2015
Medicare Reimbursement Handbook for Healthcare Professionals
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Table: Physician Fee Schedule for HCPCS Code G0248, G0249, G0250 

For Additional Information
About This Handbook

At Roche Diagnostics, we recognize that 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 in-office Prothrombin Time/International Normalized Ratio (PT/INR) testing. This handbook also provides information regarding evaluation and management (E/M) services that may be appropriate to report when rendered in conjunction with PT/INR testing and anticoagulation management when using a CoaguChek® XS System for Professional Use. There is also a section covering home PT/INR monitoring with the CoaguChek XS Patient Self Testing (PST) System.

To answer your questions, we review Medicare Part B reimbursement policies pertaining to the traditional fee-for-service Medicare program. We also summarize Medicare and CPT® guidelines regarding E/M services provided by a physician, other qualified healthcare practitioner and/or by physician staff in connection with in-office PT/INR testing and anticoagulation management.

We hope that this handbook is helpful to you and we welcome your comments.

Note: To the best of our knowledge, the information presented in this handbook is accurate and complete as of May 19, 2015. This information should not be interpreted as, and is not intended to be, legal or reimbursement advice or counsel. Questions regarding the legality or appropriateness of coding, coverage, payment, or billing procedures should be discussed with your own legal counsel. Do not proceed with any activities, including billing, with which you are uncomfortable or about which you have significant questions.

Due to sequestration, a 2% reduction will be applied to claim payments after determining applicable deductible, coinsurance, and Medicare Secondary Payer (MSP) adjustments.

Note: This handbook does not attempt to address the reimbursement requirements of commercial benefit plans, as there are over 100 different private payers offering a variety of plans from traditional fee-for-service (FFS) to preferred provider organizations (PPOs) and health maintenance organizations (HMOs). For the details of reimbursement under a private plan, consult the specific payer.
Benefits of “Real-Time” Medicine

The primary benefit of CoaguChek XS 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. 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.

CoaguChek XS 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, CoaguChek XS Systems for Professional Use 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.

6. Package Inserts for the CoaguChek XS System (05967684001-01), CoaguChek XS Plus System (05967716001-02) and the CoaguChek XS Pro System (05967716001-02), Indianapolis, IN, Roche Diagnostics Corporation.

Reimbursement of PT/INR Tests

The answers to the following questions will 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 the individual Medicare administrative contractors (MAC). For details about coverage determinations in your area, contact your local Medicare administrative contractor.

Patient Eligibility

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

Medicare covers individuals 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, under Medicare Part B, 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: The medical necessity for the test and the 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.
- Must be ordered by the treating physician, the results of which are used for the management of the patient’s specific medical problem.7

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7. 42 CFR §410.32.

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. Several years ago, 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. 8

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 (or ICD-10-CM code for claims with dates of service on or after October 1, 2015). 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.

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 a 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.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>85610</td>
<td>Prothrombin time</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>QW</td>
<td>CLIA-waived test</td>
</tr>
</tbody>
</table>

The QW modifier is generally required on Medicare reimbursement claims when performing CLIA-waived tests. 9 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 finger stick specimen collection.

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

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9. 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 and the specialty 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, all tests require a CLIA certification unless exempt; CLIA-certified testing includes waived and non-waived tests. Physicians performing any non-exempt type of testing 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 the CLIA section of the CMS website, http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.htm, 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 the CLIA section of the CMS website, http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.htm, or from the survey agencies in the respective state where the provider is located. State Agency and Regional CLIA Office 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 2015 National Limitation Amount for a PT/INR test is $5.35. Individual state fees are shown in the chart that follows.
## 2015 Medicare Fee Schedule for Prothrombin Time (PT/INR) Test, CPT Code 85610*

<table>
<thead>
<tr>
<th>State/Carrier</th>
<th>Fee</th>
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<tbody>
<tr>
<td>Alabama</td>
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<td>Alaska</td>
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<td>Arkansas</td>
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<td>California–1</td>
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<tr>
<td>California–2</td>
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<td>Colorado</td>
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<td>Connecticut</td>
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<td>D.C.</td>
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<td>Delaware</td>
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<td>Florida</td>
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<td>Georgia</td>
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<td>Hawaii</td>
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<td>Idaho</td>
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<td>Illinois</td>
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<tr>
<td>Indiana</td>
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<tr>
<td>Iowa</td>
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<td>Kansas</td>
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<tr>
<td>Kentucky</td>
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<th>State/Carrier</th>
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<tr>
<td>Montana</td>
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<td>Wyoming</td>
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*Fee information obtained through CMS website; no independent verification of data is claimed or implied. (Source: [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/CLinderLabFeeSchedclinlab.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/CLinderLabFeeSchedclinlab.html) / Accessed May 1, 2015)
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 CoaguChek XS Systems 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." You can obtain a copy of the NCD from your local Medicare contractor or the CMS coverage database.

