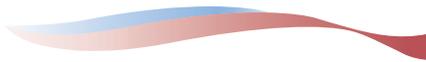




CoaguChek® Systems



**2009
Medicare Reimbursement Handbook
for Healthcare Professionals**

CoaguChek® XS System for Professional Use CoaguChek XS System for Patient Self-Testing

2009 Anticoagulation Monitoring Medicare Reimbursement Handbook for Healthcare Professionals

In-Office Testing by Professionals

- Reimbursement of PT/INR Tests page 8
- Reimbursement of Supporting Services page 13
- Reimbursement Planning page 29

Home Self-Testing by PT/INR Patients

- Reimbursement of Home Monitoring Services page 38
- Coding and Billing page 40
- Payment Policies page 42

Inside Front Cover
(blank page)

This handbook is offered for informational purposes only, as a courtesy to customers by Roche Diagnostics.

The information presented should not be interpreted as legal or regulatory advice or counsel.

©2009 Roche Diagnostics. All rights reserved. COAGUCHEK is a trademark of Roche. 573-44156-0409
Current Procedural Terminology (CPT) is copyright 2008 American Medical Association. All Rights Reserved.
No fee schedules, basic units, relative values, or related listings are included in CPT.

Contents

About This Handbook	6
Enhancing Patient Care	7
In-Office Testing by Professionals	
Reimbursement of PT/INR Tests	8
Patient Eligibility	
Who is eligible for Medicare coverage of PT/INR tests?	8
Coverage of PT/INR Tests	
Is the PT/INR test a covered service under Medicare?	8
How does Medicare define medical necessity?	8
Does Medicare have specific coverage requirements for in-office PT/INR testing?	9
How does the provider identify why the ordered test was medically necessary?	9
Coding the Test on Claims	
Under which code should reimbursement claims for a PT/INR test be filed?	9
May a provider bill under an additional code for obtaining a blood sample by means of capillary (finger, heel, ear) access?	9
CLIA Compliance	
What is CLIA?	10
Do physicians need a CLIA certificate and number to perform and bill “waived tests”?	10
How do providers find out how tests are classified under CLIA?	10
How do physicians get a CLIA certificate, and how much does it cost?	10
Reimbursement Pricing	
How does Medicare pay for PT/INR tests performed in a physician’s office?	10
Chart: Fees for Prothrombin Time Test, CPT Code 85610	11
What deductible must the individual pay before Medicare begins to reimburse claims?	12
What portion of the cost of a lab test may be charged to the patient?	12
Utilization Controls	
How often will Medicare reimburse for this test?	12
How does CMS use medical necessity in determining reimbursement?	12
Reimbursement of Supporting Services	13
Chart: E/M Considerations for Categories of Staff	14

Billing E/M Services

What specifically are E/M services?	14
Do the supporting services delivered with PT/INR tests qualify as E/M services?	15
How are E/M services coded on reimbursement claims?	15
How much does Medicare reimburse for E/M services?	15
Table: Services Rendered to New Patients	16
Table: Services Rendered to Established Patients	16

Coding E/M Services by Physicians and Advanced Practice Staff

Which healthcare professionals does Medicare define as “advanced practitioners”?	17
How are advanced practitioner services billed?	17
On what basis could a physician or advanced practice staff justify using a higher level E/M code?	17
How does a physician or advanced practice staff judge the complexity of medical decision making?	17
What documentation should the physician or advanced practice staff provide to support the E/M code they feel is appropriate?	18
How does the physician’s time with a patient enter into the determination of an appropriate E/M code?	18
Can time spent by nurses, pharmacists, etc., with the patient be added to the time spent with a patient by the physician?	18
How should physician time spent with a patient be documented?	18
Can I bill PT/INR monitoring services to Medicare under CPT codes 99363 and 99364?	18

“Incident to” Services Defined

What qualifies as an “incident to” service?	19
Where does a CoaguChek XS test fit into the “incident to” requirements?	19
What are some examples of physician staff who would be covered for performing PT/INR testing as an “incident to” service?	19
Does Medicare provide standards concerning the qualifications of personnel providing “incident to” services?	20

Coding “incident to” Services

Which E/M codes are used to claim reimbursement for “incident to” services performed under the supervision of a physician?	20
Can nonphysician healthcare professionals performing “incident to” services bill above the E/M code of 99211?	21
Can pharmacist services be billed as “incident to” a physician’s services?	21

Employment/Supervision Issues for “incident to” Billing	
For the purpose of billing “incident to” services, who is considered an employee of the physician?	21
Aren’t leased employees really employed by the leasing company or hospital?	21
What constitutes “direct personal supervision” by the physician?	21
Does the physician have to actually see the patient each time an “incident to” service is rendered?	22
Can advanced practitioners perform a supervisory role for the purpose of “incident to” services?	22
Site of Service Issues for “incident to” Billing	
If the PT/INR testing and anticoagulation management services are performed outside the physician office, can “incident to” services be billed?	22
What if the test is performed in a physician-directed clinic or group association?	22
Can “incident to” services be billed by a hospital-owned anticoagulation clinic?	23
Table: Physician Fee Schedule for E/M Service, CPT Code 99211	24
Coding and Payment of Hospital-Owned Clinic Services	
What is the Hospital Outpatient Prospective Payment System (HOPPS)?	26
Are there any special rules for PT tests done in a hospital-owned clinic?	26
How does HOPPS affect the way a hospital-owned clinic bills for clinic services?	26
Table: Ambulatory Payment Classifications (APCs) by CPT Code	27
Will the 72 hour rule apply to HOPPS for laboratory testing and inpatient admissions?	27
Coding and Payment for PT/INR Testing in Long-Term-Care Facilities	28
Can PT/INR testing performed by LTC facility staff be billed to Medicare?	28
Coding and Payment for PT/INR Testing by a Home Health Agency	28
Can PT/INR tests performed by home health agency (HHA) staff in a patient’s home be billed to Medicare?	28
Can HHAs bill PT/INR tests to Medicare Part A?	28
Reimbursement Planning	29
Scenarios	29
Additional E/M Delivery and Documentation Considerations	31
Structuring Delivery of E/M Services	36
An Example	
Determine Appropriateness of Reporting Separate E/M with PT	37

Home Self-Testing by Patients	
Reimbursement of Home PT/INR Monitoring Services	38
Eligibility	
What are the eligibility and coverage criteria for home PT/INR monitoring?	38
Physician-Directed Diagnostic Services for Home PT/INR Monitoring	
How does the physician-directed diagnostic services home PT/INR benefit work?	39
Does this mean the patient does not purchase the PT monitor and supplies?	39
How can a provider become an Independent Diagnostic Testing Facility (IDTF)?	39
Must the physician speak directly to the patient to qualify for billing for the professional component?	40
Coding and Billing Home PT/INR Monitoring Services	
Which codes must a physician use to bill home PT/INR monitoring services to Medicare?	40
Which equipment and supplies are included in the G0249 code?	41
What limits does CMS set on how often home PT/INR monitoring codes may be billed?	41
Will Medicare reimburse office visits or lab PT/INR tests that take place on the same day as a home PT/INR test?	41
Which codes can an IDTF use to bill home PT/INR monitoring services?	41
What if the patient receives the monitor and supplies from a hospital outpatient facility?	41
Which codes can hospital outpatient facilities bill under the HOPPS?	41
Payment Policies for Home PT/INR Monitoring Services	
How does Medicare pay for home PT/INR monitoring services delivered by a physician office or IDTF?	42
How are the technical components paid under the HOPPS?	42
What is the patient’s financial responsibility for home PT/INR monitoring services?	43
What if I have questions that are not answered here?	43
Table: Physician Fee Schedule for HCPCS Code G0248	44
Table: Physician Fee Schedule for HCPCS Code G0249	46
Table: Physician Fee Schedule for HCPCS Code G0250	48
For Additional Information	50
Index	51

About This Handbook

At Roche Diagnostics, we recognize that the process of obtaining proper reimbursement is a source of many unanswered questions. This handbook attempts to address many of the questions you may have about how Medicare reimburses Prothrombin Time/International Normalized Ratio (PT/INR) testing, both in-office testing by professionals and home self-testing by patients.

The first section, which covers in-office testing with the CoaguChek XS System for Professional Use, also provides information regarding Medicare and CPT® guidelines for evaluation and management (E/M) services that may be appropriate to report when rendered in conjunction with PT/INR testing and anticoagulation management.

The second section covers home PT/INR monitoring with the CoaguChek XS System for Patient Self-Testing (PST), including the recently expanded Medicare coverage policy for home PT/INR monitoring that became effective in early 2008.

The handbook also reviews Medicare Part B reimbursement policies pertaining to the traditional fee-for-service Medicare program. We hope the handbook helps you gain an understanding of Medicare reimbursement policies, and we welcome your comments.

Enhancing Patient Care Through Point-of-Care and Home PT/INR Testing

The primary benefit of the CoaguChek Systems for Professional and Home Use is that they contribute to the quality of patient care by enabling the practice of real-time medicine.

Anticoagulants have proven invaluable in treating a variety of serious conditions (such as atrial fibrillation, hip joint replacement, heart valve replacement, stroke) and in reducing the incidence of complications (including stroke, systemic embolism, and death) in persons with atrial fibrillation.^{1,2,3,4,5} But, to be effective, anticoagulant therapy with warfarin requires consistent, reliable monitoring of Prothrombin Time (PT)/International Normalized Ratio (INR), which provides the opportunity to quickly correct the treatment regimen if the PT/INR result is not in the desired range. A patient's condition can change rapidly when on warfarin therapy, and delays in obtaining PT/INR results can significantly affect the outcome of therapy.

The CoaguChek Systems for Professional Use provide easy-to-use, real-time, accurate monitoring of PT/INR. By assessing the patient's coagulation status quickly and reliably on the spot, these CoaguChek Systems enable providers to make immediate therapeutic decisions, thus optimizing the clinical benefit of the PT/INR test and improving the chance of treatment success.

Initially, the physician works with the patient to achieve the stable balance of diet, medication, and activity that must be sustained under anticoagulant therapy. Subsequent ongoing management of the patient's condition can be managed by the physician and/or qualified employees of the physician working under his/her direction and supervision. Periodic physician follow-up is also required.

Performing the PT/INR test on site brings the patient the advantage of being able to discuss the results and treatment with the physician or the physician's staff. Similarly, with home monitoring where the patient is empowered to self-test, the patient calls the physician's office to discuss results and appropriate management. On-site testing or physician-managed home PT/INR monitoring may increase patient understanding and the likelihood of compliance with a treatment regimen. For the physician office, on-site testing or the physician-managed home PT/INR monitoring, may help to avoid costly complications and enables the physician to receive reimbursement for services that enhance patient care.

Notes

- 1) To the best of our knowledge, the information presented in this handbook is accurate and complete as of January 2009. This information should not be interpreted as, and is not intended to be, legal or regulatory advice or counsel. Questions regarding the legality or appropriateness of coding, coverage, payment or billing procedures should be discussed with your own legal counsel. We recommend that you do not proceed with any activities, including billing, with which you are uncomfortable or about which you have significant questions.**
- 2) This handbook does not attempt to address the reimbursement requirements of commercial benefit plans, as there are over 1000 different private payers offering a variety of plans, from traditional fee-for-service to preferred provider organizations (PPOs) and health maintenance organizations (HMOs). For the details of reimbursement under a private plan, consult the specific payer.

1. Atrial Fibrillation Investigators. Risk factors for stroke and efficacy of antithrombotic therapy in atrial fibrillation. *Arch Intern Med.* 1994;154:1449-1457.
2. Petersen F, Boysen G, Godtfredsen J, Andersen ED, Andersen B. Placebo controlled, randomized trial of warfarin and aspirin for prevention of thromboembolic complications in chronic atrial fibrillation: the Copenhagen AFASAK Study. *Lancet.* 1989;1:175-179.
3. Stroke Prevention in Atrial Fibrillation Investigators. Stroke Prevention in Atrial Fibrillation Study: final results. *Circulation.* 1991;84:527-539.
4. Ezekowitz MD, Bridgers SL, James KE, et al. Warfarin in the prevention of stroke associated with nonrheumatic atrial fibrillation. *N Engl J Med.* 1992;327:1406-1412.
5. The Boston Area Anticoagulation Trial for Atrial Fibrillation Investigators. The effect of low-dose warfarin on the risk of stroke in patients with nonrheumatic atrial fibrillation. *N Engl J Med.* 1990;323:1505-1511.

