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Magruder C. Donaldson, M.D.
Metro West Medical Center
85 Lincoln Street
Framingham, MA 01702
508-383-1553 Fax: 508-383-1746
e-mail: craig.donaldson@mwmc.com

Frank B. Pomposelli, M.D.
Beth Israel Deaconess Hospital
One Deaconess Road
Boston, MA 02215
617-632-9847 Fax: 617-632-7977
e-mail: fpompose@bidmc.harvard.edu

Craig Haug M.D.
National Heritage Insurance Company
75 Sargeant William Terry Drive
Hingham, MA 02043

December 1, 2005

From: The New England Society for Vascular Surgery

Dear Dr Haug:

We have read with interest the “LCD for Endovascular Repair for Descending Thoracic Aneurysm (DTA)-DRAFT”. Overall, this is a well-written document that clearly required considerable thought and an extensive literature review. We are in agreement with the majority of the document, but would suggest a modest change in the “Indications of Coverage” section, which currently reads:

“Endovascular stent grafting for *descending* thoracic aortic aneurysms with an FDA-approved device is considered medically necessary for high-risk patients who:

- might not be candidates for open repair, and
- have adequate iliac/femoral access, and
- have an inner diameter of aorta proximal and distal to the portion needing repair sufficient to meet published device requirements, and
- have a length of aorta proximal and distal to the portion needing repair sufficient to meet published device requirements”

Our primary concern is the term “high-risk” in the first sentence, as the term could be subject to an overly stringent interpretation. The first bullet point suggesting patients “might not be candidates for open repair” may further increase the potential for an overly stringent interpretation. Of course, in a very real sense every patient is at “high risk” for open repair of the descending thoracic aorta, as the LCD draft document implies. Major series in the references listed in the LCD draft have clearly documented substantial rates of mortality and severe morbidity for open repair. Our concern is that the document might give the impression that coverage should only be allowed for extremely high-risk patients. The recent pivotal clinical trial of the Gore thoracic endograft indicates that in patients with appropriate anatomy **who are open surgical candidates**:

- the mortality rate is significantly lower for endovascular repair (1% vs 6%, and updated abstract recently reported at the national Thoracic Surgery meeting indicates mortality rates are endovascular 2% and open repair 11.7%, $p < .001^*$)
- the paraplegia/paraparesis rate is significantly lower for endovascular repair (3% vs 14%, $p = .003$)
- aneurysm-related death is lower through 2 year follow-up (3% vs 10%)
- patients undergoing endovascular repair have a shorter ICU stay (1 vs 3 days), hospital stay (3 vs 10 days) and time to return to normal activity (30 days vs 78 days)
- the rate of numerous major complications (pulmonary, renal, neurologic, cardiac, wound, bleeding, etc) are all substantially higher for open repair

Above based on references in the LCD draft document and publicly-available FDA reported data, including the Gore “Instructions for Use” document required and reviewed by the FDA. * Mitchell RS, et al. Endovascular stent grafting versus Open surgical repair of descending thoracic aortic aneurysms: A multi-center comparative trial. Presented at American Association of Thoracic Surgeons, San Francisco, April 12, 2005.

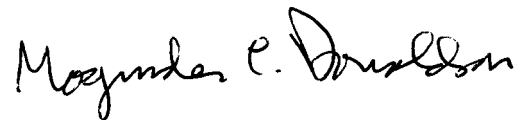
Our suggestion is to base coverage on appropriate indications, as in the LCD draft document, but allow the implanting physician to determine which patients are best suited for endovascular or open repair (as with any other procedure where a traditional open repair and a minimally-invasive option co-exist, such as endovascular or open AAA repair, laparoscopic and open cholecystectomy, etc.). We believe that this is the intent of the LCD document based on its overall content, thus the suggested change would not markedly alter content, but rather clarify the wording. As such, please consider the following for the “Indications of Coverage” section:

“Endovascular stent grafting for *descending* thoracic aortic aneurysms with an FDA-approved device is considered medically necessary for patients who:

- have adequate iliac/femoral access, and
- have an inner diameter of aorta proximal and distal to the portion needing repair sufficient to meet published device requirements, and
- have a length of aorta proximal and distal to the portion needing repair sufficient to meet published device requirements”, and
- who, in the view of the treating physician, are better suited for endovascular repair than open repair or observation, taking into account the short-term and long-term risks and benefits, and
- who after discussion of risks and benefits, concur with their physician that endovascular repair is preferable to the other options.

We believe that the suggested wording clarifies the document and retains the original intent. The suggested wording is also consistent with coverage for other minimally invasive procedures and standard medical practice. We look forward to the final document and will be happy to answer any questions that might arise from our comments.

Sincerely yours,

A handwritten signature in black ink that reads "Magruder C. Donaldson". The signature is written in a cursive, flowing style.

Magruder C. Donaldson, MD
President, New England Society for Vascular Surgery

NESVS Ad hoc Committee for Response to “LCD for Endovascular Repair for Descending Thoracic Aneurysm (DTA)-DRAFT”

Mark Fillinger MD (Committee Chair)

Professor of Surgery, Dartmouth Medical School, Section of Vascular Surgery, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Michael Belkin MD

Chief, Division of Vascular and Endovascular Surgery, Brigham and Women's Hospital
Associate Professor of Surgery, Harvard Medical School, Boston, MA

Richard P. Cambria MD

Professor of Surgery, Harvard Medical School
Chief, Division of Vascular and Endovascular Surgery,
Massachusetts General Hospital, Boston, MA

Jack Cronenwett MD

Past President, New England Society for Vascular Surgery,
Professor of Surgery, Dartmouth Medical School, Chief, Section of Vascular Surgery, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Magruder C Donaldson, MD

President, New England Society for Vascular Surgery
Associate Professor of Surgery, Harvard Medical School
Chairman, Department of Surgery
Metro West Medical Center, Framingham, MA

Frank Pomposelli MD

Secretary, New England Society for Vascular Surgery,
Chief of Vascular Surgery
Beth Israel Deaconess Medical Center, Boston MA

Marc Schermerhorn MD

Chief, Section of Interventional and Endovascular Surgery
Division of Vascular and Endovascular Surgery
Beth Israel Deaconess Medical Center, Boston MA

Andrew Stanley MD

Councilor, New England Society for Vascular Surgery,
University of Vermont, Dept of Surgery, Burlington VT

Robert Zwolak MD, PhD

Immediate Past President, New England Society for Vascular Surgery,
Professor of Surgery, Dartmouth Medical School, Section of Vascular Surgery, Dartmouth-Hitchcock Medical Center, Lebanon NH