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DURABLE MEDICAL EQUIPMENT, SUPPLIES, APPLIANCES, PROSTHETICS, ORTHOTICS & PEDORTHICS

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Chapter 13. Durable Medical Equipment, Supplies, Appliances, Prosthetics, Orthotics & Pedorthics

Rule No. 560-X-13-.01 Durable Medical Equipment, Supplies, Appliances, Prosthetics, Orthotics & Pedorthics - General

(1) Durable Medical Equipment (DME), supplies, and appliances, are available as Medicaid program benefits to eligible Medicaid beneficiaries for use in any setting in which normal life activities take place.

(2) The covered DME, supplies, appliances, and Prosthetics, Orthotics and Pedorthics (POP) are for medical therapeutic purposes, and must be ordered by the prescriber in connection with the plan of treatment, and the items will minimize the necessity for hospitalization, nursing home, or other institutional care. The prescriber of these items must comply with 42 C.F.R. § 440.70 as well as all other federal and state rules and regulations in order to receive reimbursement.

(3) DME is equipment:

(a) that can withstand repeated use;

(b) is primarily and customarily used to serve a medical purpose;

(c) generally is not useful to a person in the absence of an illness, disability or injury; and

(d) can be removable or reusable.

All requirements of the definition must be met before an item can be considered to be DME.

(4) Refer to Rule No. 560-X-13-.18 for Prosthetics, Orthotics and Pedorthics (POP) guidelines.

(5) The cost of the item must not be disproportional to the therapeutic benefits or more costly than a reasonable alternative. The item must not serve the same purpose as equipment already available to the recipient. DME may be purchased or rented for a Medicaid recipient meeting the established criteria. Please refer to Chapter 14, DME, of the Medicaid Provider Manual published on Medicaid's website.

(a) Medicaid covers the purchase of DME items for long term use. Long term use is defined as the use of DME which exceeds six months.

(b) Medicaid covers the rental of DME items for six months or less.

(6) A recipient does not have to be a Home Health Care patient in order to receive coverage for products covered under this Chapter.

(7) The provider is responsible for educating the recipient in the use of the DME. The provider is also responsible for delivery and set up of the DME.

(8) All appliances and standard DME approved for payment by Medicaid must have a warranty of a minimum of one year; this may include the manufacturer's warranty. Please refer to Rule No. 560-X-13-.19.

(9) Requirements for Placing the Initial Written Prescription or Order for Certain Medical Supplies, Equipment, and Appliances.

(a) The physician who develops the recipient's written plan of care ("the ordering physician") is required to sign and place the initial prescription or order for certain medical supplies, equipment, and appliances.

(b) The ordering physician may only place the initial written prescription or order after the required face-to-face visit is conducted and documented by an authorized practitioner.

(c) Subsequent written prescriptions or orders for refills, ancillary supplies, repairs or services, or re-certifications do not require the ordering physician's signature or an additional face-to-face visit.

(d) Either the ordering physician or one of the following authorized non-physician practitioners (NPP) may both conduct and document the clinical findings from the required face-to-face visit so that the ordering physician can place and sign the initial written prescription or order for certain medical supplies, equipment, and appliances:

1. Certified registered nurse practitioners (CRNP) or clinical nurse specialists (CNS) working under a collaboration agreement under Alabama law with the ordering physician;

2. Physician assistants (PA) under the supervision of the ordering physician; or

3. Attending acute or post-acute physicians, if recipients are admitted to home health services immediately after discharge from an acute or post-acute stay.

(e) The required face-to-face visit for the initial written prescription or order for certain medical supplies, equipment, and appliances must be related to the primary reason why the recipients require the certain medical supplies, equipment, and appliances and must occur no more than 6 months prior to the start of services. The required face-to-face visit may be conducted using telehealth systems.

(f) The ordering physician is also required to review the recipient's written plan of care annually to determine the recipient's continued need for all medical supplies, equipment, and appliances.

(g) Not all initial written prescriptions or orders for medical supplies, equipment, and appliances require a face-to-face visit be conducted. The face-to-face visit requirement is limited only to the certain medical supplies, equipment, and appliances that are also subject to a face-to-face requirement under the Medicare DME program as "Specific Covered Items" in 42 C.F.R. 410.38(g).

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services.
Authority: State Plan; 42 CFR Section 440.70; and Title XIX, Social Security Act.
History: Rule effective October 1, 1982. **Amended:** November 11, 1985, March 10, 1997, July 9, 1997, September 15, 2004. **Amended**: Filed May 11, 2012; effective June 15, 2012. **Amended:** Filed April 11, 2014; effective May 16, 2014. **Amended:** Filed November 18, 2015; effective February 25, 2016. **Amended:** Filed February 10, 2017; effective March 27, 2017.

Amended: Emergency Rule filed and effective August 1, 2018. **Amended:** Filed August 10, 2018; effective September 24, 2018.

Rule No. 560-X-13-.02 Participating Providers

(1) Participating providers (also referred to as "all providers mentioned in this chapter" or "provider") are those Home Health Agencies, pharmacies, DME, supply, appliance and POP suppliers contracted with Medicaid for this program.

(2) Participating providers must meet the Medicare criteria as specified in the regulations of the Centers for Medicare and Medicaid Services, Department of Health and Human Services at 42 C.F.R. Section 424.57, which regulations are adopted by reference. Copies of these regulations may be obtained from the U.S. Government Printing Office, Washington, DC 20402-9328.