In-Office Testing by Professionals

Reimbursement of PT/INR Tests

The answers to the following questions are designed to help you determine the likelihood of obtaining reimbursement for PT/INR testing for specific patients.

The reimbursement policies summarized here are those of the Medicare program administered by Centers for Medicare & Medicaid Services (CMS). CMS is an agency of the Department of Health and Human Services.

Keep in mind that Medicare coverage policies are often subject to interpretation by individual Medicare contractors. For details about coverage determinations in your area, contact your local Medicare contractor.

Patient Eligibility

Who is eligible for Medicare coverage of PT/INR tests?

Medicare covers U.S. citizens who are 65 years of age and older, the permanently disabled, and people with end-stage renal disease. To be eligible for coverage of PT/INR tests, the Medicare beneficiary must have elected Part B coverage.

Coverage of PT/INR Tests

Is the PT/INR test a covered service under Medicare?

To qualify for reimbursement under Medicare, a PT/INR test must meet certain criteria, including:

- The test must be ordered by a licensed medical practitioner (as allowed by the practitioner's specific license); AND
- The test must be medically necessary.

Ultimately, the decision as to whether a particular test is covered is made by CMS and its contractors.

Note: Test results must be documented in the patient's medical record.

How does Medicare define medical necessity?

A test must be "reasonable and necessary" for the diagnosis or treatment of an illness or injury. Criteria for determining whether an item or service is reasonable and necessary generally include:

- Safe, effective, accepted medical practice.
- Not experimental or investigational.
- Furnished in an appropriate setting by qualified personnel.

A test accepted as medically appropriate by the relevant medical specialty usually meets the reasonable and necessary coverage standard.

Does Medicare have specific coverage requirements for in-office PT/INR testing?

Laboratory services performed in a physician's office are covered under Medicare Part B, subject to the requirement that they be reasonable and necessary for the diagnosis or treatment of an illness or injury. Effective November 2002, CMS implemented National Coverage Determinations (NCDs) for 23 laboratory tests, including prothrombin time testing. You may obtain a copy of this NCD from your local Medicare contractor or the CMS coverage database.⁶

How does the provider identify why the ordered test was medically necessary?

Medicare requires that the reason for the test be identified on the claim using an ICD-9-CM (diagnosis) code. Medicare reimburses only if the test is deemed medically necessary in light of the diagnosis and is in accordance with frequency guidelines, limitations, and other applicable restrictions. The NCD provides a list of covered diagnosis codes for PT/INR testing and the list is updated regularly.

Coding the Test on Claims

Under which CPT code should reimbursement claims for a PT/INR test be filed?

Under Medicare Part B, CPT codes are used to identify medical tests and procedures, including laboratory tests. The PT/INR test performed with the CoaguChek XS System for Professional Use by CLIA-waived and non-waived laboratories is billed under CPT code 85610 with or without the QW modifier, as explained below.

CPT	Description
85610	Prothrombin time

Modifiers are often added to a CPT code to provide further information about a service provided. The QW modifier indicates that the laboratory test performed was CLIA-waived.

Modifier	Description
QW	CLIA-waived test.

The QW modifier is required to obtain reimbursement by Medicare for performing CLIA-waived tests.⁷ Laboratories with a CLIA certificate of waiver are permitted to perform only CLIA waived tests.

May a provider bill an additional code for obtaining a blood sample by means of capillary (finger, heel, ear) access?

No. Medicare does not reimburse for capillary specimen collections, such as fingersticks.

Note: Medicare does reimburse for venous blood sample access, when necessary and appropriate.

6. Prothrombin Time (PT); Medicare National Coverage Determinations Manual; Chapter 1, Part 3, Section 190.17 http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part3.pdf - Accessed January 6, 2009.

7. If a waived test is performed by a laboratory with a CLIA Certificate of Compliance or Accreditation or other deemed status and the laboratory chooses to perform waived test systems following requirements for non-waived systems, the laboratory may elect not to report the QW modifier.

CLIA Compliance

What is CLIA?

Under the Clinical Laboratory Improvement Amendments (CLIA), testing is allowed only in laboratories with an appropriate CLIA certificate. Under Medicare, testing is payable only if the provider meets the requirements of CLIA, Social Security Act, §1861(s)(17).

CLIA requirements apply to any provider performing testing on specimens derived from a human being for purposes of providing information for diagnosis or treatment of any disease or impairment of, or the assessment of the health of, human beings.

To bill Medicare for laboratory tests:

- The provider must have a CLIA certificate applicable to the complexity of the testing performed; AND
- The CLIA number must appear on the claim.

Do physicians need a CLIA certificate and number to perform and bill “waived” tests?

Yes, physicians performing any type of testing (e.g., urine dipstick, rapid strep, blood glucose, etc) must have a CLIA certificate and number.

How do providers find out how tests are classified under CLIA?

The best source of information on this topic is CMS's CLIA website, <http://www.cms.hhs.gov/clia/>, which also contains an updated list of applicable codes for billing waived procedures.

How do physicians get a CLIA certificate, and how much does it cost?

CLIA applications can be obtained online from CMS's CLIA website, <http://www.cms.hhs.gov/clia/>, or from the survey agencies in the respective state where the provider is located. Agency contact information is listed on the CLIA website.

Fees depend on the type of certification issued. The local surveyor can advise on the current fees for the type of CLIA certification a provider requires.

Reimbursement Pricing

How does Medicare pay for PT/INR tests performed in a physician's office?

Reimbursement for traditional outpatient coverage (Part B) is made according to a fixed fee schedule published annually by CMS. Medicare pays 100% of the allowed amount or the provider's charge, whichever is less. The 2009 National Limitation Amount for a PT/INR test is \$5.74. Individual state fees are shown in the chart that follows.

2009 Medicare Fee Schedule for Prothrombin Time PT/INR Test, CPT Code 85610*

State/Carrier	Fee	State/Carrier	Fee
Alabama	\$5.74	Montana	\$5.74
Alaska	\$5.74	Nebraska	\$5.74
Arizona	\$5.74	Nevada	\$5.74
Arkansas	\$5.74	New Hampshire	\$5.74
California	\$5.74	New Jersey	\$5.74
Colorado	\$5.74	New Mexico	\$5.74
Connecticut	\$5.74	New York	\$5.74
D.C.	\$5.74	North Carolina	\$5.74
Delaware	\$5.74	North Dakota	\$5.74
Florida	\$5.74	Ohio	\$5.74
Georgia	\$5.74	Oklahoma	\$5.74
Hawaii	\$5.74	Oregon	\$5.74
Idaho	\$5.74	Pennsylvania	\$5.74
Illinois	\$5.74	Puerto Rico	\$5.74
Indiana	\$5.74	Rhode Island	\$5.74
Iowa	\$5.11	South Carolina	\$5.74
Kansas	\$5.74	South Dakota	\$5.74
Kentucky	\$5.74	Tennessee	\$5.74
Louisiana	\$5.74	Texas	\$5.74
Maine	\$5.74	Utah	\$5.74
Maryland	\$5.49	Vermont	\$5.74
Massachusetts	\$5.74	Virginia	\$5.74
Michigan	\$5.74	Washington	\$5.74
Minnesota	\$5.74	West Virginia	\$5.74
Mississippi	\$5.74	Wisconsin	\$5.74
Missouri	\$5.74	Wyoming	\$4.64

* Fee information obtained through CMS website; no independent verification of data is claimed or implied. (Source: http://www.cms.hhs.gov/ClinicalLabFeeSched/02_clinlab.asp - Accessed January 6, 2009)

What deductible must the individual pay before Medicare begins to reimburse claims?

Persons with Medicare Part B coverage must satisfy a deductible for the calendar year for Part B covered services. However, unlike other medical services, covered laboratory services are not subject to the Part B deductible and the patient pays no coinsurance or copayment for covered laboratory testing.

What portion of the cost of a lab test may be charged to the patient?

Under Medicare, *no* portion of the cost may be charged to the patient because the usual 20% Part B patient coinsurance amount does not apply to covered laboratory tests.

Tests performed using the CoaguChek XS System for Professional Use must be billed directly to Medicare on an *assigned* basis. That is, the beneficiary assigns the claim to the physician or laboratory performing the test and the physician or laboratory must accept the Medicare reimbursement as payment in full for the test. The physician or laboratory may not bill the patient for any additional amount.

Utilization Controls

How often will Medicare reimburse for this test?

Medicare may set limits before claims are submitted (prepay utilization controls) by determining a level of typical use that it considers medically necessary. For many services these typical frequencies are often determined by individual Medicare contractors. However, for PT/INR testing, these guidelines are included in the NCD for prothrombin time testing, which states: “In a patient on stable warfarin therapy, it is ordinarily not necessary to repeat testing more than every two to three weeks”.⁸ You can obtain a copy of the NCD from your local Medicare contractor or the CMS coverage database.⁹

Medicare may also enforce limits *after* claims are submitted (postpay utilization controls) by studying patterns of claims and auditing providers to detect overutilization.

How does CMS use medical necessity in determining reimbursement?

The diagnosis code documented on the claim is the starting point for determining whether a procedure is considered medically necessary and therefore covered.

Tests that screen for asymptomatic conditions are generally considered noncovered and are not paid. Tests that are ordered to diagnose or monitor a symptom, medical condition, or treatment are generally viewed as medically necessary and are paid if the sign, symptom, or condition is one for which testing is considered reasonable and necessary.

8. The Medicare NCD for Prothrombin Time testing provides additional testing limitations including:

- When an ESRD patient is tested for PT, testing more frequently than weekly requires documentation of medical necessity, e.g., other than chronic renal failure or renal failure unspecified.
- The need to repeat this test is determined by changes in the underlying medical condition and/or the dosing of warfarin. In a patient on stable warfarin therapy, it is ordinarily not necessary to repeat testing more than every two to three weeks. When testing is performed to evaluate a patient with signs or symptoms of abnormal bleeding or thrombosis and the initial test result is normal, it is ordinarily not necessary to repeat testing unless there is a change in the patient's medical status.
- Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other than thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy. Hospital/clinic-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage.

http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=190.17&ncd_version=1&basket=ncd%3A190%2E17%3A1%3AProthrombin+Time+%28PT%29 – Accessed January 7, 2009

9. Prothrombin Time (PT); Medicare National Coverage Determinations Manual; Chapter 1, Part 3, Section 190.17 http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part3.pdf – Accessed January 6, 2009.

Reimbursement of Supporting Services

Every PT/INR test, no matter where it is performed, entails a set of supporting services. However, these supporting services, while necessary for many reasons, may not be covered as medically necessary services under Medicare or these services may be covered but not eligible for payment separate from the laboratory test or some periodic office visit payment. Examples of supporting services may include receiving, reviewing and interpreting test results, and discussing the results with a patient or caregiver, etc. Any changes in the prescribed treatment regimen (e.g., diet or dosage) must also be discussed or explained to the patient or caregiver.

While all of these tasks may be appropriate to perform (in accordance with standard of care or risk management policies, etc.), only significant, separately identifiable evaluation and management (E/M) services may be billed to Medicare. Each E/M service has specific levels of care, with assigned CPT codes as well as specific reimbursement rates for each level.

The level of E/M services and the reimbursement for these services may also depend on who actually sees the patient, what services they provide, whose employee they are, and their credentials. In particular, there is a difference between the level of reimbursement for E/M services provided by physicians, advanced practice staff and non-advanced practice staff. A listing of these positions and basic information regarding billing their E/M services are provided beginning on page 17.

E/M services rendered in conjunction with PT/INR testing using the CoaguChek XS System for Professional Use may be appropriate to report in addition to the PT/INR testing if the service is medically necessary. However, it is important to understand that it may not always be appropriate to report a separate E/M service simply because a patient presents to the physician's office for PT/INR testing.

Note: Several Medicare contractors have identified patterns of inappropriate billing and/or over utilization of E/M services on the same date of service as PT/INR testing. Providers should contact their local Contractor for additional education, guidance, and/or restrictions regarding the billing of these services on the same date of service as PT/INR testing (85610).

While certain criteria regarding E/M services are discussed in this handbook (e.g., “incident to”, E/M levels of service, etc), providers should refer to CPT and Medicare contractor guidance regarding the use and reporting of these services for Medicare billing purposes.

