Analysis of Alabama Medicaid Data – Palivizumab Utilization
October 1, 2011 – March 31, 2012

Introduction

Synagis® (palivizumab) is FDA approved for the prevention of respiratory syncytial virus (RSV) in selected infants and children. Palivizumab requires prior authorization (PA) for reimbursement through the Alabama Medicaid Agency. Prior authorization criteria are based on manufacturer labeling and current American Academy of Pediatrics (AAP) recommendations. Criteria are reviewed and evaluated annually. Health Information Designs, Inc. (HID) is contracted with the Agency to manage the PA helpdesk and the PA process, which includes palivizumab PAs.

The purpose of this analysis is to provide an overview of the most recent RSV season in terms of palivizumab utilization and cost to the Alabama Medicaid Agency. Trending information, including data from past RSV seasons, will be included in this report.

The Centers for Disease Control and Prevention (CDC) has a laboratory-based system, called the National Respiratory and Enteric Virus Surveillance System (NREVSS), which monitors patterns associated with different viruses, including respiratory syncytial virus. According to the NREVSS website, RSV activity in Alabama became significant week- ending (WE) 01/07/12, peaked WE 02/18/12, and became statistically nonsignificant WE 03/31/12 (see Appendix A for details). This information supports the Alabama Medicaid policy of limiting the palivizumab PA time frame.

Changes for 2011-2012 Season

There were no major changes for the 2011-12 Alabama Medicaid palivizumab season. Providers were still required to submit a hospital discharge summary from birth with each prior authorization request. If the discharge summary was unavailable to the requesting provider, the recipient's first office visit documentation was acceptable. All diagnoses/ICD-9 codes submitted on the prior authorization form must be found in the included documentation.

The AAP did not release or update any recommendations regarding palivizumab. The last recommendations were published in June 2009, prior to the start of the 2009-10 palivizumab season.

All policies related to palivizumab coverage are based on clinical literature and recommendations and are intended to ensure that medication is available to all children who meet the criteria.

Prior to the start of the 2011-12 palivizumab season, HID determined that having a registered, experienced pediatric nurse available to manage the palivizumab PA process would be advantageous to the provider community. Jessica O'Donnell, RN, BSN, managed the palivizumab prior authorization process for the 2011-12 season.

During the months preceding the start of palivizumab season, the Medicaid Pharmacy Specialists conducted face-to-face visits with all physicians and pharmacies that prescribe and/or dispense palivizumab to Alabama Medicaid recipients to discuss the criteria and forms. All documents related to palivizumab were posted on the Agency website so that they would be readily available to providers. To help track palivizumab patients and their doses, HID utilizes an electronic tracking system, which allows

HID to maintain a database of doses given and doses needed – the database also allows clinical personnel to monitor the recipient weight to help avoid waste.

Once the palivizumab season started, the prior authorization team made a commitment to call Synagis providers – in the event a second denial for a specific recipient was issued – to explain what was needed to complete their request. Monthly reports were provided to the Alabama Medicaid Agency so that trends could be easily identified and the PA process be carefully monitored.

Overall Utilization and Cost

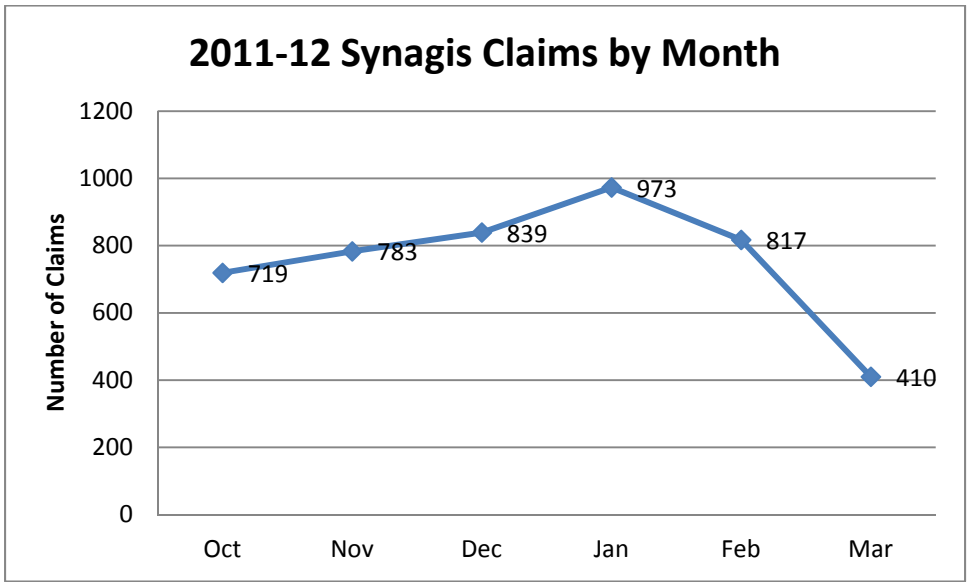
The following chart details palivizumab claims billed during the 2011-2012 season.

