



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, March 8, 2007
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Mark Balk, Pharm D.
 Derek G. Christensen R.Ph.
 Dominic DeRose, R.Ph.
 Karen Gunning, Pharm D.

Wilhlem T. Lehmann, M.D.
 Colin B. VanOrman, M.D.
 Don Hawley, D.D.S.

Board Members Excused:

Lowry Bushnell, M.D.
 Bradford D. Hare, M.D.
 Bradley Pace, PA-C

Jeff Jones, R. Ph.
 Joseph K. Miner, M.D.

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

Rae Dell Ashley, R.Ph.
 Tim Morley, R.Ph.
 Jennifer Zeleny, CPhT.

Suzanne Allgaier, R.N.
 Merelynn Berrett, R.N.
 Nanette Epstein

Other Individuals Present:

John Stockton, Genentech
 Shannon Beatty, MedImmune
 Cris Anderson, Otsuka
 Michael Measom, M.D., VMH
 Tim Hambacher, Abbott
 Lori Howarth, Berlex
 Jeff Buell, J&J
 Paul Nielsen, MedImmune

Ram Palanki, Genentech
 Sabrina Aery, BMS
 Mark Kaplan
 Tony Molchan
 Erica Brumleve, GSK
 Alan Bailey, Pfizer
 Dory Paulsen, BMS

Craig Boody, Lilly
 Fred Morse
 Michael Measom, M.D. (VMH)
 Jerry Gomez, King Pharma
 James Gaustad, Purdue
 Richard Kendall, Alpharma
 Trish McDaid-O'Neill, AZ

Meeting conducted by: Tim Morley

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1. Minutes for February 8, 2006 were reviewed, corrected and approved.
 2. Housekeeping: The Board will not be discussing the PDL, P&T Committee, or anti-epileptic drugs during this meeting.
 3. Synagis 2007-2008 RSV Season: Tim Morley addressed the Board. Medicaid wanted to review the criteria for Synagis coverage based on the current season. Medicaid provided members of the Board with the current coverage criteria and statistics reflecting what Medicaid has paid for the past five years and the current year to date. Medicaid has limits

in place on Synagis coverage that closely follow the recommendations of the American Academy of Pediatrics.

Dr. Null, M.D., neonatologist addressed the Board. RSV is a problematic disease, particularly for pre-term infants with lung damage. Emerging research demonstrates that pre-term infants on ventilators have some degree of insult to their lungs, even if they appear to be well. RSV produces long-term effects that create an asthma-like condition in children through the age of 6 or 7, in addition to problems caused by acute infection. Dr. Null suggests that both short and long-term costs of RSV infection be considered, and believes prophylaxis should start before a significant cases are reported. Studies that Dr. Null has participated in show that RSV prophylaxis is most likely to fail after the first dose. Therefore, prophylaxis should be on board before significant exposure to RSV occurs. He feels that Medicaid should not wait until there is “significant” RSV in the community. A reasonable time for starting RSV prophylaxis in Utah is mid-November. Typically, five doses provides reasonable protection since RSV season is around five months in most parts of the country. If the season gets extended, there should be a consideration for a sixth dose during that particular season. Dr. Null also felt that babies older than two years of age should be considered for coverage of Synagis. He cared for an infant who had a history of chronic lung disease and previous viral infection. This baby was denied Synagis coverage due to being over the age limit. The baby developed RSV infection this season and required ICU care and home oxygen. Dr. Null offered his services as a consultant for difficult requests for Synagis coverage. Medicaid’s concerns about providing Synagis outside of accepted parameters are justified, but exceptions should be considered due to the serious nature of RSV.

The Board asked Dr. Null where he feels that Medicaid should draw the line for coverage outside of the age parameters. Dr. Null stated that certain babies are much different than others. Babies who have had longstanding problems are much more likely to be significantly injured by RSV than babies who were pre-term but have not had significant complications.

