CABINET FOR HEALTH AND FAMILY SERVICES
Department for Medicaid Services
Division of Health Care Policy
(Amendment)

907 KAR 1:479. Medical supplies, equipment, and appliances ~~[Durable medical equipment]~~ covered benefits and reimbursement.

RELATES TO: KRS 205.520, 205.560, 205.6333, 42 C.F.R. Part 414, 424.57, 440.230, 440.70, 45 C.F.R. Part 160, 162.1002, Part 164, 42 U.S.C. 1320d, 1395m, 1395w-4, 1396d(i)

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3)

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has responsibility to administer the Medicaid program. KRS 205.520(3) authorizes the cabinet~~[, by administrative regulation,]~~ to comply with any requirement that may be imposed, or opportunity presented, by federal law to qualify for federal Medicaid funds. This administrative regulation establishes the provisions relating to coverage and reimbursement requirements for ~~[durable medical equipment,]~~medical supplies, equipment, and appliances (MSEA)~~[prosthetics, and orthotics]~~.

Section 1. Definitions.

(1) ~~["Certificate of Medical Necessity" or "CMN" means a form required by the department to document medical necessity for durable medical equipment, medical supplies, prosthetics, or orthotics.]~~

~~[(2)]~~ "CMS" means the Centers for Medicare and Medicaid Services.

(2) ~~[(3)]~~ "Covered benefit" or "covered service" means an item of MSEA~~[durable medical equipment, a prosthetic, an orthotic, or a medical supply]~~ for which coverage is provided by the department.

(3) ~~[(4)]~~ "Customized" means that an item has been constructed, fitted, or altered to meet the unique medical needs of an individual Medicaid recipient and does not include the assemblage of modular components or the addition of various accessories that do not require unique construction, fitting, or alteration to individual specifications.

(4) ~~[(5)]~~ "Date of service" means:

(a)

1. The date the MSEA~~[durable medical equipment, prosthetic, orthotic, or supply (DMEPOS)]~~ is provided to the recipient; or
2. Thirty (30) days from the scheduled date of delivery with:
   a. Proof from the provider the recipient was unable to be reached after a good faith effort to deliver; and
   b. Product is unable to be resold due to customization for the recipient;

(b) For mail order MSEA~~[DMEPOS]~~, the later of the shipping date or the date the recipient was discharged home or to a place where normal life activities take place, except as limited by 42 C.F.R. 440.70(c)(1)~~[from an inpatient hospital stay or nursing facility]~~;

(c) For MSEA~~[DMEPOS]~~ delivered to a recipient's home immediately subsequent to a hospital inpatient stay, the date of final discharge; or

(d) Up to two (2) calendar days prior to discharge from a hospital or nursing facility if:

1. The item was provided for purposes of fitting or training of the patient;
2. The item is ready for use in the recipient's home; and
3. Billing is not done prior to the date of the recipient's discharge from the facility.

(5) ~~[(6)]~~ "Department" means the Department for Medicaid Services or its designee.

(6) ~~[(7)]~~ "DMEPOS" means durable medical equipment, prosthetics, orthotics, or supplies.

(7) ~~[(8)]~~ "Durable medical equipment" or "DME" means medical equipment that:

(a) Withstands repeated use;

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

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

(d) Is appropriate for use in the home or community.

(8) ~~[(9)]~~ "Healthcare common procedure coding system" or "HCPCS" means a collection of codes acknowledged by the Centers for Medicare and Medicaid Services (CMS) that represents procedures or items.

(9) ~~[(10)]~~ "Home" means a place in which normal life activities take place, and as limited by 42 C.F.R. 440.70(c)(1)~~[where the recipient resides excluding:]~~

~~[(a)] [A nursing facility;]~~

~~[(b)] [A hospital;]~~

~~[(c)] [An intermediate care facility for individuals with an intellectual disability; or]~~

~~[(d)] [An institution for mental diseases as defined by 42 U.S.C. 1396d(i)]~~.

(10) ~~[(11)]~~ "Incidental" means that a medical procedure or service:

(a) Is performed at the same time as a more complex primary procedure or service; and

(b)

1. Requires little additional resources; or
2. Is clinically integral to the performance of the primary procedure or service.

(11) [(12)] "Invoice price" means an itemized account of a manufacturer's actual charges that are billed to a supplier for goods or services provided by the manufacturer or distributor.

(12) [(13)] "Medicaid Program MSEA[DME] Fee Schedule" means a list, located at https://www.chfs.ky.gov/agencies/dms/Pages/feesrates.aspx[http://chfs.ky.gov/dms], that:

(a) Contains the current Medicaid maximum allowable amount established by the department for a covered item of MSEA[durable medical equipment, a prosthetic, an orthotic, or a medical supply]; and

(b) Is updated at least yearly[quarterly to coincide with the quarterly updates made by the Centers for Medicare and Medicaid Services as required by 42 U.S.C. 1395m and 1395w-4 and 42 C.F.R. Part 414].