Medicare may also enforce limits after claims are submitted (post-pay 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 non-covered 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 are ones for which testing is considered reasonable and necessary.

10. 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.
- Since the INR is a calculation, it will not be paid in addition to the PT when expressed in seconds, and is considered part of the conventional prothrombin time.
- 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.

11. Prothrombin Time (PT); Medicare National Coverage Determinations Manual; Chapter 1, Part 3, Section 190.17

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 (e.g., standard of care, risk management, 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 is provided beginning on page 16.

E/M services rendered in conjunction with PT/INR testing using CoaguChek XS Systems 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 overutilization 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 30.
### E/M Considerations for Categories of Staff

<table>
<thead>
<tr>
<th>Face-to-face encounter is by:</th>
<th>Physician</th>
<th>Nonphysician Practitioner¹</th>
<th>Nonphysician Employee²*</th>
</tr>
</thead>
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<tr>
<td>Key Components</td>
<td>Intensity of patient history/exam</td>
<td>Intensity of patient history/exam</td>
<td>Intensity of patient history/exam</td>
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<tr>
<td></td>
<td>Complexity of medical decision making</td>
<td>Complexity of medical decision making</td>
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<tr>
<td></td>
<td>Nature of presenting problem(s)</td>
<td>Nature of presenting problem(s)</td>
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</tr>
<tr>
<td>E/M Billing</td>
<td>May bill any E/M code level based on services provided</td>
<td>May bill any E/M code level based on services provided</td>
<td>May bill only one E/M code level regardless of service provided—99211</td>
</tr>
<tr>
<td></td>
<td>Time spent with patient (only a factor when counseling and/or coordination of care)</td>
<td>Same considerations as physician apply: history/exam, medical decision making, etc.</td>
<td>May bill only if a level of service other than lab testing is performed</td>
</tr>
<tr>
<td>Issues</td>
<td>Medical necessity</td>
<td>&quot;Incident to&quot; physician's service or may bill under own name</td>
<td>&quot;Incident to&quot; physician's service only</td>
</tr>
<tr>
<td></td>
<td>Significant, separately identifiable service</td>
<td>Significant, separately identifiable service</td>
<td>Significant, separately identifiable service</td>
</tr>
<tr>
<td></td>
<td>Contractor policies</td>
<td>Medical necessity</td>
<td>Medical necessity</td>
</tr>
<tr>
<td></td>
<td>Employment/supervision</td>
<td>Employment/supervision</td>
<td>Employment/supervision</td>
</tr>
<tr>
<td></td>
<td>Licensure and scope of practice requirements</td>
<td>Licensure and scope of practice requirements</td>
<td>Licensure and scope of practice requirements</td>
</tr>
<tr>
<td></td>
<td>Site of service</td>
<td>Site of service</td>
<td>Site of service</td>
</tr>
<tr>
<td></td>
<td>Contractor policies</td>
<td>Contractor policies</td>
<td>Contractor policies</td>
</tr>
</tbody>
</table>

¹ Nonphysician practitioners are defined as physician assistants (PA), nurse practitioners (NP), certified nurse midwife (CNM), certified nurse specialist (CNS), and clinical psychologist.
² Nonphysician employees include registered nurses, licensed practical nurses, medical assistants, pharmacists (including PharmDs), and aides.
* Established patients only.

### Billing E/M Services

**What specifically are E/M services?**

These are evaluation and management services provided to a patient during the course of a patient encounter. E/M services may be provided by the physician, by a nonphysician practitioner, or they may be provided by nonphysician employees 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 such services may qualify. For example, anticoagulation clinic services may meet E/M requirements when the level of service provided and documented, such as a history, examination and recommendation to change warfarin dosage; dietary counseling and or re-education; evaluation of patient complaints of abnormal bruising or bleeding, etc., necessitate assessment and management by a physician or nonphysician practitioner, or by a member of the physician’s staff.

How are E/M services coded on reimbursement claims?

