TMA DoD Pharmacoeconomic Center
Fort Sam Houston, TX

MTF Quarterly Webcast
September 9, 2011

CDR Joe Lawrence
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

Outline

- Introduction
- MTF Corner: Tallman Lettering in CHCS (LTC Carrillo)
- Review of May 2011 P&T Meeting (Dr Meade)
- Overview of August 2011 P&T Meeting (Dr Meade)

MTF Corner

Tall Man Lettering: Look-Alike/Sound-Alike Strategy

LTC Jorge D. Carrillo, PharmD, MS, BCPS
Manager, Army Patient Safety Center

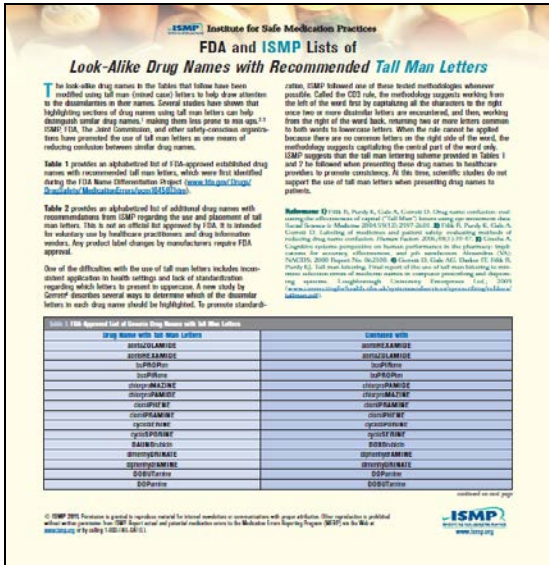
BRIEFING OUTLINE

PURPOSE: To provide an overview of how to implement Tall Man Lettering in the CHCS Drug File.

1. Review The Joint Commission Look-Alike/Sounds-Alike (LASA) medication requirements
2. Change Drug Name to Tall Man Lettering in the CHCS Drug File
3. Run report to produce list of LASA medications with Tall Man Letting
4. Future Tall Man Lettering strategies

LASA Medications

- TJC Requirements
  - **MM.01.02.01 – develop LASA medication list, take actions to prevent errors and review list annually**
  - **MM.04.01.01 – precautions for ordering LASA medications**
- FDA–approved Tall Man Lettering list
- ISMP Tall Man Lettering Recommendations



ISMP Institute for Safe Medication Practices

FDA and ISMP Lists of

Look-Alike Drug Names with Recommended Tall Man Letters

The look-alike drug names in the tables that follow have been modified using tall man (mixed case) letters to help draw attention to the dissimilarities in their names. Several studies have shown that highlighting sections of drug names using tall man letters can help distinguish similar drug names,[1] making them less prone to mix-ups.[2-5] ISMP, FDA, The Joint Commission, and other safety-conscious organizations have promoted the use of tall man letters as one means of reducing confusion between similar drug names.

Table 1 provides an alphabetized list of FDA-approved established drug names with recommended tall man letters, which were first identified during the FDA Name Differentiation Project (www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm094815.htm).

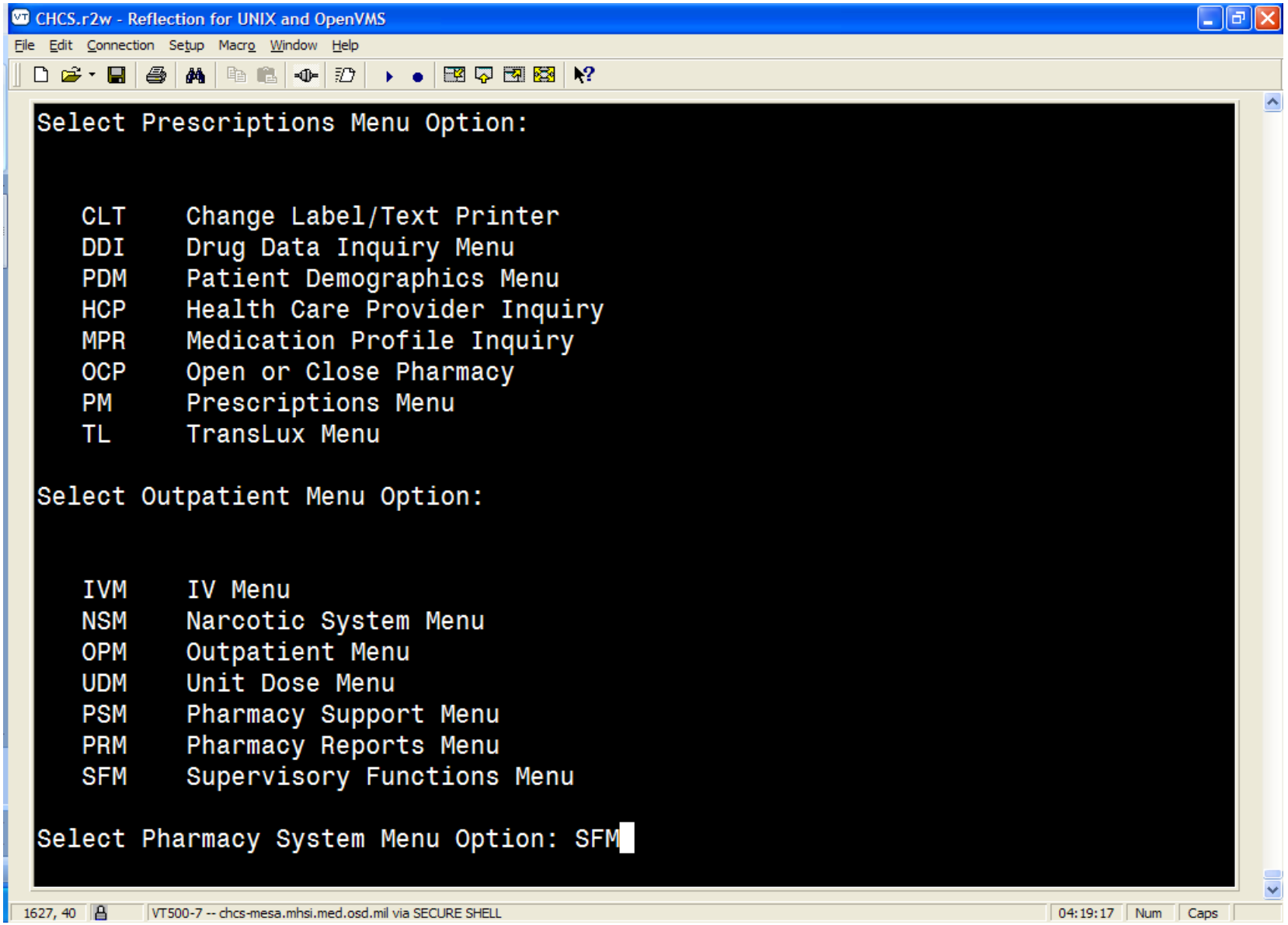
Table 2 provides an alphabetized list of additional drug names with recommendations from ISMP regarding the use and placement of tall man letters. This is not an official list approved by FDA. It is intended for voluntary use by healthcare practitioners and drug information vendors. Any product label changes by manufacturers require FDA approval.

One of the difficulties with the use of tall man letters includes inconsistent application in health settings and lack of standardization regarding which letters to present in uppercase. A new study by Gemme[6] describes several ways to determine which of the dissimilar letters in each drug name should be highlighted. To promote standardization, ISMP followed one of these tested methodologies whenever possible. Called the CDS rule, the methodology suggests working from the left of the word first by capitalizing all the characters to the right once two or more dissimilar letters are encountered, and then, working from the right of the word back, returning two or more letters common to both words to lowercase letters. When the rule cannot be applied because there are no common letters on the right side of the word, the methodology suggests capitalizing the central part of the word only. ISMP suggests that the tall man lettering scheme provided in Tables 1 and 7 be followed when presenting these drug names to healthcare providers to promote consistency. At this time, scientific studies do not support the use of tall man letters when presenting drug names to patients.

