

# ProTime<sup>®</sup>

Microcoagulation System



## Reimbursement Module

Reference guide to answer questions on reimbursement, coding and cost benefits

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## LIMITS ON COVERAGE AND PAYMENT

Reimbursement information is provided to help customers understand billing for home prothrombin time (PT) monitoring for anticoagulation management. This document is meant to provide information as a guide and not a statement of ITC or any other policy. Providers of home PT/INR or anticoagulant management services should direct all inquiries regarding billing issues directly to the respective payer. Some insurers publish policies with respect to coding, coverage, and payment. Providers should fully comply with guidance provided by particular insurers, including Medicaid and Medicare. It is the provider's responsibility to submit claims in a manner that accurately reflects the products and services provided using the codes that appropriately describe the patient's condition. Providers should contact the appropriate insurer to confirm codes and coverage.

## BENEFITS OF HOME MONITORING OF PT/INR

The ITC ProTime Microcoagulation System has been shown to be an accurate, reliable method for home monitoring of PT/INR. Home testing has proven to be highly effective in improving patient outcomes and avoiding potentially serious and costly complications due to fluctuating INR values. You and your patients will appreciate these facts:

- Patients who test regularly maintain their therapeutic range more often. CMS states "...in order to achieve time in therapeutic range of >90%, a patient most likely needs to be tested once a week."\*
- Frequent testing can help reduce the incidence of anticoagulation-related complications, thereby reducing the cost of therapy.\*\*
- The ability to quickly obtain test results makes it possible for you to intervene before an adverse event might occur.
- Eliminating the need for patients to travel to a medical facility or lab for routine blood tests is more convenient for patients and improves patient compliance.

The following pages provide information on reimbursement for home monitoring of PT/INR.

\*Home INR Monitor Decision Memorandum issued by the Centers for Medicare and Medicaid Services (CMS) in September 2001.

\*\*Ansell J. An international perspective on advances in the management of oral anticoagulation. Proceedings of the XVII Congress of the International Society on Thromb and Haemostasis, 1999.

## PROTIME PATIENT SELECTION CRITERIA

A key to making patient self-testing a win-win strategy for you and your patients begins with an understanding of how to identify patients who are the appropriate candidates for the ITC ProTime Microcoagulation HomeTest™ Program. This decision-making process can directly impact your patient's medical outcome, his or her quality of life, and your ability to receive reimbursement.

Consider the following as you evaluate which of your patients can benefit from home testing:

- Patients or caregivers who are capable of understanding anticoagulation management, and who demonstrate a willingness to participate in patient training and an education program prior to self-testing at home.
- Patients or caregivers who have the ability to understand and perform the test at home.
- Patients or caregivers who are willing to make a commitment to be compliant in performing weekly home testing.

## COVERAGE FOR HOME PT/INR TESTING

Coverage is the threshold issue of whether an issuer will pay for the procedure and/or product. Coverage is based on the insurers determination that the procedure/product is reasonable and necessary for the particular patient.

There are three types of payers:

- Medicare
- Medicaid
- Private Insurers/Payers

### **Medicare Coverage for Home Testing**

- The patient must have a mechanical heart valve;
- The monitor and self-testing must be prescribed by a physician;
- The patient must have been anticoagulated for at least three (3) months;
- The patient or caregiver must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and
- Coverage of home PT/INR testing with the device is limited to a frequency of once (1) per week.

### **Medicaid Coverage**

- Medicaid reimbursement is based on State and Federal guidelines for services rendered to patients with low incomes.

### **Private Insurers/Payers**

Private insurers often follow Medicare. However, they offer a wide array of fee for service for managed care programs. Providers should contact the appropriate payer for the particular patient.

**Note: As with all medical procedures, we recommend that you evaluate your patient's coverage and discuss coverage with your patient before rendering services so as to avoid misunderstandings and potential issues associated with payment.**

## PRACTICE REMINDER

Payment for services related to home PT/INR testing requires that:

- The test and service is medically necessary
- The correct codes are used:
  - Diagnosis codes
  - Procedure codes
- The appropriate levels of documentation is made for the level of services provided to the patient

## PATIENT'S ROLE IN PROTIME HOME TESTING

- The patient is identified as a candidate that could benefit from home self-testing.
- If the patient demonstrates the capacity to take an active role in reporting their INR values with home testing, the physician makes the decision to allow them to “graduate” to home testing.
- The patient completes training with an IDTF, a nurse, or a physician. The primary purpose of this training is to ensure that the patient demonstrates the ability to use the ProTime and what to do based on the results.
- Once the patient begins home testing for PT/INR, the patient reports results to an IDTF or directly to the physician.
- Patient continues to follow-up with the physician as medically necessary.

