
Table of Contents

General Information.....	1
Virginia Medicaid Web Portal	1
Freedom Of Choice	1
Managed Care.....	2
Covered Services	2
Dme Covered Through Early And Periodic Screening, Diagnostic, And Treatment (EPSDT)	3
Medical Necessity.....	4
Generally Non-Covered Dme And Supplies	4
Certificate Of Medical Necessity (Cmn)/Dmas-352	5
LENGTH OF CERTIFICATION ON THE CMN/DMAS-352	7
RETROACTIVE ELIGIBILITY.....	7
CMN EXCEPTIONS.....	7
Face-To-Face Requirments For DME – Fee-For-Service.....	7
Dme And Supplies Listing -Appendix B.....	8
Payment Methodologies	9
MISCELLANEOUS HCPCS AND CODES PRICED AS INDIVIDUAL CONSIDERATION (Ic).....	10
BILLING E1399 – MISCELLANEOUS HCPCS CODE	11
MISCELLANEOUS CODES – CATEGORY SPECIFIC	12
Provider Responsibilities For Provision Of Dme And Supplies.....	12
Interqual® Requirements For All Dme.....	13
Coverage Criteria For Specific Dme And Supplies	14
PATIENT LIFTS	14
WHEELCHAIRS AND COMPONENTS	14
Power Wheelchairs.....	15
Power Operated Vehicle (Pov)/Scooter.....	16
All Single-Power Option Wheelchairs	17
All Multiple-Power Option Wheelchairs.....	17
Power Seating	17
Push-Rim Activated Power Assist Device	17
AUGMENTATIVE COMMUNICATION DEVICES	21
Collaborative Funding For Communication Devices.....	22
ADAPTIVE EQUIPMENT	23
BLOOD GLUCOSE MONITORS	24
For Pregnant Women	26
BREAST PUMPS FOR PREGNANT AND POSTPARTUM WOMEN	26
DISPOSABLES TO CARRY OUT INFECTION CONTROL PROCEDURES.....	28
ENTERAL NUTRITION (EN)	29
Enteral Nutrition - Early Periodic Screening, Diagnostic, And Treatment (EPSDT)	31
HOME INFUSION THERAPY	32
Provider Eligibility	32

Therapy Coverage.....	33
Service Day Rate Definition.....	33
Special Considerations.....	34
Nursing Visits	34
Multiple Therapies	34
Hydration Therapy.....	35
Pain Management	35
Chemotherapy.....	36
Drug Therapy	36
Total Parenteral Nutrition - TPN	36
Codes For Purchased I.V. Pumps.....	37
Codes For Incompatible Drug Therapy.....	37
REHABILITATION EQUIPMENT.....	38
RESPIRATORY EQUIPMENT AND SERVICES.....	39
Apnea Monitors	39
Criteria For Home Monitoring	40
Guidelines For Discontinuation Of Monitor Reimbursement.....	40
Pneumograms/Downloads, Polysomnograms, And Multi-Channel Sleep Studies	41
Criteria For Rental Versus Purchase Ofof An Apnea Monitor.....	41
Non-Compliant Behavior	42
Service Maintenance Agreements For Purchased Apnea Monitors	42
CO ₂ Monitors.....	43
Humidification Systems	44
Oxygen.....	45
Evidence Ofof Medical Necessity	45
Health Conditions	47
Laboratory Evidence.....	49
Evidence Ofof Medical Necessity	50
Reimbursement	51
Pulse Oximetry (Continuous Pulse Oximeter)	52
Laboratory Evidence.....	52
Certificate Of Medical Necessity.....	52
Reimbursement For Daily Use Pulse Oximetry	53
Pulse Oximetry (Periodic Or Intermittent Pulse Oximeter Studies).....	53
Suction Machines	54
Non-Invasive Airway Assistive Devices	55
Non-Invasive Airway Assistive Devices For Other Respiratory Disorders	56
Documentation And Coverage	57
Home Invasive Mechanical Ventilators.....	59
Primary Ventilator Criteria	59
Documentation And Coverage	59
Criteria For Back-Up Ventilators.....	61
Service Maintenance For Ventilators.....	61
Home Non-Invasive Ventilators	62
Non-Invasive Ventilator Criteria.....	62
Documentation And Coverage	65
Service Maintenance For Ventilators.....	67
HOSPITAL BEDS	68
THERAPEUTIC PRESSURE REDUCING MATTRESSES	69
Staging Of Pressure Ulcers	70
Group I Pressure Reducing Support Surfaces	70
Group Ii Pressure Reducing Support Surfaces.....	71
Group Iii Pressure Reducing Support Surface.....	73

WOUND CARE SUPPLIES	75
INCONTINENCE PRODUCTS	78
Disposables Related To Incontinent Supplies	78
Types Of Urinary Incontinence	80
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATORS (TENS)	81
Coverage Of Orthotics.....	82
GENERAL MEDICAID POPULATION	82
MEDICAID INDIVIDUALS PARTICIPATING IN AN INTENSIVE REHABILITATION PROGRAM.....	83
EPSDT (CHILDREN UNDER 21 YEARS OF AGE).....	84
Coverage Of Prosthetics	84
GENERAL INFORMATION	84
SERVICE AUTHORIZATION	84
COVERAGE AND LIMITATIONS.....	84
NON-COVERED SERVICES	84
PAYMENT FOR SERVICES	85
PAYMENT METHODOLOGY	85
COST SHARING.....	85
DME COVERED IN INTENSIVE REHABILITATION SETTINGS	85
DME COVERED IN NURSING FACILITIES.....	86
Ventilators And Associated Supplies	87
HOME HEALTH CARE.....	88
HOSPICE CARE	88
PACE	88
Equipment Repairs	88
Repair Versus Replacement/Purchase Guidelines.....	89
Rental And Purchase Guidelines.....	90
Replacement Of Dme Following A Natural Disaster	91
Payment For Services	91
GENERAL INFORMATION	91
COST SHARING.....	93
Ordering Forms	93

GENERAL INFORMATION

This chapter describes the Durable Medical Equipment (DME) and Supplies available under the Commonwealth of Virginia's *State Plan for Medical Assistance* (Medicaid). DME services are provided in accordance with the requirements of 42 CFR §§ 440.70 and 441.15 and are available to all categorically and medically needy individuals determined to be eligible for assistance. DME services under Virginia Medicaid must not be of any less or greater duration, scope, or quality than that provided individuals not receiving state and/or federal assistance for those DME services covered by Virginia Medicaid. All items and supplies must meet the DME coverage criteria and the Virginia Administrative Code (VAC).

For the purpose of the Virginia Medical Assistance Program, a DME provider is a Medicaid enrolled provider that is primarily engaged in durable medical equipment and supplies outside of an institutional setting.

VIRGINIA MEDICAID WEB PORTAL

The Virginia Medicaid Web Portal is the gateway for providers to transact all Medicaid and FAMIS (Family Access to Medical Insurance Security Plan) business via one central location on the Internet. The web portal provides access to Medicaid Memos, Provider Manuals, providers search capabilities, provider enrollment applications, training and education. Providers must register through the Virginia Medicaid Web Portal in order to access and complete secured transactions such as verifying Medicaid eligibility, service limits and service authorization or by submitting a claim. The Virginia Medicaid Web Portal can be accessed at: www.virginiamedicaid.dmas.virginia.gov.

FREEDOM OF CHOICE

Virginia Medicaid fee-for-service individuals are free to choose a Medicaid enrolled DME and supply provider when medical equipment and supplies are a covered service. Provision of “free” supplies or items to Medicaid individuals as an enticement for their business may violate federal law and is prohibited. If a DME provider is utilizing this practice, the Department of Medical Assistance Services (DMAS) may impose a civil money penalty sanction against the DME provider.

NOTE: If a provider accepts a Medicaid individual as a client, the provider must provide all of the DME services that are provided to the general population.

MANAGED CARE

Managed Care Enrolled Individuals

Most individuals enrolled in the Medicaid program for Medicaid and FAMIS have their services furnished through contracted Managed Care Organizations (MCOs) and their network of providers. All providers should check eligibility (Refer to Chapter 3) prior to rendering services to confirm which MCO the individual is enrolled in. The MCO may require a referral or prior authorization for the individual to receive services. All providers are responsible for adhering to this manual, their provider contract with the MCOs, and state and federal regulations.

There are two different managed care programs, Cardinal Care and Program for All-Inclusive Care for the Elderly (PACE)), for Medicaid individuals. Go to the websites below to find which health plan participates in each managed care program in your area:

- [http://www.dmas.virginia.gov/#/cccplusCardinal Care Managed Care \(CCMC\) Cardinal Care Managed Care | DMAS - Department of Medical Assistance Services \(virginia.gov\)](http://www.dmas.virginia.gov/#/cccplusCardinal%20Care%20Managed%20Care%20(CCMC)%20Cardinal%20Care%20Managed%20Care%20|%20DMAS%20-%20Department%20of%20Medical%20Assistance%20Services%20(virginia.gov))
- Program of All-Inclusive Care for the Elderly (PACE)
<http://www.dmas.virginia.gov/#/longtermprograms>

COVERED SERVICES

DME and supplies are a covered service available to the entire Medicaid population including both Fee for Service and Managed Care enrollees *as described in this manual*. In addition, the Department of Medical Assistance Services (DMAS) may cover DME services when the individual is under age 21 and the item or supply could be covered under the Virginia *State Plan for Medical Assistance* (the *State Plan*) through the Early and Periodic Screening, Diagnostic, and Treatment benefit (EPSDT).

All medically necessary medical equipment and supplies under the *Virginia Administrative Code* (12VAC30-50-165) may be covered only if they are necessary to carry out a treatment prescribed by a practitioner (MD, Doctor of Osteopathy (DO), physician assistant (PA) or nurse practitioner (NP). Unusual amounts, types, and duration of usage must be authorized by DMAS, or its contractor in accordance with published policies and procedures. When determined to be cost-effective by DMAS, or its contractor, payment may be made for rental of the equipment in lieu of purchase. Individuals shall be notified of their right to appeal any denial determinations.

DME providers shall adhere to all applicable DMAS policies, laws, and Federal and State regulations for durable medical equipment and supplies, including the face-to-face requirements in 42 CFR 410.38. DME providers shall comply with all other applicable Virginia laws and regulations requiring licensing, registration, or permits. Failure to comply with such laws and regulations shall result in denial of reimbursement or retraction

of payments made, for durable medical equipment and supplies that are regulated by licensing agency or agencies. (12 VAC 30-50-165)

No provider shall have a claim of ownership on DME reimbursed by Virginia Medicaid once it has been delivered to the Medicaid individual. Providers shall only be permitted to recover DME, for example, when DMAS determines that it does not fulfill the required medically necessary purpose as set out in the Certificate of Medical Necessity (CMN), when there is an error in the ordering practitioner's CMN, or when the equipment was rented.

NOTE: The provider must accept Medicaid payment as payment in full and may not bill the individual, including shipping and handling charges. Costs incurred for shipping and handling, except when otherwise noted, are considered to be a part of the DME provider's overhead/business expenses.

The provider and all employees shall adhere to the DMAS policies and regulations. The provider must also ensure that all requirements for services are met in order to receive payment from DMAS. If it is found during a post-payment audit that the DME provider has not met all of the requirements, the provider may be required to refund the payment to DMAS.

DME COVERED THROUGH EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT (EPSDT)

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federally mandated benefit that provides screening and treatment for Medicaid individuals who are under the age of 21. Some DME not otherwise available to Medicaid individuals may be available for this age group through the EPSDT benefit, if medically necessary. **NOTE:** Children who are eligible for Medicaid/FAMIS Plus may be eligible for DME.

EPSDT is not a separate Medicaid program. EPSDT is distinguished only by the scope of treatment services available to children who are under the age of 21. Because EPSDT criteria must be applied to each service that is available to EPSDT eligible children, EPSDT criteria must be applied to all requests requiring service authorization for Medicaid services. The criteria requires that the service/item is practitioner ordered and is medically necessary to correct, ameliorate ("make better") or maintain the individual's condition. For example, coverage under EPSDT may be requested when a child needs a device that is not covered under the DME and supplies benefit or the child needs a device that exceeds the frequency limitations defined in the DME program then the devices may be requested for coverage through the EPSDT benefit.

When the DME service needs of an individual fall outside of coverage rules described in this manual, providers should send the service authorization request directly to the DMAS service authorization contractor for consideration under the EPSDT benefit. Additional information on the EPSDT benefit can be accessed by submitting any questions via e-

mail to EPSDT@dmas.virginia.gov.

MEDICAL NECESSITY

Only supplies, equipment, and appliances that are determined medically necessary may be covered for reimbursement by DMAS. (12VAC30-50-165) The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to DMAS, or its contractor. Medically necessary DME and supplies shall be:

- Ordered by the practitioner on the CMN/DMAS-352;
- A reasonable and medically necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual;
- Not furnished for the safety or restraint of the individual, or solely for the convenience of the family, attending practitioner, or other practitioner or supplier;
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational);
- Furnished at a safe, effective, and cost-effective level; and
- Suitable for use, and consistent with 42 CFR 440.70(b)(3), that treats a diagnosed condition or assists the individual with functional limitations.

GENERALLY NON-COVERED DME AND SUPPLIES

As described above, for individuals under age 21, coverage must be explored under EPSDT.

Supplies, equipment and appliances that are generally not covered include, but are not limited to, all of the following: (12VAC30-50-165)

- Space conditioning equipment, such as room humidifiers, air cleaners, and air conditioners;
- DME and supplies for any hospital patient or nursing facility resident, except ventilators and the associated supplies that are approved by DMAS, or its contractor, and provided to nursing facility residents (see Nursing Facility Manual for DME covered for nursing facility residents);
- Furniture or appliances not defined as medical equipment (such as blenders, bedside tables, mattresses other than for a hospital bed, pillows, blankets or other bedding, special reading lamps, chairs with special lift seats, hand-held shower devices, exercise bicycles, geri-chairs, and bathroom scales);
- Items that are only for the individual's comfort and convenience or for the convenience of those caring for the individual (e.g., a hospital bed or mattress because the individual does not have an adequate bed, a wheelchair tray used as a desk surface); and mobility items used in addition to the primary assistive mobility aid for the convenience of the individual or his caregiver (e.g., an

electric wheelchair plus a manual chair); underpads (such as Chux) in addition to incontinence briefs, unless there is a specific medical need for using both; and cleansing wipes;

- Items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or for improving the functioning of a malformed body extremity (for example, over-the-counter drugs, dentifrices, toilet articles, shampoos which do not require a practitioner's prescription, dental adhesives, electric toothbrushes, cosmetic items, soaps, and lotions which do not require a practitioner's prescription; sugar and salt substitutes; non-compression type support stockings; and non-legend drugs);
- Home or vehicle modifications;
- Equipment for which the primary function is vocationally or educationally related (e.g., computers, environmental control devices, speech devices, etc.).

NOTE: For orthotics refer to coverage addressed later in this chapter. Refer to Prosthetics manual for coverage criteria.

CERTIFICATE OF MEDICAL NECESSITY (CMN)/DMAS-352

All DME and supplies must be ordered by a practitioner on the CMN/DMAS-352 (revised 2017) and must be medically necessary to treat a health condition. The CMN/DMAS-352 may be completed by the practitioner, DME provider, or other health care professionals, but the practitioner must sign and date the completed CMN. (12VAC30-60-75) The CMN and any supporting verifiable documentation must be completed (signed and dated by the practitioner) within 60 days from the time the ordered DME and supplies are initially furnished to the individual by the DME provider. DMAS will not reimburse the DME provider for services provided prior to the date of the practitioner's signature when the signature is not obtained within 60 days of the first day the DME supplies are furnished to the individual. (12 VAC 30-50-165)

NOTE: Initially furnished is defined as begin service date.

There are some supplies and/or equipment that can be provided at the time of request while other supplies and/or equipment may take several days or up to several weeks to be delivered to the individual. For example, a custom wheelchair may take up to six (6) months to be delivered to the individual but the begin service date starts when the service is initiated. For additional clarification regarding the completion of the CMN, refer to the instructions on how to complete the CMN.

A CMN shall contain a practitioner's diagnosis of an individual's medical condition and an order for the durable medical equipment and supplies that are medically necessary to treat the diagnosed condition and the individual's functional limitation(s). The order for DME or supplies must be justified in the written documentation either on the CMN or on an attachment to the CMN.

A complete order on the CMN consists of the description of the item, quantity ordered, frequency of use (for expendable supplies), practitioner signature and complete date. If

any of these components are missing the CMN will be considered invalid and a new CMN should be obtained additional documentation to justify the DME or supplies must coincide with the date of service for the item(s) ordered and the name and title must identify the practitioner. The CMN must also be completed for equipment repairs. (12 VAC 30-50-165)

NOTE: In order to obtain Medicaid reimbursement, specific fields of the DMAS-352 form shall be completed as specified in 12VAC30-60-75. (See Ch. VI of this manual for instructions to complete a DMAS-352)

DME and supplies must be furnished exactly as ordered by the attending practitioner on the CMN (12 VAC 30-50-165). The practitioner must specifically order each component of the DME on the CMN. The CMN shall not be changed, altered, or amended after the attending practitioner has signed it. If changes are necessary for the ordered DME or supplies, as indicated by the individual's condition, the DME provider must obtain a new CMN. The attending practitioner must sign and date the new CMNs within 60 days from the time the ordered supplies are furnished by the DME provider. Supporting documentation, signed and dated by the practitioner, may be attached to the CMN, but the attending practitioner's entire order must be on the CMN. (12 VAC 30-50-165)

NOTE: If technical information changes on the CMN, a new CMN is not required because it does not affect the practitioner's order or delivery of services. Technical information includes changes to an individual's address, phone number, or provider's address, phone number or provider enrollment number. The next CMN renewal must include this updated technical information. Faxed copies of the CMN are acceptable.

All practitioners' documentation must be completely signed with title and dated (with the month, day, and year). A required practitioner signature for Medicaid purposes may include signatures, computer entry, or rubber stamp initialed by the practitioner. These methods do not preclude other requirements that are not for Medicaid purposes. If a practitioner chooses to use a rubber stamp on documentation requiring his or her signature, the practitioner whose signature the stamp represents must provide the agency with a signed statement to the effect that he or she is the only person who has the stamp and is the only person who will use it. The practitioner must initial and completely date (with day, month, and year) all rubber-stamped signatures. The DME provider shall retain a copy of the CMN and all supporting verifiable documentation on file for DMAS' purposes of the DMAS post payment audit review. (12 VAC 30-50-165)

The practitioner shall never back date a CMN or supporting documentation in order for the CMN or supporting documentation to comply with the requirements. The date the practitioner actually signs the CMN or supporting documentation is the valid date for services.

The CMN/DMAS-352 can be found on the Medicaid web portal (www.viriniamedicaid.dmas.virginia.gov) link identified as "Provider Forms Search."

LENGTH OF CERTIFICATION ON THE CMN/DMAS-352

The CMN shall be valid for a maximum period of six (6) months for Medicaid individuals under 21 years of age. The maximum validity time for Medicaid individuals 21 years and older is twelve (12) months. DMAS has the authority to determine an alternative length of time different from the required time frames (stated above) that a CMN may be valid based on medical documentation submitted on the CMN. The validity of the CMN shall terminate when the individual's medical need for the prescribed DME or supplies is no longer needed or expires. (12 VAC 30-50-165)

RETROACTIVE ELIGIBILITY

DMAS may make an exception to the 60-day practitioner signature requirement if retroactive eligibility is determined. All remaining criteria (e.g., fully completed CMN, documentation requirements, and specific coverage criteria) must be satisfied in accordance with the *State Plan* and DMAS policy guidelines.

CMN EXCEPTIONS

A CMN is not required for individuals for whom Medicare is the primary insurance carrier and Medicaid is the secondary carrier. In those instances, if Medicare approves the DME item(s), the provider must bill on the DMAS-30 invoice. Medicaid will pay the appropriate deductible and/or co-insurance, and no CMN is needed for this Medicare crossover coverage. *If the item(s) is not covered by Medicare and is covered by Medicaid, the fully completed CMN is required in order for Medicaid to pay as the primary carrier.*

For private primary insurance where Medicaid is secondary payer, or payer of last resort, the CMN is required, even if it only applies to a co-payment. Medicare is the only exception where a CMN and service authorization would not be required (e.g., crossover claim).

FACE-TO-FACE REQUIRMENTS FOR DME – FEE-FOR-SERVICE

Face-to-face requirements only apply to FFS members and not those enrolled in one of DMAS' managed care organizations (MCO), unless otherwise stated in the MCO contract with the provider.

Effective July 1, 2017, DMAS shall not reimburse for DME (as defined in [12VAC30-50-165](#)) unless a face-to-face encounter has been performed by an approved practitioner (outlined below), within no more than six (6) months prior to the begin service date. The face-to-face encounter shall be related to the primary reason for which the Medicaid individual enrolled in Medicaid requires the DME.

The face-to-face encounter for DME must be conducted by one of the following four (4) practitioners:

- A physician licensed to practice medicine;

- A licensed nurse practitioner or licensed clinical nurse specialist acting within the scope of their practice under state law;
- A licensed physician assistant within the scope of their practice under state law and working under the supervision of the physician who orders the individual's services; or
- For individuals requiring DME immediately after an acute or post-acute stay, the attending acute or post-acute physician.

The practitioner performing the face-to-face encounter must document the clinical findings in the individual's medical record and communicate the clinical findings of the encounter to the ordering physician.

The face-to-face encounter may occur through telehealth, which is defined as the real-time or near real-time two-way transfer of medical data and information using an interactive audio/video connection for the purposes of medical diagnosis and treatment (DMAS Medicaid Memo dated May 20, 2014). Telehealth shall not include by telephone or email.

Providers must use the most up-to-date version of the DMAS CMN form (found on the DMAS Virginia Medicaid portal) to document the requirements. Completion of all elements related to the face-to-face requirements on the CMN will satisfy the face-to-face encounter documentation requirements. For DME items that require service authorization as indicated in the table below, providers must, during the service authorization process, "attest" that the face-to-face encounter requirement has been met. For those items that do not require a service authorization, the CMN with the face-to-face encounter documentation should be maintained in the individual's medical record.

NOTE: A face-to-face encounter is only required for Medicaid DME items that also require a face-to-face encounter under the Medicare program. If a face-to-face encounter is not required for a specific DME item under the Medicare program, then it is not required for the Medicaid program.

The list of HCPCS codes that require a face-to-face encounter under the Medicare program may also be found here: <https://www.cms.gov/files/document/required-face-face-encounter-and-written-order-prior-delivery-list.pdf>.

DME AND SUPPLIES LISTING -APPENDIX B

The Appendix B is a listing of Healthcare Common Procedure Coding System (HCPCS) which describe equipment and supplies, coverage limitations, and service authorization (SA) requirements. The HCPCS codes listed in Appendix B of this manual must be used for all Medicaid claims, regardless of whether Medicare uses the same HCPCS code for the item.

NOTE: Service authorization by Medicaid is not required when Medicare is the primary

payer. Reimbursement for Medicare crossover claims will be made in accordance with established Medicare HCPCS codes and guidelines.

In Appendix B, codes marked with an 'N' in the SA column do not require service authorization unless they exceed the service limit in Appendix B. The service limit informs the provider at what point service authorization is required. If a code is marked with a 'Y' in the SA column, SA is always required, so the service limit is a guideline for normal use. The service limit may be exceeded, or equipment purchased prior to the service limit expiring. In situations when the request is over the service limit or prior to the service limit, SA is required, and the determination will be made based on documentation submitted by the provider.

Instructions regarding service authorization (SA) may be found in the Appendix D of the DME and Supplies Manual. DMAS does not use all available HCPCS codes. Items not identified in the listing require SA and may be submitted for SA under the appropriate miscellaneous HCPCS code. Lack of a specific HCPCS code for an item does not impact coverage. The appropriate miscellaneous code may be used and submitted for SA for items that are not included in this manual.

