- Venous insufficiency ulcers:
  1. Compression bandages and/or garments have been consistently applied, and
  2. Leg elevation and ambulation have been encouraged.
- Non-healing surgically created or traumatic wounds:
  1. Documentation of medical necessity for accelerated formation of granulated tissue which cannot be achieved by other topical wound treatments.

Non-covered conditions:

- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
- Untreated osteomyelitis within the vicinity of the wound;
- Cancer present in the wound,
- The presence of a fistula to an organ or body cavity within the vicinity of the wound.

Documentation requirements (for continuation of services):

- Documentation of wound evaluation and treatment, recorded in the member's medical record, must indicate regular evaluation and treatment of the member's wounds and must be available upon request.
- Documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth and amount of wound exudate (drainage), indicating progress of healing must be entered at least weekly.
- If treatment beyond the initial approved period of service is indicated by the treating physician upon review of the clinical progress, this documentation must be submitted with the new prior approval request. Lack of improvement of a wound is defined as a lack of progress in quantitative measurements of wound characteristics including wound length and width (surface area), or depth measured serially and documented, over the approved period of service.
- Wound healing is defined as improvement occurring in either surface area or depth of the wound. If detailed documentation is insufficient or if any measurable degree of wound healing has failed to occur, prior approval beyond the initial approved period of service will not be granted.
- Upon completion of treatment, documentation regarding the outcome of treatment with NPWT must be submitted to the prior approval office.

SPEECH GENERATING DEVICES

Prior approval (PA) is the process of evaluating the request for Durable Medical Equipment (DME) in order to determine the medical necessity and appropriateness of the DME according to policies and regulations. Requests for PA are submitted through DME providers enrolled in New York State Medicaid. The DME provider is responsible for submitting all necessary documentation

required for the PA request in accordance with 18 New York State Codes, Rules and Regulations ("NYCRR") Part 513. Please refer to Title: Section 513.0 Policy, purpose and scope at https://regs.health.ny.gov/content/section-5130-policy-purpose-and-scope for further information.

The following guidelines were developed to assist DME providers, ordering practitioners, Medicaid members, caregivers, and evaluating clinicians with the PA process for Speech Generating Devices (SGD). The purpose of these guidelines is to provide detailed coverage criteria for SGDs and accessories so that medically necessary equipment is provided to Medicaid beneficiaries in a timely manner in compliance with applicable Federal. Laws, policies and New York State Codes, Rules and Regulations. These guidelines are the product of collaboration with practitioners, therapists, medical equipment providers, advocates and New York State Medicaid medical review staff, utilizing state and national standards and are the basis for compliance with applicable Medicaid policies.

As outlined in 18 NYCRR Section 513.0(b)(2), the Department retains the authority and responsibility to exercise administrative discretion in the supervision of the program and make decisions with respect to the application of the rules, regulations and policies of the Medicaid program.

SGDs are one strategy used for augmentative alternative communication (AAC). AAC employs strategies to assist individuals who are unable to effectively use their own speech to communicate. Successful use of a device requires the ability to functionally communicate using the device's output in addition to physical ability to activate and manipulate the device. A detailed and individualized assessment of a person's communication, cognitive, language, motor, and visual abilities is required to determine which device will meet the person's medical needs and abilities.

New York State Medicaid coverage includes only dedicated devices. Dedicated AAC devices are limited to primarily serve a medical need (e.g., solely for the purpose of expressive communication) such that they are generally NOT useful in the absence of disability, illness, or injury. Non-dedicated devices are non-medical devices designed for a non-medical purpose and are generally useful in the absence of disability, illness, or injury; however, they may also include functionality for use as a communication tool.