**Note: Physicians may test for PT/INR either in their office or send to the lab without affecting the home testing program or reimbursement. Office PT/INR testing is paid under the lab fee schedule and not the Medicare Physician Fee Schedule. The lab fee schedule is a distinct and separate system by which Medicare pays providers who provide certain laboratory tests such as PT/INR.**

## INDEPENDENT DIAGNOSTIC TESTING FACILITIES (IDTF)

An Independent Diagnostic Testing Facility (IDTF) is defined as an entity that is independent of a hospital or a physician's office that can perform diagnostic testing by licensed or certified non-physician personnel under appropriate physician supervision and is independent of the patient's physician or a hospital.

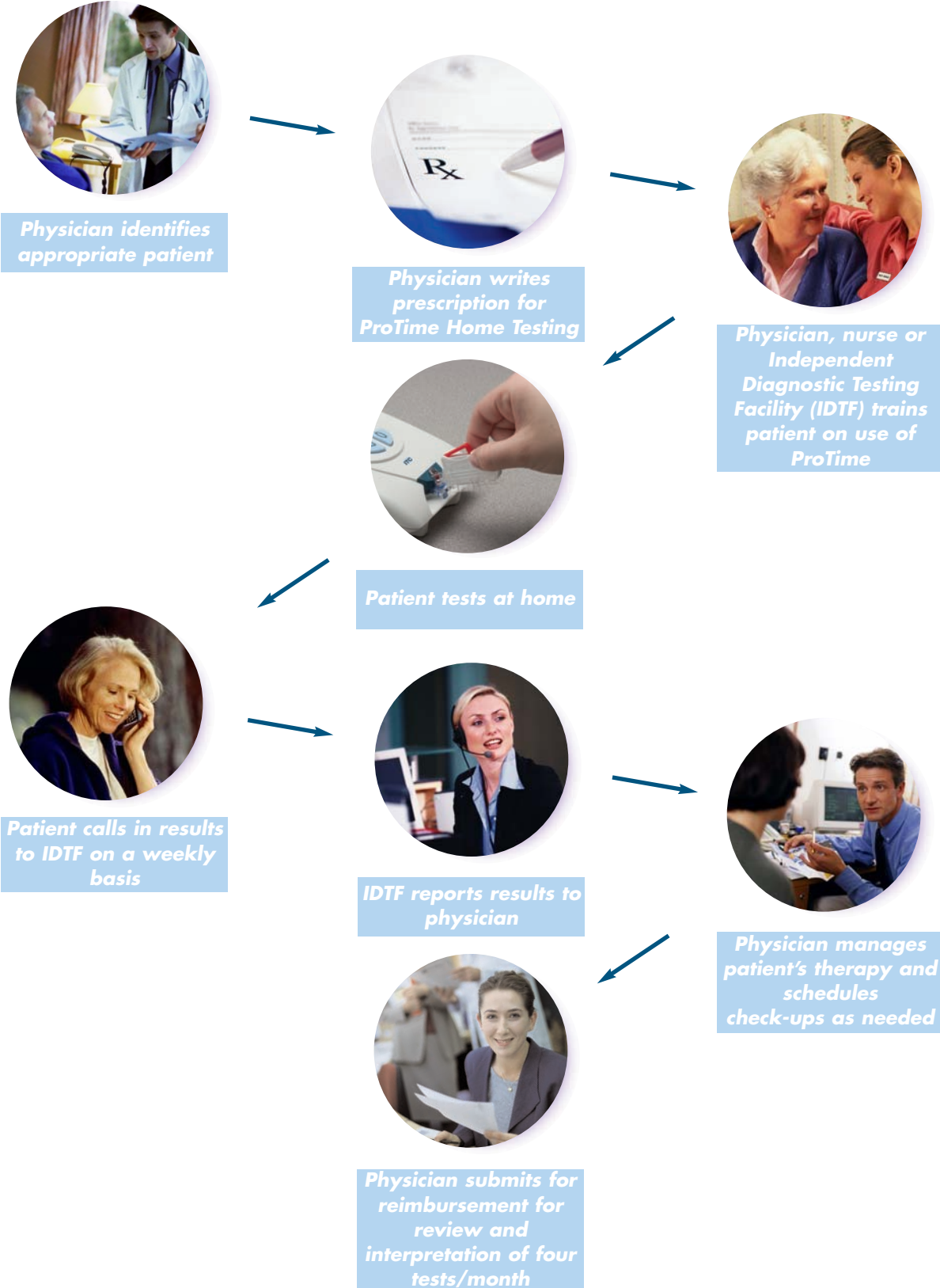
The IDTF must comply with the applicable laws of any state in which it operates. The IDTF in this model provides patient oversight with the monitoring services and supplies meters and test cuvettes to patients. The IDTF functions as the primary liaison between the patient and physician by monitoring the patient on a weekly basis and by providing results to the physician for evaluation and interpretation. The IDTF may submit claims directly to the payer for supplying the patient with PT/INR home test equipment. The IDTF can also provide training to patients and receive reimbursement for the training.

