET insertion, a unique indication.

CO2 lasers specifically for the purposes of laser-assisted myringotomy and tympanostomy received FDA clearance in 1996 through the 510(k) process. According to the FDA summary of safety and effectiveness, these lasers are “are intended for soft tissue incision in ENT for the specific indication of myringotomy/tympanostomy.”

---

Policy

Laser-assisted tympanostomy with insertion of a pressure-equalizing tube (PET) may be considered medically necessary in patients with chronic otitis media who meet criteria for conventional insertion of a PET.

Laser-assisted myringotomy (without insertion of a PET) is considered not medically necessary as a treatment of acute otitis media.

Laser-assisted myringotomy (also called laser-assisted tympanic membrane fenestration or LTMF) is considered investigational as an alternative to tympanostomy with PET insertion.

---

Policy Guidelines

There is no specific CPT code for laser-assisted tympanostomy and myringotomy. The following CPT codes might be used:

69420: Myringotomy including aspiration and/or eustachian tube inflation.

69433: Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia

In 2004, the following HCPCS code was introduced that specifically describes laser-assisted myringotomy

S2225: Myringotomy, laser-assisted
Rationale

Chronic Otitis Media

A laser-assisted myringotomy (also called laser-assisted membrane fenestration or LTMF) is a unique procedure when it is considered an alternative to a conventional tympanostomy with tube insertion. Pressure-equalizing tubes (PETs) can provide aeration for 6–12 months, while the duration of laser-assisted myringotomies is not known, but will vary with the size of the fenestration spot. In addition, the minimal time of aeration leading to resolution of chronic otitis media, while also reducing the risk of recurrent disease, is not precisely known, and may be variable for different subgroups of patients. For example, children with upper airway obstruction caused by adenotonsillar hypertrophy may be incidentally found to have chronic otitis media; these patients may not require prolonged aeration. A controlled clinical trial among homogeneous groups of patients is required to resolve this issue. At the present time, no such trial has been reported, and the published literature is dominated by case series.

Brodsky and colleagues reported on a case series of 54 patients (96 ears), aged 6 months to 23 years, who met criteria for insertion of a pressure-equalizing tube (PET) and underwent laser-assisted myringotomy. (1) These criteria included recurrent otitis media, chronic otitis media with effusion, or eustachian tube dysfunction. All patients had failed medical management. All procedures were performed in the office with the use of topical anesthesia. Pain was described as absent in 39%, tolerable in 30%, and severe in 30% immediately after the procedure. Within 5 minutes the pain was reported absent in 75%, tolerable in 22%, and severe in 5%. Ninety-two percent of parents were highly satisfied with the procedure as an alternative to PET insertion using general anesthesia. The average time of the procedure was 8.57 minutes. The authors concluded that office-based laser-assisted tympanostomy with PET insertion is possible in a broad range of patients. The same group of authors published a subsequent study that focused on the duration of patency of laser myringotomy in patients with acute otitis media or otitis media with effusion. (2) This outcome is critical to determine whether or not patency is maintained for an adequate period of time such that patients can forego insertion of PETs. The case series included 251 children (430 ears), of which fenestration closure was evaluable in 201 ears. The spot size of the myringotomy was variable in the children (from 1.8 mm to 2.8 mm), and the authors also sought to evaluate the optimal size of the myringotomy fenestration. Increased duration of patency was accomplished with spot sizes of 2.4 and 2.6 mm compared with smaller spot sizes. The authors conclude that laser-assisted myringotomy provides intermediate duration fenestration, but that additional investigation is required to determine optimum spot size and duration of fenestration.

