Drug Utilization Review Board

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

Wednesday
November 10, 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 – November 10, 2010**

DATE: November 4, 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'S NEW OFFICES IN SHEPHERD MALL. (NORTH ENTRANCE)

Enclosed are the following items related to the November 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 on 2011 Meeting Dates - See Appendix C.

Action Item – Vote to Change Criteria for Growth Hormone PBPA Category – See Appendix D.

Action Item – Vote to Prior Authorize Butrans™, Primlev™, Xolox®, Exalgo™ ER, Rybix™ ODT, and Suboxone® / Subutex® – See Appendix E.

Action Item – Vote to Prior Authorize Vimovo™ – See Appendix F.

Action Item – Annual Review of Ocular Allergy PBPA Category and Vote to Prior Authorize Bepreve™ and Lastacaft™ – See Appendix G.

30 Day Notice to Prior Authorize Metozolv ODT – See Appendix H.

30 Day Notice to Prior Authorize Special Formulations and Application of Age Restriction of Alzheimer's Medications – See Appendix I.

Utilization Review of Benign Prostate Hyperplasia (BPH) Medications – See Appendix J.

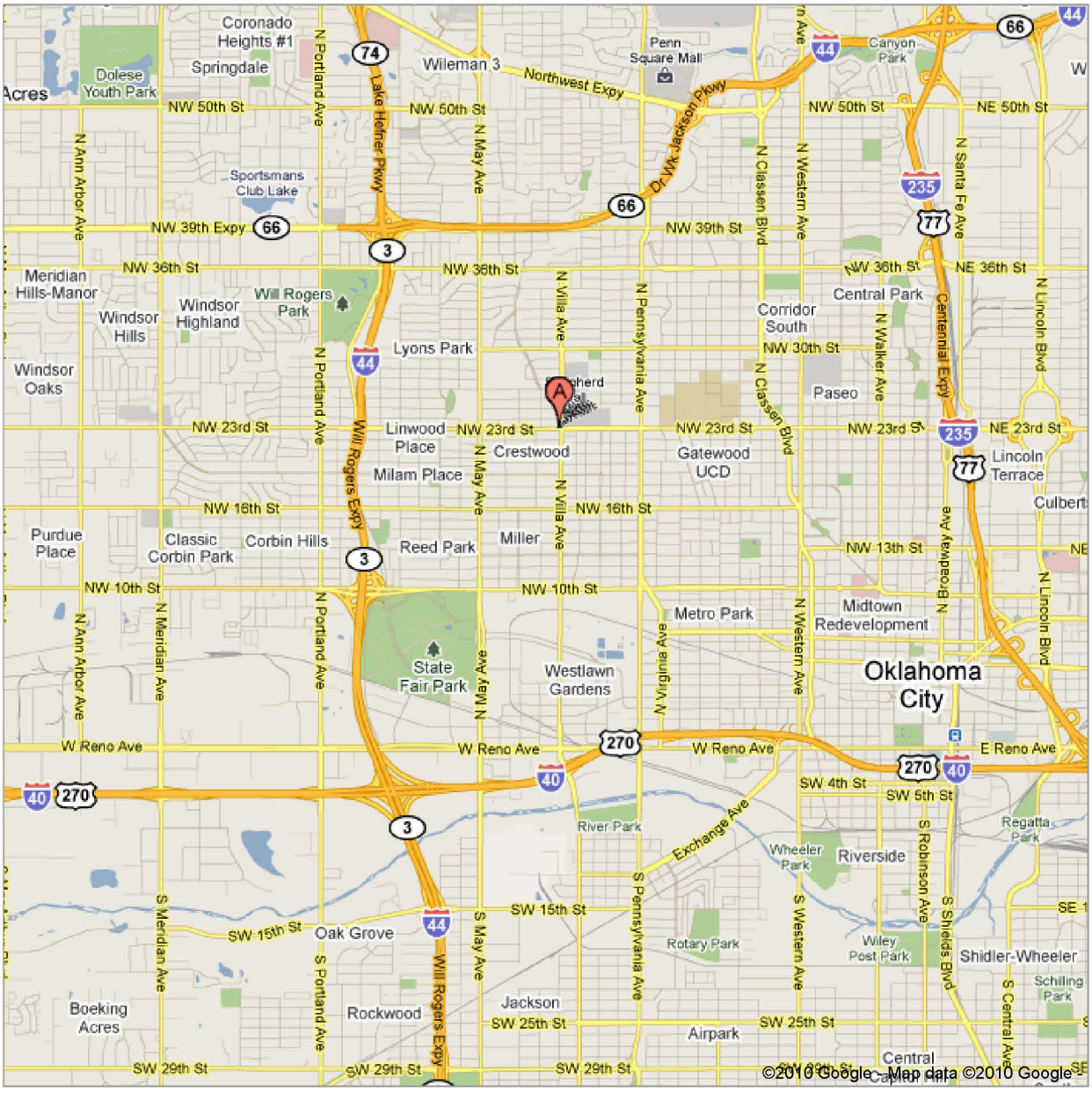
FDA and DEA Updates – See Appendix K.

Future Business

Adjournment

OHCA is now located at the north end of Shepherd Mall, at the intersection of NW 23rd Street and Villa.

Address **2501 NW 23rd St**
Oklahoma City, OK 73107



Please use the entrance on the north side of the building.

