5160-10-01 **Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions.**

(A) This rule sets forth general coverage and payment policies for durable medical equipment (DME), prostheses, orthotic devices, medical/surgical supplies, and supplier services. Policies set forth in other rules in this chapter of the Administrative Code supersede any provisions in this rule with which they conflict.

(B) Definitions that apply to rules in this chapter of the Administrative Code.

(1) "Certificate of medical necessity (CMN)" is a written statement by a practitioner attesting that a particular item or service is medically necessary for an individual.

(a) Unless a separate prescription is required, a CMN may serve also as a prescription for medicaid payment purposes.

(b) If no other form or format is specified, the CMN form specified in the relevant rule in this chapter of the Administrative Code is the default that must be used.

(c) A rendering or billing provider must obtain a required CMN before a claim can be submitted.

(d) A CMN is not invalidated by a change in an individual's status from one medicaid eligibility category to another (e.g., from fee-for-service medicaid to medicaid managed care).

(e) Renewal of lifetime certification is not required.

(f) An illegible CMN will not be accepted.

(2) "Department" is the Ohio department of medicaid or its designee. The address of the department's web site is http://medicaid.ohio.gov.

(3) "DMEPOS item" is a collective term for a covered durable medical equipment (DME) item, prosthetic device, orthotic device, or medical supply item furnished by an eligible provider to an eligible recipient.

(4) "DMEPOS service" is a covered service, such as labor for repair or replacement, that is furnished by an eligible provider and is related directly to a DMEPOS item.

(5) "Invoice price" is the price printed on the invoice sent by the manufacturer to the provider. The provider must not enter, modify, obscure, or obliterate the invoice

price on any supporting document submitted to the department. Documentation of an invoice price is subject to approval by the department.

(6) "List price" is the most current price recommended by the manufacturer for retail sale. A provider that is also a manufacturer may set the list price for a custom product so long as this figure is not greater than the prices of comparable products. The provider must not enter, modify, obscure, or obliterate the list price on any supporting document submitted to the department. Documentation of a list price is subject to approval by the department.

(7) "Need verification" is a process by which the department determines whether to make payment for a DMEPOS item or service that exceeds the established cost threshold or frequency guideline. Because need verification is applied only to items or services for which medical necessity has been established or presumed, no extensive or in-depth clinical assessment is necessary (as it is with prior authorization). One purpose of need verification is to enable the department to consider whether the purchase of a new piece of equipment might be more cost-effective than continued repair.

(8) "Private residence" is a recipient's place of residence other than a hospital or a long-term care facility (LTCF).

(C) Providers.

(1) Prescribers. Eligible medicaid providers of the following types having prescriptive authority under Ohio law may certify the medical necessity of a DMEPOS item:

(a) A physician;

(b) A podiatrist;

(c) An advanced practice registered nurse with a relevant specialty (e.g., clinical nurse specialist, certified nurse practitioner); or

(d) A physician assistant.

(2) Rendering providers. The following eligible providers may furnish a DMEPOS item or service:

(a) For equipment considered by the state of Ohio board of pharmacy to be subject to licensure or certification in accordance with Chapter 4752. of the Revised Code or the rules promulgated under it, a provider enrolled in medicaid as a DME supplier with specialized state of Ohio board of pharmacy certification or licensure;

(b) For orthotic or prosthetic devices requiring compliance with section 4779.02 of the Revised Code, a provider enrolled in medicaid as a DME supplier with orthotic/prosthetic specification; or

(c) For all other items and services, a provider enrolled as a basic DME supplier.

(3) Billing providers. The following eligible providers may receive medicaid payment for submitting a claim for a DMEPOS item or service:

(a) For equipment considered by the state of Ohio board of pharmacy to be subject to licensure or certification in accordance with Chapter 4752. of the Revised Code or the rules promulgated under it, a provider enrolled in medicaid as a DME supplier with specialized state of Ohio board of pharmacy certification or licensure;

(b) For orthotic or prosthetic devices requiring compliance with section 4779.02 of the Revised Code, a provider enrolled in medicaid as a DME supplier with orthotic/prosthetic specification; or

(c) For all other items and services, a provider enrolled as a basic DME supplier.

(4) Additional provider requirements specific to a particular DMEPOS item or service may be set forth in other rules in this chapter of the Administrative Code.

(D) Coverage.

(1) In most cases, the provision of or payment for a medically necessary DME item or medical supply for a resident of a LTCF is the responsibility of the LTCF. In turn, the LTCF receives medicaid per diem payment on the basis of its cost report. Therefore, claims submitted for such items or supplies furnished to LTCF residents will be denied. Any exceptions are set forth in other rules in this chapter of the Administrative Code.