**Note: Physicians can also provide meters, test cuvettes and training to patients and receive payment for these services.**

# REIMBURSEMENT STRATEGIES

## **Scenario Number One – Physician Refers Patient to an IDTF to Help Manage the Patient**

In this scenario, the physician performs ProTime testing in the office. However, in an effort to improve patient flow and enhance care for existing patients, the physician may refer a patient to an IDTF. The IDTF can dispense the home PT/INR equipment and supplies to the patient and report the results to the physician.



### **Physician's Role:**

- Identifies appropriate patients for home testing
- Provides training to the patient or refers patient to an IDTF for training

### **Physician's Reimbursement:**

- Reviewing and managing the home PT/INR results each month
- Periodic in-office evaluation and management and ProTime testing as needed

### **Example Scenario Number One:**

Patient John Doe is a mechanical heart-valve patient who has Medicare coverage and has been on warfarin therapy for more than three months. After discussion with patient during a follow-up visit, the physician decides that John Doe is a good candidate for home testing. Physician/staff provide John training on the use of the home testing equipment. Physician chooses to use an IDTF to provide the supplies.

- The Physician's Office Laboratory (POL) also uses a ProTime and tests John Doe's PT during scheduled visits.

The properly completed claim form could include the following:

### **Diagnosis Code**

<b>Code Type</b>	<b>Code</b>	<b>Description</b>	<b>2005 Payment*</b>
ICD-9-CM	V43.3	Organ or tissue replaced by other means; heart valve	NA

