



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, July 12, 2012
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Mark Balk, PharmD.
 Neal Catalano, R.Ph.
 Cris Cowley, M.D.
 Tony Dalpiaz, PharmD.

Brad Hare, M.D.
 Joseph Yau, M.D.
 Joseph Miner, M.D.
 Mr. Kumar Shah

Board Members Excused:

Kathy Goodfellow, R.Ph
 Peter Knudson, D.D.S.

George Hamblin, R.Ph.

Dept. of Health/Div. of Health Care Financing Staff Present:

Robyn Seely, PharmD.
 Lisa V Hunt, R.Ph.
 Bobbi Hansen, CPhT
 Marisha Kissell, R.N.

Richard Sorenson, R.N.
 Annette Leonard, R.N.
 Heather Santacruz, R.N.

Other Individuals Present:

Joanita Lake, UofU
 Gary Oderda, UofU
 Scott Larson, BMS
 Vincent Haynes, M.D, Medimmune
 Pat Wiseman, Medimmune
 Carrie Byington, M.D, UofU
 Bill Cosgrove, M.D, Wasatch Pediatrics
 Mark Crosby, IHC Home Care
 Paul Nielsen, Medimmune

Bryan Larson, UofU
 Lori Howarth, Bayer
 Charissa Anne, J&J
 J. Miller, Medimmune
 Jim Canes, Medimmune
 Kim Eggert, Gilead
 Aron Brown
 Mark German, Novartis

Meeting conducted by: Neal Catalano, R.Ph.

1. Neal Catalano opened the meeting. He reminded all of the board and guest that the meeting is recorded. He also asked all board members and guest to sign in.
2. May meeting minutes reviewed and approved with a motion from Joe Miner. Seconded by Kumar Shah. Approved unanimously.
3. Pharmacy & Therapeutics (P&T) Committee Report: Lisa V. Hunt addressed the Board. New Preferred Drug List (PDL) effective July 1, 2012 is now available and effective. She also reported that the upcoming P&T meeting will be reviewing the second part of sedative

hypnotics.

4. Review of current Synagis (palivizumab) prior authorization criteria.

Expert/Guest Comments: Dr. Vincent Haynes, M.D. (*Medical Science Director-Medimmune*): Dr. Haynes states that, "Like many of my colleagues, whenever there is a pediatric infectious disease question for which I do not know the answer I reach for the *Red Book*. For many of us it represents the definitive word in pediatrics infectious diseases. It is with this in mind that I ask that you evaluate all of the available data and that you proceed with careful deliberation as you make a recommendation to the State of Utah regarding RSV prophylaxis." He also asked the board to consider the following:

- RSV is the leading cause of hospitalization in children under 1 year old in United States.
- Infants in Medicare programs have twice the odds of RSV hospitalization than privately insured term and pre-term infants.
- 60% of infants receiving palivizumab are covered by Medicaid.
- Palivizumab is the first and only monoclonal antibody approved in the United States for the prevention of an infectious disease and has been shown to be safe and effective in reducing hospitalization secondary to severe RSV infections in premature infants, infants with congenital heart disease and infants with bronchopulmonary dysplasia.
- Infants who are 32-35 weeks gestation at birth have an 80% reduction in RSV hospitalization in the phase 3 randomized clinical trial of palivizumab.
- There has been no published randomized clinical trial data evaluating the efficacy of palivizumab when 1, 2, or 3 doses maximum are administered at the start of the RSV season and terminated at 90 days of age during the RSV season as currently recommended by the American Academy of Pediatrics (AAP) *Red Book*.
- Recent data from a Medicaid study across 12 states, 6 RSV seasons, involving more than 8,000 pre-term infants was presented at PAS (Pediatric Academic Societies), in this Medimmune supported study infants who received partial season prophylaxis had a statistically significant increase in RSV hospitalization compared to infants who received full season prophylaxis.
- The FDA has added new language to the package insert, "the efficacy of palivizumab at doses less than 15mg/kg or of dosing less frequently than monthly throughout the RSV season has not been established."
- Finally, a fact that has remained in dispute, 'the use of palivizumab when used in populations identified for prophylaxis in the 2006 and 2009 AAP *Red Book* and dosed according to the package insert is cost effective.'

