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Comments and Responses Regarding Draft Local Coverage Determination: Partial Thromboplastin TIme

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As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Partial Thromboplastin Time LCD. The official notice period for the final LCD begins on October 17, 2009, and the final determination will become effective on December 1, 2009.

Comment:
Physicians from the Department of Radiology at the University of Chicago Medical Center recommend the addition of an Indication for Pre-operative screening for coagulopathy to the proposed policy for Partial Thromboplastin Time (PTT) (DL30179).

Our Department can not support the statements below from the limitations section of the proposed policy for PTT (DL30179):

• The routine screening of PTT in patients about to undergo a surgical procedure is not indicated in patients other than those noted in the "Indications" section above, or "...for patients who cannot cooperate with an adequate clinical assessment and for those who are to undergo procedures in which even minimal postoperative hemorrhage could be hazardous." [Goldman: Cecil Medicine 23rd edition, Chapter 178].
AND Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other than thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy. Hospital/clinic-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage.

We perform interventional procedures on a wide patient population, often acutely without adequate history. Unsuspected coagulopathy or preceding anticoagulant therapy that the patient is not aware of

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is far too common, and not having access to such laboratory information would put our patients at undo risk. Please see reference at the end of this comment.

Additionally, consensus guidelines are attached which are currently in press (Att. Malloy preprocedural lab document). While this document stratifies risk based on procedures, as noted above, our population here at UCMC differs from most in that as a tertiary referral center with a large population of oncology patients, we see a high percentage of coagulopathic patients. Further, we see a significant number of patients with unsuspected coagulopathy. Finally, in the realm of risk benefit analysis, we are certain that the cost of even one malpractice case, far exceeds the cost of obtaining pre-procedural labs.

Reference: Preoperative screening for coagulopathy using prothrombin time and partial thromboplastin time in patients requiring primary cranial vault remodeling. GENECOV David G. (1) ; POR Yong-Chen (1) ; BARCELO Carlos Raul (1) ; SALYER Kenneth E. (1) ; MULNE Arlynne F. (1) ; MORAD Ammar B. (1) ;. Plastic and reconstructive surgery ISSN 0032-1052.2005, vol. 116, no2, pp. 389-394 [6 page(s) (article)] (28 ref.).

The authors conclude that even though the prevalence of abnormal screening partial thromboplastin time in these patients was low (3.57 percent), detection of an abnormal result required preoperative correction of coagulopathy in 80 percent of cases.

Article submitted with comments: ***Consensus Guidelines for Periprocedural Management of Coagulation Status and Hemostasis Risk in Percutaneous Image-guided Interventions.***

Response:

We appreciate the concern of these commenters. Review of the cited article (Genecov DG, et al, Plastic and Reconstructive Surgery 2005; 116(20):389-394) does indicate a small incidence (3.7%) of abnormal testing associated with increased bleeding in 80% of the patients identified, who were undergoing primary cranial vault remodeling surgery. The article does not include the age of the patients (pediatric versus adult) nor indicate whether these patients were in the typical Medicare age group. The second article cited, Consensus Guidelines for Periprocedural Management of Coagulation Status and Hemostasis Risk in Percutaneous Image-guided Interventions (accepted for publication, Journal Vascular Interventional Radiology) reviews multiple studies of different procedures including angiography, placement and removal of central venous catheters, nephrostomy tube placement, and liver biopsies and found that pre-procedural coagulation testing was either not indicated or that a conclusion about need could not be drawn. They noted that there was an increased incidence of bleeding in patients with thrombocytopenias undergoing lumbar punctures. A panel of experts identified procedures that in the absence of history and clinical indications would not require pre-procedural INR or PTT (in the absence of receiving heparin) , that would require only the INR and that would require INR and PTT (and platelet counts). They also recommended remedial measures.

