

P&T Webcast 12 June 2014



“Medically Ready Force...Ready Medical Force”

Introduction



- Greetings from the PEC-Branch
- 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
- Final slides and Questions/Answers posted to PEC Website in a few days

Outline



- DHA Shared Service Purchasing Metrics
- Protest Update: Test Strips
- Review of Feb 2014 P&T Committee Meeting
 - UF Class Reviews
 - New Drugs in Previously Reviews Class
 - Duloxetine (Cymbalta) Update
 - Utilization Management
- Overview of May 2014 P&T Committee Meeting
- Quick Look at August 2014 P&T Committee Meeting
- Questions



DHA Shared Services Purchasing Metrics

Shana Trice, PharmD, BCPS

Pharmacy Cost Savings Metrics



- Prescription movement from retail to mail/MTF
- P&T formulary management processes
- Brand-to-Generic (B2G) switches
- Contract compliance

Brand-to-Generic (B2G)

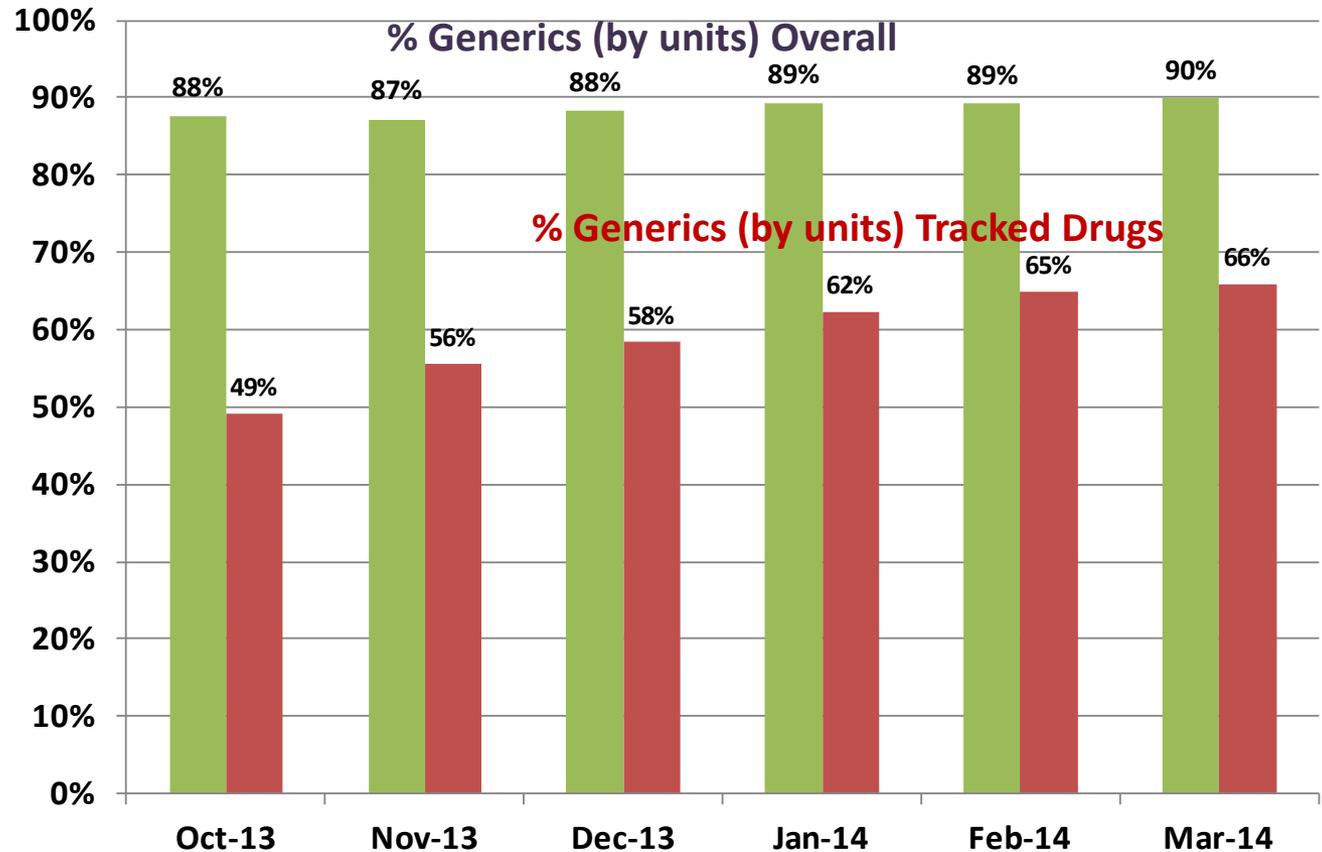
- DLA currently reports on generic use at facility & Service level for select set of tracked drugs
 - Saving based on how much would have been spent on brand (for tracked drugs only)
- PEC-Branch calculates overall MTF percent use of generics for both tracked drugs (actual metric) & all drugs where both generics and brand were purchased in a given month & generics cost < brand cost

