

Clinical Laboratory Managers Association Meeting  
September 15, 2006  
Wisconsin Physicians Service (WPS) - Madison

**Questions for WPS Medicare**

1. There are 18 Clinical Laboratory Interpretations Services listed in the Pathology – Physician Services policy (PATH-002, Section E). The payment criteria indicate the services need to:
  - Be reported with modifier 26 and are paid under the physician fee schedule if they are furnished to a patient by a hospital pathologist or independent laboratory.
  - Be requested by the patient’s attending physician but a hospital’s standing order policy can be used for the attending physicians order.
  - Result in a written narrative report in the patient’s medical record.
  - Require exercise of medical judgment by the pathologist.

The Payment Conditions for Pathology Services (Section I.A.1) indicates payment can be made for services furnished by hospital physicians, usually pathologists, or independent laboratories to hospital inpatients or outpatients.

Is Payment for these interpretation services limited to hospital inpatient or outpatient or are they payable for non-hospitalized patients when a pathologist is employed by an independent laboratory? Is there any other payment or coding information providers should be aware of before reporting these services?

**Answer:** Path-002 “Pathology Services,” section I.A.1 states *Payment can be made under the fee schedule for the professional component of physician laboratory or pathology services furnished by hospital physicians, usually pathologists, or independent laboratories to hospital inpatients or outpatients.*

**Medicare also reimburses the professional component of these procedure codes under the Medicare Physicians Fee Schedule to physicians or qualified practitioners in the office setting. Physicians order laboratory services and interpret the results for use in their plan of care for the patient. The purpose for reimbursing the professional component in the inpatient or outpatient setting under the Medicare Fee Schedule is to reimburse the physician for the interpretation under the Medicare Part B for use in their plan of care for the patient. Medicare Part A is responsible for the reimbursement for clinical laboratory services in the inpatient or outpatient setting.**

**While Medicare may reimburse the professional component of these procedure codes by pathologists employed by an independent laboratory for non-hospital**

**patients, these are physician or qualified practitioner services and must be medically necessary.**

2. We are receiving letters requesting additional information documentation and/or ICD-9 when submitting claims that include CPT's with either the GA or GZ modifier attached. In some cases, it appears as though the processing of the claim is suspended and in some cases, the other CPT's submitted without any modifiers are processed.
- What is the intent of the letters?
  - Should our responses to these letters be different than if denied on an EOB? E.g., do we send the info back with the letters?
  - What should we do if we are looking for the PR denial to bill the patient? e.g., test is ordered for a reason Medicare will not pay and patient has signed an ABN.

Examples are: ICN: 02062350300008 and 02062370223701

**Answer: The intent of the letters is to gather documentation and/or diagnosis information to allow the claim to process and pay.**

**You should respond to the letters by sending back the information that is requested, with a copy of the letter.**

**If your intent is to have a PR denial on these charges due to medical necessity, you may also indicate that on the letter when returning. You must continue to append the GA or GZ modifier. The GZ modifier will NOT change the liability of the claim however; it does indicate that you did not give the patient one and that you understand that it should have been furnished in that circumstance.**

**After reviewing the claims, it is not the GA or GZ modifiers that suspended these claims. The examples provided needed more information.**

#### **Questions from 5/12/06 meeting:**

HCV Genotyping is being used as an integral part of decision making prior to initiating therapy for HCV infection. Guideline policies are written by various organizations including the American Association for the Study of Liver Diseases' (AASLD), the American Gastroenterological Association, and the Infectious Diseases Society of American specifying preferred approaches to the diagnostic, therapeutic and preventive aspects of care. These recommendations include determining HCV genotyping in all HCV-infected persons prior to treatment in order to determine the duration of therapy and likelihood of response. Test kits are not yet FDA approved, but are available for clinical use. Validation studies have been completed with the Bayer VERSANT HCV Genotype Assay (LiPa) and we are enrolled in proficiency testing. Can we submit claims to Medicare for HCV genotyping when the patient is diagnosed with HCV infection and the physician order to determine treatment?

