BlueCross BlueShield of Alabama

Name of Policy:

Intratympanic Dexamethasone for the Treatment of Ménière's Disease and/or Sudden Hearing Loss

Policy #: 238
Category: Medicine

Latest Review Date: April 2010
Policy Grade: **Active Policy but no longer scheduled for regular literature reviews and updates.**

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Ménière's disease, also known as endolymphatic hydrops, is a disorder of the inner ear of unknown origin. It is speculated the Ménière's disease may be an immune-mediated disorder. Symptoms include tinnitus, vertigo, heightened sensitivity to loud sounds, fluctuating loss of hearing, headache, and aural fullness. In acute phases, nausea, vomiting, and disabling dizziness may occur. Usually attacks are sudden and may last several hours. The disease usually lasts a few years and in most cases, occurs in only one ear. Diagnosis is difficult because its symptoms are often present in other conditions.

Treatment initially consists of diuretics, elimination of nicotine and a low-sodium, non-caffeine diet to reduce fluid retention. Acute exacerbations may be treated with anti-emetics, anti-vertigo medications and systemic steroids. When these medical and dietary treatments are unsuccessful, other medical and surgical interventions may be considered which include labyrinthectomy, endolymphatic sac shunt or decompression, vestibular neurectomy, and intratympanic gentamicin (which ablates vestibular function).

Most recently, intratympanic dexamethasone has been used for anti-inflammation and immunosuppression to decrease the incidence of acute attacks. Intratympanic dexamethasone may be considered in patients who wish to avoid destructive surgical procedures and systemic steroid use. Intratympanic dexamethasone injections are made via tympanostomy or myringotomy with or without placement of ventilation tubes. Disadvantages of intratympanic dexamethasone may include the need for repeated offices visits, potential infection, and potential persistent perforation of the tympanic membrane.

Oral steroids are frequently employed in the treatment of sudden sensorineural hearing loss (SSHL) and autoimmune inner ear disease (AIED). Patients who can tolerate systemic steroids are initially treated with oral steroids first. If patients do not fully respond after two weeks of oral steroids, then inner ear perfusion with dexamethasone can be used. In theory, patients who have a medical contraindication to steroids such as diabetes, hypertension, or peptic ulcer disease can be treated primarily with direct inner ear perfusion while avoiding the systemic effects of the drug.

Policy:

Intratympanic dexamethasone for the treatment of Ménière's disease meets Blue Cross and Blue Shield of Alabama's medical criteria for the following:

- Patient has **tried and failed conservative treatment** such as
    - Dietary salt restriction and diuretics;
    - Treatment of allergies**;**
    - Anticholinergics;
    - Vestibular sedatives (e.g., Antivert);
    - High dose oral steroids.

OR

- Patient has a medical **condition that prohibits the use of oral steroids**, including but not limited to the following:

- Diabetes mellitus;
- Immunosuppressed patients;
- Hypertension;
- Active or latent peptic ulcer disease;
- Renal insufficiency;
- Osteoporosis;
- Myasthenia gravis;
- Some psychiatric disorders (e.g. severe depression or psychosis);
- Ocular herpes;
- Active tuberculosis;
- Serious infections;
- Systemic fungal infections, varicella;
- Administration of liver virus vaccines;
- Pregnancy;
- Lactation;
- Known hypersensitivity or adverse reaction.

Intratympanic dexamethasone for the treatment of **sudden hearing loss meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the following:

- Patient has **tried and failed conservative treatments** such as:
  - Aspirin;
  - Antiviral mediations;
  - Diuretics;
  - Vasodilators;
  - High dose oral steroids;

OR

- Patient has a medical **condition that prohibits the use of oral steroids**, including but not limited to the following:
  - Diabetes mellitus;
  - Immunosuppressed patients;
  - Hypertension;
  - Active or latent peptic ulcer disease;
  - Renal insufficiency;
  - Osteoporosis;
  - Myasthenia gravis;
  - Some psychiatric disorders (e.g. severe depression or psychosis);
  - Ocular herpes;
  - Active tuberculosis;
  - Serious infections;
  - Systemic fungal infections, varicella;
  - Administration of liver virus vaccines;
  - Pregnancy;
  - Lactation;
  - Known hypersensitivity or adverse reaction.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Corticosteroids are commonly used in the management of several inner ear disorders, including sudden sensorineural hearing loss (SSHL) from idiopathic, vascular, viral, or traumatic causes, Ménière's disease, autoimmune inner ear disease, and certain vestibulopathies.

