Ultravoice II™ Intraoral Device

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied.

Suppliers are to follow The Health Plan requirements for precertification, as applicable.

The UltraVoice™ requires precertification across all product lines and a physician assessment.

National Coverage Determination Policy	None
Local Coverage Determination Policy	None
Effective Date	10/01/10
Revision/Review Date	01/19, 11/18, 06/07/18, 07/01/17, 09/28/16, 10/31/13
The Health Plan	Will review on a case-by-case basis per The Health Plan criteria.

DESCRIPTION

The Ultravoice™ is a battery-operated device that is placed in the upper denture or in a dental retainer. The modified denture produces sound in the individual's mouth and he/she uses the lips and tongue to articulate words. There is a control box and a collar microphone. The control box is worn by the individual, which signals the denture to produce sound. The control box includes off/on signals and pitch, inflection, and amplification abilities when used with the collar microphone.

COVERAGE GUIDELINES

For members that have had their larynx partially or totally removed or disabled, or for patients who are respirator dependent and still have a larynx, but are unable to produce a usable voice due to their respiratory condition. The UltraVoice™ allows individuals to talk again by providing a voice tone inside the mouth that is formed into words by the tongue and lips just like normal speaking. This is different from a speech generating device, where a computer and keyboard are used to play pre-recorded phrases.

Must have use of tongue and lips to use device.

Per review of the literature, The Health Plan has determined that there may be situations where the UltraVoice™ is medically necessary and appropriate.

STATEMENT OF NONCOVERAGE

The UltraVoice™ is contraindicated in members who cannot do not have use of the lips or tongue

The UltraVoice™ is contraindicated if the member has an intolerance to an intraoral prosthesis

The UltraVoice™ is not covered when the member can use other communication alternatives such as a speech generating device, electrolarynx, TEP or other type artificial larynx coded L8500.

CODING INFORMATION

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS CODES COVERED IF COVERAGE GUIDELINES ARE MET

L8499	MISCELLANEOUS PROSTHETICS

ICD-10 CODES COVERED IF SELECTION CRITERIA ARE MET

C32.0-C23.9	MALIGNANT NEOPLASM OF THE LARYNX
D14.1	BENIGN NEOPLASM OF THE LARYNX
D02.0	CARCINOMA IN SITU OF THE LARYNX
Z85.21	HISTORY OF MALIGNANT NEOPLASM OF LARYNX

The diagnoses or ICD-10 codes that support medical necessity are indicated above.

Purchase item. Invoice and description of item required with precertification.

DOCUMENTATION REQUIREMENTS

For the purposes of this policy it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other health care professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
    a. Member's name
    b. Date
    c. Description of item. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required. Clinical documentation of the medical condition and surgical procedure performed, if any, is also required

d. Order must include diagnosis code
e. Physician signature - with date. Date stamps are not appropriate
f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used. If no precertification was required, as within allowable quantities, the provider is to submit this information with the claim

2. There must be documentation in the supplier's records to support the medical necessity of that item. Documentation from the medical record of why other communication alternatives (TEP, esophageal speech, electrolarynx) have been considered, ruled out or tried, failed, and why.

   This information must be available upon request usually with precertification per The Health Plan policy.

3. Proof of delivery to be kept on file by the provider of the item.

   Note: If templates or forms are submitted, (e.g. A Medicare Certificate of Medical Necessity, and /or a provider created form), and all of the required information is not included, The Health Plan reserves the right to request the medical record that may include, but not limited to, the physician office notes, hospital and nursing facility records, home health records.

   Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

ULTRAVOICE™ PROVIDED TO A MEMBER WHILE IN A PART A COVERED STAY

Reimbursement for an UltraVoice™ provided to a member while the member is covered in a Part A facility is based on specific contract information with the individual facility, and whether or not the device is intended for use while the member is in the facility.

KX, GA, and GZ MODIFIERS

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

ADVANCED BENEFICIARY NOTICE

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or Advanced Beneficiary Notification (ABN) to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Please refer to PDAC website for the appropriate product classification list. dmepdac.com/

AMA CPT/ADA CDT COPYRIGHT STATEMENT

INTERNET LINKS AND SOURCES

Letter from Medicare Palmetto Government Benefit Administrators

UltraVoice website

MedLearn Matters. Change in Claims Filing Jurisdiction for Tracheo-Esophageal Voice Prostheses Healthcare Common Procedure Coding System (HCPCS) Code. MM6743. Updated 11/20/12. Last accessed 11/5/8. Retrieved from cms.gov/MLNMattersArticles/downloads/MM6743.pdf

FDA U.S. Food and Drug Administration website. Medical Devices Exemptions 510(k) and GMP Requirements. Updated 06/02/13. Last accessed 11/5/18. Retrieved from accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/315.cfm?GMPPart=874

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Blom, Eric. "Current Status of Voice Restoration Following a Total Laryngectomy". Oncology. Cancer network.com. 6/1/2000. Last accessed 09/28/16. Retrieved from

http://www.cancernetwork.com/search/solr/voice%20restoration