Drug Name	NDC	Total Number of Claims	Total Reimbursement Amount	Total Number of Patients*
Synagis 50mg/0.5mL vial	60574411401	1459	$1,909,443	**
Synagis 100mg/1mL vial	60574411301	3082	$8,264,451	**
Total		**4541**	**$10,173,894**	**1088**

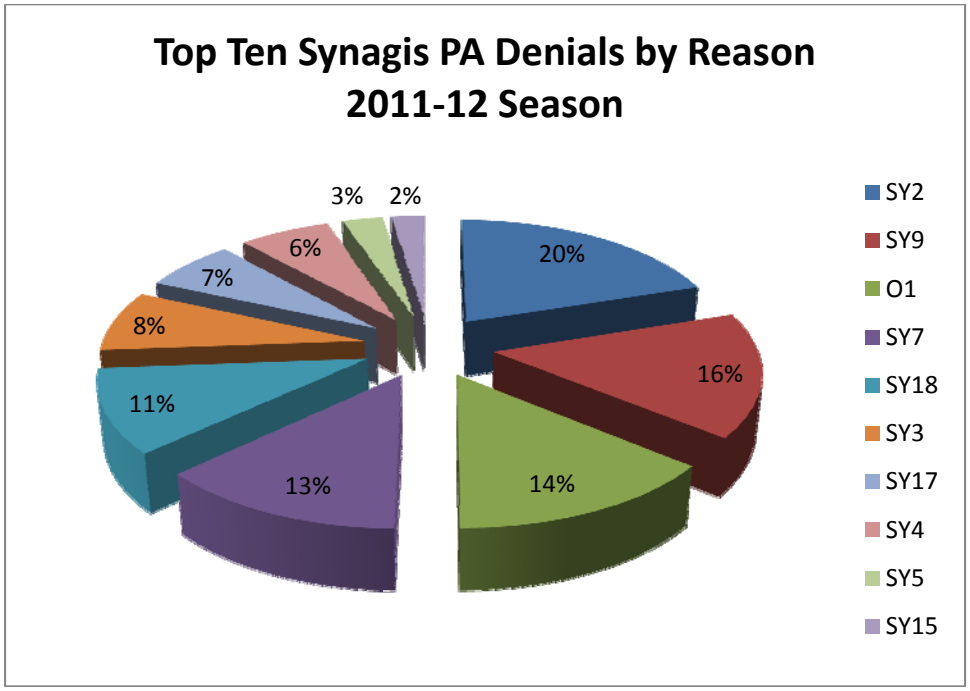
*Recipients are counted only once in a season.

Post Season Analysis Results

The chart below details claims paid per month.



During the review of palivizumab prior authorization requests, several reasons for PA denial were identified. The following table details those denials.

