

UnitedHealthcare® West Benefit Interpretation Policy

Shoes and Foot Orthotics

Policy Number: BIP168.N Effective Date: March 1, 2025

•	Instructions	for	Use

Table of Contents	Page
Federal/State Mandated Regulations	1
State Market Plan Enhancements	3
Covered Benefits	3
Not Covered	4
Definitions	
References	5
Policy History/Revision Information	5
Instructions for Use	5

Related Benefit Interpretation Policies

- Diabetic Management, Services and Supplies
- Durable Medical Equipment (DME), Prosthetics, <u>Corrective Appliances/Orthotics (Non-Foot</u> Orthotics) and Medical Supplies
- Durable Medical Equipment (DME) Prosthetics, <u>Corrective Appliances/Orthotics (Non-Foot</u> Orthotics) and Medical Supplies Grid
- Foot Care and Podiatry Services

Federal/State Mandated Regulations

Note: The most current federal/state mandated regulations for each state can be found in the links below.

Oklahoma

Oklahoma Statutes Title 36, Section 6060.2, Coverage for Diabetes Treatment

http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=87360

- A. 1. Every health benefit plan issued or renewed on or after November 1, 1996, shall, subject to the terms of the policy contract or agreement, include coverage for the following equipment, supplies and related services for the treatment of Type I, Type II, and gestational diabetes, when medically necessary and when recommended or prescribed by a physician or other licensed health care provider legally authorized to prescribe under the laws of this state:
 - I. Podiatric appliances for prevention of complications associated with diabetes.
 - 2. The State Board of Health shall develop and annually update, by rule, a list of additional diabetes equipment, related supplies and health care provider services that are medically necessary for the treatment of diabetes, for which coverage shall also be included, subject to the terms of the policy, contract, or agreement, if the equipment and supplies have been approved by the federal Food and Drug Administration (FDA). Additional FDA-approved diabetes equipment and related supplies, and health care provider services shall be determined in consultation with a national diabetes association affiliated with this state, and at least three (3) medical directors of health benefit plans, to be selected by the State Department of Health.
 - 3. All policies specified in this section shall also include coverage for:
 - a. Podiatric health care provider services as are deemed medically necessary to prevent complications from diabetes.

Texas

Texas Administrative Code (TAC) Title 28, Section 21.2605, Diabetes Equipment and Supplies

https://texreg.sos.state.tx.us/public/readtac\$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac= &ti=28&pt=1&ch=21&rl=2605

- a) A health benefit plan shall provide coverage for equipment and supplies for the treatment of diabetes for which a physician or practitioner has written an order, including:
 - 12) Podiatric appliances, including up to two pairs of therapeutic footwear per year, for the prevention of complications associated with diabetes

Texas Insurance Code (TIC) Title 8, Sections 1358.051, 1358.054, and 1358-056

https://statutes.capitol.texas.gov/Docs/IN/htm/IN.1358.htm

Section 1358.051, Definitions

In this subchapter:

- (1) "Diabetes equipment" means:
 - A) Blood glucose monitors, including noninvasive glucose monitors and glucose monitors designed to be used by blind individuals;
 - B) Insulin pumps and associated appurtenances;
 - C) Insulin infusion devices; and
 - D) Podiatric appliances for the prevention of complications associated with diabetes.

Section 1358.054, Coverage Required

- a) A health benefit plan that provides coverage for the treatment of diabetes and conditions associated with diabetes must provide to each qualified enrollee coverage for:
 - (1) Diabetes equipment;
 - (2) Diabetes supplies; and
 - (3) Diabetes self-management training in accordance with the requirements of Section 1358.055.

Section 1358.056, Coverage for New or Improved Equipment and Supplies

A health benefit plan must provide coverage for new or improved diabetes equipment or supplies, including improved insulin or another prescription drug, approved by the United States Food and Drug Administration if the equipment or supplies are determined by a physician or other health care practitioner to be medically necessary and appropriate.

TIC Title 8, Sections 1371.001 and 1371.003

https://statutes.capitol.texas.gov/Docs/IN/htm/IN.1371.htm

Section 1371.001, Definitions

In this chapter:

- (1) "Enrollee" means an individual entitled to coverage under a health benefit plan.
- (2) "Orthotic device" means a custom-fitted or custom-fabricated medical device that is applied to a part of the human body to correct a deformity, improve function, or relieve symptoms of a disease.
- (3) Prosthetic device" means an artificial device designed to replace, wholly or partly, an arm or leg.

