

**Drug Utilization Review Board  
Meeting Minutes, Open Session  
October 21, 2009**

<p><b>Drug Utilization Review Board</b> Meeting Minutes, Open Session HP Enterprise Services Capital / Cedar Crest Room Topeka, KS</p>	<p><b>Members Present:</b> Michael Burke, M.D., Ph.D., Chair Judy McDaniel Dowd, PA-C Dennis Grauer, Ph.D. Daniel Sutherland, R.Ph. Roger Unruh, D.O. Kevin Waite, Pharm.D. <b>KHPA Staff Present:</b> LeAnn Bell, Pharm.D. Aimee Grubb, Recorder Brenda Kuder, R.N. Shelly Liby <b>HP Enterprise Services Staff Present:</b> Karen Kluczykowski, R.Ph. Deb Quintanilla, R.N. Lisa Todd, R.Ph. <b>HID Staff Present</b> Nicole Churchwell, Pharm.D. <b>PERC:</b> Tammy Demmitt, KHPA Chris English, KHPA Janelle Garrison, R.N., KHPA Brandon Kennedy, M.D. Sue Laudert, M.D. Sallie Page-Goertz, A.R.N.P. Jeff Pierce, Pharm.D. Jan Provost, HP Enterprise Services Pam Shaw, M.D. Donna Sweet, M.D. Wayne Wallace, M.D. Susan Wood, R.N., KHPA</p>	<p><b>Representatives:</b> Teresa Blair, Amgen Cyndee Davies, AstraZeneca Don Larsen, Forest Patty Laster, Gennetech, Inc. William Dozier, Gilead Brenda Koops, Hein Law Firm Dave Walters, J &amp; J Patricia Harwood, MedImmune Mary Schefchyk, NNI David Topham, NNI Jim Baumann, Pfizer Joe Summers, Takeda Teri Kramer, Taro Annie Palmer, Taro</p>
<p><b>TOPIC</b></p>	<p><b>DISCUSSION</b></p>	<p><b>DECISION AND/OR ACTION</b></p>
<p>I. Call to Order</p>	<p>Dr. Burke, Chair called the meeting to order at 10:04 a.m.</p>	
<p>II. Announcements</p>	<p>Dr. Bell asked the public to fill out the conflict of interest forms if they wanted to speak to the board. There is a limit of five minutes per drug.</p>	

<p>III. Old Business</p> <p>A. Review and Approval of July 8, 2009 Meeting Minutes</p> <p>B. Synagis®</p> <ul style="list-style-type: none"> <li>i. Revised PA Criteria</li> <li>ii. *Public Comment</li> <li>iii. Board Discussion/Action</li> </ul>	<p><b><u>Review and Approval of July 8, 2009 Minutes</u></b></p> <p>No Changes.</p> <p><b><u>Synagis®</u></b></p> <p>Synagis criteria for use were updated at July DUR meeting based on publications summarizing the 2009 American Academy of Pediatrics guidelines for use of Synagis; the full guidelines had not yet been released at the time. The full guidelines were released in September and were provided for board review. Particular interest has been shown in revisiting the age/total dose recommendations for babies born at 32-35 weeks gestation.</p> <p>Dr. Unruh asked to revisit the updated criteria for use of Synagis approved at the July DUR Board meeting. Since the meeting, he has heard much discussion on the subject in the pediatric world. He indicated the pro for keeping the updated criteria would be that there is no evidence it reduces hospitalizations after a baby is 90 days old; con is that there is no efficacy evidence for limiting therapy to 3 months.</p> <p>Patricia Harwood, MedImmune, said full guidelines were published in September and requested that the committee review the guidelines and reference list. MedImmune believes there is no evidence behind changing the criteria and it is based on expert opinion. .</p> <p>Pam Shaw M.D., F.A.A.P., reports that she was at the American Academy of Pediatrics (AAP) conference where there was discussion of the revised guidelines. Once a 32-35 week baby with no complications reaches 90 days of age, there is no evidence of greater risk of RSV than any full-term baby. The pediatric infectious disease committee voted unanimously for approval of the updated guidelines.</p> <p>Deb Quintanilla gives stats on Synagis requests so far this flu season (one month of data). 76% PAs were approved, 13% denied, 3 were pending. Those denied failed to meet criteria. Dr. Bell states that a survey of other state Medicaid pharmacy administrators found that most are staying with the updated guidelines.</p> <p>Dr. Burke stated that it is important that our criteria are consistent with specialty consensus guidelines. Hearing no major concerns among the committee members, he recommended that we should leave the criteria as is and review utilization data in January. Dr Burke added that a prescriber can always request therapy beyond the three month guideline through the appeal process. There was no movement by committee members and the current PA criteria stands.</p>	<p>Ms. Dowd moved to approve the minutes.</p> <p>Mr. Sutherland seconded and it carried with a unanimous vote.</p> <p>No changes were made to the Synagis® PA criteria.</p>
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<p>D. Onsolis®</p> <ul style="list-style-type: none"> <li>i. New PA Criteria</li> <li>ii. *Public Comment</li> <li>iii. Board Discussion/Action</li> </ul>	<p>No public comment.</p> <p>Proposed PA CRITERIA: (must meet all of the following)</p> <ol style="list-style-type: none"> <li>1. Patient must have diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) including: <ul style="list-style-type: none"> <li>a. Familial Cold Auto-inflammatory Syndrome (FCAS)</li> <li>or</li> <li>b. Muckle-Wells Syndrome (MWS)</li> </ul> </li> <li>2. Patient must be 4 years of age or older.</li> <li>3. Patient should have a negative tuberculosis screen.</li> <li>4. Patient must not be taking another IL-1 blocking agent.</li> <li>5. Patient must not be taking a Tumor Necrosis Factor (TNF) Inhibitor.</li> <li>6. Quantity limit of one vial (180mg) every 8 weeks.</li> </ol> <p>All approved requests will be valid for 1 year.</p> <p><b><u>Onsolis®</u></b></p> <p>Onsolis is a fentanyl buccal film approved for the management of breakthrough pain in patients with cancer, 18 years &amp; older, who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain. Currently, both buccal forms of fentanyl, Fentora® and Actiq®, require prior authorization. The Fentora®, Actiq®, and Onsolis package inserts and proposed PA criteria were included for board review.</p> <p>No public comment.</p> <p>Proposed PA CRITERIA: (must meet all of the following)</p> <ol style="list-style-type: none"> <li>1. Must be prescribed by Oncologist or pain specialist who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.</li> <li>2. Patient must have a diagnosis of malignant cancer.</li> <li>3. Use of Onsolis requires the prescriber, patient, and pharmacy be enrolled in the FOCUS Program.</li> <li>4. Age restrictions as follows: <ul style="list-style-type: none"> <li>a. Patient must be at least 16 years old. (Actiq only)</li> <li>b. Patient must be at least 18 years old. (Fentora and Onsolis)</li> </ul> </li> </ol>	<p>Dr. Grauer moved to accept the PA criteria for Onsolis® with the changes discussed.</p> <p>Mr. Sutherland seconded and it carried with a unanimous vote.</p>
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5. Patient must already be receiving opioid therapy and considered opioid tolerant (defined as taking at least 60 mg of oral morphine/day, 25mcg transdermal fentanyl/hour, 30mg of oxycodone daily, 8mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer).