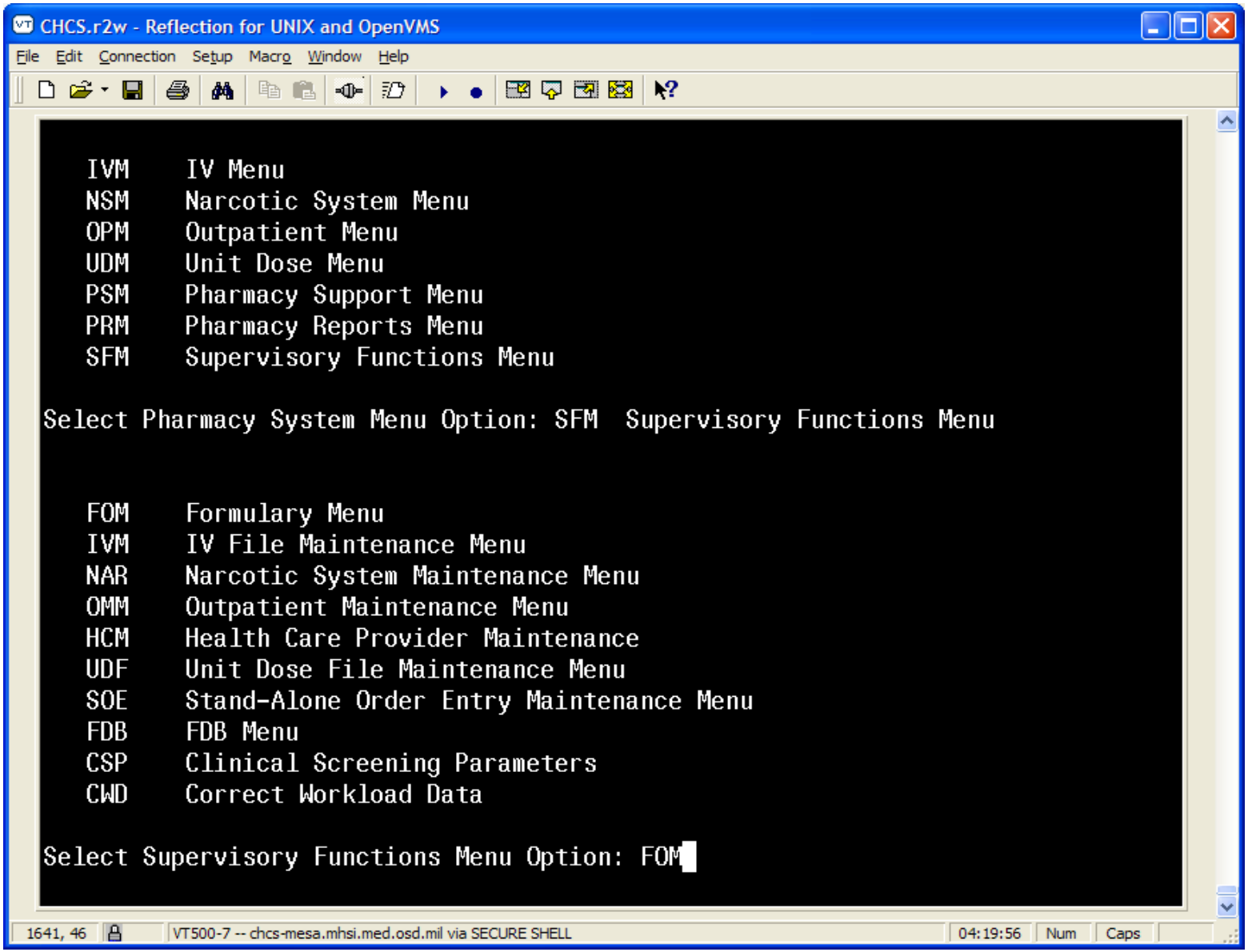
References 1) Filik R, Purdy K, Gale A, Gerrett D. Drug name confusion: evaluating the effectiveness of capital ("Tall Man") letters using eye movement data. *Social Science & Medicine* 2004;59(12):2397-2410. 2) Filik R, Purdy K, Gale A, Gerrett D. Labelling of medicines and patient safety: evaluating methods of reducing drug name confusion. *Human Factors* 2006;48(1):39-47. 3) Cohelia A. Cognitive systems perspective on human performance in the pharmacy: implications for accuracy, effectiveness, and job satisfaction. Alexandria (VA): NACDS; 2000 Report No. 06-2000. 4) Gerrett D, Gale AG, Darker IT, Filik R, Purdy KJ. Tall man lettering. Final report of the use of tall man lettering to minimize selection errors of medicine names in computer prescribing and dispensing systems. Loughborough University Enterprises Ltd.; 2009 (www.connectingforhealth.nhs.uk/systemsandservices/gpsoc/ref/tallmanletters.pdf).

Drug Name with Tall Man Letters	Confused with
acetaZOLAMIDE	acetoHEXAMIDE
acetoHEXAMIDE	acetaZOLAMIDE
buPROPion	buPIRone
buPIRone	buPROPion
chlorproMAZINE	chlorproPAMIDE
chlorproPAMIDE	chlorproMAZINE
clomiPHENE	clomiPRAMINE
clomiPRAMINE	clomiPHENE
cyclobenzaprine	cyclosporine
cyclosporine	cyclobenzaprine
DAUNOrubicin	DOXOrubicin
dimenhyDRINATE	diphenhydrAMINE
diphenhydrAMINE	dimenhyDRINATE
DOBUTamine	DOPamine
DOPamine	DOBUTamine

CHCS Drug File



CHCS Drug File



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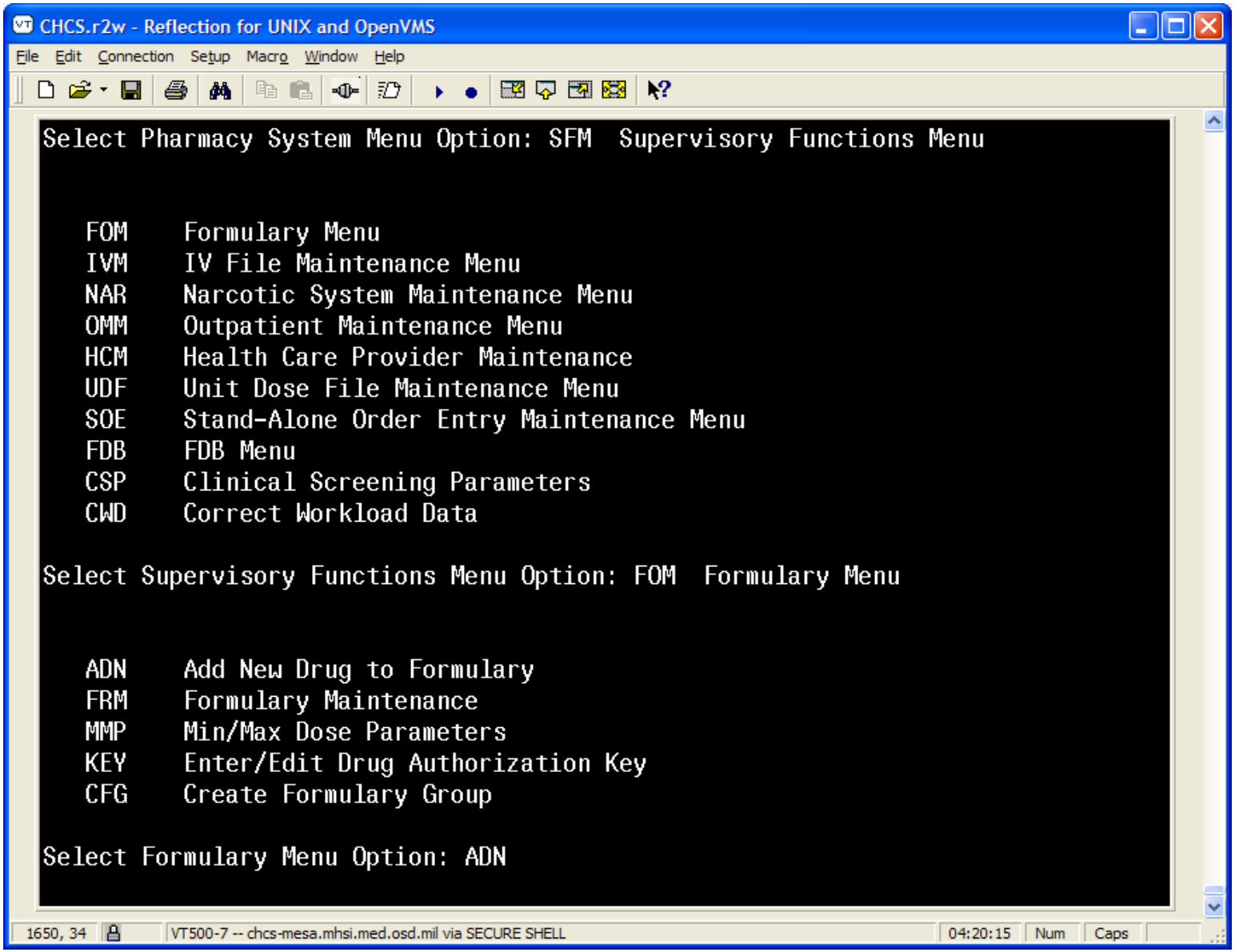