The Board pointed out that many of the claims for clients demonstrate problems with compliance and parental follow up. Dr. Null stated that home health is a better way to ensure that clients will follow up and receive the appropriate number of doses. Medicaid should still expect some clients that do not receive five doses because the statistics may represent babies discharged from the hospital during RSV season.

Dr. Null stated that Medicaid should be adaptable to start RSV prophylaxis early, should the season start earlier than normal in Utah. Tim Morley stated that Medicaid traditionally starts RSV prophylaxis based on five cases reported in one week based on Primary Children’s Medical Center reporting. This year Medicaid opened Synagis coverage November 1, 2006. Dr. Null felt that this was a reasonable trigger to start the season. RaeDell Ashley stated that providers in St. George felt that they needed Synagis coverage earlier in the season and Medicaid accommodated these providers. Dr. Null felt that this was reasonable. St. George may have a different RSV season due to differences in climate.

Tim Morley asked if Dr. Null knew the number of patients that were likely to get significant asthma as a result of RSV infection. Dr. Null stated that it is typically the infants that are already prophylaxed against RSV. Some healthy children still get asthma as a result of RSV. However, it is not reasonable to vaccinate healthy children. Because of the cost, the high-risk pre-term infants with undeveloped lungs should be prophylaxed since they are

more likely to suffer long term pulmonary disability from RSV.

The Board asked Dr. Null if there is an upper age where children no longer benefit by receiving Synagis. The available data does not provide a clear answer to this. Babies that are still on home ventilators or multiple medications would be reasonable to continue prophylaxis until age four or five. However, there are not enough patients to do a controlled study. The only evidence to support this is anecdotal.

The Board was asked if changes to the current Prior Authorization criteria were recommended. Medicaid stated that the Synagis season would start the earlier of November 1 or five cases in one week reported by Primary Children's Medical Center. The Board asked if St. George would be different. Providers in St. George requested to start in Mid-October this year; however their season is usually later rather than earlier. Medicaid will cover Synagis for all infants born earlier than 28 weeks gestation. Infants born at 29-35 weeks gestation can receive it during this first six months of life. This is less restrictive than the American Academy of Pediatrics. Medicaid will also cover Synagis for children under the age of 24 months with CLD, BPD, or hemodynamically significant heart disease that requires ongoing treatment. Exceptions can be made on a case-by-case basis for children that are barely over the age limit.

The Board requested that Medicaid be flexible as to when the RSV season starts. The Board also requested that Medicaid allow Dr. Null to review the past year's denials. The Board asked Medicaid about the type of providers that are making the requests for Synagis. A majority of requests are being made by pediatricians seeing children in their office. The Board requested that Medicaid provide education about compliance. It was suggested that Medicaid consider home health to improve compliance. Medicaid will continue to provide Synagis coverage under the current criteria.

4. Lucentis/Avastin for Macular Degeneration: Tim Morley addressed the Board. Avastin has a significant potential for off-label use with macular degeneration. Medicaid wanted to bring the off-label use before the Board, since there is some interest in this use. It is still being studied, but there is substantial data supporting the use of Avastin for this purpose. There is great potential for cost savings by using Avastin rather than Lucentis. Medicaid asked the Board to consider this off-label use as Medicaid policy, instead of case-by-case. The Board asked if Avastin and Lucentis are the same medication. They are not, but they are very similar.

Ram Palanki from Genentech addressed the Board. Lucentis and Avastin are not the same molecule. They are designed for different diseases - Avastin for cancer and Lucentis for AMD. They have the same activity, but different pharmacokinetic profiles. Lucentis is a fragment of an antibody. It was designed this way for safety. Avastin is a full antibody molecule, and it's half-life is 21 days. Lucentis was engineered to be metabolized quickly in systemic circulation - its half-life is two hours. Lucentis is designed to be small for better retinal penetration. Lucentis is also designed without a fixed complement portion to avoid cytotoxicity. They have been developed through two different cell cultures. This makes Avastin a more stable molecule.