Oklahoma Health Care Authority
Drug Utilization Review Board
(DUR Board)
Meeting – November 10, 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. October 13, 2010 DUR Minutes – Vote
- B. October 14, 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 September 2010
- B. Retrospective Drug Utilization Review Response for July 2010
- C. Medication Coverage Activity Audit for October 2010
- D. Pharmacy Help Desk Activity Audit for October 2010

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

5. Action Item – Vote on 2011 Meeting Dates – See Appendix C.

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

6. Action Item – Vote to Change Criteria for Growth Hormone Product Based Prior Authorization Category – See Appendix D.
- A. COP Recommendations

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

7. Action Item – Vote to Prior Authorize Butrans™, Primlev™, Xolox®, Exalgo™ ER, Rybix™ ODT, and Suboxone®/Subutex® – See Appendix E.
- A. COP Recommendations

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

8. Action Item – Vote to Prior Authorize Vimovo™ – See Appendix F.

A. Product Summary
B. COP Recommendations

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

9. Action Item – Annual Review of Ocular Allergy Product Based Prior Authorization Category and Vote to Prior Authorize Bepreve™ and Lastacaft™ – See Appendix G.

A. Current Authorization Criteria for Ocular Allergy Products
B. Utilization Review
C. COP Recommendations
D. Product Details

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

10. 30 Day Notice to Prior Authorize Metozolv® ODT – See Appendix H.

A. Product Summary
B. COP Recommendations
C. Product Details

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

11. 30 Day Notice to Prior Authorize Special Formulations and Application of Age Restriction of Alzheimer's Medications – See Appendix I.

A. Overview
B. Utilization Review
C. COP Recommendations

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

12. Utilization Review of Benign Prostate Hyperplasia (BPH) Medications – See Appendix J.

A. Overview
B. Utilization Review
C. COP Recommendations

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

13. FDA and DEA Updates – See Appendix K.

14. Future Business

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

15. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of OCTOBER 13, 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): Nick Young, Kitty Lee	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:

Lloyd Crownover, AstraZeneca	Evan Leonard, AstraZeneca	Nicole Petrila, Teva
Toby Thompson, Pfizer	M. Patty Laster, Genentech	Donna Erwin, Bristol-Myers-Squibb
Richard Ponder, J&J	Greg Hoke, Reckitt Benckiser	Warren Tayes, Merck
Debbie Hayes, Sanofi Aventis	Frances Bauman, Novo Nordisk	Nikki Goff, Novo Nordisk
Emerald Groom, Alcon		

PRESENT FOR PUBLIC COMMENT:

Agenda Item No. 7	Greg Hoke, Reckitt Benckiser
Agenda Item No. 8	Kim Lonergan, R.N., AstraZeneca

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. 7 Greg Hoke, Reckitt Benckiser

Agenda Item No. 8 Kim Lonergan, R.N., AstraZeneca

ACTION: NONE REQUIRED

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

3A: September 8, 2010 DUR Minutes

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

ACTION: MOTION CARRIED

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

4A: Retrospective Drug Utilization Review: August 2010

4B: Medication Coverage Activity Audit: September 2010

4C: Help Desk Activity Audit: September 2010

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **ANNUAL REVIEW OF GROWTH HORMONES**

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

Board members discussed indications and treatment therapies.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **ANNUAL REVIEW OF ERYTHROPOIETIN STIMULATING AGENTS**

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

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

AGENDA ITEM NO. 7: **ANNUAL REVIEW OF NARCOTICS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BUTRANS™, PRIMLEV™, XOLOX®, EXALGO™ ER, RYBIX™ ODT AND SUBOXONE®/SUBUTEX®**

For Public Comment, Greg Hoke: I just have a quick, quick comment. Looking at the criteria for Suboxone, our company, and I met with Ron and the College of Pharmacy people last week, we are very concerned with diversion and abuse of this product, and in that light, we want to make sure that there are strict limitations on who can get this and who can prescribe it, and we totally agree with the proposals here as far as physicians must have their X DEA number to be able to prescribe Suboxone. They have to get that waiver from the DEA. We suggest maybe some tightening up just a little bit. I think 24 mg a day is already listed. If it's not, maybe it could just be tightened up a little bit. That seems to be the maximum dose that anyone needs. The other thing is for Subutex, to be able to get Subutex, which is a stand-alone buprenorphine product which can be crushed, snorted, injected, diverted. We're making the suggestion that only patients who have a documented pregnancy or a documented allergy to naloxone be able to get Subutex. These patients by nature are diverters and that risk is always there, that they're going to divert the product. With Suboxone, you have the buprenorphine and the naloxone. If you crush it, inject it, you're going to get sick, because the naloxone is going to knock everything off the receptor site. And the other thing, I don't know, is the new dosage form which is Suboxone film, a sublingual film instead of the sublingual tablet, and the safety there is in terms of pediatrics exposures. The packaging will prevent that, or at least as much as we can. The other thing is, it cannot be crushed or burned, or it'll just, it won't go into any kind of solution, so they can't inject it, so we think that's a safer product as well. Same price, there's no difference there, so we agree with what you're doing, just maybe tighten it up a little.

Dr. Muchmore: Is the film buprenorphine only or …….

Mr. Hoke: No, buprenorphine and naloxone. There is not a Subutex film, just the Suboxone film.