A number of additional articles were also reviewed (Schramm B, et al, Anaesthesia and Intensive Care 2001; 29:388-394; Rohrer MJ et al, Annals of Surgery 1988; 208:554-557; NG KFJ et al, World J Surg 2002;

26:515-520; and Eisenberg JM et al, Arch Surg 1982; 117: 48-51). Each of these articles indicated that there appeared to be little indication for preoperative testing in the absence of history or other clinical indications demonstrating need.

The identified paragraph, "*Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other than thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy. Hospital/clinic-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage"* is a direct quote from the CMS National Coverage Determination (NCD) (190.16). Contractors are required to follow all NCDs and are not authorized to change them. We would like to point out that this limitation is not absolute and specifically suggests exceptions (as medically necessary) by stating "will generally be considered."

We agree that pre-operative testing may be necessary in patients recently on anticoagulation therapy or anticipated to require anticoagulation intra- or post-operatively.

We do note that the NCD does indicate the availability of coverage for the PTT or PT/INR when there is a history of bleeding or coagulation abnormalities, or clinical indications suggesting them. Furthermore, the indications specifically include patients about to undergo surgical procedures or similar interventions associated with increased risk of bleeding or thrombosis. We firmly believe that it is the responsibility of the physician to obtain the best history possible (including all medications recently prescribed, and a complete history from the referring physicians whom they acknowledge as an important source of these patients); and still recognize that such history may need to be supplemented by clinically appropriate testing. The LCD specifically includes coverage for *"...patients who cannot cooperate with an adequate clinical assessment and for those who are to undergo procedures in which even minimal postoperative hemorrhage could be hazardous."* We believe that this language is an interpretation of the NCD that is sufficiently broad to allow pre-procedural testing in those patients in whom bleeding during the anticipated procedure would subject the patient to an unwarranted risk <u>based upon the performing physician's clinical judgment</u>.

Although the commenters suggest risks of not performing preoperative testing, we note that this LCD does not prohibit the testing. Rather it addresses reimbursement when performed routinely without medical necessity. Furthermore, a number of possible scenarios may involve inpatient procedures for which testing may included in the DRG.

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<u>Comment</u>:
A physician from Indiana suggested that both PTT and PT LCDs should have ICD-9 code 585.3 (chronic kidney disease, stage III (moderate) added as so many are nephrotic and this is not separately coded.

<u>Response:</u>
The addition or deletion of specific diagnoses or ICD-9 diagnosis codes for laboratory tests that are covered under a laboratory NCD is not at the discretion of a local contractor, and may only be

performed through a change in the NCD itself. The commenter is advised to seek a change to the NCD to add the desired ICD-9 code.

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Comment:
Another physician from Indiana wanted to ensure that for the PT and PTT, these tests are covered prior to vascular surgery since they modify these numbers during the case by giving anticoagulants and the risk of post operative bleeding when operating on blood vessels is high. He believes that this must be clearing stated in the indications rather than implied since it could impact every operation we plan as vascular surgeons.

Response:
We agree that the anticipated use of anticoagulant therapy is an indication for the obtaining baseline tests of coagulation function. We will clarify the LCDs accordingly.

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Comments from the NY CAC Meeting:

Comment:
The CAC representative for Urology asked if pre-op clearance was a reason for performing both tests.

Response:

They are not medically necessary for pre-op clearance in the absence of a personal or family history or clinical evidence of bleeding disorders. In hospitals, these tests are often part of testing, during the global pre-operative period, and if so, may not be billed separately.

Comment:
The CAC representative for Anesthesia wanted to confirm that pre-op testing is not reason alone for the tests, but if there is another medically necessary condition, they could be done as part of pre-op testing.

Response:
These tests will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy. We also note in the LCD that testing may be considered medically necessary for patients who cannot cooperate with an adequate clinical assessment and for those who are to undergo procedures in which even minimal postoperative hemorrhage could be hazardous. We also believe that pre-operative testing may be necessary in patients recently on anticoagulation therapy or anticipated to require anticoagulation intra- or post-operatively.

