

Balloon Dilation of the Eustachian Tube

Policy # 00613

Original Effective Date: 05/16/2018

Current Effective Date: 04/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider balloon dilation of the eustachian tube (BDET) for treatment of chronic obstructive eustachian tube dysfunction (ETD) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for balloon dilation of the eustachian tube (BDET) for treatment of chronic obstructive eustachian tube dysfunction (ETD) may be considered when **ALL** of the following criteria are met:

- Adults (age 18 years and older) with symptoms of obstructive ETD (aural fullness, aural pressure, otalgia, and/or hearing loss) for 12 months or longer in one or both ears that significantly affects quality of life or functional health status
 - Aural fullness and pressure must be present (see Policy Guidelines);

AND

- The individual has undergone a comprehensive diagnostic assessment; including patient-reported questionnaires, history and physical exam, tympanometry if the tympanic membrane is intact, nasal endoscopy, and comprehensive audiometry, with the following findings:
 - Abnormal tympanogram (Type B or C);
 - Abnormal tympanic membrane (retracted membrane, effusion, perforation, or any other abnormality identified on exam);

AND

- Failure to respond to appropriate medical management of potential co-occurring conditions, if any, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4-6 weeks of a nasal steroid spray, if indicated;

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AND

- Other causes of aural fullness such as temporomandibular joint disorders, extrinsic obstruction of the eustachian tube, superior semicircular canal dehiscence, and endolymphatic hydrops have been ruled out;

AND

- If the individual had a history of tympanostomy tube placement, symptoms of obstructive ETD should have improved while tubes were patent;

AND

- The individual does not have patulous ETD or another contraindication to the procedure (see Policy Guidelines);

AND

- The individual's ETD has been shown to be reversible (see Policy Guidelines);

AND

- Symptoms are continuous rather than episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying);

AND

- The individual has not had a previous BDET procedure.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of balloon dilation of the eustachian tube (BDET) when patient selection criteria are not met is considered to be **investigational**.*

Policy Guidelines

Symptoms of obstructive eustachian tube dysfunction may include aural fullness, aural pressure, otalgia, and hearing loss. Nearly all individuals will have aural fullness and aural pressure. Many individuals will have otalgia, but hearing loss may not be present in all individuals (e.g., patients with Type C tympanograms).

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Contraindications to Balloon Dilation of the Eustachian Tube

- The following individuals should not be considered for balloon dilation of the eustachian tube:
 - Individuals with patulous eustachian tube dysfunction (ETD).
 - A diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and/or aural fullness.
 - Individuals with extrinsic reversible or irreversible causes of ETD including but not limited to:
 - craniofacial syndromes, including cleft palate spectrum;
 - neoplasms causing extrinsic obstruction of the eustachian tube;
 - history of radiation therapy to the nasopharynx;
 - enlarged adenoid pads;
 - nasopharyngeal mass;
 - neuromuscular disorders that lead to hypotonia/ineffective eustachian tube dynamic opening;
 - systemic mucosal or autoimmune inflammatory disease affecting the mucosa of the nasopharynx and eustachian tube (e.g. Samter's triad, Wegener's disease, mucosal pemphigus) that is ongoing/active (i.e. not in remission).
 - Individuals with aural fullness but normal exam and tympanogram.
 - Individuals with chronic and severe atelectatic ears.

Reversibility of Eustachian Tube Dysfunction

Reversibility of ETD can be demonstrated by several means, including any of the following:

- The individual states that they are able to relieve the pressure by performing a Valsalva maneuver to "pop" their ears;
- Performing a Valsalva maneuver produces temporary improvement of the individual's tympanogram to Type A tympanogram;
- Performing a Valsalva maneuver causes the member's middle ear to aerate, which is indicated by the provider visualizing lateral movement of the tympanic membrane on otoscopy.

Balloon Dilation of the Eustachian Tube Used in Combination with Other Procedures

- Individuals undergoing balloon dilation of the eustachian tube (BDET) concurrent with sinus ostial dilation should meet the same diagnostic criteria for BDET as those undergoing BDET alone.
- Individuals with a middle ear effusion at the time of BDET may benefit from concurrent myringotomy with or without tympanostomy tube placement.

