Drug Utilization Review Board

Oklahoma Health Care Authority
2401 N.W. 23rd Street, Suite 1A
Oklahoma City, Oklahoma 73107
Ponca Room

Wednesday
December 8, 2010
6:00 p.m.

The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review Board Members

FROM: Shellie Keast, Pharm.D., M.S.

SUBJECT: **Packet Contents for Board Meeting – December 8, 2010**

DATE: December 1, 2010

NOTE: THE DUR BOARD WILL MEET AT 6:00 P.M. THE MEETING WILL BE HELD IN THE PONCA ROOM AT THE OKLAHOMA HEALTH CARE AUTHORITY OFFICES IN SHEPHERD MALL. (NORTH ENTRANCE)

Enclosed are the following items related to the December meeting. Material is arranged in order of the Agenda.

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – See Appendix A.

Update on DUR / MCAU Program – See Appendix B.

Action Item – Vote to Prior Authorize Metozolv ODT® - See Appendix C.

Action Item – Vote to Prior Authorize Alzheimer's Medications – See Appendix D.

Action Item – Annual Review of Singulair® and 30 Day Notice to Prior Authorize Zyflo CR®– See Appendix E.

Action Item – Post-Implementation Utilization Review of Atypical Antipsychotics and 30 Day Notice to prior Authorize Latuda™ – See Appendix F.

60 Day Notice to Prior Authorize Benign Prostate Hyperplasia (BPH) Products – See Appendix G.

FDA and DEA Updates – See Appendix H.

Future Business

Adjournment

Oklahoma Health Care Authority
Drug Utilization Review Board
(DUR Board)
Meeting – December 8, 2010 @ 6:00 p.m.

Oklahoma Health Care Authority
2401 N.W. 23rd Street, Suite 1-A
Oklahoma City, Oklahoma 73107
Ponca Room (North Entrance)

AGENDA
Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

1. Call To Order
- A. Roll Call – Dr. Graham

Items to be presented by Dr. Muchmore, Chairman:

2. Public Comment Forum
- A. Acknowledgment of Speakers and Agenda Items

Items to be presented by Dr. Muchmore, Chairman:

3. Action Item – Approval of DUR Board Meeting Minutes – See Appendix A.
- A. November 10, 2010 DUR Minutes – Vote
- B. November 11, 2010 DUR Recommendation Memorandum
- C. Correspondence

Items to be presented by Dr. Keast, Dr. Muchmore, Chairman:

4. Update on DUR / Medication Coverage Authorization Unit – See Appendix B.
- A. Retrospective Drug Utilization Review for October 2010
- B. Retrospective Drug Utilization Review Response for August 2010
- C. Medication Coverage Activity Audit for November 2010
- D. Pharmacy Help Desk Activity Audit for November 2010

Items to be presented by Dr. Sipols, Dr. Muchmore, Chairman

5. Action Item – Vote to Prior Authorize Metozolv ODT® – See Appendix C.
- A. COP Recommendations

Items to be presented by Dr. Le, Dr. Muchmore, Chairman

6. Action Item – Vote to Prior Authorize Alzheimer's Medications – See Appendix D.
- A. COP Recommendations

Items to be presented by Dr. Le, Dr. Muchmore, Chairman

7. Action Item – Annual Review of Singulair® and 30 Day Notice to Prior Authorize Zyflo CR® – See Appendix E.

A. Introduction
B. Utilization Review
C. COP Recommendations

Items to be presented by Dr. Keast, Dr. Muchmore, Chairman

8. Action Item – Post-Implementation Utilization Review of Atypical Antipsychotics and 30 Day Notice to Prior Authorize Latuda™ – See Appendix F.

A. Current Authorization Criteria
B. Utilization Review
C. Prior Authorizations Review
D. Behavioral Health Data
E. Metabolic Monitoring Questionnaires
F. COP Recommendations
G. Utilization Details
H. Latuda™ Product Details

Items to be presented by Dr. Keast, Dr. Muchmore, Chairman

9. 60 Day Notice to Prior Authorize Benign Prostate Hyperplasia (BPH) Products – See Appendix G.

A. Utilization Review
B. COP Recommendations

Items to be presented by Dr. Graham, Dr. Muchmore, Chairman

10. FDA and DEA Updates – See Appendix H.

11. Future Business

A. Annual Review of Advair® / Symbicort®
B. Annual Review of Antihypertensives
C. Annual Review of Hypnotics
D. New Product Reviews

12. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of NOVEMBER 10, 2010

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.: Vice-Chairman	X	
Mark Feightner, Pharm.D.	X	
Anetta Harrell, Pharm.D.	X	
Evelyn Knisely, Pharm.D.	X	
Thomas Kuhls, M.D.	X	
John Muchmore, M.D., Ph.D.: Chairman	X	
Paul Louis Preslar, D.O., MBA	X	
James Rhymer, D.Ph.		X
Bruna Varalli-Claypool, MHS, PA-C	X	
Eric Winegardener, D.Ph.	X	

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Metha Chonlahan, D.Ph.; Clinical Pharmacist	X	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	X	
Ronald Graham, D.Ph.; Pharmacy Director	X	
Shellie Keast, Pharm.D, M.S..; DUR Manager	X	
Chris Le, Pharm.D.; Clinical Pharmacist/Coordinator	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Neeraj Patel, Pharm.D.; Clinical Pharmacist	X	
Lester A. Reinke, Ph.D.; Associate Dean for Graduate Studies & Research	X	
Leslie Robinson, D.Ph.; PA Coordinator	X	
Jennifer Sipols, Pharm.D.; Clinical Pharmacist	X	
Visiting Pharmacy Student(s): Ann Nguyen, Molina Mhatre	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mike Fogarty, J.D., M.S.W.; Chief Executive Officer		X
Nico Gomez; Director of Gov't and Public Affairs		X
Garth Splinter, M.D., M.B.A.; Director of Medicaid/Medical Services		X
Nancy Nesser, Pharm.D., J.D.; Pharmacy Director	X	
Howard Pallotta, J.D.; Director of Legal Services		X
Lynn Rambo-Jones, J.D.; Deputy General Counsel III	X	
Rodney Ramsey; Drug Reference Coordinator	X	
Jill Ratterman, D.Ph.; Pharmacy Specialist	X	
Kerri Wade, Senior Pharmacy Financial Analyst	X	

OTHERS PRESENT:

Mark DeClerk, Lilly	Sam Smothers, MedImmune	Frances Bauman, Novo Nordisk
Nikki Goff, Novo Nordisk	Monica Jacobucci, AstraZeneca	Jeff Himmelberg, GSK
M. Patty Laster, Genentech	John Omick, NVS	Charlene Kaiser, Amgen
Brad Burgstahler, Elan	Esther Liu, Lilly	Lisa Buck, Pfizer
Jim Dunlap, Lilly	Kelly Rogers, Taro	Pat Trahan, Taro
Aaron Mays, Alcon	Mark Veerman, JNJ	Carlos Palasciano, Hawthorn
Scott Estes, Forest	Jane Stephen, Allergan	Donna Erwin, BMS

PRESENT FOR PUBLIC COMMENT:

Agenda Item No. 6	Charles DiPaula, Novo Nordisk
Agenda Item No. 6	Lee Ding, Genentech
Agenda Item No. 11	Elson Kim, Forest Labs

AGENDA ITEM NO. 1: **CALL TO ORDER**

1A: Roll Call

Dr. Muchmore called the meeting to order. Roll call by Dr. Graham established the presence of a quorum.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**

Dr. Muchmore recognized the speakers for public comment.