Expediting Brand-to-Generic Conversions

How are we doing?



- % use of generics has increased slightly
- % use of generics within a smaller pool of high value targets (tracked drugs) shows more substantial improvement & offers a more sensitive metric; this pool will change over time
- Tracked drugs reported by DLA at Service level (CPOC Bulletin)



B2G Information



DEFENSE LOGISTICS AGENCY TROOP SUPPORT MEDICAL Customer Pharmacy Operations Center (CPOC)

Contact CPOC
CPOC@dla.mil

Access DMMonline:
https://www.medical.dla.mil
April 2014

CPOC website:
https://www.medical.dla.mil/Portal/Pharmaceuticals/CPOC.aspx

Brand to Generic (B2G) Conversion Update (Gov't contract options)

(SOURCE: PPV sales as of 31 March 2014)

Brand to Generic (B2G) Conversion Update (Gov't contract options)	(SOURCE: PPV sales as of 31 March 2014)			
<p>Mirapex IR (Pramipexole IR) 68%</p> <p>Innovator MFT basis/brand Mirapex Avg. Brand Cost: \$2.54/tab</p> <p>Alkare 42291-0680-90 0.125 mg 90 ct \$0.76/tab Alkare 42291-0681-90 0.25 mg 90 ct \$0.72/tab Alkare 42291-0682-90 0.5 mg 90 ct \$0.88/tab Alkare 42291-0683-90 1 mg 90 ct \$0.87/tab Alkare 42291-0684-90 1.5 mg 90 ct \$0.90/tab</p>	<p>Skelaxin (Metaxalone) 73%</p> <p>Innovator MFT basis/brand Skelaxin Avg. Brand Cost: \$3.10/tab</p> <p>Cora 64720-0311-10 800mg 100 ct \$1.54/tab</p>	<p>Seroquel IR (Quetiapine IR) 54%</p> <p>Innovator MFT basis/brand Seroquel Avg. Brand Cost: \$5.57/tab</p> <p>GENS 02429-0773-01 50mg 100 ct \$9.16/tab GENS 02429-0773-01 100mg 100 ct \$9.29/tab GENS 02429-0773-01 200mg 100 ct \$9.30/tab GENS 02429-0773-01 300mg 100 ct \$9.42/tab GENS 02429-0773-01 400mg 100 ct \$9.57/tab Roche 0006-4928-25 25mg 100 ct \$8.14/tab Roche 0006-4928-25 50mg 100 ct \$8.14/tab Roche 0006-4928-25 100mg 100 ct \$8.31/tab Roche 0006-4928-25 200mg 100 ct \$8.30/tab Roche 0006-4928-25 300mg 100 ct \$8.47/tab Roche 0006-4928-25 400mg 100 ct \$8.54/tab</p>	<p>Lidoderm (Lidocaine 5% TD Patch) 1%</p> <p>Innovator MFT basis/brand Lidoderm Avg. Brand Cost: \$3.85/patch</p> <p>Actavis 0093-3125-30 5% 30ct \$3.67/patch</p>	<p>Stalvo (Carbidopa/Levodopa/Enkephalin) 32%</p> <p>Innovator MFT basis/brand Stalvo Avg. Brand Cost: \$2.47/tab</p> <p>Wockhardt 64679-0782-01 12.5/200/100 50 mg .ct /tab Wockhardt 64679-0783-01 12.5/200/100 50 mg .ct /tab Wockhardt 64679-0784-01 25/200/100 50 mg .ct /tab Wockhardt 64679-0785-01 37.5/200/100 50 mg .ct /tab Wockhardt 64679-0786-01 50/200/100 50 mg .ct /tab Wockhardt 64679-0787-01 75/200/100 50 mg .ct /tab Mylan 0378-8305-01 200mg .ct /tab</p>
