**SCOPE:** All Company-affiliated hospitals performing and/or billing for laboratory services. Specifically, the following departments:

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<tr>
<th>Department</th>
<th>Revenue Integrity</th>
<th>Medical Staff</th>
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<tbody>
<tr>
<td>Shared Services Centers</td>
<td>Laboratory</td>
<td>Administration</td>
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</table>

**PURPOSE:** To outline the requirements for the use of laboratory test panels and profiles so that Medicare will be billed only for those tests that it considers to be reasonable and necessary.

**POLICY:** Hospitals may recognize panels developed by the American Medical Association (AMA) and adopted for reimbursement by Centers for Medicare and Medicaid Services (CMS). Hospitals may choose to permit custom profiles provided they are valid, documented, medically necessary, and monitored for appropriateness.

**DEFINITIONS:**

**Custom Profiles:** A custom profile is a physician specific group of commonly ordered laboratory tests or panels which have not been defined by the AMA or CMS that are medically necessary in treating a patient’s condition. Custom profiles are for use by the defining physician only and an acknowledgement must be signed by the physician on an annual basis. Please refer to Attachment A – Physician Acknowledgement for a Custom Profile.

**Organ or Disease-Oriented Panels:** A group of medically necessary laboratory tests defined by the AMA and approved for reimbursement by CMS. (Reference the Hematology Procedures, Urinalysis Procedures, and Organ or Disease-Oriented Panels Policy, REGS.LAB.026.)

**PROCEDURE:**

The following steps must be performed when establishing and utilizing custom profiles.

**IMPLEMENTATION AND ANNUAL REVIEW:**

1. Laboratory personnel must review and verify applicable revisions are made to the chargemaster and related Laboratory and Order Entry masterfiles/dictionaries to ensure all custom profiles are established and maintained in accordance with this policy.

2. A custom profile is established as defined by the requesting physician and may be used only by that physician. Laboratory Directors are responsible for validating custom profiles by obtaining a signed Physician Acknowledgement annually from each physician for each custom profile utilized in the treatment of his/her patients. Hospitals that allow the use of custom profiles must educate physicians...
regarding this policy as well as the Medicare – National and Local Coverage Determinations Policy (REGS.GEN.011). Please refer to Attachment A – Physician Acknowledgement for a Custom Profile.

3. All staff responsible for ordering, registering, performing, charging, coding, and billing laboratory tests must be educated on the contents of this policy.

4. The requirements and implementation of this policy must be reviewed on an annual basis. This review should be documented.

DAILY

Individuals responsible for registering and/or ordering laboratory services must review each component test of a custom profile for medical necessity according to the Local Coverage Determinations (LCD) and National Coverage Determinations (NCD). If the laboratory test order for a custom profile does not include a specific diagnosis, sign, symptom, and/or ICD-CM code, or does not meet the criteria as defined in the LCD and/or the NCD, an Advance Beneficiary Notice of Noncoverage (ABN) should be obtained from the patient for the non-covered component test(s). The process for obtaining an ABN is defined in the Advance Beneficiary Notice of Noncoverage Policy, REGS.GEN.003.

The Facility Ethics and Compliance Committee is responsible for implementation and monitoring of this policy within the facility.

REFERENCES:

OIG Model Compliance Plan for Clinical Labs (March, 1997 & August 1998)
Hematology Procedures, Urinalysis Procedures, and Organ or Disease-Oriented Panels Policy, REGS.LAB.026
PHYSICIAN ACKNOWLEDGEMENT FOR A CUSTOM PROFILE

In allowing the use of custom profiles, we are required to obtain annually, your signature below acknowledging you have read and understand all the requirements surrounding custom profiles. In the event we do not receive this signed acknowledgement, we will not be able to recognize your custom profile listed below. Should you have any questions, please contact our Lab Director ______________________ at ______________________.

The custom profile you have requested, __________________________, includes the following components which when medically necessary, will be reimbursed as follows:

<table>
<thead>
<tr>
<th>Component Test Names and CPT Codes</th>
<th>Medicare Reimbursement</th>
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This acknowledgement is also to remind you that:

1. When ordering tests for which Medicare reimbursement will be sought, you, as the physician, should only order those tests which you believe are medically necessary for each patient.

2. Utilizing a custom profile may result in the ordering of tests for which Medicare or other federally funded payers may deny payment.

3. Only those tests medically necessary in treating a patient’s condition should be ordered. Therefore, when all of the components of a custom profile are not medically necessary, you should order only those individual tests or a less inclusive profile which are medically necessary in treating a patient.

4. The Office of Inspector General (OIG) takes the position that a physician who orders medically unnecessary tests for which Medicare reimbursement is claimed may be subject to civil penalties.

Our facility has a clinical consultant available to assist you in ensuring appropriate tests are ordered. You may contact our clinical consultant as follows:

Name: ______________________________

Phone Number: _______________________

_______________________________

Physician Signature

__________________________

Date