JOHNS HOPKINS	Medical Policy Manual Medical Policy	Policy Number	CMS15.04
		Effective Date	02/01/2024
		Approval Date	11/21/2023
HEALTH PLANS	<u>Subject</u>	Supersedes Date	02/01/2023
	Foot Orthotics	Page	1 of 7

This document applies to the following Participating Organizations:

Advantage MD EHP Johns Hopkins Health Plan of Virginia Priority Partners

Inc. (JHHPVA)

US Family Health Plan

Keywords: Foot Orthotics, Orthotics, Shoe Insert

Table of Contents		Page Number
I.	ACTION	1
II.	POLICY DISCLAIMER	1
III.	POLICY	1
IV.	POLICY CRITERIA	2
V.	BACKGROUND	3
VI.	CODING DISCLAIMER	4
VII.	CODING INFORMATION	4
VIII.	REFERENCE STATEMENT	5
IX.	REFERENCES	5
X.	APPROVALS	7

I. ACTION

	New Policy	
X	Revising Policy Number	CMS15.04
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

For Advantage MD, refer to: Medicare Coverage Database

- Local Coverage Determination (LCD) L33641 Orthopedic Footwear
- Local Coverage Determination (LCD) L33369 Therapeutic Shoes for Persons with Diabetes

For Employer Health Programs (EHP) refer to:

• Plan specific Summary Plan Descriptions (SPD's)

For Johns Hopkins Health Plan of Virginia Inc. (JHHPVA) refer to: Medicare Coverage Database

[©] Copyright 2024 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University

	*	Policy Number	CMS15.04
	Medical Policy Manual Medical Policy	Effective Date	02/01/2024
JOHNS HOPKINS	·	Approval Date	11/21/2023
HEALTH PLANS	<u>Subject</u>	Supersedes Date	02/01/2023
	Foot Orthotics	Page	2 of 7

- Local Coverage Determination (LCD) L33641 Orthopedic Footwear
- Local Coverage Determination (LCD) L33369 Therapeutic Shoes for Persons with Diabetes

For Priority Partners (PPMCO) refer to: Code of Maryland Regulations

Code of Maryland Regulations (COMAR) 10.67.06.24 Benefits- Diabetes Prevention and Care Services

For US Family Health Plan (USFHP) refer to: Tricare Policy Manuals

- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 8, Section 3.1 Orthoses (Braces and Splints)
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 8, Section 8.2 Therapeutic Shoes for Diabetics

IV. POLICY CRITERIA

- A. <u>General Considerations</u>: When benefits are provided under the member's contract, JHHP considers custom foot orthotics medically necessary when the following criteria are met:
 - 1. The individual could not be fitted with a prefabricated foot orthosis, OR;
 - 2. The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months), OR;
 - 3. The individual has a documented neurological, circulatory, or orthopedic problem that requires custom fabrication in order to prevent tissue injury, AND;
 - 4. The member meets one of the medically necessary indications in B below.
- B. <u>Medically Necessary Indications</u>: When benefits are provided under the member's contract, JHHP considers custom foot orthotics medically necessary when one of the following diagnoses is documented:
 - 1. Diabetes
 - 2. Proximal Lower Extremity Pathology including:
 - a. Shin Splint Syndrome (Periosteal Myositis)
 - b. Stress fractures
 - c. Periositis
 - d. Tendonitis (Tenosynovitis)
 - e. Posterior Tibial Dysfunction
 - 3. Arthritis:
 - a. Inflammatory Arthritis (The degree of deformity or abnormal motion that is manifested precludes the use of over-the-counter orthotics or attempts to use over-the-counter orthotics have failed.)
 - b. Osteoarthritis (for management of lower extremity deformities and dysfunctions)
 - 4. Mechanically Induced Pain and Deformities:
 - a. Pes Cavus
 - b. Haglund's Deformity
 - c. Functional Hallux Limitus, Hallux Rigidus, Hallux Valgus
 - d. Plantar Fasciitis (also known as Heel Spur Syndrome) when the following conditions have been met and adherence is clearly documented:
 - i. Member has had a 3-month trial and failure using prefabricated foot orthotics, AND;
 - ii. Member has strictly followed a plantar fascia-specific stretching protocol with home stretching exercises for 3 months, AND;
 - iii. Treatment plan includes the use of supportive shoes.