Agenda Item No. 6 Charles DiPaula, Novo Nordisk

Agenda Item No. 6 Lee Ding, Genentech

Agenda Item No. 11 Elson Kim, Forest Labs

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MINUTES**

3A: October 13, 2010 DUR Minutes

Dr. Bell moved to approve as submitted; seconded by Dr. Kuhls.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON DUR/MEDICATION COVERAGE AUTHORIZATION UNIT**

4A: Retrospective Drug Utilization Review: September 2010

4B: Retrospective Drug Utilization Review Response: July 2010

4C: Medication Coverage Activity Audit: October 2010

4D: Help Desk Activity Audit: October 2010

Reports included in agenda packet; presented by Dr. Keast.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE ON 2011 MEETING DATES**

Presented by Dr. Keast:

January 12, 2011	February 9, 2011	March 9, 2011
April 13, 2011	May 11, 2011	June 8, 2011
July 13, 2011	August 10, 2011	September 14, 2011
October 12, 2011	November 9, 2011	December 14, 2011

Dr. Kuhls moved to approve as submitted; seconded by Ms. Varalli-Claypool.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO CHANGE CRITERIA FOR GROWTH HORMONE PRODUCT BASED PRIOR AUTHORIZATION CATEGORY**

For Public Comment: Charles DiPaula: I'd like to thank you for your time. I am Charles DiPaula. I'm a PharmD and a growth hormone medical science liaison for Novo Nordisk. As you know, growth hormone therapy involves years of daily injections and that may be challenging for Oklahoma Medicaid patients. Norditropin, the Novo Nordisk brand of somatropin, is currently available to Oklahoma Medicaid patients and maintains a significant market share. During the September meeting, your group was presented market share data that indicated that Norditropin had the highest utilization in the State. I would like to take a few minutes to just outline a couple of reasonable potential preference. I will be providing a brief product overview discussing Norditropin delivery devices and support programs, and I'll try to demonstrate our Flexpro. Norditropin is a polypeptide hormone with DNA origin. Chemically, Norditropin contains phenol as a preservative which is not contraindicated in infants. It contains histidine as a buffer, which has not been associated with injection site reactions or stinging. Norditropin has had FDA approval for four pediatric indications and one adult indication. It is the only growth hormone that has longterm safety and efficacy data to adult height and three indications included in its' package insert. The four pediatric indications are growth failure due to growth hormone deficiency, and short stature associated with Turner Syndrome, Noonan Syndrome and SGA. Devices are very important, obviously, to this when discussing growth hormone administration. Novo Nordisk has developed and manufactured its' own devices for decades, enabling full visibility of a product following. Our devices are convenient and easy to use, key needs for patients taking growth hormone. The Oklahoma Health Care Authority will receive bids for two of our products, NordiFlex and FlexPro. Norditropin NordiFlex is the first prefilled, premixed, multidose liquid growth hormone disposable pen. Unlike many other devices, each new pen does not require, does not have to be reconstituted. There's no mixing or changing of cartridges. It requires no battery device. The patient also doesn't have to keep track of a pen device.

Norditropin FlexPro, approved in March 2010, offers enhanced features compared to NordiFlex like better dosing accuracy, such as an easy to push dose button with an end of dose signal to alert the patient when the entire dose has left the pen. In a study designed to evaluate the usability of the product, 100% of the patients found it easy to learn how to use Norditropin FlexPro, while 99% of the patients found it easy to push the button and inject the dose. FlexPro also delivers demonstrated overfill to optimize the deliverable doses to help insure patients receive a full label volume. Norditropin comes in three strengths which allows for 5 mg dosing increments. Doses may be as low as .025 mg and as high as 8 mg, and fine dosing increments provide great flexibility and positions to provide the optimal dose, potentially reducing product wastage and generating cost savings. The high maximum dose can help patients to avoid taking multiple daily injections. Occasionally patients may forget to return their pen to the refrigerator, and after they initially use the 5 to 10 mg Norditropin pen, may be left out of the refrigerator for up to three weeks at 77°F. This may be a benefit to patients who travel and patients who move, children who move between households. It also may help reduce product wastage. Novo Nordisk provides comprehensive patient support services through NordiCare. NordiCare is staffed with dedicated case managers who assist patients with reimbursement and training with Norditropin therapy. NordiCare services extend as long as the patient requires Norditropin and for eligible patients, NordiCare is authorized to prevent gaps in treatment due to weather, shipping or supply issues or life changes. Also if patients forget to reapply and lose Medicaid coverage, NordiCare is authorized to provide free interim therapy while they reapply. In summary, Novo Nordisk has 22 year history of serving the needs of growth hormone patients and you can be sure that Novo Nordisk will work hard to continue to improve their device and products and services to better meet the needs of Oklahoma Medicaid patients in the future, and for that reason, I would appreciate your consideration of Norditropin as you deliberate. Thank you for your time. Do you have any questions?

For Public Comment: Lee Ding: Hi, good evening. I'm going to be really short actually. My name is Lee Ding. I am a PharmD. I'm working for Genentech Medicaid department. So basically I'm here, I was also a pharmacy director for a couple of health plans in the Midwest, so I'm basically here today to offer anything to support your team if needed, or if you have any questions about Nutropin.

Dr. Muchmore: Since vendor support is an issue for some of our pediatricians, what do you offer in that regard? Vendor support for teaching patients and family.

Dr. Ding: Yes, we do have, we have a couple of programs actually. We have a endocrinology nurse that actually is available to train a patient and also we have an 800, toll free phone line that patients can call in if they have any question about anything about growth hormone Nutropin device.

Dr. Graham: Do you have an indigent program?

Dr. Ding: Advantage program? Indigent program. You know what, I am sure we do. I'm not too familiar with that. I'm from the medical side, so …… most manufacturers do have a certain kind of indigent program.

Dr. Muchmore: One other thing I might say as we go through this, many Medicaid state programs do not allow growth hormone for idiopathic short stature or retarded gestational development, and that's one of the things that we need to decide to either not allow or to allow or to make it special review, so that you would pick the most egregious cases. And it's a matter of, you know, you've got so many dollars to spend, and so many states have made that election. Just be aware of that as she goes through this.

Materials included in agenda packet; presented by Dr. Moore.

The Board discussed and agreed upon several changes to the criteria.

Dr. Bell moved to approve as amended; seconded by Dr. Winegardener.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE BUTRANS™, PRIMLEV™, XOLOX®, EXALGO™ ER, RYBIX™ ODT AND SUBOXONE®/SUBUTEX®**

Materials included in agenda packet; presented by Dr. Keast.

