TO: All Medicare Providers

FROM: Andy DePirro, Director, Program Relations

SUBJECT: NEW HCPCS “QP” MODIFIER FOR LABORATORY SERVICES; AND QUESTIONS/ANSWERS REGARDING LABORATORY SERVICES

ATTENTION MEDICARE BUSINESS OFFICE: Please distribute to all appropriate health care facility personnel.

General Medicare Bulletin G-230, dated August 30, 1996, informed Medicare participating providers of the Health Care Financing Administration’s (HCFA’s) instructions pertaining to laboratory tests that are frequently done as groups and combinations on automated profile equipment. HCFA’s instructions, which were effective for services rendered on and after October 1, 1996, require that all tests in an automated profile be medically necessary. This constitutes a change from previous policy which allowed all tests to be paid as long as at least one test was medically necessary.

These instructions require providers and their physician clients to think more carefully about what is being billed using automated profile codes. The ordering physician should order only those tests that are related to specific symptoms or disease conditions. HCFA’s intent is to ensure that the Medicare program is only used for problem pertinent testing, in that Medicare generally does not reimburse for “routine” testing or tests related to “screening” only.

In the event that Medicare questions the medical necessity of the laboratory service(s), the billing provider will be held accountable and must be prepared to support the medical necessity of the services billed on the outpatient claim. Although the physician (or other authorized health professional) orders the test(s), the provider is held accountable since they are the entity receiving reimbursement from Medicare for performing the test(s).

As a result of HCFA’s instructions, some laboratory providers have implemented business office procedures to require that each test be individually ordered, rather than accepting orders for automated multi-channel tests. It should be noted that this is an individual business decision, not a HCFA directive. Further, the individual ordering of tests alone does not attest to the actual “medical necessity” of the tests. There is an assumption, however, that individually ordered tests are targeting only those tests that are related to specific symptoms or disease conditions. For this reason, HCFA established a national HCPCS modifier (“QP”) that may be entered on an outpatient claim and will allow laboratory providers to attest that documentation exists to show that the ordering physician (or authorized health professional) ordered the test(s) individually or as a CPT-recognized panel (e.g. thyroid panel - 80091).
HCPCS “QP” MODIFIER FOR LABORATORY SERVICES
The definition of this new “QP” modifier is as follows:

QP: Documentation is on file showing that the laboratory test(s) was ordered individually or ordered as a CPT-recognized panel other than automated profile codes 80002-80019, G0058, G0059, and G0060.

The QP modifier may be reported on an outpatient claim and permits laboratory providers to attest that documentation exists to validate that the ordering physician (or authorized health professional) ordered the test(s) individually or as a CPT-recognized panel. The modifier may not be used with automated profile CPT codes (80002-80019, G0058, G0059, and G0060) unless the laboratory provider has documentation showing that the component tests included under those codes were ordered individually by the physician. In this case, the laboratory provider bundles the tests into the correct CPT code (i.e., CPT 80002-80019, G0058-G0060) for billing purposes and may report the QP modifier with the automated profile codes. HCFA has no requirement that laboratory providers use the “QP” modifier. Its use is optional and does not assure payment. However, use of the “QP” modifier does mean that the laboratory provider’s documentation will confirm that each of the tests billed with the modifier were individually ordered.

While Medicare contractors (intermediaries/carriers) may accept the modifier as sufficient evidence of medical necessity, they still have the option to request additional medical documentation, such as diagnosis information, in order to support the medical necessity of laboratory services. When additional medical documentation is requested from the laboratory provider to substantiate medical necessity for testing, the documentation should clearly establish a relationship between the test(s) ordered and the condition or symptom at issue.

This does not mean that supporting documentation (i.e., medical records) should accompany the claim at the time it is submitted for processing. Medical review of claims may be performed on a pre-payment or post-payment basis. Therefore, providers are encouraged to submit all Medicare claims electronically. The intermediary will initiate development for claims that are selected for pre-payment review via the Additional Development Request (ADR) process. In the rare instance when a paper/hardcopy claim must be submitted, it is not necessary to submit medical documentation with your initial bill submission.

The attachment to this bulletin provides a series of frequently asked provider questions and intermediary answers regarding laboratory services and the revised medical necessity guidelines.

Questions regarding this bulletin may be addressed to the Medicare Part A Customer Service Department by calling (904)355-8899.
Q1. **What documentation should be submitted with an outpatient lab claim to support medical necessity?**

A1. Medical review of claims may be performed on a pre-payment or post-payment basis. Therefore, providers are encouraged to submit all Medicare claims electronically. The intermediary will initiate development for claims that are selected for pre-payment (or post-payment) review via the Additional Development Request (ADR) process. When a hardcopy (paper) claim must be submitted, it is not necessary to submit medical documentation with the initial bill submission. In fact, submission of hardcopy (paper) claims, for any reason, impacts how quickly the intermediary may release payment for Medicare claims. Based on the Payment Floor Standards, mandated by HCFA, the Medicare intermediary “may not pay, issue, mail, or otherwise release payment for any claim it receives for processing within the established waiting period,’ which is determined by the date a claim is received.” The current payment floors are established as follows:

- 13 days for electronic media claims (EMC); and
- 27 days for hardcopy (paper) claims.

