

TMA DoD Pharmacoeconomic Center Fort Sam Houston, TX

MTF Quarterly Webcast June 14, 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

- MTF Corner- PMART (Mr. Morales)
- Review of February 2012 P&T Committee Meeting (Dr Meade)
- Overview of May 2012 P&T
 Committee Meeting (Dr Meade)
- Questions

Prescription Medication Analysis & Reporting Tool (PMART)

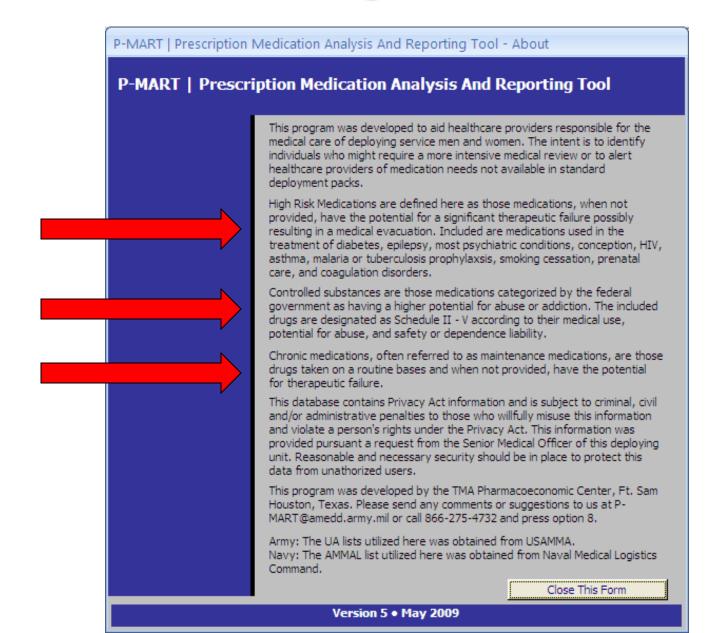
Report Tool Summary

- Medication profile snapshot for deploying SMs
 - Pre-deployment medication screening
 - Identification of high-risk SMs
 - Identification of SMs who require CENTCOM waiver
- Menu-driven, Microsoft Access database with lookup features and reports
- Pharmacy Data Transaction Service (PDTS) is data source
 - All DoD Pharmacy points of service
- Report turn-around 24 72 hours