An overview of the process for assigning E/M codes to services provided ancillary to a PT/INR test is included on page 37.

E/M Considerations for Categories of Staff

Face to face encounter is by:	Physician	Advanced Practice Staff	Non-Advanced Practice Staff*
Key Components	Intensity of patient history/exam Complexity of medical decision making Nature of presenting problem(s)	Intensity of patient history/exam Complexity of medical decision making Nature of presenting problem(s)	Intensity of patient history/exam
E/M Billing	May bill any E/M code level based on services provided Time spent with patient (only a factor when counseling and/or coordination of care)	May bill any E/M code level based on services provided Same considerations as physician apply: history/exam, medical decision making, etc.	May bill only one E/M code level regardless of service provided—99211 May bill only if a level of service other than lab testing is performed
Issues	Medical necessity Significant, separately identifiable service Contractor policies	“Incident to” physician’s service or may bill under own name Significant, separately identifiable service Medical necessity Employment/supervision Licensure and scope of practice requirements Site of service Contractor policies	“Incident to” physician’s service only Significant, separately identifiable service Medical necessity Employment/supervision Licensure and scope of practice requirements Site of service Contractor policies

*Established patients only.

Billing E/M Services

What specifically are E/M services?

Evaluation and management (E/M) services are provided to a patient during the course of a patient encounter. They may be provided by the physician or by an advanced practitioner, or they may be provided by the physicians’ employees (advanced practice or non-advanced practice staff) as “incident to” services.

The three key components of E/M services are:

- Taking the patient’s history.
- Examining the patient.
- Making medical decisions.

Other components are:

- Counseling the patient.
- Coordinating patient care.
- Nature of presenting problem (complexity).
- Time spent with the patient.

Do the supporting services delivered with PT/INR tests qualify as E/M services?

Many supporting services may qualify. For example, anticoagulation clinic services may meet E/M requirements when the level of service provided and documented necessitates assessment and management by a physician or advanced practitioner, or by a member of the physician’s staff. Examples include: history, examination and recommendation to change warfarin dosage; dietary counseling and/or re-education; evaluation of patient complaints of abnormal bruising or bleeding, etc.

How are E/M services coded on reimbursement claims?

Physicians and advanced practitioners may bill for E/M services provided by themselves or their staff using CPT codes. For office visits, only one E/M code may be used to report E/M services for a specific patient encounter on any date of service.

For physicians and advanced practitioners, a range of E/M codes may be reported reflecting different levels of service. The nature and amount of work and documentation reflected in an E/M code varies by the intensity of the service, place of service, and the patient’s status as a new or established patient.

When the face-to-face service is performed by the non-advanced practice staff, only one E/M code may be reported: CPT code 99211.

If a significant and separately identifiable service is provided by the physician, advanced practitioner or non-advanced practice staff (as an “incident to” service of the physician) in addition to PT/INR monitoring, CPT modifier 25 must be added to the appropriate E/M code.

Modifier Description

25	Significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service
----	--

How much does Medicare reimburse for E/M services?

Reimbursement varies considerably depending on the E/M code that appropriately describes a specific patient encounter. The Medicare reimbursement allowances for E/M codes for new versus established patients are shown in the following charts.

Note: Time spent is defined as “face-to-face” time with the physician. Time is not considered a key or controlling factor in selecting the appropriate E/M code level unless counseling and/or coordination of care dominates more than 50% of the physician-patient encounter.

For additional information regarding E/M services, please refer to the current edition of the *American Medical Association: CPT, Evaluation and Management Services Guidelines*, the *CMS website* and/or your local Medicare contractor

Services Rendered to New Patients

Office/outpatient visit... which requires these three key components:	E/M Code				
	99201	99202	99203	99204	99205
History	Problem focused	Expanded problem focused	Detailed	Comprehensive	Comprehensive
Examination	Problem focused	Expanded problem focused	Detailed	Comprehensive	Comprehensive
Medical decision making	Straight-forward	Straight-forward	Low complexity	Moderate complexity	High complexity
Nature of presenting problem(s)	Self-limited or minor	Low to moderate severity	Moderate severity	Moderate to high severity	Moderate to high severity
Time spent (time is only a factor in determining the E/M service when counseling or coordination of care is 50% or more of service)	10 minutes face-to-face with patient and/or family	20 minutes face-to-face with patient and/or family	30 minutes face-to-face with patient and/or family	45 minutes face-to-face with patient and/or family	60 minutes face-to-face with patient and/or family
Medicare Allowed Amount*	\$36.79	\$63.48	\$91.97	\$141.74	\$178.89

* 2009 Medicare Physician Fee Schedule payment amounts effective January 1, 2009 2009 National Physician Fee Schedule Relative Value File - Accessed December 10, 2008 - Payment allowances listed do not reflect geographic adjustments; local allowances will vary.

Note: For new patients, history, exam, and medical decision making must meet or exceed listed intensity level in order to report specific intensity level code.

Services Rendered to Established Patients

Office/outpatient visit... which requires at least two of these three key components:	E/M Code				
	99211 [†]	99212	99213	99214	99215
History	NA	Problem focused	Expanded problem focused	Detailed	Comprehensive
Examination	NA	Problem focused	Expanded problem focused	Detailed	Comprehensive
Medical decision making	NA	Straight-forward	Low complexity	Moderate complexity	High complexity
Nature of presenting problem(s)	Minimal	Self-limited or minor	Low to moderate severity	Moderate to high severity	Moderate to high severity
Time spent (time is only a factor in determining the E/M service when counseling or coordination of care is 50% or more of service)	5 minutes performing/supervising services	10 minutes face-to-face with patient and/or family	15 minutes face-to-face with patient and/or family	25 minutes face-to-face with patient and/or family	40 minutes face-to-face with patient and/or family
Medicare Allowed Amount*	\$18.75	\$37.15	\$61.31	\$92.33	\$124.79

* 2009 National Physician Fee Schedule Relative Value File - Accessed December 10, 2008 Payment amounts listed do not reflect geographic adjustments; local rates will vary.

† Some contractors may require some intensity of history, physical examination, and medical decision making to support coverage for 99211 level of E/M service.

Note: For established patients, at least two of history, exam, and medical decision making must meet or exceed specified intensity level in order to report intensity level code.

Coding E/M Services by Physicians and Advanced Practice Staff

Which healthcare professionals does Medicare define as “advanced practitioners”?

Medicare specifies that codes representing more intense services than 99211 may be used only for services provided by the physician or by the following four categories of staff:¹⁰

§110 Physician Assistant (PA) §120 Clinical Nurse Specialist (CNS)
 §120 Nurse Practitioner (NP) §130 Certified Nurse-Midwife

How are advanced practitioner services billed?

Advanced practitioner services may be billed either directly or as “incident to” a physician’s services.

To be able to bill Medicare directly, PAs, NPs, and CNSs must obtain their own National Provider Identifier or NPI from CMS.¹¹ Once they have an NPI, these advanced practitioners can bill Medicare directly and be paid directly. If they bill directly, reimbursement depends on whichever is less—the actual charge, or 85% of the physician fee schedule. Medicare reimburses 80% of the lesser amount and the patient is responsible for the remainder. Even when advanced practitioners have their own NPI and bill Medicare directly, some states may require that they see patients only with the physician present or under the physician’s supervision.

If advanced practitioner services are billed under the physician’s NPI, all “incident to” rules apply (see page 19).

Note: If an advanced practitioner bills Medicare directly for services rendered, the physician is not allowed to submit a separate claim for any E/M services they may provide on the same date of service.

On what basis could a physician or advanced practice staff justify using a higher level E/M code?

E/M codes vary not just by the content of the service rendered, but also by the complexity of *medical decision making*—that is, the complexity of establishing a diagnosis and/or selecting a management option. CPT codes recognize four levels of complexity in medical decision making:

- Straightforward
- Low complexity
- Moderate complexity
- High complexity

How does a physician or advanced practitioner judge the complexity of medical decision making?

Complexity of medical decision making is measured by

- The number of possible diagnoses and/or the number of management options that must be considered;
- The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained, reviewed, and analyzed; AND
- The risk of significant complications, morbidity, and/or mortality, as well as comorbidities, associated with the patient’s presenting problem(s); with the diagnostic procedure(s); and/or with the possible management options.

10. Medicare Claims Processing Manual, Chapter 12, Section 30.6 <http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf> - Accessed January 7, 2009. (Pub. 100-04, Ch. 12, §30.6).

11. http://www.cms.hhs.gov/NationalProvIdentStand/downloads/npi_fs_geninfo_010906.pdf - Accessed January 7, 2009.

What documentation should the physician or advanced practice staff provide to support the E/M code they feel is appropriate?

For E/M services reported in conjunction with PT/INR testing and anticoagulation management, the patient's medical record should include documentation describing:

- Intensity of history and reported symptoms,
- Intensity of exam and reported signs,
- That a PT/INR test was performed at the time of the E&M encounter,
- That results were interpreted and discussed with the patient,
- Whether treatment changes and additional diagnostic procedures were ordered on the basis of the test (itemize these), and
- The level of risk associated with the presenting problem (minimal, low, moderate, or high risk of complications and/or morbidity or mortality) and the possible management options (for example, continue same regimen, change dose, change diet).

How does the physician's time spent with a patient enter into the determination of an appropriate E/M code?

The duration of a patient encounter with the physician (in an office or outpatient setting) does not control the level of the service to be billed *unless more than 50% of the face-to-face time* is spent providing counseling or coordination of care.

If time spent providing counseling and/or coordination of care is used to determine the level of service reported, this must be physician time. Counseling by other staff is not considered part of the face-to-face physician/patient encounter time.

Can time spent by nurses, pharmacists, etc., with the patient be added to the time spent with a patient by the physician?

No, this is not permissible. Only the physician's time is billable. This time is billed under the E/M code appropriate for the level of service provided directly by the physician. As noted above, the duration of a patient encounter does not control the level of service to be billed unless more than 50% of the face-to-face time is spent providing counseling or coordination of care.

How should physician time spent with a patient be documented?

If time spent is used to justify E/M services, patient records should document both the time spent counseling or coordinating care, the nature of the counseling or coordination of care and the total duration of the visit.

Can I bill PT/INR monitoring services to Medicare under CPT codes 99363 and 99364?¹²

No. Medicare bundles the payment for these codes into other services and does not cover or pay for these services separately. When significant, separately identifiable and medically necessary E/M services related to PT/INR testing and anticoagulation management are provided to Medicare patients in the physician office setting, these services should be billed under the appropriate E/M CPT codes (e.g., 99201-99205, 99211-99215).

12. 99363: Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions dosage adjustment (as needed), and ordering of additional tests; initial 90 days of therapy (must include a minimum of 8 INR measurements) 99364: each subsequent 90 days of therapy (must include a minimum of 3 INR measurements)

“Incident to” Services Defined

Under Medicare, services and supplies provided “incident to” physician professional services are services and supplies furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness. Physicians, nonphysicians and hospitals can provide services beyond the direct physician face-to-face encounter and these services are covered as “incident to” the services of a physician if certain rules are followed.

What qualifies as an “incident to” service?

Medicare regulations specify that services are covered as “incident to” a physician's services when they are:¹³

- An integral, although incidental, part of the physician's professional service (§60.1);
 - Commonly rendered without charge or included in the physician's bill (§60.1A);
 - Of a type commonly furnished in physicians' offices or clinics (§60.1A);
- AND
- Furnished by the physician or by auxiliary personnel (advanced practice or non-advanced practice) under the physician's direct supervision (§60.1B).

To qualify as an “incident to” service, the service must meet all of the above requirements.

Where does a CoaguChek XS System test fit into the “incident to” requirements?

Services associated with in-office PT/INR testing with a CoaguChek XS System may fit under these reimbursement requirements:

- The services are part of the physician's professional services in the course of diagnosis or treatment of an injury or illness.
- The services provided represent an expense incurred by the physician.
- They are a type of service commonly furnished in a physician office setting.
- The services are furnished by the physician or physician's staff.

Other reimbursement-related issues might include who performs the face-to-face service and how the physician exercises direct personal supervision.

What are some examples of physician staff who would be covered for performing PT/INR testing as an “incident to” service?

