***APPEAL TEMPLATE LETTER #2***

***FIRST APPEAL (FOR PRIOR-AUTHORIZATION OR PAYMENT)***

***FOR EUSTACHIAN TUBE BALLOON DILATION***

***[INSERT LETTERHEAD]***

[INSURANCE NAME]
[APPEAL ADDRESS]

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

Dear [INSERT INDIVIDUAL, DEPARTMENT OR PAYOR NAME],

This letter is regarding your denial for [SELECT PRIOR AUTHORIZATION/PRE-DETERMINATION OR PAYMENT] of benefits for the Eustachian tube balloon dilation (ETBD) procedure [SELECT PROPOSED OR PERFORMED] for the above-referenced patient. According to the denial letter dated [XX/XX/XX], this procedure has been denied because it has been deemed "investigational." [IF NOT DENIED AS "INVESTIGATIONAL", INSERT DENIAL REASON] I am writing to appeal this denial to a higher level of review and to reiterate some important facts about this procedure.

1. Persistent Eustachian tube dysfunction (ETD) is characterized by chronic ear pressure, pain often times with clogged or muffled sensations. [i]

2. The ACCLARENT AERA ™ Eustachian Tube Balloon Dilation System is intended for use in dilating the cartilaginous portion of the Eustachian tube using an inflatable balloon catheter in order to treat persistent ETD that is non-responsive to medical management alone. [i]

3. The Food and Drug Administration (FDA) has cleared the ACCLARENT AERA™ Eustachian Tube Balloon Dilation System for use in dilating the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in adults ages 22 and older. [ii]

4. Patients treated with the ACCLARENT AERA™ Eustachian Tube Balloon Dilation System following medical management showed higher rates of Tympanogram normalization at 6 weeks. 51.8% for ETBD compared to 13.9% of the patients who received only medical management. [i]

5. 56.1% of patients who received Eustachian Tube Balloon Dilation and medical management reported a mean ETDQ-7 score of less than 2.1 at 6 weeks compared to only 8.5% of those patients treated with medical management alone. [i]

6. Patients reported greater improvements at 6 weeks when treated with the ACCLARENT AERA™ Eustachian Tube Balloon Dilation System and medical management of ETD when compared to medical management alone. A Minimally Important Difference (MID) level change for the ETDQ-7 was reported at 90.6% for ETBD and medical management and 45.1% for patients receiving medical management alone. [i]

7. ETDQ-7 Scores, the number of patients achieving MID level improvement and the proportion of patients presenting without symptomatic dysfunction were sustained at 24 weeks. [i]

Based on this rationale and the clinical documentation outlining the need for this procedure, I respectfully request your reconsideration of this request for coverage/payment of the Eustachian Tube Balloon Dilation procedure performed using the ACCLARENT AERA™ Eustachian Tube Balloon Dilation System. Thank you in advance for your thorough review of this information. 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 referenced in the denial, 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.

Sincerely,

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

[ii] *De novo* Clearance Summary