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7/30/2008 - 9/28/2008

Potential NCD Topics

BACKGROUND

In the guidance document, "Factors CMS Considers in Opening a National Coverage Determination," we committed to posting potential NCD topics to the coverage web site. The guidance document encouraged the public to comment on potential topics and provide relevant evidence on whether a review should or should not proceed prior to the formal decision to open an NCD.

Following is a list of potential NCD topics. CMS used the circumstances outlined in the guidance document referenced above to vet topics and generate the list. Those circumstances include: 1) a significant number of inquiries from the public, providers, or patients; 2) new evidence or a reexamination of previously available evidence; 3) inconsistent or conflicting local coverage policies; 4) program integrity concerns; 5) substantial clinical advances; 6) technologies for which rapid diffusion could have a significant programmatic impact; or 7) significant uncertainty about the health benefit, patient selection, or appropriate facility and staffing requirements for a new technology.

We encourage comments on the below potential NCD topics. Please submit all comments to http://www.cms.hhs.gov/mcd/ncpc_public_comment.asp?id=19&from=viewindex&doc_type_id=2.

POTENTIAL NCD TOPIC LIST FOR THIRD QUARTER 2008

Thrombopoiesis stimulating agents (platelet growth factors e.g. romiplostim) may elicit safety concerns similar to the erythropoiesis stimulating agents (ESAs). Long term safety data are lacking.

ESAs have known serious adverse effects in patients who have cancer or pre dialysis chronic kidney disease (CKD). Their long term benefits and harms in the ESRD population are unclear. ESAs are a large cost in current ESRD treatment strategies.

CKD uses of ESAs have known adverse effects. Medicare recently implemented anemia reporting requirements that include the reporting of hemoglobin or hematocrit information on claims for ESA uses in CKD. It is unclear if ESAs are being used appropriately in this population.

Levocarnitine has unclear benefits in the ESRD population. Recent revisions of K-DOQI guidelines suggest a paucity of evidence to support some uses.

Parenteral iron supplementation may be accomplished with a variety of iron containing preparations. Iron overload and hypersensitivity reactions are not uncommon.

Bisphosphonates, particularly longer acting parenteral preparations, have been associated with osteonecrosis of the mandible (jaw) in patients who have dental procedures. Given the ready

availability of oral preparations it is unclear if the convenience afforded by the less frequent administration parenteral agents outweighs the potential harms.

A limited body of evidence informs **gene expression profiling tests** to inform cancer therapy decisions. It is unclear if the widespread addition of such testing to the evaluation of patients with would result in a meaningful change in disease management and improved health outcomes.

Treatment of wet AMD, central vein occlusion and diabetic retinopathy by anti-VEGF agents including but not limited to Avastin and Lucentis. This clinical field is growing by leaps and bound and we believe there is a need to systematically consider the evidence.

Proton beam therapy for prostate cancer: Proposed as means to concentrate radiation therapy and reduce side effects. Very high upfront cost to build these facilities and thus only at very few facilities. For prostate cancer treatment, no current comparative trials comparing to usual therapy.

Artificial cervical discs are being developed in an effort to treat symptomatic degenerative disc disease more effectively. The goal of this type of technology is to maintain spinal motion following anterior discectomy, to reduce the incidence of degeneration of adjacent disc levels of the spine (adjacent-segment disease), and to permit more rapid return to normal activity. Is the evidence adequate that this procedure results in improved health for the Medicare population?

Minimally invasive methods for bariatric surgery, such as minimally invasive Roux-en-Y gastric bypass is a procedure that is being performed with increasing frequency. It is an advanced laparoscopic procedure with a steep learning curve. Is current evidence sufficient to demonstrate that it results in improved health outcomes for morbidly obese patients?

Biological therapies for treatment of chronic wounds: Clinicians' understanding of and ability to achieve wound healing has increased significantly over the past few years, particularly as a result of advances in molecular biology such as the use of growth factors, the ability to grow cells in vitro and the development of bioengineered tissue. Is the evidence for any specific modalities adequate to demonstrate improved health outcomes for selected wound patients while avoiding side effects seen with other growth hormones?