Providers must maintain documentation in accordance with the coverage criteria, documentation requirements, and CMN requirements, as described in this manual, regardless of whether or not service authorization is required. Issuance of a service authorization does not exempt a claim from post payment audit. Documentation requirements are located in Chapter VI of this manual.

PAYMENT METHODOLOGIES

For HCPCS codes that do not have a Medicare Competitive Bid Rate, the reimbursement rate shall be the DMERC rate minus 10%. The rates have been incorporated into the Appendix B of this Manual. This listing will be updated periodically and is found on the Medicaid web portal located at www.viriniamedicaid.dmas.virginia.gov. If a national code becomes available for an item, the miscellaneous code can no longer be used for those items. The following table outlines the applicable payment methodology for various DME items.

DME ITEM	RATE
1. DME items that have a national code and a DMERC rate	Rate will be Medicare Competitive Bid Rate if available or the DMERC rate minus 10%.
2. DME items that have a July 1, 2010 rate, but do not have a national code	Bill the E1399 code (miscellaneous). The rate will be the July 1, 2010 rate. The rate will be posted in Appendix B of this manual.
3. DME items that have a national code, but do not have a DMERC or a July 1, 2010 rate	Rate will be Individual Consideration (IC). Manufacturer's charge to the provider, less shipping and handling, plus 30%,
4. DME items that do not have a national code, and do not have a July 1, 2010 rate	Bill the E1399 code (miscellaneous). Rate will be IC. The manufacturer's charge to the provider, less shipping and handling, plus 30%
5. DME items that have a national code and a July 1, 2010 rate from the previous local code crossover.	The rate will be the July 1, 2010 rate. The rate will be posted in Appendix B of this manual.

MISCELLANEOUS HCPCS AND CODES PRICED AS INDIVIDUAL CONSIDERATION (IC)

Miscellaneous codes will not be recognized for the sole purpose of cost variances unless approved by DMAS and/or the MCO. If a HCPCS code is not listed in the Appendix B, the provider can use an appropriate miscellaneous code for coverage consideration. In order for the service authorization contractor and the post payment auditing contractor(s) to determine the appropriate reimbursement for miscellaneous items and HCPCS codes priced as IC, all of the following must be provided and kept on file in the individual's record:

- A complete description of the item(s) being supplied;
- A copy of the supplier's invoice or the dealer cost information to document the cost of the item(s), this must include MSRP in order for the service authorization contractor and the post payment auditors to be able to determine the provider's cost; and
- Any discount received must be indicated.

The manufacturer's invoice, the dealer's price list showing the dealer's cost of the item, or a statement from the manufacturer detailing estimates of cost for specially designed items, are all acceptable documentation. The documentation must include the manufacturer's cost, any discounts provided to the provider, and the provider's ancillary cost of providing the DME and or supplies to the individual. The reimbursement amount is determined by adding 30% to the providers cost for the item, unless this amount exceeds MSRP. **DMAS will not reimburse over MSRP.**

Providers should not bill any claim for a miscellaneous code or HCPCS codes prices as IC prior to verifying invoice cost. Claims with cost less than that submitted on the service authorization should have billed amounts adjusted to comply with DMAS guidelines (i.e. net cost + 30%). If an estimate is used for specially constructed items, upon receipt of the manufacturer's invoice, if the cost is less than reported on service authorization, the provider must only bill 30% over the cost of that item. Likewise, if the cost is more than the original estimates, the provider may submit a change request to the service authorization contractor for consideration (See Appendix D for more service authorization information). Documentation of the actual cost of the item billed must be in the individual's record.

BILLING E1399 – MISCELLANEOUS HCPCS CODE

HCPCS code E1399 will generate a summary line that includes the total number of E1399 units, and the total fees associated with those lines. The service authorization (SA) file in VAMMIS combines all like miscellaneous DME codes into one 'summary' line, which carries the status of AC (approved combined). Providers can view the AC line on their SA notification report and in order to bill for miscellaneous DME lines, providers will need to total the authorized amounts as well as the authorized units for each of the miscellaneous codes and submit this total or 'summary line' amount as one line item on the claim.

The provider should bill the total number of units and the total authorized fee once all supplies are delivered. If the provider does not deliver all units at one time, the provider can follow the instructions below:

1. Submit a change request to the service authorization contractor. The provider will request a change to the line item that was not delivered by either decreasing the number of units or voiding the line item for the DME/supplies that was not delivered and if necessary, create a new service authorization for item not delivered; *or*
2. Wait until all DME/supplies are delivered to submit the claim for reimbursement; *or*
3. If the provider has already billed for all DME/supplies but has not delivered all units, the provider will need to adjust the claim. If it is found on post payment audit that the provider has billed all units but did not deliver all units, the provider may have funds retracted.

For monthly supplies the provider will need to divide the total units amount by the total authorized dollar amount to get the unit price. If there are several items with different dollar amounts the roll up line unit price will not match. If the provider does not bill for all units in the roll up line, the provider will need to adjust the final claim(s).

NOTE: There is a power point training presentation on the DMAS website at www.viriniamedicaid.dmas.virginia.gov that gives additional information on the roll up line with several examples.

Providers may contact the DMAS helpline for questions related to claims adjustment. Refer to Chapter I of this manual for contact information.

MISCELLANEOUS CODES – CATEGORY SPECIFIC

DMAS added five (5) additional miscellaneous codes to the Appendix B that are more category specific and will allow for better understanding of usage by category. Providers will be required to use these miscellaneous codes instead of E1399. E1399 will still be accepted; however, providers should only use E1399 if the item supplied does not fall under one of the new miscellaneous codes. See additional information below.

- **B9998 Enteral Miscellaneous** – This code should be used for any item that falls under the Feeding Pumps, Nutritional Supplements, Feeding Kits and Tubes section that has not been assigned a HCPCS code.
- **A4421 Ostomy Supply Miscellaneous** – This code should be used for any item that falls under the Ostomy, Cecostomy and Colostomy Pouches and Accessory Supplies section that has not been assigned a HCPCS code.
- **K0108 Wheelchair Accessory NOS** – This code should be used for any item that falls under the Wheelchairs and Accessories section that has not been assigned a HCPCS code.
- **S8189 Tracheostomy Supplies NOS** – This code should be used for any item that falls under the Apnea Monitors, Respiratory, Oxygen and Ventilators section that has not been assigned a HCPCS code.
- **A4335 Incontinence Miscellaneous** - This code should be used for any items other than incontinence supplies, that are not covered under an established HCPC code, such as bedpans, urinals, catheters and irrigation equipment and supplies, vendors should use the appropriate miscellaneous code.

These new miscellaneous codes listed above will work just like the E1399 code in the VAMMIS system. The service authorization file in VAMMIS combines all like miscellaneous DME codes into one 'summary' line, which carries the status of AC (approved combined). Providers will see the AC line on their service authorization notification report and in order to bill for miscellaneous DME lines, providers will need to total the authorized amounts as well as the authorized units for each of the miscellaneous codes and submit this total or 'summary' line amount as one line item on the claim.

PROVIDER RESPONSIBILITIES FOR PROVISION OF DME AND SUPPLIES

The Durable Medical Equipment and Supplies provider may not bill for items or services that have not been provided to the member and documented as received by the individual.

To receive reimbursement, the DME provider must:

- Verify the individual's Medicaid eligibility, on a monthly basis;
- Determine whether the item is covered and if so, does it require service authorization;
- Deliver only the item(s) ordered by the physician and approved by DMAS or its contractor;
- Deliver only the quantities ordered by the physician on the CMN and approved by DMAS or its contractor;
- Deliver only the item(s) for the periods of service covered by the physician's order and approved by DMAS or its contractor.

INTERQUAL® REQUIREMENTS FOR ALL DME

All items and supplies must meet the coverage criteria outlined in this manual and the Virginia Administrative Code. DMAS requires specific categories of items to meet InterQual® criteria. These categories are: adaptive strollers, nebulizers (including compressors), augmentative communication devices (AAC and speech generating devices), continuous passive motion devices, cranial molding orthosis, oxygen, hospital beds, insulin pumps, lower extremity orthosis (knee braces and immobilizers), lymphedema compression devices, manual wheelchairs, negative pressure wound therapy devices, non-invasive airway assistive devices, CPAP and BiPAP devices, power wheelchairs and scooters, seat lift mechanisms (not lift chairs), secretion clearance devices, standing frames, support surfaces, TENS, wheelchair cushions and seating systems.

The above list is subject to change with InterQual® updates and at the discretion of DMAS. Interqual criteria information may be obtained through:

Change Healthcare
Website: <https://www.changehealthcare.com/>

There must be a practitioner-generated diagnosis and treatment order which demonstrates the need for the recommended item(s). Additional supporting documentation above the current requirements may be necessary, especially for expendables which are beyond the established guidelines for use.

If the amount requested exceeds the limit specified in the Appendix B, the provider must request service authorization for those items exceeding the limit. The provider may supply the individual with the amount of items up to the limit prior to obtaining service authorization from DMAS, or its contractor, for the overages. If the practitioner orders items or quantities that are not consistent with the standard in medical or nursing practice, additional supporting documentation (above the current requirements) must be provided to justify the order.

NOTE: DMAS and its contractors have a responsibility to verify that the individual is

receiving adequate and medically justified services, that services are provided with fiscal responsibility and to monitor for possible fraud. Without adequate documentation neither DMAS nor its contractors can meet these responsibilities.

Specialized DME, such as specialized wheelchairs, augmentative communication devices, adaptive equipment, and rehabilitative therapy equipment, must be accompanied by an individual assessment performed by a qualified therapist who details the individual's functional abilities and disabilities, therapy goals, rehabilitation potential, suitability for use in the home environment, and how the equipment will be used in the individual's home. (See Chapter VI of this manual for specific documentation requirements). If in-home rehabilitative therapy equipment is ordered, the in-home therapy plan must be included.

For items that may be either used for the convenience of the caregiver or individual or to treat or manage a medical condition (e.g., hospital beds), supporting documentation of the medical need and use of the equipment must be included. Medicaid does not cover items for restraint of the individual or for the convenience or safety of the individual, the family, the attending practitioner, other practitioners, or the supplier. (12 VAC 30-50-165)

COVERAGE CRITERIA FOR SPECIFIC DME AND SUPPLIES

In addition to the Medical Necessity guidelines described in this chapter, and the described documentation requirements for all DME, additional specific medical justification and/or documentation requirements are in place for the following DME and supplies. Specific documentation requirements can be found in Chapter VI.

PATIENT LIFTS

A patient lift and sling are an assistive device that will help transfer an individual, with limited mobility, from the bed to a chair or wheelchair and back to the bed. Patient lifts are operated by hydraulic-manual pumping or an electric motor.

A total electric lift and/or multi-positional patient transfer system may be covered in limited circumstances and will be reviewed based on medical necessity, on a case-by-case basis.

The sling is the key component when using a lift. The sling is what holds the individual and connects to the lift. Slings come in many shapes and fabrics and are designed for different support levels and uses. When choosing a sling the provider should consider the support needs of the individual and the activity of the individual, be it for transferring only or using the bathroom or for bathing.

WHEELCHAIRS AND COMPONENTS

DMAS will reimburse DME providers for wheelchairs and components when the follow criteria are met:

- The practitioner must prescribe the equipment as medically necessary;
- Document that the individual's condition is such that without the use of a

wheelchair the individual would be essentially bed, chair, or home confined;

- The wheelchair is expected to increase mobility and independence.

A standard wheelchair must be requested unless documentation supports the need for any variation from the standard wheelchair. All customized manual wheelchairs are required to have had a comprehensive “hands on” evaluation completed by a healthcare professional with experience in fitting wheelchairs and making recommendations based on the individual’s needs (specifically, a practitioner, physical therapist, occupational therapist, or a rehab engineer in coordination with a physical or occupational therapist). The evaluation must be performed prior to ordering the final equipment and should be signed and dated by the ordering practitioner. DMAS requires the evaluation to be performed by a physical or occupational therapist especially for wheelchairs with specialized seating and positioning components and features. The physical or occupational therapy wheelchair evaluation is a covered rehabilitation program service that may be billed to DMAS.

Specialized or customized wheelchairs may include HCPCS codes in the Appendix B which do not require service authorization, but that may require a specialty hands on evaluation. *Customized equipment is defined as equipment that is uniquely constructed or substantially modified by the provider from the standard product for a specific individual according to the description and orders of a practitioner, and in such a way that the equipment can only be used by the specific individual.* See the power wheelchair section for evaluation requirements.

DMAS will not pay for repairs or replace a damaged wheelchair if the damage done to a wheelchair or component is considered intentional individual abuse or misuse of the equipment.

Power Wheelchairs

DMAS will cover most power (motorized) wheelchairs. All power wheelchairs and scooters must be preauthorized by the service authorization contractor. All conditions listed below must be met as follows:

- The individual has a mobility limitation that impairs his or her ability to perform one or more mobility related activities of daily living (MRADLs); and
- The limitation cannot be resolved with a cane or walker; and
- The individual does not have sufficient upper extremity strength to functionally operate an optimally configured manual wheelchair in the home; and
- The individual has the mental and physical capabilities to safely operate a power wheelchair or has a caregiver who is unable to propel an optimally configured manual wheelchair but is available, willing and able to safely operate the power wheelchair; and
- The individual’s weight is less than or equal to the weight capacity of the power chair to be provided; and,
- The individual’s home has adequate access, maneuvering space and surfaces for

the operation of the power wheelchair to be provided.

Power Operated Vehicle (POV)/Scooter

The following criteria should be used to rule out POV/Scooter as follows:

- The individual cannot transfer to and from a POV, operate the tiller on a POV *or* maintain stability, balance and position while operating a POV; *or*
- The individual's mental and physical capabilities are insufficient to operate a POV in the home; *or*
- Does not meet weight requirements per manufactures specifications; *or*
- The individual's home does not provide adequate access, space or surface to operate a POV in the home.

Below are the descriptions for Groups 1 through 5 power wheelchairs:

- Group 1 power wheelchairs are designed for light duty and are generally for intermittent use indoors, typically used two hours or less per day. Group 1 power chairs do not accommodate seating and positioning items.
- Group 2 power wheelchairs are for daily indoor basic mobility, typically 8 hours per day or longer. Wheelchairs in this group are capable of accommodating seating and positioning items. Some examples of diagnoses that may qualify under a group 2 power wheelchair include but are not limited to, COPD, congestive heart failure, diabetes, osteoarthritis, amputation, weakness, and fatigue.
- Group 3 power wheelchairs are for complex rehab and are designed for indoor use by individuals with complex disabilities (neurological condition, myopathy, or congenital skeletal deformity). Some examples of diagnosis that may qualify under a group 3 include but are not limited to: Multiple Sclerosis (MS), Amyotrophic Lateral Sclerosis (ALS), spinal cord injury, spinal muscular atrophy, osteogenesis imperfecta and Cardiovascular Accident (CVA). The Appendix B includes HCPCS codes, with the "U1" modifier, that will be reimbursed at a higher rate if included as an accessory to a Group 3 and above power wheelchair. Providers will need to document the wheelchair type/group when submitting a request for these accessories using a "U1" modifier.
- Group 4 power wheelchairs have added capabilities that are not typically considered for use in the home. **Please note these wheelchairs will be considered on a case-by-case basis.**
- Group 5 power wheelchairs are for pediatric use when the individual is expected to grow in height.

All Single-Power Option Wheelchairs

The following criteria must be met for all single-power wheelchairs as follows:

- The individual requires a drive control interface other than a hand or chin-operated standard proportional joystick; *and* the individual has had a specialty “hands on” evaluation performed *and* the documentation states the medical necessity for the wheelchair and its special features *or*;
- The individual meets coverage criteria for a power tilt or recline-seating system *and* the system is being used on the wheelchair; *and* the individual has had a specialty “hands on” evaluation performed *and* the documentation states the medical necessity for the wheelchair and its special features.

All Multiple-Power Option Wheelchairs

The following criteria must be met for all multiple-power option wheelchairs as follows:

- The individual meets criteria for a power tilt and recline-seating system and the system is being used on the wheelchair; *and* the individual has had a specialty hands on evaluation performed and the documentation states the medical necessity for the wheelchair and its special features; *or*
- The individual uses a ventilator mounted on the wheelchair; *and* the individual has had a specialty hands on evaluation performed and the documentation states the medical necessity for the wheelchair and its special features.

Power Seating

A power tilt, recline or tilt and recline system, with or without power elevating leg rests, is covered if the following criteria is met:

- The individual meets all the criteria for a power wheelchair; *and*
- A specialty evaluation has been completed by a licensed/certified healthcare professional such as a physical or occupational therapist or practitioner, who can access the individual’s specific seating and positioning needs; plus at least one of the following criteria points are met.
 1. The individual is at high risk for development of a pressure ulcer and is unable to perform a functional weight shift for pressure relief; *or*,
 2. The individual utilizes intermittent catheterization for bladder management and is unable to independently transfer from wheelchair to bed; *or*,
 3. The power seating system is needed to manage increased tone or spasticity.

Push-Rim Activated Power Assist Device

All of the following criteria must be met for all push-rim activated power assist devices:

- The individual meets the criteria for a power wheelchair; *and*
- The individual has been self-propelling in a manual wheelchair for at least one year; *and*
- The individual has had a specialty “hands on” evaluation performed and documentation states the medical necessity.

The following wheelchair related items are not covered: mobility devices used in addition to the primary means of mobility; wheelchairs for restraint purposes; and home or vehicle modifications, i.e., permanent wheelchair ramps. (12 VAC 30-50-165)

COMPLEX REHABILITATION TECHNOLOGY (CRT) WHEELCHAIRS FOR MEMBERS IN A NURSING FACILITY

As of January 1, 2024, DMAS will provide for the initial purchase or replacement of Complex Rehabilitation Technology (CRT) manual and power wheelchair bases and related accessories, as defined by the agencies current DME policy, for patients who reside in a nursing facility.

Complex Rehabilitation Technology (CRT) is designed to meet the needs specific and unique medical and functional needs of an individual with a primary diagnosis resulting from a congenital disorder, progressive or degenerative neuromuscular disease, or from certain types of injury or trauma.

Complex Rehabilitation Technology (CRT) will be defined as wheelchairs and other seating systems classified as medical equipment within the Medicaid program that:

1. Are customized and individually configured for individuals to meet their specific and unique medical, physical, and functional needs including basic activities of daily living, as determined to be medically necessary.
2. Are primarily used to a) serve a medical purpose and are generally not useful to an individual in the absence of an illness or injury; b) maximize an individual's function and independence; and c) are subject to medical necessity review and approval and not provided solely for caregiver convenience.
3. Require certain services necessary for appropriate design, configuration, and use of such items, including individual evaluation, equipment fitting and configuration of the CRT wheelchair. The following standards for a CRT evaluation include the following:
 - a. The evaluation is performed by a licensed physical or occupational therapist, with experience performing wheelchair seating and mobility, not directly employed by the DME provider.
 - b. The evaluation is done in conjunction with an assessment by, at a minimum, one Assistive Technology Professional (ATP) or Rehabilitation Engineering Technologist (RET) who is employed by the DME provider to analyze the needs and capacities and provide training in the use of the selected covered CRT items. The ATP or RET must be certified by the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA).
 - c. The ATP or RET must be physically present for the evaluation and determination of the appropriate individually configured CRT for the complex need's member.

The following HCPCS codes and their accessories have been defined by DMAS as CRT:

- K0835-K0843 Group 2 Power Chairs
- K0848-K0864 Group 3 Power Chairs
- K0868-K0871 and K0877-K0886 Group 4 Power Chairs
- E0986 push-rim activated power assist option for a manual wheelchair
- E1161 Manual Chairs
- E1231-E1238 Pediatric Manual Chairs
- K0005 Ultralight weight Wheelchair

DMAS' service authorization contractor will utilize the same criteria for nursing facility members as they would for members living at home.

Any DME purchased by Virginia Medicaid is property of the Medicaid member. The DME provider, Nursing Facility nor the MCO has any right to take equipment once it has been purchased by Medicaid. If the member passes away the family may make the determination if the equipment is kept or donated.

MEDICAL CAR SEATS

Medical Car seats for use in vehicles may be covered with prior authorization for individuals with special orthopedic or medical needs related to positioning that cannot be met using conventional car seats or with needs that make conventional car seats medically inappropriate. A positioning seat may be medically necessary for a recipient with an inability to maintain an unsupported sitting position independently which is caused by a medical condition such as the following (list is not all-inclusive):

- Severe head and trunk instability;
- Severe hypotonicity, hypertonicity, spasticity or muscle spasms which result in uncontrollable movement and position changes;
- Severe seizure activity that results in uncontrollable movement and position changes
- Orthopedic disease processes resulting in significant bony fragility;
- Significant contractures that would result in an inability to perform postural corrections due to vehicle motion;
- Orthopedic condition, such as a curvature of the spine, which interferes with proper positioning;
- Long term, neurological, developmental, or other chronic health conditions which makes the use of standard, commercially available child restraints or vehicle seat belts impossible.

The individual must be within the manufacturer guidelines for height and weight.

Documentation for the authorization request for a positioning seat for use in vehicles must include an evaluation by a physical therapist or occupational therapist, the medical condition that causes the need for the positioning seat, other interventions that have been tried to meet the recipient's needs, and less costly positioning seats that have been considered and rejected. Document the recipient's current height and weight, and the weight capacity and growth potential for the requested seat.

WHEELCHAIR TIEDOWNS

Tiedowns, also known as transit options and transport brackets, are required for individuals and their wheeled mobility to be safely transported in a vehicle within the community.

Tiedowns may be covered if the following are met:

1. The wheelchair or stroller has passed ANSI/RESNA WC19 or ISO 7176-19.^{1 2}
2. The wheelchair needs to be effectively secured to the vehicle using a 4-point strap-type tiedown or docking system that complies with SAE J2249³ or ISO 10542^{4 5}.

Tiedowns reduce the potential for injury while the individual or equipment is being transported in a vehicle or public transportation. Tiedowns may be covered for wheelchairs and strollers, occupied or unoccupied. Prior authorization will be required for tie downs and documentation must include a statement from a physical or occupational therapist that include the medical need to be used in conjunction with the mobility device.

¹ ANSI/RESNA, *ANSI/RESNA WC19: Wheelchairs Used as Seats in Motor Vehicles*. 2000, American National Standards Institute (ANSI)/Rehabilitation Engineering and Assistive Technology Society of North America (RESNA).

² ISO, *ISO 7176/19: Wheelchairs Used as Seats in Motor Vehicles*. 2000, International Organization for Standardization: Geneva, Switzerland.

³ Society of Automotive Engineers, *SAE J2249: Wheelchair Tiedowns and Occupant Restraint Systems - Surface Vehicle Recommended Practice*. 1999, Society of Automotive Engineers: Warrendale, PA.

⁴ISO, *ISO 10542-2: Technical systems and aids for disabled or handicapped persons - Wheelchair tiedown and occupant-restraint systems - Part 2: Four point strap type tiedown systems*. 1999, International Organization for Standardization: Geneva, Switzerland.

⁵ ISO, *ISO 10542-3: Technical systems and aids for disabled or handicapped persons - Wheelchair tiedown and occupant-restraint systems - Part:3: Docking type tiedown systems*. 2005, International Organization for Standardization: Geneva, Switzerland.

Easy lock systems for conversion vans are **not** covered.

PORTABLE RAMPS

Portable ramps are placed over inclines, steps, and other uneven surfaces to provide passage for individuals who use assistive mobility devices. A portable ramp may be covered for an individual with an order from a practitioner and prior authorization when it is required to support transfer and performance of activities of daily living in the home and community.

Two types of portable ramps may be covered, portable ramps and threshold ramps, with prior authorization and an evaluation from physical therapist, occupational therapist or certified Assistive Technology Professional (ATP) must document the medical need for the ramp.

1. Portable ramps – For use in the home or for vehicle transportation. Typically constructed of metal or fiberglass.
2. Removable threshold ramps – For use in the home to cross over interior or exterior thresholds. Must be removable (not permanently affixed). Typically constructed of rubber or aluminum.

Portable ramps will not be covered if the individual already has a permanent ramp at the individual's residence or the individual's vehicle is already wheelchair accessible. Permanent and modular ramps are not covered under the DME benefit.

