



Medical Assistance BULLETIN

ISSUE DATE February 6, 2026	EFFECTIVE DATE February 6, 2026	NUMBER 01-26-48, 08-26-48, 09-26-48, 10-26-07, 24-26-48, 25-26-07, 31-26-48
SUBJECT Prior Authorization Guidelines for Tracheostomy Speaking Valves and Voice Prosthetic Devices		BY <i>Sally G. Kozak</i> Sally Kozak Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.pa.gov/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents>

PURPOSE:

The purpose of this bulletin is to advise providers of new handbook pages that include guidelines for prior authorization to support the medical necessity of prescriptions for tracheostomy speaking valves and voice prosthetic devices.

SCOPE:

This bulletin applies to physicians, physician assistants, certified registered nurse practitioners, acute care hospitals, inpatient medical rehabilitation hospitals, inpatient medical rehabilitation units, hospital-based medical clinics, Federally Qualified Health Centers, Rural Health Clinics, independent medical surgical clinics, pharmacies, and durable medical equipment suppliers enrolled in the Medical Assistance (MA) Program who order, refer, prescribe, or render tracheostomy speaking valves and voice prosthetic devices to MA beneficiaries in the Fee-for-Service delivery system. Providers who order, refer, prescribe, or render these services in the MA managed care delivery system should address any prior authorization questions to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is mandated by Title XIX of the Social Security Act to implement a statewide utilization review program that safeguards against unnecessary or inappropriate use of services and excessive payments, assesses the quality of those services, and controls utilization of services. Prior authorization is meant to ensure that services are medically necessary and appropriate. Additionally, section 443.6(b)(1) of the act

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
<https://www.pa.gov/agencies/dhs/departments-offices/omap-info>

of June 13, 1967, (P.L. 31, No. 21) (62 P.S. §443.6), referred to as the Human Services Code, requires MA providers to obtain prior authorization for prostheses.

A tracheostomy speaking valve is a medical device that connects to a tracheostomy tube, allowing individuals with a tracheostomy to voice and produce speech sounds by redirecting airflow through the vocal cords.

A voice prosthetic device is used to help individuals who have lost their ability to speak by enabling them to produce speech through alternative means. They provide a means for individuals to regain their ability to communicate verbally after losing their natural voice.

On June 24, 2025, the Department advised providers of the change to Milliman Care Guidelines (MCG) in MA Bulletin 99-25-03 titled, "Updates to Screening Guidelines for Prior Authorization." There are no MCG guidelines for tracheostomy speaking valves and voice prosthetic devices. Therefore, the Department is advising providers of clinical guidelines to be utilized for prior authorization of tracheostomy speaking valves and voice prosthetic devices for MA beneficiaries.

PROCEDURE:

Effective with the issuance of this bulletin, providers are to refer to the attachments for the guidelines for the prior authorization review of tracheostomy speaking valves and voice prosthetic devices. Providers may also refer to the Department's website to access the PROMISe™ Provider Handbook 837 Professional/CMS-1500 Claim Form at: <https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/providers/promise-guides/documents/837-professional-cms-1500-claim-form.pdf>, or the PROMISe™ Provider Handbook 837 Institutional/UB-04 Claim Form at: <https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/providers/promise-guides/documents/837%20Institutional%20UB-04%20Claim%20Form.pdf>.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for products that require prior authorization.

ATTACHMENTS:

Attachment 1 - PROMISe™ Provider Handbook 837 Professional/CMS-1500 Claim Form, Section 7.1.2.11, Prior Authorization of Prior Authorization of Tracheostomy Speaking Valves and Voice Prosthetic Devices, Effective February 6, 2026.

Attachment 2 - PROMISe™ Provider Handbook 837 Institutional/UB-04 Claim Form, PROMISe™ Provider Handbook, Section 7.1.2.9, Prior Authorization of Prior Authorization of Tracheostomy Speaking Valves and Voice Prosthetic Devices, Effective February 6, 2026.

7.1.2.11 Prior Authorization of Tracheostomy Speaking Valves and Voice Prosthetic Devices

- I. General Requirements for Prior Authorization of Tracheostomy Speaking Valves and Voice Prosthetic Devices
 - A. Prescriptions that Require Prior Authorization
 - B. Documentation for Review
 - C. Review of Documentation for Medical Necessity
 - D. Clinical Review Process
 - E. References

I. GENERAL REQUIREMENTS FOR PRIOR AUTHORIZATION OF TRACHEOSTOMY SPEAKING VALVES AND VOICE PROSTHETIC DEVICES**A. Prescriptions that Require Prior Authorization**

All prescriptions for tracheostomy speaking valves.
All prescriptions for voice prosthetic devices.