[©] Copyright 2024 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University

JOHNS HOPKINS

	Johns Hopkins Health Plans	Policy Number	CMS15.04
	Medical Policy Manual Medical Policy	Effective Date	02/01/2024
S	•	Approval Date	11/21/2023
	<u>Subject</u>	Supersedes Date	02/01/2023
	Foot Orthotics	Page	3 of 7

- e. Sinus Tarsi Syndrome
- f. Metatarsalgia
- g. Excessive pronation with resultant skeletal pain
- h. Morton's Neuroma (also known as Intermetatarsal Neuroma)
- i. Sesamoiditis
- 5. Pediatric Conditions:
 - a. Tarsal Coalition
 - b. Metatarsus Adductus
 - c. Pes planus with foot pain (flat feet)
- 6. Sensory Neuropathies:
 - a. Peripheral Neuropathy (also includes neuropathic ulcers)
 - b. Charcot Neuroarthropathy (also known as Charcot Foot)
- 7. Congenital or Traumatic Painful and Disabling Deformities
- 8. Some Complications of Peripheral Vascular Disease
- C. When benefits are provided under the member's contract, JHHP considers replacement of custom foot orthotics medically necessary:
 - 1. When there is growth, OR;
 - 2. A documented change in the patient's condition, OR;
 - 3. Every 12 months due to documented wear and tear.

V. BACKGROUND

Foot orthotics include devices used to support, align, balance and improve the function of the foot. In addition to correcting compensatory joint motions, foot orthotics may also delay or prevent deformity. They may also eliminate the need for surgery or, in some cases, prevent the recurrence of deformities after surgery. Foot orthotics are available as off-the-shelf pre-fabricated and custom fitted shoe inserts and are used in the treatment of many conditions including plantar fasciitis.

Plantar fasciitis, a common foot condition, produces symptoms often described as burning or stabbing pain in the heel that is worse in the mornings with first steps. The pain typically will lessen with a gradual increase in activity, but then worsens after a day of prolonged weight-bearing (Buchbinder, 2023). The condition is more prevalent among individuals who are obese, lead sedentary lifestyles, runners, in the military and those with occupations requiring prolonged standing (Lewis, 2015). In a literature review conducted by Lewis in 2015, limited to randomized controlled trails and systematic reviews, it was concluded that foot orthotics reduce pain and improve function in acute plantar fasciitis and that similar relief was found with the use of either prefabricated or custom-fitted orthotics. A randomized control trail of the short and long-term effectiveness of foot orthotics in the treatment of chronic plantar fasciitis showed both the prefabricated and customized orthoses produced statistically significant improvements in function. In the short-term, pain was reduced with use of both types of orthotics as compared to a sham orthotic:, however, the differences were small and not statistically significant. Long-term effects on pain and function were negligible and the effects of prefabricated and custom orthotics were similar (Landorf, 2006). In a small randomized control trail comparing pre-fabricated full-length silicone insoles to ultrasound-guided corticosterone injection in the management of plantar fasciitis, the prefabricated shoe inserts were considered to be an effective first-line treatment option for plantar fasciitis (Yucel, 2013).

The American College of Foot and Ankle Surgeons (ACFAS) in their 2018 Clinical Consensus Statement: Diagnosis and Treatment of Adult Acquired Infracalcaneal Heel Pain recommended stretching as safe and effective in the treatment of plantar fasciitis. The type of stretching, home stretching exercises, stretching with use of a night splint, or physical therapy would vary depending on severity and patient preference. All panel members agreed that an aggressive stretching protocol is preferred in the treatment of plantar fasciitis. A consensus was reached that biomechanical support is a safe and effective treatment for

[©] Copyright 2024 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University

