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The Department of Vermont Health Access Clinical Criteria

Subject: Prosthetics and Orthotics
Last Review: November 8, 2023*
Past Revisions: August 30, 2022, March 26, 2021, January 28, 2020, March 21, 2017, April 11, 2016, January 2, 2015, January 10, 2014, June 10, 2013.

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

Per Health Care Administrative Rule 4.212:

> "Prosthetic devices" means replacement, corrective, or supportive devices to: artificially replace a missing portion of the body, prevent or correct physical deformity or malfunction, or support a weak or deformed portion of the body.
>
> This definition is in accordance with the federal definition found at 42 CFR 440.120c."
>
> "Orthotic devices" means devices fashioned to support, correct, or improve the function of a body part.

Prefabricated devices are manufactured in a quantity without a specific patient in mind. They may be modified for use by a specific member ("custom fitted"). **A device assembled from prefabricated parts is considered prefabricated.**

Prefabricated off the shelf devices are those which require "minimal self-adjustment" at the time of fitting by the member, caretaker for the member, or supplier. This minimal self-adjustment does not require the services of a certified orthotist or an individual who has specialized training. From CMS Local Coverage Article A52457 (2021) "For example, adjustment of straps and closures, bending or trimming for final fit or comfort (not all-inclusive) fall into this category."

Prefabricated custom-fitted devices are "Items requiring substantial modification by a qualified practitioner" (CMS LSA A52457, 2021).

Custom devices are manufactured to fit a specific member and require a prescription. The device is fabricated from basic materials and involves ***substantial modification*** to customize it to the specific patient. It may include some prefabricated components (CMS LCA A52457, 2021).

DVHA has specific criteria for neuroprosthetics and neurorthotics.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertain to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules

7102.2	Prior Authorization Determination
7603.3	Ancillary Services in a Nursing Facility
4.101	Medical Necessity for Covered Services
4.104	Medicaid Non-Covered Services
4.106	Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services
4.212	Prosthetic and Orthotic Devices
4.209	Durable Medical Equipment

Coverage Position

Prosthetics/orthotics may be covered for members:

- When the device is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website*, Statute, or rule who is knowledgeable regarding Prosthetics/orthotics, and who provides medical care to the member AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: https://sos.vermont.gov/opr/

Coverage Criteria

Prosthetics/orthotics may be covered for members who:

- Have a medical condition that requires a prosthetic or orthotic to address that condition as determined by a face-to-face evaluation per HCAR 4.209;
- When the need cannot be met by non-medical commercially available technology.

For custom devices only: Custom devices are covered only when prefabricated devices cannot meet the medical need. The device must be properly evaluated by a qualified professional practitioner with specialized skills in the evaluation of prosthetics/orthotics. Depending on the nature of the device, this practitioner may be a physical therapist, occupational therapist, physician, physician assistant, or nurse practitioner. Complex devices must be customized by a certified prosthetist/orthotist. Fitting of the device must be performed

by one of the above listed professionals or by a supplying provider who has been certified to ensure that the prescription is properly fulfilled.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence- based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

Medicaid expects that members will care for their prosthetics/orthotics properly so that the device will be usable for at least the duration recommended by the manufacturer. Most prefabricated devices have a reasonable useful lifetime of at least 1-3 years. Custom devices are expected to have a reasonable useful lifetime of at least 3 years.

Coverage for replacement equipment will be provided only when the existing device or system no longer effectively addresses the member's medical needs. A police report is required for items that are lost, stolen, or irreparably damaged in an accident. Devices will be covered for repair if the repair price is less than 50% of the replacement price.
Per HCAR 4.212.4(c):

- Coverage of Medicaid-approved shoes is limited to two pairs per adult member per calendar year unless additional pairs are medically necessary.

Please refer to the DME quantity limitations guidance list, available at: http://www.vtmedicaid.com/#/resources, for all other quantity guidance information.

Type of service or procedure covered

Covered prosthetics/orthotics include, but are not limited to: artificial limbs, artificial larynxes, post-mastectomy breast forms, prosthetic/orthotic shoes, braces and trusses, aircast splints, shoe lifts, elevation heels, and wedges, and orthotic arch supports.

Custom items are covered only when prefabricated devices cannot meet the medical need. Medicaid rule 7102.2 requires that the least expensive, medically appropriate item be supplied. Therefore, in situations where a prefabricated device is available, the ordering and dispensing of a custom device requires physician documentation that demonstrates the medical need for a custom device.

Prior authorization is required for certain prosthetic/orthotic devices. Please refer to the VT Medicaid fee schedules for prior authorization requirements. Regardless of whether prior authorization is required or not, a completed medical necessity form that is current for the billed date of service and a written order must be available in the provider's files for legal and auditing purposes.

Per Medicaid Rule 7603.3:

- For individuals not covered by Medicare residing in a nursing facility, Medicaid covers prosthetic devices and leg, arm, back and neck braces.

Additional Information

It is a DVHA expectation that the referring and supplying provider will provide education to the member on all of the following:

- Care and use of the device;
- Appropriate skin/body part care related to the device use;
- Appropriate wear schedule;
- Customer support for any problem with the device, throughout the life of the device.

Documentation of this education must be kept in the provider record.