Physicians and nonphysician 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 nonphysician 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 nonphysician employee, only one E/M code may be reported, CPT code 99211.

If a significant and separately identifiable service is provided by the physician, nonphysician practitioner or nonphysician 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.

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Significant, separately identifiable evaluation and management service by the same physician or other qualified healthcare professional on the same day of the procedure or other service</td>
</tr>
</tbody>
</table>

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*

<table>
<thead>
<tr>
<th>Office/outpatient visit which requires these three key components:</th>
<th>E/M Code</th>
<th>99201</th>
<th>99202</th>
<th>99203</th>
<th>99204</th>
<th>99205</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>Problem focused</td>
<td>Expanding problem focused</td>
<td>Detailed</td>
<td>Comprehensive</td>
<td>Comprehensive</td>
<td></td>
</tr>
<tr>
<td>Examination</td>
<td>Problem focused</td>
<td>Expanding problem focused</td>
<td>Detailed</td>
<td>Comprehensive</td>
<td>Comprehensive</td>
<td></td>
</tr>
<tr>
<td>Medical decision making</td>
<td>Straight-forward</td>
<td>Straight-forward</td>
<td>Low complexity</td>
<td>Moderate complexity</td>
<td>High complexity</td>
<td></td>
</tr>
<tr>
<td>Nature of presenting problem</td>
<td>Self-limited or minor</td>
<td>Low to moderate severity</td>
<td>Moderate to high severity</td>
<td>Moderate to high severity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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)</td>
<td>10 minutes face-to-face with patient and/or family</td>
<td>20 minutes face-to-face with patient and/or family</td>
<td>30 minutes face-to-face with patient and/or family</td>
<td>45 minutes face-to-face with patient and/or family</td>
<td>60 minutes face-to-face with patient and/or family</td>
<td></td>
</tr>
<tr>
<td>Medicare Allowed Amount**</td>
<td>$44.20</td>
<td>$75.46</td>
<td>$109.60</td>
<td>$166.73</td>
<td>$209.49</td>
<td></td>
</tr>
</tbody>
</table>

* A new patient is defined as one who has not received any professional services from the physician/qualified health care professional or another physician/qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past three years.


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*

<table>
<thead>
<tr>
<th>Office/outpatient visit which requires two of these three key components:</th>
<th>E/M Code</th>
<th>99211†</th>
<th>99212</th>
<th>99213</th>
<th>99214</th>
<th>99215</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>NA</td>
<td>Problem focused</td>
<td>Expanding problem focused</td>
<td>Detailed</td>
<td>Comprehensive</td>
<td></td>
</tr>
<tr>
<td>Examination</td>
<td>NA</td>
<td>Problem focused</td>
<td>Expanding problem focused</td>
<td>Detailed</td>
<td>Comprehensive</td>
<td></td>
</tr>
<tr>
<td>Medical decision making</td>
<td>NA</td>
<td>Straight-forward</td>
<td>Low complexity</td>
<td>Moderate complexity</td>
<td>High complexity</td>
<td></td>
</tr>
<tr>
<td>Nature of presenting problem</td>
<td>Minimal</td>
<td>Self-limited or minor</td>
<td>Low to moderate severity</td>
<td>Moderate to high severity</td>
<td>Moderate to high severity</td>
<td></td>
</tr>
<tr>
<td>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)</td>
<td>5 minutes face-to-face with patient and/or family</td>
<td>20 minutes face-to-face with patient and/or family</td>
<td>15 minutes face-to-face with patient and/or family</td>
<td>25 minutes face-to-face with patient and/or family</td>
<td>40 minutes face-to-face with patient and/or family</td>
<td></td>
</tr>
<tr>
<td>Medicare Allowed Amount**</td>
<td>$20.12</td>
<td>$44.20</td>
<td>$73.30</td>
<td>$108.88</td>
<td>$146.97</td>
<td></td>
</tr>
</tbody>
</table>

* An established patient is defined as one who has received professional services from the physician/qualified health care professional or another physician/qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past three years.


† 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.

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Coding E/M Services by Physicians and Nonphysician Practitioner Staff

Which healthcare professionals does Medicare define as “nonphysician 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 five categories of staff:¹²

- Physician Assistant (PA)
- Nurse Practitioner (NP)
- Clinical Psychologist¹³
- Clinical Nurse Specialist (CNS)
- Certified Nurse Midwife (CNM)

How are nonphysician practitioner services billed? Nonphysician practitioners’ services may be billed either directly or as “incident to” a physician’s services.