(13) "Medical supplies, equipment, and appliances" or "MSEA":

(a) Means:

1. Durable medical equipment;
2. DMEPOS;
3. Orthotics; and
4. A medical supply item;

(b) Includes:

1. Prosthetics;
2. Orthotics;
3. Beds;
4. Canes;
5. Walkers;
6. Wheelchairs;
7. Traction equipment;
8. Oxygen;
9. Oxygen equipment; and
10. Routine maintenance of a rental item; and

(c) Does not mean:

1. Items which are covered under other areas and disciplines within Title 907 KAR, such as frames, lenses, hearing aids, and pacemakers; or
2. Routine maintenance of a purchased item. Routine maintenance includes testing, cleaning, regulating, and accessing equipment described as the type of servicing an owner may perform in the operator's manual for the item.

(14) "Medical supply" means an item that is:

(a) Consumable;

(b) Nonreusable;

(c) Disposable; and

(d) Primarily and customarily used to serve a medical purpose.

(15) "Medically necessary" or "medical necessity" means that a covered benefit is determined to be needed in accordance with 907 KAR 3:130.

(16) "Medicare accreditation" means having met the quality standards established in 42 U.S.C. 1395m(a)(20).

(17) "Mutually exclusive" means that two (2) MSEA[DMEPOS] items:

(a) Are not reasonably provided in conjunction with each other during the same patient encounter on the same date of service;

(b) Represent duplicate or very similar items; or

(c) Represent medically inappropriate use of HCPCS codes.

(18) "Nutritional supplement" means a liquid or powder administered enterally or orally that is specially formulated to supply complete diagnosis-appropriate nutrition, including kilocalories, protein, vitamins, and minerals.

(19) "Orthotic" means a mechanical device or brace that is designed to support or correct a defect or deformity or to improve the function of a movable part of the body.

(20) "Prescriber" means a physician, podiatrist, optometrist, dentist, advanced practice registered nurse, physician assistant, or chiropractor who:

(a) Is acting within the legal scope of clinical practice under the licensing laws of the state in which the health care provider's medical practice is located;

(b) If the individual is an enrolled Kentucky Medicaid provider, is in compliance with all requirements of:

1. 907 KAR 1:671; and
2. 907 KAR 1:672;

(c) Is in good standing with the appropriate licensure board and CMS; and

(d) Has the legal authority to write an order for a medically necessary item of MSEA[durable medical equipment, a medical supply, a prosthetic, or an orthotic] for a recipient.

(21) "Prior authorization" means approval that a supplier shall obtain from the department before being reimbursed.

(22) "Prosthetic" means an item that replaces all or part of the function of a body part or organ.

(23) "Reasonableness" means:

(a) The expense of the item does not exceed the therapeutic benefits that could ordinarily be derived from use of the item;

(b) The item is not substantially more costly than a medically-appropriate alternative; and

(c) The item does not serve the same purpose as an item already available to the recipient.

(24) "Supplier" means a Medicare-certified provider of MSEA[~~durable medical equipment, medical supplies, prosthetics, or orthotics~~] who is enrolled in the Kentucky Medicaid Program.

(25) "Usual and customary charge" means the uniform amount that a supplier bills to the general public for a specific covered benefit.

Section 2. General Coverage.

(1) Except as provided in subsection (2) of this section, coverage for an item of MSEA[~~durable medical equipment, a medical supply, a prosthetic, or an orthotic~~] shall:

(a) Be based on medical necessity and reasonableness;

(b) Be clinically appropriate pursuant to the criteria established in 907 KAR 3:130;

(c) Require prior authorization in accordance with Section 7 of this administrative regulation;

(d) Be provided in compliance with 42 C.F.R. 440.230(c); and

(e) Be restricted to an item used primarily in the home and community.

(2)

(a) Except as provided in paragraph (b) of this subsection, the criteria referenced in subsection (1) of this section that was in effect on the date the MSEA[~~durable medical equipment, prosthetic, orthotic, or medical supply~~] is provided shall be used as the basis for the determination of coverage, subject to medical necessity override by the department to ensure compliance with 42 C.F.R. 440.230(c).

(b) If criteria referenced in subsection (1) of this section does not exist or is unavailable for a given item or service, the Medicare criteria in effect on the date the MSEA[~~durable medical equipment, prosthetic, orthotic, or medical supply~~] is provided shall be used as the basis for the determination of coverage, subject to medical necessity override by the department to ensure compliance with 42 C.F.R. 440.230(c).

(3) [~~Unless specifically exempted by the department, a DME item, medical supply, prosthetic, or orthotic shall require a CMN that shall be kept on file by the supplier for the period of time mandated by 45 C.F.R. 164.316.~~]

[~~(4)~~] An item [~~for which a CMN is not required ~~]shall require a prescriber's written order.