<p>Divon HCT (Valsartan/HCTZ) 40%</p> <p>Innovator MFT basis/brand Divon HCT Avg. Brand Cost: \$0.48/tab</p> <p>Sandoz 00781-5949-01 12.5mg/100mg 90ct 0.15/tb Sandoz 00781-5950-01 25mg/100mg 90ct 0.15/tb Sandoz 00781-5949-01 12.5mg/90mg 90ct 0.15/tb Sandoz 00781-5951-01 12.5mg/30mg 90ct 0.15/tb Sandoz 00781-5952-01 25mg/30mg 90ct 0.15/tb</p>	<p>Malarone (Atovaquone/Proguanil) 78%</p> <p>Innovator MFT basis/brand Malarone Avg. Brand Cost: \$4.53/tab</p> <p>Pharco 66999-0060-27 100 24 ct \$2.25/mg .ct .tab Pharco 66999-0060-02 100 100 ct \$2.97/mg .ct .tab</p>	<p>Lotrel (Amlodipine/Benzepiril) 44%</p> <p>Innovator MFT basis/brand Lotrel Avg. Brand Cost: \$0.56/tab</p> <p>Mylan 00378-6895-01 2.5/20mg 100 ct \$0.08/tab Mylan 00378-6896-01 5/20 mg 100 ct \$0.08/tab Mylan 00378-6897-01 5/20 mg 100 ct \$0.08/tab Mylan 00378-6898-01 5/40 mg 100 ct \$0.12/tab Mylan 00378-6898-01 10/20 mg 100 ct \$0.10/tab</p>	<p>Provigil (Modafinil) 72%</p> <p>Innovator MFT basis/brand Provigil Avg. Brand Cost: \$37.50/tab</p> <p>GENS 60429-0581-05 100mg 500 ct \$1.02/tab Mylan 00378-5578-05 100mg 500 ct \$2.22/tab GENS 60429-0581-05 100mg 30 ct \$2.28/tab Mylan 00378-5578-93 200mg 30 ct \$2.40/tab Teva 5025-0802-90 200mg 90 ct \$1.54/tab Mylan 00378-4950-01 100mg 100 ct \$5.16/tab Sandoz 00781-5271-01 5/20mg 100 ct \$0.25/tab Sandoz 00781-5272-01 5/20 mg 100 ct \$0.25/tab Sandoz 00781-5273-01 5/20 mg 100 ct \$0.25/tab Sandoz 00781-5274-01 10/20 mg 100 ct \$0.12/tab</p>	<p>Imitrex Nasal Spray (Sumatriptan NS) 60%</p> <p>Innovator MFT basis/brand Imitrex Nasal Avg. Brand Cost: \$205.73/tab</p> <p>Sandoz 00781-6524-86 5mg 6 ct \$31.70/ea Sandoz 00781-6524-86 20mg 6 ct \$31.70/ea</p>
<p>Generic to Generic (G2G) Cost Effective NDCs</p> <p>Potassium Chloride 10mEq Extended Release tablets (C2G) NDC 00074-7804-13 100ct \$0.12/tab NDC 00074-7804-19 1000ct \$0.12/tab Special Note: not all extended release K+ is bioequivalent</p> <p>Zoledronic Acid 4mg NDC 42029-0661-01 \$128.42/5ml vial</p>	<p>Bisphosphonate 50mg 30ct NDC: 42291016830 \$0.40/tab 500ct NDC: 42291016850 \$0.38/tab</p> <p>Fluoroquinolone 500mg tablets NDC: 42291-0280-90 30ct \$0.28/tab NDC: 42291-0280-90 90ct \$0.28/tab</p>	<p>Soft Comfort Insulin Pen Needles 29G x 1/2" (12.7mm) 100ct NDC: 86227-0101-06 \$12.26/box 30G x 5/16" (9mm) 100ct NDC: 86227-0111-69 \$11.26/box 31G x 3/16" (5mm) 100ct NDC: 86227-0121-08 \$12.26/box 31G x 5/16" (9mm) 100ct NDC: 86227-0121-66 \$12.26/box 32G x 1/4" (6mm) 100ct NDC: 86227-0130-55 \$12.26/box 32G x 5/32" (4mm) 100ct NDC: 86227-0130-85 \$12.26/box</p>		