	±	Policy Number	CMS15.04
	Medical Policy Manual Medical Policy	Effective Date	02/01/2024
JOHNS HOPKINS	·	Approval Date	11/21/2023
HEALTH PLANS	<u>Subject</u>	Supersedes Date	02/01/2023
	Foot Orthotics	Page	4 of 7

plantar fasciitis, including support through taping, strapping, over-the-counter and custom orthoses. The panel also advised avoidance of non-supportive shoes (Schneider, et al. 2018). In an UpToDate report, Buchbinder reports the general approach to therapy includes stretching exercises of the plantar fascia and calf muscles, avoidance of flat shoes and barefoot walking, and use of prefabricated, over-the-counter silicone heel shoe inserts. In addition, life-style modifications are recommended, including a decrease in physical activities that may be causative or aggravating, including excessive running, dancing, or jumping (Buchbinder, 2023).

VI. CODING DISCLAIMER

CPT[®] Copyright 2023 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

<u>Note:</u> The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require pre-authorization.

Adherence to the provisions in this policy may be monitored and addressed through post payment data analysis and/or medical review audits

Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.

Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.

Johns Hopkins Health Plan of Virginia Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.

Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.

US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

VII. CODING INFORMATION

HCPCS CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
HCPCS CODE	DESCRIPTION
L3000	Foot insert, removable, molded to patient model, UCB type, Berkeley shell, each
L3001	Foot insert, removable, molded to patient model, Spenco, each
L3002	Foot insert, removable, molded to patient model, Plastazote or equal, each
L3003	Foot insert, removable, molded to patient model, silicone gel, each

[©] Copyright 2024 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University

	Johns Hopkins Health Plans	Policy Number	CMS15.04	
	Medical Policy Manual Medical Policy	Effective Date	ote 02/01/2024	
JOHNS HOPKINS		Approval Date	11/21/2023	
HEALTH PLANS	Subject	Supersedes Date	02/01/2023	
	Foot Orthotics	Page	5 of 7	
L3010	Foot insert, removable, molded to patient model, longitudinal arch support	, each		
L3020	Foot insert, removable, molded to patient model, longitudinal/metatarsal st	l support, each		
L3030	Foot insert, removable, formed to patient foot, each			

VIII. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

IX. REFERENCES

Aetna. (2023, April 11). Foot Orthotics. Medical Clinical Policy Bulletin Number: 0451. https://www.aetna.com/

Arias-Martín, I., Reina-Bueno, M., & Munuera-Martínez, P. V. (2018). Effectiveness of custom-made foot orthoses for treating forefoot pain: a systematic review. *International Orthopaedics*, 42(8), 1865–1875. https://doi.org/10.1007/s00264-018-3817-y

Blue Cross Blue Shield North Dakota. (2023, May 23). Foot Orthotics for Conditions Other Than Diabetes. Policy ID: O-12-035. https://www.bcbsnd.com

Buchbinder, R. B. (2023). Plantar fasciitis. UpToDate. Retrieved October 20, 2023 from www.uptodate.com

Callahan, L.R., Atkinson, B. (2023). Running injuries of the lower extremities: Risk factors and prevention. *UpToDate*. Retrieved October 20, 2023 from https://www.uptodate.com/

Centers for Medicare & Medicaid Services (CMS). (2023). *Durable Medical Equipment, Prosthetics/Orthotics & Supplies Fee Schedule*. Retrieved October 25, 2023 from https://www.cms.gov/

Cigna. (2023, October 15 15).) Orthotic Devices and Shoes. Medical Coverage Policy Number: 0543. https://static.cigna.com/

Chorley, J. (2023). Forefoot and midfoot pain in the active child or skeletally immature adolescent: Overview of causes. *UpToDate*. Retrieved October 20, 2023 from https://www.uptodate.com

Clugston, J.R., & Hatch, R.L. (2023). Stress fractures of the metatarsal shaft. *UpToDate*. Retrieved October 20, 2023 from http://www.uptodate.com

Coheña-Jiménez, M., Pabón-Carrasco, M., & Pérez Belloso, A.J. (2021). Comparison between customized foot orthoses and insole combined with use of extracorporeal shock wave therapy in plantar fasciitis, medium-term follow-up results: A randomized controlled trial. *Clinical Rehabilitation*, *35*(5), 740-749. https://doi.org/10.1177/0269215520976619

