



Laboratory and Pathology

Published September 2009



Part B



IMPORTANT



The information provided in this manual was current as of August 2009. Any changes or new information superseding the information in this manual, provided in newsletters/eBulletins, MLN articles, listserv notices, Local Coverage Determinations (LCDs) or CMS Internet-Only Manuals with publication dates after August 2009, are available at:

<http://www.trailblazerhealth.com/Medicare.aspx>

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INTRODUCTION

Pathology and laboratory CPT coding includes services primarily reported to evaluate specimens obtained from patients (body fluids, cytological specimens or tissue specimens obtained by invasive/surgical procedures) to provide information to the treating physician. This information, coupled with information obtained from history and examination findings and other data, provides the physician with the background upon which medical decision-making is established.

Generally, pathology and laboratory specimens are prepared and/or screened by laboratory personnel with a pathologist assuming responsibility for the integrity of the results generated by the laboratory. The pathologist personally reviews certain types of specimens and tests. CPT coding for pathology services includes few codes requiring patient contact or Evaluation and Management (E/M) services rendered directly by the pathologist. On the occasion that a pathologist provides E/M services, appropriate coding should be rendered from the E/M section of the CPT book.

If after a test is ordered and performed, additional related procedures are necessary to provide or confirm the result, these procedures would be considered part of the ordered test.

Clinical Laboratory Services

Clinical laboratory services involve the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the diagnosis, prevention or treatment of a disease or assessment of a medical condition.

The following are Medicare Part B policies for clinical laboratory services:

- The laboratory must be approved by CMS to provide the specific type of test being performed.
- Physicians and independent labs are mandated to bill clinical lab tests as assigned claims.
- Payment for clinical lab tests is made at 100 percent of the laboratory fee schedule.

Diagnostic Laboratory Services

Diagnostic laboratory and pathology services are surgical pathology, specific cytopathology, hematology and blood banking services, which require performance by a physician or other certified professionals. Payment is 80 percent of the fee schedule.

Diagnostic laboratory services also include:

- Clinical consultation services.
- The professional component of diagnostic laboratory or pathology services

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furnished by hospital physicians, pathologists or independent laboratories to hospital inpatients or outpatients.

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CMS SPOTLIGHTS THE CLINICAL LAB CENTER

The CMS Clinical Lab Center includes links to the following information:

- Billing/payment.
- Demonstration.
- Coverage.
- Policies/regulations.
- Education.
- Coding.
- Program transmittals.
- Program Integrity/Medical Review.
- Enrollment/participation.
- Contacts.
- How to stay informed: <http://www.cms.hhs.gov/center/clinical.asp>.

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LABORATORY COMPETITIVE BIDDING DEMONSTRATION

The implementation of a laboratory competitive bidding demonstration is being implemented in multiple phases. The first Competitive Bidding Demonstration Area (CBA), the San Diego-Carlsbad-San Marcos, California metropolitan statistical area, was implemented on April 1, 2007.

Laboratory firms with \$100,000 or more in annual Medicare Part B (fee-for-service) payments as of Calendar Year (CY) 2005 for “demonstration tests” provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) will be required to bid in the demonstration. These laboratory firms will be referred to as “required bidders.”

Small laboratories or laboratory firms with less than \$100,000 in annual Medicare Part B (fee-for-service) payments for demonstration tests provided to beneficiaries residing in the CBAs will not be required to bid in the demonstration. These laboratories are considered “passive” laboratories.

Passive laboratory firms exceeding the annual ceiling of \$100,000 by \$25,000 or more will be:

- Terminated from the demonstration project.
- Will not be paid anything by Medicare for demonstration tests provided to beneficiaries residing in the CBAs (regardless of where the laboratory firm is located) for the duration of the demonstration.

Laboratories or laboratory firms providing clinical laboratory services exclusively to beneficiaries with End Stage Renal Disease (ESRD) residing in the CBA will not be required to bid in the demonstration. These laboratories are considered “passive-ESRD” laboratories.

Claims submitted by non-winner laboratories for dates of service of April 1, 2007, through March 31, 2010, for Medicare beneficiaries in CBA1 will be denied using:

- Reason code 96 (non-covered charges).
- Remark code M114. (This service was processed in accordance with rules and guidelines under the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project. If you would like more information regarding this project, you may contact your local contractor.)
- Remark code N83. (No appeal rights. Administrative decision based on the provisions of a demonstration project.)

Using these same reason and remark codes, Medicare will reject any laboratory claims with a date of service between April 1, 2007, and March 31, 2010, with a modifier of 90, submitted by laboratories for demonstration-covered services provided to beneficiaries

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residing in the CBA, regardless of the referring laboratory's participation status.

Medicare will pay claims during the demonstration period submitted by non-demonstration laboratories for beneficiaries residing in the CBA who receive services outside those areas (e.g., "snow birds") according to the laboratory competitive bidding demonstration.

Non-winning laboratories should know that Advance Beneficiary Notices of Noncoverage (ABNs) and Notices of Beneficiary Exclusion from Medicare Benefits (NEMBs) are not to be used to transfer liability to beneficiaries when services under the demonstration are obtained at non-winner laboratories. The complete article is available on the CMS MLN Matters Web page at:

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5359.pdf>

Change Request (CR) 5772 – Establishes the project implementation dates; changes the requirements for referring and reference laboratory services, Skilled Nursing Facility (SNF) and Home Health services; and provides Medicare contractors a detailed record layout for the quarterly report, for listing laboratories in the CBA with their CB status.

- Under this statute, Pap smears and colorectal cancer screening tests are excluded from this demonstration.
- Requirements under the Clinical Laboratory Improvement Amendments (CLIA), as mandated in Section 353 of the Public Health Service Act, are applicable.
- The payment basis determined for each CBA will be substituted for payment under the existing clinical laboratory fee schedule. Multiple winners are expected in each CBA.
- Two previous CRs, 5205 and 5359, were issued to implement the necessary system requirements to accomplish this project. CR 5772 changes some of those requirements and establishes the implementation dates in the first CBA (CBA1).

The complete article is available on the CMS MLN Matters Web page at:

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5772.pdf>

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DEFINITIONS

Independent Laboratory – An independent laboratory is one that is independent both of an attending or consulting physician’s office and of a hospital that meets at least the requirements to qualify as an emergency hospital as defined in Section 1861(e) of the Social Security Act (the Act).

Physician Office Laboratory – A physician office laboratory is a laboratory maintained by a physician or group of physicians for performing diagnostic tests in connection with the physician practice.

Clinical Laboratory – Sections 1833 and 1861 of the Act provide for payment of clinical laboratory services under Medicare Part B. Clinical laboratory services involve the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the diagnosis, prevention or treatment of a disease or assessment of a medical condition. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments (CLIA) of 1988, as set forth at 42 CFR Part 493. Section 1862(a)(1)(A) of the Act provides that Medicare payment may not be made for services that are not reasonable and necessary. Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 CFR 410.32(a), or by a qualified non-physician practitioner, as described in 42 CFR 410.32(a)(3).

Laboratory Services Furnished to Non-Hospital Patients – A non-hospital patient is an individual who is neither an inpatient nor outpatient of the hospital furnishing the service. Non-hospital patients primarily are individuals from whom a specimen has been taken and sent to the hospital for analysis. Such services are covered to the extent appropriate.

Referring Laboratory – A Medicare-approved laboratory that receives a specimen to be tested and that refers the specimen to another laboratory for performance of the test.

Reference Laboratory – A Medicare-enrolled laboratory that receives a specimen from another referring laboratory for testing and that actually performs the test.

Billing Laboratory – The laboratory that submits a bill or claim to Medicare.

Service – A clinical diagnostic laboratory test. Service and test are synonymous.

Test – A clinical diagnostic laboratory service. Service and test are synonymous.

CLIA – The CLIA and CMS implementing regulations and processes.

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Certification – A laboratory that has met the standards specified in the CLIA.

Draw Station – A place where a specimen is collected, but no Medicare-covered clinical laboratory testing is performed on the drawn specimen.

Medicare-Approved Laboratory – A laboratory that meets all the enrollment standards as a Medicare provider including the certification by a CLIA certifying authority.

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NEGOTIATED RULEMAKING – COVERAGE AND ADMINISTRATIVE POLICIES

Administrative policies for clinical diagnostic laboratory services were implemented November 25, 2002, based on guidelines published in the *Federal Register* (November 23, 2001, 66 FR 58788). Section 4554(b)(1) of the Balanced Budget Act (BBA), Public Law 105-33, mandated the use of a Negotiated Rulemaking Committee to develop national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B. The BBA required that these national policies be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory services payable under Part B.

The administrative policies apply to every diagnostic clinical laboratory service that is payable under Medicare Part B. Neither the place where the service was performed nor the type of contractor that will process the request for payment has any effect on the applicability of these policies. A service done in a hospital laboratory, independent laboratory, physician/practitioner office laboratory or other type of Clinical Laboratory Improvement Amendments (CLIA)-approved laboratory is subject to these administrative policies.

The treating physician must be the physician who orders any clinical diagnostic laboratory service.

List of topics for some of the changes made:

- Limitation on number of diagnosis codes.
- Narrative diagnosis.
- Diagnosis and procedure codes matching.
- Ordering practitioner.
- Multiple services.
- Documentation requirements.
- Signature on requisition form.

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CLINICAL LABORATORY FEE SCHEDULE

Change Request (CR) 6070 provides instructions for the Calendar Year (CY) 2009 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests and updates for laboratory costs subject to the reasonable charge payment.

In accordance with the Social Security Act (Section 1833(h)(2)(A)(i)) and as amended by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Section 628), the annual update to the local clinical laboratory fees for CY 2009 is 4.5 percent.

Under Medicare Part B, for services rendered on or after July 1, 1984, clinical laboratory tests performed in a physician's office by an independent laboratory or by a hospital laboratory for its outpatients are reimbursed on the basis of fee schedules. Medicare pays the lesser of the following:

- Actual charges.
 - The fee schedule amount for the state or a local geographic area.
- Or,
- A National Limitation Amount (NLA) for the HCPCS code as provided by Section 1834(h) of the Social Security Act.

Annually, CMS furnishes to carriers and Fiscal Intermediaries (FIs) the proper amount to pay for each HCPCS code for each local geographic area. This includes a calculation of whether a national limitation amount or the local fee schedule amount is to be used. The clinical laboratory fee schedule is published each November and becomes effective January 1 of the next year.

For services January 1, 2004, through 2008, the clinical laboratory fee schedule remained the same as 2003. Section 628 of the Medicare Prescription Drug, Improvement and Modernization Act (DIMA) of 2003 specifies that the fee update for clinical laboratory services for Fiscal Years (FYs) 2004 through 2008 is zero percent. The revised fee update for clinical laboratory services requires revised fees for traveling to perform a specimen collection for either a nursing home or homebound patient. The clinical laboratory fee schedule can be downloaded from the TrailBlazer Health Enterprises® Web site at:

<http://www.trailblazerhealth.com/Tools/Fee%20Schedule/ClinicalLabFeeSchedule.aspx>

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CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)

Background

The Clinical Laboratory Improvement Amendments (CLIA) was established to strengthen federal oversight of clinical laboratories to ensure the accuracy and reliability of patient test results. A laboratory is defined as a facility that performs certain testing on human specimens in order to obtain information that can be used for the diagnosis, prevention or treatment of any disease or impairment of a human being; or the assessment of the health of a human being; or procedures to determine, measure or otherwise describe the presence or absence of various substances or organisms in a human body (42 CFR 493.2). CLIA's regulatory requirements vary according to the kind of test(s) each laboratory conducts. Tests are categorized as waived, moderate complexity or high complexity. Moderate and high complexity tests are collectively referred to as "non-waived" testing.

The CLIA of 1988 mandates that all laboratory testing sites must have a CLIA certificate to legally perform clinical laboratory testing anywhere in the United States.

To enroll in the CLIA program, laboratories must register by completing an application, pay fees, be surveyed (if applicable) and become certified. Registration is obtained through the Health Facility and Licensure division of the Department of Health and Human Services.

