CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Coverage Policy Number 0330

Subject **Laser-Assisted Myringotomy**

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Hyperlink to Related Coverage Policies

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Coverage Policy

CIGNA does not cover laser-assisted myringotomy because it is considered experimental, investigational or unproven.

General Background

Otitis media is an inflammation of the middle ear. This is a common and prevalent illness in children. Acute otitis media (AOM) is usually accompanied by signs and symptoms of infection, which may include pain in the ear, fever and hearing loss. Otitis media with effusion (OME) is the presence of fluid in the middle ear and may or may not be accompanied by signs and symptoms of acute ear infection. OME may also be referred to as glue ear, secretory otitis media, and/or serous otitis media. These two types of otitis media are interrelated. The infection may be followed by residual inflammation and effusion, which in turn may lead to recurrent infection. OME may be due to poor eustachian tube function, or may be an inflammatory response following acute otitis media. Many cases of OME resolve spontaneously within a few months; however, approximately 30–40% of all cases will have recurrent OME, with approximately 5–10% of these cases lasting one year or longer. The rationale for treating OME is to prevent loss of hearing, effects on speech and language, and retraction of the tympanic membrane, which can lead to other, more severe complications of the middle ear.

The clinical practice guidelines for OME, published in May 2004 by the American Academy of Family Physicians (AAFP), the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) and the American

Academy of Pediatrics (AAP) Subcommittee on OME, recommend that unless the patient is at risk, initial treatment of OME should be observation for three months. After this time, the guidelines recommend that children with persistent OME who are not at risk should be re-examined at three- to six-month intervals until effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected. Surgical consideration depends on hearing status, associated symptoms, the child's developmental risk and the anticipated chance of timely, spontaneous resolution of the effusion. Candidates for surgery will usually include children with otitis media with effusion lasting four months or longer, with persistent hearing loss or other signs and symptoms; recurrent or persistent OME in children at risk, regardless of hearing status; and OME with structural damage to the tympanic membrane or middle ear. The guidelines state that when a child with OME is a surgical candidate, tympanostomy tube insertion is the preferred initial procedure.

Laser-assisted myringotomy is a recent development proposed as an alternative to conventional myringotomy for the treatment of OME. A carbon dioxide (CO_2) laser system, OtoScan™ (Lumenis Inc., Santa Clara, CA), has been developed to perform OtoScan™ Laser-Assisted Myringotomy, also referred to as OtoLAM™. The procedure is performed in an office setting or outpatient clinic with topical anesthetic and generally does not require general anesthesia. Utilizing the CO_2 laser system, a hole is created in the tympanic membrane for the purpose of providing ventilation to the middle ear. Contact diode laser systems have also been investigated as a method of performing laser-assisted myringotomy. It is thought that this type of laser may remain patent longer than CO_2 laser and have potential for medium-duration middle ear ventilation (D'Eredita and Shah, 2005).

The standard established treatment for OME has long been myringotomy with placement of tympanostomy tubes. The tubes are also referred to as myringotomy tubes, ventilation tubes, pressure equalization (PE) tubes and grommets. Myringotomy, the process of making an incision or opening in the tympanic membrane, is also referred to as tympanostomy or fenestration. Myringotomy alone is not recommended because the incision will close within several days. Laser-assisted myringotomy has the advantage of not requiring general anesthesia and will extend the ventilation time over myringotomy but does not extend it to the length of time that is necessary to treat the condition. It has been noted that tympanostomy tubes will provide ventilation for an average of 12–14 months.

U.S. Food and Drug Administration (FDA)
Carbon dioxide laser systems for laser-assisted myringotomy/tympanostomy received 501(k) clearance from the FDA as a Class II device in 1996.

Literature Review
D'Eredita and Shah (2005) conducted a prospective, randomized controlled study to compare contact diode laser for myringotomy to traditional myringotomy with tube insertion for management of OME in children. It was thought that it was possible that contact diode laser would provide longer middle ear ventilation than CO_2 laser. Thirty children for whom tube insertion was indicated were randomized for treatment with one of these methods. Middle ear ventilation by contact diode laser myringotomy was maintained for an average of 3.5 months, compared to the duration of middle ear ventilation of 6.3 months. The authors concluded that contact diode laser myringotomy allows for medium-duration middle ear ventilation when compared to traditional myringotomy with tube placement. It was noted in the analysis that further study to clarify the role of laser myringotomy in children with OME is indicated.