6. Quantity limit of 4 units per day (defined as 24 hours)

7. Authorization for more than 4 units per day may be granted for periods of dose titration only.

All approved requests will be valid for 1 year.

Dr. Waite asked how you determine what a dose titration is. Dr. Bell said it would be a one time limit for dose titrating and every month after only four doses.

Dr. Grauer noted that the PA doesn't say they can't take Onsolis<sup>®</sup> with Actiq<sup>®</sup> or Fentora<sup>®</sup> at the same time.

Dr. Burke suggested making bullet 7 more specific. Special authorization may be granted for periods of titration for more than 4 units per day with requests by prescribing provider.

E. Health Information Designs

**Health Information Designs**

Dr. Churchwell, HID, presented the program assessment. Following the presentation the board was asked to select the remaining three topics for intervention for the Fiscal Year 2010 RetroDUR program. Two topics were selected for interventions at previous meetings. A total of five interventions will be completed in FY2010.

i. Program Assessment

*Program Assessment*

Yearly Totals

During the State Fiscal Year (SFY) of 2009 (July 1, 2008 through June 30, 2009), the Kansas Health Policy Authority (KHPA) Medical Programs paid over \$175 million (rebates not included) on approximately two million prescriptions for fee-for-service (FFS) beneficiaries. This is a nearly \$16 million increase in prescription expenditures from SFY 2008, when KHPA Medical Programs paid nearly \$159 million on prescription claims.

KHPA Medical Programs averaged 142,493 members (beneficiaries) per month. Beneficiary eligibility types include not only Title 19 (TXIX), but also Medically Needy, MediKan, the AIDS Drug Assistance Program (ADAP), and Presumptive Eligibility 19. KHPA Medical Programs covers other eligibility types through its Managed Care choices (not included in this

report).

While KHPA Medical Programs averages 142,493 members per month, the average user per month was much lower at 47,414 (“user” is defined as a member who received at least one prescription). By using this distinction, a better picture of what KHPA Medical Programs pays per user for drug expenditures is seen—a cost that is typically much higher than per member cost.

For SFY 2009, KHPA Medical Programs paid an average per member per month cost of \$102.44, and an average per user per month cost of \$307.73. The average cost per claim for SFY 2009 was \$85.94.

The total claims cost increase was 9.3%, total claims increase was 5.2%, and average cost per claim increase was 4.3%.

The average cost per claim decreased from \$87.02 in July 2008 to \$80.65 in June 2009. This was possibly due to the increase in the generic availability of several major drug classes, including atypical antipsychotics and anticonvulsants, during SFY 2009.