Comment:
The Clinical Lab representative noted that he had tried to control the use of these tests together several years ago but commercial labs are at a disadvantage because when the physician orders the tests, the lab is obliged to perform the requested tests, or the physician will go elsewhere. The lab slips may list PT and PTT together, so both are circled by the physician.

Response:
We appreciate the comments of the CAC representative, and industry recognition of the issue. We believe that education of ordering providers by the laboratories and the physician community itself will help to correct unnecessary ordering of these tests. We agree that the presence of both tests on a requisition may result in both tests being ordered, and suggest that separating these tests on the lab slips may help to prevent the unnecessary performance of both tests.

Medicare may not pay for services which are not medically necessary.

Comment:
The representative for Medical Hematology/Oncology commented that ASCO felt that acute and chronic leukemias should also be listed as indications for PTT.

Response:
The addition or deletion of specific diagnoses or ICD-9 diagnosis codes for laboratory tests that are covered under a laboratory NCD is not at the discretion of a local contractor, and may only be performed through a change in the NCD itself. The commenter is advised to seek a change to the NCD to add the desired ICD-9 code.

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Comments from the Connecticut CAC Meeting:

Comment:
The representative for orthopaedic surgery asked about the laboratory requisition slip which includes the PT/PTT tests together.

Response:
We believe that physicians may have developed a habit of ordering both tests together during in-hospital training in which they are titrating a change in the patient's medication from intravenous heparin to warfarin.

We believe that education of ordering providers by the Medicare contractors, the laboratories and the physician community will help to correct unnecessary ordering of these tests. We agree that the presence of both tests on a requisition may result in both tests being ordered, and suggest that separating these tests on the lab slips may help to prevent the unnecessary performance of both tests.

Comment:
The Nephrology representative stated that there is an infrequent need for a PTT for dialysis patients on warfarin to assist in determining whether a markedly elevated PT/INR was due to excess warfarin effect or the result of residual heparin effect.

Response:
We are unable to identify a specific ICD-9 code to identify this situation. However, then NCD does indicate that in rare situations it may be necessary to perform a PTT when a PT/INR is unusually elevated. The medical record should document these instances.

Comment:
The CT Medical Society representative asked if there was a strategy in place for implementing these LCDs.

Response:
In addition to working with the laboratory community, NGS anticipates identifying ordering providers from their NPI and directing educational efforts towards them individually. NGS welcomes additional educational suggestions from the membership.

Comment:
The representative for Internal Medicine indicated PTT performed prior to surgery was unnecessary. He questioned if the claims were submitted by ambulatory surgical centers (ASCs). If so, we need to educate the ASCs on the medical necessity for the test.

Response:
NGS agrees and will ask its Provider Outreach and Education group to address the issue with the ASCs and hospitals.

Comment:
The CT Medical Society representative stated the three to seven day pre-operative rule was not economically driven but rather to be certain that the needed test results are available prior to the planned surgery.

Response:
We appreciate the Society's clarification of the pre-operative testing schedule.

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Comment:
A Kentucky CAC member commented that he thought these were good policies as it does not make sense to order those tests together.

Response:

We appreciate the CAC member's review of this LCD and support for it.

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Comment:

An Indiana CAC member commented that radiologists often require these tests prior to a biopsy even though they are not both required unless there is a history of liver disease, coagulopathy or bleeding. They will have to be educated as they often order those tests together for all patients. In addition, some labs have PT/PTT grouped together as a lab test.

Response:

The Medical Director from Illinois pointed out that Medicare does not have a benefit for screening and these tests should only be utilized for diagnosis and treatment.

The Indiana/Kentucky Medical Director stated that data has not shown that this is a large problem in Indiana and Kentucky. We agree that the presence of both tests on a requisition may result in both tests being ordered, and suggest that laboratories separate these tests on the requisitions so to help prevent the unnecessary performance of both tests when ordered for monitoring and regulation of anticoagulation medication.

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