Examples fall into two categories: non-advanced practice staff and advanced practice staff.*

- *Non-advanced practice* staff are those physician employees whose services ordinarily would be charged on the physician's bill, such as registered nurses, licensed practical nurses, medical assistants, pharmacists (including PharmDs), and aides. E/M services of these categories of staff can only be billed, when appropriate, using CPT code 99211.

* Must meet criteria within the authorized scope of practice under the state licensure laws.

13. Medicare Benefit Policy Manual, Chapter 15, Section 60. <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf> - Accessed January 7, 2009. (Pub. 100-02, Ch. 15, §60).

- *Advanced practice* staff are certain state-licensed nonphysician practitioners employed by the physician. For purposes of billing “incident to” services, advanced practice staff are limited to physician assistants (§110), nurse practitioners (§120), clinical nurse specialists (§120), and certified nurse-midwives (§130).¹⁴

Although the specified advanced practice staff are licensed to assist or act in the place of the physician, their “incident to” services would still need to be rendered under the physician’s direct supervision (see page 21) in order to be billed under the physicians’ name and paid at the full physician rate.

Note: PAs, NPs, and CNSs are required to have an NPI to bill their services under Medicare. If these providers bill Medicare directly, they are *not* considered as providing “incident to” services, so the physician cannot bill for their services.

Does Medicare provide standards concerning the qualifications of personnel providing “incident to” services?

No. Medicare does not specify any qualifications of personnel allowed to bill E/M services at the lowest E/M service level of 99211. However, state laws may limit the scope of practice of these personnel. For example, with respect to medical assistants, certain state laws may specify the training they must have, the sites where they may work, the types of medications they may dispense, and the tests they may perform.

Note: Medicare does specify the qualifications of personnel who may bill over the E/M level of 99211 as only those advanced practice staff identified in the next section.

Coding “incident to” Services¹⁵

Note: This section applies to physician offices. For hospital clinic billing guidelines, see Coding and Payment of Hospital-Owned Clinic Services on page 26.

Which E/M codes are used to claim reimbursement for “incident to” services performed under the supervision of a physician?

The code used depends on the category of nonphysician staff that provides the “incident to” services:

- When the services are furnished by a physician assistant (§110), nurse practitioner (§120), clinical nurse specialist (§120), or certified nurse-midwife (§130)¹⁶ the physician may bill the CPT code that describes the specific level of E/M service furnished.¹⁷
- When the services are furnished by non-advanced practice staff or by advanced practice staff other than the four categories listed above, the physician may bill only code 99211 for their services.

Can nonphysician healthcare professionals performing “incident to” services bill above the E/M code of 99211?

The only health professionals whose services can be reported listing E/M codes higher than 99211 are physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse-midwives.

Can pharmacist services be billed as “incident to” a physician’s services?

Assuming that the services are medically necessary covered services and all other “incident to” requirements are met and documented, the services of pharmacists (and PharmDs) would be billable in the same manner as the services of any other non-advanced auxiliary medical personnel employed and supervised by a physician. That is, their services may be billed under CPT code 99211, when appropriate.

Employment/Supervision Issues for “incident to” Billing

Note: This section applies only to physician offices. For hospital clinic billing guidelines, see Coding and Payment of Hospital-Owned Clinic Services on page 26.

For the purpose of billing “incident to” services, who is considered an “employee” of the physician?

The Medicare Benefit Policy Manual states that both the supervising physician and the auxiliary personnel furnishing “incident to” services may be an employee, a leased employee, or an independent contractor of the physician or legal entity billing and receiving payment for the services or supplies (§60.1B).¹⁸ Legal counsel should be consulted about requirements for meeting “employee” status.

Aren’t leased employees really employed by the leasing company or hospital?

Yes, but it is understood that they provide services as the leased employee of the supervising physician, who exercises control over their performance of “incident to” services just as if they were in that physician’s direct employ. Physicians with arrangements involving “leased employees” should check with their legal counsel if they have questions about the appropriateness of billing for “incident to” services performed by those staff.

What constitutes “direct personal supervision” by the physician?

Direct personal supervision by a physician does not mean that the physician must be in the same room when the employee performs the “incident to” service. However, the physician must be present in the office suite (e.g., not across the street) and immediately available to provide assistance and direction throughout the time that the service is being performed.

14. Medicare Claims Processing Manual, Chapter 12, <http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf>, accessed January 7, 2009. (Pub. 100-04, ch. 12).

15. Medicare Claims Processing Manual, Chapter 12, Section 30.6 <http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf>, - Accessed January 7, 2009. (Pub. 100-04, ch. 12, §30.6).

16. Medicare Claims Processing Manual, Chapter 12, <http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf> - Accessed January 7, 2009. (Pub. 100-04, ch. 12).

17. If the advanced practice staff has a distinct provider number and can bill separately under his/her own number, the physician should consider documenting when it was appropriate to provide the services as “incident to” the physician service.

18. Medicare Benefit Policy Manual, Chapter 15, Section 60. <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf> - Accessed January 7, 2009. (Pub. 100-02, ch. 15, §60.1B)

Does the physician have to actually see the patient each time an “incident to” service is rendered?

No. The physician must perform an initial service and must subsequently render services with sufficient frequency that demonstrates the physician’s active participation in the management of the patient. Under these circumstances, follow-up may be provided by nonphysician staff. Although the physician is not required to see the patient each time the “incident to” service is rendered, the physician must be in the office during each visit to meet the “incident to” supervision requirement. Note, if the physician sees the patient during a visit, only the physician’s E/M service may be billed.

Can advanced practitioners perform a supervisory role for the purpose of “incident to” services?

Only under specific circumstances. Nonphysician advanced practitioners assist or act in the place of the physician if they are licensed under state law to provide those services. However, for the purposes of defining “incident to” services, they cannot act as supervisors in place of the physician unless they have their own NPI and bill independently. Under those circumstances the same requirements with respect to supervision applies to the advanced practitioner as otherwise would apply to the physician and the “incident to” services would be billed under the advanced practitioner’s billing number.

Site of Service Issues for “incident to” Billing

If the PT/INR testing and anticoagulation management services are performed outside the physician’s office, can “incident to” services be billed?

An “incident to” service is generally covered outside the office only if the physician provides a face-to-face service and supervises any associated “incident to” service by his/her staff. Under any other scenario, it is unclear whether or not the physician may bill for “incident to” services furnished by his/her staff. Questions regarding services provided in these sites of service should be directed to your local Medicare contractor. Physicians who maintain an office in an institution may consult §20.5.1 and 60.1 of the Medicare Benefit Policy Manual for more detail.

What if the test is performed in a physician-directed clinic or group association?

The same rules of direct supervision apply, except that in highly organized, departmentalized clinics, the physician who orders the “incident to” service may not be the physician who supervises the “incident to” service. Medical management of all services provided in the clinic is assured under the definition of a physician-directed clinic, namely a clinic where:

- One or more physicians is present to perform medical (rather than administrative) services whenever the clinic is open;
- Each patient is under the care of a clinic physician; AND
- The nonphysician services are under physician supervision.

Can “incident to” services be billed by a hospital-owned anticoagulation clinic?

Services “incident to” physician services may also be covered in the hospital outpatient setting. These services must be furnished: (1) on the order of a physician, (2) by hospital personnel, and (3) under physician supervision. During any course of treatment provided by non-physicians, the physician must personally see the patient initially and then periodically sufficient to assess the course of treatment and the patient’s progress. “Direct supervision” means the physician must be on the premises of the location, the provider-based department of the hospital, and immediately available. In the hospital outpatient setting, the hospital can bill only for services provided by its personnel or personnel provided under arrangements. A physician cannot bill in the hospital outpatient setting for “incident to” services performed by his own staff. If the services are provided by advanced practice professionals, these professionals may bill their professional services independent from the hospital facility fee, provided these services are within their scope of practice under state law and the advanced practitioners have an NPI, but only if the salary, benefits, and expenses of the advanced practice professionals are excluded from the hospitals’ cost report to Medicare and the advanced practice professionals’ services are not also billed by the hospital. Note, if an anticoagulation clinic located in a hospital setting is established and bills as a physician practice rather than a hospital outpatient department, the “incident to” rules described in the section above for physician practice-based anticoagulation clinics would apply.

Because the billing issues in hospital outpatient departments can be complex, hospitals and physicians with employment arrangements in hospital-owned anticoagulation clinics may wish to check with their legal counsel for guidance on billing issues.

2009 Medicare Fee Schedule - Evaluation and Management, CPT Code 99211*

State/Carrier	Fee Schedule Area	Allowed Amount
Alabama	Statewide	\$16.77
Alaska	Statewide	\$22.80
Arizona	Statewide	\$18.16
Arkansas	Statewide	\$16.67
California	Anaheim/Santa Ana	\$22.19
California	Los Angeles	\$21.69
California	Marin/Napa/Solano	\$22.01
California	Oakland/Berkley	\$22.38
California	Rest of State [†]	\$19.35
California	San Francisco	\$24.31
California	San Mateo	\$24.29
California	Santa Clara	\$22.64
California	Ventura	\$22.09
Colorado	Statewide	\$18.53
Connecticut	Statewide	\$21.25
Delaware	Statewide	\$19.27
District of Columbia	DC + MD/VA Suburbs	\$21.73
Florida	Fort Lauderdale	\$19.43
Florida	Miami	\$20.38
Florida	Rest of State	\$18.27
Georgia	Atlanta	\$18.92
Georgia	Rest of State	\$17.26
Hawaii/Guam	Statewide	\$20.61
Idaho	Statewide	\$17.16

State/Carrier	Fee Schedule Area	Allowed Amount
Illinois	Chicago	\$20.23
Illinois	East St. Louis	\$18.05
Illinois	Rest of State	\$17.36
Illinois	Suburban Chicago	\$19.92
Indiana	Statewide	\$17.60
Iowa	Statewide	\$16.96
Kansas	Statewide [†]	\$17.15
Kentucky	Statewide	\$16.91
Louisiana	New Orleans	\$19.28
Louisiana	Rest of State	\$17.22
Maine	Rest of State	\$17.26
Maine	Southern Maine	\$18.88
Maryland	Baltimore/Surr. Cntys	\$19.56
Maryland	Rest of State	\$18.49
Massachusetts	Metropolitan Boston	\$22.42
Massachusetts	Rest of State	\$20.01
Michigan	Detroit	\$19.79
Michigan	Rest of State	\$17.84
Minnesota	Statewide	\$18.27
Mississippi	Statewide	\$16.90
Missouri	Metropolitan Kansas City	\$18.15
Missouri	Metropolitan St. Louis	\$17.94
Missouri	Rest of State [†]	\$16.56
Montana	Statewide	\$16.76

State/Carrier	Fee Schedule Area	Allowed Amount
Nebraska	Statewide	\$17.13
Nevada	Statewide	\$19.12
New Hampshire	Statewide	\$19.04
New Jersey	Northern NJ	\$21.94
New Jersey	Rest of State	\$20.60
New Mexico	Statewide	\$17.44
New York	Manhattan	\$22.80
New York	NYC Suburbs/Long Island	\$22.70
New York	Poughkpsie/N NYC Suburbs	\$19.72
New York	Queens	\$21.96
New York	Rest of State	\$17.58
North Carolina	Statewide	\$17.70
North Dakota	Statewide	\$16.62
Ohio	Statewide	\$17.94
Oklahoma	Statewide	\$16.78
Oregon	Portland	\$18.76
Oregon	Rest of State	\$17.67
Pennsylvania	Metropolitan Philadelphia	\$20.26
Pennsylvania	Rest of State	\$17.86
Puerto Rico	Puerto Rico	\$14.73
Rhode Island	Statewide	\$19.91
South Carolina	Statewide	\$17.40
South Dakota	Statewide	\$16.88
Tennessee	Statewide	\$17.25

State/Carrier	Fee Schedule Area	Allowed Amount
Texas	Austin	\$18.55
Texas	Beaumont	\$17.35
Texas	Brazoria	\$18.00
Texas	Dallas	\$18.86
Texas	Fort Worth	\$18.22
Texas	Galveston	\$18.33
Texas	Houston	\$18.81
Texas	Rest of State	\$17.29
Utah	Statewide	\$17.62
Vermont	Statewide	\$18.36
Virgin Islands	Virgin Islands	\$18.49
Virginia	Statewide	\$17.92
Washington	Rest of State	\$18.33
Washington	Seattle (King Cnty)	\$19.78
West Virginia	Statewide	\$16.76
Wisconsin	Statewide	\$17.57
Wyoming	Statewide	\$16.78

* Fee information obtained through CMS website; no independent verification of data is claimed or implied.
 (Source: <http://www.cms.hhs.gov/PhysicianFeeSched/PFSNPAF/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=ascending&itemID=CMS1217859&intNumPerPage=10> - Accessed January 7, 2009)

† Payment locality is serviced by two carriers.