Providers who perform clinical laboratory testing and have not received CLIA information should contact:

Provider Location	Contact Information	
Colorado	Colorado Department of Public Health & Environment Laboratory Services Division 8100 Lowry Blvd. Denver, CO 80230-6928	(303) 692-3681 (303) 344-9965 Fax Contact: Jeff Groff E-mail: Jeff.Groff@state.co.us
New Mexico	Health Facility Licensing & Certification Bureau Bank of the West Building 5301 Central Avenue NW, Ste. 400 Albuquerque, NM 87108	(505) 222-8646 (505) 841-5834 Fax Contact: Julie Aragon
Oklahoma	Oklahoma State Department of Health Protective Health Services Medical Facilities 1000 NE 10th St. Oklahoma City, OK 73117-1299	(405) 271-6576 Contact: Dean Bay E-mail: medicalfacilities@health.ok.gov

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Provider Location	Contact Information	
Texas	Health Facility Compliance Division Patient Quality Care Unit Texas Department of State Health Services 1100 West 49th St. Austin, TX 78756-3199	(512) 834-6792 Internet: http://www.dshs.state.tx.us
Virginia	Virginia Department of Health Office of Licensure and Certification 3600 W Broad St., Ste. 216 Richmond, VA 23230	(804) 367-2107 (804) 367-2524 Fax
West Virginia	Office of Laboratory Services 167 11th Ave. South Charleston, WV 25303-1137	(304) 558-3530, Extension 2103 (304) 558-2006 Fax Contact: Jerry Gross E-mail: jerrygross@wvdhhr.org

Providers not in one of the above-listed states can go to the following CMS Web site to determine who to contact:

<http://www.cms.hhs.gov/CLIA/>

Guidelines

Effective January 1, 1998, the CLIA number must be included on all claims submitted for laboratory services, including purchased tests. CLIA mandates that virtually all laboratories, including Physician Office Laboratories (POLs), meet applicable federal requirements and have a CLIA certificate in order to receive reimbursement from federal programs.

The CLIA number must be submitted on all claims for laboratory services, including tests granted a “waived” status under CLIA and tests covered under the Provider Performed Microscopy Procedures (PPMP) certificates.

Claims for clinical laboratory services submitted by laboratories that have failed to receive CLIA certification will be denied.

‘Part B Crosswalk to the CMS-1500 Claim Form’ Job Aid

Throughout this manual are excerpts from the “Part B Crosswalk to the CMS-1500 Claim Form” job aid. The job aid is available on the TrailBlazerSM Web site at:

<http://www.trailblazerhealth.com/Publications/Job%20Aid/Crosswalkto1500ClaimForm.pdf>

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TrailBlazer created the following cross-reference guide (excerpt) for providers who submit electronic claims.

Item #	Claim Description	Loop	Segment	Electronic Instructions	Status	Example	Requirements			
22	Not Required	Not Mapped								
23	Prior Authorization Number	2300	REF01	Reference Identification Qualifier	C	G1	G1 = Prior Authorization Number			
			REF02 (G1)	QIO Number		###	Prior Authorization Number			
			REF01	Reference Identification Qualifier		LX	LX = Qualified Products Lists			
			REF02 (LX)	IDE Number		###	Investigational Device Exemption Number			
		2310D or 2420C	NM101 (FA) NM108 (XX) NM109	HHA/Hospice Number		C	Not Required at This Time	Home Health/Hospice Number. Until further notice, DO NOT submit an HHA or hospice provider number when billing for CPO services.		
									2420C	REF01 (LU)
										REF02
		2300 or 2400	REF01 (X4)	Reference Identification Qualifier			X4	10-Digit Clinical Laboratory Improvement Act (CLIA) Number for Lab Services		
			REF02	CLIA Certification Number			####			
		2420C	N403	ZIP Code			ZIP Code	Ambulance Enter ZIP Code for Point of Pickup		

The CLIA number of the **billing** lab must be reported in Item 23 of the paper CMS-1500 claim form.

CLIA Certification Categories

All types of certificates are effective for two years. The different types of certificate categories are as follows:

Certificate of Waiver (COW)

Issued to a laboratory that performs only waived tests.

Certificate for Provider Performed Microscopy Procedures (PPMP)

Issued to a laboratory in which a physician, mid-level practitioner or dentist performs specific microscopy procedures during the course of a patient's visit. A limited list of microscopy procedures is included under this certificate type, and these are categorized as moderate complexity.

Certificate of Registration

Issued to a laboratory to allow the laboratory to conduct non-waived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.

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Certificate of Compliance (COC)

Issued to a laboratory once the State Department of Health conducts a survey (inspection) and determines that the laboratory is compliant with all the applicable CLIA requirements. The type of certificate is issued to a laboratory that performs non-waived (moderate and/or high complexity) testing.

Certificate of Accreditation (COA)

Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. This type of certificate is issued to a laboratory that performs non-waived (moderate and/or high complexity) testing.

To obtain further information, providers should contact their state survey agency or CMS Regional Office.

Waived Tests

Guidelines

Under CLIA, entities holding a certificate of waiver are limited to performing only those tests authorized as waived tests.

Waived Tests – As defined by CLIA, waived tests are categorized as “simple laboratory examinations and procedures that have an insignificant risk of erroneous results.” The Food and Drug Administration (FDA) determines the criteria for tests being simple with a low risk of error and approves manufacturer's applications for test system waiver.

Waived Tests – tests for certificate of waiver must meet the following descriptive criteria.

Test systems are simple laboratory examinations and procedures which:

- Are cleared by FDA for home use.
- Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible.
- Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

The following is a link to the Lab and Pathology Specialty page that contains the waived tests link, which is updated periodically:

<http://www.trailblazerhealth.com/Special%20Provider%20Types/Lab%20and%20Pathology/>

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QW Modifier

Periodically, the Centers for Disease Control (CDC) approves new waived tests. CMS has established the QW modifier for all waived tests approved by the CDC on or after January 23, 1996. Laboratories holding a CLIA-waived certificate when billing for those waived tests approved on or after January 23, 1996, must use this modifier. The QW modifier is not required on tests approved prior to January 23, 1996.

PPMP Guidelines

A laboratory that is certified for provider-performed microscopy procedures may perform only those tests specified as provider-performed microscopy procedures and waived tests.

Procedure Codes

Use the following codes to report physician-performed microscopy procedures.

81000©	Urinalysis, nonauto w/scope
81001©	Urinalysis, auto w/scope
81015©	Microscopic exam of urine
81020©	Urinalysis, glass test
89190©	Nasal smear for eosinophils
89055©	Leukocyte assessment, fecal (effective January 1, 2004)
G0027	Semen analysis; presence and/or motility of sperm excluding Huhner
Q0111	Wet mounts, including preparations of vaginal, cervical or skin specimens
Q0112	All potassium hydroxide (KOH) preparations
Q0113	Pinworm examinations
Q0114	Fern test
Q0115	Post-coital direct, qualitative examinations of vaginal or cervical mucous

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Questions and Answers Regarding CLIA

- 1. Can I bill the beneficiary for clinical laboratory services denied for lack of CLIA certification?**
 - A. No. The beneficiary should not be held financially liable for such services. In addition, having a patient sign an advance notice of Medicare's possible denial of service does not place the financial burden of such denials on the beneficiary.

- 2. If I am billing for lab work performed by another laboratory, do I use my CLIA number or that of the lab where the work was performed?**
 - A. Always use the CLIA number assigned to the lab where the work was performed. The purpose of the CLIA is to validate that the lab is qualified and certified to perform the tests rendered.

- 3. Will Medicare accept multiple CLIA numbers on one claim?**
 - A. No. If more than one CLIA number is required, separate claims must be submitted.

- 4. Do I need a CLIA number for every physician in my practice?**
 - A. No. CLIA numbers are assigned to laboratories, not physicians.

- 5. If I only do a few simple tests like urinalysis, do I need a CLIA number?**
 - A. Yes. Even the simplest tests require the CLIA number.

- 6. If I am only doing blood draws, do I need a CLIA number?**
 - A. No. Medicare does not require a CLIA number if the facility only collects specimens and performs no testing.

- 7. If I only do waived tests, why do I need a CLIA number?**
 - A. The law requires that all laboratories performing testing, no matter what type of testing they perform, must have a certificate and obtain a CLIA number.

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MEDICAL NECESSITY

Medical necessity is defined as those services that are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member and are not excluded under another provision of the Medicare program.

Medicare notifies the providers of limited coverage and medical necessity in the Medicare Part B newsletters/eBulletins. The newsletters/eBulletins are found on TrailBlazer's Web page at:

<http://www.trailblazerhealth.com/Publications/Newsletters/>

ICD-9-CM Diagnosis Codes

ICD-9-CM codes are required on all claims submitted to carriers and must be coded to the highest level of specificity for that date of service.

Effective October 1, 2003, all claims submitted to carriers by independent clinical diagnostic laboratories must contain a diagnosis code. Carriers must reject claims submitted by independent clinical diagnostic laboratories that do not contain a diagnosis code.

Narrative Diagnosis

Section 4317 of the Balanced Budget Act of 1997 provides, with respect to diagnostic laboratory and certain other services, that, "if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the services to provide diagnostic or other medical information to the entity, the physician or practitioner ordering the service shall provide that information to the entity at the time the service is ordered by the physician or practitioner."

If a lab receives a requisition with a narrative description rather than an ICD-9-CM as the diagnosis, the lab may translate that narrative to the appropriate ICD-9-CM diagnosis code. The lab must maintain the requisition with the translated narrative description.

If the ordering physician submits an ICD-9-CM code on the requisition, the laboratory must use that code unless there is a reason to question the ordering physician.

Note: If a diagnosis or narrative diagnosis is not submitted by the physician/practitioner, laboratories must request this information from the physician/practitioner who ordered the service.

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Diagnosis Coding Requirements

Probable, Suspected, Questionable, Rule-Out Diagnoses

Diagnoses documented as probable, suspected, questionable, rule-out or working should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit.

Clarification of the Use of the Term ‘Screening’ or ‘Screen’

The final rule clarifies that effective February 21, 2002, the use of the term “screening” or “screen” in CPT code descriptor does not necessarily describe a test performed in the absence of signs and symptoms of illness, disease or condition.

Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease or injury are not covered except when there is a statutory provision that explicitly covers a test for screening as described.

If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test.

Limitation on Number of Diagnosis Codes

Up to eight diagnosis codes may now be submitted when billing electronically or up to four diagnosis codes may be submitted on the CMS-1500 claim form.

If a review is made on a laboratory claim, all diagnosis codes submitted will be used for the determination.

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Part B Crosswalk to the CMS-1500 Claim Form

TrailBlazer created the following cross-reference guide (excerpt) for providers who submit electronic claims.

Item #	Claim Description	Loop	Segment	Electronic Instructions	Status	Example	Requirements
21+	Diagnosis/Condition	2300	H101-1	Diagnosis Code	C	BK	Principal Diagnosis
			H101-2			DX Code	Primary Diagnosis Code
			H102-1			BF	BF = Diagnosis Code
			H102-2			DX Code	Second Diagnosis Code
			H103-1			BF	BF = Diagnosis Code
			H103-2			DX Code	Third Diagnosis Code
			H104-1			BF	BF = Diagnosis Code
			H104-2			DX Code	Fourth Diagnosis Code
			H105-1			BF	BF = Diagnosis Code
			H105-2			DX Code	Fifth Diagnosis Code
			H106-1			BF	BF = Diagnosis Code
			H106-2			DX Code	Sixth Diagnosis Code
			H107-1			BF	BF = Diagnosis Code
			H107-2			DX Code	Seventh Diagnosis Code
			H108-1			BF	BF = Diagnosis Code
			H108-2			DX Code	Eighth Diagnosis Code

The diagnosis code(s) must be reported in Item 21 of the paper CMS-1500 claim form.

When billing for these services in a non-covered situation (e.g., does not meet indications of the related Local Coverage Determination (LCD)), use the appropriate modifier.

To bill the patient for services that are not covered (investigational/experimental or not reasonable and necessary) will generally require an Advance Beneficiary Notice of Noncoverage (ABN) to be obtained before the service is rendered.

Matching of Diagnosis to Procedure

- If there is an LCD or National Coverage Determination (NCD) for one or more of the services included on the claim, review all of the diagnosis codes in making a determination regarding medical necessity of the service.
- Even though a claim matches diagnosis to procedure in accordance with an NCD, other rules of adjudication may apply which could result in denial.

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Part B Crosswalk to the CMS-1500 Claim Form

TrailBlazer created the following cross-reference guide (excerpt) for providers who submit electronic claims.