Bone morphogenetic protein (BMP): Members of the BMP family are potentially useful as therapeutics in areas such as spinal fusion. BMP-2 and BMP-7 have been shown in clinical studies to beneficial in the treatment of a variety of bone-related conditions including delayed union and non-union. BMP-2 and BMP-7 have received Food and Drug Administration (FDA) approval for human clinical uses. Certain off-label uses in cervical spine fusion may be associated with life-threatening complications. Is the evidence adequate to demonstrate health improvements in the Medicare population?

Hip resurfacing may be an alternative to total hip replacement that might offer an interim option to patients. Although many patients can expect to outlive the treatment's effectiveness, hip resurfacing may have the advantage of preserving enough healthy bone to allow for a future total hip implant. Is the evidence adequate to demonstrate health benefits in the patients who receive the procedure?

Ablation for atrial fibrillation: If medication is not effective or not tolerated for atrial fibrillation, a nonsurgical procedure called catheter ablation may be chosen. Focal and circumferential catheter ablation for atrial fibrillation is still being studied in investigational trials but may be done in selected

patients to try to cure atrial fibrillation. Is the evidence adequate to demonstrate health benefits in the patients who receive the procedure?

Off label use of drug eluting coronary stents: Limited data are available on the off-label use of drug-eluting stents (DESs) in clinical practice. Is that evidence adequate to specify groups of patients that do benefit from treatment with coronary stents or clearly do not benefit?

Vertebroplasty and kyphoplasty: Vertebroplasty and kyphoplasty are radiologic procedures for the treatment of the intense pain caused by vertebral compression fracture in patients whose pain has been refractory to medical management or other therapy. Vertebroplasty and kyphoplasty involve the intraosseous injection of acrylic cement under local anesthesia and fluoroscopic guidance to control the pain of vertebral fractures associated with osteoporosis, tumors, and trauma. Typically, vertebroplasties are performed in an outpatient setting, while kyphoplasty typically requires hospital admission. Is the evidence adequate to demonstrate health benefits from pain reduction in selected patients?

Lumbar fusion for degenerative disc disease: For certain patients, a two level spinal fusion may be an effective treatment for debilitating back pain from two degenerated lumbar discs. Multilevel fusion as a primary treatment for low back pain from degenerated discs is a controversial topic in spine medicine. However, lumbar fusion of three or more levels of the low back as a primary treatment for back pain is rarely recommended, and many surgeons recommend against it in all cases of multilevel degenerative disc disease. Is the evidence adequate to specify groups that do and do not benefit from the lumbar fusion procedure?

Peripheral arterial stenting and vascular intervention: Angioplasty and angioplasty with vascular stenting are commonly used to treat conditions that involve a narrowing or blockage of arteries throughout the body, including 1) narrowing of large body arteries due to atherosclerosis, or hardening of the arteries, a gradual process in which cholesterol and other fatty deposits, called plaques, build up on the artery walls and 2) peripheral vascular disease (PVD) and peripheral artery disease (PAD), a narrowing of the arteries in the legs or arms. In patients with PVD or PAD, angioplasty alone or angioplasty with stenting may be used to open up a blocked artery in the pelvis, leg or arm. Is the evidence adequate to specify groups that do and do not benefit from angioplasty and stenting in the peripheral vascular system?

Pharmacogenomic testing: Pharmacogenomic testing detects DNA variants that are associated with altered response to therapeutic drugs, in order to optimize drug selection or modify drug dosage to improve effectiveness and/or to avoid adverse drug events. As examples, testing for certain variants in VKORC1 and CYP2C9 genes (and possibly others) may permit more accurate calibration of warfarin dosage for individuals to prevent thrombosis or thromboembolism; testing for a certain variant in the UDT1A1 gene may highlight greater risk of neutropenia in those receiving the drug irinotecan as part of their anti-cancer chemotherapy. However, there is a relative scarcity of high-quality published evidence from outcome-related clinical trials about the clinical utility due to pharmacogenetic testing at this time.