(3) Medicaid's fiscal agent enrolls providers and issues provider contracts to applicants who meet the licensure or certification requirements of the State of Alabama, Code of Federal Regulations, Alabama Medicaid Administrative Code, and Alabama Medicaid Provider Manual.

(4) All providers within this chapter should contact the applicable licensing or accreditation board(s) to determine the licensure requirements for each of the specialties. The appropriate documentation must be submitted during the Alabama Medicaid provider enrollment or re-enrollment process. If the appropriate licensure documentation is not submitted, the provider will not be assigned the selected specialty. Please refer to Chapter 14, DME, of the Medicaid Provider Manual for additional licensure information.

(5) All providers mentioned in this chapter, except pharmacy providers as outlined in subparagraph (d) (ii) below, must submit the following documentation to the Medicaid fiscal agent prior to enrollment:
   (a) Copy of a current Home Medical Equipment (HME) license or documentation that the provider meets an exemption to the licensure requirements outlined in Ala. Code § 34-14C-5 (1975);
   (b) copy of a current business license;
   (c) copy of the approved Medicare enrollment application or Medicare enrollment letter; and
   (d) copies of the Medicare Accreditation and the Medicare Surety Bond(s).
      (i.) Effective October 1, 2010, all participating providers are required to have a $50,000 Surety Bond for each National Provider Identifier (NPI) unless the provider meets an exemption in paragraph (6) below. In order to qualify for the exemption in (6) (f) below, the provider must have a Surety Bond for three years prior.

(ii.) Pharmacy providers seeking to enroll as Alabama Medicaid DME providers are required to submit their Medicare enrollment letter only. They are not required to submit a Medicare Surety Bond, Medicare Accreditation letter or Medicaid Surety Bond.

(6) Provider(s) are exempt from surety bond requirements if the provider(s):
- (a) is a DME supplier who has been a Medicaid provider for five years or longer with no record of impropriety, and whose refund requests have been repaid as requested. If Medicaid identified a problem with improper billing or fraudulent activity the provider will be required to obtain a Surety Bond; or
- (b) is a government-operated DME, Prosthetics, Orthotics and Supplies (DMEPOS) provider; or
- (c) is a state-licensed orthotic and prosthetic personnel in private practice making custom-made orthotics and prosthetics; or
- (d) are physicians and non-physician practitioners, as defined in Section 1842(b)(18) of the Social Security Act; or
- (e) are physical and occupational therapists in private practice; or
- (f) are providers who received $100,000 or less Medicaid payment in the previous two calendar years; or
- (g) are pharmacy providers; or
- (h) are phototherapy providers who only provide phototherapy services for infants; or
- (i) are Federally Qualified Health Centers.

(7) Alabama Medicaid DME, supply, appliance, and POP providers must renew their required surety bonds annually, before the day and month that the first bond was effective to avoid a lapse in coverage, a denial of Medicaid reimbursements and termination as a Medicaid provider.
- (a) Proof of the renewal must be submitted to Medicaid's fiscal agent at least 30 days prior to the individual bond's termination date. The assigned Medicaid provider location number and current physical location address must be included on the surety bond renewal document for the individual DME, supply, appliance, or POP business location being bonded.
- (b) If there is a lapse in surety bond coverage dates, the provider will be denied payment for services that may have been otherwise covered by Medicaid, and the individual location without a current surety bond on file will be terminated as a Medicaid provider.

(8) The provider's business must be physically located within the state of Alabama or within a 30-mile radius of the state of Alabama. This requirement does not apply to Medicare crossover-only providers or providers described below.
- (a) Providers located more than 30-miles from the border of Alabama may be enrolled only as follows:
  - (i.) for specialty equipment and supplies such as augmentative communication devices, automatic external defibrillators, high

frequency chest wall oscillation air pulse generator systems which are not readily available in state; or

(ii.) for supplies and equipment needed as the result of a transplant or unique treatment approved out of state as the result of an Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) referral or medical necessity. Suppliers will be enrolled by the Medicaid fiscal agent on a temporary basis for these situations.

(9) All providers must maintain a physical facility on an appropriate site in accordance with all applicable federal and state regulations or requirements.

(a) The provider's business location must be accessible to the public, Medicaid recipients, recipient's representatives and Alabama Medicaid and its agents. (The location must not be in a gated community or other area where access is restricted.)

(b) The location may be a "closed door" business, such as a pharmacy or supplier providing services only to recipients residing in a nursing home that complies with all applicable federal and state regulations or requirements.

(10) All providers mentioned in this chapter must remain open to the public for a minimum of 30 hours per week during normal business hours except physicians, physical and occupational therapists or a provider working with custom made orthotics and prosthetics. A provider must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited. Providers (as related to the provider specialty) must have DME, appliances or supply items stocked in the physical store location that are readily available to Medicaid recipients presenting prescriptions or orders for these items.

(11) All providers in this chapter must maintain a permanent visible sign in plain view and post the hours of operation. If the provider's place of business is located within a building complex, the sign must be visible at the main entrance of the building.

(12) Satellite businesses affiliated with a provider are not covered under the provider contract; therefore, no reimbursement will be made to a provider doing business at a satellite location.

(13) The provider must not have any felony convictions or record of noncompliance with Medicaid or Medicare regulations.

(14) All providers mentioned in this chapter must notify Medicaid's fiscal agent in writing of any changes to the information contained in its application at least 30 business days prior to making such changes. These changes may include, but are not limited to, changes in ownership or control, federal tax identification number, or business address changes.