Dr. Feightner: So the quantity limit of 90 and 30 days on Suboxone, you don't agree with, it should be less than that, is that what you're saying?
Mr. Hoke: We're saying a 24 mg per day dose, which I think you achieve with your ……. yeah, eight times three (8 x 3). About 95% of the receptors are covered at 16 mg. I mean, you could even tighten it up at 20 mg a day maximum daily dose if you want to. Rarely would a patient need more than 20, but 24 allows for ….
Dr. Feightner: TID dosing of the …….
Mr. Hoke: BID dosing.
Dr. Muchmore: We don't state on these criteria, the COP recommendations don't mention allergy to naloxone for the Subutex. I mean, mostly, you know, if people are getting this, the Subutex could be used for pain relief in persons that were not users, right?
Mr. Hoke: It's not indicated for pain, so we can't go there.
Dr. Muchmore: That's right. Its' indications don't include that, so we should just say only if allergic to, or adverse reactions to naloxone or are pregnant.
Mr. Hoke: And I think most of the providers who use this, if a patient is pregnant, they will put her on methadone until the delivery, and then transition her back to Suboxone.
Dr. Muchmore: As long as it's somebody who knows how to titrate methadone. Because there's been a lot of casual use of methadone that wasn't done right. But this is limited to people with that special DEA number, but we've had some that were dispensed with an ordinary DEA number? And Shellie's going to see that that never happens again.
Mr. Hoke: And we would highly encourage it. Thank you.
Materials included in agenda packet; presented by Dr. Keast.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 8: **ANNUAL REVIEW OF NSAIDS AND 30-DAY NOTICE TO PRIOR AUTHORIZE VIMOVO™**

For Public Comment; Kim Lonergan, R.N.: I'll just be real brief. I had a chance to present some of this information to the College of Pharmacy so I'll do the Reader's Digest version. I just wanted to let you know some key points about this product that really AstraZeneca feels like differentiate the product and some rationale around why the company collaborated to develop this sequential delivery system with this NSAID and with the esomeprazole. So basically, this is an immediate release esomeprazole with the naproxen and the esomeprazole is not the branded Nexium, the extended release branded Nexium. It has no effect to the Nexium brand at all, so there's no patent extension there. Basically this was recognized as an unmet need. The FDA did approve this drug for treatment of signs and symptoms associated with OA, RA and ankylosing spondylitis, and the primary reason that the product was looked at and developed this way is because about 40% or even fewer patients are compliant with the PPI when on long-term NSAID therapy. So the sequential delivery system is actually allows the esomeprazole to be released into the system in about 45 minutes, and the coating around the naproxen is actually pH sensitive, so that is not even released until the pH is above 5.5, which is about four hours time. So this is not a chronic pain medication, this is not for weekend warriors; this is strictly for patients who need to be on long-term NSAID therapy. A couple of unique things around this particular study; it was a 6-month primary endoscopy endpoint looking at gastric ulcer development; and the results of the two studies, 301 and 302, and a pylori identical design trials, about 4 to 7% of the patients taking Vimovo developed gastric ulcers, well about 24% on the enteric coated naproxen developed gastric ulcers. We also, one of the other interesting factors around this particular drug is about 25% of the patients continued on their low dose aspirin and that was not changed from how it was prescribed for them; so that was more naturalistic for these patients to stay on the low dose aspirin, and the results for those patients were very consistent with the other results for the two other trials. About 3% of the patients on the Vimovo and their low dose aspirin developed gastric ulcers at that primary endpoint of six months, while 30% who were on the enteric coated naproxen and low dose aspirin actually developed ulcers. The other interesting feature is that in this study, the 18 to 49 year old age group, these patients did have a history of non-serious gastric events within the previous five year time frame, so we didn't select out patients who were at risk or who had a history. Another interesting feature is that we did include patients up to age 90 in this particular clinical study, so we have some good data that shows how this drug works and this is really an unmet need and information that we felt like was very important. Another feature in closing is that we looked at the length of time that patients stayed on therapy. So for Vimovo, on average, patients stayed on the therapy 154 days versus 124. And when you're looking at keeping people compliant, keeping them out of the situation of disability and switching to other opiods or other more expensive options, this can be a really important therapeutic option for both patients and clinicians. One thing that I do want to mention to the folks that I had presented, this publication is now available and I can provide that to you if you do want to review that data. Any questions or comments? Thank you.
Materials included in agenda packet; presented by Dr. Patel.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 9: **ANNUAL REVIEW OF OCULAR ALLERGY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BEPREVE™ AND LASTACAFT™**

TABLED TO NOVEMBER 10, 2010
ACTION: TABLED

AGENDA ITEM NO. 10: **FDA & DEA UPDATES**

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: **FUTURE BUSINESS**

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

A: Utilization Review of Alzheimer's Medications
B: Utilization Review of BPH Medications
C: Annual Review of Antihypertensives
D: New Product Reviews

ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: **ADJOURNMENT**

The meeting was adjourned at 7:46 p.m.

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

Memorandum

Date: October 14, 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 October 13, 2010

Recommendation 1: Annual Review of Growth Hormone Prior Authorization

MOTION TABLED.

The action was tabled pending review of discussion and editing of current criteria.

Recommendation 2: Annual Review of ESAs

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends continuation of the current criteria with an increase in the duration of approval from every 8 weeks to every 16 weeks.

Recommendation 3: Annual Review of Narcotics

MOTION TABLED.