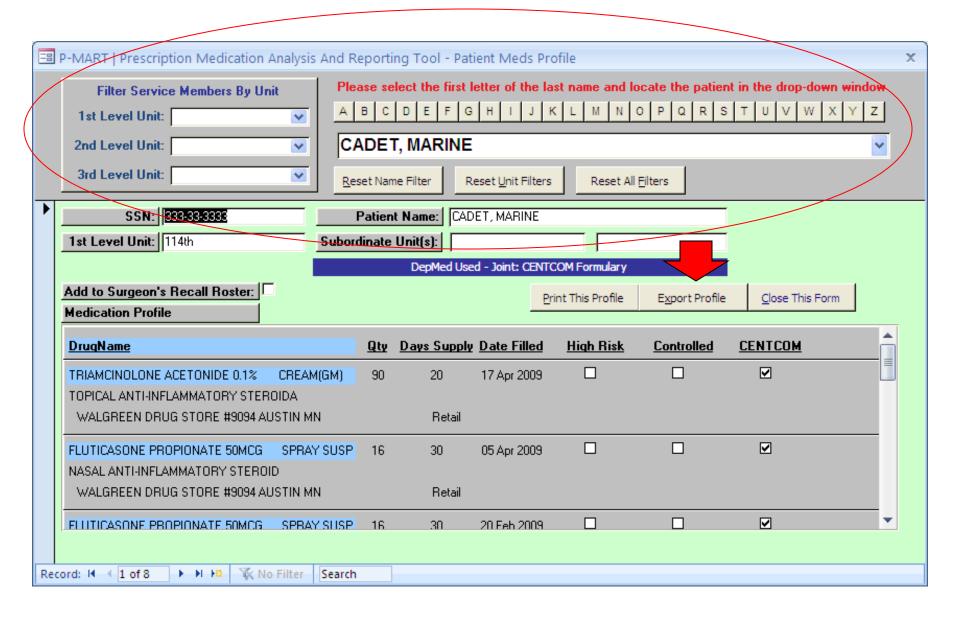
Deployment PMART Homepage



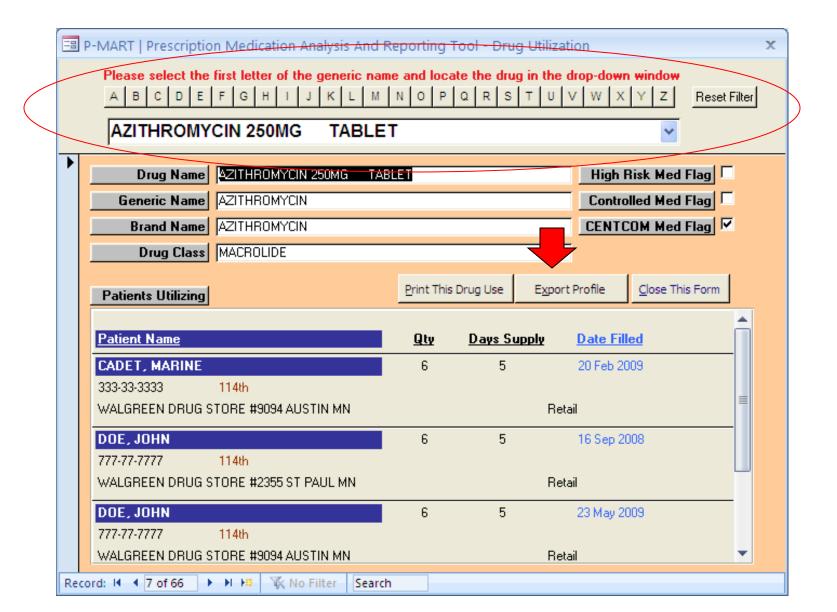
About This Program Button



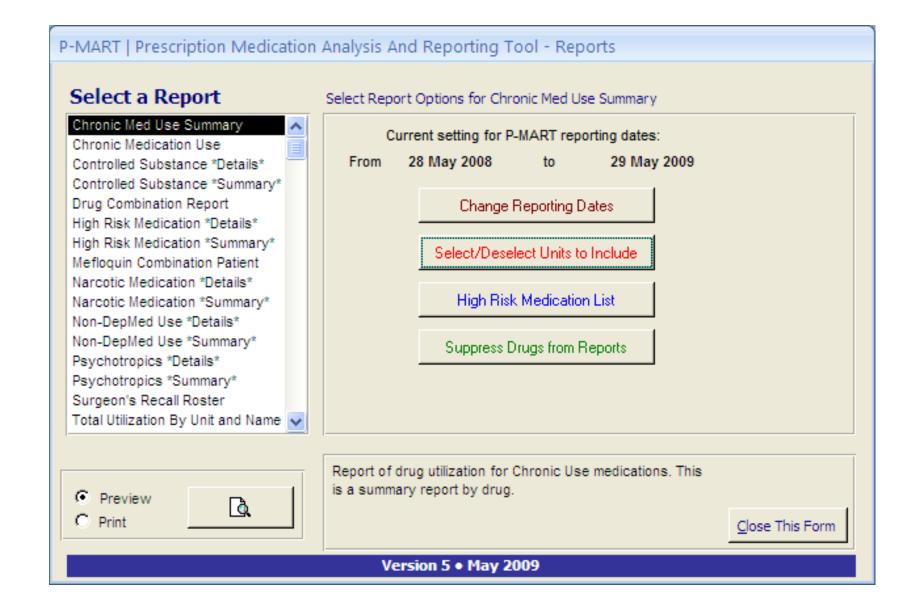
Patient Medication Profiles Button



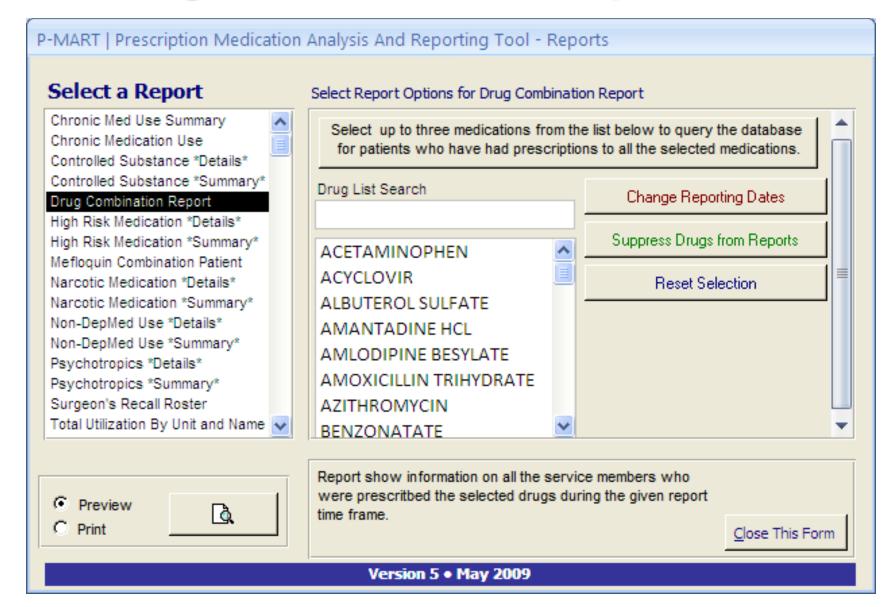
Utilization by Drug Button



Master Reports Selection Button



Drug Combination Report



User Defined Combination Report

Drug Combination Report

Data current as of 6/3/2009

Date Range: 12/5/2009 - 6/1/2009

Service Members with Prescriptions for ALPRAZOLAM, OXYCODONE HCL, and SIMVASTATIN

SAILOR, NAVY 222222222

Drug Name: ALPRAZOLAM 1MG TABLET Date Filled: 06 Jan 2009

Qty: 60 Days Supplied: 30 Pharmacy: RITE AID PHARMACY 07231#07231 M CCOMB M Retail

