TMA DoD Pharmacoeconomic Center
Fort Sam Houston, TX

MTF Quarterly Webcast
December 9, 2010

LTC Stacia Spridgen
Director, DoD Pharmacoeconomic Center

Introduction

- Greetings from the PEC
- Purpose of the Quarterly MTF Webcast
- DCO Ground Rules
  - Type questions into the DCO system
  - Put on mute, not on hold
  - Contingency plan if DCO system quits working

Topic Outline

- MTF corner "best practices" – Norco Program at NMCP (LT Waugh)
- Review of August 2010 P&T Meeting (Dr Meade)
- Overview of November 2010 P&T Meeting (Dr Meade)
- New guidelines on Plavix and PPI interaction (Dr Allerman)
- CHCS template for a WTU/SPP drug entry (Dr Hearin)
- Update on managed care residency
  Quarterly ACPE continuing education programs (Dr Lugo)

MTF Corner

Norco Initiative at Naval Medical Center Portsmouth

LT Ian Waugh, PharmD
Pharmacist

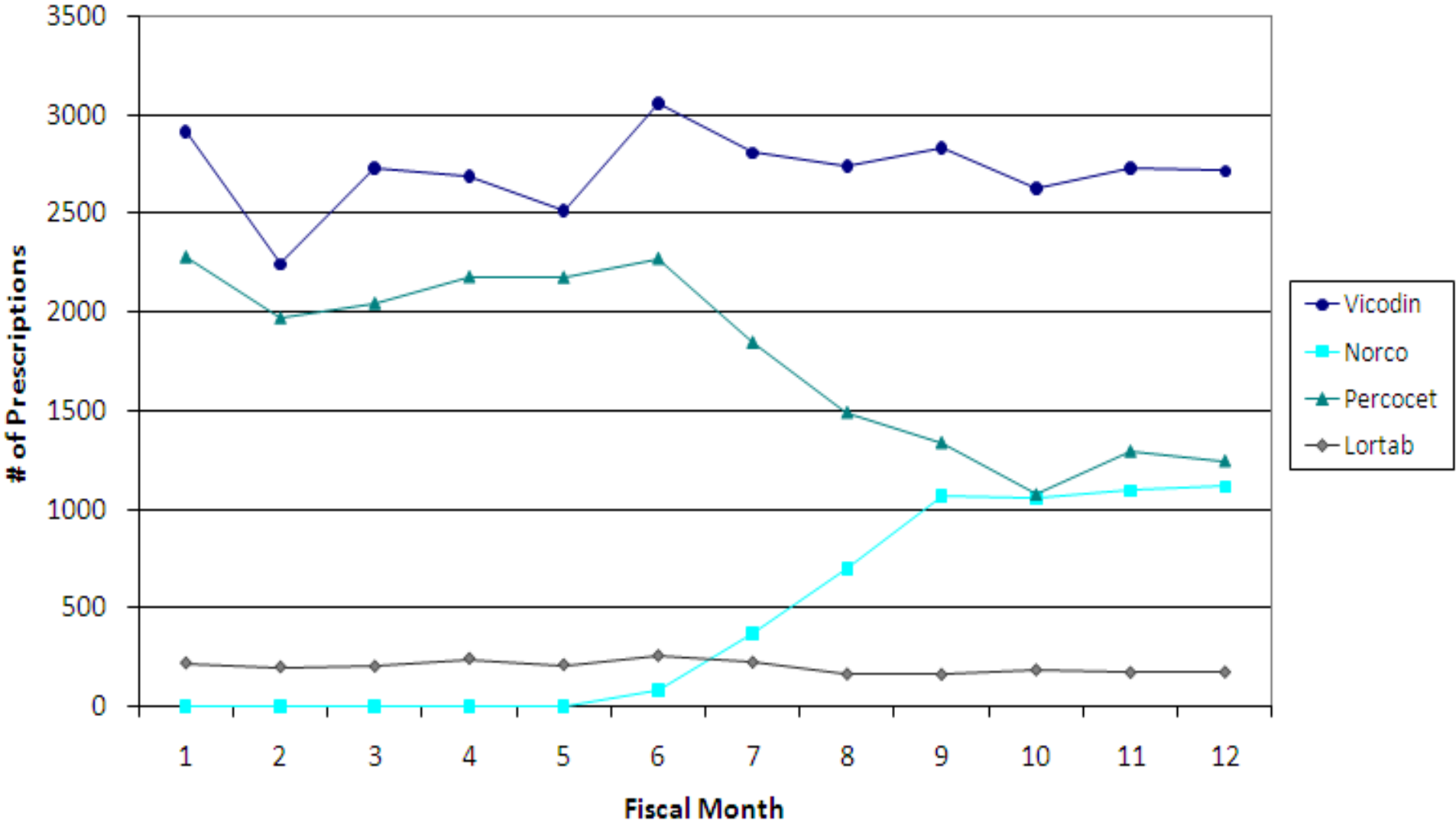
Why Not Norco®?

- **Avg. delay to fill Percocet®**
  - 15 minutes
- **CII vs. CIII and chapter 21**
- **Refills**
- **Less APAP than Vicodin®**
- **Percocet® $0.04 & Norco® $0.12**

Implementation

- **Educating the providers**
  - Check-in process
  - Email
- **Peak Percocet® prescribers list**
  - Phone calls
  - Email
  - CHCS
- **P&T**

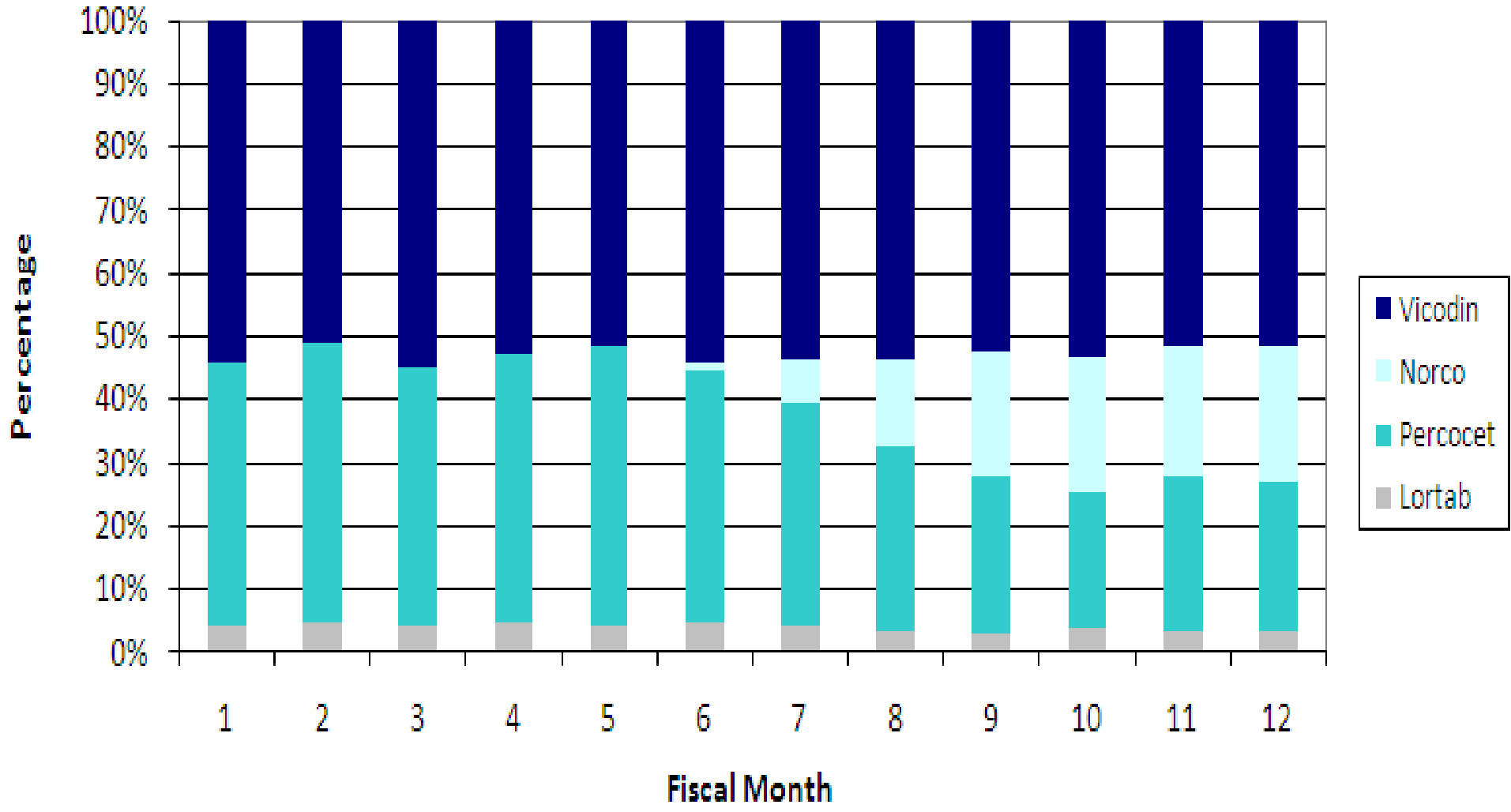
NMCP Monthly Prescription Counts from CHCS, FY2010



Source: CHCS, November 2010

Note: **Lortab** includes: Hydrocodone 10/APAP 500 (Lortab *10*) Tab, Hydrocodone 7.5/APAP 500 (Lortab *7.5**), and Hydrocodone 10/APAP 500 Lortab UD. **Norco** includes: Hydrocodone/Acetaminophen 7.5-325 MG TAB. **Vicodin** includes: Hydrocodone 5/APAP 500 (Vicodin) Tab, Hydrocodone Bit/Acetaminophen 7.5/750 MG, Hydrocodone/Acetaminophen 5/500 unit dose tab. **Percocet** includes: Oxycodone/Acetaminophen U/D 5/325 (Percocet) and Oxycodone/Acetaminophen 5-325 (Percocet).

NMCP Monthly Prescription Percentage Breakdown, FY2010



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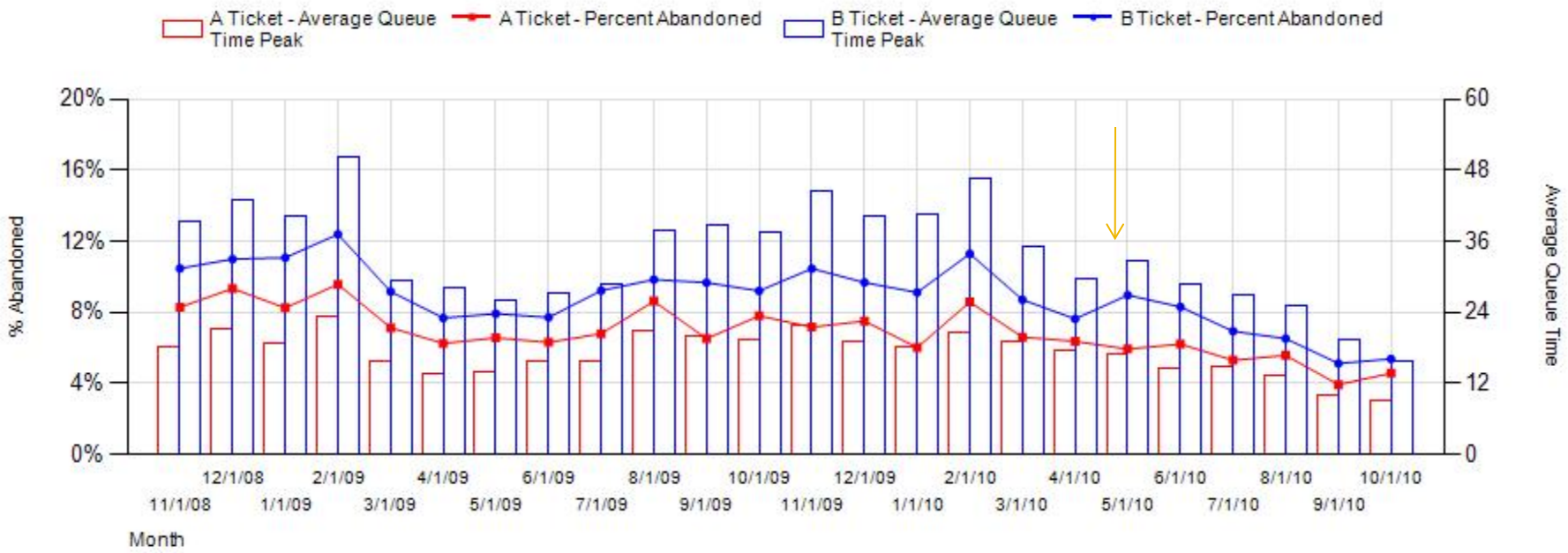
Average Transaction Time by Ticket Type by Month