Coding and Payment of Hospital-Owned Clinic Services

What is the Hospital Outpatient Prospective Payment System (HOPPS)?

The Balanced Budget Act of 1997 required the implementation of a prospective payment system for hospital outpatient services. The hospital outpatient prospective payment system (HOPPS) went into effect August 1, 2000, and was developed to encourage more efficient delivery of care and to ensure more appropriate payment for services by Medicare and its beneficiaries.

Payment for hospital outpatient services is based on the assigned Ambulatory Payment Classification (APC) group for the services provided and the pre-determined rates assigned to those APCs. CPT codes describing services provided will be assigned by the Medicare Administrative Contractor (MAC) or Fiscal Intermediary to the appropriate APC.

Hospital services that are directly related and integral to performing a procedure or service and are billed separately may be packaged into an APC. Services that are part of an APC cannot be reimbursed separately.

It is important to note that laboratory tests are *not* included in APCs and may be billed and reimbursed separately.

Are there any special rules for PT/INR tests done in a hospital-owned clinic?

No. Laboratory tests, including medically necessary PT/INR tests, are excluded from HOPPS and for most hospitals will be reimbursed according to Medicare's (Part B) Clinical Laboratory Fee Schedule.

How does HOPPS affect the way a hospital-owned clinic bills for clinic services?

Under HOPPS, providers are required to bill hospital-owned clinic visits using a range of CPT codes that define the intensity of the visit. When the hospital submits a claim, the MAC or Fiscal Intermediary determines which APC code(s) will be assigned for services rendered by the clinic, and payment to the hospital is made accordingly.

Clinics must still perform the described services to justify the coding level selected. Examples of hospital clinic visits and corresponding APCs are shown in the following table.

Ambulatory Payment Classifications (APCs) by CPT Code

HCPCS Code	Description	Assigned APC	Title	Rate*
99201	Office or other OP visit, new patient	0604	Level 1 hospital clinic visits	\$54.68
99202	Office or other OP visit, new patient	0605	Level 2 hospital clinic visits	\$68.96
99203	Office or other OP visit, new patient	0606	Level 3 hospital clinic visits	\$89.74
99204	Office or other OP visit, new patient	0607	Level 4 hospital clinic visits	\$113.57
99205	Office or other OP visit, new patient	0608	Level 5 hospital clinic visits	\$161.69
99211	Office or other OP visit, established patient	0604	Level 1 hospital clinic visits	\$54.68
99212	Office or other OP visit, established patient	0605	Level 2 hospital clinic visits	\$68.96
99213	Office or other OP visit, established patient	0605	Level 2 hospital clinic visits	\$68.96
99214	Office or other OP visit, established patient	0606	Level 3 hospital clinic visits	\$89.74
99215	Office or other OP visit, established patient	0607	Level 4 hospital clinic visits	\$113.57

* 2009 Hospital Outpatient Prospective Payment System rates effective January 1, 2009 (<http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1216689&intNumPerPage=10>) Accessed December 19, 2008. Payment rates listed do not reflect geographic adjustments; local rates will vary.

Will the 72 hour rule apply to HOPPS for laboratory testing and inpatient admissions?

Yes. There is no separate reimbursement for outpatient services performed by a hospital within 72 hours of an inpatient admission to that hospital. Hospitals must bundle charges for these outpatient services into the charges for the inpatient stay. This requirement results in no separate payment for these services because the entire admission, including outpatient services within 72 hours of admission, are reimbursed at a predetermined rate for the Diagnosis-Related Group (DRG/MS-DRG) under the Inpatient Prospective Payment System.

Note: Beginning in 2009, definitions of new and established patients as they relate to reporting hospital outpatient visits under the OPPS, pertain to whether or not the patient has been registered as an inpatient or outpatient of the hospital within the past three years.

Coding and Payment for PT/INR Testing in Long-Term-Care Facilities

Can PT/INR testing performed by LTC facility staff be billed to Medicare?

PT/INR testing may be separately billable if the Medicare program is not paying for the patient's care under a covered Medicare Part A stay. Additionally, Medicare rules and payment systems vary by the type of long-term-care facility (e.g., skilled nursing, intermediate, custodial, assisted-living, etc.). Please check with your own legal and billing counsel and your local Medicare contractor for more information specific to your facility structure.

When coverage and payment for medically necessary PT/INR testing provided in a LTC facility is not prohibited, the facility has the appropriate CLIA certification, and the patient is enrolled in Medicare Part B, the test is eligible for coverage and payment under Medicare Part B.

What is the payment amount for PT/INR testing in those instances in which Medicare coverage is available?

Medicare payment will be based on the Part B Clinical Laboratory Fee Schedule (CLFS). In 2009, the Medicare National Limitation Amount (NLA) for PT/INR testing (85610) is \$5.74. See page 11 for the 2009 payment amount for specific states.

Coding and Payment for PT/INR Testing by a Home Health Agency

Can PT/INR tests performed by home health agency (HHA) staff in a patient's home be billed to Medicare?

Yes. While most services provided under an HHA plan of care are paid under a prospective payment system (PPS), laboratory tests are excluded from the PPS. This means that medically necessary PT/INR testing ordered by a physician and performed in the patient's home by an HHA with the appropriate CLIA certification are eligible for Medicare coverage and payment.

Can HHAs bill PT/INR tests to Medicare Part A?

No. PT/INR testing performed by HHAs in the patient's home must be billed to Medicare Part B under the HHA's Medicare Part B provider number.

Note: The HHA must own the PT/INR testing equipment and supplies and use them in the patient's home to perform the testing.

Contact your local Part B contractor for more information regarding HHA billing for laboratory testing performed in the patient's home.

Reimbursement Planning

The following scenarios may help you understand some of the ways the CoaguChek XS System for Professional Use could be used in a physician office or hospital-owned clinic, and how medically necessary E/M supporting services might be delivered. As you will see, each scenario has different reimbursement implications. The actual services you provide and may bill will vary.

Scenario A

A physician or a member of the physician's staff draws a blood sample in the office by performing a venipuncture and sends it to a reference lab for processing. The PT/INR results are returned that afternoon or up to three days later. The physician interprets the results and makes treatment decisions. Then a staff member phones the patient to report the results and to explain any change in the treatment regimen.

Physician or physician staff services are not reimbursed because telephone calls to patients are not reimbursed by Medicare separate from any E/M service that may be provided before or after the calls.

The office can seek reimbursement only for the blood draw. At the time of the blood draw while the patient is in the office, there are no patient complaints, there is no medical need to evaluate or examine the patient, and the staff has no test results available to review or discuss, therefore, there is no treatment decision to be made and no patient counseling takes place which might justify reporting a separate E/M service.

Scenario B

A nurse in a physician's office performs a PT/INR test as ordered by the treating physician with the CoaguChek XS System for Professional Use. During the encounter, the nurse briefly examines the patient and observes that the patient has a number of bruises. The PT/INR result is outside of the target range for the patient. On brief history, the patient advises the nurse that he has changed his diet recently and has reduced his intake of green leafy vegetables. The nurse reviews the necessary dietary restrictions and treatment regimen with the patient, discusses necessary changes in warfarin dosing, and documents the discussion and the provision of these services in the patient's medical record. The treating physician, who is on site but does not see the patient, is notified and agrees with the recommended changes in the patient's course of treatment.

In addition to billing for the PT/INR test—CPT code 85610QW—the physician may be able to bill for the “incident to” E/M services provided by the nurse, as long as the patient required a level of medically necessary E/M services and the physician did not also see the patient during that visit. (Only one E/M code may be billed for a visit.) Because the nurse is a non-advanced practice employee as specified by Medicare, the low level E/M code, 99211, if substantiated, may be reported.

This scenario applies to any non-advanced practice employee of the physician, working within the scope of practice allowed in their state. Medically necessary PT/INR testing and significant, separately identifiable and medically necessary face-to-face E/M services are eligible for reimbursement under Medicare.

Contrast this with the previous scenario, in which staff members had to receive the results, assess the risk factors, review the results and treatment regimen with the treating physician, call the patient to report the results and any change of regimen, and document and review the additional complaints presented during the phone call with the treating physician—all with no potential for additional reimbursement because the requirements to report an E/M service were not met.

Scenario C

A physician performs a PT/INR test with the CoaguChek XS System for Professional Use (or orders that it be performed by his/her staff) during an office visit for a problem unrelated to the patient's anticoagulation status. The PT/INR result is outside the target range for the patient. Besides administering the test, the physician interprets the result, discusses the result with the patient, and, upon further history taking by the physician, learns the patient has recently started taking a new medication that is known to interact with warfarin. The physician conducts an exam to look for signs of inadequate or excessive anticoagulation control, determines the appropriate course of action based on this information and explains the necessary treatment changes with the patient. These services could factor into the components of the required history, exam and/or complexity of medical decision making, thus potentially impacting the level of E/M service that appropriately describes the physician/patient encounter. Because the results are immediately available, the physician has an opportunity to examine and evaluate the patient immediately and to adjust treatment as needed during the office encounter.

This scenario applies not only to physicians but also to specific advanced practice staff (listed on page 17) who might render E/M services.

Scenario D

A hospital-owned anticoagulation clinic performs a PT/INR test on a patient with the CoaguChek XS System for Professional Use. A qualified hospital employee, working within the scope of his/her license, performs the test. While the patient is still in the clinic, the hospital employee also takes a history, performs a limited physical exam and provides counseling (see CPT code book on specific requirements for E/M coding). All this is done in the same patient visit.

This scenario applies to a nonphysician employee of an outpatient hospital-owned clinic working within the scope of their state issued license. The laboratory service will continue to be reimbursed separately; the medically necessary clinic E/M services (including the medical visit) performed by the nonphysician employee could be eligible for reimbursement at the appropriate APC rates (see page 27).

Note: All services must be medically necessary and at intensity adequate to justify the coding level selected.

Additional E/M Delivery and Documentation Considerations

Note: The following examples were obtained from individual Medicare Part B Contractor or CMS websites regarding E/M services and prothrombin time testing. Consult your local contractor for additional guidance.

Trailblazer Enterprises, LLC (Medicare)*

Clinical Circumstance

Prothrombin time evaluation for patients on chronic warfarin anticoagulation

Adequate Documentation for Code 99211

1. Reason for the visit. A physician visit is not routinely necessary to draw blood for prothrombin time or other laboratory tests. Therefore, the documentation for code 99211 or any other E/M code in this circumstance must demonstrate a need for clinical evaluation and management. In this case, services that would serve to demonstrate that evaluation and management was performed include an evaluation of significant new symptoms (such as excessive bruising or hemorrhage). Alternatively, for patients who have no new clinical concerns, documentation that contemporaneous laboratory values were obtained, reviewed, and used to guide current and/or future therapy documents that a separately payable E/M service has been performed.
2. Current medications listed (with notation of level of compliance).
3. Indication of doctor's evaluation of the information about signs/symptoms and laboratory test result and his management recommendation.
4. Identity and credentials of provider(s) as listed in text above.

* (excerpted from Documentation Requirements for CPT Code 99211, published February 2008, accessed December 16, 2008) <https://www.ouhsc.edu/bc/secure/documents/documentationfor99211.pdf>

Noridian Medicare Administrative Services, LLC*

If the sole purpose of a visit to the physician's office is to draw blood or receive an injection, then 99211 should not be billed and only the appropriate injection or blood drawing code should be billed.

Was There a Change in or Review of Treatment or Prescription?

Conversely, if the patient presents for a prescription refill, blood pressure monitoring, injection, immunotherapy or anticoagulation monitoring where there is a documented, medically necessary decision by the physician to change or maintain medication dosage, 99211 may be appropriate. In this case, the medical record must document that the history and/or exam required a decision and that the physician made the decision, even though the physician did not personally see the patient. CPT 99211 should not be used for routine in-person prescription renewals unless the patient's condition requires reevaluation prior to the renewal determination.