(15) Failure of providers to comply with these requirements will result in their termination from the Alabama Medicaid Program.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services.
Authority: State Plan Attachment 3.1-A; 42 CFR Section 434.6; and Title XIX, Social Security Act.
History: Rule effective October 1, 1982. **Amended**: Filed December 17, 2001; effective March 15, 2002. **Amended:** Filed November 19, 2002. Effective February 14, 2003. **Amended:** Filed September 20, 2006; effective December 13, 2006. **Amended:** Filed February 20, 2008; effective May 16, 2008. **Amended:** Filed October 20, 2008; effective January 16, 2009. **Amended:** Filed October 20, 2009; effective January 15, 2010. **Amended:** Filed April 20, 2010; effective July 16, 2010. **Amended:** Filed May 11, 2012; effective June 15, 2012. **Amended**: Filed November 9, 2012; effective December 14, 2012. **Amended:** Filed November 18, 2015; effective February 25, 2016.

Rule No. 560-X-13-.03 Method of Requesting DME, Supplies, Appliances and POP

(1) A written order or a signed prescription (as defined by the Medicare Program Integrity Manual Chapter 5) signed by the prescriber is required for covered items. An EPSDT or Patient 1st primary physician (PMP) referral may be submitted as an order when written according to practice guidelines and state or federal law and must include the date and signature of the prescriber, the item(s) ordered and the recipient name. For acceptable formats of provider signature, refer to Medicaid Administrative Code, Rule No. 560-X-1-.18.

(2) A prescription or order is considered to be outdated by Medicaid when it is presented to the provider or Medicaid's fiscal agent past 90 days from the date it was written.

(3) Medicaid considers a prescription to be valid for the dispensing of supplies for a period of twelve months. After the twelve month period of time, the recipient must be reevaluated by the prescriber to determine medical necessity for continued dispensing of medical supplies.

(4) Certain DME, supplies and appliances require prior authorization by Medicaid. Please refer to Chapter 14, DME, of the Medicaid Provider Manual published on Medicaid's website. Repairs or replacement of parts, after the first year the equipment or appliance is issued, require prior authorization unless otherwise specified by Medicaid. A provider's failure to go through the process of obtaining prior authorization for repairs or replacement does not by itself constitute a non-covered service.

(5) Procedures for requesting and dispensing DME, supplies and appliances that require a prior authorization are as follows:

(a) The prescriber must complete and sign a written order or prescription and give to the recipient or sponsor to take to the provider of their choice. The prescriber may also fax the prescription or order to the provider of the recipient's choice.

(b) The provider must submit the following documentation by electronic submission, fax or mail to the Medicaid fiscal agent:

(i.) the appropriate Alabama Prior Review and Authorization Request Form,

(ii.) the EPSDT or Patient 1st PMP Referral Form, if applicable,

(iii.) all necessary documentation to justify medical necessity, and

(iv.) current prescription or order.

(c) Medicaid or its designee will review the request and assign a status of approved, denied or pending.

(i.) If the request is approved, the provider will receive an approval letter with the ten-digit prior authorization number.

(ii.) If the request is denied, written notice will be sent to the provider and the recipient indicating the reason(s) for denial. Information giving them their right to appeal is also included in this notice.

(iii.) If the request is placed in pending or conditionally approved status, the prior authorization letter will provide information and a timeframe for submission of the invoice.

(d) All prior authorization requests for DME must be received by the Medicaid fiscal agent within 30 calendar days after equipment is dispensed. All prior authorization requests received beyond the 30 calendar days after equipment is dispensed will be denied.

(e) The provider may not bill the recipient for an item for which a prior authorization has been denied due to provider error or the provider's failure to submit the necessary medical documentation for the prior authorization request.

(6) Suppliers requesting approvals for medical items must provide Medicaid with an expected date of delivery. For medical items approved, Medicaid will indicate the time frame allowed for providers to dispense equipment on the approval letter.

(a) When a provider is unable to dispense equipment within the timeframe specified on the approval letter, an extension may be requested with written justification as to the specific reason(s) why the equipment cannot be supplied timely. All requests for extensions must be submitted to Medicaid prior to the expiration date indicated on the approval letter.

(b) Medicaid will cancel conditional approvals (PA's in "pending" status) for medical items that are not dispensed timely when there is no justifiable reason for delay.

(7) Procedures for requesting and dispensing DME, supplies and appliances that do not require a prior authorization are as follows:

(a) It is the responsibility of the recipient or authorized representative to obtain the signed prescription or order from the physician and take to a participating provider.

(b) Upon receipt of the prescription or order, the provider must:

(i.) verify Medicaid eligibility. Recipient's eligibility must be verified on a monthly basis. Medicaid will not reimburse providers for items supplied to recipients in months where recipients have no eligibility;
(ii.) obtain necessary managed care or EPSDT referrals;
(iii.) furnish the covered item(s) as prescribed;
(iv.) collect the appropriate co-payment amount;
(v.) retain all documentation, including, but not limited to, the prescription or order, referral forms, PA forms, etc. on file for a period of three years plus the current year; and
(vi.) submit the proper claim form to Medicaid's fiscal agent.

(8) DME, supplies, and appliances not listed as covered services in Chapter 14, DME, of the Medicaid Provider Manual may be requested for coverage by submitting the request to Medicaid for review and consideration. It will be the provider's responsibility to supply Medicaid with the necessary medical documentation to support the medical necessity of the requested item(s).

