Program Memorandum Carriers

Department of Health and Human Services (DHHS) HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal B-01-07 Date: FEBRUARY 7, 2001

CHANGE REQUEST 1521

SUBJECT: Apligraf (Graftskin)

On August 12, 2000, Apligraf (Graftskin) was approved for inclusion in the United States Pharmacopeia. The FDA labeling for Apligraf states that the indications for its use are the treatment of venous leg ulcers and diabetic foot ulcers. There is no national coverage decision regarding Apligraf. Carriers and intermediaries have discretion regarding coverage of Apligraf.

Under the hospital outpatient prospective payment system, Apligraf is reportable with HCFA Common Procedure Coding System (HCPCS) code C1305. Current Procedural Terminology (CPT) codes describing the services delivered are reported on the bill. The CPT codes to describe services associated with the use of Apligraf can include 15000 for the wound site preparation and 15342 and 15343 for application of the bilaminate skin substitute. Apligraf has been recognized as a biologic and will be paid at 95 percent of its average wholesale price (AWP) effective January 1, 2001.

Code Q0185 should be used for Apligraf for claims submitted to the carriers. CPT codes 15000, 15342, and 15343 can be used to describe the services delivered when Apligraf is used. For these services, physicians should not bill Apligraf using HCPCS code C1305 since this code has been approved solely for use under the hospital outpatient prospective payment system. The payment mechanism for Q0185 is 95 percent of its AWP since Apligraf has met the statutory requirement as a biologic.

The effective date for this Program Memorandum (PM) is February 7, 2001.

The *implementation date* for this PM is February 7, 2001.

These instructions should be implemented within your current operating budget.

This PM may be discarded after January 31, 2002.

If you have any questions, contact your local regional office.