



Independent Laboratory Provider Specific Policy

Revision Table

Revision Date	Sections Revised	Description
7/1/02	All	Complete manual revision to reflect changes related to the MMIS and HIPAA compliance.
7/19/07	7.8	Updated hematology billing instructions.
9/18/08	Overview	Removed obsolete numbering.

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Independent Laboratory Provider Specific Policy Manual

Table of Contents

[Main Menu](#)

1.0 Overview

- 1.1 General Information

2.0 Reimbursement

- 2.1 Methodology

3.0 License/Certification

- 3.1 Requirements

4.0 Billing For Specific Laboratory Services

- 4.1 CLIA Certificate of Waiver Tests
- 4.2 CLIA Certificate for Provider-Performed Microscopy Procedures (PPMP)
- 4.3 CLIA Certificate of Registration Tests
- 4.4 Specific Billing Instructions

5.0 Appendix A - Reserved

6.0 Appendix B - CLIA Certificate for Provider-Performed Microscopy Procedures (PPMP)

- 6.1 Covered Procedures
- 6.2 Non-Covered Procedures

7.0 Appendix C – Specific Billing Instructions

- 7.1 Multiple Units of Service
- 7.2 Pregnancy Tests
- 7.3 Organ or Disease Oriented Panels
- 7.4 Drug Testing (80100-80103)
- 7.5 Therapeutic Drug Assays (80150-80299)
- 7.6 Urinalysis (81000-81099)
- 7.7 Chemistry And Toxicology (82000-84999)
- 7.8 Hematology (85000 - 85999)
- 7.9 Immunology (86000 - 86999)
- 7.10 Microbiology (87001 - 87999)

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Independent Laboratory Provider Specific Policy

1.0 Overview

Health care services are provided to the majority of Medicaid clients through a Managed Care Organization (MCO). Independent laboratory services are included in the MCO benefits package. All Medicaid clients who are enrolled with an MCO must receive independent laboratory services through the MCO.

This manual reflects the policies as they relate to Medicaid clients who are exempt from managed care coverage (see list of those exempt from managed care coverage in the Managed Care section of the General Policy).

1.1 General Information

- 1.1.1 The DMAP reimburses enrolled providers for properly ordered, medically necessary, non-experimental, non-investigational, Clinical Laboratory Improvement Amendments (CLIA) certified laboratory services when properly performed, documented, and billed.
 - 1.1.1.1 The Clinical Laboratory Improvement Amendments of 1988 were enacted by Congress to improve the quality and reliability of clinical laboratory testing.
 - 1.1.1.2 CLIA applies to any provider who performs any laboratory test used for health purposes, no matter how simple or routine.
- 1.1.2 All tests performed by an independent laboratory must be documented in the patient's medical record by a written order from the ordering practitioner.
 - 1.1.2.1 Phoned-in orders for laboratory tests must be followed with a written order within 30 days.
- 1.1.3 An independent laboratory may use a reference laboratory to perform a test for which the independent lab is not certified.
- 1.1.4 Tests sent to a reference laboratory should be identified with a modifier of "90" defined as "reference (outside) laboratory".

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2.0 Reimbursement

2.1 Methodology

- 2.1.1 Reimbursement for independent laboratory services is based on rates established by Center for Medicare and Medicaid Services (CMS).
- 2.1.2 Providers must bill using CPT codes and will be paid the lower of the established rate for the code or their charge.

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3.0 License/Certification

3.1 Requirements

- 3.1.1 To be certified to perform testing on human specimens an independent laboratory must meet the conditions under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
- 3.1.2 The independent laboratory must be licensed by the state agency as meeting standards for licensing established under state law.

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4.0 Billing For Specific Laboratory Services

4.1 CLIA Certificate of Waiver Tests

4.1.1 An independent laboratory that holds a CLIA Certificate of Waiver may bill the DMAP for clinical diagnostic laboratory tests granted waived status under CLIA.

4.1.2 Clinical diagnostic laboratory tests considered to be CLIA Certificate of Waiver tests are listed on the CLIA web site at:
www.hcfa.gov/medicaid/clia/cliahome.htm.

These are the only procedure codes that may be billed to the DMAP by a provider who holds a CLIA Certificate of Waiver.

NOTE: The DMAP does not cover any services relating solely to the treatment of infertility.