(9) Automatic refills are not permitted by the Medicaid Agency. Violations may result in unauthorized charges. The provider may be held liable, or Medicaid may recoup the unauthorized charges, or cancel the provider agreement.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services
Authority: State Plan Attachment 3.1-A; 42 CFR Section 440.70; and Title XIX, Social Security Act.
History: Rule effective October 1, 1982. **Amended**: November 11, 1985. Effective date of this amendment January 13, 1993. **Amended:** Filed October 20, 2008; effective January 16, 2009. **Amended:** Filed May 11, 2012; effective June 15, 2012. **Amended:** Filed November 18, 2015; effective February 25, 2016.

Rule No. 560-X-13-.04 Reserved

Rule No. 560-X-13-.05 Reserved

Rule No. 560-X-13-.06 Reserved

Rule No. 560-X-13-.07 Non-covered Items and Services

Non-covered items and services include, but are not limited to:
(1) Items of a deluxe nature.

(2) Replacement of usable equipment.

(3) Items for use in hospitals, nursing homes, or other institutions. However, DME items may be provided in nursing homes or other institutions for children through the EPSDT Program.

(4) Items for the patient or patient's caregiver's comfort and convenience.

(5) Items not listed as covered by Medicaid.

(6) Rental of equipment, with the following exceptions:
   (a) Rental for six months or less, or
   (b) Medicare crossover, or
   (c) Certain intravenous therapy equipment, or
   (d) Short term use due to institutionalization, or
   (e) Short term use due to death of a recipient.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services
Authority: State Plan Attachment 3.1-A; 42 CFR Section 441.15; and Title XIX, Social Security Act.
History: Rule effective October 1, 1982. Effective date of this amendment March 10, 1997. **Amended:** Filed February 20, 2008; effective May 16, 2008. **Amended:** Filed November 18, 2015; effective February 25, 2016.

Rule No. 560-X-13-.08 Reserved

Rule No. 560-X-13-.09 Reserved

Rule No. 560-X-13-.10 Reimbursement and Signatures

(1) Medicaid will reimburse for only those DME, supply, appliance or POP items indicated on the approval letter from Medicaid or its designee.

(2) Reimbursement will be made for purchases or rentals in accordance with the DME Fee Schedule on the Medicaid website.

(3) Request for reimbursement must be submitted on the appropriate claim form. Please refer to Chapter 14, DME, of the Medicaid Provider Manual.

(4) The provider agrees to accept as payment in full the amount paid by Medicaid for covered items.
   (a) The provider (or provider's staff) must advise each patient prior to services being rendered when Medicaid payment will not be accepted and the patient will be responsible for the bill.

(b) The fact that Medicaid payment will not be accepted must be recorded in the patient's record. Refer to Rule No. 560-X-1-.07.

(5) Medicaid recipients may be billed for non-covered items.

(6) Medicaid recipients may be billed for items provided by non-enrolled suppliers.

(7) Refer to Rule No. 560-X-1-.18, Provider/Recipient Signature Requirement, for signature requirements. Recipient signatures are required for all DME, supply, appliance and POP claims to validate the billed and reimbursed service was rendered to the recipient. For DME, supply, appliance and POP items that have been delivered, the provider must ensure that the delivery service obtains the recipient's signature or the signature of the recipient's designee. For purposes of this Rule, designee is defined as: "Any person who can sign and accept the delivery on behalf of the recipient." The relationship of the designee should be noted on the delivery slip (i.e. spouse, power of attorney, etc.). The signature of the designee should be legible. If the signature is not legible, the name of the person should be printed on the delivery slip. When payment has been made on claims for which a signature is not available and one of the exceptions in Rule No. 560-X-1-.18 is not applicable, the funds paid to the provider will be recovered.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services
Authority: State Plan, Attachment 4.19-B, page 5; 42 C.F.R., Section 447.50; Section 447.252; and Title XIX, Social Security Act.
History: Rule effective October 1, 1982. **Amended** July 9, 1984 and June 8, 1985. **Amended**: Filed August 21, 2001; effective November 16, 2001. **Amended:** Filed June 21, 2004; effective September 15, 2004. **Amended:** Filed October 20, 2008; effective January 16, 2009. **Amended:** Filed November 18, 2015; effective February 25, 2016.

Rule No. 560-X-13-.11 Non-reimbursement of DME, Supplies, Appliances and POP

(1) Item(s) furnished by a provider without receipt of an authorization to purchase by Medicaid will not be approved for reimbursement.

(2) Item(s) supplied to an individual who is not eligible during the month in which the item(s) are furnished, are not reimbursable.

(3) Medicaid recipients cannot be reimbursed directly by Medicaid.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services
Authority: 42 C.F.R., Section 447.252; and Title XIX, Social Security Act.
History: Rule effective October 1, 1982. **Amended** January 8, 1985 and March 10, 1997. **Amended:** Filed June 21, 2004; effective September 15, 2004. **Amended:** Filed November 18, 2015.

Rule No. 560-X-13-.12 Cost-Sharing

(1) Medicaid recipients are required to pay and suppliers are required to collect the designated co-pay amount for the rental or purchase of DME, supplies, appliances and POP, including crossover claims.

(2) The co-payment fee does not apply to in certain situations in accordance with Rule No. 560-X-1-.25.

(3) A provider may not deny services to any eligible recipient due to the recipient's inability to pay the cost-sharing amount imposed.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services
Authority: State Plan Attachment 4.19-B, page 5; 42 CFR Section 447.50; and Title XIX, Social Security Act.
History: Rule effective June 8, 1985. **Amended**: Filed March 20, 2001; effective June 15, 2001. **Amended:** Filed October 20, 2008; effective January 16, 2009. **Amended:** Filed November 18, 2015; effective February 25, 2016.

