Voice Prosthesis for Voice Rehabilitation Following Total Laryngectomy

Policy Number: HS-083

Original Effective Date: 2/16/2009

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. All links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com. All guidelines can be found at this site as well but selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

Approximately 136,000 cases of cancer of the larynx are diagnosed each year worldwide, with an estimated overall five-year survival rate of 68%, making it one of the more curable types of cancer of the upper aerodigestive tract. Members with advanced or recurrent squamous cell carcinoma of the larynx typically undergo total laryngectomy in the course of treatment. Total laryngectomy profoundly alters speech, respiration, and the senses of smell and taste. Members benefit from preoperative evaluation and counseling that addresses postoperative functional limitations and includes specific strategies to adjust to these limitations and function maximally. Short-term strategies such as non-verbal modes of communication and longer-term rehabilitation plans should be included. Pretreatment counseling is important for the patient and family to help adjust to post-treatment conditions which
may be immediate and severe. The speech/language pathologist may demonstrate devices that will be required for speaking, swallowing or breathing after treatment and provide information about the communication options available after surgery. Effective voice restoration is an important part of post-laryngectomy rehabilitation. Methods of speech available for members who have undergone total laryngectomy are through the use of the electronic artificial larynx or through tracheoesophageal speech.

**Artificial Larynx.** The artificial larynx, is frequently used to restore speech in post-laryngectomy patients. There are two types of artificial larynx devices: neck and intraoral. The neck type is placed against the skin on the side of the neck, under the chin, or on the cheek. Sound is conducted into the oropharynx and articulated. Intraoral devices are used for members who cannot achieve sufficient sound conduction on the skin. A small tube is placed in the posterior oral cavity, and the generated sound is articulated. The artificial larynx allows immediate voice restoration after surgery and is easy to learn. The device needs little maintenance but does rely on batteries and produces a mechanical sound. Artificial larynx devices are Class I devices and are therefore exempt from U.S. Food and Drug Administration (FDA) premarket approval (PMA) requirements. There are a number of devices available, including the UltraVoice (UltraVoice), the OptiVox (Bivona Medical Technologies), the Servox Inton® (Siemens Hearing Instruments), and the TruTone™ and SolaTone™ (Griffin Laboratories).

**Tracheoesophageal Speech and Devices.** Tracheoesophageal speech is accomplished by a surgical voice restoration technique that evolved as a result of a procedure developed by Singer and Blom in 1979. A tracheoesophageal puncture creates a surgical fistula or tract in the wall separating the trachea and esophagus. A catheter is inserted in the tract as a stent. A speech pathologist measures the length of the puncture tract and selects an appropriate size and type of prosthesis. Several days after surgery, the catheter is removed, and a one-way valved prosthesis is placed in the puncture tract. The one-way valve allows air to pass into the esophagus while preventing food and liquid from entering the trachea. The prosthesis allows air from the lungs to pass into the esophagus. Exhalation from the lung then vibrates the pharyngoesophageal segment to produce sound.

To produce speech, the patient occludes the tracheostoma to direct air through the prosthesis into the esophagus. Hands-free external-airflow valves are also available that eliminate the need for finger occlusion. The tracheoesophageal voice prosthesis produces more natural-sounding speech and allows speech restoration within two weeks of surgery.

Tracheoesophageal puncture for speech rehabilitation performed at the time of total laryngectomy is referred to as primary tracheoesophageal puncture. The procedure may also be performed weeks, or even years, following laryngectomy and is referred to as secondary tracheoesophageal puncture. The success rate for voice rehabilitation is generally higher when primary tracheoesophageal puncture is performed. One prospective case series evaluated the timing of placement of a Blom-Singer voice prosthesis for speech rehabilitation in 71 total laryngectomy patients. The rate of success for voice rehabilitation was 97% for patients who underwent primary tracheoesophageal puncture and 78% for patients who underwent secondary tracheoesophageal puncture. The use of radiotherapy and the age of the patient did not appear to impact the success rate.

There are several types of prostheses available. While some can be changed independently by the patient or caregiver, indwelling prostheses must be changed by a clinician. The patient, family, physician, and speech pathologist should select the prosthesis in concert. Phonation should be sampled with a patent puncture tract. Postoperative voice rehabilitation is usually provided by a speech and language pathologist. The patient and family are instructed in removal, cleaning and reinserion of standard prostheses, and the patient is instructed in finger occlusion. Yeast colonization caused by constant exposure to esophageal contents in radiated patients eventually destroys the integrity of the valve. Aspiration may occur if fluids leak through a malfunctioning valve. A voice prosthesis should therefore be changed every three to six months and should be replaced sooner if signs of leakage or increased airflow pressure are present. Several devices have received FDA PMA approval and are available. These include the Hood VoiceMaster (E. Benson Hood), Provox 2® (Atos Medical), and several Blom-Singer devices (Helix Medical, Inc.).
Standard or indwelling tracheoesophageal voice prostheses are considered medically necessary if ALL of the following criteria are met:
- Recommended by an otolaryngologist or speech/language pathologist; AND,
- Member has undergone a total laryngectomy; AND,
- Member or caregiver is willing and able to maintain and replace the device.

The replacement of standard or indwelling tracheoesophageal voice prostheses is medically necessary:
- Every three to six months; OR,
- There is evidence of leakage; OR,
- Increased airflow pressure is present.

Handheld electronic artificial larynx devices are considered medically necessary if the following criteria are met:
- Recommended by an otolaryngologist or speech/language pathologist; AND,
- Member has undergone a total laryngectomy

COVERED CPT®* Code
31611 Construction of tracheoesophageal fistula and subsequent insertion of an alaryngeal speech prosthesis (e.g., voice button, Blom-Singer prosthesis)

COVERED HCPCS CODES
L8500 Artificial larynx, any type
L8501 Tracheostomy speaking valve
L8505 Artificial larynx replacement battery/accessory, any type
L8507 Tracheoesophageal voice prosthesis, patient inserted, any type, each
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, each
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, each
L8514 Tracheoesophageal puncture dilator, replacement only, each
L8515 Gelatin capsule, application device for use with tracheoesophageal voice prosthesis, each

COVERED ICD-10-CM Diagnosis Codes
C32.0 - C32.9 Malignant neoplasm of larynx
D02.0 Carcinoma in situ of larynx
Z85.21 Personal history of malignant neoplasm of larynx

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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