Drug Name: ALPRAZOLAM 0.5MG TABLET Date Filled: 06 May 2009

Qty: 10 Days Supplied: 10 Pharmacy: WALGREENS DRUG STORE #10835 MCCOMB M Retail

Drug Name: OXYCODONE HCL 20MG TAB.SR 12H Date Filled: 14 May 2009

Qty: 15 Days Supplied: 8 Pharmacy: RUCKER MAIN PHCY FT RUCKER AL MTF

Narcotic "By Drug" Detail Report

Narcotic Medication Report					Da	ta current as of 6/8/2009
Person	nal Data	- Privacy Ac	at of 1974 (PL 93-579)			
HYDROCODONE BIT/ACETAMINOPHEN	CEN	тсом 🗹	HYDRO CO DO NE-A CETAMINO PH	Q ty		DS
SAILOR, NAVY 222-22-	-2222	GUIDEPOI	INT PHARMACY#102 ROCHEST	ER MN	Retail	
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500	OMG TA	ABL 03	Apr 2009	120		30
SHIP, GUNNER 666-66-	-6666	WALGREE	EN DRUG STORE #10501 VIRGIN	MM AIN	Retail	
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500	OMG TA	ABL 28	0 dt 2008	30		5
SOLDIER, ARMY 111-11-	-1111	DULUTH C	CLINIC-PHARMACY DULUTH MN		Retail	
HYDROCODONE BIT/ACETAMINOPHEN 10MG-50	00MG T	ABL 20	Aug 2008	18		3
SOLDIER, ARMY 111-11-	-1111	WALGREE	EN DRUG STORE #3064 SUPER	IOR WI	Retail	
HYDROCODONE BIT/ACETAMINOPHEN 10MG-50	00MGT	ABL 23	0 ct 2008	30		8
SOLDIER, ARMY 111-11-	-1111	DULUTH C	CLINIC-PHARMACY DULUTH MN		Retail	
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500	OMG TA	ABL 07	Nov 2008	40		5
SOLDIER, ARMY 111-11-	-1111	DULUTH C	CLINIC-PHARMACY DULUTH MN		Retail	
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500	OMG TA	ABL 12	Nov 2008	40		5
SOLDIER, ARMY 111-11-	-1111	DULUTH C	CLINIC-PHARMACY DULUTH MN		Retail	
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500	OMG TA	ABL 26	Nov 2008	28		4
WOUNDED, WARRIOR 555-55-	-5555	WALGREE	ENS DRUG STORE #11125 HIBB	ING MN	Retail	
HYDROCODONE BIT/ACETAMINOPHEN 7.5-500M	MG TAB	BLET 15	Aug 2008	16		2
WOUNDED, WARRIOR 555-55-	-5555	WALGREE	ENS DRUG STORE #11125 HIBB	ING MN	Retail	
HYDROCODONE BIT/ACETAMINOPHEN 7.5-500M	MG TAE	BLET 20	Aug 2008	16		2
MORPHINE SULFATE	CEN	тсом 🗹	MORPHINE SULFATE	Q ty		DS
SAILOR, NAVY 222-22-	-2222	GUIDEPOI	INT PHARMACY#102 ROCHEST	ER MN	Retail	
MORPHINE SULFATE 30MG TABLET SA		13	Apr 2009	20		10
OXYCODONE HCL	CEN	тсом 🗆	OXY CO DO NE HCL	Q ty		DS
SAILOR, NAVY 222-22-	-2222	KASSON [DRUG STORE KASSON MN		Retail	
OXYCODONE HCL 5MG TABLET		03	Jun 2008	40		20
SAILOR, NAVY 222-22-	-2222	KASSON [DRUG STORE KASSON MN		Retail	
OXYCODONE HCL 5MG TABLET		23	Jun 2008	40		20

Narcotic "By Drug" Summary Report

Narcotic Utilization Summary			Data current as of 6/8/200.
HYDROCODONE BIT/ACETAMINOPHEN			
HYDROCODONE BIT/ACETAMINOPHEN 10MG-500MG TABLE #	ofRxs: 2	Unique Pts: 1	CENTCOM □
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500MG TABLET #	ofRxs: 5	Unique Pts: 3	CENTCOM ✓
HYDROCODONE BIT/ACETAMINOPHEN 7.5-500MG TABLET #	ofRxs: 2	Unique Pts: 1	CENTCOM
MORPHINE SULFATE			
MORPHINE SULFATE 30MG TABLET SA #	ofRxs: 1	Unique Pts: 1	CENTCOM 🗹
OXYCODONE HCL			
OXYCODONE HCL 5MG TABLET #	ofRxs: 6	Unique Pts: 1	CENTCOM
OXYCODONE HCL/ACETAMINOPHEN			
OXYCODONE HCL/ACETAMINOPHEN 5MG-325MG TABLET #	ofRxs: 2	Unique Pts: 2	CENTCOM ∠
TRAMADOL HCL			
TRAMADOL HCL 50MG TABLET #	ofRxs: 7	Unique Pts: 3	CENTCOM ✓

Psychotropic "By Drug" Detail Report

ersonal Data - Privacy Act of 1974 (PL	93-579)		Date	Date Range: 12/5/2009 - 6/1/2009		
ALPRAZOLAM		ALPRAZOLAM	POS	Q ty	DS	
SAILOR, NAVY	222-22-2222		Retail	60	30	
ALPRAZOLAM 1MG TAE	LET	06 Jan 2009				
RITE AID PHARMACY 07231	#07231 MCCOMB M					
Provider ID: MA1149574	ALDRIDGE, MARCENIA P NE)				
SAILOR, NAVY	222-22-2222		Retail	10	10	
ALPRAZOLAM 0.5MG TAI	BLET	06 May 2009				
WALGREENS DRUG STORE	#10835 M C C O M B M					
Provider ID: BS4069161	STONNINGTON, MICHAEL J	AMES MD				
SHIP, GUNNER	666-66-6666		MTF	60	30	
ALPRAZOLAM 0.5MG TA	BLET	31 Mar 2009				
RUCKER MAIN PHCYFT RU	CKER AL					
Provider ID: BD8160157	DIEL, KE VIN RAY MD					
SHIP, GUNNER	666-66-6666		MTF	60	30	
ALPRAZOLAM 0.5MG TA	BLET	01 Jun 2009				
RUCKER MAIN PHCYFT RU	CKER AL					
Provider ID: FD0656883	DIEL, KE VIN RAY MD					
ARIPIPRAZOLE		ABILIFY	POS	Q ty	DS	
SOLDIER, ARMY	111-11-1111		Retail	30	30	

Psychotropic "By SM" Detail Report

Psychotropic Medi	ication D	ispensing Report	<u> </u>		Data current as of 6/8/2009
_		Personal Data - Privacy Act of	f 1974 (PL 93-579)		
DOE, JOHN		777	777777	Q ty	DS
BUDE PRION SR		3/2/2009	Retail	60	30
BUPROPION HCL 150MG	TABLET SA	WALGE	EENS DRUG STO	RE #11125 HIBBING	MN
BUDE PRION SR		1/28/2009	Retail	60	30
BUPROPION HCL 150MG	TABLET SA	WALGE	EEN DRUG STOR	E #9094 AUSTIN MN	
BUDE PRION XL		9/21/2008	Retail	30	30
BUPROPION HCL 300MG	TAB.SR 24H	CVS/PH	ARAMCY#05998#	#05998 SAINT PAUL I	MN
BUDE PRION SR		3/29/2009	Retail	60	30
BUPROPION HCL 150MG	TABLET SA	WALGE	EEN DRUG STOR	E #9094 AUSTIN MN	
BUDE PRION XL		6/24/2008	Retail	60	30
BUPROPION HCL 150MG	TAB.SR 24H	RITE A	D PHARMACY 118	60 #11860 MIDLAND	GA
BUDE PRION XL		8/20/2008	Retail	60	30
BUPROPION HCL 150MG	TAB.SR 24H	WAL-M	ART PHARMACY#	100913 DECORAH IA	4
BUDE PRION XL		7/14/2008	Retail	30	30
BUPROPION HCL 300MG	TAB.SR 24H	WALGE	EEN DRUG STOR	E #9094 AUSTIN MN	
BUDE PRION XL		10/20/2008	Retail	30	30
BUPROPION HCL 300MG	TAB.SR 24H	WALGE	EEN DRUG STOR	E #4882 INVER GRO	VE HE
BUDE PRION XL		11/21/2008	Retail	30	30
BUPROPION HCL 300MG	TAB.SR 24H	WALGE	EEN DRUG STOR	E #9094 AUSTIN MN	
BUDE PRION SR		4/18/2009	Mail Order	180	90
BUPROPION HCL 150MG	TABLET SA	EXPRE	SS SCRIPTS TEMP	PE AZ	
PILOT, COMBAT		444	1444444	Q ty	DS
CLO NAZE P AM		5/11/2009	Retail	90	30

