



October 29, 2004

Steve Phurrough, M.D., Director
Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard, C1-09-06
Baltimore, MD 21244

Dear Dr. Phurrough,

On behalf of the University of Wisconsin in Madison, this submission is a formal Request for Reconsideration of the Centers for Medicare and Medicaid Services' National Coverage Decision (NCD) on Intestinal and Multivisceral Transplantation (#CAG-00036N). Our request is based on the fact that CMS' decision materially misinterpreted the existing evidence on the effect of intestinal transplant volume on one-year survival at the time the NCD was made, and that additional material medical and scientific information that was not considered in the initial review is now available.

Each of these issues is discussed in detail with supporting Exhibits in our Request for Reconsideration. We also note significant public policy considerations that support expanding Medicare coverage to centers other than the six transplant centers currently certified by Medicare to perform intestinal and multivisceral transplants.

We propose that CMS revise its NCD to adopt the following standard: centers that have performed 10 cumulative intestinal transplants with one year patient survival of 65% using the Kaplan-Meier technique could become eligible for Medicare coverage for intestinal and multivisceral transplantation. The University of Wisconsin, one of the nation's leading clinical transplantation centers, meets the proposed revised standard. In addition, the outcomes of our Medicare-approved liver, kidney, pancreas, heart and lung transplant programs, compiled by UNOS in its center-specific data, are either the best or among the best in the country in every category.

The University of Wisconsin has a long and distinguished record of basic research in many areas of transplantation science. Funded by the National Institutes of Health for more than 25 years, we are pioneers in many areas, including the development of improved immunosuppressive therapy for intestinal transplants. We also have gained a body of valuable experience relevant to intestinal transplantation issues through our leadership in pancreaticoduodenal transplantation. Our clinical as well as research background has allowed us to build a programmatic infrastructure that supports all aspects of transplantation medicine and surgery.

We respectfully request your expeditious consideration and appreciate the opportunity to present more recent information as you consider the University of Wisconsin's Request for Reconsideration of CMS' National Coverage Decision on Intestinal and Multivisceral Transplantation. If we can provide any additional information or documentation, please feel free to contact me at 608-263-2527 or Martha Kendrick at 202-457-6520.

Sincerely,

A handwritten signature in black ink, appearing to read "A. D'Alessandro". The signature is fluid and cursive, with a large initial "A" and a long, sweeping underline.

Anthony M. D'Alessandro, M.D.
Professor of Surgery
Director of Intestinal Transplantation
University of Wisconsin Hospital and Clinics

cc: The Honorable Tommy G. Thompson
The Honorable Mark McClellan, M.D.