Dr. Haynes reported that many studies have been published regarding the cost effectiveness of palivizumab. Until recently there was no published cost utility analysis in a Medicaid population. No studies have used the true cost of the drug which takes into account the federally mandated rebates to states, which in the case of palivizumab is about 50% for each vial. There is now a published article that Dr. Haynes request the DURB have independently reviewed. The study "Cost Effectiveness Analysis of palivizumab Among Pre-term Infant Populations Covered by Medicaid in the United States" published in August 2012 in the *Journal of Medical Economics: Volume 15, Number 4* was conducted in accordance with the standards set forth by the U.S. panel on cost effectiveness in health and medicine. The study

was funded by Medimmune and concludes that palivizumab when used in guideline eligible pre-term infants identified for prophylaxis in the 2006 and 2009 AAP *Red Book* and dosed according to the package insert is cost effective.

Dr. Carrie Byington, M.D. (*Pediatrician-University of Utah and Primary Children's Medical Center, Vice Chair-American Academy of Pediatrics committee on infectious diseases, Co-author-2009 and 2012 Red Book including the policy on palivizumab*): Dr. Byington agrees with Dr. Haynes report that palivizumab is an effective intervention in reducing RSV hospitalization to high risk populations. She states however that the benefits of palivizumab prophylaxis are limited and must be balanced with issues of therapy, including timing of administration, need for multiple dosing, and the cost. In order to optimize therapy infants must be identified that are at risk for RSV hospitalization and provide palivizumab prophylaxis during the months of peak circulation in our community.

Dr. Byington offers that in adherence with evidence based AAP guidelines is the best way to optimize palivizumab prophylaxis in our community. She then states that the current Utah Medicaid prior authorization criteria for palivizumab (dated 9/20/10) is not in alignment with the 2009 AAP recommendations. Dr. Byington confirms that the 2009 AAP criteria were recently recertified with the publication of the 2012 *Red Book*. She ascertains that the Utah Medicaid prior authorization criteria should reflect the current AAP recommendations, as they represent the best evidence synthesis in the United States. Areas of the prior authorization criteria she mentions should be considered include:

- Definition of the RSV season. The AAP recommends November through March for most of the United States, however they acknowledge regional variations. She reports that Utah benefits from one of the most comprehensive viral surveillance programs in the United States. RSV activity is monitored daily and published on the germwatch website, which is available locally and publically through intermountainphysicians.org. Data over 20 years suggests that the Utah RSV season begins in CDC (Centers for Disease Control and Prevention) week 50 to 52 of the year (sometime in mid- to late-December). November doses of palivizumab are not indicated based on Utah's epidemiology. Dr. Byington advises that use of regional surveillance can help align administration with circulation of RSV in our community.
- The eligibility criteria of Utah Medicaid, or prior authorization criteria for Synagis (palivizumab), do not follow the AAP recognized categories of risk. The AAP recognizes risk by gestational age in two categories, less than 32 weeks of gestation or 32 to less than 35 weeks of gestation (34 weeks and 6 days). Dr. Byington reports that the majority of obstetricians in Utah document the weeks and days of gestation at the time of delivery. She suggests that the prior authorization criteria should reflect these categories. Additionally, she points out that the AAP recognizes infants with congenital abnormalities of the airway or neuromuscular conditions as qualified for prophylaxis; these are not included in the current Utah Medicaid prior authorization guidelines.
- The number of doses. The AAP recommends a maximum of three doses for infants born between 32 to 34 and 6/7 weeks gestation who are less than 90 days old at the start of the RSV season or who are born during the RSV season. They also include that these qualified infants should have at least one additional risk factor, either child care or a sibling under five years old living in the household. Prophylaxis after 90 days of age is not recommended for this age group, this is based off the timing of hospitalizations as well as the pharmacokinetics of palivizumab which indicates

significant protection after the doses are given.

Dr. Byington suggests that recent data does not show that palivizumab is cost effective in the 32 to 35 week population and further restrictions for this age group may be forthcoming. She points out that in the article cited by Dr. Haynes it is also suggested that palivizumab is not cost effective for this age population.

Dr. William Cosgrove, M.D. (*Pediatrician-Wasatch Pediatrics*): Dr. Cosgrove reports that in a given Synagis season he has about 3-4 patients on Synagis prophylaxis. He offers that he is not able to speak to the breadth or effectiveness, however for the few patients he has on palivizumab each season it seems to always work. What he finds hindering for these patients is the cumbersomeness of paperwork necessary to obtain payment and the high cost to procure the medication can be a burden, especially for small clinics. He pleads that in addition to considering clinical effectiveness that the board also considers access for the patients, an easy and guaranteed system that can offer coverage beyond the end of each month. Due to eligibility issues Dr. Cosgrove reports that he has advised his staff to not administer Synagis during the first 2 weeks of each month, until current eligibility can be confirmed. This being due to the fact that if their office procures the drug and the patient turns out to be not eligible then the office must “eat” the cost.