Percentage of Tickets Abandoned Vs. Queue Time by Service by Month



Contact Information

LT Ian Waugh

Naval Medical Center Portsmouth

Phone: 757-953-7294/5903

Email: ian.waugh@med.navy.mil

Review of August P&T Activities

Dave Meade, PharmD, BCPS
Clinical Pharmacist

August 2010
DoD P&T Committee Meeting

- **Uniform Formulary Class Reviews**
  - Renin Angiotensin Antihypertensives (RAAs)
    - Angiotensin II receptor blockers (ARBs)
    - Angiotensin-converting enzyme inhibitors (ACE Inhibitors)
    - Direct Renin Inhibitors (DRIs)
    - Fixed Dose Combinations (FDC) products with hydrochlorothiazide (HCTZ), calcium channel blockers (CCBs), or other RAAs
  - Ophthalmic-1s
    - Ophthalmic antihistamines (AHs)
    - Mast cell stabilizers (MCS)
    - Dual action AH/MCS
    - Nonsteroidal anti-inflammatory drugs (NSAIDs)

August 2010
DoD P&T Committee Meeting

- **Utilization Management- Quantity Limits (QL)**
  - Tramadol ODT (Rybix)
  - Ondansetron soluble film (Zuplenz)
  - Certolizumab Pegol Injection (Cimzia Starter Kit)
  - Nilotinib Capsules (Tasigna)

- **Other Issues**
  - Prior Authorization for Quinine Sulfate Safety Update

Uniform Formulary Class Review

Renin Angiotensin Antihypertensives Agents

RAAs: Drugs in the Class

ACE Inhibitors

Drug	Brand	Generics	Available with HCTZ	FDA approval date
Benazepril	Lotensin	Yes	Yes	1991
Captopril	Capoten	Yes	Yes	1981
Enalapril	Vasotec	Yes	Yes	1985
Fosinopril	Monopril	Yes	Yes	1991
Lisinopril	Zestril/Prinvil	Yes	Yes	1987
Moexipril	Univasc	Yes	Yes	1995
Perindopril	Aceon	Yes	No	1993
Quinapril	Accupril	Yes	Yes	1991
Ramipril	Altace	Yes	No	1991
Trandolapril	Mavik	Yes	No	1996

RAAs: Drugs in the Class ARBs

Generic Name (abbreviation)	Brand (company)	FDA Approval Date	Patent Exp.
Losartan (LOS)	Cozaar (Merck)	1995	2010
Valsartan (VAL)	Diovan (Novartis)	1996	2012
Irbesartan (IRB)	Avapro (BMS/Sanofi)	1997	2012
Candesartan (CAN)	Atacand (AstraZeneca)	1998	2012
Telmisartan (TEL)	Micardis (Boehringer)	1998	2014
Eprosartan (EPR)	Teveten (Biovail)	1999	2016
Olmesartan (OLM)	Benicar (Sankyo/Forest)	2002	2016

- All are available in combo with HCTZ
- All are approved for hypertension

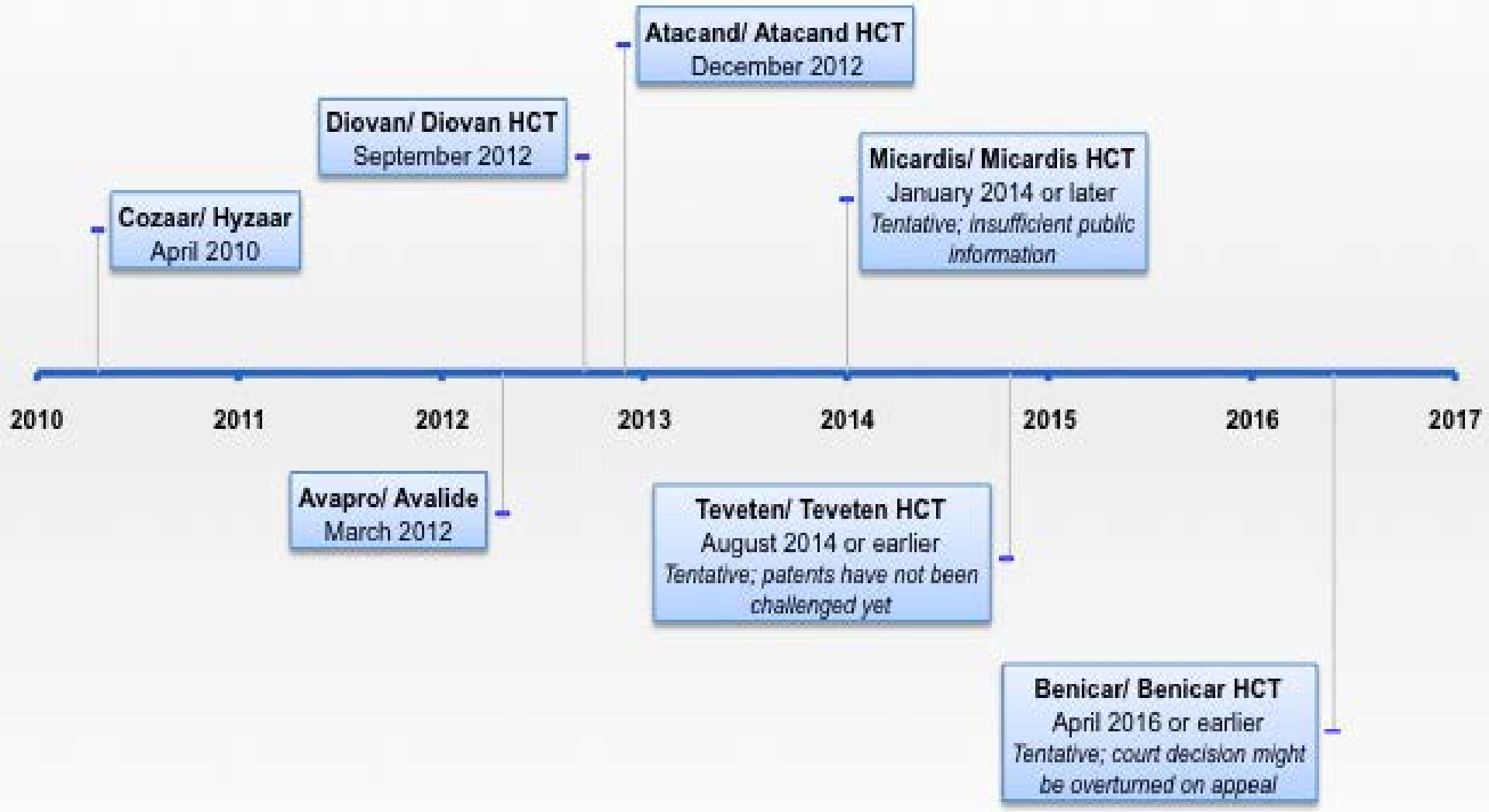
RAAs: Drugs in the Class

Fixed Dose Combos / Direct Renin Inhibitors

Generic Name (abbreviation)	Brand (company)	FDA Approval Date	Patent Exp.
Direct Renin Inhibitors (DRI)			
Aliskiren +/- HCTZ	Tekturna; Tekturna HCT (Novartis)	May 2007 Jan 2008	2018/2015
Dual Fixed Dose Combos: ARB+CCB			
Telmisartan/amlodipine	Twynsta (BI)	Oct 2009	2014
Olmesartan/amlodipine	Azor (Sankyo)	Oct 2007	2016
Valsartan/amlodipine	Exforge (Novartis)	Jul 2007	2012-2019
Dual Fixed Dose Combos: DRI + ARB			
Aliskiren/valsartan	Valturna (Novartis)	Sep 2009	2012-2018
Triple Fixed Dose Combos: ARB+CCB+HCTZ			
Valsartan/amlodipine/HCTZ	Exforge HCT	Apr 2009	2012-2017

Generic Forecast

Projected Schedule for Availability of Generic ARBs *(as of October 2009)*



Overall Clinical Effectiveness Conclusion

- **Hypertension:**
  - All ARBs ↓ BP to similar degree
  - Average BP lowering (-8 mmHg SBP / -5 mm Hg DBP)
  - HCTZ addition ↑ efficacy
- **CHF: Valsartan and Candesartan and Losartan**
  - Positive data with all three agents
  - Losartan is generic but not FDA-approved
- **Type 2 DM renal disease: Irbesartan and Losartan**
  - Losartan and irbesartan are both FDA approved, similar results in outcome trials
  - No positve data for olmesartan looking at clinically significant outcomes
  - Other ARBs not conducting trials in this area

Overall Clinical Effectiveness Conclusion

- **FDC vs. taking individual components**
  - Pros - Convenient to pt, ↑ compliance & persistence
  - Cons - Sacrifice dosing flexibility for dosage initiation and titration
- **ARB/CCB combos (Twynsta/Exforge/Azor) and ACE/CCB combos (Lotrel, Tarka)**
  - No evidence that any one ARB/CCB combo is more effective or better tolerated than another
- **ACE/CCB combo Lotrel is only one with positive clinical outcomes other than HTN**
  - Decrease CV morbidity/mortality in High risk HTN pts
- **ACE vs. ARB vs. DRI**
  - Degree of BP lowering is similar (-8/-5 mm Hg)

Overall Clinical Effectiveness Conclusion

- **Triple drug combo (Exforge HCT)**
  - Most efficacious at decreasing BP, due to three drugs, but orthostatic hypotension and dizziness
- **DRIs**
  - Place in therapy: not 1st line
  - 300 mg aliskerin more effective than 150 mg
  - Trials assessing clinical, rather than surrogate outcomes, are still in-progress
- **DRI + HCTZ**
  - Improved BP lowering compared with DRI alone
  - Thiazide component consistent with JNC VII guidelines
- **DRI / ARB**
  - Place in therapy??
  - ↑ Hyperkalemia

