PreferredOne®

Department of Origin: Integrated Healthcare Services	**Effective Date:** 11/21/23
Approved by: Chief Medical Officer	**Date Approved:** 11/10/23
Clinical Policy Document: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)	**Replaces Effective Clinical Policy Dated:** 11/09/22
Reference #: MP/D004	**Page:** 1 of 5

PURPOSE:
The intent of this clinical policy is to provide coverage guidelines for durable medical equipment (DME), prosthetics, orthotics, and non-durable supplies (DMEPOS).

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
The Plan covers eligible medically necessary**,** provider prescribed durable medical equipment, prosthetics, orthotics and supplies subject to the coverage statements listed below.

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

COVERAGE:

I. Coverage for DME, prosthetics, orthotics and supplies is subject to the following:

   A. Is ordered for the diagnosis or treatment of sickness or injury or is a preventive service.

   B. Is listed as eligible on the Plan's durable medical equipment list (DMEPOS list).

   C. The requested frequency is within the allowable quantity reflected on the DMEPOS List, unless otherwise specified.

   D. Is necessary for *activities of daily living*, when required by the COC/SPD.

   E. Is the acceptable standard model that is medically necessary for the member's condition. Unacceptable, non-standard models that are not medically necessary include, but are not limited to, the following:
      1. DMEPOS that is not proven to be effective by scientific medical literature, and does not demonstrate benefit over standard, less costly equipment.

      2. Any more costly device, which falls under the FDA classification as substantially equivalent to another less costly device.

   F. The item is not used primarily for convenience, activities related to leisure, recreation or employment.

   G. Equipment, prosthetics, orthotics, supplies, and services being ordered by a provider is for the treatment of conditions that are allowable by benefits (ie, a chiropractor can only order supplies or equipment used to treat acute musculoskeletal conditions when benefits limit the services of chiropractors to the treatment of acute musculoskeletal conditions)

II. Coverage for repair/revision or replacement of durable medical equipment or prosthetics is based on the length of time the equipment has been in service and must satisfy the following, as applicable:

A. The request meets the specific plan language for repair/revision or replacement

B. The request is ordered by a provider

C. The request is due to normal wear and tear or a change in the member's condition

D. There is no evidence of damage due to member misuse, abuse or carelessness

E. The item was not lost or stolen

F. The item is no longer functional, including *malfunctioning*[15] or when no longer being manufactured (eg, Abbott Freestyle Libre Flash and 10-day sensor no longer available)

G. The request is not due to desire for newer technology

H. The cost of repair/revision is equal to or less than 60% of the cost of a replacement device, or of the part being repaired/revised

I. The device/component is not covered under warranty

J. Unless otherwise stated, DME has a Reasonable Useful Lifetime (RUL) of 5 years

K. Device specific requests - any of the following:
1. Request for replacement of a prosthesis is allowed when due to a change in the member's physiologic condition.

2. Request for replacement of an insulin pump is allowed for children who require a larger insulin reservoir.

III. The fact that a provider has prescribed or recommended an item does not guarantee that the item is medically necessary and/or a covered benefit under the terms of the member's benefit plan.

IV. All provider-prescribed, medically appropriate and necessary federal and/or state-mandated DMEPOS is covered. Coverage is limited to the most cost effective acceptable standard equipment.

V. Custom-made braces are eligible for coverage only when off-the-shelf items cannot be modified to fit or function properly.

VI. Rental only:

A. The health plan reserves the right to determine when an item is appropriate for rental only.

B. The vendor assumes responsibility and liability for duplicates, maintenance, servicing, replacement and supplies necessary for the safety and operation of the item (eg, breathing circuit, filters, PEEP valve, sterile water, tubing, heated wire circuit, water trap, water chamber, etc.).

VII. Off label use of devices

A. Off label use of a device that is being investigated as part of a qualifying clinical trial will not be eligible for coverage per guidelines in Clinical Policy MP/C008 Clinical Trials.

B. Off label use of devices not in a clinical trial may be approved for one of the following:
   1. Device has unrestricted FDA approval (this does not include Compassionate and Humanitarian Use FDA approvals)

   2. *Reliable evidence* supports the therapeutic benefit or diagnostic value

EXCLUSIONS (not limited to):
Refer to the member's Certificate of Coverage or Summary Plan Description

DEFINITIONS:
Activities of Daily Living (ADL):
Activities related to personal self-care and independent living, which include eating, bathing, dressing, transferring, walking/mobility, and toileting/continence.

Durable Medical Equipment:
A piece of equipment for a specific therapeutic purpose in the treatment of an illness and that can withstand repeated use and is not disposable; is primarily and customarily used to serve a medical purpose; generally would not be useful to the member in the absence of an illness.

Health Care Services:
Medical or behavioral services including pharmaceuticals, devices, technologies, tests, treatments, therapies, supplies, procedures, hospitalizations, or *provider* visits.

