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91 Percent of Oncologists Polled Report Adverse Patient Events as Result of CMS National Coverage Decision on ESAs

(Houston, January 30, 2008) In a national poll of medical oncologists and hematologists, 91 percent reported the occurrence of adverse patient events in the 12-week period following the implementation of the new CMS coverage criteria for Erythropoiesis Stimulating Agents (ESAs).

Sponsored by US Oncology and conducted by KJT Group, a national healthcare research company, the blinded, quantitative national survey of community-based oncologists included closed and open-ended questions about the impact of the new CMS National Coverage Decision on Medicare patients, treatment protocols, and physician practices. The number of US Oncology affiliated physicians were limited to less than 20 percent of all respondents to ensure the survey results were representative of the national oncology community. With a total sample size of 307 oncologists and hematologists, the overall margin of error is +/- 5.6 percent.

Dr. Kenneth J. Tomaszewski, an Adjunct Assistant Professor at the University of Rochester's School of Medicine and founder of the KJT Group, said, "the need to determine how policy change affects real life practice is critical to understanding its true impact. This study provides evidence that the National Coverage Decision, as it relates to ESAs, may have costs associated with quality of life decrements and increased treatment times that may outweigh the benefits for some patients."

Among the adverse outcomes reported by the oncologists and hematologists participating in the poll, transfusions were the primary event experienced by Medicare patients.

- 73 percent Potentially avoidable transfusions
- 65 percent Patient remained symptomatic of anemia despite ESA use according to the National Coverage Decision
- 54 percent Interruption of chemotherapy, dose reduced or changed due to anemia
- 39 percent ESA treatment terminated due to failure to meet the mandated hemoglobin (Hgb) response rates within 8 weeks.

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“We have heard anecdotal accounts of adverse patient events resulting from the new national coverage decision on ESAs, but it was important to statistically quantify the effects the decision is having on patients,” said Michael Kolodziej, M.D., chairman of the US Oncology network’s P&T physician committee and a practicing medical oncologist in the Albany, NY area.

“Highly respected oncology professional organizations like ASCO and ASH (American Society of Clinical Oncologists and American Society of Hematologists) have already weighed in on the ESA guidelines they think are appropriate based on the prevailing medical evidence. We believe it is also important to capture what practicing medical oncologists and hematologists are seeing in their offices – with real patients on a daily basis.”

The respondents estimated that the average number of patients requiring potentially avoidable transfusions accounted for approximately 17 percent of their Medicare patients in the 12-week period preceding the research study. However, nine percent of the respondents indicated that it was impacting an average of 50 percent of their Medicare patients.

When asked whether they had found it necessary, under NCD-mandated ESA use, to reduce or modify chemotherapy treatments that may not be optimal given the patients’ health status or disease stage, 30 percent answered affirmatively. On average, responding oncologists estimate that one of every five Medicare patients had their chemotherapy altered to a less than optimal regimen, and 43 percent reported that they’d had to modify the chemotherapy regimens for as many as 30 percent of their Medicare patients. The physicians also voiced their strong consensus (78 percent completely or somewhat agreed) that the current NCD guidelines impact the quality of care they are able to deliver to their patients.

“The results of this study provide supporting evidence to the beliefs of many practicing medical oncologists (73 percent), that the national coverage decision is creating a two-tiered system of health care where Medicare patients do not have access to the same quality of treatment or quality of life as non-Medicare patients,” said Dr. Roy Beveridge, a practicing medical oncologist in the Fairfax, Va. area.

“There is published medical evidence that demonstrates how to safely and more effectively use ESAs in cancer patients and now, this study suggests there is also a real patient care need to find a better way for all patients.”