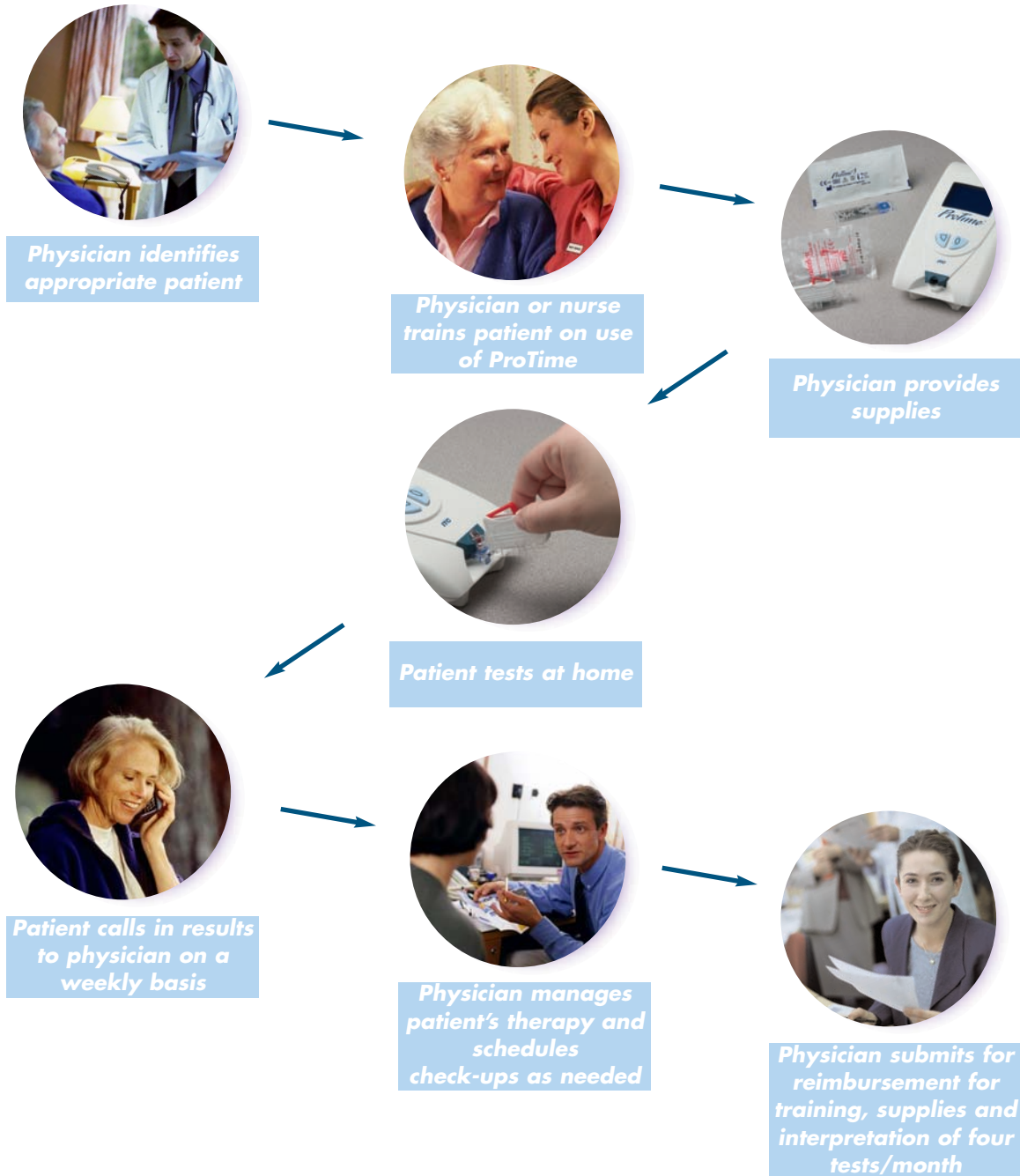
### **Procedure Code**

<b>Code Type</b>	<b>Code</b>	<b>Description</b>	<b>2005 Payment*</b>
CPT	99211-99215	Evaluation and Management (E&M) of Established Patient (as needed)	\$21.60 - \$120.14
	85610QW	Prothrombin Time (QW indicates a CLIA-waived test)	\$5.49
HCPCS	G0250	Physician review and interpret test results at four tests/month	\$9.47
	G0248	Physician demonstrates use of the home device	\$250.88

\*Payments are intended as a reference. Payment rates are updated annually. Refer to the Physician Fee Schedule at <http://www.cms.hhs.gov/providers> for more details.

## **Scenario Number Two – Physician Provides the Home PT/INR Supplies**

Some physicians prefer to be highly involved in the INR monitoring of patients from the initial training, and then on a monthly basis after the patient graduates to home PT/INR testing. In this scenario, the physician may perform PT/INR testing in the office. In addition, the physician may purchase and supply the home equipment to their patients, and provide continuous surveillance and tracking of all the PT/INR test results.



### **Physician's Role:**

- Identifies and trains patient for home PT/INR testing
- Provides test kits and supplies for home testing

### **Physician's Reimbursement:**

- Training the patient
- Providing the home PT/INR test kit and supplies
- Reviewing the weekly INR results phoned in by the patient
- Periodic in-office patient check-ups and ProTime PT testing

### **Example Scenario Number Two:**

Patient John Doe is a mechanical heart-valve patient who has Medicare coverage and has been on warfarin therapy for more than three months. After review of the patient's situation and discussion with patient during a follow-up visit, the physician decides that John Doe is a good candidate for home testing.

- The physician or a nurse gives the patient a demonstration and training on how to use the home test equipment.
- A ProTime PT test is performed in the office.
- The physician provides home test equipment.

The properly completed claim form could include the following:

### **Diagnosis Code**

<b>Code Type</b>	<b>Code</b>	<b>Description</b>	<b>2005 Payment*</b>
ICD-9-CM	V43.3	Organ or tissue replaced by other means; heart valve	NA

### **Procedure Code**

<b>Code Type</b>	<b>Code</b>	<b>Description</b>	<b>2005 Payment*</b>
CPT	99211-99215	Evaluation and Management (E&M) of Established Patient (as needed)	\$21.60 - \$120.14
	85610QW	Prothrombin Time (QW indicates a CLIA-waived test)	\$5.49
HCPCS	G0248	Demonstrate use home INR monitor (one-time only)	\$250.88
	G0249	Provision of test material and equipment at four tests/month	\$150.45
	G0250	Physician review and interpret test results at four tests/month	\$9.47

\*Payments are intended as a reference. Payment rates are updated annually. Refer to the Physician Fee Schedule at <http://www.cms.hhs.gov/providers> for more details.

### ***Scenario Number Three – PT/INR Monitoring in Physician’s Office Laboratory (POL) or Anticoagulation Clinic (AC)***

The physician or a registered nurse provides standard Evaluation and Management (E&M) services, performs the scheduled ProTime test in the office, discusses patient’s treatment, and updates the patient record. For this service the physician is reimbursed for the office visit and the ProTime test performed. The physician may also choose to send the patient to an anticoagulation clinic. If a clinic is doing the testing, the physician is only reimbursed for the periodic in-office patient check-up at their discretion. The clinic is able to bill for the ProTime test.