Ms. Tiffany Bean, R.N. (*Nurse Manager-Wasatch Pediatrics*): No additional comments to add.

Round Table Discussion: Robyn Seely addressed the board and guests and reported that she has included in each meeting packet a compare and contrast of current prior authorization criteria, the 2003 and 2009 AAP *Red Book* guidelines and the Synagis prescribing information for reference throughout the discussion. She then opened the discussion with a question directed to Dr. Byington, she asked her to describe her role in the development of the AAP *Red Book* guidelines. Dr. Byington responded that the committee on infectious disease is convened by the American Academy of Pediatrics, she applied to be a member of this committee and it is made up of 12 members. The committee meets several times each year and reviews all guidelines related to infectious disease found in the *Red Book*. As vice chairperson she has involvement in all discussions and decisions made by the committee. The committee includes representation from the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), as well as various pharmaceutical companies. The pharmaceutical representatives’ present data to the committee and they then synthesize the data and present it as guidelines for practicing pediatricians.

Robyn Seely then asked Dr. Haynes when the “Cost Effectiveness Analysis of palivizumab Among Pre-term Infant Populations Covered by Medicaid in the United States” article was published. Dr. Haynes replied that the publication date is August 2012 (next month). Robyn Seely then directed to Dr. Byington that this article would not have likely been used or considered in the most recent review by the AAP. Dr. Byington confirmed that this particular study was not taken into account; however she did acknowledge that she has had an opportunity to read the study. She recounts that in the last line of the abstract it states that palivizumab is not cost effective in infants 32-35 weeks gestational age with less than or equal to one risk factor. Dr. Haynes retorted that the statement is true and it is not recommended against the AAP guidelines. He states that

in agreement with AAP guidelines the study is suggesting that prophylaxis is not recommended or cost effective for patients with less than or equal to one risk factor. He adds however, in the 32-35 week group where the *Red Book* does recommend prophylaxis, it is cost effective. Dr. Haynes adds that the reason it is cost effective in this age group is due to two factors. One is that approximately 60% of the infants that receive palivizumab are covered by Medicaid. The other point not taken into consideration in previous studies is the rebates required by the federal government, for Synagis it is approximately 50% for every vial, in order to do business with Medicaid manufacturers must offer a rebate back to the federal government. He states that after taking those two points into consideration and looking at cost utility rather than cost effectiveness, which is just prevention of hospitalization, that cost utility considers prevention of hospitalization and quality adjusted life years or quality. Dr. Haynes ascertains that when you take all this into consideration as well as indirect cost it is cost effective.

Robyn Seely reminded all members present that this is an open discussion and any input is appreciated.

Dr. Cosgrove posed a question to Dr. Haynes, he asked if when the cost effectiveness studies are done, if they only look at hospitalizations during that specific season that they don't look at subsequent hospitalizations related to asthma or other respiratory illnesses. Dr. Haynes answered that the time frame taken into consideration in this study is one year, any cost associated with RSV for one year. This being that it is known that there are costs after leaving the hospital that are associated with having RSV. However, it does not take into account wheezing or mortality.

Robyn Seely asked Dr. Cosgrove with his limited prescribing of Synagis each season if it appears to work well and how well it has worked for his colleagues within Wasatch Pediatrics. Dr. Cosgrove responded that it is like magic, it has worked very well for each time he has prescribed it. He did not have specific information as to how it has worked for his colleagues. He did however include that many times there are lots of subsequent visits following RSV hospitalization for 2-3 years. He included that many of times these are daycare attending patients and each time they get a cold it seems to lead to asthma and wheezing and it becomes challenging to keep them out of the hospital. He concludes that getting the patient through an RSV related hospitalization is not difficult; it is the subsequent care that is the challenge.

Robyn Seely ask both Dr. Cosgrove and Ms. Bean how the process of applying for prior authorization for Synagis from Utah Medicaid relates to private insurance processes. Ms. Bean answered that although both processes require lots of paperwork that Utah Medicaid seems to be one of the easiest to get approved. She added that the hard part is getting the prior authorization, medication ordered and patient treated all within the one month span they can be sure of eligibility. Dr. Byington added that she spends a good amount of time practicing general pediatrics at the South Main Public Health Center, where all the patients are either uninsured or covered by Utah Medicaid. She stated that during the Synagis season they devote a half time Registered Nurse to prior authorization of palivizumab, this being because their clientele is primarily Medicaid covered and or high risk. She stated that this staffing addition each year is one of the greatest expenses for their clinic.

