# Drug Utilization Review Board

Oklahoma Health Care Authority

4545 N. Lincoln Suite 124

Oklahoma City, Oklahoma 73105

OHCA Board Room

March 8, 2006 @ 6:00 p.m.

THE UNIVERSITY OF OKLAHOMA

THE UNIVERSITY OF OKLAHOMA

# MEMORANDUM

**TO:** Drug Utilization Review Board Members

**FROM:** Shellie Gorman, Pharm.D.

**SUBJECT:** **Packet Contents for Board Meeting – March 8, 2005**

**DATE:** March 1, 2005

**NOTE:** **THE DUR BOARD WILL MEET AT 6:00 P.M.**

Enclosed are the following items related to the March 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** – Review of Narcotic Utilization – **See Appendix C.**

**Action Item** – Vote to Prior Authorize Muscle Relaxants – **See Appendix D.**

**Action Item** – Vote to Prior Authorize Ultram® ER and ODT – **See Appendix E.**

**Action Item** – Annual Review of Plavix® – **See Appendix F.**

**Action Item** – Annual Review of Xolair® – **See Appendix G.**

Review of Diabetes in the Oklahoma SoonerCare Population – **See Appendix H.**

New Product Reviews and Notices – **See Appendix I.**

FDA and DEA Updates – **See Appendix J.**

Future Business

Adjournment

# Drug Utilization Review Board

(DUR Board)

**Meeting – March 8, 2006 @ 6:00p.m.**

Oklahoma Health Care Authority
4545 N. Lincoln Suite 124
Oklahoma City, Oklahoma 73105
**Oklahoma Health Care Authority Board Room**

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## AGENDA

Discussion and Action On the following Items:

Items to be presented by Dr. Whitsett, Chairman:

**1. Call To Order**

A. Roll Call – Dr. Graham

Items to be presented by Dr. Whitsett, Chairman:

**2. Public Comment Forum**

A. Acknowledgment of Speakers and Agenda Item

Items to be presented by Dr. Whitsett, Chairman:

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

A. February 8, 2006 DUR Minutes – Vote
B. February 8, 2006 DUR Recommendations Memorandum

Items to be presented by Dr. Whitsett, Chairman:

**4. Update on DUR/MCAU Program – See Appendix B.**

A. Retrospective Drug Utilization Review for November 2005
B. Medication Coverage Activity Audit for February 2006
C. Help Desk Activity Audit for February 2006

Items to be presented by Dr. Flannigan, Dr. Whitsett, Chairman:

**5. Action Item – Review of Narcotic Analgesics – See Appendix C.**

A. Guest Speaker – Hal Vorse, MD
   Medical Director, The Referral Center
B. Guest Speaker – Debbie A. Spaeth, LMFT, LPC, LADC
   Behavior Health Services Manager
C. Utilization Review
D. Lock-In Program
E. COP Recommendations

Items to be presented by Dr. Le, Dr. Whitsett, Chairman:

**6. Action Item – Vote to Prior Authorize Muscle Relaxant Products – See Appendix D.**

A. COP Recommendations

Items to be presented by Dr. Gorman, Dr. Whitsett, Chairman:

**7. Action Item – Vote to Prior Authorize Ultram® ER and Ultram® ODT – See Appendix E.**

A. Product Summary
B. COP Recommendations
C. Price Comparison

Items to be presented by Dr. Flannigan, Dr. Whitsett, Chairman:

**8. Action Item – Annual Review of Plavix® – See Appendix F.**

A. Current Prior authorization Criteria
B. Utilization Review
C. COP Recommendations

Items to be presented by Dr. Le, Dr. Whitsett, Chairman:

**9. Action Item – Annual Review of Xolair® – See Appendix G.**

A. Current Prior authorization Criteria
B. Utilization Review
C. COP Recommendations

Items to be presented by Dr. Gorman, Dr. Whitsett, Chairman:

**10. Review of Diabetes in the Oklahoma SoonerCare Population – See Appendix H.**

A. Introduction and Treatment of Diabetes
B. Diabetes Medication Utilization
C. Prevalence and Therapy Review
D. COP Recommendations

Items to be presented by Dr. Gorman, Dr. Whitsett, Chairman:

**11. New Product Reviews and Notices – See Appendix I.**

A. Product Summaries

**12. FDA and DEA Updates – See Appendix J.**

**13. Future Business**

A. Contraceptive Utilization Review
B. Antiinfectives Utilization Review
C. Antipsychotic Utilization Review
D. Annual Reviews
E. New Product Reviews and 30 Day Notices
F. OTC Formulary

**14. Adjournment**

# APPENDIX A

# OKLAHOMA HEALTH CARE AUTHORITY
# DRUG UTILIZATION REVIEW BOARD MEETING
# MINUTES of MEETING of FEBRUARY 8, 2006

| BOARD MEMBERS: | PRESENT | ABSENT |
|---|---|---|
| Brent Bell, D.O., D.Ph. | X | |
| Dorothy Gourley, D.Ph. | X | |
| Anetta Harrell, D.Ph. | X | |
| Kyle Hrdlicka, D.O. | X | |
| Dan McNeill, Ph.D., PA-C | X | |
| Clif Meece, D.Ph. | X | |
| James Rhymer, D.Ph | X | |
| Dick Robinson, D.Ph., Vice-Chair | X | |
| Thomas Whitsett, M.D., Chair | | X |

| COLLEGE of PHARMACY STAFF: | PRESENT | ABSENT |
|---|---|---|
| Leslie Browning, D.Ph./PA Coordinator | X | |
| Metha Chonlahan, D.Ph./Clinical Pharmacist | X | |
| Karen Egesdal, D.Ph./SMAC-ProDUR Coordinator/OHCA Liaison | X | |
| Kelly Flannigan, Pharm.D../Operations Manager | X | |
| Shellie Gorman, Pharm.D./DUR Manager | X | |
| Ronald Graham, D.Ph./Pharmacy Director | X | |
| Chris Le, Pharm.D., Clinical Pharmacist | X | |
| Carol Moore, Pharm.D., Clinical Pharmacist | X | |
| Neeraj Patel, Pharm.D., Clinical Pharmacist | | X |
| Lester A. Reinke, Ph.D. | X | |
| Visiting Pharmacy Students: Amanda Bias, Marcy Cox, Lauren Hromas | X | |

| OKLAHOMA HEALTH CARE AUTHORITY STAFF: | PRESENT | ABSENT |
|---|---|---|
| Alex Easton, M.B.A./ Pharmacy Operations Manager | X | |
| Mike Fogarty, J.D., M.S.W./Chief Executive Officer | X | |
| Nico Gomez/Director of Governmental & Public Affairs | | X |
| Lynn Mitchell, M.D., M.P.H/Director of Medical Services | X | |
| Nancy Nesser, D.Ph., 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 | |

**OTHERS PRESENT:**

| | | |
|---|---|---|
| Jim Fowler, Astra Zeneca | Mark Edwards, Astra Zeneca | Jim Ross, KOS |
| Marcie Wright, Pfizer | Whitney McFadden, Aventis | Raelynn Herron, KOS |
| Michelle Gauldine, JOM | Jonathan Klock, GSK | Steve Higgins, TAP |
| Aaron Walker, Schering Plough | Rachelle Wan, Amgen | Dale Roof, Takeda |
| John Rolls, Pricara | Jim Dunlap, Lilly lobbyist | Donna Erwin, BMS |
| Patrick Evans, BMS | | |

**PRESENT FOR PUBLIC COMMENT:**

| | |
|---|---|
| Amy Darter, M.D. | Agenda Item No. 7 |
| David B. Domek, M.D. | Agenda Item No. 11 |

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

**1A: Roll Call**

Dr. Robinson 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**

**2A: Acknowledgement of Speakers and Agenda Item**

Dr. Robinson acknowledged speaker for Public Comment.

**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 3:** **OHCA ANNUAL REPORT, STRATEGIC PLANNING & ACCOMPLISHMENTS**

Report submitted by Carol McFarland, C.P.A.

**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 4:** **APPROVAL OF DUR BOARD MINUTES**

**4A: January 11, 2006 DUR Minutes**

Dr. Meece moved to approve minutes as submitted; seconded by Dr. Gourley.

**ACTION:** MOTION CARRIED.

**AGENDA ITEM NO. 5:** **UPDATE ON DUR/MCAU PROGRAM**

**5A: Retrospective Drug Utilization Review Report: October 2005**

**5B: Medication Coverage Activity Report: January 2006**

**5C: Help Desk Activity Report: January 2006**

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

**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 6:** **MEDICAID PHARMACY PROGRAM OVERVIEW & DUR PLUS**

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

**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 7:** **VOTE TO PRIOR AUTHORIZE NASAL ALLERGY PRODUCTS**

For Public Comment, Amy Darter, M.D.. *Hello, I'm Amy Darter and I'm a board certified allergist and immunologist in private practice in Edmond, and I'm here on behalf of Rhinocort Aqua or budesonide nasal spray. I'm going to give you three reasons why I suggest, based on evidence and based on the literature that I think this would be a good option as a Tier 1 medication for the Medicaid population which consists of a lot of pregnant women and children. Number one I think, safety. This medication is a Class B pregnancy drug so it's indicated by the FDA for a lot of this patient population. So in a litigious society I think this is important. So one thing to take into consideration, the only intranasal corticosteroid with that pregnancy rating. Number two I think, from a cost standpoint we have to look at this medication as a very effective drug. The indicated dosage is one squirt with each nostril dose daily. The prescription at that dosage would actually last two months rather than one month, so from a cost effective standpoint I think that's something to definitely consider. And then number three, in the allergy world, compliance is an issue, so sensory attributes are important. With this nasal spray, we have no taste, we have no smell, and we also shoot very little volume down the back of the nose and throat. When it comes to compliance, this is a very effective medication, especially in children that don't tolerate a large volume up the nose and down the back of the throat. And so in this day and age when 40% of our children are allergic it becomes a very effective medication in that sense. And we also use, this compound, this budesonide compound is tried and true. We've used the inhaled version in the lung all the way down to the age of one, although the nasal indication is only down to the age of six. So I think those are three important reasons in this population to consider moving this medication to Tier 1. I'd be happy to entertain any questions.*

Dr. McNeill: *I think would that a couple of those reasons be a, would be satisfactory reasons to approve it like in pregnancy or in children. Might automatically kick it into approved category.*

Dr. Gorman: *Pregnancy would be a clinical exception . . . it's the only one with that pregnancy rating.*

Dr. McNeill: *The only one?*

Dr. Robinson: *You say 40% of the kids have allergies? What has it been in the past . . . has that changed . . .*

Dr. Darter: *Yes. It's increasing on a regular basis. There are multiple theories and . . . there's not a best theory. Western inflation of society happens to be a big important one but there are multiple factors other than genetic and environmental that are playing a role.*

Dr. McNeill: *We heard a little about Rhinocort by the allergist. I would like to hear her perspective on Flonase versus the other ones for a couple of minutes.*
Dr. Darter: *Sure, I'd be happy to. The other nasal sprays shoot about 50 mcg of volume down the back of the nose so there are many patients that will not tolerate that. For sore throat reasons they feel like they're choking, lots of reasons for non-compliance. There's also in the other nasal sprays issues of smell. Many of the patients that we're treating with allergy also have odor induced disorders and they don't tolerate smells. It annoys them, makes them irritable. Can actually, certain smells can actually cause nasal congestion from a different sort of physiology. So especially by the time patients get to my office, they've already often times been tried on one of those and when I switch to something with better sensory attributes, the compliance rate is much, much better and the thing about the budesonide is you get very little volume down the back and so they, they don't get that sensation down the back of the throat which adds a lot to complying and I think it's really a compliance issue.*
Dr. McNeill: *I've used all of these in my practice and they seem to all be very efficacious.*
Dr. Darter: *Equally efficacious.*
Dr. McNeill: *Is that your practice as well, or do you . . . ?*
Dr. Darter: *Absolutely. I think it's a compliance issue and equally efficacious. Absolutely. I just think you know, when you're looking at different classes, equal, especially this patient population, this drug just makes a lot of sense for a lot of different reasons.*
Materials included in agenda packet; presented by Dr. Gorman.
Dr. Gourley moved to approve; seconded by Dr. Meece.
**ACTION:** MOTION CARRIED.

**AGENDA ITEM NO. 8: 30-DAY NOTICE TO PRIOR AUTHORIZE MUSCLE RELAXANTS PRODUCTS**
Materials included in agenda packet; presented by Dr. Le.
**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 9: ANNUAL REVIEW OF HYPERTENSIVE PBPA CATEGORY**
Materials included in agenda packet; presented by Dr. Le.
**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 10: ANNUAL REVIEW OF SMOKING CESSATION PRODUCTS**
Materials included in agenda packet; presented by Dr. Chonlahan.
**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 11: ANNUAL REVIEW OF GROWTH HORMONES**
For Public Comment: David B. Domek, M.D.: *My name is Dr. David Domek. I'm a pediatric endocrinologist and clinical geneticist in private practice at Baptist Medical Center and as such have had several patients on human growth hormone unintelligible this product. It has come to my attention that there is been a proposal to change some of the diagnostic criteria for growth hormone coverage; namely the institution of a requisite delay in bone age. That's what I'd like to speak to you about today. I have no issue with the provocative testing and the oxylogical report measuring data that we collect but it is the requirement for a bone age delay that is somewhat troubling for a couple of reasons. One, it does not, it is not diagnostic of anything. A delay in bone age is a indication of an underlying problem. A delay in physical maturation can reflect not only growth hormone deficiency but other conditions including chronic illnesses and normal variations. So as such it does not, you know, specific to growth hormone deficiency. Also it's a very subjective test. There is absolutely no one in this room who would come to the same conclusion when reading a bone age. It is a comparison between the x-ray at hand and a book of standards, and pediatric radiologists would agree that it is subjective so that all endocrinologists that we often do not get the same values when we look at it. It is somewhat interpretive or flavored by our experience and the actual height of the child and our probably subconscious desire to treat somebody whom we really want to, or whatever reason is not a specific test. By requiring a specific delay of for example an arbitrary number like two standard deviations from normal, it is also discriminatory. If a child, for example, a newborn or an infant, has growth hormone deficiency, they'll present with hypoglycemia and if the diagnosis of growth unintelligible or infantile growth hormone deficiency is made, there is no time to accrue a substantial delay in bone age. And if a child would ever be denied growth hormone because he did not meet the bone age criteria and died of a hypoglycemic seizure, I don't want to be held liable because I'm going to run from that one as far as I can. In terms of the older child, if a child is diagnosed with for example let's say, a malignancy or has an acute injury to the pituitary gland resulting in growth hormone deficiency, that child wouldn't have time to accrue a bone age delay either. Now that child, the window of opportunity for therapy is rapidly diminishing and if we wait for them to have a delay in bone age, we may then start therapy and often have no positive outcome, and so that child has been doomed to shorter stature because of requirement to have a two standard deviation delay in bone age. They're not the same for different age groups. A child, an infant is going to have a bone age delay standard deviation of a matter of months, whereas an older child, teenage approaching child, is going to have a standard deviation of approximately a year. So one child might have to wait two years, one child has to wait, for example, a few months; that's not exactly fair. For those reasons I think that to actually have a requirement for a specific amount of bone age delay won't work, and no endocrine body that I know of or any other pediatric group that I know of has bone age delay as a requirement for the*

*diagnosis of growth hormone deficiency. And if such a rule was adopted you could place yourself as well above all the pediatric endocrinologists in the country and they would not necessarily find that in good favor, so not that I have a better alternative. I just don't think that a requirement for a specific amount of bone age delay is a reasonable request. The presence of a bone age delay probably is going to be present in everybody with growth hormone deficiency, but depending on specifics of the case, length of time of process, age of the patient, etc., those may vary considerably. Growth hormone deficiency as a diagnosis is an individual basis as I'm sure you're all aware, and it's an imprecise science. We don't have an agreement in the community, in the endocrine community, about what constitutes growth hormone normality in terms of biochemical numbers. We don't have a lot of consensus as to what type of provocative tests are best, what type of other markers are the best for diagnosis. It's an individual diagnosis and hard to put a precise number on an imprecise science. Questions?*

Dr. McNeill: *A couple of things. I don't know if you have this chart, if you've seen this chart. Of 215 claims, 18 of them were for people over 20 years of age. This is way above my head. What would that be?*

Dr. Domek: *Those would be individuals who more likely than not have got adult, who had childhood onset growth hormone deficiency who now have reached adulthood and in the endocrine community, adult growth hormone deficiency is a emerging and hot topic.*

Dr. McNeill: *I understand that, but there's one person here between the age of 65 and 79 years old.*

Dr. Domek: *Well they're not seen by me. Adult growth hormone deficiency is a recognized entity.*

Dr. McNeill: *What age, the certainly the most common, 83 . . . 200 cases up to age 19. Where, 19 seems kind of high. If you want a really big iliac crest I guess you would . . .*

Dr. Domek: *You're asking what age is the most common diagnois made?*

Dr. McNeill: *Yeah. If you were to put a more realistic figure here on utilization . . .*

Dr. Domek: *Well children who are diagnosed most commonly are just early school age children.*

Dr. McNeill: *And they would receive injections through the age of . . . ?*

Dr. Domek: *Well that varies practitioner to practitioner. I'll give you my particular case. I tell families, all of them, at the institution of growth hormone therapy, we will continue therapy under three circumstances, or we'll discontinue under three circumstances. One, if I'm giving you growth hormone and you don't grow faster with it than without it after six months, we're going to stop . . . it ain't working. It wasn't the diagnosis. Second is, we can treat to epiphyseal closure which in boys generally, is about age seventeen, in girls probably fifteen to sixteen. Or three, we can treat until you reach a satisfactory height. Now in my twenty years, I've never taken a child to epiphyseal closure. They've all stopped well short of that. Because when you've treated them early, made the diagnosis appropriately and treated early, you get a better result and the child who is now a teenage boy who is fifteen and as tall as his dad, and maybe he's still got two more years of therapy potentially we could do, I sell them against it. I say, look, you're 5' 7" today, your dad is 5' 8", even without growth hormone you're going to grow some. You don't want to keep taking the shots. And you know what they all say? No. I say, we're done. Hopefully other endocrinologists will tell you the same thing because we don't treat just because we still can. And most of the time I will always stop or ask the kid even if they're at 5'8" . . . if I make you 5' 9", is your life going to be any different? And they all say honestly, no. I say well would you rather have that money for a car or you want the money for mom and dad to pay the co-pay on the growth hormone so that, you know, you get an extra inch and you know what they all say? I want the car.*

