

by Bryan Cote

In the saga playing out over CMS's decision last summer to restrict treatment using erythropoietin stimulating agents (ESAs), we've cast Sharon Bromley as the analyst. "You want hemoglobin at 13 or 14—not wait until it's at 10," Bromley, administrator at Summit Cancer Care in Savannah, Ga., begrudgingly told us last August in the wake of CMS' national policy decision. "More patients will require blood transfusions because they'll be anemic...this policy could have an adverse effect on quality of life."

Six months after Bromley's prognostication, a national poll of 300-plus medical oncologists and hematologists conducted by the KJT Group and commissioned by US Oncology revealed anecdotal evidence to support her claim: adverse patient events—namely blood transfusions—were on the rise in the 12-week period following the ESA policy.

Of the 307 respondents to the KJT Group study:

- 73% reported transfusions that would have been potentially avoidable without the policy
- 65% reported that patients remained symptomatic of anemia, despite ESA use, according to the National Coverage Decision
- 54% said they interrupted chemotherapy and reduced or changed doses due to anemia
- 43% reported that they'd had to modify the chemotherapy regimens for as many as 30% of their Medicare patients

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

This is survey research, not hard data, acknowledged Dan Cohen, Senior Vice President of Government Relations and Public Policy at US Oncology. To quantify and add to the research base, US Oncology is reviewing data prospectively from 600 of its network physicians using an existing electronic medical record. "We're tracking the change in chemo treatment patterns and what that has meant to issues such as tumor progression and mortality since the coverage decision was announced," said Cohen.

Increases Seen in Hospital Blood Transfusions

Reported increases in blood transfusions have had a ripple effect on practice operations and business operations in other healthcare settings. "Physicians are clearly changing therapy patterns in Medicare patients to avoid having to order transfusions," says Cohen.

In addition, one point the study did not address, is the surge of patients redirected to local hospitals for transfusions, further crowding emergency departments in some cases. Bridgeport Hospital, Bridgeport, CT reported that blood transfusions increased nearly 30% on average per month since September 2007. Complicating matters, if CMS requires each ESA administration to be billed separately for outpatient oncology services, hospitals may pay a price. "This could

Nursing staff are spending additional time telling Medicare-age patients that they can't receive the same treatment as the younger, non-Medicare patient one infusion seat to the left.

have a significant operational effect on those hospitals that bill monthly for outpatient oncology,” says Hugh Aaron, JD, MHA, CPC, a regulatory consultant.

“For the elderly, you just can’t give blood quickly—the heart can’t compensate the way it can for a healthy, younger patient,” says Roy Beveridge, MD, a medical oncologist with Fairfax Northern Virginia Hem/Onc. “You can’t give 2 liters in 4 hours. We all have to admit more patients to hospitals ... and many are already near capacity like Fairfax Hospital. [Since the policy started], you have to give people blood over 8 to 10 hours, give them diuretics, and fluids.”

CMS Stance

CMS remains confident in its decision. Mounting evidence, including two clinical studies casting more doubt on the safety of the ESA drugs, backs the original policy, Dr. Barry Straube, the chief medical officer at CMS, said at the Reuters Regulation Summit February 7. “I think that our national coverage decision has been shown, with even more evidence coming out since we made it, to have been the right thing to do,” said Straube.


Smaller practices appear less insulated from the policy. Groups with three or fewer physicians have purportedly contacted US Oncology in greater numbers recently about joining its network. “This may be reaching a tipping point,” Cohen said of the ESA coverage change.

It’s About the Patients

Nursing staff are spending additional time telling Medicare-age patients that they can’t receive the same treatment as the younger, non-Medicare patient one infusion seat to the left. Practices are using two sets of orders in a decision-tree approach to care, one that Beveridge and Bromley both say has strained patient communication. About half of the Medicare patients have needed additional caregiver support—a sign that the decision has financial implications for patients and the health system, says Bromley.

“Patients next to each other have similar cancers, but they’re getting different treatment , [not just the ESA], but for supportive care drugs and different treatment models,” says Dr. Beveridge.

The drugs at issue include Amgen’s Aranesp and J&J’s Procrit. CMS issued its payment restrictions in July 2007 after two large studies and four clinical trials raised safety concerns, and the Food and Drug Administration required a stronger warning on the drugs’ labels. The drugs can boost risk of heart problems and even death especially at high doses. CMS’s Dr. Straube said one likely option he believes the FDA will consider is to restrict use of the drug in some cancer patients.

“We should all be concerned about safety signals,” Dr. Beveridge says. “But at this point, it’s hard to understand the signals.” 

OBR UPDATE

Foregoing ASP: Small Practice Oncologists Enroll in CAP

Signifying a change from 2007 enrollment trends, small practice oncology groups are enrolling directly in the Medicare Part B competitive acquisition program (CAP), BioScrip and several practices shared with OBR in February confirmed.

In early 2007, the Medicare Part B program’s vendor, BioScrip, reported that oncology scripts were written under the program, but very few oncology practices had signed up. “We had almost 300 internal medicine specialists enrolled in 2006,” said Russell Corvese, a BioScrip administrator. “Many had an oncologist in their practice writing the chemotherapy script.”

In 2008, however, oncologists—including several in the New York City area—enrolled during Medicare’s latest sign-up period, January 1 to February 15, according to BioScrip. This means that some oncologists are choosing to forego buying and billing drugs under the average sales price system (ASP) for their Medicare population and, for the moment, are sending a significant portion of their business to BioScrip.

Across specialties, there are approximately 3000 total physicians enrolled in the CAP. OBR will have an exclusive oncology enrollee breakdown, interviews, and analysis in an upcoming issue.



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