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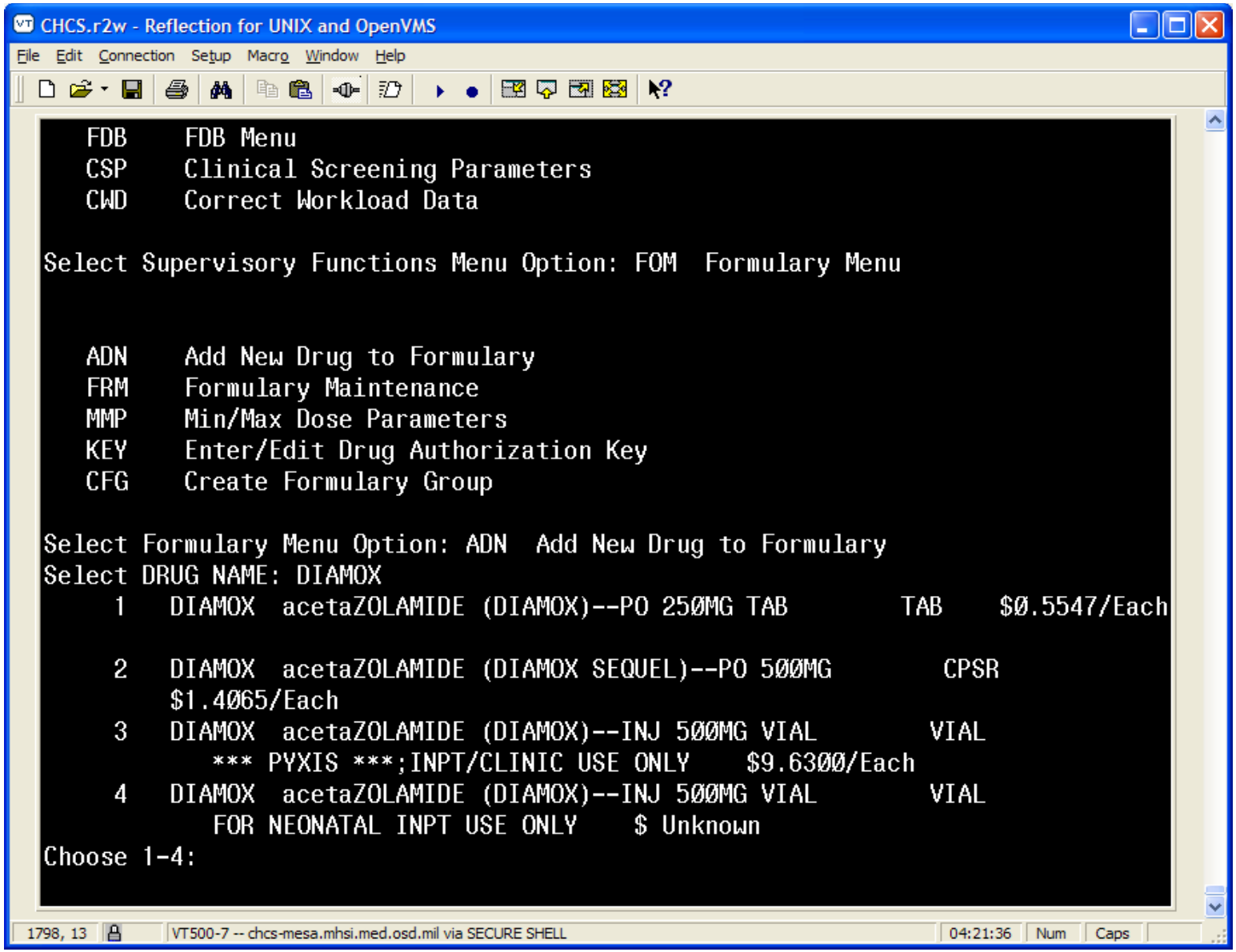

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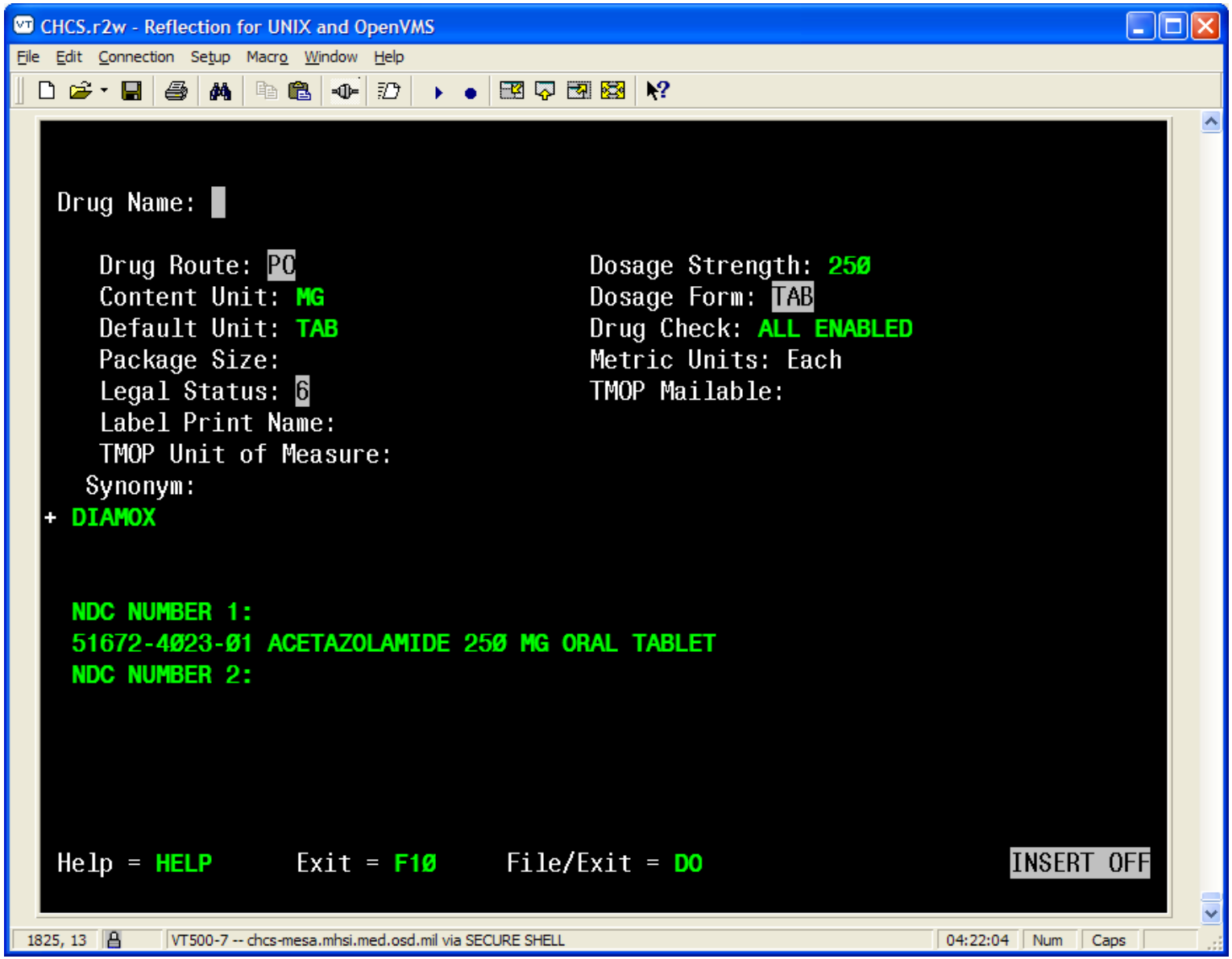