Prokopakis et al. (2005a) conducted a study to evaluate prognostic factors related with cure rate in pediatric patients with serous otitis media treated with laser-assisted myringotomy without ventilation tubes. The procedure was performed on 124 ears in 84 patients from three to 14 years old. Analysis indicated that presence of a thick tympanic membrane is significantly correlated with pure outcome in children with serous otitis media when this procedure is performed. The overall cure rate at the end of a two-month follow-up period was 54.83%, whereas 45.17% still suffered from otitis media and required a second treatment. In addition, a 41% parental dissatisfaction rate was noted. The authors concluded that they were not convinced that laser-assisted myringotomy provides significant, if any, benefits both to parents and physicians in terms of time and cost savings.

Zanetti et al. (2005) conducted a prospective case-control study to analyze the closure time of diode laser-assisted myringotomies, the incidence of complications and the hearing results in comparison with myringotomies performed with knife and ventilation tubes in adults. Twenty-eight patients, 39 ears, were included in the study, from age one to 76 years. Inclusion criteria included three months or more history of OME

resistant to medical therapy. A control group of 22 patients (34 ears) underwent myringotomies with knife and ventilation tubes. Outcome measures included timing of closure of the myringotomy, hearing results, incidence of complications, and recurrence of OME. The myringotomy opening remained patent for seven to 25 days. Immediate improvement of hearing was achieved in every patient. Recurrence of OME was observed in 36 ears within one month from healing. In the control group, healing of the eardrum was observed between 126 and 301 days, and recurrence of OME was observed in eight ears. The authors concluded that the functional benefit of laser myringotomy appears to be comparable to conventional tympanostomies with tubes, but the duration of patency is too short to achieve long-term clearance of the effusion in adults.

Lin et al. (2005) conducted a prospective clinical cohort study to evaluate the clinical application of CO_2 laser myringotomy in children with OME under topical anesthesia in an office setting. Laser myringotomy was performed on 54 children (73) ears. The mean healing time of laser myringotomy was 2.51 weeks, with a range of one to five weeks. Resolution of OME was accomplished in 53 of the 73 ears (73%). Ventilation tube insertion was arranged for ten patients with persistent OME. The authors note that limiting potential use of laser myringotomy has been the paucity of studies that have examined the exact closure times for particular perforation diameters in large patient populations. The study notes that the observed resolution rate of 73% was not related to patient age, effusion content or perforation healing time, but possibly may have been related to factors such as adenoid hypertrophy, Eustachian tube function and nasal allergy which have not yet been studied. The authors concluded that laser myringotomy may be feasible for pediatric patients in office setting, providing intermediate duration middle-ear ventilation.

Prokopakis et al. (2005b) conducted a prospective case series with two-month follow-up for the purpose of assessing outcome in adult individuals undergoing laser-assisted tympanostomy without ventilation tube placement. CO_2 laser-assisted tympanostomy was performed with local anesthetic on 108 individuals (142 ears). The indications included serous OME, functional Eustachian tube dysfunction, acute otitis media and endoscopic visualization of the middle ear. Outcome measures included patency time of the tympanostomy, presence of fluid after the closure of the typanostomy, tympanometry and tone audiometry findings, and relief of symptoms. Middle ear disease was resolved after the closure of typanostomy in 47.9% of the patients with serous OME. In 79.1% of the patients with functional Eustachian tube dysfunction, the symptoms were diminished. All patients with acute otitis media appeared to improve. The study concluded that laser-assisted tympanostomy may be as effective as an initial surgical approach in treatment for adults with serous otitis media.

Cotter et al. (2004) conducted a retrospective study to evaluate the effectiveness of laser-assisted myringotomy for acute otitis media and chronic OME in children. The procedure was performed on 47 patients (79 ears). It was noted that a total of 57.4% were considered treatment failures. Failures occurred in 53.6% of patients with refractory acute otitis media and in 63.2% of patients with chronic OME. The conclusion states that the laser-assisted myringotomy performed on these patients was associated with a high incidence of recurrence or persistence of disease and with perforation of the tympanic membrane. It recommended that use of OtoLAM™ should include discussion with the patient of high failure rates and the strong likelihood of subsequent ventilation tube insertion.

Koopman et al. (2004) conducted a study to determine the effectiveness of laser-assisted myringotomy versus the ventilation tube in children with chronic OME. Two hundred and eight children received laser-assisted myringotomy in one ear and a ventilation tube placed in the other ear, and both procedures were performed under general anesthesia. Follow-up was in six months. Success was defined as absence of effusion or aural discharge. The mean success rate was 40% for the laser-assisted myringotomy and 78% for the ventilation tube. The study concluded that laser-assisted myringotomy is a safe method to treat chronic OME; however, this procedure is less effective than a ventilation tube for treatment of chronic OME. It appears that the difference may be explained by the duration of ventilation of the middle ear.