Robyn Seely posed the question that aside from the time and amount of paperwork required if it is difficult to obtain approval or a delay in receiving Medicaid response for patients the office truly feels needs this medication. There seemed to be a consensus among the practitioners that the approval is not difficult to obtain. However, Dr. Byington reiterated that it is the issue of month-to-month eligibility that is the biggest challenge. Dr. Cosgrove suggested that there may be offices, small offices in particular, that are going to hesitate to or not offer this medication due to the strain of staffing, hassle of paper work and the financial risk associated with not obtaining approval and getting the medication administered during that eligibility timeframe.

Lisa Hunt explained that there has been telephone survey conducted in the past to assist offices with Synagis billing issues. She also reported that beginning this Synagis season Utah Medicaid will be moving away from the buy and bill through the physician's office process and begin reimbursing through the pharmacy point-of-sale. Dr. Cosgrove responded that it would be helpful for physician's office if that financial risk is removed and placed onto the pharmacy. Lisa Hunt pointed out that the issue of eligibility will be lessened due to the fact that the pharmacy gets a response back within seconds notifying them if the client is eligible or not.

Robyn Seely asked for clarification as to the presented issues at hand. One being the month-to-month eligibility, which is not an issue the DUR board can address or change. The other, being the requirement to obtaining a prior authorization for payment of Synagis. She also asked Dr. Haynes in regards to the payment assistance program through Medimmune what the utilization of the program is like in Utah or even the surrounding region including Utah. Dr. Haynes deferred the question to another Medimmune representative, Pat Wiseman. Pat Wiseman shared that there is a payment assistance program through Medimmune for Synagis for patients that can't otherwise afford the medication however there is not specific data as to its usage in Utah. She asked another audience member, Mark Crosby with Intermountain Homecare, who has utilized the payment assistance program for any feedback. Mr. Crosby stated that there are no issues with obtaining payment assistance for non-covered patients; it just requires a phone call to Medimmune. Pat Wiseman offered she can collect data as to the utilization of the payment assistance program for Utah if it would be helpful. Robyn Seely requested that data, she stated it would be helpful to see if there are Medicaid patients being denied coverage through the state that are then turning to this payment assistance program.

Brad Hare said that it seems there are issues beyond the scope of the DUR board being discussed and that the issue they can try to resolve is that of the prior authorization criteria. He suggested that the board consider aligning the Utah Medicaid criteria with that of the AAP, in the *Red Book*.

Dr. Haynes commented that he agrees that the criteria should align with the AAP *Red Book* guidelines, however he suggested that sometimes organizations get thing wrong and in this particular aspect (cost effectiveness) he feels the AAP 'got it wrong.' He adds that he hopes that the next time the AAP committee meets they will review all of the available data and that the recommendations will change. Dr. Hayne offered an explanation as where he feels the AAP strayed; there are several categories of patients recommended for

palivizumab prophylaxis (according to the AAP *Red Book*) all of which are recommended for dosing throughout the season. All of the different categories, those with congenital heart disease, those with chronic lung disease, those that are pre-mature (less than 32 weeks gestation), those who have neuromuscular disease, those who have congenital anomalies of the airways are all recommended for full season dosing. He ascertains that none of these groups are recommended for 90 day dosing. He supplements that those patients had an efficacy rate less than that of the 32-35 week gestational age group. The 32-35 week gestation age group (representing the largest number of patients) in the phase-3 clinical trial had an 80% reduction in hospitalization. He articulates that it is stated in the *Red Book* that the truncated dosing is recommended due to the high number of patients and the cost. Dr. Haynes states that there is no published randomized clinical trial data to support the truncated recommendation and he suggests that it was based strictly off expert testimony.

Dr. Haynes states that within the Medicaid population the rate of hospitalization is twice that of the non-Medicaid patients, and when this population is not dosed according to regular recommended dosing (greater than 35 days between doses) or fewer than the recommended dosing that the hospitalization rate goes up. He adds that there is no published data proving the efficacy in doses of 1, 2 or 3 or for less than 15mg/kg. He also adds that on the FDA package insert it states that doses of less than 15mg/kg or less than throughout the season that efficacy has not been established.