Item #	Claim Description	Loop	Segment	Electronic Instructions	Status	Example	Requirements
24e*	Diagnosis Code Reference	2400	SV107-1	Diagnosis Code Pointer	R		A submitter must point to the primary diagnosis for each service line.
			SV107-2				
			SV107-3				
			SV107-4				

The diagnosis code pointer must be reported in Item 24e of the paper CMS-1500 claim form.

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NATIONAL COVERAGE DETERMINATION (NCD) FOR CLINICAL DIAGNOSTIC LABORATORY SERVICES

Section 4554(b)(1) of the Balanced Budget Act (BBA), Public Law 105-33, mandated the use of a Negotiated Rulemaking Committee to develop national coverage and administrative policies for clinical diagnostic laboratory services payable under Part B of Medicare. The BBA required that these national policies be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory services payable under Part B.

Under the negotiations, CMS developed 23 laboratory National Coverage Determinations (NCDs). These NCDs are different than most other Medicare NCDs in that they include lists of ICD-9-CM codes. All codes are included on one of three lists:

- List 1 – Covered codes: “ICD-9-CM Codes Covered by Medicare,” which includes codes where there is a presumption of medical necessity, but the claim may be subject to review to determine whether the test was in fact reasonable and necessary.
- List 2 – Non-covered codes: “ICD-9-CM Codes Denied,” and includes codes that are never covered. If a code from this section is given as the reason for the test, the test may be billed to the Medicare beneficiary by the lab without billing Medicare first because the service is not covered by statute. The beneficiary, however, does have a right to have the claim submitted to Medicare upon request. When such a claim is submitted, the edit table will deny the claim.
- List 3 – Codes that do not support medical necessity: contains “ICD-9-CM Codes That Do Not Support Medical Necessity,” and includes diagnoses that generally are not covered for the test, but for which there are limited exceptions. Additional documentation could support a determination of medical necessity in certain circumstances. It would be appropriate for the ordering physician or the laboratory to obtain an advance beneficiary notice from the beneficiary when billing for tests for diagnoses included in this list. Claims from this third list can be submitted hard copy with additional documentation appended. This will permit medical review of these claims. Otherwise, the edit table will deny claims with these diagnoses.

The NCDs were published under the Administrative Procedures Act in the *Federal Register* of November 23, 2001.

CMS announced a mechanism for keeping the NCD code list current. CMS updates the NCD code list quarterly as necessary to incorporate new codes, correct ministerial errors, incorporate the results of Coding Analysis published elsewhere on the CMS Web site, and incorporate reconsideration of the NCDs that alter covered indications. The quarterly updates are published in the *NCD Coding Policy Manual*.

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What Is a National Coverage Policy?

An NCD sets forth the extent to which Medicare will cover specific services, procedures or technologies on a national basis. Medicare contractors are required to follow NCDs. If an NCD does not specifically exclude/limit an indication or circumstance, or if the item or service is not mentioned at all in an NCD or in a Medicare manual, it is up to the Medicare contractor to make the coverage decision.

Diagnostic laboratory tests are generally covered under Part B, unless excluded from coverage by the Social Security Act (the Act). Services that are generally excluded from coverage include routine physical examinations and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury. CMS interprets these provisions to prohibit coverage of screening services, including laboratory tests furnished in the absence of signs, symptoms or personal history of disease or injury, except as explicitly authorized by statute. A test may be considered medically appropriate, but nonetheless be excluded from Medicare coverage by statute.

A national coverage policy for diagnostic laboratory test(s) is a document notating CMS' policy with respect to the circumstances under which the test(s) will be considered reasonable and necessary, and not screening, for Medicare purposes. Such a policy applies nationwide. A national coverage policy is neither a practice parameter nor a statement of the accepted standard of medical practice. Words such as "may be indicated" or "may be considered medically necessary" are used for this reason. Where a policy gives a general description and then lists examples (following words like "for example" or "including"), the list of examples is not meant to be all-inclusive but merely to provide some guidance.

Where Can I Find the NCDs?

The NCDs, complete with the covered and non-covered ICD-9-CM codes, are available on the CMS Web site at:

http://www.cms.hhs.gov/mcd/index_section.asp?ncd_sections=40#B

CMS Lab NCD Index Overview

Below is an overview of the headings for the National Coverage Index:

- Publication Number.
- Manual Section Number.
- Version Number.
- Effective Date of this Version.
- Implementation Date.

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- Benefit Category.
Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.
- Coverage Topic.
- Item/Service Description.
- Indications and Limitations of Coverage.
Note: Scroll down for the links to the quarterly Covered Code Lists (including narrative)*.
- Cross Reference.
- Transmittal Number.
- Transmittal Link.
- Revision History.
- Other.
- Covered Code Lists (including narrative)*.
- Changes to Lab NCD Edit Software.

* **Note:** The Covered Code list (including narrative) is a link to the chronological list of quarterly updated NCD manuals.

The Format for the National Coverage Policies NCD Manual

Below are the headings for national coverage policies developed by the Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests.

Other Names/Abbreviations

This section identifies other names for the policy. It generally reflects more colloquial terminology.

Description

This section includes a description of the test(s) addressed by the policy and provides a general description of the appropriate uses of the test(s).

HCPCS Codes

The descriptor(s) used in this section is (are) the CPT or other CMS HCPCS. The CPT is developed and copyrighted by the American Medical Association (AMA). If a descriptor does not accurately or fully describe the test, a more complete description may be included elsewhere in the policy, such as in the Indications section.

ICD-9-CM Codes Covered by Medicare Program

This section includes covered codes — those where there is a presumption of medical necessity, but the claim is subject to review to determine whether the test was in fact

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reasonable and necessary. The diagnosis codes are from the *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM). Where the policy takes an “exclusionary” approach, this section reads: “Any ICD-9-CM code not listed in either of the ICD-9-CM code sections below.”

Indications

This section lists detailed clinical indications for Medicare coverage of the test(s).

Limitations

This section lists any national frequency expectations, as well as other limitations on Medicare coverage of the specific test(s) addressed in the policy — for example, if it would be unnecessary to perform a particular test with a particular combination of diagnoses.

ICD-9-CM Codes That Do Not Support Medical Necessity

This section lists/describes generally non-covered codes for which there are only limited exceptions. However, additional documentation could support a determination of medical necessity in certain circumstances. Subject to Section 1879 of the Act, 42 CFR 411, Subpart K, Section 7330 of the *Medicare Carriers Manual*, Section 3440–3446.9 of the *Medicare Fiscal Intermediary Manual* and any applicable rulings, it would be appropriate for the ordering physician or the laboratory to obtain an ABN from the beneficiary. Where the policy takes an “inclusionary” approach, this section reads: “Any ICD-9-CM code not listed in either of the ICD-9-CM sections above.”

Other Comments

This section may contain any other relevant comments that are not addressed in the sections described above.

Documentation Requirements

This section refers to documentation requirements for clinical diagnostic laboratory tests at 42 CFR 410.32(d) and includes any specific documentation requirements related to the test(s) addressed in the policy.

Sources of Information

Relevant sources of information used in developing the policy are listed in this section.

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NAME AND CPT CODES OF 23 CLINICAL DIAGNOSTIC LABORATORY NCDs

Name	CPT
Alpha-fetoprotein (AFP)	82105
Blood Counts (CBC)	85004, 85007, 85008, 85013, 85014, 85018, 85025, 85027, 85032, 85048, 85049
Blood Glucose Testing	82947, 82948, 82962
Carcinoembryonic Antigen (CEA)	82378
Collagen Crosslinks, Any Method	82523
Culture, Bacterial, Urine	87086, 87088, 87184, 87186
Digoxin Therapeutic Drug Assay	80162
Fecal Occult Blood	82272
Gamma Glutamyl Transferase (GGT)	82977
Glycated Hemoglobin/Glycated Protein	82985, 83036
Hepatitis Panel/Acute Hepatitis Panel	80074
Human Chorionic Gonadatropin (HCG)	84702
HIV Testing (Prognosis including Monitoring)	87536, 87539
HIV Testing (Diagnosis)	86689, 86701, 86702, 86703, 87390, 87391, 87534, 87535, 87537, 87538
Lipids	80061, 82465, 83700, 83701, 83704, 83718, 83721, 84478
Partial Thromboplastin Time (PTT)	85730
Prostate-Specific Antigen (Total PSA)	84153
Prothrombin Time (PT)	85610
Serum Iron Studies	82728, 83540, 83550, 84466
Thyroid Testing	84436, 84439, 84443, 84479
Tumor Antigen by Immunoassay – CA 125	86304

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LOCAL COVERAGE DETERMINATION (LCD)

Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book. The American Medical Association (AMA) and CMS require the use of short CPT descriptors in policies published on the Web.

Overview

Medical Necessity

Medical necessity is defined as those services that are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member, and are not excluded under another provision of the Medicare program.

Medicare notifies providers of limited coverage and medical necessity in the Medicare Part B newsletters or the new TrailBlazer eBulletins. The newsletters/eBulletins can be found on TrailBlazer's Newsletters Web page at:

<http://www.trailblazerhealth.com/Publications/Newsletters/>

What Is an LCD?

A Local Coverage Determination (LCD), as established by Section 522 of the Benefits Improvement and Protection Act, is a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the service is reasonable and necessary).

Definition of Limited Coverage

Coverage of certain procedures is limited by the diagnosis. If the diagnosis listed on the claim is not the same as one of those listed as covered for the procedure, the procedure is denied.

Limited coverage may be the result of national policy or an LCD.

Neither CMS nor TrailBlazer develops medical necessity policy for every service or procedure covered by Medicare. Absence of an LCD does not mean non-coverage for a service or procedure that fits a Medicare benefit category. It means that currently TrailBlazer has not identified the service(s) to require a local policy.

Nevertheless, Medicare relies on providers to report services appropriately so that payment is made only for services that "meet the general definition of medically reasonable and necessary."

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LCD Development/Maintenance Requirements

Since Medicare is a fee-for-service payment system and does not perform predeterminations or precertification, many beneficiaries, physicians and other providers would like to know the interpretation of the phrase “reasonable and necessary.” Various coverage policies, both local and national, are developed to assist in this interpretation. In other words, use of an LCD helps avoid situations in which claims are paid or denied without a provider having a full understanding of the basis for payment and denial.

In the absence of a national policy, Medicare contractors may use discretion to establish medical policy, currently known as LCDs. Each Medicare contractor may develop LCDs pertinent to his area of jurisdiction.

Related TrailBlazer LCDs

The following TrailBlazer LCDs pertain to laboratory and pathology services:

- Assays for Vitamins and Metabolic Function.
- Flow Cytometry.
- Free Prostrate Specific Antigen Testing.
- Frequency for Laboratory Tests.
- Helicobacter Pylori Testing.
- Infectious Disease Molecular Diagnostic Testing.
- Mohs’ Micrographic Surgery (MMS).
- Non-Covered Services.
- Wet Mounts.

These LCDs may be accessed from TrailBlazer’s LCD page at:

<http://www.trailblazerhealth.com/Tools/LCDs.aspx>

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ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)/LIMITED COVERAGE/ MEDICAL NECESSITY

Definition of Limited Coverage

Coverage of certain procedures is limited by the diagnosis. If the diagnosis listed on the claim is not the same as one of those listed as covered for the procedure, the procedure is denied.

Limited coverage may be the result of national policy or a Local Coverage Determination (LCD). National Coverage Determinations (NCDs) are published on the CMS Web site at:

<http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS014961>

The official version of LCDs may be viewed on the TrailBlazer Web site, <http://www.trailblazerhealth.com/Tools/LCDs.aspx>, and the summary is published in Medicare newsletters/eBulletins.

What Is an ABN?

An Advance Beneficiary Notice of Noncoverage (ABN) is a written notice that a provider/supplier gives to a Medicare patient before items or services are rendered when the provider/supplier believes that Medicare probably/certainly will not pay for some or all of the items or services for one of the following reasons:

- Medical necessity.
- Screening mammography, Pap smear or pelvic exam or screenings for prostate cancer, colorectal cancer or glaucoma that are performed more often than allowed by Medicare.
- Screening mammogram is being performed in an unapproved facility.

ABNs should only be provided to Medicare beneficiaries. The ABN allows the beneficiary to make an informed decision about whether to receive services that he may be financially responsible for paying. The ABN serves as proof that the patient had knowledge prior to receiving the service that Medicare might not pay. If a provider does not deliver a proper ABN to the patient, the patient cannot be billed for the service.