Uniform Formulary status of RAAs Agents

BCF drugs - MTFs must have on formulary	MTFs may have on formulary	MTFs must not have on formulary
ACE-Inhibitors ▪Lisinopril (Prinvil, Zestril, generic) Lisinopril HCT (Prinzide, Zestoretic generic) ▪Captopril (Capoten, generic) ▪Ramipril (Altace, generic) **ACE Inhibitor/CCB** ▪Benazepril/amlodipine (Lotrel, generic) **ARBs** ▪Losartan (Cozaar, generic) ▪Losartan/HCTZ (Hyzaar, generic) ▪Telmisartan (Micardis) ▪Telmisartan/ HCTZ (Micardis HCT) ▪Valsartan (Diovan) ▪Valsartan/HCTZ (Diovan HCT)	**ACE Inhibitors** ▪Benazepril +/- HCTZ (Lotensin, Lotensin HCT generic) ▪Captopril/HCTZ (Capozide, generic) ▪Enalapril, Enalapril/HCTZ (Vasotec, Vasoretic, generic) ▪Fosinopril, fosinopril HCTZ (Monopril, Monopril HCT generic) ▪Moexipril +/- HCTZ (Univasc, Uniretic generic) ▪Perindopril (Aceon, generic) ▪Quinapril+/- HCTZ (generic) ▪Trandolapril (Mavik, generic) **ACE-Inhibitor/CCB** ▪Verapamil SR/trandolapril (Tarka, generic) **ARBs** ▪Candesartan, Candesartan/HCTZ (Atacand, Atacand HCT) ▪Eprosartan, Eprosartan/ HCTZ (Teveten, Teveten HCT) ▪Irbesartan, Irbesartan/HCTZ (Avapro, Avalide) ▪Olmesartan, Olmesartan/HCTZ (Benicar +/- HCT) **ARB/CCB** ▪Telmisartan/amlodipine (Twynsta) ▪Olmesartan/amlodipine (Azor) ▪Valsartan/amlodipine (Exforge) **ARB/CCB/HCTZ** ▪Valsartan/amlodipine/HCTZ (Exforge HCT) **Direct Renin Inhibitors (DRIs)** ▪Aliskiren (Tekturna) ▪Aliskiren/HCTZ (Tekturna HCT) ▪Aliskiren/valsartan (Valturna	**None (no NF drugs)**

Uniform Formulary Class Review

Ophthalmic-1 Agents

Ophthalmic 1
Drugs in the Class

Generic Name	Brand	Mfg	Generic	Strength	FDA Approval	Patent Expiration
Antihistamines						
Emedastine	Emadine	Alcon	No	0.05%	1997	2013
Mast Cell Stabilizers						
Pemirolast	Alamast	Vistakon	No	0.01%	1999	2011
Nedocromil	Alocril	Allergan	No	2%	1999	2012
Cromolyn	Crolom/ Opticrom	-	Yes	4%	1995/1984	-
Lodoxamide	Alomide	Alcon	No	0.1%	1993	2012
Dual Action Antihistamines/Mast Cell Stabilizers						
Ketotifen	Zaditor	-	Yes OTC	0.025%	1999	2006
Bepotastine	Bepreve	Ista	No	1.5%	2009	2014
Olopatadine	Patanol	Alcon	No	0.1%	1996	2015
	Pataday	Alcon	No	0.2%	2004	2024
Azelastine	Optivar	-	Yes	0.05%	2000	-
Epinastine	Elestat	Allergan	No	0.05%	2003	2020

Ophthalmic 1
Drugs in the Class

Generic Name	Brand	Mfg	Generic	Strength	FDA Approval	Patent Expiration
NSAIDs						
Ketorolac	Acular	-	Yes	0.5%	1992	-
	Acular PF	-	D/C	0.5%	-	-
	Acular LS	-	Yes	0.4%	2003	-
	Acuvail	Allergan	No	0.45%	2009	2012
Bromfenac	Xibrom	Ista	No	0.09%	2005	2009
Diclofenac	Voltaren	-	Yes	0.1%	1991	-
Flurbiprofen	Ocufen	-	Yes	0.03%	1986	-
Nepafenac	Nevanac	Alcon	No	0.1%	2005	2014

Acular PF: Preservative-free
Acular LS: Lower strength

Overall Clinical Effectiveness Conclusion

- **FDA indications**
  - AH, MCS, and the dual action AH/MCS are FDA-approved for treating allergic conjunctivitis
  - One NSAID, ketorolac 0.5% is approved for allergic conjunctivitis
  - Trial data supports bromfenac use for allergic conjunctivitis

Overall Clinical Effectiveness Conclusion (contd)

- **Efficacy**
  - Meta-analysis reported that MCS and AH are superior to placebo
  - Insufficient evidence to conclude one agent is superior to another
  - Interpretation of clinical efficacy differences is difficult due to small patient enrollment, short term treatment or use of single dose studies
  - No head-to-head trials comparing bepotastine with another ophthalmic 1 agent
  - Overall for relief of ocular itching, there does not appear to be clinically relevant differences between the dual action AH/MCS, and between the MCSs

Overall Clinical Effectiveness Conclusion (contd)

- **Adverse events**
  - Difficulties in determining true direct differences in adverse events between agents because the overall adverse event rate is low, and the drugs are used short term to treat an acute condition
  - Bepotastine -taste perversion: 25%
  - Ketotifen –hyperemia: 10-25%
  - Nedocromil -burning/stinging and taste perversion: 10-30%
  - Ketorolac 0.5%- burning/stinging: up to 40%

Overall Clinical Effectiveness Conclusion (contd)

- **Other factors**
  - Olopatadine 0.2% (Pataday) is the only dual action AH/MCS that is dosed once daily; the other drugs in the subclass are dosed BID
  - For the MCS, nedocromil is dosed BID, while the others are dosed 4-6 times daily
  - The long term effects of whether the substitution of CMC for the BAK preservative in Acuvail or the lower concentration of BAK in bepotastine are associated with benefits or a lower risk has yet to be determined

Safety/Tolerability Conclusion

- Existing evidence does not support any clinically relevant differences between agents concerning safety and tolerability
- One meta-analysis did not assess adverse events and the head-to-head trials were too small to determine significant differences between products
- All agents are considered safe and well tolerated

Uniform Formulary status of Ophthalmic-1 Agents

Uniform Formulary (UF) Ophthalmic-1 Agents		Non-Formulary Ophthalmic-1 Agents
Ophthalmic-1s on BCF **MTFs <u>must</u> have on formulary**	**Ophthalmic-1s not on BCF MTFs <u>may</u> have on formulary**	**MTFs <u>must not</u> have on formulary**
Dual Action AH/MCS •Patanol (olopatadine 0.1%)	**Dual Action AH/MCS** •Bepreve (bepotastine 1.5%) •Elestat (epinastine 0.05%) •Emadine (emedastine 0.05%) •Pataday (olopatadine 0.2%) •Optivar (azelastine 0.05%) **Mast Cell Stabilizers** •Alamast (pemirolast 0.1%) •Alocril (nedocromil 2%) •Alomide (lodoxamide 0.1%) •Crolom/Opticrom (cromolyn 4%), generic **NSAIDs** •Acular (ketorolac 0.5%); generic •Acular LS (ketorolac 0.4%) •Acuvail (ketorolac 0.45%) •Nevanac (nepafenac 0.1%**)** •Ocufen (flurbiprofen 0.03%), generic •Voltaren (diclofenac 0.1%) •Xibrom (bromfenac 0.09%)	**None**

Quantity Limits

Sumatriptan oral dissolving film (Zuplenz)

- **Sumatriptan (Zuplenz)**
  - Oral dissolving film
  - Approved July 2010, launched July 2010
  - 4 mg and 8 mg doses, box of 10 (foil pack)
  - Dosing: Same as other oral dosage forms

- **QLs established for the class – safety & pkg labeling**
  - Ondansetron ODT and tablets: #60/30 days and #180/90 days
  - Mail: #180/90 days
  - Retail: #60/30 days
  - Rationale
    - Precedence in the class
    - Consistent with dosing in package insert
    - Avoids breaking up packages

Tramadol ODT (Rybix)

- **Tramadol ODT (Rybix)**
  - Oral dissolving tablet
  - Approved Dec 2009; Launched May 2010
  - 50 mg tablet
  - Dosing: up to 400 mg/day

- **QLs established for the class – safety & pkg labeling**
  - Tramadol and combos : 240/30 and 720/90
  - Mail: # 720/90
  - Retail: # 240/30
  - Rationale
    - Precedence in the class
    - Consistent with dosing in package insert

Certolizumab Pegol (Cimzia)

- **Certolizumab Pegol (Cimzia starter kit)**
  - Launched July 2010
  - 6 syringe kit
  - Dosing:
    - Crohn's: 400mg repeated at 2 and 4 weeks followed by 400 mg every 4 weeks
  - Must be refrigerated

- **QLs established for the class – safety & pkg labeling**
  - One time use for starter kit
  - Mail: 1 kit with no refills
  - Retail: 1 kit with no refills
  - Rationale
    - Precedence in the class
    - Consistent with dosing in package insert

Nilotinib HCL (Tasigna)

- **Nilotinib HCL (Tasigna)**
  - Indicated for the treatment for resistant or tolerant chronic myelogenous leukemia and newly diagnosed Philadelphia chromosome + CML
  - 150 mg and 200 mg capsule
  - Dosing:
    - Resistant : 400 mg bid
    - Newly diagnosed: 300 mg bid

- **QLs established for the class – safety & pkg labeling**
  - Unit dose packaging- qty of 28
  - Mail: 224/56 days
  - Retail: 112/28 days
  - Rationale
    - Consistent with dosing in package insert
    - UD packaging

Qualaquin Safety Follow-up

Review of Qualaquin

- **May 2010 DoD P&T Committee meeting**
  - Voted to require Prior Authorization for Qualaquin for safety reasons
  - Restricted to FDA-approved use for malaria
- **8 July 2010 FDA Safety Communication**
  - Stated that Qualaquin should only be used for treatment of malaria
  - Warned patients of safety issues with use of quinine
  - Required manufacturer to develope REMS

Qualaquin Risk Evaluation and Mitigation Strategy (REMS)

- **Key Elements**
  - A dear prescriber letter
  - Communications to major professional societies
  - Patient medication guide to be dispensed with all Qualaquin prescriptions
  - Follow-up evaluations at 18 months, 3 years and 7 years after start of REMS program

