Attached is the new Chapter III, Coverage and Limitations, of the Laboratory manual. It encompasses all laboratory changes to date.

Since the Department of Community Health (DCH) is no longer publishing the Medicaid Procedure Manual (MPC), a section has been added in Chapter III titled, Test Reports. The section now incorporates many of the comments and instructions that were previously found in the MPC manual with the procedure codes. Following are the test reporting instructions used for billing laboratory services:

**Specimen Source**

The tested entity may be from any source unless the source is specified in the procedure code description.

**Calculated Results**

The mathematical calculation of two or more results to produce an index or ratio or any other result may not be billed as a separate independent test.

**Test Results**

Reimbursement will be made for tests performed using a method that will yield quantitative results unless the nomenclature specifies a different method.
Panel Tests

Only AMA-approved organ- or disease-oriented panels may be billed. All tests within the panel must be medically necessary. Unless the complete panel is ordered and performed, bill as individual tests.

Complete Procedures and Unbundling

In some instances, a procedure is listed both in its entirety and also with component services specified. If the entire procedure is performed, the code for the entire procedure must be reported. Do not bill for component services when the entire procedure is performed.

Urinalysis

In the event a single urine specimen is tested for the same entity (chemical, element, compound, substance) by more than one method, the procedure code used to denote the entity may be reported only once.

Anatomic Pathology

Cryopreservation, (frozen cell storage and thawing) are covered services for bone marrow transplants only.

Evocative/Suppression Testing

The program does not cover these codes. Report the individual tests.

Another section has been added that refers to the Physician Self-Referral legislation. The DCH has defined the terms of Physician’s Office Laboratory, Dual Physician’s Office/Independent Laboratory and Independent Laboratory. Following are the new definitions as defined by the Department of Community Health:

Physician’s Office Laboratory (POL):

A physician’s office laboratory meets the following parameters:

- A physician or a group practice owns the laboratory.
- The laboratory performs testing only on specimens generated by the physician owner.

The laboratory is subject to the following policies:

- Laboratory claims must be billed using the physician's billing provider identification number.
- Laboratory claims are subject to the practitioner daily laboratory limit.
- The laboratory must not accept referrals from physicians outside of the physician's practice or group practice.
**Dual Physician's Office/Independent Laboratory:**

A dual physician's office/independent laboratory meets the following parameters:

- A physician(s) or a group practice owns the laboratory.
- The laboratory is a physician's office laboratory for those specimens generated by the physician owner(s).
- The laboratory is an independent laboratory for those specimens that are referred by physicians outside of the physician's practice or group practice.

The dual physician's office/independent laboratory is subject to the following policies:

- Laboratory claims generated by the physician owner(s) must be billed using the physician's billing provider identification number. These claims are subject to the *physician daily laboratory limit*.
- Laboratory claims generated by physicians outside of the physician's practice or group practice must be billed using the independent laboratory identification number. These claims are subject to the *independent laboratory daily limit*.
- The laboratory must not accept referrals from immediate family members.

**Independent Laboratory:**

An independent laboratory meets the following parameters:

It may be owned by:

- A physician(s) or a group practice
- A non-physician

The physician(s) owned independent laboratory is subject to the following policies:

- The laboratory must not accept referrals from the physician owner(s) or their immediate family members.
- Laboratory claims are billed using the independent laboratory identification number.
- Laboratory claims are subject to the *independent laboratory daily limit*.

The non-physician owned independent laboratory is subject to the following policies:

- The laboratory must not accept referrals from the owner(s) immediate family members
- Laboratory claims are billed using the independent laboratory identification number.
- Laboratory claims are subject to the *independent laboratory daily limit*. 
Manual Maintenance

Laboratory Manual: Insert the new Chapter III, dated 02/01/02. Discard the previous Chapter III, dated 4/1/92.

Manual pages for laboratory services for Practitioner, Hospital, and Family Planning Clinics will be updated in the future. Please retain this Bulletin.

Questions

Any questions regarding this bulletin should be directed to: Provider Inquiry, Medical Services Administration, P.O. Box 30479, Lansing, Michigan 48909-7979, or e-mail at ProviderSupport@michigan.gov. When you submit an e-mail, be sure to include your name, affiliation, and a phone number so you may be contacted if necessary. Providers may phone toll free 1-800-292-2550.

