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
• 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 7.5-525 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

Fiscal Month

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: Oxycodeone/Acetaminophen U/D 5/325 (Percocet) and Oxycodone/Acetaminophen 5-325 (Percocet).
Contact Information

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Naval Medical Center Portsmouth
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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)
• 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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Brand</th>
<th>Generics</th>
<th>Available with HCTZ</th>
<th>FDA approval date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benazepril</td>
<td>Lotensin</td>
<td>Yes</td>
<td>Yes</td>
<td>1991</td>
</tr>
<tr>
<td>Captopril</td>
<td>Capoten</td>
<td>Yes</td>
<td>Yes</td>
<td>1981</td>
</tr>
<tr>
<td>Enalapril</td>
<td>Vasotec</td>
<td>Yes</td>
<td>Yes</td>
<td>1985</td>
</tr>
<tr>
<td>Fosinopril</td>
<td>Monopril</td>
<td>Yes</td>
<td>Yes</td>
<td>1991</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>Zestril/Prinvil</td>
<td>Yes</td>
<td>Yes</td>
<td>1987</td>
</tr>
<tr>
<td>Moexipril</td>
<td>Univasc</td>
<td>Yes</td>
<td>Yes</td>
<td>1995</td>
</tr>
<tr>
<td>Perindopril</td>
<td>Aceon</td>
<td>Yes</td>
<td>No</td>
<td>1993</td>
</tr>
<tr>
<td>Quinapril</td>
<td>Accupril</td>
<td>Yes</td>
<td>Yes</td>
<td>1991</td>
</tr>
<tr>
<td>Ramipril</td>
<td>Altace</td>
<td>Yes</td>
<td>No</td>
<td>1991</td>
</tr>
<tr>
<td>Trandolapril</td>
<td>Mavik</td>
<td>Yes</td>
<td>No</td>
<td>1996</td>
</tr>
</tbody>
</table>
# RAAs: Drugs in the Class ARBs

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

- All are available in combo with HCTZ
- All are approved for hypertension
## RAAs: Drugs in the Class
### Fixed Dose Combos / Direct Renin Inhibitors

<table>
<thead>
<tr>
<th>Generic Name (abbreviation)</th>
<th>Brand (company)</th>
<th>FDA Approval Date</th>
<th>Patent Exp.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Renin Inhibitors (DRI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aliskiren +/- HCTZ</td>
<td>Tekturna; Tekturna HCT (Novartis)</td>
<td>May 2007</td>
<td>2018/2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Jan 2008</td>
<td></td>
</tr>
<tr>
<td>Dual Fixed Dose Combos: ARB+CCB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telmisartan/amlodipine</td>
<td>Twynsta (BI)</td>
<td>Oct 2009</td>
<td>2014</td>
</tr>
<tr>
<td>Olmesartan/amlodipine</td>
<td>Azor (Sankyo)</td>
<td>Oct 2007</td>
<td>2016</td>
</tr>
<tr>
<td>Valsartan/amlodipine</td>
<td>Exforge (Novartis)</td>
<td>Jul 2007</td>
<td>2012-2019</td>
</tr>
<tr>
<td>Dual Fixed Dose Combos: DRI + ARB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aliskiren/valsartan</td>
<td>Valturna (Novartis)</td>
<td>Sep 2009</td>
<td>2012-2018</td>
</tr>
<tr>
<td>Triple Fixed Dose Combos: ARB+CCB+HCTZ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Valsartan/amlodipine/HCTZ</td>
<td>Exforge HCT</td>
<td>Apr 2009</td>
<td>2012-2017</td>
</tr>
</tbody>
</table>
Projected Schedule for Availability of Generic ARBs (as of October 2009)