Dr. McNeill: *A couple of other points here. One is other than in your opinion, other than a pediatric endocrinologist, who should be prescribing this stuff?*

Dr. Domek: *No one.*

Dr. McNeill: *So that's another criteria, instead of bone age, that you might . . .*

Dr. Domek: *I think it is, I would definitely . . . only because we've got some more experience with it and you know, and yeah, I would think that that is the criteria that I would use.*

Dr. McNeill: *OK, so, but let me say that because they're probably no more than what . . . two dozen pediatric endocrinologists in the State . . .*

Dr. Domek: *Generous, is five.*

Dr. McNeill: *OK, so there's a . . . .*

Dr. Hrdlika: *How many endocrinologists do we have?*

Dr. Domek: *There's a lot more. And there's adult endocrinologists who do some pediatrics.*

Dr. Hrdlika: *You probably have a lot of adult endocrinologists that use this on occasion, too?*

Dr. Domek: *On occasional children, yes. But not, the vast majority are pediatric endocrinologists.*

Dr. McNeill: *So when you come back next time, can we see who's what speciality . . . because if fity of these are coming from family practice, that might not be a good thing.*

Dr. Domek: *My suspicion is, sure you can cull the data, but the vast majority is going to come from pediatric endocrinologists. Only knowing that from home health care providers that dispense the growth hormone, they'll kind of set you on it. We've got some guy out there in Nowhere, Oklahoma who's got a whole football team on growth hormone. They don't like that either.*

Dr. Hrdlika: *Two questions. One, can you drive a child to grow taller than he would ordinarily?*

Dr. Domek: *Not with the recommended doses, no.*

Dr. Hrdlika: *Secondly, what is the purpose in this rule being discussed? In other words, why are we discussing changing this criteria to a bone age of two standard deviations. What brought that about? Are we trying to prevent abuse of this medication? Are we trying . . . what are we trying to accomplish?*

Dr. Moore: *We're trying to loosen it a little bit because right now it's set at 2-year delay.*

Dr. Domek: *And the point is that neither one of those should be . . .*

Dr. Hrdlika: *I was going to say, this is a situation where the vast majority of kids that are going to be put on it are going to be treated by an expert in this field and as far as I'm concerned, if they feel like he needs it, he needs it and I wouldn't put any criteria on it.*

Dr. McNeill: *I was just told back here that the current requirement is that it's prescribed by an endocrinologist or pediatric endocrinologist, so that satisfies everything we're . . .*

Dr. Moore: *Or a nephrologist.*

Dr. Domek: *Nephrologist . . .. for the indication of chronic renal insufficiency.*
Dr. Robinson: *But is the two years in the criteria?*
Dr. Gorman: *Yes, yes . . right now it is.*
Dr. Domek: *. . . . putting a specific time on it, the standard deviations over the years may not be appropriate because it may put the pinch on certain children who need their medicine now.*
Dr. Hrdlika: *Are families going to their local pharmacy and getting this? Do you write a script for it and they go down to the pharmacy?*
Dr. Domek: *No. Usually speciality pharmacies. Retail pharmacies, to my knowledge, don't carry this because of its' expense. And that's why we're so judicious in how it's used is that because it is costly.*
Dr. McNeill: *Cranial pharyngioma makes a lot of sense in not waiting for bone age delay.*

Materials included in agenda packet; presented by Dr. Moore.
Discussion was to change criteria for initiation of therapy of growth hormone FROM "bone age delay of two years or more" TO "evidence of bone age delay or evidence of open epiphyses".
Dr. Hrdlicka moved to approve criteria changes; seconded by Dr. McNeill.
**ACTION:** MOTION CARRIED.

**AGENDA ITEM NO. 12:** **FUZEON® FOLLOW UP**
Materials included in agenda packet; presented by Dr. Browning.
**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 13:** **NEW PRODUCT REVIEWS AND NOTICES**
Materials included in agenda packet; presented by Dr. Gorman.
**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 14:** **FDA & DEA UPDATES**
Materials included in agenda packet; presented by Dr. Graham.
**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 15:** **FUTURE BUSINESS**
**15A: Contraceptive Utilization Review**
**15B: Antidiabetic Utilization Review**
**15C: Antiinfectives Utilization Review**
**15D: Analgesic/Narcotic Utilization Review**
**15E: Antipsychotic Utilization Review**
**15F: Annual Reviews**
**15G: New Product Reviews**
**15H: OTC Formulary**
Materials included in agenda packet; submitted by Dr. Graham.
**ACTION:** NONE REQUIRED.

**AGENDA ITEM NO. 16:** **ADJOURNMENT**
The meeting was declared adjourned.

# The University of Oklahoma College of Pharmacy

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# Memorandum

**Date:** February 13, 2005

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

**From:** Shellie Gorman, Pharm.D.
Drug Utilization Review Manager
Pharmacy Management Consultants

**Subject:** DUR Board Recommendations from Meeting of February 08, 2005.

## Recommendation 1: Vote to Prior Authorize Nasal Allergy Products

MOTION CARRIED by unanimous approval.

| Nasal Allergy Products | |
|---|---|
| ***Tier-1**** | ***Tier-2*** |
| Flonase®<br>flunisolide<br>Ipratropium bromide | Nasonex®<br>Beconase® AQ<br>Nasacort® AQ<br>Rhinocort® AQ<br>Astelin® |

*Brand products are subject to the Brand Name Override where generic is available.

The following criteria are recommended for approval of a Tier-2 product:

1. Documented adverse effect or contraindication to the preferred products.
2. Failure with at least one Tier-1 medication defined as no beneficial response after at least two weeks of use during which time the drug has been titrated to the recommended dose.
3. Approvals will be for the duration of three months, except for clients with chronic diseases such as asthma or COPD, in which case authorizations will be for the duration of one year.

**Recommendation 2: Annual Review of Hypertensive PBPA Category**

No action required.

**Recommendation 3: Annual Review of Smoking Cessation Products**

No action required.

**Recommendation 4: Annual Review of Growth Hormone Products**

MOTION CARRIED by unanimous approval.

## GUIDELINES FOR COVERAGE OF GROWTH HORMONE

### COVERED INDICATIONS

- Classic hGH Deficiency
- Short Stature (including Prader-Willi Syndrome)
- Short Stature associated with chronic renal insufficiency
- Small for Gestational Age (SGA)
- Turner's Syndrome or 45 X, 46 XY mosiacism in males
- Hypoglycemia associated with hGH insufficiency
- AIDS wasting (Serostim only)

### FOR INITIATION OF hGH THERAPY

A client must be evaluated by an Endocrinologist, Pediatric Nephrologist, or an Infectious Disease Specialist before consideration will be given for coverage of Growth Hormone therapy.

Information must be provided to predict the child's PROJECTED HEIGHT [Definition: final adult height without hGH therapy] with hGH therapy and the TARGET HEIGHT [Calculation: (Total of father's and mother's height in cm, divided by 2) plus 6.5cm for boys and minus 6.5cm for girls]. COVERED HEIGHT will refer to the individual's height to which coverage of hGH therapy will be provided [152.4cm for girls, 165.1cm for boys].

### I. DIAGNOSIS OF CLASSIC hGH DEFICIENCY

A. Criteria for Initiation of Therapy

1. Pediatric Clients
   - Height below the third percentile on growth chart
   - Subnormal growth velocity: current height more than two standard deviations below the mean and/or growth velocity of less than 5cm/yr
   - Evidence of delayed bone age ~~of two or more years when compared to chronological age~~ or open epiphysis

- No contributing medical condition, i.e. chronic diseases (cystic fibrosis, chronic renal failure), malnutrition, psychosocial deprivation, etc
- Subnormal response of 10ng/ml or less on two provocative growth hormone stimulation tests

2. Adult Clients
   - Childhood or Adult onset of hGH deficiency
   - Age < 60 years
   - No evidence of active malignancy
   - Other hormone deficiencies have been ruled out or stabilized with adequate replacement
   - Subnormal response of 5ng/ml or less to insulin hypoglycemia growth hormone stimulation test

B. Accepted GH Screening Test
   1. Insulin-like growth factor 1 (IGF-1)
   2. Insulin-like growth factor – binding protein 3 (IGFPB-3)

C. Accepted Pharmacologic GH Stimulation Tests
   1. Propranolol with exercise
   2. Levodopa
   3. Insulin hypoglycemia test
   4. Arginine HCl infusion
   5. Clonidine (not accepted for adults)

D. Continuation of Therapy
   1. Pediatric Clients
      - Clients should be evaluated every 6 months to determine increase in growth velocity and monitor for adverse effects and compliance
   2. Adult Clients
      - Clients should be evaluated every 6 months to monitor for adverse effects and compliance

E. Discontinuation of Therapy
   1. Pediatric Clients

      Client therapy may be discontinued when one of the following criteria is met:
      - Growth velocity less than 2.5cm/yr
      - Covered height has been reached
      - Inadequate compliance
      - Significant adverse effects
   2. Adult Clients
      - Inadequate compliance
      - Significant adverse effects

## II. DIAGNOSIS OF SHORT STATURE (INCLUDING PRADER-WILLI SYNDROME)

A. Initiation of Therapy

The client should meet three of the criteria listed:

- Evidence of delayed bone age ~~of two or more years when compared to chronological age~~ or open epiphysis
- Subnormal growth velocity: current height more than two standard deviations below the mean and/or growth velocity of less than 5cm/yr
- Subnormal response of 10ng/ml or less on two provocative growth hormone stimulation tests
- Projected height below Target height and Covered height

B. Continuation of Therapy

Clients should be evaluated every six months to determine the increase in growth velocity.

C. Discontinuation of Therapy

Client 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 epiphysial fusion for girls
- Bone age of 16 or epiphysial fusion for boys
- Slow growth rate (< 5cm in the previous year)
- Inadequate compliance
- Significant adverse effects

## III. DIAGNOSIS OF SHORT STATURE ASSOCIATED WITH RENAL INSUFFICIENCY

A. Initiation of Therapy

The client 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

Clients should be evaluated every six months to determine the increase in growth velocity.

C. Discontinuation of Therapy

Client 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 epiphysial fusion for girls
- Bone age of 16 or epiphysial fusion for boys
- Slow growth rate (< 5cm in the previous year)
- Inadequate compliance
- Significant adverse effects
- Transplantation

## IV. DIAGNOSIS OF SMALL FOR GESTATIONAL AGE (SGA)

A. Initiation of Therapy

The client should meet the following criteria:

- Diagnosis of Small for Gestational Age
- Client over 2 years of age
- Subnormal growth velocity: current height more than two standard deviations below the mean and/or growth velocity of less than 5cm/yr

B. Continuation of Therapy

Clients should be evaluated every six months to determine the increase in growth velocity.

C. Discontinuation of Therapy

Client 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 epiphysial fusion for girls
- Bone age of 16 or epiphysial fusion for boys
- Slow growth rate (< 5cm in the previous year)
- Inadequate compliance
- Significant adverse effects

## V. DIAGNOSIS OF TURNER'S SYNDROME OR 45X, 46XY MOSIACISM

A. Initiation of Therapy

The client should meet the following criteria:

- Chromosome analysis diagnosing either Turner's syndrome in female clients or 45X, 46XY mosiacism in males
- Height below the third percentile on growth charts

B. Continuation of Therapy

Clients should be evaluated every six months to determine the increase in growth velocity.

C. Discontinuation of Therapy

Client 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 epiphysial fusion for girls
- Bone age of 16 or epiphysial fusion for boys
- Slow growth rate (< 5cm in the previous year)
- Inadequate compliance
- Significant adverse effects

## VI. DIAGNOSIS OF HYPOGLYCEMIA ASSOCIATED WITH hGH INSUFFICIENCY

Hypoglycemia is a symptom that is present in some clients 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 clients with normal hGH levels who happen to be hypoglycemic.

A. Initiation of Therapy

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 client information has been received, a retroactive authorization will be given for any emergency doses dispensed.

B. Continuation and Discontinuation of Therapy

Clients 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.

## VII. DIAGNOSIS OF AIDS-RELATED WASTING SYNDROME (SEROSTIM ONLY)

A. Initiation of Therapy

Clients must have documentation showing that they fulfill all of the following criteria. Clients meeting the criteria will be approved for an initial 4 week course of therapy.

- 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
- Client is receiving optimal antiretroviral therapy
- Client does not have a reversible cause of weight loss (e.g. infection, GI bleed or obstruction, or malnutrition)
- Client is receiving aggressive nutritional intake or supplementation
- Client does not have an active malignancy (except localized Kaposi's Sarcoma)
- Client has had a poor response to therapy with megestrol acetate and/or dronabinol
- Male clients have had serum testosterone levels evaluated and treated as needed

B. Continuation of Therapy

- At four weeks, the client will be evaluated for response to therapy (weight gain), side effects, and compliance. If client response is favorable, another 4 weeks of therapy will be authorized.

- Subsequent follow up evaluations will be required every 4 weeks to assess response, side effects, and compliance. The client may receive another 4 weeks of therapy for a maximum of 12 weeks of continuous therapy.

C. Discontinuation of Therapy

Therapy may be discontinued if the client meets any of the following criteria:

- Completion of the FDA approved 12 weeks of therapy
- 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.
- Client non compliance
- Adverse effects that are refractory to dose reduction
- New or progressive Kaposi's Sarcoma
- Client weight exceeds 10% of pre-morbid weight

# APPENDIX B

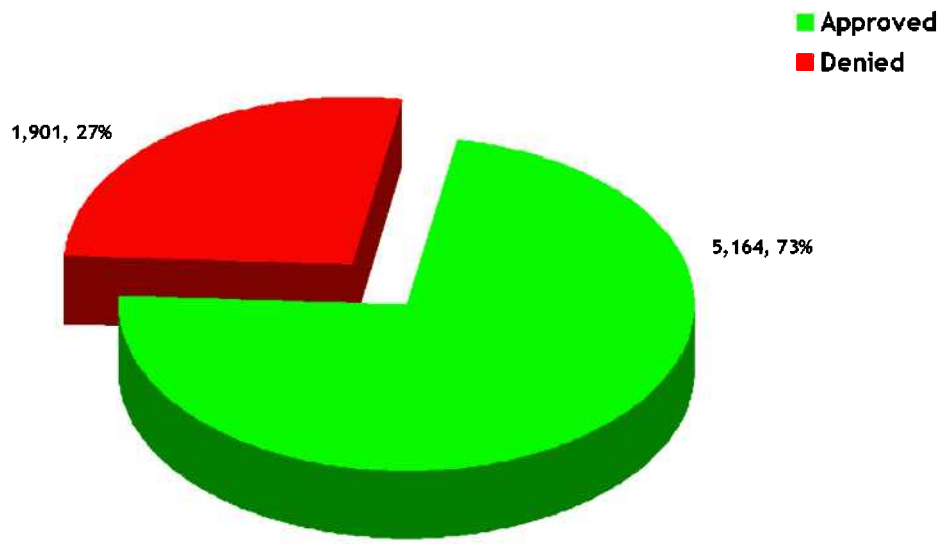
# Retrospective Drug Utilization Review Report

***Claims Reviewed for November 2005***

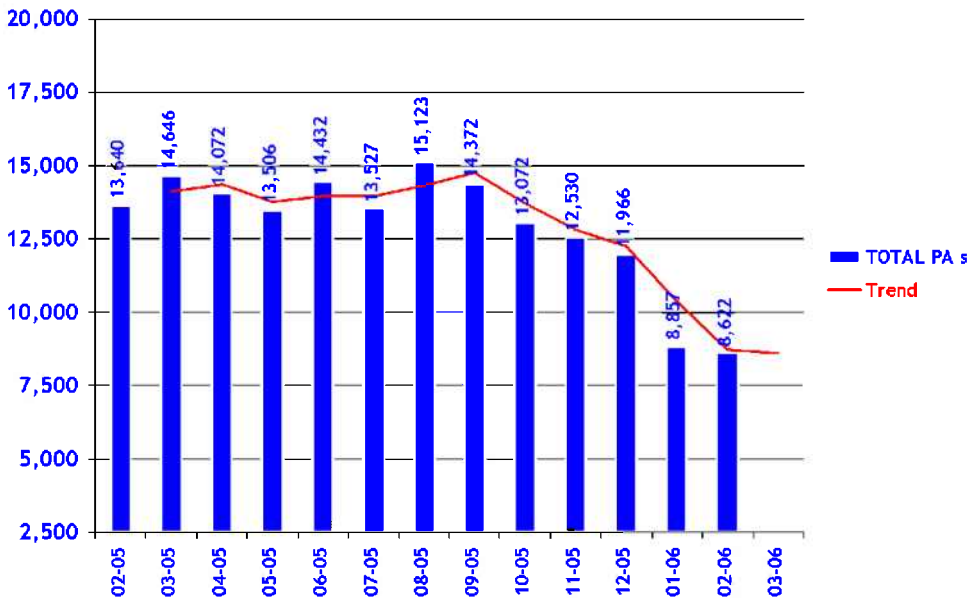
| Module | Drug Interaction | Duplication of Therapy | Drug-Disease Precautions | Dosing & Duration |
|---|---|---|---|---|
| **Total # of messages returned by system when no limits were applied** | 113,993 | 777,767 | 1,113,391 | 51,260 |
| **Limits which were applied** | Established, Major, Females 46-52 | Narcotics, Females 27-30 | Contraindicated, age 36-50, with Asthma | High dose, Centrally acting SKR, Males and Females, Age 0-21 |
| **Total # of messages after limits were applied** | 43 | 165 | 5 | 15 |
| **Total # of members reviewed after limits were applied** | 70 | 279 | 12 | 15 |

| LETTERS | | | |
|---|---|---|---|
| **Prescribers** | | **Pharmacies** | |
| **Sent** | **Responded** | **Sent** | **Responded** |
| 187 | | 97 | |