- DLA Customer Pharmacy Operations Center (CPOC) Bulletins
- Reports on specific drugs via service consultants
- Best Pharm report
- www.medical.dla.mil

See CPOC SITREP for more information on National Contract updates	National Contract Compliance	National Contract Compliance Top MTFs
<p>National Contract Product Shortages</p> <p>DRUG MFR STRENGTH EST. QTY WELL DATE ALTERNATE PRODUCT CONSIDERATION</p> <p>Atorvastatin* Ranbaxy 40mg, 20mg, 10mg, 2mg NDC expires 30 Apr 2014 40mg 9970-0283-01, 42291-0443-90, 0443-0220-90 20mg 9970-0283-01, 42291-0443-90, 0443-0220-90 10mg 9970-0283-01, 42291-0443-90, 0443-0220-90 2mg 9970-0283-01, 42291-0443-90, 0443-0220-90</p> <p>Donepezil* Ranbaxy 5mg, 10mg NDC expires 18 Jun 2014 5mg 0389-0240-90, 0389-0240-90 10mg 0389-0240-90</p> <p>Famotidine* Mylan 20mg & 40mg N/A 20mg 0006-8780-61</p> <p>Meloxicam* Mylan 7.5mg & 15mg May 2014 7.5 mg & 15mg - replace items in 0309A 15mg 5379-0861-01 use case</p> <p>Burnettide* Sandoz 0.5mg, 1mg, 2mg CY 2015 0.5mg 5379-0861-01 use case 1mg & 2mg - check PPV for availability</p>	<p>85% 95% 81% 81%</p> <p>*Percentage adjusted for Nat'l Contract product shortages</p>	<p>1. BROOKS ARMY MEDICAL CENTER, FT. SAM HOUSTON, TX 2. T3ST MAF/SGL, VANCE AFB, TX 3. NAVAL HOSPITAL, MILLINGTON, TN</p> <p>NEW NATIONAL CONTRACTS</p> <p>Afluzotinib tablets, Exlatan effective: 01 May 2014 Methocarbamol tablets, GSMS effective: 15 May 2014</p> <p>Fencopidine tablets, Quiflast effective: 02 May 2014 Fluoxetine tablets, Exlan effective: 23 May 2014</p> <p>Metoprolol Tartrate tablets, Costardata effective: 15 May 2014 Enalapril Tartrate tablets, GSMS effective: 23 May 2014</p> <p>*Initial usage statistics start to PPV for these items between 27 Mar - 04 Apr 2014</p>

Use Parent DODAAC Medical Master Catalog Sourcing and PSR submissions.

Product Sourcing: Helpful Hints
 2 Types of PSRS
 PRODUCT SOURCING REQUEST. Used to establish pricing agreement & request addition to the Pharmaceutical Prime Vendor (PPV) Program.
 PPV STOCK NDC REQUEST. Used for product already on gov't pricing agreement, request for addition to PPV distribution center stock.

Multiple Product Identifiers
 Include product nomenclature, description, and NDC or Part number when submitting PSRs or requesting assistance from the CPOC.