Dr. Feightner moved to approve as submitted; seconded by Ms. Varalli-Claypool.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE VIMOVO™**

Materials included in agenda packet; presented by Dr. Patel.

Dr. Kuhls moved to approve as submitted; seconded by Dr. Harrell.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **ANNUAL REVIEW OF OCULAR ALLERGY PRODUCT BASED PRIOR AUTHORIZATION CATEGORY AND VOTE TO PRIOR AUTHORIZE BEPREVE™ AND LASTACAFT™**

Materials included in agenda packet; presented by Dr. Robinson.

Dr. Winegardener moved to approve as submitted; seconded by Ms. Varalli-Claypool.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: **30-DAY NOTICE TO PRIOR AUTHORIZE METOZOLV® ODT**

Materials included in agenda packet; presented by Dr. Sipols.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: **30-DAY NOTICE TO PRIOR AUTHORIZE SPECIAL FORMULATIONS AND APPLICATION OF AGE RESTRICTION OF ALZHEIMER'S MEDICATIONS**

For Public Comment: Elson Kim: Good evening. I've been asked to refresh the Committee's exposure to our product. My name is Elson Kim. I'm a PharmD with Forest Labs. I'm here to discuss recent data for Namenda, Memantine, for the treatment of Alzheimer's Disease. The USP Model Guidelines, Version 4, specify glutamate pathway modifiers as a separate class from cholinesterase inhibitors in the larger therapeutic category of anti-dementia agents. Meantime, Memantine, which is an NMDA receptor antagonist, is the only glutamate pathway modifier approved for the treatment of moderate to severe Alzheimer's disease, with proven efficacy both as monotherapy and in combination with cholinesterase inhibitors. Previous clinical studies have found that Memantine treated patients have significant improvements in cognition, function and behavior as well as a reduction in caregiver burden. A recently published NIH-sponsored study was conducted by Dr. Atri's group at Massachusetts General Hospital. They analyzed data from 382 Alzheimer's disease patients seen at their Memory Disorders Unit over a 15 year period. They took longterm data on patient's cognition and function and created a statistical model to predict disease progression for patients in three treatment paradigms: those receiving no treatment vs. a cholinesterase inhibitor alone vs. combination therapy of Memantine plus a cholinesterase inhibitor. The results show that on measures of cognition and function, the group receiving combination therapy of Memantine plus a cholinesterase inhibitor showed the slowest rate of decline in their four-year predictive model. Furthermore, the effect size between the groups grew larger from year to year. In contrast, patients who received cholinesterase inhibitor monotherapy showed no benefit in function compared to untreated patients, and only a small effect on cognition. This study suggests that the use of combination therapy of Memantine with a cholinesterase inhibitor is superior to using a cholinesterase inhibitor alone or no treatment in slowing decline of cognition and function in Alzheimer's disease. I have another article that I just want to go over briefly. This one is Dr. Atri, published in ….. I'm sorry, Dr. Rountree, published in 2009: 641 probable patients from 1989 to 2005. They created a persistency index reflecting total years of drug use divided by total years of symptoms. Basically, it's an adherence study. The annual change in slope of the neuropsychological and functional test as predicted by follow-up time, persistence index and interaction of these two variables was evaluated. I'll cut to the chase. The magnitude of the favorable effect of the rate of change and the persistency index was reduced by one point per year and all the other factors are also reduced. The change in the mean test scores and added in for the follow-up period, which is three years, sorry it's two years. In conclusion, they say the persistence, drug treatment had a positive impact on Alzheimer's disease progression, assessed by multiple cognitive, functional and global outcome measures, and that the magnitude of the treatment effect was clinically significant, and the positive treatment effects were even found in those with advanced disease. Basically you had a treatment group with no drug, cholinesterase inhibitor, and combination therapy, and the results pretty much mimic what you saw in the Atri studies of the NIH group. And they finally just required safety information. The most common adverse events with Memantine are dizziness, confusion, headache and constipation. In patients with severe renal impact, a dosage reduction is recommended. Caution is advised to patients with severe hepatic impairment or under conditions that raise urinary pH. In closing, patients treated with Memantine for moderate to severe Alzheimer's disease have shown improvement on cognitive, functional, communication, behavioral and global measures. Memantine is safe and well tolerated and can be used effectively as monotherapy or in combination with cholinesterase inhibitors.

Dr. Muchmore: Question …. is Forest Lab doing any studies on application of Memantine to the pediatric population?

Dr. Kim: Okay, Forest ….. as you know, the product is not indicated in the pediatric population.

Dr. Muchmore: Right, but I just wondered if there's any on-going evaluation of that.

Dr. Kim: There is on-going evaluation in pediatric populations

Dr. Muchmore: Any particular diseases they're focused on?

Dr. Kim: The current studies, if you go to clinicaltrials.gov you can look those up and do Memantine and pediatrics and you'll find that we have open recruitment for one study on Down's Syndrome and several studies in autism.

Dr. Muchmore: Interesting. That's just a glimpse of the future.

Dr. Kim: Yeah, I think there are several studies out there to give us some signals that we're looking at, so …..

Dr. Muchmore: Thank you very much.

Materials included in agenda packet; presented by Dr. Le.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: **UTILIZATION REVIEW OF BENIGN PROSTATE HYPERPLASIA (BPH) MEDICATIONS**

Materials included in agenda packet; presented by Dr. Chonlahan.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: **FDA & DEA UPDATES**

Materials included in agenda packet; presented by Dr. Graham.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: **FUTURE BUSINESS**

Materials included in agenda packet; submitted by Dr. Graham.

A: Annual Review of Antihypertensives
B: Utilization Review of Antipsychotics
C: Annual Review of Advair® / Symbicort®
D: New Product Reviews

ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: **ADJOURNMENT**

The meeting was adjourned at 9:05 p.m.

The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: November 11, 2010

To: Nancy Nesser, Pharm.D., J.D.
Pharmacy Director
Oklahoma Health Care Authority

From: Shellie Keast, Pharm.D., M.S.
Drug Utilization Review Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting of November 10, 2010

Recommendation 1: Vote on 2011 Meeting Dates

MOTION CARRIED by unanimous approval.