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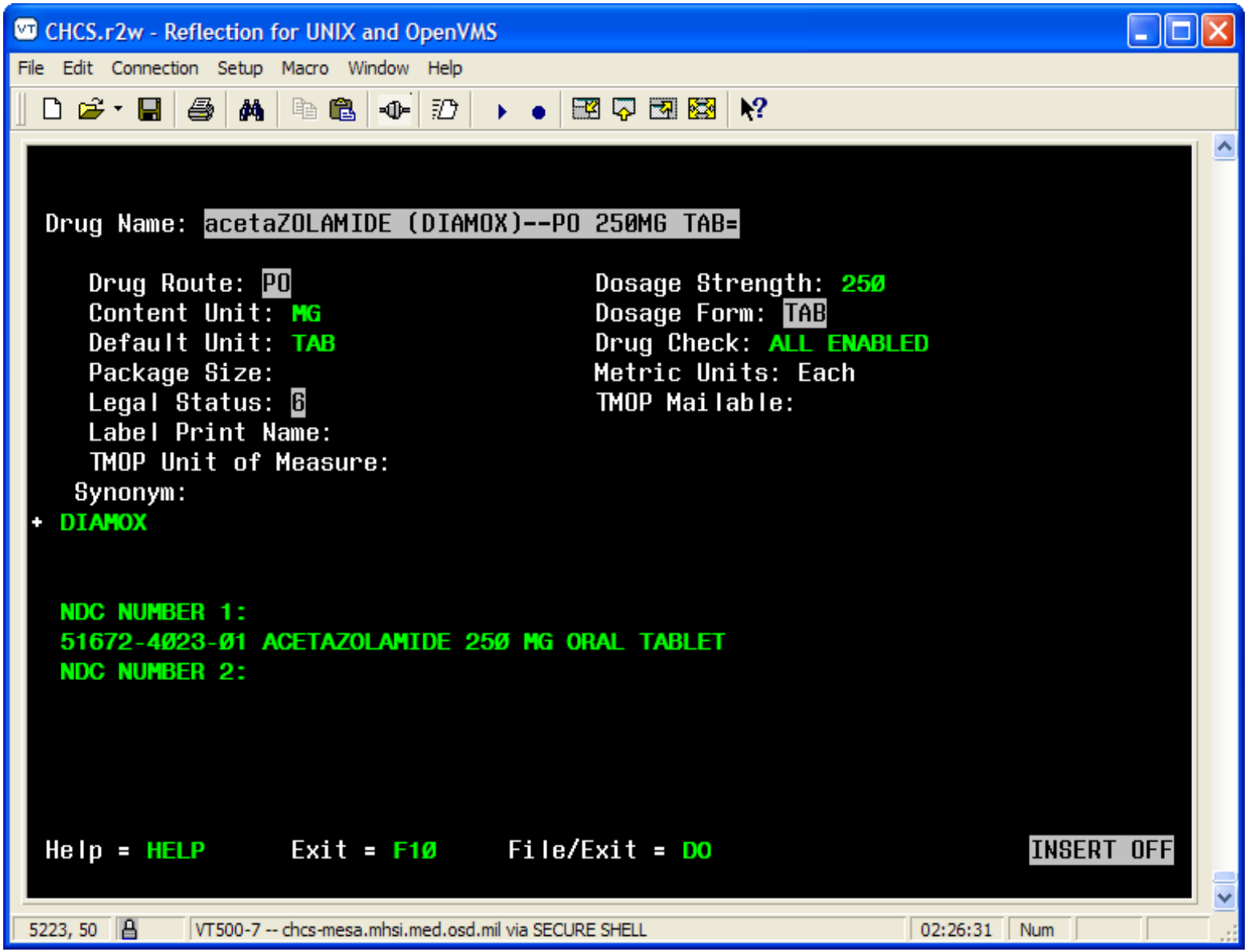
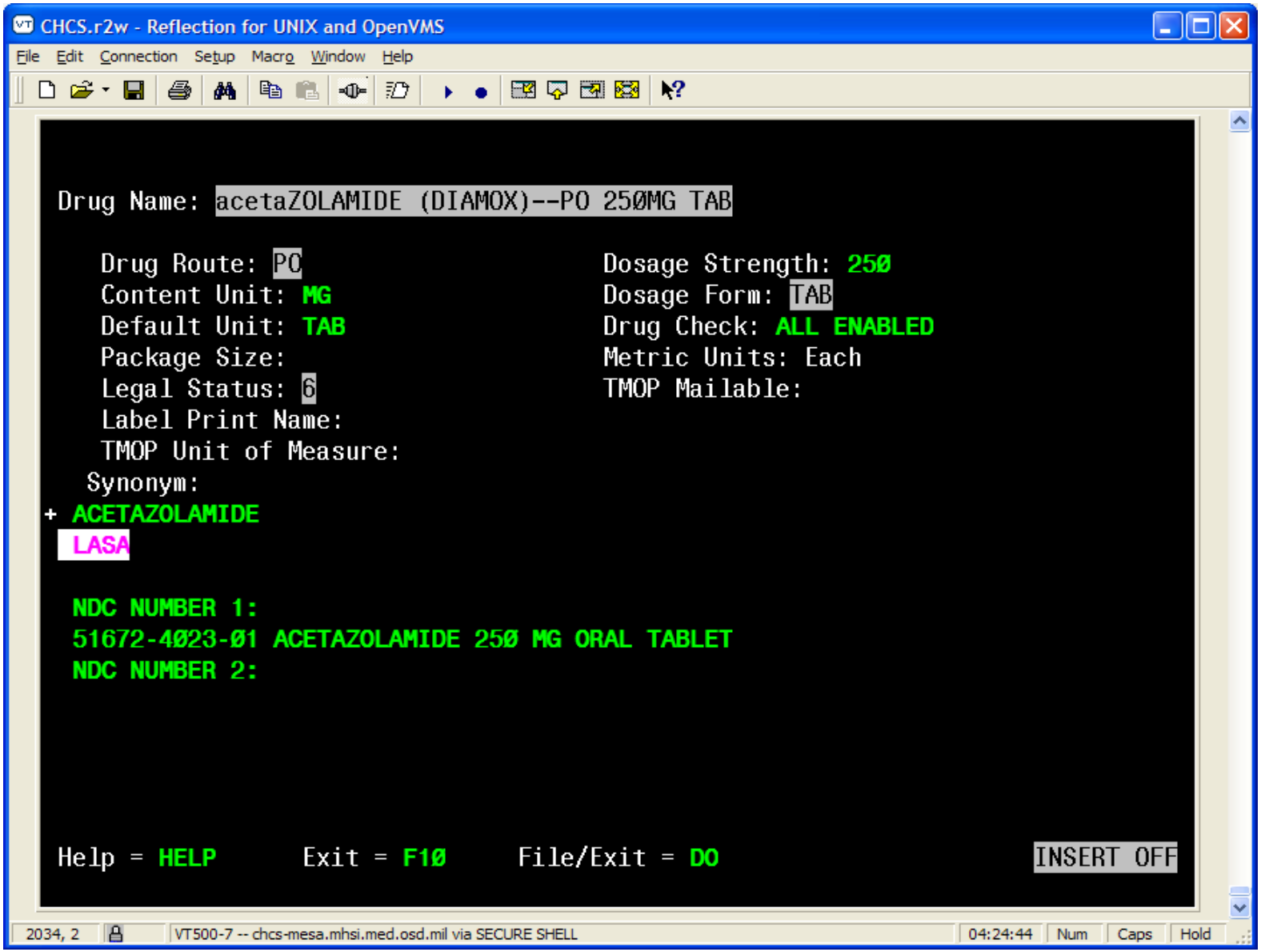
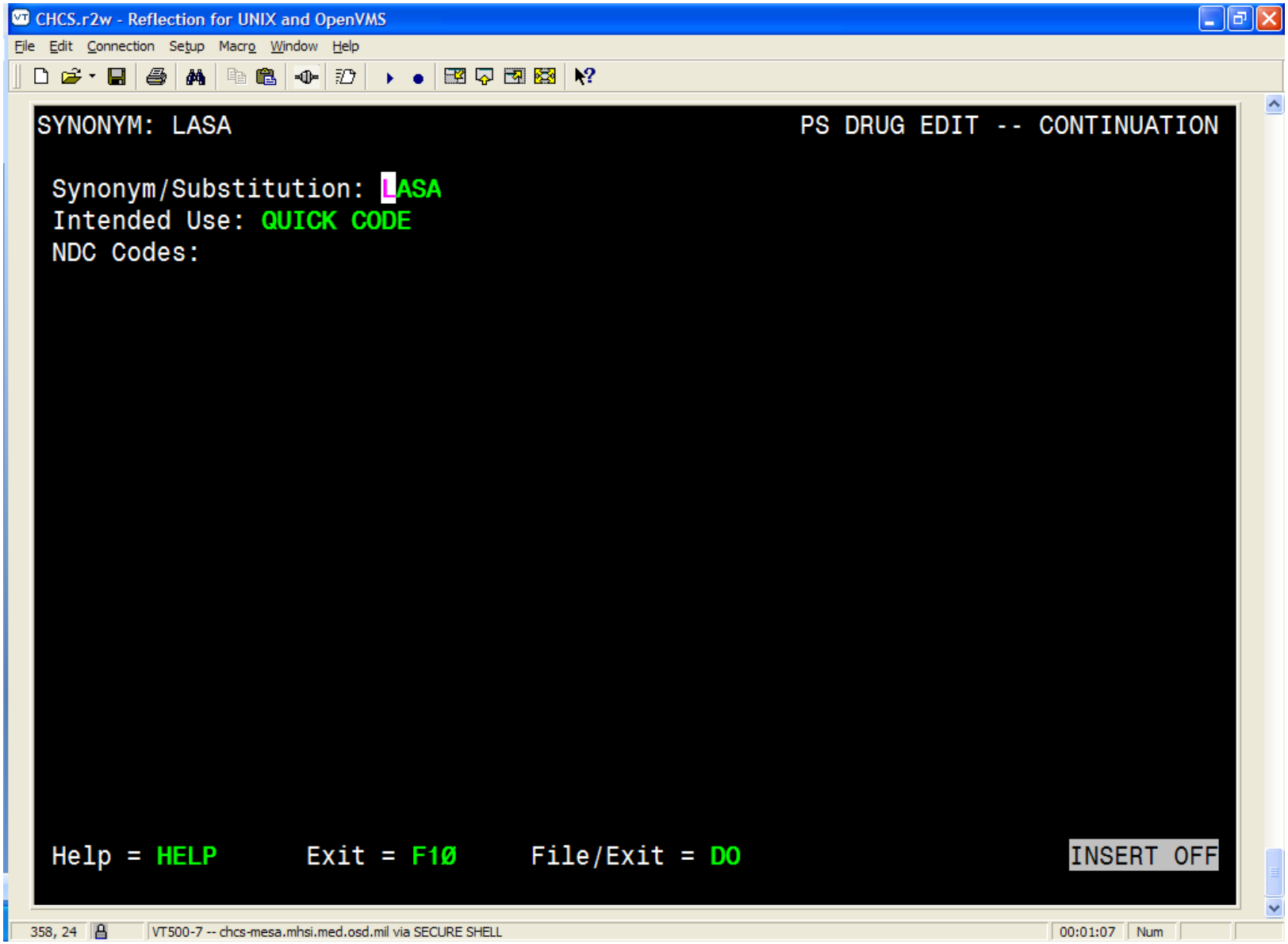


