



TMA DoD Pharmacoeconomic Center Fort Sam Houston, TX

MTF Quarterly Webcast March 1, 2012

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 stops working

Outline

- ▶ Review of November 2011 P&T Committee Meeting (Dr Meade)
- ▶ Overview of February 2012 P&T Committee Meeting (Dr Meade)
- ▶ Questions

Review of November 2011 P&T Committee Meeting

Dave Meade, PharmD, BCPS
Clinical Pharmacist

November 2011

DoD P&T Committee Meeting

▶ **Uniform Formulary Class Reviews**

- Depression and Non-Opioid Pain Syndromes
- Short-Acting Beta Agonist (SABA)
- PDE-5 Inhibitors

November 2011

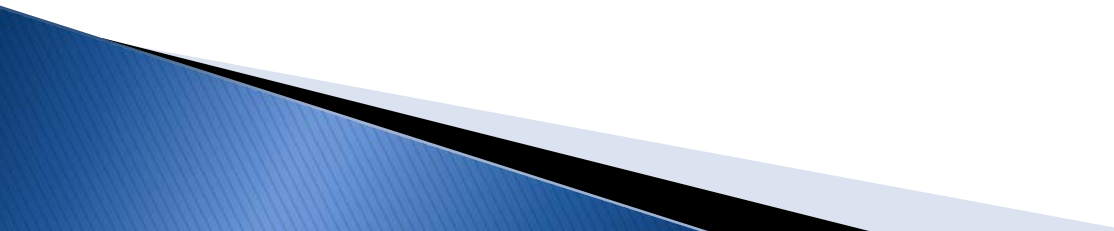
DoD P&T Committee Meeting

- ▶ **New Drugs in Previously Reviewed Classes**
 - Risedronate Delayed Release (Atelvia)
- ▶ **Utilization Management**
 - Abatacept SQ (Orencia)
 - Sunitinib (Sutent)
 - Tramadol ER (Conzip)

Uniform Formulary Class Reviews: Depression and Non-Opioid Pain Syndromes

**Antidepressants
Non-opioid Pain Syndromes
Tricyclic Antidepressants/Cyclobenzaprine**

Bottom-Line Up Front

- ▶ No striking net differences in antidepressant efficacy/safety between agents/subclasses
 - ▶ For pain syndromes, low-dose TCAs are more efficacious at much lower cost
 - ▶ For Lyrica, benefits over generic gabapentin in efficacy, dosing/titration, AEs have not been realized
- 

Bottom-Line Up Front

- ▶ For Cymbalta, Lyrica, Pristiq, and Savella
 - Addition of a Step therapy process to the NF status facilitate more cost effective patterns of use
- ▶ For Cymbalta
 - Though an FDA approved use, chronic musculoskeletal pain is not considered a cost effective indication for use

Antidepressant-1 s

Drugs in the Class

Generic	Brand	Manufacturer	FDA Approval Date	Patent Expiration
Selective Serotonin Reuptake Inhibitor (SSRI)				
Citalopram	Celexa	Forest, generics	17 July 98	-
Escitalopram	Lexapro	Forest, generic	14 Aug 02	March 14, 2012
Fluoxetine	Prozac	Lilly, generics	29 Dec 87	-
Fluoxetine 90 mg caps (weekly regimen)	Prozac Weekly	Lilly, generics	26 Feb 01	-
Fluoxetine (special packaging)	Sarafem	Lilly	6 Jul 00	-

Drugs in the Class

Generic	Brand	Manufacturer	FDA Approval Date	Patent Expiration
Fluvoxamine	Luvox	Jazz (Solvay), Generics	5 Dec 94	-
Paroxetine HCl	Paxil	GSK, generics	29 Dec 92	-
Paroxetine HCl controlled release	Paxil CR	GSK, generic	16 Feb 99 (02 launch)	2017
Paroxetine mesylate	Pexeva	Synthon	11 Mar 02	Patents through 2017; no unexpired exclusivity; no generics
Sertraline	Zoloft	Pfizer, generics	30 Dec 91	-