Approved

James K. Haveman, Jr.
Director

Robert M. Smedes
Deputy Director for
Medical Services Administration
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GENERAL

The Program will reimburse the laboratory only for those services it is CLIA- (Clinical Laboratory Improvement Act) certified to perform and are ordered by physicians, nurse practitioners, nurse-midwives, podiatrists, or dentists. The ordering practitioner must document the medical necessity of laboratory tests in the beneficiary's medical record regardless of where the test(s) is performed. The Program covers only those medically-necessary laboratory tests needed to diagnose a specific condition, illness, or injury. The Program will **not** cover any laboratory tests ordered by a chiropractor.

The ordering practitioner will be held responsible if they order excessive or unnecessary laboratory tests regardless of who actually renders the services. The ordering practitioner will also be held responsible for the medical necessity of each and every laboratory test that is ordered as part of a custom- or laboratory-designed profile. The ordering practitioner may be subject to any corrective action related to these services, including recoupment of funds. The laboratory also may be subject to corrective action, including the recoupment of funds, if it submits a claim for laboratory services not specifically ordered by a practitioner.

Screening or routine laboratory testing, except as specified for the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program, or by Program policy, is not a benefit. Ordering or rendering of "profiles", "batteries" or "panels" of tests that include tests not necessary for the diagnosis or treatment of the beneficiary's specific condition is considered random screening and is not covered. Multiple laboratory tests carried out as a part of the evaluation of the beneficiary, when the results of the history and physical examination do not suggest the need for the tests, are considered screening and are not covered.

Laboratory services performed by a laboratory or its employees may not be billed to the ordering practitioner.
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MEDICAL NECESSITY

The medical record and any attachment to a claim must contain documentation of medical necessity describing the beneficiary’s symptoms and other findings that led the practitioner to order the laboratory test(s). An explanation of the laboratory testing method or the results of the diagnostic tests, whether normal or abnormal, is not documentation of medical necessity. For approval of payment, the laboratory procedure(s) must be specific and appropriate to the beneficiary's documented condition and diagnosis.

STARK LEGISLATION

Physician Self-Referral

42 USC 1395nn, commonly referred to as Stark Legislation or Physician Self-Referral Legislation, limits certain physician referrals made to entities where the physician has a financial interest. A physician should make no referrals of laboratory tests to a laboratory in which the physician (or the physician’s immediate family members) has a financial interest unless the referral falls under the “in-office ancillary services” exception.

The following terms are defined by the DCH as they relate to the Physician Self-Referral portion of the Stark Legislation.

Physician’s Office Laboratory (POL):

A physician's office laboratory meets the following parameters:

- A physician or a group practice owns the laboratory.
- The laboratory performs testing only on specimens generated by the physician owner.

The laboratory is subject to the following policies:

- Laboratory claims must be billed using the physician's billing provider identification number.
- Laboratory claims are subject to the practitioner daily laboratory limit.
- The laboratory must not accept referrals from physicians outside of the physician's practice or group practice.

Dual Physician’s Office/Independent Laboratory:

A dual physician's office/independent laboratory meets the following parameters:

- A physician or a group practice owns the laboratory.
- The laboratory is a physician's office laboratory for those specimens generated by the physician owner.
- The laboratory is an independent laboratory for those specimens that are referred by physicians outside of the physician's practice or group practice.
The dual physician's office/independent laboratory is subject to the following policies:

- Laboratory claims generated by the physician owner must be billed using the physician's billing provider identification number. These claims are subject to the *practitioner daily laboratory limit*.
- Laboratory claims generated by physicians outside of the physician's practice or group practice must be billed using the independent laboratory identification number. These claims are subject to the *independent laboratory daily limit*.
- The laboratory must not accept referrals from immediate family members.

**Independent Laboratory:**

An independent laboratory meets the following parameters:

It may be owned by

- A physician or a group practice
- A non-physician

The physician-owned independent laboratory is subject to the following policies:

- The laboratory must not accept referrals from the physician owner or their immediate family members.
- Laboratory claims are billed using the independent laboratory identification number.
- Laboratory claims are subject to the *independent laboratory daily limit*.

The non-physician owned independent laboratory is subject to the following policies:

- The laboratory must not accept referrals from the owner or their immediate family members
- Laboratory claims are billed using the independent laboratory identification number.
- Laboratory claims are subject to the *independent laboratory daily limit*.