January 12, 2011
February 9, 2011
March 9, 2011
April 13, 2011
May 11, 2011
June 8, 2011
July 13, 2011
August 10, 2011
September 14, 2011
October 12, 2011
November 9, 2011
December 14, 2011

Recommendation 2: Vote to Update Growth Hormone Prior Authorization Category

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following three items:

1. Update criteria for coverage, continuation, and discontinuation of growth hormone products based on recommendations from Board Members and specialists (see attachment).
2. Develop a preferred drug list based on best bids submitted from manufacturers participating in the supplemental rebate program. The following is the tier list and proposed criteria for using a non-preferred product:

Tier 1	Tier 2
Based on Supplemental Rebate	**Accretropin®** (Cangene)
	Genotropin® (Pfizer) - Cartridge, MiniQuick
	Humatrope® (Eli Lilly) - Vials, Cartridge kits
	Norditropin® (NovoNordisk) - NordiPen cartridges, NordiFlex pens, FlexPro pens
	Nutropin® and Nutropin AQ® (Genentech) - vials, Pen Cartridge
	Omnitrope® (Sandoz) - Vials, Cartridge
	Saizen® (EMD Serono) - Vials, Cartridges for Easypod, Cool.click, Click.easy
	Serostim® (EMD Serono) - Vials
	Zorbtive® (EMD Serono) - Vials
	Tev-Tropin® (Gate/Teva) - Vials

All products contain the identical 191 amino acid sequence found in pituitary-derived hGH (Increlex® and Iplex® not included)

Prior Authorization Criteria:

a) Documented allergic reaction to non-active components of all available Tier 1 medications.
b) Clinical exception applies to members with a diagnosis of AIDS wasting syndrome, in which case Serostim can be used, regardless of its current Tier status.

3. Determine if members currently on Tier 2 products should be grandfathered when the preferred drug list becomes effective. DUR Board recommended not to grandfather for this category.

Recommendation 3: Vote to Prior Authorize Butrans™ (buprenorphine), Primlev™ (oxycodone/APAP), Xolox® (oxycodone/APAP), Exalgo™ ER (hydromorphone), Rybix™ ODT (tramadol), and Suboxone(buprenorphine/naloxone)®/Subutex®(buprenorphine)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends all prescriptions for Suboxone® (buprenorphine/ naloxone) tablets and film or Subutex® (buprenorphine), and their generic equivalents if available, require prior authorization.

Criteria for coverage are as follows:

- Prescribed by a licensed physician who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a DEA (X) number.
- Diagnosis of opiate abuse/dependence.
- Combination with benzodiazepines, hypnotics, and opioids (including tramadol) will be denied.
- Approval will be for 90 days to allow for concurrent medication monitoring.
- The following limitations will apply:
    - **Suboxone®** 2mg/0.5mg and 8mg/2mg tablets and film: A quantity limit of 90 per 30 days.
    - **Subutex®** 2mg tablets and 8mg tablets will only be approved if the member is pregnant (product may be used for the duration of the pregnancy only), or has a documented serious allergy or adverse reaction to naloxone.

The College of Pharmacy also recommends placement of the following products in the current Tier structure:

Butrans™ (buprenorphine): to be placed in Tier 3 of the long-acting products Tier structure, with a quantity limit of 4 patches every 28 days.

Exalgo™ (hydromorphone): to be placed in Tier 3 of the long-acting products Tier structure, with a quantity limit of 1 tablet daily for the 8mg, 3 tablets daily for the 12mg, and 4 tablets daily for the 16mg.

Primlev™ and Xolox®(oxycodone/APAP): to be placed in Tier 3 of the short-acting products Tier structure, with a quantity limit based on 3,250 mg of acetaminophen daily and a clinical reason why member cannot use currently available similar generic products.

Rybix™ ODT (tramadol): to be placed in Tier 3 of the short-acting products Tier structure, with a quantity limit of 4 tablets per day and a diagnosis indicating the member has a condition that prevents them from swallowing tablets.

Additionally, the College recommends moving the hydrocodone/APAP products, Xodol® and Zamicet™, from Tier 2 to Tier 3 with additional criteria requiring a clinical reason why the member cannot use currently available similar generic products. The College also recommends

that any brand-only formulations of currently available generic narcotic products be placed in Tier 3 with similar criteria.

Recommendation 4: Vote to Prior Authorize Vimovo (esomeprazole/naproxen)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends to place Vimovo™ (Esomeprazole Mg - Naproxen) in the special PA category of the NSAIDS with the same criteria for the NSAIDS in the Special PA Category:

a) Special indications, such as the diagnosis of gout for indomethacin, OR
b) Previous use of at least two Tier 1 NSAID (from different product lines) AND
c) Reason why a special formulation is needed over a Tier 1 product

Recommendation 5: Annual Review of Ocular Allergies and Vote to Prior Authorize Bepreve™ (bepotastine) and Lastacaft™ (alcaftadine)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends a three tier structure for this category with all medications currently available in generic in Tier 1 and all others in Tier 3. Tier 2 will consist of medications whose manufacturer participates in the supplemental rebate program. In addition the College of Pharmacy recommends addition of Bepreve™(bepotastine) and Lastacaft™ (alcaftadine) to Tier 3 of the Ocular Allergy PBPA Category. The following prior authorization criteria will apply.

Tier 2 authorization criteria:

1. FDA approved diagnosis
2. A trial of one Tier 1 product for a minimum of two weeks in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects
3. Contraindication to lower tiered medications

Tier 3 authorization criteria:

1. FDA approved diagnosis
2. Recent trials of one Tier 1 product and all available Tier 2 medications for a minimum of two weeks each that did not yield adequate relief of symptoms or resulted in intolerable adverse effects
3. Contraindication to lower tiered medications

Tier 1	Tier 2	Tier 3
cromolyn (Crolom®) **ketotifen (Alaway®,Zaditor OTC®)**	Supplemental Rebated Tier 3 medications	nedocromil (Alocril®) pemirolast (Alamast®) emedastine (Emadine®) loteprednol (Alrex®) olopatadine (Pataday®) olopatadine (Patanol®) lodoxamide (Alomide®) epinastine (Elestat®) azelastine (Optivar®) bepotastine besilate (Bepreve™) alcaftadine (Lastacaft™)

Growth Hormone Prior Authorization Criteria

Pediatric Members

Covered indications (prior to epiphyseal closure)

1) Classic hGH deficiency as determined by childhood hGH stimulation tests outlined below
2) Panhypopituitarism with history of pituitary or hypothalamic injury due to tumor, trauma, surgery, irradiation, hemorrhage or infarction or a congenital anomaly, and
    a. ≥ 3 pituitary hormones deficient and IGF-1 ≤ 2.5 SD below the mean.
    b. 0, 1, or 2 hormones deficient and IFG-1 < 50^{th} percentile (midline) and failure of a growth hormone stimulation test as outlined below
3) Panhypopituitarism in children with height <2.25 SD below mean for age and MRI evidence for empty sella, pituitary stalk agenesis or ectopic posterior pituitary "bright spot"
4) Short stature associated with Prader-Willi Syndrome
5) Short stature associated with chronic renal insufficiency (pre-transplantation)
6) History of intrauterine growth restriction who have not reached a normal height (≥ 2.25 SD below mean for age/gender) by age 2 years
7) idiopathic short stature (ISS) who are ≥ 2.25 SD below mean for height and are unlikely to catch up in height.
8) Turner syndrome or 45X, 46XY mosaicism
9) Hypoglycemia with evidence for hGH deficiency
10) SHOX deficiency (with genetic evidence for short stature homeobox-containing gene deficiency)
11) Other evidence for hGH deficiency submitted for panel review and decision

Transitional indications for clients on childhood hGH therapy (after reaching target height or epiphyseal closure) Transitional patients must be phased down to adult hGH doses over a year.