Section 1371.003, Required Coverage for Prosthetic Devices, Orthotic Devices, and Related Services

- (a) A health benefit plan must provide coverage for prosthetic devices, orthotic devices, and professional services related to the fitting and use of those devices that equals the coverage provided under federal laws for health insurance for the aged and disabled under Sections 1832, 1833, and 1834, Social Security Act (42 U.S.C. Sections 1395k, 1395l, and 1395m), and 42 C.F.R. Sections 410.100, 414.202, 414.210, and 414.228, as applicable.
- (b) Covered benefits under this chapter are limited to the most appropriate model of prosthetic device or orthotic device that adequately meets the medical needs of the enrollee as determined by the enrollee's treating physician or podiatrist and prosthetist or orthotist, as applicable.
- (c) Subject to applicable copayments and deductibles, the repair and replacement of a prosthetic device or orthotic device is a covered benefit under this chapter unless the repair or replacement is necessitated by misuse or loss by the enrollee.
- (d) Coverage required under this section:
 - (1) Must be provided in a manner determined to be appropriate in consultation with the treating physician or podiatrist and prosthetist or orthotist, as applicable, and the enrollee;
 - (2) May be subject to annual deductibles, copayments, and coinsurance that are consistent with annual deductibles, copayments, and coinsurance required for other coverage under the health benefit plan; and
 - (3) May not be subject to annual dollar limits.
- (e) Covered benefits under this chapter may be provided by a pharmacy that has employees who are qualified under the Medicare system and applicable Medicaid regulations to service and bill for orthotic services. This chapter does not preclude a pharmacy from being reimbursed by a health benefit plan for the provision of orthotic services.

Washington

Revised Code of Washington Section 48.44.315, *Diabetes Coverage – Definitions*

https://app.leg.wa.gov/rcw/default.aspx?cite=48.44.315

The legislature finds that diabetes imposes a significant health risk and tremendous financial burden on the citizens and government of the state of Washington, and that access to the medically accepted standards of care for diabetes, its treatment and supplies, and self-management training and education is crucial to prevent or delay the short and long-term complications of diabetes and its attendant costs.

- (1) The definitions in this subsection apply throughout this section unless the context clearly requires otherwise.
 - (a) "Person with diabetes" means a person diagnosed by a health care provider as having insulin using diabetes, noninsulin using diabetes, or elevated blood glucose levels induced by pregnancy; and
 - (b) "Health care provider" means a health care provider as defined in RCW 48.43.005.
- (2) All health benefit plans offered by health care Service contractors shall provide benefits for at least the following services and supplies for persons with diabetes:
 - (a) For health benefit plans that include coverage for pharmacy services, appropriate and medically necessary equipment and supplies, as prescribed by a health care provider, that includes but is not limited to insulin, syringes, injection aids, blood glucose monitors, test strips for blood glucose monitors, visual reading and urine test strips, insulin pumps and accessories to the pumps, insulin devices, prescriptive oral agents for controlling blood sugar levels, foot care appliances for prevention of complications associated with diabetes, and glucagon emergency kits.

State Market Plan Enhancements

Foot Orthotics/Footwear

Coverage for specialized footwear for foot disfigurement may be available if the subscriber's employer purchased a footwear supplemental benefit. If your health plan includes a footwear supplemental benefit, a brochure describing it will be enclosed with these materials.

Covered Benefits

Important Note: Covered benefits are listed in Federal/State Mandated Regulations, State Market Plan Enhancements, and Covered Benefits sections. Always refer to the Federal/State Mandated Regulations and State Market Plan Enhancements sections for additional covered services/benefits not listed in this section.

Refer to the member's Evidence of Coverage (EOC)/Schedule of Benefit (SOB) for additional information.

Shoes and foot orthotics are covered in the following scenarios: (CMS 2003)

- Prosthetic shoe when used as a structural device to replace all of a foot or when a large portion of the member's • forefoot (front part) is missing.
- Orthopedic shoe is covered when it is permanently attached to a medically necessary orthopedic brace. •
- Therapeutic shoe. .
 - One pair of Depth or one pair of Custom-Molded therapeutic Shoes per calendar year for members diagnosed 0 with diabetes:
 - The shoes must be prescribed, fitted, and furnished by a podiatrist or other qualified individual (e.g., a pedorthist, orthotist, or prosthetist);
 - The shoes must meet this policy's definition for Depth or Custom-Molded Shoes (refer to the Definitions section):
 - The managing physician, who is responsible for diagnosing and treating the member's systemic condition, must do all the following:
 - Document in the medical record that the member has diabetes;
 - Certify that the member is being treated under a comprehensive plan of care for his/her diabetes;
 - Certify that the member needs therapeutic shoes;
 - Document in the member's record that the member has one or more of the following conditions:

Page 3 of 5

- Peripheral neuropathy with the evidence of callus formation
- History of previous ulceration
- History of pre-ulcerative calluses
- Foot deformity
- Previous amputation of the foot or part of the foot

Shoes and Foot Orthotics UnitedHealthcare West Benefit Interpretation Policy Effective 03/01/2025 Proprietary Information of UnitedHealthcare. Copyright 2025 United HealthCare Services, Inc.