The College of Pharmacy recommends moving the hydrocodone/APAP products, Xodol® and Zamicet® to Tier 3 of the Narcotic Product Based Prior Authorization Category with additional criteria requiring a clinical reason why the member cannot use available similar generic products. This recommendation will be voted on next month with the new products for this category.

Recommendation 4: Annual Review of NSAIDs

No action was required.

The College of Pharmacy does not recommend changes at this time.

Recommendation 5: Annual Review of Ocular Allergies

MOTION TABLED.

The action was tabled until the following month due to time constraints.

Dear Dr. Graham,

It has been brought to my attention that the Oklahoma DUR board plans on reviewing and making changes to the criteria for growth hormone use is chronic kidney disease. I have reviewed the suggestions below but have concerns about these changes.

The first concern is initiation of therapy with an estimated creatinine clearance <50ml/min. Although height velocity generally decreases when the eGFR is < 30ml/min. In the North American Pediatric Renal Trials and Collaborative Studies 2006 in moderate CKD (eGFR 50-75ml/min/1.73m2), 22% had a height standard deviation </= -1.88. Therefore maximizing growth prior to transplant is ideal and limiting use of growth hormone to eGFR < 50ml/min could only increase the need for post transplant n4eed for growth hormone. Currently the recommendation from Harambat el al, Pediatric Nephrology 2009 is to stop growth hormone therapy for 1 year post renal transplant then re-evaluate based on the criteria for starting growth hormone. It seems the new criteria is limiting us on both chronic kidney disease and post transplant. I am against these changes without more clarification.

The new change also requires continuation of therapy to be evaluated by an endocrinologist at least yearly. Pediatric nephrologist have and do managed growth hormone without the assistance of endocrinologist. It is unclear what or if this will add any benefit to care or cost reduction.

Attached are the Criteria I am referring.

Sincerely,

Dwayne D. Henry M.D.

University of Oklahoma Health Science Center

Assistant Professor Pediatric

Section Pediatric Nephrology

DIAGNOSIS OF SHORT STATURE ASSOCIATED WITH RENAL INSUFFICIENCY

A. Initiation of Therapy

The member should meet the following criteria:

- Documented chronic renal insufficiency with an estimated creatinine clearance less than 50ml/min
- Subnormal growth velocity: current height more than two standard deviations below the mean and/or growth velocity of less than 5cm/yr
- Projected height below Target height and Covered Height

B. Continuation of Therapy

Members should be evaluated every six months to determine the increase in growth velocity. (See above)

C. Discontinuation of Therapy

Member therapy may be discontinued when one of the following criteria is met:

- Target height or Covered height has been reached
- Bone age of 15 or epiphyseal fusion for girls
- Bone age of 16 or epiphyseal fusion for boys
- Slow growth rate (< 5cm in the previous year) unless associated with another growth-limiting and treatable medical condition (i.e. hypothyroidism) $
- Inadequate compliance
- Significant adverse effects
- Transplantation

From: Cooksey, Kristi [mailto:kcooksey@nrh-ok.com]
Sent: Wednesday, November 03, 2010 2:41 PM
To: Keast, Shellie L. (HSC)
Subject: Norditropin and Medicaid

Dear Dr. Graham,

I am an RN and the Endocrine Nurse Navigator for a busy adult endocrine practice. We occasionally see adult patients with Medicaid and commercial plans.

Over the past years I learned a great deal about growth hormone and have become familiar with all the products on the market. As a practice we show our patients all the different pen devices and give our patients a choice of which product they would like to use.

Most all of our patients choose Norditropin. They feel it is easier pen to use and they enjoy the storage flexibility. Also, Norditropin does not require patients to mix the medication before use. With the adult practice some patients have other disabilities: for example osteoarthritis in their hands.

Novo Nordisk's is compassionate and has a great patient assist program to help when no insurance coverage available.

I would like to see Norditropin remain as a choice for our patients that are on Medicaid. Please consider Norditropin as an option and for your upcoming meeting on November 10th, 2010.

Sincerely yours,

Kristi Cooksey, RN Nurse Navigator

November 3, 2010

Drug Utilization Review Manager
Shellie Keast, PharmD
Pharmacy Management Consultants
ORI-W4403, P.O. Box 26901
Oklahoma City, OK, 73126-0901

Re: Formulary for growth hormone therapy

Dear Dr. Keast,

It is our understanding that OHCA is considering selection of specific growth hormone products for their formulary. On behalf of the pediatric and adult endocrinology in our office, I'm writing to request that OHCA take into consideration the following before changing or limiting the selection of growth hormone products.

When prescribing growth hormone, we take into account the ease of administration and avoid having patients mix the medication. As we saw before reconstituted products were available, dosing errors are more likely to occur when patients have to mix medication. Especially since the instructions for dilution change as the patient grows. They are also likely to occur when patients are forced to change brands of growth hormone as the pens used to administer the medication do not all measure growth hormone in the same way. We have experienced these problems in patients who have been forced to change their therapy which results in poor growth.

We also have noted changes in compliance when patients are forced to switch their brand of growth hormone therapy. Several of the growth hormone medications have a preservative which causes stinging or burning with the injection. For those naïve to therapy, this may not be noticed but when a patient is changed from a non-stinging medication to one that burns, compliance and patient/parent satisfaction decline. Nutropin AQ and Humatrope are known to cause burning with injection.