4.1.3 If there are specific product names and manufacturers listed, a provider who holds a CLIA Certificate of Waiver may only bill if the test is done using one of those specified. The modifier “QW” defined as “CLIA waived test” must be added to the procedure code when billing the DMAP for a waived test using the specific product and manufacturer as listed.

4.2 CLIA Certificate for Provider-Performed Microscopy Procedures (PPMP)

4.2.1 An independent laboratory that holds a CLIA Certificate for PPMP may bill the DMAP for any clinical diagnostic laboratory test categorized as a provider-performed microscopy procedure.

4.2.2 Clinical diagnostic laboratory tests considered CLIA provider-performed microscopy procedures are listed in Appendix B. A provider who holds a CLIA Certificate for Provider-Performed Microscopy may bill the DMAP for these tests in addition to the Certificate of Waiver tests.

NOTE: The DMAP does not cover any services relating solely to the treatment of infertility.

NOTE: The DMAP considers some provider-performed microscopy procedures to be part of the physician evaluation and management service. Therefore, they are not separately reimbursable by DMAP (refer to Appendix B for specific tests).

4.3 CLIA Certificate of Registration Tests

- 4.3.1 An independent laboratory that holds a CLIA Certificate of Registration may bill the DMAP for any clinical diagnostic laboratory test for which they have received CLIA certification.

4.4 Specific Billing Instructions

- 4.4.1 Refer to Appendix C for specific billing instructions for:

4.4.1.1 Multiple Units of Service

4.4.1.2 Pregnancy Tests

4.4.1.3 Panels and Profiles

4.4.1.4 Drug Testing

4.4.1.5 Therapeutic Drug Assays

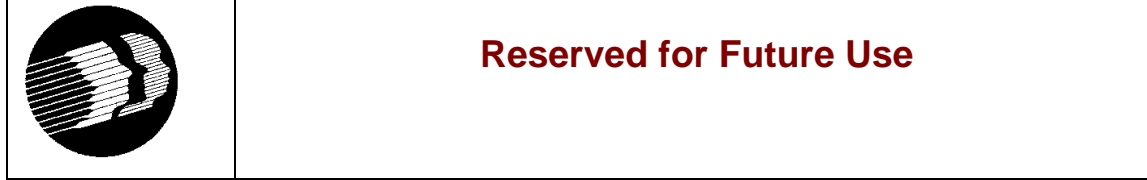
4.4.1.6 Urinalysis

4.4.1.7 Chemistry and Toxicology

4.4.1.8 Hematology

4.4.1.9 Immunology

4.4.1.10 Microbiology



5.0 **Appendix A - Reserved**

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Provider-Performed Microscopy Procedures

6.0 Appendix B - CLIA Certificate for Provider-Performed Microscopy Procedures (PPMP)

6.1 Covered Procedures

Code	Description
81000	Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy
81001	Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy (NOTE: May only be used when the lab is using an automated dipstick urinalysis instrument approved as waived.)
81015	Urinalysis; microscopic only
81020	Urinalysis; two or three glass test
89190	Nasal smear for eosinophils
G0026	Fecal leukocyte examination

6.2 Non-Covered Procedures

NOTE: The DMAP considers the following provider-performed microscopy procedures to be part of the physician evaluation and management service. Therefore, the following are not separately reimbursable by DMAP:

Code	Description
Q0111	Wet mounts, including preparations of vaginal, cervical or skin specimen
Q0112	All potassium hydroxide (KOH) preparations
Q0113	Pinworm examinations

NOTE: The DMAP does not cover any services relating solely to the treatment of infertility. Therefore, the following provider-performed microscopy procedures are not reimbursable by DMAP:

Code	Description
Q0114	Fern test
Q0115	Post-coital direct, qualitative examinations of vaginal or cervical mucous
G0027	Semen analysis; presence and/or motility of sperm excluding Huhner test

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Independent Laboratory Provider Specific Billing Instructions

7.0 Appendix C – Specific Billing Instructions

7.1 Multiple Units of Service

The following restrictions apply when billing for multiple units of service:

- Repetition of the same test on the same specimen must not be billed.
- When the same test is performed on separate specimens collected on the same day from the same patient, bill the second test with a modifier of “91” defined as “repeat clinical diagnostic laboratory test”.
- When different procedures are described by one HCPCS procedure code, bill for multiple units of service. In block 19 of the HCFA 1500 or the comment section of the 837 Professional claim (loop 2300, Claim Information in the NTE segment), identify the procedures performed.