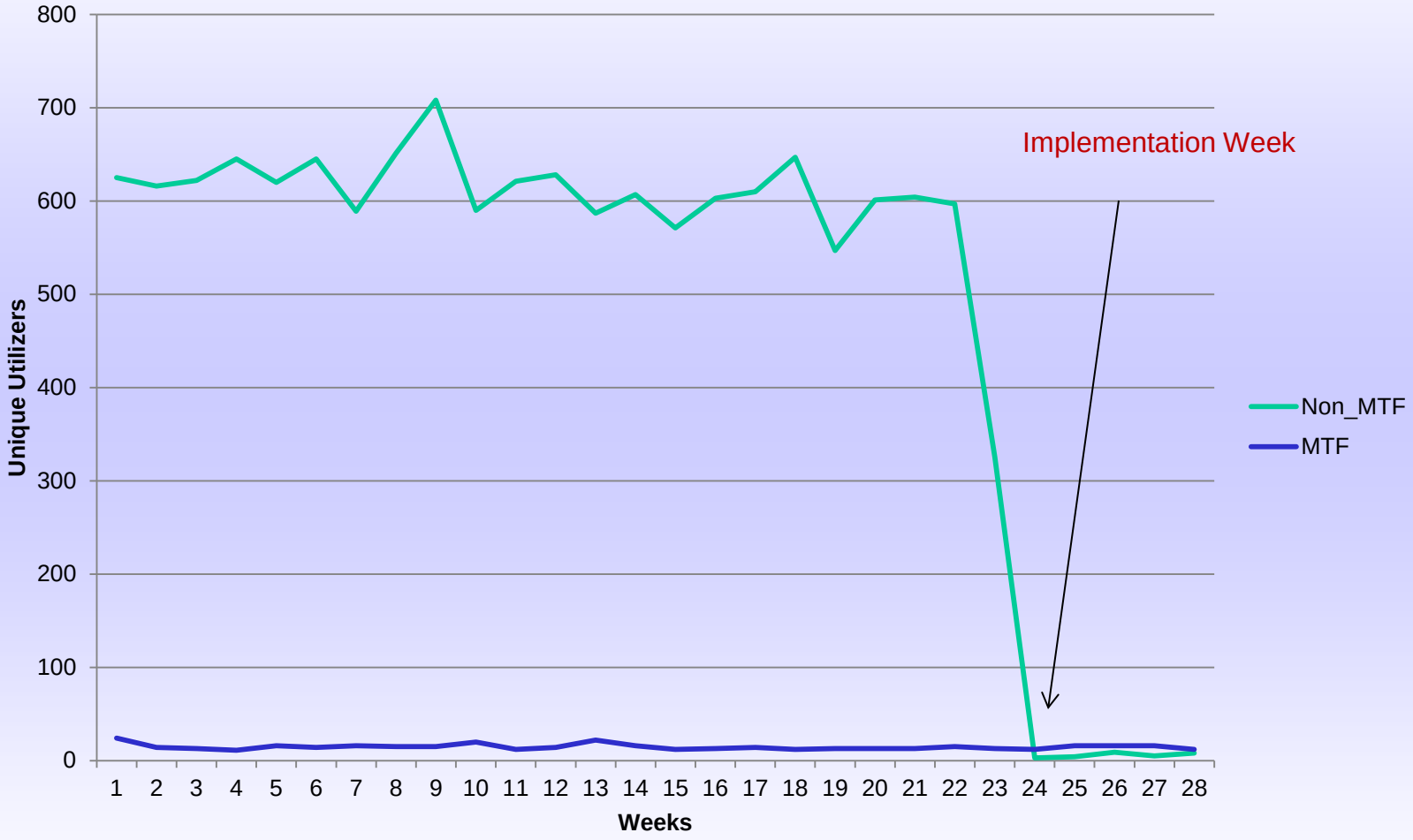
DoD Qualaquin PA Implementation

- **Letters mailed in late September 2010**
- **PA requirement went live on 6 October 2010**
- **ESI contacts report:**
  - "Lots" of PA reviews for this agent
  - Callers are passionate about this issue
  - Physicians are concerned. Even seeing recent warnings, most feel that their patients have been using for years without ill effects

Qualaquin PA Implementation Data

- **Preliminary results**
  - Data period 6 through 31October
  - 660 patients were stopped by PA requirement
  - 23 of these patients subsequently received Qualaquin fill paid by TRICARE, 637 were denied
  - Unknown why the 23 patients were approved (malaria?)

Weekly Qualaquin Utilization May 2 – November 13



Conclusion and Next Steps

- **PA requirement appears to have stopped majority of patients from receiving Rx's for Qualaquin paid by TRICARE**
  - Average of 602 Rx fills/week pre-implementation, 6 Rx fills/week post implementation
- **Need more data to determine reasons for PA approvals**
- **Will monitor and if necessary, report**

Overview of November P&T Activities

Dave Meade, PharmD, BCPS
Clinical Pharmacist

Reviewed Non-Insulin Anti-Diabetic Agents

Incretin Mimetics	DPP-4 Inhibitors	Sitagliptin (Januvia)* Saxagliptin (Onglyza)*+
	GLP-1 Receptor Agonists	Exenatide (Byetta) Liraglutide (Victoza)
Insulin Sensitizers	Biguanides	Metformin (Glucophage)+
	Thiazolidinediones	Pioglitazone (Actos)*+ Rosiglitazone (Avandia)*+
Insulin Secretagogues	Sulfonylureas	Glipizide*+ Glimepiride# Glyburide*
	Meglitinides	Nateglinide (Starlix) Repaglinide (Prandin)*
Other	Alpha-glucosidase Inhibitors	Acarbose (Precose) Miglitol (Glyset)
	Amylin Agonist	Pramlintide (Symlin)

* Combination with metformin # Combination with TZD
+ XR formulation

New Drugs in Previously Reviewed Classes

- Doxepin HCl (Silenor)
- Estradiol valerate and dienogest tablets (Natazia)
- Fenofibric acid tablets(Fibricor)
- Hydromorphone extended release tablets (Exalgo)
- Mometasone/formoterol oral inhaler (Dulera)
- Pitavastatin tablets (Livalo)

Utilization Management

- **Fenofibrate meltdose (Fenoglide)**
  - BCF removal
- **High dose Opioid Step Edit**
  - Fentanyl citrate

Fenofibrate meltdose (Fenoglide) update

- **Fenoglide will be blocked from use at all points of service**
  - Fenoglide NDCs are not included in the FSS/VHCA pricing program
  - The affected NDCs are:
    - Fenoglide 40mg 52725-0490-90
    - Fenoglide 120mg 52725-0495-90

- **Generics (Mylan, Global) are available**
  - Different technology and strengths
  - Should be adequate for a majority of our beneficiaries requiring fenofibrates

Fenofibrate meltdose (Fenoglide) update (contd)

- **Gemfibrozil (Lopid) remains on the BCF**
- **Other Fenofibrates on the UF:**
  - Fenofibrate IDD-P (Triglide)
  - Fenofibrate micronized / non-micronized (Lofibra, generics)
  - Fenofibrate (Lofibra, generics)
- **NF agents:**
  - Fenofibrate micronized (Antara)
  - Fenofibrate nanocrystallized (Tricor)
- **The Lip-2s class will to be reviewed in February 2011**
- **Tricor should be available as a generic formulation in March 2011**

Upcoming UF Class Reviews

- **Feb 2011**
  - Pancreatic Enzymes
  - IBS/IBD
  - LIP-2
- **May 2011**
  - Antipsychotics
  - Nasal Allergy Drugs

Closing the Loop
Following up on DoD P&T Decisions

Josh Devine, PharmD, BCPS
Clinical Pharmacist

Antilipidemics I

- **Last Reviewed**
  - May 2010
    - All UF
    - BCF: simvastatin, pravastatin, atorvastatin (Lipitor), niacin ER (Niaspan)
    - Automated Prior Authorization / Step Therapy
      - Step preferred: atorvastatin (Lipitor), simvastatin, pravastatin, generic lovastatin
      - "Behind the Step": antilipidemics in this class other than generics and Lipitor (atorvastatin):
        - Rosuvastatin (Crestor); pitavastatin (Livalo; not yet launched at time of meeting); amlodipine/atorvastatin (Caduet); fluvastatin (Lescol, Lescol XL); simvastatin/niacin ER (Simcor); branded lovastatin products (w/niacin ER = Advicor, lovastatin ER = Altoprev); simvastatin/ezetimibe (Vytorin)
      - Dose-specific provisions apply

Dose-Specific Step Therapy
Effective Date 6 Nov 2010

- **Minute language**
  - The patient has received a prescription for a preferred agent targeting similar LDL reduction at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days

Dose-Specific Step Therapy
Effective Date 6 Nov 2010

- **General principles**
  - New user of a non-preferred (NP) agent = no Rx for any strength of that NP agent in the last 180 days
  - Based on %LDL lowering
    - Low to moderate intensity: < 45%
    - High intensity: ≥ 45%
  - Low-to-moderate intensity NP LIP-1s require a trial of *any* preferred LIP-1
  - High intensity NP LIP-1s require a trial of a *high-intensity* preferred LIP-1

Expected Mean LDL Reductions By Statin and Dose

Expected Mean LDL Reduction	Statin					
	Mevacor, Altoprev (lovastatin)	Pravachol (pravastatin)	Zocor (simvastatin)	Lescol, Lescol XL (fluvastatin)	Lipitor (atorvastatin)	Crestor (rosuvastatin)
25 to 30%	20 mg	20 mg	10 mg	40 mg		
30 to 40%	40 – 80 mg	40 mg	20 mg	80 mg (XL only)	10 mg	
40 to 45%	IR: 80 mg (40 mg x 2) ER: 60 mg	80 mg	40 mg or Vytorin 10/10 mg		20 mg	5 mg
45 to 50%	Please note: ezetimibe (Zetia) or niacin generally decrease LDL up to an additional 15%		80 mg or Vytorin 10/20 mg		40 mg	10 mg
50 to 55%			Vytorin 10/40 mg		80 mg	20 mg
>55%			Vytorin 10/80 mg			40 mg

IR = immediate release; ER = extended release

Vytorin = simvastatin/ezetimibe

Dose-Specific Step Therapy Set-up

Rx presented	Passes Step if Rx last 180 days
Advicor 1000/40mg (niacin ER/lovastatin)	Atorvastatin; lovastatin ≥ 40mg; pravastatin ≥ 40mg; simvastatin ≥ 20mg; Advicor
Advicor 20mg (niacin ER/lovastatin 500/, 750/, 1000/20 mg)	Atorvastatin; lovastatin ≥ 20mg, pravastatin ≥ 20mg; simvastatin ≥ 10mg; Advicor
Altoprev 10mg (lovastatin ER)	Atorvastatin; lovastatin (including Altoprev); pravastatin; simvastatin
Altoprev 20mg	Atorvastatin; lovastatin (including Altoprev); pravastatin ≥ 20mg; simvastatin ≥ 10mg
Altoprev 40mg	Atorvastatin; lovastatin (including Altoprev); pravastatin ≥ 40mg; simvastatin ≥ 20mg
Altoprev 60mg	Atorvastatin ≥ 20mg; lovastatin (including Altoprev); pravastatin 80mg; simvastatin ≥ 40mg

Dose-Specific Step Therapy Set-up

Rx presented	Passes Step if Rx last 180 days
Caduet 10mg (amlodipine/atorvastatin 2.5/10, 5/10, 10/10 mg)	Atorvastatin; lovastatin 40mg; pravastatin ≥ 40mg; simvastatin ≥ 20mg; Caduet
Caduet 20mg (2.5/20, 5-20, 10/20)	Atorvastatin; pravastatin 80mg; simvastatin ≥ 40mg; Caduet
Caduet 40mg and greater (2.5/40, 5/40, 10/40, 5/80, 10/80 mg)	Atorvastatin; simvastatin 80mg; Caduet
Crestor 5mg (rosuvastatin)	Atorvastatin ≥ 20mg; pravastatin 80mg; simvastatin ≥ 40mg; rosuvastatin
Crestor 10mg and greater 10,20,40 mg	Atorvastatin ≥ 40mg; simvastatin 80mg; rosuvastatin

Dose-Specific Step Therapy Set-up

Rx presented	Passes Step if Rx last 180 days
Lescol 20mg (fluvastatin)	Atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin
Lescol 40mg	Atorvastatin, fluvastatin, lovastatin ≥ 20mg, pravastatin ≥ 20mg, simvastatin ≥ 10mg
Lescol XL 80mg (fluvastatin ER)	Atorvastatin, fluvastatin, lovastatin ≥ 40mg, pravastatin ≥ 40mg, simvastatin ≥ 20mg
Livalo 1mg (pitavastatin)	Atorvastatin, lovastatin ≥ 20mg; pitavastatin; pravastatin ≥ 20mg; simvastatin ≥ 10mg
Livalo 2mg	Atorvastatin, lovastatin ≥ 40mg; pitavastatin; pravastatin ≥ 40mg; simvastatin ≥ 20mg
Livalo 4mg	Atorvastatin ≥ 20mg, pitavastatin; pravastatin 80mg; simvastatin ≥ 40mg

Dose-Specific Step Therapy Set-up

Rx presented	Passes Step if Rx for product containing following last 180 days
Simcor 20mg (niacin ER/simvastatin 500/20, 750/20, 1000/20 mg)	Atorvastatin, lovastatin 40 mg, pravastatin ≥ 40mg; simvastatin ≥ 20mg; Simcor 20mg
Simcor 40mg (500/40, 1000/40 mg)	Atorvastatin ≥ 20mg; pravastatin 80mg; simvastatin ≥ 40mg; Simcor
Vytorin 10mg (ezetimibe/simvastatin 10/10 mg)	Atorvastatin ≥ 20mg; pravastatin 80mg; simvastatin; Vytorin
Vytorin 20mg and greater (10/20, 10/40, 10/80 mg)	Atorvastatin ≥ 40mg, simvastatin, Vytorin

Messages if Patient Does Not Meet Criteria

Rx presented	Message*
Altoprev 10mg, Lescol 20mg	"Must try Simvastatin, Pravastatin, Lovastatin or Lipitor first.
Advicor 20mg, Altoprev 20mg, Lescol 40mg, Livalo 1 mg	"Must try Simvastatin > 10mg, Pravastatin > 20mg, Lipitor > 10mg, or Lovastatin > 20mg first.
Advicor 1000/40mg, Altoprev 40mg, Caduet 10mg, Lescol XL 80mg, Livalo 2 mg, Simcor 20mg	"Must try Simvastatin > 20 mg, Pravastatin > 40 mg, Lipitor > 10 mg, or Lovastatin 40mg first.
Altoprev 60mg, Caduet 20mg, Crestor 5mg, Livalo 4mg, Simcor 40mg, Vytorin 10mg	"Must try Simvastatin > 40 mg, Pravastatin 80 mg, or Lipitor > 20 mg first.
Caduet 40mg and greater, Crestor 10mg and greater, Vytorin 20mg and greater	"Must try Lipitor > 40 mg or Simvastatin 80 mg first.
*All messages end with: "Prescribers may call ESI at 1-866-684-4466 for override if not appropriate."	

