

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



Sue Borondy
Blatchford, Inc. (Endolite North America)
1031 Byers Road
Miamisburg, OH 45342

NOV 20 2018

Re: 18.097

Request to establish a new Level II HCPCS "Addition" code to describe the function and benefit of the Silcare Breathe Prosthetic Liner, Trade Name: Endolite/Blatchford Silcare Breathe.

Applicant's suggested language: LXXXX-"Addition for moisture, temperature, air, and skin management interface liner with natural vacuum/suction suspension for volume control."

Dear Ms. Borondy:

On behalf of the Centers for Medicare and Medicaid Services (CMS), I would like to thank you for your application to modify the HCPCS Level II code set. The HCPCS Level II code set is available for use by all payers, and is maintained by CMS taking into consideration the national program operating needs of all payers, including Medicare, Medicaid, and Private Insurers.

CMS reviewed your application and published the following preliminary coding recommendation:

A new "addition" code to identify perforated liners is not approved. Perforation of liners is not new technology. Applicant claims of significant therapeutic distinction for temperature regulation of suspension is not substantiated. Existing L.E. codes L5673, L5679, L5681 and L5683; and U.E. codes L6694, L6695, L6696 and L6697 describe existing insert. These are inclusive of perforation technology.

CMS received comments on behalf of the applicant. These comments discussed the effect of moisture at residuum interface for persons with limb amputation; the additional cost of fabrication of liner with laser-drilled holes; and independent studies which "quantify the reduction in dermatological problems."


CMS upheld its decision. A new "addition" code to identify perforated liners is not approved. Perforation of liners is not new technology. Applicant claims of significant therapeutic distinction for temperature regulation of suspension is not substantiated. Existing L.E. codes

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The HCPCS Level II codes describe categories of like items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as listed above are inclusive of liners with perforation technology, as a general rule, the CMS does not classify individual items into code categories on behalf of insurers. Individual insurers have the necessary flexibility to classify specific products into HCPCS Level II code categories and establish their own coding instructions in accordance with their policies and program operating needs. Questions regarding classification of products into HCPCS Level II code categories should be submitted to the insurer in whose jurisdiction a claim would be filed. For private sector health insurance systems, please contact the individual private insurance entity. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: <http://www.dmepdac.com>. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

Sincerely,



Cynthia Hake
Director, CMS National Level II HCPCS Coding Program and
Deputy Director, Division of DMEPOS Policy