MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
NEW MEDICAL TECHNOLOGY (NEWTAC) ADVISORY COMMITTEE MEETING

Tuesday, August 30, 2007

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call To Order

Chairperson Marc Keshishian called the meeting to order at 1:11 p.m.

A. Members Present:

Yvonne Abdoo, PhD, RN, School of Nursing Faculty Member
Raymond Breiding, Health Care Provider Organization Representative Concerned With Licensed
Thomas Cooper, School of Osteopathy Faculty Member
David Ellis, Member Knowledgeable in Medical Technology
John Fox, MD, Third Party Payer Organization Representative (Arrived @ 1:14 p.m.)
Marc Keshishian, MD, Chairperson, CON Commission
Toshiki Masaki, Purchasing Organization Representative
Gordan Morlan, Health Care Consumer Organization Representative
Conrad Nagle, MD, Health Care Provider Organization Representative Concerned With Licensed
Predrag Sukovic, PhD, Member Knowledgeable in Medical Technology (Arrived @ 1:14 p.m.)
Don VeCasey, Health Care Consumer Organization Representative
Michael Witt, PharmD, Member Knowledgeable in Medical Technology

B. Members Absent:

Maureen Halligan, Health Care Provider Organization Representative Concerned With Licensed
Terry Keys, Health Care Provider Organization Representative Concerned With Licensed
Suresh Mukherji, MD, School of Medicine Faculty Member
Roland Palmer, Health Care Provider Organization Representative
Manuel Valdivieso, MD, Health Care Provider Organization Representative

C. Michigan Department of Community Health Staff Present:

Umbrin Ateequi
John Hubinger
Irma Lopez
Taleitha Pytlowanyj
Brenda Rogers
Matt Weaver

II. Declaration of Conflicts of Interests

No conflicts were declared at this time.

III. Review of Agenda

Mr. Keshishian recommended that an additional public comment portion be added to the agenda after item VII.

Motion by Mr. Breiding, seconded by Mr. Ellis, to accept the agenda as amended. Motion Carried.

IV. Review of Minutes – August 14, 2007

Motion by Dr. Nagle, seconded by Mr. VeCasey, to accept the minutes as presented. Motion Carried.

V. Criteria/Guidelines for Determining Whether a Clinical Service Should be Covered Under CON – Discussion

Ms. Rogers stated the Committee is starting basically from scratch. She also stated that the Department had polled other states that have CON and has not received very many responses. Dr. Nagle, Mr. Witt, and Mr. Ellis volunteered to work with Chairperson Keshishian to develop criteria/guidelines for determining whether a clinical service should be covered under CON. Discussion followed.

VI. Neurointerventional Facilities – Discussion

Ms. Rogers stated that the Department polled other CON states to determine who regulates neurointerventional facilities and vascular surgery, and only three responses had been received – no specific regulations. Dr. Nagle raised some concern regarding whether or not to regulate this service. Discussion followed.

VII. Public Comment

Dennis McCafferty, Economic Alliance for Michigan

VIII. Neurointerventional Facilities – Discussion and Action Continued

Motion by Dr. Nagle, seconded by Mr. Ellis, to report to the Commission that at this time, there is a lack of evidence that demonstrates there is a need to regulate this service and should reconsider regulation in the future if data is provided that proves otherwise. Motion Carried.

Break from 2:30 p.m. to 2:46 p.m.

IX. Vascular Surgery – Discussion

Chairperson Keshishian provided brief information on vascular surgery (Attachment A). Dr. Nagle provided the Committee with background information on vascular surgery. He also recommended inviting the appropriate medical physicians to come speak in order to gain more information. Mr. Witt requested data regarding the volume of diagnostic procedures that are repeated when they do therapeutic procedures. Ms. Abdoo requested data regarding reimbursement rates. Discussion followed.

X. Public Comment

Bob Meeker, Spectrum Health

XI. FDA Pre-Market Overview

Mr. Sukovic provided a brief overview of the FDA's approval process. He stated that FDA is primarily concerned with safety and efficacy. Discussion followed.

XII. Next Steps

The Committee members and Department staff will continue to research services that are regulated in other states and bring more data to the Committee.

XIII. Adjournment

Motion by Mr. Breiding, seconded by Ms. Abdoo, to adjourn the meeting at 3:55 p.m. Motion Carried.

Mayo Clinic -Vascular Surgery

Experienced vascular surgeons at Mayo Clinic offer comprehensive, diagnosis and repair for damaged or diseased blood vessels. Patients with vascular-related medical needs receive care from a team of specialists that may include cardiologists, neurologists and diagnostic radiologists. Mayo Clinic in Rochester has a special Vascular Center that brings together experts from many specialties in a physical space and using technology dedicated to treatment of patients with vascular disorders.