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Outcomes

Table 1. Outcome Assessment of Chronic Obstructive Eustachian Tube Dysfunction

Outcome Measure	Description	MCID, if known
Eustachian Tube Dysfunction Questionnaire (ETDQ-7)	<p>Validated, standardized, 7-item patient-reported questionnaire to assess symptom severity associated with ETD. Pressure, pain, feeling clogged, cold/sinusitis problems, crackling/popping, ringing, and muffled hearing.</p> <p>Patients rate the severity of 7 symptoms on a scale ranging from 1 (no problem) to 7 (severe problem). Dividing the total score by 7 yields the mean item score.</p> <p>A total score of ≥ 14.5 and mean item score of ≥ 2.1 indicate ETD</p> <p>Scores in the range of 1 to 2 indicate no to mild symptoms, 3 to 5 moderate symptoms, and 6 to 7 severe symptoms.</p>	<p>0.5 point improvement</p> <p>Normalization is defined as a mean item score < 2.1 or a total score < 14.5</p>
Valsava maneuver	<p>Patient breathes out while closing the nose and mouth to direct air to the eustachian tube and help them open.</p> <p>Modified: gentle nose blow with simultaneous swallow</p>	<p>Positive (ability to perform the maneuver when needed)</p> <p>Negative (unable to perform the maneuver)</p>
Tympanometry	<p>Measures the mobility of the tympanic membrane and graphically displays results in tympanograms. Tympanograms are classified by the height and location of the tympanometric peak.</p> <p>Type A indicates normal middle ear and eustachian tube function; type B indicates poor tympanic membrane mobility (“flat” tympanogram), and type C indicates the presence of negative middle ear pressure.</p>	<p>Type A (normal)</p>
Otoscopy findings	<p>Visual examination of the tympanic membrane using an otoscope.</p> <p>Classifies tympanic membrane as abnormal (retracted membrane, effusion, perforation, or any other abnormality identified on exam) or normal</p>	<p>Normal tympanic membrane</p>

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ETD: eustachian tube dysfunction; MCID: minimal clinically important difference.

Background/Overview

Eustachian Tube Function and Dysfunction

The eustachian tube connects the middle ear space to the nasopharynx. It ventilates the middle ear space to equalize pressure across the tympanic membrane, clears mucociliary secretions, and protects the middle ear from infection and reflux of nasopharyngeal contents. Normally, the tube is closed or collapsed and opens during swallowing, sneezing or yawning. Eustachian tube dysfunction (ETD) occurs when the functional valve of the eustachian tube fails to open and/or close properly. This failure may be due to inflammation or anatomic abnormalities. Symptoms of chronic obstructive ETD can include aural fullness, aural pressure, hearing loss, and otalgia. In milder cases, ETD may only be apparent in situations of barochallenge (inability to equalize with rapid barometric pressure changes), with otherwise normal function in stable ambient conditions.

Diagnosis

Because the symptoms of ETD are nonspecific, clinical practice guidelines emphasize the importance of ruling out other causes of ETD with a comprehensive diagnostic assessment that includes patient-report questionnaires, history and physical exam, tympanometry, nasal endoscopy, and audiometry to establish a diagnosis.

Medical and Surgical Management of Eustachian Tube Dysfunction

Medical management of ETD is directed by the underlying etiology. Treatment of identified underlying conditions, such as systemic decongestants, antihistamines, or nasal steroid sprays for allergic rhinitis; behavioral modifications and/or proton pump inhibitors for laryngopharyngeal reflux; or treatment of mass lesions, may be useful in resolving ETD.

Patients who continue to have symptoms following medical management may be treated with surgery such as myringotomy with the placement of tympanostomy tubes or eustachian tuboplasty. These procedures create an alternative route for ventilation of the middle ear space but do not address the functional problem at the eustachian tube. There is limited evidence and no randomized controlled trials (RCTs) supporting use of these surgical techniques for this indication. Additionally, surgery may be associated with adverse events such as infection, perforation, and otorrhea. Tympanostomy tube placement may be a repeat procedure for the life of the patient, and the risk of complications from tympanostomy tubes increases with increasing numbers of tube placements and duration of tube placement.

Balloon Dilation of the Eustachian Tube

Balloon dilation is a tuboplasty procedure intended to improve the patency of the cartilaginous eustachian tube to cause local dilation. During the procedure, a saline-filled balloon catheter is introduced into the eustachian tube through the nose using a minimally invasive transnasal endoscopic method. Pressure is maintained for 2 minutes or less, after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.