AUGMENTATIVE COMMUNICATION DEVICES

DMAS will consider reimbursement for electronic or manual augmentative communication devices when evidence of medical necessity has been submitted by the provider for service authorization (SA) to the DMAS SA contractor for review. Communication devices to improve educational and/or vocational abilities are **not** covered services by Medicaid. (12 VAC 30-50-165)

One of the following criteria must be met before an augmentative communication device can be considered for approval:

- The individual cannot functionally communicate basic needs verbally or through gestures due to medical conditions, and expressive language is not expected to be restored. Basic needs include eating, drinking, toileting, and indicating discomfort or pain; *or*
- The individual cannot verbally or through gestures participate in medical care, i.e., indicate decisions regarding medical care or indicate medical needs; *or*
- The individual cannot verbally or through gestures functionally communicate informed consent on medical decisions. (12 VAC 30-50-165)

In accordance with the Virginia State Plan for Medical Assistance, all of the following must

be met before an augmentative communication device can be considered for approval. The communication device must be:

- Ordered by the practitioner on the CMN/DMAS-352;
- A reasonable and medically necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual;
- Not furnished solely for the convenience of the individual, the family, the attending practitioner, or other practitioner or supplier;
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational); *and*
- Furnished at a safe, effective, and cost effective level, primarily for use in the individual's home or community environment.

Requests for augmentative communication devices must be submitted on a DMAS-363 Outpatient Service Authorization Request Form as described in Appendix D of this manual. Requests must be accompanied by documentation of a systematic and comprehensive speech/language evaluation, completed by a speech-language pathologist licensed by the Department of Health Professions and signed and dated by the individual's practitioner.

The speech-language pathologist may not be a provider of augmentative communication systems nor have a financial relationship with a provider/manufacturer.

A 30 to 60-day trial rental period must be considered for all electronic devices to assure that the chosen device is the one most appropriate to meet the individual's medical needs. (Note: For those individuals whose needs can be clearly defined by the comprehensive speech-language pathologist's evaluation, a trial rental period is not necessary.) At the end of the trial rental period, if purchase of the device is recommended, documentation by the speech-language pathologist of the individual's ability to use the communication device must be provided.

If the communication device(s) supplied for the required two-month rental period is new upon delivery, DMAS will consider paying the full purchase price listed in the DME Listing in addition to the initial two-month rental period for these items.

Collaborative Funding for Communication Devices

Based on House Joint Resolution 697 (1995), an effort should be made to promote the removal of identified barriers and seek to broaden and improve access to assistive technology devices and services to persons with disabilities, within the guidelines established in the Virginia Administrative Code (VAC). When the requested device is needed partially for medical purposes and partly for educational, vocational, or social needs, the communication assessment team must pursue the possibility of a collaboration

of funding sources. In addition to DMAS, these funding sources may include a local school division, the Department of Aging and Rehabilitative Services, private foundations, the individual's family/friends, and charities or other non-profit groups.

If the individual/family requests to act as a funding source for portions of the device found to be "not medically necessary" and therefore, not covered by Medicaid, the DME provider must maintain documentation that the individual/family was charged, per their request, for Medicaid non-covered services. However, the individual/family may not be charged for services that are medically necessary and covered by Medicaid. The DME provider must accept Medicaid's payment as payment in full for services that are medically necessary and covered by Medicaid.

Once another funding source is identified, DMAS must be contacted to negotiate a collaborative funding formula. When pursuing collaborative funding of a communication device, the speech/language pathologist must include previously described documentation and must delineate which components are felt to be medically necessary and which are educational, vocational, etc. If a device is determined to be medically necessary, DMAS, or its contractor, will approve the level of funding for a device that meets the individual's medical needs. If a more complex device is required to meet the educational/social/vocational needs as well as the medical needs of the individual, the remainder of the funding must be provided by an alternative funding source.

Each request for collaborative funding will be reviewed or authorized on an individual basis. The assessment team must notify DMAS, or its contractor, as soon as possible of a situation that might require collaborative funding so that acquisition of the device by the individual will not be delayed.

Payments toward funding of the device must be made directly to the provider and not to the individual. Payments to the individual may be viewed as "income" and could potentially affect the individual's eligibility for Medicaid.

Note: Although collaborative funding is primarily utilized for communication devices, there may be other DME for which collaborate funding is appropriate and will be reviewed on a case-by-case basis.

ADAPTIVE EQUIPMENT

Adaptive equipment includes, but is not limited to, adaptive utensils, wall-mounted insulin delivery devices, and automatic feeder systems. All adaptive equipment must be medically necessary and essential for the treatment of illness or injury. Adaptive equipment does not include home modifications (e.g., devices that are permanently affixed to the walls of the home such as grab bars, ramps, barrier free lifts, and widening of doorways); furniture and appliances not defined as medical equipment such as bathroom scales and hand-held shower devices; items that are not for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body part; and equipment when the primary function is vocationally or educationally related (e.g.,

computers and environmental control devices). (12 VAC 30-50-165)

The following conditions must be met for DMAS to approve reimbursement of adaptive equipment. These conditions are applicable whether the equipment is for initial use or replacement. Approval may occur under one of the following categories:

1. Individual-Based Outcomes (one of the following must be met):
 - An identified, realistic goal exists that makes necessary the use of the adaptive equipment for the treatment of the medical condition; *or*
 - Anticipated stabilization of the medical condition or progress toward goal achievement is clearly related to the use of the equipment.

2. Supportive Activities to Accomplish Outcomes (all of the following must be met):
 - Goal(s) must be a part of an active, rehabilitative, therapeutic plan of care in place at the initiation of the use of the equipment. The goal(s) must be realistic in that it is consistent with the individual's cognitive, environmental, and physical status;
 - The individual or caregiver demonstrates the ability cognitively, motivationally, and physically to effectively utilize the equipment toward goal achievement. Someone is available to regularly assist the individual as necessary in the use of the equipment to facilitate progress toward the goal ;
 - Within the plan of care, documentation exists that other equipment and/or health care alternatives have been considered and rejected as not appropriate for the treatment of the medical condition;
 - The individual does not have a deficient level of "energy" or other systemic condition (e.g., CHF, COPD) that adversely impacts the ability to participate in the use of the equipment; *and*
 - The equipment must reduce the need for other reimbursed health care (such as personal care, private duty nursing, rehabilitation services, and/or home health services).

BLOOD GLUCOSE MONITORS

DMAS will reimburse for blood glucose monitors and associated supplies for individuals eligible for the DME program or EPSDT when all of the following criteria are met:

- The individual has a condition that requires adjustment of insulin dosage based on at least daily blood glucose findings, or the individual has clinically demonstrated unstable glucose readings and must report frequent findings to a practitioner for adjustment of hypoglycemic medications; *and*
- There must be written verification that the individual and/or caregiver have participated in diabetic training (diet, medication, monitoring, etc.) and that the individual and/or caregiver have demonstrated the ability to appropriately use the prescribed blood glucose monitor. (This requirement is applicable for initial

blood glucose monitors and is not required for future monitors unless the practitioner feels additional education is necessary).

DMAS has implemented the Medicare established competitive rates for select diabetic supplies. The select HCPCS codes will be marked in blue in the Appendix B section. As part of this implementation, **providers are now permitted to ship a 90-day supply for the following diabetic supplies: A4206, A4245, A4250, A4233, A4234, A4235, A4236, A4253, A4256, A4258 and A4259.**

Starting January 1, 2024, Insulin pumps (i.e., Omnipod) will also be covered under the pharmacy benefit. DMAS will be updating the CGM criteria and associated HCPCS codes in the next manual update coming soon.

Continuous Glucose Monitors (CGM)

A CGM reveals short-term trends in the blood sugar as they happen. The monitor reads a constant stream of glucose data every 1 to 5 minutes. CGMs have 3 basic components: a sensor (A9276), a transmitter (A9277) and a receiver (A9278). The receiver and transmitter are durable devices that are reused each time the sensor is changed. Sensors are disposable and approved for 3 to 7 days of use depending on the manufacturer.

Coverage will be limited to members with:

- 1) Type 1 Diabetes , no age limitations
- 2) Type II Diabetes > 16 years of age
- 3) Pregnant women with Type 1 or Type 2 diabetes, who are injecting insulin

The DMAS Medical Support Unit (MSU) will review all service authorizations. The authorizations are to be faxed to the MSU unit at 804-452-5450. An approved service authorization allows the DME provider to receive reimbursement from DMAS for members enrolled in the Medicaid, FAMIS, or FAMIS MOMS Fee-for-Service programs.

The following criteria will be used for all CGM devices:

Type I diabetes, no age limitations, **ALL** of the following are met:

- Inadequate glycemic control despite self-monitoring at least 4 x/day, with fasting glucose >150; **and**
- Recurring episodes of severe hypoglycemia <50 mg/dl **or** hypoglycemic unawareness; **and**
- Insulin injections are required three (3) or more times per day or an insulin pump is used for maintenance of blood sugar control.

Authorization is for purchase of DME.

Type 2 diabetes, age >16, **ALL** of the following are met:

- Inadequate glycemic control despite self-monitoring at least 4 x/day, with fasting glucose >150; **and**
- Recurring episodes of severe hypoglycemia <50 mg/dl **or** hypoglycemic unawareness; **and**

- Insulin injections are required three (3) or more times per day or an insulin pump is used for maintenance of blood sugar control.

Authorization is for purchase of DME.

Pregnant individuals with Type 1 or Type 2 diabetes who are injecting insulin, **ALL** of the following are met:

- Inadequate glycemic control despite self-monitoring at least 4 x/day, with fasting glucose >150; **and**
- Recurring episodes of severe hypoglycemia <50 mg/dl **or** hypoglycemic unawareness; **and**
- Insulin injections are required three (3) or more times per day or an insulin pump is used for maintenance of blood sugar control.

Authorization is for rental of DME for up to 12 months

For Pregnant Women

DMAS will reimburse for blood glucose monitors and test strips for pregnant women suffering from diabetes for which the practitioner determines nutritional counseling alone will not be sufficient to assure a positive pregnancy outcome.

The Certificate of Medical Necessity (CMN-352) is required. The maternity risk screen is no longer required; however, 12VAC 30-50-510 requires that pregnant women who receive a blood glucose meter covered by DMAS must be referred for nutritional counseling.

BREAST PUMPS FOR PREGNANT AND POSTPARTUM WOMEN

Coverage of lactation counseling services and breast pumps, for pregnant and postpartum women enrolled in the fee-for-service Medicaid/FAMIS/FAMIS MOMS benefits is effective January 1, 2016. (Refer to DMAS Memo dated December 2015.) Effective July 1, 2022, continuous coverage for Medicaid and FAMIS MOMS is provided during pregnancy and for a 12-month postpartum period beginning on the last day of the pregnancy and including any remaining days of the calendar month in which the 12-month period ends. See Appendix B of this manual for HCPCS codes.

DMAS will cover a manual or standard electric breast pump as medically necessary for the initiation or continuation of breastfeeding (up to the child's first birthday). These breast pump codes are available as of January 1, 2016:

- E0602 Manual breast pump, purchase – does **not** require service authorization;
- E0603 Single user electric breast pump, purchase – requires service authorization;
- E0604 Multi-user (Hospital grade) electric pump, rental – requires service authorization;
- E1399 Additional collection kit for use with the single and multi-user electric breast pumps - requires service authorization.

E0603 - Single user electric breast pumps - purchase

A personal use electric breast pump is designed for mothers who are breastfeeding without problems. A personal use electric breast pump is defined as a double electric (AC and/or DC) pump, intended for a single user and is capable of being used multiple times per day. Payment includes supplies necessary for operation of the pump (pump,

adapter/charger, breast shields, bottles, lids, tubing, locking ring, connectors, valves, filters and membranes). DMAS medical necessity criteria is as follows:

- Mother must express the desire to breastfeed;
- The pump must be FDA registered;
- The pump has a minimum one year manufacturer's warranty; and
- The pump must have a mechanism to prevent suction beyond 250 mm Hg to prevent nipple trauma.

Limits: One purchase every 3 years. Request must be medically justified. Request duration is 30 days (for pick up/delivery). DMAS allows for one additional purchase every three years with medical justification.

E0604 – Multi-user (Hospital grade) electric pumps - rental

Multi-user/Hospital grade electric pumps are designed to initiate and maintain a milk supply when a baby is not feeding well. The pump must be FDA registered and have a mechanism to prevent suction beyond 250 mm Hg to prevent nipple trauma.

DMAS coverage of hospital grade rental pumps must meet one of the medical necessity criteria listed below:

- When the infant is premature at 24-34 weeks of gestation, and the mother is pumping breast milk, awaiting the baby's ability to nurse directly from the breast, *or*
- When the infant is premature at 35-37 weeks of gestation and continues to experience difficulty coordinating suck and swallow, and the mother is pumping breast milk, awaiting the baby's ability to nurse directly from the breast, *or*
- For infants with cleft lip and/or palate or ankyloglossia who are not able to nurse directly from the breast, *or*
- For infants with cardiac anomalies or any medical condition that makes them unable to sustain breast feeding due to poor coordination of suck and swallow or fatigue, *or*
- For multiples (including twins), until breast-feeding at the breast is established consistently, *or*
- When the mother has an anatomical breast problem, which may resolve with the use of breast pump, such as insufficient glandular tissue, *or*
- For any infants for medical reasons who are temporarily unable to nurse directly from the breast, such as NICU babies, or during any hospitalization of the mother or baby which will interrupt nursing, *or*
- When the infant has poor weight gain related to milk production and pumping breast milk is an intervention in the provider's plan of care and infant has a documented weight loss of 7% or greater despite use of conventional breast pump.

A hospital grade breast pump is not medically necessary when one of the above criteria are not met or when it is requested solely to allow for the mother's return to work or mother's or family convenience.

Limits: Up to 6-month initial rental period based on medical necessity; 12-month

maximum rental period per member with medical justification. Requests for additional months after the initial 6 months must include why purchase of a single user electric pump (E0603) will not meet member's needs.

E1399 – Collection kits for use with the single and multi-user electric breast pumps

One collection kit for electric breast pumps includes necessary supplies and collection containers. The service limit is one additional kit per single or multi-user electric breast pump authorization. Providers must include medical justification when requesting an additional kit. Each breast pump includes an initial collection kit. Providers must bill their Usual and Customary Charge (UCC). Additional collection kits have a maximum reimbursement rate; 1 unit equals 1 kit. **There is no 30% mark up for additional collection kits.**

Limits: One (1) per service limit period for single-use and multi-use electric pumps. Request must be medically justified; provider must indicate pump is owned or rental and that the additional collection kit is appropriate for member owned (or rental) pump. Request duration: 30 days (for pick up/delivery).

DME providers must submit medical justification to DMAS or its contractor when requesting these codes. Providers must have a completed CMN (DMAS 352) on file. NOTE: Please note that Medicaid and FAMIS MOMS is effective for the duration of the pregnancy and for 12-months postpartum period beginning on the last day of the pregnancy and including any remaining days of the calendar month in which the 12-month period ends. If they need additional coverage of a hospital grade pump, refer the individual to their local Women, Infants and Children (WIC) office in their county for assistance. If a hospital grade breast pump is no longer needed but the mother has the desire to continue breast feeding, DMAS may consider the purchase of a manual or standard electric pump prior to coverage ending.

DISPOSABLES TO CARRY OUT INFECTION CONTROL PROCEDURES

The following recommendations regarding disposable items are based on current guidelines from the Centers for Disease Control (CDC). Disposable items, including, but not limited to, gloves, gowns, and masks, will be covered only when necessary to carry out universal precautions. If the caregiver (e.g., family individual) is in contact with the individual's blood and/or other body fluids containing visible blood, a documented communicable disease, or for the specific and medically documented symptoms of impaction.

For individuals enrolled in the Medicaid-funded Technology Assisted Waiver, non-sterile gloves may be used when performing tasks related to tracheostomy care, such as suctioning. The reason for this exception in the use of non-sterile gloves is to reduce the risk of coming in contact with blood and reducing the risk of infection. Individuals in the Technology Assisted Waiver are more susceptible to serious infection and possible repeated hospitalizations due to their fragile respiratory needs.

Disposable items will not be covered for use by the caregiver (e.g., family or provider agency) in carrying out routine infection control procedures (e.g., gloves to clean an incontinent individual, handle soiled linen, clean or empty a bedside commode, empty a urinary drainage bag, or to bathe an individual). (12 VAC 30-50-165)

DMAS will not provide reimbursement for items necessary to carry out either routine or universal precautions when the care is being supplied by a provider agency. The provider will be responsible for the provision of equipment and supplies necessary to minimize the risk of infection including the transmission of the HIV virus and other blood-borne pathogens.

ENTERAL NUTRITION (EN)

Coverage of enteral nutrition, that does not include a legend drug, shall be limited to when the nutritional supplement is administered orally or through a nasogastric or gastrostomy tube; and is necessary to treat a medical condition. Enteral nutrition is reviewed based on medical necessity. DMAS shall provide coverage for nutritional supplements for enteral feeding only if the nutritional supplements are not available over the counter (OTC). (DMAS only considers Pediasure, Boost, and Ensure retail formulations as OTC)

Additionally, DMAS shall cover medical foods that are:

1. Specific to inherited diseases, metabolic disorders, PKU, etc.,;
2. Not generally available in grocery stores, health food stores, or the retail section of a pharmacy;
3. Not used as food by the general population.

Coverage of medical foods shall not extend to regular foods prepared to meet particular dietary restrictions, limitations, or needs, such as meals designed to address the situation of individuals with diabetes or heart disease. Coverage of oral administration does not include the provision of routine infant formula or feeding as meal replacement only. (12 VAC 30-50-165). DMAS will reimburse under EPSDT for medically necessary formula and medical foods when used under a practitioner's direction to augment dietary limitations or provide primary nutrition to individuals via enteral or oral feeding methods (OTC brands may be considered for this population based on medical necessity). A nutritional assessment shall be required for all individuals for who nutritional supplements/medical foods are ordered.

MCOs will cover enteral nutrition for children enrolled in Medicaid managed care.

“Enteral nutrition” refers to any method of feeding that uses the gastrointestinal tract to deliver part or all of an individual’s caloric requirements. “Enteral nutrition” may include a routine oral diet, the use of liquid supplements, or delivery of part or all of the daily requirements by use of a tube, which is called “tube feeding.”

All of the following shall apply to the provision of enteral nutrition:

- Enteral nutrition shall be reimbursed only to enrolled DME providers. If a pharmacy is currently providing enteral nutrition, but is not enrolled as a DME provider, the pharmacy must become an enrolled DME provider in order to be reimbursed for services;
- Enteral nutrition shall be based on categories of nutritional components (refer to the DME Listing/Appendix B: Feeding Pumps, Nutritional Supplements, Feeding Kits and Tubes);
- The practitioner's order (the CMN/DMAS-352) must specify either a brand name of the supplement being ordered or the category of enteral nutrition which must be provided. If a practitioner orders a specific brand of supplement, the DME provider must supply the brand prescribed. (Due to ongoing formula shortages the DME provider may substitute an equivalent formula as long as it falls under the same HCPCS code being requested. The DME provide must document equivalent substitute on the order line and will need to get substitution written or verbal order from the ordering practitioner. For verbal approval the DME provider should document the date, time and person who gave the verbal order in the member's record.) The practitioner's order must include the daily caloric order and the route of administration for the supplement, if this is not written on the CMN it must be contained in the medical record. If a substitution is needed and the product falls under the same HCPCS code a new CMN is not required. Where applicable, existing Medicare codes and reimbursement rates will be utilized. An additional category has been added to Appendix B to include certain pediatric supplements that are not covered by Medicare;

The practitioner's order (the CMN/DMAS-352) is valid for a maximum of six (6) months regardless of the individual's age. The order shall not be backdated to cover prior dispensing of enteral nutrition products. A face-to-face nutritional assessment completed by trained clinicians (e.g., practitioner, registered nurse, or a registered dietitian) must be completed as required documentation of enteral nutrition for both the initial order and every six (6) months. (Telehealth visits may be used for face-to-face nutritional assessments.)

NOTE: Home health visits for the sole purpose of performing a nutritional assessment for individuals whose conditions are stable and chronic in nature will not be covered under the home health program. Telehealth visits should be considered for these cases and for those who are not able to travel due to complex health conditions.

Service authorization (SA) of enteral nutrition is not required. The DME provider must assure that there is a valid practitioner's order (CMN/DMAS-352) completed every six months in accordance with DMAS policy and on file for any Medicaid individual for whom enteral nutrition is provided. The DME provider is further responsible for assuring that enteral nutrition is provided in accordance with DMAS reimbursement criteria. Upon post payment review, DMAS will deny or retract reimbursement for any supplements that are

not provided and billed in accordance with the criteria described in this manual.

The required medical justification can be included in the supporting documentation that is signed and dated by the practitioner. See Chapter VI for a listing of all the specific documentation requirements for the CMN/supporting documentation.

See the “Medicaid DME and Supplies Listing” in Appendix B of this manual for a current listing of the supplements covered by DMAS. If the supplement that has been ordered by the practitioner is not found on the list, contact the DMAS Provider HELPLINE. The Provider HELPLINE will assist the DME provider in obtaining a classification for all supplements not listed.

NOTE: Codes B4100, B4102, B4103, and B4104 are covered under DME based on medical necessity, however, they are not considered enteral nutrition.

Enteral Nutrition - Early Periodic Screening, Diagnostic, and Treatment (EPSDT)

The Early Periodic Screening Diagnosis and Treatment (EPSDT) benefit allows DMAS to provide medically necessary formula and medical foods to EPSDT eligible children under the age of 21, based on medical necessity. Medical foods are considered (i) specific to inherited diseases, metabolic disorders, PKU, etc.; not generally available in grocery stores, health food stores, or the retail section of a pharmacy; and not used as food by the general population. Refer to the section titled, “Enteral Nutrition” previously identified in this chapter for EPSDT formula criteria. Routine infant formula is not covered. DMAS will reimburse for medically necessary formula and medical foods when used under practitioner direction to augment dietary limitations or provide primary nutrition to individuals via enteral or oral feeding methods.

Referral Process:

- The child’s parent or responsible party should contact their practitioner or metabolic treatment center to determine the medical need for medical formula or medical foods.
- Children under five (5) years who require medical formula must use a DME enrolled provider for dispensing the medical formula. This will include WIC offices.
- Children aged five or older may receive medical formula and nutritional supplements through either DMAS enrolled DME providers or their MCO providers depending upon their Medicaid enrollment status.
- The Certificate of Medical Necessity (CMN/DMAS-352) and supporting documentation must be completed by a regional metabolic treatment center or a primary care practitioner who is treating the child’s medical condition related to the nutritional supplements.
- Deliver the forms to the DME provider.

- The DME provider will provide the formula according to the DME Manual specifications and retain the DMAS 352 and nutritional assessment forms.
- Formula that is not priced in Appendix B of the DME Manual will be reimbursed at the amount of the providers' cost plus a 30% mark up.

HOME INFUSION THERAPY

Home Infusion Therapy is the administration of fluids, drugs, chemical agents, or nutritional substances to individuals in the home setting via intravenous (IV), central line, or implanted pump/port. DMAS will reimburse for the services, supplies, and drugs only when they are determined to be:

- Ordered by the licensed practitioner on the CMN Medically necessary to treat an individual's medical condition;
- A reasonable and necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition
- In accordance with accepted medical practice; and
- Not for the convenience of the individual or the individual's caregiver.

The individual must:

- Reside in either a private home or an assisted living facility (ALF). Individuals in hospitals, nursing facilities, rehabilitation centers, and other institutional settings are not eligible for this service;
- Be under the care of a practitioner who prescribes the home infusion therapy and monitors the progress of the therapy;
- Have body sites available for I.V. catheter or needle placement or have central venous access or an implanted pump; and
- Be capable of self-administering or have a caregiver who can be adequately trained, is capable, and is willing to administer/monitor home infusion therapy safely and efficiently following the appropriate teaching and adequate monitoring. In those cases where the individual is incapable of administering or monitoring the prescribed therapy, and there is no adequate or trained caregiver, it may be appropriate for a home health agency to administer the therapy.