Psychotropic "By SM" Dispensing Summary Report

Psychotropic Pati	sychotropic Patient Dispensing Summary							
	Personal Data - Privacy Act of 1974 (PL 93-579)							
DOE, JOHN	7							
BUDE PRION SR	BUPROPION HCL 150MG TABLET SA	# of Rx's	4					
BUDE PRION XL	BUPROPION HCL 150MG TAB.SR 24H	# of Rx's	2					
BUDE PRION XL	BUPROPION HCL 300MG TAB.SR 24H	# of Rx's	4					
PILOT, COMBAT	4	4444444						
CLON AZE PAM	CLONAZEPAM 1MG TABLET	# of Rx's	2					
SAILOR, NAVY	2:	22222222						
LORAZEPAM	LORAZEPAM 1MG TABLET	# of Rx's	5					
SERTRALINE HCL	SERTRALINE HCL 100MG TABLET	# of Rx's	1					

Psychotropic "By Drug" Summary Report

Psychotropic Medication Utilization Su	mmary		Data current as of 6/3/2009
Personal Data - Privacy Act of 1974 (PL 93-579)			Date Range: 12/5/2009 - 6/1/2009
ALPRAZOLAM			
ALPRAZOLAM 0.5MG TABLET	#ofRxs: 3	Unique Pts:	2
ALPRAZOLAM 1MG TABLET	#ofRxs: 1	Unique Pts:	1
ARIPIPRAZOLE			
ARIPIPRAZOLE 15MG TABLET	#ofRxs: 5	Unique Pts:	1
BUPROPION HCL			
BUPROPION HCL 150MG TABLET SA	#ofRxs: 2	Unique Pts:	1
CITALOPRAM HYDROBROMIDE			
CITALOPRAM HYDROBROMIDE 20MG TABLET	#ofRxs: 5	Unique Pts:	1
CLONAZEPAM			
CLONAZE PAM 0.5MG TABLET	#ofRxs: 3	Unique Pts:	1
DIVALPROEX SODIUM			
DIVALPROEXSODIUM 250MG TAB.SR 24H	#ofRxs: 6	Unique Pts:	1
DIVALPROEXSODIUM 500MG TAB.SR 24H	#ofRxs: 6	Unique Pts:	1
ESCITALOPRAM OXALATE			
ESCITALOPRAM OXALATE 10MG TABLET	#ofRxs: 1	Unique Pts:	1

Chronic Medication "By SM" Report

Chronic Medication	Report by Patient		Data current as of 6/4/2009 Date Range: 12/5/2008 - 6/1/2009		
Personal Data - Privacy Act of 1974 (PLS	93-579)				
CADET, MARINE	33333333	POS	Qty	DS	
CAPECITABINE 500MG TABLE	ET	Retail	105	15	
XELODA	11 Dec 2008				
MARTINS PHARMACY OXFOR	RD AL				
Provider ID: BP 5706304	POSEY, JAMES ARTHUR III MD				
CAPECITABINE 500MG TABLE	ET	Retail	105	15	
XELODA	28 Apr 2009				
MARTINS PHARMACY OXFOR	RD AL				
Provider ID: BP 5706304	POSEY, JAMES ARTHUR III MD				
CAPECITABINE 500MG TABLE	ET	Retail	105	15	
XELODA	27 May 2009				
MARTINS PHARMACY OXFOR	RD AL				
Provider ID: BP 5706304	POSEY, JAMES ARTHUR III MD				
DOE, JOHN	77777777	POS	Q ty	DS	
ALENDRONATE SODIUM 70MG	TABLET	Retail	12	83	
ALENDRONATE SODIUM	17 Dec 2008				
WAL-MART PHARMACY#100	329 ANNISTON AL				
Provider ID: AT2486466	THOMAS, CARLA NEWBERN MD				
EDCOCALCIEEDOL 50000 UNIT	CARCILLE	Dotail	00	07	

"Unavailable at Mail Order" Report

Service Members with Medications Unavailable at Mail Order

Data current as of 6/8/2009

Service Member: DC	DE, JANE	SSN: 888888888
Unavailable Med:	отс	OXYMETAZOLINE HCL 0.05% SPRAY
Unavailable Med:	отс	BENZOYL PEROXIDE 5% GEL
Unavailable Med:	отс	EUCALYPTUS OIL/MENTHOL 7.6MG LOZENGE
Unavailable Med:	отс	GUAIFENESIN 100MG/5ML LIQUID
Unavailable Med:	отс	GUAIFENE SIN/P-E PHE D H CL 1200-120MG TAB.SR 12H
Unavailable Med:	отс	IBUPROFEN 200MG TABLET
Unavailable Med:	отс	LANOLIN/MINERAL OIL LOTION
Unavailable Med:	отс	ACETAMINOPHEN 325MG TABLET
Unavailable Med:	отс	METHYL SALICYLATE/MENTHOL 15%-10% CRE AM(GM)
Unavailable Med:	отс	PADIMATE O STICK (EA)
Unavailable Med:	отс	PHENOL/SODIUM PHENOLATE SPRAY
Unavailable Med:	отс	PHENYLEPHRINE HCL 10MG TABLET
Unavailable Med:	отс	POLYVINYL ALCOHOL/POVIDONE 1.4-0.6% DROPERETTE
Unavailable Med:	отс	PSEUDOEPHEDRINE HCL 30MG TABLET
Unavailable Med:	отс	MEDICAL SUPPLIES BANDAGE
Service Member: SA	ILOR, NAVY	SSN: 222222222
Unavailable Med:	TEMP SENSITIVE	PROMETHAZINE HCL 25MG SUPP.RECT
Unavailable Med:	отс	DOCUSATE SODIUM 100MG CAPSULE

"Your PMART Statistics Report"

Medication Use Statistics

Date Range: 5/28/2008 - 5/29/2009

Personal Data - Privacy Act of 1974 (PL 93-579)

Current Number of Service Members :

Current Number of Prescriptions: 129

Current Number of Service Members with Prescriptions: 8 100.09

The below statistics are all subject to available filtering. If you have deselected units or changed the reporting date range on the previous window (Details/Admin window), the counts below will report within these restrictions. The percentages below use Current Number of Service Members/Prescriptions as the denominator.