To be able to bill Medicare directly, PAs, NPs, CNSs, and CNMs must obtain their own National Provider Identifier or NPI from CMS.¹⁴ Once they have a NPI, these nonphysician practitioners can bill Medicare directly and be paid directly. Even when nonphysician 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 nonphysician practitioner services are billed under the physician’s NPI, all “incident to” rules apply (see page 19).

Note: If a nonphysician 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 non-physician practitioner 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 nonphysician 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.

¹³ While clinical psychologists are defined as non-physician practitioners, given that they are not typically involved in the delivery of PT/NPI services, they will not be mentioned in the remainder of this document.
What documentation should the physician or nonphysician practitioner 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.

In determining the appropriate E/M code for a physician/patient encounter, 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?¹⁵

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).

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¹⁵ 99363: Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ration (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 or nonphysician practitioner 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, that are commonly included in the physician’s bills, and that are not separately paid under another benefit category. Physicians, non-physicians, 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 may be covered as “incident to” services when they are:16

• An integral, although incidental, part of the physician’s professional service (see §60.1);
• Commonly rendered without charge or included in the physician’s bill (see §60.1A);
• Of a type commonly furnished in physicians’ offices or clinics (see §60.1A);
• Furnished by the physician or by auxiliary personnel (nonphysician practitioners and nonphysician employees) under the physician’s direct supervision (see §60.1B).

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

Where might E/M services associated with PT/INR testing using CoaguChek XS Systems for Professional Use fit into the “incident to” requirements?

These services may fit under these 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 might be covered for performing services related to PT/INR testing and/or anticoagulation management “incident to” a physician service?

Examples fall into two categories: nonphysician practitioner staff and nonphysician employee staff.*

• Nonphysician employee 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.

• Nonphysician practitioner staff includes certain state-licensed nonphysician practitioners employed by the physician. For purposes of billing “incident to” services, nonphysician practitioner staff are limited to physician assistants (§110), nurse practitioners (§120), clinical nurse specialists (§120), certified nurse-midwives (§130), and clinical psychologists.17

Even if the specified nonphysician practitioner staff is 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 physician’s name and paid at the full physician rate.

Note: PAs, NPs, CNSs, CNMs, and CPs 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 nonphysician practitioner staff identified in the next section.

Coding “incident to” Services18

Note: This section applies to physician offices. For hospital clinic billing guidelines, see Coding and Payment of Hospital-Owned Clinic Services on page 24.

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 employee staff that provides the “incident to” services:

• When the services are furnished by a physician assistant (§110), nurse practitioner (§120), clinical nurse specialist (§120), certified nurse-midwife, or clinical psychologist (§130)19, the physician may bill the CPT code that describes the specific level of E/M service furnished20.

• When the services are furnished by nonphysician employee staff or by nonphysician practitioner staff other than the five categories listed above, the physician may bill only code 99211 for their services.

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Can nonphysician healthcare professionals bill above the E/M code of 99211?
The only healthcare professionals whose services can be reported listing E/M codes higher than 99211 are physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, and clinical psychologists.

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 24.

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). Legal counsel should be consulted about requirements for meeting “employee” status.

Aren’t leased employees really employed by the leasing company?
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 supervision” by the physician?
Direct 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.
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. As noted above, 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” direct supervision requirement. Note, if the physician performs the E/M service during a visit, only the physician’s E/M service may be billed. If the E/M service is a shared/split encounter between a physician and a non-physician practitioner, the E/M service may only be billed under the physician if the “incident to” requirements are met. If the requirements are not met, the shared/split E/M services must be billed under the non-physician practitioner.

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

They can only under specific circumstances. Nonphysician 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 are authorized under the Social Security Act to receive payment for services incident to his own services. Under those circumstances, the same requirements with respect to supervision apply 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 §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 generally apply to services performed in a physician direct clinic or group association. Per Medicare rules, a physician directed clinic is one 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.

In highly organized, departmentalized clinics, the physician who orders the initial service and the follow-up with “incident to” services may not be the physician who supervises the “incident to” service. However, the physician or nonphysician practitioner that supervises the “incident to” services must be part of the same practice in the same location as the ordering physician such that medical management of all services provided in the clinic is assured.
Can “incident to” services be billed by a hospital-owned anticoagulation clinic?

