

**UGS/WPS
CLMA Meeting
May 12, 2006
Milwaukee, WI**

UGS, LLC Questions and Answers

1. Is UGS currently involved in any “Pay for Performance” projects (example: CMS/Premier Hospital Quality Incentive Demonstration). Do you have any plans to implement or have a demonstration project in the future using “Pay for Performance” measures?

Answer: We are not involved in a pay for performance project. We do not have plans or foresee being involved at this time.

2. When we refer a test from the hospital to a reference lab, we bill the patient/Medicare through the hospital based upon the CPT code that the reference lab supplies. Often the referred test is a battery consisting of multiple components so the hospital bills the multiple components. The components may contain a pathology interpretation done at the reference lab. We get denied on CPT codes that are a professional component. However, the reference lab is billing the hospital for this work. Is there anyway the hospital can get reimbursed for these codes? The two codes below are examples of codes for referred tests that the hospital has received rejections on:

85060- Blood smear, peripheral, interpretation by physician with written report
88291- Cytogenetics and mole cytogenetics, interpretation and report

Answer: HCPCS 85060 is not allowed under OPPI. It has a status indicator of “B”. HCPCS code 88291 has a status indicator of “M” service not billable to FI.

3. The reference laboratory that we utilize screens for 32 Cystic Fibrosis mutations by PCR, oligonucleotide ligation assay (OLA) fluorescent hybridization probes, and capillary electrophoresis methods. The referenced CPT codes for this procedure are:

83890- Molecular diagnostics; molecular isolation
83900 – Molecular diagnostics; amplification of patient nucleic acid, multiplex, first two nucleic acid sequences
83901 x 30 – Molecular diagnostics; amplification of patient nucleic acid, a multiplex, each additional, nucleic acid sequence (use 83901 in conjunction with 83900)
83914 x 32 – Mutation identification by enzymatic ligation or primer extension, single segment, each segment (e.g. oligonucleotide ligation assay)

83909 – Molecular diagnostics; separation and identification by high resolution technique (e.g. capillary electrophoresis)

83912 – Molecular diagnostics; interpretation and report

Are the newly defined codes of 83901 and 83914 able to quantity billed? Do we need to submit with a quantity modifier? (We are already submitting with the 90 modifier to indicate a purchased test).

Answer: Both codes have a status indicator of “A” which means they are paid on a fee schedule times number of units billed. A quantity modifier is not required. FYI CPT code 83914 was effective 1-1-2006.

4. The Roche COBAS Amplicor HCV Test, V2.0 has FDA approval for the qualitative detection of Hepatitis C RNA in human serum or plasma from blood collected in EDTA. This same test kit can also provide quantitative HCV results to predict the likelihood of response to treatment, and to monitor treatment response. As this application of the kit falls outside the FDA approval criteria, all quantitative results provided to ordering physicians are labeled “Research Use Only”. We have a statement from Roche that we are using the kit as specified by the Roche Molecular Systems Research Use Certification Program for the COBAS Amplicor HCV Monitor Test V2.0. Validation studies were completed as well as enrollment in proficiency testing. Can we submit claims to Medicare for the quantitative determination of HCV when the patient has active infection and physician orders to monitor treatment response? If initial HCV qualitative test is positive and subsequently the physician orders the quantitative test for establishing a baseline, may both CPTs (87521 and 87522) be submitted with a 59 modifier to override the NCCI edits?

Answer: After a discussion with the medical director, modifier 59 on CPT codes 87521 and 87522 should by-pass the NCCI edits, as always make sure it is appropriate and medically necessary.

5. 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 Disease 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 orders to determine treatment?

Answer: Since this is not FDA approved, UGS would like more information. Is there a CPT code assigned to it, etc?

6. These are general questions regarding lab procedures that have 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 ASRs (analyte specific reagents) and the performing lab has high complexity CLIA license and follows all test validation procedures and is enrolled in proficiency testing.
 - The test does not require FDA approval (some genetic procedures). What about tests 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 trails? 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: If the test has a CPT code, Medicare may consider covering it. Medicare provides limited information clinical trails at the link below.

7. A patient is in a skilled nursing facility under a Medicare Part A stay. The patient is transported to a free standing dialysis center during the Part A stay and while there receives a blood transfusion (HCPCS P9016)-Leukocyte poor paced cells. The laboratory has provided the blood to the dialysis center. The dialysis center has consulted with UGS previously and was told that P9016 is not included in the SNF PPS payment under Part A and that the lab should bill directly to Medicare Part B. Medicare Part B paid and then recouped the money indicating that the service is included in SNF PPS Part A payment. Who should bill for P9016 Part A or Part B?

Answer: The dialysis facility should bill the FI for the technical component of the blood transfusion. The CMS IOM Manual 100-4, Chapter 8, ESRD Manual indicates that blood, supplies used to administer blood, and blood processing fees may be billed. UGS would need an example of a claim to assist the provider further.

Note: This link will take the providers directly to information specific to laboratories:
<http://www.cms.hhs.gov/CLIA/>