- **Cozaar/ Hyzaar**: April 2010
- **Avapro/ Avalide**: March 2012
- **Atacand/ Atacand HCT**: December 2012
- **Diovan/ Diovan HCT**: September 2012
- **Micardis/ Micardis HCT**: January 2014 or later (Tentative; insufficient public information)
- **Teveten/ Teveten HCT**: August 2014 or earlier (Tentative; patents have not been challenged yet)
- **Benicar/ Benicar HCT**: April 2016 or earlier (Tentative; court decision might be overturned on appeal)
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 positive 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 (Twynda/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

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

Ophthalmic-1 Agents
# Ophthalmic 1

## Drugs in the Class

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand</th>
<th>Mfg</th>
<th>Generic</th>
<th>Strength</th>
<th>FDA Approval</th>
<th>Patent Expiration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antihistamines</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emedastine</td>
<td>Emadine</td>
<td>Alcon</td>
<td>No</td>
<td>0.05%</td>
<td>1997</td>
<td>2013</td>
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<tr>
<td><strong>Mast Cell Stabilizers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pemirolast</td>
<td>Alamast</td>
<td>Vistakon</td>
<td>No</td>
<td>0.01%</td>
<td>1999</td>
<td>2011</td>
</tr>
<tr>
<td>Nedocromil</td>
<td>Alocril</td>
<td>Allergan</td>
<td>No</td>
<td>2%</td>
<td>1999</td>
<td>2012</td>
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<tr>
<td>Cromolyn</td>
<td>Crolom/ Opticrom</td>
<td>-</td>
<td>Yes</td>
<td>4%</td>
<td>1995/1984</td>
<td>-</td>
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<tr>
<td>Lodoxamide</td>
<td>Alomide</td>
<td>Alcon</td>
<td>No</td>
<td>0.1%</td>
<td>1993</td>
<td>2012</td>
</tr>
<tr>
<td><strong>Dual Action Antihistamines/Mast Cell Stabilizers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ketotifen</td>
<td>Zaditor</td>
<td>-</td>
<td>Yes OTC</td>
<td>0.025%</td>
<td>1999</td>
<td>2006</td>
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<tr>
<td>Bepotastine</td>
<td>Bepreve</td>
<td>Ista</td>
<td>No</td>
<td>1.5%</td>
<td>2009</td>
<td>2014</td>
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<tr>
<td>Olopatadine</td>
<td>Patanol</td>
<td>Alcon</td>
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<td>0.1%</td>
<td>1996</td>
<td>2015</td>
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<tr>
<td></td>
<td>Pataday</td>
<td>Alcon</td>
<td>No</td>
<td>0.2%</td>
<td>2004</td>
<td>2024</td>
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<tr>
<td>Azelastine</td>
<td>Optivar</td>
<td>-</td>
<td>Yes</td>
<td>0.05%</td>
<td>2000</td>
<td>-</td>
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<tr>
<td>Epinastine</td>
<td>Elestat</td>
<td>Allergan</td>
<td>No</td>
<td>0.05%</td>
<td>2003</td>
<td>2020</td>
</tr>
</tbody>
</table>
## Ophthalmic 1
### Drugs in the Class

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

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
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

