BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

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

Policy #238
Latest Review Date: February 2024
Category: Medicine

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage, the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD, are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual, Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat intratympanic dexamethasone for the treatment of **Ménière's disease** as a **covered benefit** 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

Blue Advantage will treat intratympanic dexamethasone for the treatment of **sudden hearing loss as a covered benefit** 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 Advantage 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 their patient. Blue Advantage administers benefits based on the members' contract and 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.

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 that Ménière's disease may be an immune-mediated disorder. Symptoms include tinnitus, vertigo, heightened sensitivity to loud sounds, fluctuating hearing loss, 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 antiemetics, 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).

Oral steroids are frequently employed in the treatment of sudden sensorineural hearing loss (SSHL) and autoimmune inner ear disease (AIED). Individuals who can tolerate systemic steroids are initially treated with oral steroids first. If individuals do not fully respond after two weeks of oral steroids, then inner ear perfusion with dexamethasone can be used. It is proposed that individuals 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.

KEY POINTS:

The literature search for this policy was performed through February 15, 2024.

Summary of Evidence:
Intratympanic dexamethasone has been used for anti-inflammation and immunosuppression to decrease the incidence of acute attacks. Intratympanic dexamethasone may be considered in individuals who wish to avoid 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.

Practice Guidelines and Position Statements:
In 2020, the American Academy of Otolaryngology-Head and Neck Surgery published a clinical practice guideline on Meniere's Disease. The guidelines are for all healthcare providers who diagnose, treat and monitor individuals with this condition. The authors concluded, "The primary purpose of this CPG is to improve the quality of the diagnostic workup and treatment outcomes of Meniere's disease." To achieve this goal, the guideline is to be the best available published scientific and/or clinical evidence to enhance diagnostic accuracy and appropriate therapeutic interventions while reducing unindicated diagnostic testing.

U.S. Preventive Services Task Force Recommendations
Not applicable.

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:

U.S. Food and Drug Administration has granted approval for Dexamethasone.

BENEFIT APPLICATION:

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

CURRENT CODING:

CPT Codes:

69801	Labyrinthotomy, with perfusion of vestibuloactive drug(s); transcanal

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POLICY HISTORY:

Adopted for Blue Advantage, May 2006
Available for comment May 30-July 13, 2006
Medical Policy Group, April 2008
Medical Policy Group, April 2010
Medical Policy Group, December 2010
Medical Policy Group, September 2012: Effective September 14, 2012, this policy is no longer scheduled for regular literature reviews and updates.
Medical Policy Group, October 2013
Medical Policy Group, November 2019
Medical Policy Group, March 2021: Reviewed by consensus. No new published peer-reviewed literature is available that would alter the coverage statement in this policy.
Medical Policy Group, January 2023: Reviewed by consensus. No new published peer-reviewed literature is available that would alter the coverage statement in this policy.
Medical Policy Group, February 2024: Reviewed by consensus. No new published peer-reviewed literature is available that would alter the coverage statement in this policy.