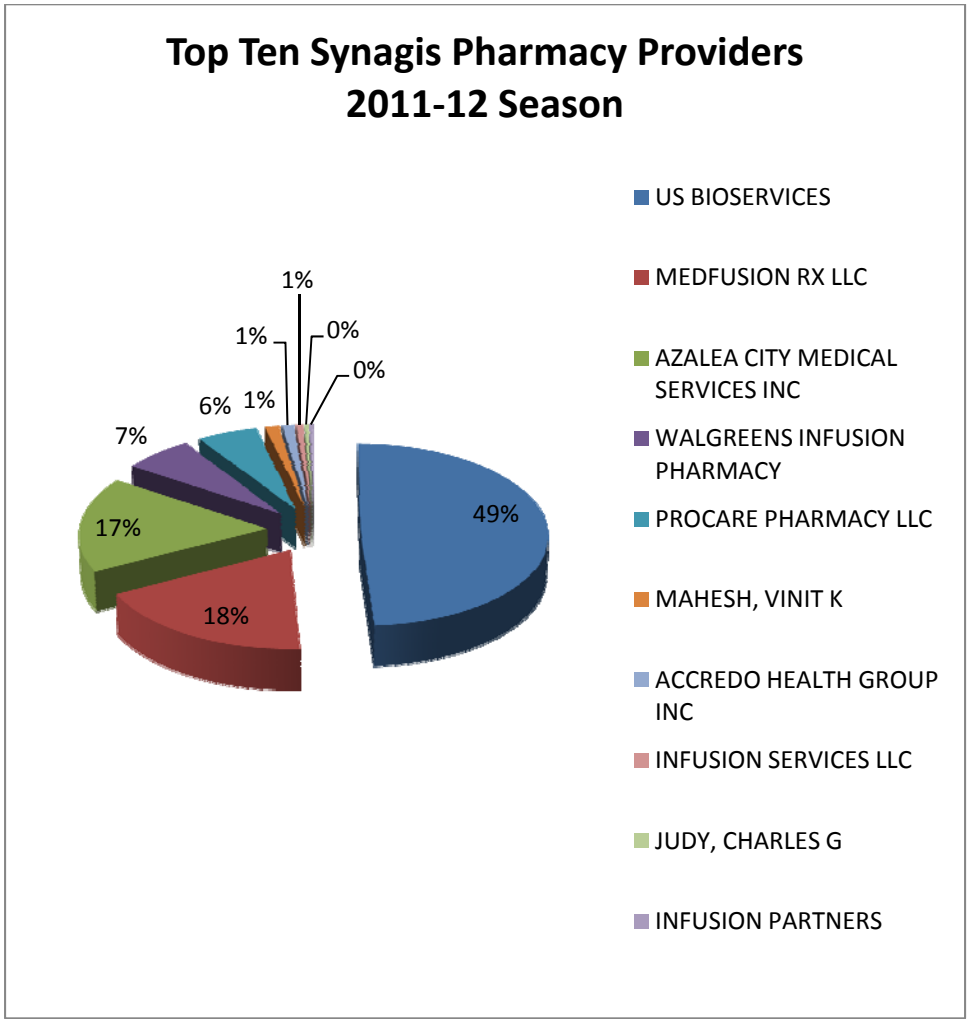


*There were 870 total palivizumab denials in the 2011-12 season.

The expanded denials are below:

SY2	Does not meet chronological/gestational age requirement
SY9	Hospital discharge summary from birth must be resubmitted with AL Medicaid Synagis request form (form 351).
O1	Other Failed Criteria
SY7	Required documentation of one (1) AL Medicaid approved risk factor
SY18	Physician must sign AL Medicaid Synagis request form 351. Use of stamped/copied physician's signature is not allowed.
SY3	Recipient must be born < (less than) 3 months before or during the RSV season
SY17	Please provide the appropriate ICD-9 code for CHD.
SY4	Requires documentation of appropriate medication, including start and stop dates.
SY5	Must indicate current weight
SY15	Synagis not covered for ICD-9 code indicated on form 351

There were several providers closely involved with the distribution of palivizumab during the RSV season. The following chart details those pharmacies and physicians and the percentage of palivizumab PAs approved for each.



Trending

Comparative annual data is presented in an effort to identify and evaluate trends related to palivizumab use among Alabama Medicaid recipients over several years. To fully understand the trending information, it is important to note that criteria is reviewed and refined each season. For example, during the 2005-06 season, following the American Academy of Pediatrics (AAP) recommendation, the number of doses was decreased from 6 per season to 5 per season. The length of the season (6 months) remained the same, to allow providers flexibility of dosing. For 2008-09, it was determined that the chronological age would be the patient's age at the beginning of the season. For the 2009-10 season, criteria were changed according to updated AAP guidelines.

All policies related to palivizumab coverage are based on clinical literature and recommendations and are intended to ensure that medication is available to all children who meet the criteria.

The chart below shows palivizumab utilization during previous seasons.

Drug Name	NDC	Total Number of Claims	Total Reimbursement Amount	Total Number of Patients*
2005-06 Season				
Synagis 50mg vial	60574411201	717	$514,354	-
Synagis 50mg/0.5mL vial	60574411401	1443	$1,043,190	-
Synagis 100mg vial	60574411101	1512	$2,266,982	-
Synagis 100mg/1mL vial	60574411301	2825	$4,256,705	-
Total		*6497*	*$8,081,231*	*1279*
2006-07 Season				
Synagis 50mg/0.5mL vial	60574411401	2739	$2,113,735	-
Synagis 100mg/1mL vial	60574411301	5450	$8,945,261	-
Total		*8189*	*$11,058,996*	*1559*
2007-08 Season				
Synagis 50mg/0.5mL vial	60574411401	3673	$3,101,902	-
Synagis 100mg/1mL vial	60574411301	7018	$13,431,560	-
Total		*10,691*	*$16,533,462*	*1980*
2008-09 Season				
Synagis 50mg/0.5mL vial	60574411401	3156	$2,940,434	-
Synagis 100mg/1mL vial	60574411301	6265	$12,851,931	-
Total		*9421*	*$15,792,365*	*2050*
2009-10 Season				
Synagis 50mg/0.5mL vial	60574411401	1311	$1,360,792	-
Synagis 100mg/1mL vial	60574411301	2782	$5,972,010	-
Total		*4093*	*$7,332,802*	*959*
2010-11 Season				
Synagis 50mg/0.5mL vial	60574411401	1441	$1,705,147	-
Synagis 100mg/1mL vial	60574411301	3022	$7,333,287	-
Total		*4463*	*$9,038,434*	*1072*
2011-12 Season				
Synagis 50mg/0.5mL vial	60574411401	1459	$1,909,443	-
Synagis 100mg/1mL vial	60574411301	3082	$8,264,451	-
Total		*4541*	*$10,173,894*	*1088*

*Recipients are counted only once in a season.

The chart below details palivizumab usage and other information pertinent for trending purposes.