(4) [~~(5)~~] [~~If Medicare is the primary payor for a recipient who is dually eligible for both Medicare and Medicaid, the supplier shall comply with Medicare's CMN requirement and a separate Medicaid CMN shall not be required.~~]

[~~(6)~~] [~~A required CMN shall be:~~]

[~~(a)~~] [~~The appropriate Medicare CMN in use at the time the item or service is prescribed;~~]

[~~(b)~~] [~~A MAP-1000, Certificate of Medical Necessity, Durable Medical Equipment; or~~]

[~~(c)~~] [~~A MAP-1000B, Certificate of Medical Necessity, Metabolic Formulas and Foods.~~]

[~~(7)~~] [~~A CMN shall contain:~~]

[~~(a)~~] [~~The recipient's name and address;~~]

[~~(b)~~] [~~A complete description of the item or service ordered;~~]

[~~(c)~~] [~~The recipient's diagnosis;~~]

[~~(d)~~] [~~The expected start date of the order;~~]

[~~(e)~~] [~~The length of the recipient's need for the item;~~]

[~~(f)~~] [~~The medical necessity for the item;~~]

[~~(g)~~] [~~The prescriber's name, address, telephone number, and National Provider Identifier (NPI), if applicable; and~~]

[~~(h)~~] [~~The prescriber's signature and date of signature.~~]

[~~(8)~~] Except as specified in subsections (5)[~~(9)~~] and (6)[~~(10)~~] of this section, a prescriber shall examine a recipient within sixty (60) calendar days prior to the initial order of a MSEA[~~DME item, medical supply, prosthetic, or orthotic~~].

(5) [~~(9)~~] [~~Except as specified in subsection (11) of this section,~~] A prescriber shall not be required to examine a recipient prior to subsequent orders for the same MSEA[~~DME~~] item[~~, medical supply, prosthetic, or orthotic~~] unless there is a change in the order.

(6) [~~(10)~~] A prescriber shall not be required to examine a recipient prior to the repair of MSEA [~~a DME item, prosthetic, or orthotic~~].

(7) [~~(11)~~] [~~A change in supplier shall require a new CMN signed and dated by a prescriber who shall have seen the recipient within sixty (60) calendar days prior to the order.~~]

[~~(12)~~] [~~A CMN shall be updated with each request for prior authorization.~~]

[~~(13)~~] The department shall only purchase a new MSEA[~~DME~~] item.

(8) [~~(14)~~] A new MSEA[~~DME~~] item that is placed with a recipient initially as a rental item shall be considered a new item by the department at the time of purchase.

(9) [~~(15)~~] A used MSEA[~~DME~~] item that is placed with a recipient initially as a rental item shall be replaced by the supplier with a new item prior to purchase by the department.

(10) [~~(16)~~] A supplier shall not bill Medicaid for the MSEA[~~a DME item, medical supply, prosthetic, or orthotic~~] before the item is provided to the recipient.

(11) [~~(17)~~] A supplier shall not ship supplies to a recipient unless the supplier has:

(a) First had direct contact with the recipient,[~~or ~~]the recipient's caregiver, or an authorized representative, such as a case manager for a 1915(c) waiver participant; and

(b) Verified:

1. That the recipient wishes to receive the shipment of supplies;
2. The quantity of supplies in the shipment; and
3. Whether or not there has been a change in the use of the supply.

(12) ~~[(18)]~~ A verification referenced in subsection (11)~~[(17)]~~ of this section for each recipient shall be documented in a file regarding the recipient.

(13) ~~[(19)]~~ If a supplier ships more than a one (1) month supply of an item, the supplier shall assume the financial risk of nonpayment if the recipient's Medicaid eligibility lapses or a HCPCS code is discontinued.

(14) ~~[(20)]~~ A supplier shall have an order from a prescriber before dispensing any MSEA~~[DMEPOS]~~ item to a recipient.

(15) ~~[(21)]~~ A supplier shall have a written order on file prior to submitting a claim for reimbursement.

Section 3. Purchase or Rental of Medical Supplies, Equipment, and Appliances~~[Durable Medical Equipment]~~.

(1) Except as established on the Medicaid Program MSEA~~[DME]~~ Fee Schedule, MSEA~~[durable medical equipment]~~ shall be covered through purchase or rental based upon anticipated duration of medical necessity.

(2)

(a) A MAP 1001 form shall be completed if a recipient requests an item or service not covered by the department.

(b) A recipient shall be financially responsible for an item or service requested by the recipient via a MAP 1001 that is not covered by the department.

(c) A MAP 1001 shall be completed as follows:

1. The MSEA~~[DME]~~ supplier shall ensure that the recipient or authorized representative reads and understands the MAP 1001;
2. The recipient or authorized representative shall indicate on the MAP 1001 if the recipient chooses to receive a noncovered service;
3. The MSEA~~[DME]~~ supplier shall complete the supplier information on the MAP 1001;
4. The MSEA~~[DME]~~ supplier shall provide a copy of the completed MAP 1001 to the recipient; and
5. The MSEA~~[DME]~~ supplier shall maintain the completed MAP 1001 on file for at least the period of time mandated by 45 C.F.R. 164.316.