Patients Affected, 6 Oct 2010 – 5 Nov 2010

- **Effective date 6 Oct 2010**
- **Methods**
  - Data pull: all antilipidemic-1 Rxs for patients who received a 75 reject for a non-preferred agent from 6 Oct 2010 to 5 Nov 2010
  - Analysis groups
    - All patients with 75 rejects (31 to 0 days of follow-up data)
    - Patients with at least 14 days of follow-up data
      - Last 75 reject 6-22 Oct 2010

Results So Far

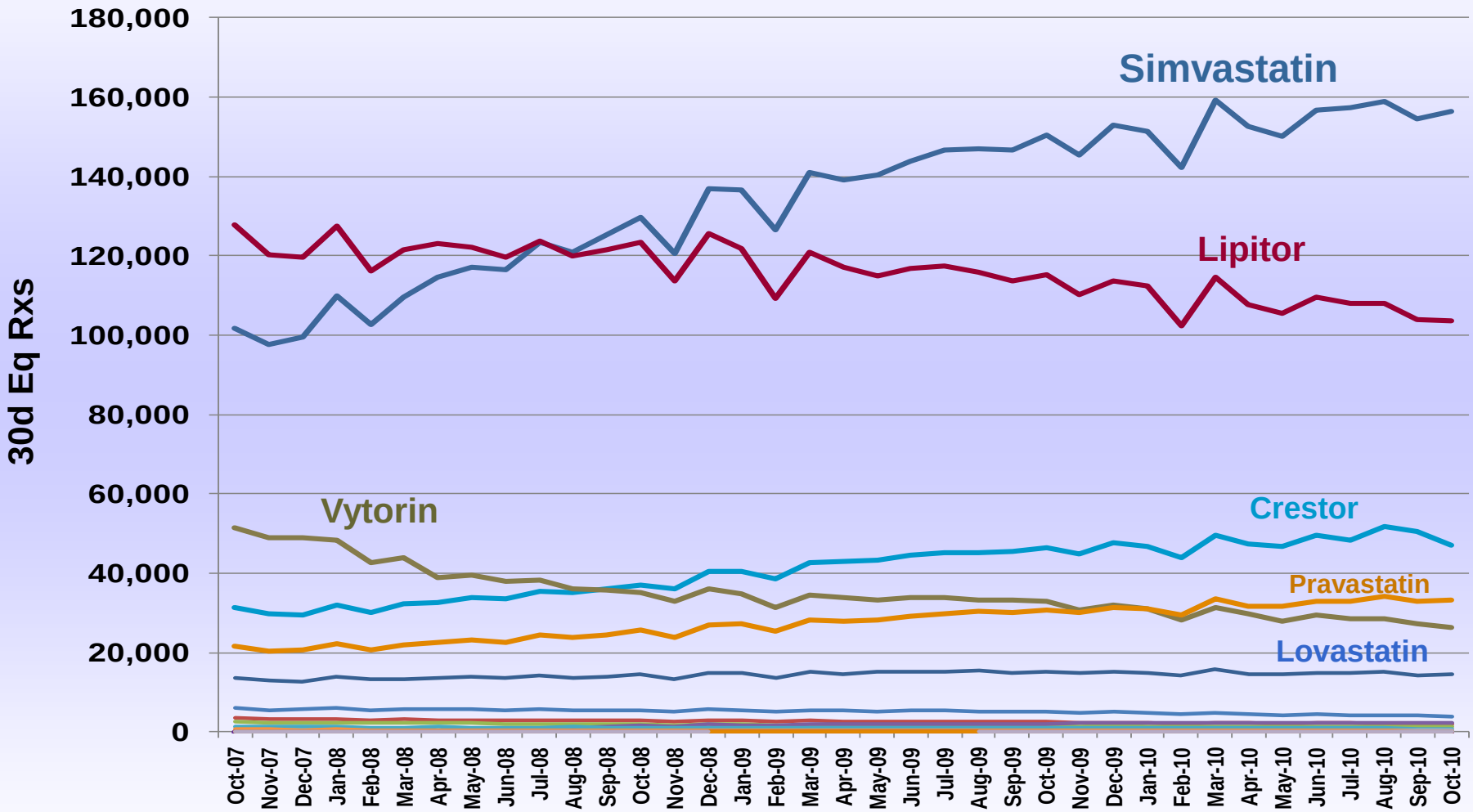
- **6429 patients with rejects, total**
  - 4688 (73%) with rosuvastatin (Crestor) Rxs
    - 5mg – 1110 (24%)
    - 10mg – 2152 (46%)
    - 20mg – 1075 (23%)
    - 40mg – 351 (7%)
  - 991 (15%) ezetimibe/simvastatin (Vytorin)
    - 10/10 – 103 (10%)
    - 10/20 – 330 (33%)
    - 10/40 – 404 (41%)
    - 10/80 – 154 (16%)
  - 281 (4%) pitavastatin (Livalo); 227 (4%) niacin/simvastatin (Simcor); 122 (2%) amlodipine/atorvastatin (Caduet); 76 (1%) fluvastatin (Lescol, Lescol XL); 39 (<1%) niacin/lovastatin (Advicor); 5 (<<1%) lovastatin (Altoprev)

≥ 14 Days Follow-up (n = 2976)

- **Drugs requested similar**
  - 72% Crestor; 16% Vytorin 4% Livalo, etc.
- **1948 (65%) had a paid claim for an antilipidemic-1; 1028 (35%) did not**
  - Of those with a paid claim,
    - 75% occurred within 7 days
    - 1106 (57%) received a preferred agent; 842 (43%) received a non-preferred agent
      - Preferred agents: 56% atorva, 20% simva, 4% prava, 1% lovastatin
      - Non-preferred agents: 97% same as initially requested