Guldemond, N. A., Leffers, P., Sanders, A.P., Emmen, H., Schaper, N. C., & Walenkamp, G. H. (2006). Casting methods and plantar pressure: effects of custom-made foot orthoses on dynamic plantar pressure distribution. *Journal American Podiatric Medical Association*, *96*(1), 9-18. https://doi.org/10.7547/0960009

Gupta, R., Malhotra, A., Masih, G. D., Khanna, T., Kaur, H., Gupta, P., & Kashyap, S. (2020). Comparing the role of different treatment modalities for plantar fasciitis: a double blind randomized controlled trial. *Indian Journal of Orthopaedics*, *54*(1), 31–37. https://doi.org/10.1007/s43465-019-00038-w

[©] Copyright 2024 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University



Hawke, F., Burns, J., Radford, J. A., & du Toit, V. (2008). Custom-made foot orthosis for the treatment of foot pain. *Cochrane Database of Systematic Reviews*, 3. Art. No.: CD006801.https://www.cochranedatabase.com

Hordon, L.D. (2023). Diabetic neuroarthropathy. UpToDate. Retrieved October 20, 2023 from https://www.uptodate.com/

Kang, P. (2023). Charcot-Marie-Tooth disease: Management and prognosis. *UpToDate*. Retrieved October 20, 2023 from https://www.uptodate.com

Karimi, M., Kavyani, M., Tahmasebi, R. (2022). Conservative Treatment for Metatarsus Adductus, A Systematic Review of Literature. *The Journal of Foot and Ankle Surgery: Official Publication of the American College of Foot and Ankle Surgeons*, 61(4), 914-919. https://www.sciencedirect.com

Koc, T.A., Bise, C.G., Neville, C., Martin, R.L., McDonough, C.M., and Clinical Practice Guidelines Linked to the International Classification of Functioning, Disability, and Health from the Academy of Orthopaedic Physical Therapy and American Academy of Sports Physical Therapy of the American Physical Therapy Association. Heel pain-plantar fasciitis: revision 2023. *J Orthop Sports Physical Therapy*. https://www.orthopt.org/uploads/content_files/files/Heel Pain Plantar Fasciitis Revision 2023.pdf

Landorf, K. B., Keenan, A. M., Herbert, R. D. (2006). Effectiveness of Foot Orthoses to Treat Plantar Fasciitis: A Randomized Trial. *Archives of Internal Medicine*, *166*(12), 1305-10. https://doi.org/10.1001/archinte.166.12.1305

Landorf, K. B., Menz, H. B. (2008). Plantar heel pain and fasciitis. *BMJ Clinical Evidence*, 2008, 1111. https://www.ncbi.nlm.nih.gov

Lewis, R. D., Wright, P., & McCarthy, L. H. (2015). Orthotics compared to conventional therapy and other non-surgical treatments for plantar fasciitis. *Journal of Oklahoma State Medical Association 108*(12), 596-598. https://www.ncbi.nlm.nih.gov

Martin, J. E., Hosch, J. C., Goforth, W. P., Murff, R. T., Lynch, D. M., & Odom, R. D. (2001). Mechanical treatment of plantar fasciitis. A prospective study. *Journal of the American Podiatric Medical Association*, 91(2), 55-62. https://doi.org/10.7547/87507315-91-2-55

Martin, R. L., Davenport, T. E., Reischl, S. F., McPoil, T. G., Matheson, J. W., Wukich, D. K., McDonough, C. M., & American Physical Therapy Association (2014). Heel pain-plantar fasciitis: revision 2014. *The Journal of Orthopaedic and Sports Physical Therapy*, 44(11), A1–A33. https://doi.org/10.2519/jospt.2014.0303

O'Connor, F.G., & Mulvaney S. W. (2023). Patellofemoral pain. *UpToDate*. Retrieved October 24, 2023 from https://www.uptodate.com