For complete ABN requirements and guidelines, please refer to the following TrailBlazer Provider Outreach and Education material link at:

<http://www.trailblazerhealth.com/Publications/Training%20Manual/abn.pdf>

Beginning March 3, 2008, providers (including independent laboratories), physicians, practitioners and suppliers may use the revised ABN for all situations where Medicare

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payment is expected to be denied. The revised ABN replaces the existing ABN-G (Form CMS-R-131G), ABN-L (Form CMS-R-131L) and Notice of Exclusions from Medicare Benefits (NEMB) (Form CMS-20007). Beginning March 1, 2009, the ABN-G and ABN-L will no longer be valid.

The revised ABN can be found on the following CMS Web site link:

http://www.cms.hhs.gov/BNI/02_ABN.asp

Modifiers

GA Modifier Item or service expected to be denied as not reasonable and necessary and the provider did have the beneficiary sign an ABN.

GZ Modifier Item or service expected to be denied as not reasonable and necessary and the provider did not have the beneficiary sign an ABN.

GY Modifier Item or service statutorily excluded or does not meet the definition of any Medicare benefit.

Part B Crosswalk to the CMS-1500 Claim Form

TrailBlazer created the following cross-reference guide (excerpt) for providers who submit electronic claims.

Item #	Claim Description	Loop	Segment	Electronic Instructions	Status	Example	Requirements
24d	Procedure Code/Modifiers	2400	SV101-1	Service ID Qualifier	R	HC	HC = Healthcare Common Procedural Coding
			SV101-2	Procedure Code		####	
			SV101-3	Procedure Modifier 1			Procedure Code and Modifier
			SV101-4	Procedure Modifier 2			
			SV101-5	Procedure Modifier 3			
			SV101-6	Procedure Modifier 4			

Enter a valid CPT or HCPCS code for each service rendered in Item 24d. When applicable, a valid modifier must be reported on the paper CMS-1500 claim form.

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LABORATORY'S RESPONSIBILITY AND LIABILITY FREQUENTLY ASKED QUESTIONS (FAQs)

- 1. A physician orders a lab test, and the lab does both the specimen collection and lab test/processing. Is the lab or physician responsible for executing the Advance Beneficiary Notice of Noncoverage (ABN)?**
 - A. Because the laboratory has the risk of financial liability in the case of a denial, it is the laboratory's responsibility to execute the ABN. The physician may execute the ABN, but it is not a requirement. If the physician had executed an ABN, the lab need not repeat it.

- 2. A physician orders a lab test; the specimen collection is done in the physician's office and is sent to the lab for processing. Is the lab or physician responsible for executing the ABN?**
 - A. Whether the physician or the laboratory collects the specimen, it is still the laboratory's responsibility to execute the ABN because the laboratory has the risk of financial liability in the case of a denial. However, we encourage physicians to execute ABNs in these situations since the physician has the better opportunity to give notice.

- 3. If the physician does not execute the ABN, what recourse does the lab have?**
 - A. The lab may contact the beneficiary to execute an ABN in person or by telephone (with immediate mail notice follow up). If the beneficiary: (i) cannot be reached; (ii) refuses to sign an ABN; or (iii) initially agrees via telephone and then refuses to sign, the laboratory has two options. The lab may either perform the test with the likelihood that it may not be able to collect from the beneficiary or may choose not to perform the test (this may be a state law violation in some states).

- 4. If a physician is "not responsible" to execute an ABN when a laboratory will bill Medicare for the test, why do you encourage the physician to execute an ABN in these situations?**
 - A. By "not responsible" we only mean the physician is "not required by law" to execute an ABN for a test for which payment to the laboratory is likely to be denied. Nevertheless, a physician endeavoring to provide the best care to patients may wish to deliver an ABN in such a case. In this situation, the physician has immediate contact with the patient during the office visit or specimen collection, and is thus in the best position to have a meaningful dialogue with him regarding the choices to be made in going forward with the test or declining it. By delivering the ABN, the physician also is working in partnership with the laboratory that serves the practice (since the laboratory may not even encounter the patient), and this will help the laboratory remain financially solvent and available to the patients of the practice. While we do not mandate this partnering between physicians and their affiliated labs,

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we certainly encourage it. The best practice in this situation is for the patient to receive any necessary ABN at the physician's office.

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MEDICALLY UNLIKELY EDITS (MUEs)

Formerly known as “Medically Unbelievable Edits.”

CMS developed Medically Unlikely Edits (MUEs) to reduce the paid claims error rate for Part B claims. An MUE for a HCPCS/CPT code is the maximum units of service that a provider would report under most circumstances for a single beneficiary on a single date of service. All HCPCS/CPT codes do not have an MUE.

MUE was implemented January 1, 2007.

CMS is pleased to announce that beginning October 1, 2008, coincident with implementation of MUE version 2.3, the majority of existing MUEs were made public and posted on the CMS Web site, accessed through the MUE Web page at:

http://www.cms.hhs.gov/NationalCorrectCodInitEd/08_MUE.asp#TopOfPage

For additional information regarding MUEs, the MLN Matters Article may be viewed on the CMS Web site at:

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5402.pdf>

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ORDERING PRACTITIONER

Any administrative policies that relate to the individual who orders the service applies to a physician or a non-physician practitioner qualified under 42 CFR 410.32(a)(3) to order diagnostic services.

Ordering practitioners include non-physician practitioners such as clinical nurse specialists, clinical psychologists, clinical social workers, nurse midwives, nurse practitioners and physician assistants who furnish services that would be physician services if furnished by a physician and who work within the scope of their authority under state law and within the scope of the Medicare statutory benefit.

Documentation Requirements

The ordering physician must maintain documentation of medical necessity in the beneficiary's medical record.

The laboratory must maintain the documentation it receives from the ordering physician and must ensure the information listed on the claim accurately reflects the documentation it received from the ordering physician.

Part B Crosswalk to the CMS-1500 Claim Form

TrailBlazer created the following cross-reference guide (excerpt) for providers who submit electronic claims.

Item #	Claim Description	Loop	Segment	Electronic Instructions	Status	Example	Requirements
17+	Name of Referring or Ordering Physician	2310A or 2420F	NM101	Entity Identifier Code	C	DN	DN = Referring Provider
			NM102	Entity Type Qualifier		1	1 = Person
			NM103	Referring Provider Last Name (DN)		Name	Enter the name of the referring physician if the service was referred by a physician.
			NM104	Referring Provider First Name			
			NM105	Referring Provider Middle Name			
		2420E	NM101	Entity Identifier Code	C	DK	DK = Ordering Provider
			NM102	Entity Type Qualifier		1	1 = Person
			NM103	Ordering Provider Last Name (DK)		Name	Enter the name of the ordering physician if the service was ordered by a physician.
			NM104	Referring Provider First Name			
			NM105	Referring Provider Middle Name			
17a	UPIN Number	No Longer Used by Medicare					
17b+	NPI Number of Ordering or Referring Provider	2310A or 2420F	NM108	Identifier Code Qualifier	C	XX	XX = CMS NPI
			NM109	Referring NPI ID (DN)		NM108 must = XX NM101 must = DN	NPI #
		2420E	NM108	Identifier Code Qualifier	C	XX	XX = CMS NPI
			NM109	Ordering NPI ID (DK)		NM108 must = XX NM101 must = DK	NPI #

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An NPI for an ordering/referring/attending/operating provider was mandatory effective May 23, 2008. Legacy/Provider Transaction Access Number (PTAN) numbers cannot be reported on any claims sent to Medicare on or after May 23, 2008. An NPI is required regardless of whether the provider participates in the Medicare program or not or is a covered entity. It is the responsibility of the claim/bill submitter to obtain the ordering/referring/attending/operating NPI for health care providers. Claims received without an NPI in Item 17b are rejected.

Signature on Requisition Form

Medicare does not require the signature of the ordering physician on a laboratory service requisition. While the signature of a physician on a requisition is one way of documenting that the treating physician ordered the service, it is not the only permissible way of documenting that the service has been ordered. For example, the physician may document the ordering of specific services in the patient's medical record.

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DATE OF SERVICE FOR LABORATORY TESTING

In the final physician fee schedule published in the *Federal Register* on November 27, 2007, CMS revised the Date of Service (DOS) policy for clinical laboratory test and added the technical component of physician pathology service effective January 1, 2009 (42 CFR 414.510).

General Rule: The DOS of the test/service must be the date the specimen was collected.

Variation: If a specimen is collected over a period that spans two calendar days, the DOS must be the date the collection ended.

Exceptions: The following two exceptions apply to the DOS policy for either a clinical laboratory test or the technical component of physician pathology service:

A. DOS for Tests/Services Performed on Stored Specimens:

In the case of a test/service performed on a stored specimen, if a specimen was stored for less than or equal to 30 calendar days from the date it was collected, the DOS of the test/service must be the date the test/service was performed only if:

- The test/service is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital.
- The specimen was collected while the patient was undergoing a hospital surgical procedure.
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted.
- The results of the test/service do not guide treatment provided during the hospital stay.

And,

- The test/service was reasonable and medically necessary for treatment of an illness.

If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived and the DOS of the test/service must be the date the specimen was obtained from storage.

B. DOS for Chemotherapy Sensitivity Tests/Services Performed on Live Tissue:

In the case of a chemotherapy sensitivity test/service performed on live tissue, the DOS of the test/service must be the date the test/service was performed only if:

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- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge.
 - The specimen was collected while the patient was undergoing a hospital surgical procedure.
 - It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted.
 - The results of the test/service do not guide treatment provided during the hospital stay.
- And,
- The test/service was reasonable and medically necessary for treatment of an illness.

For purposes of applying the above exception, a “chemotherapy sensitivity test” is defined as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. CMS identifies such tests through program instructions issued to the Medicare contractors.

For additional information regarding date of service for laboratory testing, the MLN Matters article may be viewed on the CMS Web site at:

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6018.pdf>

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MULTIPLE SERVICES – MODIFIERS

There are two CPT modifiers to identify multiple services, same beneficiary and same day.

59 Modifier Distinct procedural service

Used to report multiple service submissions. These situations usually involve microbiology where samples or cultures are taken from a patient from different anatomical sites or different wounds, and then are tested the same day.

See the CMS Web site at <http://www.cms.hhs.gov/NationalCorrectCodInitEd/> for a complete listing of the National Correct Coding Initiative (NCCI) policy.

76 Modifier Repeat procedure by the SAME physician on the same day. (Used for anatomical laboratory services.)

91 Modifier Indicates repeat clinical diagnostic laboratory services

If an ordering physician requests a laboratory test that requires several of the same services (CPT code) be performed for the same beneficiary on the same day, the lab should use modifier 91 to indicate that multiple clinical diagnostic lab tests were done on the same day.

Example: 82947© – Glucose; quantitative, blood is ordered on a patient at three different intervals on the same day, and the blood testing is performed three times that same day. The 91 modifier would be used on subsequent procedures.

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CLARIFICATION OF STANDING ORDERS

The Medicare program considers payment for services performed based on medical necessity of the patient. Lab services are not exempt from this requirement. Patient records must support the medical necessity for performing the ordered lab service. Many facilities have “standing orders” for testing and other services for all residents of their facility. The problem with this type of standing order is the lack of patient-specific signs/symptoms/medical needs prompting the laundry list of tests. This type of standing order does not meet the requirement of documented medical necessity required by Medicare for reimbursement.

The term “standing order” is sometimes used for anticipated scheduled testing required for some drug therapies. Some drug therapies require monitoring of therapeutic levels. This type of standing order is patient-specific and medically necessary to monitor patient-specific conditions. This is not to be confused with facility standing orders since medical records will support the need for this type of repetitive testing. The patient’s medical record must support the continued monitoring of the patient based on the lab findings that prompt drug therapy dose and frequency adjustments along with lab frequency adjustments to meet the changing needs of the patient. This type of standing order is not prohibited in connection with an extended course of treatment (i.e., Coumadin therapy). Laboratories must be vigilant about this and take appropriate steps to prevent abuse. The laboratory should monitor existing standing orders to ensure their continuing validity. The physician has to evaluate the patient and then authorize the order for the service or procedure and subsequent ones. The medical necessity for and the nature of each service or procedure must be clearly documented by a physician and the physician’s authorization must be in the patient’s medical records.