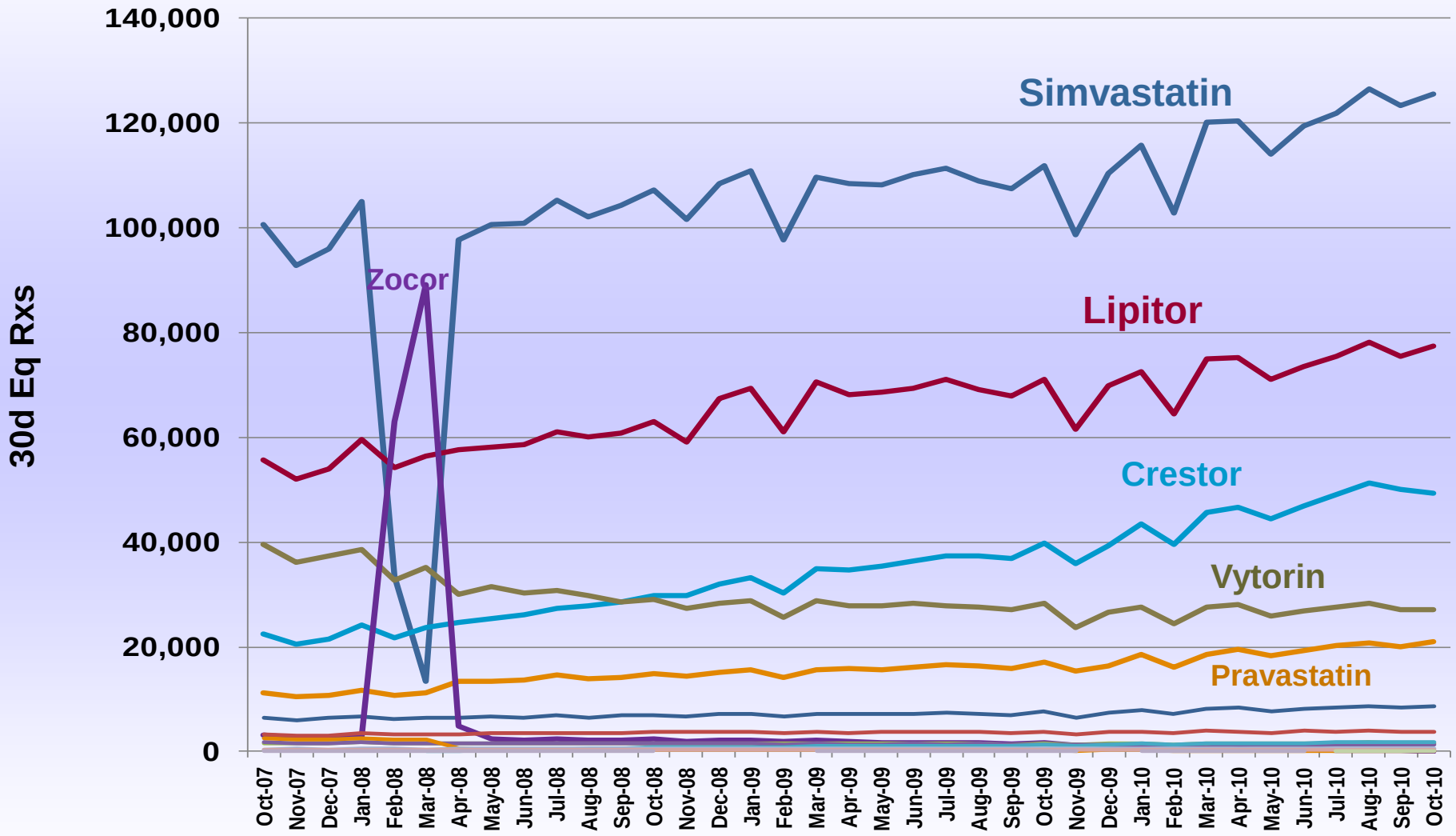
Antilipidemic I Utilization, Retail

Brand Names, by 30-day Eq Rxs, FY08 – Oct 2010



Antilipidemic I Utilization, Mail

Brand Names, by 30-day Eq Rxs, FY08 – Oct 2010

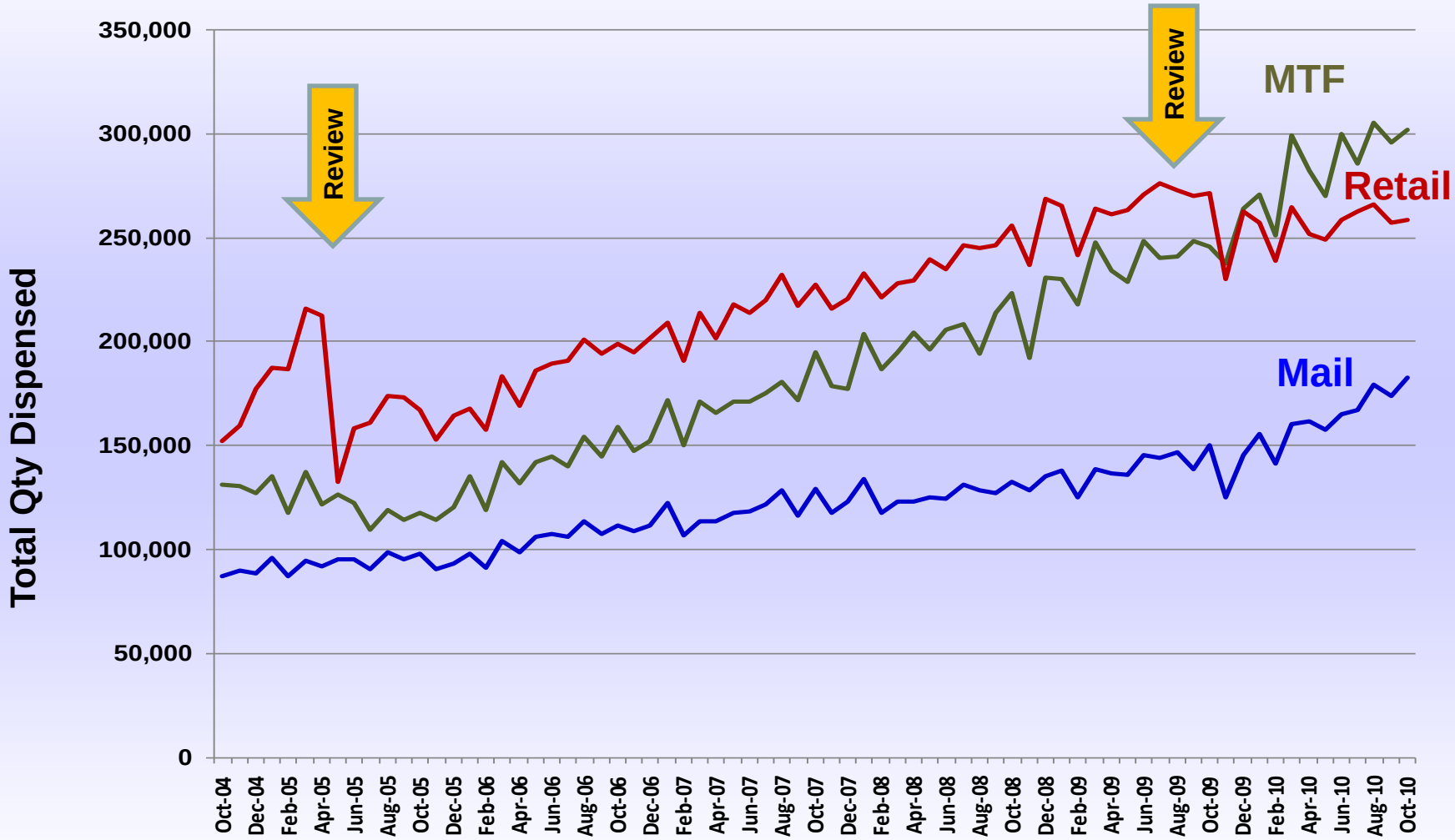


PDE-5s

- **~$63M/year class (Viagra, Cialis, Levitra) + ~$13M/year for PAH (Revatio, Adcirca)**
  - unadjusted PDTS data, Nov 09 – Oct10
- **Last reviewed Aug 09/Nov 09 – changes were vardenafil BCF, step therapy for Viagra, Cialis**
  - UF: vardenafil (Levitra), [sildenafil (Revatio) remained UF for PAH]
  - NF: sildenafil (Viagra), tadalafil (Cialis), tadalafil (Adcirca)
  - BCF: vardenafil (Levitra) immediately on minute signing
  - Automated PA: PA required for any PDE-5 for ED unless patient meets one of following criteria:
    - Existing user – PDE-5 (Levitra, Viagra, Cialis) last 180 days OR
    - Male ≥40 years of age
  - QL: collective 18 per 90 days in mail; 6 per 30 days in retail for ED; 90- or 30-day supply for post-prostatectomy or Raynauds