Specialty services offered through Vascular Surgery include:

- Doppler testing
- Endovascular surgical intervention such as angioplasty or stents
- Exercise assessment of the arterial circulation
- Hemodialysis access
- Invasive and noninvasive interventional techniques
- Lower extremity/limb salvage
- Measurement of cold sensitivity
- Plethysmographic studies
- Transcutaneous oxygen measurements
- Vascular surgery

Stanford - Division of Vascular Surgery

The Vascular Center and the Division of Vascular Surgery were founded in 1993. Since then the Division has grown to include interdisciplinary clinical teaching and research programs with close interaction among faculty, community vascular surgeons, interventional radiologists, cardiologists, cardiac surgeons, podiatrists, rehabilitation specialists, basic scientists, engineers and computer scientists. These unique collaborations have promoted remarkable academic and clinical productivity involving new and dramatically improved techniques for the diagnosis and treatment of vascular disease. Daily interactions between these diverse specialists have gained the Division national and international recognition as a Center of Excellence.

Yale Vascular Surgery is a group of doctors with superior skill in the treatment and management of patients with peripheral vascular disease, chronic and complex wounds, and potential limb loss. We emphasize prevention, risk factor evaluation and reduction, patient education, comprehensive diagnostic evaluation, and advanced care. Our surgeons specialize in open, endovascular, minimally invasive and bloodless non-invasive procedures for the full range of vascular disease and conditions:

- Carotid artery stenosis
- Visceral artery disease, including renal arteries
- Abdominal and thoraco-abdominal aortic aneurysm
- Vascular access for hemodialysis
- Aortoiliac occlusive disease
- Lower extremity arterial and venous problems

- Diabetic foot salvage
- Non-healing wounds
- Limb salvage and preservation

Yale Vascular Surgeons and their colleagues offer novel treatment options to patients for whom traditional methods might have been unsuccessful. Specialists in interventional and diagnostic radiology, podiatry, nephrology, endocrinology and cardiology work with our vascular surgeons on a case-by-case basis to diagnose, manage, and follow patients. We see patients at our offices at Yale Physicians Building ; perform operations at Yale-New Haven Hospital , Temple Surgical Center , and at the Veterans Administration Medical Center ; train students, fellows and residents; and, conduct research into the pathophysiology of vascular disease.

Indiana University - The **Vascular Surgery Service** provides comprehensive care to patients with diseases of the blood vessels (arteries, veins, and lymphatics). Our staff physicians are specifically trained and board certified to diagnose and treat all varieties of blood vessel disorders. We train the next generation of Indiana physicians in the care of these patients. We also provide post-graduate training to physicians, surgeons, and medical scientists.

Our expertise is enhanced by an active **Non-invasive Clinical Vascular Laboratory** equipped with state-of-the-art technology. Furthermore, optimal hospital-based facilities allow for innovative approaches to the treatment of vascular diseases, such as **endovascular surgery** (e.g. aortic stent-grafts for the treatment of aortic aneurysms).

The Cleveland Clinic Department of Vascular Surgery cares for patients with a broad spectrum of vascular diseases. The year 2004 marked a milestone for staff in the Department of Vascular Surgery, having performed more than 5,000 procedures. In addition to the Cleveland Clinic's main campus, our staff also provides care in six neighboring locations in Northeast Ohio.

While nearly one-third of our services are currently performed to treat those with peripheral occlusive disease, we also provide a significant number of patients with care for aneurysms of the abdominal and thoracic aortas, and in increasing numbers, for those with venous disease. Our staff also provides dialysis access to allow those individuals with end-stage renal disease to begin treatment. Many patients are also treated for cerebrovascular disease to reduce the risk of stroke.

Cleveland Clinic - Percutaneous and Endoscopic Interventions for Heart and Vascular Disease - Non-surgical approaches

As cardiologists and heart surgeons search for new techniques to treat heart and vascular disease in less invasive ways, many new percutaneous (also called endovascular) procedures are evolving that will provide non-surgical treatment options for patients in the future.

Instead of the large incision required for traditional heart or vascular surgery, percutaneous approaches use special catheters and devices to treat the problem through one or more small puncture sites through the skin.

Endoscopic approaches are a subset of percutaneous approaches that use one or more small puncture sites and a thin video instrument with a small camera at the tip. This scope transmits a picture of the internal organs on a video monitor to give the surgeon a close-up view of the surgical area as he performs the procedure.

For the patient, percutaneous procedures mean very small incisions and a much quicker recovery time. Even better, they may offer options for some patients who could not undergo conventional surgerydue to poor heart function or additional medical problems.

The following are current procedures that may be performed percutaneously at the Cleveland Clinic Heart and Vascular Institute. Some may be used in current practice. Others are being evaluated in research studies:

- Percutaneous valve repair and percutaneous valve replacement surgery
- Percutaneous coronary artery angioplasty and stenting
- Percutaneous carotid artery stenting
- Percutaneous and endoscopic atrial fibrillation procedures
- Percutaneous adult congenital heart disease treatment - ASD and PFO
- Percutaneous ventricular assist device placement
- Endovascular aortic stenting
- Endoscopic lead placement for defibrillator or pacemaker devices
- Endoscopic radial artery and saphenous vein harvesting for bypass surgery