The Authors Respond:

In response to our study,¹ Stewart describes several methodological limitations that are inherent in retrospective study designs. Although many of these limitations were addressed in our original article, some warrant further discussion. Stewart is concerned that our relatively small sample size could possibly lead to a Type II error. Although it would have been feasible to increase our sample size by including multiple respiratory syncytial virus (RSV) seasons, we chose to limit our study to 1 RSV season due to subsequent changes in the American Academy of Pediatrics (AAP) guidelines for palivizumab² as well as our health plan's prior authorization policy. Accordingly, the compliance patterns observed in our cohort correspond to the specific policies in place during the RSV season under study.

Stewart made errors in his interpretation of our data. As Stewart points out, the retrospective nature of administrative claims data does inherently limit the ability to control for treatment indication. Nonetheless, the difference in RSV-related outpatient visits highlighted by Stewart was not found to be statistically significant between the 2 groups. Stewart also points out the differences in length of patient follow-up as a potential influence on cost data. Because we reported all cost data on a per member per month (PMPM) basis, the differences in length of membership were thereby controlled.

Additionally, our assumption that the first dose of palivizumab was given in the neonatal intensive care unit (NICU) was appropriate and necessary as part of conducting research with administrative claims data. As a health plan we often do not have access to medical claims until months after the date of service. And, we do not have the claim level detail on inpatient visits to know whether or not a specific dose of a specific medication was given. As a result, compliance for our study could take into consideration only outpatient doses.

Finally, our comments questioning the cost-effectiveness of palivizumab prophylaxis were based on the finding that compliant infants continued to have RSV-related outpatient visits. We feel that this is an important issue that warrants further investigation considering the need to control rising costs in today's health care environment. Only by raising these issues and performing the appropriate studies can we properly develop the strategies, such as prior authorization, utilized by managed care organizations to identify the most appropriate patient populations for high-cost drugs.

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DISCLOSURES

The authors report no conflicts of interest related to the subjects or products discussed in this response.

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The Editors Respond:

Stewart predictably advocates for unrestricted use of palivizumab in response to our publication of 2 articles that described evaluation of clinical and cost outcomes associated with quality improvement initiatives in 2 unrelated managed care organizations. It is worth noting that the utilization management program described by Buckley et al.¹ was developed in a health system that is celebrated for its commitment to continuous quality improvement² and has been ranked consistently in the top 5 integrated health systems each year for the last decade.³ Second, this utilization management program was based on the best evidence as evaluated by infectious disease experts writing for the American Academy of Pediatrics (AAP) in 2006⁴ and was developed by clinicians in this integrated health system who have a focus on quality improvement including the elimination of waste. The results of evaluation of this intervention involving a prior authorization (PA) requirement for coverage of palivizumab include palivizumab drug cost savings of more than \$2.4 million over 3 years without evidence of adverse clinical outcomes. Although preliminary because of its exploratory and descriptive design, this study by Buckley et al. is good news for health plans, including the 85 health plans that ranked prevention of respiratory syncytial virus (RSV) infection as the fourth highest-priority therapy category for utilization management of specialty pharmaceuticals in 2009, and the 10% of these health plans that reported “recently” adding a PA for palivizumab for RSV in 2009.⁵

Stewart complains of “confounding by indication.” We agree that the treated group in Buckley et al. met the PA criteria based on the AAP guideline. Therefore, the treated group