1) Classic childhood hGH deficiency who fail an adult hGH stimulation test after a month or more withholding hGH therapy.
2) Persons who have initiated growth hormone therapy in childhood because of pituitary damage, agenesis or anomaly.

Contraindications to therapy

1) Presence of active malignancy, diabetes out of control, or intracranial hypertension
2) Prader-Willi patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment

Dose of hGH (doses must be individualized and titrated)

1) Children – 25 to 100 mcg/kg/day (in 3 to 7 doses per week) according to current pediatric guidelines
2) Adults - 0.1 to 0.5 mg per day – lower doses in older clients. Doses should be evaluated and titrated at 1 to 2 month intervals targeting an IGF-1 level at or below the mean reference value for age and gender.

Requirements for initiation of Growth Hormone Therapy – All indications

1) Evaluated and prescribed by an Endocrinologist, Pediatric Nephrologist, or Infectious Disease Specialist
2) Covered indication
3) Age of 2 years or older (exceptions: hypoglycemia related to GHD, any age, and ISS, 8 years old or older)
4) Height >2.25 SD below the mean for age (excludes chronic renal failure)
5) Evidence of delayed bone age (excludes chronic renal failure) and open epiphyses.
6) The following information must be provided
    a. Growth Chart
    b. Parental heights

INDIVIDUAL INDICATIONS (in addition to the above requirements)

Panhypopituitarism

1) History of pituitary or hypothalamic injury due to tumor, trauma, surgery, irradiation, hemorrhage or infarction or a congenital anomaly and
    a. ≥ 3 pituitary hormones deficient and IGF-1 ≤ 2.5 SD below the mean.
    b. 0, 1, or 2 hormones deficient and IFG-1 < 50^{th} percentile (midline) and failure of a growth hormone stimulation test as outlined below
2) MRI evidence for pituitary stalk agenesis, empty sella, pituitary stalk agenesis or ectopic posterior pituitary "bright spot"

Growth hormone deficiency

1) Serum IGF-1 below the mean
2) No contributing medical condition, i.e. chronic diseases (cystic fibrosis, chronic renal failure), malnutrition, psychosocial deprivation, etc
3) Subnormal response of 10ng/ml or less on two provocative growth hormone stimulation tests (glucagon not approved for use in children)
    a. Propranolol with exercise
    b. Levodopa
    c. Insulin hypoglycemia test
    d. Arginine HCl infusion
    e. Clonidine

Note: this criterion may be waived when a clinical diagnosis of panhypopituitarism, based on diagnostic radiographic and clinical findings (see below*) is made. In addition, children with a profoundly low growth velocity who are at high risk for GHD due to CNS radiation or other organic causes (termed "neurosecretory dysfunction") may demonstrate "normal" responses to provocative tests, often for several years, yet often benefit from GH treatment.

Neurosecretory dysfunction

1) Serum IGF-1 below the mean for age

Short Stature associated with Prader-Willi

1) Chromosome analysis diagnosing Prader-Willi

Turner Syndrome or 45X, 46XY mosaicism

1) Chromosome analysis diagnosing either Turner's syndrome in female members or 45X, 46XY mosaicism in males

Short Stature associated with chronic renal insufficiency

1) Estimated creatinine clearance <50 ml/min
2) Pre -transplant

Small for Gestational Age

1) Documentation of birth weight of less than 2,500 g at gestational age of more than 37 weeks or birth weight or length below the 3rd percentile for gestational age
2) Member over 2 years of age

Idiopathic Short Stature

1) Age of 8 years old or older

SHOX (short stature homeobox-containing gene) deficiency

1) Chromosomal analysis diagnosing SHOX gene anomaly
2) Normal endocrine screen
3) No evidence of GH deficiency or insensitivity, tumor activity, diabetes mellitus, history of impaired glucose tolerance, or other serious illness known to interfere with growth

Hypoglycemia associated with hGH insufficiency

Hypoglycemia is a symptom that is present in some members as a result of low growth hormone levels. Because of the severity of problems related to this form of hypoglycemia (permanent neurologic morbidity, septo-optic dysplasia), it will be given separate consideration from short stature issues. Coverage will not be provided for growth hormone used to treat members with normal hGH levels who happen to be hypoglycemic.

1) Initiation of Therapy
   a. Due to the severity of this condition, initial doses may be administered without receiving a medication coverage authorization first. However, appropriate information must be provided within 30 days for coverage consideration. When all member information has been received, a retroactive authorization will be given for any emergency doses dispensed.
2) Continuation and Discontinuation of Therapy
   a. Members should be evaluated every six months to monitor for efficacy and side effects. Therapy should not be discontinued if there is a probability of the hypoglycemic condition reoccurring once hGH replacement therapy is withdrawn.

Continuation of hGH therapy

1) Evaluation by an endocrinologist /pediatric nephrologist at least every 6 months, with monitoring for adverse effects and compliance and documentation of indications for continuation of therapy.
2) Evidence of compliance
3) Improvement in height percentile on growth chart

Discontinuation of Therapy (at least one) or transition to adult therapy

1) Failure to show improvement in height percentile on growth chart after one year of treatment
2) Growth velocity less than 2.5cm/yr unless associated with another growth-limiting and treatable medical condition (i.e. hypothyroidism)
3) Epiphyseal closure
4) Covered height has been reached
    a. 152.4cm(60 inches) for girls
    b. 165.1cm (65 inches) for boys.
5) Inadequate compliance
6) Significant adverse effects

Adult members

Covered indications

1) Persons with other childhood indications for hGH therapy who fail an adult hGH stimulation test.
2) Persons who have initiated growth hormone therapy in childhood because of pituitary damage, agenesis or anomaly.
3) History of pituitary or hypothalamic injury due to tumor, trauma, surgery, irradiation, hemorrhage or infarction
    a. ≥ 3 pituitary hormones deficient and IGF-1 ≤ 2.5 SD below the mean.
    b. 0, 1, or 2 hormones deficient and IFG-1 < 50^{th} percentile (midline) and failure of a growth hormone stimulation test as outlined below
4) AIDS wasting syndrome (12 weeks therapy only.)

Initiation of therapy

1) Age < 60 years
2) No evidence of active malignancy
3) Other hormone deficiencies have been ruled out or stabilized with adequate replacement
4) Provocative testing using one of the following:
    a. Insulin tolerance test: 0.1 units per Kg insulin IV, with hGH samples at baseline and every 30 minutes to 120 minutes. hGH response of <5 ng/ml is evidence for hGH deficiency.

b. Glucagon stimulation test: 1 mg glucagon IM with hGH samples at baseline and every 30 minutes to 180 minutes. hGH response of <3 ng/ml is evidence for hGH deficiency.