Services “incident to” physician services may also be provided by hospitals on an outpatient basis. These services must be furnished: (1) by the hospital and its personnel or under arrangements, (2) as an integral, although incidental, part of a physician’s or certain non-physician practitioner’s professional services, (3) in the hospital or in a department of the hospital that has provider-based status in relation to the hospital, (4) on the order of a physician or non-physician practitioner, and (5) under appropriate (generally direct) supervision. During any course of treatment provided by auxiliary personnel, the physician must personally see the patient initially and then periodically, sufficient to assess the course of treatment and the patient’s progress and, when necessary, to change the treatment regimen. “Direct supervision” means the physician must be immediately available and able to furnish assistance or direction through the procedure. While this does not require the physician to be present in the room where the procedure is performed, he must not be so far away that he cannot immediately assist.

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 hospital’s 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.
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) to the appropriate APC.

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

Since January 1, 2014, payment for most laboratory tests that are directly related and/or integral to a hospital outpatient service is packaged (i.e., bundled) into the APC for the applicable hospital outpatient service. Laboratory testing that is part of an APC is no longer reimbursement separately. For example, laboratory testing, including PT/INR testing, is generally not eligible for separate reimbursement, when performed in conjunction with a hospital clinic visit provided on the same date of service. Exceptions apply.22

Will HOPPS affect the way a hospital-owned clinic can bill for E/M services?

Effective January 1, 2014, under HOPPS, providers are required to bill hospital-owned clinic visits using Level II Healthcare Common Procedure Coding System (HCPCS) code G0463.23 The descriptor for Level II HCPCS code G0463 follows below:

- G0463 - Hospital outpatient clinic visit for assessment and management of a patient

In 2015, G0463 is assigned to APC 0634. The 2015 national payment amount for APC 0634 is $96.25.24 APC payment rates vary by geographic locality and facility.

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23 ibid

Under what circumstances may a hospital be reimbursed separately for PT/INR testing?

PT/INR testing may be reimbursed separately under the CLFS in the following circumstances:

- Specimen on which the PT/INR test is performed is from a beneficiary that is neither an inpatient nor an outpatient of the hospital;
- The hospital only provides the PT/INR (and/or other laboratory tests) to the patient and the patient does not also receive other hospital outpatient services during that same visit; or
- The hospital provides a PT/INR test, during the same encounter as other hospital outpatient services, that is clinically unrelated to the other hospital outpatient services, and the PT/INR test is ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services provided in the hospital outpatient setting.25

PT/INR tests performed by a hospital that are eligible for separate reimbursement must be submitted differently than other hospital services.26

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

Yes. There is generally no separate reimbursement for outpatient diagnostic laboratory tests performed by a hospital within 72 hours of an inpatient admission to that hospital. For those laboratory tests, including PT/INR tests, that would otherwise be eligible for separate reimbursement, hospitals must bundle these charges 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, is reimbursed at a predetermined rate for the Diagnosis-Related Group (DRG/MS-DRG) under the Inpatient Prospective Payment System.

26 Ibid
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 a separately billable service 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. Please check with your own legal and billing counselors 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 in available?

Medicare payment will be based on the Part B Clinical Laboratory Fee Schedule amount. In 2015, the Medicare NLA for PT/INR testing (85610) is $5.35. See page 11 for the 2015 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 is 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 Medicare 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 CoaguChek XS Systems for Professional Use could be used in a physician office or hospital-owned clinic, and how supporting medically necessary E/M 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 a 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 supervising the nurse and agrees with the recommended changes in the patient’s course of treatment.

In addition to reporting the PT/INR test—CPT code 85610—the physician may be able to bill for the incident to E/M services provided by the nurse, as long as the E/M services were medically necessary. Only one E/M code may be billed for a visit. Because the nurse is a nonphysician employee as specified by Medicare, the low level E/M code, 99211, if substantiated, may be appropriate to report. Only one E/M code may be billed for a visit.

This scenario applies to any nonphysician 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 a separately, identifiable E/M service were not met.

**Scenario C**

A physician performs a PT/INR test with a 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 nonphysician practitioner and nonphysician employee staff (listed on page 17) who might render E/M services.

