

# PALAVIZUMAB (SYNAGIS®) USE AND OUTCOMES AMONG MEDICAID BENEFICIARIES

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Evidence-Based DUR Initiative

The University of Mississippi School of Pharmacy



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Quality Health Care Services, Improving Lives

## 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).<sup>1</sup> It is a seasonal infection, epidemics of which occur annually from October to March.<sup>1</sup>
- Palavizumab (Synagis®) is recommended for the prevention of severe lower respiratory tract infections caused by RSV in high risk infants.<sup>2</sup> It is indicated for monthly use during the RSV season and is administered by intramuscular injection.<sup>1</sup>
- Previous studies assessing outcomes of palavizumab have been unable to demonstrate its benefit for the costs associated with its use.<sup>3,4</sup> For example, a study by Buckley et al. reported that over the 3 RSV seasons, the mean number of palivizumab doses and mean allowed palivizumab cost per treatment episode (per infant per season) were 3.64 and \$6,950, respectively. Total per infant costs for palivizumab, RSV hospitalizations, and RSV-related ER visits were \$8,534 for infants receiving palivizumab compared with \$223 for those denied palivizumab coverage.<sup>3</sup> Also, previous studies have not assessed the use of palavizumab in the high-risk Medicaid population.

## OBJECTIVES

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

## METHODS

- 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 for 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 9 codes: 765.21 - 765.28), CLD (ICD 9 code 770.7), or CHD (ICD 9 codes: 748.3, 748.4, 745, 746, 747.1 - 747.4).
  - Users were identified 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 user.

### Outcomes:

- Outcomes assessed among users and non-users of palavizumab (within 30 days after the index date) included pneumonia (ICD 9 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 till the end of each 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.

## RESULTS

- In the 2009-2010 season, 337 palavizumab users were identified, and matched to 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.

Table 1. Characteristics of Palavizumab Users after Matching

Characteristic	2009-2010 (N = 337)	2010-2011 (N = 317)
Age, Mean (SD)	0.50 (0.25)	0.49 (0.29)
Gender, N (%)		
Male	173 (51.34)	169 (53.31)
Female	164 (48.66)	148 (46.69)
Race, N (%)		
White	74 (21.96)	76 (23.97)
Other	263 (78.04)	241 (76.03)
CLD/CHD		
Yes	11 (3.26)	10 (3.15)
No	326 (96.74)	307 (96.85)

CLD: Chronic lung disease; CHD: Congenital heart disease; SD: Standard deviation

- Table 2 displays the results of conditional logistic regression analysis for pneumonia and bronchiolitis. Palavizumab use did not significantly impact diagnosis of pneumonia and bronchiolitis.

Table 2. Conditional Logistic Regression Analysis for a Diagnosis of Pneumonia among Palavizumab Users and Non-users

Characteristic	Pneumonia					
	2009-2010			2010-2011		
	OR	CI	p value	OR	CI	p value
Palavizumab						
Users	0.480	0.21 – 1.08	0.07	0.595	0.28 – 1.27	0.180
Non-users	Ref			Ref		
Gestational age						
<= 28 weeks	2.480	0.67 – 9.19	0.46	1.377	0.41 – 4.62	0.667
>28 to <32 weeks	2.813	0.71 – 11.17	0.303	1.181	0.33 – 4.30	0.991
>= 32 weeks	Ref			Ref		
Characteristic	Bronchiolitis					
	2009-2010			2010-2011		
	OR	CI	p value	OR	CI	p value
Palavizumab						
Users	0.596	0.33 – 1.07	0.08	0.621	0.35 – 1.11	0.108
Non-users	Ref			Ref		
Gestational age						
<= 28 weeks	0.612	0.23 – 1.60	0.14	0.590	0.21 – 1.6	0.643
>28 to <32 weeks	1.306	0.57 – 2.99	0.16	0.788	0.35 – 2.99	0.777
>= 32 weeks	Ref			Ref		

OR: Odds ratio; CI: 95% Confidence Interval; Ref: Reference level for logistic regression.

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

Table 3. All-cause Costs among Palavizumab Users and Non-users

Characteristic	2009-2010			2010-2011		
	Users, Mean	Non-users, Mean	p value	Users, Mean	Non-users, Mean	p value
Pharmacy costs	4,432.16	192.73	<0.0001*	4,465.64	149.54	<0.0001*
Medical costs	1,773.40	7,044.94	<0.0001*	1,294.93	6,412.89	<0.0001*
Total costs	6,205.56	7,237.67	<0.0001*	5,760.57	6,562.43	<0.0001*

CLD: Chronic lung disease; CHD: Congenital heart disease; SD: Standard deviation

## CONCLUSIONS

- Palavizumab users had slightly lower odds of having a diagnosis of pneumonia and bronchiolitis. However, this failed to reach statistical significance.
- 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 lower than non-users thus indicating that palavizumab may be instrumental in preventing other expenses due to hospitalizations, ER visits etc.

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