Coverage Guidelines

1) Speech Generating Devices (SGDs) and Related Accessories

An SGD will be considered medically necessary when documentation demonstrates all of the following:

a) The member has a severe expressive communication impairment related to a medical condition or developmental disability that interferes with the member's ability to meet daily functional communication, AND;
b) The member's ability to communicate using speech and/or writing is insufficient to meet daily functional communication needs, AND;
c) The member cannot meet daily functional communication needs with any unaided means of communication, AND;
d) The recommended device can be used to communicate with multiple individuals in multiple settings within the trial location while conveying varying message types without being fully dependent on prompting or assistance in producing the communication, AND;
e) The member has the cognitive, auditory, visual, language, and physical abilities to use the recommended SGD for functional communication, AND;
f) A licensed Speech Language Pathologist (SLP) experienced in AAC service delivery has made the recommendation for the device and a licensed physician, nurse practitioner, or physician's assistant enrolled as a NY State Medicaid provider has prescribed the device or software, AND;
g) The member has demonstrated the ability to use the recommended device and accessories or software for functional communication as evidenced by a data-driven device trial showing that skills can be demonstrated repeatedly over time, beyond a single instance or evaluation session, AND;
h) The SGD and related accessories are the adequate, less expensive alternative to enable the member to meet daily functional communication needs. There must be clear explanation of why other alternatives were ruled out. (See 18 NYCRR 513.4(d)), AND
i) The SGD and related accessories must allow members to improve their communication to a functional level not achievable without a SGD or less costly device.

2) Eye Control/Eye Gaze Accessory

An eye gaze accessory should be considered only after all other methods of accessing the SGD have been evaluated and ruled out. The recommendation for an eye gaze accessory must be based on an assessment by the SLP and either a PT or OT. Other professionals also may be needed for members who present additional issues, such as vision impairment that interferes with the ability to use eye gaze to access a SGD. An eye gaze accessory will be considered medically necessary when objective documentation demonstrates the following:

a) Scanning and head pointing systems have been tried repeatedly over time (within a single evaluation session or in several sessions) were ruled out as not appropriate.
b) The member demonstrates abilities to use eye gaze technology beyond cause and effect activation, simple eye tracking activities, and learning tools. A recent vision assessment may be required.

c) The member has the physical ability to activate the system and demonstrate meaningful/functional use of the device without being fully dependent on prompting or assistance in producing the communication
d) A data driven objective trial with the requested eye gaze access device has occurred.
e) Documentation shows that other eye gaze access devices from multiple manufacturers have been considered.
f) The member can use the eye gaze technology to communicate significantly beyond the capabilities of a light technology eye gaze system such as an eye gaze board or E-Tran system with less partner assistance.
g) A PT and/or OT with assistive technology (AT) experience has explored the member's positioning needs and head control abilities and all potential less costly access methods, including non-voice output eye gaze boards.

3) Mounts

Mounts are used to secure SGDs for access and safety. Reimbursement is for one mount that meets the member's needs in all customary environments. Selection should be based on medical necessity and 18 NYCRR Section 513.4(d)

Indication for Non-Coverage

1) The member fails to demonstrate during the trial period or at any subsequent time the ability to learn to use the device or software functionally for communication.
2) The requested device does not meet the member's current and reasonably foreseeable communication abilities and needs.
3) The intention is to unlock the device for uses other than communication or for use by other individuals.
4) The request includes reimbursement for the installation of the software/program or technical support of a non-dedicated device. (Communication software/program is a covered benefit when all other coverage criteria are met.)
5) The request is for reimbursement for a device or maintenance of a device (e.g. laptop, tablet) for which Medicaid-funded communication software has been installed.
6) The request is for reimbursement for repairs of a device and the minimum coverage requirements for the SGD are not met.
7) The request is for repairs, cleaning or other services for non-dedicated communication devices.
8) The request is for an upgrade to new technology that is not medically necessary.
9) The request is for replacement of a device due to new technology or replacement based on a manufacturer's recommended replacement schedule when the beneficiary's current SGD meets his/her medical and functional communication needs.

10) The request is for multiple devices, back up or duplicate accessories.
11) The request is for environmental control devices such as switches and control boxes.