**Scenario D**

A hospital outpatient department anticoagulation clinic performs a PT/INR test on a patient with a 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. 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 is generally not reimbursed separately; however, the medically necessary clinic visit performed by the nonphysician employee could be eligible for reimbursement at the appropriate APC rates.
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/INR Test

PT/INR test performed in physician office with supporting E/M service

Was patient seen by the physician on that visit?  
- No
  Did employee or contractor of physician provide medically necessary E/M services?  
    - No
      It would not be appropriate to report a separate E/M service.
    - Yes
      Did separate and distinct services meet “incident to” criteria?  
        - No
          Physician may be able to report employee’s separate and distinct medically necessary E/M service using CPT code 99211. Physician supervision requirements must be met.
        - Yes
          Was employee a nonphysician practitioner?  
            - No
              Nonphysician practitioner may be able to bill independently for separate and distinct medically necessary E/M services using an E/M code that reflects the level of service. Physician supervision requirements must be met.*
            - Yes
              It may be appropriate to report physician’s medically necessary E/M services using E/M code that reflects the level of service.

* Nonphysician practitioners are defined as physician assistants (PA), nurse practitioners (NP), certified nurse midwife (CNM), certified nurse specialist (CNS), and clinical psychologist. Nonphysician employees include registered nurses, licensed practical nurses, medical assistants, pharmacists (including PharmDs), and aides.
Reimbursement of Home PT/INR Monitoring

Since 2008, Medicare has covered home PT/INR monitoring for eligible patients with mechanical heart valve, chronic atrial fibrillation and venous thromboembolism (VTE). These services are covered and reimbursed by Medicare 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.

Patient Eligibility

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

Medicare coverage is available for home 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.

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; and,
- 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; and,
- The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring; and,
- Self-testing with the device should not occur more frequently than once a week.

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

<table>
<thead>
<tr>
<th>Benefit Component</th>
<th>Provider</th>
<th>Code</th>
<th>Short Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide face-to-face training on the use of the home PT/INR monitor</td>
<td>Provider or IDTF</td>
<td>G0248</td>
<td>Demonstrate use home INR mon</td>
</tr>
<tr>
<td>Issue PT/INR monitoring equipment and supplies to the patient for home testing</td>
<td>Provider or IDTF</td>
<td>G0249</td>
<td>Provider INR test mater/equip</td>
</tr>
<tr>
<td>Physician review and interpretation of results and patient management</td>
<td>Provider</td>
<td>G0250</td>
<td>MD INR test review inter mgmt</td>
</tr>
</tbody>
</table>

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 under the reimbursement of G0249.

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 codes), patients still need to confer with their physician for review and interpretation of the results (the professional code) as well as any follow-up treatment planning.

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

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

CMS has designated three Level II Healthcare Common Procedure Coding System (HCPCS) codes for billing home PT/INR monitoring. These codes are paid under the Medicare physician fee schedule.

G0248 Demonstration, prior to initiation 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’s ability to perform testing and report results

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; testing not occurring more frequently than once a week; testing materials, billing units of service include 4 tests

G0250 Physician review, interpretation, and patient management of home INR testing for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; testing not occurring more frequently than once a week; billing units of service include 4 tests

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, generally, 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 services?
An IDTF can provide and bill the technical codes—G0248 and G0249. It cannot provide the professional code—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 codes—G0248 and G0249—are billable by the hospital. The professional code—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
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:

<table>
<thead>
<tr>
<th>Code</th>
<th>Short Descriptor</th>
<th>2015 Medicare Allowed Amount*</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0248</td>
<td>Demonstrate use home INR mon</td>
<td>$112.83</td>
</tr>
<tr>
<td>G0249</td>
<td>Provide INR test mater/equipm</td>
<td>$112.47 per 4 tests</td>
</tr>
<tr>
<td>G0250</td>
<td>MD INR test review inter mgmt</td>
<td>$9.34 per 4 tests</td>
</tr>
</tbody>
</table>

* 2015 Medicare Physician Fee Schedule payment amounts effective July 1, 2015
Source: 2015 Physician Fee Schedule Relative Value File (PPRVU15_UP05_0515.xlsx). Payment rates listed do not reflect geographic adjustments; local rates will vary.
How are the technical codes paid under the HOPPS?
Under the hospital outpatient prospective payment system, home PT/INR testing services are reimbursed under Ambulatory Payment Classifications (APCs).

<table>
<thead>
<tr>
<th>HCPSC Code</th>
<th>2015 APC</th>
<th>Short Descriptor</th>
<th>2015 National Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0248</td>
<td>0632*</td>
<td>Demonstrate use home INR mon</td>
<td>$106.27</td>
</tr>
<tr>
<td>G0249</td>
<td>0632*</td>
<td>Provide INR test mater/equip</td>
<td>$106.27 per 4 tests</td>
</tr>
</tbody>
</table>

* 2015 Hospital Outpatient Prospective Payment System rates effective January 1, 2015
  http://www.cms.gov/Medicare/Medicare-Fee-for-Service-
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.