**Answer: Based on the information in the question, it appears that this provider is part of the studies to approve the test: "Validation studies have been completed with the Bayer VERSANT HCV Genotype Assay (LiPa) and we are enrolled in proficiency testing. " These tests then would be paid by the manufacturer as part of there study and would not be paid by Medicare. Generally, we do not cover devices or drugs that are not FDA approved. CLIA may also have rules governing this.**

General questions regarding lab procedures that have not been approved through the FDA. As I understand the process, if a test has not gone through FDA approval, it may still be reimbursable if:

The procedure uses ASR's

- (Analyte specific reagents) and the performing lab has a high complexity CLIA license and follows all test validation procedure and is enrolled in proficiency testing.
- The test not require FDA approval (some genetic procedures)

What about test that do not fall within these exceptions? If a test is considered research (RUO) or investigational (IUO), is it only reimbursable if a clinical trial exists? Who sets up the clinical trial – the test manufacturer, the performing lab, or the ordering physician? Is there a database for clinical trials? If the test is labeled as 'research' and no clinical trial exists, can it still be submitted for reimbursement if medical necessity can be documented? Must a beneficiary sign an ABN before being billed for a test not approved by FDA?

**Answer: CLIA guidelines must indicate, the procedure may still be reimbursable if it uses ASR's**

- (Analyte specific reagents) and the performing lab has a high complexity CLIA license and follows all test validation procedure and is enrolled in proficiency testing.
- The test not require FDA approval (some genetic procedures)

**The tests that fall outside of these guidelines are not considered reimbursable for Medicare purposes. These tests are considered investigational. We consulted with the Medicare Policy department, if a test labeled 'research' or 'investigational' and there is not a validation study then the claim should not be submitted to Medicare. Medicare does not generally pay for tests or devices that are not FDA approved.**

**Clinical Trial rules really do not apply to Laboratory tests. Medicare reimburses for Routine Costs for beneficiaries in clinical trials. Routine costs associated with clinical trials are all items and services that are otherwise generally available to a Medicare beneficiary. There is not a database for clinical trials. There is a National Coverage Determination (NCD) on clinical trials. You may reference this on our Website. "Clinical Trials", PHYS-077 may be viewed at:**

**<http://www.wpsmedicare.com/policies/wisconsin/phys077.pdf>**

**Majority of these tests do not have true codes to submit to Medicare. If submitting to Medicare based on insistence of the beneficiary, append modifier GY. Tested**

**labeled ‘investigational’ or ‘research’ are statutorily excluded by the Medicare program. An Advanced Beneficiary Notice (ABN) is not required. You may provide you patients with a Notice of Exclusion of Medicare Benefits (NEMB). Best practice has found that patients have a higher level of understanding when told up front that the services are not covered.**

**To UGS:**

1. We have an Urgent Care Center that is within our hospital and it is a distinct area from our emergency room. There are set times the Urgent Care Center is open. During this time when a patient presents to the ER Urgent Care reception area, they are seen by a triage nurse and depending on their condition are sent to either Emergency Room or Urgent Care. The facility and professional charges are billed under the hospital’s Federal Tax ID number. Physician Assistants under the supervision of a physician see patients in Urgent Care and only physicians see patients in the Emergency Room.

What is the appropriate “Place of Service” code to use? Is it 20 for Urgent Care or 22 for Outpatient Hospital?

Commercial insurance carriers view “Place of Service” 22 as an elective procedure. When someone presents to the Urgent Care, it is normally for a condition that does not meet the definition of emergency (Life or Limb) but is a condition that does require treatment. During the hours that the Urgent Care is not open, these patients will be seen in the emergency room with a “Place of Service” of 23.

Please clarify the definition of an Urgent Care Facility that can use the “Place of Service” of 20.

**Answer:** WPS Medicare prepared an answer for this question, as Medicare Part A technically does not have “Place of Service” codes. The Medicare Part B definition of Urgent Care Facility is considered a freestanding facility. All overhead expenses are the responsibility of the Urgent Care Facility and there is not another entity able to bill for these charges. All overhead expenses are calculated into the Medicare Physician Fee Schedule.

When the facility (hospital) is submitting charges, the correct “Place of Service” to use for the professional charge is 22, for Outpatient. Providers use the “Place of Service” of 20, Urgent Care when there are not facility charges billed by any facility.

Incident To” guidelines do not apply to in/outpatient hospital setting. When submitting the professional charges are you using the Physician Assistant’s number? “