(2) Separate payment may be made for a prosthesis or orthotic device supplied to a resident of a LTCF.

(3) The provision of a medically necessary DMEPOS item requires a prescription.

(a) Before writing a prescription for certain DMEPOS items, a practitioner must conduct a face-to-face encounter with the medicaid recipient. A list of such DMEPOS items may be found on the website of the centers for medicare and medicaid services (CMS) at http://www.cms.gov.

(b) The date of a prescription cannot precede the date of the related encounter nor can it be more than one hundred eighty days afterward.

(c) The encounter must be documented in the recipient's medical record.

(d) Unless a different length of time is specified, the date of a prescription cannot precede the first date of service by more than sixty days.

(e) The medical practitioner acting as prescriber must be actively involved in managing the recipient's medical care. The department may disallow a prescription written by a practitioner who has no professional relationship with the recipient.

(f) The prescribed DMEPOS item must be directly related to a medical condition of the recipient that the practitioner evaluates, assesses, or actively treats during the encounter.

(g) With proper documentation, a single encounter can serve as the basis for more than one prescription.

(h) No additional face-to-face encounter is necessary for a separate DMEPOS item if an encounter conducted within the preceding twelve months addresses the medical condition for which the DMEPOS item is being prescribed.

(i) Each prescription must specify a quantity (e.g., "TID," "thirty per month"). An unstated quantity is assumed to be one unit.

(4) Certain DMEPOS items require prior authorization (PA). A list of such items is posted on the department's web site.

(a) The following DMEPOS items always require PA:

(i) A custom or a specialized DMEPOS item;

(ii) A "not otherwise specified," "miscellaneous," or "unlisted" item or service; and

(iii) Used DME.

(b) When PA is given, it may specify a quantity, manufacturer, model, part number, or other information identifying a particular item. When such identifying information is present, a provider may supply and subsequently submit claims for the specified items only. No changes

or substitutions are allowed without explicit authorization by the department.

(c) The department, on the basis of clinical indications, may grant PA for an item other than one that has been requested.

(d) For items requiring PA, the provider must submit the following documentation:

(i) A certification, signed and dated not more than sixty days before the first date of service, in the form of a fully completed CMN or, if the need for a CMN is not specified, a prescription;

(ii) Pertinent related information, such as a full description of any similar item currently in possession of the recipient or an explanation of a change in the recipient's condition that warrants a change in equipment;

(iii) For a "not otherwise specified," "miscellaneous," or "unlisted" item, a complete description of the item (including, as applicable, the manufacturer, model or style, and size), a list of all bundled components, and an itemization of all charges; and

(iv) Any other information required or requested by the department, as detailed in this chapter of the Administrative Code.

(e) A request for PA of a preparatory prosthesis must include the reason for the amputation, the date of the amputation, and an explanation of the benefit to be derived from having the recipient use a preparatory prosthesis before a definitive prosthesis is designed.

(f) A claim for an item or service that exceeds the specified maximum quantity or frequency but does not otherwise require PA may be subject to need verification before payment will be considered.

(g) A request for PA or need verification may be denied in cases involving malicious damage, neglect, culpable irresponsibility, or wrongful disposition.

(5) For items not requiring PA, the provider must keep on file a certification, signed and dated not more than sixty days before the first date of service, in the form of a fully completed CMN or, if the need for a CMN is not specified, a prescription.

(6) For an item that is shipped directly to a recipient, the shipping date is the dispensing date.

(7) For an item that requires multiple fittings and special construction, the first date of service is the dispensing date.

(8) If a recipient dies after measurements for a prescribed custom item have been taken but before the item has been dispensed, then payment for the item may be made under the following conditions:

(a) The code set description for the item indicates that it is designed or intended for a specific individual;

(b) The item is substantially complete and cannot be modified for use by another individual;

(c) No information available to the provider indicated that the death of the recipient was imminent;

(d) The provider can document the date of measurement; and

(e) On the claim, the provider reports the date of measurement as the date of service.

(9) Any request for a DMEPOS item or service must originate with an individual recipient, the recipient's authorized representative, or a medical practitioner acting as prescriber and must be made with the recipient's full knowledge and consent.

(10) A request that is determined by the department to have resulted from a mass screening or examination will be denied.

(11) When instruction must be given in the safe and appropriate use of a particular DMEPOS item, it is the responsibility of the provider to ensure that the recipient or someone authorized to assist the recipient has received such instruction.