# PRIOR AUTHORIZATION ACTIVITY REPORT
## February 2006




# PRIOR AUTHORIZATION REPORT
## February 2005 - February 2006



# Activity Audit for

February 01 2006 Through February 28 2006

| Date | Antiulcers app. | Antiulcers den. | Anxiolytic/ Hypnotics app. | Anxiolytic/ Hypnotics den. | Antihistamine app. | Antihistamine den. | Growth Hormones app. | Growth Hormones den. | Stimulant app. | Stimulant den. | Nsaids app. | Nsaids den. | ACE Inhibitors app. | ACE Inhibitors den. | HTN Combos app. | HTN Combos den. | Calcium Channel Blockers app. | Calcium Channel Blockers den. | Plavix app. | Plavix den. | ARB app. | ARB den. | Anti-depressants app. | Anti-depressants den. | Daily Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| App. | 17 | | 2455 | | 882 | | 33 | | 674 | | 30 | | 8 | | 1 | | 22 | | 148 | | 2 | | 128 | | |
| Den. | | 4 | | 349 | | 417 | | 0 | | 212 | | 112 | | 14 | | 0 | | 56 | | 19 | | 0 | | 147 | |
| Average Length of Approvals in Days | 22 | | 91 | | 95 | | 170 | | 198 | | 323 | | 191 | | 2 | | 230 | | 347 | | 184 | | 189 | | |

| | |
|---|---|
| Changes to existing PA's | 644 |
| Total (Previous Year) | 13640 |

| * Denial Codes | |
|---|---|
| 762 = Lack of clinical information | 28.72% |
| 763 = Medication not eligible | 1.37% |
| 764 = Existing PA | 19.41% |
| 772 = Not qualified for requested Tier | 4.73% |
| 773 = Requested override not approved | 15.73% |

| SUPER PA's | |
|---|---|
| Admitted to Nursing Home | 22 |
| Early Refill Attempts | 24613 |
| Dosing Change | 326 |
| High Dose | 8 |
| Lost/Broken Rx | 105 |
| Stolen | 5 |
| Other | 57 |
| Wrong D.S. on Previous Rx | 5 |
| Quantity vs. Days Supply | 959 |
| Brand | 65 |
| -- Approved | 24 |
| -- Denied | 15 |

Monthly Totals

| | Number | Percent of Total |
|---|---|---|
| Approved | 5155 | 59.79% |
| Additional PA's | 6 | 0.07% |
| Emergency PA's | 3 | 0.03% |
| Duplicates | 384 | 4.45% |
| Incompletes | 1173 | 13.60% |
| Denied * | 1901 | 22.05% |
| Total | 8622 | 100.00% |

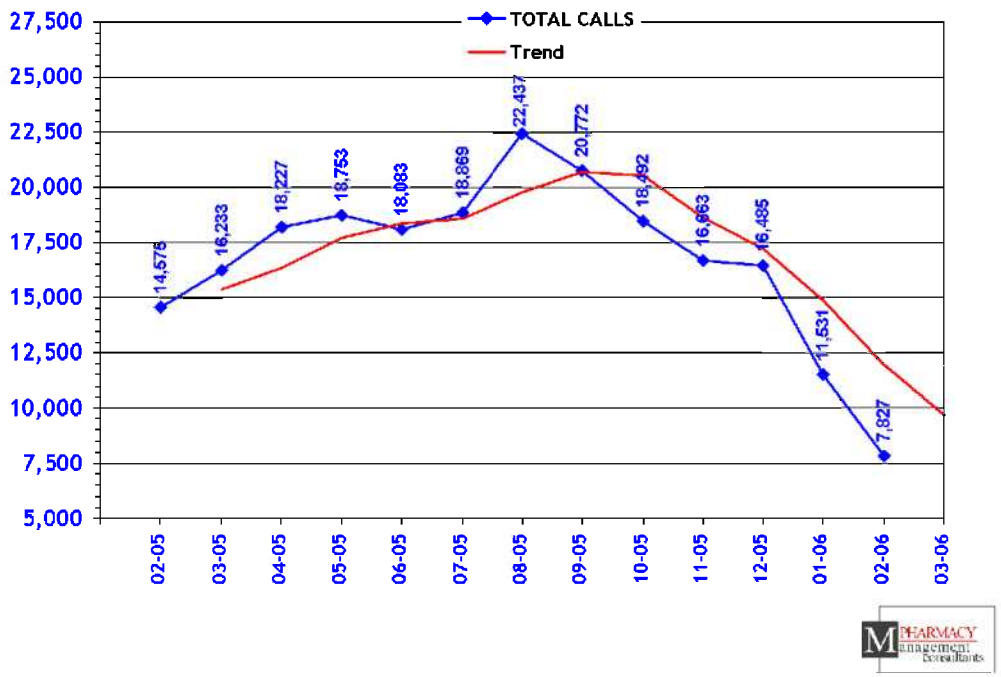
Daily Average of 391.91 for 22 Days

*Changes to existing PA's: Backdates, changing units, end dates, etc.*

*Additional PA's: Done by the help desk (doctor letter responses, PA ran for the wrong person)*

*Incompletes: Missing necessary information (NDC, SIG, Diagnosis, etc.)*

# CALL VOLUME MONTHLY REPORT
## February 2005 - February 2006



# APPENDIX C

# Review of Narcotic Utilization

## January 2005 to December 2005

Oklahoma Health Care Authority
March 2006

### Current Narcotic Quantity Limits

| Drug | Quantity Limit |
|---|---|
| Butorphanol nasal spray | 10ml per 30days |
| Fentanyl transdermal<br>25, 50, 75, & 100mcg/hr patches | 25, 50, & 75 mcg – 10 units per 30 days |
| Fentanyl oral transmucosal (Actiq®)<br>All strengths | 120 units per 30 days |
| Hydromorphone tabs<br>All strengths | 2 or 4mg – 180 units per 30 days<br>8mg – 120 units per 30 days |
| Meperidine tabs<br>All strengths | 60 units per 30 days |
| Methadone tabs<br>All strengths | 240 units per 30 days |
| Morphine sulfate ER (Avinza®) caps<br>All strengths | 30 units per 30 days |
| Morphine sulfate SR (Kadian®) caps<br>All strengths | 60 units per 30 days |
| Oxycodone/ibuprofen<br>5-400mg tabs | 28 units per 30 days |
| Oxycodone IR tabs and caps<br>All strengths | 240 units per 30 days |
| Oxycodone controlled release tabs<br>10, 20, 40 & 80mg | 10, 20, & 40mg – 60 units per 30 days<br>80mg – no limit |

### Changes in Market

During CY'05, Palladone™ was withdrawn from the market due to safety concerns.

Generics became available during CY'05 for the following drugs:

- Duragesic® patches – all strengths except the 12.5mcg/hr
- OxyContin® tabs – all strengths
- Ultracet® tabs

## Utilization – January 2005 to December 2005

For the period of January 2005 through December 2005, a total of 153,068 members received narcotic medications through the fee-for-service program. The chart below is a summary of the utilization. A detailed chart can be found at the end of this report.

| Product | # of Claims | Total Units | Total Days | Total Cost | Per Diem |
|---|---|---|---|---|---|
| Codeine | 182 | 14,841 | 3,678 | $8,084.18 | 2.20 |
| Fentanyl | 22,645 | 291,047 | 634,838 | $6,605,918.90 | 10.40 |
| Hydromorphone | 2,062 | 223,595 | 46,255 | $180,898.36 | 3.91 |
| Levorphanol | 8 | 1,881 | 220 | $1,792.49 | 8.15 |
| Meperidine | 2,623 | 102,664 | 30,084 | $50,358.30 | 1.67 |
| Methadone | 8,456 | 1,028,840 | 244,634 | $148,880.81 | 0.61 |
| Morphine | 17,296 | 1,559,662 | 453,033 | $2,206,926.62 | 4.87 |
| Oxycodone | 36,605 | 3,033,518 | 1,013,562 | $9,352,943.42 | 9.23 |
| Oxymorphone | 1 | 500 | 30 | $1,436.55 | 47.89 |
| Propoxyphene | 2,390 | 160,210 | 37,857 | $64,983.63 | 1.72 |
| Tramadol | 49,236 | 3,689,195 | 858,168 | $416,225.11 | 0.49 |
| Buprenorphine | 33 | 1,510 | 849 | $4,687.46 | 5.52 |
| Butorphanol | 1,017 | 3,868 | 18,917 | $40,135.31 | 2.12 |
| Nalbuphine | 202 | 9,567 | 1,883 | $11,615.19 | 6.17 |
| Pentazocine | 2,192 | 144,731 | 34,270 | $118,738.55 | 3.46 |
| Oxycodone Combos | 42,462 | 2,477,427 | 515,606 | $1,272,434.63 | 2.46 |
| Codeine Combos | 51,193 | 3,633,973 | 356,223 | $361,593.22 | 1.02 |
| Misc Codeine Combos | 5,292 | 257,916 | 53,277 | $249,011.05 | 4.67 |
| Hydrocodone Combos | 337,308 | 21,920,885 | 4,495,817 | $3,500,325.18 | 0.78 |
| Propoxyphene Combos | 74,572 | 3,994,890 | 935,723 | $576,235.12 | 0.62 |
| Misc Combos | 680 | 35,892 | 8,528 | $25,432.31 | 2.98 |
| Tramadol Combos | 11,141 | 810,623 | 175,310 | $729,663.29 | 4.16 |
| **All Products** | **667,596** | **43,397,235** | **9,918,762** | **$ 25,928,319.68** | **2.61** |

| | *Calendar Year 2004* | *Calendar Year 2005* | *Percent Change* |
|---|---|---|---|
| **Total Cost** | **$ 23,606,156.45** | **$25,928,319.68** | **+ 9.8%** |
| **Total Claims** | **571,665** | **667,596** | **+ 16.8%** |
| **Total Members** | **137,313** | **153,068** | **+ 11.5%** |
| **Per Diem** | **$ 2.96** | **$2.61** | **- 11.8%** |

Calendar Year 2005

| | # of Members | # of Claims | Total Units | Total Days | Total Cost | Per Diem |
|---|---|---|---|---|---|---|
| *Duals* | 43,090 | 311,392 | 22,636,710 | 5,683,554 | $15,703,573.04 | 2.76 |
| *Non-Duals* | 109,978 | 356,204 | 20,760,525 | 4,235,208 | $10,224,746.64 | 2.41 |

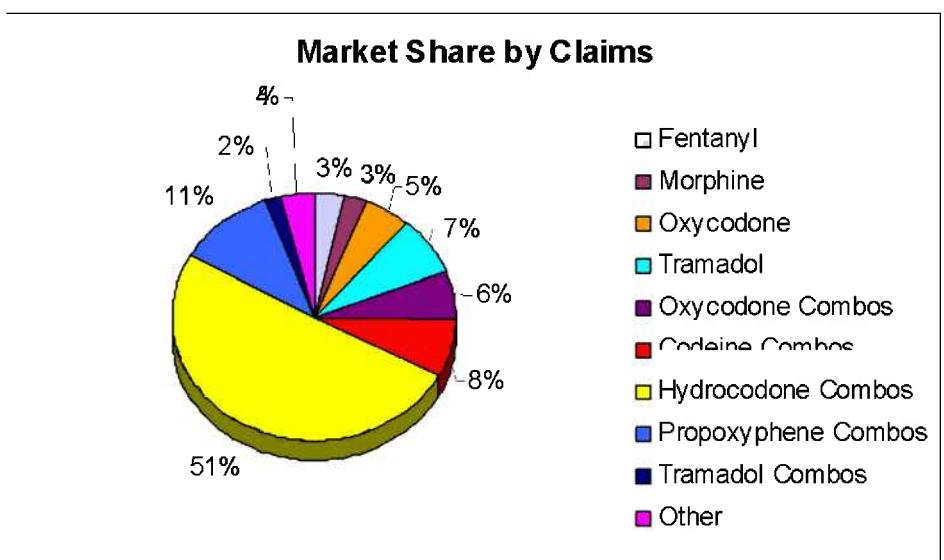
The average number of units per day for the non-dual population (4.9 units/day) is higher than for the duals (4.0 units/day). The average number of units dispensed per claim is higher in the dual population (72.7 units/claim) versus the non-duals (58.3 units/claim). Additionally, the number of claims per client is lower in the non-dual population (3.2 claims/member) than the dual population at (7.2 claims/member). This might suggest that the majority of the non-dual population is using narcotic medications for acute pain relief.

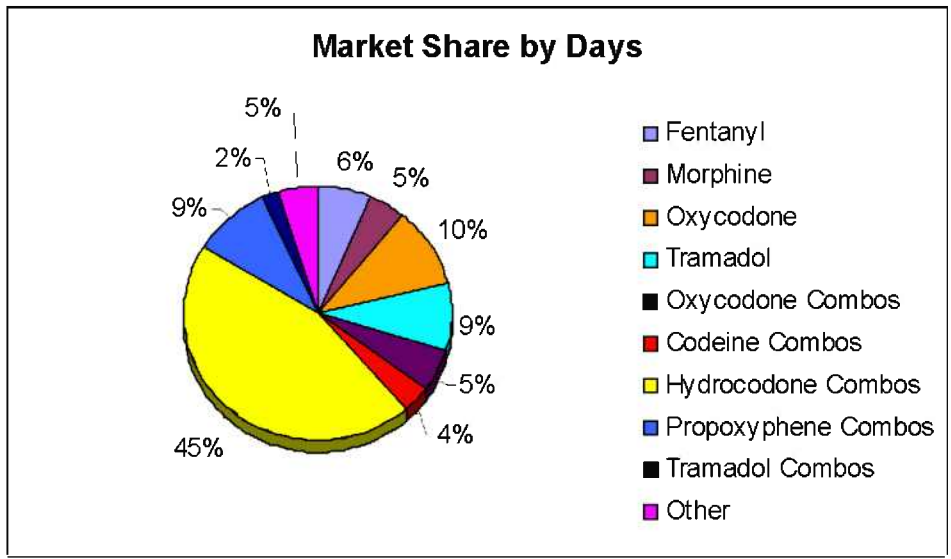
Claims were reviewed to determine the age of the members.

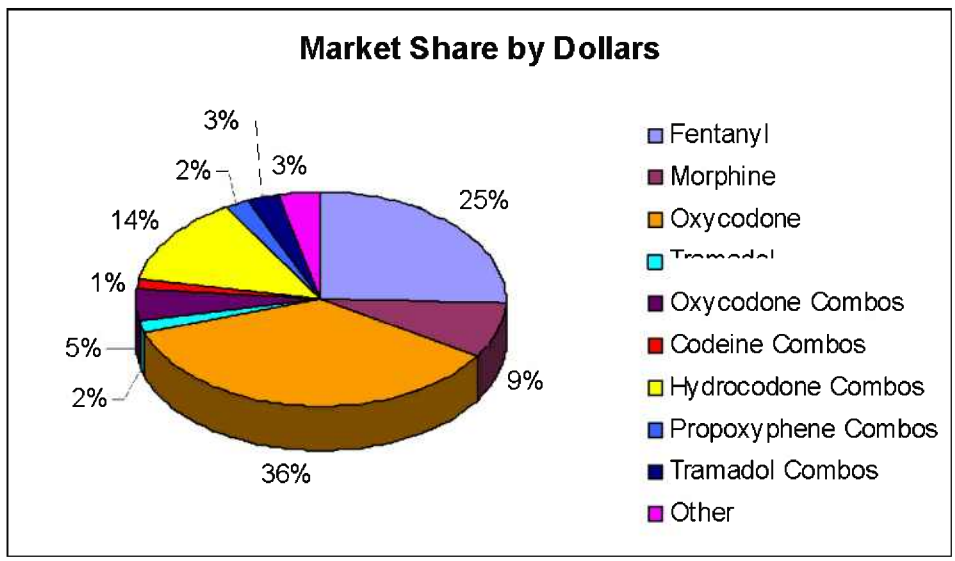
| All Members | | |
|---|---|---|
| Age | Female | Male |
| 0 to 9 | 8,962 | 11,147 |
| 10 to 19 | 19,653 | 13,101 |
| 20 to 34 | 31,052 | 3,084 |
| 35 to 49 | 15,200 | 6,429 |
| 50 to 64 | 12,708 | 6,180 |
| 65 to 79 | 11,343 | 4,203 |
| 80 to 94 | 7,852 | 1,464 |
| 95 and over | 614 | 76 |
| **Totals** | **107,384** | **45,684** |

| Non-Dual Members | | |
|---|---|---|
| Age | Female | Male |
| 0 to 9 | 8,959 | 11,144 |
| 10 to 19 | 19,641 | 13,084 |
| 20 to 34 | 29,751 | 2,091 |
| 35 to 49 | 11,334 | 3,259 |
| 50 to 64 | 6,369 | 3,258 |
| 65 to 79 | 427 | 212 |
| 80 to 94 | 322 | 92 |
| 95 and over | 31 | 4 |
| **Totals** | **76,834** | **33,144** |