Provider Eligibility

Providers must have a valid Medicaid national provider identification (NPI) number to participate in the home I.V. therapy program. Providers eligible to participate in this program are:

- I.V. therapy providers;
- Home health agencies;
- Pharmacies; *and*

- DME providers.

A provider must be enrolled as a Medicaid provider, to include all of the following:

- Meet any state licensing and certification requirements;
- Render infusion therapy covered services;
- Use Medicaid-established billing guidelines;
- Accept Medicaid reimbursement as payment in full.

Therapy Coverage

Medicaid has assigned a service day rate code and reimbursement rate for each of the covered therapies:

- Hydration therapy;
- Pain management;
- Chemotherapy;
- Drug therapy; and
- Total parenteral nutrition (TPN)

Service Day Rate Definition

This payment methodology provides a fixed amount for each day of infusion therapy. The service day rate (per diem) reimburses for all services delivered in a single day. This payment methodology will be mandatory for the reimbursement of all I.V. therapy services, unless the individual is enrolled in one of the waived services outlined under "Special Considerations." Service day rates are based on an average day of service, and there will be no additional reimbursement for special or extraordinary services. In the event of incompatible drug administration, the provider should use separate HCPCS codes (see Appendix B of this Manual for the appropriate HCPCS codes) to allow for the rental of a second infusion pump and the purchase of extra administration tubing.

When applicable, DMAS may be billed in addition to the service day rate codes for the rental of the second infusion pump and extra administration tubing. There must be documentation to support the use of these codes in addition to the service day rate on the I.V. Implementation Form (DMAS-354). Proper documentation includes the need for pump administration of the medications ordered, the frequency of administration to support that they are ordered simultaneously, and an indication of incompatibility. The service day rate payment will be in two service categories: durable medical equipment (DME) and pharmacy.

Items in the DME service day rate include all supplies required to administer I.V. therapy, including, but not limited to, the following:

- I.V. pump/pole rental/control devices;
- Tubing's, adapters, caps, needles, filters, cannulas, extension sets, and alcohol

swabs; *and*

- I.V. start kits and central venous catheter dressing kits.

Items in the pharmacy service day rate include the following:

- Diluent for the therapeutic agent;
- Mixing and compounding;
- Flush kits and solutions (heparin and saline); *and*
- Cassettes and bags/mini-bags.

See the Medicaid Pharmacy Provider Manual for instructions regarding billing pharmacy services day rate available through the Medicaid portal at www.virginiamedicaid.dmas.virginia.gov.

Drugs used in addition to I.V. therapy, such as intramuscular and subcutaneous injections (Compazine, insulin, etc.) and subcutaneous therapies for hydration and/or pain management, are not covered under the I.V. service day rate policy. These medications and their associated DME supplies must be ordered and billed separately according to current Medicaid guidelines.

Special Considerations

Providers of I.V. therapy services to those individuals enrolled in special or waived Medicaid programs must abide by all the guidelines of the program in which the individual is enrolled.

Nursing Visits

Nursing visits for I.V. therapy are reimbursed under home health services. To receive reimbursement for the I.V. therapy nursing services, the provider must be a Medicaid home health provider with a valid home health provider NPI number. If a nurse from a company that is a non-participating Medicaid home health provider acts as a “back up” for the nurse at the home health agency, the two companies must make arrangements between themselves for reimbursement. The home health visit reimbursement for all nursing services, includes but is not limited to, travel time, individual education, and I.V. administration. A home health nurse must be present delivering a service that is deemed medically necessary in order to receive reimbursement. Supplies used by the nurse during the course of the home health visit for I.V. therapy, such as I.V. start kits, angiocaths, midline catheters, etc., will be reimbursed under the DME service day rate allowance to whichever provider furnishes the supplies.

Multiple Therapies

Multiple therapies of the same therapy are included in one service day rate of reimbursement. For example, if an individual receives two antibiotics under drug therapy on the same day, the provider may only bill one service day rate for the DME and pharmacy services. In the event of incompatible drug administration, the provider should use separate HCPCS codes (see Appendix B of this Manual for the appropriate HCPCS codes to use) to allow for the rental of a second infusion pump and the purchase of extra administration tubing. When applicable, DMAS may be billed in addition to the service

day rate codes for the rental of the second infusion pump and extra administration tubing. There must be documentation to support the use of these codes in addition to the service day rate on the I.V. Implementation Form (DMAS-354).

Proper documentation includes the need for pump administration of the medications ordered, the frequency of administration to support that they are ordered simultaneously, and an indication of incompatibility.

Multiple therapies of different therapies under DME will be reimbursed at 100% for the most expensive therapy and 50% for the second and each additional therapy. For example, if an individual receives chemotherapy, hydration, and pain management on the same day, the DME provider may bill \$44.00 for pain management, \$18.50 for chemotherapy, and \$15.00 for hydration, based on current rates.

Hydration Therapy

Definition: Hydration therapy is the intravenous administration of fluids, electrolytes, and/or other additives.

The pharmacy service day rate includes, but is not limited to:

- Covered drugs: Electrolytes and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

The hydration solution is billed on the most current version of the Daily Pharmacy Drug Claim Ledger (DMAS-173), Point-of-Service (POS) on-line billing or approved electronic billing method.

The DME service day rate includes, but is not limited to:

- The I.V. pump/pole rental, administration sets, tubing's, adapters, cannulas, extension sets, gloves, alcohol wipes, needles, dressing/start kits, etc.

Special Notes:

- There is no additional reimbursement for special or extraordinary services.
- The pharmacy service allowance includes containers (cassettes/bags/minibags) and flushes (heparin and saline).

Pain Management

Definition: Pain management is the intravenous administration (or subcutaneous administration via patient-controlled analgesia (PCA) or CAAD ambulatory infusion pump) of narcotics and other drugs to relieve pain.

The pharmacy service day rate includes, but is not limited to:

- Covered drugs: Diluent, electrolytes, and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

The DME service day rate includes, but is not limited to: I.V. pump/pole rental, administration sets, tubings, adapters, cannulas, extension sets, remote reservoirs, needles, alcohol wipes, gloves, dressing/start kits, etc.

Special Notes:

- There is no additional reimbursement for special or extraordinary services.
- The pharmacy service allowance includes containers (cassettes/bags/minibags) and flushes (heparin and saline).

Chemotherapy

Definition: Chemotherapy is the administration of chemical agents designed to have a specific effect upon disease causing cells or organisms.

The pharmacy service day rate includes, but is not limited to:

- Covered drugs: Diluent, electrolytes, and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

The DME service day rate includes, but is not limited to:

- The I.V. pump/pole rental, administration sets, tubings, adapters, cannulas, extensions sets, needles, alcohol wipes, gloves, dressing/start kits, spill kits, etc.

Special Notes:

- There is no additional reimbursement for special or extraordinary services.
- The pharmacy service allowance includes containers (cassettes/bags/minibags) and flushes (heparin and saline).
- Multiple chemotherapies are included in the one service day rate.
- Hydration solutions may be billed separately.

Drug Therapy

Definition: Drug therapy is the intravenous administration of antibiotics or **other drugs**.

The pharmacy service day rate includes, but is not limited to:

- Covered drugs: Diluent, electrolytes, and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

The DME service day rate includes, but is not limited to, the:

- I.V. pump/pole rental, administration sets, tubings, cannulas, extension sets, adapters, needles, remote reservoirs, alcohol wipes, gloves, dressing/start kits, etc.

Special Notes:

- There is no additional reimbursement for special or extraordinary services.
- The pharmacy service allowance includes containers (cassettes/bags/minibags) and flushes (heparin and saline).
- Multiple drug therapies are included in the one service day rate.

Total Parenteral Nutrition - TPN

Definition: TPN is the administration of nutritional substance by intravenous infusion to nourish individuals who are malnourished or may develop malnutrition and who are not candidates for enteral support.

The pharmacy service day rate includes, but is not limited to:

- Covered drugs: Diluent, electrolytes, nutritional additives, lipids, and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

The DME service day rate includes, but is not limited to:

- I.V. pump/pole rental, administration sets, tubings, cannulas, extension sets, adapters, needles, alcohol wipes, gloves, dressing/start kits, etc.

Special Notes:

- There is no additional reimbursement for special or extraordinary services.
- The pharmacy service allowance includes containers (cassettes/bags/minibags) and flushes (heparin and saline).
- The pharmacy service allowance includes solutions, additives (such as KCL and MVI), and lipids. Refer to the Medicaid Pharmacy Provider Manual for additional information on the Medicaid web portal at www.virginiamedicaid.dmas.virginia.gov.

Codes for Purchased I.V. Pumps

For those cases where an individual owns an I.V. pump for the long-term administration of I.V. therapy, two DME codes have been created to reimburse for service day rate services.

Use HCPCS code defined in Appendix B of this Manual for those individuals who own their own IV pump and require IV drug therapy. The reimbursement does not include the pump rental, but does include an allowance for battery reimbursement.

DMAS will not reimburse the DME provider for any DME and supplies provided prior to the date of the practitioner's signature when the signature is not obtained within 60 days of the first date of service. Under the item/service and HCPCS code on the CMN/DMAS-352, list the proper code and therapy service as well as the estimated length of time needed. The I.V. Therapy Implementation Form (DMAS-354) must be completed, signed, and dated by the practitioner within 60 days of the therapy start date. Additionally, a copy of the doctor's order for discontinuing the therapy must also be attached to each CMN/DMAS-352 and I.V. Therapy Implementation form upon completion of the therapy.

Codes for Incompatible Drug Therapy

In the event of incompatible drug administration, the provider may bill the rental of a second infusion pump for each day of service and extra administrative tubing. There must be documentation to support the use of the second pump on the I.V. Therapy Implementation Form (DMAS-354). Proper documentation includes the need for pump administration of the medications ordered, the frequency of administration to support that they are ordered simultaneously, and an indication of incompatibility.

REHABILITATION EQUIPMENT

Rehabilitation equipment includes, but is not limited to, tilt tables, prone standers, parallel bars, and balance balls. This equipment is designed to bring an individual into an upright position or to stimulate vestibular function, or to stimulate balance.

The following conditions must be met for DMAS or its contractor to approve reimbursement of these types of rehabilitation equipment. These conditions are applicable whether the equipment is for initial use or replacement. (12 VAC 30-50-165)

1. Individual-Based Outcomes (at least one of the following must be met):
 - An identified, realistic goal of functional ambulation exists and/or the individual has achieved progressive mobility goals at the time the equipment is requested (i.e., the individual is able to come from supine to sit, able to maintain dynamic sitting balance, and to right balance; the individual is actively pursuing ambulation goals; and there is a reasonable expectation the goal(s) will be achieved, such as with the use of tilt tables, prone standers, etc.); *or*
 - An identified goal of a level of functional independence in activities of daily living exists, the achievement of which depends upon the individual's maintaining an upright position in order to maximize the use of the upper extremities and/or to increase visual/perceptual integration, such as with the use of tilt tables, prone standers, etc.; *or*
 - An identified goal of a level of functional independence in ambulation and/or activities of daily living exists, the achievement of which is dependent upon the stimulation of vestibular function, balance, and/or neurodevelopmental progression, such as with the use of balance balls, etc.

2. Supportive Activities to Accomplish Outcomes (all of the following must be met):
 - Goal(s) must be part of an active, rehabilitative, therapeutic plan of care in place at the initiation of use of the equipment. The goal(s) must be realistic in that it is consistent with the individual's cognitive, environmental, and physical status;
 - The individual and/or caregiver demonstrates the ability cognitively, motivationally, and physically to effectively utilize the equipment toward goal achievement. Someone is available to regularly assist the individual as necessary in the use of the equipment in order that progress toward goal achievement can occur;
 - The individual does not have a deficient level of "energy" or other systemic condition (e.g., CHF, COPD) that adversely impacts the ability to participate in the use of the equipment; *and*
 - The equipment must reduce the need for other reimbursed health care such as personal care, private duty nursing, rehabilitation services, and/or home

health services.

RESPIRATORY EQUIPMENT AND SERVICES

Apnea Monitors

Apnea monitor usage for individuals with one of the following diagnoses or identified high-risk conditions may be approved for payment if the diagnosis/condition is supported with a completed CMN/DMAS-352 and includes appropriate supporting and verifiable documentation:

- Those who have experienced a brief unexplained event (BRUE) and are NOT characterized as low risk* (see below for low risk factors). If monitored due to BRUE, use of an apnea monitor is considered medically necessary until event free for 2-3 months;
- Apnea of prematurity, defined as sudden cessation of breathing that lasts for at least 20 seconds, or is accompanied by bradycardia (heart rate less than 80 beats per minute), or oxygen desaturation less than 90 % or cyanosis in an infant with early home discharge prior to term (38 weeks). Continued use is considered medically necessary up to 43 weeks postmenstrual age or event free for two (2) weeks, whichever comes later;
- Bronchopulmonary dysplasia/chronic lung disease of infancy with oxygen dependency;
- Respiratory control disorder such as: congenital hypoventilation, obstructive sleep apnea, central apnea, obstructive airway disease;
- Infant or child with tracheostomy;
- Those discharged home on a schedule of weaning narcotics;
- Congenital anomalies, at risk of airway obstruction;
- Those with a diagnosis of pertussis and are < six (6) months old, with positive cultures. If monitored for pertussis, use of monitor is considered medically necessary for up to one (1) month post diagnosis;
- Those with bradycardia on caffeine, theophylline, or similar agents, until event free for two (2) weeks off medication;
- Those with diagnosis of gastroesophageal reflux disease (GERD) that results in apnea (at least 20 seconds), bradycardia (heart rate less than 80 beats per minute), or oxygen desaturation (O2 saturation less than 90%, or cyanosis), until event free for six (6) weeks.

BRUE is defined as an event occurring in an infant < one (1) year of age when the observer reports a sudden, brief, and now resolved episode of > one (1) of the following:

- Cyanosis or pallor
- Absent, decreased or irregular breathing
- Marked change in tone (hyper or hypotonia)
- Altered level of responsiveness

BRUE Low Risk Factors:

1. Age > 60 days
2. Prematurity with gestational age of > 32 weeks and postconceptional age of > 45 weeks
3. First BRUE (no previous BRUE ever and not occurring in clusters)
4. Duration of event < one (1) minute
5. No CPR required by trained medical provider
6. No concerning historical features
7. No concerning physical examination findings

NOTE: Information specific to all documentation requirements related to the use of apnea monitors can be found in Ch. VI of this manual.

If the individual does not have any of the above diagnoses, the request will be reviewed in accordance with the following criteria below:

Criteria for Home Monitoring

The instrument recommended for home use must monitor both cardiac and respiratory status. Apnea mattresses or displacement pads are not covered. The individual may use either the recording or non-recording monitor. At least one of the following must be evident for an initial and/or ongoing continued use, with appropriate, supporting, individual documentation:

- Observed or recorded episode of prolonged apnea with no identifiable and/or treatable cause, or an inadequate response to treatment; or
- Documented apnea associated with bradycardia, cyanosis, pallor; or
- History of apnea described by parent or caretaker and documented in the medical records; or
- Evidence of abnormal respiratory control.

Guidelines for Discontinuation Of Monitor Reimbursement

Unless timeframe is specified in the above criteria, initial approval for reimbursement will be for a period up to four months (120 days). If continued use is indicated by medical necessity, supporting and verifiable medical documentation must be submitted to DMAS or its contractor for review and service authorization.

Reimbursement for apnea monitors will be discontinued when a clinical evaluation (including neurological, developmental and physical examinations) shows that the initial problems or conditions requiring the monitor have been resolved or stabilized. Reimbursement will be discontinued when one of the following scenarios occurs:

- The individual has been free of events requiring stimulation or resuscitation for 2-4 months; *or*
- The individual has experienced significant stressors such as respiratory illness or immunizations without apnea; *or*

- There is normalization of a previously abnormal respiratory pattern or no prolonged apnea episodes for 2-4 months.

Pneumograms/Downloads, Polysomnograms, and Multi-Channel Sleep Studies

Definitions:

A pneumogram is a 2-channel study of breathing and heart rate, including EKG signal and chest wall movement. A download serves the same purpose as a pneumogram if the individual is monitored on a recording apnea monitor.

A multi-channel sleep study contains three or more signal sources that may include: cardiac EKG signal, respiratory air flow, body position, oximetry, esophageal pH, and quantitative end tidal CO₂.

A polysomnogram includes cardiac EKG signal, respiratory chest wall movement, respiratory abdominal wall movement, respiratory air flow, body position, oximetry, esophageal pH, and quantitative end tidal CO₂, EEG x2, EOG x2, and EMG, attended by a technologist.

Reimbursement for these studies will be considered by DMAS or its contractor based on the number of channels in the study. Criteria for determining the number of appropriate channels to be studied must be determined by the attending or ordering practitioner.

If a recording monitor is being used and downloaded, a pneumogram is not needed to document the continuing need for the monitor. This information will be obtained from the download summary report. Should an individual with a recording monitor need a pneumogram, the DME provider must submit a request for service authorization to DMAS or its contractor.

Criteria for Rental Versus Purchase Of an Apnea Monitor

DMAS does not require service authorization for the initial 120 days of use of an apnea monitor. If the practitioner determines that the individual will need the apnea monitor beyond 120 days, but less than eight (8) months, the DME provider must obtain service authorization for continued rental from the DMAS service authorization contractor. To obtain service authorization, the DME provider must submit supporting documentation for the additional time requested. If the practitioner determines that the individual will need the apnea monitor eight (8) months or longer, and the member has Medicaid only, the DME provider must request purchase of the apnea monitor. This SA request must include supporting documentation at the initiation of service or at the time of determination of long-term usage. At the time of purchase, the DME provider is required to provide a new monitor with a full manufacturer's warranty. (12 VAC 30-50-165) (If the primary insurance allows a continuous rental, then DMAS will allow a continuous rental. If a continuous rental is used, the service and maintenance agreement is not billable as those services and supplies are covered by the rental reimbursement.)

The provider must submit a clinical description to DMAS or its contractor for review of what happened during the first 120 days and why the monitor continues to be needed.

This description is comprised of a history and physical, interpreted downloads or pneumograms that show a test history, indication of special considerations (need for oxygen, need to receive immunization stressors, or need to reach significant age for a sibling with SIDS), and a practitioner's assessment of what happened during the first 120 days of monitoring to warrant continued use. It is the responsibility of the individual's practitioner to interpret the data. It is the responsibility of the provider to obtain the interpretation from the practitioner and submit the interpretation to DMAS or its contractor. Additional information specific to all documentation required for continued use of apnea monitors and diagnostic studies can be found in Ch. VI of this manual.

Non-Compliant Behavior

The provider shall document the individual's non-compliant use of the apnea monitor in the individual's file. Non-compliant use of the apnea monitor by the individual or the individual's caregiver is a refusal to provide care necessary for the individual's health and creates a substantial risk of death for the individual. The provider shall report non-compliant behavior to the attending practitioner or health care professional. There shall be compliance with 12 VAC 30-50-165. DMAS shall continue to reimburse for the monitor while reasonable efforts to ensure compliant behavior are taken.

Service Maintenance Agreements for Purchased Apnea Monitors

Use the appropriate HCPCS code, which covers the service and maintenance of purchased apnea monitors and requires service authorization. The service maintenance agreement will allow for trouble-shooting and download visits (18 visits per six [6] months). Downloading can be done during a "trouble-shooting" visit. The provider can utilize these 18 visits for any combination of "trouble-shooting" or download visits. (See the "Medicaid DME and Supplies Listing" in Appendix B for the allowable limits and reimbursement information.)

Providers must agree to send the purchased monitor to the manufacturer for necessary servicing. The cost for servicing, shipping, and handling is covered in HCPCS code and service authorization is required. A copy of the manufacturer's invoice for servicing must be attached to the claims invoice. The claim invoices will pend for manual review before reimbursement is made.

The service maintenance agreement does not include repairs. All repairs must be requested under the established HCPCS code for repairs.

All of the following services must be included as part of the service maintenance agreement:

- The provider agrees to employ or contract with staff that are available to make timely necessary home visits related to the use of the apnea monitor. The provider must assure that the staff is qualified to render the necessary services;
and
- The provider agrees to perform routine maintenance of the apnea monitor in the home, replacing rib belts, lead wires, and electrodes (disposable or reusable)

associated with this routine maintenance. Supplies that must be provided under this agreement are:

- 12 disposable electrodes or 2 reusable electrodes
- Two (2) lead wires and 2 rib belts.

Additional supplies that are medically justified must be preauthorized;

- The costs for “trouble-shooting” and download visits will be included in the service maintenance agreement fee (18 visits per six [6] months). Downloading can be done during a “trouble-shooting” visit. These 18 visits can be used by the provider for any combination of trouble-shooting or download visits;
- The provider agrees to provide a back-up apnea monitor throughout the period of apnea monitor repairs or services. The provider may bill DMAS for a rental apnea monitor for up to one month during routine repairs/services using the established HCPCS code. The rental must only be for the actual time the monitor is out of the home being serviced by the manufacturer;
- The cost of parts which constitute a repair must be billed separately, as a repair, using the established HCPCS codes for repairs; *and*
- The provider agrees to send the apnea monitor for necessary servicing by the manufacturer. The cost for servicing, shipping, and handling will be covered in a separate HCPCS code (S8189). The provider must attach a copy of the CMN/DMAS-352 and manufacturer’s invoice to the claim in order for the claim to be paid. DMAS will pend claims for the HCPCS code (S8189) for manual review.

CO₂ Monitors

CO₂ monitors are typically used for ventilator dependent individuals in the acute care setting, often in conjunction with a pulse oximeter. The term capnography refers to the noninvasive measures of the partial pressure of carbon dioxide in exhaled breath expressed as the C02 concentration over time. These results are usually represented through a capnograph that is a waveform that shows how much C02 present at each phase of the respiratory cycle. The results must be reviewed by the practitioner before nursing intervention is performed based on the study. These studies will not be approved for obstructive sleep apnea. Capnography is generally used in the inpatient setting to verify endotracheal tube placement after intubation, change in the clinical status of an intubated individual, and during procedural sedation.

Use of a C02 monitor in the home has been demonstrated in certain *limited* circumstances. The cost of conducting a capnography study, when ordered by the practitioner, will be covered in the following circumstances:

- Weaning from a ventilator
- Individuals who have a history of C02 retention which requires periodic monitoring
- Monitoring of members with congenital central alveolar hypoventilation syndrome

There has been recent research involving capnography in the detection of nocturnal hypoventilation and initial assessment of mechanical ventilation efficiency in individuals with neuromuscular disorders. These areas are currently considered investigational and further research will be needed to determine the standard of care.

All requests must be preauthorized. The DME provider must obtain a CMN/DMAS-352, completed by the practitioner who treats the individual's pulmonary condition. The CMN/DMAS-352 must address the reason for the study, the length of time the study will require, and the frequency requested within the six-month service authorization period. Two nights will be the maximum length of the study which will be reimbursed. The CO₂ monitor reading must be submitted to the practitioner for assessment, and the practitioner must report back to the DME provider regarding any changes to be made based upon the practitioner's evaluation of the reading taken. Requests for further studies after the first request must include documentation of the progress toward weaning or evidence of continued CO₂ retention. If the practitioner does not indicate that progress toward weaning is shown or can be expected, the SA request may be denied.

The amount of reimbursement for the CO₂ study will depend on whether DMAS is reimbursing for the professional component necessary to assure an accurate reading is obtained. For an individual receiving in-home nursing care (e.g., individuals enrolled in the CCC+ Waiver (for vent or complex trach care), the health care coordinator will discuss with the nursing agency and DME provider whether the private duty nurse is knowledgeable and comfortable with the use of the equipment for the study. If the nurse is able to assure an adequate reading, the DME provider will be reimbursed for the cost of the delivery of the equipment, a one-day rental of the equipment, and a scoring fee for the CO₂ study. If the nurse is not able to assure the accurate reading, or the individual does not receive nursing services during the time the study would be conducted, DMAS reimbursement will be limited to the time spent by the respiratory therapist, who must be present during the entire period of the study (8-10 hours), rental of the equipment for one day, and the scoring fee. In all cases, the CO₂ monitor must be equipped with a printer, and the DME provider must send the results of the study to the practitioner for interpretation.