Robyn Seely asked if there is published data regarding mortality. Dr. Haynes answered that Synagis has not been linked with decreased mortality in any published data that he is aware of.

Dr. Byington offer a response to Dr. Haynes statements, she agreed that there are no randomize control trials on different dosing schedules. She adds that there will likely never be this type of trial due to extremely high costs. She also states that all the data that the AAP uses is published, including pre-publications, abstracts, and other data presented by individual investigators. Dr. Byington demonstrates that they pharmacokinetic data for palivizumab indicates that at the current dosing of 15mg/kg once per month you will maintain a protective level well beyond 30 days. Because these doses are protective many people have questioned the need for five doses, the duration of dosing and the time between doses. She adds that additional data was presented at the Pediatric Academic Society in 2012, in addition to the information referenced by Dr. Haynes, indicating that 3 doses were equivalent to 5 doses in this population. The data also indicated that the pharmacokinetic data would allow lower or few doses. She states that there is a great deal of evidence indicating 3 doses are safe in the 32-35 gestational age group. She also states that the reason the AAP choose 90 days for dosing is that the risk of hospitalization goes down significantly after 90 days.

Dr. Byington declares that due to limited resources every infant can't receive palivizumab prophylaxis. She adds that if that were possible RSV hospitalizations would decrease. She states that the vast majority of hospitalizations happen to term infants with no risk factors, they are the population that is not covered to receive palivizumab prophylaxis. The AAP feels that fewer doses are a safe policy. In the 3 years since the guidelines have changed there is no evidence suggesting 32-35 week gestational age infants are suffering

higher rates of hospitalization and mortality rates have not increased. In Utah over the last 15 years there have been 12 deaths out of 79,000 encounters. The data also suggests that among those 12 deaths it is unclear if RSV was the precipitating cause, each had multiple congenital anomalies.

Dr. Byington declares that cost analysis can be done in many ways and by many different groups. The vast majority of what has been done does not prove cost effectiveness in the 32-35 week gestational age group.

Robyn Seely asked that each of the guest speakers offer any closing statements for the board members to consider.

Dr. Haynes spoke that there were some things mentioned that were not being suggested or recommended. First, that dosing every infant is not something he is suggesting nor is it recommended by anyone. Second, that there is no argument that Synagis has any effect on mortality. Third, that 3 doses or 90 days of dosing is equivalent to 5 doses is not a study he has seen evidence of within a Medicaid population. He explained that the reason the Medicaid population is important to consider individually is due to higher rates of non-compliance and a higher hospitalization rate. In respect to cost effectiveness, previous studies did not take into consideration the rebates required. Now that a study does exist with rebate information calculated in, it is Dr. Haynes hope that cost effectiveness (among the Medicaid population) will be better understood.

Robyn Seely asked all the guest speakers to review the current Utah Medicaid prior authorization criteria and suggests any changes to the board that they see necessary.

Dr. Haynes responded that he would agree with Dr. Byington's recommendation to include the group with congenital anomalies of the airway and neuromuscular affected infants show higher rates of hospitalization and should be included for coverage. He adds that he would recommend continuing to dose according to the package insert, not to allow 90 day dosing.

Dr. Byington reiterates that the criteria should mirror the 2012 AAP recommendations (found in the *Red Book*).

Mark Balk suggested using the AAP start date of December 1st as the start of the Synagis season. Dr. Cosgrove questioned how to determine the length of the season. Dr. Byington stated that the official end of Synagis season is posted on the germwatch website.

Dr. Cosgrove agrees with the proposed changes (to mirror the *Red Book*). He adds that he also agrees with changing the season start and end dates to match the germwatch reports.

Neal Catalano restates that the proposed changes are to follow the 2012 AAP recommendations (found in the *Red Book*), change the start of the season to December 1st, monitor the germwatch website for the end of the season and to limit to a maximum of 5 doses.

Board Action: Brad Hare made a motion to adopt the 2012 American Academy of Pediatrics

guidelines for the administration of Synagis and to change the start of season date to December 1st. Joseph Miner seconded the motion. The motion was approved unanimously.

Robyn Seely will draft up a new Synagis prior authorization sheet and circulate it (with any applicable studies used to determine criteria) to the board members and guest speaker for final review before any criteria changes become effective.

The next DUR Board meeting is scheduled for Thursday, August 9, 2012.
Minutes prepared by Bobbi Hansen.