(d) If an item or service was denied due to the supplier not meeting the timeframes to obtain a prior authorization or the item or service does not meet medical necessity for a prior authorization, the MAP 1001 shall not be used to obligate the recipient for payment.

Section 4. Special Coverage.

(1) An augmentative communication device or other electronic speech aid shall be covered for a recipient who is permanently unable to communicate through oral speech if:

(a) Medical necessity is established based on a review by the department of an evaluation and recommendation submitted by a speech-language pathologist; and

(b) The item is prior authorized by the department.

(2) A customized MSEA~~[DME]~~ item shall be covered only if a noncustomized medically appropriate equivalent is not commercially available.

(3) A physical therapy or occupational therapy evaluation shall be required for:

(a) A power wheelchair; or

(b) A wheelchair for a recipient who, due to a medical condition, is unable to be reasonably accommodated by a standard wheelchair.

(4) Orthopedic shoes and attachments shall be covered if medically necessary for:

(a) A congenital defect or deformity;

(b) A deformity due to injury; or

(c) Use as a brace attachment.

(5) A therapeutic shoe or boot shall be covered if medically necessary to treat a nonhealing wound, ulcer, or lesion of the foot.

(6) An enteral or oral nutritional supplement shall be covered if:

(a) The item is prescribed by a licensed prescriber;

(b) Except for an amino acid modified preparation or a low-protein modified food product specified in subsection (7) of this section, it is the total source of a recipient's daily intake of nutrients;

(c) The item is prior authorized;~~[and]~~

(d) Nutritional intake is documented on the medical record; and~~[on the CMN]~~

(e) The Women, Infants and Children's Program (WIC) is unable to provide coverage of a formula. A letter from WIC shall be obtained and submitted with a prior authorization request.

(7) An amino acid modified preparation or a low-protein modified food product shall be covered:

(a) If prescribed for the treatment of an inherited metabolic condition specified in KRS 205.560(1)(c);

(b) If not covered through the Medicaid outpatient pharmacy program;

(c) Regardless of whether it is the sole source of nutrition; and

(d) If the item is prior authorized.

(8) An MSEA ~~[A DME]~~ item intended to be used for postdischarge rehabilitation in the home may be delivered to a hospitalized recipient within two (2) calendar days prior to discharge home for the purpose of rehabilitative

training.

(9) An electric breast pump shall be covered:

(a)

1. Within six (6) weeks prior to birth; or
2. Within six (6) weeks after birth; and

(b) For up to one replacement per child. ~~[for the following:]~~

~~[(a)] [Medical separation of mother and infant;]~~

~~[(b)] [Inability of an infant to nurse normally due to a significant feeding problem; or]~~

~~[(c)] [An illness or injury that interferes with effective breast feeding.]~~

(10) Rental of an airway clearance vest system for a three (3) month trial period shall be required before purchase of the equipment.

(11) Non-sole source nutrition:

(a) Shall be provided for a twelve (12) month period; and

(b)

1. For adults, shall be medically necessary; or
2. For children, services shall be determined by assessing the child via a growth chart as measured by height and weight. The following criteria shall be utilized, a child that is:

a. Below the 50th percentile shall meet the guidelines for receiving non-sole source nutrition;

b. Above the 50th percentile, but has a valid diagnosis to support the request, shall meet the guidelines for receiving non-sole source nutrition. For example, disorders of significant mental or physical health including trauma, significant weight loss, chronic illness, or cancers; and

c. Above the 50th percentile and without a supporting diagnosis shall be referred to the medical director who may approve non-sole source nutrition services.

Section 5. Coverage of Repairs and Replacement of Equipment.

(1) The department shall not be responsible for repair or replacement of the MSEA~~[a DME item, prosthetic, or orthotic]~~ if the repair or replacement is covered by a warranty.

(2) Reasonable repair to a purchased MSEA~~[DME item, prosthetic, or orthotic]~~ shall be covered:

(a) During a period of medical need;

(b) If necessary to make the item serviceable;

(c) If a warranty is not in effect on the requested repair; and

(d) In accordance with Section 6(3) of this administrative regulation.

(3) Extensive maintenance to purchased equipment, as recommended by the manufacturer and performed by an authorized technician, shall be considered to be a repair.

(4) The replacement of a medically necessary MSEA~~[DME item, medical supply, prosthetic, or orthotic]~~ shall be covered for the following:

(a) Loss of the item;

(b) Irreparable damage or wear; or

(c) A change in a recipient's condition that requires a change in equipment.

(5) Suspected malicious damage, culpable neglect, or wrongful disposition of MSEA~~[a DME item, medical supply, prosthetic, or orthotic]~~ shall be reported by the supplier to the department if the supplier is requesting prior authorization for replacement of the item.

Section 6. Limitations on Coverage.