The properly completed claim form could include the following:

#### ***Diagnosis Code***

<b>Code Type</b>	<b>Code</b>	<b>Description</b>	<b>2005 Payment*</b>
ICD-9-CM	V43.3	Organ or tissue replaced by other means; heart valve	NA

#### ***Procedure Code***

<b>Code Type</b>	<b>Code</b>	<b>Description</b>	<b>2005 Payment*</b>
CPT	99211-99215	Evaluation and Management (E&M) of Established Patient (as needed)	\$21.60-\$120.14
	85610QW	Prothrombin Time (QW indicates a CLIA-waived test)	\$5.49

\*Payments are intended as a reference. Payment rates are updated annually. Refer to the Physician Fee Schedule at <http://www.cms.hhs.gov/providers> for more details.

# GLOSSARY OF CODING AND REIMBURSEMENT TERMS

Reimbursement covers diagnostic laboratory tests like the prothrombin time (PT) when clinical data and patient care documentation support medical necessity. However, reimbursement (coverage, coding, and payment) policies can vary. The following glossary of key coding and reimbursement terms is provided as an overview to help in understanding the codes and reimbursement:

- **Coding** – Coding describes the procedures, products, and services provided to the patient.
- **Coverage** – Coverage refers to whether a payer will consider the test/service medically necessary.
- **Diagnosis** – Diagnosis codes determine whether procedures and drugs are necessary and covered.
- **Payment** – Payment determines who and how much is paid. Payment and payment methods vary depending on the practice setting. For example, Medicare has developed different payment systems for various practice settings.

The basic coding for reimbursement of the ProTime Microcoagulation System includes the following:

- **CPT® Codes** – Current Procedural Terminology (CPT) codes describe the services, tests and supplies furnished to the patient. CPT codes are copyrighted and updated annually by the American Medical Association (AMA).
- **ICD-9-CM Codes** – International Classification of Diseases, Ninth Revision, and Clinical Modifications (ICD-9-CM) codes refer to the diagnosis code that accurately describes the patient's condition and is required to ensure payment and coverage.
- **ICD-9 Codes** – Identify the patient's disease, or diagnosis, to justify medical necessity and explain "why" the service was provided.
- **HCPCS Codes** – HealthCare Common Procedure Coding System (HCPCS) codes describe a number of procedures, services, and supplies that are provided to the patient.
- **POS Codes** – Place of Service (POS) codes refer to coding for services provided either in a physician's office or an independent laboratory.

## REIMBURSEMENT CODING AND PAYMENT EXPLAINED

### ***Coding, Coverage, and Payment for Anticoagulation Management and PT Testing***

Management of a patient's anticoagulation therapy requires more than simply performing a laboratory test to check a patient's PT. A health care practitioner must review and interpret the test results, sometimes change the drug dose, and overall, evaluate the patient. Patient evaluations may include physical examinations, drug prescription, dose adjustments, and patient education.

### ***Payment***

Reimbursement for PT testing and all other medical management services require that:

- The test and service is covered
- The correct codes are used; and
- The appropriate level of documentation is completed.

## Coding and Billing

In every practice setting, providers need to submit a bill or claim to the payer (insurer) in order to receive reimbursement. The bill or claim form must list the services, tests, and supplies that were furnished to the patient.

Medicare and other payers have adopted a coding system (short-hand) for reporting these services and items. The basic coding systems include:

- Current Procedural Terminology (CPT) codes are used to describe the services and tests furnished to the patient. CPT codes are updated annually by the American Medical Association (AMA).
- International Classification of Diseases, Ninth Revision, Clinical Modifications (ICD-9-CM) Diagnosis Codes are used to describe why it is medically necessary to provide care.
- HealthCare Common Procedure Coding System (HCPCS) codes, describe a number of procedures, services, and supplies.

Many Medicare and private insurers have established policies for PT/INR testing. These policies will list an array of diseases where PT/INR testing is appropriate. Examples of ICD-9 Codes are listed below. Please consult with payer for current ICD-9 Codes and report the ICD-9 Code that most accurately reflects the patient's disease or condition.

