

**Medicare Coding and Reimbursement  
for Platelet Aggregation Testing  
in the Presence of Antiplatelet Medications**

**Contents**

1. Medicare Billing Rules .....	2
2. Procedure (CPT) Code for Platelet Aggregation.....	2
3. Coding for VerifyNow Tests .....	2
4. Procedure Code Modifiers.....	3
5. Diagnosis (ICD-9) Codes.....	3
6. Medicare Reimbursement for Platelet Aggregation Testing .....	4
7. Medicare Reimbursement for Laboratory Testing by Site of Service.....	4
8. National and Local Coverage Policy.....	5
9. Use of Advance Beneficiary Notices (ABNs).....	5
10. Evaluation and Management (E&M) Coding .....	6
11. CLIA Certification Requirements .....	7

## Medicare Billing Rules

Medicare consists of two parts: Medicare Part A covers inpatient hospitalization costs. Inpatient costs are paid prospectively on a fixed fee basis based on diagnosis related groups (DRGs). DRGs do not apply to physician services. Laboratory tests performed for Medicare inpatients are considered part of the DRG payment.

Medicare Part B covers physician services, outpatient clinical laboratory tests not covered under Part A. There is an annual deductible and a 20% co-payment for all Part B services except outpatient clinical laboratory services.

Before Medicare pays for any test or diagnostic service, two basic criteria must be met:

- (1) the service must be covered by Medicare (e.g., certain procedures such as routine screening tests are not covered), and
- (2) the service must be medically necessary or indicated.

Once these two criteria are met, Medicare pays for most clinical laboratory tests, including platelet aggregation tests, based on the Medicare Laboratory Fee Schedule.

Direct billing is also required for all Medicare-reimbursed laboratory tests. Tests must be billed directly to Medicare by the laboratory, physician or other entity performing the test. If an outside laboratory performs a test referred by a physician, only the outside laboratory may legally bill Medicare for the procedure.

## Procedure (CPT) Code for Platelet Aggregation

The procedure code is one of the most important parts of a Medicare claim. The CPT (Current Procedural Terminology) code determines what will be paid for any given test or procedure. CPT Codes are revised and published annually by the American Medical Association. The CPT code for the Accumetrics platelet aggregation test is:

**85576 Platelet, aggregation (in vitro), each agent**

## Coding for VerifyNow Tests

Product	CLIA Status	CPT Code	Modifier Codes	Quantity
VerifyNow Aspirin Test	Waived	85576	- QW - 91	1 (arachidonic acid)
VerifyNow P2Y12 Test	Non-Waived	85576	- 91	2 (ADP and TRAP agonists)
VerifyNow IIb/IIIa Test	Non-Waived	85576	- 91	1 (TRAP agonist)

## Procedure Code Modifiers

Procedure code modifiers are two digits or letters added to the basic five-digit CPT code. Modifiers are used to describe unusual circumstances or provide additional information regarding a test or procedure. The following modifiers also apply to laboratory testing.

**-QW** *CLIA Waived Category Test*: This modifier is used to indicate a CLIA waived test was used.

**-GA** *Waiver of Liability Statement on File*: This modifier is used to indicate that the provider has obtained a signed Advance Beneficiary Notice (ABN) from a Medicare patient stating that payment may be denied by Medicare and may be billed to the patient.

**-91** *Repeat Clinical Diagnostic Laboratory Test*: This modifier is used when it is medically necessary to repeat the same laboratory test for the same patient on the same day to obtain subsequent (multiple) test results. Under such circumstances, the –91 modifier is added to the second and all subsequent CPT codes reported.

**-26** *Professional component*: This modifier is used to identify a physician's professional interpretation and report for certain laboratory tests.

An additional clinical laboratory interpretation fee is payable for CPT code 85576 by reporting 85576-26 in addition to the unmodified code under the specific circumstances as noted below. (See Medicare Carriers Manual, Chap 15, Section 15020 D and E for regulations.)

- The interpretation must be performed by a consulting physician, usually a pathologist (the interpretation may not be provided by the patient's treating physician).
- The interpretation must be requested by the treating physician or via a valid standing order.
- A separate written report (consultation) must be sent to the treating physician and included in the patient's medical record. This report must provide clinical information not available from the standard laboratory report requiring the consulting physician's medical judgment. The consultation report should be a separate document, not a notation or initials on the laboratory results.

## Diagnosis (ICD-9) Codes

An appropriate diagnosis (ICD-9) code must be supplied for each laboratory test billed under Medicare Part B. ICD-9-CM is an acronym for International Classification of Diseases, 9th Revision, Clinical Modification.

When a patient presents with an undiagnosed illness, the ICD-9 code is determined by the "signs and symptoms" present. Symptoms are defined as what the patient tells the physician. Signs are what the physician observes as part of his examination of the patient.

