

Study evaluates the factors underlying Medicare decisions on coverage of medical technology

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A new study by researchers at Tufts Medical Center provides unique insight into factors that affect Medicare decisions on whether to pay for medical technologies. The study, published online by the journal *Medical Care*, underscores that the Centers for Medicare and Medicaid Services has incorporated evidence-based medicine into its decision making, highlighting the importance of the strength and quality of the supporting clinical evidence. Further, the research provides important insight into the "reasonable and necessary" criteria, illustrating the significance of the availability of alternative therapies, while suggesting that CMS accounts for value in coverage decisions.

By law, Medicare is mandated only to cover medical technology deemed "reasonable and necessary" for the diagnosis of illness or injury in Medicare beneficiaries. CMS makes 10-15 national coverage determinations (NCDs) each year on technologies deemed to have a substantial impact on the program. Because CMS has not provided formal guidance on the interpretation of the "reasonable and necessary" criteria, it has not always been clear what factors play a role in technology coverage decisions. The new study is the first of its kind to evaluate quantitatively the factors underlying Medicare decisions.

The research also shows that CMS's coverage of medical technology has become more restrictive over time. When controlling for other factors, CMS was ten times less likely to cover a technology from 2006 through



2007 than it was in the early 2000s.

"This research offers the <u>medical community</u> a better understanding of the type of evidence that <u>Medicare</u> considers in NCDs," said lead author James D. Chambers of Tufts Medical Center, "thus providing a valuable insight into the reasonable and necessary criteria." He added that "CMS and other payers can also benefit from this kind of external review of coverage decisions as it can help ensure the consistency of decisions and the integrity and accountability of the coverage process."

The authors used data from the Tufts Medical Center NCD database, and conducted a logistic regression analysis to evaluate how various factors affect the likelihood of positive coverage.

Key findings include:

- --CMS is favoring proven interventions. Compared to interventions with <u>clinical evidence</u> deemed "insufficient", interventions with good or fair quality supporting evidence were approximately six times more likely to receive a positive decision.
- -- Interventions with available alternatives are less likely to be covered. Compared with interventions with no available alternative, those for which an alternative was available were approximately eight times less likely to receive a positive decision.
- -- CMS accounts for value in coverage decisions. Compared with technologies estimated to be dominant, i.e., more effective and less costly than the competing intervention considered, those with no published estimate of cost-effectiveness were approximately five times less likely to receive a positive coverage decision.
- -- Coverage decisions have become more restrictive over time.



Compared with coverage decisions made in the years 1999 to 2001, decisions made from 2002 to 2003 were more than three times less likely to be positive. Decisions made from 2004 to 2005 were also more than three times less likely to be positive, and from 2006 to 2007 decisions were almost ten times less likely to be positive.

Provided by Tufts Medical Center

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