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Balloon dilation of the eustachian tube can be done as a stand alone procedure or in conjunction with other procedures such as adenoidectomy, intranasal surgery (e.g. septoplasty, turbinate procedures or sinus surgery), surgery for obstructive sleep apnea or sleep disturbed breathing, and myringotomy with or without tympanostomy tube placement. This medical policy addresses balloon dilation of the eustachian tube as a stand alone procedure.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Table 2. Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Acclarent Aera Eustachian Tube Balloon Dilation System	Acclarent, Inc.	01/16/2018	K171761; K230742	Eustachian tube dilation
Xpress ENT Dilation System	Entellus Medical, Inc.	04/05/2017	K163509	Eustachian tube dilation
Nuvent Eustachian Tube Dilation Balloon	Medtronic Xomed, Inc.	08/16/2021	K210841	Eustachian tube dilation
Audion Et Dilation System	Entellus Medical, Inc.	04/12/2022	K220027	Eustachian tube dilation
Vensure Balloon Dilation System	Fiagon GmbH	05/26/2023	K230065	Eustachian tube dilation

Multiple devices have been given a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (class II, FDA product code: PNZ) (Table 1).

In September 2016, the AERA^{®‡} (Acclarent) was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (class II, FDA product code: PNZ). The new classification applies to this device and substantially equivalent devices of this generic type. The AERA^{®‡} is cleared for dilating the eustachian tube in patients ages 22 and older with persistent ETD.

In December 2016, the XprESS^{™‡} ENT Dilation System (Entellus Medical, Plymouth, MN) was cleared for marketing by the FDA through the 510(k) process (K163509). The FDA determined this device was substantially equivalent to existing devices for use in ETD. The predicate devices are XprESS^{™‡} Multi-Sinus Dilation System (K152434) and AERA^{®‡} Eustachian Tube Balloon Dilation System.

In December 2023, Acclarent^{™‡}, Inc., part of Johnson & Johnson MedTech, has received clearance from the U.S. Food and Drug Administration (FDA) for the Acclarent^{™‡} AERA Eustachian Tube Balloon Dilation System in the treatment of children, ages 8-17, with persistent obstructive Eustachian tube dysfunction.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Description

Eustachian tube dysfunction (ETD) occurs when the functional valve of the eustachian tube fails to open and/or close properly. This failure is frequently due to inflammation and can cause symptoms such as muffled hearing, ear fullness, tinnitus, and vertigo. Chronic obstructive ETD can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas. Balloon dilation of the eustachian tube (BDET) is a procedure intended to improve patency by inflating a balloon in the cartilaginous part of the eustachian tube to cause local dilation.

Summary of Evidence

For individuals who have chronic obstructive ETD despite medical management who receive BDET, the evidence includes randomized controlled trials (RCTs), prospective observational studies, case series, and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Two 6-week RCTs found more improvement with balloon dilation plus medical management than medical management alone on patient-reported symptoms, ability to perform a Valsalva maneuver, proportion of patients with normalized tympanograms, and otoscopy findings. Durability of these effects was demonstrated at 52 weeks in the uncontrolled extension phase of both RCTs. No serious device- or procedure-related adverse events were reported through 52 weeks of followup. Multiple observational studies and case series have reported that patients experienced improvement when comparing symptoms before and after balloon dilation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

There are currently no published prospective studies of BDET in children and adolescents. The 2021 systematic review and meta-analysis and 2024 retrospective chart review concluded that further analysis and future prospective randomized controlled trial may help better determine the best candidates for BDET in the pediatric population. There is insufficient credible scientific evidence published in peer-reviewed medical literature to permit reasonable conclusions concerning the effect of BDET in children and adolescents 8-17 years of age.

Supplemental Information

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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2020 Input

Clinical input was sought to help determine whether the use of balloon dilation of the eustachian tube (BDET) for individuals with chronic obstructive eustachian tube dysfunction (ETD) despite medical management would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 4 respondents, including 1 specialty society-level response including physicians with academic medical center affiliation and 3 physician-level responses affiliated with an academic medical center.