Rule No. 560-X-13-.13 Reserved

Rule No. 560-X-13-.14 Augmentative Communication Devices

(1) Coverage is provided for Augmentative Communication Devices (ACD) for eligible individuals who meet criteria set out herein. Prior authorization for the ACD service is required. Requests for prior authorization must be made on the appropriate Alabama Prior Review and Authorization Request Form. The request must include documentation regarding the medical evaluation by the physician and speech language pathologist and recipient information.

(2) ACDs are defined as portable electronic or non-electronic aids, devices, or systems determined to be necessary to assist a Medicaid-eligible recipient to overcome or improve severe expressive speech-language impairments or limitations due to medical conditions in which speech is not expected to be restored, and which enable the recipient to communicate effectively. These impairments include but are not limited to: apraxia of speech, dysarthria, and cognitive communication disabilities. These devices are reusable equipment items which must be a necessary part of the treatment plan consistent with the diagnosis, condition or injury, and not furnished for the convenience of the recipient or his family. ACD components or accessories prescribed or intended primarily for vocational, social, or academic development or enhancement and which are not necessary as described above will not be covered.

(3) The scope of services includes the following elements:
    (a) Screening and evaluation,
    (b) ACD, subject to limitations, and
    (c) Training on use of equipment.

(4) Candidates under the age of 21 must meet all of the following criteria:
    (a) EPSDT referral by Medicaid-enrolled EPSDT provider. Referral must be within one year of application for ACD. The EPSDT provider must obtain a referral from the *Patient 1st* PMP (where applicable);
    (b) Medical condition which impairs ability to communicate;
    (c) Evaluation by required qualified, experienced professionals as defined below; and
    (d) Physician prescription or order to be obtained after the evaluation and based on documentation contained in the evaluation.

(5) Candidates over the age of 21 must meet all of the following criteria:
    (a) Referral from a *Patient 1st* PMP (where applicable). Referral must be within one year of application for ACD;
    (b) Medical condition which impairs ability to communicate;
    (c) Evaluation required by qualified experienced professionals as defined below; and
    (d) Physician prescription or order to be obtained after the evaluation and based on documentation provided in the evaluation.

(6) The candidate must be evaluated by qualified interdisciplinary professionals. Interdisciplinary professionals ***must*** include all of the following:
    (a) Speech-Language Pathologist: This professional must meet all of the following criteria:
        (i) Have a master's degree in speech-language pathology from an accredited institution;
        (ii) Have a Certificate of Clinical Competence in speech-language pathology from the American Speech, Language, Hearing Association;
        (iii) Have a current Alabama license in speech-language pathology;
        (iv) Have no financial or other affiliation with a vendor, manufacturer, or manufacturer's representative of ACDs
    (b) Physician: This professional must meet all of the following criteria:
        (i) Be a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the state in which the doctor performs such functions; and
        (ii) Have no financial or other affiliation with a vendor, manufacturer, or manufacturer's representative of ACDs.

Interdisciplinary professionals ***should*** also include, but may not be limited to, the following:
    (c) Physical Therapist: This professional must meet all of the following criteria:

(i) Have a bachelor's degree in physical therapy from an accredited institution;
(ii) Have an Alabama license in physical therapy; and
(iii) Have no financial or other affiliation with a vendor, manufacturer, or manufacturer's representative of ACDs.

(d) Social Worker: This professional must meet all of the following criteria:
(i) Have a bachelor's degree in social work from an accredited institution;
(ii) Have an Alabama license in social work; and
(iii) Have no financial or other affiliation with a vendor, manufacturer, or manufacturer's representative of ACDs.

(e) Occupational Therapist: This professional must meet all of the following criteria:
(i) Have a bachelor's degree in occupational therapy from an accredited institution;
(ii) Have an Alabama license in occupational therapy; and
(iii) Have no financial or other affiliation with a vendor, manufacturer, or manufacturer's representative of ACDs.

(7) ACDs and services are only available through the Alabama Medicaid Agency prior authorization process. Requests for authorization must be submitted to Medicaid for review. Documentation must support that the client is mentally, physically, and emotionally capable of operating and using an ACD. The request must include documentation regarding the medical evaluation by the physician and recipient information:

(a) Medical Evaluation by Interdisciplinary Professionals must meet all of the following criteria:
(i) Medical examination by physician to assess the need for an ACD to replace or support the recipient's capacity to communicate;
(ii) Status of respiration, hearing, vision, head control, trunk stability, arm movement, ambulation, seating and positioning or ability to access the device; and
(iii) Must have been conducted within 90 days of request for ACD.

(b) Recipient Information must include all of the following:
(i) Name;
(ii) Medicaid number;
(iii) Date(s) of assessment;
(iv) Medical diagnoses (primary, secondary, tertiary); and
(v) Relevant medical history.

(c) Sensory Status (by physician) must include all of the following:
(i) Vision status;
(ii) Hearing status; and
(iii) Description of how vision, hearing, tactile, or receptive communication impairments affect expressive communication (e.g., sensory integration, visual discrimination).

(d) Postural, Mobility, and Motor Status must include all of the following:

(i) Motor status;
(ii) Optimal positioning;
(iii) Integration of mobility with ACD; and
(iv) Recipient's access methods (and options) for ACD.

(e) Developmental Status must include all of the following:
(i) Information on the recipient's intellectual, cognitive, and developmental status; and
(ii) Determination of learning style (e.g., behavior, activity level).