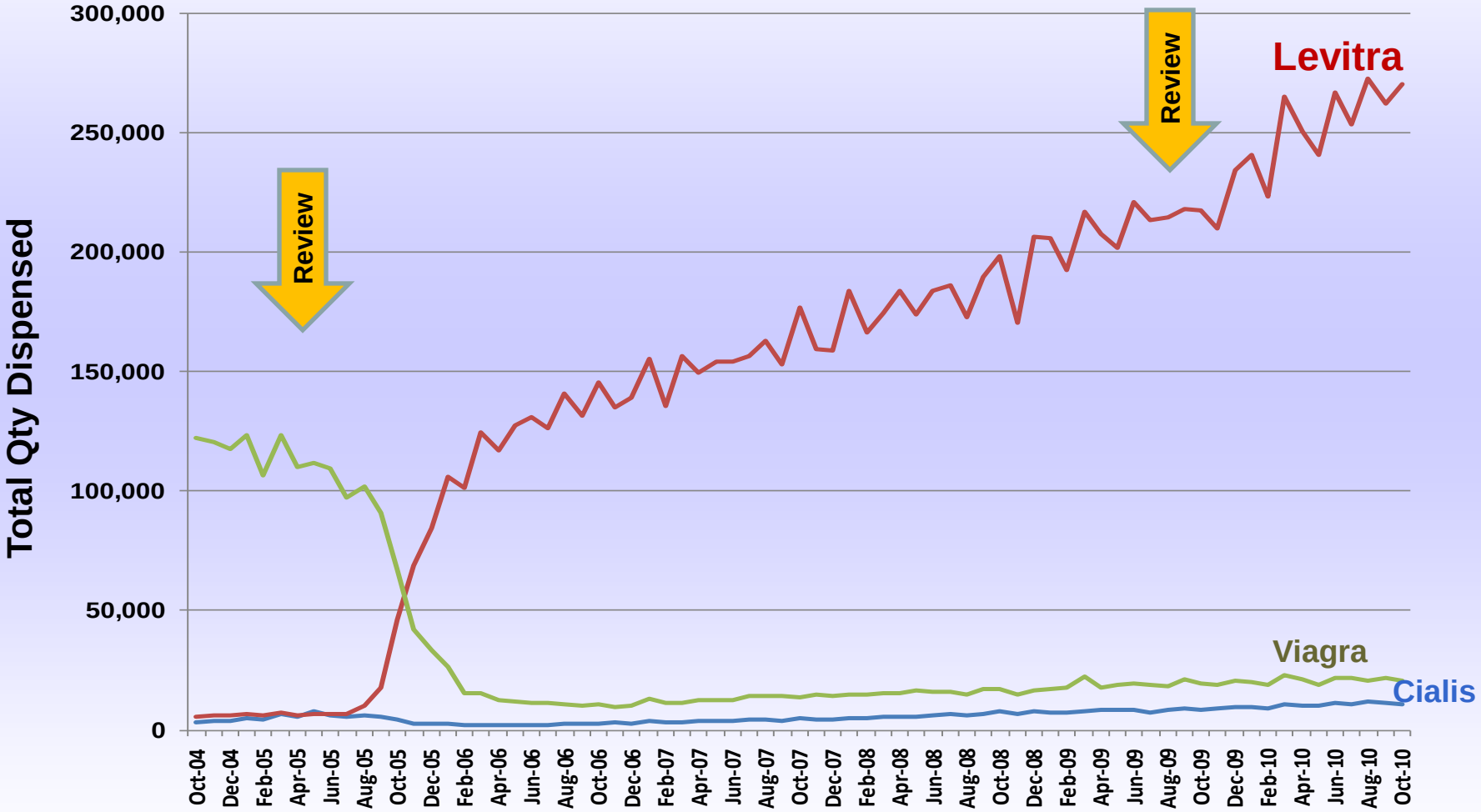
PDE-5s for ED By POS

By Tabs/Caps Dispensed, FY05-Oct10



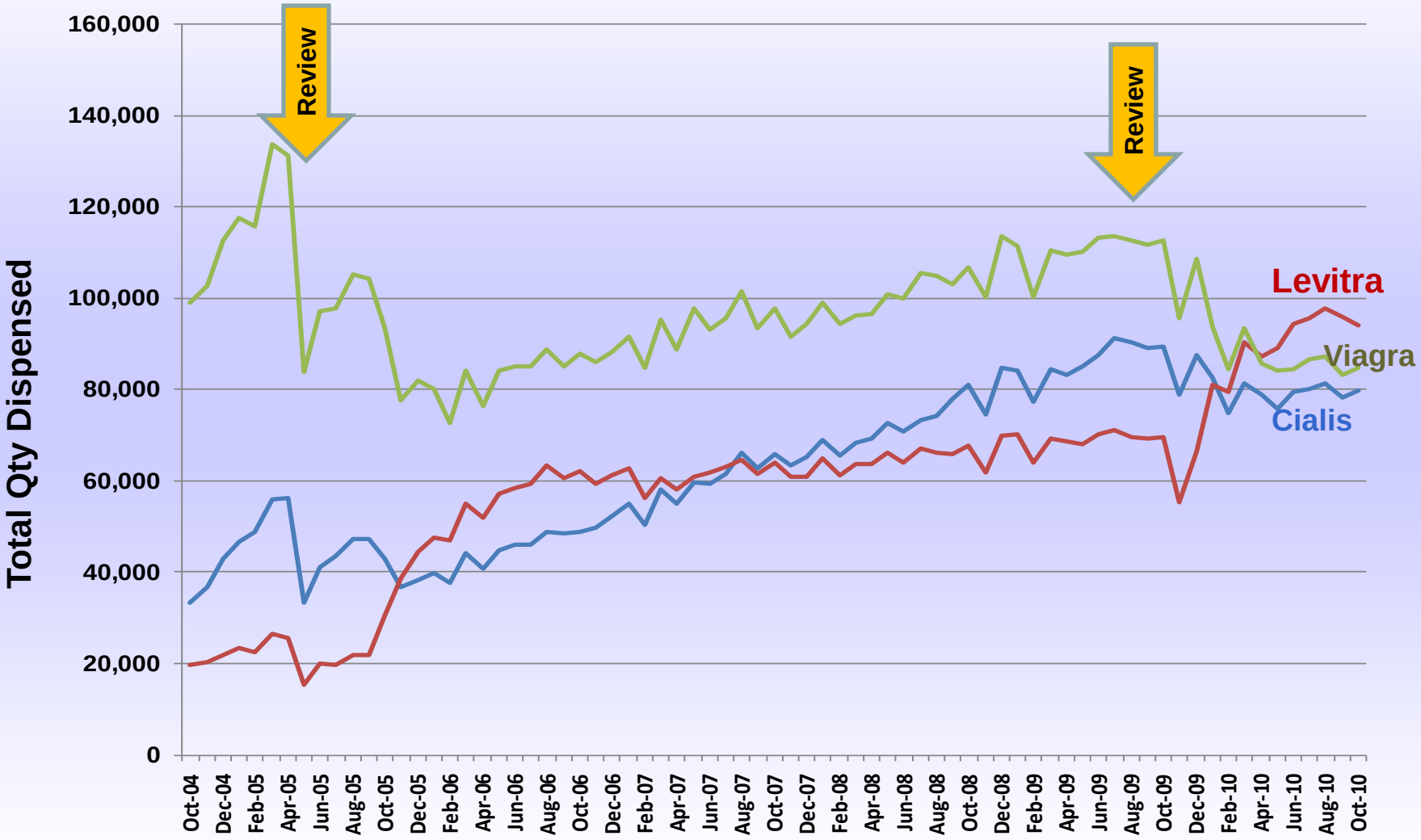
PDE-5s for ED Utilization, MTF

By Tabs/Caps Dispensed, FY05-Oct10



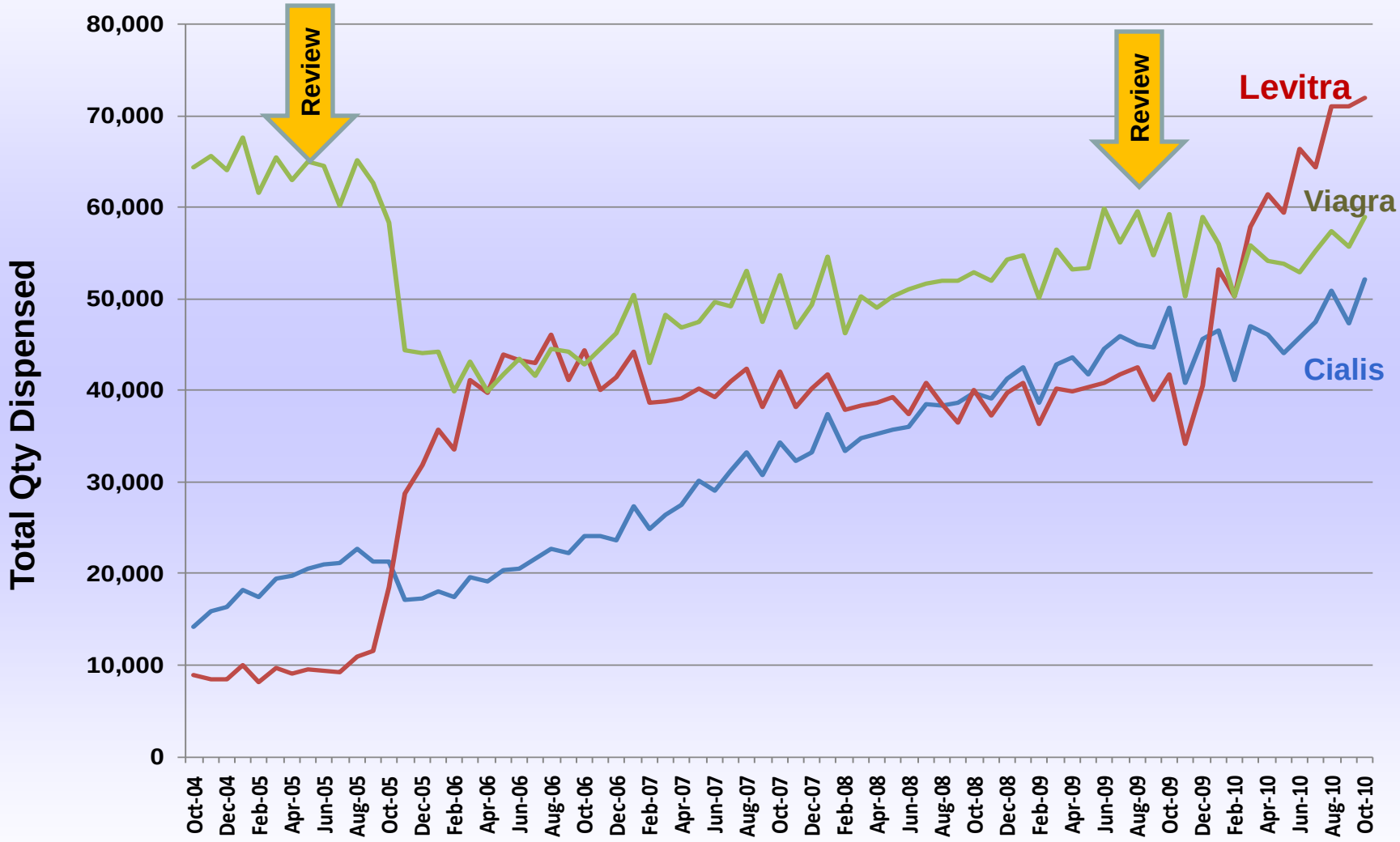
PDE-5s for ED Utilization, Retail

By Tabs/Caps Dispensed, FY05-Oct10



PDE-5s for ED Utilization, Mail

By Tabs/Caps Dispensed, FY05-Oct10



Proton Pump Inhibitor / Clopidogrel Drug Interaction Update

Angela Allerman, PharmD, BCPS
Clinical Pharmacist

PPI Prior Authorization & Medical Necessity
Background

- **2007 - Step-therapy instituted for PPI class**
  - Requires trial of generic omeprazole or Nexium prior to other Non-formulary PPIs
- **Drug interaction btw clopidogrel and PPIs reported in literature**
  - ↓ antiplatelet efficacy in certain populations, potential ↑ CV events
- **May 2009**
  - Updated information provided to Committee
  - Committee agreed evidence was not sufficient to recommend changing existing PPI PA/Medical Necessity to expand the criteria to obtain NF PPIs?
- **Nov 2010 - another updates on literature**

Clopidogrel-PPI Interaction Previous and New Data

- **Platelet reactivity assays - ? if relate to clinically meaningful differences**
- **Retrospective Rx database studies reported pts receiving PPIs with clopidogrel had increased CV events**
- **Prospective trial recently published – COGENT trial**
  - R, DB trial of clopidogrel 75 mg/omeprazole 20 mg fixed-dose combination
  - Objective: Does PPI reduce GI events in pts on clopidogrel
  - Event-driven trial with >5k pts
  - Jan 2009: trial terminated early – funding (~3200 pts enrolled;
  - GI endpoints: GIB, occult GIB ↓ Hgb >2 or HCG >20%, confirmed GI ulcer
  - CV endpoints: composite of CV death, non-fatal MI, CABG or PCI, or ischemic stroke

Bhatt NEJM 2010; 363:1909-17

Clopidogrel-PPI Interaction COGENT results

Preliminary Results

	CGT-2168	Placebo	Adjusted HR (95% CI)
CV death, MI or stroke	69 events	67 events	1.02 (0.70-1.51)
Myocardial infarction	37 events	36 events	0.96 (0.59-1.56)
Revascularization	69 events	67 events	0.95 (0.59-1.55)
GI events	38 events	67 events	0.55 (0.36-0.85)

Bhatt DL. TCT Late Breaking Trials 2009

Limitations: not powered to detect differences in CV events; terminated early after median 133 days (max 365 days)

ACC / AHA / ACG Expert Consensus Document Nov 2010

- **Concomitant use of PPIs and Thienopyridines**
  - PPIs appropriate in pts with multiple risk factors for GIB and who require antiplatelet therapy
    - Hx/o ulcer disease / ulcer complication
    - GI bleeding
    - Dual antiplatelet therapy (stent placement)
    - Concomitant anticoagulant therapy, steroids, NSAIDs
    - *H. pylori* infection
    - Advanced age
  - PPIs *not* recommended in pts with lower risk of GIB - ↓ benefit from prophylactic PPI therapy
  - Clinical decision for combined therapy required to balance overall risks & benefits, including CV and GI
  - Pharmacogenetic testing possibly helpful for pts on combined therapy, *but not yet definitively established*

JACC 2009;56 (24) XX-XX – publication on 7 Dec 2010

CHCS/AHLTA: Drug Seeking Beneficiary (DSB) Edit

Libby Hearin, PharmD, BCPS
Clinical Pharmacist

PDTS Drug Seeking Beneficiary (DSB) Edit

- **CHCS DSB edit is associated with the MTF Prescription Restriction Program**
- **Beneficiary restrictions:**
  - Restrict all meds to a specific pharmacy and/or provider
  - Restrict controlled meds to a specific provider or list of providers
  - Exclude controlled substances or specific non-controlled substance(s)

PDTS Drug Seeking Beneficiary (DSB) Edit: Locked into a pharmacy

PDTS WARNINGS

1. LOCKED-IN

ENTER WARNING # FOR DETAILS: 1

Conflict: LOCKED-IN

Additional Information:

PHARMACY NOT AUTHORIZED FOR THIS BENEFICIARY.
CALL 1-866-275-4732 OR DSN (312) 471-8274 OPTION 8.

OVERRIDE WARNING (Y/N)? No//

Note: providers are presented with clinical reasons for not overriding the warning in AHLTA and through ORE pathway

PDTS Drug Seeking Beneficiary (DSB) Edit: Warning Message Detail

Restriction (Locked into)	Message
Pharmacy	PHARMACY NOT AUTHORIZED FOR THIS BENEFICIARY. CALL 1-866-275-4732 OR DSN (312) 471-8274 OPTION 8.
Prescriber	PRESCRIBER NOT AUTHORIZED FOR THIS BENEFICIARY. CALL 1-866-275-4732 ……
Prescriber for certain drugs	PRESCRIBER/DRUG NOT AUTHORIZED FOR THIS BENEFICIARY. CALL 1-866-275-4732 ……
Locked-out of certain drugs (not able to obtain at any pharmacy through TRICARE)	MEMBER/DRUG NOT AUTHORIZED FOR THIS BENEFICIARY. CALL 1-866-275-4732……

PDTS Drug Seeking Beneficiary (DSB) Edit: Implementation

- **Estimated implementation: January 2011**
- **Phased approach: selected sites initially, then enterprise-wide**
- **Educational materials will be distributed and available on the PEC website**
  - Will focus on the prescription restriction program and intended meaning of the warning messages
  - Will not focus on incorporation into local processes