Drugs in the Class

Generic	Brand	Manufacturer	FDA Approval Date	Patent Expiration
Serotonin/Norepinephrine Reuptake Inhibitor (SNRI)				
Duloxetine	Cymbalta	Eli Lilly	2004	June 2013
Venlafaxine	Effexor	Pfizer, generics	1993	N/A
Venlafaxine ER	Effexor XR	Pfizer, generics	1997	N/A
Desvenlafaxine	Pristiq	Pfizer	2008	2022

Drugs in the Class

Generic	Brand	Manufacturer	FDA Approval Date	Patent Expiration
Serotonin-2 Antagonist/Reuptake Inhibitors (SARIs)				
Nefazodone	Generics only*		22 Dec 94	-
Trazodone	Desyrel, generics	BMS	24 Dec 81	-
Trazodone ER	Oleptro	Labopharm	02 Feb 10	Patents Jun 2020-Mar 2027: Exclusivity Feb 2013
Norepinephrine and Dopamine Reuptake Inhibitors (NDRIs)				
Bupropion	Wellbutrin, generics	GSK	30 Dec 85	-
Bupropion sustained release	Wellbutrin SR, generics	GSK	4 Oct 96	-
Bupropion extended release	Wellbutrin XL	GSK	28 Aug 03	Patents through 2018; generics unclear
Bupropion HBr	Aplenzin	Sanofi Aventis	23 Apr 08	Jun 2026

Drugs in the Class

Generic	Brand	Manufacturer	FDA Approval Date	Patent Expiration
Alpha-2 Receptor Antagonists				
Mirtazapine tablets	Remeron, generics	Organon	14 Jun 96	-
Mirtazapine ODT	Remeron SolTab, generics	Organon	12 Jan 01	-
Serotonin-1a Partial Agonist/Reuptake Inhibitors				
Vilazodone	Viibryd	Forest	21 Jan 11	Sep 2014 to Jun 2022; Exclusivity to Jan 2016

Overall Clinical Effectiveness Conclusion

- ▶ High non-responder rates for each of the agents necessitates a variety of agents on the uniform formulary
- ▶ Fluoxetine, and possibly escitalopram, are the only agents found to have a favorable risk: benefit profile in the treatment of MDD for children and adolescents
- ▶ Trials including duloxetine show no differences in efficacy with the comparator agents despite maximal doses of duloxetine and sub-maximal doses of the comparators
- ▶ Vilazodone is efficacious versus placebo for the treatment of MDD. Its unique mix of receptors may be beneficial to some patients
- ▶ Trazodone ER is efficacious versus placebo for the treatment of MDD. The effect appears to be heavily influenced by its sedating properties
- ▶ Mirtazapine consistently demonstrates the most rapid onset of action
- ▶ Beyond the FDA-indications, there is insufficient evidence to draw conclusions about the comparative efficacy of the second-generation antidepressants with respect to GAD, OCD, Panic Disorder, or PTSD

Overall Clinical Effectiveness Conclusion

- ▶ Most agents are highly therapeutically interchangeable for efficacy
- ▶ Discontinuation rates are similar between agents
- ▶ There is wide variation in the specific side effects profiles of the antidepressant agents
- ▶ Factors like activation/sedation, weight changes, sexual dysfunction, drug interactions (most commonly based on protein-binding, CYP isoenzyme induction/inhibition or therapeutic duplication) may guide treatment decision
- ▶ Rare serious adverse events for mirtazapine, nefazodone, and trazodone typically limit them to second-line status
- ▶ It is reasonable to limit access to specific agents when similar agents (different salt, delivery mechanism, or parent: metabolite relationship) are included on the formulary

Non-Opioid Pain Syndromes

Drugs in the Class

Generic Name	Brand	Manufacturer	FDA Approval Date	Patent Expiration
Duloxetine	Cymbalta	Eli Lilly	2004	12/11/2013
Venlafaxine	Effexor	Pfizer	1993	-
Desvenlafaxine	Pristiq	Pfizer	2008	2/11/2022
Milnacipran	Savella	Forest	2009	11/5/2021
Gabapentin	Neurontin	Multiple	1994	-
Pregabalin	Lyrica	Pfizer	2004	10/8/2013-12/13/2018