What is the patient’s financial responsibility for home PT/INR testing?
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 2015, the minimum unadjusted copayment amount is $21.26.

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.
<table>
<thead>
<tr>
<th>State Name</th>
<th>Locality Name</th>
<th>G0248: Demonstrate use home INR monitoring</th>
<th>G0249: Provide INR test materials/equipment</th>
<th>G0250: MD INR test review, interpretation, management</th>
</tr>
</thead>
<tbody>
<tr>
<td>National</td>
<td>National</td>
<td>$112.83</td>
<td>$112.47</td>
<td>$9.34</td>
</tr>
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<td>$99.77</td>
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<td>$97.39</td>
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<td>Anaheim/Santa Ana</td>
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<td>$136.66</td>
<td>$10.08</td>
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<td>Los Angeles</td>
<td>$130.82</td>
<td>$130.49</td>
<td>$10.02</td>
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<tr>
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<td>Marin, Napa, Solano</td>
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<td>$144.35</td>
<td>$10.26</td>
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<td>Oakland/Berkeley</td>
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<td>Ventura</td>
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<td>$132.59</td>
<td>$9.93</td>
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<tr>
<td>California</td>
<td>All Other Areas</td>
<td>$121.89</td>
<td>$121.65</td>
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<tr>
<td>Colorado</td>
<td>Statewide</td>
<td>$114.13</td>
<td>$113.74</td>
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<td>$126.56</td>
<td>$126.12</td>
<td>$9.89</td>
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<td>Delaware</td>
<td>Statewide</td>
<td>$116.37</td>
<td>$115.98</td>
<td>$9.53</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>DC + MD/VA Suburbs</td>
<td>$136.02</td>
<td>$135.56</td>
<td>$10.29</td>
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<td>Miami</td>
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</tr>
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<td>All Other Areas</td>
<td>$108.57</td>
<td>$108.10</td>
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<td>Atlanta</td>
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<td>Georgia</td>
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<td>Statewide</td>
<td>$101.04</td>
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</table>

* Fee information obtained through CMS website; no independent verification of data is claimed or implied. (Source: http://www.cms.gov/apps/physician-fee-schedule/overview.aspx – Accessed July 1, 2015). This information does not apply to hospital outpatient facilities.
### 2015 Medicare Physician Fee Schedule, HCPCS Code G0248, G0249, G0250*

<table>
<thead>
<tr>
<th>State Name</th>
<th>Locality Name</th>
<th>G0248: Demonstrate use home INR monitoring</th>
<th>G0249: Provide INR test materials</th>
<th>G0250: MD INR test review, interpretation,</th>
</tr>
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<tr>
<td>Illinois</td>
<td>East St. Louis</td>
<td>$106.07</td>
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<tr>
<td>Illinois</td>
<td>Suburban Chicago</td>
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<tr>
<td>Indiana</td>
<td>Statewide</td>
<td>$103.70</td>
<td>$103.48</td>
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</tr>
<tr>
<td>Iowa</td>
<td>Statewide</td>
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<table>
<thead>
<tr>
<th>State Name</th>
<th>Locality Name</th>
<th>G0248: Demonstrate use home INR monitoring</th>
<th>G0249: Provide INR test materials</th>
<th>G0250: MD INR test review, interpretation</th>
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2015 Medicare Physician Fee Schedule, HCPCS Code G0248, G0249, G0250*

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<tbody>
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For Additional Information

• Healthcare professionals with reimbursement questions concerning CoaguChek XS Systems for Professional or Home Use may contact the Roche Diagnostics Corporation Health Policy & Reimbursement Team by telephone or email:

  Reimbursement Email Inquiries:
  diagnostics.reimbursement@roche.com

  Reimbursement Inquiry Line:
  1-800-428-5074 x 13967
  (24/7 voicemail inquiry system)

• For details regarding the Medicare policies and guidelines discussed in this handbook, consult the “Manuals” pages of the CMS web site or contact your local Medicare contractor.

• To contact the Medicare Administrative Contractor, Medicare Fiscal Intermediary or Medicare Part B Carrier in your specific locality, consult the CMS web site at: www.cms.gov.