The following are examples of when CPT 99211 might be used:

Office visit for an established patient with a new or concerning bruise which is checked by the nurse (whether or not the patient is taking anticoagulants), and patient is advised on how to care for the bruise and what to be concerned about, and, if on anticoagulants, continuing or changing current dosage is advised. History, exam, dosage and instructions are recorded and reviewed by the physician.

Office visit for an established patient with atrial fibrillation who is taking anticoagulants and having no complaints. Patient is queried by the nurse, vital signs are obtained, patient is observed for bruises and other problems, prothrombin time is obtained, physician is advised of prothrombin time and medication dose, and medication is continued at present dose with follow up prothrombin time in one month recommended. History, vital signs, exam, prothrombin time, INR, dosage and physician's decision and follow up instructions are recorded.

In each of the above examples, the deciding factor in whether or not an independent E/M service may be billed is whether there were provided and documented medically necessary services, including clinical history, clinical exam and/or making a clinical decision, and physician supervision.

The following is an example of when CPT 99211 should not be used:

Office visit for an established patient with a previous stroke who comes to a coagulation clinic staffed by a lab technician or pharmacist. There is no physician in the facility at the time that the blood is drawn. Flow sheet records the date, prothrombin time, INR and Coumadin dosage. After results are available, they are sent to the patient's doctor, who contacts the patient by phone.

In the above example, some or all of the following items are not present and criteria for 99211 are not met. There is no medical necessity for the visit, no documentation of clinical history, no clinical exam, no clinical decision, and/or no physician supervision.

* Excerpted from "Incident to" Clarification for Evaluation and Management Code CPT 99211, updated and reprinted in 2008 from Medicare B News, Issue 201 dated January 27, 2003, accessed January 8, 2009.
https://www.noridianmedicare.com/provider/updates/docs/incident_to_billing_99211_acro.pdf

Wisconsin Physician Service (WPS) Medicare*

Evaluation & Management Services and Laboratory Testing

Home Provider Part B Education

Wisconsin Physicians Service (WPS) Medicare continues to receive claims where providers bill a low-level E&M service (99211) when performing a blood draw or a finger stick test in the office. An Evaluation & Management (E/M) service is not medically necessary when the test is the main reason for the patient encounter. We see this situation with many different types of blood tests, including a prothrombin time (CPT Code 86510.)

Services billed to Medicare must be reasonable and necessary for the diagnosis and treatment of an illness or injury. A face-to-face encounter with a patient consisting of elements of both evaluation and management is required. The record substantiates the Evaluation portion when the record includes documentation of a clinically relevant and necessary exchange of information between the provider and patient. The record substantiates the Management portion when the record demonstrates an influence on patient care. The documentation for this subsequent E/M service must support the provider performing at least two out three components: history, exam, and/or medical decision-making.

Here are some examples of documentation that does not support the use of CPT 99211:

- The documentation shows the PT/INR test results, but no additional patient complaint or any action by the nurse.
- There is missing documentation to support the use of code 99211. Examples are vital signs, weight, patient recent history, etc.
- There is no documentation to show the patient's condition required any level of E/M service for this date.
- There is insufficient documentation to indicate the provider performed any E/M service.
- The documentation shows the reason for the encounter was exclusively for the purpose of venipuncture.
- There is not documentation of any face-to-face encounter.

Question: Is it appropriate for a hospital to bill a visit code under the Outpatient Prospective Payment System (OPPS) for care provided to a registered outpatient if the patient was not seen by a physician?*

Answer: Under the OPPS, unless indicated otherwise, we do not specify the type of hospital staff (for example, nurses, pharmacists, etc.) who may provide services in hospitals because the OPPS only makes payments for services provided "incident to" physicians' services. Hospitals providing services "incident to" physicians' services may choose a variety of staffing configurations to provide those services, taking into account other relevant factors such as State and local laws and hospital policies.

Billing a visit code in addition to another service merely because the patient interacted with hospital staff or spent time in a room for that service is inappropriate. A hospital may bill a visit code based on the hospital's own coding guidelines, which must reasonably relate the intensity of hospital resources to the different levels of HCPCS codes. Services furnished must be medically necessary and documented.

For example, CPT code 86510 (Prothrombin time) is a code that describes performance of the prothrombin time test. If the only service provided is a venipuncture and lab test to determine the prothrombin time, then this is all that should be billed. If a hospital provides a distinct, separately identifiable service in addition to the test, the hospital is responsible for billing the code that most closely describes the service provided. Billing a visit code in addition to another service merely because the patient interacted with hospital staff or spent time in a room for that service is inappropriate. Providers should work with their local FIs regarding the medical necessity for these visits.

* http://www.wpsmedicare.com/part_b/education/em_lab_test.shtml - Accessed December 16, 2008

* Source: CMS website - http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=8810&p_created=1198085740&p_sid=0WK7XLj&p_accessibility=0&p_redirect=&p_lva=&p_sp=cF9zcm NoPTEmcF9zb3J0X2J5PSZwX2dyaWRzb3J0PSZwX3Jvd19jbnQ9MTgsMTgmcF9wcm9kcz 04LDU3LDYxNCZwX2NhdHM9JnBfcHY9My42MTQmcF9jdj0mcF9zZWYy2hfdHlwZT11bnN3ZXJzLn NIYXJjaF9ubCZw X3BhZ2U9MSZwX3NIYXJjaF90ZXh0PVZpc2I0IENvZGVz&p_li=&p_topview=1 - Accessed December 19, 2008

Structuring the Delivery of Medically Necessary E/M Services with PT/INR Testing

No matter where the coagulation test is performed, *someone* has to perform the duties of interpretation and/or discussion of PT/INR test results. When these services are combined with medically necessary history, examination and medical decision making, etc., and are documented, they may represent billable E/M services. Payers are more likely to consider these services medically necessary when there are new symptoms or signs or there is a change in treatment resulting from the assessment performed as part of the E/M service.

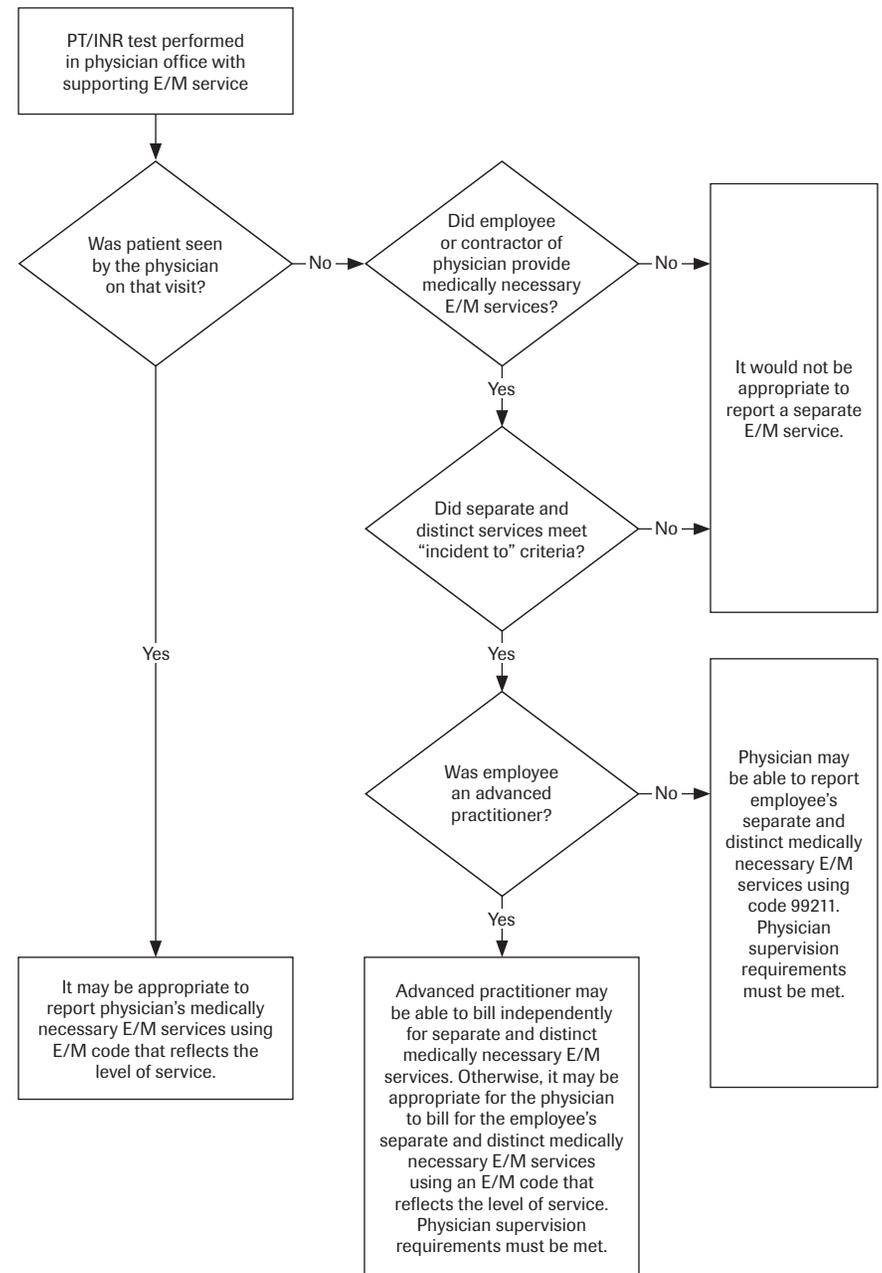
Questions to think through include:

- Are medically necessary E/M services related to PT/INR testing adequately documented?
- Which individuals are performing the tests and/or delivering the E/M services? If not the physician, are they non-advanced practice employees or advanced practice employees?
- Where and how are E/M services being delivered?
- Are E/M services being billed under codes that appropriately represent the level of services delivered consistent with E/M guidelines, and are they significant, separately identifiable and medically necessary?
- Is the E/M code assigned to these medically necessary services well supported by medical record documentation?

Remember that you may be eligible to receive reimbursement only if E/M services are medically necessary for an individual patient on an individual date of service, and are appropriately documented in your patients' medical records. Because of increased focus regarding inappropriate reporting of 99211 and other E/M services, in particular, your local Medicare contractor may request information to validate: the site of service; the medical necessity and appropriateness of the diagnostic and/or therapeutic services provided; and/or that services provided have been accurately reported.

Note: Special rules such as 'incident to' direct supervision, employer/employee arrangements, advanced practice staff billing under their own NPI, etc., may apply.

Example Flow Chart to Determine Appropriateness of Reporting Separate E/M Service with PT



Home Self-Testing by Patients

Reimbursement of Home PT/INR Monitoring Services

Since 2002, Medicare has covered home PT/INR monitoring for eligible patients with a **mechanical heart valve**. In early 2008, CMS expanded the coverage of home PT/INR monitoring to include the additional conditions of **chronic atrial fibrillation** and **venous thromboembolism**¹⁹ (**VTE**). In keeping with the original coverage policy, these services are covered and reimbursed as *physician-directed diagnostic services* and not as durable medical equipment (DME).

This section outlines the CMS Medicare policy regarding coding, coverage and payment for home PT/INR monitoring services.

Eligibility

What are the eligibility and coverage criteria for home PT/INR monitoring?

For services effective **July 1, 2002 through March 18, 2008**, Medicare covered home PT/INR monitoring for patients who met all of the following criteria²⁰:

- Had a prescription for the monitor and home testing.
- Had a mechanical heart valve and were on warfarin.
- Had been anticoagulated for at least three months prior to the use of the home INR device.
- Had undergone an educational program on anticoagulation management and the use of the device prior to its use in the home.
- Limited the self-testing frequency to once per week.

Effective for claims with **dates of service on and after March 19, 2008**, CMS revised the coverage policy to provide for home coverage of PT/INR monitoring for chronic, oral anticoagulation management for patients with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism (including deep venous thrombosis and pulmonary embolism) on warfarin.²¹

The monitor and the home testing must be prescribed by a treating physician and the patient must meet all of the following requirements:

- The patient must have been anticoagulated for at least 3 months prior to use of the home INR device.
- The patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated the correct use of the device prior to its use in the home.
- The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring.
- Self-testing with the device should not occur more frequently than once a week.