Overall Clinical Effectiveness Conclusion

▶ Fibromyalgia

- Strong evidence for efficacy of antidepressants
TCAs >>> SNRIs > SSRIs ~ MAOIs
 - ↓ pain; ↓ sleep disturbance; ↓ depressed mood; Improve HRQoL; All effect sizes were small except TCAs
- In one meta-analysis, only 24% of FM patients taking pregabalin (at higher doses, 450mg–600mg) obtained at least 50% pain relief
 - The pregabalin dose–response relationship for efficacy in FM was not as striking as that seen in other conditions

Overall Clinical Effectiveness Conclusion

- ▶ Efficacy measures used in these conditions are subjective and while statistical significance often exists, clinical significance is unclear
- ▶ No direct head-to-head studies in DPN, FM, or PHN
- ▶ Meta-analyses and systematic reviews are the primary sources for data analysis among agents

Tricyclic Antidepressants

Drugs in the Class

Generic Name	Brand	Manufacturer	FDA Approval Date
Amitriptyline	Elavil	generic	1961
Nortriptyline	Pamelor, Aventyl	generic	1977, 1964
Doxepin	Sinequan	generic	1969, 2010
Imipramine	Tofranil, Tofranil-PM	generic	1984, 1973
Desipramine	Norpramin	generic	1964
Protriptyline	Vivactil	generic	1967

Depression and Non-Opioid Pain Syndromes Agents– Final Decision

DoD PEC Drug Class	On BCF MTFs <u>must</u> have on formulary	Not on BCF MTFs <u>may</u> have on formulary	MTFs <u>must not</u> have on formulary
Depression and Non-Opioid Pain Syndrome Agents	SSRIs: citalopram fluoxetine sertraline SNRIs: venlafaxine IR venlafaxine ER SPARIs: trazodone NDRIs: bupropion HCl IR bupropion HCl SR bupropion HCl ER GABA analogs: gabapentin TCAs: amitriptyline doxepin imipramine HCl nortriptyline	SSRIs: paroxetine HCl IR paroxetine HCl CR paroxetine mesylate sertraline SNRIs: venlafaxine ER tablets SARIs: nefazodone TCAs: desipramine doxepin imipramine pamoate protriptyline A2RAs: mirtazapine tablets mirtazapine ODT GABA analogs: Gabapentin (Horizant , Gralise)	SSRIs: escitalopram (Lexapro) fluoxetine (Sarafem) fluoxetine weekly (Prozac Weekly) SNRIs: desvenlafaxine (Pristiq) duloxetine (Cymbalta) milnacipran (Savella) SARIs: trazodone ER (Oleptro) SPARIs: vilazodone (Viibryd) NDRIs: bupropion HBr (Aplenzin) GABA analogs: pregabalin (Lyrica)

Depression

Step Therapy Set Up

Subclasses	Prescribed Medication	Step 1 Look-Back (180 days)	Message to Pharmacy
SNRI	Cymbalta for Depression	Any SSRI, SNRI (except milnacipran), TCA, mirtazapine, bupropion, SARI, MAOI	Must try at least one of the following first: SSRIs, SNRIs (except milnacipran), TCAs, mirtazapine, bupropion, SARIs, MAOIs.
SNRI	Pristiq	Venlafaxine	Must try venlafaxine first

Non-Opioid Pain Syndromes

Step Therapy Set Up

Subclasses	Prescribed Medication	Step 1 Look-Back (180 days)	Message to Pharmacy
SNRI	Cymbalta for Pain	Any SNRIs, milnacipran, TCAs, cyclobenzaprine, GABAs (gabapentin, pregabalin)	Must try at least one of the following first: SNRIs, milnacipran, TCAs, cyclobenzaprine, gabapentin, or pregabalin.
GABAs	Lyrica	Gabapentin	Must try gabapentin first.
SNRI	Savella	Any SNRIs, milnacipran, TCAs, cyclobenzaprine, GABAs (gabapentin, pregabalin)	Must try at least one of the following first: SNRIs, milnacipran, TCAs, cyclobenzaprine, gabapentin, or pregabalin.

