The appropriate application of criteria for the use of palivizumab can save health plans a significant amount of money.

A Health Care Management Company's Experience With Palivizumab – 1 Year Later

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INTRODUCTION

On June 19, 1998, the Food and Drug Administration licensed palivizumab, the first monoclonal antibody introduced into clinical practice for the prevention of an infectious disease — respiratory syncytial virus (RSV) disease. In the November 1998 issue of *Pediatrics*, the American Academy of Pediatric Committee on Infectious Diseases and Committee on Fetus and the Newborn published guidelines for the use of palivizumab.

Horizon/Mercy is a health care management company, with approximately 280,000 members.

This membership comprises publicly insured enrollees, including those enrolled in Medicaid and NJ-FamilyCare (SCHIP: State Children's Health Insurance Program).

In the January 2002 issue of Managed Care, the principal investigator and his staff reviewed the data on palivizumab following its second season of use (October 1, 2000 through April 30, 2001).

The purpose of this current study is to report on the data from the following season (October 1, 2001 through April 30, 2002).

RESULTS

When making a determination as to the approval of palivizumab, our medical directors consider the recommendations of the American Academy of Pediatrics. After a review of the literature on the subject, however, our group determined that it would be appropriate not to approve palivizumab if the only risk factors mentioned were considered "additional risk factors" (see table below).

Our group approved those requests if the children were characterized by any of the following risk factors:

- Children under 2 years of age who have chronic lung disease and who require medical therapy for their disease in the 6 months prior to the RSV season.
- Infants born under 29 weeks' gestational age, who are less than 12 months old at the onset of the RSV season.
- Infants born under 29 weeks' gestational age, who have chronic lung disease and are less than 24 months of age at the onset of the RSV season.
- Infants born between 29 and 32 weeks' gestational age, who are less than 6 months of age at the onset of the RSV season.
- Infants born between 32 and 35 weeks' gestational age, if they

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Examples of reported additional risk factors for RSV infection in patients who were between 32 –35 weeks' gestational age

Reported additional risk factors	Number of patients*
School-age sibling	47
Multiple births	32
Exposure to tobacco smoke in the home	26
History of reactive airway disease	24
Crowding in the home	19
Day care	13
History of respiratory distress syndrome	11
Cyanotic congenital heart disease	10
History of apnea, apnea monitor	5
Gastro-esophageal reflux disease	5
History of patent ductus arteriosus	5
History of RSV in previous season	2

*Total number exceeds 152 patients, because some patients had more than one factor.

have other risk factors such as immunodeficiency (SCIDS or AIDS) or acyanotic, asymptomatic congenital heart disease.

Enrollees include about 6,700 newborns a year. Of these, 1.4 percent are less than 32 weeks' gestational age and 2.9 percent are between 32 and 35 weeks' gestational age.

During the 2000–2001 RSV season, we approved 212 requests for palivizumab, utilizing the outlined criteria. We denied 79 requests. These denials were for children who are between 32 and 35 weeks' gestational age, and the only risk factors were the additional risk factors that we have outlined in the accompanying table. Of the 79 members for whom the request for palivizumab was denied, none required hospitalization for RSV-related lower respiratory illness.

We reported this information in the January 2002 issue of MANAGED CARE, and we concluded that those results demonstrated that we made the appropriate decision not to approve palivizumab for the above-mentioned additional risk factors. We felt that we had demonstrated that by appropriate application of criteria for the use of palivizumab, a significant amount of money, approximately $474,000, was saved, while at the same time, we demonstrated no additional risks to the patients. At that time, we also mentioned our view that the issue of the additional risk factors should be revisited, and we hoped that other manage care organizations would supply data that would be helpful in making a decision in this matter.

To my knowledge, there have been no articles in the medical literature that address these issues. Accordingly, we felt that it was important that we review the following season's results on the utilization of palivizumab, namely the 2001–2002 RSV season, running from October 1, 2001 through April 30, 2002.

During the 2001–2002 RSV season, we approved 276 requests for palivizumab. Two of these members, .72 percent, required hospitalization for proven RSV lower respiratory tract disease. Again the question was: What about the patients who were between 32 and 35 weeks' gestational age, whose only risk factors were "additional risk factors" listed in the accompanying table. Of the 152 members for whom the requests for palivizumab were denied, none required hospitalization for RSV-related lower respiratory tract illness.

DISCUSSION

The results of this review again demonstrate to the author and his staff that they made the appropriate decision not to approve palivizumab for the above-mentioned additional risk factors. The importance of this managed care organization's results with the use of palivizumab to other managed care organizations is that it demonstrates that, by appropriate application of criteria for the use of palivizumab, a significant amount of money (in this case, $851,000) can be saved while also demonstrating no additional risk to the patients, and no compromise in quality of care.

Again, the investigators hope that the issue of these additional risk factors will be revisited, and that other managed care organizations and medical institutions will come forward with data that will be helpful in making a decision on this matter.

SOURCES

American Academy of Pediatrics Committee on Infectious Diseases. Prevention of respiratory syncytial virus infections: Indications for the use of palivizumab and update on the use of RSV-IGIV. *Pediatrics*. 1998; 102: 1211–1216.

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