	Number o	f Rxs	Number of SMs	s on a	at least one
High Risk Medications:	25	19.4%		4	50.0%
Non-Deployment Medications:	60	46.5%		8	100.0%
Chronic Medications:	59	45.7%		8	100.0%
Controlled Medications:	25	19.4%		6	75.0%
Narcotic Medications:	25	19.4%		5	62.5%

PMART Facts and Findings

- 700 PMART/WTU reports completed resulting in 8.4 million reviewable prescriptions for 1.8 million service members
- Completed 479 Army, 154 Navy, 37 Air Force, 29 Marine, & 1 Coast Guard PMART/WTU reports
- Identified 408,658 (23%) service members who were taking high-risk medications

How To Order PMART Report?

- Contact PEC at DSN 471-8274 COMM 210-221-8274 or email p-mart@amedd.army.mil
- Provide Unit Alpha Roster via PEC Secure Server
- Complete Sensitive Data Request Form
- Located at:

www.pec.ha.osd.mil/pmart

Sensitive Data Request Form

DOCUMENT	Original Author:	Hector Morales, Director TMA Pharmacy Operations Center
INFORMATION	Date:	August 2011
P-MART TYPE	P-MART	
	WTU P-MART	
Date of Request		
Date Required		(3-5 Business Day Turn-Around)
Requestor	Name:	
	Phone Number:	
	MTF Installation:	
	Title:	
	Email:	
	Eman.	
Signature	Mines	

PMART Summary

- PMART is a tool to assist in the predeployment medical screening process
- Fast and efficient tool for screening medication use
- Easy to navigate and no additional cost to use
- Specialized to a particular audience, for a specific purpose

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
 - ADHD/Wakefulness Promoting Agents
 - Antiplatelet Agent
 - DPP-4 Subclass Non Insulin Antidiabetic Agents
- New Drugs in Previously Reviewed Classes
 - Alcaftadine (Lastacaft) Ophthalmic
 - Nucynta ER (Tapentadol ER) Narcotic Analgesics

February 2012 DoD P&T Committee Meeting

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

Uniform Formulary Class Reviews: ADHD/Wakefulness Promoting Agents

Class Definition ADHD - Wakefulness Promoting

- 3 Subclasses
 - ADHD Stimulants
 - ADHD Non-stimulants
 - Wakefulness Promoting Agents

ADHD Stimulants

ADHD Stimulants Drugs in the Class

Generic Name	Brand Name	Frequency	Duration, Hrs	FDA Approval	Generic Availability
Mixed amphetamine salts XR	Adderall XR	QD	10	10/11/2001	Authorized generic
Methylphenidate OROS	Concerta	QD	12	12/8/2000	Authorized generic
Lisdexamphetamine	Vyvanse	QD	10-12	12/10/2007	N
Dexmethylphenidate ER	Focalin XR	QD	8-12	8/1/2006	N
Methylphendiate CD	Metadate CD	QD	6-8	2/19/2006	N
Methylphenidate LA	Ritalin LA	QD	6-8	generic	Υ
Methylphenidate ER	Metadate ER	QD	8	6/1/1988	N
Methylphenidate ER	Methylin ER	QD	8	5/9/2000	N
Methylphenidate IR	Ritalin	BID-TID	3-5	generic	Y
Dextroamphetamine sulfate	Dexedrine Procentra	BID-TID BID-TID	4-6 3-5	Generic 1/29/2008	Y N
Methylphenidate chewable	Methylin	BID-TID	3-5	12/9/2002	N
Dexmethylphenidate IR	Focalin	BID	3-5	generic	Y
Methylphenidate SR	Ritalin SR	BID	2-6	generic	Υ
Methamphetamine HCI	Desoxyn	BID	4-5	generic	Υ
Mixed amphetamine salts	Adderall	BID	6	generic	Y
Methylphenidate transdermal	Daytrana	Apply for 9 hrs	11-12	4/6/2006	N

ADHD Non-stimulants

ADHD Non-Stimulants Drugs in the Class

Generic Name	Brand Name	Frequency	Duration, Hours	FDA Approval	Generic Availability
Atomoxetine HCL	Strattera	QD-BID	10-12	11/26/2002	N
Clonidine HCL XR	Kapvay	QD-BID	10-12	9/28/2010	N
Guanfacine HCL XR	Intuniv	QD	10-12	9/2/2009	N
Clonidine IR	generic	BID-QID	3-5	generic	Y
Guanfacine IR	generic	BID-TID	4-8	generic	Y

Overall Clinical Effectiveness Conclusion ADHD Stimulants and Non-stimulants

Efficacy

- Preschool-aged children (4 –5 years of age):
 - The Preschool ADHD Treatment Study (PATS) showed MPH IR was more effective than placebo in improving ADHD symptoms in preschoolers who still had moderate to severe ADHD symptoms after 10 sessions of Parental Behavioral Training (PBT)
- Children and Adolescents (6-17 years of age):
 - No clinically relevant difference between IR stimulants
 - No clinically relevant differences between IR vs. SR stimulants
 - No clinically relevant differences between SR vs. SR stimulants, however some SR stimulants showed benefit over comparators at specific times of day depending on the pharmacokinetics of the specific formulation, but overall differences were not found

