PALAVIZUMAB (SYNAGIS®) USE AND OUTCOMES AMONG MEDICALLY BENEFICIARIES

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BACKGROUND
- Respiratory syncytial virus (RSV) is the leading cause of lower respiratory tract infection and is subsequently responsible for hospitalization among infants aged less than 24 months who are born prematurely, have chronic lung disease (CLD), or congenital heart disease (CHD). It is a seasonal infection, epidemics of which occur annually from October to March.1
- Palavizumab (Synagis®) is recommended for the prevention of severe lower respiratory tract infections caused by RSV in high-risk infants.2 It is indicated for monthly use during the RSV season and is administered by intramuscular injection.3
- Previous studies assessing outcomes of palavizumab have been unable to demonstrate its benefit for the costs associated with its use.4 For example, a study by Budly et al. reported that over the 3 RSV seasons, the median palavizumab doses and mean allowed palavizumab cost per treatment episode (per infant per season) were $3.64 and $6.95, respectively. Total per infant costs for palavizumab, RSV hospitalization, and cardiovascular ER visits were $8,584 for infants receiving palavizumab compared with $2,033 for those denied palavizumab coverage.5 Also, previous studies have not assessed the use of palavizumab in the high-risk Medicaid population.

OBJECTIVES
1. To assess the impact of palavizumab use on pneumonia, and bronchiolitis among infants.
2. To compare all-cause costs associated for palavizumab users and non-users who were qualified for use.

RESULTS
- Study Design:
  - A retrospective observational design encompassing a matched cohort analysis was used for the purpose of this study.
- Data:
  - Mississippi Division of Medicaid prescription and medical claims data from the period October 1 - March 31 for 2009-2010 and 2010-2011 were used.
  - Analyses were conducted separately for season 2009-2010 - 2010-2011.

- Sample Selection Criteria:
  - Medicaid beneficiaries were included in the study if they:
    - Were less than 2 years of age at the end of each study period.
    - Had a diagnosis of lower gestational age at birth (ICD codes: 765.21 - 765.28), CLD (ICD code 770.7), or CHD (ICDs: 743.8, 748.4, 745, 746, 747.1 - 747.4).
    - Were allowed as eligible beneficiaries with pharmacy claims for palavizumab. The first date of palavizumab use was identified as the index date for use.
  - Users were matched (1:1) on age, gender, race, presence of CLD, and presence of CHD with eligible beneficiaries who did not have a claim for palavizumab. Non-users were assigned the index date for the corresponding palavizumab users.

- Outcomes:
  - Outcomes assessed among users and non-users of palavizumab (within 30 days after the index date) included pneumonia (ICD codes: 480 - 486) and bronchiolitis (ICD 9 code: 466.1) which were identified from the medical claims file.
  - All-cause costs after the index date were assessed until the end of the study year were calculated.

- Data analysis:
  - Costs associated with users and non-users of palavizumab were compared using paired t-tests.
  - Conditional logistic regression was used to assess the impact of palavizumab on prevention of pneumonia and bronchiolitis when controlling for pre-term stage of the infant.
  - All analyses were conducted using SAS version 9.3.

- In the 2009-2010 season, 337 palavizumab users were identified, and non-users, while in the 2010-2011 season, 317 palavizumab users were identified and matched.
- The characteristics of palavizumab users and non-users after matching are displayed in Table 1. In the matched sample, the majority of the patients were male, White, and did not have CHD/CLD. The mean age of infants in both the seasons was approximately 6 months.

- Medical and total costs of palavizumab users were found to be significantly lower than non-users (Table 3).

2. Palivizumab (Synagis®) Use and Outcomes among Medicaid Beneficiaries - Mississippi Division of Medicaid. 2009-2010.

REFERENCES
2. Palivizumab (Synagis®) Use and Outcomes among Medicaid Beneficiaries - Mississippi Division of Medicaid. 2009-2010.

ACKNOWLEDGEMENT
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Table 1. Characteristics of Palavizumab Users and Non-users

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Users</th>
<th>Mean</th>
<th>Non-users</th>
<th>Mean</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, Mean (SD)</td>
<td>0.50 (0.26)</td>
<td>0.34 (0.26)</td>
<td>0.50 (0.26)</td>
<td>0.34 (0.26)</td>
<td>0.86</td>
</tr>
</tbody>
</table>

Table 2. Costs of Palavizumab Among Pneumonia and Bronchiolitis Users

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Users</th>
<th>Mean</th>
<th>Non-users</th>
<th>Mean</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumonia users</td>
<td>2.99</td>
<td>2.99</td>
<td>2.99</td>
<td>2.99</td>
<td>0.16</td>
</tr>
<tr>
<td>Bronchiolitis users</td>
<td>2.99</td>
<td>2.99</td>
<td>2.99</td>
<td>2.99</td>
<td>0.16</td>
</tr>
</tbody>
</table>

Table 3. All-Cause Costs Among Palavizumab Users and Non-users

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Users, Mean</th>
<th>Non-users, Mean</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palavizumab cost</td>
<td>4,342.16</td>
<td>2,046.40</td>
<td>0.0001*</td>
</tr>
<tr>
<td>Total cost</td>
<td>6,205.56</td>
<td>4,450.37</td>
<td>0.0001*</td>
</tr>
</tbody>
</table>

CONCLUSIONS
- Palavizumab users had slightly lower odds of having a diagnosis of pneumonia and bronchiolitis. However, this failed to reach statistical significance.
- The pharmacy costs among palavizumab users were significantly higher than non-users. This may be due to the cost of the drug during the season. However, medical and total costs of palavizumab users were significantly higher in non-users who did not receive palavizumab, indicating that palavizumab may be instrumental in preventing other expenses due to hospitalizations, ER visits etc.

2. Palivizumab (Synagis®) Use and Outcomes among Medicaid Beneficiaries - Mississippi Division of Medicaid. 2009-2010.

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