EXAMPLE: When both a wound culture and an eye culture are performed on the same day, bill for two units of the appropriate code. In block 19 of the HCFA 1500 or the comment section of the 837 Professional claim, state that one wound culture and one eye culture were performed.

7.2 Pregnancy Tests

The following restrictions apply:

- HCPCS procedure code 81025 (Urine pregnancy test, by visual color comparison methods) should be used for pregnancy tests performed on urine samples that are reported as positive or negative by a visual color comparison.
- HCPCS procedure code 84703 [Gonadotropin, chorionic (hCG); qualitative] should be used for pregnancy tests reported as positive or negative.

- HCPCS procedure code 84702 [Gonadotropin, chorionic (hCG); quantitative] should be used when determining the range of values of the beta sub-unit of the chorionic gonadotropin. Do not use this code for routine pregnancy tests.

7.3 Organ or Disease Oriented Panels

Panels are groups of laboratory tests that are performed and billed as a single unit. Laboratories must use the appropriate single procedure code that describes the group of tests being performed.

The CPT codes for Organ or Disease Oriented Panels will be used for dates of service 7/1/02 and after.

The following billing instructions are to be used for billing services for dates of service prior to 7/1/02

The individual HCPCS procedure codes for the 22 tests listed below are NOT used by the DMAP.

Name of Test	Individual HCPCS Not Used
Alanine aminotransferase (ALT, SGPT)	84460
Albumin	82040
Aspartate aminotransferase (AST, SGOT)	84450
Bilirubin; direct	82248
Bilirubin; total	82247
Calcium	82310
Carbon dioxide content	82374
Chloride	82435
Cholesterol	82465
Creatine kinase (CK, CPK)	82550
Creatinine	82565
Glucose (Sugar)	82947
Gammaglutamyltransferase (GGT)	82977
Lactate dehydrogenase (LD)	83615
Phosphatase, alkaline	84075
Phosphorus (inorganic phosphate)	84100
Potassium	84132
Protein, total	84155, 84160
Sodium	84295
Triglyceride	84478
Urea nitrogen (BUN)	84520
Uric acid	84550

HCPCS procedure codes 80002-80019 and G0058-G0060 have been deleted in the CPT book but Delaware Medicaid will continue to use this coding series for automated multichannel testing

for billing dates of service prior to 7/1/02. For example: code 80048 use 80008, for 80053 use 80016, for 80069 use 80010.

When reporting any of these 22 tests, regardless of whether the tests are performed using manual or semi-automated methods, or on automated multichannel equipment, use the appropriate profile code 80002 - G0060 listed below:

Code	Description
80002	Automated multichannel test; 1 or 2 clinical chemistry tests
80003	Automated multichannel test; 3 clinical chemistry tests
80004	Automated multichannel test; 4 clinical chemistry tests
80005	Automated multichannel test; 5 clinical chemistry tests
80006	Automated multichannel test; 6 clinical chemistry tests
80007	Automated multichannel test; 7 clinical chemistry tests
80008	Automated multichannel test; 8 clinical chemistry tests
80009	Automated multichannel test; 9 clinical chemistry tests
80010	Automated multichannel test; 10 clinical chemistry tests
80011	Automated multichannel test; 11 clinical chemistry tests
80012	Automated multichannel test; 12 clinical chemistry tests
80016	Automated multichannel test; 13 - 16 clinical chemistry tests
80018	Automated multichannel test; 17 - 18 clinical chemistry tests
80019	Automated multichannel test; 19 clinical chemistry tests
G0058	Automated multichannel test; 20 clinical chemistry tests
G0059	Automated multichannel test; 21 clinical chemistry tests
G0060	Automated multichannel test; 22 clinical chemistry tests

EXAMPLE: If a BUN and a glucose were run on the same specimen, the correct code would be one unit of 80002. If only a glucose was ordered, the correct code would still be one unit of 80002. If a glucose was run a 9 AM and again at 2 PM on the same day on different specimens, two units of 80002 would be billable.

EXAMPLE: If five of the above tests are ordered, the correct code would be one unit of 80005. Fifteen tests would be billed as one unit of 80016 while twenty-one tests would be one unit of G0059. In each case, the unit of service would be one, not the number of tests actually performed.