Documentation Requirements

Each SGD request is reviewed on an individual basis. Please refer to 18NYCRR Section 513.0(b)(2). Medicaid reserves the right to request an evaluation of a member from another licensed medical professional, other than the SLP, for supporting the appropriateness of the device being recommended. In addition to the specific requirements stated below, the documentation submitted in support of a funding request for a SGD, mount or related accessories must establish that all the standards stated in the Coverage Guidelines are met. Documentation submitted should include the following:

1) Detailed Fiscal Order including the make and model of equipment requested (see "Filling Orders for DMEPOS at https://www.emedny.org/ProviderManuals/DME/PDFS/DME_Policy_Section.pdf)
2) A cost quote from the manufacturer of all the equipment and components as ordered (e.g., make, model). Include the usual and customary price charged to the general public and all dealer discounts.
3) Individualized Education Plan (IEP) for school aged members
4) Formal face to face evaluation and assessment written by a SLP within 6 months prior to the date of PA submission that includes:
   a) Background information
      i. Medical diagnosis; course and prognosis
      ii. Significant history and medications
      iii. Communication disorder(s)/diagnosis and severity; course and prognosis
      iv. Past speech/ spoken language treatment
      v. Member's history, school, vocational status
      vi. Member's living environment
      vii. Members' attitude and motivation to communicate
   b) Current communication abilities
      i. Speech/articulation and intelligibility
      ii. Expressive language skills
      iii. Receptive language skills
      iv. Current mode of communication including nonverbal communication methods
      v. Current method of communicating pain, discomfort or other medical emergencies
      vi. Previous use of AAC including devices, dates utilized, and explanation why the currently used device does not meet the member's current and reasonably foreseeable daily functional communication needs
      vii. Currently used functions of communication (e.g. requesting, protesting, commenting, describing, etc.),

viii. Reading, writing, and spelling abilities

c) Sensory functioning
   i. visual abilities (e.g. tracking ability, acuity for symbol size, etc.)
   ii. auditory abilities as they relate to a SGD system

d) Psychometric or developmental assessment characterizing cognitive and learning abilities and levels of function (include results of most recent evaluation, name of test, IQ or developmental levels, and date performed). NOTE: Members who do not exhibit cognitive deficits may not need to participate in assessments, however Medicaid reserves the right to request additional documentation regarding cognitive functioning after initial review of PA submission.

e) Behavioral and Learning abilities
   i. Executive-functioning skills, including attention span
   ii. Memory
   iii. Problem solving skills
   iv. Understanding of cause and effect

f) Motor abilities
   i. Gross motor abilities: ambulatory, uses walker or wheelchair, head control and trunk mobility
   ii. Positioning and Seating: current DME used, positioning needs as related to SGD use including eye gaze access if necessary (including primary positions in which the member spends a typical day and percentage of time in each position)
   iii. Fine Motor and upper extremity abilities and functional use (including strength and endurance for carrying SGD)
   iv. Alternative access (except for access via gaze), e.g., head mouse, single switch or multiple switch scanning, or other alternative access method) should be evaluated by a PT, OT or other health professional when necessary.

g) Formal evaluation of AAC by evaluating SLP
   i. Description of need, short and long-term goals for device use; primary communication partners; current and reasonably foreseeable communication environments
   ii. Treatment options considered including past use of communication supports and why each does not meet the member’s communication needs
   iii. Description of consideration of more than one device by multiple manufacturers within the same HCPCS category that includes explanation of why devices were selected or ruled out.
   iv. Data driven AAC device trial of the recommended device. The following items should be addressed:
      1) Length and dates of trial, amount of time device was accessed during the trial
      2) Time framed measurable goals for functional communication set for trial and criteria for measurement
      3) Empirical data including baseline performance and results of trial period goals

4) Description of environments in which device was trialed such as, but not limited to, home, school, and community
5) Whether communication occurred in both structured and unstructured settings
6) Manner in which the device was accessed (e.g. eye gaze, direct selection, scanning-type)
7) Description of the member's ability to use the SGD for functional communication (ability to use training software, including but not limited to cause and effect games does not demonstrate functional communication)
8) Sampling of multiple messages communicated including the frequency, type (e.g. verbal, physical, gesture), and level of cueing required
9) Number of messages expressed in a time period including the type and level of cueing required
10) Communicative intents and functions expressed
11) If recommending eye gaze access: the member's endurance to maintain gaze, ability to calibrate or obstacles to calibration

v. Description and rationale for the software or language system recommended including specific page sets/layout/symbols per page/vocabulary organization.
vi. Description of recommended device; the rationale for the selection including a cost comparison among devices considered from more than one manufacturer; and how the recommendation meets the current communication needs of member.
vii. Description of environmental supports for SGD use: capacity of family/caregivers/friends to assist in care and maintenance of SGD; need for their training.
viii. Documentation that device is configured to limit use to the purpose of communication.
ix. Explanation of how the device is the adequate, less expensive alternative to meet the member's medical need.