**Market Share All Members**

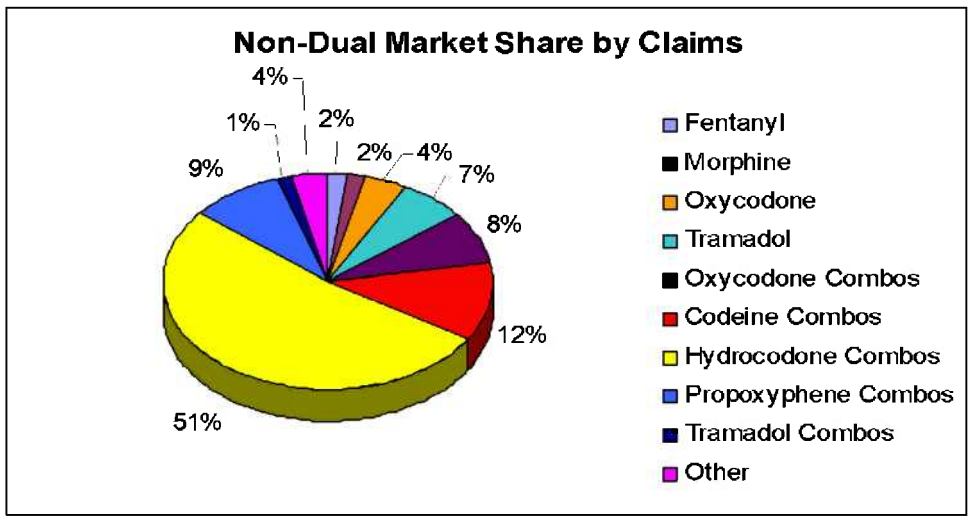


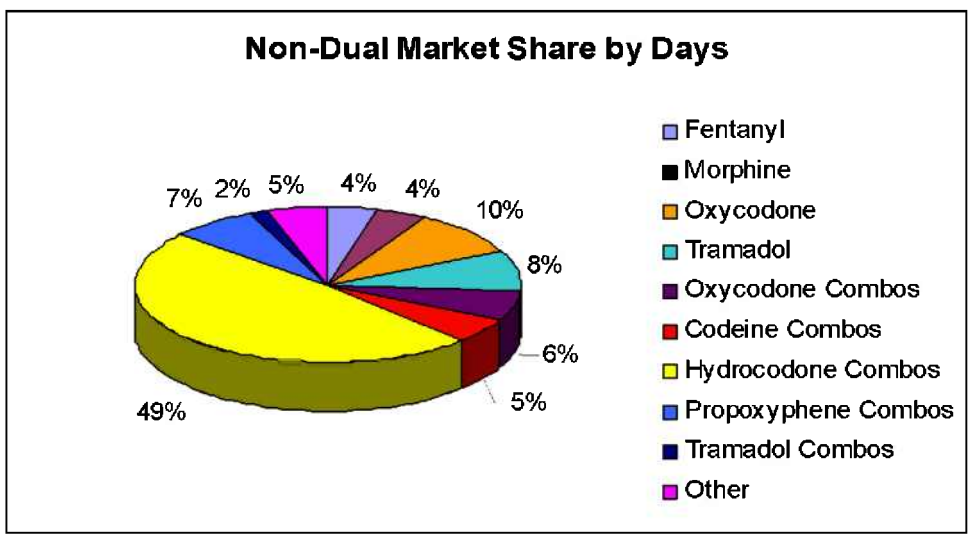


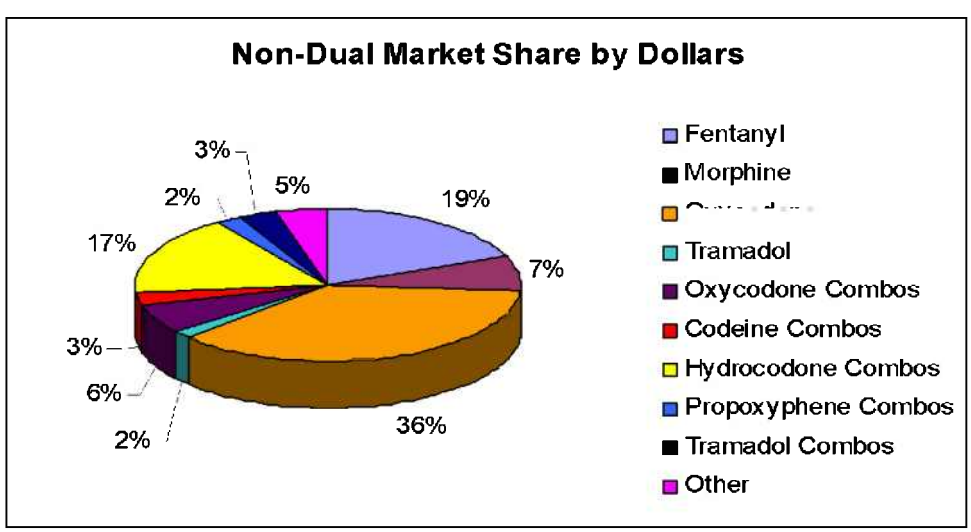




| Market Share | Total Claims | Total Days | Total Dollars |
|---|---|---|---|
| 1st | Hydrocodone Combos (51%) | Hydrocodone Combos (45%) | Oxycodone (36%) |
| 2nd | Propoxyphene Combos (11%) | Oxycodone (10%) | Fentanyl (25%) |
| 3rd | Codeine Combos (8%) | Propoxyphene Combos (9%) & Tramadol (9%) | Hydrocodone Combos (14%) |

## Market Share for Non-Dual Members



| Market Share | Total Claims | Total Days | Total Dollars |
|---|---|---|---|
| 1st | Hydrocodone Combos (51%) | Hydrocodone Combos (49%) | Oxycodone (36%) |
| 2nd | Codeine Combos (12%) | Oxycodone (10%) | Fentanyl (19%) |
| 3rd | Propoxyphene Combos (9%) | Tramadol (8%) | Hydrocodone Combos (17%) |

## Lock-In Program

An additional strategy to optimize care and patient safety would be to study the individuals over-utilizing narcotic medications and refer these members to the Lock-In Program for evaluation. These members would be screened for different variables such as high utilization of narcotic medications, high utilization of medical services (inpatient, emergency department, and physician visits), along with the members medical history and diagnoses. Appropriate members would be locked into one pharmacy.

## Recommendations

The College of Pharmacy has several recommendations for this category.

1. A quantity limit of 10 units per 30 days to be set on Duragesic® (fentanyl) 12.5mcg/hr to bring it in line with the other fentanyl patch strengths.
2. Encourage provider and prescriber referrals to the Lock-In Program for evaluation of those members that may have narcotic over-utilization issues.
3. Monitor this category over the next year to gauge the effect of the change in member population upon utilization patterns.
4. Explore the possibility of a controlled trial on the effects of intervention on Lock-In clients.
5. Review any recommendations by the DUR Board.

As a note of interest, OBNDD will implement a new tracking system within the coming year that will track schedule drugs including hydrocodone prescriptions.

# Detailed Narcotic Utilization for CY'05 for All Members

| | Total Claims | Total Units | Total Days | Member | Total Paid |
|---|---|---|---|---|---|
| **Codeine** | | | | | |
| Codeine Soln | 6 | 450 | 170 | 3 | $338.68 |
| Codeine Sulf Tab 15mg | 5 | 200 | 44 | 5 | $94.07 |
| Codeine Sulf Tab 30mg | 112 | 8,819 | 2,019 | 54 | $3,556.55 |
| Codeine Sulf Tab 60mg | 59 | 5,372 | 1,445 | 10 | $4,094.88 |
| **Fentanyl** | | | | | |
| Duragesic® Patch 12.5mcg/hr | 102 | 894 | 2,699 | 53 | $10,767.19 |
| Fentanyl Patch 25mcg/hr | 6,273 | 57,709 | 172,316 | 2,585 | $607,659.41 |
| Fentanyl Patch 50mcg/hr | 6,497 | 61,257 | 183,401 | 2,463 | $1,242,325.52 |
| Fentanyl Patch 75mcg/hr | 3,936 | 40,324 | 112,161 | 1,310 | $1,125,440.67 |
| Fentanyl Patch 100mcg/hr | 4,912 | 62,208 | 142,133 | 1,302 | $2,486,293.02 |
| Fentanyl Inj 50mcg/ml | 2 | 720 | 60 | 1 | $285.50 |
| Fentanyl Powder | 6 | 900 | 180 | 1 | $10,927.11 |
| Actiq® Loz 200mcg | 147 | 5,606 | 2,020 | 65 | $43,556.49 |
| Actiq® Loz 400mcg | 198 | 10,514 | 4,507 | 59 | $122,348.97 |
| Actiq® Loz 600mcg | 149 | 13,277 | 4,106 | 33 | $182,939.92 |
| Actiq® Loz 800mcg | 224 | 18,317 | 6,053 | 37 | $311,837.93 |
| Actiq® Loz 1200mcg | 119 | 11,077 | 3,169 | 17 | $237,951.83 |
| Actiq® Loz 1600mcg | 80 | 8,244 | 2,033 | 9 | $223,585.34 |
| **Hydromorphone** | | | | | |
| Hydromorphone Tab 2mg | 381 | 27,682 | 6,121 | 218 | $5,539.09 |
| Hydromorphone Tab 4mg | 1,229 | 134,918 | 28,848 | 401 | $39,319.91 |
| Hydromorphone Tab 8mg | 304 | 39,397 | 8,852 | 78 | $42,350.31 |
| Hydromorphone Inj 2mg/ml | 24 | 2,309 | 151 | 4 | $2,105.60 |
| Hydromorphone Inj 4mg/ml | 2 | 580 | 44 | 2 | $649.12 |
| Hydromorphone Inj 10mg/ml | 42 | 16,120 | 560 | 8 | $51,450.80 |
| Hydromorphone Powder | 23 | 403 | 185 | 5 | $20,762.81 |
| Hydromorphone Supp 3mg | 5 | 421 | 85 | 3 | $1,470.91 |
| Palladone™ Cap 12mg | 13 | 565 | 364 | 10 | $3,851.80 |
| Palladone™ Cap 16mg | 18 | 434 | 454 | 12 | $3,285.19 |
| Palladone™ Cap 24mg | 8 | 315 | 225 | 6 | $3,452.01 |
| Palladone™ Cap 32mg | 13 | 451 | 366 | 10 | $6,660.81 |
| **Levorphanol** | | | | | |
| Levorphanol Tab 2mg | 8 | 1,881 | 220 | 1 | $1,792.49 |
| **Meperidine** | | | | | |
| Meperidine Tab 50mg | 1,467 | 57,196 | 19,963 | 929 | $22,395.64 |
| Meperidine Tab 100mg | 408 | 21,638 | 7,036 | 158 | $17,977.52 |
| Meperidine Syrup 50mg/5ml | 586 | 17,464 | 1,294 | 488 | $4,780.74 |
| Meperidine Inj 25mg/ml | 17 | 224 | 179 | 13 | $246.81 |
| Meperidine Inj 50mg/ml | 103 | 5,462 | 1,043 | 61 | $4,189.79 |
| Meperidine Inj 75mg/ml | 2 | 4 | 2 | 2 | $10.91 |
| Meperidine Inj 100mg/ml | 39 | 675 | 561 | 18 | $741.64 |
| Meperidine Powder | 1 | 1 | 6 | 1 | $15.25 |

| **Methadone** | | | | | |
|---|---|---|---|---|---|
| Methadone Tab 5mg | 1,147 | 100,165 | 32,442 | 379 | $10,249.15 |
| Methadone Tab 10mg | 5,660 | 765,011 | 163,688 | 1,260 | $86,901.77 |
| Methadone Tab 40mg | 1,598 | 157,413 | 47,502 | 313 | $51,007.87 |
| Methadone Con Sol 10mg/ml | 17 | 3,892 | 431 | 4 | $379.49 |
| Methadone Sol 5mg/5ml | 30 | 1,230 | 471 | 26 | $198.57 |
| Methadone Sol 10mg/5ml | 4 | 1,130 | 100 | 3 | $143.96 |
| **Morphine** | | | | | |
| Morphine Sulfate IR Cap 15mg | 8 | 730 | 131 | 7 | $259.11 |
| Morphine Sulfate IR Cap 30mg | 3 | 276 | 64 | 3 | $176.01 |
| Morphine Sulfate IR Tab 15mg | 2,091 | 192,997 | 40,631 | 741 | $24,461.96 |
| Morphine Sulfate IR Tab 30mg | 1,916 | 244,741 | 42,709 | 419 | $36,779.81 |
| Morphine Sulf Inj 2mg/ml | 20 | 150 | 87 | 12 | $214.48 |
| Morphine Sulf Inj 4mg/ml | 3 | 22 | 5 | 3 | $33.56 |
| Morphine Sulf Inj 5mg/ml | 8 | 114 | 36 | 4 | $109.30 |
| Morphine Sulf Inj 8mg/ml | 1 | 0 | 1 | 1 | $4.31 |
| Morphine Sulf Inj 10mg/ml | 28 | 1,436 | 371 | 15 | $1,541.40 |
| Morphine Sulf Inj 15mg/ml | 15 | 2,840 | 308 | 7 | $524.27 |
| Morphine Sulf Inj 25mg/ml | 6 | 13,682 | 56 | 3 | $2,669.56 |
| Morphine Sulf Inj 50mg/ml | 47 | 11,815 | 658 | 7 | $16,288.47 |
| Astramorph Inj 1mg/ml | 1 | 2 | 1 | 1 | $14.13 |
| Morphine Sulf Sol 10mg/5ml | 56 | 20,080 | 615 | 31 | $1,672.32 |
| Morphine Sulf Sol 20mg/5ml | 21 | 5,250 | 210 | 14 | $675.92 |
| Morphine Sulf Sol 20mg/ml | 514 | 80,167 | 6,361 | 309 | $28,662.28 |
| Morphine Sulf Powder | 45 | 70,058 | 444 | 19 | $2,337.16 |
| Morphine Sulf Supp 5mg | 3 | 36 | 7 | 1 | $50.34 |
| Morphine Sulf Supp 10mg | 5 | 108 | 31 | 4 | $150.68 |
| Morphine Sulf Supp 20mg | 6 | 136 | 16 | 6 | $225.39 |
| Kadian® Cap 20mg | 459 | 27,719 | 13,606 | 156 | $66,733.52 |
| Kadian® Cap 30mg | 388 | 20,090 | 11,175 | 139 | $51,833.04 |
| Kadian® Cap 50mg | 429 | 26,637 | 12,584 | 118 | $113,711.84 |
| Kadian® Cap 60mg | 247 | 15,446 | 7,743 | 69 | $75,625.56 |
| Kadian® Cap 100mg | 499 | 42,565 | 14,679 | 101 | $328,180.10 |
| Morphine Sulf Tab 10mg | 149 | 15,821 | 2,367 | 73 | $5,087.71 |
| Morphine Sulf Tab 15mg | 12 | 1,050 | 305 | 8 | $393.12 |
| Morphine Sulf Tab 30mg | 11 | 920 | 236 | 9 | $555.20 |
| Morphine Sulf Tab SR 15mg | 1,630 | 117,898 | 44,770 | 635 | $48,295.33 |
| Morphine Sulf Tab SR 30mg | 3,572 | 277,625 | 102,280 | 1,060 | $262,325.45 |
| Morphine Sulf Tab SR 60mg | 2,013 | 168,659 | 59,122 | 500 | $244,953.36 |
| Morphine Sulf Tab SR 100mg | 1,119 | 109,357 | 32,984 | 204 | $282,224.37 |
| Morphine Sulf Tab SR 200mg | 98 | 20,904 | 2,804 | 24 | $162,313.01 |
| Morphine/D5W Inj 1mg/ml | 1 | 500 | 5 | 1 | $20.38 |
| Avinza® Cap CR 30mg | 497 | 17,056 | 14,886 | 216 | $47,033.50 |
| Avinza® Cap CR 60mg | 508 | 17,083 | 15,048 | 218 | $88,943.85 |
| Avinza® Cap CR 90mg | 398 | 13,789 | 11,826 | 124 | $108,841.85 |
| Avinza® Cap CR 120mg | 466 | 21,782 | 13,867 | 112 | $200,716.08 |
| DepoDur 15mg/1.5ml | 3 | 121 | 4 | 2 | $2,288.89 |