Sections 42 CFR 410.32 and 411.15 specify that for a laboratory service to be reasonable and necessary it must not only be ordered by the physician but the ordering physician must also use the result in the management of the beneficiary’s specific medical problem. Implicitly, the laboratory result must be reported to the physician promptly for the physician to use the result and instruct continuation or modification of patient care; this includes the physician’s order for another laboratory service. Compliance program guidance for laboratory services sets forth conditions under which a physician’s order for a repeat laboratory service can qualify as an order for another covered laboratory service. A standing order as described in the first paragraph is not usually acceptable documentation for a covered laboratory service.

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STAT SERVICES

At times, a physician will order laboratory services “stat.” Stat services are not reimbursed by Medicare.

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PHYSICIAN SIGNATURE REQUIREMENTS FOR DIAGNOSTIC TESTS

A physician's signature is not required on orders for clinical diagnostic tests (including X-ray, laboratory and other diagnostic tests) that are paid on the basis of the clinical laboratory fee schedule, the Medicare Physician Fee Schedule or for physician pathology services. While a physician order is not required to be signed, the physician must clearly document in the medical record his intent that the test be performed.

Office, billing and/or laboratory staffs should be aware of the updated guidance regarding the signature requirement for diagnostic tests.

Information regarding physician signature requirements for diagnostic tests is found in Change Request (CR) 6100:

<http://www.cms.hhs.gov/Transmittals/downloads/R94BP.pdf>

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SPECIMEN COLLECTION

A specimen collection fee for physicians is allowed only when:

- It is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen.
- It is the customary practice of the physician performing such services to bill separate charges for them.

A specimen collection fee is not allowed when the cost of collecting the specimen is minimal, such as a throat culture or a routine capillary puncture for clotting or bleeding time. Stool specimen collection for an occult blood test is usually done by the patient at home, and a fee for such collection is not allowed. Costs such as media (e.g., the slides) and labor are included in the payment for the test.

The 2005 clinical laboratory fee schedule will no longer include code G0001 and will include code 36415 – collection of venous blood by venipuncture. Code 36415 has now been activated to be payable by Medicare effective January 1, 2005.

The following HCPCS codes and terminology must be used:

G0001	Routine venipuncture for collection of specimen(s) (for dates of service prior to January 1, 2005)
36415©	Routine venipuncture (for dates of service on or after January 1, 2005)
P9612	Catheterization for collection of specimen, single patient
P9615	Catheterization for collection of specimen(s) (multiple patients)

Specimen Collection Guidelines

Consider the following guidelines when billing for specimen collections:

- The maximum allowance for specimen collection is \$3. No additional allowance will be made for specimens referred to other labs for testing.
- The specimen collection fee allowance cannot be made to anyone who has not extracted a specimen from the patient.
- Only one collection fee is allowed for each patient encounter regardless of the number of specimens drawn. When a series of specimens is required to complete a single test (e.g., glucose tolerance test), the series is treated as a single encounter.
- A specimen collection fee is not paid when the cost of collecting the specimen is minimal, such as throat culture or routine capillary punctures for clotting or bleeding time.

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HANDLING CHARGES POLICY

Routine handling charges are not allowed when a specimen is referred by one laboratory to another. Preparatory services where a referring laboratory prepares a specimen before transfer to a reference laboratory are considered an integral part of the testing process and the costs of such services are included in the charge for the total testing service. The beneficiary cannot be charged for these services.

Procedure Codes

The following laboratory handling charges are denied when billed to Medicare Part B:

99000©	Specimen handling
99001©	Specimen handling
99002©	Device handling

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TRAVEL ALLOWANCE POLICY

In addition to the specimen collection fee for drawing specimens from homebound and nursing home patients, a travel allowance will be allowed to cover the costs of collecting a specimen from the patient. The travel allowance is intended to cover the estimated travel cost and technician's salary associated with collecting the specimen.

The additional allowance can be made only when a specimen collection fee is also payable, i.e., no travel allowance is made when the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel. The travel allowance may not be paid to a physician unless the trip to the home or to the nursing home was solely for the purpose of drawing a specimen. Otherwise, travel costs are considered to be associated with the other purposes of the trip.

Procedure Codes

Use the following procedure codes to bill for travel allowances:

P9603	Travel allowance one way in connection with medically necessary laboratory (should not be used unless trip totals 20 or more miles).
P9604	Travel allowance one way in connection with medically necessary laboratory. Specimen collection drawn from homebound or nursing home-bound patient; prorated trip charge.

Note: The LR modifier may be used to indicate roundtrip laboratory travel.

Travel Allowance: The travel codes allow for payment either on a per-mileage basis (P9603) or on a flat-rate, per-trip basis (P9604). Payment of the travel allowance is made only if a specimen collection fee is also payable. The travel allowance is intended to cover the estimated travel costs of collecting a specimen including the laboratory technician's salary and travel expenses.

When one trip is made for multiple specimen collections at a single address (e.g., at a nursing home), the travel payment component is prorated based on the number of specimens collected on that trip.

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Medicare Travel Allowance Fees for Collection of Specimens

Per CR 6524, Transmittal 1790, dated August 7, 2009, the following travel allowance rates are effective for dates of service January 1, 2009, through December 31, 2009:

Implementation date: October 5, 2009

From the Medicare Learning Network

Per Mile Travel Allowance (HCPCS Code P9603)

The per mile travel allowance is to be used in situations where the average trip to the patients' homes is longer than 20 miles round trip, and is to be prorated in situations where specimens are drawn from non-Medicare patients in the same trip.

*CR 6524 instructs that Medicare contractors will pay for **HCPCS code P9603**, where the average trip to the patients' homes exceeds 20 miles round trip, at a total of **\$1 per mile**. This includes:*

- The federal mileage rate of \$0.55 per mile.*
- Plus,***
- An additional \$0.45 per mile to cover the technician's time and travel costs.*

Contractors shall have the option of establishing a higher per-mile rate for HCPCS code P9603, in excess of the minimum \$1 per mile, if local conditions warrant it. The minimum mileage rate will be reviewed and updated in conjunction with the Clinical Laboratory Fee Schedule (CLFS) as needed. At no time will the laboratory be allowed to bill for more miles than are reasonable or for miles that are not actually traveled by the laboratory technician.

Per Flat-Rate Trip Basis Travel Allowance (HCPCS Code P9604)

*CR 6524 also instructs that Medicare contractors shall pay for **HCPCS code P9604** on a flat-rate trip basis travel allowance of **\$10 per trip**.*

Consider the following guidelines when billing for travel allowance:

- The additional allowance is only payable when the specimen collection fee is also payable.*
- It must be medically necessary for a laboratory technician to draw a specimen from either a nursing home or homebound patient.*
- The technician must personally draw the specimen.*
- No allowance can be made when the laboratory technician merely performs a messenger service to pick up specimens drawn by a physician or nursing home personnel.*

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- The appropriate specimen collection procedure code and travel allowance procedure code must be indicated on the same claim.

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NURSING HOME AND HOMEBOUND SPECIMEN COLLECTION POLICY

When medically necessary, a specimen collection is allowed to be drawn from either nursing home or homebound patients.

Consider the following guidelines when billing for specimen collections for nursing home and homebound patients:

- The technician must personally draw the specimen.
- The patient must be confined to the home or facility where the specimen is drawn.
- The nursing home must not have on-duty, qualified personnel to perform the specimen collection.
- A \$3 fee is allowed for drawing a specimen from a homebound patient or single nursing home patient, or from multiple nursing home patients (per patient) during the same nursing home visit.
- Enter the word "homebound" in Item 19 when an independent lab obtains a specimen from a homebound or institutionalized patient.

Note: An individual does not have to be bedridden to be considered as confined to his home. However, the condition of the patient should be such that there exists a normal inability to leave home, and consequently, leaving home would require a considerable and taxing effort.

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SKILLED NURSING FACILITY (SNF) PATIENTS AND CONSOLIDATED BILLING (CB)

Congress enacted the Balanced Budget Act (BBA) of 1997, Public Law 105-33, Section 4432(b). This section of the law contains the Skilled Nursing Facility (SNF) Consolidated Billing (CB) requirements. Under the CB requirement, **an SNF must submit all Medicare claims for the services its residents receive** (except for specifically excluded services).

For detailed information concerning CB, please see the “Skilled Nursing Facility Consolidated Billing” section in the *Welcome to Medicare* manual on the TrailBlazer Web site at:

<http://www.trailblazerhealth.com/Publications/Training%20Manual/welcome%20to%20medicare.pdf>

Laboratory and Pathology

GUIDELINES FOR REFERRAL LABORATORIES

Claims for referred laboratory services may be made only by suppliers having specialty code 69 (i.e., independent clinical laboratories). Claims for referred laboratory services made by other entities will be returned as unprocessable. Medicare defines a referred clinical diagnostic laboratory service/test as a service performed by one laboratory at the request of another laboratory. "Referring laboratory" is defined as the laboratory that refers a specimen to another laboratory for testing. "Reference laboratory" is defined as the laboratory that receives a specimen from another laboratory and that performs one or more tests on such a specimen.

A referring laboratory can bill for tests performed by a reference laboratory only if it meets one of the following exceptions:

- It is located in, or is part of, a rural hospital.
 - The referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly owned by a third entity.
- Or,
- The referring laboratory does not refer more than 30 percent of the clinical laboratory tests for which it receives requests for testing during the year (not counting referrals made under the wholly owned condition described above).

Examples of 30 Percent Exception:

1. A laboratory receives requests for 200 tests, performs 139 tests and refers 61 tests to a non-related laboratory. All tests referred to a non-related laboratory are counted. Thus, 30.5 percent (61/200) of the tests are considered tests referred to a non-related laboratory. Since this exceeds the 30 percent standard, the referring laboratory may not bill for any Medicare beneficiary laboratory tests referred to a non-related laboratory.
2. A laboratory receives requests for 200 tests, performs 139 tests and refers 15 to a related laboratory and 46 to a non-related laboratory. Only 23 percent of the tests were referred to non-related laboratories. Since this is less than 30 percent, the referring laboratory may bill for all tests.

If it is later found that a referring laboratory does not, in fact, meet an exception criterion, the carrier should recoup payment for the referred tests improperly billed.

Note: This provision of Section 6111(b) of Omnibus Budget Reconciliation Act (OBRA) of 1989 has no effect on hospitals that are paid under Section 1833(h)(5)(A)(iii).

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Note: Laboratory services provided to a Skilled Nursing Facility (SNF) inpatient under Part A are billed by the SNF, not the laboratory, due to consolidated billing for SNFs.

Only one laboratory may bill for a referred laboratory service. It is the responsibility of the referring laboratory to ensure that the reference laboratory does not bill Medicare for the referred service when the referring laboratory does so (or intends to do so). In the event the reference laboratory bills or intends to bill Medicare, the referring laboratory may not do so.

When the billing laboratory is the referring laboratory, it must:

- Identify the referred service as such by use of modifier 90.
- Identify the reference laboratory by specifying its Clinical Laboratory Improvement Amendments (CLIA) number and the address where the test actually was performed.

Only one laboratory may bill for a referred laboratory service. It is the responsibility of the referring laboratory to ensure that the reference laboratory does not bill Medicare for the referred service when the referring laboratory does so (or intends to do so). In the event the reference laboratory bills or intends to bill Medicare, the referring laboratory may not do so.

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CMS-1500 CLAIM FORM/ELECTRONIC SUBMISSION

Paper Claim Submitters

Effective July 1, 2005 – Please see MLN Matters Number: 3440 – Administrative Simplification Compliance Act (ASCA) Enforcement of Mandatory Electronic Submission of Medicare Claims.

Electronic Claim Submitters

The Clinical Laboratory Improvement Amendments (CLIA) number is required on all American National Standards Institute (ANSI) claims for laboratory testing. If tests are referred to another laboratory, the CLIA number of the laboratory where the testing is rendered must also be on the claim.

The clinical diagnostic laboratory will not have to submit separate claims for referred and performed services. The presence of the 90 modifier with the line item service identifies the referral tests.

An ANSI claim for laboratory testing requires the presence of the performing and billing laboratory's name and address. An ANSI electronic claim for laboratory testing must be submitted using the following format:

Part B Crosswalk to the CMS-1500 Claim Form

TrailBlazer created the following cross-reference guide (excerpt) for providers who submit electronic claims.