Since platelet aggregation tests are typically used to assess a patient's response to aspirin or other anti-platelet therapy prescribed as a part of cardiac care, ICD-9 codes describing cardiac conditions or symptoms are usually employed.

For example:

272.2	Mixed hyperlipidemia
401.1	Benign hypertension
414.8	Other specified forms of chronic ischemic heart disease
428.0	Congestive heart failure
429.2	Heart disease, unspecified

The following ICD-9 codes specifically apply to aspirin resistance testing, but are typically used in addition to the patient's primary diagnosis (illness or other reason for presenting):

- V58.63 Long-term (current) use of antiplatelets/antithrombotics
- V58.66 Long-term (current) use of aspirin

### Medicare Reimbursement for Platelet Aggregation Testing

The 2010 Medicare Laboratory Fee Schedule amount for platelet aggregation testing (CPT 85576) is **\$30.77** in all states except the following:

Maryland	\$29.83	Ohio	\$14.27
Missouri	between \$30.01 and \$30.77	South Carolina	\$21.45
New Mexico	\$21.32	West Virginia	\$15.74

### Medicare Reimbursement for Laboratory Testing by Site of Service

Hospital Inpatients	Reimbursed as part of DRG No separate payment is allowed Includes tests performed within 72 hours of admission
Ambulatory Surgery	Reimbursed as part of surgical payment package No separate payment allowed
Hospital Outpatients	Paid according to Medicare Laboratory Fee Schedule
Physician Offices	Paid according to Medicare Laboratory Fee Schedule
Home Health Care	Paid according to Medicare Laboratory Fee Schedule
Skilled Nursing Facilities	No separate payment for Part A patients Part B patients paid according to Medicare Laboratory Fee Schedule

Skilled Nursing Facilities (SNFs) are reimbursed using a Prospective Payment System for Part A coverage (initial 100 days after a qualified hospital discharge). A fixed daily rate is paid to the SNF according to the Resource Utilization Group (RUG) in which the patient is classified. RUG payments vary according to the severity of condition and anticipated resources that will be required to care for the patient.

No additional payment is allowed for laboratory testing for a SNF patient during their initial Part A coverage period. The SNF is responsible for the cost of all laboratory tests as part of the daily rate determined by the patient's RUG. This includes charges from outside laboratories as well as the cost of using point-of-care devices. After the initial 100 days of Part A coverage is exhausted, SNF patients are covered under Medicare Part B in the same manner as any other Medicare patient, i.e., laboratory tests are reimbursed according to the Medicare Laboratory Fee Schedule.

### **National and Local Coverage Policy**

Medicare has not published any national or local coverage determinations (NCDs or LCDs) for platelet aggregation testing. Thus, no specific required ICD-9 codes are designated as covered. All medically necessary tests (as documented in the patient's medical record) should be covered.

### **Use of Advance Beneficiary Notices (ABNs)**

An Advance Beneficiary Notice (ABN) is used to document that the patient is aware that Medicare may not pay for a test or procedure, and has agreed to pay the provider in the event payment is denied. Each ABN must be specific to the service provided and the reason that Medicare may not pay for the service. Blanket waivers for all Medicare patients are not allowed.

Medicare patients may be billed for services that are clearly not covered, for example, routine physicals or screening tests when there is no indication that the test is medically necessary. However, when a Medicare carrier is likely to deny payment because of medical necessity policy as stated in a NCD, LCD or based on previous experience, the patient must be informed and consent to pay for the service before it is performed. Otherwise, the patient has no obligation to pay for the test.

As noted above, there are currently no published NCDs or LCDs for platelet aggregation tests. Thus, the only time an ABN would be required is if medical necessity requirements were not met, for example, the patient presented with no signs or symptoms of disease or the test was performed as part of a routine physician examination.

When a patient is placed on chronic aspirin therapy as a preventive/prophylactic measure to prevent an ischemic event, and a platelet aggregation test is performed to assess aspirin resistance, the test would be assumed medically necessary and an ABN would not be required. However, if a history of denials exists for specific diagnosis codes or frequency of testing, then an ABN would be appropriate since there is a reasonable belief that the test may be denied under similar circumstances.

The CPT code modifier, -GA (Waiver of Liability Statement on File), is used to indicate that the provider has notified the Medicare patient that the test performed may not be reimbursed by Medicare and may be billed to the patient.

## Evaluation and Management (E&M) Coding

E&M codes may be billed in addition to CPT code 85576 when platelet aggregation tests are performed in a physician office laboratory. Physician interpretation of test results is considered to be part of the E&M services provided to a patient during an office visit and is not separately billable.

Testing for aspirin or P2Y12 would usually be ordered during either an “existing patient” or “established patient” office visit, and there are various categories of E&M codes that may be applicable. The codes and unadjusted Medicare payments for these services are listed below. Accordingly, each type of office visit has multiple levels of service depending on the severity and complexity of the patient’s presenting problem.