Pfeffer, G., Bacchetti, P., Deland, J., Lewis, A., Anderson, R., Davis, W. Alvarez, R., Brodsky, J., Cooper, P., Frey, C., Herrick, R., Myerson, M., Sammarco, J., Janecki, C., Ross, S., Bowman, M., & Smith, R. (1999). Comparison of custom and prefabricated orthoses in the initial treatment of proximal plantar fasciitis. *Foot & Ankle International*, 20(4). 214-221. Retrieved: https://doi.org/10.1177/107110079902000402

[©] Copyright 2024 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University

	1	Policy Number	CMS15.04
	Medical Policy Manual Medical Policy	Effective Date	02/01/2024
JOHNS HOPKINS	· · · · · · · · · · · · · · · · · · ·	Approval Date	11/21/2023
HEALTH PLANS	<u>Subject</u>	Supersedes Date	02/01/2023
	Foot Orthotics	Page	7 of 7

Richie, D.H., Jr (2007). Effects of Foot Orthoses on Patients with Chronic Ankle Instability. *Journal of the American Podiatric Medical Association*, 97(1) 19-30. https://doi.org/10.7547/0970019

Richie, D. (2015). Orthosis for plantar fasciitis: What the evidence reveals. *Podiatry Today*. https://www.hmpgloballearningnetwork.com

Rasenberg, N., Riel, H., Rathleff, M. S., Bierma-Zeinstra, S., & van Middelkoop, M. (2018). Efficacy of foot orthoses for the treatment of plantar heel pain: a systematic review and meta-analysis. *British journal of sports medicine*, *52*(16), 1040–1046. https://doi.org/10.1136/bjsports-2017-097892

Schneider, H. P., Baca, J., Carpenter, B., Dayton, P., Fleischer, A. E., Sachs, B. D. (2018). American College of Foot and Ankle Surgeons Clinical Consensus Statement: Diagnosis and Treatment of Adult Acquired Infracalcaneal Heel Pain. *The Journal of Foot and Ankle Surgery: official publication of the American College of Foot and Ankle Surgeons*, *57*(2), 370-381. https://pubmed.ncbi.nlm.nih.gov/29284574/

Wexler, D. J. (2023). Evaluation of the diabetic foot. *UpToDate*. Retrieved on October 24, 2023 from https://www.uptodate.com

Whittaker, G. A., Landorf, K. B., Munteanu, S. E., & Menz, H. B. (2020). Predictors of response to foot orthoses and corticosteroid injection for plantar heel pain. *Journal of Foot and Ankle Research*, *13*(1), 60. https://doi.org/10.1186/s13047-020-00428-6

Whittaker, G. A., Munteanu, S. E., Menz, H. B., Tan, J. M., Rabusin, C. L., & Landorf, K. B. (2018). Foot orthoses for plantar heel pain: a systematic review and meta-analysis. *British Journal of Sports Medicine*, *52*(5), 322–328. https://doi.org/10.1136/bjsports-2016-097355

Xiang, L., Mei, Q., Wang, A., Fernandez, J., & Gu, Y. (2022). Gait biomechanics evaluation of the treatment effects for hallux valgus patients: A systematic review and meta-analysis. *Gait & Posture*, *94*, 67-68. https://www.sciencedirect.com

Yucel, U., Kucuksen, S., Cingoz, H. T., Anliacik, E., Ozbek, O., Salli, A., & Ugurlu, H. (2013). Full-length silicone insoles versus ultrasound-guided corticosteroid injection in the management of plantar fasciitis: a randomized clinical trial. *Prosthetics and Orthotics International*, *37*(6), 471-476. https://doi.org/10.1177/0309364613478328

X. APPROVALS

Historical Effective Dates: 06/01/2000, 10/22/2003, 10/22/2004, 10/21/2005, 10/19/2006, 06/25/2008, 06/04/2009, 04/02/2010, 04/06/2011, 05/29/2012, 03/06/2015, 03/03/2017, 05/01/2020, 02/01/2022, 02/01/2023, 02/01/2024

[©] Copyright 2024 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University