**CLIA CERTIFICATION**

All providers that submit claims must have CLIA (Clinical Laboratory Improvement Act) certification. The CLIA number must be present on the claim. Providers are limited to billing the lab services that they are CLIA-certified to perform. This includes the specialties as listed under their CLIA certificate.

**Billing Instruction:** Providers performing tests that use waived methodologies must enter the QW modifier with the appropriate CPT code to denote the waived test.

Questions regarding CLIA certification should be addressed to the Department of Consumer and Industry Services, Hospital, Laboratory and Medical Facilities Section. The telephone number for information is 517-241-2648.
PROCEDURE CODES

The laboratory should refer to the current edition of the CPT™ (Current Procedural Terminology) manual published by the American Medical Association for the appropriate procedure code to use when billing the Program. The laboratory will also be subject to the Pathology and Laboratory guidelines that provide definitions and/or instruction for specific sections in the manual.

COMPONENT BILLING

Most pathology procedures are billed together as a total service; a single charge is made for both professional and technical components. Some pathology procedures are composed of professional and technical components that are billed separately by the facility and the provider. In these instances, the procedure code requires the use of a 2-character modifier to accurately identify the service provided. Do not bill for component services when the entire procedure is performed.

Technical Component: Payment for the technical component to the laboratory includes personnel, materials, space, equipment, report of test results, and other items. The modifier TC (Technical Component) must be reported along with the procedure code.

Professional Component: The professional component represents the professional services of a pathologist/hematologist. These are limited to certain services in a facility setting. The modifier 26 (Professional Component) must be reported along with the procedure code. Payment for this component includes:

- examination of the beneficiary, when indicated,
- performance and supervision of the procedure,
- reading, interpretation, and written report of the findings, and/or
- consultation with the referring physician.

When the laboratory performs services for hospital inpatients, only the professional component (the pathologist's services) can be billed directly to the Program by the pathologist. The technical component is included in the reimbursement to the hospital for the inpatient services.

MEDICARE-RELATED BILLING

Medicaid will reimburse the laboratory for the co-insurance and deductible amounts subject to Medicaid's reimbursement limitations on all Medicare-approved claims even if Medicaid does not normally cover the service.
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COVERAGE LIMITS

Reimbursement for laboratory services includes the collection of the specimen(s), the analysis, and the lab test results. The Program will perform pre- and/or post-payment reviews to monitor laboratory procedures for medical necessity and appropriate practitioner orders.

A beneficiary cannot be charged for any covered laboratory procedures, including those that are determined to be not medically necessary or for those laboratory procedures that exceed the laboratory daily reimbursement limit.

The Program limits laboratory payments when rendered by the same provider, for the same beneficiary, on a single date of service. Coverage is limited to only those laboratory procedures which do not exceed the daily reimbursement limits specified in the following table.

<table>
<thead>
<tr>
<th>PROVIDER TYPE</th>
<th>PROVIDER DESCRIPTION</th>
<th>DAILY LIMIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 or 11</td>
<td>Physician (MD, DO), Nurse-Midwife, Nurse Practitioner</td>
<td>$50</td>
</tr>
<tr>
<td>13</td>
<td>Podiatrist</td>
<td>$50</td>
</tr>
<tr>
<td>23</td>
<td>Family Planning Clinic</td>
<td>$50</td>
</tr>
<tr>
<td>77</td>
<td>Medical Clinic</td>
<td>$50</td>
</tr>
<tr>
<td>16</td>
<td>Independent Laboratory</td>
<td>$125</td>
</tr>
<tr>
<td>40</td>
<td>Outpatient Hospital</td>
<td>$75</td>
</tr>
</tbody>
</table>

The following selected laboratory services identified by CPT™ procedure codes (or code ranges) are exempt from the daily dollar limit. Payment for these medically-necessary services will not be included in the reimbursement calculation for a single date of service.