<table>
<thead>
<tr>
<th>Uniform Formulary (UF) Ophthalmic-1 Agents</th>
<th>Non-Formulary Ophthalmic-1 Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ophthalmic-1s on BCF</strong></td>
<td><strong>Ophthalmic-1s not on BCF</strong></td>
</tr>
<tr>
<td>MTFs must have on formulary</td>
<td>MTFs may have on formulary</td>
</tr>
<tr>
<td><strong>Dual Action AH/MCS</strong></td>
<td><strong>Dual Action AH/MCS</strong></td>
</tr>
<tr>
<td>• Patanol (olopatadine 0.1%)</td>
<td>• Bepreve (bepotastine 1.5%)</td>
</tr>
<tr>
<td></td>
<td>• Elestat (epinastine 0.05%)</td>
</tr>
<tr>
<td></td>
<td>• Emadine (emedastine 0.05%)</td>
</tr>
<tr>
<td></td>
<td>• Pataday (olopatadine 0.2%)</td>
</tr>
<tr>
<td></td>
<td>• Optivar (azelastine 0.05%)</td>
</tr>
<tr>
<td><strong>Mast Cell Stabilizers</strong></td>
<td><strong>Mast Cell Stabilizers</strong></td>
</tr>
<tr>
<td>• Alamast (pemirolast 0.1%)</td>
<td>• Alocril (nedocromil 2%)</td>
</tr>
<tr>
<td>• Alomide (lodoxamide 0.1%)</td>
<td>• Crolom/Opticrom (cromolyn 4%), generic</td>
</tr>
<tr>
<td>• Crolom/Opticrom (cromolyn 4%), generic</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>NSAIDs</strong></td>
</tr>
<tr>
<td></td>
<td>• Acular (ketorolac 0.5%); generic</td>
</tr>
<tr>
<td></td>
<td>• Acular LS (ketorolac 0.4%)</td>
</tr>
<tr>
<td></td>
<td>• Acuvail (ketorolac 0.45%)</td>
</tr>
<tr>
<td></td>
<td>• Nevanac (nepafenac 0.1%)</td>
</tr>
<tr>
<td></td>
<td>• Ocufen (flurbiprofen 0.03%), generic</td>
</tr>
<tr>
<td></td>
<td>• Voltaren (diclofenac 0.1%)</td>
</tr>
<tr>
<td></td>
<td>• Xibrom (bromfenac 0.09%)</td>
</tr>
</tbody>
</table>

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
  - One time use for starter kit
  - Mail: 1 kit with no refills
  - Retail: 1 kit with no refills

- **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 develop 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 31 October
  - 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

Graph showing weekly Qualaquin utilization with green and blue lines representing Non_MTF and MTF, respectively. Implementation Week is indicated with a red arrow.
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

<table>
<thead>
<tr>
<th>Class</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incretin Mimetics</strong></td>
<td>DPP-4 Inhibitors</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>GLP-1 Receptor Agonists</td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Insulin Sensitizers</strong></td>
<td>Biguanides</td>
</tr>
<tr>
<td></td>
<td>Thiazolidinediones</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Insulin Secretagogues</strong></td>
<td>Sulfonylureas</td>
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<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Meglitinides</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>Alpha-glucosidase Inhibitors</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Amylin Agonist</td>
</tr>
</tbody>
</table>

* 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 (Fenogllide) update

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

<table>
<thead>
<tr>
<th>Expected Mean LDL Reduction</th>
<th>Mevacor, Altoprev (lovastatin)</th>
<th>Pravachol (pravastatin)</th>
<th>Zocor (simvastatin)</th>
<th>Lescol, Lescol XL (fluvastatin)</th>
<th>Lipitor (atorvastatin)</th>
<th>Crestor (rosuvastatin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 to 30%</td>
<td>20 mg</td>
<td>20 mg</td>
<td>10 mg</td>
<td>40 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 to 40%</td>
<td>40 – 80 mg</td>
<td>40 mg</td>
<td>20 mg</td>
<td>80 mg (XL only)</td>
<td>10 mg</td>
<td></td>
</tr>
<tr>
<td>40 to 45%</td>
<td>IR: 80 mg (40 mg x 2)</td>
<td>80 mg</td>
<td>40 mg or Vytorn 10/10 mg</td>
<td>20 mg</td>
<td>5 mg</td>
<td></td>
</tr>
<tr>
<td>45 to 50%</td>
<td>Please note: ezetimibe (Zetia) or niacin generally decrease LDL up to an additional 15%</td>
<td></td>
<td>80 mg or Vytorn 10/20 mg</td>
<td>40 mg</td>
<td>10 mg</td>
<td></td>
</tr>
<tr>
<td>50 to 55%</td>
<td></td>
<td></td>
<td>Vytorn 10/40 mg</td>
<td>80 mg</td>
<td>20 mg</td>
<td></td>
</tr>
<tr>
<td>&gt;55%</td>
<td></td>
<td></td>
<td>Vytorn 10/80 mg</td>
<td></td>
<td></td>
<td>40 mg</td>
</tr>
</tbody>
</table>