Intratympanic dexamethasone for treatment of Ménière's has been described in the medical literature since 1991. Until recently there was only one published randomized, controlled trial available for review. Silverstein and colleagues conducted a prospective, randomized double blind, crossover trial of 20 patients with unilateral Ménière's disease. Patients were randomized to receive either intratympanic dexamethasone (0.2-0.3ml of 8mg/ml dexamethasone concentration mixed 1:1 with sodium hyaluronate) or placebo injections daily for three days via tympanostomy and followed up for three weeks. This was followed by the crossover portion of the study, which followed the same protocol and follow-up for three weeks. A telephone survey of all patients was subsequently conducted one month later. The authors reported finding no statistically significant changes in hearing, electronystagmography data or tinnitus when intratympanic dexamethasone was compared to placebo. Vertigo was not assessed. The authors also noted the potential for a placebo effect with injection since only five of nine patients that were confident they identified the dexamethasone group were correct.

Garduño-Anaya et al in their 2005 prospective, randomized double blind study, found that dexamethasone inner ear perfusion in patients with unilateral Ménière's disease showed 82% of complete control of vertigo over placebo. There was also a subjective improvement in tinnitus, (48%), Hearing loss (35%), and aural fullness (48%) in the dexamethasone group compared with 20%, 10%, and 20% respectively in the control group.

Earlier prospective studies have reported mixed results. Barrs and colleagues reported on 21 patients with Ménière's disease treated with 0.3-0.5 mL of 4mg/mL dexamethasone injected intratympanically through a pressure equalizing tube placed after myringotomy. Patients received dexamethasone twice on day one, once on day two and weekly for three weeks thereafter. Follow up at three and six months demonstrated complete relief of vertigo at 52% and 42% respectively. However, patients lost an average of 2.7 dB in hearing and one patient lost a significant 35 dB in pure-tone average. Sennaroglu, et al reported on 24 Ménière's disease patients that received 0.25 mg instillations of dexamethasone intratympanically at the time of placement of a ventilation tube and by the patient every other day for three months thereafter. The authors reported vertigo control in 63% of patients in the first month and in 25% of patients in the second month of treatment. Hearing improved in 17% of patients although 37% reported a pure-tone average decrease. In another report, Sennaroglu, et al compared these same 24

patients to 16 patients who received intratympanic gentamicin and 25 patients who had endolymphatic sac decompression (ESD) during different time periods. The gentamicin group achieved complete vertigo control in 50% of patients whereas; the ESD group only achieved 28% complete control. There were no significant differences between the three treatment approaches when complete and substantial control of vertigo was considered. Comparisons of hearing in the three groups of intratympanic dexamethasone, intratympanic gentamicin and ESD showed no change in hearing levels of 46%, 38%, and 72%, and hearing loss of 38%, 13%, and 10% respectively. Shea and Ge reported hearing improvements in 67.9% (19 of 28) of patients followed for one year after treatment with intratympanic, intravenous and oral dexamethasone. However, the effects of intratympanic dexamethasone cannot be isolated in this uncontrolled study since three routes of administration of dexamethasone were used, thereby confounding results.

Recent studies have continued to demonstrate mixed results in using IT dexamethasone to treat Ménière's disease. However, the majority of studies show positive effects when patients are unresponsive to conventional therapies and are willing to return for multiple sessions.

Typically, steroids for the treatment of hearing loss have been administered systemically. Delivery of steroids by the middle ear route, however, has been reported to result in significantly higher perilymphatic drug levels.

Slattery et al found improved pure-tone average or speech discrimination scores for patients with sudden hearing loss that had failed to respond to oral steroids. These findings are consistent with those of Gianoli, Ho, and Kopke.

In 2004, the Hearing Committee of the American Neurotology reviewed the available literature concerning intratympanic steroid treatment of inner ear disease. Doyle, et al concluded, "Because some patients improve and side effects/risk are uncommon as reported, intratympanic steroids should rise in the hierarchy of treatment options for Ménière's disease, idiopathic sudden hearing loss, and autoimmune or immune mediated sensorineural hearing loss. The most promising results have been obtained in patiens with idiopathic sudden sensorineural hearing loss who have failed oral steroid treatment. The level of evidence is weak for the intratympanic steroid treatment of Ménière's disease and tinnitus. More prospective, controlled studies are needed to determine the optimum timing for treatment, dosage, delivery method, drug, and possible adverse side effects of this treatment."