Prior to prescribing growth hormone to our patients, we consider their lifestyle and their physical needs. Many of our patients benefit from the use of Genotropin Mini-Quick or Norditropin Nordiflex as refrigeration is not required and they travel back and forth between their parents' home on such a frequent basis that it would be difficult to keep the medication refrigerated at all times. Additionally, medication can not always be in use at both residences as the medication is only stable at room temp for a limited amount of time which varies depending on the medication used. Norditropin and Genotropin have the most flexibility in regards to storage of medication both before and during use.

Some of our patients are visually impaired. They benefit from a device that can safely administer the correct dose either by counting clicks or using pre-filled, unit dose

packaging. There are so many things that we take into account, we respectfully request that you leave the formulary open.

We recently noted that a pharmacy was billing a private insurer over $1,000 for ALCOHOL SWABS, because "it is what insurance allows." It would be good for you to ensure that this is not being allowed to happen to our Sooner Care patients either because this pharmacy serviced a lot of Sooner Care patients.

We appreciate your consideration of your formulary and request that the decision of which drug to use be left to the physician, nurse practitioner, and patient.

Sincerely,

David Jelley, MD
Laura Chalmers, MD
Dana Greer, ARNP, CPNP, CDE
Stephen Ludiker, ARNP, CDE

Appendix B

RETROSPECTIVE DRUG UTILIZATION REVIEW REPORT
September 2010

MODULE	DRUG INTERACTION	DUPLICATION OF THERAPY	DRUG-DISEASE PRECAUTIONS	DOSING & DURATION
Total # of messages	52,488	64,289	1,044,192	30,001
Limits applied	Established, Major, Males and Females, Age 36-50	Males and Females, Acne Antibiotics, Age 0-150	Contraindicated, Pregnancy, Males and Females, Age 36-150	High & Low Dose, Duration, Males and Females, Age 0-150, Oxazolidinediones (Zyvox®)
Total # of messages after limits were applied	93	11	60	14
Total # of members reviewed	93	11	56	14

LETTERS

Category	Prescribers	Pharmacies	Total Letters
Drug Interaction	11	3	14
Duplication of Therapy	8	5	13
Drug-Disease Precautions	2	0	2
Dosing & Duration	8	2	10
Total Letters Sent	29	10	39

Retrospective Drug Utilization Review Report

Claims Reviewed for July 2010

Module	Drug Interaction	Duplication of Therapy	Drug-Disease Precautions	Dosing & Duration
Limits which were applied	Established, Major, Males and Females, Age 0-18	Anorexients/Stimulants, Males and Females, Age 0-4	Contraindicated, Pregnancy, Females, Age 0-18	High Dose, Anabolic Steroids and Androgens, Males and Females, Age 0-150

Response Summary (Prescriber)
Letters Sent: 18
Response Forms Returned: 14

The response forms returned yielded the following results:

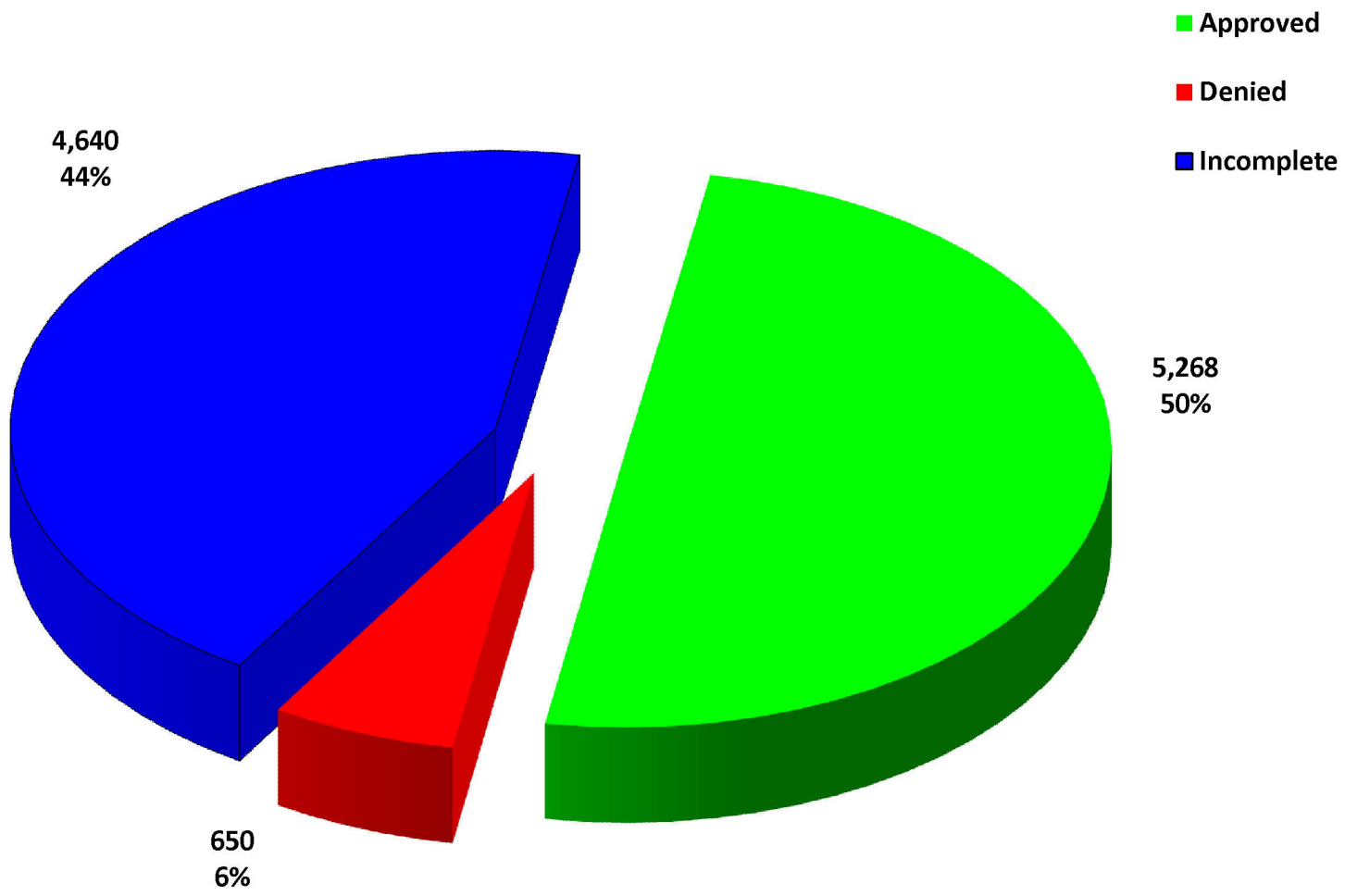
0 (0%)	*Record Error—Not my patient.*
0 (0%)	*No longer my patient.*
1 (7%)	*Medication has been changed prior to date of review letter.*
5 (36%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
7 (50%)	*I am aware of this situation and will plan to continue monitoring therapy.*
1 (7%)	*Other*