Uniform Formulary Class Reviews: Short-Acting Beta Agonist (SABA)

Drugs in the Class

Generic Name	Brand Name/Dose	FDA Approval	Generic	Mfg.	Patent Expiration
Albuterol	Inhalation Solution				
	0.5% (2.5 mg/0.5 mL) 0.083% (2.5 mg/3 mL)	Various	Yes	Multiple	NA
	Accuneb 0.021% (0.63 mg/3mL) 0.042% (1.25 mg/3mL)	Apr 2001	Yes	Multiple	NA
	Metered dose inhaler				
	Proair HFA 0.09mg	Oct 2004	No	Teva	Feb 2014
	Proventil HFA 0.09mg	Aug 1996	No	Schering Plough	Jun 2015
	Ventolin HFA 0.09mg	Apr 2001	No	Glaxo	Dec 2021
Levalbuterol	Inhalation Solution				
	Xopenex 0.31, 0.63, 1.25mg	Mar 1999	Only concentrate (1.25 mg)	Sunovion Mylan (1.25 mg)	Mar 2021
	Metered dose inhaler				
	Xopenex HFA 0.045 mg	Mar 2005	No	Sunovion	Nov 2017
Pirbuterol	Maxair Autohaler CFC 0.2mg	Nov 1992	No	Graceway	Expired

HFA=hydrofluoroalkane; MDI=metered-dose inhaler; INH=inhalation; Soln=solution

Overall Clinical Effectiveness Conclusion

▶ Asthma

- In adults, there is little evidence to suggest that there are clinically relevant differences between albuterol vs. Xopenex nebs
- In children, the evidence for comparative efficacy is mixed and inconclusive for albuterol vs. levalbuterol
- No studies comparing efficacy of albuterol vs. Xopenex MDIs

▶ EIB

- Albuterol MDI taken 15–30 min before exercise prevents EIB significantly better than placebo
- Although Xopenex is not currently approved by the FDA for EIB, phase III trials point to similar effect size as with albuterol

▶ COPD

- SABAs are more efficacious than placebo.
- Insufficient evidence to compare the agents

Overall Clinical Effectiveness Conclusion

► Safety & Tolerability

- Insufficient evidence to suggest clinically relevant differences in tachycardia, or nervousness caused by albuterol nebs compared to levalbuterol nebs
- Although there is a lack of comparative safety data between levalbuterol and albuterol MDIs, there is no evidence to suggest clinically relevant differences between both stereoisomers
- AEs and drug interactions are similar across the SABAs

► Other factors

- Ventolin has a dose counter
- Proventil has a round mouthpiece that may be awkward to use with spacers
- Maxair is breath actuated; only commercially available till 2013

Short-Acting Beta Agonist– Final Decision

BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary
<p>No change from previous review November 2008</p> <ul style="list-style-type: none">• albuterol nebulizing solution (0.083% [2.5 mg/3 mL])• Ventolin HFA MDI	<ul style="list-style-type: none">• albuterol nebulizing solution (0.5% [2.5 mg/0.5 mL])• albuterol nebulizing solution (Accuneb)• Proair HFA• Proventil HFA• Levalbuterol HFA (Xopenex HFA)• Levalbuterol nebulizing solution (Xopenex)	<ul style="list-style-type: none">• pirbuterol CFC (Maxair)

Uniform Formulary Class Reviews: PDE-5 Inhibitors for ED

Drugs in the Class

Phosphodiesterase Inhibitors (PDE-5)
Vardenafil (Levitra)
Vardenafil ODT (Staxyn)
Sildenafil (Viagra)
Tadalafil (Cialis)