Overall Clinical Effectiveness Conclusion ADHD Stimulants and Non-stimulants

Efficacy

- Children and Adolescents (6-17 years of age):
 - Atomoxetine was not superior to some ER stimulants MPH OROS (Concerta) and MAS XR (Adderall XR)
 - ER clonidine and ER guanfacine have no comparative efficacy evidence to date. Both are superior to placebo for monotherapy and as adjuncts to stimulants
- Adults (18 years and older)
 - No clinically relevant differences between switching to MPH OROS vs. continuing with MPH IR

Overall Clinical Effectiveness Conclusion ADHD Stimulants and Non-stimulants

Safety

- Black box warnings for stimulants (abuse and dependency) and atomoxetine (suicidal ideation)
- Atomoxetine has increased risk of suicidal behavior compared with placebo (DERP)
- Atomoxetine resulted in higher rates of vomiting and somnolence, similar rates of nausea and anorexia, and lower rates of insomnia than stimulants (DERP)
- Stimulants showed no significant increased risk for serious cardiovascular events in children, adolescents, and adults (up to age 64) based on large retrospective, population based cohort study (JAMA and NEJM)
- The Multimodal Therapy Study of ADHD (MTA) showed a decrease in growth velocity with stimulants at 36 months
- An uncommon but significant adverse effect of stimulants is the occurrence of hallucinations and other psychotic symptoms in children
- ER clonidine and ER guanfacine have no comparative safety evidence, however their most common adverse events include somnolence and fatigue

Overall Clinical Effectiveness Conclusion ADHD Stimulants and Non-Stimulants

Other Factors:

- Evidence on abuse, misuse, and diversion was limited, but indicated that stimulant use during childhood is not associated with increased risk of substance abuse later
- Misuse and diversion rates varied by age and were highest among college students, and rates of diversion were highest with amphetamine-based products but similar among methylphenidate products
- AAP ADHD Guidelines recommend prescribing nonstimulants or stimulants with less abuse potential (lisdexamfetamine [Vyvanse], methylphenidate transdermal system [Daytrana], methylphenidate OROS [Concerta] for adolescents due to abuse/diversion concerns (AAP 2011 ADHD Guidelines)
- One stimulant (lisdexamfetamine) can be dissolved in water, and several other stimulants can be sprinkled on food

ADHD Stimulants - Final Decision

BCF UF		NF
Long-acting stimulants - Mixed amphetamine salts ER (Adderall XR generics) - Methylphenidate LA (Ritalin LA, generic) - Methylphenidate OROS (Concerta) Short-acting stimulants - Methylphenidate IR (Ritalin, generic)	 Short-acting stimulants Mixed amphetamine salts IR (Adderall, generic) Dexmethylphenidate IR (Focalin, generic) Dextroamphetamine (Dexedrine, Dextrostat, Procentra solution) Methylphenidate CD (Metadate CD) Methylphenidate ER (Metadate ER, Methylin ER, generic) Methylphenidate chewable tablets, solution (Methylin, generic) Methylphenidate SR (Ritalin SR, generic) Methamphetamine HCI (Desoxyn) 	 Long-acting stimulants Dexmethylphenidate ER (Focalin XR) Lisdexamphetamine (Vyvanse) Methylphenidate transdermal system (Daytrana)

ADHD Non-Stimulants - Final Decision

BCF	UF	NF	Comments
Not applicable	 Atomoxetine (Strattera) Clonidine ER (Kapvay) Guanfacine ER (Intuniv) 	 Not applicable (no nonformulary drugs) 	Clonidine IR tabs are BCF Clonidine Patches and guanfacine IR (Tenex, generic are UF) in Misc Anti-hypertensive Drug Class

Wakefulness Promoting Agents

Wakefulness Promoting Agents Drugs in the Class

Generic Name	Brand Name	FDA Approval	Patent Expiration	Generic Availability
Armodafinil	Nuvigil	6/15/2007	2024	No
Modafinil	Provigil	12/24/1998	4/6/2012	April 2012
Sodium Oxybate	Xyrem	7/17/2002	2019-2024	No

Overall Clinical Effectiveness Conclusion Wakefulness-Promoting Agents

- No direct comparison of modafinil and armodafinil for the indications of narcolepsy and OSA
- One head to head trial, comparing modafinil 200mg/day to armodafinil 150mg/day, showed that both drugs have similar efficacy for shift work sleep disorder
- Armodafinil did not receive FDA approval for the indication of jet lag disorder
- No significant differences in safety/tolerability between armodafinil and modafinil

Overall Clinical Effectiveness Conclusion Wakefulness-Promoting Agents

- Sodium oxybate (Xyrem) fills a unique niche in therapy for cataplexy associated with narcolepsy
- Sodium oxybate did not receive FDA approval for fibromyalgia due to abuse and safety concerns
- Sodium oxybate (Xyrem) has a black box warning for abuse/misuse/diversion potential and has a restricted distribution system which uses one centralized pharmacy
- Most common adverse events leading to discontinuation of sodium oxybate were headache, nausea, vomiting, and anxiety

Wakefulness Promoting Subclass Prior Authorization Recommendation

- Provigil
 - No change to current PA
- Nuvigil
 - Add Jet Lag disorder to "not covered" off-label use part of PA
 - Trial of Provigil first will be added to PA ("Has the patient tried Provigil – if no, then coverage denied")
 - Patients would not be grandfathered
- Xyrem
 - Covered for FDA- approved indication of cataplexy associated with narcolepsy diagnosed by polysomnogram and MSLT
 - Should try Provigil prior to using for excessive sleepiness associated with narcolepsy without cataplexy
 - Not covered for any off label uses including fibromyalgia, insomnia, or excessive sleepiness not associated with narcolepsy

Wakefulness Promoting Agents-Final Decision

BCF	UF	NF	Comments
Not applicable	 Modafinil (Provigil) Sodium oxybate (Xyrem) – restricted distribution 	Armodafinil (Nuvigil)	All current and new users of Nuvigil must go through PA process