(12) Payment for repair of a DME item, prosthetic device, or orthotic device or for purchase of a related medical supply item or service can be made only if the medical necessity of the DME item, prosthetic device, or orthotic device itself has been established. The medical necessity of an item purchased by the department is established during the purchasing process. For an item not purchased by the department, medical necessity may be documented on an appropriate medicaid certificate of medical necessity, on a prescription that addresses all specified criteria, or on any other form that is acceptable to the

department. No additional documentation of medical necessity is necessary for subsequent repairs made to an item. The determination that an item not purchased by the department is medically necessary does not indicate that the item would be authorized for purchase.

(13) Payment may be made for covered repair, maintenance, parts, accessories, or supplies for a DME item that is owned by an individual but has not been purchased by the department. Payment for the initial service or delivery requires PA; payment for subsequent service or deliveries does not require PA.

(14) Unless otherwise specified elsewhere in this chapter of the Administrative Code, for each claim submitted for payment, a provider must keep the following supporting documents on file:

(a) A completed CMN, if required;

(b) If no CMN is required, a legible prescription that specifies a diagnosis;

(c) Any other information, such as practitioner orders or chart notes, used to establish the medical necessity of the DMEPOS item;

(d) Any record indicating a change in an individual's needs or plan of care;

(e) Proof of delivery;

(f) Confirmation that the recipient or the recipient's authorized representative has been instructed in the safe use of the DMEPOS item, if applicable;

(g) A copy of the manufacturer's or dealer's warranty, if applicable; and

(h) A record of any repair or service that has been performed on equipment not paid for by medicaid, if applicable.

(15) The default CMN form for general DME items and supplies is the ODM 01913, "Certificate of Medical Necessity / Request for Need Verification: General Medical Supplies and Equipment" (rev. 7/2018).

(16) Proof is required to show that a DMEPOS item has been delivered to the intended recipient.

(a) Providers, their employees, and anyone else having a financial interest in the delivery of DMEPOS items are prohibited from accepting delivery of an item on behalf of a medicaid recipient.

(b) If a provider delivers directly to a recipient, then proof of delivery must include the signature of the recipient or the recipient's authorized representative. For a DMEPOS item delivered to a resident of a LTCF, the LTCF is responsible for furnishing proof of delivery.

(c) If a provider uses a third-party shipper, then acceptable proof of delivery includes the shipper's tracking slip or a returned postage-paid delivery invoice.

(d) If a signature obtained physically at the time of delivery is not legible, then the provider or shipper must record the name of the person accepting delivery and the relationship of the person to the recipient. If the provider or shipper records such information for a particular person and maintains it in a readily accessible format, then on subsequent deliveries only the signature is required.

(17) No unnecessary extra payment will be made for a DMEPOS item or service. If more than one DMEPOS item or service will meet a recipient's needs equally well, then the maximum payment amount may not exceed the lowest of the respective costs.

(18) No separate payment will be made under this chapter of the Administrative Code for the following items or services:

(a) Items presumed to be nonmedical in nature and for which no medical necessity can therefore be demonstrated, including but not limited to the following examples:

(i) Environmental control devices;

(ii) Items that have no medical benefit but are intended solely for the comfort or convenience of the user;

(iii) Physical fitness equipment;

(iv) Precautionary items (e.g., emergency alert systems);

(v) Training equipment (e.g., speech-teaching machines);

(vi) Communication aids, except as specified elsewhere in this chapter of the Administrative Code;

(vii) Educational aids; and

(viii) Hygiene equipment (e.g., bidets);

(b) Routine over-the-counter treatment supplies (e.g., adhesive bandages, antiseptic solutions, antibiotic ointments) and personal hygiene items (e.g., soap, diapers for children younger than three years of age);

(c) Medical supplies or DME items that are used during a visit with a medical practitioner (i.e., that are incident to a professional service) in the practitioner's office, in a clinic, or in the recipient's private residence;

(d) Items or services that are covered under manufacturer or dealer warranty;

(e) Items or services for which full remuneration is made through other payment mechanisms (e.g., diagnosis-related groups, per diem payments, workers' compensation, commercial insurance);

(f) Costs of delivery (including postage), setup and assembly, pickup, and routine cleaning and maintenance associated with a covered DME item;

(g) Labor, measuring, casting, fitting, travel by the supplier, and shipping or mailing associated with a covered orthotic device or prosthesis;

(h) Maintenance and repair of equipment during a rental period;

(i) Supporting wires, power supplies, cables, or attachment kits;

(j) Related supplies and accessories that are furnished either during a rental period or with the dispensing or delivery of a purchased equipment item and for which no payment amount exists for separate purchase or rental;

(k) A service call in addition to materials and labor;

(l) Repairs, adjustments, or modifications that are made within ninety days after delivery or during the total rental period, unless necessitated by major changes in the recipient's condition;

(m) Instruction of the recipient or the recipient's authorized representative in the safe use of an item; and

(n) Education, training, instruction, counseling, or monitoring conducted in support of an individual's ordered treatment plan.