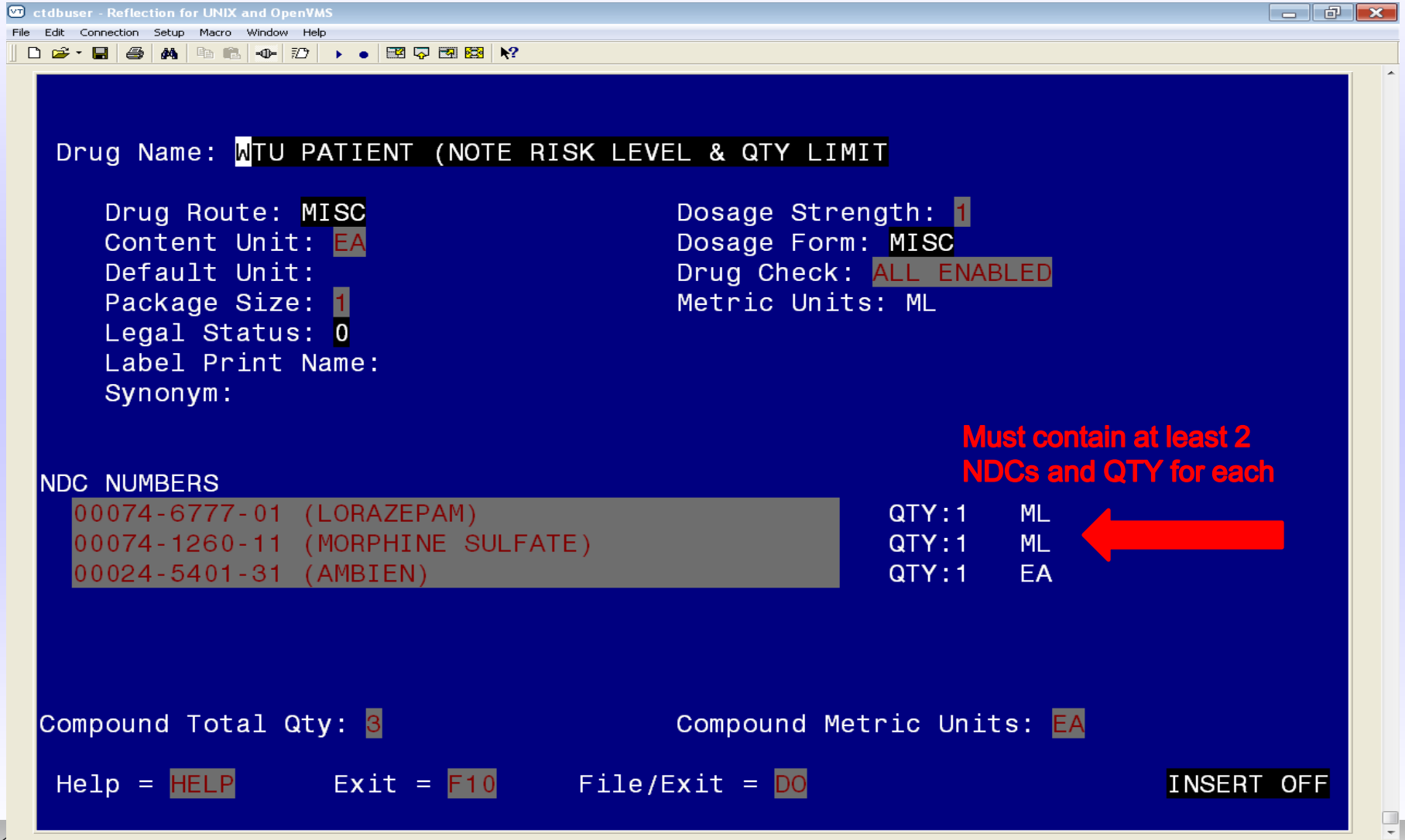
CHCS:
WTU/SPP Drug Entry

Libby Hearin, PharmD, BCPS
Clinical Pharmacist

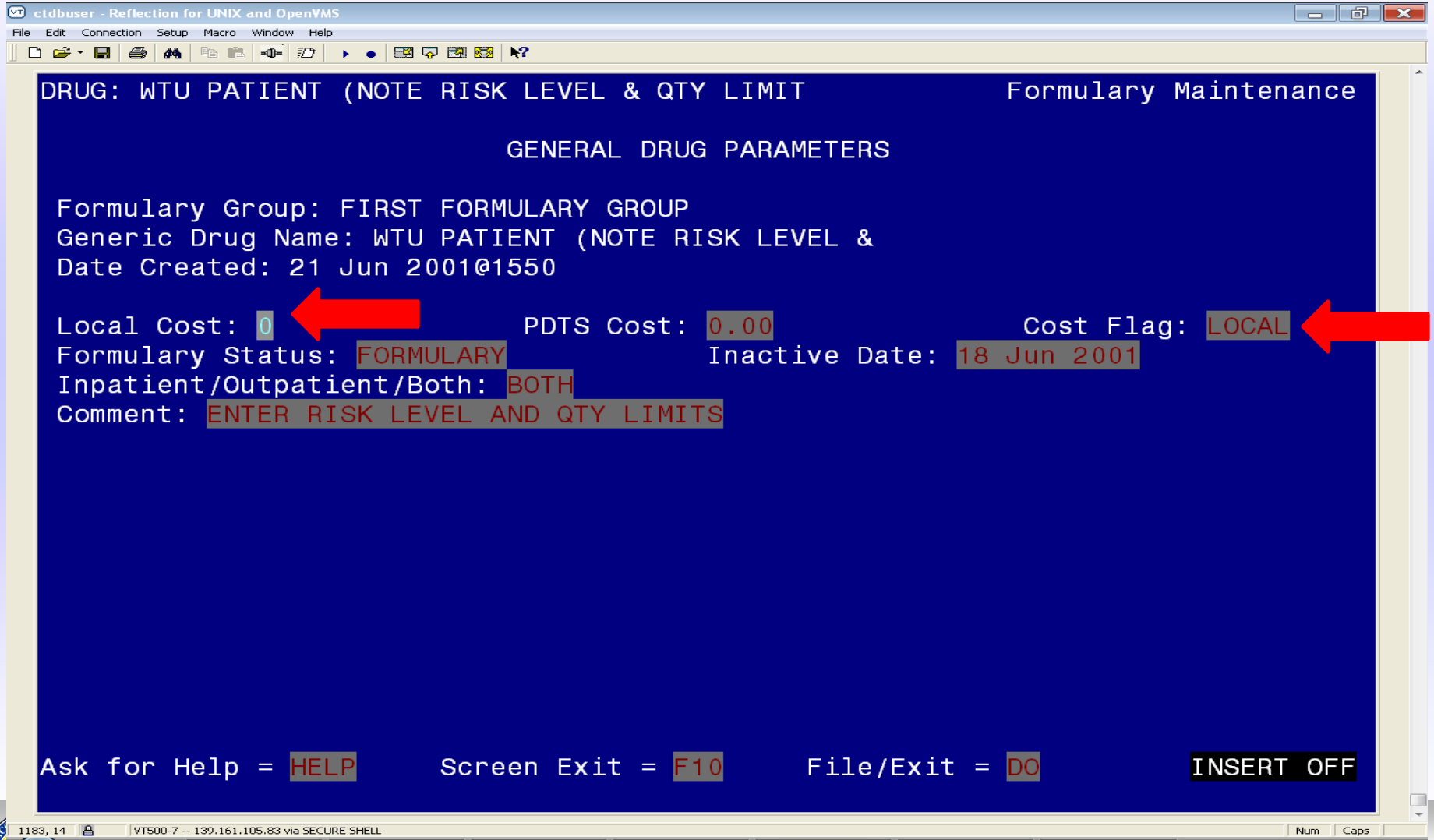
CHCS WTU/SPP Drug Entry

- **Background:**
  - Used as a tool to trigger warnings and to get the attention of the medical staff
  - Creates a valid prescription to include the NDC, prescriber's info, and costs on PDTS and other data sources used for reporting
- **Goal:**
  - Standardize the drug entry to minimize the unintended impact on PDTS while maintain the usefulness of the tool if MTFs choose to use it

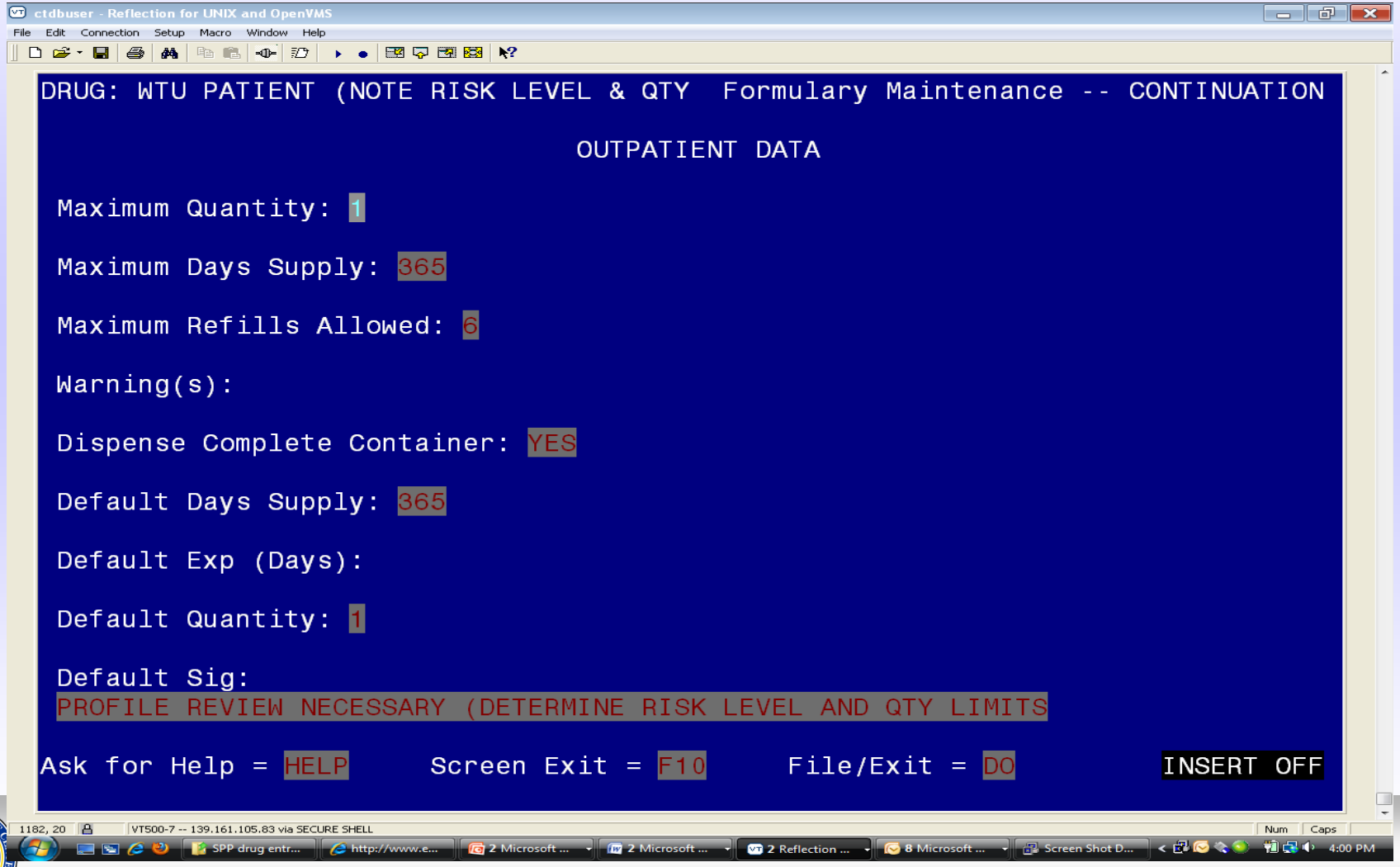
DRAFT CHCS WTU/SPP Drug Entry: Add New Drug (ADN)



DRAFT CHCS WTU/SPP Drug Entry: Formulary Maintenance (FRM)



DRAFT CHCS WTU/SPP Drug Entry: Formulary Maintenance (FRM)



CHCS WTU/SPP Drug Entry: Implementation

- Current status: testing all fields with MTFs
- Follow-up will occur with individual sites
- Educational materials will be distributed and available on the PEC website
- If you are interested in being a test site, please contact Libby Hearin

Contact Information

Libby Hearin

210-295-2452

DSN: 312-421-2452

Elizabeth.hearin@amedd.army.mil

Update on managed care residency

Amy Lugo, PharmD, BCPS
Clinical Pharmacist

PEC Pharmacy Residency

- **PGY1 Managed Care Pharmacy Residency**
- **Update**
  - Civilian
    - Still pursuing civilian position
  - Active duty
    - Discuss with your pharmacy specialty leader
  - Website
    - http://www.pec.ha.osd.mil/Residency/residency.php?submenuheader=0

Quarterly ACPE continuing education programs

Amy Lugo, PharmD, BCPS
Clinical Pharmacist

PEC Educational Series

- **What: PEC Educational Series**
  - Webinar: 1 contact hr of ACPE Continuing Education
- **Who**
  - Health professionals, initially CE only provided for pharmacists, goal to expand to provide CME also
- **When: Wednesdays, at least quarterly**
- **Where: Webinar offered via DCO**

Diabetes Update

- **Topic**
  - "Are you down with DPP? Get up to speed on DPP-4 inhibitors"
  - 0800 and 1600
- **When: Wednesday, February 23rd, 2011**
  - 0800 and 1600
- **Where: Webinar offered via DCO**
  - https://connect.dco.dod.mil/pecdpp4

Questions?

PEC Contact Info

- **210-295-1271 (DSN 421-1271)**
  - For PEC Clinical Staff

  1-866-ASK 4 PEC (275-4732)
  - Pharmacy Operation Center
  - PECWEB@amedd.army.mil
    - Website issues
  - pdts.ameddcs@amedd.army.mil
    - Questions, assistance with PDTS, Business Objects
  - PECUF@amedd.army.mil
    - Clinical, formulary questions