Humidification Systems

DMAS will reimburse for an aerosol humidification system when the individual's upper airway is bypassed. A vapor phase humidification system will be reimbursed when the individual is on a ventilator. The components of the aerosol system are:

- Reusable dry nebulizer;
- Water trap;
- Compressor;
- Swivel adapter; and
- Corrugated tubing.

A disposable dry nebulizer will only be considered for reimbursement when it is expected that the need for the humidification system will be short-term; (it is expected that the tracheostomy will be closed).

A vapor phase humidification system will be considered for reimbursement for treatment of humidity deficit for an individual with a tracheostomy only when there is justification for the necessity of this device versus an aerosol humidification system, and the aerosol humidification system is documented as contraindicated.

All humidification systems must be purchased except in those instances when humidification is expected to be required for less than nine (9) months. Reimbursement will be a bundled rate for all the components of the system.

Oxygen

DMAS provides reimbursement to DME providers for medically necessary respiratory/oxygen equipment and supplies. Any respiratory/oxygen equipment and supplies must be practitioner-ordered via the CMN/DMAS-352. The flow rate, frequency, and duration of use (an order for PRN use of oxygen must identify the circumstances under which oxygen is to be used) must be identified on the CMN/DMAS-352 as part of the practitioner's order. For portable systems, documentation must provide a description of the activities in which the individual participates, on a regular basis, that require a portable system in the home, and the therapeutic purpose served by that portable system that cannot be met by a stationary system. Coverage of home oxygen and oxygen equipment will be considered reasonable and necessary only for individuals with significant hypoxemia who evidence the following laboratory results, health conditions and for whom the required medical documentation exists. (12 VAC 30-50-165)

Evidence of Medical Necessity

While there is no substitute for oxygen therapy, it is appropriate that each individual should receive optimum therapy before long-term home oxygen therapy is ordered. The practitioner must have examined the individual recently (within 30 days of the start of therapy).

Reasonable and necessary oxygen items and equipment for home use must meet **all** of these criteria:

1. The treating practitioner examined the individual and determined that he or she has one of these conditions that might be expected to improve with oxygen therapy:

A. Short term supplemental home oxygen therapy is medically necessary for treatment of hypoxemia related symptoms with qualifying laboratory values associated with acute conditions including, but not limited to any of the following:

- Bronchiolitis; or
- Chronic obstructive pulmonary disease exacerbation; or
- Pneumonia.

B. Long term supplemental home oxygen therapy is medically necessary for treatment of hypoxemia related symptoms with qualifying laboratory values from chronic lung conditions including, but not limited to any of the following:

- Bronchiectasis; or
 - Chronic lung disease; or
 - Chronic obstructive pulmonary disease; or
 - Cystic fibrosis; or
 - Diffuse interstitial lung disease; or
 - Pulmonary hypertension; or
 - Pulmonary neoplasm (primary or metastatic); or
 - Recurring congestive heart failure due to chronic cor pulmonale.
2. The treating physician or a qualified provider or supplier of laboratory services conducted the qualifying blood gas study. A qualified provider or supplier of laboratory services is:
- Certified to conduct blood gas studies or
 - A hospital certified to conduct blood gas studies
3. The qualifying blood gas study value was obtained under these conditions:
- During an inpatient hospital stay - Closest to, but no earlier than, two (2) days prior to the hospital discharge date, with home oxygen therapy beginning immediately following discharge; or
 - During an outpatient encounter - Within 30 days of the date of initial certification while the individual is in a chronic stable state, which is when the individual is not in a period of acute illness or an exacerbation of his or her underlying disease.
4. The treating physician tried or considered alternative treatments and they were deemed clinically ineffective.

Conditions for which oxygen therapy is not covered are:

- Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments.
- Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen is sometimes prescribed to relieve this condition, it is potentially harmful and may be psychologically contraindicated.
- Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO₂ will improve the oxygenation of tissues with impaired circulation.
- Terminal illnesses that do not affect the lungs.
- Treatment of headaches, including migraines.

- Treatment of other conditions in which oxygen therapy is determined to be experimental or investigational.

Health Conditions

Coverage is available for individuals with significant hypoxemia in a chronic and stable state if the following **three (3)** conditions are met:

1. The practitioner has determined that the individual has one of the following health conditions:

- A severe lung disease, such as chronic obstructive pulmonary disease (COPD), diffuse interstitial lung disease of known or unknown etiology; cystic fibrosis, bronchiectasis; and symptoms of widespread pulmonary neoplasm; or
- Hypoxia-related diagnoses or symptoms that might be expected to improve with oxygen therapy. Examples of these are pulmonary hypertension, recurring congestive heart failure (CHF) due to chronic cor pulmonale, erythrocytosis, impairment of cognitive processes, nocturnal restlessness, and morning headache.

2. For initial certifications, the patient's blood gas study (either an arterial blood gas or an oximetry test) values meet one of these criteria:

Group I Criteria:

- Individual on room air while at rest (awake) when tested:
 - Arterial oxygen saturation (pulse ox) is at or below 88 percent or
 - Arterial Partial Pressure of Oxygen (P02) is at or below 55 mm Hg
- Individual tested at rest while awake or during exercise, arterial P02 is at or above 56 mm Hg or an arterial oxygen saturation is at or above 89 percent:
 - Arterial P02 is at or below 55 mm Hg or an arterial oxygen saturation is at or below 88 percent; and
 - Documented improvement of hypoxemia during exercise with oxygen.
- Individual tested during sleep and if arterial P02 is at or above 56 mm Hg or an arterial oxygen saturation is at or above 89 percent while awake, additional testing must show:
 - Arterial P02 is at or below 55 mm Hg or an arterial oxygen saturation is at or below 88 percent; or
 - Decrease in arterial P02 of more than 10 mm Hg or a decrease in arterial oxygen saturation more than 5 percent for at least 5 minutes associated with symptoms or signs more than 5 percent from baseline saturation for at least 5 minutes taken during sleep associated with symptoms or

signs reasonably attributable to hypoxemia (some examples of symptoms are impairment of cognitive processes and nocturnal restlessness or insomnia and some examples of signs are cor pulmonale, "P" pulmonale on electrocardiogram [EKG], documented pulmonary hypertension, and erythrocytosis reasonably attributable to hypoxemia) or

For infants and children:

- Arterial oxygen saturation is at or below 92 percent; or
- Arterial Partial Pressure of Oxygen (P02) is at or below 60 mm Hg.

Initial coverage of Group I home oxygen therapy is limited to 12 months or the treating physician-specified length of need for oxygen, whichever is shorter.

Group II Criteria:

Includes portable oxygen systems if the patient is mobile within the home and the qualifying blood gas study is performed at rest while awake or during exercise. Portable oxygen will not be covered as reasonable and necessary if the only qualifying blood gas study is performed during sleep:

1. Individual on room air at rest while awake when tested:
 - Arterial oxygen saturation of 89 percent at rest (awake) **or**
 - Arterial P02 of 56-59 mm Hg **and**
 - a. Dependent edema suggesting congestive heart failure or
 - b. Hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF) or
 - c. Erythrocythemia with a hematocrit greater than 56 percent or
2. Individual tested during exercise:
 - Arterial oxygen saturation of 89 percent **or**
 - Arterial P02 of 56-59 mm Hg **and**
 - a. Dependent edema suggesting congestive heart failure
 - b. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF) or
 - c. Erythrocythemia with a hematocrit greater than 56 percent or
3. Individual tested during sleep for at least 5 minutes:
 - Arterial oxygen saturation of 89 percent **or**
 - Arterial P02 of 56-59 mm Hg **and**
 - a. Dependent edema suggesting congestive heart failure
 - b. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III,

- or AVF) or
- c. Erythrocythemia with a hematocrit greater than 56 percent or

For infants and children:

- Arterial oxygen saturation is at or below 92 percent or
- Arterial Partial Pressure of Oxygen (P02) is at or below 60 mm Hg

Initial coverage of Group II home oxygen therapy is limited to 3 months or the treating physician-specified length of need for oxygen, whichever is shorter.

The individual has appropriately tried other alternative treatment measures without demonstrable success or other forms of treatment have not been tried, but oxygen therapy is needed as part of the individual's initial treatment.

Coverage of home oxygen not included in the above criteria must be preauthorized by DMAS or its contractor. The practitioner must submit documentation, in addition to the CMN/DMAS-352, which specifies why oxygen is medically necessary. (Exceptions will be made, on a case-by-case basis, for children under the age of 21 and members who have complex care needs with a Letter of Medical Necessity (LMN) when laboratory evidence can't be safely obtained. Back-up oxygen will be covered if the member has an artificial airway with medical necessity provided on the CMN or LMN. If service authorization is not required for the appropriate HCPCS codecode the LMN must be on file in the member's record. The DME provider can request review by the DME subject matter expert for medically fragile children and adults via email to the appropriate MCO or DMAS.)

Laboratory Evidence

The CMN/DMAS-352 or supporting documentation signed and dated by the practitioner must also include the results of a blood gas study ordered and evaluated by the attending practitioner. This will usually be in the form of a measurement of the partial pressure of oxygen (PO₂) in arterial blood. A measurement of arterial oxygen saturation obtained by ear or pulse oximetry; however, will also be acceptable when ordered and conducted by a qualified provider or supplier of laboratory services and evaluated by the attending practitioner. The conditions under which the laboratory tests are performed must be specified in writing and submitted with the CMN/DMAS-352 or supporting documentation (i.e., at rest, while sleeping, while exercising, on room air, or if while on oxygen, the amount, body position during testing, and any similar information necessary for interpreting the evidence).

In situations when the arterial blood gas and the oximetry studies are both used to determine the medical need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source for this determination.

A DME supplier is not considered a qualified provider or supplier of laboratory services

for purposes of these guidelines. This prohibition does not extend to the results of an arterial blood gas test conducted by a hospital certified to do such tests. The preferred sources of laboratory evidence are existing practitioner and/or hospital records that reflect the individual's medical condition. If more than one arterial blood gas test is performed during the individual's hospital stay, the test result obtained closest to the hospital discharge date must be submitted. The attending practitioner's statement of recent hospital test results is acceptable in lieu of copies of the actual hospital records.

A DME provider may be the provider of pulse oximetry services, in accordance with the established DMAS pulse oximetry criteria, for an individual with a progressive disease who may require oxygen at night. The DME provider can be the same provider but must be sure the criteria is met for each type of service. The overnight pulse oximetry study must be ordered by the practitioner, and the DME provider must send a copy of the pulse oximetry readings to the attending practitioner for interpretation. If the practitioner determines that oxygen therapy is medically indicated, the oximetry test results and the practitioner's order for oxygen therapy must be recorded on the CMN/DMAS-352 or in supporting documentation. DMAS will reimburse the DME provider for the oxygen therapy as ordered by the practitioner, and in accordance with the coverage criteria for oxygen therapy.

A repeat arterial blood gas or oximetry study will normally be necessary only when evidence indicates that an individual receiving oxygen has undergone a major change relevant to the home use of oxygen. For example, if there has been a significant increase in the amount of oxygen required (e.g., an increase to more than 4 liters per minute), a repeat blood gas or oximetry study may be necessary.

Evidence Of Medical Necessity

The practitioner must document on the CMN/DMAS-352, or in supporting documentation, all of the following:

- A diagnosis of the disease requiring home use of oxygen;
- The oxygen flow rate; and
- An estimate of the frequency, duration of use (e.g., 2 liters per minute, 12 hours a day) and duration of need (e.g., six months or lifetime). Oxygen that is ordered PRN must include justification to determine the amount of oxygen that is reasonable and necessary for the individual.

The practitioner must also specify the type of oxygen delivery system to be used (i.e., gas, liquid, or concentrator). If the type of system is not specified, the provider must provide services in the most cost-effective manner to carry out the practitioner's order and meet the needs of the individual.

The practitioner must submit a new CMN whenever there is a revision to the oxygen requirements based on a change in condition and the subsequent need for oxygen therapy. In the absence of any revision, the CMN authorization is valid for a 12-month

period for adults and six months for children. The practitioner may only certify the need for oxygen therapy if the individual has been examined by a practitioner within the past 12 months.

Reimbursement

DMAS will not provide reimbursement for respiratory/oxygen equipment and supplies which do not meet medical necessity guidelines. Furthermore, DMAS will not provide reimbursement for oxygen and equipment which is not being used by the individual, unless the individual meets **all** the following criteria for an emergency backup system:

1. An individual who requires a ventilator for 12 hours or more per day and is using oxygen, or;
2. The individual is on continuous oxygen use for 12 hours or more per day, and the individual would have decreasing oxygen saturation levels that would place them in a life threatening emergency should the primary oxygen source not be available.

The provider must document on the CMN/DMAS-352 or in supporting documentation signed and dated by the practitioner the circumstances in which the above criteria would be met.

The DME provider must monitor utilization and report to the practitioner when oxygen is not being used as prescribed. This notification must be in writing, and a follow-up must be submitted to the DMAS or its contractor, which shows that either the individual has resumed compliance with medical orders or continues to be non-compliant. If non-compliance continues, DMAS or its contractor will notify the individual of the effective date that coverage of the oxygen will cease.

DMAS will reimburse for the stationary oxygen system (gas, liquid or concentrator) using a daily rate. The reimbursement for daily rental of the system (with or without humidification) includes:

- Oxygen set-up;
- Rental;
- Container;
- Contents for gas or liquid;
- Regulator;
- Nebulizer;
- Nasal cannulas or mask;
- Extension tubings;
- Humidifier, if needed; and
- Bubble bottle for humidification, if needed:

A separate portable oxygen code can be used for reimbursement for portable oxygen

service authorization. Documentation must provide a description of the activities in which the individual participates on a regular basis that require a portable system. Portable oxygen contents (E0443 and E0444) are separately payable only when the coverage criteria for home oxygen have been met and:

1. The individual owns or rents a concentrator and a portable system, or;
2. The individual rents or owns a portable system and has no stationary system (concentrator, gas or liquid).

DMAS does not cover oxygen analyzers.

Pulse Oximetry (Continuous Pulse Oximeter)

Coverage for daily pulse oximetry may be available when ordered by a practitioner who can document that the individual meets one of the following criteria:

- The individual is dependent on both a ventilator and oxygen; or
- The individual has a tracheostomy and is oxygen dependent; or
- The individual has a tracheostomy and is unable, due to some factor such as age, developmental delay, cognitive status, or neuromuscular involvement, to summon assistance thereby placing the individual at risk of obstruction of the tracheostomy; or
- The individual requires supplemental oxygen and has unstable saturations. The desired saturation level will depend on the individual's diagnosis and must be documented by the practitioner at the time continuous pulse oximetry is ordered. At the time of the next service authorization period, the saturation levels will be reviewed for stability.

Laboratory Evidence

Documentation of the individual's current SaO₂ with and without oxygen therapy must be submitted on the CMN/DMAS-352 and must demonstrate desaturation. A desaturation is considered SaO₂ equal to or less than 88% for adults equal to or less than 92% for infants and children. This documentation is required for initial set up or if there has been a change in medical condition.

Certificate of Medical Necessity

The practitioner must document on the CMN/DMAS-352 or in supporting documentation that the individual's condition meets:

- One of the above criteria, and;
- Pulse oximetry readings are necessary on a daily basis in order for the individual to remain in the home;
- *and*
- Evidence of why periodic pulse oximetry readings (e.g., pulse oximetry reading submitted bimonthly showing SaO₂ trends over a specified period of time) would

not meet the practitioner's need for monitoring.

In addition, the practitioner must specify the current oxygen flow rate and the assessment parameters: the setting at which the device should be set to alarm and the intervention response or corrective action to be taken (e.g., increase oxygen to 50%, increase oxygen to 2 L/min.).

Exceptions: DMAS will consider requests for daily pulse oximetry for individuals who do not meet the health condition criteria, but who require daily pulse oximetry due to complications presented (e.g., acute illness, weaning from oxygen use). These will be evaluated on a case by case basis and will need to be resubmitted after one month to evaluate for further medical necessity.

An individual who is ventilator-dependent with room air and who is stable does not qualify for daily pulse oximetry coverage.

Reimbursement for Daily Use Pulse Oximetry

Reimbursement for pulse oximeters determined to be medically necessary in the home on a continuous basis will be reimbursed on a rental basis for a maximum of three months. The decision to rent the equipment must be based on the practitioner's attempt to wean the individual from a tracheostomy or a ventilator, or when the individual requires supplemental oxygen and has unstable saturations, but does not have a tracheotomy or ventilator, and the practitioner is unable to determine the length of time the individual will require the continuous pulse oximetry. DMAS will purchase the pulse oximeter for any rental that exceeds two authorizations of three months each when the practitioner cannot definitely state how much longer the individual will require the continuous pulse oximetry.

Reimbursement will be established for the oximeter with a recording device and a permanent probe (unless documented inability to attain an accurate reading exists which would justify use of disposable probes). The rental code E0445RR can be used for all four types of oximeter devices which include: one for the use of the permanent probe, one for the use of disposable probes, and for the inclusion of a battery pack, one with a disposable probe and one with a permanent probe, when determined medically necessary for the individual who requires transport and is at risk of desaturation when transported. There are additional E1399 codes that can be used for replacement parts/accessories for a purchased unit. The rental code should include all necessary parts and accessories. A copy of the pulse oximetry printout must be attached to the request for the rental service authorization.

Pulse Oximetry (Periodic or Intermittent Pulse Oximeter Studies)

Coverage of pulse oximetry on a periodic or intermittent basis is available for any of the following conditions:

- Any individual on a ventilator or on continuous oxygen when periodic pulse oximetry is ordered by the practitioner as a necessary component of monitoring due to a change in clinical status or need to reassess oxygen therapy; or

- Any individual with a progressive disease that may require oxygen in the future (e.g., emphysema or neuromuscular disease affecting respiration; *or*
- Any individual with severe cardiac or pulmonary disease (excluding obstructive sleep apnea) where there is a high likelihood of nocturnal hypoxia; *or*
- Any individual for whom oxygen has been recently discontinued and for whom the oxygen saturation level is needed to indicate successful weaning.

The practitioner must order the frequency of pulse oximetry readings and the period of time over which the reading must be taken. The pulse oximetry reading must be submitted to the practitioner for assessment, and the practitioner must report back to the DME provider regarding any changes to be made based upon the reading taken.

Service authorization of periodic pulse oximetry will only be given if there are persons in the home environment who are approved by the practitioner as trained and capable of recording accurate readings. It is the practitioner's responsibility to assure that the persons who will be in the home during the periodic pulse oximetry are capable of assuring the accurate reading before authorization of the pulse oximetry is requested. There is no DMAS reimbursement for the personnel who may be required to assure that the pulse oximetry readings are accurate. In the event that the practitioner is not satisfied that the family individual can adequately monitor to assure that the reading is accurate, the periodic pulse oximetry may have to be performed in a sleep lab or hospital setting. Children who receive private duty nursing through the CCC Plus (for ventilator or complex trach) Waiver or EPSDT may have access to nursing services which can assure the accurate reading. All periodic pulse oximetry must be preauthorized by the DMAS or its contractor. The maximum allowable number of studies will be 12 in a 12-month period. (It is the practitioner's responsibility to assure that the persons who will be in the home during the periodic pulse oximetry are capable of assuring the accurate reading before authorization of the pulse oximetry is requested.)

Reimbursement to the DME provider for pulse oximetry studies includes a two-day rental of the monitor. To bill for pulse oximetry studies, a respiratory therapist must set up the equipment in the home. This rate will be all-inclusive; there will be no further reimbursement for printer, paper, probes or any other supplemental equipment. The DME provider will be responsible for sending a copy of the readings to the practitioner for interpretation.

Suction Machines

Suction machines are covered by DMAS for any individual who has a tracheostomy or who cannot manage his or her own secretions. Suction machines will only be rented when the CMN/DMAS-352 indicates the expected length of use is three months or less. Rental includes the cost of the rental of the machine, tubing, collection jars, a battery, and a charger. Suction machines must be purchased whenever the expected use exceeds three months. Purchase of the suction machine will include the cost of one set of tubing, two collection jars, a battery, and a charger. Supplies can be purchased as necessary according to the limits in the "Medicaid DME and Supplies Listing" in Appendix B. DMAS may provide reimbursement for a portable backup suction machine.

Non-Invasive Airway Assistive Devices

Non-invasive airway assistive devices include continuous positive airway pressure (CPAP) and Bi-level positive airway pressure (BiPAP) equipment. CPAP is defined as ventilator assistance equipment that provides continuous positive airway pressure with or without oxygen, which is intended to keep the individual's airway patent. BiPap is ventilator assistance equipment that has the capability of providing two different levels of continuous positive airway pressure, with or without oxygen, which is intended to assist to the keep the individual's airway open to allow breathing. BiPap ST is BiPap that includes a back-up rate feature to ensure continuing ventilation.

CPAP/ BiPAP in the setting of Obstructive Sleep Apnea (OSA)

Criteria for individuals greater than or equal to 18 years old for CPAP:

To be diagnosed with OSA, individual must have a complete polysomnogram (sleep study) within the previous year in which the respiratory disturbance index (RDI) or apnea-hypopnea index (AHI) is based on a minimum of two hours of actual recorded sleep and is not extrapolated or projected **and** at least **one** of the following criteria is met:

- AHI or RDI > 15 events per hour with a minimum of 30 events
- AHI or RDI > 5 events per hour with a minimum of 10 events with at least **one** of the following associated symptoms or conditions:
 - Hypertension
 - History of stroke
 - Ischemic heart disease
 - Excessive daytime sleepiness
 - Impaired cognition
 - Mood disorder
 - Insomnia

Criteria for individuals from 1-17 years old for CPAP

To be diagnosed with OSA, individual must complete a polysomnogram (sleep study) performed within the previous year that demonstrates **one or both** of the following:

1. Greater than or equal to one apnea (mixed or obstructive) or hypopnea per hour of sleep
2. EtCO₂ > 50 mmHg for > 25% of total sleep time and one or more of the following:
 - Snoring
 - Flattening of inspiratory nasal pressure waveform
 - Irregular breathing pattern

Individual must also undergo surgical evaluation and demonstrate **one** of the following:

- Adenotonsillectomy performed and obstructive sleep apnea persists
- Adenotonsillar tissue ruled out as etiology of obstructive sleep apnea
- Adenotonsillectomy contraindicated or inappropriate due to other cause such as craniofacial abnormalities, neuromuscular disease, chronic lung disease, sickle cell disease or Down syndrome

Bi-PAP in the setting of OSA

The individual must meet the criteria for CPAP, there must be documentation of failed CPAP, and meet **all** the following criteria:

- Initial sleep study where CPAP was ineffective during study despite proper mask fitting and selection and appropriate pressure settings, or
- Documented individual's intolerance, pressure discomfort due to high pressures, or CPAP fails to improve the condition, and
 - Documented adherence to > 4 hours of use on > 21 out of 30 consecutive nights on positive airway pressure, and
 - Face to face reevaluation by provider occurred at:
 - 31 days and <91 days after start of initial trial period, or
 - 91 days after start of initial trial period and documented benefit from PAP device

Bi-PAP ST or Bi-PAP with a back-up rate is not medically necessary for obstructive sleep apnea and will not be covered by DMAS for OSA.

Additional clinical scenarios such as replacement of parts, request for re-trial and reauthorization for CPAP/Bi-PAP use for obstructive sleep apnea will be reviewed under the Change Healthcare InterQual criteria for medical necessity.

Non-Invasive Airway Assistive Devices for Other Respiratory Disorders

Non-invasive airway assistive devices are also used in the treatment of other respiratory disorders such as, but not limited to, central sleep apnea, severe chronic obstructive respiratory disease with no or mild COPD, restrictive thoracic disorder, hypoventilation syndrome without OSA or central sleep apnea being primary cause. Devices that are used for treatment of the above diagnosis include but are not limited to, CPAP, BiPAP, BiPAP-ST, and oral devices. The device which is appropriate for an individual is determined by the practitioner based on underlying diagnosis and severity of the disease.

