
**The Authors Respond:**

We think that Stewart has missed the point of our study. We did not set out to determine the efficacy of palivizumab in prophylaxis for respiratory syncytial virus (RSV) as measured by resource utilization. Rather, the objective was to analyze the outcomes of a prior authorization (PA) program designed to reduce inappropriate RSV prophylaxis with palivizumab by requiring the use of this drug in accordance with guidelines from the American Academy of Pediatrics (AAP). Because prophylaxis with palivizumab is widely accepted as the standard of care to prevent serious RSV disease in high-risk infants, it would not be acceptable to conduct a study that would deny this population coverage of prophylactic therapy. In our study population, there were no babies denied access to palivizumab who met the AAP criteria for risk.

Our PA process was directed at inappropriate use of palivizumab in babies who did not meet AAP criteria. The infants included in the PA-approved and PA-denied groups did not undergo a randomization process for the variable of interest. As a result, hidden confounding elements may impact the outcomes in unpredictable ways. Multivariate analysis would not be able to control for all risk factors defined by the 2006 AAP guidelines based solely on medical and pharmacy claims data. Currently, there are still inconsistencies that exist among studies that attempt to define risk factors identifying children at greatest risk of serious RSV lower respiratory tract disease. Additionally, all PAs are initiated by the infant’s health care provider. Regardless of the infant’s fulfillment of the health plan’s PA criteria, one could assume that the requesting provider considered the infant was at some level of increased risk of severe RSV disease.

In the design of this study we chose only the RSV-specific International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM) codes. This method was used to focus on only documented RSV disease. Incorporating nonspecific codes for bronchiolitis, pneumonia, and unspecified bronchiolitis codes would have the potential to overestimate the incidence of documented RSV disease and associated hospitalizations, emergency room (ER) visits, and overall costs. Certainly palivizumab has not been shown to prevent bronchiolitis secondary to other viruses (influenza, parainfluenza, metapneumovirus, bocavirus, adenovirus, and possibly rhinovirus).

Our integrated health system has embraced viral testing both for limiting unnecessary antibiotic use and for cohorting. As a health care system, 68.2% of all children presenting with respiratory symptoms with a subsequent hospital admission underwent viral testing which includes RSV for the 2005-2008 study period.

Compliance was not a pre-defined endpoint of our study and was not assessed for the PA-approved group that went on to receive at least 1 dose of palivizumab. However, this study still provides real-world palivizumab utilization patterns for a 500,000-member health plan.

Ours is the first published study to determine rates of hospitalizations, ER visits, and drug cost avoidance associated with the application of PA criteria for coverage determination of palivizumab. We acknowledge the limitations inherent in using administrative claims data. However, claims data accurately reflect hospitalizations, ER visits, and medication costs, all of which were study endpoints. Our study provides a foundation for the conduct of research by others to further inform about resource utilization and identification of the high-risk groups most likely to benefit from prophylaxis of severe RSV.

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**DISCLOSURES**

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

**REFERENCES**