In an effort to expedite cash flow, providers are encouraged to submit all Medicare claims transactions via electronic media.

Q2. **Does use of the QP modifier qualify as meeting the HCFA’s requirement to show that all tests in an automated profile were “medically necessary”?**

A2. The national HCPCS modifier “QP,” established by HCFA, indicates that the laboratory test(s) billed were ordered individually or ordered as a CPT-recognized panel (other than automated profile codes 80002-80019 and G0058-G0060); and that documentation is on file to support that the test(s) were ordered individually. The “QP” modifier does not certify “medical necessity” of the test(s), only that the test(s) were individually ordered. Although the individual ordering of tests alone does not attest to the actual “medical necessity” of the tests, there may be an assumption that individually ordered tests are targeting only those tests that are related to specific symptoms or disease conditions. While Medicare contractors (intermediaries/carriers) may accept the modifier as sufficient evidence of medical necessity, they still have the option to request additional medical documentation, such as diagnosis information, in order to support the medical necessity of laboratory services.

HCFA has no requirement that laboratory providers use the “QP” modifier. Its use is optional and does not assure Medicare payment. However, use of the “QP” modifier does mean that the laboratory provider’s documentation will confirm that each of the tests billed with the modifier were individually ordered.
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Q3. **What diagnosis codes are approved for multi-channel tests?**

A3. There is no list of “approved diagnosis codes” for multi-channel tests. The condition/diagnosis/medical justification that the physician (or other authorized health professional) furnishes to the provider, either at the time the test is ordered or when documentation is requested by the intermediary, must substantiate the need for the test. If it does not, then the beneficiary should be notified, prior to performing the service (either by the provider or the physician’s office), that the test is non-covered by the Medicare program and they will be responsible for payment. However, if the provider (lab) does not give written notice to the beneficiary and relies on the physician’s office to do so, and the notice does not meet the criteria for notification of non-coverage, then the provider of service will be held responsible. [Reference General Medicare Bulletin G-230, dated August 30, 1996, for more information.]

Q4. **If the diagnosis code reported is not acceptable for the automated laboratory test will you deny all of the outpatient claim, or will you pay the test(s) of the multi-channel that is/are necessary for the diagnosis?**

A4. If the diagnosis code(s) and/or other supportive documentation (such as office records) from the physician (or other authorized health professional) indicating the patient’s condition, or other physician notes which indicate the need for the test(s), do not justify all of the tests that are included in the multi-channel panel, then the entire panel will be denied. If the only line item (revenue code/HCPCS) on the outpatient claim is for the multi-channel panel, then the entire claim will be denied. Payment will not be made for the multi-channel test, or any portion of the panel test, even though the claim may contain a diagnosis code that would justify one or more of the tests performed. Providers should make the determination, prior to billing, that the diagnosis/condition of the patient does/does not substantiate the need for the multi-channel panel and then bill Medicare only for those tests that are medically necessary.

Q5. **What are the guidelines for CBC tests? What diagnosis codes are acceptable?**

A5. The HCFA guidelines currently in place for a Complete Blood Count (CBC) are that the test must be medically necessary and ordered by a doctor. There is no list of approved or acceptable diagnosis codes for CBC tests. However, HCFA has instructed all intermediaries to adopt Medicare Part B Carrier local medical review policies (LMRPs), to the extent possible. The Part B Carrier is in the process of developing LMRPs for CBCs and other lab tests. Therefore, prior to Part A Intermediary implementation of LMRPs, providers will be given a 30-day minimum advance notification via the Medicare bulletin mechanism. It is anticipated that the LMRP for CBC will include coverage guidelines and conditions and/or diagnosis codes substantiating medical necessity.
Q6. Do providers have to adhere to non-coverage notification guidelines for lab tests ordered by physicians and performed by laboratory providers only as “reference lab” work?

A6. Under the current Medicare statute, a provider is protected from liability for tests that are denied Medicare payment on the basis that they are not medically necessary and reasonable, if the provider gives that beneficiary proper written notice that Medicare will not pay for the service(s). The notification must be issued prior to performing the service and clearly state the service/test is non-covered and that the beneficiary is financially responsible for payment. There may be circumstances in which the ordering physician provides the beneficiary with proper advance written notice that a test will not be covered under Medicare. In these instances, the notice issued by the ordering physician may relieve the provider of its liability because the notice is proof of the beneficiary’s prior knowledge that the services were non-covered. The provider should obtain a copy of the notice and place it in the beneficiary’s medical records. If the laboratory provider relies on advance notice to the beneficiary by the ordering physician, and that notice turns out to be unacceptable, the provider will not be protected by that notice and would be held liable.