Item #	Claim Description	Loop	Segment	Electronic Instructions	Status	Example	Requirements			
23+	Prior Authorization Number	2300	REF01	Reference Identification Qualifier	C	G1	G1 = Prior Authorization Number			
			REF02 (G1)	QIO Number		###	Prior Authorization Number			
			REF01	Reference Identification Qualifier		LX	LX = Qualified Products Lists			
			REF02 (LX)	IDE Number		###	Investigational Device Exemption Number			
		2310D or 2420C	NM101 (FA) NM108 (XX) NM109	HHA/Hospice Number		C	Not Required at This Time	Home Health/Hospice Number. Until further notice, DO NOT submit an HHA or hospice provider number when billing for CPD services.		
									2420C	REF01 (LU)
		REF02								
		2300 or 2400	REF01 (X4)	Reference Identification Qualifier					x4	10-Digit Clinical Laboratory Improvement Act (CLIA) Number for Lab Services
			REF02	CLIA Certification Number					####	
		2420C	N403	ZIP Code					ZIP Code	Ambulance Enter ZIP Code for Point of Pickup

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Reminder: The ANSI electronic claim will not be split; CLIA numbers from both the billing and reference laboratories must be submitted on the same claim. The presence of the 90 modifier at the line item service identifies the referral tests. Referral laboratory claims are only permitted for independently billing clinical laboratories, specialty code 69.

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NEW REMITTANCE ADVICE (RA) MESSAGE FOR REFERRED CLINICAL DIAGNOSTIC/PURCHASED DIAGNOSTIC SERVICE DUPLICATE CLAIMS

Effective with claims processed on or after July 1, 2005, CMS implemented a new Remittance Advice (RA) message for referred clinical diagnostic/purchased diagnostic service duplicate claims. Carriers will use the following remark code on RA notices generated for a referred clinical diagnostic/purchased diagnostic service claim line item denied as a duplicate of a previously paid service: "Your claim for a referred clinical diagnostic/purchased diagnostic service cannot be paid because payment has been made for this service in another carrier jurisdiction."

Claims submitted for referred clinical diagnostic/purchased diagnostic services will be considered duplicate when:

- The claims contain different carrier numbers.
- All data matches on the following claim fields:
 - Beneficiary name.
 - Beneficiary Health Insurance Claim Number (HICN).
 - CPT/HCPCS code.
 - Date of service.
 - CPT/HCPCS code modifier.

The Common Working File (CWF) duplicate claim edit will apply only to:

- Claims containing a CPT code that is included on the clinical laboratory fee schedule.
- A HCPCS code that is included on the Abstract File for Purchased Diagnostic Tests implemented in April 2005.

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PURCHASED DIAGNOSTIC TESTS

Independent Laboratory

When an independent laboratory bills for the Technical Component (TC) of a physician pathology service purchased from a separate physician or supplier, the payment for the TC is based on the lower of the billed charge or the Medicare Physician Fee Schedule. The purchased diagnostic test payment provision does not apply; thus, the purchase service information shall not be entered on the claim.

All purchased diagnostic services are based on the Medicare Physician Fee Schedule and are subject to the jurisdiction rules for that fee schedule.

The independent laboratory must perform at least one of the component services. If it purchases both the Professional Component (PC) and the TC services, only the physician or supplier that performed those services may bill.

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REFERENCE LABORATORY AND PURCHASED DIAGNOSTIC SERVICES PERFORMED OUTSIDE THE BILLING JURISDICTION

Change Request (CR) 6362 – Establishes an exception to the standard reporting of the National Provider Identifier (NPI) on Medicare fee-for-service claims for reference laboratory and purchased diagnostic services performed by a provider located outside the jurisdiction of the Medicare contractor. When a provider bills either of these services (reference laboratory services listed on the Clinical Laboratory Fee Schedule or purchased diagnostic services) and the services were performed by a provider located in another Medicare contractor’s jurisdiction, the provider must report his own NPI on the Medicare claim **as the performing provider** and annotate the claim with the performing provider’s name, address and ZIP code. The performing provider’s NPI must be recorded in the clinical records for auditing purposes.

When a provider bills for diagnostic services that have been purchased from a provider location in another contractor jurisdiction, the billing provider must, in addition to reporting his own NPI on paper or an electronically submitted Medicare claim (as the billing provider – Item 33), also report his own NPI as the performing provider with the name, address and ZIP code of the performing provider (Items 32 and 32a).

Part B Crosswalk to the CMS-1500 Claim Form

TrailBlazer created the following cross-reference guide (excerpt) for providers who submit electronic claims.

Item #	Claim Description	Loop	Segment	Electronic Instructions	Status	Example	Requirements	
32+	Service Facility Location	2310D or 2420C	NM101	Entity Identifier Code	C	FA	77 = Service Location, FA = Facility, LI = Independent Lab, TL = Testing Lab	
			NM102	Entity Type Qualifier		2	2 = Non-Person Entity	
			NM103	Facility Name		Name	Organization Name	
			N301	Address		Address	Address of Service Facility	
			N401, 02, 03	City, State, ZIP code		C/S/Z	City, State and ZIP	
32a	Service Facility NPI	2310D or 2420C	NM108	Identification Code Qualifier		XX	XX = CMS NPI	
			NM109	Laboratory/Facility Primary Identifier		NPI #	NPI Number	
		2310C or 2420B	2400	PS101		Purchased Service Provider Identifier	###	Provider Identification Number
			NM101	Entity Identifier Code		QB	QB = Purchase Service Provider	
			NM108	Identification Code Qualifier		XX	Only Required for Transplants, Teaching Hospitals and IDTF - Purchased Tests	
		2400	NM109 (QB)	Identification Code		NPI #		
			REF01	Reference Identification Qualifier		EW	EW = Mammography Certification Number	
	REF02	Mammogram Certification	####	Enter six-digit Food and Drug Administration (FDA)-approved certification number.				
32b	Service Facility PIN	Leave Blank Not Required by Medicare						

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CODES WITH TECHNICAL COMPONENTS (TCs)

Following is a list of laboratory codes that include a Technical Component (TC). When these codes are billed as TC only or global (no modifier), purchased test information must be present on the claim.

Laboratory Tests with TCs				
88104	88182	88314	88347	88367
88106	88300	88318	88348	88368
88107	88302	88319	88349	88380
88112	88304	88323	88355	88384
88125	88305	88331	88356	88385
88160	88307	88332	88358	88386
88161	88309	88333	88360	
88162	88311	88334	88361	
88172	88312	88342	88362	
88173	88313	88346	88365	

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PURCHASED INTERPRETATIONS

A person or entity that provides diagnostic tests may submit the claim and (if assignment is accepted) receive the Part B payment for diagnostic test interpretations, which that person or entity purchases from an independent physician or medical group, if:

- The tests are initiated by a physician or medical group that is independent of the person or entity providing the tests and of the physician or medical group providing the interpretations.
- The person or entity providing the tests and purchasing the interpretations submits either an assigned or unassigned claim for both the tests and the interpretations thereof.
- The physician or medical group providing the interpretations does not see the patient.
- The purchaser (or employee, partner or owner of the purchaser) performs the technical component of the test.
- The interpreting physician must be enrolled in the Medicare program. No formal reassignment is necessary.

The purchaser must keep on file the name, provider identification number and address of the interpreting physician. The National Provider Identifier (NPI) of the interpreting physician must be in Item 19 of the CMS-1500 claim form or the electronic equivalent.

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PROFESSIONAL COMPONENT (PC) LABORATORY TESTS

The following clinical laboratory tests are considered by Medicare to have a Professional Component (PC).

PC Tests		
Code	Modifier	Description
83020©	26	Hemoglobin electrophoresis
83912©	26	Genetic examination
84165©	26	Protein e-phoresis, serum
84166©	26	Protein e-phoresis/urine/csf
84181©	26	Western blot test
84182©	26	Protein, western blot test
85390©	26	Fibrinolysins screen
85576©	26	Blood platelet aggregation
86255©	26	Fluorescent antibody, screen
86256©	26	Fluorescent antibody, titer
86320©	26	Serum immunoelectrophoresis
86325©	26	Other immunoelectrophoresis
86327©	26	Immunoelectrophoresis assay
86334©	26	Immunofix e-phoresis, serum
86335©	26	Immunifix e-phorsis/urine/csf
87164©	26	Dark field examination
87207©	26	Smear, special stain
88371©	26	Protein, western blot tissue
88372©	26	Protein analysis w/probe
89060©	26	Exam, synovial fluid crystals

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INDEPENDENT LABORATORY BILLING FOR THE TECHNICAL COMPONENT (TC) OF PHYSICIAN PATHOLOGY SERVICES TO HOSPITAL PATIENTS

Change Request (CR) 5210, Transmittal 1046, dated September 1, 2006

Independent laboratories may not bill for the Technical Component (TC) of physician pathology services furnished to a patient of a hospital after December 31, 2006. This policy enforces the regulation at 42 CFR 415.130.

The TC of physician pathology services refers to the preparation of the slide, involving tissue or cells that a pathologist will interpret. (In contrast, the pathologist's interpretation of the slide is the Professional Component (PC) service. If this service is furnished by the hospital pathologist for a hospital patient, it is separately billable. If the independent laboratory's pathologist furnishes the PC service, it is usually billed with the TC service as a combined service.)

In the final physician fee schedule regulation published in the *Federal Register* on November 2, 1999, CMS indicated that it would implement a policy to pay only the hospital for the TC of physician pathology services furnished to hospital patients. Prior to this proposal, any independent laboratory could bill the carrier under the physician fee schedule for the TC of physician pathology services for hospital patients. As pointed out in the final rule, this policy has contributed to the Medicare program paying twice for the TC service, first through the inpatient prospective payment rate to the hospital where the patient is an inpatient, and again to the independent laboratory that bills the carrier, instead of the hospital, for the TC service.

The final 1999 regulation (42 CFR 415.130) provided that, for services furnished on or after January 1, 2001, the carriers would no longer pay claims to the independent laboratory under the physician fee schedule for the TC of physician pathology services for hospital patients. Ordinarily, the provisions in the final physician fee schedule are implemented in the following year. In this case, the provision was delayed one year, at the request of the industry, to allow independent laboratories and hospitals sufficient time to negotiate arrangements.

Before this regulation was implemented, the Benefits Improvement and Protection Act of 2000 (BIPA) was enacted. Section 542 of BIPA provided that the carrier could continue to pay for the TC of physician pathology services when an independent laboratory furnishes this service to an inpatient or outpatient of a covered hospital. (Covered hospital refers to a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the TC of physician pathology services to fee-for-service Medicare beneficiaries who were inpatients or outpatients and submitted claims for payment for the TC to a carrier.)

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The BIPA-542 provision was effective for services furnished in 2001 and 2002. CMS administratively extended this provision for 2003 and 2004. Section 732 of the Medicare Modernization Act (MMA) extended this provision for services furnished in 2005 and 2006. When this provision expires, the regulation at 42 CFR 415.130 will take effect as this regulation's implementation has only been delayed by the legislation.

CR 6042, Transmittal 1561, dated July 25, 2008

Qualifying independent laboratories may continue to bill Medicare directly for the TC of certain physician pathology services provided to patients as part of a covered hospital inpatient stay or outpatient hospital service through December 31, 2009, regardless of the beneficiary's hospitalization status, in accordance with the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

See MLN Matters article MM 6042 at:

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6042.pdf>

CR 6042 also instructs the carriers/Medicare Administrative Contractors (MACs) not to implement the business requirements of CR 5347 with respect to action for physician pathology services.

See MLN Matters article MM 5943 at:

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5943.pdf>

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CLINICAL LABORATORY CONSULTATIONS

Codes

Use the following procedure codes to report clinical laboratory consultations:

80500©	Lab pathology consultation
80502©	Lab pathology consultation

Claim Requirements

To reimburse laboratory consultations, the services must:

- Be requested by the patient's attending physician.
- Relate to a test result that lies outside the clinically significant normal or expected range in view of the condition of the patient.
- Result in a written narrative report included in the patient's medical record.
- Require medical judgment by the consulting physician.

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ORGAN AND DISEASE-ORIENTED PANELS

The following is a list of the organ- or disease-oriented panels and the minimum test content required to report each panel. An organ- or disease-oriented panel should only be reported if it includes at least those specific tests listed. Otherwise, the individual tests should be reported instead of the panel. Organ panels are not covered when performed for routine screening purposes.

