Use of Palivizumab for Prevention of Respiratory Syncytial Virus (RSV) in the New York State (NYS) Medicaid Population

Irene S Reilly, PharmD, BCPS[1], Barbara A Rogler, PharmD, MS[1], Terry E Dunn, PharmD[1], Holly V Coe, PharmD[1], Walter E Gibson, MS[1], Steven G Feuerstein, MS[1]

[1]Department of Pharmacy Practice, State University of New York at Buffalo, Buffalo, NY

Introduction

- RSV is the most common cause of bronchiolitis in infants and infects most children by age 2 years
- Occurrence of RSV is seasonal, varying by geography and climate
- Palivizumab is the only pharmacologic option for prevention of serious RSV infection
- The American Academy of Pediatrics (AAP) has recommendations on RSV prophylaxis, updated in July 2014 with regard to eligible risk groups
- In the NYS Medicaid Program, palivizumab use is subject to criteria which historically were influenced by AAP recommendations

2014 AAP Recommendations		2009 AAP Recommendations
Risk group	**Criteria**	
Pre-term infants, no other risk factors	GA <29 weeks, and Age <12 months at season onset	Pre-term infants with no other risk factors and: • GA <29 weeks + age <12 months at season onset • GA ≥29 weeks and <32 weeks + age <6 months at season onset Pre-term infants (GA ≥32 weeks and <36 weeks + age <6 months at season onset) and ≥1 of following: • Attends childcare/daycare • Lives in household with ≥1 child aged <5 years
Pre-term infants and children with chronic lung disease	GA <32 weeks, and Requires >21% oxygen for ≥28 days post-birth, and Age <12 months at season onset, or Age <24 months and: • Meets above criteria for chronic lung disease of prematurity and • Requires medical support (chronic corticosteroids, diuretics, or supplemental oxygen) during 6 months prior to second season onset	Age <24 months at season onset with chronic lung disease of prematurity (ill-defined), and Requires medical support during 6 months prior to season onset
Infants with hemodynamically significant congenital heart disease	Age <12 months at season onset Most likely to benefit are patients with: • Acyanotic heart disease, receiving medication to control congestive heart failure and requiring cardiac surgery • Moderate-to-severe pulmonary hypertension Cyanotic heart disease – may consult with cardiologist	Age <24 months at season onset and hemodynamically significant cyanotic or acyanotic congenital heart disease
Possibly eligible for RSV prophylaxis		
Infants with anatomic pulmonary abnormalities or neuromuscular disease	Age <12 months at season onset, and Abnormality or disease impairing clearance of secretions from upper respiratory tract	GA <35 weeks, and Age <12 months at season onset Otherwise consistent
Immuno-compromised infants and children	Age <24 months at season onset, and Profoundly immunocompromised	Consistent

AAP=American Academy of Pediatrics; GA=gestational age; RSV=respiratory syncytial virus

Objectives

- Determine changes in palivizumab utilization and RSV-related outcomes in the NYS Medicaid population, comparing RSV seasons prior to and after publication of the 2014 AAP guidance

