

APPEAL TEMPLATE LETTER #3
SECOND LEVEL APPEAL/REQUEST FOR EXTERNAL REVIEW OF EUSTACHIAN TUBE BALLOON DILATION
[INSERT OFFICE LETTERHEAD]

[INSERT INSURANCE NAME]
[INSERT INSURANCE ADDRESS]
[INSERT CURRENT DATE]

Re: [PATIENT NAME]
[PATIENT IDENTIFIER FOR PAYOR]
[IDENTIFYING INFORMATION FOR PAYOR – GROUP, POLICY OR CLAIM NUMBER]
[DATE OF BIRTH]

Dear [INSERT INDIVIDUAL, DEPARTMENT OR PAYOR NAME],

It is our understanding that the [INSERT LEVEL 1 OR LEVEL 2] Appeal related to the above-referenced patient was denied. Please accept this [LEVEL 2 APPEAL OF THIS DECISION] [OR OUR REQUEST FOR EXTERNAL EXPERT REVIEW BY AN INDEPENDENT REVIEW ORGANIZATION].

Please be advised that this patient's treatment plan was developed with conscientious consideration for their unique medical condition and the current standards of quality care for persistent Eustachian tube dysfunction (ETD). Your response to our [FIRST OR SECOND] appeal does not specifically address an in depth discussion of this patient's individual clinical needs.

[INSERT A THOROUGH SUMMARY OF PATIENT'S HISTORY OF DISEASE, INCLUDING DURATION, DIAGNOSTIC STUDIES, PRIOR TREATMENTS ATTEMPTED, SYMPTOMATOLOGY, DISABILITY, ETC.]

When medical management alone has failed to relieve the patient's symptoms, Eustachian tube balloon dilation (ETBD) offers an additional form of therapy with numerous clinical benefits that have been demonstrated in a prospective, multi-center, randomized controlled trial. These benefits include¹:

- Greater rates of improved outcomes
 - Patients receiving ETBD reported greater improvement in ETDQ-7 Scores. ETBD patients reported a -2.3 (1.4) mean (SD) improvement in ETDQ-7 scores at 6 weeks compared to -0.5 (1.2) for patients receiving medical management.
 - Fifty-six point one percent (56.1% 78/139) of ETBD patients reported an ETDQ-7 mean item score of less than 2.1 at 6 weeks compared to 8.5% (6/71) for medical management alone.
- Long term relief of symptoms associated with ETD.
 - Sustained outcomes were demonstrated for over 170 patients who were treated with ETBD, 62.2% (61/98) and 58.1% (43/74) lead-in patients demonstrated tympanogram normalization at 24 weeks post-procedure compared to 51.8% (73/141) and 40.0% (30/75) at 6 weeks, respectively.
 - Durability was consistently demonstrated across efficacy outcome measures. Improvement was sustained at 24 weeks following the procedure for the following measures: ETDQ-7 scores,

the proportion of patients achieving a MID level improvement, and the proportion of patients without symptomatic dysfunction.

- A strong safety profile demonstrated by an absence of serious device or procedure related adverse events.
 - Out of 444 dilated Eustachian tubes (299 patients), 0 serious device- or procedure-related adverse events were reported
- Low occurrence of non-serious device and procedure related events.
 - Sixteen (16) non-serious device or procedure-related adverse events occurred in 13 ETBD patients out of the 299. Four 4 of these events were related to the anesthesia portion of the procedure.

[INSERT A STATEMENT REGARDING THIS PHYSICIAN’S EXPERIENCE WITH ETBD PROCEDURES – E.G. NUMBER OF PROCEDURES, OUTCOMES DATA CAPTURED WHICH SUPPORT THE OUTCOMES DESCRIBED ABOVE, ETC.]

In order to ensure patient access to a thorough and responsible appeal process, we request expert review and discussion of the clinical options suitable for this patient and likelihood of success of the recommended alternative treatments given the patient’s history of medical treatment resistance. The credentials of the reviewer and the evidence utilized in their decision-making process should be made available for review by the provider and the patient. We request the reviewer’s independent clinical determination based upon the evidence presented and this patient’s condition, separate and apart from the health plan’s coverage policy.

If the evidence submitted to justify the recommendation for this procedure is deemed insufficient, we request disclosure of the clinical rationale used in making the decision, qualifying credentials of the reviewer, copies of all articles, technology assessments and expert opinions used in the determination that benefits are experimental or not medically necessary. Additionally, we request a complete description of the procedures, time frames, and consumer rights for grievance/appeals.

Thank you for your continued assistance in reviewing this matter.

Sincerely,

i Instructions for Use, Acclarent AERA™ Eustachian Tube Balloon Dilation System