April 2008 Update

Controlled trials from outside the United States assess the efficacy of intratympanic steroids for the treatment of sudden hearing loss. One study compared outcomes from 10 consecutive patients who received initial treatment of intratympanic dexamethasone with 21 consecutive patients who were treated with intravenous dexamethasone. All 10 patients treated with intratympanic steroids ere reported to have improved more than 10 dB, with an average improvement of 41 dB. Fourteen (67%) patients in the intravenous treatment group showed improvement of > 10 dB with a mean change of 25 dB.

Xanellis and colleagues randomized 37 patients who failed intravenous prednisolone into treatment with intratympanic dexamethasone or no treatment controls. Nine of 19 treated patients showed an improvement in pure tone average of > 10 dB, compared with none of the controls at 1.5 months after the last treatment. A third study compared 33 prospectively treated patients who were refractory to a course of oral steroid therapy with historical age and sex matched controls (assessed four and eight weeks following oral steroids). Thirteen of the patients treated with intratympanic dexamethasone (four times over two weeks) showed an improvement of more than 10 dB in pure tone average compared with two patients in the control group. Of note, for 20 patients who had no objective change of hearing after intratympanic dexamethasone, 16 reported subjective improvements in either hearing or tinnitus. Because of variable recovery rates and a high rate of spontaneous recovery, placebo-controlled double-blinded trials are needed to establish the efficacy of intratympanic steroid treatment for sudden hearing loss. A Cochrane Review of steroids for idiopathic sudden sensorineural hearing loss also agrees that the evidence is unclear from randomized controlled trial and some are contradictory and that additional studies are needed as the studies include too few a number of patients.

Weber reports that intratympanic steroids are being evaluated for the treatment of sudden sensorineural hearing loss (SSNHL). A trial in 29 patients who did not improve with 10 days of oral corticosteroids randomly assigned patients to treatment with intratympanic dexamethasone injected once a week for three weeks or to a control group. Hearing improvement was seen in 8 of 15 patients (four had complete recovery and four had improvement of > 30 dB) who were treated with dexamethasone and in one in 14 in the control group. In a nonrandomized study of 18 patients who did not recover hearing following five days of intravenous steroids , intratympanic steroid injection resulted in hearing improvement in five of nine patients who received three weekly injections; nine patients declined the intratympanic treatment and showed no hearing improvement.

In the United States, the National Institutes of Health is currently recruiting participants to compare the efficacy of oral prednisone versus methylprednisolone injected into the middle ear for the treatment of moderate-to-severe, sudden sensorineural hearing loss (inner ear hearing loss affecting one ear that occurs over less than 72 hours). Weber recommends that while awaiting more definitive evidence from clinical trials, that patients who do not improve with 10 days of oral corticosteroids be considered for intratympanic corticosteroid injection.

April 2010 Update
No new studies were identified that would alter the coverage statement of this policy.

Key Words:

Intratympanic, intratympanic dexamethasone, intratympanic steroids, IT dexamethasone, IT steroids, Ménière's disease, sudden hearing loss, sudden loss of hearing, MicroWick

Approved by Governing Bodies:

Dexamethasone is FDA approved

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: Federal mandates regarding off-label uses of drugs approved by the FDA may supersede this policy.
Pre-certification requirements: Not applicable

Current Coding:

CPT codes:

69801 Labyrinthotomy, with perfusion of vestibuloactive drug(s); transcanal. **(Effective January 1, 2011)**

Previous Coding:

CPT codes:

69801 Labyrinthotomy, with or without cryosurgery including other nonexcisional destructive procedures or perfusion of vestibuloactive drug(s) (single or multiple perfusions); transcanal**. (Effective for dates of service prior to January 1, 2011)**

References:

1. Banerjee A, Parnes LS. The biology of intratympanic drug administration and pharmacodynamics of round window drug absorption. Otolaryngol Clin N Am 2004;27:1035-51.
2. Banerjee A, Parnes LS. Intratympanic Corticosteroids for sudden idiopathic sensorineural hearing loss. Otol Neurotol 2005;26:878-81.
3. Barrs DM. Intratympanic corticosteroids for Ménière's disease and vertigo. Otolaryngol Clin N Am 2004;37(5).
4. Barrs DM, Keyser JS, et al. Intratympanic steroid injections for intractable Ménière's disease. Laryngoscope 2001;111(12):2100-4.
5. Choung YH, Park K, Shin YR and Cho MJ. Intratympanic dexamethasone injection for refractory sudden sensorineural hearing loss. Laryngoscope 2006; 116(5): 747-752.
6. Cochrane Review. Steroids for idiopathic sudden sensorineural hearing loss. www.medscape.com/viewarticle/534092_print. Accessed March 19, 2008.
7. Doyle KJ, Bauch C, Battista R, et al. Intratympanic steroid treatment: a review. Otol Neurotol 2004;25(6):1034-39.
8. Garduño-Anaya MA, De Toledo HC, Hinojosa-González, et al. Dexamethasone inner ear perfusion by intratympanic injection in unilateral Ménière's disease: a two-year prospective, placebo-controlled, double-blind, randomized trial. Otolaryngol Head Neck Surg 2005;133(2):285-94.