h) Outline of a training and implementation plan that will be used to ensure the most appropriate use of the device over time, including plans for maintaining the system, implementing programming updates and modifications due to changing language, environmental, or motoric needs.
i) A signed and dated attestation by the SLP that the licensed/certified medical professional (LCMP) has no financial relationship with the Medicaid provider or SGD manufacturer
j) Dated signature of SLP, license number and pertinent contact information.
k) All other professionals directly involved in the evaluation should sign, date, and provide their license numbers.

Documentation for Consideration for Coverage of:
1) Upgrade

The Medicaid-funded or member-owned device is no longer clinically effective at meeting functional communication needs. Documentation must include

a) Statement addressing why the device is no longer clinically effective in meeting member's functional communication needs
b) Statement of significant changes that have occurred in the member's physical or linguistic abilities, or social environment, and how these changes impact the member's ability to functionally communicate with the currently owned device.
c) Establish why the replacement device is required (not solely due to advances in technology or other factors that are not medical in nature).

2) Repairs

a) The minimum coverage criteria for SGDs are met.
b) The request includes a quote from the manufacturer of the initially covered device for the cost of the repairs (The decision whether to repair or replace a device will be based on a determination of which will be most cost effective.)
c) When repair is required due to accidental or non-accidental trauma to the device, the SLP or ordering Physician must provide a statement indicating the cause of damage and what reasonable measures will be taken to prevent a recurrence.

The reimbursement for a new SGD includes all necessary screen protectors, batteries, power source components, software, stands (not including mounts: e.g. wheelchair or desk mounts) and any type of carrying case.

E2500[F2] *'-RR'*	**#Speech generating device, digitized speech, using pre-recorded messages, less than or equal to 8 minutes recording time**
E2502[F2] *'-RR'*	**#Speech generating device, digitized speech, using pre-recorded messages, greater than 8 minutes but less than or equal to 20 minutes recording time**
E2504[F2] *'-RR'*	**#Speech generating device, digitized speech, using pre-recorded messages, greater than 20 minutes but less than or equal to 40 minutes recording time**
E2506[F2] *'-RR'*	**#Speech generating device, digitized speech, using pre-recorded messages, greater than 40 minutes recording time**
E2508[F2] *'-RR'*	**#Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device**
E2510[F2]	**Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access**
E2511[F2]	**Speech generating software program, for personal computer or personal digital assistant**

E2512[F3] **Accessory for speech generating device, mounting system**

E2599[F3] **Accessory for speech generating device, not otherwise classified**

References

- American Speech-Language Hearing Association (ASHA) Practice Portal: Augmentative and Alternative Communication available at http://www.asha.org/PRPSpecificTopic.aspx?folderid=8589942773&section=Key_Issues. Accessed February 15, 2018.
- ASHA Position Statement on Access to Communication Services and Supports: Concerns Regarding the Application of Restrictive "Eligibility" Policies available at http://www.asha.org/policy/PS2003-00227/. Accessed February 15, 2018
- ASHA Medical Necessity for Speech-Language Pathology and Audiology Services available at https://www.asha.org/practice/reimbursement/medical-necessity-for-audiology-and-SLP-services/. Accessed February 15, 2018
- MassHealth Guidelines for Medical Necessity Determination for Augmentative and Alternative Communication Devices and Speech Generation Devices. http://www.mass.gov/eohhs/docs/masshealth/guidelines/mng-aac.pdf

K0601[F8] **#Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each**

K0602[F8] **#Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each**

K0603[F8] **#Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each**

K0604[F8] **#Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each**

K0605[F8] **#Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each**

K0606[F9] **Automatic external defibrillator, with integrated electrocardiogram analysis, garment type**
See following link: K0606 General Coverage Guidelines

L7900[F2] **Vacuum erection system**
- Limited to diagnosis of impotence, with an order from a urologist or neurologist.

L8500[F2] **#Artificial larynx, any type**