DMAS considers CPAP medically necessary for the treatment of tracheomalacia and these cases will be reviewed. Additional diagnoses that are not covered under Change Healthcare InterQual criteria will be reviewed on a case by case basis.

In some cases, a ventilator with a noninvasive interface is medically necessary for severe neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease where interruption or failure of respiratory support would lead to death. In these cases, DMAS follow the Center for Medicare & Medicaid (CMS) policy on ventilators with non-invasive interfaces for the above diagnoses. CMS distinguishes BiPAP devices from ventilation in an individual for whom interruption or failure of respiratory support leads to death. These describe clinical conditions that require intermittent and relatively short durations of respiratory support. Thus, any type ventilator would not be considered medically necessary for any of the conditions described above for BiPAP devices even though the ventilator equipment may have the capability of operating in a BiPAP mode.

Documentation and Coverage

Initial authorization of CPAP or BiPAP requires the following documentation on the CMN/DMAS-352 or in supporting documentation:

- A face-to-face clinical evaluation by the treating licensed practitioner prior to the sleep study test
- Documentation that the individual meets the clinical criteria for the above respiratory disorders
- Sleep study results (exception for neuromuscular disease where a pneumogram or overnight oximetry study that demonstrates hypoventilation or hypoxemia is acceptable)
- If a CPAP or BiPAP is ordered upon discharge from an inpatient hospital stay the provider may use records from the hospital stay (that are signed and dated by the physician) in lieu of the required documentation in addition to a CMN/ DMAS-352

Coverage of a non-invasive airway assistive device for an adult shall be for a two-month rental period. At the end of this period, the practitioner must determine whether continued use is indicated. In an adult, weight loss is usually the most significant factor to consider. If the individual continues to need the respiratory support at the end of the two-month period, the equipment must be purchased as long as there is documentation that the individual is compliant with the treatment and documentation clearly indicates individual benefit (e.g., SaO₂, ABG's). If the CPAP/BiPAP supplied for the required two-month rental period is new upon delivery, DMAS will consider paying the full purchase price listed in the DME listing in addition to the initial two-month rental period for these items.

Coverage of a non-invasive airway assistive device for a child shall be based upon the expected length of use. Any time the CMN/DMAS-352 indicates that the CPAP/BiPAP is to be used for a period which will exceed nine months, the equipment must be purchased. Purchase of the CPAP/BiPAP will include the cost of filters, tubing, headgear, and masks. The DMAS or its contractor will pre-authorize a service maintenance contract for all individuals for whom a ventilator/CPAP/BiPAP is purchased. (Note: Children below the FDA-approved weight threshold for traditional CPAP or BiPAP may use a non-invasive ventilator in CPAP or BiPAP mode until they reach the FDA weight threshold. **The provider should use a continuous rental in these cases.**)

Service Maintenance for CPAP, BiPAP, and BiPAP S/T

Service Maintenance for CPAP, BIPAP and BiPAP S/T is not billable if the provider is monitoring the device using the remote patient monitoring feature. The vast majority of devices now come with an internal modem that allow the device to be monitored remotely and maintenance is very limited. The provider is still required to employ or contract with a registered or certified respiratory therapist who will be available, in a timely manner, on a 24-hour basis for emergency care for members using a BiPAP S/T.

Compliance records should be maintained in the member's record. Adherence to therapy is defined as using CPAP, BiPAP or BiPAP S/T for at least 4 hours per day for 70% of days in a month.

The service maintenance agreement is required if the device does not have remote monitoring capability. If the provider chooses to monitor the member in person documentation should be kept in the member's record for visits performed according to the guidelines below.

In accordance with the DMAS participation agreement, the DME provider agrees to provide authorized service maintenance for purchased CPAP, BiPAP, and BiPAP S/T equipment for Medicaid-eligible individuals. The service maintenance requires service authorization by DMAS in order for the provider to be reimbursed. Following service authorization of service maintenance, the provider may bill using the HCPCS codes listed in the "Medicaid DME and Supplies Listing" in Appendix B.

All the following services must be included as part of the service maintenance agreement:

- The provider agrees to employ or contract with registered or certified respiratory therapists who will be available in a timely manner on a 24-hour-a-day basis for emergency care. The respiratory therapist will make regular home visits to conduct respiratory assessments and to check equipment.
- For CPAP and BiPAP, visits shall be a minimum of once each month for the first three months, or as ordered by the prescribing practitioner. After the first three months, visits must be made at a minimum of once every three months. For BiPAP S/T, visits shall be a minimum of once each month for the first three months, or as ordered by the prescribing practitioner. After the first three months, visits must be made at a minimum of once every other month.
- The provider agrees to abide by the recommended manufacturer maintenance schedule as defined in the "Manufacturer's Individual Product Pamphlet" and "Service Manual."
- The provider agrees to provide a back-up CPAP/BiPAP throughout the period of service or repair; the DME provider may bill DMAS for a rental CPAP/BiPAP during the period of non-routine service or repair. If a service maintenance agreement is

not being billed because of remote monitoring the DME provider can get reimbursement for the rental of a device during this time.

The cost of parts which would constitute a repair may be billed separately as a CPAP/BiPAP repair under the appropriate HCPCS code. Claims for service maintenance agreements must be submitted for the calendar month in which the service is rendered per the authorization.

Home Invasive Mechanical Ventilators

Home invasive mechanical ventilators (HIMV) are covered items when ordered by a practitioner and preauthorized by the DMAS or its contractor. This section refers to the indications and service for home ventilators that require an invasive interface. Per the American Association of Respiratory Care (AARC) guidelines “the patient eligible for invasive long-term mechanical ventilation in the home requires a tracheostomy tube for ventilator support, but no longer requires intensive medical and monitoring services.”

Primary Ventilator Criteria

A home invasive mechanical ventilator will be considered medically necessary when an individual demonstrates all of the following:

- The inability to be completely weaned from ventilator support or a progression of disease that requires increasing ventilator support and a medical condition such as:
 - Neuromuscular disorders; or,
 - Chest wall deformity; or,
 - Central hypoventilation syndrome; or,
 - Chronic obstructive pulmonary disease; or,
 - Restrictive lung disease; or,
 - Cardiac disorders, including congenital anomalies; and,
 - Optimal medical therapy has been provided for the underlying respiratory disorder(s); and
 - Reversible contributing factors have been treated; and,
 - Medical and respiratory stability have been achieved; and,
 - A diagnosis of chronic respiratory failure (patients who develop symptomatic nocturnal hypercapnia in the absence of daytime hypercapnia may qualify for nocturnal ventilator support; hypoxemia may or may not be present).

Documentation and Coverage

Initial authorization of a ventilator requires the following documentation on the CMN/DMAS-352 or in supporting documentation:

- Documentation that the patient meets the clinical criteria for the above respiratory disorders
- Prognosis for weaning of the ventilator together with the expected length of use of the ventilator
- Stability of the patient on the ventilator at the time of discharge from the hospital
- Need for continuous or periodic pulse oximetry and/or capnography, if on home

oxygen

Reimbursement of a ventilator for a child and adult shall be based upon on purchase or continuous rental:

Option 1: The DME provider may choose to purchase the device for the member if the ventilator is needed for more than 9 months for a child (under the age of 21) or longer than 6 months for an adult via HCPCS codes E0465 (invasive) or E0466 (non-invasive). Reimbursement for the purchase of E0465 or E0466 will include the ventilator device along with any non-invoiced supply or accessories included in the initial purchase of the ventilator by the DME provider from the manufacturer. Ventilator devices have unique serial numbers. Once the ventilator device is purchased, the member will own their specific ventilator that is identified by its unique serial number. The DME provider may bill for the service maintenance agreement of a member's specific ventilator once the ventilator is purchased and owned by the member.

In regards to ventilation supplies and accessories, any item that connects to the ventilator to support the therapy provided by the device to the member that has its own purchase cost from the manufacturer to the DME provider (and verifiable by manufacturer invoice) including (but not limited to) the battery, charger, circuits, stands, mounts, valves, filters, heaters, wires, probes, humidifiers, chambers, tracheostomy tube, tracheostomy supplies, tracheostomy care kits, masks, water, sterilizers, cleaners, moisteners, adapters, etc. should be submitted as unique purchase items separate from the purchase of the ventilator device.

Option 2: DMAS will allow a continuous rental of the ventilator using E0645 or E0466 and the ventilator is not owned by the member but instead part of the DME business. If a continuous rental is used for the member, then the provider may not bill for the service maintenance agreement. The DME provider will be responsible for performing the routine maintenance and routine servicing of the ventilator in the home, replacing filters, cartridges, and any other disposable supplies associated with routine maintenance of the ventilator device. The DME provider will be responsible for the repair, replacement, and all preventative maintenance of the ventilator device used by the member. The DME provider cannot submit reimbursement requests for ventilator repairs, parts, or service. The Included in the rental rate for E0465 or E0466 is any item included by the manufacture to the DME provider with no itemized cost on the purchase invoice of the ventilator device. For example, if the DME provider purchases the ventilator device from the manufacturer and the charger and battery do not have an independent cost on the manufacturer invoice to the DME provider because they are included in the cost of the ventilator device, then the charger and battery are included in the rental reimbursement for the E0465 or E0466. However, if either the charger or the battery was to have an itemized cost on the purchase invoice from the manufacturer to the DME provider, then they are excluded from being included in the E0465 or E0466 rental reimbursement and should be billed as purchases independently.

In regards to ventilation supplies and accessories, any item that connects to the ventilator to support the therapy provided by the device to the member that has its own purchase cost from the manufacturer to the DME provider (and verifiable by manufacturer invoice) including (but not limited to) the battery, charger, circuits, stands, mounts, valves, filters, heaters, wires, probes, humidifiers, chambers, tracheostomy tube, tracheostomy supplies, tracheostomy care kits, masks, water, sterilizers, cleaners, moisteners, accessories, adapters, etc. should be submitted as unique purchase items separate from the purchase of the ventilator device.

Criteria for Back-Up Ventilators

The use of a back-up (second) ventilator in the home setting is considered medically necessary when **one** of the following criteria are met:

- The individual is on a ventilator 12 hours or more continuously per day; **or**,
- The individual lives in an area where a replacement ventilator cannot be provided within two (2) hours

The use of a back-up (second) ventilator in the home setting is considered medically necessary for the following additional indication, when applicable:

- For individuals who require mechanical ventilation during mobility, as prescribed in their plan of care.

Service Maintenance for Ventilators

In accordance with the DMAS DME participation agreement, the DME provider agrees to provide authorized service maintenance for purchased ventilators for Medicaid-eligible individuals. The service maintenance requires service authorization in order for the provider to be reimbursed. Following service authorization, the provider may bill using the HCPCS codes in the DME Listing/Appendix B. All of the following services must be included as part of the service maintenance agreement:

- The provider agrees to employ or contract with registered or certified respiratory therapists who will be available in a timely manner on a 24-hour-a-day basis for emergency care. The respiratory therapist will conduct monthly home visits to conduct a respiratory assessment and to check equipment.
- The provider agrees to perform routine maintenance of the ventilator in the home, replacing filters, cartridges or any other disposables associated with this routine maintenance. Routine maintenance supplies are not billed separately to DMAS by the DME provider; such items are included in the reimbursement for the service agreement.
- The provider agrees to send the ventilator to the manufacturer for routine servicing as recommended by the manufacturer. For example, LTV ventilators should be sent every 10,000 hours/or 2 years, whichever comes first. The cost for this routine servicing, including shipping and handling, are included in the service maintenance agreement fee. If an individual has a backup ventilator in the home as well as the primary ventilator, the provider may bill DMAS

- separately for the manufacturers recommended maintenance. The provider should use E1399 and provide their cost for the preventative maintenance on the back-up ventilator and it will be marked up 30% by the service authorization contractor.
- The cost of parts which would constitute a repair may be billed separately, as a ventilator repair, under the HCPCS code E1399, which has an assigned fee. Any ventilator repairs which exceed \$500.00 must also be preauthorized by the service authorization contractor.
 - The cost of a back-up ventilator during the period of time that the purchased ventilator is at the manufacturer for routine servicing is included in the reimbursement for the service maintenance agreement.
 - The provider agrees to provide a back-up ventilator throughout the period of ventilator service or repair; the DME provider may bill DMAS for a rental ventilator during the period of non-routine service or repair.

Provider participation requirements for DME related to ventilators can be found in Chapter II of this manual.

Home Non-Invasive Ventilators

Home non-invasive ventilators (NIV) are covered items when ordered by a practitioner and preauthorized by the DMAS or its contractor. This section refers to the indications and service for home ventilators that **do not** require an invasive interface. NIV support is provided through a non-invasive interface, such as a mask that fits over the mouth and nose. NIV can be used in the home environment in order to employ continuous daily support for ventilator dependent individuals (neuromuscular diseases, thoracic cage abnormalities, severe chronic obstructive pulmonary disease, and obesity hypoventilation syndrome).

Examples of home non-invasive ventilators include but are not limited to Trilogy™, Newport™, VELA®, iVent, Puritan Bennett 540™, and LTV®. These ventilators may be used for the treatment of respiratory insufficiency and are considered medically necessary based on the medical criteria below. DMAS distinguishes BiPAP devices from ventilation. Though ventilator equipment has the capability to operate with a BiPAP mode it should not be used for the sole purpose of administering BiPAP or BiPAP ST especially in the setting of isolated obstructive sleep apnea with no other associated diagnoses. Home use of a non-invasive ventilator for the treatment of all other conditions/diseases are considered investigational.

Non-Invasive Ventilator Criteria

Home use of a non-invasive ventilator is considered medically necessary when **all** the following are met:

- Patient is alert and oriented;
- Patient is able to cough or uses an assist device to clear secretions; and
- Absence of **all** of the following:
 1. Anatomic abnormality that precludes mask fitting;

2. Excessive secretions; and
 3. Swallowing disorder
- Documentation of **any one** of the following:
 1. **Progressive neuromuscular disease** (e.g. muscular dystrophy, myasthenia gravis, polio, amyotrophic lateral sclerosis) resulting in respiratory insufficiency with **all** of the following:
 - Documentation of symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, or dyspnea;
 - If present, Chronic obstructive pulmonary disease (COPD) does not contribute significantly to the pulmonary limitation; and
 - Documentation of **any one** of the following:
 - An arterial blood gas PaCO₂, done while awake and breathing the prescribed FIO₂ is greater than or equal to 45 mm Hg; or
 - Nocturnal PaCO₂ greater than or equal to 45 mm Hg, or
 - Nocturnal hypercapnia with PaCO₂ greater than or equal to 50 mm Hg for over 30 minutes; or
 - Daytime normocapnia with a rise in PtcCO₂ of greater than or equal to 10 mm Hg during the night, or
 - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the prescribed recommended FIO₂
 - Documentation of **any one** of the following:
 - Maximal inspiratory pressure is less than 60 cm H₂O; or
 - Forced vital capacity is less than 50% predicted; or
 - When FVC < 70% and a rapid reduction in FVC of > 10% of the initial value within 3 months
 2. **Thoracic-Restrictive Lung Diseases** (e.g., post-thoracoplasty for TB, Fibrothorax, Asphyxiating thoracic dystrophy) resulting in respiratory insufficiency with **all** of the following:
 - Documentation of symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, or dyspnea;

- Chronic obstructive pulmonary disease does not contribute significantly to pulmonary limitation; and
 - Documentation of **any one** of the following:
 - An arterial blood gas PaCO₂, done while awake and breathing the prescribed FIO₂ is greater than or equal to 45 mm Hg; or
 - Nocturnal hypercapnia with PaCO₂ greater than or equal to 50 mm Hg; or
 - Daytime normocapnia with a rise in PtcCO₂ of greater than or equal to 10 mm Hg during the night; or
 - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the prescribed recommended FIO₂
3. **Hypoventilation Syndrome** resulting in respiratory insufficiency with **all** of the following:
- Documentation of symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, or dyspnea;
 - An initial arterial blood gas PaCO₂, done while awake and breathing the prescribed FIO₂, is greater than or equal to 45 mm Hg;
 - Spirometry shows a forced expired volume in 1 second (FEV₁) or forced vital capacity (FVC) greater than or equal to 70%; and
 - A failed initial attempt at CPAP treatment under polysomnographical conditions should take place in patients without significant co-morbidities. The following constitutes a failed CPAP trial:
 - An arterial blood gas PaCO₂, done during sleep or immediately upon awakening, and breathing the prescribed FIO₂, shows the PaCO₂ worsened by 7 mm HG or more compared to the initial arterial blood gas
 - A facility-based polysomnogram testing demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events, AHI apnea-hypopnea index less than 5

4. Severe **Chronic Obstructive Pulmonary Disease (COPD)** resulting in respiratory insufficiency with **all** of the following:
- Documentation of symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, or dyspnea;
 - Obstructive Sleep Apnea (OSA) has been ruled out as a predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation (Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the individual does not suffer from some form of sleep apnea such as Central Sleep Apnea and/or Complex Sleep Apnea desaturation);
 - Compliant with a continuous positive airway pressure device (CPAP) use and CPAP has failed to relieve symptoms, improve awake hypercapnia and/or nocturnal arterial oxygen desaturation; and
 - Documentation of **any one** of the following:
 - Documentation of an arterial blood gas PaCO₂, done while awake and breathing the prescribed FIO₂, is greater than or equal to 52 mm Hg AND sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the prescribed FIO₂ (whichever is higher); or
 - Nocturnal hypercapnia with a PaCO₂ greater than or equal to 55 mmHg; or
 - Mild diurnal hypercapnia with 46-50 mm Hg and an increase in PtcCO₂ greater than or equal to 10 mm Hg during sleep; or
 - When persistent hypercapnia (PaCO₂ > 53 mmHg) is present at least 14 days after finishing acute ventilation therapy for acute respiratory acidosis; or
 - When decannulation after prolonged weaning is only possible with the help of NIV, and this is necessary for long-term monitoring of symptoms and prevention of hypercapnia, even after discharge from the hospital

Documentation and Coverage

Initial authorization of a ventilator requires the following documentation on the CMN/DMAS-352 or in supporting documentation:

- Documentation that the patient meets the clinical criteria for the above respiratory disorders;
- Prognosis for weaning of the ventilator together with the expected length of use of the ventilator; and
- Need for continuous or periodic pulse oximetry and/or capnography

Reauthorization will be considered when **all** of the following are documented:

- A signed and dated statement completed by the provider no sooner than 61 days after initiating use of the device stating **all** of the following:
 - Evaluation has been completed;
 - Member is compliant using the device; and
 - Member is benefitting from its use

Coverage for a non-invasive ventilator shall be based on initial trial period and the expected length of use. Reimbursement of a non-invasive ventilator, after the trial period, for a child and adult, shall be based on purchase or continuous rental:

Option 1: The DME provider may choose to purchase the device for the member if the ventilator is needed for more than 9 months for a child (under the age of 21) or longer than 6 months for an adult via HCPCS codes E0465 (invasive) or E0466 (non-invasive). Reimbursement for the purchase of E0465 or E0466 will include the ventilator device along with any non-invoiced supply or accessories included in the initial purchase of the ventilator by the DME provider from the manufacturer. Ventilator devices have unique serial numbers. Once the ventilator device is purchased, the member will own their specific ventilator that is identified by its unique serial number. The DME provider may bill for the service maintenance agreement of a member's specific ventilator once the ventilator is purchased and owned by the member.

In regards to ventilation supplies and accessories, any item that connects to the ventilator to support the therapy provided by the device to the member that has its own purchase cost from the manufacturer to the DME provider (and verifiable by manufacturer invoice) including (but not limited to) the battery, charger, circuits, stands, mounts, valves, filters, heaters, wires, probes, humidifiers, chambers, tracheostomy tube, tracheostomy supplies, tracheostomy care kits, masks, water, sterilizers, cleaners, moisteners, adapters, etc. should be submitted as unique purchase items separate from the purchase of the ventilator device.

Option 2: DMAS will allow a continuous rental of the ventilator using E0645 or E0466 and the ventilator is not owned by the member but instead part of the DME business. If a continuous rental is used for the member, then the provider may not bill for the service maintenance agreement. The DME provider will be responsible for

performing the routine maintenance and routine servicing of the ventilator in the home, replacing filters, cartridges, and any other disposable supplies associated with routine maintenance of the ventilator device. The DME provider will be responsible for the repair, replacement, and all preventative maintenance of the ventilator device used by the member. The DME provider cannot submit reimbursement requests for ventilator repairs, parts, or service. The Included in the rental rate for E0465 or E0466 is any item included by the manufacturer to the DME provider with no itemized cost on the purchase invoice of the ventilator device. For example, if the DME provider purchases the ventilator device from the manufacturer and the charger and battery do not have an independent cost on the manufacturer invoice to the DME provider because they are included in the cost of the ventilator device, then the charger and battery are included in the rental reimbursement for the E0465 or E0466. However, if either the charger or the battery was to have an itemized cost on the purchase invoice from the manufacturer to the DME provider, then they are excluded from being included in the E0465 or E0466 rental reimbursement and should be billed as purchases independently.

In regards to ventilation supplies and accessories, any item that connects to the ventilator to support the therapy provided by the device to the member that has its own purchase cost from the manufacturer to the DME provider (and verifiable by manufacturer invoice) including (but not limited to) the battery, charger, circuits, stands, mounts, valves, filters, heaters, wires, probes, humidifiers, chambers, tracheostomy tube, tracheostomy supplies, tracheostomy care kits, masks, water, sterilizers, cleaners, moisteners, accessories, adapters, etc. should be submitted as unique purchase items separate from the purchase of the ventilator device.

Service Maintenance for Ventilators

In accordance with the DMAS DME participation agreement, the DME provider agrees to provide authorized service maintenance for purchased ventilators for Medicaid-eligible individuals. The service maintenance requires service authorization in order for the provider to be reimbursed. Following service authorization, the provider may bill using the HCPCS codes in the DME Listing/Appendix B.

All of the following services must be included as part of the service maintenance agreement:

- The provider agrees to employ or contract with registered or certified respiratory therapists who will be available in a timely manner on a 24-hour-a-day basis for emergency care. The respiratory therapist will conduct monthly home visits to conduct a respiratory assessment and to check equipment;
- The provider agrees to perform routine maintenance of the ventilator in the home, replacing filters, cartridges or any other disposables associated with this routine maintenance. Routine maintenance supplies are not billed

separately to DMAS by the DME provider; such items are included in the reimbursement for the service agreement;

- The provider agrees to send the ventilator to the manufacturer for routine servicing as recommended by the manufacturer. For example, LTV ventilators should be sent every 10,000 hours/or 2 years, whichever comes first. LP10 ventilators should be sent to the manufacturer every 6,000 hours/or every 12 months, whichever comes first. The cost for this routine servicing, including shipping and handling, are included in the service maintenance agreement fee. If an individual has a backup ventilator in the home as well as the primary ventilator, the provider may bill DMAS separately for the manufacturers recommended maintenance on the backup ventilator. The provider should use E1399 and provide their cost for the preventative maintenance on the back-up ventilator and it will be marked up 30% by the service authorization contractor;
- The cost of parts which would constitute a repair may be billed separately, as a ventilator repair, under the HCPCS code E1399, which has an assigned fee. Any ventilator repairs which exceed \$500.00 must also be preauthorized by the service authorization contractor;
- The cost of a back-up ventilator during the period of time that the purchased ventilator is at the manufacturer for routine servicing is included in the reimbursement for the service maintenance agreement; and
- The provider agrees to provide a back-up ventilator throughout the period of ventilator service or repair; the DME provider may bill DMAS for a rental ventilator during the period of non-routine service or repair

HOSPITAL BEDS

A fixed height hospital bed may be covered if one or more of the following criteria are met:

- The member has a medical condition which requires positioning of the body in ways not feasible with an ordinary bed. Elevation of the head/upper body less than 30 degrees does not usually require the use of a hospital bed, *or*
- The member requires positioning of the body in ways not feasible with an ordinary bed in order to alleviate pain, *or*
- The member requires the head of the bed to elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease, or problems with aspiration, or other justified medical conditions, *or*
- The member requires traction equipment, which can only be attached to a hospital bed.