<table>
<thead>
<tr>
<th>EXEMPT PROCEDURE CODE(S) OR CODE RANGES</th>
<th>LABORATORY SECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>80500</td>
<td>Limited Pathology Consultation</td>
</tr>
<tr>
<td>80502</td>
<td>Comprehensive Pathology Consultation</td>
</tr>
<tr>
<td>85097</td>
<td>Bone Marrow, smear interpretation</td>
</tr>
<tr>
<td>88104 - 88108</td>
<td>Cytopathology</td>
</tr>
<tr>
<td>88141 - 88199</td>
<td>Cytogenetics</td>
</tr>
<tr>
<td>88230 - 88299</td>
<td>Electron Microscopy</td>
</tr>
<tr>
<td>88348</td>
<td>Genotype and Phenotype analysis</td>
</tr>
<tr>
<td>87901-87904</td>
<td>Virtual Phenotype analysis</td>
</tr>
</tbody>
</table>

If the coverage limit is exceeded, the laboratory must request an exception to the daily reimbursement limit by submitting documentation of medical necessity for each laboratory procedure. All services provided on that date of service will be manually reviewed for medical necessity and payment determined accordingly.

When it is determined that Program payments for testing ordered from a laboratory will exceed the coverage limit, the ordering practitioner must forward medical necessity documentation to the laboratory for submission with the claim.
Billing Instructions:  THE DATE OF SERVICE INDICATED ON THE CLAIM MUST BE THE DATE THE SPECIMEN IS COLLECTED. For prompt payment of laboratory procedures that exceed the coverage limit, all claims for a single date of service should be submitted together with one copy of the accompanying documentation for each invoice.
CSHCS COVERAGE

The daily reimbursement limits do not apply to beneficiaries with only Children's Special Health Care Services (CSHCS) eligibility. The coverage limits do apply to beneficiaries with dual Medicaid and CSHCS eligibility if the laboratory procedures are not related to the beneficiary's CSHCS qualifying diagnosis.

BLOOD HANDLING

The fee for blood handling is usually included in the reimbursement for the blood test. Situations in which the drawing, packaging, and mailing of a blood specimen are the only services provided will be rare. They are:

- A beneficiary may be referred to a laboratory for the sole purpose of drawing, packaging, and mailing a blood sample to the Michigan Department of Community Health for blood lead analysis. The State provides lead-free vacutainers for the analysis. Requests for vacutainers and the samples for analysis should be sent to:
  
  Trace Metal Section/Bureau of Laboratories  
  Division of Chemistry and Toxicology  
  Michigan Department of Community Health  
  PO Box 30035  
  Lansing, Michigan 48909

- A beneficiary occasionally requires blood tests that are not performed in conjunction with other reimbursable services. Whenever possible, the beneficiary should be sent to the laboratory that is to perform the test(s). If this is not practical (i.e., the laboratory is not a local facility) and the sole purpose of a visit is to draw, package, and mail the sample to a laboratory, the blood handling fee may be billed by the practitioner. The blood handling fee is not a benefit when any other service is reimbursable on the same date of service.

- A beneficiary may be referred to a laboratory for the sole purpose of drawing, packaging, and mailing a blood sample to the Michigan Department of Community Health for HIV-1 viral load analysis and/or CD4/CD8 enumeration. The State provides specimen containers and mailing kits for the analysis. Requests for supplies and samples for analysis should be sent to:
  
  Bureau of Laboratories  
  Michigan Department of Community Health  
  PO Box 30035  
  Lansing, Michigan 48909

Billing Instructions: Blood handling may be billed if the drawing, packaging, and mailing of a blood sample are the only services provided as described above. Procedure Code 36415, "routine venipuncture for collection of specimen(s)," and the usual and customary charge for the service must be used. On the HCFA 1500 claim form, Box 19, Reserved for Local Use, must indicate the reason the blood was obtained as a separate service and the reason the laboratory that performed the testing could not also perform the venipuncture. For electronic claims, ANSI X12 837, Professional, documentation should be entered in the 2300 Loop, segment NTE02.
<table>
<thead>
<tr>
<th>MANUAL TITLE</th>
<th>LABORATORY</th>
<th>CHAPTER</th>
<th>SECTION</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>III</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>CHAPTER TITLE</td>
<td>COVERED SERVICES</td>
<td>SECTION TITLE</td>
<td>SPECIAL COVERAGE</td>
<td>DATE</td>
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<td></td>
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<td></td>
<td>MSA 02-06</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>02-01-02</td>
</tr>
</tbody>
</table>
HEMATOLOGY STUDIES

A practitioner's order for a complete blood count (CBC) with white blood cell (WBC) differential includes the RBC and WBC count, Hgb, Hct, MCH, MCHC, MCV, RBC morphology, platelet estimate, and WBC differential only. If three or more of the component tests are performed on a single blood sample, the code that most closely represents the entire procedure must be reported. If automated instrumentation yields additional test parameters, the results are not reimbursable unless medically necessary and specifically ordered by a practitioner.