9. Gianoli GJ, et al. Transtympanic steroids for treatment of sudden hearing loss. Otolaryngol Head Neck Surg 2001;125(3):142-6.
10. Ho HG. Effectiveness of intratympanic dexamethasone injection in sudden-deafness patients as salvage treatment. Laryngoscope 2004;114(7):1184-9.
11. Itoh A, Sakata E. Treatment of vestibular disorders. Acta Otolaryngol Suppl 1991;481:617-23.
12. Jackson LE, Silverstein H. Chemical perfusion of the inner ear. Otolaryngol Clin North Am 2002;35(3):639-53.
13. Kopke RD, Hoffer ME, Wester D, et al. Targeted topical steroid therapy in sudden sensorineural hearing loss. Otol Neurotol 2001;22(4):475-9.
14. Light JP. Transtympanic perfusion: indications and limitations. Curr Opin Otolaryngol Head Neck Surg 2004;12(5):378-83.
15. Lustig LR. The history of intratympanic drug therapy in otology. Otolaryngol Clin N Am 2004;37:1001-17.
16. McEvoy GK, ed. AHFS: Drug Information. Bethesda, MD: American Society of Health-System Pharmacist;2004:2885-98.
17. Rauch SD. Intratympanic steroids for sensorineural hearing loss. Otolarynogol Clin North Am 2004;37(5):1061-74.
18. Seidman MD & Vivek P. Intratympanic treatment of hearing loss with novel and traditional agents. Otolarynogol Clin North AM 2004;37)5).
19. Selivanova OA, Gouveris H, Victor A, et al. Intratympanic dexamethasone and hyaluronic acid in patiens with low-frequency and Ménière's-associated sudden sensorineural hearing loss. Otol Neurotol 2005;26:890-95.
20. Sennaroglu L, Sennaroglu G, et al. Intratympanic dexamethasone, intratympanic gentamicin, and endolymphatic sac surgery for intractable vertigo in Ménière's disease. Otolaryngol Head Neck Surg. 2001;125(5):537-43.
21. Sennaroglu L, Dini FM, et al. Transtympanic dexamethasone application in Ménière's disease: an alternative treatment for intractable vertigo. J Laryngol Otol 1999;113(3):217-21.
22. Shea J, Ge X. Dexamethasone perfusion of the labyrinth plus intravenous dexamethasone for Ménière's disease. Otolaryn Clin N Am 1996;29:353-8.
23. Silverstein H, Isaacson JE, Olds MJ, et al. Dexamethasone inner ear perfusion for the treatment of Ménière's disease: a prospective, randomized, double-blind, crossover trial. Am J Otol 1998;19(2):196-201.
24. Slattery WH, Fisher LM, Iqbal Z, et al. Intratympanic steroid injection for treatment of idiopathic sudden hearing loss. Otolaryngol Head Neck Surg 2005;133(2):251-9.
25. Sudden deafness treatment trial (SSNHL). www.clinicaltrials.gov. Accessed March 19, 2008.
26. Weber PC. Sudden sensorineural hearing loss. www.UpToDate.com. Accessed March 12, 2008.
27. Xenellis J, Papadimitriou N, et al. Intratympanic steroid treatment in idiopathic sudden sensorineural hearing loss: A control study. Otolaryngology Head and Neck Surgery, June 2006; 134(6): 940-945.

Policy History:

Medical Policy Group, June 2005 **(2)**
Medical Policy Administration Committee, July 2005
Available for comment July 28-September 10, 2005
Medical Policy Group, October 2005
Medical Review Committee, December 2005
Medical Policy Group, January 2006 **(2)**
Medical Review Committee, March 2006
Medical Policy Administration Committee, May 2006
Available for comment April 25-June 8, 2006
Medical Policy Group, April 2008 **(1)**
Medical Policy Group, April 2010 **(1):** No studies identified to change policy
Medical Policy Group, December 2010, 2011 Code update
Medical Policy Group, September 2012 **(3)**: **Effective September 14, 2012 this policy is no longer scheduled for regular literature reviews and updates.**
Medical Policy Group, October 2013 **(3)**: Removed ICD-9 Diagnosis codes; Removed reference to Medical Policy Reference Manual; no change to policy statement.
