ABMSPSDO
AMERICAN NATIONAL
STANDARD

Inserts for Diabetic Footwear ABMSPSDO ASN-001-2018

More Information: To learn more about ABMSP SDO, see http://www.abmsp-sdo.org
To learn more about the ABMSP, see http://www.abmsp.org

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Preface

Adherence to American National Standards create product uniformity and consistency. Currently, there are no American National Standards for the manufacture of either off-the-shelf (OTS), pre-fabricated, or custom inserts for diabetic footwear. The majority of shoes worn by patients with Diabetes use inserts that, depending on their construction, may or may not provide enduring and consistent medical outcomes. On the other hand, custom inserts are often unavailable or may be out of reach for a variety of reasons including access to appropriate prescribers and cost. OTS, pre-fabricated, and custom inserts for patients with Diabetes, manufactured in conformance with this American National Standard, provide product consistency and are more likely to fulfill provider expectations and support patient wellness.

ANSI/ABMSPSDO®ASN-001-2018 provides a standard for the manufacture of inserts for diabetic footwear. The standard applies to custom fabricated, off-the-shelf (OTS), and "Library" inserts and is supported by current, widely accepted medical practice. It is based on scientific research documented by relevant, peer-reviewed literature, and provider outcomes.

ANSI/ABMSPSDO®ASN-001-2018 requires the applicant organization to

- A written [1], documented statement of the insert's technical specifications for which accreditation by this standard is sought,
- Written proof of Current FDA Registration and Licensure to manufacture the insert for which accreditation by this standard is sought,
- Written proof of product validation by the Centers for Medicare & Medicaid Services (CMS) of the insert for which accreditation by this standard is sought, and
- Written proof that clearly documents either an in-house or out-sourced product quality assurance program for the manufacturing process of the insert for which accreditation by this standard is sought.

CMS is the world's largest payer for approved medical devices. Clearly stated product specifications, combined with FDA registration and licensure, CMS product validation and a qualified product quality assurance program, assures that product specifications for the inserts recognized by this standard consistently meet the manufacturer's advertised specifications.

ANSI/ABMSPSDO®ASN-001-2018 enables prescribers to make more productive choices for their patients based on clear and proven product specifications. Adherence to this standard assures that the manufacturer's product claims better align with provider-anticipated results. This in turn leads to more consistent medical outcomes which improve public acceptance and confidence in the products manufactured under and conforming to this standard.

[1] "Written" includes statements provided in electronic formats

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Section 1.0 Introduction

The American Board of Multiple Specialties in Podiatry (ABMSP) is an American National Standards Institute (ANSI) accredited medical specialty board providing board certifications in Primary Care, Foot and Ankle Surgery, Limb Salvage, Diabetic Foot Wounds and Lower Extremity Geriatric Podiatry. The board provides a certification in diabetic foot wounds and actively supports standards development for the care and treatment of the diabetic foot. This interest prompted the board to initiate development, beginning in 2016, of the ABMSP Standards Development Organization (SDO) which presents this standard designated as *ANSI/ABMSPSDO®ASN-001-2018: Inserts for Diabetic Footwear.* Both the ABMSP and the ABMSP SDO are accredited by ANSI. ABMSP is accredited as a professional podiatric certification board. The ABMSP SDO is accredited as a standards developer for orthotics of the lower limb, foot and ankle.

Standards developed by ANSI accredited organizations are designated by the United States Government as American National Standards.[2] ANSI is the sole representative from the United States to the International Organization for Standards (ISO).[3] Therefore, standards developed by ANSI accredited SDOs are also eligible to become international standards as accreditation by ANSI signifies that the procedures used in the development of the standard meet ISO requirements.

To achieve and maintain ANSI accreditation as a standards developer, the ABMSPSDO follows "due process" and adheres to ANSI and ISO criteria as defined by: ANSI *Essential Requirements: due process for development of American National* Standards.[4] Our policies and procedures are ratified by nation-wide public assessment through their publication for review and comment in the nationally distributed, weekly publication, *Standards Action*.

Due process requires that all steps in the standards development process be achieved by consensual representation of the community of interest[5] potentially impacted by the standard under development. The community of interest includes medical device manufacturers and distributors, researchers, professional boards, public and private licensing organizations, payers, local, state and Federal regulatory agencies, medical providers, prescribers of diabetic footwear and end-users of the standard, in this case, consumers of inserts for diabetic footwear.

Before this standard, there were no industry-wide, consensus-based voluntary American National Standards to address the many and wide variations in material properties and manufacturing processes that can significantly impact therapeutic efficacy and durability of inserts for diabetic

[2] An American National Standard (ANS) is a consensus based, voluntary standard developed by a community of invested stakeholders to assure product consistency and excellence.

[3] ISO

[4] *ANSI Essential Requirements: due process for development of American National* Standards is published by ANSI and updated annually.

[5] Community of Interest refers individuals and organizations potentially impacted by a standard.

footwear. Community vetted specifications addressed by this standard designate footwear that is more predictive of positive clinical outcomes for patients.

The rationale for development of this standard is based on the value of augmenting current CMS validation requirements with quality assurance programs in order to assure product consistency of the elements enumerated above. This standard may also assist in establishing an appropriate Healthcare Common Procedure Coding System (HCPCS)[6] code for Medicare billing.

Section 2.0 Background

The ABMSP SDO conducted a thorough review of the literature to assure that this standard does not duplicate existing standards. The SDO then encouraged and recruited participation in this standard's development from the community of interest that the standard impacts. *ANSI/ABMSPSDO®ASN-001-2018: Inserts for Diabetic Footwear* is the result of a voluntary, consensual development process, with broad representation on our SDO committees from the community of interest.

ABMSPSDO committees include the ABMSPSDO Steering Committee, National Standards Board, the ANSI/ABMSPSDO®ASN-001-2018 Standard Specific Workgroup and its Technical Subcommittee. This committee structure is required by our policy and procedures manual and outlined in our organizational chart.[7] Participation on these committees is open to members of the community of interest and the general public. Development was led by the ANSI/ABMSPSDO®ASN-001-2018 Technical Sub-committee and its Workgroup (Workgroup I).

This standard for diabetic footwear inserts serves the medical community by addressing currently known needs of clinical practice for diabetic patients, confirmed by review of relevant peer-reviewed literature. Final determination of the validity of this standard is governed by the ANSI Board of Standards Review (ABSR).[8]

Section 3.0 Rationale for Development

The Medicare validation process has no statutory authority to oversee non-Medicare third-party payers. Payers other than Medicare do not necessarily follow Medicare policy. Currently there are no voluntary, industry-vetted consensus-based, American National Standards to address the wide

[6] See Section VIII, Glossary of Acronyms and Terms

[7] The ABMSPSDO organization chart may be found on our website, www.abmspsdo.org

[8] ABSR The *ANSI Board of Standards Review* is responsible for the approval and withdrawal of American National *Standards* and for other responsibilities that may be delegated to it by the *Board* of Directors. See: *https://www.ansi.org/about_ansi/structure_management/committees/bsr/bsr*