IR = immediate release; ER = extended release

Vytorin = simvastatin/ezetimibe
# Dose-Specific Step Therapy Set-up

<table>
<thead>
<tr>
<th>Rx presented</th>
<th>Passes Step if Rx last 180 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advicor 1000/40mg (niacin ER/lovastatin)</td>
<td>Atorvastatin; lovastatin $\geq$ 40mg; pravastatin $\geq$ 40mg; simvastatin $\geq$ 20mg; Advicor</td>
</tr>
<tr>
<td>Advicor 20mg (niacin ER/lovastatin 500/, 750/, 1000/20 mg)</td>
<td>Atorvastatin; lovastatin $\geq$ 20mg, pravastatin $\geq$ 20mg; simvastatin $\geq$ 10mg; Advicor</td>
</tr>
<tr>
<td>Altoprev 10mg (lovastatin ER)</td>
<td>Atorvastatin; lovastatin (including Altoprev); pravastatin; simvastatin</td>
</tr>
<tr>
<td>Altoprev 20mg</td>
<td>Atorvastatin; lovastatin (including Altoprev); pravastatin $\geq$ 20mg; simvastatin $\geq$ 10mg</td>
</tr>
<tr>
<td>Altoprev 40mg</td>
<td>Atorvastatin; lovastatin (including Altoprev); pravastatin $\geq$ 40mg; simvastatin $\geq$ 20mg</td>
</tr>
<tr>
<td>Altoprev 60mg</td>
<td>Atorvastatin $\geq$ 20mg; lovastatin (including Altoprev); pravastatin 80mg; simvastatin $\geq$ 40mg</td>
</tr>
</tbody>
</table>
# Dose-Specific Step Therapy Set-up

<table>
<thead>
<tr>
<th>Rx presented</th>
<th>Passes Step if Rx last 180 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caduet 10mg (amlodipine/atorvastatin 2.5/10, 5/10, 10/10 mg)</td>
<td>Atorvastatin; lovastatin 40mg; pravastatin ≥ 40mg; simvastatin ≥ 20mg; Caduet</td>
</tr>
<tr>
<td>Caduet 20mg (2.5/20, 5-20, 10/20)</td>
<td>Atorvastatin; pravastatin 80mg; simvastatin ≥ 40mg; Caduet</td>
</tr>
<tr>
<td>Caduet 40mg and greater (2.5/40, 5/40, 10/40, 5/80, 10/80 mg)</td>
<td>Atorvastatin; simvastatin 80mg; Caduet</td>
</tr>
<tr>
<td>Crestor 5mg (rosuvastatin)</td>
<td>Atorvastatin ≥ 20mg; pravastatin 80mg; simvastatin ≥ 40mg; rosuvastatin</td>
</tr>
<tr>
<td>Crestor 10mg and greater 10,20,40 mg</td>
<td>Atorvastatin ≥ 40mg; simvastatin 80mg; rosuvastatin</td>
</tr>
<tr>
<td>Rx presented</td>
<td>Passes Step if Rx last 180 days</td>
</tr>
<tr>
<td>------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Lescol 20mg (fluvastatin)</td>
<td>Atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin</td>
</tr>
<tr>
<td>Lescol 40mg</td>
<td>Atorvastatin, fluvastatin, lovastatin $\geq$ 20mg, pravastatin $\geq$ 20mg, simvastatin $\geq$ 10mg</td>
</tr>
<tr>
<td>Lescol XL 80mg (fluvastatin  ER)</td>
<td>Atorvastatin, fluvastatin, lovastatin $\geq$ 40mg, pravastatin $\geq$ 40mg, simvastatin $\geq$ 20mg</td>
</tr>
<tr>
<td>Livalo 1mg (pitavastatin)</td>
<td>Atorvastatin, lovastatin $\geq$ 20mg; pitavastatin; pravastatin $\geq$ 20mg; simvastatin $\geq$ 10mg</td>
</tr>
<tr>
<td>Livalo 2mg</td>
<td>Atorvastatin, lovastatin $\geq$ 40mg; pitavastatin; pravastatin $\geq$ 40mg; simvastatin $\geq$ 20mg</td>
</tr>
<tr>
<td>Livalo 4mg</td>
<td>Atorvastatin $\geq$ 20mg, pitavastatin; pravastatin 80mg; simvastatin $\geq$ 40mg</td>
</tr>
</tbody>
</table>
### Dose-Specific Step Therapy Set-up