Malfunctioning:
The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.

Non-Durable Equipment/Supplies:
Medical supplies for a specific therapeutic purpose in the treatment of an illness or injury, or are needed for the operation of approved *durable medical equipment* and that are disposable and usually used only one time.

Orthotic Device:
Rigid or semi-rigid devices used to support a weak or deformed body part or to restrict or eliminate motion in a diseased or injured body part.

Off-label Use:
Device/equipment/drug used in a manner that is different from its approved purpose

Prosthetic:
An external device that temporarily or permanently replaces all or part of an external body part, or a device that permanently replaces all or part of the function of an inoperative or malfunctioning internal body part.

Reliable Evidence:

1. Whether there is a final approval from the appropriate government regulatory agency, if required. This includes whether a drug or device can be lawfully marketed for its proposed use by the FDA; or if the drug, device or medical treatment or procedure is under study or if further studies are needed to determine its maximum tolerated dose, toxicity, safety or efficacy as compared to standard means of treatment or diagnosis; and
2. Whether there are consensus opinions or recommendations in relevant scientific and medical literature, peer-reviewed journals, or reports of clinical trial committees and other technology assessment bodies. This includes consideration of whether an oncology treatment is included in the applicable National Comprehensive Cancer Network (NCCN) guideline, as appropriate for its proposed use, or whether a drug is included in any *authoritative compendia* as identified by the Medicare program such as, the National Comprehensive Cancer Network Drugs and Biologics Compendium, as appropriate for its proposed use; and
3. Whether there are consensus opinions of national and local health care providers in the applicable specialty as determined by a sampling of providers, including whether there are protocols used by the treating facility or another facility, studying the same drug, device, medical treatment or procedure.

PreferredOne®

Department of Origin: Integrated Healthcare Services	**Effective Date:** 11/21/23
Approved by: Chief Medical Officer	**Date Approved:** 11/10/23
Clinical Policy Document: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)	**Replaces Effective Clinical Policy Dated:** 11/09/22
Reference #: MP/D004	**Page:** 5 of 5

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy Clinical Trials (MP/C008)
3. Clinical Policy Coverage Determination Guidelines (MP/C009)
4. Clinical Policy DMEPOS, Continuous Glucose Monitoring Systems (MC/L008)
5. Clinical Policy DMEPOS, Dressing Supplies (MP/D008)
6. Clinical Policy DMEPOS, Insulin Infusion Pump (MC/L011)
7. Clinical Policy DMEPOS, Lower Limb Prostheses (MC/D005)
8. Clinical Policy DMEPOS, Pneumatic Compression Devices and Heat/Cold Therapy Units (MC/D006)
9. Clinical Policy DMEPOS, Standing Systems and Gait Trainers (MC/D007)
10. Clinical Policy DMEPOS, Upper Limb Prostheses (MC/D004)
11. Clinical Policy DMEPOS, Wheelchairs and Mobility Assistive Equipment MC/D003
12. Clinical Policy Levels of Evidence and the Evaluation of Health Care Services (MP/L004)
13. US Food and Drug Admin. Code of Federal Regulations Title 21, Chapter I, Subchapter H Medical Devices.
    Retrieved from https://www.ecfr.gov/cgi-bin/text-idx?gp=&SID=fe806d7a100a38de62ca9cbcb13f3bb6&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl.
    Accessed 10-20-22.

DOCUMENT HISTORY:

Created Date: 08/95
Reviewed Date: 02/21/07, 08/10/11, 08/08/12, 08/08/13, 09/19/13, 09/19/14, 09/11/15, 09/09/16, 09/08/17, 09/07/18, 02/18/19, 02/10/20, 11/05/20, 11/05/21, 10/14/22, 10/13/23
Revised Date: 05/11/05, 03/28/06, 11/01/07, 12/31/07, 03/17/08, 08/15/08, 01/28/09, 01/11/10, 08/12/10, 03/01/11, 6/15/11, 10/27/11, 09/24/13, 09/19/14, 11/24/14, 12/07/16, 02/18/19, 06/25/20, 03/30/21,11/19/21

PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan ("PCHP") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው: 763.847.4013).

ဟသျှဉ်ဟသး– နမ့်ကတိ၊ ကညီ ကျိာ်အယိ, နမၤန့် ကျိာ်အတ်မၤစၢၤလ၊ တလၫ်ဘူဉ်လၫ်စ့၊ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013).។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

PreferredOne Insurance Company Nondiscrimination Notice

PreferredOne Insurance Company ("PIC") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PIC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PIC:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው: 763.847.4013).

ဟသူဉ်ဟ်သး– နမ့ါကတိၤ ကညီ ကျိာ်အယိ, နမၤန့ါ ကျိာ်အတ၊်မၤစၢၤလၢ တလၢာ်ဘူဉ်လၢာ်စ့ၤ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).