| **Oxycodone** | | | | | |
|---|---|---|---|---|---|
| Oxycodone Cap 5mg | 2,967 | 282,357 | 59,590 | 985 | $44,947.95 |
| Oxycodone Tab 5mg | 2,348 | 263,344 | 54,264 | 790 | $54,336.54 |
| Oxycodone Tab 15mg | 1,843 | 218,994 | 43,705 | 378 | $103,408.25 |
| Oxycodone Tab 30mg | 1,159 | 148,688 | 29,111 | 187 | $111,535.58 |
| Oxycodone Con Sol 20mg/ml | 397 | 69,106 | 6,053 | 180 | $37,886.28 |
| Oxycodone Sol 5mg/5ml | 20 | 5,640 | 266 | 13 | $446.02 |
| Oxycodone Powder | 16 | 1,554 | 269 | 9 | $3,069.94 |
| Oxycodone Tab CR 10mg | 3,489 | 219,317 | 100,363 | 1,695 | $285,322.79 |
| Oxycodone Tab CR 20mg | 9,265 | 625,618 | 273,813 | 3,811 | $1,531,090.85 |
| Oxycodone Tab CR 40mg | 9,158 | 664,890 | 270,201 | 3,385 | $2,867,155.67 |
| Oxycodone Tab CR 80mg | 5,942 | 533,920 | 175,897 | 1,774 | $4,312,282.76 |
| Oxycodone Tab CR 160mg | 1 | 90 | 30 | 1 | $1,460.79 |
| **Oxymorphone** | | | | | |
| Oxymorphone Inj 1mg/ml | 1 | 500 | 30 | 1 | $1,436.55 |
| **Propoxyphene** | | | | | |
| Propoxyphene HCl Cap 65mg | 2,159 | 137,496 | 34,352 | 758 | $42,527.10 |
| Propoxyphene Nap Tab 100mg | 231 | 22,714 | 3,505 | 83 | $22,456.53 |
| **Tramadol** | | | | | |
| Tramadol Tab 50mg | 49,236 | 3,689,195 | 858,168 | 17,247 | $416,225.11 |
| **Buprenorphine** | | | | | |
| Buprenorphine Tab 2mg | 2 | 68 | 68 | 2 | $205.39 |
| Buprenorphine Inj 0.325mg/ml | 3 | 60 | 15 | 1 | $210.99 |
| Buprenorphine/Nalox Tab 2-0.5mg | 17 | 1,014 | 428 | 11 | $2,604.01 |
| Buprenorphine/Nalox Tab 8-2mg | 11 | 368 | 338 | 3 | $1,667.07 |
| **Butorphanol** | | | | | |
| Butorphanol Inj 1mg/ml | 1 | 4 | 2 | 1 | $27.49 |
| Butorphanol Inj 2mg/ml | 16 | 92 | 423 | 5 | $610.74 |
| Butorphanol Sol 10mg/ml | 1,000 | 3,772 | 18,492 | 189 | $39,497.08 |
| **Nalbuphine** | | | | | |
| Nalbuphine Inj 10mg/ml | 118 | 6,273 | 986 | 43 | $7,054.86 |
| Nalbuphine Inj 20mg/ml | 84 | 3,294 | 897 | 11 | $4,560.33 |
| **Pentazocine** | | | | | |
| Pentazocine Inj 30mg/ml | 33 | 2,394 | 507 | 9 | $13,855.21 |
| Pentazocine/Nalox Tab | 2,159 | 142,337 | 33,763 | 920 | $104,883.34 |
| **Oxycodone Combinations** | | | | | |
| Oxycodone/APAP Cap 5-500mg | 4,704 | 258,257 | 52,736 | 2,884 | $59,576.00 |
| Oxycodone/APAP Tab 2.5-325mg | 32 | 1,079 | 209 | 31 | $1,312.91 |
| Oxycodone/APAP Tab 5-325mg | 21,541 | 940,135 | 176,575 | 15,548 | $131,528.32 |
| Oxycodone/APAP Tab 5-500mg | 2 | 90 | 50 | 2 | $95.54 |
| Oxycodone/APAP Tab 7.5-325mg | 3,675 | 215,891 | 43,285 | 2,360 | $211,375.50 |
| Oxycodone/APAP Tab 7.5-500mg | 2,723 | 178,305 | 42,777 | 1,456 | $121,835.17 |
| Oxycodone/APAP Tab 10-325mg | 4,950 | 474,835 | 99,853 | 1,852 | $430,165.89 |
| Oxycodone/APAP Tab 10-650mg | 3,549 | 327,729 | 79,185 | 1,216 | $258,809.67 |
| Oxycodone/APAP Sol 5-325mg/5ml | 5 | 1,340 | 39 | 3 | $126.69 |
| Oxycodone/Aspirin Tab | 984 | 71,990 | 18,505 | 435 | $46,462.80 |
| Oxycodone/Ibuprofen 5-400mg | 297 | 7,776 | 2,392 | 253 | $11,146.14 |

| **Codeine Combinations** | | | | | |
|---|---|---|---|---|---|
| APAP/Codeine Tab 300-15mg | 462 | 12,762 | 3,126 | 332 | $2,923.90 |
| APAP/Codeine Tab 300-30mg | 28,392 | 926,200 | 200,647 | 18,340 | $193,204.83 |
| APAP/Codeine Tab 300-60mg | 2,487 | 191,295 | 43,299 | 667 | $40,056.45 |
| APAP/Codeine Tab 650-30mg | 94 | 2,910 | 711 | 74 | $1,656.19 |
| APAP/Codeine Elixir 120-12mg/5ml | 70 | 8,325 | 474 | 65 | $407.89 |
| APAP/Codeine Susp 120-12mg/5ml | 187 | 44,207 | 975 | 155 | $6,204.30 |
| APAP/Codeine Sol 120-12mg/5ml | 19,448 | 2,443,831 | 105,839 | 17,192 | $116,272.75 |
| ASA/Codeine Tab 325-30mg | 37 | 2,693 | 693 | 8 | $419.76 |
| ASA/Codeine Tab 325-60mg | 16 | 1,750 | 459 | 3 | $447.15 |
| **Misc Codeine Combinations** | | | | | |
| APAP/Butalbital/Caffeine/Codeine | 599 | 39,291 | 8,169 | 205 | $27,158.16 |
| ASA/Butalbital/Caffeine/Codeine | 1,564 | 115,882 | 22,090 | 386 | $115,697.37 |
| Panlor DC | 1,174 | 38,454 | 6,727 | 863 | $33,537.46 |
| Panlor SS | 1,955 | 64,289 | 16,291 | 1,342 | $72,618.06 |
| **Hydrocodone Combinations** | | | | | |
| APAP/Hydrocodone Cap 500-5mg | 76 | 4,912 | 785 | 54 | $1,131.51 |
| Hydrocodone/APAP Tab 10-325 | 9,848 | 976,695 | 197,379 | 2,435 | $280,704.63 |
| Hydrocodone/APAP Tab 2.5-500mg | 2,441 | 110,988 | 29,481 | 1,100 | $21,344.79 |
| Hydrocodone/APAP Tab 5-500mg | 81,522 | 3,045,435 | 701,627 | 39,557 | $447,023.61 |
| Hydrocodone/APAP Tab 7.5-500mg | 135,814 | 7,114,126 | 1,691,624 | 43,539 | $912,826.72 |
| Hydrocodone/APAP Tab 10-500mg | 60,286 | 5,160,332 | 1,203,023 | 12,272 | $1,082,775.50 |
| Hydrocodone/APAP Tab 7.5-650mg | 5,660 | 319,288 | 76,565 | 1,852 | $41,709.71 |
| Hydrocodone/APAP Tab 10-650mg | 17,125 | 1,506,971 | 357,003 | 3,847 | $171,071.04 |
| Hydrocodone/APAP Tab 10-660mg | 198 | 15,445 | 4,072 | 64 | $5,219.37 |
| Hydrocodone/APAP Tab 7.5-750mg | 2,889 | 165,051 | 38,086 | 1,212 | $21,596.06 |
| Hydrocodone/APAP Tab 10-750mg | 136 | 6,434 | 1,521 | 100 | $5,771.83 |
| Hydrocodone/APAP Tab 5-325mg | 2,919 | 108,610 | 23,146 | 1,702 | $42,544.15 |
| Hydrocodone/APAP Tab 7.5-325mg | 2,973 | 175,474 | 36,915 | 1,389 | $68,037.19 |
| Hydrocodone/APAP Tab 7.5-400mg | 1 | 90 | 25 | 1 | $58.03 |
| Hydrocodone/APAP Tab 10-400mg | 30 | 4,260 | 766 | 6 | $3,321.94 |
| Hydrocodone/APAP Tab 10-300mg | 376 | 18,216 | 3,969 | 239 | $15,705.68 |
| Hydrocodone/APAP Sol 7.5-325mg | 135 | 33,891 | 890 | 84 | $6,251.71 |
| Hydrocodone/APAP Sol 2.5-167/5ml | 10,558 | 2,930,522 | 70,923 | 7,181 | $173,176.56 |
| Hydrocodone/Ibup Tab 5-200mg | 100 | 4,356 | 952 | 44 | $5,546.34 |
| Hydrocodone/Ibup Tab 7.5-200mg | 4,221 | 219,787 | 57,065 | 1,940 | $194,508.81 |
| **Propoxyphene Combinations** | | | | | |
| Propoxy/ASA/Caffeine 32-389-32mg | 1 | 40 | 6 | 1 | $27.34 |
| Propoxy/ASA/Caffeine 65-389-32mg | 253 | 23,194 | 5,372 | 69 | $16,257.50 |
| Propoxy/APAP Tab 65-650mg | 296 | 17,151 | 3,636 | 157 | $2,292.07 |
| Propoxy-N/APAP Tab 50-325mg | 586 | 25,931 | 5,691 | 363 | $12,984.57 |
| Propoxy-N/APAP Tab 100-325mg | 413 | 19,035 | 4,265 | 305 | $20,912.40 |
| Propoxy-N/APAP Tab 100-500mg | 255 | 19,826 | 4,242 | 98 | $20,672.03 |
| Propoxy-N/APAP Tab 100-650mg | 72,768 | 3,889,714 | 912,511 | 29,134 | $503,089.21 |
| **Misc Combinations** | | | | | |
| Meperidine/Prometh Cap 50-25mg | 113 | 4,211 | 1,163 | 81 | $1,812.72 |
| Pentazocine/APAP 25-650mg | 567 | 31,681 | 7,365 | 253 | $23,619.59 |
| Tramadol/APAP 37.5-325mg | 11,141 | 810,623 | 175,310 | 5,602 | $729,663.29 |

# APPENDIX D

# Vote to Prior Authorize Skeletal Muscle Relaxants

**Oklahoma HealthCare Authority**
**March 2006**

## Recommendations

The College of Pharmacy recommends the addition of the Skeletal Muscle Relaxant class to the Product Based Prior Authorization program. The following Tier-1 drug list has been reviewed and determined to be an acceptable combination for use as initial therapy for the majority of members. The College of Pharmacy recommends this list to the Drug Utilization Review Board for approval before referral to the Oklahoma Healthcare Authority for final limitations or additions based on cost and clinical effectiveness.

| Skeletal Muscle Relaxants | | |
|---|---|---|
| *Tier-1** | *Tier-2* | *Hard PA* |
| cyclobenzaprine (Flexeril®)<br>baclofen (Lioresal®)<br>tizanidine (Zanaflex®)<br>methocarbamol (Robaxin®)<br>chlorzoxazone (Parafon Forte®, Paraflex®)<br>orphenadrine (Norflex®) | metaxolone (Skelaxin®) | carisoprodol (Soma®)<br>carisoprodol w aspirin<br>carisoprodol, ASA, codeine |

*Brand products are subject to the Brand Name Override where generic is available.

The following criteria are recommended for approval of a Tier-2 product:

1. FDA approved indication. Skeletal muscle relaxants are recommended as adjunct to rest, and/or physical therapy for the relief of musculoskeletal pain.
2. Documentation of failed withdrawal attempt within past three months defined as increase in pain and debilitating symptoms when medication was discontinued.
3. Failure with at least two Tier-1 medications within the past 90 days defined as no beneficial response after at least two weeks of use during which time the drug has been titrated to the recommended dose.
4. Approvals will be for the duration of three months, except for members with chronic diseases such as multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or other chronic musculoskeletal diagnosis confirmed with diagnostic results, in which case authorizations will be for the duration of one year.

The following criteria are recommended for approval of carisoprodol or carisoprodol combination products:

A cumulative 90 therapy day window per 365 days will be in place for these products, further approval will be based on the following:

1. An additional approval for 1 month will be granted to allow titration or change to a Tier-1 muscle relaxant, further authorization will not be granted, or
2. Indication of multiple sclerosis, cerebral palsy, muscular dystrophy, and/or paralysis with approvals granted for the duration of one year.

# APPENDIX E

# Vote to Prior Authorize Ultram® ER (tramadol HCl) Extended-Release Tablets and Ultram® ODT (tramadol HCl) Orally Disintegrating Tablets

**Oklahoma Health Care Authority**
**March 2006**

| | |
|---|---|
| **Manufacturer** | Biovail Corporation |
| **Distributor** | PriCara, Unit of Ortho-McNeil, Inc. |
| **Classification** | Centrally acting synthetic opioid analgesic<br>Status: prescription only |


## Summary

Ultram® ER is an extended release form of tramadol. It is indicated for the treatment of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time (up to 300mg/day).

Ultram® ODT is an orally disintegrating formulation of tramadol. It is indicated for the treatment of moderate to moderately severe pain in adults and will be available in a 50 mg dosage form. It is expected to be launched in the second quarter of 2006.


## Recommendations

The College of Pharmacy recommends Prior Authorization of Ultram® ER and ODT. Criteria for approval of the ER formulation would include an FDA approved diagnosis for the use of Ultram® ER, a diagnosis indicating that the member has a condition that requires extended pain treatment with an around-the-clock dosing schedule, the reason immediate release tramadol is inappropriate, and the physician's signature. Maximum covered dose of 300 mg daily due to lack of efficacy and increased risk for side effects and seizures.

Criteria for approval of the ODT formulation would include an FDA approved diagnosis for the use of Ultram® ODT, a diagnosis indicating that the member has a condition that prevents them from swallowing tablets, and the physician's signature.

Approvals will be for 90 days, with the exception of members with a cancer related diagnosis where an approval will be granted for one year.

The College of Pharmacy also recommends quantity limits of 30 units for 30 days for the ER and 240 units for 30 days for the ODT (unless another FDA dosage is approved). Currently Ultram® has a quantity limit of 240 units for 30 days.

**Cost comparison**

| | Estimated Acquisition Cost (EAC) / Unit | Daily Dose | Monthly Dose (30 day supply) | Cost for 30 day supply |
|---|---|---|---|---|
| Tramadol 50 mg tablets | $ 0.05488* | Up to 400 mg | 240 tablets | $ 13.17 |
| Ultram® 50 mg tablets | $ 1.16670 | Up to 400 mg | 240 tablets | $ 280.01† |
| Ultram® ER 100mg tablets | $ 2.86000 | Up to 300mg | 30 tablets | $ 85.80 |
| Ultram® ER 200mg tablets | $ 4.73000 | Up to 200mg | 30 tablets | $ 141.90 |
| Ultram® ER 300mg tablets | $ 6.60000 | Up to 300mg | 30 tablets | $ 198.00 |
| Ultram® ODT | Unavailable | Unavailable | Unavailable | Unavailable |

*SMAC Pricing
†DAW Rule Applies

**Reference**


1. Ultram® ER Prescribing Information. PriCara, Unit of Ortho-McNeil, Inc. 2005.
2. Biovail, Ortho-McNeil Partnership Receives Hart-Scott-Rodino Regulatory Clearance. December 2, 2005. Available at: http://www.biovail.com/english/Investor%20Relations/Latest%20News/default.asp?s=1&state=showrelease&releaseid=792341. Accessed January 28, 2006.

# APPENDIX F

# Prior Authorization Annual Review – Fiscal Year 2005
## Plavix®
**Oklahoma Health Care Authority**
**March 2006**

### Category Criteria for FY'04

Plavix® requires prior authorization for all members. Plavix® therapy will be approved for members meeting approved diagnostic criteria that have failed aspirin therapy (due to either side effects or event recurrence), or have a documented aspirin allergy, or use Plavix® concomitantly with aspirin. The approved diagnoses are as follows:

- Recent stroke
- Recent myocardial infarction
- Established peripheral artery disease
- Acute coronary syndrome (unstable angina/non-Q-wave MI)
- Percutaneous coronary intervention with stent placement (aspirin trial not required)
- Transient ischemic attacks

Members are approved for 12 months of therapy per authorization.

### Utilization

For the period of July 2003 through June 2004, a total of 6,657 members received Plavix® through the fee-for-service program.

| Product | # of Claims | Total Units | Total Days | Total Cost | Per Diem |
|---|---|---|---|---|---|
| *Plavix® 75 mg* | 33,293 | 1,321,921 | 1,315,540 | $ 5,385,643.91 | $ 4.09 |

| | *Fiscal Year 2004* | *Fiscal Year 2005* | *Percent Change* | |
|---|---|---|---|---|
| **Total Cost** | **$ 3,956,165.24** | **$ 5,385,643.91** | **Increased** | **36.1%** |
| **Total Claims** | **24,721** | **33,293** | **Increased** | **34.7%** |
| **Total Members** | **5,429** | **6,657** | **Increased** | **22.6%** |
| **Per Diem** | **$ 3.93** | **$ 4.09** | **Increased** | **4.1%** |

| | # of Members | # of Claims | Total Units | Total Days | Total Cost | Per Diem |
|---|---|---|---|---|---|---|
| *Duals* | 5,345 | 27,356 | 1,082,858 | 1,078,481 | $ 4,409,573.34 | $ 4.09 |
| *Non-Duals* | 1,312 | 5,937 | 239,063 | 237,059 | $ 976,070.57 | $ 4.12 |

Total petitions submitted in for this category during specified time period:

| | |
|---|---|
| *Approved* | *7,994* |
| Denied | 2,045 |
| Incomplete | 2,187 |
| Number of denied/incomplete petitions later approved | 3,649 |

| Plavix Members | | |
|---|---|---|
| Age | Female | Male |
| 0 to 9 | 0 | 0 |
| 10 to 19 | 3 | 2 |
| 20 to 34 | 21 | 13 |
| 35 to 49 | 283 | 236 |
| 50 to 64 | 1,143 | 680 |
| 65 to 79 | 1,770 | 767 |
| 80 to 94 | 1,341 | 298 |
| 95 and over | 87 | 13 |
| **Totals** | **4,648** | **2,009** |

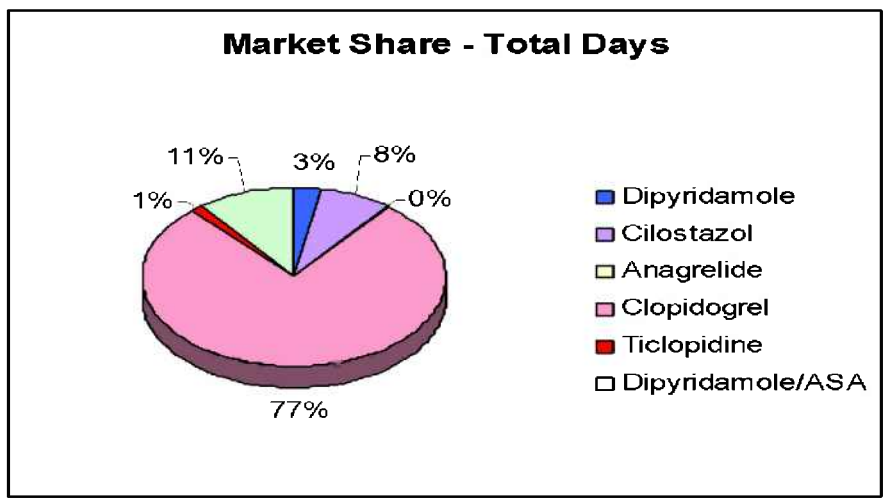
| Non Dual Plavix Members | | |
|---|---|---|
| Age | Female | Male |
| 0 to 9 | 0 | 0 |
| 10 to 19 | 3 | 2 |
| 20 to 34 | 13 | 12 |
| 35 to 49 | 152 | 107 |
| 50 to 64 | 492 | 349 |
| 65 to 79 | 57 | 36 |
| 80 to 94 | 64 | 18 |
| 95 and over | 5 | 2 |
| **Totals** | **786** | **526** |