A **variable height hospital bed** may be covered if the member meets one of the above criteria for a fixed height hospital bed and requires a bed height different than a fixed height hospital bed to permit transfers to chair, wheelchair or standing position.

A **semi-electric hospital bed** is covered if the member meets one of the above criteria for a fixed height bed and requires frequent changes in body position and/or has an immediate need for a change in body position.

A **heavy duty extra wide hospital bed** is covered if the member meets one of the above criteria for a fixed height hospital bed and the member's weight is more than 350 pounds but does not exceed 600 pounds.

An **extra heavy duty hospital bed** is covered if the member meets one of the above criteria for a hospital bed and the member's weight exceeds 600 pounds.

A **total electric hospital bed** may be covered in limited circumstances and will be reviewed on a case-by-case basis.

THERAPEUTIC PRESSURE REDUCING MATTRESSES

DMAS will provide coverage for pressure reducing support surfaces when medical necessity criteria are met through the following guidelines and InterQual criteria. Service authorization is required and will be performed by DMAS or its service authorization contractor.

A pressure ulcer is the result of a pathologic change in the blood supply to the dermal and underlying tissues, usually because of compression of the tissue over a bony prominence. Chronic ulcers of the skin include arterial ulcers, venous stasis ulcers, diabetic ulcers, and pressure ulcers. Pressure ulcers will generally appear in the soft tissue areas mostly over a bony prominence.

Initial treatment for pressure ulcers generally includes frequent turning and repositioning of the individual to relieve pressure over the compromised area. A practitioner must coordinate the home treatment regimen, which will include the use of other treatment modalities, where applicable, including, but not limited to, nursing care, appropriate nutrition, the creation of a tissue-growth environment, and caregiver training/participation. The DME provider must document this information.

A number of medical devices are designed to relieve pressure. The choice of the device should be determined by the practitioner based on each individual and other treatment modalities being used to treat the pressure ulcer.

NOTE: A check for "bottoming out" should generally be done for all devices.

The treatment regimen must be evaluated, and its continued use recertified, at least every 60 days, by the practitioner. There must be written documentation describing all areas of skin breakdown. Documentation must be updated at least every 30 days to include the total number of wounds, location, size (circumference and depth), drainage (amount, appearance and odor), and the presence of tunneling. Staging must be documented by the practitioner.

Staging of Pressure Ulcers

When evaluating pressure ulcers, a staging system is typically used that measures tissue destruction by classifying wounds according to the tissue layers involved.

Stage I: An observable, pressure-related alteration of intact skin. Skin changes may include one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel), and or sensation (pain, itching). The skin appears as a defined area of persistent redness in lightly pigmented skin and may be persistent red, blue or purple hues in darker skin. These changes are not relieved within 15-30 minutes of pressure relief.

Stage II: Partial-thickness skin loss involving the epidermis, dermis or both. The ulcer is superficial and usually presents as a blister, abrasion or shallow crater.

Stage III: Full-thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down, but not through, underlying fascia. The ulcer presents as a deep crater with or without undermining of adjacent tissue and can produce serosanguineous drainage.

Stage IV: Full-thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

Group I Pressure Reducing Support Surfaces

The HCPCS codes included in this group stand for static overlays and mattress replacements. Group I pressure reducing support surfaces are covered as medically necessary when the individual shows early skin changes consistent with the development of a pressure ulcer **OR** cannot independently make changes in body position significant enough to relieve pressure **AND** is at risk for developing a pressure ulcer **AND** one of the following criteria is met:

- Fecal or urinary incontinence; or
- Altered sensory perception; or,
- Compromised circulatory status.

For Group I Support Surfaces, HCPCS Codes Fall Into 3 Categories:

Pressure pads for Mattresses: Code E0185 and codes E0197, E0198 and E0199, termed pressure pad for mattresses, represent nonpowered pressure reducing mattress overlays. These devices are designed to be placed on top of a standard hospital or home mattress.

- (E0185) A gel mattress overlay is a gel layer with a height of two or more inches.
- (E0197) An air mattress overlay is characterized by interconnected air cells

that have a cell height of three or more inches and are inflated with an air pump.

- (E0198) A water mattress overlay is characterized by a filled height of three or more inches.
- (E0199) A foam mattress overlay typically possesses the following characteristics:

Base thickness of two or more inches and either of the following:

1. Peak height of three or more inches if the overlay is convoluted (e.g. eggcrate)
2. Overall height of at least three inches if the overlay is not convoluted.
3. Foam of such density or other qualities that it provides adequate pressure reduction.
4. Durable water proof cover.

Nonpowered Pressure Reducing Mattresses: An air, water or gel mattress (E0186, E0187, and E0196) has the following characteristics:

- Height of five or more inches of air, water or gel layer.
- Durable, waterproof cover.
- Can be placed directly on a hospital frame.
- A foam mattress (E0184) has the following characteristics:
 1. Height of five or more inches.
 2. Foam of such density and other qualities that it provides adequate pressure reduction.
 3. Durable, waterproof cover.
 4. Can be placed directly on a hospital bed frame.

Powered Pressure Reducing Mattress Overlay Systems: Codes E0181, E0182 and A4640 represent powered pressure reducing mattress overlay systems (alternating pressure or low air loss) that have the following characteristics:

- An air pump or blower provides either, sequential inflation and deflation of air cells or low interface pressure throughout the overlay.
- The inflated cell height of the air cells through which air circulates is 2.5 inches or more.
- The height of the air chambers, proximity of the air chambers to one another, frequency of air cycling (for alternating pressure overlays), and air pressure provide adequate individual lift, reduce pressure and prevent bottoming out.

Group II Pressure Reducing Support Surfaces

Group II pressure reducing support surfaces are covered as medically necessary when **ONE** of the following criteria is met:

1. Large or multiple Stage III or IV pressure ulcers are present on the trunk or pelvis.

2. A myocutaneous flap or skin graft has been performed within the last 60 days for a pressure ulcer on the trunk or pelvis **AND** the individual has been on a Group II or III support surface immediately prior to a recent discharge from a hospital or nursing facility (discharged in the last 30 days). Following a myocutaneous flap or skin graft, coverage is usually limited to 60 days from the date of surgery.
3. Multiple Stage II pressure ulcers are located on the trunk or pelvis and have not improved over the past month despite the use of an appropriate Group I support surface **AND** a comprehensive ulcer treatment program which includes all of the following:
 - Education of the individual and caregiver on the prevention and or management of pressure ulcers.
 - Regular assessment by a nurse, practitioner or other licensed health care practitioner (usually at least twice weekly for individuals with a Stage III or IV).
 - Appropriate turning and positioning.
 - Appropriate wound care for Stage II, III or IV ulcer.
 - Appropriate management of moisture/incontinence.
 - Nutritional assessment and intervention consistent with the overall plan of care.

HCPCS codes included in Group II are defined as follows:

Powered Pressure Reducing Mattress: Code E0277 stands for a powered pressure reducing mattress (alternating pressure, low air loss, or powered flotation without low air loss) that has the following characteristics:

- An air pump or blower provides either sequential inflation and deflation of the air cells or low interface pressure throughout the mattress.
- The inflated cell height of the air cells through which air circulates is five inches or more.
- The height of the air chambers, proximity of the air chambers to one another, frequency of air cycling (for alternating mattresses), and air pressure provides adequate individual lift, reduce pressure and prevent bottoming out.
- The surface is designed to reduce friction and shear.
- The surface can be placed directly on a hospital bed frame.

Code E0193 (RR) describes a semi-electric or total electric hospital bed with a fully integrated powered pressure reducing mattress which has all of the characteristics defined above.

NOTE: This code is available for use as a rental option only.

Advanced Nonpowered Pressure Reducing Mattress Overlay: Code E0371 describes an advanced, nonpowered pressure reducing mattress overlay with the

following characteristics:

- The height and design of the individual cells provide significantly more pressure reduction than a Group I overlay and prevent bottoming out.
- The total height is three inches or more.
- The surface is designed to reduce friction and shear.
- There is documented evidence to substantiate that the product is effective in treating conditions described by the coverage criteria for Group II support surfaces.

Powered Pressure Reducing Mattress Overlay: Code E0372 describes a powered pressure reducing mattress overlay (low air loss, powered flotation without low air loss, or alternating pressure) with the following characteristics:

- An air pump or blower provides either sequential inflation or deflation of the air cells or low interface pressure throughout the overlay.
- The inflated cell height of the air cells through which air circulates is 3.5 inches or more.
- The height of the air chambers, proximity of air chambers to one another, frequency of air cycling (for alternating pressure overlays), and air pressure provide adequate individual lift, reduce pressure and prevent bottoming out.
- The surface is designed to reduce friction and shear.

Advanced Nonpowered Pressure Reducing Mattress: Code E0373 describes an advanced, manually powered pressure reducing mattress with the following characteristics:

- The height and design of the individual cells provide significantly more pressure reduction than those in a Group I mattress and prevent bottoming out.
- The total height is five inches or more.
- The surface is designed to reduce friction and shear.
- There is documented evidence in treating conditions described by the coverage criteria for Group II support surfaces.
- The mattress can be placed directly on a hospital bed frame.

Group III Pressure Reducing Support Surface

Group III pressure reducing support surface is covered as medically necessary when **ALL** of the following criteria are met:

- The individual has a Stage III or Stage IV pressure ulcer.
- The individual is bedridden or chair-bound as a result of severely limited mobility.
- Without an air-fluidized bed, the individual would require institutionalization.

- The air-fluidized bed is ordered following a comprehensive assessment and evaluation of the individual after at least 30 days following conservative medical management has been attempted without success.
- Education of the individual and caregiver on the prevention and or management of pressure ulcers.
- Assessment by a practitioner, nurse or other licensed health care practitioner at least weekly.
- Appropriate turning and repositioning
- Use of a Group II support surface, if appropriate.
- Appropriate wound care.
- Appropriate management of moisture/incontinence.
- Nutritional assessment and intervention consistent with the overall plan of care.

Group III pressure reducing support surfaces are described by a single HCPCS code (E0194 RR, rental only), and are defined by all of the following characteristics:

- The bed employs circulation of the filtered air through silicone-coated ceramic beads, creating the characteristics of fluid.
- The bed consists of a tank filled with silicone-coated microsphere beads that resemble grains of sand.
- The tank is covered with a loose fitting bed sheet that separates the individual from the micro beads.
- Room air is drawn into the base unit, then filtered, heated and pushed into the tank through a diffuser board.
- The bed sheet moves freely underneath the individual. Usually, the individual sinks only 4-6 inches into the beads, and the pressure put on the skin is well below capillary closing pressure.
- The sheet is permeable to the downward flow of body fluids (e.g., wound drainage, urine, and perspiration). As body fluids come in contact with beads, the beads clump and drop to the bottom of the tank, where the alkaline environment kills the bacteria. The clumps are removed during routine maintenance.
- Individual transfers in and out of the bed may be difficult and, in most models, the head cannot be elevated.
- When airflow is turned off, the beads settle into a mold around the body, creating a support surface that stabilizes the individual for nursing care, wound cleaning and other care needs.

The DME provider must certify that:

- The home's electrical system is sufficient to meet the requirements of the proposed bed.
- The housing structure is adequate to support the weight of the bed or mattress as well as will accommodate entrance of the bed into the house.

Use of an air-fluidized bed is contraindicated if the following pertain:

- There is severe coexisting pulmonary disease (lack of firm back support makes coughing ineffective, and dry air inhalation thickens pulmonary secretions).
- The bedding system being used does not meet the positioning needs of the individual.
- Treatment is required that utilizes wet soaks or moist dressings that are not protected by an impervious covering, such as a plastic wrap or other occlusive material.

Authorizations for therapeutic beds, mattresses and overlays will be considered in 60 day maximum increments. To request continued authorization, the item must continue to meet the InterQual and above criteria. In addition, progress towards healing must be documented. If progress has not been made, documentation regarding the practitioner's changes or efforts in the treatment program to promote healing is required.

NOTE: Please refer to Appendix B of this manual for coverage limitations for the HCPCS codes noted above. Some codes are available as rental only.

WOUND CARE SUPPLIES

Wound Care supplies are protective covers or fillers for openings on the body caused by surgical procedures, wounds, ulcers or burns. DMAS will cover wound care supplies that are medically necessary to treat these wounds. Coverage of wound care supplies include both primary and secondary dressings based on the individuals wound care needs. Primary dressing are covering applied directly to wounds or lesions on the skin or wounds caused by an opening in the skin. Secondary dressings include adhesive tape, roll gauze and bandages.

The quantity and type of dressings dispensed at any one time must take into account the current status of the wound(s), the likelihood of change, and the recent use of dressings. Dressing may need changed frequently in the early phases of wound treatment and/or with heavily draining wounds. DME providers are also expected to have a mechanism for determining the quantity of dressing that the individual is actually using and to adjust their deliver of dressings according to what the individual still have available for use in the current treatment.

Dressing size should be based on the type and size of the wound. For wound covers, the pad size is usually about 2 inches greater than the dimensions of the wound. For example, a 5x5 cm (2in x 2in) wound requires a 4 x 4 in pad size. Surgical dressings must be tailored to the specific individual and the wound treatment needs. When surgical dressings are provided in a kit, only those components of the kit that meet the definition of a surgical dressing, that are ordered by the practitioner, and that are medically

necessary are covered.

Surgical dressings are covered for as long as medically necessary. Dressing over a percutaneous catheter or tube (e.g. intravascular, epidural, nephrostomy etc) are covered as long as the catheter or tube remains in place and after removal until the wound heals. When a wound cover with adhesive border is being used, no other dressing is needed on top of it and additional tape is usually not required. Reasons for use of additional tape must be well documented. An adhesive border is usually more binding than that obtained with separate taping and is therefore indicated for use with wounds requiring less frequent dressing changes.

Use of more than one type of wound filler or more than one type of wound cover in a single wound is rarely medically necessary and the reasons must be well documented. An exception is an alginate or other fiber gelling dressing wound cover or a saline, water, or hydrogel impregnated gauze dressing which might need an additional wound cover. It may not be appropriate to use some combinations of a hydrating dressing on the same wound at the same time as an absorptive dressing (e.g. hydrogel alginate). Because composite dressings, foam and hydrocolloid wound covers, and transparent film, when used as secondary dressing, are meant to be changed at frequencies – less than daily. Appropriate clinical judgement should be used to avoid their use with primary dressings which require more frequent dressing changes. Changes greater than once every other day for these dressings is not considered medically necessary. While a highly exudative wound might require such a combination initially, with continued proper management the wound usually progressed to a point where the appropriate selection of these products results in the less frequent dressing changes which they are designed to allow. An example of an inappropriate combination is the use of a specialty absorptive dressing on top of non-impregnated gauze being used as a primary dressing.

Alginate or other fiber gelling dressing (A6196-A6199)

Alginate or other fiber gelling dressing covers are covered for moderately to highly exudative full thickness wounds (e.g. stage III or IV ulcers). They are not medically necessary on dry wounds or wounds covered with eschar. Usual dressing change is up to once per day. A wound cover sheet of approximate size of the wound or up to 2 units of wound filler (1 unit = 6 inches of alginate or other fiber gelling dressing rope) is usually used at each dressing change. It is usually inappropriate to use alginates or other fiber gelling dressings in combination with hydrogels.

Composite Dressing (A6203-A6205)

Usual composite dressing changes are up to 3 times per week, one wound cover per dressing change.

Contact Layer (A6206-A6208)

Contact layer dressings are used to line the entire wound; they are not intended to be

changed with each dressing change. Usual dressing change is up to once per week.

Foam Dressing (A6209-A6215)

Foam dressings are covered when used on full thickness wounds (e.g. stage III or IV ulcers) with moderate to heavy exudate. Usual dressing change for a foam wound cover used as a primary dressing is up to 3 times per week. When a foam wound cover is used on a secondary dressing for wounds with very heavy exudate, dressing change may be up to 3 times per week. Usual dressing change for foam wound fillers is up to once per day.

Gauze, non-impregnated (A6216-A6221, A6402-A6404, A6407)

Usual non-impregnated gauze dressing change is up to 3 times per day for a dressing without a border. It is usually not necessary to stack more than 2 gauze pads on top of each other in any one area. Usual dressing change for gauze, impregnated, with other than water, normal saline, hydrogel or zinc paste (A6222-A6224, A6266) is up to once per day.

Gauze, impregnated, water or normal saline (A6228-A6230)

There is no medical necessity for these dressings compared to non-impregnated gauze which is moistened with bulk saline or sterile water.

Hydrocolloid dressing (A6234-A6241)

Hydrocolloid dressings are covered for use on wounds with light to moderate exudate. Usual dressing change for hydrocolloid wound covers or hydrocolloid wound fillers is up to 3 times per week.

Hydrogel Dressing (A6231-A6233, A6242-A6248)

Hydrogel dressings are covered when used on full thickness wounds with minimal or no exudate (e.g. stage III or IV ulcers). Hydrogel dressings are not usually medically necessary for stage II ulcers. Documentation must substantiate the medical necessity for use of hydrogel dressings for stage II ulcers (e.g. location of ulcer is sacro-coccygeal area). Usual dressing change for hydrogel wound covers **without** adhesive border or hydrogel wound fillers is up to once per day. Usual dressing change for hydrogel wound covers **with** adhesive border is up to 3 times per week.

The quantity of hydrogel filler used for each wound must not exceed the amount needed to line the surface of the wound. Additional amounts used to fill a cavity are not medically necessary. Documentation must substantiate the medical necessity for code A6248 billed in excess of 3 units (fluid ounces) per wound in 30 days. Use of more than one type of hydrogel dressing (filler, cover, or impregnated gauze) on the same wound at the same

time is not medically necessary.

Specialty absorptive dressing (A6251-A6256)

Specialty absorptive dressings are covered when used for moderately or highly exudative wounds (e.g. stage III or IV ulcers). Usual specialty absorptive dressing change is up to once per day for a dressing without an adhesive border and up to every other day for a dressing with a border.

Transparent Film (A6257-A6259)

Transparent film dressings are covered when used on open partial thickness wounds with minimal exudate or closed wounds. Usual dressing change is up to 3 times per week.

Wound filler, not elsewhere classified (A6261-A6262)

Usual dressing change is up to once per day.

Wound pouch (A6154)

Usual dressing change is up to three (3) times per week.

INCONTINENCE PRODUCTS

The Department of Medical Assistance Services (DMAS) made modifications to the Durable Medical Equipment and Supplies (DME) Program related to incontinence supplies, specifically, incontinent briefs, pull-ups, liners and underpads (i.e. "chux").

If any Medicaid individual is enrolled in a Virginia Medicaid Managed Care Organization (MCO), the MCO is responsible for their DME incontinent supplies.

Disposables Related to Incontinent Supplies

DMAS will not provide reimbursement for the routine use of diapers for children under three (3) years of age. Service authorizations for diapers for children must be associated with a medical condition and will not be approved solely because toilet training has not been accomplished. The billing unit for incontinence products changed from 'case' to 'each'. This change affected incontinent briefs, pull-ups and panty liners. As a result of this change, the DME provider may now break cases, but for sanitation reasons, the inner seal packages may not be broken. The DME provider is not required to break cases; however, by breaking cases the provider should be able to provide a more accurate amount of products per month to decrease the amount of overage needed. Providers are required to obtain Service Authorization (SA) for incontinence products over the allowable limit.

NOTE: The allowable limit per month (listed in Appendix B) does not allow the provider to send every individual who needs incontinence products that amount each month. The

amount of incontinence products is dependent on the frequency of use. DMAS understands that an individual package cannot be broken so the individual may receive more than needed; however, if the individual has left over products, then the next month's delivery would be adjusted, based on the number of products left over. The provider determines the product amounts during the monthly call to the individual prior to the next delivery. The provider should contact the individual/caregiver prior to the next month's delivery and document the need for any overage in the individual's record. If the individual's needs remain the same, the individual would need less products delivered the next month.

Once the provider determines the individual meets medical necessity, (i.e., incontinence) the decision to use tab briefs or pull-ups shall be left to the individual or caregiver.

If an individual requires more than one kind of incontinence product each month, the provider should document why each product is necessary in the same month. This applies to incontinent briefs, pull-ups and panty liners. For example, an individual may use pull-ups during the day and use a diaper at night. Providers must demonstrate the frequency of use to justify the quantity ordered. (Note: Sizing for briefs and pull-ons can vary by product. If a child is wearing a pediatric large pull-on during the day, they may wear an adult small brief at night. The DME provider should make sure the sizing is appropriate based on each individual product.)

The CMN/DMAS-352 must include all of the following information:

- A complete order that includes the type of incontinence product(s), quantity, and the frequency of use. (Frequency of use means – how often something is used. Quantity means – total. The provider will need to know frequency in order to determine quantity. Quantity and Frequency are separate required entities).
- A description of the individual's incontinent condition including the degree and type of incontinence. (Degree of incontinence can be given in terms of light, moderate or heavy. Other terms may apply and can be subjective, so it is important to make the member feel comfortable in describing their condition so accurate products are given to meet the member's needs).
- Functional limitations that may affect the individual's incontinence, amount and type of product required per month.

NOTE: Frequency of use is part of the practitioner's order and describes how often an individual uses a supply and provides the justification for the quantity ordered per month. Documentation of the frequency of use (how often the supplies are used) should be on the CMN. For example, the individual needs incontinent briefs and changed seven (7) times per day. Seven times per day is the frequency of use. The frequency of use multiplied by 31 days should justify the quantity ordered per month on the CMN. Documentation of usage can be by the day, the week or the month depending on the type of supply and the individual's needs. The frequency of supplies may be once per week or twice per month; if an item is needed less than monthly the provider should document

accordingly. The provider can give a usage range, for example, 6-7 times per day but should **never** use PRN or as needed.

To ensure against stockpiling of incontinence products beyond the needed amount, the provider must make affirmative contact, document the contact with the individual/caregiver prior to the next monthly delivery, and document in the individual's record the amount of product the individual has left over each month. In addition, the provider must contact the individual/caregiver prior to the recertification CMN/DMAS-352 to assure that the quantity, frequency and product are appropriate.

Unless the individual has a specific medical need, in addition to incontinence, for using an underpad (Chux) along with the incontinence briefs, DMAS will not provide reimbursement for underpads when used in conjunction with incontinent briefs since a washable pad serves the same purpose as the disposable underpad. (12 VAC 30-50-165)

NOTE: Providers are not allowed to alternate diapers/pull-ups and Chux to avoid this criteria. For example, if an individual received pull-ups for a month, then switched to Chux for a month, then back to pull-ups, eventually the individual may have either too much of one of the products or not enough to last until the next delivery. The individual could potentially receive too many supplies that would last until the next delivery or not receive enough supplies to last until the next delivery. If the individual/caregiver wants only Chux that decision should be documented in the record.

DMAS has created an optional continence assessment form for use in conjunction with the CMN to assess and document the need for incontinence products. Use of this optional form provides an option for the providers to document specific information to support the requested incontinence supply on the CMN. This form must be signed and dated by the practitioner.

Types of Urinary Incontinence

Functional Incontinence affects people with medical problems that interfere with thinking, moving, or communicating. Functional incontinence is the result of these physical and medical conditions.

Overactive Bladder occurs when abnormal nerves send signals to the bladder at the wrong time, causing its muscles to squeeze without warning. Specifically, the symptoms of overactive bladder include:

- Urinary frequency – bothersome urination eight or more times a day or two or more times at night.
- Urinary urgency – the sudden, strong need to urinate immediately
- Urge incontinence – leakage or gushing of urine that follows a sudden, strong urge

- Nocturia – awaking at night to urinate.

Overflow Incontinence happens when the bladder does not empty properly, causing it to spill over. A practitioner can check for this problem. Weak bladder muscles or blocked urethra can cause this type of incontinence.

Stress Incontinence is more common in women and in many cases, is treatable. Physical changes from pregnancy, childbirth and menopause often cause stress incontinence resulting in leakage of small amounts of urine during physical movement (coughing, sneezing, and exercising).