(f) Caregiver and Community Support Systems must include all of the following:
(i) A detailed description identifying caregivers and support;
(ii) The extent of their participation in assisting the recipient with use of the ACD; and
(iii) Their understanding of the use and their expectations of the ACD.

(g) Current Speech, Language, and Expressive Communication Status must include all of the following:
(i) Identification and description of the recipient's expressive or receptive (language comprehension) communication impairment diagnosis;
(ii) Speech skills and prognosis;
(iii) Communication behaviors and interaction skills (i.e., styles and patterns);
(iv) Description of current communication strategies, including use of an ACD, if any; and
(v) Previous treatment of communication problems.

(h) Communication Needs Inventory must include all of the following:
(i) Description of recipient's current and projected (e.g., within five years) speech-language needs;
(ii) Communication partners and tasks, including partners' communication abilities and limitations, if any; and
(iii) Communication environments and constraints which affect ACD selection or features.

(i) Summary of Recipient Limitations which must contain a description of the communication limitations.

(j) ACD Assessment Components must contain a justification for and use to be made of each component and accessory requested.

(k) Identification of *at least* three ACDs considered for recipient to include all of the following:
(i) Identification of the significant characteristics and features of the ACDs considered for the recipient;
(ii) Identification of the cost of the ACDs considered for the recipient (including all required components, accessories, peripherals, and supplies, as appropriate);
(iii) Identification of manufacturer;
(iv) Justification stating why a device is the least costly, equally effective alternative form of treatment for the recipient; and
(v) Medical justification of device preference, if any.

(l) Treatment Plan and Follow-Up must include all of the following:

(i) Description of short-term and long-term therapy goals;
(ii) Assessment criteria to measure the recipient's progress toward achieving short-term and long-term communication goals;
(iii) Expected outcomes and description of how device will contribute to these outcomes; and
(iv) Training plan to maximize use of ACD.

(m) Documentation of recipient's trial use of equipment must include all of the following:
(i) Amount of time;
(ii) Location; and
(iii) Analysis of ability to use equipment.

(n) Documentation of qualifications of speech-language pathologists and other professionals submitting portions of the evaluation must be present. Physicians are exempt from this requirement.

(o) A signed statement by submitting professionals that they have no financial or other affiliation with manufacturer, vendor, or sales representative of ACDs must be present. One statement signed by all professionals will suffice.

(8) Medicaid reserves the right to request additional information or evaluations by appropriate professionals.

(9) ACDs are subject to the following limitations. ACDs, including components and accessories, will be modified or replaced only under the following circumstances:

(a) Medical Change: Upon the request of recipient if a significant medical change occurs in the recipient's condition which significantly alters the effectiveness of the device.

(b) Age of Equipment: ACDs outside the manufacturer's or other applicable warranty which do not operate to capacity will be repaired. At such time as repair is no longer cost-effective, upon request by the recipient, replacement of identical or comparable component or components will be made. Full documentation of the history of the service, maintenance, and repair of the device must accompany such requests.

(c) Technological Advances: No replacements or modifications will be approved based on technological advances unless the new technology would meet a significant medical need of the recipient which is currently unmet by the present device.

(10) All requests for replacement or modification as outlined in A-C above will require a new evaluation and complete documentation. If new equipment is approved, the old equipment must be turned in.

(11) Invoice: The manufacturer's invoice must be forwarded to the Medicaid Agency or its designee before the prior authorization is approved.

(12) Trial Period: No communication components will be approved unless the client has used the equipment and demonstrated an ability to use the equipment. Prior

authorization for rental may be obtained for a trial period. This demonstrated ability can be documented through periodic use of sample or demonstration equipment. Adequate supporting documentation must accompany the request.

(13) Repair: Repairs are covered only to the extent not covered by the manufacturer's warranty. Repairs must be prior authorized. Battery replacement is not considered repair and does require prior authorization.

(14) Loss or Damage: Replacement of identical components due to loss or damage must be prior authorized. These requests will be considered only if the loss or damage is not the result of misuse, neglect, or malicious acts by the users.

(15) Component or Accessory Limits: Components or accessories which are not medically required will not be approved. Examples of non-covered items include, but are not limited to, printers, modems, service contracts, office or business software, software intended for academic purposes, workstations, or any accessory that is not medically required.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services
Authority: State Plan Attachment 4.19-A; 42 CFR, Section 440.70; Title XIX, Social Security Act.
History: April 26, 1999. **Amended**: Filed August 21, 2001; effective November 16, 2001. **Amended:** Filed October 20, 2008; effective February 3, 2009. **Amended:** Filed November 18, 2015; effective February 25, 2016.

Rule No. 560-X-13-.15 Oxygen Therapy Coverage

(1) Oxygen Therapy is covered for the entire Medicaid population based on medical necessity and must be prior authorized by Medicaid. Requests for prior authorization must be made on the appropriate Alabama Prior Review and Authorization Request Form. The request must be accompanied by appropriate medical and other required documentation in accordance with Rule No. 560-X-13-.03.

(2) The medical diagnosis must indicate a chronic debilitating medical condition, with evidence that other forms of treatment (such as medical and physical therapy directed at secretions, bronchospasm and infection) were tried without success and that continuous oxygen therapy is required. Oxygen will not be approved for as needed (PRN) use only.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services
Authority: State Plan Attachment 4.19-A; 42 CFR, Section 440.70; Title XIX, Social Security Act.
History: New Rule: Filed August 21, 2001; effective November 16, 2001. **Amended:** Filed October 20, 2008; effective January 16, 2009. **Amended:** Filed November 18, 2015; effective February 25, 2016.