19. <https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=209&> - Accessed January 14, 2009

20. Ibid.

21. <http://www.cms.hhs.gov/transmittals/downloads/R1663CP.pdf> - Accessed January 15, 2009

Note: Porcine valves are not included in this NCD, so this means while there is no Medicare national coverage policy for home PT/INR monitoring for patients with porcine valves, the decision to cover home PT/INR monitoring for patients with porcine valves is left to the discretion of local Medicare contractors.

Physician-Directed Diagnostic Services for Home PT/INR Monitoring

In order to obtain reimbursement from Medicare for home PT/INR monitoring services, the services must be provided under the direction of a physician, with equipment and supplies dispensed by the physician (or designated entity as explained below). That is, the equipment and supplies are not purchased by the patient. Payment is made to the physician or designated entity and differentiates between technical and professional components of the diagnostic services.

How does the physician-directed diagnostic services home PT/INR benefit work?

The benefit involves three components which are defined as either technical or professional. The technical components can be performed by a physician or through referral to an Independent Diagnostic Testing Facility (IDTF). The professional component can be provided by the physician only.

Benefit Component	Type	Provider	Code	Short Descriptor
Provide face-to-face training on the use of the home PT/INR monitor	Technical	Physician or IDTF	G0248	Demonstrate use home inr mon
Issue PT/INR monitoring equipment and supplies to the patient for home testing	Technical	Physician or IDTF	G0249	Provide INR test mater/equip
Physician review and interpretation of results and patient management	Professional	Physician only	G0250	MD INR test revie inter mgmt

Does this mean the patient does not purchase the PT/INR monitor and supplies?

Yes, the physician or IDTF purchases the equipment and supplies, not the patient. Medicare reimburses the physician or IDTF for the equipment and supplies and the related services.

How can a provider become an Independent Diagnostic Testing Facility (IDTF)?

Providers that want to enroll with Medicare as an IDTF should contact their local or regional Medicare contractor for qualifications and instructions.

Although an IDTF can purchase and issue home PT/INR testing equipment and supplies and perform the associated educational services (the technical components), patients still need to confer with their physician for review and interpretation of the results (the professional component) as well as any follow-up treatment planning.

Must the physician speak directly to the patient to qualify for billing for the professional component?

No. Qualified personnel of the physician may obtain test results from the patient, but the physician must review and interpret the results. These test results must be documented in the patient record. It is recommended that the physician acknowledge his/her review of all test results thus documented.

Note: The physician is responsible for reviewing and interpreting the test results and for making patient management decisions based on each test result.

Coding and Billing Home PT/INR Monitoring Services

Which codes must a physician use to bill home PT/INR services to Medicare?

CMS has designated three “temporary” Level II HCPCS codes for billing home PT/INR monitoring. These codes are paid under the Medicare physician fee schedule. (For billing by hospital outpatient departments, see next page.)

Note: The following code descriptors are effective for dates of service March 19, 2008, and thereafter.

- G0248 Demonstration, prior to initial use, of home INR monitoring for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing prior to its use.
- G0249 Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; not occurring more frequently than once a week
- G0250 Physician review, interpretation, and patient management of home INR testing for a patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes face-to-face verification by the physician at least once a year (e.g. during an evaluation and management service) that the patient uses the device in the context of the management of the anticoagulation therapy following initiation of the home INR monitoring; not occurring more frequently than once a week.

Which equipment and supplies are included in the G0249 code?

Code G0249 includes all equipment and supplies necessary to provide home PT/INR monitoring. The equipment and supplies may not be billed separately to Medicare. Covered equipment and supplies may include, but are not limited to, the following home PT/INR monitoring equipment and supplies:

- CoaguChek XS PST System
- CoaguChek XS PST Strips
- CoaguChek XS Controls
- Alcohol swabs
- Lancets
- Lancing device
- Software for analysis and reporting of results

What limits does CMS set on how often home PT/INR codes may be billed?

Code G0248 may be billed only once, as it refers to initial training in the use of the home PT/INR testing monitor.

Codes G0249 and G0250 may be billed only once every four tests.

To support medical necessity, all services must be documented in the patient record. (*Note:* Self-testing frequency is limited to once per week.)

Will Medicare reimburse office visits or lab PT/INR tests that take place on the same day as a home PT/INR test?

It may arise that covered services coincide on the same day. For example, a patient performs a home PT/INR test and is seen by a physician later that day or has a lab PT/INR test done later that day.

CMS does not specify which services are billable in these situations. Check with your local Medicare contractor for guidance.

Which codes can an IDTF use to bill home PT/INR monitoring services?

An IDTF can provide and bill the technical components—G0248 and G0249. It cannot provide the professional component—G0250—which is to be provided by a physician.

What if the patient receives the monitor and supplies from a hospital outpatient facility?

When physician-directed diagnostic services are delivered from a hospital outpatient clinic (i.e., one that bills for its services as hospital outpatient services), payment falls under the guidelines of Medicare’s Hospital Outpatient Prospective Payment System (HOPPS). This affects which codes may be billed and how they are paid.

Which codes can hospital outpatient facilities bill under the HOPPS?

The technical components—G0248 and G0249—are billable by the hospital. The professional component—G0250—is not billable under HOPPS. However, the patient’s physician may bill for the G0250 service under the Medicare Physician Fee Schedule.

Payment Policies for Home PT/INR Monitoring Services

How does Medicare pay for home PT/INR services delivered by a physician office or IDTF?

Home PT/INR services are paid under the Medicare Physician Fee Schedule. CMS payment for the technical and professional components of the physician-directed diagnostic benefit is as follows:

Code	Short Descriptor	Component	2009 Medicare Allowed Amount*
G0248	Demonstrate use home INR mon	Technical	\$148.59
G0249	Provide INR test mater/equipm	Technical	\$126.23 per 4 tests
G0250	MD INR test revie inter mgmt	Professional	\$9.74 per 4 tests

* 2009 Medicare Physician Fee Schedule payment amounts effective January 1, 2009 Source: 2009 Physician Fee Schedule Relative Value Files (www.cms.hhs.gov/PhysicianFeeSched/PFSRVF/) Accessed January 8, 2009

Payment rates listed do not reflect geographic adjustments; local rates will vary.

How are the technical components paid under the HOPPS?

Under the hospital prospective payment system, home PT/INR testing services are reimbursed under Ambulatory Payment Classifications (APCs).

HCPCS Code	APC Assigned	Description	Component	2009 Medicare Allowed Amount
G0248	0607*	Demonstrate use home INR mon	Technical	\$113.57
G0249	0607*	Provide INR test mater/ equip	Technical	\$113.57 per 4 tests
G0250	N/A	MD INR test revie inter mgmt	Professional	N/A

* Federal Register / Vol. 73, No. 223 / Tuesday, November 18, 2008 / 42 CFR Parts 410, 416, and 419 Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Final Rule; Accessed January 14, 2009

Payment rates listed do not reflect geographic adjustments; local rates will vary

Note: When billing for G0249, CMS will allow hospitals to bill for up to three units of G0249 at a time in order to cover up to 12 tests so that the service is billable on a date when a patient would attend the clinic for a face-to-face visit.

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

What is the patient's financial responsibility for home PT/INR monitoring services?

This depends on where the service is provided, whether in a physician office, IDTF, or hospital outpatient clinic:

- For services paid under the physician fee schedule (physician office or IDTF), patients are responsible for 20% of the Medicare allowed amount after they satisfy the annual Medicare Part B deductible. (Slightly higher copayments may be charged if the services are billed by a non-participating physician who does not accept assignment. Charges are subject to the limiting charge rules under these circumstances.)
- For services paid under APCs (hospital outpatient clinic), patients are responsible for a copayment for each billable service after they satisfy the annual Medicare Part B deductible. In 2009, the minimum unadjusted copayment amount is \$22.72.

What if I have questions that are not answered here?

Providers should consult with their local Medicare contractor for further clarification and instructions on billing.

2009 Medicare Physician Fee Schedule, HCPCS Code G0248*

State/Carrier	Fee Schedule Area	Allowed Amount
Alabama	Statewide	\$126.62
Alaska	Statewide	\$161.81
Arizona	Statewide	\$142.16
Arkansas	Statewide	\$125.57
California	Los Angeles	\$181.88
California	Marin/Napa/Solano	\$187.67
California	Oakland/Berkley	\$190.78
California	Rest of State**	\$157.03
California	San Francisco	\$213.75
California	San Mateo	\$212.56
California	Santa Clara	\$191.95
California	Ventura	\$187.79
California	Anaheim/Santa Ana	\$188.40
Colorado	Statewide	\$147.28
Connecticut	Statewide	\$176.01
Delaware	Statewide	\$155.30
District of Columbia	DC + MD/VA Suburbs	\$180.92
Florida	Miami	\$159.60
Florida	Rest of State	\$139.81
Florida	Fort Lauderdale	\$151.71
Georgia	Rest of State	\$131.19
Georgia	Atlanta	\$150.61
Hawaii/Guam	Statewide	\$172.34
Idaho	Statewide	\$131.09

State/Carrier	Fee Schedule Area	Allowed Amount
Illinois	East St. Louis	\$136.87
Illinois	Rest of State	\$130.89
Illinois	Suburban Chicago	\$158.90
Illinois	Chicago	\$160.79
Indiana	Statewide	\$136.29
Iowa	Statewide	\$129.12
Kansas	Statewide**	\$130.94
Kentucky	Statewide	\$127.72
Louisiana	Rest of State	\$130.47
Louisiana	New Orleans	\$155.10
Maine	Rest of State	\$132.55
Maine	Southern Maine	\$152.12
Maryland	Rest of State	\$145.88
Maryland	Baltimore/Surr. Cntys	\$157.07
Massachusetts	Rest of State	\$164.22
Massachusetts	Metropolitan Boston	\$191.65
Michigan	Rest of State	\$137.21
Michigan	Detroit	\$154.85
Minnesota	Statewide	\$145.80
Mississippi	Statewide	\$126.88
Missouri	Metropolitan St. Louis	\$138.39
Missouri	Rest of State**	\$122.06
Missouri	Metropolitan Kansas City	\$140.51
Montana	Statewide	\$125.80

State/Carrier	Fee Schedule Area	Allowed Amount
Nebraska	Statewide	\$132.02
Nevada	Statewide	\$152.48
New Hampshire	Statewide	\$154.18
New Jersey	Rest of State	\$167.31
New Jersey	Northern NJ	\$182.43
New Mexico	Statewide	\$132.32
New York	NYC Suburbs/Long Island	\$191.52
New York	Poughkpsie/N NYC Suburbs	\$159.94
New York	Queens	\$184.10
New York	Rest of State	\$136.68
New York	Manhattan	\$192.77
North Carolina	Statewide	\$137.34
North Dakota	Statewide	\$125.25
Ohio	Statewide	\$137.86
Oklahoma	Statewide	\$126.22
Oregon	Rest of State	\$137.58
Oregon	Portland	\$150.63
Pennsylvania	Rest of State	\$137.51
Pennsylvania	Metropolitan Philadelphia	\$163.20
Puerto Rico	Puerto Rico	\$102.96
Rhode Island	Statewide	\$161.64
South Carolina	Statewide	\$134.46
South Dakota	Statewide	\$128.23
Tennessee	Statewide	\$132.00

State/Carrier	Fee Schedule Area	Allowed Amount
Texas	Beaumont	\$130.19
Texas	Brazoria	\$137.11
Texas	Dallas	\$148.78
Texas	Fort Worth	\$141.67
Texas	Galveston	\$142.60
Texas	Houston	\$146.64
Texas	Rest of State	\$130.68
Texas	Austin	\$146.21
Utah	Statewide	\$134.82
Vermont	Statewide	\$145.89
Virgin Islands	Virgin Islands	\$145.34
Virginia	Statewide	\$139.87
Washington	Rest of State	\$144.63
Washington	Seattle (King Cnty)	\$161.09
West Virginia	Statewide	\$123.08
Wisconsin	Statewide	\$136.67
Wyoming	Statewide	\$125.13

* Fee information obtained through CMS website; no independent verification of data is claimed or implied.
 (Source: <http://www.cms.hhs.gov/PhysicianFeeSched/PFSNPAF/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=ascending&itemID=CMS1217859&intNumPerPage=10,%20accessed%2017/09> - Accessed January 8, 2009)

** Payment locality is serviced by two carriers.

This information does *not* apply to hospital outpatient facilities.