(19) Payment is not available for DMEPOS items that duplicate or conflict with another item currently in the recipient's possession, regardless of payment or

supply source. Providers are responsible for ascertaining whether duplication or conflict exists.

(20) Certain DMEPOS items may be dispensed on a recurring basis. A provider must confirm a recipient's current need before the next delivery. If DMEPOS items are routinely delivered without necessary confirmation of need, then any payment for excess quantities is subject to recovery.

(21) No prescription for disposable items dispensed on a recurring basis (e.g., incontinence garments, wound dressings) can be renewed earlier than ninety days before the expiration of the current prescription.

(22) Most covered DME items are purchased and become the property of the recipient. Some covered DME items that require ongoing servicing are rented exclusively. Some covered DME items may be rented on a short-term basis, purchased, or rented and then purchased.

(a) The short-term rental of a covered DME item other than a wheelchair requires PA, which may be given if rental is determined to be more cost-effective than purchase.

(b) Unless a different length of time is specified elsewhere in this chapter of the Administrative Code, the initial rental period must not exceed six months.

(c) PA may be given for additional rental periods.

(d) Regardless of its authorized length, a rental period ends when the rented item is no longer medically necessary.

(e) A monthly rental payment secures the rented item for the entire calendar month.

(f) During a rental period and for ninety days afterward, all rental amounts paid apply toward purchase.

(g) The department reserves the right to determine whether an item will be rented or purchased.

(h) The provider must notify the recipient when an item in effect has been purchased through rental.

(23) Certain medical supply items (e.g., gauze pads, wound fillers/packing) are dispensed in bulk. No payment amount per unit has been established for such items; instead, an overall payment limit per period is specified. The charge

submitted by the provider must not exceed the manufacturer's suggested list price for the quantity of the item.

(24) The purchase of torsion cables may be authorized only for the treatment of children with neuromuscular diseases and related conditions. Requests for torsion cables to treat positional deformities will be denied because of anticipated resolution that occurs with maturation.

(25) No provider may submit a claim for a DMEPOS item or service before the item or service has been supplied.

(E) Claim payment.

(1) The payment amount specified in another rule in this chapter of the Administrative Code supersedes any payment amount established by provisions in this rule.

(2) For a covered DMEPOS item or service represented by a new healthcare common procedure coding system (HCPCS) procedure code that takes effect at the beginning of a calendar year, the initial maximum payment amount is established in accordance with rule 5160-1-60 of the Administrative Code.

(3) For any other covered DMEPOS item or service, the payment amount is the lesser of the submitted charge (which must reflect any discounts or rebates available to the provider at the time of claim submission but need not reflect subsequent discounts or rebates) or the first applicable medicaid maximum from the following ordered list:

(a) For a "by report" DMEPOS item or service, an amount determined on a case-by-case basis;

(b) For a supply item for which payment is determined by PA, whichever of the following two figures applies or the lesser of the two if both apply:

(i) Seventy-two per cent of the list price; or

(ii) One hundred forty-seven per cent of the invoice price (minus discounts or rebates);

(c) For a non-supply DMEPOS item or service for which payment is determined by PA, an amount determined on a case-by-case basis;

(d) For a bulk item having an overall payment limit per period, the submitted charge;

(e) For the authorized purchase of a DMEPOS item in used condition, eighty per cent of the payment amount for the item in new condition;

(f) For monthly payment for a "rental/purchase" DME item, ten per cent of the medicaid maximum specified for purchase;

(g) For a professional service for which separate payment is made (e.g., a certain type of evaluation), the applicable amount listed in appendix DD to rule 5160-1-60 of the Administrative Code; or

(h) The amount listed in the appendix to this rule.

Replaces: 5160-10-01, 5160-10-02, 5160-10-03, 5160-10-05, 5160-10-06, 5160-10-20, 5160-4-27

Effective:

Five Year Review (FYR) Dates:

_____

Certification

_____

Date

Promulgated Under: 119.03
Statutory Authority: 5164.02
Rule Amplifies: 5164.02, 5165.47
Prior Effective Dates: 04/07/1977, 12/21/1977, 12/30/1977, 01/08/1979, 01/01/1980, 02/01/1980, 03/01/1984, 05/19/1986, 07/01/1987, 10/01/1987, 04/01/1988, 10/01/1988, 09/01/1989, 05/01/1990, 06/20/1990 (Emer), 09/05/1990, 02/17/1991, 12/10/1993, 09/01/1998, 09/01/2002, 12/12/2002, 07/01/2004, 07/01/2006, 10/15/2006, 04/16/2007, 11/20/2007, 01/01/2010, 08/02/2011, 03/29/2012, 07/01/2013