

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

- (1) This rule sets forth general coverage and payment policies for durable medical equipment (DME), prostheses, orthotic devices, medical supplies, and supplier services dispensed or rendered by an enrolled DMEPOS provider.
- (2) Additional conditions specific to a particular DMEPOS item or service may be set forth in other rules in this chapter of the Administrative Code.
- (3) Policies set forth in other rules in this chapter supersede any provisions in this rule with which they conflict.

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

- (1) "Base invoice charge" is the amount charged for an item to a DMEPOS provider by a distributor or manufacturer before the application of any discounts, rebates, or adjustments.
- (2) "Certificate of medical necessity (CMN)" is a written statement by a prescribing practitioner that presents clinical information about an item and about the person for whom it was prescribed. This information, which often is not included in the prescription itself, aids in the determination of whether the particular item is the most medically appropriate for an individual (or even medically necessary).
 - (a) For many DMEPOS items, a specific CMN form is identified in the relevant rule in this chapter of the Administrative Code. Each identified CMN form bears the designation 'ODM' with a five-digit numeral. If no CMN form is identified, form ODM 01913, "Certificate of Medical Necessity / Request for Need Verification: General Medical Supplies and Equipment," may be used.
 - (b) 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).
 - (c) An illegible CMN will not be accepted.
- (3) "Coverage" is the principle that medicaid payment is routinely made for a particular medically necessary item or service. The department maintains several payment schedules of covered items and services, which are posted for reference on the department's web site. These schedules are neither all-

inclusive nor exclusive. Neither the appearance of an item or service on a payment schedule nor its absence determines, in and of itself, coverage or non-coverage.

- (4) "Date of service" is the date on which a DMEPOS service is furnished or a DMEPOS item is dispensed directly to an individual.
- (a) For an item that is shipped directly to a medicaid-eligible individual, the date of service is either the shipping date or the delivery date. When the individual is to be discharged from a hospital or long-term care facility, the date of service is the date of discharge.
- (b) For an item that needs multiple fittings and special construction, the date of service is the date of the first fitting.
- (5) "Department" is the Ohio department of medicaid or, when applicable, its designee. The address of the department's web site is <http://medicaid.ohio.gov>.
- (6) "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 a medicaid-eligible individual.
- (7) "DMEPOS provider" is a collective term for the following eligible providers:
- (a) A basic DME supplier, which furnishes items other than life-sustaining or technologically sophisticated equipment in accordance with Chapter 4752. of the Revised Code;
- (b) A specialized DME supplier, which furnishes life-sustaining or technologically sophisticated equipment in accordance with Chapter 4752. of the Revised Code; and
- (c) An orthotics and prosthetics (O&P) supplier, which furnishes orthotic and prosthetic devices in accordance with section 4779.02 of the Revised Code.
- (8) "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.
- (9) "Frequency limit" is the average expected useful life of a DMEPOS item. A frequency limit is not an absolute restriction but a general guideline and therefore may be exceeded with medical justification. For certain DMEPOS

items that can be dispensed in multiple units (such as fasteners or items with left/right orientation), a frequency limit applies to each unit that is requested.

(10) "Long-term care facility (LTCF)" is a collective term for a nursing facility (NF), a skilled nursing facility (SNF), and an intermediate care facility for individuals with intellectual disabilities (ICFID).

(11) "Medical supplies."

(a) For purposes of this chapter of the Administrative Code, this term applies to healthcare-related items delineated by the following criteria:

(i) They have a short useful life. They are expendable, disposable, or non-durable. They are intended either for a single use or for limited repeated use by one individual.

(ii) They are adjunctive in nature. They aid in the treatment or management of an illness, injury, or condition.

(iii) Their therapeutic effect is achieved through application to the body and not through ingestion.

(b) Medical supplies include but are not limited to the following non-exhaustive list of examples:

(i) Incontinence garments;

(ii) Syringes;

(iii) Wound dressings, including gauze;

(iv) Catheters and other urological items;

(v) Ostomy care items; and

(vi) Feeding bags.

(c) The following items are not medical supplies:

(i) Enteral nutrition products; and

(ii) Parenteral nutrition products.

- (d) The use of the term 'supply' meaning "quantity" (as in 'the supply of wheelchairs on hand' or 'a three-month supply') does not make the items in question medical supplies.
- (e) This definition is useful only in the consideration of items for which no standard medicaid maximum payment amount has been established.
- (12) "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 already 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 DME might be more cost-effective than continued repair.
- (13) "Prior authorization (PA)" has the same meaning as in rule 5160-1-31 of the Administrative Code.
- (14) "Private residence" is a medicaid-eligible individual's place of residence other than a long-term care facility (LTCF).
- (15) "Provider cost" is the amount paid for an item by a DMEPOS provider to a distributor or manufacturer after the application of any discounts, rebates, and adjustments that are available to the provider at the time of claim submission. Documentation of provider cost is subject to approval by the department; a figure that has been entered, superimposed, modified, obscured, or obliterated by the provider will not be accepted. Suitable documents for substantiating provider cost include but are not limited to the following examples:
- (a) An invoice submitted by the distributor or manufacturer to the provider;
- (b) A bona fide quotation (quote) submitted by the distributor or manufacturer to the provider; or
- (c) A standard distributor or manufacturer price list that can be independently verified by the department.
- (16) "Starting date for dispensing" is the first date on which a DMEPOS item is anticipated to be dispensed on an ongoing basis. The date of signature does not determine the starting date for dispensing.