7.4 Drug Testing (80100-80103)

HCPCS procedure code 80100 (Drug screen, qualitative; multiple drug classes chromatographic method, each procedure) should be used for a qualitative drug screen that detects multiple drug classes in a single procedure. HCPCS procedure code 80101 (Drug screen, qualitative; single drug class method [e.g., immunoassay, enzyme assay], each drug class) should be used for a qualitative drug screen that detects a single drug class. HCPCS procedure code 80102 (Drug, confirmation, each procedure) should be used for confirmation (by a second method) of any drugs detected in a drug screen.

HCPCS procedure code 83518 (Immunoassay for analyte other than infectious agent antibody or infectious agent antigen, qualitative or semiquantitative; single step method [e.g., reagent strip]) should be used for a qualitative or semiquantitative immunoassay of an analyte other than an antibody. This includes quick screens, using low technology testing (e.g., reagent strips, dip stick, etc.).

Confirmed drugs may be quantitated using the appropriate code in the chemistry section (82000-84999) or therapeutic drug assay section (80150-80299).

7.5 Therapeutic Drug Assays (80150-80299)

Use the specific procedure code listed in the CPT book for individual quantitative assay. For non-quantitative testing, use codes 80100-80103.

7.6 Urinalysis (81000-81099)

When performing a urinalysis on one specimen, bill one and only one of the following codes: 81000, 81001, 81002, 81003, 81005, or 81015. Any stick, dip, or tablet tests performed on a single specimen are considered to be part of the 81000, 81001, 81002, or 81003 and are not eligible for separate reimbursement. In order to bill for an 81000 or 81001, a microscopy must be performed.

7.7 Chemistry And Toxicology (82000-84999)

For dates of service prior to 7/1/02, when billing for any specific chemistry test that is noted under the list of automated, multichannel tests, do not use the individual HCPCS procedure codes regardless of whether the tests are performed using manual methods or automated, multichannel equipment. The laboratory should bill using the appropriate profile code.

7.8 Hematology (85000 - 85999)

7.8.1 When billing codes for a complete blood count (CBC), identified as HCPCS procedure codes 85025 and 85027, do not bill for any code that is a component of a CBC for the same specimen. The following are the HCPCS procedure codes for components: 85013, 85014, 85018, 85032, 85041, 85048, and 85049.

7.8.2 Providers are reminded not to use multiple procedure codes when a single procedure code accurately describes the service rendered.

7.8.3 When a complete blood count is billed on the same date as HCPCS procedure code 85007, 85008, or 85009, test results for the CBC must be attached that document the medical necessity of the microscopic evaluation code.

7.9 Immunology (86000 - 86999)

When there is no specific code for an immunology procedure, the code for the methodology is to be used. Certain codes can be used to describe many different tests. When two or more different tests are described by the same code and are performed on the same patient on the same day, bill on a single line using multiple units of service. In Block 19 of the HCFA 1500 or in the comment section of the 837 Professional claim, identify the procedures performed.

7.10 Microbiology (87001 - 87999)

The following policies apply:

- A screening culture is one in which a single pathogen is

isolated but may or may not be definitively identified (CPT codes 87081 or 87084).

EXAMPLE: When a throat culture is screened for the presence or absence of group A beta streptococci using a low concentration bacitracin disc, bill for one unit of 87081. Identification aids such as bacitracin and neomycin discs are considered part of the screen and should not be billed in addition to the 87081.

- Presumptive identification of microorganisms is defined as identification by colony morphology, growth on selective media, Gram stains, or up to three tests (e.g., catalase, oxidase, indole, urase). Presumptive codes are: 87040, 87045, 87046, 87070, 87071, 87073, 87075, 87076, or 87078.
- Definitive identification of microorganisms is defined as an identification to the genus or species level that requires additional test (e.g., biochemical panels, slide cultures). Codes 87076 and 87077 may be used in addition to the above presumptive codes, when additional testing has been performed.
- If additional studies involve molecular probes, chromatography, or immunologic techniques, these should be separately coded in addition to definitive identification codes (CPT codes 87140, 87143, 87147, 87419, 87152, and 87158).
- Direct sensitivities are not reimbursable. A direct sensitivity is inoculated directly from the specimen at the time of the initial culture. DO NOT use HCPCS procedure codes 87181, 87184, 87186, or 87188 to describe direct sensitivities. Sensitivities will only be reimbursed after a pathogen has been isolated and set up for sensitivities.
- When performing chlamydia and GC by DNA Probe, bill for one unit of 87490 (Chlamydia trachomatis, direct probe technique) and one unit of 87590 (Neisseria gonorrhoeae, direct probe technique).

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