<table>
<thead>
<tr>
<th>Rx presented</th>
<th>Passes Step if Rx for product containing following last 180 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simcor 20mg (niacin ER/simvastatin 500/20, 750/20, 1000/20 mg)</td>
<td>Atorvastatin, lovastatin 40 mg, pravastatin ≥ 40mg; simvastatin ≥ 20mg; Simcor 20mg</td>
</tr>
<tr>
<td>Simcor 40mg (500/40, 1000/40 mg)</td>
<td>Atorvastatin ≥ 20mg; pravastatin 80mg; simvastatin ≥ 40mg; Simcor</td>
</tr>
<tr>
<td>Vytorin 10mg (ezetimibe/simvastatin 10/10 mg)</td>
<td>Atorvastatin ≥ 20mg; pravastatin 80mg; simvastatin; Vytorin</td>
</tr>
<tr>
<td>Vytorin 20mg and greater (10/20, 10/40, 10/80 mg)</td>
<td>Atorvastatin ≥ 40mg, simvastatin, Vytorin</td>
</tr>
</tbody>
</table>
# Messages if Patient Does Not Meet Criteria

<table>
<thead>
<tr>
<th>Rx presented</th>
<th>Message*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altoprev 10mg, Lescol 20mg</td>
<td>“Must try Simvastatin, Pravastatin, Lovastatin or Lipitor first.</td>
</tr>
<tr>
<td>Advicor 20mg, Altoprev 20mg, Lescol 40mg, Livalo 1 mg</td>
<td>“Must try Simvastatin &gt; 10mg, Pravastatin &gt; 20mg, Lipitor &gt; 10mg, or Lovastatin &gt; 20mg first.</td>
</tr>
<tr>
<td>Advicor 1000/40mg, Altoprev 40mg, Caduet 10mg, Lescol XL 80mg, Livalo 2 mg, Simcor 20mg</td>
<td>“Must try Simvastatin &gt; 20 mg, Pravastatin &gt; 40 mg, Lipitor &gt; 10 mg, or Lovastatin 40mg first.</td>
</tr>
<tr>
<td>Altoprev 60mg, Caduet 20mg, Crestor 5mg, Livalo 4mg, Simcor 40mg, Vytorin 10mg</td>
<td>“Must try Simvastatin &gt; 40 mg, Pravastatin 80 mg, or Lipitor &gt; 20 mg first.</td>
</tr>
<tr>
<td>Caduet 40mg and greater, Crestor 10mg and greater, Vytorin 20mg and greater</td>
<td>“Must try Lipitor &gt; 40 mg or Simvastatin 80 mg first.</td>
</tr>
</tbody>
</table>

*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

30d Eq Rxs

Simvastatin
Lipitor
Vytorin
Crestor
Pravastatin
Lovastatin
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 Utilization, MTF
By Tabs/Caps Dispensed, FY05-Oct10

Total Qty Dispensed


Review

Levitra
Viagra
Cialis
PDE-5s for ED Utilization, Retail
By Tabs/Caps Dispensed, FY05-Oct10

Total Qty Dispensed


Review

Levitra
Viagra
Cialis
PDE-5s for ED Utilization, Mail
By Tabs/Caps Dispensed, FY05-Oct10

Total Qty Dispensed

Levitra
Viagra
Cialis

Review
Review
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
### Preliminary Results

