REX HEALTHCARE

Laboratory Bulletin...

Updates and Information from Rex Healthcare and Rex Outreach

March 1998 *Issue Number 30*

More on Prestorage Leukocyte Reduced Blood Products

Allogeneic cellular blood component transfusions contain leukocytes which are associated with several undesirable patient outcomes in hematology/oncology patients, surgical patients and to some extent in all transfusion recipients. White blood cell filters for use at the time of transfusion, so-called “bed-side” filters, have been available for some time and have proven effective in significantly decreasing the adverse effects of leukocytes on the transfused patient. However, bed-side filters have several disadvantages. They require special training for proper use by the transfusionist. They do not remove white blood cell breakdown products like cytokines, histamines or HLA-containing membrane fragments, all of which may cause adverse effects in the recipient. In addition, the bed-side filters restrict flow rates, limiting their use when faster infusion rates would be clinically beneficial.

Pre-storage leukocyte depletion offers advantages. The white blood cells are removed in the blood donor center within hours of collection, thereby reducing the problem of WBC breakdown products remaining in the transfused unit. The leukocyte depletion can be performed under more controlled conditions than at the bed-side, and quality control measures will assure that the final content of white blood cells in the bag is below the clinically established threshold values. Furthermore, the blood may be transfused at any time with a standard administration set allowing rapid infusion as necessary; for example, in the operative or trauma setting.

The Rex Blood Plan is now preparing pre-storage leukocyte depleted blood products in addition to standard non-depleted units. These pre-storage leukocyte reduced products can be ordered in HELP according to the physician’s written order. It is important to remember that since the white cells are removed in the blood donor center, a leukocyte filter will no longer be issued with these pre-filtered components. The blood bag will be labeled “leukocyte reduced by filtration” as a reminder that the leukocytes have already been removed. It is counterproductive to use an additional bedside leukocyte filter since this will only remove more red cells or platelets from the product with no further improvement in leukocyte reduction (Note that fresh frozen plasma and cryoprecipitate do not require any type of leukocyte reduction).

Prestorage leukocyte reduced cellular products are indicated for a variety of patients including immunocompromised patients or anyone expected to receive multiple blood products, since they reduce the incidence of transfusion reactions and, more importantly, reduce the incidence of alloimmunization. Alloimunization occurs when the patient develops antibodies against HLA antigens that destroy subsequently transfused platelets, making them refractory to platelet count increases with subsequent transfusions. Such patients include oncology and hematology patients, dialysis patients, newborn and pediatric patients, HIV positive patients, and solid organ transplant patients. Home transfusion patients also benefit by significantly

reducing the chance of transfusion reaction. As discussed in a previous Lab Bulletin, surgery patients (including colorectal, orthopedic and cardiac) benefit by reducing the incidence of postoperative infection.

In addition, with the current generation leukocyte filtration technology, published studies continue to indicate that these products are equivalent to the use of screened CMV negative blood components for the prevention of transfusion-transmitted cytomegalovirus infection.

It is important to note that although Graft Versus Host Disease (GVHD) is a leukocyte mediated transfusion complication, even the best leukocyte reducing filters are **NOT** currently considered sufficient to reduce the risk of GVHD. Irradiation of the cellular blood products is still required for patients at risk for GVHD, since even the very small number of residual white cells in a filtered product are still capable of cell division and growth. Only irradiation can render these cells incapable of cell division and proliferation in the recipient.

Timothy R. Carter, MD

HCFA Authorized Lab Panels

The Healthcare Financing Administration (HCFA) has announced new guidelines for multichannel chemistry panels with CPT codes 80002-80019. The Government is concerned that the continued use of the old panels would result in the ordering of medically unnecessary tests. In response, the American Medical Association's CPT Editorial Panel has eliminated the series of CPT codes between 80002-80019, and replaced them with the new panels outlined below.

Effective April 1, 1998, all providers must use the new panel codes for Medicare/Medicaid reimbursement. Rex Healthcare's new outreach requisitions and the Rex HELP computer order entry system will have these new panels. Other lab tests ordered, in addition to a panel, will be billed individually. Conversely, if individually ordered chemistry lab tests constitute a panel, the insurance carrier (not the laboratory) will bundle the individual tests into the appropriate payment codes.

When ordering tests on Medicare patients, physicians should only order tests that are medically necessary for the diagnosis or treatment of the patient, rather than for screening purposes. If all the tests included in a panel listed below are not medically necessary for your patient, you should order a less inclusive panel or individual tests.

Below are six Medicare defined test panels offered by Rex Healthcare Laboratory. Each of the panels has a listing of the components and the CPT code used to bill Medicare. The laboratory will bill Medicare based on the CPT codes listed. A diagnosis code (ICD-9) that is appropriate for any one of the individual components of the panel is necessary to accompany the request. An "advanced beneficiary notice" (ABN) form must be completed if the ICD-9 code is not appropriate for any lab test. Medicare will not reimburse for lab tests done without the appropriate ICD-9 code.

