I. POLICY

It is the policy of MedStar Health, Inc. to cover voice prostheses and laryngeal devices after a surgical laryngectomy when it is medically necessary (refer to CRM .015.MH-Medical Necessity policy) as detailed in this policy and covered under the member’s specific benefit plan.

II. DEFINITIONS

Laryngeal Devices (aka: Electronic or artificial larynx, tracheostomy speaking valve)—
Laryngeal devices are hand held augmentative communication devices, which have a diaphragm at one end that vibrates. This end of the device is held over the side of the neck or floor of mouth when the patient starts to articulate their tongue and lip musculature. The sounds of these movements are amplified by this device and speech is produced.

Voice Prostheses – are communication devices that can be indwelling or non-indwelling. A transesophageal puncture for speech rehabilitation is performed and a catheter is inserted at the time of a total laryngectomy. A speech pathologist measures the puncture tract and selects the appropriate size and type of prosthesis, removes the catheter and inserts the one way valve prosthesis after the patient’s surgery.
III. PURPOSE

The purpose of this policy is to define coverage for voice prostheses and laryngeal devices after a surgical laryngectomy.

IV. SCOPE

This policy applies to various MedStar Health departments as indicated by the Benefit and Reimbursement Committee. These include, but are not limited to, Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description

Total laryngectomy, most commonly performed because of laryngeal cancer, is potentially a debilitating surgery resulting in compromise of some of the most basic functions of life including speech and swallowing. Progress in voice rehabilitation, following total laryngectomy, has made an enormous difference in the whole concept of laryngeal cancers. Currently there are various options available for these patients, namely, esophageal speech, artificial larynx, and tracheoesophageal (TE) speech.

Esophageal speech requires the ability to swallow air into the upper esophagus. This is a challenging task, often involving prolonged speech therapy. Coordinated release of this air into the mouth produces vibrations in the mucosal wall of the pharynx and the pharynseophageal segment and generates sound. The resulting voice is rough and breathy with a low pitch and reduced loudness. Patients are only able to speak short phrases.

The artificial larynx is an alternative which provides a mechanical sound quality, which many patients dislike. However, it is particular useful for those unable to learn or use esophageal speech or TE speech. It works by applying handheld electronic or pneumatic vibrating devices to the side of the throat/cheek or less commonly intraorally.

Some of the newer devices, such as UltraVoice, consist of an oral unit which is built into an upper denture or a retainer and a hands free controller which transmits radio waves to the oral unit. The radio waves carry the tone of the human voice which is reproduced in the mouth by the oral unit.

Examples: Servox®, UltraVoice™, OptiVox®, TruTone™, SolaTone™, and Nu-Vois
TE valve speech approximates near normal laryngeal voice in laryngectomies. A silicone prosthesis allows air to flow from the trachea into the esophagus. At the same time a “duckbill” valve prevents aspiration of food and liquid into the trachea. The air reservoir available for TE speech is significantly greater than that for esophageal speech.

An indwelling prosthesis (Transesophageal (TE) Voice Prosthesis) is placed surgically between the airway in the neck and the esophagus. By covering the stoma with a finger, a patient is able to force air through the valve into the esophagus and out of the mouth. Relatively normal speech is achievable. The valve can be inserted at the time of the surgery or later on if the patient does not develop esophageal speech. The device is removed and re-fitted in the tracheoesophageal puncture by a Speech Pathologist every 3-6 months. Examples of the indwelling prosthesis include: Provox 2®, VoiceMaster, and Blom-Singer Indwelling Low-Pressure Voice Prosthesis.

A non-indwelling prosthesis is removed and changed by the patient. A dilator is used to open the tracheoesophageal puncture when changing the prosthesis. This type of prosthesis is secured to the neck with a safety strap to prevent accidental aspiration. Examples of the non-indwelling prosthesis include: a duckbill or low pressure prosthesis which uses a dissolvable gel capsule insertion system to cap the retention collar and eliminate insertion problems. A hands-free speaking valve is available which eliminates the need for digital occlusion of the stoma when using tracheo-esophageal speech. It is attached to the stoma via a base plate. During non-speech breathing, the valve stays in the open position. Increased pressure during exhalation required for speech, pushes the valve to a closed position, which channels the pulmonary air flow through the voice prosthesis.

B. Indications

1. Initial Voice Prostheses and Laryngeal Devices are covered when all of the following indications are met:

- The member is status post laryngectomy or the larynx is permanently inoperative; and
- The device is recommended by a laryngologist, otolaryngologist or a speech-language pathologist for voice rehabilitation; and
- The member or caregiver is able and willing to maintain the device and replace it when needed.
2. Replacement Voice Prostheses and Laryngeal Devices are covered every three to six (3-6 months) or when needed (i.e., when there are signs of increased airflow pressure or leakage).

C. Limitations

N/A

D. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Covered Codes
- L8500 Artificial larynx, any type
- L8505 Artificial larynx replacement battery/accessory, any type
- L8507 Tracheo-esophageal voice prosthesis, patient inserted, any type
- L8509 Tracheoesophageal voice prosthesis, inserted by a licensed health care provider, any type
- L8511 Insert for indwelling tracheoesophageal prosthesis, with or without valve, replacement only
- L8512 Gelatin capsules or equivalent, for use with tracheoesophageal voice prosthesis, replacement only, per 10
- L8513 Cleaning device used with tracheoesophageal voice prosthesis, pipet, brush, or equal, replacement only
- L8514 Tracheoesophageal puncture dilator, replacement only
- L8515 Gelatin capsule, application device for use with tracheoesophageal voice prosthesis

E. Variations

N/A
F. Quality Audit

Quality Audit may monitor policy compliance or billing accuracy at the request of the MedStar Health’s Technology Assessment Committee or the Benefits Reimbursement Committee.

G. Records Retention

Records Retention for documents, regardless of medium are provided within the MedStar Health, Inc. Policy and Procedure CORP.028.MH Records Retention.

H. References

Medical Literature/Clinical Information:

Regulatory/Government Source:


Disclaimer:

MedStar Health Inc. medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health Inc. and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health Inc. reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of UPMC Health Plan. Any sale, copying, or dissemination of said policies is prohibited.