In one section of the study, the respondents were asked to list the benefits of the NCD on ESA. In these open-ended responses, perceptions of the NCD were not generally positive, however, there was some agreement that it could help address the financial issues associated with ESA use. Few respondents named positive value or benefit to the patients they serve. The most frequently cited responses included:

- 31 percent No benefits/none.
- 24 percent Less abuse and/or more efficient use
- 14 percent Cost savings
- 13 percent Limiting negative side effects and/or improving survival
- 11 percent Saving the federal government money
- 6 percent Avoiding Hgb levels that exceed clinically safe limits

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The surveyed physicians were asked to identify issues and/or challenges associated with the NCD. In this open-ended question, a substantial number of patient care issues and/or challenges were provided. The most frequently provided responses included:

- 29 percent More transfusions
- 25 percent Lower quality of life
- 20 percent Anemic patients
- 21 percent Patient cannot maintain Hgb level
- 17 percent Too restrictive and/or complicated guideline
- 15 percent Not able to personalize or to provide best treatment
- 10 percent Compliance/implementation time and cost

In another section, the physicians were asked to indicate their agreement or disagreement with a series of statements about the NCD on a five-point scale. When asked if they agreed or disagreed with the statement that the “ESA Guidelines Have Improved the Safety of ESA Use in Cancer Patients”, only 25 percent of physicians somewhat or completely agreed. The respondents were also asked if they agreed or disagreed with the statement, “The NCD is Representative of the Medical Evidence Surrounding the Use of ESAs and Their Value to Cancer Patients,” only 21 percent completely or somewhat agreed.

“The oncology community is well aware of the escalating costs of cancer care in relation to the rising patient population and to the dramatic new therapies available to treat this horrible disease. Evidence-based medicine is generally accepted as the best approach for ensuring patients receive clinically-proven treatments to improve survival rates, while also reducing the cost variability of care,” said Peter G. Ellis, M.D, Clinical Associate Professor of Medicine at the University of Pittsburgh School of Medicine and the Director of Medical Oncology Network at UPMC Cancer Centers. “Many leading organizations, such as ASCO, NCCN, ASH and US Oncology have established evidence-based guidelines that are in alignment with the FDA label. And in this instance, it is not surprising that the community is expressing such discontent with a policy that they believe does not represent the prevailing medical evidence, or the best interests of their patients.”

Tomaszweski added, “The importance of this type of research is rapidly increasing as public and private institutions come to grips with the need to balance cost and benefits in a world with limited resources and increasing demand. It is always important to understand and to measure the intended and unintended consequences. The evidence in this study points rather sharply to the need for more clarity about how the NCD is affecting Medicare patients.”

Study Methodology

KJT Group conducted this survey among a cross section of U.S.-based medical oncologists and hematologists who replied to a USPS-mailed invitation to participate. The quantitative survey was blinded (no sponsor was identified) and was completed in December 2007. The survey was completed by 307 medical oncologists and hematologists. Respondents to the survey represented large and small office or clinic-based practices and 72 percent were practice presidents or physician partners in their respective practices.

The full survey instrument and findings are available upon request.

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About US Oncology, Inc.

US Oncology, headquartered in Houston, works closely with physicians, manufacturers and payers to identify and deliver innovative services that improve patient access to integrated cancer care in the community setting. US Oncology supports one of the nation's largest cancer treatment and research networks with services that help participating oncologists advance care through shared best practices and all phases of research.

US Oncology's expertise in every aspect of the cancer care delivery system—from drug development to treatment and outcomes measurement—enables the company to help increase the efficiency and safety of cancer care. According to the company's last quarterly earnings report, US Oncology is affiliated with 1,164 physicians operating in 443 locations, including 91 radiation oncology facilities in 39 states. For more information, visit the company's Web site, www.usoncology.com.

About KJT Group

KJT Group, headquartered in Honeoye Falls, NY, is a growing research and consulting firm focusing on the health services research market. Founded by Dr. Kenneth J. Tomaszewski, KJT Group blends academic rigor and practical market research techniques. Areas of specialization include market analysis and health outcomes research. As Adjunct Assistant Professor at the University of Rochester's School of Medicine, Dr. Tomaszewski is the course director for Survey Research, and guest lecturer in cost effectiveness. For more information, visit www.kjtgroup.com.

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