Uniform Formulary Class Reviews: Antiplatelet Agent

Drugs in the Class

Generic name	Brand name	Approval date	Generic availability?		
Thienopyridines					
Ticlopidine	Ticlid	October 31, 1991	Yes		
Clopidogrel	Plavix	November 17, 1997	No		
Prasugrel	Effient	July 10, 2009	No		
Cyclopentyltriazolopyrimidines					
Ticagrelor	Brilinta	July 20, 2011	No		
Phosphodiesterse inhibitors					
Dipyridamole	Persantine	December 6, 1961	Yes		
Aspirin/ER dipyridamole	Aggrenox	November 22, 1999	No		
Cilostazol	Pletal	January 15, 1999	Yes		
Hemorrheologic Agent - Blood Viscosity Reducer Agent					
Pentoxifylline	Trental, Pentopak, Pentoxil	August 30, 1984	Yes		

Efficacy

ACS

- Prasugrel and ticagrelor are less susceptible to genetic variation and drug-drug interactions with PPI, have faster onset of action and exhibit more complete platelet inhibition compared to clopidogrel
- Prasugrel decreases major coronary events including nonfatal MI and stent thrombosis in ACS patients undergoing PCI, when compared with clopidogrel therapy
- Prasugrel only approved for ACS patients suitable for PCI
- Ticagrelor decreases major coronary events including nonfatal MI and stent thrombosis, when compared with clopidogrel therapy
 - US patients; no significant difference in the rate of primary outcome between the two groups (10.1% vs 12.6%, p=0.1459) (attributed to high aspirin dose)

Efficacy

- Stroke/TIA
 - No significant difference between Aggrenox and clopidogrel for all-cause mortality, CV mortality, and recurrent stroke
 - No significant difference between clopidogrel and ticlopidine in reduction of all-cause mortality, CV death, or cerebral infarction
- Peripheral artery disease (PAD)
 - Cilostazol is the first-line agent to improve walking distance while pentoxifylline is the second-line alternative
 - Clopidogrel and aspirin are recommended to reduce the risk of MI, stroke or vascular death in patients with symptomatic PAD

TIA: Transient Ischemic Attack

Safety and Tolerability

- Prasugrel is associated with significant increase in bleeding vs. clopidogrel
 - Increased risk in low-weight, elderly patients
 - Avoid use around CABG or other surgical or invasive procedures
- Ticagrelor: rate of major bleeding, life-threatening or CABGrelated major bleeding was similar to clopidogrel
 - Ticagrelor had a higher rate of non-CABG major bleeding
 - More episodes of dyspnea in the ticagrelor group and more d/c due to this adverse effect
- Unlike clopidogrel and ticagrelor, prasugrel is contraindicated in patients with previous stroke or TIA
- Ticlopidine's therapeutic use limited by neutropenia/agranulocytosis, TTP and aplastic anemia
- Clopidogrel had lower rate of major bleeding and withdrawal due to AEs compared with ER dipyridamole/aspirin

Antiplatelet Agent- Final Decision

BCF UF		NF
Clopidogrel (Plavix)	 Prasugrel (Effient) Ticagrelor (Brilinta) Aspirin/dipyridamole ER (Aggrenox) Ticlopidine (Ticlid, generics) Cilostazol (Pletal), generics) Dipyridamole (Persantine, generics) Pentoxifylline (Trental, generics) 	No drug designated nonformulary

Clopidogrel generics are now available (May 2012)

Uniform Formulary Class Reviews: DPP-4 Subclass Non Insulin Antidiabetic Agents

Drugs in the Class

Active Ingredient	Brand (Manufacturer)	Strengths
Sitagliptin	Januvia (Merck)	25mg, 50mg, 100mg
Sitagliptin/ Metformin	Janumet (Merck)	50mg/500mg, 50mg/1000mg
Sitagliptin/ Metformin ER	Janumet XR (Merck)	50mg/500mg, 50mg/1000mg, 100mg/1000mg
Sitagliptin/ Simvastatin	Juvisync (Merck)	100mg/10mg, 100mg/20mg, 100mg/40mg
Saxagliptin	Onglyza (BMS)	2.5mg, 5mg
Saxagliptin/ Metformin ER	Kombiglyze XR (BMS)	2.5mg/1000mg, 5mg/500mg, 5mg/1000 mg
Linagliptin	Tradjenta (Boehringer Ingelheim)	5mg
Linagliptin/ Metformin	Jentadueto (Boehringer Ingelheim)	2.5/500mg, 2.5mg/850mg, 2.5mg/1000mg

Efficacy

- All 3 agents have similar A1c lowering effect when used as monotherapy ~0.4-0.9%
- Combined with metformin, mean ↓ A1c is 0.4–2.5%
- Combined with TZD mean ↓ A1c is 0.7–1.06%
- Combined with SU the mean ↓ A1c is 0.5-0.6%
- SIT fixed dose combination with metformin provides a ↓
 A1c of 1.9% from baseline
- One head-to-head trial did not show clinically significant differences in efficacy or safety between SIT and SAX
- DPP-4 inhibitors are weight neutral, lipid neutral, and have minimal impact on blood pressure
- Juvisync is a combination drug that may benefit patients requiring both sitagliptin and a statin

SIT: sitagliptin; SAX: saxagliptin; TZD: thiazolidinedione; SU: sulphonylurea

Safety and Tolerability

- DPP-4 inhibitors are generally well-tolerated with few side effects and few drug interactions
- Pancreatitis has been reported with sitagliptin and saxagliptin
- Acute renal failure has been reported with sitagliptin
- Linagliptin is the only DPP-4 inhibitor that does not require dose adjustments

DPP-4 Subclass- Final Decision

	BCF	UF		NF	Comments
■ Si	itagliptin (Januvia) itagliptin/Metformin anumet)	 Sitagliptin/Simvastatin (Juvisync) Linagliptin (Tradjenta) 	-	Saxagliptin (Onglyza) Saxagliptin/Metformin ER (Kombiglyze XR)	Must try metformin and sulfonylurea 1st before any DPP-4 drug Must try sitagliptin-containing product 1st before Onglyza, Kombiglyze XR, and Tradjenta