Response Summary (Pharmacy)
Letters Sent: 24
Response Forms Returned: 14

The response forms returned yielded the following results:

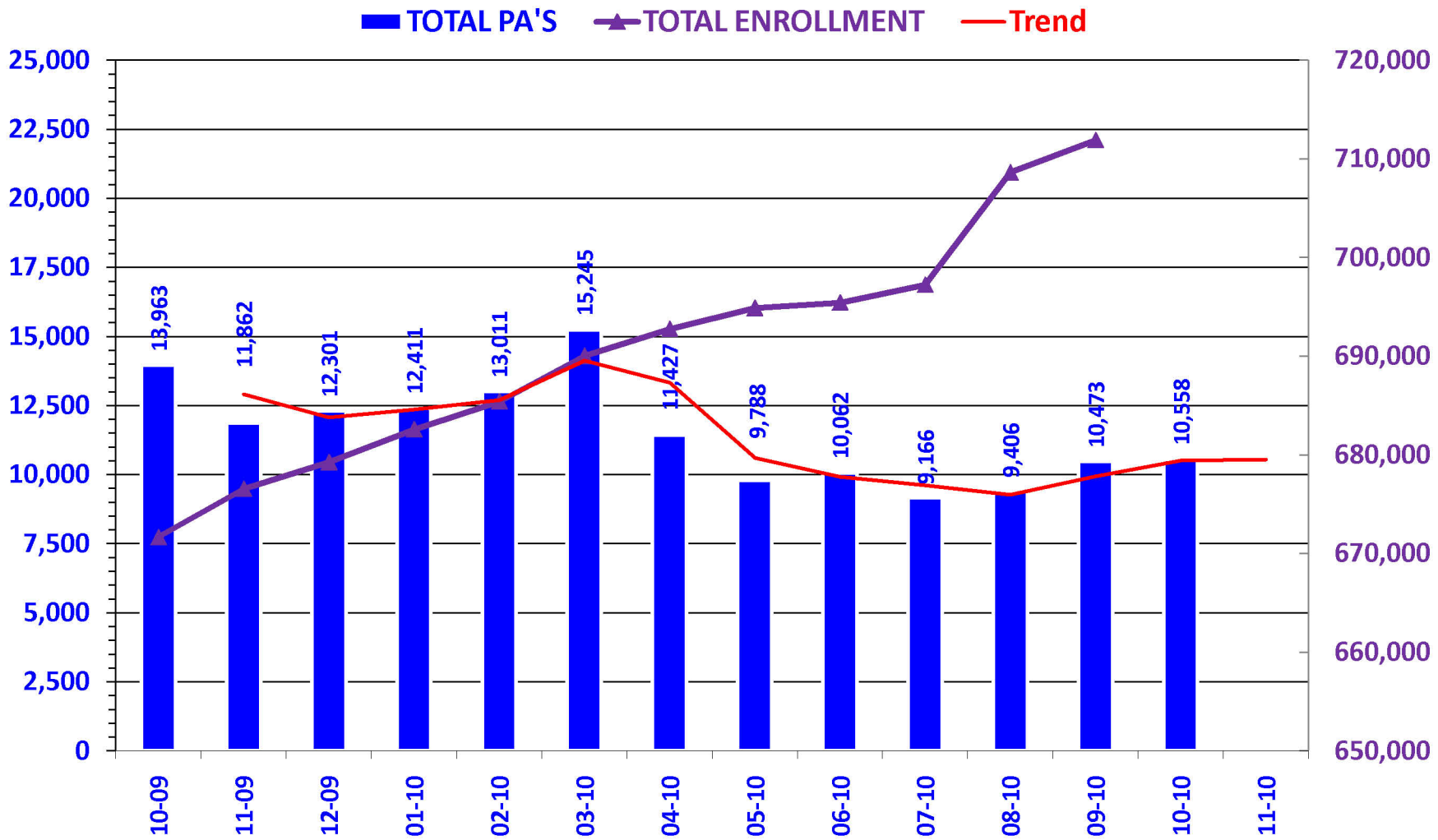
0 (0%)	*Record Error—Not my patient.*
0 (0%)	*No longer my patient.*
1 (7%)	*Medication has been changed prior to date of review letter.*
7 (50%)	*I was unaware of this situation & will consider making appropriate changes in therapy.*
5 (36%)	*I am aware of this situation and will plan to continue monitoring therapy.*
1 (7%)	*Other*