Dr. Michael Teske, vitreal retinal specialist from the Moran Eye Center, addressed the Board. Lucentis has been an excellent drug that represents a significant improvement in the treatment of macular degeneration. While Lucentis was being developed, retina specialists

tried Avastin, both systemically and intravitreally, with impressive results. The use of Avastin expanded due to this success and is considered a standard of care worldwide. Retina specialists do not, in general, feel that either Avastin or Lucentis is a better drug, nor do they feel that one is necessarily safer than the other. The major advantage of Avastin is cost. It is endorsed by the American Academy of Ophthalmology for use in macular degeneration and local Medicare payers cover the use of Avastin in macular degeneration. There is no known clinical benefit of using Avastin versus Lucentis. The National Institute of Health has sponsored a study to compare the two; however results of that trial will not be available for several years. Dr. Teske uses both drugs, mostly based on what is available to him at his practice. Avastin is used on a smaller level at the University of Utah, because it is not always readily available. In his private practice, it is bought from compounding pharmacies on a larger scale. Other neovascular diseases of the eye also appear to be responding well to Lucentis and Avastin in cases where lasers and surgery are not appropriate.

Tim Morley asked if there is a particular patient profile that directs him to use Lucentis versus Avastin. Dr. Teske stated that there is no particular profile from the standpoint of disease state. Good responsiveness is seen with either drug. In the case of under-insured patients, Avastin is advantageous due to cost.

RaeDell Ashley asked if there are insurances that mandate the use of one over the other. No insurances mandate the use of Avastin over Lucentis, but they sometimes will only pay for the FDA-approved drug (Lucentis).

The Board asked if there is a time line that establishes non-responders, and the typical duration of treatment. The best available data comes from Anchor-Morena trials that lasted 12 months. 24-month data is also available. Monthly injections for twelve months in all patients are not the standard of care. Most specialists do a monthly injection for three months. After that, the patient is either continued on therapy on a month-to-month basis or observed during remission. There limited data available on the best course of therapy. If no response after 3 injections, combination therapies with an older therapy should be considered. The vast majority of patients show some response after 3 injections of either drug.

Tim Morley asked if there was a typical dose and if titration was appropriate. Dr. Teske stated that the usual dose is 1.25mg (0.5ml). The dose does not usually deviate from that.

The Board asked how Dr. Teske assures the integrity of compounded drugs and if there were any types of certifications that pharmacies have to have in order for the practice to buy it. The Board recommended that Dr. Teske assure the integrity of the product by asking the State Board of Pharmacy about the qualifications of the compounding pharmacy. Dr. Teske stated that he is aware of the risks involved from both the use of compounded ophthalmic preparations and the injection procedure itself.

Medicaid has received some claims for small amounts of Avastin. This suggests that Medicaid may have paid claims for Avastin for macular degeneration. In comparison, Medicaid has only received a single claim for Lucentis.

There is data to support the off-label use of Avastin in large clinical trials and several smaller clinical trials. This meets the federal requirements for Medicaid covering the off-label use. The Board voted to accepted the off-label use of Avastin in light of the available clinical

evidence.

5. Ziana: Tim Morley addressed the Board. Ziana is a new topical drug used for the treatment of Acne Vulgaris in patients age 12 and older. Ziana contains clindamycin and tretinoin, which are both available as generics, although not the same concentrations as in Ziana. The two generics separately are more cost-effective than Ziana alone. Medicaid is proposing that Ziana be placed on a Prior Authorization that requires patients to fail first on the combination of the two generics. The PA would be handled in the same way as name-brand PA's are currently handled. Ziana would be available for patients age 12-19. The Board recommended that Medicaid adopt these Prior Authorization criteria.

There were no petitions for the DUR Board to consider this month.

Next meeting set for April 12, 2007

Meeting adjourned.