Overall Clinical Effectiveness Conclusion

▶ ED

- No head-to-head trials; cannot make direct efficacy comparisons among the four drugs
- There is insufficient evidence to conclude that there are clinically relevant differences in efficacy of PDE-5 inhibitors for ED
- Based on meta-analyses by AHRQ, Cochrane, and BMC, indirect comparisons suggest that there are similar improvements between the four PDE-5 inhibitors in endpoints:
 - IIEF “EF” domain change
 - % of patients responding “Yes” to GAQ-Q1
 - % of patients with improved erections
- One cochrane analysis found that PDE-5 inhibitors improve erections in DM patients
- There is insufficient evidence to conclude that daily therapy for ED is superior to on demand therapy

Overall Clinical Effectiveness Conclusion

- ▶ Staxyn
 - 2 studies demonstrated that the three primary endpoints show a difference between the vardenafil group and the placebo group
 - The improvement in IIEF score with Staxyn appears similar to that seen in the AHRQ review based on indirect comparison

Overall Clinical Effectiveness Conclusion

▶ Safety & Tolerability

- PDE-5 are generally well tolerated
- The relationship of PDE-5 inhibitors to NAION or hearing loss are uncertain at this time
- There is insufficient evidence to conclude that there are clinically relevant differences in safety between PDE-5 inhibitors for ED
- Clinical trials for Staxyn have identified no safety issues that were not previously identified in the studies of the vardenafil film-coated tablets
- Does not appear to be clinically relevant differences in safety between Staxyn and Levitra
- **Staxyn not recommended in hepatic or renal impairment**

Tadalafil (Cialis) for Benign Prostatic Hypertrophy

Overall Clinical Effectiveness Conclusion

▶ Cialis for BPH

- IPSS improved from baseline in a statistically and clinically significant way with tadalafil 5 mg daily over 12 weeks
 - Mean reduction in IPSS with tadalafil was –5.6 points
 - Improvements from baseline in IPSS scores were clinically significant with both tadalafil and placebo
- Patient and clinician perception of improvement in urinary symptoms occurred 16.25% more on average with tadalafil than with placebo
- Patients with higher BPH–LUTS severity may experience greater benefit from tadalafil than those with more moderate symptoms
 - Mean reductions in IPSS with terazosin and doxazosin in similar patient populations were –6.1 and –8.3 points
- Efficacy with A1Bs and tadalafil cannot be directly compared, but evidence indicates tadalafil is no better and possibly less efficacious for reducing BPH urinary symptoms

A1B – alpha 1 blockers (doxazosin, alfuzosin, terazosin)

IPSS international prostate symptoms score

LUTS lower urinary tract symptoms

Overall Clinical Effectiveness Conclusion

► Safety Conclusions

- Over 12 weeks, tadalafil 5 mg daily for BPH was associated with low AE rates that were similar to placebo
- Tadalafil 5 mg daily was not associated with an increased risk of orthostatic hypotension compared to placebo
- Rare but serious adverse effects remain a concern
 - Auditory disturbances including tinnitus and hearing loss
 - Visual disturbances including vision loss due to nonarteritic anterior ischemic optic neuropathy (NAION)
- FDA label for tadalafil (Cialis) states
 - “Use of Cialis with alpha blockers, antihypertensives or substantial amounts of alcohol (≥ 5 units) may lead to hypotension “
 - “Cialis is not recommended in combination with alpha blockers for the treatment of BPH because efficacy of the combination has not been adequately studied and because of the risk of blood pressure lowering”

PDE-5 Inhibitors – Final Decision

BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary
<ul style="list-style-type: none">• sildenafil (Viagra)		<ul style="list-style-type: none">• tadalafil (Cialis)• vardenafil (Levitra, Staxyn)

Step therapy

- ED
 - Must try sildenafil (Viagra) first- BCF and step – preferred
 - tadalafil (Cialis) and vardenafil (Levitra, Staxyn) are NF and non step - preferred
- BPH
 - Must try a preferred alpha-1 blocker prior to use of tadalafil (Cialis) for BPH

PDE-5 Inhibitors – Quantity Limits

- ▶ Cialis, Levitra, Viagra
 - Maximum quantity
 - Retail: 6 tabs/30 days
 - Mail/MTF: 18 tabs/90 days
- ▶ Staxyn
 - Maximum quantity
 - Retail: 6 tabs/30 days
 - Mail/MTF: 16 tabs/90 days
- ▶ Daily therapy for PAH, Raynaud's phenomenon, post-prostatectomy preservation/restoration of erectile function, BPH
 - Retail: 30-day supply
 - Mail/MTF: 90-day supply