Panel Code		Must Include	
80047©	Metabolic panel ionized ca (Effective January 1, 2008)	82330©	Assay of calcium
		82374©	Assay, blood carbon dioxide
		82435©	Assay of blood chloride
		82565©	Assay of creatinine
		82947©	Assay, glucose, blood quant
		84132©	Assay of serum potassium
		84295©	Assay of serum sodium
		84520©	Assay of urea nitrogen
		Note: In accordance with the Internet-Only Manual 100-04, Chapter 16, 40.6.1, the new panel code 80047 cannot be billed for services ordered through an End Stage Renal Disease (ESRD) facility. All tests billed for services ordered through an ESRD facility must be billed individually, not in an organ disease panel. (Change Request (CR) 5813)	
80048©	Metabolic panel total ca	82310©	Assay of calcium
		82374©	Assay, blood carbon dioxide
		82435©	Assay of blood chloride
		82565©	Assay of creatinine
		82947©	Assay, glucose, blood quant
		84132©	Assay of serum potassium
		84295©	Assay of serum sodium
		84520©	Assay of urea nitrogen

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Panel Code		Must Include	
80051©	Electrolyte panel	82374©	Assay, blood carbon dioxide
		82435©	Assay of blood chloride
		84132©	Assay of serum potassium
		84295©	Assay of serum sodium
80053©	Comprehen metabolic panel	82040©	Assay of serum albumin
		82247©	Bilirubin, total
		82310©	Assay of calcium
		82374©	Assay, blood carbon dioxide
		82435©	Assay of blood chloride
		82565©	Assay of creatinine
		82947©	Assay, glucose, blood quant
		84075©	Assay alkaline phosphatase
		84132©	Assay of serum potassium
		84155©	Assay of protein, serum
		84295©	Assay, of serum sodium
		84450©	Transferase (ast) (sgot)
		84460©	Alanine amino (alt) (sgpt)
84520©	Assay of urea nitrogen		
80061©	Lipid panel	82465©	Assay, bld/serum cholesterol
		84478©	Assay of triglycerides
		83718©	Assay of lipoprotein *
80069©	Renal function panel	82040©	Assay of serum albumin
		82310©	Assay of calcium
		82374©	Assay, blood carbon dioxide
		82435©	Assay of blood chloride
		82565©	Assay of creatinine
		82947©	Assay, glucose, blood quant

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Panel Code		Must Include	
		84100©	Assay of phosphorus
		84132©	Assay of serum potassium
		84295©	Assay of serum sodium
		84520©	Assay of urea nitrogen
80076©	Hepatic function panel	82040©	Assay of serum albumin
		82247©	Bilirubin, total
		82248©	Bilirubin, direct
		84075©	Assay alkaline phosphatase
		84155©	Assay of protein, serum
		84450©	Transferase (ast) (sgot)
		84460©	Alanine amino (alt) (sgpt)

* CPT code 83718 is a non-automated test. It is included with Organ/Disease Panel 80061 but is not included in the AMCC bundling.

Automated Panel Tests

Automated panel tests are those tests frequently performed as groups and combination “profiles” on automated multichannel equipment. The chart below lists the automated panel tests.

Tests Frequently Combined as Automated Panel Tests

82040©	Assay of serum albumin
82247©	Bilirubin, total
82248©	Bilirubin, direct
82310©	Assay of calcium
82330©	Calcium; ionized
82374©	Assay, blood carbon dioxide
82435©	Assay of blood chloride
82465©	Assay, bld/serum cholesterol
82550©	Assay of ck (cpk)
82565©	Assay of creatinine

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82947©	Assay, glucose, blood quant
82977©	Assay of ggt
83615©	Lactate (ld) (ldh) enzyme
84075©	Assay alkaline phosphatase
84100©	Assay of phosphorus
84132©	Assay of serum potassium
84155©	Assay of protein, serum
84295©	Assay of serum sodium
84450©	Transferase (ast) (sgot)
84460©	Alanine amino (alt) (sgpt)
84478©	Assay of triglycerides
84520©	Assay of urea nitrogen
84550©	Assay of blood/uric acid

Laboratory tests that are subject to laboratory paneling pricing will be reimbursed at the lowest possible pricing level for the total of the laboratory details submitted after the duplicate services are eliminated by the system. The pricing method will include all laboratory services for the same beneficiary on the same day by the same performing provider, even if some of the services were billed on another claim.

Medicare will not combine the tests or change the code, but the pricing will be prorated among the individually billed tests based on the number of automated tests being billed. If any combination of the automated panel tests is billed, the provider will not be paid the fee schedule amount.

When a combination for the above tests is billed, the pricing will be prorated among the individually billed tests. If any combination of the above tests is billed, providers will not be paid the fee schedule amount.

Reimbursement for the tests billed individually will be the same as the reimbursement for those same codes billed as a panel.

To determine reimbursement, count the number of automated tests, link them to the appropriate code and determine the fee for the total of the automated tests using the following:

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2008 Automated Test Panel (ATP)

One through two automated panel tests	\$7.28
Three automated panel tests	\$9.29
Four automated panel tests	\$9.80
Five automated panel tests	\$10.93
Six automated panel tests	\$10.96
Seven automated panel tests	\$11.42
Eight automated panel tests	\$11.83
Nine automated panel tests	\$12.13
Ten automated panel tests	\$12.13
Eleven automated panel tests	\$12.34
Twelve automated panel tests	\$12.62
Thirteen through 16 automated panel tests	\$14.77
Seventeen through 18 automated panel tests	\$14.87
Nineteen automated panel tests	\$15.45
Twenty automated panel tests	\$15.95
Twenty-one automated panel tests	\$16.45
Twenty-two automated panel tests	\$16.95
Twenty-three automated panel tests (Effective January 1, 2008)	\$16.95

2009 Automated Test Panel (ATP)

One through two automated panel tests	\$7.61
Three automated panel tests	\$9.70
Four automated panel tests	\$10.24
Five automated panel tests	\$11.42
Six automated panel tests	\$11.46
Seven automated panel tests	\$11.93
Eight automated panel tests	\$12.36
Nine automated panel tests	\$12.68
Ten automated panel tests	\$12.68
Eleven automated panel tests	\$12.90
Twelve automated panel tests	\$13.19
Thirteen through 16 automated panel tests	\$15.44
Seventeen through 18 automated panel tests	\$15.54
Nineteen automated panel tests	\$16.15
Twenty automated panel tests	\$16.66
Twenty-one automated panel tests	\$17.19
Twenty-two automated panel tests	\$17.72
Twenty-three automated panel tests (Effective January 1, 2008)	\$17.72

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Example 1

80061 = \$19.57. Panel consists of one manual (83718 allowed at \$11.96) and two automated tests (82465, 84478) (ATP02 allowed at \$7.61).
The sum of the parts 83718 + ATP02 = \$19.57.

Example 2

A provider bills codes 82040, 82248, 82310 and 82374. The allowed amount would be based on code ATP04. The allowable for code ATP04 will be prorated among the billed codes after elimination of any duplicate services.

Example 3

A provider bills codes 80061, 84520, 82565, 82947 and 80051. The following payment logic will apply (panels are broken down to show automated and manual).

Panels	Automated	Manual
80061	82465	
		83718
	84478	
80051	82374	
	82435	
	84132	
	84295	
(Other Tests)	84520	
	82565	
	82947	

Totals: Count the number of automated tests (9) and add in any manual test.

9 automated = \$12.68 (ATP09)
1 manual = \$11.96
\$24.64 This will be the total allowed, then prorated among codes.

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COMPLETE BLOOD COUNT (CBC) TESTING

A Complete Blood Count (CBC) consists of measuring a blood specimen for levels of hemoglobin, hematocrit, red blood cells, white blood cells and platelets. Also, a differential White Blood Cell (WBC) count measures the percentages of different types of white blood cells. This hematology testing is commonly ordered by physicians to diagnose and treat a wide array of disorders such as liver, heart and pulmonary disease, hemorrhage, dehydration and infections.

CPT codes representing component tests of CBC testing (with differential WBC testing) include:

85004©	Automated diff wbc count
85007©	BI smear w/diff wbc count
85008©	BI smear w/out diff wbc count
85013©	Spun microhematocrit
85014©	Hematocrit
85018©	Hemoglobin
85032©	Manual cell count, each
85048©	Automated leukocyte count
85049©	Automated platelet count

CPT codes representing the bundled testing services include:

85025©	Complete cbc w/auto diff wbc
85027©	Complete cbc, automated

National Correct Coding Initiative (NCCI) edits have been established to promote correct coding and prevent inappropriate payments. For example, test codes 85027 and 85004 should not be billed with code 85025 which represents the bundled testing service.

Further information on the NCCI edits is available at:

<http://www.cms.hhs.gov/NationalCorrectCodInitEd/>

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Coverage criteria for blood counts can be located on the CMS Web site at:

<http://www.cms.hhs.gov/center/clinical.asp>

Based on comments, codes G0306 and G0307 have been established to permit continued billing of common bundled CBC testing services without a platelet count.

G0306	Complete CBC, automated
G0307	Complete CBC, automated

If additional CBC component tests are medically necessary, only the medically necessary components (e.g., hemoglobin (Hgb) or hematocrit (Hct)) should be ordered and performed. Billing modifiers can assist in reporting additional medically necessary CBC component tests or bundling testing service for the same patient on the same date of service, such as modifier 91, repeat clinical laboratory test.

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PREVENTIVE AND SCREENING SERVICES

CPT and HCPCS Coding

The same services and tests provided for screening and preventive care purposes are also performed to diagnose an illness or injury. In most cases, specific procedure codes have been developed to indicate whether the test is a screening test or a diagnostic test. Many of the tests or services performed for screening purposes have been assigned an HCPCS level II procedure code. When the same test or service is performed for a diagnostic or treatment purpose (i.e., to evaluate a sign, symptom, illness or injury), a CPT code is used. The procedure code reported on the claim depends on the purpose of the test. This manual will only address Medicare guidelines regarding screening and preventive services. If the same tests are being performed for diagnostic purposes, please refer to the appropriate policy regarding the diagnostic service.

Information concerning tests provided for screening and preventive care can be found in the *Screening and Preventive Services* manual located at:

<http://www.trailblazerhealth.com/Publications/Training%20Manual/screening.pdf>

Pap Smears

Reporting the Physician Service for a Diagnostic Pap Smear

Report the physician interpretation of a diagnostic Pap smear using the following code:

88141©	Cytopath, c/v, interpet
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Separate payment is allowed under the physician fee schedule for patients in any setting if the laboratory screening personnel suspect an abnormality and the physician reviews and interprets the Pap smear.

Diagnostic Pap Smears

Diagnostic Pap smears, which are used to find the absence or presence of trauma, infection, carcinogens and/or viruses, are eligible for reimbursement under the following circumstances:

- Previous cancer of the cervix, uterus or vagina that has been or is presently being treated.
- Previous abnormal Pap smear.
- Any abnormal finding of the vagina, cervix, uterus, ovaries or adnexa.
- Any signs or symptoms that might be, in the physician's judgment, reasonably related to a gynecologic disorder.

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- Any significant complaint by the patient related to the female reproductive system.

Diagnostic Pap Smear Codes

Use the following procedure codes to bill for diagnostic Pap smears:

88142©	Cytopath, c/v, thin layer
88143©	Cytopath c/v thin layer redo
88147©	Cytopath, c/v, automated
88148©	Cytopath, c/v, auto rescreen
88150©	Cytopath, c/v, manual
88152©	Cytopath, c/v, auto redo
88153©	Cytopath, c/v, redo
88154©	Cytopath, c/v, select
88155©	Cytopath, c/v, index add-on
88164©	Cytopath tbs, c/v, manual
88165©	Cytopath tbs, c/v, redo
88166©	Cytopath tbs, c/v, auto redo
88167©	Cytopath tbs, c/v, select
88174©	Cytopath, c/v auto, in fluid
88175©	Cytopath c/v auto fluid redo

PAP Smear Slide Preparation

Code Q0091 is allowed with an Evaluation and Management (E/M) visit if the visit is separate from the Q0091 service. The services billed must meet the criteria for the E/M service and the Pap smear when billing both services by the same physician on the same date of service. When both services occur at the same encounter for distinct reasons, use modifier 25 on the claim when billing the E/M visit.

Q0091	Screening Papanicolaou smear, obtaining, preparing and conveyance of cervical or vaginal smear to laboratory
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Prostate Specific Antigen (PSA) Laboratory Testing

Diagnostic

Under Section 4554(b)(1) of the Balanced Budget Act (BBA), Public Law 105-33 mandated the use of negotiated rulemaking with interested parties in the laboratory community to promote uniformity, administrative simplicity and program integrity regarding coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B. As a result of this negotiated rulemaking, a National Coverage Determination (NCD) was developed for the diagnostic Prostate Specific Antigen (PSA) test, which is a tumor marker for adenocarcinoma of the prostate and may be useful in the differential diagnosis of men with yet undiagnosed disseminated metastatic disease.