Continuation of Therapy

1) Members should be evaluated every 6 months to monitor for adverse effects and compliance

Discontinuation of therapy

1) Inadequate compliance
2) Significant adverse effects

OTHER

AIDS-related wasting syndrome (Serostim only)

1) Initiation of Therapy
   a. Members must have documentation showing that they fulfill all of the following criteria. Members meeting the criteria will be approved for an initial 4 week course of therapy.
   b. Unintentional weight loss of more than 10% if baseline pre-morbid weight was <120% of Ideal Body Weight OR unintentional weight loss of more than 20% if baseline pre-morbid weight was > 120% of Ideal Body Weight
   c. Member is receiving optimal antiretroviral therapy
   d. Member does not have a reversible cause of weight loss (e.g. infection, GI bleed or obstruction, or malnutrition)
   e. Member is receiving aggressive nutritional intake or supplementation
   f. Member does not have an active malignancy (except localized Kaposi's Sarcoma)
   g. Member has had a poor response to therapy with megestrol acetate and/or dronabinol
   h. Male members have had serum testosterone levels evaluated and treated as needed

2) Continuation of Therapy
   a. At four weeks, the member will be evaluated for response to therapy (weight gain), side effects, and compliance. If member response is favorable, another 4 weeks of therapy will be authorized.
   b. Subsequent follow up evaluations will be required every 4 weeks to assess response, side effects, and compliance. The member may receive another 4 weeks of therapy for a maximum of 12 weeks of continuous therapy.

3) Discontinuation of Therapy (any of the following)
   a. Completion of the FDA approved 12 weeks of therapy
   b. Treatment failure as measured by EITHER no weight gain despite 8 weeks of therapy OR continued/resumed weight loss at any time following 8 weeks of therapy when other potential causes have been resolved or ruled out.

c. Member noncompliance
d. Adverse effects that are refractory to dose reduction
e. New or progressive Kaposi's Sarcoma
f. Member weight exceeds 110% of pre-morbid weight

IGF-1 Analog Products - Increlex™ and Iplex™ (mecasermin)

1) Initiation of therapy
   a. Therapy initiated by an endocrinologist
   b. Diagnosis of Primary IGF-1 Deficiency with all of the following:
      i. Height >3 SD below the mean
      ii. Basal IGF-1 >3 SD below the mean
      iii. Normal or elevated GH
   c. Documentation of mutation in GH receptor (GHR) or mutation in post-GHR signaling pathway or IGF-1 gene defects (Laron Syndrome)
   d. Not approved for use in secondary IGF-1 deficiencies related to GH deficiency, malnutrition, hypothyroidism, or chronic steroid therapy.

2) Discontinuation of therapy
   a. Epiphyses closed
   b. Covered height has been reached
      i. 152.4cm(60 inches) for girls
      ii. 165.1cm (65 inches) for boys.
   c. Sensitivity to mecasermin
   d. Noncompliance

JONATHAN R.L. SCHWARTZ, M.D., F.A.C.P.
DIPLOMATE AMERICAN BOARD OF INTERNAL MEDICINE
DIPLOMATE AMERICAN BOARD OF INTERNAL MEDICINE - PULMONARY DISEASE
DIPLOMATE AMERICAN BOARD OF INTERNAL MEDICINE - CRITICAL CARE
DIPLOMATE AMERICAN BOARD OF SLEEP DISORDERS MEDICINE

OKLAHOMA PULMONARY PHYSICIANS, INC.
4200 S. DOUGLAS AVE. SUITE 313 • OKLAHOMA CITY, OKLAHOMA 73109 • OFFICE (405) 636-1111 • SERVICE 231-8800

November 22, 2010

Nancy Nesser, DPh., J.D.
Oklahoma Healthcare Authority
Lincoln Plaza, Suite 124
Oklahoma City, OK 73105

Dear Ms. Nesser:

I am requesting that a minimum of two products in the short acting beta agonist (SABA) class, have preferred status on the Medicaid Formulary. This request is in the interest of patient preference, clinical benefit, and confidence in their rescue inhaler.

Various SABA metered dose inhalers have different characteristics and delivery. I think it would be prudent to have at least two different SABA inhalers on the Medicaid Formulary. If you have any questions, please contact me.

Sincerely,

Jonathan R. L. Schwartz, M.D.

Richard T. Hatch, M.D.
Oklahoma Allergy and Asthma Clinic
750 NE 13
Okc, Ok 73104

November 23, 2010

Nancy Nesser, D.Ph., J.D.
Oklahoma Healthcare Authority
Lincoln Plaza Suite 124
Oklahoma City, OK 73105

Dear Ms. Nesser

I wanted to request that a minimum of two products be available on the Medical Formulary in the SABA class of products. This request is in the best interest of patient preference and confidence in their rescue inhalers.

Within the class short acting beta agonist metered dose inhalers do have different characteristics. Therefore, when prescribing a rescue inhaler it is important to have options.

Thank you.

Sincerely,

Richard T. Hatch, M.D.

Santiago Reyes, M.D.

Respiratory Diseases of Children and Adolescents

Suite 330 Baptist Medical Plaza Bldg. D
3366 N.W. Expressway
Oklahoma City, Oklahoma 73112
Telephone (405) 945-4495
Fax (405) 945-4376

November 22, 2010

To Whom It May Concern:

I am writing you in favor of keeping 2 options available for the SABA class for next years State Medicaid choices. Due to managed care, insurance and patient preference it would allow me to continue to give patients the best care possible.

Thank you,

Dr. Santiago Reyes de la Rocha

Warren V. Filley, M.D.
Oklahoma Allergy and Asthma Clinic
750 NE 13
Okc, Ok 73104

November 23, 2010

Nancy Nesser, D.Ph., J.D.
Oklahoma Healthcare Authority
Lincoln Plaza Suite 124
Oklahoma City, OK 73105

Dear Ms. Nesser

I would like to take this opportunity to request that there be a minimum of two products in the SABA class, have preferred status on the Medicaid formulary. Having more than one option is in the best interest of my patients.

Short acting beta agonist metered dose inhalers are different from each other and when prescribing them it is important to have options.

Thank you.

Sincerely,

Warren V. Filley, M.D.

From: Turman, Martin (HSC)
Sent: Tuesday, November 09, 2010 3:18 PM
To: Graham, Ronald D. (HSC)
Subject: Growth Hormone (GH) for chronic kidney disease (CKD)

Dear Dr. Graham,
I understand there is a meeting to discuss the criteria for use of GH tomorrow. I would like to point out some problems with the criteria as it pertains to chronic kidney disease (CKD).

1. Infants with CKD can have short stature even during the first year of life. Infants in the the 2nd year of life respond very well to GH as indicated in the attached article by Franke et al. Therefore, I request that for CKD the criteria should be lowered to 1 year of age instead of 2 y.o.
2. The criteria states that growth velocity (Gv) must be less than 5 cm/year, but the 3rd% for Gv in a 1 year old is 10 cm/y and for a 2 year old, 6 cm and for a 3 y.o it is 5.3 cm. (See attached Gv chart). Therefore, I believe the Gv criteria is too strict for the 1-3 year old age group. The 3rd % for Gv does drop to 5 cm/year, but not until the 4th year.
3. The requirement for delayed bone age should not apply to CKD patients. In the National Cooperative Growth Study (NCGS) sponsored by Genentech, of 906 patients enrolled for GH treatment of short stature due to CKD, 37.3% did NOT have delayed bone age. We have several extremely short children (-4 SD below normal) who are currently not eligible for GH because of this criteria. This is the one criteria that I feel most strongly about.
4. Another criteria that may need adjusting is for a GFR of < 50 ml/min/1.73 M2. However, in the North American Pediatric Renal Trials and Collaborative Studies report of 2006 it woas found that 22% of children with a GFR of 50-75 had a height SD < 1.88, so short stature from CKD can occur at an even earlier stage of CKD. I would suggest making 75 ml/min/1.73 M2 the criteria that needs to be met.