	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
# of Recipients	1279	1559	1980	2050	959	1072	1088
# of Claims	6497	8189	10,691	9421	4093	4463	4541
Cost/vial – 50mg/0.5mL	$705.10	$773.49	$843.10	$926.56	$1030.93	$1159.80	$1288.77
Cost/vial – 100mg/1mL	$1331.40	$1460.55	$1592.00	$1749.61	$1946.69	$2190.02	$2433.58
Average Cost Per Claim	$1244	$1350	$1546	$1676	$1792	$2025	$2240
Total Cost	$8,081,231	$11,058,996	$16,533,462	$15,792,365	$7,332,802	$9,038,434	$10,173,894
Avg Cost Per Recip	$6318	$7094	$8350	$7704	$7646	$8431	$9351
Total PAs Requested	4633	4355	5240	8686	3078	3037	2753
# of PAs Approved	2546	2894	3562	3245	1696	1891	1883
# of PAs Denied	2087	1461	1678	5441	1382	1146	870
% of PAs Approved	55.0%	66.5%	68.0%	37.4%*	55.0%	62.3%	68.4%

*Due to potential inaccuracies, in late October and November 2008, all approved PAs for palivizumab were deactivated and physicians were asked to resubmit the patient information. This may account for the increased number of PAs requested, and denied.

The table below gives an estimated number of doses per recipient for each season.

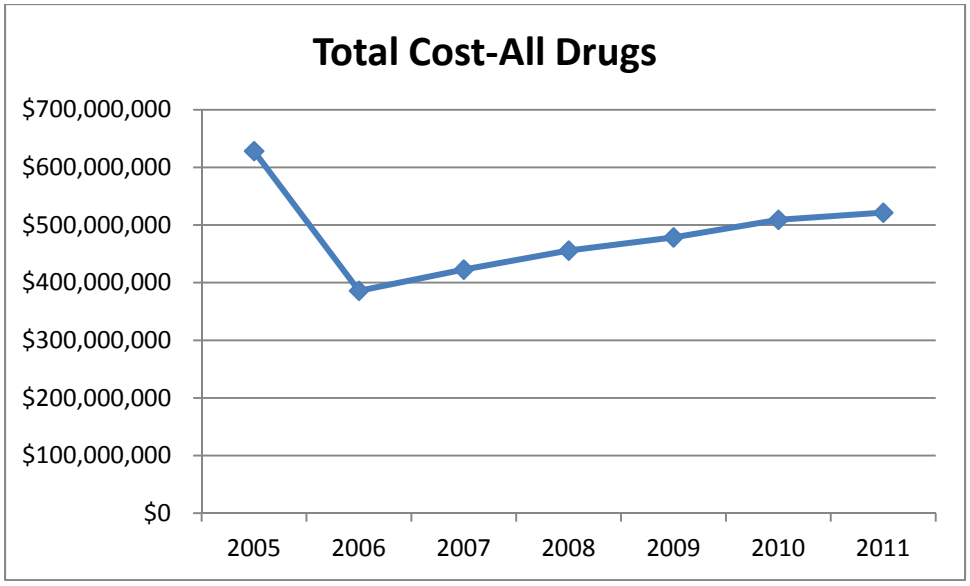
	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
# of Recipients	1279	1559	1980	2050	959	1072	1088
Est. # of Doses	4803	5938	7491	6746	3051	3396	3472
Est. # Doses/Recip	3.8	3.8	3.8	3.3	3.2	3.2	3.2
Total Cost	$8,081,231	$11,058,996	$16,533,462	$15,792,365	$7,332,802	$9,038,434	$10,173,894
Avg Cost/Dose	$1683	$1862	$2207	$2341	$2403	$2661	$2930

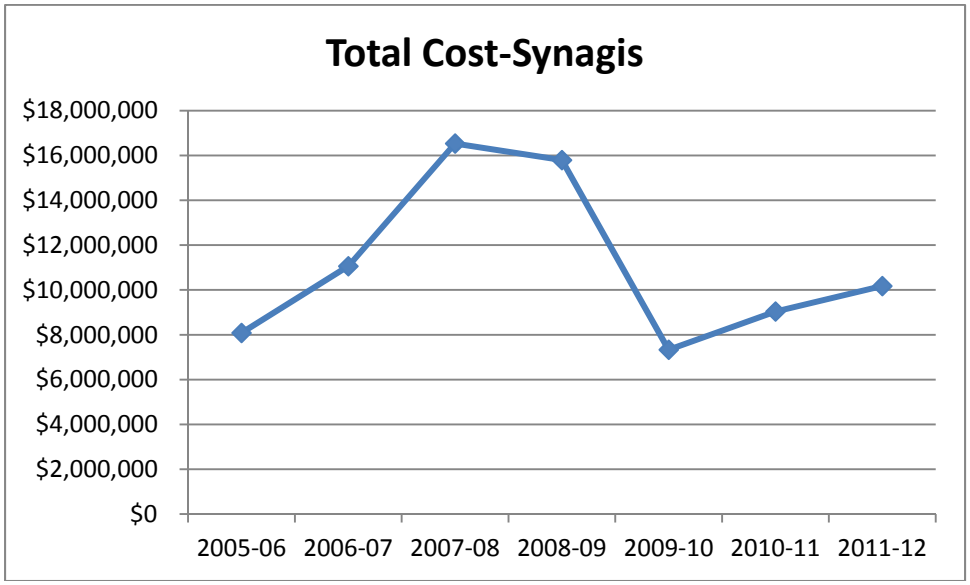
*Number of doses was estimated by reviewing recipient ID numbers and palivizumab NDC numbers. Each instance of a palivizumab NDC was counted as one dose, unless there was another claim billed within one day. In that instance the two claims were counted as one dose. Each season was independently evaluated. These numbers were verified by random audit checks.