(1) The following items shall be excluded from Medicaid coverage through the MSEA~~[DME]~~ program:

(a) An item covered for Medicaid payment through another Medicaid program;

(b) Equipment that is not primarily and customarily used for a medical purpose;

(c) Physical fitness equipment;

(d) Equipment used primarily for the convenience of the recipient or caregiver;

(e) A home modification;

(f) Routine maintenance of MSEA~~[DME]~~ that includes:

1. Testing;
2. Cleaning;
3. Regulating; and
4. Assessing the recipient's equipment;

(g) Except as specified in Section 7(1)(j) of this administrative regulation, backup equipment; or

(h) An item determined not medically necessary, clinically appropriate, or reasonable by the department.

(2) Except if Medicare is the primary payer, the following diabetic supplies (HCPCS codes) shall be covered as a pharmacy benefit at the point of sale:

(a) A4206, a syringe with needle (sterile, 1cc or less);

(b) A4250, urine test or reagent strips or tablets;

(c) A4252, blood ketone test or reagent strip;

(d) A4253, blood glucose test or reagent strips;

(e) A4256, calibrating solutions;

(f) A4258, lancet device;

(g) A4259, lancets; or

(h) E0607, home blood glucose monitor.

(3) An estimated repair shall not be covered if the repair cost equals or exceeds:

(a) The purchase price of a replacement item; or

(b) The total reimbursement amount for renting a replacement item of equipment for the estimated remaining period of medical need.

(4) MSEA ~~[Durable medical equipment, prosthetics, orthotics, and medical supplies]~~ shall be included in the facility reimbursement for a recipient residing in a hospital, nursing facility, or intermediate care facility or institution for individuals with an intellectual or developmental disability.

Section 7. Prior Authorization Requirements and Process.

(1) Prior authorization shall be required for the following:

(a) An item or repair billed to the department at $500 or more;

(b) Rental of equipment as indicated on the Medicaid Program MSEA~~[DME]~~ Fee Schedule excluding oxygen services after twelve (12) ~~[continuous]~~months of service;

(c) Orthopedic shoes;

(d) An adjustment to a prosthetic or orthotic;

(e) An augmentative communication device;

(f) A customized MSEA~~[DME]~~ item;

(g) A replacement MSEA~~[DME item, prosthetic, or orthotic]~~ if replacement is prior to the:

1. Usual and customary lifetime of the item; or

2. Limitation set by the department as indicated in the Medicaid Program MSEA~~[DME]~~ Fee Schedule;

(h) A nutritional supplement;

(i) An amino acid modified preparation or a low-protein modified food product;

(j)

1. A loaner item for a member-owned piece of equipment that is being repaired; and

2. Any loaner item for a member-owned piece of equipment shall be the equivalent or better of the item that is being repaired;

(k) A MSEA~~[DMEPOS]~~ item denoted by a general or nonspecific HCPCS code;

(l) An item designated on the Medicaid Program MSEA~~[DME]~~ Fee Schedule as requiring prior authorization;

(m) An item that exceeds the quantity limitation established in the Medicaid Program MSEA~~[DME]~~ Fee Schedule; or

(n) An item designated by an HCPCS code not indicated on the Medicaid Program MSEA~~[DME]~~ Fee Schedule that is determined by the department to be a covered benefit.

(2)

(a) If an item requires prior authorization, a supplier shall:

1.

a. Submit all required documentation prior to the date of service; or

b. Within one (1) year from the date of service with department approval; and

2. Submit a written request to the department for prior authorization, which shall include the prescriber's order~~[; and]~~

~~[3.] [Submit a completed CMN to the department within ninety (90) business days of the date of the request for prior authorization]~~.

(b) If the required prior authorization submittals required by paragraph (a) of this subsection are not submitted within the established time frames, the prior authorization request shall be denied.

(3) If an item requires an evaluation or recommendation by a specialist, the evaluation or recommendation shall be in writing and submitted with a prior authorization~~[with the CMN]~~.

(4) The supplier shall not bill a recipient for the MSEA~~[a DME item, medical supply, prosthetic, or orthotic]~~ if the supplier has not completed the prior authorization process within the timeframe specified in subsection (2) of this section.

(5) If a supplier provides an item that requires prior authorization before the prior authorization is received, the supplier shall assume the financial risk that the prior authorization might not be subsequently approved.

(6) ~~[A supplier may initially obtain a faxed CMN from a prescriber to expedite the prior authorization process, but a signed, original CMN subsequently shall be required.]~~

~~[(7)]~~ A supplier shall request prior authorization by mailing, faxing, or electronically submitting the following information to the department:

(a) A completed prior authorization form MAP-9; and

(b) ~~[A completed CMN; and]~~

~~[(c)]~~ If requested by the department, additional information required to establish medical necessity, clinical appropriateness, or reasonableness.

