Part B Insider (Multispecialty) Coding Alert

LUNG-VOLUME REDUCTION: Study Suggests Who Gains From Disputed Surgery

The **Centers for Medicare & Medicaid Services** opened a national coverage determination process on lung-volume reduction surgery in the wake of a five-year study that showed some useful results for the procedure.

The five-year National Emphysema Treatment Trial was a historic attempt by the federal government to obtain evidence regarding the effectiveness of LVRS, whose costs had threatened to overwhelm the Medicare budget. So far, the study has found that patients with emphysema in the upper lobes of their lungs and limited capacity to exercise may live longer and healthier as a result of LVRS.

Among emphysema patients generally, the surgery "increases the chance of improved exercise capacity but does not confer a survival advantage over medical therapy," says the study published on the Web site of the New England Journal of Medicine. Low exercise capacity "was an unanticipated predictor of a survival benefit," write the researchers in the large, multicenter trial. "The better survival ... appears to be due to the very high mortality and marked progressive functional limitation of the patients with low exercise capacity in the medical therapy group."

With improved surgical techniques, LVRS - first used as early as the 1950s - experienced a quick strong resurgence in the 1990s. But although some studies suggested significant benefit, doubt about its effectiveness also dogged the procedure. Facing high costs for an unproven treatment and evidence of high mortality rates from the surgery at some sites, Medicare in 1995 announced that it wouldn't cover LVRS without more evidence. The NETT was launched to test whether and for whom LVRS could work. In the NETT, cost-effectiveness was calculated "as the ratio of the difference in costs between the surgery group and the medical-therapy group divided by the difference in quality-adjusted life-years gained between the two groups," the NEJM report states. Excluding one subset of high-risk patients who were deemed ineligible for enrollment beginning in May 2001, the estimated cost-effectiveness ratio is $190,000 per QALYgained during the three years after initiation of treatment. Patients in the subgroup that benefited most from the procedure - upper-lobe-disease patients with low exercise capacity - have the best cost-effectiveness ratio, $98,000 per QALYgained. "Although the average total health-related costs were higher in this subgroup ... the relative improvement in quality-adjusted survival" resulted "in improved cost-effectiveness," the researchers say.

The "well-designed and well-conducted trial" was a rare case in which researchers "went beyond an overall comparison of outcomes ... to search systematically for subgroups of patients who might benefit from, or be disadvantaged by, surgery," says **Harvard School of Public Health** biostatistician **James Ware** in an accompanying report in NEJM. It's the nature of such a project to produce slightly ambiguous results, Ware says. Nevertheless, the findings "offer clues for future research and guidance to clinicians."

Study results make plain that "additional long-term research is needed to obtain good information on which to base decisions," write NEJM editor **Jeffrey Drazen, MD,** and policy editor **Arnold Epstein, MD**. "If the benefits observed at three years are sustained for 10 years," the cost-effectiveness ratio is estimated to be about $53,000 per QALYgained for all patients and $21,000 for the subgroup with the best outcomes.

Long-term results still aren't known, however, and if the benefits fade with time, "the ratios are much higher" and LVRS "could become another drain on limited healthcare resources without providing much benefit for patients," Drazen and Epstein say.