(C) Coverage.

- (1) In general, in accordance with Chapter 5160-3 of the Administrative Code, a LTCF is responsible for ensuring that a resident of the LTCF gets medically necessary DME items and medical supplies, either by providing such items and supplies itself or by paying a DMEPOS provider to dispense them. In turn, the LTCF receives medicaid per diem payment on the basis of its cost report. Therefore, claims submitted to ODM or its designee by a DMEPOS provider 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) A medically necessary DMEPOS item can be dispensed only by prescription. The following provisions apply:

 - (a) Eligible medicaid providers of the following types having prescriptive authority under Ohio law may prescribe a DMEPOS item:

 - (i) A physician;
 - (ii) A podiatrist;
 - (iii) An advanced practice registered nurse with a relevant specialty; or
 - (iv) A physician assistant.
 - (b) Before writing a prescription for certain DMEPOS items, a practitioner conducts a face-to-face encounter with the medicaid-eligible individual and documents it in the individual's medical record. Items for which an encounter is a prerequisite are listed on the web site of the centers for medicare and medicaid services (CMS) at <http://www.cms.gov>.
 - (c) A single encounter can serve for twelve months as the basis for a single prescription or for more than one prescription addressing the same medical condition for which a DMEPOS item is being prescribed.
 - (d) The prescribing practitioner needs to be actively involved in managing the medicaid-eligible individual's healthcare. The department may disallow a prescription written by a practitioner who has no professional relationship with the individual.
 - (e) There needs to be a direct relationship between the prescribed DMEPOS item and a medical condition of the medicaid-eligible individual that the practitioner evaluates, assesses, or actively treats during the encounter.

- (f) Each prescription should specify a quantity (e.g., "TID," "thirty per month").
An unstated quantity is assumed to be one unit.
- (g) Unless a law, regulation, rule, or the prescription itself states otherwise, a
prescription is assumed to be valid for one year.
- (4) DMEPOS items and services for which payment is subject to PA are so indicated
in the applicable DMEPOS payment schedule.

 - (a) The following DMEPOS items are always subject to PA:

 - (i) A "not otherwise specified," "miscellaneous," or "unlisted" item or
service; and
 - (ii) 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.
- (5) If a medicaid-eligible individual 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
individual 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.

- (6) Any request for a DMEPOS item or service needs to originate with an individual medicaid-eligible individual, the individual's authorized representative, or a medical practitioner acting as the prescriber with the individual's full knowledge and consent. A request that is determined by the department to have resulted from a mass screening or examination will be denied.
- (7) When instruction in the safe and appropriate use of a particular DMEPOS item is indicated, it is the responsibility of the provider to ensure that the medicaid-eligible individual or someone authorized to assist the individual has received such instruction.
- (8) 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.
- (a) The medical necessity of an item purchased by the department is established during the purchasing process.
- (b) 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.
- (c) No additional documentation of medical necessity is needed for subsequent repairs made to an item.
- (d) The determination that an item not purchased by the department is medically necessary does not indicate that the item would be authorized for purchase.
- (9) The initial payment 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 is subject to PA. Whether payment for subsequent items or services is subject to PA depends on the item or service.
- (10) Proof is needed to show that a DMEPOS item has been delivered to the intended medicaid-eligible individual.
- (a) Providers, their employees, and anyone else having a financial interest in the delivery of DMEPOS items are not permitted to accept delivery of an item on behalf of an individual.

- (b) If a provider delivers directly to a medicaid-eligible individual, then acceptable proof of delivery includes the signature of the individual or the individual'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 records the name of the person accepting delivery and the relationship of the person to the medicaid-eligible individual. 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 needed.
- (11) If more than one DMEPOS item or service will meet a medicaid-eligible individual's needs, then the maximum payment amount cannot exceed the least costly alternative, in accordance with rule 5160-1-01 of the Administrative Code.
- (12) No separate payment will be made under this chapter of the Administrative Code for the following items or services:

 - (a) Items presumed to be non-medical 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 are intended solely for the comfort or convenience of the user and have no medical benefit;
 - (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 healthcare practitioner (i.e., that are incidental to a professional service) in an appropriate healthcare setting or in the medicaid-eligible individual'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:
 - (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 DME during a rental period:
 - (i) Supporting wires, power supplies, cables, or attachment kits:
 - (j) Related supplies and accessories that are dispensed either during a rental period or with the dispensing or delivery of a purchased DME 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 medicaid-eligible individual's condition:
 - (m) Instruction of the medicaid-eligible individual or the individual'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.
- (13) The use of an item in conjunction with a piece of DME does not in itself make the item an accessory. A smart phone, for example, is not an accessory.