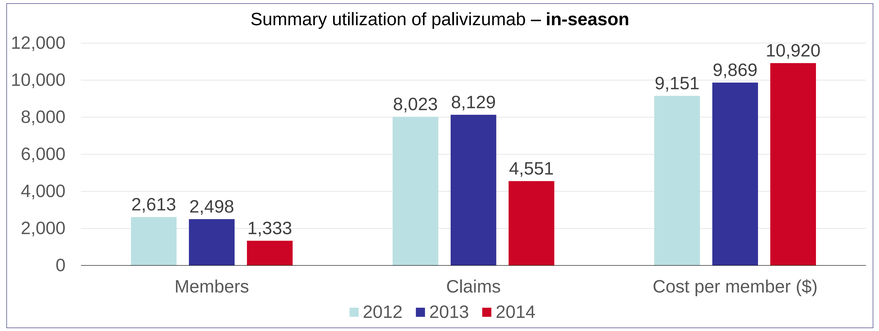
Study Design

- Retrospective analysis of NYS Medicaid claims data

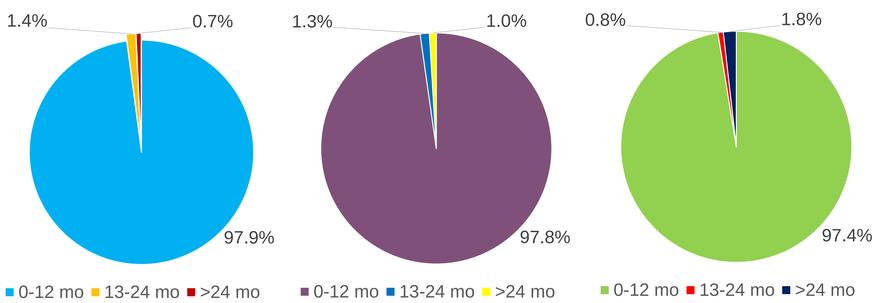
Methods

- NYS Medicaid members with a paid prescription claim for palivizumab between October 16, 2012 and October 15, 2015 were identified from the Medicaid Data Warehouse
- RSV season was defined as October 16 to March 31, in accordance with surveillance data from the Centers for Disease Control and Prevention
- Overall utilization was assessed for the 2012, 2013, and 2014 RSV seasons
- Number of members with a diagnosis of RSV, as well as members with gestational age <29 weeks were identified using ICD-9 codes
- Number of members with hospitalizations attributed to RSV or respiratory illness during these periods was determined using inpatient claims data and ICD-9 codes

Results



Proportion of members with **in-season** utilization, distributed by age



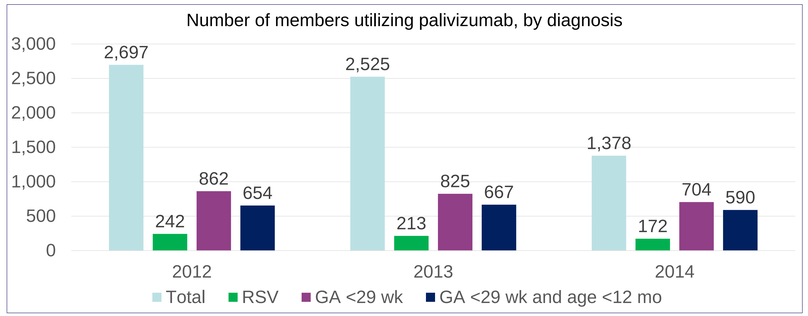
In all periods, >97% of palivizumab users were aged 0-12 months at the start of the season

Results

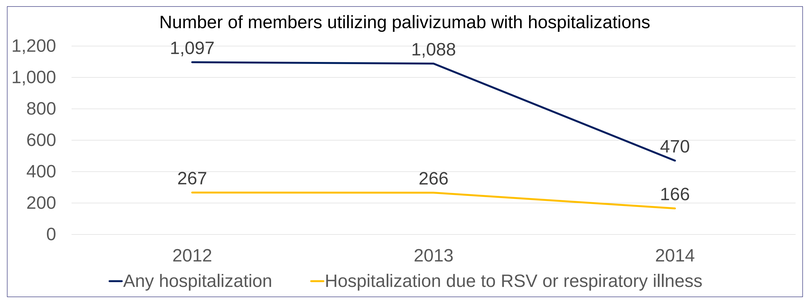
Claims per member, **in-season**, distributed by age

Ages	Claims per member		
	2012	2013	2014
All	3.1	3.3	3.4
0-12 mo	3.1	3.3	3.4
13-24 mo	3.9	3.5	4.3
>24 mo	3.2	3.0	2.8

The mean number of claims per member dispensed in-season was <5 (within AAP- and manufacturer-recommended limits)



The proportion of members meeting some of the AAP criteria increased from 2012 to 2014



The number of total hospitalizations and hospitalizations attributed to RSV or respiratory illness decreased from 2012 to 2014

Conclusions

- Palivizumab is approved for prevention of RSV in infants and children at high risk of RSV disease
- In 2014, the AAP released guidance on the use of palivizumab, revising several of their recommendations from 2009
- Previously eligible patients who are no longer eligible under the 2014 guidance are: pre-term infants of GA ≥29 weeks and no other risk factors; children aged ≥1 year at season onset with congenital heart disease (except those undergoing cardiac transplantation)
- Observed trends in palivizumab utilization and RSV-related outcomes among NYS Medicaid members appeared to be in-line with the 2014 AAP recommendations
- NYS Medicaid clinical criteria for palivizumab were later revised to be more consistent with these recommendations