PSR Application: https://www.medical.dla.mil/Forms/FormsPages/PSR.aspx

DMMOnline Access: https://www.medical.dla.mil/Registration/Start.cfm.aspx

Contract Compliance



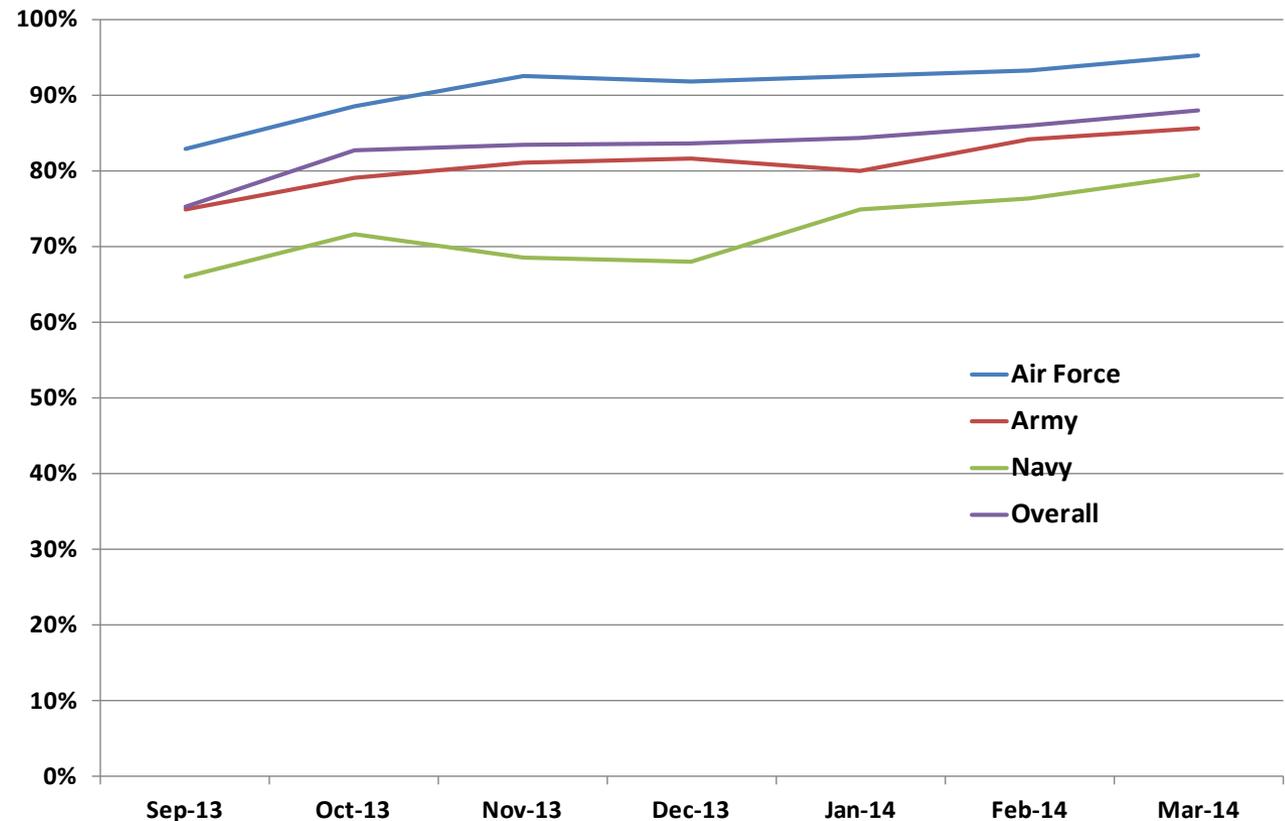
- DLA reports percent compliance at facility & Service level; does not report overall cost savings
- Cost Savings Methodology
 - Currently, cost savings based on cumulative decreases in opportunity cost month-to-month
 - Opportunity cost = actual cost - theoretical cost at contract price
 - Opportunity cost very sensitive to shortages, new contracts; costs savings measure may not fairly represent improvements in contract compliance over last 6 months
 - Alternate method under development; would tie cost savings to improvements in percent compliance

Improving Contract Compliance

How are we doing?



- Contract compliance improving overall
- Air Force now above 90%; overall compliance above 80%; improvement starting to result in detectable savings
- Product shortages shrink the pool of attainable savings and hamper analysis