Q7. Is there required text for the patient non-coverage notification form?

A7. There is no required text or format for the non-coverage notification; however, HCFA offers (via the Medicare manuals) suggested language/paragraphs to use for provider and intermediary notification of non-coverage. Providers are instructed, via their respective HCFA manuals, of the requirements for notifying patients of non-coverage. Essentially, the letter of non-coverage must clearly state that the service/test (must state the name of the test/service) being performed is non-covered by the Medicare program and it must advise the beneficiary that they are responsible for payment. (Reference Q6)

Q8. Are there some V diagnosis codes that should be appropriate for tests? Can you provide them?

A7. There is no list of appropriate “V” codes; all valid ICD-9 “V” codes are acceptable on outpatient claims (the same is not true for inpatient claims). Any known disease or condition should be indicated on the claim via a diagnosis code. Therefore, if a “V” code describes a disease or condition (i.e., V1582 = Tobacco abuse) then the use of this code on the outpatient claim may substantiate the need for the test without a secondary diagnosis. However, if the “V” code is vague or indicates that the test is routine then the “V” code alone will not substantiate the need for the test without supplemental diagnosis coding to justify medical necessity.

Q9. Are “V” codes related to family history, transplant, replacement valid?

A9. If an ICD-9 “V” code related to family history, transplant, replacement, etc., describes a disease or condition then the use of this code on the outpatient claim could substantiate
the need for the test without an additional diagnosis. However, if the “V” code is vague then the use of this code alone will not substantiate the need for the test without an additional diagnosis(es) code(s). (Reference Q8)

Q10. If the tests are for pre-admission testing will they be paid with the diagnosis for the subsequent surgery?

A10. The beneficiary must have a diagnosis or condition that would warrant pre-operative testing for Medicare reimbursement. In other words, there must be medical necessity to substantiate each test. Medicare does not cover pre-operative “screening” services or “routine” pre-operative services.

Q11. If the tests are for “screening” does the provider have to submit to Medicare?

A11. If the provider knows that the test is for screening purposes (i.e., an annual Prostate Antigen or PSA test) they are not required to submit the outpatient claim for these non-covered services to Medicare. If, however, the beneficiary requests that a claim be submitted, then the provider must submit the claim as a “demand bill” to Medicare (condition code 20 reported in form locators 24-30 of the HCFA-1450 (UB-92) claims format). The reporting of this condition code indicates that the provider of service knows that the service is non-covered by the Medicare program. The claim will be denied and denial notification will be forwarded to the beneficiary via the Medicare Summary Notice (MSN) form. If the beneficiary has secondary insurance coverage then a copy of the MSN can be submitted to the secondary insurance carrier for payment. In addition, the MSN will advise the beneficiary of any applicable appeal rights.

Q12. What constitutes valid medical necessity documentation for multi-channel automated chemistry testing?

A12. A variety of “documents” may contain information supporting the medical necessity of the tests included in a multi-channel panel. These include the physician’s statement of condition/diagnosis; the narrative statement of signs and symptoms necessitating the tests requested; and the records for the evaluation and management services at which time the test(s) were ordered.

Q13. How will audits for this (medical necessity) be conducted?

A13. Medicare medical review policy may be applied to Medicare claims on either a pre-payment or post-payment basis. HCFA regulations require, however, that the intermediary use a variety of medical review activities to “audit” for compliance of Medicare medical policy. These activities include data analysis to target pre-payment focused medical review, comprehensive medical review, and review for fraud referrals.
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Data analysis will routinely be performed several times a year to review diagnosis coding submitted for laboratory services. For those outpatient claims that are identified that do not have diagnosis codes or have codes that do not clearly identify the need for the laboratory services, providers may be asked to submit supporting documentation to justify the laboratory services.

Note: Medicare does not currently mandate the submission of a diagnosis code on outpatient diagnostic/reference laboratory claims (e.g., type of bill code 14X). Diagnosis coding is required on all other bill types (e.g., 13X, 83X). However, providers are encouraged to submit diagnosis coding information if it is available, which could substantiate medical necessity without the intermediary requesting medical documentation.

Q14. What are strategies used by (large) commercial labs to meet this (medical necessity)?