Rule No. 560-X-13-.16 External Breast Prostheses

(1) External breast prostheses following mastectomy for breast cancer are covered for all Medicaid-eligible recipients meeting the criteria. Please refer to Chapter 14, DME, of the Medicaid Provider Manual published on Medicaid's website.

(2) Providers of external breast prostheses devices for adults must be enrolled as a Medicaid provider, and Mastectomy Fitters must be licensed by the Alabama Board of Prosthetics, Orthotics and Pedorthics.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services
Authority: State Plan; 42 CFR, Section 440.70; Title XIX, Social Security Act.
History: New Rule: Filed October 12, 2001; effective November 16, 2001. **Amended:** Filed August 11, 2004; effective September 15, 2004. **Amended:** Filed May 11, 2012; effective June 15, 2012. **Amended:** Filed April 11, 2014; effective May 16, 2014. **Amended:** Filed November 18, 2015; effective February 25, 2016.

Rule No. 560-X-13-.17 Wheelchairs

(1) Wheelchairs are a covered benefit for patients who meet full Medicaid eligibility criteria and medical necessity. The patient must meet criteria applicable to wheelchairs pursuant to this chapter, and Chapter 14, DME, of the Medicaid Provider Manual.

(2) All requests for wheelchairs are subject to the Medicaid prior approval provisions in accordance with Rule No. 560-X-13-.03 and any additional requirements in Chapter 14, DME, of the Medicaid Provider Manual.

(3) Limitations and Exclusions
   (a) Patients may be approved for one manual or power/motorized wheelchair every five years for children ages 0-20 and every seven years for adults ages 21-99 based on medical necessity.
   (b) Home, environmental and vehicle adaptations, equipment and modifications are not covered.
   (c) Repairs or replacement of parts require prior authorization unless otherwise specified by Medicaid.
   (d) Within the five year period for children ages 0-20 and seven year period for adults ages 21-99, Medicaid will not repair or replace equipment that is lost, destroyed, or damaged as a result of misuse, neglect, loss or wrongful disposition or equipment by the recipient, the recipient's caregiver(s), or the provider. At a minimum, examples of equipment misuse, neglect, loss or wrongful disposition by the recipient, recipient's caregiver, or the provider include, but are not limited to the following:

(i) Loss of wheelchair or parts.
(ii) Selling or loaning wheelchair or parts.
(iii) Damage due to weather.
(iv) Failure to store the wheelchair in a secure and covered area when not in use.
(v) Use on public roadways where the speed limit is greater than 25 miles per hour.
(vi) Loss, destruction or damage caused by the malicious, intentional or negligent acts.

(4) Patient Education
(a) Providers are responsible for patient education and documentation of appropriate usage of wheelchair. Patient education shall include, but not be limited to, proper storage, usage on or off public roadways, battery life, cleaning, warranty, etc.
(b) Documentation of patient education and understanding by both the servicing provider and the recipient or caregiver shall be kept in the patient file for the life of the wheelchair.

(5) Reimbursement for wheelchair, except as outlined in this section for EPSDT-referred wheelchairs, will be made in accordance with the DME Fee Schedule located on the Medicaid website.

(6) Reimbursement for EPSDT-referred Wheelchair Systems
(a) All requests for EPSDT-referred wheelchairs are subject to the Medicaid prior approval provisions in accordance with Rule No. 560-X-13-.03 and the following additional provisions:
(i) If no Medicare price is available for EPSDT-referred wheelchair systems, the reimbursement rate is established based on a discount from Manufacturers Suggested Retail Price (MSRP) instead of a "cost-plus" basis.
(ii) Providers are required to submit MSRPs from three manufacturers for wheelchair systems (excluding seating system and add-on products) appropriate for the individual's medical needs.
(iii) Requests submitted with less than three prices from different manufacturers must contain documentation supporting the appropriateness and reasonableness of equipment requested for a follow-up review by Medicaid staff or designee. Provider must document non-availability of required MSRPs to justify not sending in three prices.
(b) The established rate will be based on the MSRP minus the following discounts:
(i) Manual wheelchair systems – 20% discount from MSRP
(ii) Power wheelchair system – 15% discount from MSRP
(iii) Ancillary (add-on) products:
1. Electronic ancillary products – 15% discount from MSRP
2. Non-electronic ancillary products – 20% discount from MSRP

Author: Keisha Hawkins, PDL Administrator, Clinical Services & Support
Authority: State Plan Attachment 4.19-A; 42 CFR, Section 440.70; Title XIX, Social Security Act.
History: New Rule: Emergency Rule filed and effective June 20, 2003. **Amended**: Filed July 21, 2003; effective October 24, 2003. **Amended**: Filed June 21, 2004; effective September 15, 2004. **Amended:** Filed July 20, 2005; effective October 14, 2005. **Amended:** Filed October 20, 2008; effective January 16, 2009. **Amended:** Filed January 21, 2009; effective April 17, 2009. **Amended:** Filed November 9, 2012; effective December 14, 2012. **Amended:** Filed November 18, 2015; effective February 25, 2016. **Amended:** Filed June 9, 2017; effective July 24, 2017.