MEDICARE DEFINED PANELS	**CPT Code**
Basic Metabolic Panel (M7)	**80049**
CO2/Creatinine/Glucose/Sodium/Chloride/BUN/Potassium	
Comprehensive Metabolic Panel	**80054**
Albumin/Glucose/Sodium/Bilirubin, Total/Alk-Phos/SGOT(AST)/Calcium/Potassium/ BUN/Chloride/Protein, Total/Creatinine	
Electrolyte Panel	**80051**
CO2/Chloride/Potassium/Sodium	
Lipid Panel	**80061**
Cholesterol, Total/LDL (calculated)/HDL/VLDL (calculated)/Triglycerides HDL/LDL Ratio (calculated)	
Hepatic Function Panel	**80058**
Albumin/Bilirubin, Direct/Alk Phos/SGPT(ALT)/Bilirubin, Total/SGOT(AST)	
Hepatitis Panel	**80059**
Hepatitis B surface antigen/Hepatitis B core antibody, Total (IGG + IGM) Hepatitis B surface antibody/Hepatitis A antibody, Total (IGG + IGM)	

Hepatitis C antibody

Medicare inpatients' laboratory tests are reimbursed under the DRG payment to the Hospital. All of the current Rex Lab defined panels are available to inpatients. The Hospital pathologists may be contacted for consultation on the appropriateness of testing and test ordering by calling (919) 784-3201 or (919) 784-3040. Customized lab panels that are not currently defined by HCFA or Rex may be requested by a physician by consulting with the Chairman of the Department of Pathology and completing a "CUSTOM PROFILE REQUEST FORM." A detailed booklet explaining Medicare compliance, fraud and abuse issues as they relate to ordering lab tests and ABN forms will be delivered to your office.

Stephen V. Chiavetta, MD, Chairman, Pathology Department
Sharon M. Logue, MT, MBA, Admin. Laboratory Director

Update on HCFA Guidelines, Medical Necessity, and Coding Requirements

FRAUD AND ABUSE UPDATE

For a number of years, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) has focused on clinical laboratory testing in their fraud and abuse enforcement activities. These efforts have included OIG's "Lab Scam" which to date has recovered over $800 million in civil fines and penalties from several well known clinical laboratories. As a result, all clinical laboratories are at increased risk for federal investigation of their billing practices. Recent legislation has mandated changes in ordering, coding, and the billing of certain laboratory tests for patients covered by HCFA reimbursement such as Medicare and Medicaid.

Federal Health Care Program Criminal Provisions

We have included a brief overview of the Fraud and Abuse developments as they relate to the provision of clinical laboratory and pathology services. The cornerstone fraud and abuse provision is 42 U.S.C. 1320a-7b. Violations of this provision include the following:

- False Statements for Reimbursement which prohibits the knowing and willful making of a false statement which affects reimbursement under a federal health program.
- Illegal Remuneration which prohibits the knowing and willful payment or receipt of " any remuneration directly or indirectly in cash or kind" in return for referrals.
- Criminal False Claims Statute which prohibits presenting any claim upon or against the United States or any department or agency thereof, knowing such claim to be false, fictitious or fraudulent. Violations of this provision are punishable by imprison ment for up to five years and fines of up to $10,000.
- Civil Monetary Penalties Act provides for penalties of $10,000 plus three times the amount claimed. This act prohibits claims for services not provided as claimed; false or fraudulent claims; claims for physician services not furnished by physicians; or claims for services furnished by an excluded physician or provider.
- False Claims Act permits the government to recover a civil penalty against any person who knowingly presents a false or fraudulent claim for payment by the government. The penalty for each violation is not less than $5,000 and not more than $10,000 plus three times the amount of damages the government sustains.

Update on Medical Necessity and Medical Appropriateness

OIG believes that clinical laboratories should help ensure that claims are only submitted for services that are medically necessary. The laboratory must also audit

and monitor the utilization of tests, so as to determine if in fact all tests are clinically necessary and appropriate. You may still order all tests that you feel are appropriate for your patients, and we will continue to work with you to customize specific panels, by contacting Stephen Chiavetta, MD, Chairman of the Department of Pathology. For Medicare patients, however, only "medically necessary" tests should be ordered, unless the patient does agree to sign an Advance Beneficiary Notice (ABN) before the test is ordered. We will not deny services to any patient even without an ABN signed in advance; however, we encourage you to order only those tests that meet criteria for reimbursement. The criteria that is required is either a correct ICD-9 code, or a narrative of diagnosis. We ask that you discuss this with your patient, and indicate a reason that you may feel denial of reimbursement is likely on the ABN Form.

Update on Coding Requirements

The Balanced Budget Act of 1997 requires every clinical lab to submit diagnostic information in order to be reimbursed for its services, and the physician must provide that information to the laboratory at the time of service. This went into effect on January 1, 1998. Our laboratory will contact all providers for this information, if it is not already included with the written order. We will accept a fax request, an applicable ICD-9 code for a panel, or applicable ICD-9 codes for every individual test, or a narrative that supports the medical necessity of all ordered tests. Our new requisition includes space for these codes, and includes a CPT code for every common test, to facilitate coding. Our personnel will be happy to assist you, as correct coding is very important to the success of our training program. We will continue to keep you informed of information about our training programs, and updates on Federal legislation.

Sharon M. Logue, MT, MBA, Admin. Laboratory Director

Acid Phosphatase Assay Discontinued

The Laboratory has discontinued the acid phosphatase assay due to lack of clinical interest. The superior sensitivity and specificity of prostate specific antigen as a tumor marker for prostatic adenocarcinoma presaged this development. Specimens yearning for acid phosphatase analysis will be referred to Mayo Medical Laboratories ("prostatic acid phosphatase" by microparticle enzyme immunoassay). Old enzymes never die, they simply run out of substrate.

John D. Benson, MD

For further information, call the Laboratory (783-3040). Telephone extensions are: Pathologists' Direct Line (3201), Dr. Kleeman (3063), Sharon Logue (Lab Director 3055), Robin Ivosic (Core Lab Manager 3053), Linda Lompa (Blood Services Manager 785-4770), Kimberly Skelding (Customer Services Manager 3318), Rex Outreach (783-3040), Karen Sanderson (Lab Compliance Specialist 3396).