Program Memorandum Intermediaries/Carriers

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

Transmittal AB-00-94 **Date: OCTOBER 5, 2000**

CHANGE REQUEST 1335

SUBJECT: Urokinase (Abbokinase®) Shortage

Abbokinase® is a thrombolytic agent indicated for the restoration of patency to intravenous (IV) catheters, including central venous catheters, obstructed by clotted blood or fibrin. This drug has been used to open central venous catheter occlusions for end-stage renal disease (ESRD) patients who are on dialysis, playing an integral role in restoring and securing vascular access for Medicare's dialysis patients.

On January 25, 1999, the Food and Drug Administration (FDA) issued a letter to inform healthcare providers of the agency's safety concerns regarding the manufacturing of Abbokinase® by Abbott Laboratories. Because of these concerns, the FDA has recommended that Abbokinase® be reserved for "only those situations where a physician has considered the alternatives and has determined that the use of Abbokinase® is critical to the care of a specific patient in a specific situation" (FDA "Letter to Healthcare Providers", January 25, 1999).

Since the FDA has recommended a restriction on its use to patients with critical care needs, Abbokinase® is no longer available in the U.S. for regular use in ESRD patients, resulting in a shortage of the drug. Dialysis facilities must find alternative medications to treat clotted central venous catheters. The following is a list of other thrombolytic products currently available in the U.S.: Streptokinase (Streptase® and Kabikinase®), Alteplase (Activase®), Anistreplase (Eminase®), and Reteplase (Retavase®). These medications could serve as possible alternatives to treat thrombotic dialysis catheters until Abbokinase® becomes available again. Updates on the FDA's deliberations on Abbokinase® can be monitored at the agency's website (www.fda.gov/medwatch/safety.htm).

Use of these five drugs for the restoration of patency to obstructed IV central venous catheters is not listed as an indication on their FDA-approved labels. Please evaluate the appropriateness of these medications for use in the treatment of clotted central venous catheters when making medical necessity determinations, using the guidance provided in §2049.4 of the Medicare Carriers Manual (MCM) on unlabeled uses of a drug.

As described in §3168(B) in the Medicare Intermediary Manual (MIM), thrombolytic agents used to treat clotted central venous catheters are not covered under the composite rate and therefore are separately billable. Thrombolytic agents used to treat clotted ESRD shunts, peripheral lines, or arteriovenous (AV) fistulas are covered under the composite and cannot be separately billed, according to §3169.1 of the MIM and §2710.4 of the Provider Reimbursement Manual.

The *effective date* for this Program Memorandum (PM) is November 1, 2000.

The *implementation date* for this PM is November 1, 2000.

These instructions should be implemented within your current operating budget.

This PM may be discarded after November 1, 2001.

If you have any questions, contact Svati Patel at (410)-786-2875.

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