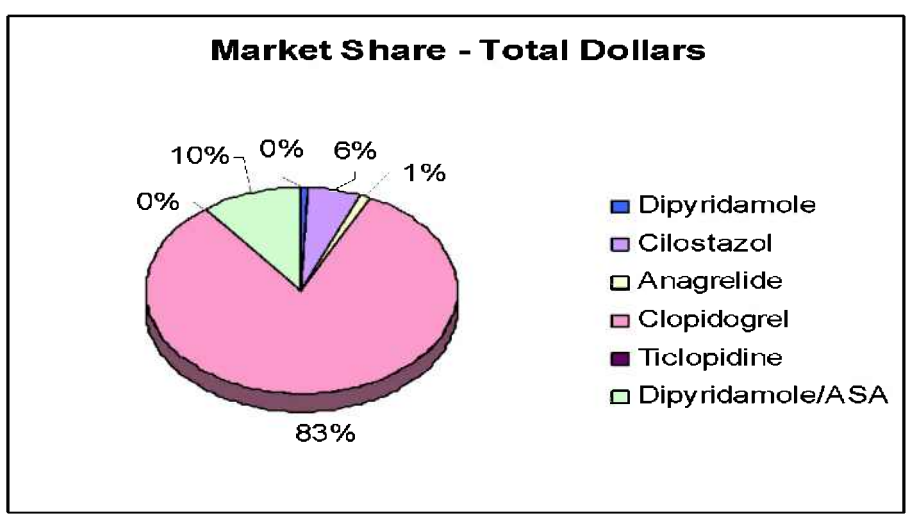
## Non-Dual Anti-platelet Use

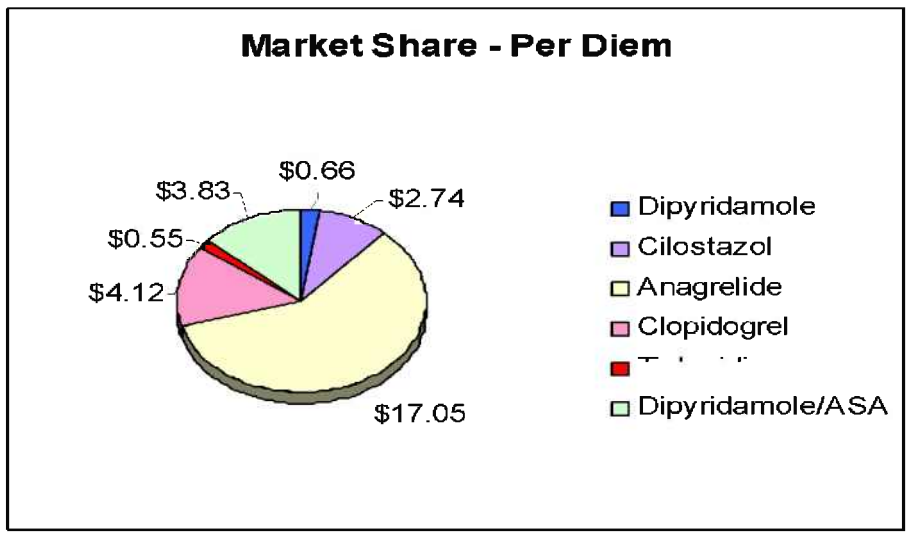
| Non-dual Anti-platelet Members | | |
|---|---|---|
| Age | Female | Male |
| 0 to 9 | 4 | 0 |
| 10 to 19 | 6 | 4 |
| 20 to 34 | 25 | 13 |
| 35 to 49 | 199 | 132 |
| 50 to 64 | 613 | 440 |
| 65 to 79 | 76 | 54 |
| 80 to 94 | 80 | 25 |
| 95 and over | 8 | 3 |
| **Totals** | **1,011** | **671** |

Non-Dual anti-platelet utilization in number of claims, total units, total days, total dollars, and per diem.

| Product | # of Claims | Total Units | Total Days | Total Cost | Per Diem |
|---|---|---|---|---|---|
| *Dypridamole* | 248 | 27,510 | 8,423 | $ 5,571.68 | $0.66 |
| *Cilostazol* | 707 | 44,676 | 24,085 | $ 66,079.62 | $2.74 |
| *Anagrelide* | 31 | 2,926 | 902 | $ 15,378.01 | $17.05 |
| *Clopidogrel* | 5,937 | 239,063 | 237,059 | $ 976,070.57 | $4.12 |
| *Ticlopidine* | 107 | 7,348 | 3,584 | $ 1,963.69 | $0.55 |
| *Dipyridamole/ASA* | 1,017 | 60,996 | 32,455 | $ 124,380.12 | $3.83 |






## Recommendations

At this time, the College of Pharmacy does not recommend any changes to the prior authorization of Plavix®.

# APPENDIX G

# Annual Review of Xolair® for Fiscal Year 2005

**Oklahoma Health Care Authority**
**March 2006**

## Prior Authorization of Xolair® (Omalizumab)

Xolair®, marketed on June 20, 2003, is a recombinant DNA-derived humanized monoclonal antibody that selectively binds to human immunoglobulin E (IgE). Xolair® inhibits the binding of IgE to the high-affinity IgE receptor on the surface of mast cells and basophils. Reduction in surface-bound IgE on FcεRI-bearing cells limits the degree of release of mediators of the allergic response.[i]

Xolair® is indicated for adults and adolescents (12 years of age and older) with moderate to severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with ICS. Safety and efficacy have not been established in other allergic conditions.

Prior Authorization of this category was implemented on February 17, 2004. The approval criteria for Xolair® are as follows:

1. Member must be between 12-75 years of age.
2. Member must have a diagnosis of severe persistent asthma (as per NAEPP guidelines).
3. Member must have a positive skin test to at least one perennial aeroallergen. Positive perennial allergens must be listed on the petition.
4. Member must have a pretreatment serum IgE level between 30-700 IU/ml.
5. Member weight must be between 30-150kg.
6. Member must have been on high dose ICS (as per NAEPP Guidelines) for at minimum the past 3 months.
7. Medication must be prescribed by either a pulmonary or an allergy/asthma specialist.
8. Member must have been in the ER or hospitalized, due to an asthma exacerbation, twice in the past 6 months (date of visits must be listed on petition), or have been determined to be dependent on systemic steroids to prevent serious exacerbations.

A Universal Petition must be submitted along with a Statement of Medical Necessity for Xolair[1] which specifically requests the above required information.

### Approval Guidelines:

- Petitions meeting criteria for coverage will be approved for 12 months of therapy.
- Renewal petitions after 12 months will be assessed for client compliance. If two or more doses have been missed, the member will not be approved for continuing therapy.

## Utilization of Xolair®

[1] Please see **Attachment A**

For the period of July 2004 through June 2005, a total of 5 members received Xolair® through the Medicaid fee-for-service program.

| *Product* | *Claims* | *Units* | *Days* | *Units/Day* | *Total Cost* | *Clients* | *Per-Diem* |
|---|---|---|---|---|---|---|---|
| Xolair® | 42 | 132 | 1,176 | 0.11 | $ 65,927.04 | 5 | $ 56.06 |

| | *Fiscal Year 2004* | *Fiscal Year 2005* | *Percent Change* | |
|---|---|---|---|---|
| **Total members** | **19** | **5** | **Decreased** | **73.7 %** |
| **Total Claims** | **90** | **42** | **Decreased** | **53.3 %** |
| **Total Cost** | **$ 147,027.15** | **$ 65,927.04** | **Decreased** | **55.2 %** |
| **Cost per Claim** | **$ 1,633.64** | **$ 1,569.69** | **Decreased** | **3.91 %** |
| **Per-Diem Cost** | **$ 57.75** | **$ 56.06** | **Decreased** | **2.92 %** |
| **Cost per Member** | **$ 7,738.27** | **$ 13,185.41** | **Increased** | **70.4 %** |
| **Total Units** | **308** | **132** | **Decreased** | **57.1 %** |
| **Total Days** | **2,546** | **1,176** | **Decreased** | **53.8 %** |

There were 29 total petitions submitted by 15 members for this category during fiscal year 2005:

**Approved ..... 6**
**Denied ..... 12**
**Incomplete .....11**

The table below shows the prior authorization status of 15 members who submitted petitions for Xolair® and the criteria which were not met.

| Criteria | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Age between 12-75 years | D/A | | | | A | A | I/A | D/A | | | | | N | | N |
| Dx - severe persistent asthma | D/A | N | | N | A | A | I/A | D/A | N | | | | | N | |
| Positive skin test to perennial aeroallergen. | D/A | N | | N | A | A | I/A | D/A | N | N | | | | N | |
| IgE level between 30-700 IU/ml | D/A | | | | A | A | I/A | D/A | | | | N | N | N | N |
| Weight between 30-150kg | D/A | | | | A | A | I/A | D/A | N | | | | | | |
| Compliant on high dose ICS for at minimum the past 3 months | D/A | N | N | | A | A | I/A | D/A | | N | N | N | N | N | N |
| Prescribed by specialist | D/A | | | | A | A | I/A | D/A | | | N | | | N | |
| ER or hospitalization | D/A | | N | | A | A | I/A | D/A | N | N | | | | N | N |

N = criteria not met
I = incomplete, information not submitted.
D/A = client originally denied but approved upon appeal.

Claims were reviewed to determine the age/gender of the members.

| Age | 0 - 9 | 10 - 19 | 20 - 34 | 35 - 49 | 50 - 64 | 65 - 79 | 80 - 94 | > 95 |
|---|---|---|---|---|---|---|---|---|
| Males | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| Females | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |

## Asthma and Allergy related cost

Asthma and allergy related cost data were also reviewed for the 5 members who received Xolair®. The total cost for asthma and allergy related medical and hospital claims before the member received Xolair® was compared with the total cost for asthma and allergy related medical and hospital claims. The total amount paid for Xolair® for the selected time period were also included. The following table shows the summary of costs.

| Asthma and Allergy Related Medical and Hospital Costs | | |
|---|---|---|
| 6-12 months Before | 6-12 months After | Cost of Xolair® |
| $5,610.21 | $649.43 | $18,299.10 |
| $1,082.13 | $477.28 | $2,989.75 |
| $1,154.86 | $1,523.20 | $23,410.99 |
| $582.66 | $1,101.88 | $11,932.35 |
| $1,401.38 | $1,583.72 | $7,255.76 |
| $9,831.24 | $5,335.51 | $63,887.95 |

There were 5 fewer hospitalizations (ER visits and hospitalizations) in the 6-12 month after Xolair® was started.

## Conclusions and Recommendations

During FY 2004, the majority of members using Xolair® were started on therapy before the prior authorization was implemented. A significant number of those members did not meet one or more of the clinical criteria and have discontinued therapy. The decrease in the number of members from FY 2004 to FY 2005 was expected.

The College of Pharmacy recommends continuation of the Xolair® prior authorization program with no changes to the current criteria.

[1] Genentech/Novartis Pharmaceuticals. Package Literature Xolair®. March 2005. Available online at: http://www.xolair.com/hcp/prescribing_information.jsp

Attachment A

# Oklahoma Medicaid Prescription Drug Program
# Statement of Medical Necessity for Xolair

Pharmacy Management Consultants
Prior Authorization Unit

Phone: 405-271-6349 or 1-800-831-8921
Fax: 405-271-4014 or 800-224-4014

After completing the request form please **fax** to Pharmacy Management Consultants to process this authorization.

**PART 1: TO BE COMPLETED BY PHYSICIAN**

| PHYSICIAN INFORMATION | CLIENT INFORMATION |
|---|---|
| Physician Name: | Client ID Number: |
| Address: | Patient Name: |
| City: State: Zip: | Address: |
| Phone ( ) | City: State: Zip: |
| FAX ( ) | Patient's date of birth: / / |

**Compliance with all of the prior authorization criteria is a condition for payment for this drug by Oklahoma Medicaid.**

**All information must be provided and Oklahoma Medicaid may verify through further requested documentation and the client's drug history will be reviewed prior to approval.**

1. **Detailed description of diagnosis:** _____
2. **Date diagnosed:** _____
3. **List daily medications and dose prescribed for the treatment of this diagnosis:**

   **Drug/Dose:** _____ **Drug/Dose:** _____

   **Drug/Dose:** _____ **Drug/Dose:** _____
4. **Was a spacer for inhaled medications used?** _____ **If 'No', why not?** _____
5. **Compliant on daily inhaled corticosteroids for a minimum of 3 months prior to request?** _____
6. **List frequency of: Exacerbations – Number** _____**Per**_____**; AND Nightly Symptoms -- Number** _____**Per**_____
7. **List place and dates of asthma related hospitalizations and/or ER visits in the past 6 months:** _____

   _____
8. **Patients weight:** _____**kg; Baseline IgE Level:** _____**IU/ml; Xolair Dose:** _____
9. **Asthma reaction due to food or peanut allergy?** _____**; Or List the perennial aeroallergen** _____
10. **Physician's specialty?** _____

**The above format is to assist the physician to provide medical documentation that Oklahoma Medicaid needs to review this request.**

**This information should come directly from the prescriber and NOT the pharmacy provider.**

**** Please provide copies of medical documentation supporting the information above.**

**Physician Signature:** _____ **Date:** _____

**(By signature, the physician confirms the criteria information above is accurate and verifiable in patient records.)**

# APPENDIX H

# Review of Diabetes in the Oklahoma SoonerCare Population

**Oklahoma HealthCare Authority**
**March 2006**

## Introduction

Diabetes is an insidious disease which affects a large number of Oklahomans at an ever-increasing cost to the state's healthcare system. Total prevalence of diabetes is estimated to be 7.0% of the population of the United States.[1] In Oklahoma, the estimated number of adults with diabetes is 402,566 with only half that number having been officially diagnoses. It is the 7th leading cause of death, and over 1,800 Oklahomans die from diabetes each year. Oklahoma ranks 35th in the nation with 11.3% age-adjusted rate per 100,000 population and 19.4% per 100,000 standardized population crude death rate.[2]

In 2002, the total annual economic cost of diabetes was an estimated $132 billion. The direct expenditures on medical care for diabetes were $92 billion with $23.2 billion for the care of diabetes itself and an additional $24.6 billion for chronic diabetes-related complications. Indirect costs from lost workdays, restricted activity, permanent disability and mortality totaled $40.8 billion.[3]

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### Diabetes

There are two main classifications of diabetes: Type 1 and 2. Type 1 is caused by the destruction of β-cells leading to an absolute deficiency of insulin. Type 2 develops from increased insulin resistance and progresses to secretory defects of insulin itself. Other causes can include genetic defects of the β-cells or insulin action, diseases of the pancreas, drug/chemical causes, or organ transplantation.

Diagnosis can be made in three ways with the oral glucose tolerance test (OGTT) being the most sensitive and specific.

1. Casual plasma glucose 200 mg/dl and accompanying symptoms of diabetes, or
2. Fasting Plasma Glucose (FPG) 126 mg/dl, or
3. 2-hr plasma glucose 200 mg/dl during an OGTT[4]

Testing for diabetes should be considered in all individuals age 45 and over, especially with a BMI of 25 $km/m^2$ or more. If normal, the test should be repeated every three years. More frequent or earlier testing should be done in individuals who have additional risk factors and are overweight[4].

- Habitually inactive
- First-degree relative with diabetes
- Members of high-risk ethnic population
- Delivery of baby weighing over 9 pounds or have been diagnosed with gestational diabetes (GDM)
- Hypertensive
- HDL level of less than 35 mg/dl or triglyceride levels greater than 250 mg/dl
- Polycystic ovary disease (PCOS)
- Previously testing positive for impaired fasting glucose (IFG) or impaired glucose tolerance (IGT)
- Other conditions associated with insulin resistance
- History of vascular disease

### Diabetic Complications

The complications that arise due to the presence of diabetes are often serious or life-threatening and may be diagnosed before the diabetes itself. The following are the most common complications arising from diabetes[5]:

- Increased risk for infections which can lead to amputations
- Cataracts, glaucoma and retinopathy
- Diabetic neuropathy
- Heart Disease
  - Hypertension
  - Atherosclerosis
  - Stroke
- Hyperglycemic hyperosmolar nonketotic syndrome
- Diabetic ketoacidosis
- Diabetic nephropathy

## Treatment of Diabetes

There is no cure for diabetes. The goal of treatment is to maintain blood glucose at normal levels and reduce the risk for the complications of diabetes.

### Glycemic Control

Recommended Blood Glucose Range[4]:

- Before meals (preprandial) 90-130 mg/dL
- After meals (postprandial) <180mg/dL
- HgA1c (every 3 months) <7%

### Pharmacological Treatment

Oral Medication[6]:

- sulfonylureas (Amaryl®, Micronase® and Glucotrol®)
- biguanides (Glucophage® and Glucophage® XL)
- sulfonylureas and biguanide combination drugs (Glucovance®, Metaglip)
- thiazolidinediones (Actos® and Avandia®)
- alpha-glycosidase inhibitors (Precose® and Glyset®)
- meglitinides (Prandin® and Starlix®)

Insulin:

- rapid-acting (Humalog®, Novolog®)
- short-acting (Regular Humulin®)
- intermediate-acting (NPH, Lente)
- long-acting (Ultralente, Lantus®)
- pre-mixed (Humulin® 70/30, Humalog ®mix 75/25)
- inhalable (Exubera®)

Other:

- incretin mimetics (Byetta®)
- amylin hormone (Symlin®)

Future Treatments[7,8,9].

- glucokinase activators
- fructose 1,6 biophosphatase inhibitors
- glycogen phosphorylase inhibitors
- protein tyrosine phosphatase 1B inhibitors
- dipeptidyl peptidase-4 (DDP-4) inhibitor
- sodium-dependent glucose (co-) transporter (SGLT) inhibitors

## Utilization of Diabetes Medications

During fiscal year 2005 a total of **$ 21,046,702.00** was spent on diabetes medications for a total of 29,617 members.

