



**MEDICARE**

Part A Intermediary  
Part B Carrier  
DME Regional Carrier

October 5, 2004

Steven Drazer, Vice President  
Dr. Zen Inc.  
156 Harston Court  
Heathrow, FL 32746

Re: Cloud (Model #727)

Dear Mr. Drazer:

This letter is in response to your recent inquiry for coding verification of the Cloud (Model #727) manufactured by your company. The Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) has reviewed the documentation and information submitted for HCPCS Coding. The SADMERC conducts reviews of products to determine the correct HCPCS code(s) of DMEPOS product(s) for Medicare billing.

It is our determination that the Medicare HCPCS code(s) to bill the four Durable Medical Equipment Regional Carriers (DMERCs) is/are

**K0628 For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees Fahrenheit or higher, total contact with patient's foot, including arch, base layer minimum of 1/4 inch material of Shore A 35 Durometer or 3/16 inch material of Shore A 40 Durometer (or higher), prefabricated, each.**

**OR**

**A5510 For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, per shoe.**

This HCPCS coding decision applies to the submitted product(s) as presented to and reviewed by the SADMERC. Any modifications to the product(s) could change the HCPCS code and would need to be reviewed for coding verification. The assignment of a HCPCS code to the product(s) should in no way be construed as an approval or endorsement of the product(s) by SADMERC or Medicare, nor does it imply or guarantee claim reimbursement or coverage. For questions regarding claim coverage or reimbursement please contact your regional DMERC.

**Palmetto GBA**

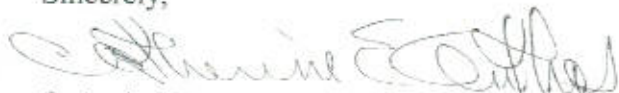
Statistical Analysis Durable Medical Equipment Regional Carrier  
Post Office Box 100143 • Columbia, South Carolina • 29202-3143

**A CMS Contracted Intermediary and Carrier**

Should you disagree with this coding decision, a re-review of the product(s) can be initiated. The SADMERC will provide a re-review if the request is made within 45 days of the date of this letter and additional documentation is provided supporting the request. If a request for a re-review is made after 45 days, the request is treated as a new Coding Verification Review and a complete application must be submitted along with the additional documentation supporting the request.

Should you have any questions regarding this decision, please contact me at the address below or by telephone at (803) 763-8215.

Sincerely,



Catherine E. Anthos, RN  
HCPCS Medical Analyst  
SADMERC

cc: DMERCs