Special Information

Foot orthotics

There is limited evidence supporting the greater benefit of custom foot orthotics as compared to prefabricated orthotics. Therefore, an unsuccessful trial/consideration of prefabricated orthotics is required before custom orthotics can be considered. Also, orthotics molded to the foot rather than molded to a model of the member's foot must also be tried/considered. Orthotics that are molded to the foot have the added value of providing total contact to the unique foot surface. A custom orthotic is molded to a model of the member's foot, not the foot itself. If a custom orthotic is required, the provider must provide sufficient evidence to demonstrate the specific type of orthotic required to meet the member's medical need:

L3000: Devices billed with this code must demonstrate the intent of the University of California Berkeley (UCB) type orthosis, which is to provide a very high level of control for the rearfoot via high medial, lateral, and posterior walls made of rigid plastic. Providers must document the medical need for this significant level of rearfoot control and have the documentation available for legal and auditing purposes in the provider's patient records.

L3010: Devices billed with this code must demonstrate the need for longitudinal arch support.

L3020: Devices billed with this code must demonstrate the need for both longitudinal and metatarsal arch support.

External breast prostheses

A breast prosthesis is only covered for a member who has had a mastectomy.

Lower extremity prosthetics

"A determination of the medical necessity for certain components/additions to the prosthesis is based on the member's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist, and treating practitioner, considering factors including, but not limited to:

1. The member's past history (including prior prosthetic use if applicable); and
2. The member's current condition including the status of the residual limb and the nature of other medical problems; and

3. The member's desire to ambulate.

Clinical assessments of member rehabilitation potential must be based on the following classification levels:

- Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
- Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
- Level 2: Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
- Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
- Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete." (CMS LCD L33787, 2020)

It is a VT Medicaid expectation that a physical therapist will be a part of the prosthetic determination, for gait and mobility training, and residual limb care.

Contraindications/Precautions:
Improperly fitted or inadequate devices may do more harm than good. It is vital that devices be appropriately assessed and reassessed, and properly constructed, to provide the appropriate level of support, proper fit, and function.

Overly aggressive devices may also do more harm than good. Orthotics may weaken a body part that may be capable of becoming stronger with proper exercise and alignment as determined by a medical practitioner or physical/occupational therapist. It is Medicaid's expectation that the provider who delivers the device to the patient is fully licensed/certified, and that the provider has witnessed and documented that the device is properly fitted to the member, that the device provides the appropriate level of support, and that it is functioning properly. This documentation must be available in the member's medical records for auditing purposes.

Type of service or procedure not covered (this list may not be all inclusive)

Per HCAR 4.212.5:
- Duplicate items are not covered (e.g., two pairs of customized orthotics)
- Prosthetics or orthotics that primarily serve to address social, recreational, or other factors and do not directly address a medical need.
- Devices that do not have a preponderance of support from current, peer reviewed medical literature at this time.

Per HCAR 4.212.4:
- Prosthetics and orthotics reimbursed as a component of an institutional payment.

Certain accessories/components cannot be covered in addition to the base code, for one or all of the following reasons:

- They are considered part of the base device
- They are considered not reasonable and necessary
- They are incompatible with the base code.

Examples of this include, but are not limited to, the following table related to knee orthotics (CMS Local Coverage Article A52465, 2023):

Base Code- prefabricated devices:	Additional codes: not separately payable due to: considered part of the base code, not reasonable and necessary, or incompatible with the base code.
L1810	L2390, L2750, L2780, L4002
L1812	L2390, L2750, L2780, L4002
L1820	L2390, L2750, L2780, L2810, L4002
L1830	K0672, L4002
L1831	K0672, L2390, L2425, L4230, L2750, L2780, L2810, L2820, L2830, L4002
L1832	K0672, L2390, L2425, L4230, L2750, L2780, L2820, L2830, L4002
L1833	K0762, L2390, L2425, L2430, L2750, L2780, L2820, L2830, L4002
L1836	K0672, L2750, L2780, L2810, L2820, L2830, L4002
L1843	K0672, L2275, L2390, L2425, L4230, L2750, L2780, L2810, L2820, L2830, L4002
L1845	K0672, L2275, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1847	K0672, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1848	K0672, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1850	K0672, L2750, L2780, L2810, L2820, L2830, L4002
L1851	K0672, L2275, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1852	K0672, L2275, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
Base code- custom devices:	Additional codes:
L1834	K0672, L2820, L2830, L4002
L1840	K0672, L2320, L2330, L2750, L2780, L2810, L2820, L2830, L4002
L1844	K0672, L2275, L2320, L2330, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1846	K0672, L2275, L2320, L2330, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1860	K0672, L2820, L2830, L4002

All additional codes that are not in the above table that describe components that cannot be physically incorporated into the device, or which are incompatible with the base orthosis are also not covered.

Providers found to have billed for the noncovered codes are subject to recoupment.

Coding guidelines

Please see the Medicaid Portal at http://vtmedicaid.com/#/feeSchedule for fee schedules, code coverage, and applicable requirements.

All generic "xxx99" codes and non-specific codes require prior authorization.
For all generic procedure codes (xxx99 codes), the number of units documented on the Notice of Decision will always be "1". If there are multiple units of an item, or multiple items listed, the specific amounts will appear in the comments section of the Notice of Decision.
Certain other codes also require prior authorization. Consult the fee schedule for requirement of prior authorization.

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