CHCS Drug File



CHCS Drug File



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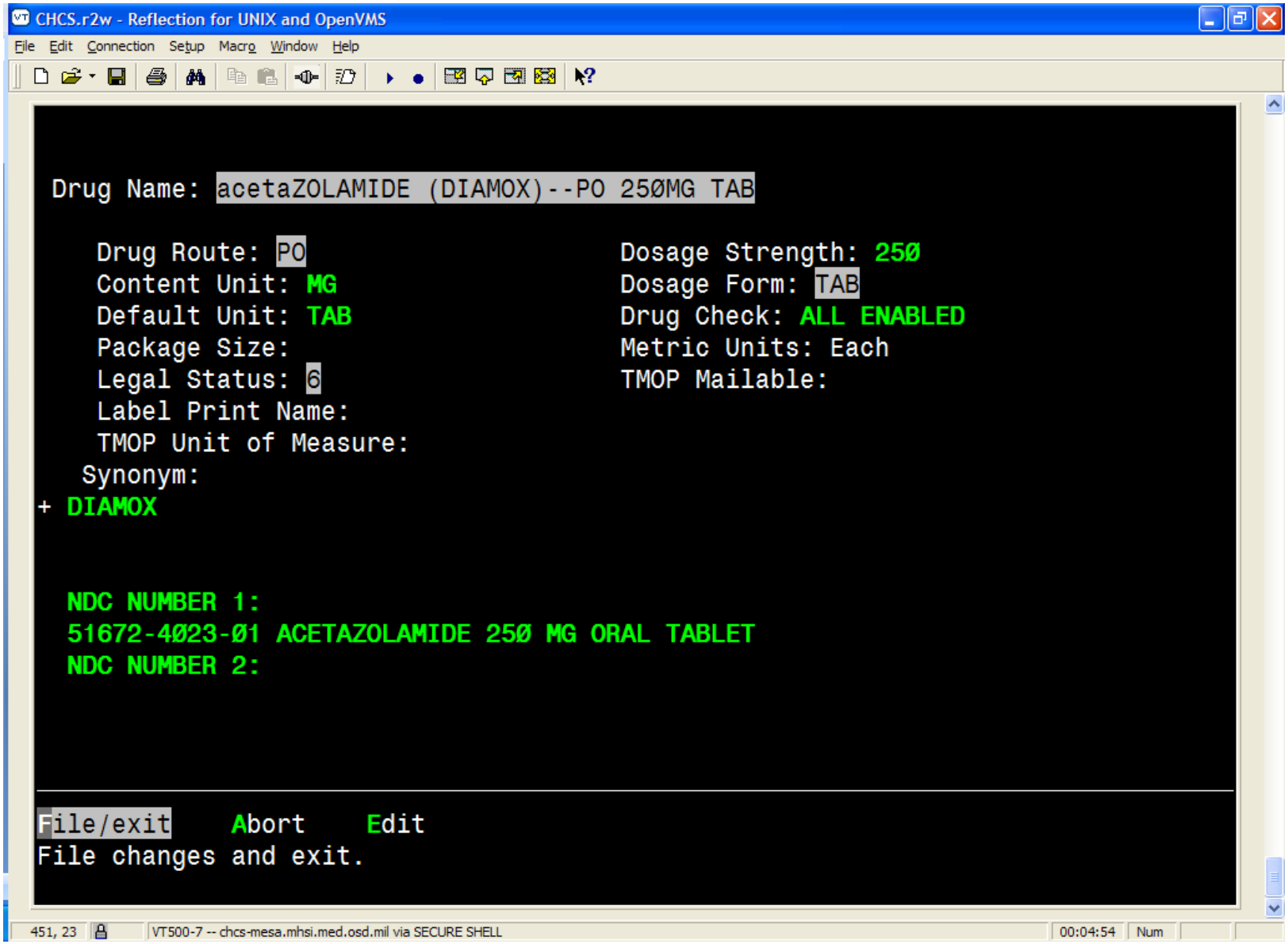