Rule No. 560-X-13-.18 Basic Level Prosthetics, Orthotics, and Pedorthics

(1) Basic level prosthetics, orthotics and pedorthics are covered benefits to Medicaid eligible recipients up to age 65 in a non-institutional and institutional setting. The recipients must meet established Medicaid criteria applicable to prosthetic, orthotic, and pedorthic devices pursuant to this chapter and Chapter 14, DME, of the Medicaid Provider Manual.
    (a) For items to be covered, recipients must meet eligibility requirements, the devices must be reasonable and necessary to improve the function of a malformed body member or replace an absent body member, and meet all other applicable Medicaid statutory and regulatory requirements.
    (b) Providers of prosthetic, orthotic, and pedorthic devices for adults must be enrolled as a Medicaid provider and licensed by the Alabama Board of Prosthetics, Orthotics and Pedorthics.
    (c) The provider must be practicing as a prosthetic, orthotic, or pedorthic practitioner in the State of Alabama at an accredited facility.
    (d) Providers must keep a copy of the written and signed prescription or order from the primary physician for the prosthetic or orthotic device in the recipient's file for a period of three years plus the current year.
    (e) The provider must have documentation of the education follow-up provided to the recipient of the use of the prosthetic and orthotic device in the recipient's file.

(2) For Medicaid to approve lower limb prosthesis, medical documentation must be maintained substantiating that a prosthesis is essential in order for the recipient to ambulate and that the recipient is motivated to ambulate.

(3) For Medicaid to approve an orthotic device, medical documentation must be maintained to show that the device supports or aligns movable parts of the body, prevents or corrects deformities, or improves functioning.

(4) For Medicaid to approve therapeutic shoes for diabetes, medical documentation must be maintained showing that the recipient has diabetes mellitus and other medical conditions justifying the need. Refer to the DME Fee Schedule on the Alabama Medicaid website for Prosthetic, Orthotics, and Pedorthic reimbursement rates and benefit limits.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services
Authority: State Plan Attachments 3.1-A and 4.19-B; 42 CFR Section 440.70; Title XIX, Social Security Act.
History: New Rule: Filed February 11, 2008; effective March 17, 2008. **Amended:** Filed December 30, 2008; effective February 3, 2009. **Amended:** Filed March 20, 2012; effective June 15, 2012. **Amended:** Filed November 18, 2015; effective February 25, 2016.

Rule No. 560-X-13-.19 Warranty, Maintenance, and Replacement

(1) All standard DME, appliances, and POP must have a warranty for a minimum of one year; this may include the manufacturer's warranty. If the provider supplies items that are not covered under a warranty, the provider is responsible for repairs, replacements and maintenance for the first year.
    (a) The warranty begins on the date of delivery (date of service) to the recipient. A statement of the warranty must be given to the recipient and the provider must keep a copy of the warranty for audit review by Medicaid. Medicaid may request a copy of the warranty.
    (b) In the event the supplying provider does not honor or provide the mandatory one year warranty and does not repair the items when needed, Medicaid may impose penalties, to include but not limited to deducting the total cost of the repairs from a check write of the supplying provider, recoupment of reimbursement paid to the provider for the equipment, or termination of the provider's contract.

(2) Medicaid covers repair and replacement of DME, supplies, appliances and POP. These services, in most cases, must be prior approved by Medicaid. The request for repair or replacement and appropriate documentation (includes PA when applicable) justifying the need for replacement must be submitted electronically to Medicaid's fiscal agent and kept in the recipient's file.

(3) Requests for replacement or repair of items that are covered by Medicaid which are outside the normal benefit limits, due to damage beyond repair or other extenuating circumstances, must be submitted to the DME Unit for review and consideration. Request for repair or replacement due to extenuating circumstances should be mailed to, Alabama Medicaid Agency, 501 Dexter Ave., DME Unit, Montgomery, AL 36103.

(4) Medicaid will not repair or replace items that are lost, destroyed, or damaged as a result of misuse, neglect, loss, or wrongful disposition of equipment by the recipient, the recipient's caregiver(s), or the provider. Requests for repair or replacement will be denied if such circumstances are confirmed. Payment for repair or replacement of items denied by Medicaid is the responsibility of the recipient. At a minimum, examples of misuse, neglect, loss or wrongful disposition by the recipient, recipient's caregiver, or the provider include, but are not limited to the following:
    (a) Loss of item or related parts

(b) Selling or loaning item or related parts
(c) Damage due to weather
(d) Failure to store the items in a secure and covered area when not in use
(e) Loss, destruction or damage caused by the malicious, intentional or negligent acts

(5) Alabama Medicaid covers replacement items due to loss by disasters, fire, theft, etc. The provider must submit the appropriate documentation (fire report, police report, etc.) with the PA (if PA is required), and keep all related documentation in the recipient's file per Agency record retention policy. The date of the report must be within 30 days of the date of the loss or event.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services
Authority: State Plan; 42 CFR Section 440.70; and Title XIX, Social Security Act.
History: New: Filed November 18, 2015; effective February 25, 2016.

Rule No. 560-X-13-.20 Specific DME, Supplies, Appliances, and POP Coverage and Policy Not Otherwise Mentioned

Specific DME and POP coverage and policy not mentioned in this chapter are described in Chapter 14, DME, of the Medicaid Provider Manual, and is located on the Medicaid website. Questions related to specific coverage and policy should be submitted in writing or email to, Alabama Medicaid Agency, Clinical Services and Support, DME Unit.

Author: Kelli Littlejohn Newman, PharmD, Director, Clinical Services
Authority: State Plan; 42 CFR Section 440.70; and Title XIX, Social Security Act.
History: New: Filed November 18, 2015; effective February 25, 2016.