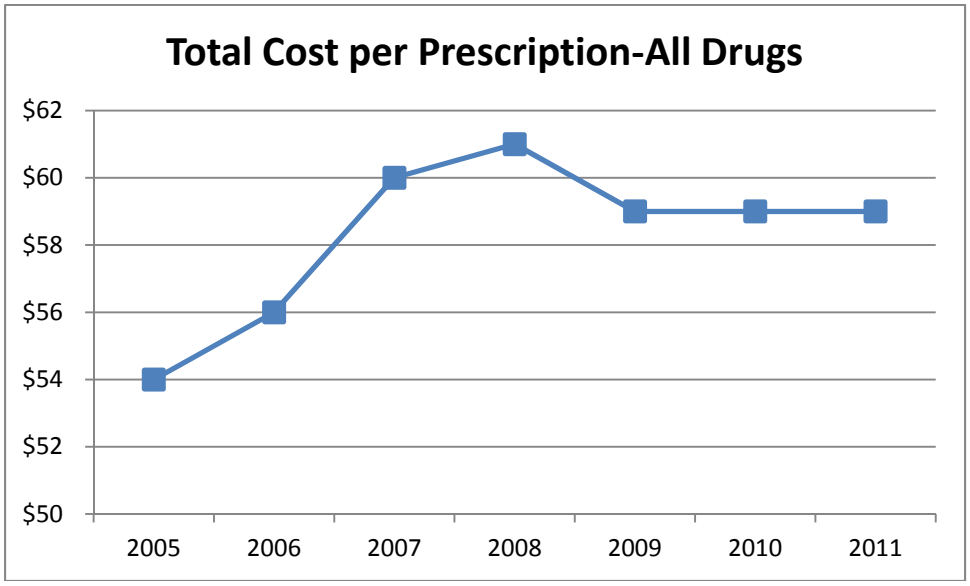
Although the number of beneficiaries and the cost of the product have increased over the past several years, it should be noted that the number of claims per recipient *and* the estimated number of doses per recipient decreased after the 2004-05 season. This trend can be directly correlated to the implementation of the 5-dose limit.

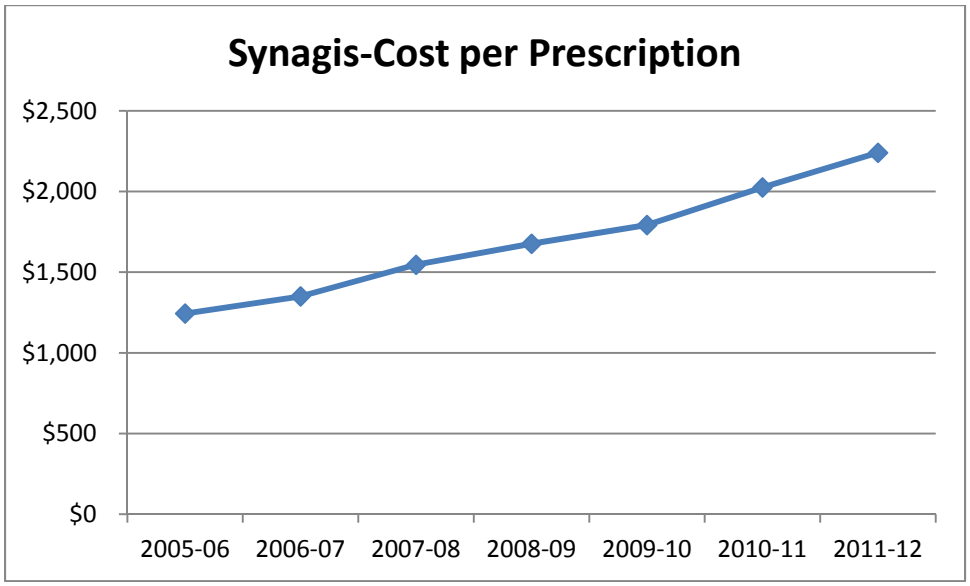
Trend Analysis

It is important to compare the utilization and cost of palivizumab to all drugs covered by the program. The charts below illustrate total cost and cost per prescription of palivizumab versus the program totals.