New Drugs in Previously Reviewed Classes

Risedronate Delayed-Release (Atelvia)

Drugs in the Class

Sub-Class	Generic Name	Brand Name Manufacturer	FDA Approval Date/Generics
Bisphosphonates	Alendronate	Fosamax (Merck)	1995 / Yes
	Alendronate / Vit D	Fosamax Plus D (Merck)	2005/ No
	Risedronate	Actonel (Warner Chilcott)	1998 / No
	Risedronate / calcium	Actonel with calcium (Warner Chilcott)	2005 / No
	Ibandronate	Boniva (Roche)	2003 / No
SERM	Raloxifene	Evista (Lilly)	1997 / No
Parathyroid Hormone	Teriparatide (SC)	Forteo (Lilly)	2002 / No
Calcitonin	Calcitonin-salmon (nasal-spray)	Miacalcin (Novartis)	1995 / No
		Fortical (Upsher-Smith)	2005 / Yes

Overall Clinical Effectiveness Conclusion

- ▶ Atelvia (risdedronate delayed release) is a formulation that is designed to be co-administered with food; is administered immediately after breakfast
- ▶ Atelvia 35 mg weekly was noninferior to risedronate IR 5 mg daily for increasing BMD in PMO patients
- ▶ Risedronate IR reduces relative fracture risk at 3 years in patients with PMO by 41–49% at the spine and 30–40% at nonvertebral sites, including the hip
- ▶ Efficacy of risedronate IR to reduce fracture risk is well-established, and represents the benefit believed to be conferred on patients taking Atelvia
- ▶ No difference in number of serious AEs between Atelvia and risedronate IR
- ▶ No head-to-head or fracture outcome studies in progress

Overall Clinical Effectiveness Conclusion

- ▶ Co-administration with acid-suppressing therapies may partially negate Atelvia's therapeutic effectiveness and advantage in patient convenience
- ▶ Class-wide bisphosphonate drug interactions pertain to Atelvia
- ▶ Precautions and contraindications of the bisphosphonate class pertain to Atelvia
- ▶ Overall adverse effect profiles are similar between Atelvia and risedronate IR
- ▶ Atelvia offers patient convenience in a weekly dosing regimen option for osteoporosis
- ▶ Atelvia may serve a niche of patients in whom fasting administration noncompliance is the primary cause of nonadherence; however, treatment alternatives exist which address all factors of nonadherence

New Drugs in a Previously Reviewed Class

Final Decisions

Drug	BCF	UF	NF
Osteoporosis Agents Subclass: bisphosphonates	<ul style="list-style-type: none">▪ No change from previous review June 2008▪ alendronate▪ alendronate with Vitamin D▪ ibandronate (Boniva)	<ul style="list-style-type: none">▪ No change from previous review June 2008▪ risedronate IR (Actonel)▪ risedronate IR with calcium (Actonel with Calcium)	<ul style="list-style-type: none">▪ risedronate DR (Atelvia)

Utilization Management

Quantity Limits (QL)

Sunitinib malate (Sutent)

Background

- ▶ Type of Drug
 - Kinase inhibitor
- ▶ FDA – Approved Indication
 - Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease (new indication–05/20/2011)
 - Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate
 - Advanced renal cell carcinoma (RCC)

Sunitinib malate (Sutent)

► Dosing

- pNET:
 - 37.5 mg orally once daily, with or without food, continuously without a scheduled off-treatment period
- GIST and RCC:
 - 50 mg orally once daily, with or without food, 4 weeks on treatment followed by 2 weeks off

► QL recommendation– Maximum quantity

- Retail:
 - 12.5mg : 120 caps/ 30 days
 - 25mg: 60 caps/ 30 days
 - 50mg: 30 caps/ 30 days
- Mail:
 - 12.5mg : 252 caps/ 84 days
 - 25mg: 120 caps/ 84 days
 - 50mg: 60 caps/84 days