- Poor circulation
- A pair of therapeutic shoes is covered even if only one foot suffers from diabetic foot disease (each shoe is equally equipped so that the affected limb, as well as the remaining limb, is protected).
- Specialized footwear, including foot orthotics and custom-made or standard orthopedic shoes, is only covered for members with diabetic foot disease or when an orthopedic shoe is permanently attached to a medically necessary orthopedic brace.
- Modifications of Custom-Molded or Depth Shoes (e.g., wedges, offset heels, Velcro closures, Inserts for missing toes, etc.) instead of obtaining a pair of Inserts in any combination.
- Replacements, repairs, and adjustments to foot orthotics are covered when medically necessary and authorized by the member's network medical group or UnitedHealthcare.

o Limitations:

- For each individual, coverage of the footwear and Inserts **is limited to one of the following within one calendar year**:
 - No more than one (1) pair of Custom-Molded Shoes (which includes Inserts provided with the shoes) and two (2) additional pairs of Inserts.
 - No more than one (1) pair of Depth Shoes and three (3) pairs of Inserts (not including the non-customized removal Inserts provided with such shoes).

Inserts.

- Substitution of modifications for Inserts.
- Inserts.
 - \circ $\;$ The member must have the appropriate footwear to accommodate the insert.
 - Limitations:
 - Three (pairs) Inserts per calendar year for Custom-Molded Shoes (including Inserts provided with the shoes);
 - Four (pairs) Inserts per calendar year for Depth Shoes (including the non-customized removable Inserts provided with the shoes).

Refer to the Benefit Interpretation Policies titled <u>Foot Care and Podiatry Services</u>, <u>DME Prosthetics</u>, <u>Corrective</u> <u>Appliances/Orthotics</u> (Non-Foot Orthotics), and <u>Medical Supplies</u> Grid, and <u>Diabetic Management</u>, <u>Services and Supplies</u>.

Not Covered

- Foot orthotics are not a covered benefit unless the member meets the above diabetic foot disease criteria or as required by state mandates or market plan enhancement (refer to the <u>Federal/State Mandated Regulations</u>, <u>State</u> <u>Market Plan Enhancements</u>, and <u>Covered Benefits</u> sections).
- Therapeutic shoes except as described above in the <u>Covered Benefits</u> section.
- Orthopedic shoes or other supportive devices for the feet except as described above in the Covered Benefits section.
- Orthopedic shoes for subluxations of the foot.
- Supportive devices for the feet other than described above in the <u>Covered Benefits</u> section.

Definitions

Custom-Molded Shoes: Shoes that are constructed over a positive model of the member's foot; made from leather or other suitable material of equal quality, have removable Inserts that can be altered or replaced as the member's condition warrants; and have some form of shoe closure.

Depth Shoes: Shoes that have a full-length heel-to-toe filler that, when removed, provides a minimum of 3/16 inch of additional depth used to accommodate custom molded or customized Inserts, are made of leather or other suitable material of equal quality, have some form of foot closure, and are available in full and half sizes with a minimum of 3 widths so that the sole is graded to the size and width of the upper portions of the shoes according to the American standard last sizing schedule (the numerical shoe sizing system used for shoes sold in the United States or its equivalent).

Inserts: Total contact, multiple density, removable inlays that are directly molded to the member's foot or a model of the member's foot or directly carved from a member-specific, rectified electronic model and that are made of suitable material with regard to the member's condition.

References

Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, § 290 Foot Care; Revised; Available at Medicare Benefit Policy Manual, Chapter 15, §290 – Foot Care. Accessed January 2025.

DME MAC LCDs for Orthopedic Footwear (L33641). Accessed January 2025.

Medicare Benefit Policy Manual, Chapter 15, §140 - Therapeutic Shoes for Individuals with Diabetes. Accessed January 2025.

Policy History/Revision Information

Date	State(s) Affected	Summary of Changes
03/01/2025	All	Routine review; no change to coverage guidelines
		Archived previous policy version BIP168.M

Instructions for Use

Covered benefits are listed in three (3) sections: *Federal/State Mandated Regulations, State Market Plan Enhancements,* and *Covered Benefits.* All services must be medically necessary. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the member's Evidence of Coverage (EOC)/Schedule of Benefits (SOB). If there is a discrepancy between this policy and the member's EOC/SOB, the member's EOC/SOB provision will govern.