(7) ~~[(8)]~~ The following additional information shall be required for prior authorization of a customized item:

(a) ~~[An estimate of the fitting time;]~~

~~[(b)]~~ ~~[An estimate of the fabrication time;]~~

~~[(c)]~~ A description of the materials used in customizing the item; and

(b) ~~[(d)]~~ An itemized estimate of the cost of the item, including the cost of labor.

(8) ~~[(9)]~~ The following additional information shall be required for prior authorization of a repair to purchased equipment:

(a) A description of the nature of the repair;

(b) An itemization of the parts required for the repair;

(c) An itemization of the labor time involved in the repair; and

(d) A copy of the manufacturer's warranty indicating the purchase date or a written notice from the MSEA~~[DME]~~ supplier stating that the requested repair is not covered by the warranty.

(9) ~~[(10)]~~ An item shall be prior authorized based on:

(a) Medical necessity and the corresponding prior-authorized period of medical necessity; and

(b)

1. Clinical appropriateness pursuant to the criteria established in 907 KAR 3:130; or

2. Medicare criteria if the criteria referenced in subparagraph 1. of this paragraph does not exist or is unavailable.

(10) ~~[(11)]~~ A prior authorization period shall be extended as indicated by~~[upon the provision of a new CMN indicating current medical necessity and]~~:

(a) Clinical appropriateness pursuant to the criteria established in 907 KAR 3:130; or

(b) Medicare criteria if the criteria referenced in paragraph (a) of this subsection does not exist or is unavailable.

(11) ~~[(12)]~~

(a) Prior authorization by the department shall not:

1. Be a guarantee of recipient eligibility; or

2. Guarantee reimbursement.

(b) Eligibility verification shall be the responsibility of the supplier.

(12) ~~[(13)]~~ Upon review and determination by the department that removing prior authorization shall be in the best interest of Medicaid recipients, the prior authorization requirement for a specific covered benefit shall be discontinued, at which time the covered benefit shall be available to all recipients without prior authorization.

(13) ~~[(14)]~~ If it is determined by the department to be in the best interest of Medicaid recipients, the department may designate that an item of MSEA~~[durable medical equipment]~~ suitable for use in the home or community may be provided, if prior authorized, to a recipient ~~[temporarily residing in a hospital that does not bill patients, Medicaid, or other third-party payers for any health care services]~~.

(14) ~~[(15)]~~

(a) For purposes of obtaining prior authorization, a signed invoice price quote from the manufacturer shall be acceptable documentation.

(b) If the invoice price differs from the manufacturer's invoice price quote, the supplier shall amend the prior authorization and shall maintain documentation of the quote and the invoice.

Section 8. Reimbursement for Covered Services.

(1) Except for an item specified in subsections (2) and (4)~~[(5)]~~ of this section, a new item that is purchased shall be reimbursed at the lesser of:

(a) The supplier's usual and customary charge for the item;

(b) The purchase price specified in the Medicaid Program MSEA~~[DME]~~ Fee Schedule; or

(c) If indicated in the Medicaid Program MSEA~~[DME]~~ Fee Schedule as manually priced, which shall be the manufacturer's suggested retail price minus eighteen (18) percent~~[invoice price plus twenty (20) percent]~~ for an item not utilizing a billing code.

(2) Pursuant to 45 C.F.R. 162.1002, the department shall recognize U.S. Department for Health and Human Services quarterly HCPCS code updates.

(a) An item denoted by an HCPCS code not currently on the Medicaid Program MSEA~~[DME]~~ Fee Schedule that has been determined by the department to be a covered service shall be manually priced, which shall be the manufacturer's suggested retail price minus eighteen (18) percent for an item not utilizing a billing code~~[using the actual invoice price plus twenty (20) percent]~~.

(b)

1. The department shall post HCPCS code change information on its Web site accessible at https://www.chfs.ky.gov/agencies/dms/Pages/feesrates.aspx~~[http://chfs.ky.gov/dms]~~.

2. The information may also be obtained by writing the Department for Medicaid Services at 275 East Main Street, Frankfort, Kentucky 40621.

~~[(3)] [If a copayment is required, copayment provisions, including any provider deduction, shall be as established in 907 KAR 1:604.]~~

(3) ~~[(4)]~~ For a service covered under Medicare Part B, reimbursement shall be in accordance with 907 KAR 1:006.

(4) ~~[(5)]~~ Reimbursement for the purchase of an item that has been rented for ~~[less than]~~ten (10) months shall be the purchase price specified in subsection (1) of this section minus the cumulative rental payment made to the supplier.

(5) ~~[(6)]~~ A rental item shall be reimbursed as follows, but reimbursement shall not exceed the supplier's usual and customary charge for the item:

(a) The rental price specified in the Medicaid Program MSEA~~[DME]~~ Fee Schedule; or

(b) If indicated in the Medicaid Program MSEA[DME] Fee Schedule as manually priced:

1. Ten (10) percent of the purchase price per month for the monthly rental of an item; or

2. Two and one-half (2.5) percent of the purchase price per week for the weekly rental of an item that is needed for less than one (1) month.