PRIOR AUTHORIZATION ACTIVITY REPORT: October 2010



PA totals include overrides

PRIOR AUTHORIZATION REPORT: October 2009 – October 2010



PA totals include overrides

Prior Authorization Activity

October 2010

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort	454	225	8	221	357
Amitiza	13	5	2	6	157
Anti-Ulcer	398	101	53	244	107
Antidepressant	381	119	18	244	339
Antihistamine	456	244	15	197	321
Antihypertensives	121	44	8	69	333
Antimigraine	98	14	8	76	247
Atypical Antipsychotics	707	322	13	372	347
Benzodiazepines	68	26	1	41	272
Bladder Control	43	13	3	27	319
Brovana (Arformoterol)	4	2	1	1	362
Byetta	12	2	1	9	359
Elidel/Protopic	44	21	1	22	95
ESA	196	137	1	58	76
Fibric Acid Derivatives	10	1	2	7	360
Fibromyalgia	120	39	9	72	327
Fortamet/Glumetza	1	1	0	0	360
Forteo	3	0	1	2	0
Glaucoma	24	10	0	14	329
Growth Hormones	48	37	5	6	163
HFA Rescue Inhalers	103	39	10	54	300
Insomnia	76	20	7	49	193
Misc Analgesics	41	5	20	16	150
Muscle Relaxant	106	42	24	40	71
Nasal Allergy	317	119	44	154	132
NSAIDS	161	42	18	101	269
Ocular Allergy	30	10	2	18	112
Ocular Antibiotics	53	9	4	40	23
Opioid Analgesic	279	146	7	126	209
Other	790	169	74	547	189
Otic Antibiotic	97	60	0	37	12
Pediculicides	119	49	5	65	11
Plavix	177	124	1	52	324
Singulair	948	517	20	411	257
Smoking Cessation	50	12	2	36	65
Statins	225	45	13	167	355
Stimulant	1,432	885	42	505	243
Synagis	532	273	143	116	140
Topical Antibiotics	7	1	0	6	15
Topical Antifungals	15	5	0	10	40
Ultram ER and ODT	10	1	2	7	181
Xolair	10	1	5	4	365
Xopenex Nebs	35	18	0	17	344
Zetia (Ezetimibe)	27	11	1	15	360
Emergency PAs	17	17	0	0	
Total	**8,858**	**3,983**	**594**	**4,281**	

Overrides					
Brand	60	31	8	21	239
Dosage Change	509	492	2	15	7
High Dose	3	2	0	1	198
IHS-Brand	44	32	2	10	129
Ingredient Duplication	8	6	0	2	9
Lost/Broken Rx	118	113	3	2	5
NDC vs Age	19	17	0	2	230
Nursing Home Issue	119	117	0	2	3
Other	48	47	0	1	16
Quantity vs. Days Supply	769	425	41	303	279
Stolen	4	4	0	0	4
Overrides Total	**1,701**	**1,286**	**56**	**359**	
Total Regular PAs + Overrides	**10,559**	**5,269**	**650**	**4,640**	

Denial Reasons

Unable to verify required trials.	2,659
Lack required information to process request.	1,965
Does not meet established criteria.	631
Drug Deemed Medically Necessary	2
Considered duplicate therapy. Member has a prior authorization for similar medication.	1