2009 Medicare Physician Fee Schedule, HCPCS Code G0249*

State/Carrier	Fee Schedule Area	Allowed Amount
Alabama	Statewide	\$107.55
Alaska	Statewide	\$137.43
Arizona	Statewide	\$120.76
Arkansas	Statewide	\$106.65
California	Los Angeles	\$154.48
California	Marin/Napa/Solano	\$159.38
California	Oakland/Berkley	\$162.03
California	Rest of State**	\$133.37
California	San Francisco	\$181.53
California	San Mateo	\$180.52
California	Santa Clara	\$163.01
California	Ventura	\$159.50
California	Anaheim/Santa Ana	\$160.02
Colorado	Statewide	\$125.10
Connecticut	Statewide	\$149.51
Delaware	Statewide	\$131.91
District of Columbia	DC + MD/VA Suburbs	\$153.68
Florida	Miami	\$135.70
Florida	Rest of State	\$118.82
Florida	Fort Lauderdale	\$128.95
Georgia	Rest of State	\$111.44
Georgia	Atlanta	\$127.94
Hawaii/Guam	Statewide	\$146.38
Idaho	Statewide	\$111.34

State/Carrier	Fee Schedule Area	Allowed Amount
Illinois	East St. Louis	\$116.32
Illinois	Rest of State	\$111.21
Illinois	Suburban Chicago	\$135.02
Illinois	Chicago	\$136.64
Indiana	Statewide	\$115.77
Iowa	Statewide	\$109.67
Kansas	Statewide**	\$111.22
Kentucky	Statewide	\$108.49
Louisiana	Rest of State	\$110.84
Louisiana	New Orleans	\$131.76
Maine	Rest of State	\$112.58
Maine	Southern Maine	\$129.20
Maryland	Rest of State	\$123.92
Maryland	Baltimore/Surr. Cntys	\$133.44
Massachusetts	Rest of State	\$139.49
Massachusetts	Metropolitan Boston	\$162.78
Michigan	Rest of State	\$116.57
Michigan	Detroit	\$131.59
Minnesota	Statewide	\$123.82
Mississippi	Statewide	\$107.79
Missouri	Metropolitan St. Louis	\$117.57
Missouri	Rest of State**	\$103.70
Missouri	Metropolitn Kansas City	\$119.38
Montana	Statewide	\$106.86

State/Carrier	Fee Schedule Area	Allowed Amount
Nebraska	Statewide	\$112.11
Nevada	Statewide	\$129.54
New Hampshire	Statewide	\$130.95
New Jersey	Rest of State	\$142.13
New Jersey	Northern NJ	\$154.97
New Mexico	Statewide	\$112.42
New York	NYC Suburbs/Long Island	\$162.69
New York	Poughkpsie/N NYC Suburbs	\$135.86
New York	Queens	\$156.40
New York	Rest of State	\$116.08
New York	Manhattan	\$163.75
North Carolina	Statewide	\$116.66
North Dakota	Statewide	\$106.38
Ohio	Statewide	\$117.13
Oklahoma	Statewide	\$107.22
Oregon	Rest of State	\$116.85
Oregon	Portland	\$127.93
Pennsylvania	Rest of State	\$116.82
Pennsylvania	Metropolitan Philadelphia	\$138.67
Puerto Rico	Puerto Rico	\$87.45
Rhode Island	Statewide	\$137.31
South Carolina	Statewide	\$114.20
South Dakota	Statewide	\$108.91
Tennessee	Statewide	\$112.12

State/Carrier	Fee Schedule Area	Allowed Amount
Texas	Beaumont	\$110.62
Texas	Brazoria	\$116.50
Texas	Dallas	\$126.40
Texas	Fort Worth	\$120.36
Texas	Galveston	\$121.15
Texas	Houston	\$124.60
Texas	Rest of State	\$111.03
Texas	Austin	\$124.21
Utah	Statewide	\$114.54
Vermont	Statewide	\$123.91
Virgin Islands	Virgin Islands	\$123.47
Virginia	Statewide	\$118.81
Washington	Rest of State	\$122.85
Washington	Seattle (King Cnty)	\$136.83
West Virginia	Statewide	\$104.58
Wisconsin	Statewide	\$116.08
Wyoming	Statewide	\$106.31

* Fee information obtained through CMS website; no independent verification of data is claimed or implied.
 (Source: <http://www.cms.hhs.gov/PhysicianFeeSched/PFSNPAF/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=ascending&itemID=CMS1217859&intNumPerPage=10,%20accessed%2017/09> - Accessed January 8, 2009)

** Payment locality is serviced by two carriers.

This information does *not* apply to hospital outpatient facilities.

2009 Medicare Physician Fee Schedule, HCPCS Code G0250*

State/Carrier	Fee Schedule Area	Allowed Amount
Alabama	Statewide	\$9.13
Alaska	Statewide	\$13.12
Arizona	Statewide	\$9.55
Arkansas	Statewide	\$9.09
California	Los Angeles	\$10.58
California	Marin/Napa/Solano	\$10.52
California	Oakland/Berkley	\$10.70
California	Rest of State**	\$9.79
California	San Francisco	\$11.18
California	San Mateo	\$11.24
California	Santa Clara	\$10.90
California	Ventura	\$10.59
California	Anaheim/Santa Ana	\$10.67
Colorado	Statewide	\$9.59
Connecticut	Statewide	\$10.51
Delaware	Statewide	\$9.83
District of Columbia	DC + MD/VA Suburbs	\$10.68
Florida	Miami	\$10.72
Florida	Rest of State	\$9.82
Florida	Fort Lauderdale	\$10.24
Georgia	Rest of State	\$9.34
Georgia	Atlanta	\$9.78
Hawaii/Guam	Statewide	\$10.08
Idaho	Statewide	\$9.24

State/Carrier	Fee Schedule Area	Allowed Amount
Illinois	East St. Louis	\$9.79
Illinois	Rest of State	\$9.47
Illinois	Suburban Chicago	\$10.27
Illinois	Chicago	\$10.47
Indiana	Statewide	\$9.36
Iowa	Statewide	\$9.16
Kansas	Statewide**	\$9.24
Kentucky	Statewide	\$9.21
Louisiana	Rest of State	\$9.35
Louisiana	New Orleans	\$9.85
Maine	Rest of State	\$9.25
Maine	Southern Maine	\$9.63
Maryland	Rest of State	\$9.64
Maryland	Baltimore/Surr. Cntys	\$10.01
Massachusetts	Rest of State	\$10.00
Massachusetts	Metropolitan Boston	\$10.68
Michigan	Rest of State	\$9.55
Michigan	Detroit	\$10.41
Minnesota	Statewide	\$9.42
Mississippi	Statewide	\$9.25
Missouri	Metropolitan St. Louis	\$9.57
Missouri	Rest of State**	\$9.22
Missouri	Metropolitan Kansas City	\$9.65
Montana	Statewide	\$9.18

State/Carrier	Fee Schedule Area	Allowed Amount
Nebraska	Statewide	\$9.15
Nevada	Statewide	\$9.86
New Hampshire	Statewide	\$9.66
New Jersey	Rest of State	\$10.42
New Jersey	Northern NJ	\$10.81
New Mexico	Statewide	\$9.46
New York	NYC Suburbs/Long Island	\$10.99
New York	Poughkpsie/N NYC Suburbs	\$9.99
New York	Queens	\$10.71
New York	Rest of State	\$9.30
New York	Manhattan	\$11.02
North Carolina	Statewide	\$9.39
North Dakota	Statewide	\$9.07
Ohio	Statewide	\$9.61
Oklahoma	Statewide	\$9.17
Oregon	Rest of State	\$9.34
Oregon	Portland	\$9.60
Pennsylvania	Rest of State	\$9.55
Pennsylvania	Metropolitan Philadelphia	\$10.34
Puerto Rico	Puerto Rico	\$8.58
Rhode Island	Statewide	\$10.07
South Carolina	Statewide	\$9.27
South Dakota	Statewide	\$9.14
Tennessee	Statewide	\$9.28

State/Carrier	Fee Schedule Area	Allowed Amount
Texas	Beaumont	\$9.50
Texas	Brazoria	\$9.72
Texas	Dallas	\$9.84
Texas	Fort Worth	\$9.64
Texas	Galveston	\$9.70
Texas	Houston	\$9.93
Texas	Rest of State	\$9.41
Texas	Austin	\$9.68
Utah	Statewide	\$9.48
Vermont	Statewide	\$9.50
Virgin Islands	Virgin Islands	\$9.68
Virginia	Statewide	\$9.45
Washington	Rest of State	\$9.55
Washington	Seattle (King Cnty)	\$9.97
West Virginia	Statewide	\$9.37
Wisconsin	Statewide	\$9.30
Wyoming	Statewide	\$9.24

* Fee information obtained through CMS website; no independent verification of data is claimed or implied.
 (Source: <http://www.cms.hhs.gov/PhysicianFeeSched/PFSNPAF/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=ascending&itemID=CMS1217859&intNumPerPage=10,%20accessed%2017/09> - Accessed January 8, 2009)

** Payment locality is serviced by two carriers.

This information does not apply to hospital outpatient facilities.

For Additional Information

- For provider (e.g., physician) reimbursement questions concerning the CoaguChek XS System for Professional or Home Use, a voicemail information inquiry line is available to customers of Roche Diagnostics.

Reimbursement Inquiry Line
1-800-428-5074, x13967
Response Generally Within One Business Day

- For end-user (patient) reimbursement questions concerning the CoaguChek XS System for Patient Self-Testing, please contact CoaguChek Care Center at 1-800-779-7616.
- To contact the MAC, Medicare Fiscal Intermediary or Medicare Part B Carrier in your local area, see the provider information line listed under “Medicare” in the business white pages of your telephone directory.
- For details regarding the Medicare guidelines discussed in this handbook, consult the “Manuals” pages of the CMS website or contact your local Medicare contractor.
- To provide feedback on this handbook, please call the Reimbursement Inquiry Line listed above.

Index

advanced practice staff
 E/M services by, 13, 17
 billing considerations for, 13
 supervisory role, 21
 PIN requirement for billing, 17
Ambulatory Payment Classification (APC), 26, 42
anticoagulants, 7
assigned claims, 12
CLFS, 28
CLIA, 10
clinics, hospital-owned, 26
coagulation test. See PT test 7, 8, 9
CPT codes, 9, 26
 and E/M services, 13, 14, 15
 modifiers, 9
deductible, 12, 43
documentation, 15, 18, 31, 40
E/M services
 of advanced practice staff, 17, 21
 billing considerations for
 categories of staff, 14
 billing examples, 29
 coding of, 17
 defined, 13
 documentation of, 18
 to new and established patients, 16
 and non-advanced practice staff, 19
 reimbursement of, 13
 structuring delivery of, 36
 and time spent, 15
employment issues, 21
fingerstick, 9
home PT monitoring services, 38
 billing, 40
 coding, 40, 42
HOPPS, 26, 27
ICD-9-CM (diagnosis) code, 9
IDTF, 39, 41, 42
“incident to” services
 coding, 20
 defined, 19
 standards for providers of, 20
INR, 7
medical decision
 making, complexity of, 17, 18
 medical necessity, 8, 12
Medicare, 8, 9, 20
 contacting, 10, 50
 eligibility, 8, 38
 modifiers to CPT codes, 9
NCD, 9, 12
NLA, 28
outpatient prospective
 payment system, 26, 41, 42
pharmacist E/M services, 21
physician-directed diagnostic
 services, 38
prothrombin time. See PT test
provider identification number (PIN), 17
PT test, 6, 7, 9
 Coding, 9
 Documentation of, 18
 And “incident to” services, 20
 National coverage policy for, 9, 12
 Reimbursement example, 29
 Reimbursement fees for, 10, 11
 And supporting services, 13
reimbursement by Medicare, 9
 planning examples, 29
 fee schedules, 11, 24, 44, 46, 48
 72 hour rule, 27
Reimbursement Inquiry Line, 50
site of service issues, 22
supervision issues, 21
utilization controls, 12

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46256

COAGUCHEK is a trademark of Roche.

© 2009 Roche Diagnostics. All rights reserved. 573-44156-0409