(6)

(a) [(7)] If reimbursement for a rental item has been made for a period of ten (10) [consecutive]months by the same provider within a two (2) year period, the item shall be considered to be purchased and shall become the property of the recipient.[,]

(b) A provider may demonstrate that a break in service or need for a rental item has occurred due to hospitalization during the two (2) year period. In the event of a successful demonstration, reimbursement shall be provided for each demonstrated month that a break in need occurred until a cumulative ten (10) month period has been reached.

(7) [(8)] Labor costs for a repair shall be billed in quarter hour increments using the HCPCS codes for labor specified in the Medicaid Program MSEA[DME] Fee Schedule and shall be reimbursed the lessor of:

(a) The supplier's usual and customary charge; or

(b) The reimbursement rate specified in the Medicaid Program MSEA[DME] Fee Schedule.

(8) [(9)] Reimbursement shall include instruction and training provided to the recipient by the supplier.

(9) [(10)] The rental price of an item shall include rental of the item and the cost of:

(a) Shipping and handling;

(b) Delivery and pickup;

(c) Setup;

(d) Routine maintenance; and

(e) Essential medical supplies required for proper use of the equipment.

(10) [(11)] The purchase price of a prosthetic or orthotic shall include:

(a) Acquisition cost and applicable design and construction;

(b) Required visits with a prosthetist,[or]orthotist, or other appropriate MSEA provider for fitting prior to receipt of the item;

(c) Proper fitting and adjustment of the item for a period of one (1) year;

(d) Required modification, if not a result of physical growth or excessive change in stump size, for a period of one (1) year; and

(e) A warranty covering defects in material and workmanship.

Section 9. Conditions for Provider Participation. A participating MSEA[DME] provider shall:

(1) Have an active Medicare MSEA[DME] provider number;

(2) Adhere to all CMS supplier standards in accordance with 42 C.F.R. 424.57;

(3)

(a) Provide proof of Medicare accreditation, by an approved Medicare accreditation entity, to the department every three (3) years unless exempt from Medicare accreditation by CMS; or

(b) If exempt from Medicare accreditation by CMS, provide a letter to the department on company letterhead that indicates the CMS exemption status;

(4) Be enrolled in the Kentucky Medicaid Program in accordance with:

(a) 907 KAR 1:671; and

(b) 907 KAR 1:672;

(5) Comply with the requirements regarding the confidentiality of personal medical records pursuant to 42 U.S.C. 1320d and 45 C.F.R. Parts 160 and 164; and

(6) Comply with the following:

(a) A supplier shall bill Medicaid rather than a recipient for a covered service;

(b) A supplier shall not bill a recipient for a service that is denied by the department on the basis that the service is incidental to, or mutually exclusive with, a covered service; and

(c) A supplier may bill a recipient for a service not covered by Medicaid if the provider informed the recipient of noncoverage prior to providing the service and a completed MAP 1001 form is signed and included in the medical record.

Section 10. Managed Care Organizations and Reimbursement. A managed care organization shall not be required to reimburse the same amount as the department reimburses for a service or item covered pursuant to this administrative regulation, except as otherwise required by applicable law, such as any reimbursement required pursuant to KRS 205.6333.

Section 11. Federal Approval and Federal Financial Participation. The department's coverage and reimbursement for services pursuant to this administrative regulation shall be contingent upon:

(1) Receipt of federal financial participation for the coverage and reimbursement; and

(2) Centers for Medicare and Medicaid Services' approval for the coverage and re-imbursement.

Section 12. Appeal Rights.

(1) If an individual is denied prior authorization for MSEA[DMEPOS] based upon an application of this administrative regulation, the MSEA[DME] supplier involved in the prior authorization request may appeal the

denial. To appeal the denial, the MSEA~~[DME]~~ supplier shall submit to the department, within thirty (30) calendar days of the prior authorization denial, a written request, by mail or fax, for a reconsideration review.

(2) Upon receipt of a reconsideration request and any supporting documentation, the department shall:

(a) Conduct a reconsideration review within thirty (30) calendar days from the receipt of the request;

(b) Base the reconsideration review decision solely upon information that is:

1. Contained in the individual's medical records; and
2. Submitted with the written request pursuant to subsection (1) of this section; and

(c) Issue a notification of approval or denial within five (5) working days of a reconsideration review.

(3) If an outcome of a services reconsideration review results in a denial, the department shall grant an appeal.

(4) An appeal of a department decision regarding a Medicaid recipient who is:

(a) Enrolled with a managed care organization shall be in accordance with 907 KAR 17:010; or

(b) Not enrolled with a managed care organization shall be in accordance with 907 KAR 1:563.

(5) An appeal of a department decision regarding a Medicaid provider based upon an application of this administrative regulation shall be in accordance with 907 KAR 1:671.