- (14) Payment is not available for DMEPOS items that duplicate or conflict with another item currently in the medicaid-eligible individual's possession, regardless of payment or supply source. Providers are responsible for ascertaining whether duplication or conflict exists.
- (15) Certain DMEPOS items may be dispensed on a recurring basis. A provider is to confirm a medicaid-eligible individual'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.
- (16) Most covered DME items are purchased and become the property of the medicaid-eligible individual. Some covered DME items that need 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 is subject to 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 does 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, the cumulative rental amounts paid for a particular "rental/purchase" DME item apply toward purchase.
- (g) The department reserves the right to determine whether an item will be rented or purchased.
- (17) Medical supply items such as gauze pads and 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 cannot exceed one hundred forty-seven per cent of the provider cost for the quantity of the item.

- (18) 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.
- (19) A provider may furnish a DMEPOS item or service before obtaining a completed CMN but cannot submit a claim until the item or service has been furnished.
- (20) A request for PA or need verification may be denied in cases involving malicious damage, neglect, culpable irresponsibility, or wrongful disposition.
- (21) Only the department can determine coverage. Providers cannot decide on their own that an item or service is not covered or would not be covered with PA. Providers should submit a PA request to obtain an official decision.

(D) Documentation.

- (1) When a request is made for PA, the following accompanying documentation is needed:
 - (a) A completed CMN:
 - (i) For a DMEPOS item that is dispensed once (such as a wheelchair), the provider submits one completed CMN; or
 - (ii) For a DMEPOS item that will be needed indefinitely, for a lifetime, or on a recurring or ongoing basis, the provider takes the following steps:
 - (a) The provider obtains and submits an initial completed CMN;
 - (b) Each year thereafter the provider obtains and submits an updated prescription no sooner than ninety days before the expiration of the current prescription; and
 - (c) If the updated prescription indicates a change in the need for a DMEPOS item, the provider obtains a new completed CMN;
 - (b) Related information, such as a full description of any similar item currently in possession of the medicaid-eligible individual or an explanation of a change in the individual's condition that warrants a change in equipment;
 - (c) For a preparatory prosthesis, the reason for the amputation, the date of the amputation, and an explanation of the benefit to be derived from having

the medicaid-eligible individual use a preparatory prosthesis before a definitive prosthesis is designed;

(d) 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

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

(2) A claim for an item or service that exceeds the specified maximum quantity or frequency but is not otherwise subject to PA is subject to need verification. Documentation of need may be made either on the CMN associated with the item or service or on form ODM 01913.

(3) For each claim, whether or not it is subject to PA or need verification, the provider cannot legitimately receive payment until necessary supporting documents have been obtained and placed in the provider's files. These documents include the prescription and any applicable items from the following non-exhaustive list of examples:

(a) A completed CMN;

(b) Practitioner orders or chart notes;

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

(d) Proof of delivery;

(e) Confirmation that the medicaid-eligible individual or the individual's authorized representative has been instructed in the safe use of the DMEPOS item;

(f) A copy of the manufacturer's or dealer's warranty; and

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

(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 or newly adopted healthcare common procedure coding system (HCPCS) procedure code, the initial maximum payment amount may be established in accordance with rule 5160-1-60 of the Administrative Code. New or newly adopted HCPCS codes are published in a separate table on the department's web site and remain there until the appropriate DMEPOS payment schedules can be updated.
- (3) For any covered DMEPOS item or service not represented by a new or newly adopted HCPCS procedure code, the payment amount is the lesser of the submitted charge (which is to 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) The amount listed in the appendix to this rule;
 - (b) For a "by report" DMEPOS item or service, an amount determined on a case-by-case basis;
 - (c) For an item for which payment is determined by PA, the relevant amount specified in the following list:
 - (i) A supply item, one hundred forty-seven per cent of the provider cost;
 - (ii) A wheelchair, wheelchair item, standing frame, gait trainer, or other DMEPOS item that incorporates complex rehabilitation technology, one hundred twenty per cent of the base invoice charge;
 - (iii) An enteral nutrition product, one hundred eighty-five per cent of the provider cost; or
 - (iv) Any other non-supply DMEPOS item or service, an amount determined on a case-by-case basis;
 - (d) For the authorized purchase of a DMEPOS item in used condition, eighty per cent of the payment amount for the item in new condition;
 - (e) For monthly payment for a "rental/purchase" DME item, ten per cent of the medicaid maximum specified for purchase; or
 - (f) For a professional service for which separate payment is made (such as an evaluation), the applicable amount listed in appendix DD to rule 5160-1-60 of the Administrative Code.

(4) In accordance with the principle stated in rule 5160-1-60 of the Administrative Code concerning correct coding, a "not otherwise specified," "miscellaneous," or "unlisted" procedure code of the appropriate DMEPOS type may be reported on a claim only if no other code listed on a payment schedule adequately represents the item or service. The department may deny a claim that omits necessary information or that includes a "not otherwise specified," "miscellaneous," or "unlisted" procedure code when an appropriate procedure-specific code is available.

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