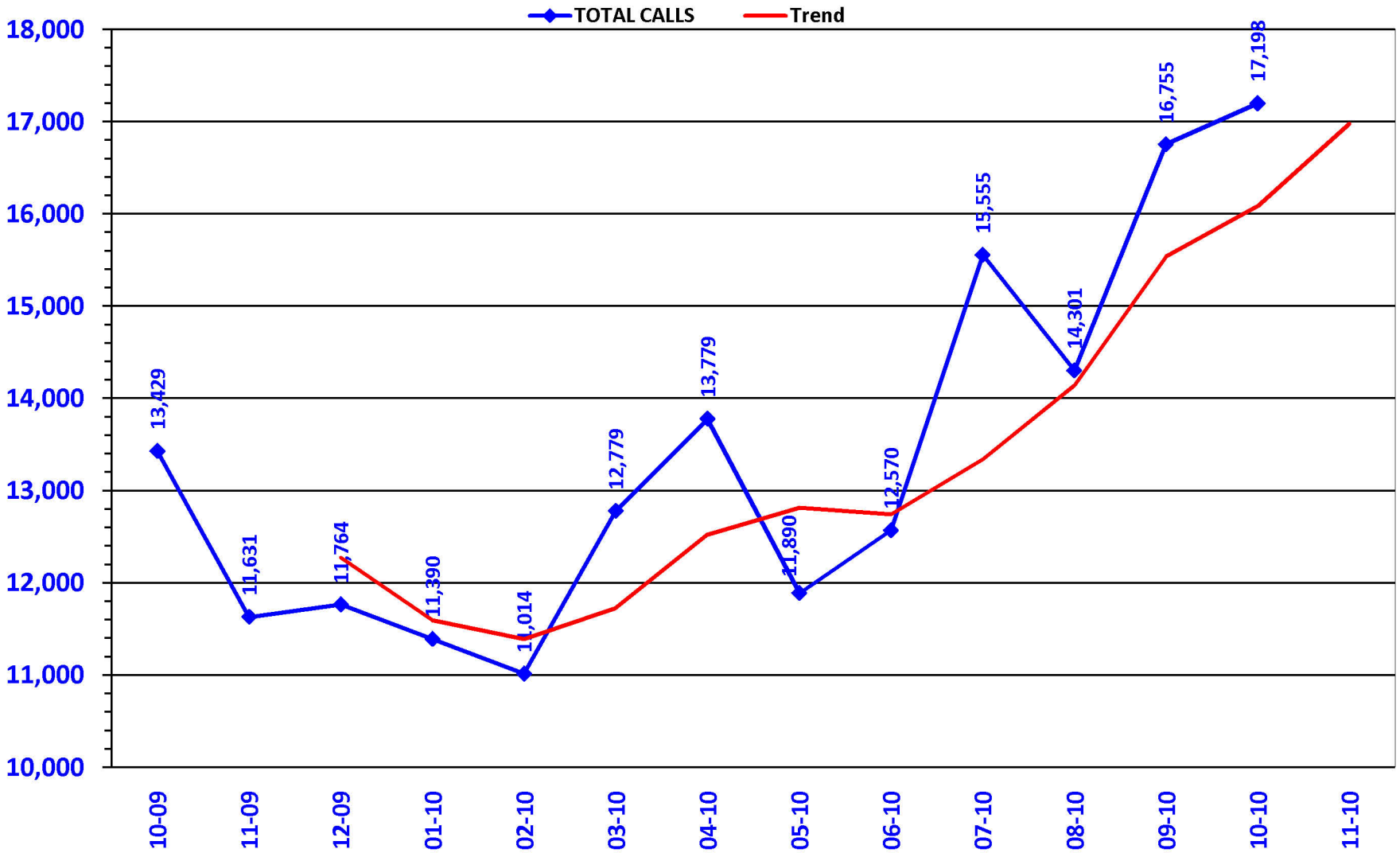
Duplicate Requests: 943

Letters: 1,298

No Process: 1,116

Changes to existing PAs: 436

CALL VOLUME MONTHLY REPORT:
October 2009 – October 2010



Appendix C

Vote on 2011 DUR Meeting Dates

Oklahoma Health Care Authority
November 2010

Meetings are held the second Wednesday of each month.

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

Appendix D

Vote to Change Criteria for the Growth Hormone Product Based Prior Authorization Category

Oklahoma Health Care Authority
November 2010

Recommendation

The College of Pharmacy recommends the following:

1. Update criteria for coverage, continuation, and discontinuation of growth hormone products based on recommendations from Board Members and specialists.

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.

Proposed Updated Criteria

The following is the current growth hormone coverage criteria. The red sections are recommended changes to the criteria from consulted physicians and the DUR Board's previous discussion. **$** indicates increased expenditures may occur if changes are implemented.

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 percentile
    b. 0,1,or 2 hormones deficient and IFG-1 < 50th percentile failure of a growth hormone stimulation test as outlined below
3) Panhypopituitarism in children with height <2.25 SD for mean for age and MRI evidence for pituitary stalk agenesis, empty sella, 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's syndrome or 45X, 46XY mosaicism
9) Short Stature associated with Noonan Syndrome
10) Hypoglycemia with evidence for hGH deficiency
11) SHOX deficiency (with genetic evidence for short stature homeobox-containing gene deficiency)
12) AIDS wasting syndrome (12 weeks therapy only.)
13) Other evidence for hGH deficiency submitted for panel review and decision

Transitional indications for members 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 tests 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 or 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) Evaluation by an Endocrinologist, Pediatric Nephrologist, or an 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
5) Growth velocity of less than 5cm/yr

6) Evidence of delayed bone age and open epiphyses.
7) 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 percentile, or
    b. 0,1,or 2 hormones deficient and IFG-1 < 50th percentile, and failure of a growth hormone stimulation test as outlined below
2) Height <2.25 SD for mean for age and 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
    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. $

Accepted childhood pharmacological hGH stimulation tests:

1) 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 <10 ng/ml is evidence for hGH deficiency.$
2) OTHER (PENDING)

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 Noonan Syndrome

1) Chromosome analysis diagnosing Noonan syndrome

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)

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), and indicated by fused epiphyses by bone age determination. $
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 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 percentile
    b. 0,1,or 2 hormones deficient and IFG-1 < 50th percentile failure of an adult 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 non compliance
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) Discontinue therapy
   a. Therapy may be discontinued when one of the following criteria is met:
   b. Epiphyses closed
   c. Covered height has been reached
      i. 152.4cm(60 inches) for girls
      ii. 165.1cm (65 inches) for boys.
   d. Sensitivity to mecasermin
   e. Member is noncompliant

Potential Economic Impact

Potential Administrative Costs
There will be no additional administrative costs associated with the proposed tiers for this category due its current prior authorization status.

Potential Program Savings
Potential additional net ingredient savings to the program based on recommended tiers is estimated to be between 5 % and 12 % of the FY 2010 total reimbursement to pharmacies for this category of drugs.

Percent of Current Reimbursement **5 % to 12 %**