When used in conjunction with other prostate cancer tests such as digital rectal examination, the PSA test may assist in the decision-making process for diagnosing prostate cancer. PSA also serves as a marker in following the progress of most prostate tumors once a diagnosis has been established as an aid in the management of prostate cancer patients and in detecting metastatic or persistent disease in patients following treatment. The test is of proven value in differentiating benign from malignant disease in men with lower urinary tract signs and symptoms (i.e., hematuria, slow urine stream, hesitancy, urgency, frequency, nocturia and incontinence) as well as patients with palpably abnormal prostate glands on physical exam, and in patients with other laboratory or imaging studies that suggest the possibility of a malignant prostate disorder.

84153©	Assay of psa, total
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The NCD for this test can be found on the CMS Web site at:

<http://www.cms.hhs.gov/center/clinical.asp>

The NCD for diagnostic PSA tests does not apply to screening PSA tests.

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MISCELLANEOUS

Influenza Testing

A variety of tests are available to diagnose influenza. Rapid diagnostic tests have been increasingly used because they can yield results in a clinically relevant time frame, i.e., approximately 30 minutes; however, the reference standard for diagnosis of influenza remains virus culture. For guidelines and recommendations see the Centers for Disease Control and Prevention Web site at:

<http://www.cdc.gov/flu/professionals/diagnosis/index.htm>

Blood Smear – Peripheral

Use the CPT code 85060 only when a physician interprets an abnormal peripheral blood smear for a hospital inpatient or a hospital outpatient, and the hospital is responsible for the technical component. When a physician interpretation of an abnormal peripheral blood smear is billed by an independent laboratory, it is considered a complete or global service, and the service should not be billed with CPT code 85060. A physician interpretation of an abnormal peripheral blood smear performed by an independent laboratory is considered a routine part of the ordered hematology service (i.e., those tests that include a different white blood count).

Multiple Tests

Multiple tests to identify the same analyte, marker or infectious agent should not be reported separately. For example, it would not be appropriate to report both direct probe and amplified probe technique tests for the same infectious agent.

Duplicate Testing

Medicare does not pay for duplicate testing. CPT code 88342©, immunocytochemistry, should not, in general, be reported for the same or similar specimens. The diagnosis should be established using one of these methods. The provider may report both CPT codes if both methods are required because the initial method is non-diagnostic or does not explain all the light microscopic findings. The provider can report both methods using modifier 59 and document the need for both methods in the medical records.

If the abnormal cells in two or more specimens are morphologically similar and testing on one specimen by one method (88342) establishes the diagnosis, the other method should not be reported on the same or similar specimen. Similar specimens would include, but are not limited to:

- Blood and bone marrow.
- Bone marrow aspiration and bone marrow biopsy.
- Two separate lymph nodes.

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- Lymph node and other tissue with lymphoid infiltrate.

Bone and Bone Marrow Evaluation

Multiple CPT codes are descriptive of services performed for bone and bone marrow evaluation. When a biopsy is performed for evaluation of bone matrix structure, the appropriate code to bill is CPT code 20220 for the biopsy and CPT code 88307 for the surgical pathology evaluation.

When a bone marrow aspiration is performed alone, the appropriate coding is CPT code 38220. Appropriate coding for the interpretation is CPT code 85097 when the only service provided is the interpretation of the bone marrow smear. When both are performed by the same provider, both CPT codes may be reported. The pathological interpretations (CPT codes 88300–88309) should not be reported in addition to CPT code 85097 unless separate specimens are processed.

When it is medically necessary to evaluate both bone structure and bone marrow, and both services can be provided with one biopsy, only one code (CPT code 38221 or 20220) can be reported. If two separate biopsies are necessary, then both can be reported using the 59 modifier on one of the codes. Pathological interpretation codes 88300–88309 may be separately reported for multiple, separately submitted specimens. If only one specimen is submitted, only one code can be reported regardless of whether the report includes evaluation of both bone structure and bone marrow morphology.

Microbial Culture Studies

The family of CPT codes 87040–87158 refers to microbial culture studies. The type of culture is coded to the highest level of specificity regarding source, type, etc. When a culture is processed by a commercial kit, report the code that describes the test to its highest level of specificity. A screening culture and culture for definitive identification are not performed on the same day on the same specimen and therefore are not reported together.

Quantitative Immunohistochemistry by Digital Cellular Imaging

Prior to January 1, 2004, report quantitative immunohistochemistry by digital cellular imaging with CPT code 88342. Beginning January 1, 2004, report this service with CPT code 88361. Digital cellular imaging includes computer software analysis of stained microscopic slides.

DNA Ploidy and S-Phase Analysis of Tumor by Digital Cellular Imaging Technique

Prior to January 1, 2004, report DNA ploidy and S-phase analysis of tumor by digital cellular imaging technique as CPT code 88313. Beginning January 1, 2004, report it with CPT code 88358. One unit of service for CPT code 88358 includes both DNA ploidy and S-phase analysis.

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Reagent Strip Policy

Measuring blood glucose by reagent strip is a common screening method of glucose testing. Reagent strip results are given in general range levels requiring additional testing for patient-specific glucose concentration. For coverage criteria, see the National Coverage Determination (NCD) on code 82948.

Calculated Percentages and/or Ratios

Medicare does not pay separately for any manually or computer-calculated ratios and/or percentages for laboratory tests (e.g., blood glucose testing by reagent strip). Any manual or computer calculations for ratios and/or percentages are considered part of the overall test and are not billable separately to Medicare or the beneficiary.

Oximetry

Certain blood gas levels are determined either by invasive means through use of a blood specimen for a clinical laboratory test or by non-invasive means through ear or pulse oximetry, which is not considered a clinical laboratory test. Use CPT code 82792 for invasive oximetry.

Preoperative Labs

The appropriate ICD-9-CM code for the condition(s) that prompted surgery must be documented on the claim. The ICD-9-CM code that appears in the line item of the pre-operative examination must be the code for the appropriate pre-operative examination.

There may be covered and non-covered procedures performed during this encounter (e.g., screening X-ray, EKG, lab tests). Some tests are restricted by limited coverage. Those procedures that are for screening for asymptomatic conditions are considered non-covered; therefore, no payment will be made.

Those procedures ordered to diagnose or monitor a symptom, medical condition or treatment must reflect a diagnosis that indicates medical necessity; Medicare will pay if those procedures are covered.

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LABORATORY SERVICES NOT PROCESSED BY MEDICARE PART B

Certain lab tests or services should not be billed to Medicare Part B. The following services fall under the jurisdiction of other CMS programs:

- Laboratory tests furnished to a hospital inpatient whose stay is covered under Medicare Part A.
- Laboratory tests performed by a Skilled Nursing Facility (SNF) for its own inpatients and reimbursed under Part A. If an independent lab performs services to a patient in a Medicare Part A covered stay at the SNF, bill these services to the SNF for payment.
- Laboratory tests furnished by hospital-based or independent End Stage Renal Disease (ESRD) dialysis facilities that are included under the ESRD composite rate payment. Bill laboratory tests that are not included under the ESRD composite rate payment and are performed by an independent laboratory for dialysis patients of independent dialysis facilities to Part B. This procedure applies to all laboratory tests furnished to home dialysis patients.
- Laboratory tests furnished to patients of rural health clinics under an all-inclusive rate.
- Claims for rural health services are reimbursed under Medicare Part A.
- Laboratory tests provided by a participating Health Maintenance Organization (HMO) or Health Care Prepayment Plan (HCPP) to an enrolled member of the plan.
- Laboratory tests furnished by a hospice.

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CLAIMS PROCESSING

National Provider Identifier (NPI) Number

Consider the following guidelines when filing Medicare claims:

- **Independent Laboratory** – The name and National Provider Identifier (NPI) number of the ordering or referring physician is required on all claims for clinical and diagnostic laboratory services.
- **Physician** – The name and NPI of the ordering or referring physician is required on all claims for clinical and diagnostic laboratory services, even if self-referred.

Note: Assigned laboratory services without a name and NPI will be rejected without appeal rights. Non-assigned claims will be developed for the referring/ordering physician's name and UPIN.

<https://nppes.cms.hhs.gov>

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REVISION HISTORY

Date	Section	Description of Revision
August 2007	Date of Service for Laboratory Testing	Added Change Request (CR) 5573 – Date of Service (DOS) for laboratory specimens information. http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5573.pdf
	Independent Laboratory Billing for the Technical Component (TC) Of Physician Pathology Services to Hospital Patients	Added CR 5675 – Technical Component (TC) for pathology services payable for inpatient admit and discharge DOS. http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5675.pdf
January 2008	Organ and Disease – Oriented Panels	Added CR 5813 - CPT 80047 – Basic metabolic panel. http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5813.pdf
	Automated Test Panel (ATP)	Added twenty-three automated panel test payment of \$16.95. http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5813.pdf
October 2008	Laboratory Competitive Bidding Demonstration	Added requirements of referring and reference labs. http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5772.pdf
	Clinical Laboratory Improvement Amendments (CLIA)	<ul style="list-style-type: none"> • Overview – Added CLIA overview. Removed Mid-Atlantic States CLIA information. Added Colorado, New Mexico and Oklahoma CLIA information. • CLIA Certification Categories – Updated/ added definitions.
	National Coverage Determination (NCD) for Clinical Diagnostic Laboratory Services	Updated NCD information.
	Medical Necessity and Limited Coverage	Added summary verbiage.

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Date	Section	Description of Revision
	Local Coverage Determination (LCD)	Removed LCD verbiage and updated LCD links.
	Advance Beneficiary Notice of Noncoverage (ABN)/Limited Coverage/Medical Necessity	Added revised ABN information and link. http://www.cms.hhs.gov/BNI/02_ABN.asp
	Date of Service for Laboratory Testing	Replaced Date of Service (DOS) information: http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6018.pdf
	Travel Allowance Policy	Updated travel allowance information.
	Medically Unlikely Edits (MUEs)	Added information regarding MUEs. http://www.cms.hhs.gov/NationalCorrectCodeEdit/08_MUE.asp#TopOfPage
	Physician Signature Requirements for Diagnostic Tests	Added information regarding physician signature requirements for diagnostic tests. http://www.cms.hhs.gov/Transmittals/downloads/R94BP.pdf
	Codes With Technical Components	Updated Lab TC component code list.
	Independent Laboratory Billing for the Technical Component (TC) of Physician Pathology Services to Hospital Patients	Added inpatient/outpatient physician pathology services information per CR 6042. http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6042.pdf
January 2009	Diagnosis Coding Requirements	Updated Item 21 for electronic claims submission.
	Modifiers	Added Loop 2400/SV101-1 HC = for HCPCS Service ID Qualifier or modifiers.
	Ordering Practitioner	Updated Item 17b for electronic claims submission.
	Referral Laboratories	Added Loop 2300 or 2400 (X4) Reference Identification Qualifier for CLIA.

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Date	Section	Description of Revision
	Panel Code	Added the manual code 83718 to lipid panel 80061 in addition to comment/information concerning this being a non-automated test.
	Automated Test Panels (ATPs)	Added 2009 ATP pricing information with examples to ATP section.
March 2009	CR 6070 Transmittal 1660	Added 2009 Clinical Lab Fee Schedule information.
	'Part B Crosswalk to 1500 Claim Form'	Updated all loops and segments references with crosswalk. Added link to the crosswalk job aid.
	CR 6362	Added outside jurisdiction for reference lab and purchased diagnostic test information.
	Name and CPT Codes of 23 Clinical Diagnostic Laboratory NCDs	Removed HCPCS code G0394 per CR 6356
July 2009	Purchased Diagnostic Tests	<ul style="list-style-type: none"> Added independent laboratory information found in IOM Pub. 100-04, Chapter 16, Section 40.2. Deleted purchased technical components information. Deleted Part B crosswalk to CMS-1500 claim form information.
<i>September 2009</i>	<i>Advance Beneficiary Notice of Noncoverage (ABN)/Limited Coverage/Medical Necessity</i>	<i>Removed reference to eBulletin for NCD reference.</i>
	<i>Travel Allowance Policy</i>	<i>Added CR 6524 travel allowance fee information: http://www.cms.hhs.gov/MLN MattersArticles/downloads/MM6524.pdf</i>