B. Documentation for Review

The following information should be submitted with an initial authorization request for tracheostomy speaking valves and voice prosthetic devices:

1. Diagnoses relevant to requested equipment, e.g., tracheostomy, laryngectomy.
2. Medical records showing assessments, evaluations, and recommendations for use by a speech language therapist, laryngologist, or otolaryngologist.
3. Medical records demonstrating current level of function of the beneficiary, including cognitive status, any behavioral problems, respiratory status, tracheostomy type and/or impairment of voice communication.

The following information should be submitted with an authorization request for replacement voice prosthetic devices or tracheostomy speaking valves:

1. Medical records demonstrating the voice protheses or laryngeal device is not working (e.g. showing signs of increased airflow pressure or leakage).

C. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization for a prescription for tracheostomy speaking valves and voice prosthetic devices, the determination of whether the requested service is medically necessary will take into account whether the beneficiary:

1. Is alert and capable of following instructions, and
2. Has had a speech therapy evaluation/assessment, and
3. Is able and willing, or the caregiver is able and willing, to maintain the device and replace it when needed.

In addition, for tracheostomy speaking valves, the determination of whether the requested service is medically necessary will take into account whether the beneficiary:

1. Has difficulty speaking due to having a tracheostomy, and
2. Has a stable respiratory/cardiovascular status to be able to tolerate the use of a speaking valve and can exhale adequately, and

3. Has no anatomical issues that may impact on upper airway patency such as tracheal stenosis or an obstructing lesion.

In addition, for voice prosthetic devices, the determination of whether the requested service is medically necessary will take into account whether the beneficiary is status post laryngectomy or the larynx is permanently inoperative.

For requests for authorization of a replacement of voice protheses and laryngeal devices, in addition to the items above, whether the existing voice prosthetic and/or laryngeal device is not functioning.

D. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section C to assess the medical necessity of a prescription for voice prosthetic devices and trach speaking valves. If the guidelines in Section C are met, the reviewer will prior authorize the service. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

E. References

1. Cancer Research UK. (n.d.). Voice prosthesis. Retrieved from <http://www.cancerresearchuk.org/about-cancer/laryngeal-cancer/living-with/speaking-after-laryngectomy/voice-prosthesis>
2. Centers for Medicare & Medicaid Services. (2010). "Change in claims filing jurisdiction for tracheo-esophageal voice prosthesis healthcare common procedure coding system (HCPCS) code". Retrieved from <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R686OTN.pdf>
3. Passy-Muir. (n.d.). Swiss Paraplegic Group policy: Instructions/procedure for use of the speaking valve. Retrieved from https://www.passy-muir.com/wp-content/uploads/2018/10/swiss_paraplegic_policy_english.pdf
4. Passy-Muir. (n.d.). Passy Muir valve placement. Retrieved from http://www.passy-muir.com/wp-content/uploads/2020/12/NWTHS_PMV-policy-procedure.pdf
5. Vlantis, A.C., Gregor, R.T., Elliot, H., & Oudes, M. (2003). "Conversion from a non-indwelling to a Provox2 indwelling voice prosthesis for speech rehabilitation: comparison of voice quality and patient preference." *Journal of Laryngology and Otology*, 117(10), 815–820. Retrieved from: <https://pubmed.ncbi.nlm.nih.gov/14653926/>

7.1.2.9 Prior Authorization of Tracheostomy Speaking Valves and Voice Prosthetic Devices

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2. Centers for Medicare & Medicaid Services. (2010). "Change in claims filing jurisdiction for tracheo-esophageal voice prosthesis healthcare common procedure coding system (HCPCS) code". Retrieved from <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R686OTN.pdf>
3. Passy-Muir. (n.d.). Swiss Paraplegic Group policy: Instructions/procedure for use of the speaking valve. Retrieved from https://www.passy-muir.com/wp-content/uploads/2018/10/swiss_paraplegic_policy_english.pdf
4. Passy-Muir. (n.d.). Passy Muir valve placement. Retrieved from http://www.passy-muir.com/wp-content/uploads/2020/12/NWTHS_PMV-policy-procedure.pdf
5. Vlantis, A.C., Gregor, R.T., Elliot, H., & Oudes, M. (2003). "Conversion from a non-indwelling to a Provox2 indwelling voice prosthesis for speech rehabilitation: comparison of voice quality and patient preference." *Journal of Laryngology and Otology*, 117(10), 815–820. Retrieved from: <https://pubmed.ncbi.nlm.nih.gov/14653926/>