A14. Due to the risk of financial liability, some laboratories now feel it is necessary to require physicians to supply medical necessity information (i.e., diagnosis code) at the time of the request for laboratory testing. Additionally, some laboratories may request an agreement with entities that it performs laboratory services for (i.e., physician office, skilled nursing facility, etc.) in which the requesting entity would ultimately accept financial responsibility should payment be denied by Medicare. Understandably, laboratories are making these types of changes to protect themselves from financial risk.

Further, some laboratory providers have implemented business office procedures to require that each test be individually ordered, rather than accepting orders for automated multi-channel tests. It should be noted that this is an individual business decision, not a HCFA directive. Although the individual ordering of tests alone does not attest to the actual “medical necessity” of the tests, there is an assumption that individually ordered tests are targeting only those tests that are related to specific symptoms or disease conditions. While Medicare contractors (intermediaries/carriers) may accept the individual ordering of tests as sufficient evidence of medical necessity, they still have the option to request additional medical documentation, such as diagnosis information, in order to support the medical necessity of the laboratory service(s).

Q15. Will diagnosis codes for tests that are subject to “AI” be published?

A15. The Artificial Intelligence (“AI”) applications that have been published with diagnosis code lists will be updated appropriately as changes are made. When local medical review policy (LMRP) is implemented via “AI” applications or as current “AI” applications are updated due to these policies, the policies will be communicated to the provider community via the bulletin mechanism. However, there are currently no plans to publish all of the diagnosis codes associated with all of the “AI” applications.
Q16. How many diagnosis codes does it take to get a 20 test chemistry profile paid?

A16. There is no specific number of diagnosis codes that are required to receive reimbursement for a 20 test chemistry panel, or other multi-channel tests. However, providers should report all known diseases or conditions that would substantiate the medical necessity for the 20 test chemistry profile or other multi-channel tests billed to Medicare.

Q17. When will BCBSF-Medicare develop organ specific panels to take the place of profiles?

A17. Blue Cross and Blue Shield of Florida (BCBSF) does not develop organ specific panels to replace profile panels. In fact, the development of the Current Procedural Terminology (CPT) are prepared by the American Medical Association (AMA) in conjunction with the CPT Editorial Panel, assistance of physicians representing all specialities of medicine, and with important contributions from many third party payers and governmental agencies (e.g., HCFA).

Q18. Is there a written policy about length of record retention and does it apply to laboratory providers?

A18. Providers are instructed via their respective HCFA Medicare manuals of the requirements regarding record retention and destruction. HCFA’s instructions apply to all Medicare participating providers. The following information is extracted from the Medicare Hospital Manual (HCFA Publication 10, Section 413):

RetentionPolicyOfHealthInsuranceRecords
Maintain health insurance materials related to services rendered under Title XVIII for the retention periods outlined below unless State law stipulates a longer period. Keep them available for reference by HCFA, intermediary, DHHS audit, or specially designated components for bill review, audit, and other references.

A. Categories of Health Insurance Records to be Retained - If these records are microfilmed, also see subsection B.

1. Billing Material. Hospital copies of forms HCFA-1450 and any other supporting documents e.g., charge slips, daily patient census records, and other business and accounting records referring to specific claims.

2. Cost Report Material. All data necessary to support the accuracy of the entries on the annual cost reports, including original invoices, canceled checks, and hospital copies of material used in preparing them. Also include other similar cost reports, schedules and related worksheets and contracts or records of dealings with outside sources of medical supplies and services or with related organizations.

3. Medical Record Material. Utilization review committee reports, physicians’
certification and recertification, discharge summaries, clinical and other medical records relating to health insurance claims.


After payment of the bill, do not retain administrative and billing work records if the material does not represent critical detail in support of summaries related to these records. These include punch cards, adding machine tapes, internal controls, or other similar material not required for record retention.

B. Microfilming Records. You may microfilm all health insurance records. Billing material and related attachments that you furnished to your intermediary may be microfilmed providing the microfilm accurately reproduces all original documents.

Retain copies of all other categories of health insurance records in their original form. If you microfilm them, store them in a low cost facility for the retention period.

C. Retention Period. Maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. Use a system of author identification and record maintenance that ensures the integrity of the authentification and protects the security of all record entries.

Retain medical records in their original or legally reproduced form for a period of at least 5 years.

**Destruction of Records:** You may destroy material which no longer needs to be retained for Title XVIII purposes, unless State law stipulates a longer period of retention.

To insure the confidentiality of the records, destroy them by shredding, mutilation or other protective measures. The method of final disposition of the records may provide for their sale as salvage. Report monies received as an adjustment to expense in the cost report for the year sold.

**Q19. Who do we contact to assist us in correctly submitting claims?**

A19. Providers who are serviced by Blue Cross and Blue Shield of Florida, as their Medicare intermediary, should contact the Medicare Part A Customer Service Department with all billing issues, questions, and concerns by calling (904) 355-8899.