Section 13. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) Form MAP-9, "Prior Authorization for Health Services", July 2010;

(b) ~~[Form MAP-1000, "Certificate of Medical Necessity, Durable Medical Equipment", July 2010;]~~

~~[(c)]~~ ~~[Form MAP-1000B, "Certificate of Medical Necessity, Metabolic Formulas and Foods", July 2010 edition; and]~~

~~[(d)]~~ Form MAP 1001, "Advance Member Notice", September 2006.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law:

(a) At the Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.; or

(b) Online at the department's Web site at https://www.chfs.ky.gov/agencies/dms/dpo/bpb/Pages/dme.aspx~~[http://www.chfs.ky.gov/dms/incorporated.htm]~~.

LISA D. LEE, Commissioner
ERIC C. FRIEDLANDER, Secretary

FILED WITH LRC: January 11, 2024 at 2:25 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on March 25, 2024, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by March 18, 2024, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until March 31, 2024. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Specialist, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-7476; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This administrative regulation establishes the provisions relating to coverage and reimbursement requirements for durable medical supplies, equipment, and orthotics.

(b) The necessity of this administrative regulation:
This administrative regulation is necessary to establish the provisions relating to coverage and reimbursement requirements for medical supplies, equipment, and appliances.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
This administrative regulation conforms with 42 C.F.R. part 414 by establishing provisions relating to coverage and reimbursement requirements for durable medical supplies, equipment, and appliances.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This administrative regulation will assist in the effective administration of the authorizing statutes by establishing the provisions relating to coverage and reimbursement requirements for medical supplies, equipment, and appliances.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:
The amendment changes the administrative regulation by updating reimbursement rates for rental items and makes updates to the rates of reimbursement for covered services. This amendment updates terminology related to medical supplies, equipment, and appliances. Furthermore, the date of service is expanded to include reimbursement for custom items. In addition, home is expanded to include the community. Additionally, the requirement of and references to a Certificate of Medical Necessity have been removed. Language related to electric breast pumps has been updated to match modern benefits. The requirement of a copayment has also been removed. Additionally, new language has been added related to the requirements for non-sole source nutrition.

(b) The necessity of the amendment to this administrative regulation:
The amendment is necessary to update the reimbursement rates and to update language associated with durable medical supplies, equipment, and appliances.

(c) How the amendment conforms to the content of the authorizing statutes:
The amendment conforms to the content of the authorizing statutes by updating the reimbursement rates and to update language associated with durable medical supplies, equipment, and appliances.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment conforms to the content of the authorizing statutes by updating the reimbursement rates and to update language associated with durable medical supplies, equipment, and appliances.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
The administrative regulation affects DME providers enrolled in the Medicaid program. DMS estimates that more than 2,900 MSEA providers are enrolled in the Medicaid program.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:
MSEA providers will not be required to take any new action to comply.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):
DMS does not anticipate any expenses for this population.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):
MSEA providers will be able to receive higher reimbursements for certain MSEA and will be able to provide some MSEA with lessened regulatory burden.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

DMS does not anticipate additional costs on an initial basis in implementing the amendments to this administrative regulation.

(b) On a continuing basis:

DMS does not anticipate additional costs on a continuing basis in implementing the amendments to this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

Sources of funding to be used for the implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX and Title XXI of the Social Security Act and state matching funds of general and agency appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

Neither an increase in fees nor funding will be necessary to implement the amendments.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

The amendment does not establish or increase any fees.

(9) TIERING: Is tiering applied?

Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.
42 C.F.R. 440.230.

(2) State compliance standards.
KRS 194A.030(2) requires the Department for Medicaid Services to "serve as the single state agency in the commonwealth to administer Title XIX of the Federal Social Security Act."

(3) Minimum or uniform standards contained in the federal mandate.
The Department for Medicaid Services is required to provide MSEA as a Medicaid benefit.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?
The amendment will not impose stricter than federal requirements.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.
The amendment will not impose stricter than federal requirements.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

The Department for Medicaid Services (DMS) will be affected by the amendment to this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 194A.030(2), 194A.050(1), 205.520(3)

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

DMS does not expect the amendment to this administrative regulation to generate revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

DMS does not expect the amendment to this administrative regulation to generate revenue for state or local government.

(c) How much will it cost to administer this program for the first year?

DMS does not anticipate additional costs in administering this program in the first year.

(d) How much will it cost to administer this program for subsequent years?

DMS does not anticipate additional costs in administering this program in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

DMS does not anticipate that cost savings will be generated for regulated entities as a result of the amendments to this administrative regulation in the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

DMS does not anticipate that cost savings will be generated for regulated entities as a result of the amendments to this administrative regulation in subsequent years.

(c) How much will it cost the regulated entities for the first year?

DMS does not anticipate that regulated entities will incur costs as a result of this amendment in the first year.

(d) How much will it cost the regulated entities for subsequent years?

DMS does not anticipate that regulated entities will incur costs as a result of this amendment in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]. The

administrative regulation will not have a major economic impact as defined by KRS 13A.010 on regulated entities.