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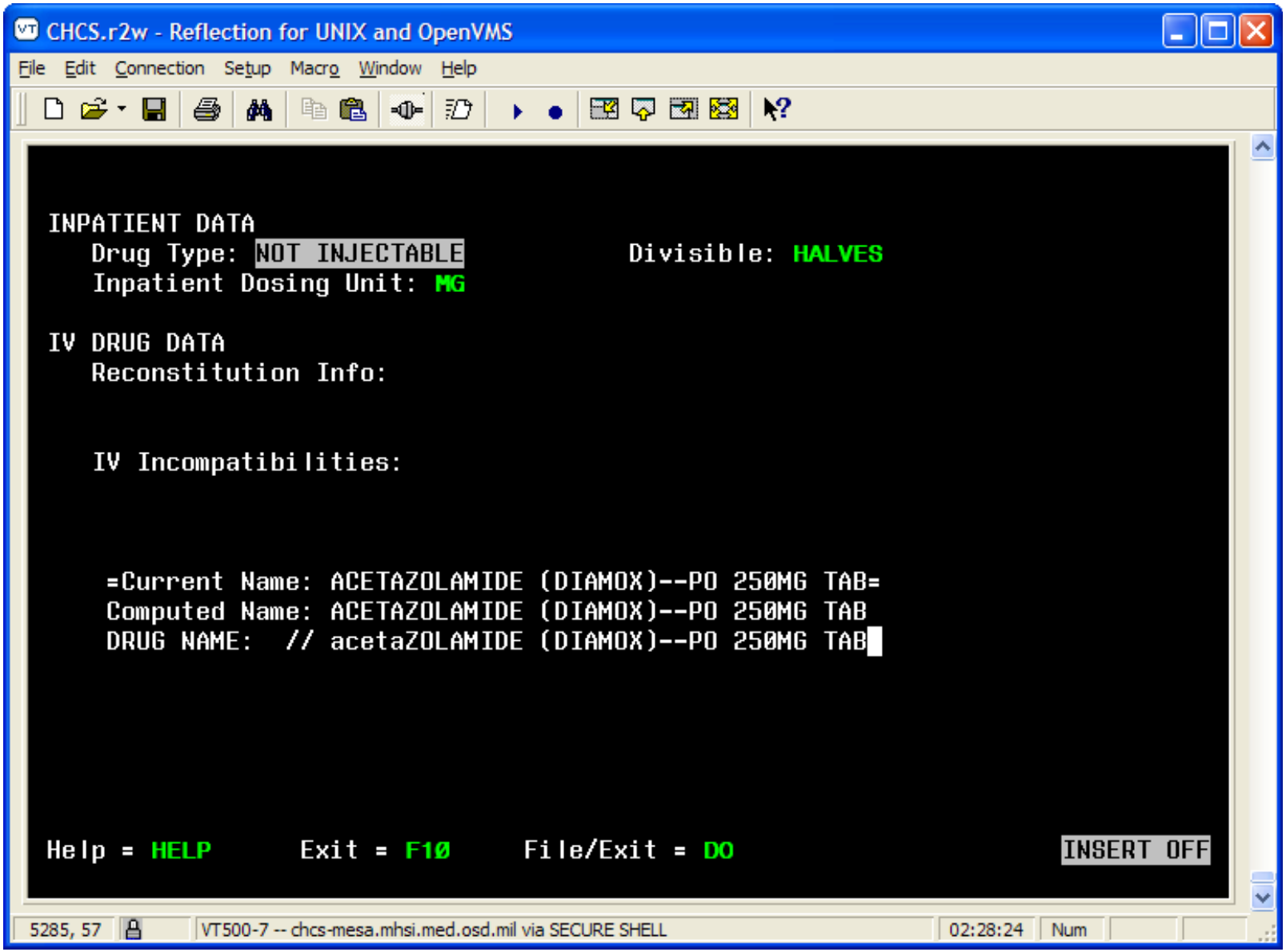

AHLTA & Tallman

- Tallman lettering appears in AHLTA to mirror the CHCS changes.

A/P Last updated by @ 26 Aug 2011 1809 CDT

1. Established Patient Age 5-11 School / Camp Physical

Procedure(s):	-Screening Test Of Visual Acuity, Quantitative, Bilateral x 1

2. ALLERGIC RHINITIS

Medication(s):	-MONTELUKAST CHEW(SINGULAIR)--PO 5MG TBCH - CHEW 1 TAB QD #90 RF1 Qt: 90 Rf: 1
	-MOMETASONE (NASONEX)--NAS 50MCG SPRA - 1 SPRAY EACH NARIES QD #1 RF0 Qt: 1 Rf: 0
	-guaiFENesin--PO 100MG/5ML SYRP - 1/2 TSP BID #1 RF0 Qt: 1 Rf: 0

Disposition Written by @ 26 Aug 2011 1809 CDT

Released w/o Limitations

AHLTA entry after tallman letterlog change

Way Ahead

- ISMP Medication Safety Alert Newsletter, 14 Jul 2011
  - **RxNorm will incorporate the ISMP list of drug names using Tall Man Letters**
  - **A system of normalized names for clinical drugs links the names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, including those of First DataBank, Micromedex, Medi-Span, Gold Standard Alchemy, and Multum**

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Contact Information

LTC Jorge D. Carrillo, PharmD, MS, BCPS
Manager, Army Patient Safety Center
HQ, U.S. Army Medical Command
Quality Management Division
Fort Sam Houston, TX 78234
Phone: 210-221-8543
E-mail: jorge.carrillo@amedd.army.mil

Review of May 2011 P&T Activities

Dave Meade, PharmD, BCPS
Clinical Pharmacist

May 2011
DoD P&T Committee Meeting

- **Uniform Formulary Class Reviews**
  - Atypical Antipsychotics Agents
  - Nasal Allergy Drugs
- **New Drugs in Previously Reviewed Classes**
  - Bromfenac (Bromday ophthalmic soln)
  - Dutasteride/tamsulosin (Jalyn)
  - Saxagliptin /metformin extended-release (Kombiglyze XR)

May 2011
DoD P&T Committee Meeting

- **Utilization Management**
  - Buprenorphine Transdermal System (Butrans) – Quantity Limits
  - Alsuma (Sumatriptan Inj) – Quantity Limits