Urge Incontinence causes urine loss for no apparent reason after suddenly feeling the need or urge to urinate. A common cause of urge incontinence is inappropriate bladder contractions. Abnormal nerve signals might be the cause of the bladder spasms.

Mixed – Usually the occurrence of stress and urge incontinence together.

Transient – Leakage that occurs temporarily because of a situation that will pass (infection, taking a new medication, colds with coughing)

When determining the appropriate incontinence product several things to be considered are: individual circumstances, medical condition, and medical need. Some important things to consider about incontinence products are:

- Level of absorbency
- Complete or partial bladder emptying
- Frequency of changes
- Intermittent or constant need
- Activity level
- Changing product with sitting, standing or lying
- Manual dexterity of the individual/caregiver
- Size

Providers should monitor the needs of the individual on a regular basis to ensure the individual's products are still appropriate to meet their care needs. The provision of incontinence supplies is dependent on the individual's ongoing clinical need.

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATORS (TENS)

Requests for transcutaneous electrical nerve stimulator units may be approved if all of the following criteria are met; these criteria are applicable to all types of transcutaneous electrical stimulators:

- Documentation verifies that other alternative equipment and conservative

treatment modalities have been exhausted without success;

- The use of the TENS unit will benefit the individual to a degree not attainable by the use of other methods of care and treatment;
- A practitioner must direct the home treatment regimen, which will include the use of treatment modalities including, but not limited to, nursing services and physical therapy;
- The treatment regimen must be evaluated at least bi-monthly and can be determined effective after one month's use;
- The absence of this device would require that the individual visit the practitioner or therapist for treatment or medications more often than with the device;
- There must be documentation that the individual or the caregiver is able to manage the application of the device; and
- Rental of the TENS unit will be approved for the first two months, and purchase will be made after that period. Rental is only applicable to the initiation of new therapy. If the TENS device supplied for the required two-month rental period is new upon delivery, DMAS will consider paying the full purchase price listed in the Appendix B in this manual in addition to the initial two-month rental period for these items.

The purchase of the TENS unit and supplies will be considered after the 60 day trial rental when all of the following occur:

- Documentation indicates that the individual is compliant with treatment;
- Documentation describes how the TENS treatment modality is effective; and
- Use of the TENS unit is not contraindicated and/or not effective.

COVERAGE OF ORTHOTICS

Orthotic device services include devices that support or align extremities to prevent or correct deformities or improve functioning and services necessary to design the device, including measuring, fitting, and instructing the individual in its use.

A licensed podiatrist is permitted to sign and date the CMN/DMAS-352 and any supporting documentation relating to orthotics needed in the treatment of the individual. The allowance of the podiatrist signature only applies to the provision of orthotics. Orders must be related to the treatment plan of the individual and the individual shall be under the care of the podiatrist for a related condition.

GENERAL MEDICAID POPULATION

Practitioners may bill for supplies and/or equipment, beyond those routinely included in the office visit, when used in the course of treatment in the practitioner's office. These supplies include, for example, ace bandage, sling, splint, rib belt, cervical collar, lumbosacral support, etc. The applicable CPT/HCPCS codes may be used when billing for a specific supply item used. See the "Durable Medical Equipment" section in the Physician/Practitioner Medicaid Provider Manual located on the DMAS portal for additional information.

Items made for the individual by an occupational therapist, including splints, slings, and any normally stocked supplies, are part of the cost of the DMAS approved outpatient rehabilitation therapy visit. These items are billed as ancillary charges on the CMS-1500 Universal Claim Form.

Orthotics, including braces, splints, and supports, are not covered for the general adult Medicaid population under the DME program, with the exception of the Intensive Rehabilitation program described below.

MEDICAID INDIVIDUALS PARTICIPATING IN AN INTENSIVE REHABILITATION PROGRAM

Coverage for both adults and children is available for medically necessary orthotics when recommended as part of an approved intensive rehabilitation program (including CORF), and when all of the following criteria are satisfied via adequate and verifiable documentation which must include:

- Ordered by the practitioner on the CMN/DMAS-352 (CMN);
- Directly and specifically related to an active, written, and practitioner-approved rehabilitation treatment or discharge plan;
- Based upon a practitioner's assessment of the individual's rehabilitation potential, where the individual's condition will improve significantly in a reasonable and predictable period of time, or shall be necessary to establish an improved functional state of maintenance; and
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational).

The orthotist participating as a DMAS DME provider coordinates completion of the CMN/DMAS-352 (CMN) with the prescribing practitioner, using the correct HCPCS "L" codes. Service authorization is required. Reference the service authorization (SA) Appendix D of this manual for instructions on how to obtain service authorization. Documentation of the provider cost will be required for "L" procedure codes that do not have an established reimbursement allowance. Reimbursement (under the HCPCS "L" codes) to the DME orthotic provider is all inclusive; no supplemental reimbursement will be made for time involved in fitting, measuring, and designing the orthotic, or for providing the individual with instructions for proper use.

EPSDT (CHILDREN UNDER 21 YEARS OF AGE)

All medically necessary orthotics are covered for children under the age of 21 years. The same program guidelines, as identified in the above paragraph, apply to this category.

COVERAGE OF PROSTHETICS

GENERAL INFORMATION

The provision of medically necessary artificial arms, legs, their necessary supportive devices, and breast prostheses for Medicaid-eligible members in the Commonwealth of Virginia requires service authorization by DMAS or its designated agent, prior to rendering service.

SERVICE AUTHORIZATION

Refer to Appendix D of this manual for further information regarding service authorization, timely submittal of requests and service specific details.

COVERAGE AND LIMITATIONS

- A. Prosthetic services shall mean the replacement of missing arms, legs, eyes, and breasts and the provision of an internal (implant) body part. Nothing in this regulation shall be construed to refer to orthotic services or devices or organ transplantation services. (12VAC30-50-210)
- B. Artificial arms and legs, and their necessary supportive attachments, implants, and breasts are provided when prescribed by a physician or other licensed practitioner of the healing arts within the scope of their professional license as defined by state law. This service, when provided by an authorized vendor, must be medically necessary, and service authorized for the minimum applicable component necessary for the activities of daily living (ADLs).
- C. Eye prostheses are provided when eyeballs are missing regardless of the age of the member or the cause of the loss of the eyeball. Eye prostheses are provided regardless of the function of the eye. Service authorization is not required, but post-payment review is conducted.

To obtain the required service authorization for coverage, the prosthetist will ask the prescribing practitioner to complete a DMAS Certificate of Medical Necessity (DMAS 352) The prosthetist will then submit the Certificate of Need, a copy of the physician's prescription, and a completed Service Authorization Request form (DMAS-363) to DMAS' Service Authorization contractor. Refer to Chapter V titled "Service Authorization Information" in the Medicaid Prosthetic Devices Manual.

Forms are located on the DMAS preauthorization contractor's web site.

NON-COVERED SERVICES

The following devices are not covered for adults:

- Orthotic Devices - Spinal
- Orthotic Devices - Cervical
- Orthotic Devices - Thoracic
- Orthotic Devices - Sacral
- Orthopedic Footwear
- Orthopedic Footwear Modifications
- Shoe Modifications
- Trusses
- Penile Prosthesis

PAYMENT FOR SERVICES

The payment criteria established for prosthetic devices are designed to enlist the participation of a sufficient number of suppliers so that Medicaid-eligible persons receive prostheses at least to the extent that they are available to the general population.

Participation as a prosthetic provider is limited to those who accept the amount paid by the Virginia Medicaid Program as payment in full.

Payment for services will not exceed the amount indicated to be paid in accordance with the policy and methods described in the State Plan for Medical Assistance, and payment will not be made in excess of the upper limits described in 42 CFR § 447.304(a).

Federal requirements prohibit Medicaid from paying prosthetic device providers more than Medicare would allow for the same service.

PAYMENT METHODOLOGY

Payment for prostheses is the lowest of Medicaid's fee schedule, the actual charge, or the Medicare allowance.

For Medicare crossover claims, the payment will be the deductible and co-insurance amounts computed by Medicare based on the Medicare-allowed charge, as reported on the Explanation of Medicare Benefits (EOMB) received from the Medicare carrier.

COST SHARING

There are no Medicaid deductible or co-insurance amounts imposed for any prosthetic device provided to Medicaid members. As previously mentioned, Medicaid will pay the deductible and co-insurance amounts imposed on Medicaid members who are also Medicare beneficiaries and whose claims the Medicare carrier processes initially.

DME COVERED IN INTENSIVE REHABILITATION SETTINGS

If the DME is for use only during the course of the rehabilitation program, these items are included in the rehabilitation provider's per diem rate and are entered on the rehabilitation hospital bill as ancillary services.

If the DME (e.g., wheelchair, hospital bed, individual lift, etc.) is required to facilitate the individual's discharge home or to an Assisted Living Facility (not to a nursing facility) authorization/reimbursement would follow the DME criteria.

If the DME (e.g., customized wheelchair) is required to facilitate discharge to a nursing facility, the three options for reimbursement follow:

- 1) The cost of the equipment can be included on the rehabilitation hospital bill as an ancillary service.
- 2) The social worker from the nursing facility can assist the individual in requesting service authorization of the equipment via the "DMAS-225 process." This is only an option if the individual has a patient-pay toward the cost of long-term care placement. (For additional information, see the Medicaid Nursing Facility Provider Manual.)
- 3) The cost of the equipment may be covered under the EPSDT program for children under the age of 21; service authorization is required.

If the individual is not eligible for any of these three options, outside resources would need to be explored (e.g., Assistive Loan Fund through the Department of Aging and Rehabilitation (DARS) Services, OBRA funding for individuals with specific disabilities with a date of onset prior to age 22, churches, civic organizations, etc.).

DME COVERED IN NURSING FACILITIES

Supplies and equipment that are medically necessary for the direct care and treatment of individuals are covered nursing facility services and are included in the cost of the nursing facility services. These include, but are not limited to, wheelchairs, walkers, trapeze bars, eggcrate and other specialized mattresses, dressing or catheter trays, suture sets, specialized beds, IV infusion pumps, incontinent supplies, etc. Coverage of resident-specific, customized items must be made through the DMAS DMAS-225 process (see the Medicaid Nursing Facility Provider Manual for further instructions).

Certain medical supplies required to facilitate discharge are covered as allowable cost to the nursing facility. These supplies do not include items such as hospital beds and wheelchairs. Deductible and coinsurance amounts will be paid when these items are covered by Medicare.

Equipment and supplies delivered for home use for individuals being discharged from a hospital or nursing facility DME may be delivered to the facility prior to discharge;

however, the claim date of service may not begin prior to the date of discharge from the hospital or nursing facility.

If a nursing facility without a DMAS specialized care contract admits a resident requiring special equipment (e.g., ambulatory infusion pump, etc.) which is medically justified and prescribed by the practitioner, the nursing facility is responsible for obtaining the equipment. No additional Medicaid reimbursement will be provided to a DME provider or to the nursing facility.

Ventilators and Associated Supplies

DMAS requires service authorization for all ventilators and associated supplies furnished to nursing facility residents who are not residing in a nursing facility with a DMAS specialized care contract. (12 VAC 30-50-165) Additional information on specialized care can be found in the Medicaid *Nursing Facility* Provider Manual, Chapter VI.

The nursing facility must supply ventilators and other special equipment or supplies needed by an individual enrolled as a “specialized care individual” and admitted to a nursing facility with a Medicaid contract for specialized services. The DME provider may not bill Medicaid for these equipment and supplies.

For those ventilator-dependent residents residing in a nursing facility without a DMAS specialized care contract, DMAS requires the nursing facility to obtain service authorization before admitting the resident. DMAS will make direct reimbursement to DME providers for the following for nursing facility usage for these residents:

- Ventilator rental
- Portable back-up suction machine
- Heated cascade humidifier system
- Ventilator circuits
- Tracheotomy tubes
- Tracheotomy care kits
- Tracheotomy dressing
- Suction machine
- Suction catheter
- Sterile water
- Oxygen and oxygen equipment
- Manual resuscitator
- IV pole or other suitable support for circuits

The reimbursement to the DME provider includes the services and consultation of and teaching of equipment usage by a respiratory therapist to the nursing facility.

Requests for Medicaid payment for ventilators for individuals expected to be placed in nursing facilities without a DMAS specialized care contract must be sent to the Supervisor, Aging and Medical Services Unit, 600 East Broad Street, Suite 1300, Richmond, Virginia 23219. The written request for authorization must include all of the following:

- The individual’s name and Medicaid number;
- The present location of the individual;

- The proposed nursing facility placement;
- The current medical status;
- The UAI, DMAS-96, and Level 1 or 2 Supplement;
- A written statement from the attending practitioner justifying the need and the type of equipment required; and
- An itemized list of the equipment required, the rental cost of machine-associated supplies and services, and the name, address, and phone number of the respiratory equipment supplier.

HOME HEALTH CARE

Medical supplies used during the course of the home health visit by personnel of the home health agency are not subject to separate reimbursement by DMAS. These expendable medical supplies (e.g., gauze, cotton, and adhesive bandages, Foley catheters and Foley insertion trays) are included in the fee paid visit to the home health agency.

The only supplies relative to the home health visit for which the DME provider may receive separate reimbursement are those supplies, which remain in the home beyond the time of the visit to allow the individual or caregiver to continue the treatment.

HOSPICE CARE

For individuals enrolled in Hospice, durable medical equipment as well as other self-help and personal comfort items related to the palliative care or management of the individual's terminal illness are covered and must be provided by the hospice provider. Medical supplies include, but are not limited to, any supplies that are included in the Hospice the written plan of care. The DME provider may not bill DMAS for these items.

PACE

The Programs of All-Inclusive Care for the Elderly (PACE) provides comprehensive medical and social services to certain frail, community-dwelling elderly individuals, most of whom are dually eligible for Medicare and Medicaid benefits. The PACE program becomes the sole source of Medicaid and Medicare benefits for PACE participants. Any individual participating in the PACE program who requires DME will access the necessary equipment through the PACE staff.

EQUIPMENT REPAIRS

The cost to repair rental equipment is considered the DME provider's responsibility. Therefore, rental repair charges, caused by normal wear and tear, abuse, or neglect, may not be billed to DMAS or to the individual. All HCPCS codes listed in Appendix B must have a CMN/DMAS-352 practitioner order, including equipment repairs.

Charges for repair(s) to medically necessary, individual owned equipment may be billed

to DMAS using the proper DMAS HCPCS code. DMAS is not responsible for repairs covered under manufacturer warranties. Any payment made by DMAS for equipment repairs covered under warranty will be recovered in post-payment reviews. The provider should document in the individual record if the equipment is individual owned. If the repair cost is less than the rate paid under the appropriate HCPCS code as defined in Appendix B of this Manual, and the repair is done by the DME provider, the DME provider must bill DMAS under the miscellaneous parts/repair code and the labor code as applicable. If the cost of the repair parts exceeds the rate paid under the appropriate HCPCS code, or if the repair requires that the item be shipped to the manufacturer, the provider must use the miscellaneous (E1399) HCPCS code, and service authorization is required.

The provider must accept Medicaid payment as payment in full and may not bill the individual for any portion of the repair, including shipping and handling charges. Costs incurred for shipping and handling, except when otherwise noted, are considered to be a part of the DME provider's overhead/business expenses. If the repair is covered under warranty, the provider serving the individual's DME needs is responsible for the cost of shipping and handling.

NOTE: If a provider accepts a Medicaid individual as a client, the provider must provide all of the DME services that are provided to the general population. Refer to Chapter 2 of this manual for provider participation requirements.

REPAIR VERSUS REPLACEMENT/PURCHASE GUIDELINES

Providers shall evaluate individual owned equipment and every effort shall be made to repair the equipment, especially if the service limit has not expired for the purchased item. The service limits in Appendix B for all HCPCS codes are guidelines for normal use. DMAS understands that some equipment may not last until the service limit has expired due to unique circumstances of each individual. If individual owned equipment needs to be replaced prior to the service limit expiring the provider will be required to justify and obtain service authorization. Documentation for service authorization should include the required information as stated in this manual and the provider shall also include additional documentation as stated below:

- What equipment the individual is currently using and why that equipment is no longer appropriate for the individual. This description shall include the reason why repairs could not be done or why the option to repair the equipment was not cost effective.
- The provider shall include a breakdown of what items need to be repaired and include the cost to repair the items to justify why the purchase of new equipment would be more cost effective; *and*
- If the item is no longer appropriate due to a change in medical condition, limitations and symptoms, or if the equipment was provided inappropriately, the provider shall give justification to describe the circumstances.

RENTAL AND PURCHASE GUIDELINES

All medically necessary supplies and equipment shall be covered. Unusual amounts, types, and duration of usage must be authorized by DMAS in accordance with published policies and procedures. When determined to be cost effective by DMAS, payment may be made for rental of the equipment in lieu of purchase. (12 VAC 30-50-165)

Equipment rental is indicated for short-term use when an individual's need or condition is expected to change, including when the individual is expected to recover. When usage is anticipated to be long-term, and the individual's need or condition is not expected to change, the items must be considered for purchase. Most items can be rented for a short time without service authorization; an extension may be requested if the continued use is expected to continue short-term. If it is determined through utilization review activities that a rented item should have been purchased, DMAS will only provide reimbursement up to the established purchase price. (12 VAC 30-50-165) A description of the equipment and limitations for rental is found in the Appendix B section of this manual.

The purchase prices listed in the Appendix B of this manual represents the amount that DMAS will pay for new equipment purchases. Unless otherwise approved by DMAS, documentation on the delivery ticket must reflect that the purchased equipment is "new" upon the date of service billed. Any warranties associated with new equipment shall be effective with the date of service billed. Medicaid is the payer of last resort; therefore, the DME provider is responsible for exploring coverage available under the warranty prior to requesting coverage of repairs, etc., through DMAS or its contractor.

DMAS will consider paying the full purchase price listed in the Appendix B in this manual in addition to the initial required two-month rental period, for communication devices, TENS Units, CPAPs, and BiPAPs, when this equipment is new upon delivery.

Medicaid reimbursement for rental items is a daily rate. DMAS will not provide rental reimbursement for days that the individual is not receiving or not using the services. DMAS will also not provide reimbursement for rental equipment that is damaged or abused by the individual.

There are a few items in Appendix B that can only be rented and will not be allowed for purchase. These items can be identified because they will only have a rental HCPCS code and will have no HCPCS code for purchase. All of these codes require service authorization and like all codes that always require service authorization; the service limit is provided as a guideline to normal use. If the individual needs the item longer and it is appropriate and medically necessary, DMAS or its contractor may allow additional rental above the service limit if purchase is not permitted. DMAS or its contractor may allow for purchase of new equipment when the previously purchased item has not reached the allowable limit. For example, if a purchased wheelchair is destroyed in a fire prior to the service limit of one (1) wheelchair per five (5) years. Therefore, the provider will submit for a new wheelchair with supporting documentation and an explanation as to why the item is required prior to the service limit guideline.

REPLACEMENT OF DME FOLLOWING A NATURAL DISASTER

Medicaid individuals who live in areas that have been declared by the Governor of the Commonwealth of Virginia as a disaster or emergency in accordance with § 44-146.16 of the Code of Virginia, who need to replace DME and supplies previously approved by Medicaid, that was damaged as a result of the disaster or emergency, may contact a DME provider (either enrolled in FFS Medicaid or a Medicaid Health Plan) of their choice to obtain a replacement.

For Medicaid enrolled providers, the provider must make a request to the Service Authorization contractor; however, a new CMN and medical documentation is not required unless the DME and supplies are beyond the service limit (e.g. the individual has a wheelchair that is older than five years). The provider should keep documentation in the individual's chart that includes the individual's current place of residence and states that the original DME or supplies were lost due to the natural disaster.

Individuals who are approved to receive DME and supplies from a DME provider in an area that has been declared by the Governor of the Commonwealth of Virginia as a disaster or emergency and with DME or supplies that were damaged as a result of the disaster or emergency in accordance with § 44-146.16 of the Code of Virginia but are unable to obtain replacement DME and supplies because the provider is no longer in business or unable to provide the approved DME and supplies may obtain the approved items from a new DME provider of their choice who is enrolled in Medicaid or contracted with a Medicaid Health Plan. The original authorization will be cancelled or amended and a new authorization will be given to the new DME provider. The DME provider will need to submit a signed statement from the Medicaid individual requesting a change in DME provider due to the declaration by the Governor of the Commonwealth of Virginia as a state of emergency due to a natural disaster and giving his or her current place of residence.

PAYMENT FOR SERVICES

GENERAL INFORMATION

The payment criteria established for medical supplies, equipment, and appliances are designed to enlist the participation of a sufficient number of suppliers so that Medicaid-eligible individuals can receive covered services at least to the extent that these services are available to the general population. Participation as a medical equipment and supply provider is limited to those who accept as payment in full the amounts paid by the Virginia Medicaid Program. Payments for services will not exceed the amounts indicated to be paid in accordance with the policy and methods described in Virginia Administrative Code, and payment will not be made in excess of the upper limits described in 42 CFR 447.304(a).

Important: DME providers must provide all of the same DME services/items to the Medicaid individual as provided to the general population, in accordance with the

established Medicaid reimbursement rate. As per the provider agreement, a Medicaid-enrolled provider must accept Medicaid payment as payment in full.

DME providers are responsible for knowing which items require service authorization and the limitation on the provision of certain items as described in the “Medicaid DME and Supplies Listing” in Appendix B of this manual. Since the Medicaid Program has established guidelines regarding which items require service authorization and the limitations that may be imposed on certain items, providers can reasonably be expected to know for which items Medicaid will pay.

The DME provider must not bill DMAS prior to the date of the physician’s signature when the signature is not obtained within 60 days of the first day (CMN/DMAS-352 begin date) of service. The DME provider will be reimbursed only for services that are provided in accordance with published policies and procedures. If reimbursement is denied for one of these reasons, the DME provider may not bill the Medicaid individual for the items/service that was provided. (12 VAC 30-50-165)

The DME provider must not provide items or extended quantities of items which require service authorization prior to obtaining the written service authorization from DMAS. Therefore, the liability for the charges for denied items or services which the provider supplied prior to obtaining the required written authorization rests with the DME provider.

A provider cannot bill an individual for Medicaid-covered services if the provider is denied reimbursement due to his or her failure to obtain service authorization or to perform other required administrative functions. (12 VAC 30-50-165)

As per the Virginia Medicaid provider agreement, a DME provider may only bill a Medicaid individual for non-covered services. The DME provider is responsible for determining if an item is covered, whether or not it requires service authorization, and for verifying Medicaid eligibility. If the DME provider does not follow the established procedure for obtaining authorization for any item, and the request is denied, the provider may not bill the individual for that item. (12 VAC 30-50-165)

Communication with the Medicaid individual is important when an item is non-covered so the individual can make a decision as to if they want to purchase and “pay out-of-pocket” for the item(s).

The DME provider must advise the Medicaid individual in writing of any fiscal liability (potential or actual) for items delivered prior to the receipt of authorization by the service authorization contractor. If all established guidelines are followed by the provider, and the request is denied, the DME provider may seek reimbursement from the individual. The provider may not require the individual to make a deposit or “pay in advance” for any item that is covered and requires service authorization. If the provider fails to follow established procedures for authorization or fails to notify the individual of any fiscal

liability and the item requested is determined not to be medically justified or does not meet criteria for reimbursement, the DME provider may not bill the Medicaid member. (12 VAC 30-50-165)

COST SHARING

No Medicaid deductible or coinsurance amounts are imposed for any medical supplies, equipment, and appliances provided to Medicaid individuals. Medicaid will pay the Medicare deductible and coinsurance amounts up to Medicaid limits imposed on Medicaid individuals whose Medicare claims are processed initially by the Medicare carrier.

ORDERING FORMS

DMAS no longer provides a supply of agency forms. Providers can download forms from the DMAS portal (www.virginiamedicaid.dmas.virginia.gov). To access the forms, click on the "Provider Search Forms" link. You may either search by form name or number. If you do not have internet access, you may request forms for copying by calling the DMAS form order desk at 1-804-780-0076.