### ICD-9 Codes that Demonstrate Medical Necessity

ICD-9 Codes	Descriptor
V43.4	Organ or tissue replaced by other means; heart valve
58.61	Long term (current) use of anticoagulants
070	Viral hepatitis
286	Coagulation defects
287	Purpura and other hemorrhagic conditions
410	Acute myocardial infarction
269.0	Deficiency in Vitamin K
286.0	Congenital Factor VIII disorder
286.1	Congenital Factor IX disorder
286.2	Congenital Factor XI disorder
286.3	Congenital deficiency with vascular defect
286.4	Factor VIII deficiency with vascular defect
286.5	Hemorrhagic disorder due to circulating anticoagulants
286.6	Diffuse or disseminated intravascular coagulation (DIC syndrome)
286.7	Acquired coagulation factor deficiency
286.9	Other and unspecified coagulation factors
571	Chronic liver disease and cirrhosis
573.9	Hepatocellular dysfunction, NEC
574	Chollelithiasis
776	Hematological disorders of fetus and newborn
790.92	Abnormal coagulation profile
964.2	Poisoning by Coumadin or warfarin sodium

## Medicare HCPCS Codes that Describe Services Related to Home INR Monitoring

HCPCS Code Payment*	Descriptor	2005 POL/HOP
G0248	Demonstration at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician. Includes demonstration 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 a patient's ability to perform testing.  Short Description: Demonstrate use home INR monitor	\$250.88/\$150
G0249	Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria. Includes provision of materials for use in the home and reporting of test results to physician; per four tests.  Short Description: Provide test material, equipment	\$150.45/\$150
G0250	Physician review; interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per four tests (does not require face-to-face service, can be done by phone). Note: Under HOPPS, this code is billed by and paid to the physician, and not paid to the hospital facility. Should not be billed more than once per four weeks.  Short Description: Physician review and interpretation of test	\$9.47/NA

\*Payments are intended as a reference. Payment rates are updated annually. Refer to the Physician Fee Schedule at <http://www.cms.hhs.gov/providers> for more details.

## CPT Code for PT/INR Test in Physician Office Lab (POL) or Hospital Outpatient Setting (HOP)

CPT Code Payment*	Description	2005
85610 or 85610QW	Prothrombin Time: Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, Coumadin or warfarin effect; screen for Vitamin K deficiency. (The QW modifier indicates a CLIA waived test)	\$5.49

\*Payments are intended as a reference. Payment rates are updated annually. Refer to the Physician Fee Schedule at <http://www.cms.hhs.gov/providers> for more details.

## **Evaluation and Management (E&M) CPT Codes for Physician's Office Laboratory (POL) or Hospital Outpatient (HOP) for NEW Patients**

Appropriate E&M codes can be determined by the patient's condition and level of service provided, and can be billed together with the HCPCS "G" codes described earlier, or the 85610/85610QW

<b>CPT Code Rate</b>	<b>E&amp;M of NEW Patients</b>	<b>2005 Payment* POL/HOP</b>
	Office and outpatient visit for the E&M of a new patient, which requires these three key components:	
99201	<ul style="list-style-type: none"> <li>• A problem-focused history</li> <li>• A problem-focused examination</li> <li>• Straightforward medical decision making</li> </ul> <p>Usually the presenting problem(s) is self-limiting or minor</p>	\$36.76/\$51.47
99202	<ul style="list-style-type: none"> <li>• An expanded problem focused history</li> <li>• An expanded problem focused examination</li> <li>• Straightforward medical decision making</li> </ul> <p>Usually the presenting problem(s) is low-to-moderate severity</p>	\$65.18/\$51.47
99203	<ul style="list-style-type: none"> <li>• A detailed history</li> <li>• A detailed examination</li> <li>• Medical decision making of low complexity</li> </ul> <p>Usually the presenting problem(s) is of moderate severity</p>	\$97.02/\$56.11
99204	<ul style="list-style-type: none"> <li>• A comprehensive history</li> <li>• A comprehensive examination</li> <li>• Medical decision making of moderate complexity</li> </ul> <p>Usually the presenting problem(s) is of moderate-to-high severity</p>	\$137.19/\$79.65
99205	<ul style="list-style-type: none"> <li>• A comprehensive history</li> <li>• A comprehensive examination</li> <li>• Medical decision making of high complexity</li> </ul> <p>Usually the presenting problem(s) is of moderate-to-high severity</p>	\$173.57/\$79.65

\*Payments are intended as a reference. Payment rates are updated annually. Refer to the Physician Fee Schedule at <http://www.cms.hhs.gov/providers> for more details.

