Evidence Lacking for Medicare Coverage Decisions

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Data reviewed by the Centers for Medicaid and Medicare Services to inform Medicare treatment coverage decisions reflect populations that are significantly different from the Medicare beneficiary population, a recent analysis has shown.

In 1998, the CMS established a panel of physicians and other professionals to review the evidence base before the agency makes national Medicare coverage decisions. The independent panel, now called the Medicare Evidence Development and Coverage Advisory Committee (MedCAC), reviews the literature described in a technology assessment and votes on the evidence to determine the health benefit of the medical procedure or device, wrote Sanket S. Dhruva and Dr. Rita F. Redberg, both of the University of California, San Francisco, which, along with the Robert Wood Johnson Foundation, provided support for the study. Dr. Redberg is a member of MedCAC, but had no financial conflicts of interest to disclose.

To examine whether the data used by MedCAC was generalizable to the Medicare population, Mr. Dhruva and Dr. Redberg looked at all six MedCAC decisions involving a cardiovascular product or service and analyzed the sample size, participant demographics, inclusion criteria, study location, and outcome stratification of the relevant technology assessments. The data in the technology assessments used for these six decisions included 141 peer-reviewed reports and 40,009 patients (Arch. Intern. Med. 2008;168:136-40).

Significant differences were found between the study populations and the Medicare population. Participants in the trials described in the technology assessments were significantly younger (mean age, 60.1 years) than were most Medicare beneficiaries (mean age 70.8 years). Several trials excluded older patients, but "the mean age in studies with explicit age exclusions (59.0 years) and those without such exclusions (60.9 years) did not differ," the authors wrote.

"Studies for each cardiovascular [technology assessment] also differed significantly from the Medicare population in terms of sex," they continued. Of the study participants, 75.4% were men, compared with 43.7% of Medicare beneficiaries. Several of the studies had excluded women, but none excluded men. Clinical trial location also was not representative of the Medicare population. Of 135 studies that reported location, 37% took place at least partly in the United States. However, most (51.1%) were done in Europe, 8.9% in Asia, and 6.7% in other locations. Overall, 40% of the technology assessment study participants were U.S. residents, compared with 100% of the Medicare population.

The trial populations are 'younger, healthier, male, non-U.S. populations,' reflecting an underrepresentation of women and the elderly.

In addition, many of the trials excluded patients with conditions such as renal insufficiency, arrhythmias, and diabetes that are common in the Medicare population.

The researchers concluded that the data used by MedCAC as evidence on which to base national treatment coverage decisions "are derived from populations that differ significantly from the Medicare beneficiary population in terms of age, sex, country of residence, and comorbid conditions." The trial populations are "younger, healthier, male, non-U.S. populations," reflecting a "persistent underrepresentation of women and elderly people" in clinical trials in general, the authors noted.

The authors suggested that all future studies include demographic information, as "the accuracy and risk-benefit profiles of many diagnostic tests and therapies differ substantially by age and often by sex." They also suggested that the CMS adopt a policy requiring data on women and the elderly. An alternative approach would be for the CMS to issue coverage decisions dependent on the addition of subgroup data within a specified period of time.

"Closer linkage of evidence to coverage would promote better value and improved outcomes" for Medicare patients, the researchers concluded. ■