CTI
Clinical Trial and Consulting Services

October Newsletter

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We are recruiting for CRAs in the US, UK, France, Belgium, Sweden and the Netherlands!

Upcoming Medical Meetings CTI will be Attending …

American College of Gastroenterology
Las Vegas, NV
October 19 – 24

Stem Cell Meeting on the Mesa
La Jolla, CA
October 29 – 31

American Society of Nephrology
San Diego, CA
November 1 – 4

Employee Update

Please welcome the newest addition to CTI:

Kyra Graham – Research Associate

The Medicare New Technology Add-On Payment Program: A Special Payment Methodology for New Medical Services and Technologies Used in Inpatient Procedures

New drug and device-related medical technologies can improve quality of care and clinical outcomes. However, the costs associated with the early adoption of breakthrough technologies may place hospitals at financial risk due to limitations of existing inpatient reimbursement systems.

For example, under Medicare Part A, inpatient hospital costs are reimbursed at a fixed, prospectively determined amount based upon Medicare severity diagnosis-related groups (DRGs). Hospitals receive fixed payments for Medicare beneficiaries based on average costs for treating patients in a defined group with similar symptoms and co-morbidities. The Centers for Medicare and Medicaid Services (CMS) revises DRGs annually using data from inpatient claims, but updates are based on data from claims provided 2 fiscal years before the fiscal year in which they will be used. While this system provides incentive to be efficient and reduce costs, *it may limit the risks hospitals are willing to take with newer medical technology that increase inpatient costs*.

In order to encourage the use of and timely access to potentially beneficial new technology that would be inadequately reimbursed under the existing DRG amount, CMS introduced the new technology add-on payment (NTAP) program in 2001. The additional payments are intended to bridge the 2 to 3 year recalibration delay by offering a temporary payment mechanism for the use of new technologies in addition to the DRG payment the hospital would otherwise receive.

Formal, detailed applications for the NTAP program are reviewed by clinical experts within CMS and are subject to opportunities for public comment. Technologies must meet 3 criteria set by CMS to be eligible for the NTAP program:

1. Newness: The technology must be "new"; the technology or service must not be reflected in the data used to establish DRGs (usually within 2 to 3 years following FDA approval).

Fatima Bouabdallah – Senior Clinical Research Associate Paris

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If you are interested in scheduling a meeting with CTI, please contact Nick Schatzman at 513-598-9290 or via email at nschatzman@ctifacts.com

2. Cost: Current payments for a DRG are inadequate to cover the additional cost of utilizing the new technology.
3. Clinical Improvement: The technology is a substantial clinical improvement in diagnosis or treatment relative to previously available technologies.

Once a new technology is reviewed and approved for the NTAP program, CMS will not automatically make an additional payment each time the new technology is used. Instead, the total payment is determined by how much it costs the hospital for the whole case, including the use of the new technology. In order for additional payments to be made, the costs of the case must be above the standard DRG payment. Also, the full extra costs of using the new technology are not paid by CMS to preserve incentives for judicious use. These limits decrease the financial risk of using the new technology while still encouraging hospital efficiency.

Only a limited number of medical devices and drugs have been approved under the NTAP program since its inception. **Recent new technologies that have qualified for NTAP include fidaxomicin (Dificid®, Optimer Pharmaceuticals, Inc.), a new treatment for *Clostridium difficile*-associated diarrhea, and glucarpidase (Voraxaze®, BTG International, Inc.), indicated for the treatment of toxic plasma methotrexate concentrations in patients with delayed methotrexate clearance due to impaired renal function.**

The NTAP program may be of interest to companies with newly approved technologies or new technologies in development that are expensive and used primarily in the inpatient setting, but provide substantial clinical benefit.

To learn more about The Medicare New Technology Add-On Payment Program and how CTI may be of assistance, please contact:

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About CTI

CTI Clinical Trial and Consulting Services is a repeat winner of "Best Places to Work" in Greater Cincinnati

CTI Clinical Trial and Consulting Services (CTI) is a unique drug and market development company offering a full range of services which encompass the entire lifecycle of drug development. These services include regulatory pathway design, clinical trial management, data analysis, medical writing, CME and training program development, market analysis and development and other consulting services. CTI focuses on the specific disease areas of solid organ transplant, hepatitis, infectious disease, end-stage organ disease and hematology/bone marrow transplant. With its combined expertise of clinical knowledge and market experience, CTI is uniquely positioned to incorporate both clinical and market driven endpoints and interpretations to provide extraordinary results.