

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-08-27
Baltimore, Maryland 21244-1850



Center for Medicare

S. Guna Gunasekaran, Ph.D.
ENCOLL Corp.
5686 Geranium Ct
Newark, CA 94560

NOV 03 2015

Re: 15.062

A. Request to establish a unique Level II HCPCS Q-code to identify an acellular dermal matrix, Helicoll™.

Applicant's suggested language: Q41XX - Helicoll™ Acellular Dermal Matrix, per square centimeter.

Dear Dr. Gunasekaran:

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 decision:

Use existing A6021 "Collagen dressing, sterile, size 16 sq. in. or less, each"; A6022 "Collagen dressing, sterile, size more than 16 sq. in. but less than or equal to 48 sq. in., each"; or A6023 "Collagen dressing, sterile, size more than 48 sq. in., each," based on size, adequately describes the product that is the subject of this request.

We appreciate the comments you provided at CMS' HCPCS Public Meeting in reaction to our preliminary decision. Specifically, you disagreed with CMS preliminary decision, commenting that unlike a wound dressing, Helicoll stimulates tissue regeneration in chronic wounds. Helicoll is recognized as a skin substitute by the FDA and AHRQ. It is marketed as a skin substitute and sold primarily to hospitals for inpatient and outpatient use. And you asked CMS to reconsider the request to establish a unique Q code.

The CMS HCPCS Workgroup reconvened to consider your input, and revised its decision. The following modification has been made to the HCPCS Level II standard, national code set:

Establish Q4164 "Helicoll, per square centimeter", effective 1/1/16

All changes to the code set are effective January 1, 2016, unless an earlier effective date is specified in the 2016 Annual HCPCS Update. The entire 2016 HCPCS Annual Update is available and can be downloaded free of charge at: <http://www.cms.hhs.gov/medhcpcsgeninfo>. The code set is searchable using the edit function and key words or code numbers.

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. For Medicare, contact the Medicare contractor.

Sincerely,



Cynthia Hake, Director
CMS National HCPCS Coding Program