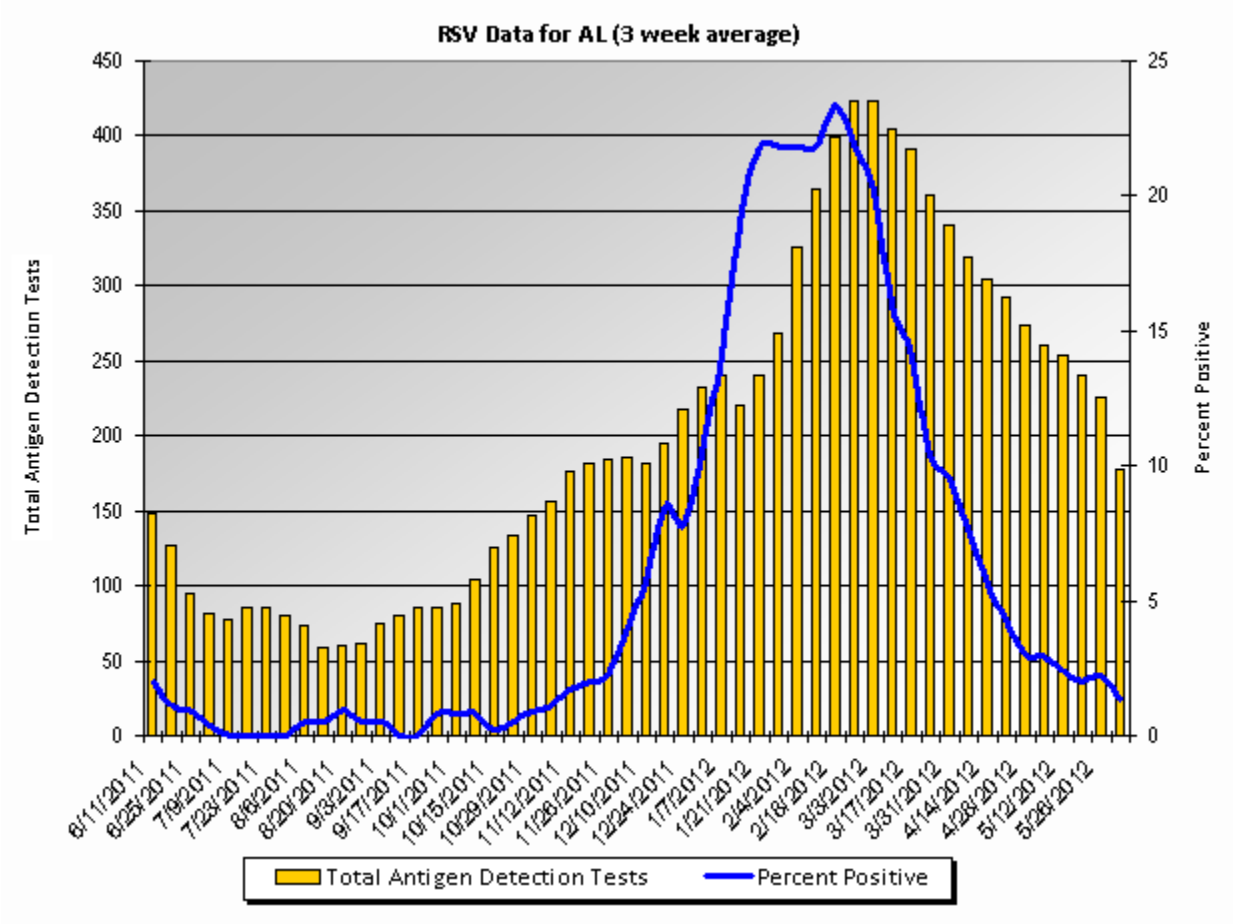

Total Cost per Prescription-All Drugs
$62
$60
$58
$56
$54
$52
$50
2005
2006
2007
2008
2009
2010
2011


Synagis-Cost per Prescription
$2,500
$2,000
$1,500
$1,000
$500
$0
2005-06
2006-07
2007-08
2008-09
2009-10
2010-11
2011-12

Conclusion

Each season, the Alabama Medicaid Agency, as well as HID, makes every effort to work with and be available to palivizumab providers. HID also strives to review palivizumab PAs in an impartial, consistent, and effective manner. Our goals are to ensure appropriate utilization of this medication, to encourage consistent compliance with the administration regimen, and to minimize waste.