Any payment for a differential includes payment for routine cell morphology and platelet estimation.

MICROBIOLOGY STUDIES

Isolation and presumptive identification procedure codes are meant to cover the usual methods recommended for the culture set up, isolation of suspected pathogens and the presumptive identification of any pathogens.

Definitive culture procedure codes may not be billed in combination with other microbiology codes that duplicate the identification of a microbe. Any reported organisms must be identified as to group, genus and species according to procedures recommended by the American Society for Microbiology (AMA), the College of American Pathologists (CAP) or the Centers for Disease Control (CDC).

Anaerobic culture procedure codes should only be reported for methods recommended by the ASM, CAP, CDC or the Virginia Polytechnic Institute (VPI) using special anaerobic media.

Microbiology smear procedure codes are to be reported only for microscopic examination of the original specimen and are not to be reported when inoculum from a culture or subculture is examined as part of the identification of an organism.

Special attention should be given to the antimicrobial susceptibility procedure code definitions when reporting the quantity. Depending on the code, the quantity is determined by the number of agents, number of plates or number of enzymes tested.

TEST REPORTS

Specimen Source

The tested entity may be from any source, unless the source is specified in the procedure code description.

Calculated Results

The mathematical calculation of two or more results to produce an index or ratio or any other result may not be billed as a separate independent test.
Test Results

Reimbursement will be made for tests performed using a method that will yield quantitative results unless the nomenclature specifies a different method.

Panel Tests

Only AMA-approved organ- or disease-oriented panels may be billed. All tests within the panel must be medically necessary. Unless the complete panel is ordered and performed, bill as individual tests.

Complete Procedures and Unbundling

In some instances, a procedure is listed both in its entirety and also with component services specified. If the entire procedure is performed, the code for the entire procedure must be reported. Do not bill for component services when the entire procedure is performed.

Urinalysis

In the event a single urine specimen is tested for the same entity (chemical, element, compound, substance) by more than one method, the procedure code used to denote the entity may be reported only once.

Anatomic Pathology

Cryopreservation, (frozen cell storage and thawing) are covered services for bone marrow transplants only.

Arsenic Testing

This testing is not covered for hair and nail sources.

Evocative/Suppression Testing

The program does not cover these codes. Report the individual tests.

PATHOLOGY CONSULTATION

Pathology Consultation Procedure Codes 80500 and/or 80502 may be billed by a hematologist/pathologist for the review of abnormal laboratory test results, but the code(s) cannot be used for routine quality control review. Refer to the current CPT™ manual for the guidelines for the provision of this service.
DIALYSIS-RELATED LAB SERVICES

Payment for laboratory services related to maintenance dialysis is included in the composite rate regardless of whether the tests are performed in the facility or an independent laboratory. The following tests are considered to be a routine part of maintenance dialysis and may not be billed separately unless it is medically necessary to perform them in excess of the frequencies indicated.

Laboratory tests for Hemodialysis, Peritoneal Dialysis, and CCPD (Continuous Cycling Peritoneal Dialysis) that are included in the composite rate:

**Per Treatment**

All hematocrit or hemoglobin tests and clotting time tests

**Weekly**

Prothrombin time for patients on anticoagulant therapy  
Serum Creatinine  
BUN

**Monthly**

CBC, including platelet count and additional indices  
Serum Calcium  
Serum Chloride  
Serum Potassium  
Serum Bicarbonate  
Serum Phosphorus  
Total Protein  
Serum Albumin  
Alkaline Phosphatase  
SGOT  
LDH

Laboratory tests for CAPD (Continuous Ambulatory Peritoneal Dialysis) that are included in the composite rate:

**Monthly**

BUN  
Creatinine  
Sodium  
CO2  
Calcium Magnesium  
Phosphate  
Potassium  
Total Protein  
Albumin  
Alkaline Phosphatase  
LDH  
AST, SGOT  
HCT  
Hgb  
Dialysate Protein
Laboratory tests not listed above may be separately billed by the dialysis facility or CLIA-certified lab performing the test.

**ICF/MR FACILITIES**

Reimbursement for laboratory services provided to patients in intermediate care facilities for the mentally retarded (ICF/MR) is included in the per diem rate paid to the ICF. DCH may not be billed by the laboratory for these services.