

**Initial Public Comments for
Autologous Stem Cell Transplantation
CAG-00050R
June 15-July 15, 2004**

Comment #1:

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Organization: Dana-Farber Cancer Inst. and Harvard Medical School

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Comment:

Dana Farber Cancer Institute is in strong agreement with the information provided by Legacy Good Samaritan Hospital in support of coverage for Autologous Stem Cell Transplantation for AL Amyloidosis. Data presented by Boston University School of Medicine, Mayo Clinic, Washington University, and the ABMTR conclude that AuSCT offers improvement in overall survival for patients age 65 and over and therefore would provide significant life-prolonging benefit to applicable patients in the Medicare population. The information provided in the request for reconsideration clearly now addresses the initial Medicare non-coverage decision that resulted from a lack of data for the Medicare population. Patient safety and other concerns are also addressed within the reconsideration request and unmistakably demonstrate support for coverage of this service.

A report published in Blood Journal in May of 2004 provides additional information regarding the patients enrolled in the Boston University Medical Center trials. This report focuses on the Improvement in Quality of Life in Patients with AL Amyloidosis Treated with High Dose Melphalen and Autologous Stem Cell Transplantation. This report confirms the measurable and sustained improvement in quality of life for AL Amyloidosis patients treated with HDM/AuSCT. This was reported for all age populations, including the Medicare population.

Benefits in both survival and quality of life as shown in recent data are not only reasonable and

necessary but also impart medically compelling rationale reasons for providing Medicare patients with coverage for this treatment option.