Sedlmaier and colleagues also examined the ventilation time associated with laser-assisted myringotomy in a case series of 81 children (159 ears) with chronic otitis media associated with adenoidal and/or tonsillar hypertrophy. (3) The spot size was approximately 2 mm in diameter. The mean closure time was 16.35 days. Otitis media recurred in 26.3% of the ears with mucous secretion and 13.5% of the ears with serous secretion. The authors conclude that laser-assisted myringotomy may be an alternative to ventilation tube placement in those with serous effusions.
Smaller case series have also suggested that laser-assisted myringotomy successfully aerates the middle ear in 46%-66% of patients for a period up to 3 months. (4-8) Due to the lack of controlled studies, laser-assisted myringotomy is considered investigational as an alternative to tympanostomy with PET insertion. However, it is recognized that there may be physician and patient acceptance for the laser procedure, based on the fact that it is an office-based procedure that only requires topical anesthesia.

**Acute Otitis Media**

Surgical aeration of the middle ear is indicated to acutely relieve pressure and to restore hearing. Symptoms suggestive of acute otitis media are ear pain, irritability, sleepiness in conjunction with bulging immobility of the tympanic membrane, erythema, loss of landmarks, and TM exudate. Conventional treatment of acute otitis media includes antibiotics. Problematic patients are those who continue to be symptomatic despite antibiotic therapy. Many times these patients may receive several courses of empirically chosen antibiotics. Laser-assisted myringotomy has been proposed as technique to simultaneously provide an accurate diagnosis with the culture results used to select an appropriate antibiotic. However, this unique role of myringotomy has not been the subject of a peer-reviewed article and it is not known whether the use of the laser procedure provides any advantage compared to the conventional office-based procedure using a myringotomy knife.

**2005 Update**

A literature search was performed for the period of 2003 through November of 2004. No additional published studies were identified that would prompt reconsideration of this policy. Therefore, the policy statement is unchanged. Cotter and Kosko conducted a retrospective review of 47 children with otitis media who underwent laser assisted myringotomy. (9) A total of 57.4% of procedures were considered treatment failures due to recurrence or persistence of disease. The authors suggest that any use of the OtoLam device should include discussion of the high likelihood of subsequent ventilation tube insertion.

**2006 Update**

A literature review of the peer-reviewed literature on MEDLINE for the period of November 2004 through June 2006 identified no controlled clinical trials that would alter the conclusions reached here. Therefore, the policy statement is unchanged.

**2007 Update**

A literature review was done using MEDLINE from June 2006 through July 2007. A European study reported on a randomized study of 30 pediatric patients with otitis media with effusion comparing laser myringotomy to tympanostomy with PET. (10) Middle ear ventilation was maintained for 3.5 months following the laser technique and for 6.3 months for placement of tubes; a difference that was statistically significant. The authors note that further study is needed to clarify the role of laser myringotomy. Thus, the policy statements are unchanged.

Related to this policy, the indications for PET tubes continue to evolve. Paradise and colleagues recently reported long-term results of a randomized study of immediate versus delayed PET placement in infants with persistent middle-ear effusions. (11) This study concluded that in otherwise healthy young children who have persistent middle-ear effusion, prompt insertion of tympanostomy tubes does not improve developmental outcomes up to 9 to 11 years of age.
References:


<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>69420</td>
<td>Myringotomy including aspiration and/or eustachian tube inflation</td>
</tr>
<tr>
<td></td>
<td>69433</td>
<td>Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia</td>
</tr>
<tr>
<td>ICD-9 Procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICD-9 Diagnosis</td>
<td>381–382</td>
<td>Otitis media code range</td>
</tr>
<tr>
<td>HCPCS</td>
<td>S2225</td>
<td>Myringotomy, laser-assisted</td>
</tr>
<tr>
<td>Type of Service</td>
<td>Surgery</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------</td>
<td></td>
</tr>
<tr>
<td>Place of Service</td>
<td>Physician Office/Ambulatory Surgery</td>
<td></td>
</tr>
</tbody>
</table>

**Index**

- Laser-Assisted Tympanic Membrane Fenestration
- Laser-Assisted Tympanostomy or Myringotomy
- Myringotomy, Laser-Assisted
- OtoLam
- Tympanostomy, Laser-Assisted