Uniform Formulary Class Reviews: Atypical Antipsychotics Agents

Atypical Antipsychotic– Drugs in the Class

Generic	Brand	Strengths/ Formulations	FDA Approval Date	Patent Expiration
Clozapine	Clozaril, Fazaclo (Novartis, multiple generics)	12.5, 25, 50, 100, 200 mg tabs; 12.5, 25, 50, 100, 150, 200 mg ODT tabs	9/26/89	02/12/2010
Risperidone	Risperdal, Risperdal Consta (Ortho McNeil Janssen, multiple generics)	0.25, 0.5, 1, 2, 3, 4 mg tabs; 0.25, 0.5, 1, 2, 3, 4 mg ODT tabs; 1mg/mL oral solution	12/29/93	05/19/2014
Olanzapine	Zyprexa, Zyprexa Zydis (Eli Lilly & Co)	2.5, 5, 7.5, 10, 15, 20mg tabs; Zydis: 5, 10, 15, 20 mg ODT tabs	9/30/96 4/06/00	10/23/2011
Quetiapine	Seroquel, Seroquel XR (Astra Zeneca)	25, 50, 100, 150, 200, 300, 400 mg tabs 50, 150, 200, 300, 400 mg XR tabs	9/26/97 5/17/07	03/26/2012
Ziprasidone	Geodon (Pfizer)	20, 40, 60, 80 mg caps; 10 mg/mL oral solution	2/5/01	03/02/2012
Aripiprazole	Abilify (Bristol-Myers Squibb)	2, 5, 10, 15, 20, 30 mg tabs; 10, 15 mg ODT tabs; 1mg/mL oral soln	11/15/02	04/20/2015
Olanzapine/ Fluoxetine	Symbyax (Eli Lilly & Co)	3-25, 6-25, 6-50, 12-25, 12-50 mg caps	12/24/03	10/23/2011
Paliperidone	Invega (Ortho McNeil Janssen)	1.5, 3, 6, 9, 12 mg XR tabs	12/19/06	10/09/2012
Iloperidone	Fanapt (Vanda Pharmaceuticals)	1, 2, 4, 6, 8, 10, 12 mg tabs	5/6/09	11/15/2011
Asenapine	Saphris (Merck)	5, 10 mg SL tabs	8/13/09	06/09/2015
Lurasidone	Latuda (Sunovion)	40, 80 mg tabs	10/28/10	07/02/2013

Comparison Chart

Drug	QD Dosing	Approved Indications Other Than Schizophrenia	MTF Market-Share > 5%	Pediatric Indication	Generic/ Upcoming Patent exp	Low Metabolic Risk Profile	Evidence for Off-Label Use
Aripiprazole	X	X	X	X		X	PTSD; Dementia
Asenapine							
Iloperidone							
Lurasidone	X					X	
Olanzapine	X	X		X	X		PTSD; Dementia
Olan/Fluox	X	X					
Paliperidone	X			X	X		
Quetiapine		X	X	X	X		PTSD; Dementia
Quetiapine XR	X	X	X				
Risperidone		X	X	X	X		PTSD; Dementia
Ziprasidone		X			X	X	

Clinical Summary

- AAPs are efficacious for the treatment of schizophrenia and have some utility in treating other conditions
- Utilization patterns indicate a rise in off-label prescribing of AAPs
- Available evidence supports the use of AAPs as adjunctive therapy to CBT and SSRIs in the treatment of PTSD
- The small benefit seen in psychosis and behavioral disturbances associated with dementia is offset by a significant risk of increased mortality in elderly patients

Clinical Summary

- In the absence of other psychiatric co-morbidities, the use of low-dose AAPs for insomnia should be discouraged
  - Strongly recommend education of providers and revision of MOD-10
- Benefits conferred by AAPs are offset by limiting adverse effects
- Choice of treatment should be influenced by the relationship between the efficacy, tolerability and individual patient characteristics

Atypical Antipsychotic Agents– 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	PA and QL Issues	Comments
Risperidone (Risperdal, generics) Quetiapine (Seroquel, Seroquel XR)	Aripiprazole (Abilify, Abilify discmelt) Clozapine (Clozaril, Fazaclo, generics) Olanzapine (Zyprexa, Zydis) Paliperidone ER (Invega) Olanzapine/fluoxetine (Symbyax) Ziprasidone (Geodon)	Asenapine (Saphris) Iloperidone (Fanapt) Lurasidone (Latuda)	None	Risperidone (all oral formulations except ODT) remains on the BCF along with quetiapine IR and ER UF status of Risperidone ODT will be clarified at the Nov 2011 P&T meeting

Uniform Formulary Class Reviews: Nasal Allergy Drugs

Nasal Allergy – Drugs in the Class

Generic name	Trade Name	Manufacturer	Patent expiration
Nasal Corticosteroids			
Fluticasone propionate	Flonase	Glaxo SmithKline, generics	--
Mometasone	Nasonex	Merck & Co.	2014-2018
Flunisolide	--	Generics	--
Beclomethasone	Beconase AQ	GlaxoSmithKline	--
Budesonide	Rhinocort Aqua	AstraZeneca	2017
Ciclesonide	Omnaris	Sunovion	2017- 2020
Fluticasone furoate	Veramyst	GlaxoSmithKline	2021
Triamcinolone	Nasacort AQ	Sanofi-Aventis	2016
Nasal Anticholinergic & Antihistamines			
Azelastine 0.1%	Astelin	MEDA Pharma, generic	--
Azelastine 0.15% with sucrose	Astepro	MEDA Pharma	Excl to Aug 2012
Ipratropium bromide	Atrovent nasal spray	Boehringer-Ingelheim, generics	--
Olopatadine HCL	Patanase	Alcon	Jun 2011, Excl to 2013

Clinical Summary

- For treatment of allergic rhinitis, all of the Nasal Allergy agents appear to be safe and clinically effective
- There is no new evidence which substantively changes the conclusions of the DoD P&T Committee class review completed in 2008

Clinical Summary

- Nasal saline is a viable therapeutic option and should be actively considered in most patients
  - Vehicle effect is *2-4 times* the magnitude of any active drug treatment effect
- Nasal steroids are first-line treatment for patients requiring medication
- No agent, within its subclass, is clearly better than another
- Non-sedating oral antihistamines should be considered before nasal antihistamines

Nasal Allergy Drugs – 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	Comments
Fluticasone propionate (Flonase, generics)	***Nasal Corticosteroids*** Flunisolide (generics) Mometasone (Nasonex) ***Nasal Antihistamines*** Azelastine 0.1% (Astelin, generic) Olopatadine (Patanase) ***Anticholinergic*** Ipratropium (Atrovent, generics)	***Nasal Corticosteroids*** Beclomethasone (Beconase AQ) Budesonide (Rhinocort Aqua) Ciclesonide (Omnaris) Fluticasone furoate (Veramyst) Triamcinolone (Nasacort AQ) ***Antihistamine*** Azelastine 0.15% (Astepro)	Azelastine 0.1% (Astelin, generic) no longer BCF Brand name at MTF is currently less expensive than the generic Olopatadine (Patanase) now UF

New Drugs in Previously Reviewed Classes

Bromfenac Ophthalmic Solution

Bromfenac Ophthalmic Solution

- **Type of Drug**
  - Non-steroidal anti-inflammatory drug (NSAID)
- **Background**
  - Supplemental New Drug Application (sNDA)
    - Changed to once-a-day dosing from BID
  - FDA discontinued Xibrom
    - Feb 28, 2011-shipments to wholesalers end
    - Generics to Xibrom (BID dosing) approved after May 2011 P&T meeting

Ophthalmic 1's— Drugs in the Class

Generic Name	Brand	Mfg	Generic	Strength	FDA Approval	Patent Expiration
NSAIDs						
Bromfenac	Bromday	Ista	No	0.09%	2005	No expired patents
Bromfenac	Xibrom	Ista	D/C	0.09%	2005	2009; generics approved 06/11
Ketorolac	Acular	-	Yes	0.5%	1992	-
	Acular PF	-	D/C	0.5%	-	-
	Acular LS	-	Yes	0.4%	2003	-
	Acuvail	Allergan	No	0.45%	2009	2012
Diclofenac	Voltaren	-	Yes	0.1%	1991	-
Flurbiprofen	Ocufen	-	Yes	0.03%	1986	-
Nepafenac	Nevanac	Alcon	No	0.1%	2005	2014

D/C: Discontinued
Acular PF: Preservative-free
Acular LS: Lower strength

Clinical Summary

- Bromday was approved using a sNDA
- In the 2 Phase III trials used to obtain FDA approval, bromfenac demonstrated superiority over placebo for the primary endpoint of cleared ocular inflammation when dosed QD
- There are no head-to-head studies of Bromday vs. other ophthalmic 1 drugs
- Based on the available safety data, there are no clinically relevant differences between bromfenac and other ophthalmic NSAID formulations
- In regards to other factors, bromfenac in the only ophthalmic NSAID that has QD dosing
- Whether the lower concentration of benzalkonium chloride in bromfenac is associated with lower risk of long-term effects is yet to be determined