► Justification

- Consistent with recommended dosing

Tramadol ER (Conzip) Background

- ▶ Type of Drug
 - An opioid agonist
 - Extended-release formulation of tramadol with an immediate release outer component
 - 100 mg capsule: 25 mg IR tablet and coated ER beads
 - 200 mg, 300 mg capsules: 50 mg IR tablet and coated ER beads
 - 505(b)(2) application
- ▶ FDA – Approved Indication
 - Management of moderate to moderately severe chronic pain in adults
- ▶ Dosing
 - Adults not on tramadol IR: Initiate at a dose of 100 mg once daily, then titrate up by 100 mg increments every 5 days
 - Adults on tramadol IR: Calculate total 24-hr IR dose, initiate at a dose rounded down to next lower 100 mg increment; then adjust dose according to need and tolerance

Tramadol ER (Conzip)

- ▶ QL recommendation
 - Maximum quantity
 - Retail: 30 capsules/30 days
 - Mail: 90 capsules/90 days

- ▶ Justification
 - Collective QL exists for tramadol ER tablets
 - Consistent with recommended dosing

Abatacept (Orencia)

Background

- ▶ Type of Drug:
 - Subcutaneous injection of T cell modulator
 - IV formulation (medical benefit) has been on the market since 2005
 - Targeted immunomodulatory biologic (TIB) drug class
 - Prior Authorization and Quantity limits apply to the TIBs
- ▶ FDA – Approved Indication:
 - Moderately to severely active RA in adults
- ▶ Dosing:
 - 125 mg subcutaneously q week

Abatacept (Orencia)

▶ Proposed PA criteria:

- Coverage provided for the treatment of moderately to severely active RA
- Coverage NOT provided for concomitant use with other TIBS (anakinra, etanercept, adalimumab, golimumab, certolizumab, or infliximab)

▶ Proposed Quantity Limits:

- Retail: Maximum of 4 syringes in 28 days
- Mail: Maximum of 8 syringes in 56 days

Review of February 2012 P&T Committee Meeting

Dave Meade, PharmD, BCPS
Clinical Pharmacist

February 2012

DoD P&T Committee Meeting

▶ **Uniform Formulary Class Reviews**

- DPP-4 Subclass – Non insulin Antidiabetic Agents
- ADHD/Wakefulness Promoting Agents
- Antiplatelet Agent

▶ **New Drugs in Previously Reviewed Classes**

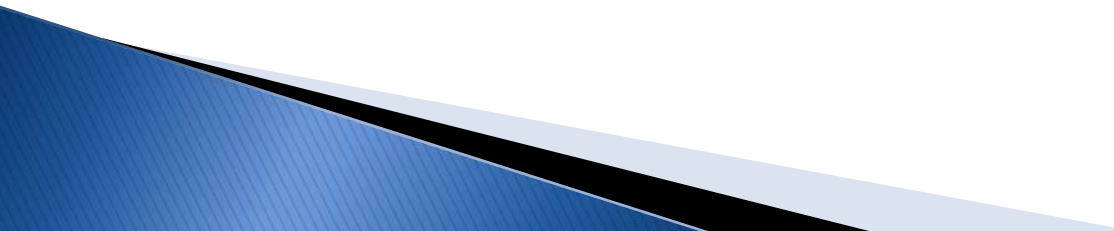
- Nucynta ER (Tapentadol ER) – Narcotic Analgesics
- Alcaftadine (Lastacast) – Ophthalmic

▶ **Utilization Management**

- Crizotinib (Xalkori)
- Vermurafenib (Zelboraf)
- Ivacaftor (Kalydeco)

Questions?

Webcast Evaluations

- ▶ Please assist us in improving the webcast presentations by completing an anonymous, 5-question survey
 - ▶ Link: <http://www.zoomerang.com/Survey/WEB22CTVSNWFRP>
 - ▶ Thank you!
- 

PEC Contact Info

- ▶ Robert.selvester@amedd.army.mil
 - For smoking cessation drug class review comments
- ▶ 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