**Evaluation and Management (E&M) CPT Codes for Physician’s Office Laboratory (POL) or Hospital Outpatient (HOP) for ESTABLISHED Patients**

Appropriate E&M codes can be determined by the patient’s condition and level of service provided, and can be billed together with the HCPCS “G” codes described earlier, or the 85610/85610QW

<b>CPT Code Rate</b>	<b>E&amp;M of ESTABLISHED Patients</b> Office/outpatient visit for the E&M of an <b>established</b> patient, which requires two of these three key components:	<b>2005 Payment*</b> <b>POL/HOP</b>
99211	May not require the presence of a physician. Usually the presenting problem(s) is minimal.	\$21.60/\$51.47
99212	<ul style="list-style-type: none"> <li>• A problem-focused history</li> <li>• A problem-focused examination</li> <li>• Straightforward medical decision making</li> </ul> Usually the presenting problem(s) is self-limited or minor	\$38.66/\$51.47
99213	<ul style="list-style-type: none"> <li>• An expanded problem focused history</li> <li>• An expanded problem focused examination</li> <li>• Medical decision making of low complexity</li> </ul> Usually the presenting problem(s) is low-to-moderate severity	\$52.68/\$56.11
99214	<ul style="list-style-type: none"> <li>• A detailed history</li> <li>• A detailed examination</li> <li>• Medical decision making of moderate complexity</li> </ul> Usually the presenting problem(s) is moderate-to-high severity	\$82.62/\$79.65
99215	<ul style="list-style-type: none"> <li>• A comprehensive history</li> <li>• A comprehensive examination</li> <li>• Medical decision making of high complexity</li> </ul> Usually the presenting problem(s) is moderate-to-high severity	\$120.14/\$79.65

\*Payments are intended as a reference. Payment rates are updated annually. Refer to the Physician Fee Schedule at <http://www.cms.hhs.gov/providers> for more details.

## FREQUENTLY ASKED QUESTIONS

### **Coding:**

**Q: What HCPCS code can be used to bill for services and supplies related to home PT/INR monitoring?**

A: Providers should bill Medicare using the following “G” codes that describe the service/product provided: GO248, GO249 and GO250. These are to be billed by the physician or IDTF.

**Q: What CPT code(s) can be used to bill for the related evaluation and management services?**

A: When a doctor (or advance practice practitioner) provides evaluation and management (E&M) services to a patient in conjunction with home PT INR monitoring, the provider can use the appropriate E&M CPT code describing the level of care provided. The E&M code reported might be one of several codes, beginning with CPT code 99201 – 99215, depending on a patient's condition and the services provided.

**Q: Do physicians report the same HCPCS codes for home PT/INR services/supplies as IDTF and hospital outpatient departments for billing purposes?**

A: Yes. Physicians, IDTFs, and hospital outpatient departments use the HCPCS and CPT codes that most accurately describe the service/items provided.

**Q: What diagnosis code(s) supports the medical necessity for home PT/INR monitoring?**

A: Providers should use the ICD-9-CM diagnosis code that most accurately describes the patient’s condition. For example, Medicare covers home PT/INR monitoring for patients with a mechanical heart valve(s) that have been on anticoagulation therapy for three months.

### **CLIA:**

**Q: Do physicians’ offices need a CLIA certificate to provide home PT/INR monitoring services?**

A: The home PT/INR monitoring coverage decision does not address CLIA certificates or other requirements that Medicare generally requires for laboratory tests. The physician does not need to obtain a CLIA certificate to provide services if the patient uses the equipment at home to perform the tests and reports the results to the physician (or IDTF). However, providers do need a CLIA certificate if they are performing prothrombin time tests in their office/facility.

### **Claims Processing/Billing:**

**Q: What can providers do to facilitate payment for home PT/INR monitoring and related services?**

A: To ensure appropriate reimbursement, claims should be coded to accurately and fully report the procedures performed and the patient's condition with the **appropriate ICD-9 diagnosis code**. Documentation in the patient records should accurately reflect the services provided to patients. If a question arises, the physician may need to prepare and send a letter of medical necessity to the insurer. Two of the most common reasons that claims are denied are:

- ICD-9-CM code was not included on the claim form.
- The claim form was not completely filled out – some elements were missing.

**Q: Does the physician need to see the patient face-to-face to bill “G0250 physician review; interpretation and patient management?”**

A: No. Face-to-face service is not required. Physicians may consult with patients by telephone.

### **Coverage:**

**Q: Does Medicare cover home PT/INR monitoring for patients with atrial fibrillation or stroke?**

A: No. Medicare currently covers home PT INR monitoring only for patients with mechanical heart valves who have been on anticoagulation therapy for three (3) months. Some private payers may cover home PT INR monitoring for additional indications. Providers should contact the applicable payer for more information.