Dr. Churchwell explained that some of the cost decrease could also be due to addition of 6,000 drugs to State Maximum Allowable Cost (SMAC) pricing. Dr. Burke asked for an explanation of SMAC pricing. Dr. Bell explained that when there are multiple manufacturers of a particular drug, we will look at the pricing of all the available manufacturers and determine a fair price based on several low-cost manufacturers and set reimbursement at that rate, regardless of what manufacturer it is, or even if it is the brand name product. Setting reimbursement this way instead of basing it on Average Wholesale Price (AWP) provides a significant cost savings. Dr. Burke asked if this is new or something we have always done. Dr. Bell said that we have always done it, however the list was greatly expanded over the last year as part of cost-savings measures necessitated by the state budget.

Trend Summary Analysis

Of note, within the top 15 therapeutic classes by total cost of claims and total number of claims there are three drug classes that appear in the top five in both measures: antipsychotics, anticonvulsants, and antidepressants. For the past several years, these three drug classes have been, and continue to be, a large expenditure and are also some of the most commonly-prescribed drug classes.

Conclusion

In SFY 2009, there was a growth in the number of members covered by KHPA Medical Programs, and the total expenditures. In SFY 2009, KHPA Medical Programs paid

<p>ii. FY 2010 Intervention Selection</p>	<p>\$175,085,301 compared to \$158,877,070 in SFY 2008—an increase of over \$16 million in prescription expenditures.</p> <p>Between SFY 2006 and SFY 2007, there was a dramatic decrease in prescription costs and prescription claims. This decrease can be primarily attributed to the shift of members into Medicare Part D.</p> <p>Several of the top therapeutic classes have been top expenditures for KHPA Medical Programs over the past several years. These include antipsychotic agents, antidepressants, anticonvulsants, hemostatics, and antiretrovirals. Hemostatics and antiretrovirals represent a small number of claims, but the cost of these medications can be tremendous, with a single claim costing as much as \$150,000.</p> <p>Prevacid® has remained in the top drugs both by total cost of claims and total number of claims over the past several years. This is most likely due to it having been a preferred Proton Pump Inhibitor since the inception of the Preferred Drug List (PDL) in 2002. Prevacid® is expected to become generically available in late 2009, which will result in a significant cost savings in this therapeutic class.</p> <p>While there are several agents that appear on both the top drugs by cost of claims and total claims, the majority of the agents on these lists are used to treat mental health conditions. This has been a trend over the past several years. The KHPA Medical Programs do not currently manage these medications due to a statutory restriction</p> <p><i>FY 2010 Intervention Selection</i></p> <p>Dr. Churchwell said she has received feedback that prescribers particularly appreciate receiving letters when there is a possible drug interaction.</p> <p>Ms. Page-Goertz asked for a definition of interventions. Dr. Churchwell explained that beneficiary profiles are looked at and letters along with the profiles are sent to prescribers. Prescribers can then send feedback.</p> <p>Dr. Burke asked if the mailings go to prescribers of all the beneficiaries that hit a quality indicator. Dr. Churchwell said we mail to the highest risk levels. She is limited by the number that can be reviewed in a certain time frame.</p> <p>Ms. Page-Goertz asked if the program works. Dr. Churchwell said that narcotics/analgesics were done last and it is too soon to see the intervention results.</p> <p>Dr. Sweet states GI meds would be a low return on investment class and recommended we review hyperlipidemic therapies.</p>	<p>Mr. Sutherland moved to select antihyperlipidemic therapies, diabetes, and antipsychotics for the DUR intervention topics.</p> <p>Ms. Dowd seconded and it carried with a unanimous vote.</p>
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	<p>Dr. Waite said there has been a recent PPI study. Healthy individuals were put on a PPI for 12 weeks. They were then weaned off. Those individuals then experienced rebound hyperacidity.</p> <p>Dr. Sweet asked why antipsychotics were not on the suggested list of retro-DUR topics. Dr. Burke said because of the state statute that restricts management of mental health drugs by the DUR board, retro-DUR interventions have focused on other drug classes. He added that Kansas is also working with the CNS program, which has a somewhat similar retro-intervention program and we didn't want providers to be receiving multiple letters from different companies about the same patients. Further discussion followed and Dr. Sweet noted that antipsychotic drugs represent a significant portion of the pharmacy budget and cross all age and gender lines.</p> <p>There was board agreement among the board that antipsychotics would be an appropriate retro-DUR intervention topic. Dr. Sweet and Dr. Kennedy suggested that there are many providers who do not know that there are black box warnings on the use of antipsychotics for dementia in the elderly and that perhaps additional data from a retro-review might influence the state to change the law exempting psychotropic drugs from DUR management.</p>	
V. Adjourn	There was no final public comment.	<p>Dr. Waite moved to adjourn.</p> <p>Dr. Unruh seconded and it was carried by a unanimous vote.</p>