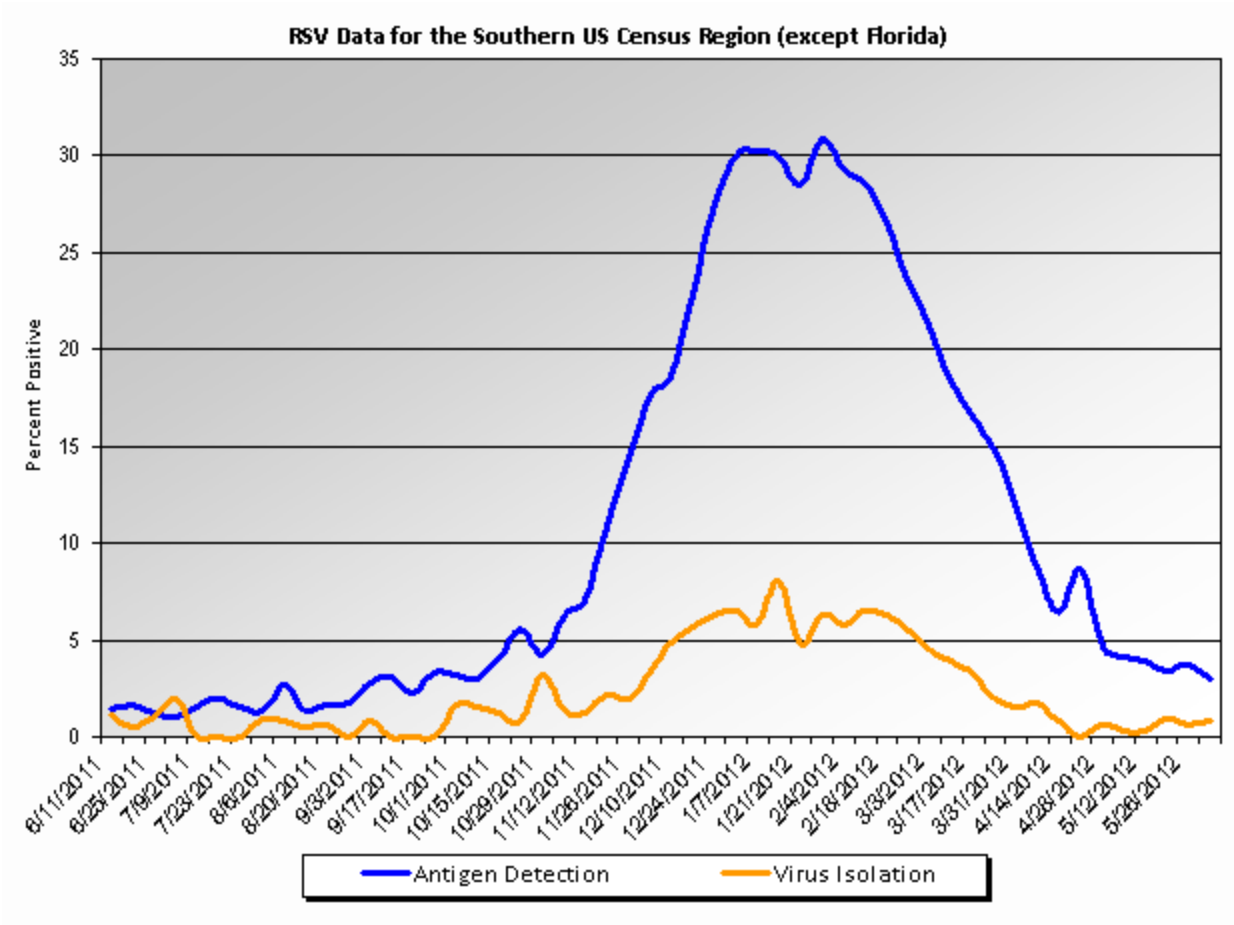
Appendix A



The NREVSS participating labs in the AL area:

- Atmore Hospital Lab - Atmore, AL
- Baptist South - Montgomery, AL
- Crestwood Medical Center - Clinical Laboratory - Huntsville, AL
- Elmore Community Hospital Laboratory - Wetumpka, AL
- Marshall Medical Center South - Boaz, AL
- NE Alabama Regional Med Center - Anniston, AL
- Springhill Memorial Hospital - Mobile, AL
- UAHSF Diagnostic Virology Laboratory - Birmingham, AL
- University of South Alabama Medical Center - Mobile, AL

Source: http://www.cdc.gov/surveillance/nrevss/rsv/state.html#AL. Accessed on 05/30/2012.



Source: http://www.cdc.gov/surveillance/nrevss/region.html#south. Accessed on 05/30/2012.