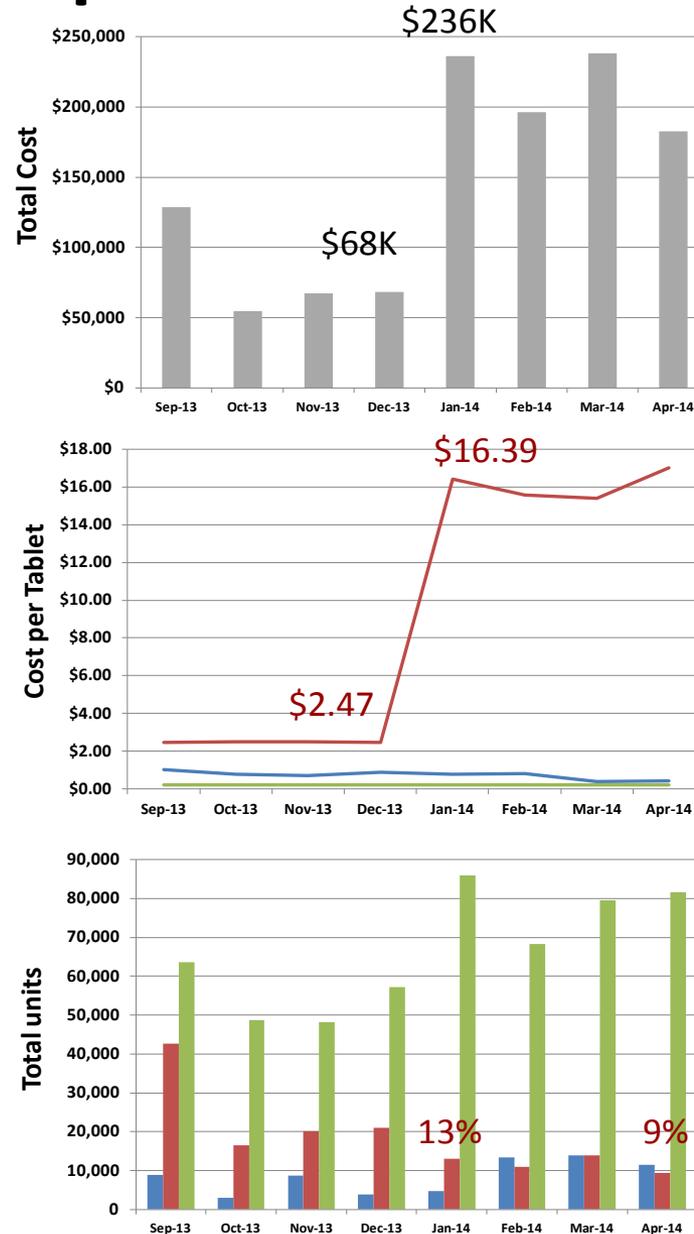


A Specific Example: Levofloxacin



■ ↑↑↑ total cost of levofloxacin Jan 14

- Attributable to sharp ↑ in cost for brand Levaquin
- Since Jan, units purchased ↓ for brand Levaquin (but ↑ for non-contract generics)



- Opportunity cost still at least ~\$82K/month (Mar 14)

Based on prime vendor purchase data

National Contract Compliance Reports & National Contract List

A screenshot of a web browser displaying the 'National Contracts' application. The browser's address bar shows 'https://www...' and the page title is 'National Contracts'. The application interface has a dark blue header with the text 'National Contracts' and navigation icons for Home, Contact, Profile, and Logout. Below the header is a 'Compliance Report' section with several form fields:

- Select Report Type:** Radio buttons for 'All Nationally Contracted Drugs and the facility's compliance' (selected) and 'Nationally Contracted Drugs with cut-off level less than 80 %'.
- Select Sort Criteria:** Radio buttons for 'By NDC (ascending)', 'By Drug Name (ascending)' (selected), 'By Percentage Compliance based on Quantity (ascending)', and 'By Excess Cost (descending)'.
- Select Facility/Service:** Radio buttons for 'By DODAAC', 'By Facility Name', and 'An entire branch of service' (selected). A dropdown menu shows 'Air Force'.
- Select Fiscal Year:** A dropdown menu showing '2014'.
- Select Time Period:** Radio buttons for 'By Fiscal Quarter' and 'By Fiscal Month (FM)' (selected). Below are checkboxes for months from Oct (FM 1) to Sep (FM 12).
- Select Report Options:** A checkbox for 'Display Non-Compliant NDCs'.
- Select Cell Highlighting:** A checkbox for 'Turn cell highlighting OFF'. Below are input fields for 'Highlight drugs at or below compliance threshold of 50 % in red' and 'Highlight drugs at or below compliance threshold of 75 % in yellow'.
- E-mail Notifications:** A checked checkbox for 'Send e-mail notifications when new compliance data is available' and an 'E-mail Address:' input field.

A 'Get Results' button is located at the bottom of the form. The footer of the application includes the 'DMMonline' logo, the text 'For Official Use Only', and a circular seal.