For individuals who have obstructive ETD who receive BDET, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected patients using the following criteria:

- Obstructive ETD for 3 months or longer in 1 or both ears that significantly affects quality of life or functional health status;
- The patient has undergone a comprehensive diagnostic assessment; including history and physical exam, tympanometry if the tympanic membrane is intact, nasopharyngoscopy, and comprehensive audiometry; and
- Failure to respond to appropriate medical management of potential co-occurring conditions, if any, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, including 4 to 6 weeks of a nasal steroid spray, if indicated.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology-Head and Neck Surgery Foundation

In 2019, the American Academy of Otolaryngology published a clinical consensus statement on BDET. The target population was defined as adults ≥ 18 years who are candidates for BDET because of obstructive ETD in 1 or both ears for 3 months or longer that significantly affects quality of life or functional health status. The expert panel concluded:

- BDET is an option for treatment of patients with obstructive ETD.
- The diagnosis of obstructive ETD should not be made without a comprehensive and multifaceted assessment, including otoscopy, audiometry, and nasal endoscopy.
- BDET is contraindicated for patients diagnosed as having a patulous ETD
- Further study will be needed to refine patient selection and outcome assessment.

The authors emphasized the importance of identifying other potentially treatable causes of ETD, including allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, and noted that medical management of these disorders is indicated prior to offering BDET. They also noted that potential

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risks of BDET that are relevant to patient counseling include bleeding, scarring, infection, development of patulous ETD, and/or the need for additional procedures.

National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence (NICE) published updated guidance on BDET. The guidance was based on a rapid review of the evidence, and stated, "Evidence on the safety and efficacy of balloon dilation for eustachian tube dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit." NICE standard arrangements recommendations mean that there is enough evidence for doctors to consider the procedure as an option.

The guidance also noted:

- The procedure was not effective in all patients, and there was little evidence on the benefit of repeat procedures.
- The procedure is only indicated for chronic ETD refractory to medical treatment.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Unpublished Clinical Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT05719207	Efficacy of Balloon Dilation of the Eustachian Tube in Eustachian Tube Dilatory Dysfunction	76	Dec 2024
NCT05998356	Long-term Assessment of Balloon Eustachian Tuboplasty for Obstructive Eustachian Tube Disease: A Multicenter Single-blinded Randomized Controlled Study	96	Jan 2027

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<i>Unpublished</i>			
NCT03499015	Balloon Dilation of the Eustachian Tube in Children: a Randomized Side-controlled Clinical Trial	50	Oct 2020 (recruitment status unknown; last update Nov 2018)
NCT04136977 ^a	XprESS Eustachian Tube Balloon Dilation Registry	169	Aug 2020 (completed; results submitted July 21, 2021, but quality control review process not yet concluded)
NCT03886740	Tympanostomy Tubes Versus Eustachian Tube Dilation	32	Aug 2021 (withdrawn, difficulty enrolling)
NCT05270031	Balloon Dilation of the Eustachian Tube	58	Feb 2026 (terminated, lack of funding)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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05/03/2018 Medical Policy Committee review

05/16/2018 Medical Policy Implementation Committee approval. New policy.

05/02/2019 Medical Policy Committee review

05/15/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

12/10/2019 Coding update

05/07/2020 Medical Policy Committee review

05/13/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

12/11/2020 Coding update

03/04/2021 Medical Policy Committee review

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- 03/10/2021 Medical Policy Implementation Committee approval. Changed coverage from investigational to eligible for coverage with criteria. Added a table at the end of the Policy Guidelines section on Outcome Assessment of Chronic Obstructive Eustachian Tube Dysfunction.
- 03/03/2022 Medical Policy Committee review
- 03/09/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Coding update
- 03/02/2023 Medical Policy Committee review
- 03/08/2023 Medical Policy Implementation Committee approval. Replaced “patients” with Individuals” in the Coverage and Policy Guidelines sections. Coverage eligibility unchanged.
- 08/09/2023 Coding update
- 03/07/2024 Medical Policy Committee review
- 03/13/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 03/06/2025 Medical Policy Committee review
- 03/12/2025 Medical Policy Implementation Committee approval. Lowered the age in the coverage criteria from adults age 22 and older to adults age 18 years and older.

Next Scheduled Review Date: 03/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	69705, 69706
HCPCS	N/A
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.