**Trends in Utilization of Diabetes Medications**

| | *Fiscal Year 2004* | *Fiscal Year 2005* | *Percent Change* | |
|---|---|---|---|---|
| **Total Members** | **27,622** | **29,617** | **Increased** | **7.2 %** |
| **Total Claims** | **242,824** | **284,437** | **Increased** | **17.1 %** |
| **Total Cost** | **$ 17,199,091.57** | **$ 21,046,702.00** | **Increased** | **22.4 %** |
| **Cost per Claim** | **$ 70.83** | **$ 73.99** | **Increased** | **4.5 %** |
| **Per-Diem Cost** | **$ 2.11** | **$ 2.21** | **Increased** | **4.7 %** |
| **Total Units** | **12,491,119** | **14,358,763** | **Increased** | **15.0 %** |
| **Total Days** | **8,143,127** | **9,522,958** | **Increased** | **16.9 %** |

**Utilization of Diabetes Medications: Solid Dosage Forms**

| DRUGNAME | CLAIMS | UNITS | DAYS | MEMBERS | COST | COST/ DAY | UNITS/ DAY |
|---|---|---|---|---|---|---|---|
| Chlorpropamide 100 mg | 35 | 1,840 | 1,146 | 7 | $312.07 | $0.27 | 1.61 |
| Chlorpropamide 250 mg | 153 | 8,932 | 6,316 | 26 | $2,154.21 | $0.34 | 1.41 |
| **Chlorpropamide** | **188** | **10,772** | **7,462** | | **$2,466.28** | **$0.33** | **1.44** |
| Glimepiride 1 mg | 513 | 18,909 | 18,310 | 166 | $7,965.72 | $0.44 | 1.03 |
| Glimepiride 2 mg | 3,407 | 160,573 | 132,579 | 1,080 | $97,047.53 | $0.73 | 0.13 |
| Glimepiride 4 mg | 6,376 | 382,374 | 256,941 | 1,949 | $399,597.83 | $1.56 | 1.49 |
| **Glimepiride** | **10,296** | **561,856** | **407,830** | | **$504,611.08** | **$1.24** | **1.02** |
| Glipizide 5 mg | 6,240 | 361,954 | 219,044 | 1,360 | $38,985.69 | $0.18 | 1.65 |
| Glulcotrol 10 mg | 6,024 | 412,132 | 209,477 | 1,205 | $49,466.93 | $0.24 | 1.97 |
| Glucotrol XL 2.5 mg | 1,499 | 64,627 | 56,857 | 402 | $28,441.75 | $0.50 | 1.14 |
| Glucotrol XL 5 mg | 6,333 | 355,505 | 248,833 | 1,388 | $137,681.43 | $0.55 | 1.43 |
| Glucotrol XL 10 mg | 9,725 | 602,831 | 381198 | 1,976 | $396,717.30 | $1.04 | 1.58 |
| **Glipizide** | **29,821** | **1,797,049** | **1,115,409** | | **$651,293.10** | **$0.58** | **1.61** |
| Glyburide 1.25 mg | 359 | 16,747 | 13,595 | 89 | $2,325.67 | $0.17 | 1.23 |
| Glyburide 2.5 mg | 3,542 | 175,307 | 127,469 | 866 | $27,192.45 | $0.21 | 1.38 |
| Glyburide 5 mg | 15,881 | 1,290,931 | 532,962 | 2,955 | $195,720.24 | $0.37 | 2.42 |
| Glyburide Micro 1.5 mg | 15 | 862 | 762 | 6 | $90.77 | $0.12 | 1.13 |
| Glyburide Micro 3 mg | 705 | 44,884 | 24,462 | 134 | $9,284.13 | $0.38 | 1.83 |
| Glyburide Micro 6 mg | 775 | 53,157 | 28,470 | 117 | $6,844.44 | $0.24 | 1.87 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Glyburide** | 21,277 | 1,581,888 | 727,720 | | $241,457.70 | $0.33 | 2.17 |
| Tolazamide 100 mg | 16 | 540 | 540 | 2 | $242.25 | $0.45 | 1.00 |
| Tolazamide 250 mg | 15 | 630 | 495 | 2 | $262.72 | $0.53 | 1.27 |
| Tolazamide 500 mg | 5 | 500 | 150 | 1 | $371.40 | $2.48 | 3.33 |
| **Tolazamide** | 36 | 1,670 | 1,185 | | $876.37 | $0.74 | 1.41 |
| Tolbutamide 500 mg | 141 | 8,120 | 4,232 | 20 | $1,280.56 | $0.30 | 1.92 |
| **Tolbutamide** | 141 | 8,120 | 4,232 | | $1,280.56 | $0.30 | 1.92 |
| Starlix 60 mg | 211 | 20,107 | 6,385 | 54 | $22,989.60 | $3.60 | 3.15 |
| Starlix 120 mg | 1,740 | 153,894 | 54,290 | 337 | $181,405.89 | $3.34 | 2.83 |
| **Starlix** | 1,951 | 174,001 | 60,675 | | $204,395.49 | $3.37 | 2.87 |
| Metformin 500 mg | 37,538 | 2,902,782 | 1,243,574 | 7,829 | $429,728.02 | $0.35 | 2.33 |
| Metformin 850 mg | 3,554 | 253,208 | 123,194 | 784 | $45,563.65 | $0.37 | 2.06 |
| Metformin 1000 mg | 15,871 | 1,078,593 | 552,250 | 3,328 | $238,926.22 | $0.43 | 1.95 |
| Metformin ER 500 mg | 6,741 | 553,055 | 236,495 | 1,380 | $145,234.71 | $0.61 | 2.34 |
| Metformin ER 750 mg | 201 | 11,580 | 7,149 | 63 | $10,554.49 | $1.48 | 1.62 |
| Fortamet 500 mg | 263 | 15,714 | 9,494 | 56 | $14,307.54 | $1.51 | 1.66 |
| Fortamet 1000 mg | 268 | 15,270 | 10,684 | 79 | $30,005.87 | $2.81 | 1.43 |
| **Metformin** | 64,436 | 4,830,202 | 2,182,840 | | $914,320.50 | $0.42 | 2.21 |
| Prandin 0.5 mg | 261 | 21,006 | 8,006 | 56 | $24,408.99 | $3.05 | 2.62 |
| Prandin 1 mg | 261 | 20,963 | 7,472 | 46 | $23,697.51 | $3.17 | 2.81 |
| Prandin 2 mg | 567 | 65,785 | 17,588 | 101 | $73,454.55 | $4.18 | 3.74 |
| **Prandin** | 1,089 | 107,754 | 33,066 | | $121,561.05 | $3.68 | 3.26 |
| Precose 25 mg | 216 | 18,511 | 6,657 | 60 | $13,326.11 | $2.00 | 2.78 |
| Precose 50 mg | 224 | 19,210 | 7,250 | 61 | $15,061.34 | $2.08 | 2.65 |
| Precose 100 mg | 85 | 7,333 | 2,586 | 17 | $6,884.59 | $2.66 | 2.84 |
| **Precose** | 525 | 45,054 | 16,493 | | $35,272.04 | $2.14 | 2.73 |
| Glyset 25 mg | 196 | 19,842 | 6,601 | 37 | $14,035.07 | $2.13 | 3.01 |
| Glyset 50 mg | 37 | 2,890 | 1,110 | 13 | $2,276.00 | $2.05 | 2.60 |
| Glyset 100 mg | 4 | 400 | 266 | 2 | $361.32 | $1.36 | 1.50 |
| **Glyset** | 237 | 23,132 | 7,977 | | $16,672.39 | $2.09 | 2.90 |
| Actos 15 mg | 4,490 | 199,587 | 189,560 | 1,169 | $671,496.24 | $3.54 | 1.05 |
| Actos 30 mg | 7,255 | 322,285 | 320,922 | 1,855 | $1,725,736.26 | $5.38 | 1.00 |
| Actos 45 mg | 5,616 | 257,927 | 257,281 | 1,329 | $1,501,833.97 | $5.84 | 1.00 |
| **Actos** | 17,361 | 779,799 | 767,763 | | $3,899,066.47 | $5.08 | 1.02 |
| Avandia 2 mg | 2,310 | 122,595 | 83,293 | 644 | $243,560.88 | $2.92 | 1.47 |
| Avandia 4 mg | 15,321 | 753,675 | 595,207 | 3,408 | $2,117,483.62 | $3.56 | 1.27 |
| Avandia 8 mg | 11,182 | 509,372 | 507,738 | 2,544 | $2,632,301.20 | $5.18 | 1.00 |
| **Avandia** | 28,813 | 1,385,642 | 1,186,238 | | $4,993,345.70 | $4.21 | 1.17 |
| Metaglip 2.5 mg / 250 mg | 59 | 5,275 | 1,953 | 10 | $4,399.76 | $2.25 | 2.70 |
| Metaglip 2.5 mg / 500 mg | 378 | 36,363 | 13,718 | 83 | $35,081.90 | $2.56 | 2.65 |
| Metaglip 5 mg / 500 mg | 568 | 54,120 | 19,618 | 122 | $52,867.56 | $2.69 | 2.76 |
| **Metaglip** | 1,005 | 95,758 | 35,289 | | $92,349.22 | $2.62 | 2.71 |
| Glyburide / Metformin 1.25 mg / 250 mg | 774 | 53,068 | 28,893 | 147 | $27,084.89 | $0.94 | 1.84 |
| Glyburide / Metformin 1.25 mg / 250 mg | 3,180 | 268,820 | 113,202 | 609 | $173,619.70 | $1.53 | 2.37 |
| Glyburide / Metformin 1.25 mg / 250 mg | 6,875 | 641,412 | 226,368 | 1,215 | $369,008.24 | $1.63 | 2.83 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Glyburide / Metformin** | **10,829** | **963,300** | **368,463** | | **$569,712.83** | **1.55** | **2.61** |
| Actoplus Met 15 mg / 500 mg | 12 | 690 | 420 | 9 | $1,771.50 | 4.22 | 1.64 |
| Actoplus Met 15 mg / 850 mg | 12 | 860 | 460 | 11 | $2,051.65 | 4.46 | 1.87 |
| **Actoplus Met** | **24** | **1,550** | **880** | | **$3,823.15** | **4.34** | **1.76** |
| Avandamet 1 mg / 500 mg | 208 | 14,106 | 7,106 | 92 | $15,657.51 | 2.20 | 1.99 |
| Avandamet 1 mg / 500 mg | 1,787 | 137,850 | 63,492 | 610 | $226,543.01 | 3.57 | 2.17 |
| Avandamet 1 mg / 500 mg | 415 | 25,441 | 13,950 | 169 | $55,671.06 | 3.99 | 1.82 |
| Avandamet 1 mg / 500 mg | 1,446 | 99,317 | 53,081 | 449 | $263,953.08 | 4.97 | 1.87 |
| Avandamet 1 mg / 500 mg | 970 | 65687 | 35380 | 379 | $214,722.55 | 6.07 | 1.86 |
| **Avandamet** | **4,826** | **342,401** | **173,009** | | **$776,547.21** | **4.49** | **1.98** |
| TOTALS | 192,855 | 12,709,948 | 7,096,531 | | $13,029,051.14 | 1.84 | 1.77 |

## Utilization of Diabetic Medications: Injectable Dosage Forms

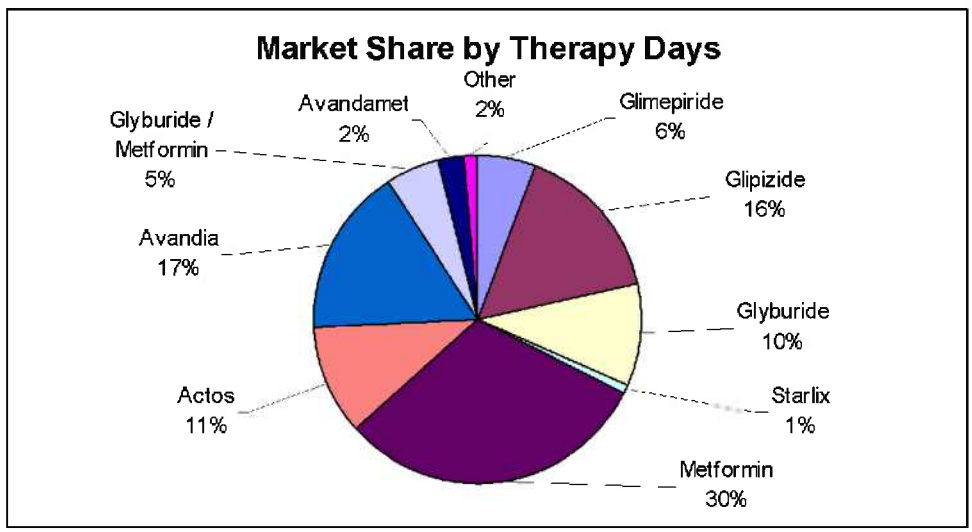
| DRUGNAME | CLAIMS | UNITS | DAYS | MEMBERS | COST | COST/ DAY |
|---|---|---|---|---|---|---|
| Insulin NPH (Pork) | 2 | 30 | 70 | 2 | $95.16 | $1.36 |
| Novolin R | 13,769 | 187,545 | 305,905 | 5,013 | $577,803.52 | $1.89 |
| Novolin N | 15,281 | 294,176 | 423,727 | 3,592 | $884,316.27 | $2.09 |
| Humulin R | 38 | 1,210 | 1,275 | 9 | $11,767.69 | $9.23 |
| Humulin L | 151 | 2,700 | 3,617 | 33 | $8,253.31 | $2.28 |
| Humulin U | 599 | 11,440 | 16,757 | 151 | $34,336.33 | $2.05 |
| Humulin 50/50 | 160 | 2,770 | 4,829 | 43 | $8,284.76 | $1.72 |
| Novolin 70/30 | 18,153 | 404,200 | 503,948 | 3,579 | $1,235,518.77 | $2.45 |
| Novolog Penfill | 4,633 | 87,008 | 113,971 | 1,241 | $637,806.47 | $5.60 |
| Novolog 70/30 | 1,207 | 27,797 | 34,525 | 429 | $215,707.16 | $6.25 |
| Lantus | 23,758 | 381,687 | 676,305 | 5,292 | $2,416,680.64 | $3.57 |
| Humalog Pen | 8,807 | 169,057 | 245,856 | 2,302 | $1,182,792.47 | $4.81 |
| Humalog Pen 75/25 | 2,646 | 59,551 | 70,565 | 500 | $421,076.24 | $5.97 |
| Symlin | 24 | 330 | 582 | 6 | $5,800.31 | $9.97 |
| Byetta | 432 | 1,766 | 12,454 | 219 | $111,811.47 | $8.98 |
| Glucogon Kit 1 mg | 1,409 | 2,458 | 8,670 | 684 | $196,645.39 | $22.68 |
| Glucogen Hypokit | 6 | 8 | 17 | 4 | $672.24 | $39.54 |
| Glucogen 1 mg | 414 | 664 | 710 | 194 | $45,751.11 | $64.44 |
| TOTALS | 91,489 | 1,634,397 | 2,423,783 | | $7,995,119.31 | $3.30 |

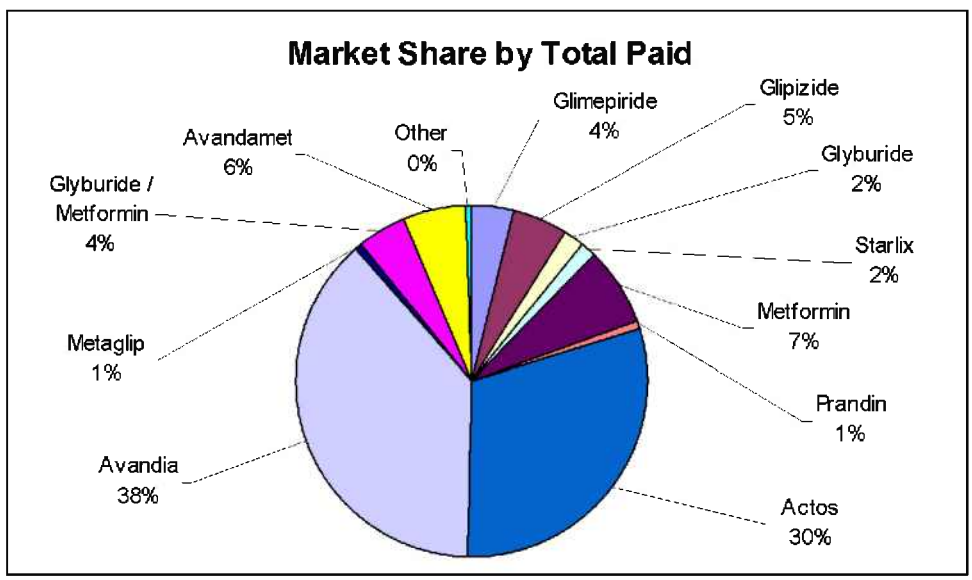
## Utilization of Diabetic Medications: Liquid Dosage Forms

| DRUGNAME | CLAIMS | UNITS | DAYS | MEMBERS | COST | COST/ DAY |
|---|---|---|---|---|---|---|
| Riomet Sol | 27 | 9,888 | 764 | 10 | $1,455.17 | $1.91 |
| Proglycem Susp | 66 | 4,530 | 1,880 | 8 | $21,076.38 | $0.36 |
| TOTALS | 93 | 14,418 | 2,644 | | $22,531.55 | $0.81 |