DM Drugs Step Therapy Defined

- Metformin/Sulfonylurea step
 - Applies to DPP-4s, GLP-1s, TZDs
 - Initially implemented in Nov 2010
- ▶ DPP-4s
 - Step therapy for the class
 - Januvia, Janumet step-preferred
 - Tradjenta behind step, but UF
 - o Onglyza, Kombiglyze XR behind step and NF
- New User: A patient who has been prescribed a Non-Preferred agent but has not tried the Non-Preferred agent
- Metformin/SU trial required when switching between classes, but not within subclasses

DM Step Therapy Set Up

Subclasses	Prescribed Medication	Step 1 Look Back (180 days)	Message to Pharmacy
DDD 4	Januvia Janumet Janumet XR Juvisync	Metformin or Sulfonylurea	Must try Metformin or a Sulfonylurea first
DPP-4	Onglyza Kombiglyze XR Tradjenta Jentadueto	Metformin or Sulfonylureas or DPP-4	Must try Januvia/Janumet /Juvisync first and have a history of metformin or a sulfonylurea
TZD	Actos	Metformin or Sulfonylureas	Must try Metformin or a Sulfonylurea first
	Byetta	Metformin or	Must try Metformin or a Sulfonylurea first
GLP-1	Victoza	Sulfonylureas or GLP-1	Must try Metformin or a Sulfonylurea and a trial of Byetta

New Drugs in Previously Reviewed Classes

Alcaftadine ophthalmic solution (Lastacaft)

Ophthalmic 1 - Drugs in the Class

Generic Name	Brand	Strength	Generic	FDA Approval	
Antihistamines					
Emedastine	Emadine	0.05%	No	1997	
Mast Cell Stabilizers					
Pemirolast	Alamast	0.01%	No	1999	
Nedocromil	Alocril	2%	No	1999	
Cromolyn	Crolom/ Opticrom	4%	Yes	1995/1984	
Lodoxamide	Alomide	0.1%	No	1993	
Dual Action Antihistamine	s/Mast Cell Stabilizer	S			
Alcaftadine	Lastacaft	0.25%	No	2010	
Ketotifen	Zaditor	0.025%	Yes OTC	1999	
Bepotastine	Bepreve	1.5%	No	2009	
Olonotodino	Patanol	0.1%	No	1996	
Olopatadine	Pataday	0.2%	No	2004	
Azelastine	Optivar	0.05%	Yes	2000	
Epinastine	Elestat	0.05%	No	2003	

Alcaftadine ophthalmic solution

- Background
 - H1 histamine receptor antagonist
 - Inhibits release of histamine from mast cells
 - 0.25% solution
- Indication
 - Prevention of itching associated with allergic conjunctivitis (AC)
- Potential Off Label Uses
 - Non-ocular symptom relief
 - Rhinorrhea
 - Nasal pruritus
 - Nasal congestion
 - Ear and/or palate pruritus

Efficacy

- Alcaftadine provides a once daily option for the prevention of symptoms associated with AC
- Superiority over placebo was demonstrated in 3 clinical trials
- Alcaftadine was effective in the prevention of ocular itching 3, 5, and 7 minutes after allergen challenge, and conjunctival redness, 7, 15, and 20 minutes after allergen challenge at Visits 3 and 4 based on statistically significant differences compared with vehicle
- A clinically relevant difference (at least 1-unit difference in mean score)
 was also seen in ocular itching at all post-challenge evaluations at Visit
 3 and Visit 4. The difference in conjunctival redness between the
 treatment groups, however, did not reach the criteria for clinical
 relevance

Safety

- Most common adverse events included eye irritation, pruritis, and redness, and instillation site burning and stinging
- In the absence of direct comparative trials between alcaftadine and other dual action AH/MCSs, there is insufficient evidence to suggest clinically relevant differences in efficacy or safety between the agents

Tapentadol Extended Release (Nucynta ER)

Nucynta ER

Background

- Tapentadol (Nucynta ER) is a twice daily mu-agonist and norepinephrine reuptake inhibitor analgesic
- Scheduled II narcotic

Indications

 Relief of moderate to severe <u>chronic</u> pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time

Dosage and Administration

- Available in 50, 100, 150, 200, and 250mg tablets
- Opioid naïve and experienced: Initial dose of 50mg twice daily (approx. 12 hours apart) with titration in 50mg increments every 3 days as needed to reach effective dose of 100-250mg twice daily (max daily dose 500mg)

- Two indirect comparisons in CLBP and OA show no clinically relevant differences b/w tapentadol ER and oxycodone CR in terms of pain control, but there was a high drop-out rate in the Oxy CR group
- Overall, clinical evidence is limited
 - No head-to-head comparisons with other opioids
- Nucynta ER in one-52 week trial showed a lower rate of GI effects, but higher incidence of CNS effects compared with oxycodone CR
- It is unknown whether NE reuptake inhibition is an advantage or disadvantage

New Drugs in a Previously Reviewed Class Final Decisions

Drug	BCF	UF	NF
Ophthalmic-1		Alcafatinde 0.25% (Lastacaft)	
 Narcotic Analgesics 		Tapentadol ER (Nucynta ER)	

Utilization Management

Drugs with genetic testing

Type of Drug:

- Crizotinib (Xalkori) is an anaplastic lymphoma kinase (ALK) inhibitor
 - Treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is ALK-positive as detected by an FDA-approved test
- Vermurafenib (Zelboraf) is an oral Kinase inhibitor
 - Treatment of patients with unresectable or metastatic melanoma with BRAF^{v600E} mutation as detected by an FDA-approved test
 - Not recommended for use in patients with wild-type BRAF melanoma
- Ivacaftor (Kalydeco)
 - Treatment of CF in patients 6 yrs and older who have a G551D mutation in the CFTR gene (4% of CF patients)
 - Not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene (~90% of CF patients)

Review of May 2012 P&T Committee Meeting

Dave Meade, PharmD, BCPS
Clinical Pharmacist

May 2012 DoD P&T Committee Meeting

- Uniform Formulary Class Reviews
 - Smoking Cessation Program
 - Newer Sedative/Hypnotics Drug Class
- New Drugs in Previously Reviewed Classes
 - Gabapentin enacarbil (Horizant)
 - Gabapentin ER (Gralise)

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

- ▶ 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