I would also like to point out that Nutropin brand of GH is the only brand that has the FDA indication for use in CKD. I am not sure if that influences your decisions on brands utilized.

Thank you for your consideration. We appreciate your careful review.

Martin A. Turman, MD, PhD
Professor and Chief, Section of Pediatric Nephrology
Department of Pediatrics
University of Oklahoma Health Sciences Center
405-271-4409
martin-turman@ouhsc.edu

Appendix B

RETROSPECTIVE DRUG UTILIZATION REVIEW REPORT
October 2010

MODULE	DRUG INTERACTION	DUPLICATION OF THERAPY	DRUG-DISEASE PRECAUTIONS	DOSING & DURATION
Total # of messages	53,663	64,762	1,021,402	31,533
Limits applied	Established, Major, Males and Females, Age 51-59	Males and Females, Narcotics, Age 21-25	Contraindicated, Males and Females, Leukemia, Age 0-150	High Dose, Low Dose, Duration, Vitamin K (Mephyton®), Males & Females, Age 0-150
Total # of messages after limits were applied	100	289	6	10
Total # of members reviewed	100	240	3	10

LETTERS			
Category	**Prescribers**	**Pharmacies**	**Total Letters**
Drug Interaction	17	0	17
Duplication of Therapy	194	19	213
Drug-Disease Precautions	3	3	6
Dosing & Duration	0	0	0
Total Letters Sent	214	22	236

Retrospective Drug Utilization Review Report

Claims Reviewed for August 2010

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 19-35	Anorexients/Stimulants, Males and Females, Age 5-6	Contraindicated, Pregnancy, Females, Age 19-35	High Dose, Androgens, Males and Females, Age 0-150

Response Summary (Prescriber)
Letters Sent: 55
Response Forms Returned: 33

The response forms returned yielded the following results:

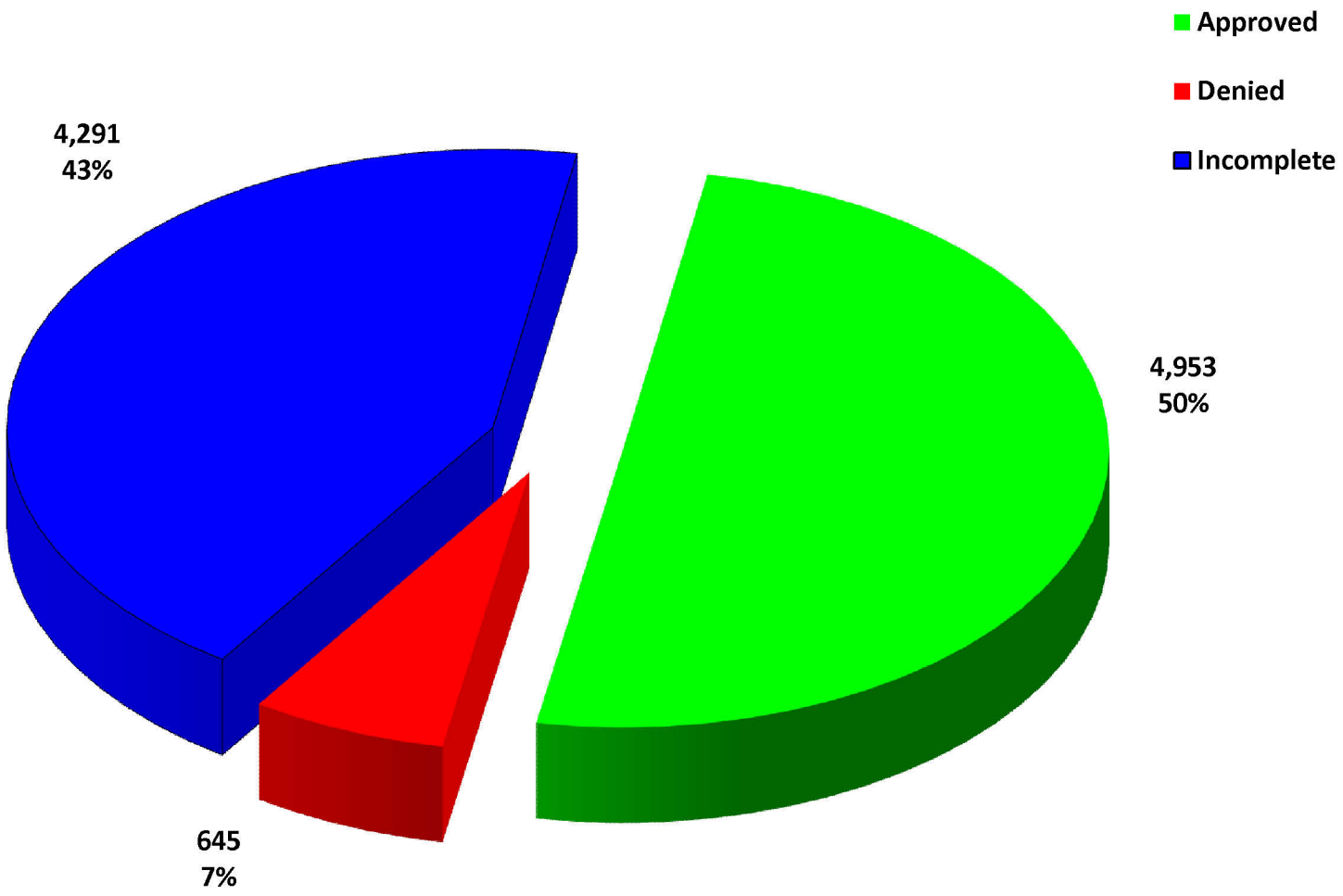
3 (9%)	*Record Error—Not my patient.*
3 (9%)	*No longer my patient.*
3 (9%)	*Medication has been changed prior to date of review letter.*
3 (9%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
12 (36%)	*I am aware of this situation and will plan to continue monitoring therapy.*
9 (27%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 23
Response Forms Returned: 23

The response forms returned yielded the following results:

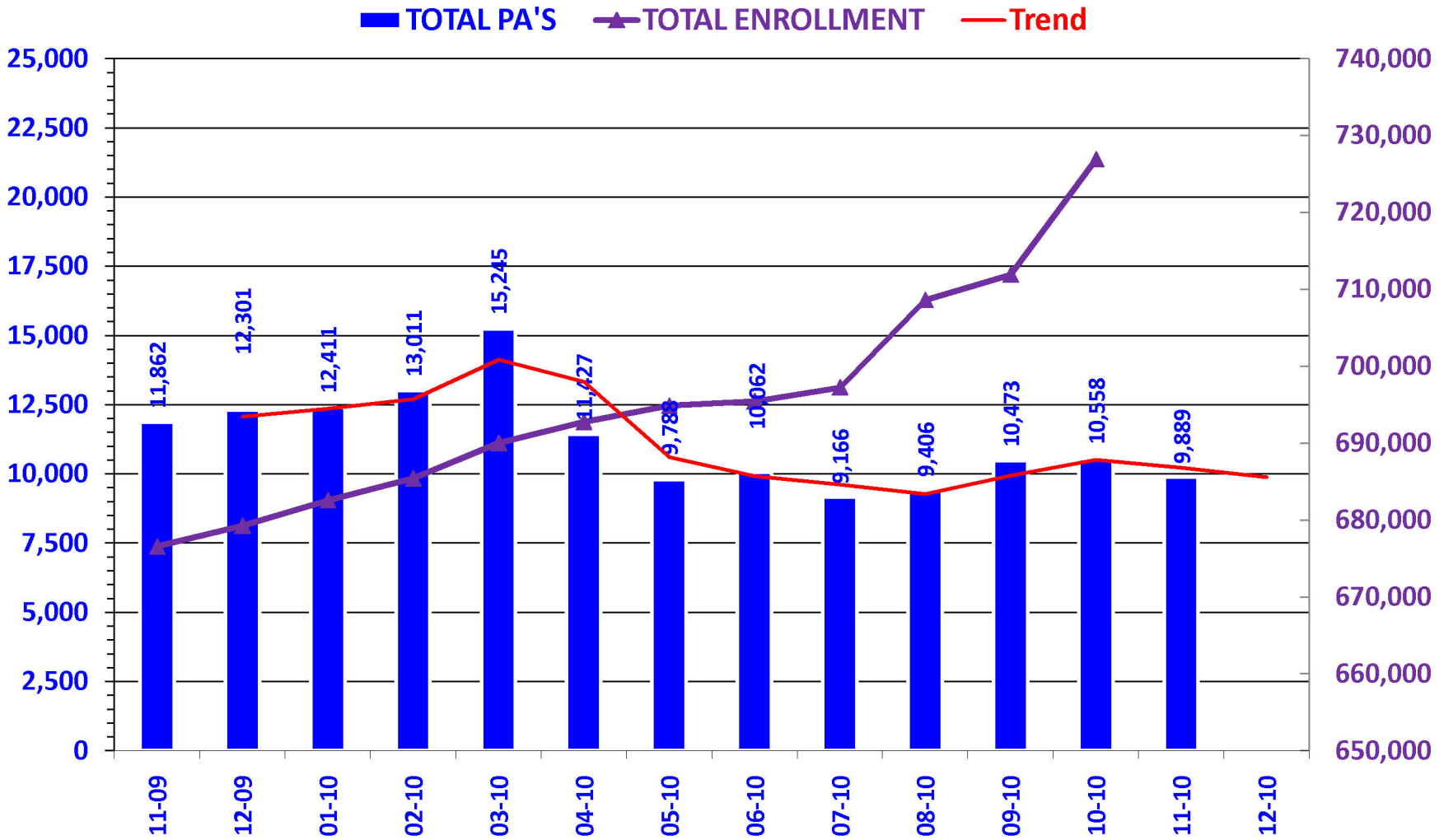
0 (0%)	*Record Error—Not my patient.*
2 (9%)	*No longer my patient.*
2 (9%)	*Medication has been changed prior to date of review letter.*
4 (17%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
7 (30%)	*I am aware of this situation and will plan to continue monitoring therapy.*
8 (35%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT: November 2010



PA totals include overrides

PRIOR AUTHORIZATION REPORT: November 2009 – November 2010



PA totals include overrides

Prior Authorization Activity

November 2010

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort	477	221	10	246	354
Amitiza	28	8	2	18	189
Anti-Ulcer	414	123	40	251	110
Antidepressant	436	121	22	293	336
Antihistamine	346	190	15	141	337
Antihypertensives	132	47	4	81	341
Antimigraine	82	14	10	58	205
Atypical Antipsychotics	664	333	18	313	349
Benzodiazepines	73	25	1	47	249
Bladder Control	84	6	10	68	361
Brovana (Arformoterol)	3	1	0	2	365
Byetta	9	3	1	5	360
Elidel/Protopic	38	16	2	20	99
ESA	160	101	2	57	96
Fibric Acid Derivatives	11	4	1	6	359
Fibromyalgia	119	39	8	72	350
Fortamet/Glumetza	3	1	0	2	349
Forteo	3	1	1	1	181
Glaucoma	10	2	1	7	360
Growth Hormones	49	37	7	5	160
HFA Rescue Inhalers	90	31	11	48	259
Insomnia	87	20	11	56	175
Misc Analgesics	40	4	23	13	218
Muscle Relaxant	138	37	41	60	66
Nasal Allergy	266	108	19	139	165
NSAIDS	145	27	16	102	236
Ocular Allergy	18	9	1	8	100
Ocular Antibiotics	38	10	1	27	50
Opioid Analgesic	402	174	18	210	226
Other	667	156	87	424	173
Otic Antibiotic	63	43	2	18	13
Pediculicides	103	49	5	49	12
Plavix	144	98	1	45	315
Qualaquin (Quinine)	3	0	2	1	0
Singulair	890	520	26	344	259
Smoking Cessation	61	15	1	45	68
Statins	170	32	9	129	319
Stimulant	1,370	840	47	483	234
Symlin	12	3	1	8	359
Synagis	423	227	98	98	122
Topical Antibiotics	15	2	0	13	30
Topical Antifungals	25	4	0	21	101
Ultram ER and ODT	5	0	0	5	0
Xolair	4	1	1	2	358
Xopenex Nebs	37	16	2	19	310
Zetia (Ezetimibe)	17	8	1	8	360
Emergency PAs	7	7	0	0	
Total	**8,381**	**3,734**	**579**	**4,068**	

Overrides					
Brand	61	49	6	6	229
Dosage Change	548	528	4	16	7
High Dose	8	8	0	0	146
IHS-Brand	27	26	0	1	159
Ingredient Duplication	8	7	0	1	8
Lost/Broken Rx	104	100	1	3	4
NDC vs Age	31	29	0	2	230
Nursing Home Issue	102	97	0	5	3
Other	45	41	0	4	23
Quantity vs. Days Supply	569	329	55	185	267
Stolen	5	5	0	0	4
Overrides Total	**1,508**	**1,219**	**66**	**223**	
Total Regular PAs + Overrides	**9,889**	**4,953**	**645**	**4,291**	

Denial Reasons	
Unable to verify required trials.	2,861
Lack required information to process request.	1,493
Does not meet established criteria.	604
Requested dose exceeds maximum recommended FDA dose.	1

Duplicate Requests: 803

Letters: 1,490

No Process: 1,078

Changes to existing PAs: 520

CALL VOLUME MONTHLY REPORT:
November 2009 – November 2010