<table>
<thead>
<tr>
<th></th>
<th>CGT-2168</th>
<th>Placebo</th>
<th>Adjusted HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CV death, MI or stroke</strong></td>
<td>69 events</td>
<td>67 events</td>
<td>1.02 (0.70-1.51)</td>
</tr>
<tr>
<td><strong>Myocardial infarction</strong></td>
<td>37 events</td>
<td>36 events</td>
<td>0.96 (0.59-1.56)</td>
</tr>
<tr>
<td><strong>Revascularization</strong></td>
<td>69 events</td>
<td>67 events</td>
<td>0.95 (0.59-1.55)</td>
</tr>
<tr>
<td><strong>GI events</strong></td>
<td>38 events</td>
<td>67 events</td>
<td>0.55 (0.36-0.85)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Restriction (Locked into)</th>
<th>Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy</td>
<td><strong>PHARMACY NOT AUTHORIZED FOR THIS BENEFICIARY. CALL 1-866-275-4732 OR DSN (312) 471-8274 OPTION 8.</strong></td>
</tr>
<tr>
<td>Prescriber</td>
<td><strong>PREScriber NOT AUTHORIZED FOR THIS BENEFICIARY. CALL 1-866-275-4732 ......</strong></td>
</tr>
<tr>
<td>Prescriber for certain drugs</td>
<td><strong>PREScriber/Drug NOT AUTHORIZED FOR THIS BENEFICIARY. CALL 1-866-275-4732 ......</strong></td>
</tr>
<tr>
<td>Locked-out of certain drugs (not able to obtain at any pharmacy through TRICARE)</td>
<td><strong>MEMBER/DRUG NOT AUTHORIZED FOR THIS BENEFICIARY. CALL 1-866-275-4732 ......</strong></td>
</tr>
</tbody>
</table>
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)

Drug Name: WTU PATIENT (NOTE RISK LEVEL & QTY LIMIT)

Drug Route: MISC
Content Unit: EA
Default Unit: 
Package Size: 1
Legal Status: 0
Label Print Name: 
Synonym: 

Dosage Strength: 1
Dosage Form: MISC
Drug Check: ALL ENABLED
Metric Units: ML

NDC NUMBERS
00074-6777-01 (LORAZEPAM) QTY:1 ML
00074-1260-11 (MORPHINE SULFATE) QTY:1 ML
00024-5401-31 (AMBIEN) QTY:1 EA

Must contain at least 2 NDCs and QTY for each

Compound Total Qty: 3
Compound Metric Units: EA

Help = HELP Exit = F10 File/Exit = DC

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

DRUG: WTU PATIENT (NOTE RISK LEVEL & QTY LIMIT)

GENERAL DRUG PARAMETERS

Formulary Group: FIRST FORMULARY GROUP
Generic Drug Name: WTU PATIENT (NOTE RISK LEVEL &
Date Created: 21 Jun 2001@1550

Local Cost: 0 PDTS Cost: 0.00 Cost Flag: LOCAL
Formulary Status: FORMULARY Inactive Date: 18 Jun 2001
Inpatient/Outpatient/Both: BOTH
Comment: ENTER RISK LEVEL AND QTY LIMITS

Ask for Help = HELP Screen Exit = F10 File/Exit = DO INSERT OFF
DRUG: WTU PATIENT (NOTE RISK LEVEL & QTY) Formulary Maintenance -- CONTINUATION

OUTPATIENT DATA

Maximum Quantity: 1
Maximum Days Supply: 365
Maximum Refills Allowed: 6
Warning(s):
Dispense Complete Container: YES
Default Days Supply: 365
Default Exp (Days):
Default Quantity: 1
Default Sig:
PROFILE REVIEW NECESSARY (DETERMINE RISK LEVEL AND QTY LIMITS

Ask for Help = HELP Screen Exit = F10 File/Exit = DO  INSERT OFF
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
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
• **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](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