**Q. Can physicians prescribe the ProTime for self-testing at home to patients with mechanical heart valves immediately upon hospital discharge?**

- A. Physicians can prescribe a home ProTime monitor for use at anytime. However, Medicare does not cover home testing devices or monitoring services during the first three months of anticoagulant therapy. The purpose of the three-month window is to ensure that patients who are new to anticoagulation therapy are appropriately monitored and that their PT/INR is stable. Since PT testing is appropriate during the first three months following a mechanical heart valve placement, Medicare does cover and pay for medically necessary PT testing performed in physician offices and independent labs if the providers are qualified to perform such tests. Medicare also reimburses physicians for patient evaluation and management services.

***Patient Co-pay Issues:***

**Q. What are the out-of-pocket patient costs for home PT supplies and services?**

- A. All Medicare patients must pay an annual Part B1 deductible amount of \$100 before Medicare will cover medical expenses. Patients are responsible to pay 20 percent of the Medicare approved amount after they meet the deductible; however, supplemental policies may cover the co-pay balance.

***Hospital Outpatient Clinic Testing:***

**Q. How does Medicare reimburse hospital outpatient clinics for PT testing?**

- A. Hospital outpatient clinics are reimbursed under the hospital outpatient prospective payment system (HOPPS).

***Private Insurance Coverage:***

**Q. Do private insurers reimburse (cover and pay) for PT home self-testing?**

- A. Many private insurers cover and pay for home PT testing devices and associated services. Private insurers generally negotiate with providers and pay for services according to contracted/negotiated rates. For more specific information regarding coverage or payment, contact a particular insurer directly.

***Veterans Administration Coverage for PT Testing:***

**Q. Are home PT testing devices available to veterans through the Veterans Administration (VA) hospital system?**

- A. The VA system is different from Medicare. VA hospitals and military hospitals purchase and pay for medical products and services and provide these items directly to their patients. Some VA medical centers provide patient self-testing options.

***Skilled Nursing Facilities (SNF):***

**Q: Does Medicare pay for PT tests in skilled nursing facilities (SNFs)?**

- A. Medicare does reimburse providers for clinical laboratory tests provided to patients in skilled nursing facilities. When a SNF and a lab enter into an arrangement for Part A clinical diagnostic laboratory tests, such as PT tests, the SNF must bill for clinical lab tests to receive payment. Under this process, the SNF pays the lab for services, according to the contracted amount. The SNF and a lab may also enter into an arrangement for Part B. In the absence of an agreement under Part B, the lab may bill the program for lab services (such as PT tests). Patient self-testing is generally not performed in a SNF.

## **Regulatory Implication for Patient Self-Testing:**

### **Q: Who is eligible for home PT testing?**

A: There is clinical evidence that any patient requiring long-term anticoagulation may benefit from a home PT program. It is critical that the patient be capable of being trained to conduct a test and report the result to the caregiver. While physicians can elect to place any long-term patient on a home PT program, it is important to recognize that insurance carriers may be selective in whom they qualify as eligible. Medicare, for example, only covers patients with mechanical heart valves.

### **Q: If a physician decides that a patient is eligible for a home PT testing program, can the physician simply give the patient a test meter and send the patient home?**

A: No. Patient self-testing is regulated by the FDA. There are strict requirements for patient registration, training documentation and regular follow-ups. If a doctor selects a patient as a candidate, the best means to begin the process is to contact ITC Customer Service at 800-631-5945, or outside the United States, at 732-548-6677, or via e-mail at [customerservice@itcmed.com](mailto:customerservice@itcmed.com).

## **ADDITIONAL RESOURCES**

### **CLIA Application for Certification:**

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

### **Clinical Laboratory Fee Schedule:**

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

### **Hospital Outpatient Prospective Payment System:**

<http://www.cms.hhs.gov/providers/hopps>

### **ITC Web Site:**

<http://www.hometestprogram.com> or [www.itcmed.com](http://www.itcmed.com)

### **Physician Fee Schedule:**

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

### **Program Memorandum:**

Home Prothrombin Time/INR Monitoring Coverage: Transmittal AB-03-089; June 20, 2003

[http://www.cms.hhs.gov/manuals/pm\\_trans/AB03089.pdf](http://www.cms.hhs.gov/manuals/pm_trans/AB03089.pdf)

If you have additional questions, we encourage you to visit [www.hometestprogram.com](http://www.hometestprogram.com), where you will find in-depth information on reimbursement. For inquiries, ITC Customer Service representatives are available Monday through Friday, 8:30 a.m. to 7:30 p.m. ET. Call toll-free at 800-631-5945, or outside the United States at 732-548-6677, or e-mail us at [customerservice@itcmed.com](mailto:customerservice@itcmed.com).

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