### New Patient E&M Codes and Medicare Reimbursement\*

Office or other outpatient visit for the evaluation and management of a new patient which involves:

		Ranges	
		<u>From</u>	<u>To</u>
99201	A problem focused history and exam and straightforward medical decision making (typically 10 min face-to-face with patient)	\$34.18	\$49.10
99202	An expanded problem focused history and exam and straightforward medical decision making (typically 20 min face-to-face with patient)	\$52.92	\$86.35
99203	A detailed history and exam and low complexity medical decision making (typically 30 min face-to-face with patient)	\$86.16	\$126.00
99204	A comprehensive history and exam and moderate complexity medical decision making (typically 45 min face-to-face with patient)	\$134.31	\$198.58
99205	A comprehensive history and exam and high complexity medical decision making (typically 60 min face-to-face with patient)	\$169.29	\$251.37

### Established Patient E&M Codes and Medicare Reimbursement

Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician:

		Ranges	
		<u>From</u>	<u>To</u>
99211	Presenting problems are minimal (typically 5 min supervision time)	\$16.60	\$24.71

Office or other outpatient visit for the evaluation and management of an established patient which involves:

		Ranges	
		<u>From</u>	<u>To</u>
99212	a problem focused history and exam and straightforward medical decision making (typically 10 min face-to-face with patient)	\$34.18	\$49.10
99213	an expanded problem focused history and exam and low complexity medical decision making (typically 15 min face-to-face with patient)	\$58.21	\$85.13
99214	a detailed history and exam and moderate complexity medical decision making (typically 25 min face-to-face with patient)	\$87.40	\$114.37
99215	a comprehensive history and exam and high complexity medical decision making (typically 40 min face-to-face with patient)	\$118.10	\$153.40

\*Medicare reimbursement varies by state. The range of payments is shown.

The lowest level office visit for an existing patient (99211) does not require the presence of a physician and may be performed by a nurse or other qualified non-physician healthcare professional. This code is often reported when patients come in for a basic check of vital signs and performance of a routine test such as PT or glucose on a regular basis.

The ordering and interpretation of the results of lab tests is considered to be part of the office visit and is not paid separately. However, if the test results are such that additional time or complexity is added to the office visit, its level may increase.

## **CLIA Certification Requirements**

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulates clinical testing to ensure that all tests performed by any provider are safe and accurate. Under CLIA rules, laboratory tests are categorized as waived, moderately complex or highly complex depending on the degree of complexity required to perform each test.

A valid CLIA certificate number must be included on all Medicare claims for laboratory tests.

The VerifyNow System is classified as a CLIA waived procedure when used to determine platelet function in the presence of aspirin. It is classified as moderately complex when used to test for platelet aggregation in the presence of other anti-platelet medications such as P2Y12 inhibitors (including Plavix and ticlopidine) or IIb/IIIa inhibitors (including ReoPro and Integrilin).

If only waived tests are performed, the only requirements are that a valid "Certificate of Waiver" be on file and that the certificate holder agrees to follow manufacturers' instructions. A Certificate of Waiver costs \$150 for two years.

Non-waived testing requires an on-site inspection of the laboratory every two years and compliance with all the applicable CLIA requirements.

One of the following certificates is required:

- Certificate of Compliance if you choose a government inspection
- Certificate of Accreditation if you choose to enroll with an accrediting agency and participate in their program

In addition, the laboratory director and other laboratory personnel must meet specific standards and the laboratory must enroll in an approved proficiency testing program for all regulated analytes on its test menu. Policy and procedure manuals, a quality assessment plan, and test method validation are also required.

Inspection and certificate fees are based on the annual test volume of the laboratory and range from \$150.00 for less than 10,000 tests per year to over \$7000.00 per year for labs performing more than one million tests per year.

Information on how to apply for a CLIA certificate are available on the CMS website at:

[www.cms.hhs.gov/CLIA/06\\_How\\_to\\_Apply\\_for\\_a\\_CLIA\\_Certificate\\_International\\_Laboratories.asp#TopOfPage](http://www.cms.hhs.gov/CLIA/06_How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.asp#TopOfPage)

If you have any questions regarding the completion of the CMS-116 form, contact the appropriate State Agency. You should also contact your State Agency for additional forms that may be necessary to complete the registration process or for any additional questions. For example, the state of California has additional licensure requirements and thus California applicants should contact their local State Agency at (213) 620-6160. Be sure to make contact with your State Agency to ensure that you have all the necessary information that is required for the application. Washington state applicants should not complete the CMS-116 form. They should contact the Washington State Agency at (206) 418-5600 for guidance.

These codes are provided for informational purposes only. It is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service. Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Accumetrics recommends that providers contact their contracted payers to determine appropriate coding and charge or payment levels prior to submitting claims. The use of these codes does not guarantee payment. For a state-by-state fee schedule, visit [www.cms.hhs.gov](http://www.cms.hhs.gov) for more information.