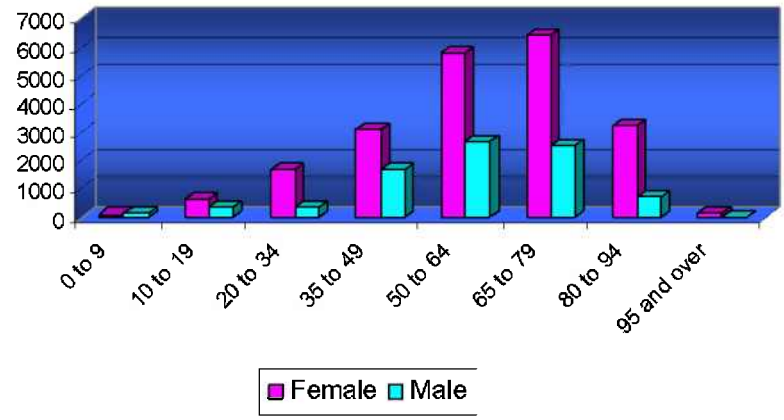
# Utilization of All Diabetes Medications

| | CLAIMS | UNITS | DAYS | MEMBERS | COST |
|---|---|---|---|---|---|
| Duals | 194,060 | 9,935,405 | 6,504,109 | 19,097 | $ 13,875,130.66 |
| Non-Duals | 90,377 | 4,423,355 | 3,018,849 | 10,520 | $ 7,171,571.34 |
| TOTALS | 284,437 | 14,358,761 | 9,522,958 | 29,617 | $ 21,046,702.00 |

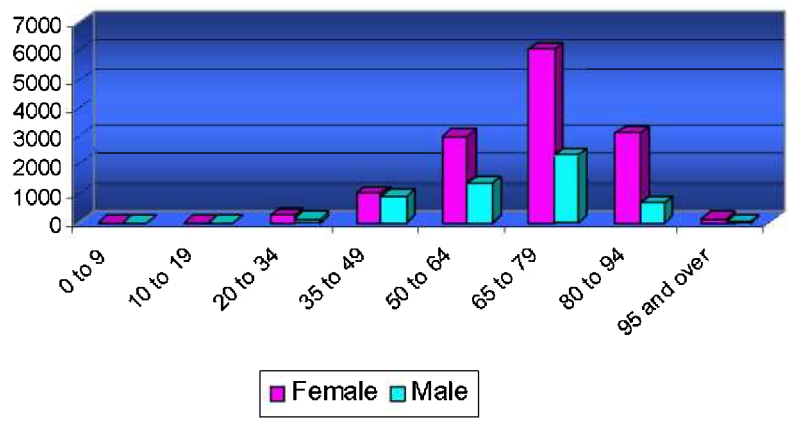


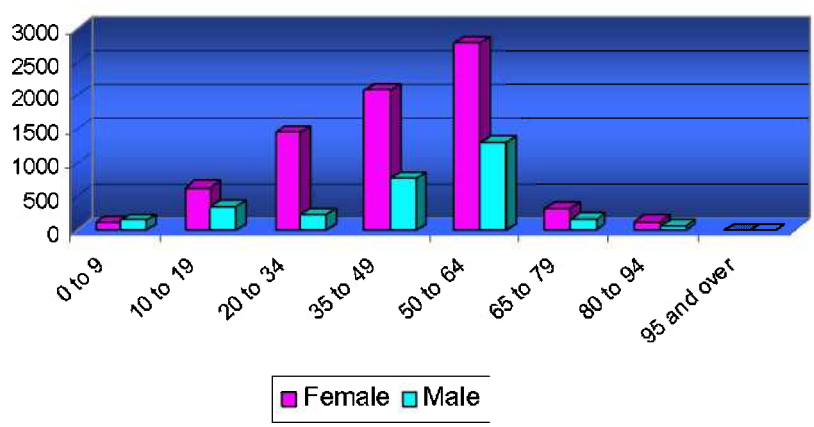
## Demographics of All Members Utilizing Diabetes Medications




## Demographics of Dual Eligible Members




## Demographics of Non Dual Eligible Members



## Prevalence and Therapy Review

Based on eligibility files from OHCA for 2005, a total of 666,708 members were eligible for pharmacy and medical benefits. Of these members, 36,438 (5.5 %) were flagged as having diabetes based on the presence of an ICD-9 code (250.XX) or a paid claim for a diabetic medication. Compared to the national average of 4.9 % for the diagnosed population, the Oklahoma SoonerCare population may have a higher prevalence rate.

### Diagnosis Rates for Dual and Non-Dual Members

| | Duals (N=86,387) | | Non-Dual (N=580,321) | |
|---|---|---|---|---|
| | *Diagnosis* | No Diagnosis | *Diagnosis* | No Diagnosis |
| DM Drug Claim | 12,460 | 6,566 | 8,969 | 1,404 |
| *No DM Drug Claim* | **3,444** | 63,917 | **3,595** | 566,353 |

Focusing on these non-dual eligible diabetic members, there were a total of 13,968 that were flagged as having diabetes. Of these members 3,595 had no diabetes related medications in their claims history. The following table lists the diagnoses associated with these members. Total cost for all medical and pharmacy claims was over $165 million for these members.

### Select Diagnoses from Medical Claims for Diabetic Non-Dual Members

| *Diagnosis* | *Description* | *Members with Diagnosis* |
|---|---|---|
| 250.01 | TYPE I (INSULIN DEPENDENT TYPE) DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, NOT STATED AS UNCONTROLLED | 3,961 |
| 250.02 | TYPE II (NON-INSULIN DEPENDENT TYPE) OR UNSPECIFIED TYPE DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, UNCONTROLLED | 3,435 |
| 250.03 | TYPE I (INSULIN DEPENDENT TYPE) DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, UNCONTROLLED | 1,071 |
| 250.0 | Diabetes mellitus without mention of complication | 531 |
| 250.1 | Diabetes with ketoacidosis | 962 |
| 250.2 | Diabetes with hyperosmolarity | 321 |
| 250.3 | Diabetes with other coma | 324 |
| 250.4 | Diabetes with renal manifestations | 1,115 |
| 250.5 | Diabetes with ophthalmic manifestations | 1,110 |
| 250.6 | Diabetes with neurological manifestations | 2,251 |
| 250.7 | Diabetes with peripheral circulatory disorders | 581 |
| 250.8 | Diabetes with other specified manifestations | 2,166 |
| 250.9 | Diabetes with unspecified complications | 1,147 |
| 272.xx | Hyperlipidemia | 4,233 |
| 401.xx | Hypertension | 7,096 |
| 414.xx | Chronic Ischemic Heart Disease | 1,863 |
| 435.xx | Transient Cerebral Ischemia | 238 |
| 585.xx | Chronic Renal Failure (includes ESRD) | 904 |
| 648.8 | Abnormal Maternal Glucose Tolerance | 774 |
| 798.xx | Sudden Death | 5 |
| v42.0 | Kidney Transplant | 20 |
| v49.6 | Upper Limb Amputation Status | 4 |
| v49.7 | Lower Limb Amputation Status | 150 |
| v72.0 | Examination of Eyes and Vision | 40 |
| V72.2 | Dental Examination | 369 |

## Direct Medical Costs for Diabetic Non-Dual Members

| | Pharmacy Costs | | Medical Costs | |
|---|---|---|---|---|
| | Total | Mean* | Total | Mean* |
| Diabetes Related | | | | |
| Paid | $7,146,591.33 | $511.64 | $35,866,308.88 | $2,567.75 |
| Claims | 90,027 | 6.5 | 267,998 | 19.2 |
| All Claims | | | | |
| Paid | $40,182,249.07 | $2,876.74 | $125,346,632.00 | $8,973.84 |
| Claims | 545,223 | 39.0 | 995,096 | 71.2** |

*Per Member Per Year
**Medical claims may include multiple claims for a single incidence.

## Treatment for Select Complications or Comorbid Conditions

| | # of Members with at least 1 claim for the following medications | | |
|---|---|---|---|
| | ACEI/ARB or Combo | Statin | Antiplatelet |
| *Hypertension (N=7,096)* | *4,627* | 2,824 | 684 |
| *Hyperlipidemia (N=4,233)* | 2,708 | *2,537* | 489 |
| *Chronic Ischemic Heart Disease (N=1,863)* | 1,246 | 985 | 468 |
| *Transient Cerebral Ischemia (N=238)* | 129 | 105 | *70* |

## Conclusion and Recommendations

The College of Pharmacy recommends:

1. A series of RetroDUR type reviews that look for the following:
   - Non-compliance/non-adherence to prescription regimen,
   - No pharmacy claims where a DM diagnosis exists on the file,
   - ACE/ARB missing from therapy,
   - Statin/other missing from therapy where hyperlipidemia diagnosis exists on file.
2. OHCA is currently making plans for disease management in adults which may include this disease state.
3. Review of any further recommendations from the DUR Board members.

## References


[1] American Diabetes Association. Total prevalence of diabetes and pre-diabetes. Retrieved February 24, 2006 from: http://www.diabetes.org/diabetes-statistics/prevalence.jsp.

[2] Oklahoma State Department of Health, Chronic Disease Service. Diabetes executive summary. Retrieved February 24, 2006 from: http://www.health.state.ok.us/program/cds/execsummary.html.

[3] American Diabetes Association. Direct and indirect costs of diabetes in the United States. Retrieved February 24, 2006 from: http://www.diabetes.org/diabetes-statistics/cost-of-diabetes-in-us.jsp.

[4] American Diabetes Association. Position statement: standards of medical care in diabetes-2006. *Diabetes Care* 2006; 29 Suppl 1:S4-S42.

[5] American Diabetes Association. Complications of diabetes in the United States. Retrieved February 24, 2006 from: http://www.diabetes.org/diabetes-statistics/complications.jsp.

[6] Inzucchi SE. Oral antihyperglycemic therapy for type 2 diabetes. JAMA 2002; 287:360-372.

[7] New diabetes drugs in the pipeline. *R&D Pipeline News* 2006 Feb 14. Retrieved February 24, 2006 from: http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3477.

[8] Merck announces FDA acceptance of new drug application for JANUVIA(TM), the company's investigationalm for type 2 diabetes. Retrieved February 24, 2006 from: http://www.merck.com/newsroom/press_releases/research_and_development/2006_0215.html.

[9] Possible new therapy for type 2 diabetes. Retrieved February 24, 2006 from: http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3457.

# APPENDIX I

# New Product Summaries

**Oklahoma Health Care Authority**
**March 2006**

| Drug | Manufacturer | Indications | Dosage | Adverse Effects | Contraindications | New Molecular Entity | AWP/ unit |
|---|---|---|---|---|---|---|---|
| **Aerospan™** (flunisolide HFA, 80 mcg) Inhalation Aerosol | 3M Pharmaceuticals, Inc. for Forest Pharmaceuticals, Inc. | Maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 6 years of age and older. Also indicated for asthma patients requiring oral corticosteroid therapy, where adding Aerospan™ Inhalation Aerosol may reduce or eliminate the need for oral corticosteroids. | Adults (age 12 and older): 160 mcg twice daily. Maximum dose of 320 mcg twice daily should not be exceeded. Children (age 6 to 11): 80 mcg twice daily. Maximum dose of 160 mcg twice daily should not be exceeded. | Headache, fever, allergic reaction, pain, accidental injury, infection, back pain, vomiting, dyspepsia, pharyngitis, rhinitis, increased cough, sinusitis, epistaxis, rash, UTI. | Primary treatment of status asthmaticus or acute episodes of asthma where extensive measures are required. Hypersensitivity to flunisolide or any of the ingredients of Aerospan™. | No | N/A |
| **Amitiza™** (lubiprostone) Soft Gelatin Capsules | Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals America, Inc. | Treatment of chronic idiopathic constipation in the adult population | 24 mcg twice daily with food. The need for continued therapy should be periodically assessed. | Nausea, diarrhea, abdominal distension, abdominal pain, flatulence, vomiting, sinusitis, UTI, URI, headache, dizziness. | Hypersensitivity to the drug or any of its excipients, and in patients with a history of mechanical gastrointestinal obstruction. | Yes | N/A |

| Drug | Manufacturer | Indications | Dosage | Adverse Effects | Contraindications | New Molecular Entity | AWP/ unit |
|---|---|---|---|---|---|---|---|
| **Ranexa™** (ranolazine) Extended-Release Tablets | DSM Pharmaceuticals, Inc. for CV Therapeutics, Inc. | Treatment of chronic angina. Renexa™ should be reserved for patients who have not achieved an adequate response with other antianginal drugs, due to prolongation of the QT interval. Renexa™ should not be used in combination with amlodipine, beta-blockers or nitrates. | Initiated at 500 mg BID and increased to 1000 mg BID as needed based on clinical symptoms. Maximum dose is 1000 mg BID. | Dizziness, headache, constipation, nausea, syncope, palpitations, tinnitus, vertigo, abdominal pain, dry mouth,, vomiting, dyspnea. | With pre-existing QT prolongation, hepatic impairment, patients on QT prolonging drugs, patients on potent and moderately potent CYP3A inhibitors (including diltiazem). | Yes | N/A |

# APPENDIX J

# FDA News

**FOR IMMEDIATE RELEASE**
P06-28
February 22, 2006

**Media Inquiries:**
Laura Alvey, 301-827-6242
**Consumer Inquiries:**
888-INFO-FDA

## FDA Approves First Generic Version of Flonase

### FDA is Committed to Providing Generic Alternatives to American Consumers

The Food and Drug Administration (FDA) today approved Fluticasone Propionate Nasal Spray, the first generic version of the brand name drug Flonase, giving American consumers an additional, lower cost alternative when choosing prescription drug products.

"Except for their price, which is much lower, generic drugs are in every way equivalent to their brand name counterparts," said Dr. Steven Galson, Director of FDA's Center for Drug Evaluation and Research. "Offering consumers a choice of safe, effective, and reasonably priced generic drug products is an extremely important priority for FDA. Today's approval is part of our ongoing commitment to provide generic forms of products to the public."

Generic drug products are used to fill over 50 percent of all prescriptions, and since they cost a fraction of the price of trade name drugs, the economic impact of FDA's generic drug program is profound. Through hard work, prioritization, and optimizing efficiencies, FDA's Office of Generic Drugs continues to make record numbers of generic products available. In 2005 alone, FDA approved 452 generic drug applications, the second highest total on record.

Fluticasone Propionate Nasal Spray treats the nasal symptoms of seasonal and chronic (long-lasting) allergic and nonallergic rhinitis, an inflammation of the lining of the nose that can make it stuffy and runny. This product is approved for use in both adults and children 4 years and older.

Fluticasone Propionate Nasal Spray contains a synthetic, trifluorinated corticosteroid with anti-inflammatory activity. Corticosteroids are natural substances found in the body that help fight inflammation. Fluticasone propionate, like other corticosteroids, does not have an immediate effect on allergic symptoms. A decrease in nasal symptoms (stuffiness, runniness, itching, and sneezing) has been noted in some patients 12 hours after initial treatment. Common side effects of fluticasone propionate nasal spray are headache, sore throat and nose bleed.

The brand name product or innovator drug for fluticasone propionate is Flonase, manufactured by GlaxoSmithKline and approved in October, 1994. The drug's patent, including the pediatric exclusivity, expired in May 2004 and the new dosing schedule exclusivity with its associated pediatric exclusivity expired on November 23, 2005.

FDA received several citizen petitions questioning the approval criteria for the drug's bioequivalence and for other aspects of nasal sprays related to today's action. The FDA submits generic drug applications to the same thorough and rigorously scientific review for safety, effectiveness and quality as the applications for new drugs. Consumers and health professionals can be assured that an approved generic drug is bioequivalent to a brand name drug and is its equal in dosage form, strength, route of administration, quality, performance characteristics, and intended use.

After reviewing the issues raised in the petitions, FDA determined that its current standards for approval are appropriate.

Fluticasone propionate nasal spray is manufactured by Roxane Laboratories of Columbus, OH.

# FDA Statement

**FOR IMMEDIATE RELEASE**
Statement
February 23, 2006

**Media Inquiries:**
Susan Cruzan, 301-827-6242
**Consumer Inquiries:**
888-INFO-FDA

## FDA and Manufacturers of Accutane and its Generics to Implement iPLEDGE Program on March 1, 2006

The iPLEDGE program, a strengthened risk management program to educate women about the risk of becoming pregnant while taking isotretinoin (Accutane and its generics), a drug to treat severe recalcitrant nodular acne, will be implemented on March 1, 2006, as planned. This comprehensive program seeks to reduce the risk of inadvertent pregnancy exposure by tightly linking negative pregnancy testing with dispensing of isotretinoin.

To date, a large number of prescribers, wholesalers, and pharmacies have registered in the iPLEDGE program in anticipation of the March 1 start date. In addition, over the past few weeks more than 1200 patients per day are registering for the iPLEDGE program.

The iPLEDGE program is a unique risk management program that is unprecedented in size and scope. It has been developed through a cooperative effort of several manufacturers of isotretinoin, a drug that has been marketed for several decades. Isotretinoin is highly effective in the treatment of severe recalcitrant nodular acne, but has known serious side effects, particularly its ability to cause birth defects when pregnant women use the drug, and more recent concerns regarding its potential to be associated with severe depression.

FDA has worked closely with isotretinoin sponsors and their vendor, Covance Inc., to maintain a critical balance between access to the drug by patients who need it and ensuring its safe use. In response to concerns about the operational aspects of the program raised by dermatologists and pharmacists in recent weeks, FDA has ensured that rapid and significant progress has been made by the sponsors and Covance to address them. Specific measures undertaken have included an increase in iPLEDGE call center staffing to handle the expected increases in call volume and user questions in the coming weeks, as well as an enhanced system to process requests for new passwords by users who have forgotten or lost their original passwords.

The iPLEDGE program is aimed at preventing use of the drug during pregnancy. To obtain the drug, in addition to registering with iPLEDGE, patients must comply with a number of key requirements that include completing an informed consent form, obtaining counseling about the risks and requirements for safe use of the drug, and, for women of childbearing age, complying with necessary pregnancy testing.

Women who are pregnant or who might become pregnant should not take the drug. Isotretinoin (Accutane and its generics) is a highly effective drug for severe recalcitrant nodular acne, but it carries a significant risk of birth defects if taken during pregnancy.

Prescribers and patients who have questions about the iPLEDGE program should contact the iPLEDGE call center at 1-866-495-0654 or on line at https://www.ipledgeprogram.com/

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