Dutasteride/tamsulosin (Jalyn)

Class Definition

- **Class: BPH Agents**
  - Subclass: Alpha-1 Blockers (A1Bs)
  - Subclass: 5-Alpha Reductase Inhibitors (5-ARIs)

- Jalyn is a combination product containing an A1B and 5-ARI

- Prior Authorization for Alpha-1 blocker subclass – must try tamsulosin or Uroxatral first

Background
Jalyn

Parameter	Comments
Type of Drug	• Combination of 5-ARI (dutasteride) and A1B (tamsulosin)
FDA Indications	• Approved June 14, 2010 • Treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate
Patent Expiration	• September 17, 2013
Generic	• Tamsulosin available as generic • Dutasteride (Avodart) not available as generic (patent expiration September 17, 2013)
Strength	• Capsule contains dutasteride 0.5mg and tamsulosin 0.4mg
Dosing	• One capsule taken 30 minutes after same meal each day

A1B Subclass Definition

Generic	Brand (manufacturer)	Generic Availability	Strengths & Formulations	FDA Approval	Earliest Patent Expiration
Terazosin	Hytrin (Abbott)	Yes	1, 2, 5 mg tablets / capsules	8/7/1987 tab 12/14/1995 cap	(-)
Doxazosin	Cardura (Pfizer)	Yes	1, 2, 4, 8 mg tablets 4, 8 mg XL tablets	11/2/1990 2/22/2005 XL	(-) (-)
Tamsulosin	Flomax (Boehringer Ingelheim)	Yes	0.4 mg capsule	4/15/1997	(-)
Alfuzosin*	Uroxatral (Sanofi-Aventis)	No	10 mg ER capsule	6/12/2003	July 2011-Aug 2017
Silodosin	Rapaflo (Watson Labs)	No	4, 8 mg capsules	8/8/2008	Oct 2013

*generics to Uroxatral approved July 2011

5-ARI Subclass Definition

Generic Name	Brand (Manufacturer)	Strength & Formulation	FDA approval date (earliest patent expiration)
Finasteride	Proscar (Merck), generics (Ivax, Teva, Dr Reddys, Mylan, Gedeon, Actavis)	5 mg tablet	6/19/1992 (-)
Dutasteride	Avodart (GSK)	0.5 mg capsule	11/20/2001 (Sep 2013)

Clinical Summary

- Based on the best available evidence, the combination of dutasteride and tamsulosin is not superior to dutasteride monotherapy for males with BPH with an enlarged prostate (>30ml) over a 4-year period, in terms of objective clinical progression, such as AUR and BPH-related surgery
- Combination therapy is superior to both tamsulosin and dutasteride monotherapy, in terms of delaying progression of IPSS symptom score
- There are no clinically relevant differences between the combination of dutasteride and tamsulosin versus monotherapy with either agent in terms of safety and tolerability

AUR : Acute Urinary Retention
IPSS: International Prostate Symptom Score

Saxagliptin /metformin extended-release (Kombiglyze XR)

DPP-4 Inhibitors & Combinations
Drugs in the Class

Active Ingredient	Brand	Strengths	FDA Approval Date	Patent Expiration Date
Sitagliptin	Januvia (Merck)	25mg, 50mg, 100mg	10/16/2006	04/24/2017
Sitagliptin/ Metformin	Janumet (Merck)	50mg/500mg, 50mg/1000mg	03/30/2007	04/24/2017
Saxagliptin	Onglyza (BMS)	2.5mg, 5mg	07/31/2009	02/16/2021
Saxagliptin/ Metformin XR	Kombiglyze XR (BMS)	2.5mg/1000mg 5mg/500mg 5mg/1000mg	11/05/2010	02/16/2021
Linagliptin	Tradjenta (Lilly/BI)	5mg	5/2/2011	-

Clinical Summary

- Sitagliptin and saxagliptin have similar A1c lowering effect when used as monotherapy ~0.4-0.79%
- Saxagliptin/metformin FDC provides a 2.5% decrease in A1c from baseline
- Sitagliptin/metformin FDC provides a 1.9% decrease in A1c from baseline
- One head-to-head trial, using metformin IR, did not show clinically significant differences in efficacy or safety between sitagliptin/met and saxagliptin/met
- One 4-week study with metformin XR and saxagliptin showed an improvement in average daily glucose compared to placebo

Clinical Summary

- DPP-4 inhibitor FDC's are weight neutral, lipid neutral, and have minimal impact on blood pressure
- DPP-4 inhibitor FDC's are generally well-tolerated, have few side effects and few drug interactions
- Initiating 2-drug regimens is not currently recommended by the ADA, however, a FDC agent may improve compliance by decreasing pill burden
- An additional metformin dose is required in addition to Kombiglyze XR to achieve target metformin doses

FDC: fixed dose combination

New Drugs in a previously reviewed class Final Decision

Drug	BCF	UF	NF	Comments- PA issues
BPH Agents Alpha 1 Blockers	None	Tamsulosin/dutasteride (Jalyn)	None	Step Therapy (automated PA) with tamsulosin or alfuzosin as the preferred agents; pt must have an inadequate response to preferred agent and require tx with both an A1B and 5-ARI (Note: Step Therapy does not apply to terazosin, doxazosin, or doxazosin ER)
Ophthalmic-1s		Bromfenac QD (Bromday)		None
Non-Insulin Diabetes Drugs DPP-4 Inhibitors		Saxagliptin/metformin ER (Kombiglyze XR)		Step Therapy (automated PA) with metformin and sulfonylureas as step- preferred drugs

Utilization Management Quantity Limits

Quantity Limits (QL)– Butrans

- **Type of Drug**
  - Mu opioid partial agonist, Schedule III controlled substance
  - Transdermal buprenorphine
- **FDA – Approved Indication**
  - Management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time
- **Dosing**
  - 5 mcg/hour, 10 mcg/hour, and 20 mcg/hour
  - Each patch intended for 7 days
- **QL recommendation**
  - Maximum quantity
    - Retail: 4 patches /28 days
    - Mail: 12 patches/ 84 days
- **Justification**
  - Consistent with recommended dosing
  - Prevent inadvertent misuse

Quantity Limits (QL)– Alsuma

- **Type of Drug**
  - Injectable sumatriptan
  - NDA (auto-injector)
- **FDA – Approved Indication**
  - Acute treatment of migraine with or without aura
  - Acute treatment of cluster headache episodes
  - NOT intended for migraine prophylaxis
- **Dosing**
  - 6mg/0.5 mL subQ injection
  - Maximum of 2 doses in 24 hours separated by at least 1 hour
- **QL recommendation**
  - Maximum quantity
    - Retail: 8 syringes /30 days
    - Mail: 24 syringes/ 90 days
- **Justification**
  - Collective QL exists for injectable sumatriptan
  - Consistent with recommended dosing

Review of August 2011 P&T Activities

Dave Meade, PharmD, BCPS
Clinical Pharmacist

August 2011
DoD P&T Committee Meeting

- **Uniform Formulary Class Reviews**
  - Contraceptive Agents
  - Oral Non-Steroidal Anti-Inflammatory (NSAID)
  - Phosphodiesterase-5 Inhibitor (PDE-5)

August 2011
DoD P&T Committee Meeting

- **New Drugs in Previously Reviewed Classes**
  - Azilsartan (Edarbi)
  - Aliskiren/amlodipine/HCTZ (Amturnide)
  - Bromocriptine quick release tablets (Cycloset)
  - Buprenorphine – (Butrans transdermal patch)

August 2011
DoD P&T Committee Meeting

- **Utilization Management**
  - Singulair Prior Authorization
  - Lovaza PA update
  - Avandia REMS (info)
  - Simvastatin 80 and Simcor BCF status

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!

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