Hassman et al. (2004) conducted a study to compare the late results of treatment with laser and classic myringotomy. The trial included three groups of children: 1) 37 were treated with laser myringotomy; 2) 29 were treated with laser myringotomy and insertion of typanostomy tubes; 3) 43 children were treated with classical myringotomy and insertion of typanostomy tubes. The indication for surgical treatment was chronic OME with conductive hearing loss lasting more than three months. The patients were not randomly chosen for treatment. Patients with serous effusion were assigned to the laser myringotomy group, and patients with mucous effusion were assigned to the groups with tube placement. All procedures were performed under general anesthesia

because adenoidectomy and/or tonsillectomy were performed at the same time. The minimum follow-up time was one year and results assessed on basis of otoscopic examination, reoccurrence of effusion, condition of the tympanic membrane and audiological examination. The recurrence rate was lowest in the laser-assisted myringotomy with tube placement group and highest in the laser myringotomy alone group. The difference between the laser myringotomy with tube placement and the classical myringotomy and tube placement group was not significant.

Deutsch et al. (2003) conducted a prospective clinical cohort effectiveness trial to evaluate the clinical and technical factors that may affect duration of laser-assisted tympanic membrane fenestration (LTMF). A volunteer sample of 251 children (430 ears) were included in the study, underwent LTMF, and were followed up to 12 weeks. The medical conditions included: treatment of acute otitis media unresponsive to medical management, recurrent acute otitis media and OME, with or without adenoidectomy. Laser fenestrations generally remained patent for two to three weeks. The duration of the LTMF appeared to be affected by spot size but not by other patient or laser characteristics. It appeared that larger spot sizes of 2.4 and 2.6 mm were associated with increased duration of patency than smaller spot sizes. The study indicated that the incidence of cure at 90 days for AOM and OME was greater than 60%. The larger spot size and longer duration of fenestration patency were associated with greater incidence of cure of otitis media at 90 days. The authors concluded that the findings suggest that LTMF may have a beneficial effect on treatment of acute otitis media and OME and that additional investigation is indicated to determine the optimum spot size and duration of fenestration to achieve the best results.

Bent et al. (2001) conducted a cross-sectional review for the purpose of describing the role of OtoScan laser-assisted myringotomy for indications other than chronic otitis media. Twenty-seven procedures were performed in 21 patients. The indications included: ear dysfunction with necessary air travel (n=10), hyperbaric oxygen treatment (n=6), mastoiditis with postauricular cellulites (n=2), canal exostosis prohibiting typanostomy (n=1), acute otitis media accompanied by seizures (n=1), and chronic middle ear effusion in a patient with hemophilia (n=1). Middle ear disease resolved with closure of the laser-assisted myringotomy in the 20 patients who were available for follow-up. Two of the patients underwent another OtoLAM procedure in another ear and four patients required repeat OtoLAM in the same or both ears. Three of the patients underwent myringotomy tube placement for recurrent middle ear dysfunction. The authors concluded that this is preliminary data but does suggest that OtoLAM may provide an alternative to myringotomy or tympanostomy tubes in situations where the underlying disease or disorder is expected to resolve in less than three weeks.

Professional Societies/Organizations
Clinical practice guidelines for OME were published in May 2004 by the American Academy of Family Physicians (AAFP), the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) and the American Academy of Pediatrics (AAP) Subcommittee on OME. These guidelines include the recommendation that when a child with OME is a surgical candidate, tympanostomy tube insertion is the preferred initial procedure. The guidelines state that myringotomy alone, without tube placement or adenoidectomy, is ineffective for chronic OME, since the incision will close within several days. As noted in the guidelines, laser-assisted myringotomy extends the ventilation period several weeks, but randomized trials with concurrent controls have not been conducted to establish efficacy. They note that, in contrast, tympanostomy tubes ventilate the middle ear for an average of 12–14 months.

Summary
While laser-assisted myringotomy has been proposed as a treatment of otitis media, myringotomy with placement of tympanostomy tubes remains the standard treatment for otitis media with effusion. It has not been demonstrated in the scientific literature that laser-assisted myringotomy is as effective as the standard, well-established procedure. Well-designed, randomized, controlled studies published in peer-reviewed medical literature are needed before laser-assisted myringotomy is considered a standard treatment.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
S2225	Myringotomy, laser-assisted

ICD-9-CM Diagnosis Codes	Description
381.0-381.9	Non-suppurative otitis media and Eustachian tube disorders
382.0-382.9	Suppurative and unspecified otitis media
	All other codes

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	4/15/2008	0330	Laser-Assisted Myringotomy