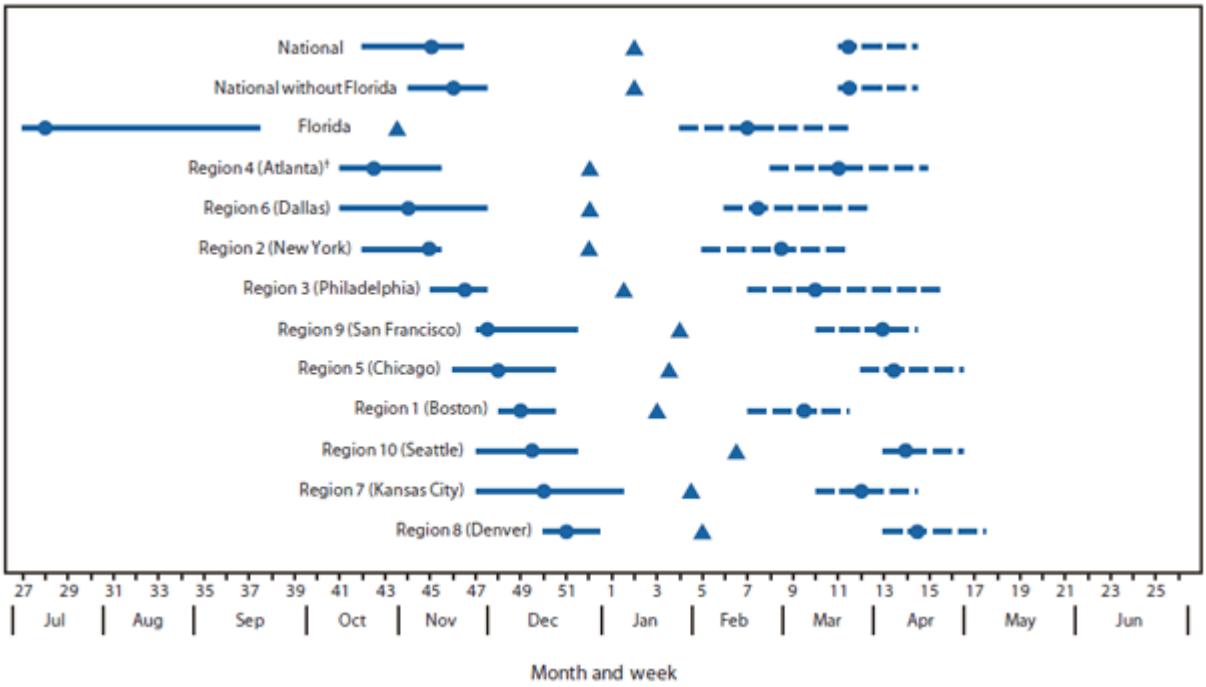
The following tables were taken from the Centers for Disease Control (CDC) Morbidity and Mortality Weekly Report, September 9, 2011; Volume 60(35); page 1189-1232.

TABLE. Summary of 2010-11 respiratory syncytial virus season, by U.S. Department of Health and Human Services Region and in Florida – National Respiratory and Enteric Virus Surveillance System, July 2010 - June 2011

HHS Region or State	States	2010—11 Season			
		No. of laboratories reporting	Onset week ending	Offset week ending	Season duration (weeks)
National	All contributing states and DC	179	11/20	4/9	21
National without FL	All contributing states and DC without FL	157	11/27	4/9	20
Florida	FL	22	9/18	3/19	27
Region 2 (New York)	NJ, NY	16	11/13	3/19	19
Region 4 (Atlanta)*	AL, GA, KY, MS, NC, SC, TN	22	11/13	4/9	22
Region 6 (Dallas)	AR, LA, NM, OK, TX	26	11/27	3/26	18
Region 9 (San Francisco)	AZ, CA, HI, NV	25	11/27	4/2	19
Region 3 (Philadelphia)	DE, DC, MD, PA, VA, WV	17	11/27	4/16	21
Region 1 (Boston)	CT, ME, MA, NH, RI, VT	6	12/18	3/12	13
Region 10 (Seattle)	AK, ID, OR, WA	7	12/18	4/2	16
Region 5 (Chicago)	IL, IN, MI, MN, OH, WI	22	12/18	4/23	19
Region 7 (Kansas City)	IA, KS, MO, NE	8	1/1	4/9	15
Region 8 (Denver)	CO, MT, ND, SD, UT, WY	8	1/1	4/30	18

*Excludes data from Florida

FIGURE. Respiratory syncytial virus (RSV) season onset and offset range and median, by U.S. Department of Health and Human Services Region* and in Florida---National Respiratory and Enteric Virus Surveillance System, July 2007—June 2011



* Listed by region number and headquarters city. Region 1 (Boston): Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. Region 2 (New York): New Jersey and New York. Region 3 (Philadelphia): Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia. Region 4 (Atlanta): Alabama, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee. Region 5 (Chicago): Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin. Region 6 (Dallas): Arkansas, Louisiana, New Mexico, Oklahoma, and Texas. Region 7 (Kansas City): Iowa, Kansas, Missouri, and Nebraska. Region 8 (Denver): Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming. Region 9 (San Francisco): Arizona, California, Hawaii, and Nevada. Region 10 (Seattle): Alaska, Idaho, Oregon, and Washington. Idaho, Maine, New Mexico, and the District of Columbia did not have any participating laboratories in the four-season (2007--2011) analysis.

† Excludes data from Florida.