- NCCR report, at Service & facility level, by month or quarter
- National contract list by month
- And other useful info:
 - Trade Agreements Act – Not Compliant List
- DLA DMMOnline
- www.medical.dla.mil

DLA CPOC Situation Reports



Defense Logistics Agency Troop Support Medical PHARMACY SUPPLY SITREP Customer Pharmacy Operations Center (CPOC)

April 2014

Last Update: March 2014

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CPOC Bulletin/ B2G Report / Nat'l Contract Update / Credit Report / Market Shortages / Product Updates

- BRAND TO GENERIC (B2G) REPORT** – attachment 1
 - B2G compliance decrease pramipexole, Stalevo generics, and Lotrel generics - intermittent MFR backorders in Mar '14.
 - Anticipated Wockhardt production problems for Stalevo generics through mid-May 2014.

- NATIONAL CONTRACT UPDATES** – attachment 2

NEW NATIONAL CONTRACT AWARDS – initial usage statistics sent to PPVs between 27 March and 14 Apr 2014.

- > **Alfuzosin tablets, Exelan** – Effective 01 May 2014
- > **Felodipine tablets, Qualitest** – Effective 02 May 2014
- > **Metoprolol Tartrate tablets, Cedardale** – Effective 15 May 2014
- > **Methocarbamol tablets, GSMS** – Effective 15 May 2014
- > **Finasteride tablets, Exelan** – Effective 23 May 2014
- > **Enalapril Tartrate tablets, GSMS** – Effective 23 May 2014

NATIONAL CONTRACT SHORTAGES – see CPOC Bulletin for specific NDC recommendations

- Atorvastatin, Ranbaxy.** National Contract products unavailable - FDA regulatory action; **VA NC expires 30 April 2014.**
- Bumetanide, Sandoz.** Sandoz confirms product backordered through CY2015. Consider therapeutic substitution of: Furosemide, Torsemide, or Ethacrynic Acid as clinically indicated.
- Donepezil, Ranbaxy.** National Contract products unavailable - FDA regulatory action; **VA NC expires 14 June 2014.** Generic MFR, Greenstone discontinues manufacture of product. Only TAA compliant alternative is Brand name Aricept.
- Famotidine, Mylan.** Backorder resolved. Famotidine 40mg tablets released by MFR on 11 April 2014. Contact PPV to ensure stock and provide usage.
- Meloxicam, Mylan.** Multiple items available on RDAPA
- Montelukast, AvKare.** AvKare reports possible, intermittent product delays through end of May 2014.
- Reimbursement forms** for market shortage National Contract products (atorvastatin, donepezil, famotidine, meloxicam, and bumetanide) are available at the [CPOC website](#). Ranbaxy reimbursement honored until the contract expiration date.

o ****National Contract items are MANDATORY PURCHASE. Notify the CPOC Team if procurement and/or pricing issues are encountered.****

- PRIME VENDOR CREDIT REPORT**

- 120-day Credits expire **30 April 2014.** 90-day Credits expire **31 May 2014.**
- March 2014 PV Credit Report sent to Service Consultants on 21 April 2014.
- Prime Vendor (PV) account changes require contract modification. Please contact your Regional DLA Contracting Officer (KO).

- ABBOTT TEST STRIPS UPDATE** – Per the Defense Health Agency: "The SMBGS formulary decision is under a Temporary Restraining Order (protest) and awaiting Federal Court hearing." Until the judge renders a decision, DHA recommends MTFs stop conversions from non-Abbott to Abbott products. MTFs are free to use any strip on their formulary prior to the decision. UF BPA pricing prior to the decision is still in effect.

57599-9695-04	PRECISION XTRA STRIPS, #50	\$12.00
57599-9694-05	PRECISION XTRA STRIPS, #100	\$23.99
99073-0710-26	FREESTYLE LITE STRIPS, #50	\$12.00
99073-0712-29	FREESTYLE INSULINX STRIPS, #50	NO ACTIVE GOV'T PRICING AGREEMENT

Visit the CPOC Website: <https://www.medical.dla.mil/Portal/Pharmaceutical/CPOC.aspx>
Contact the CPOC: CPOC@dlamil

■ DLA DMMOnline

■ www.medical.dla.mil

Review of Feb 2014 P&T Committee Meeting

Dave Meade, PharmD, BCPS

**Protest Update:
Self-Monitoring Blood Glucose
System (SMBGS) Test Strips**

Holding Pattern



- Federal Judge is reviewing
- Do not make any active conversions
- Decision pending soon

Feb 2014

DoD P&T Committee Meeting



- Uniform Formulary Class Reviews
 - Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs)
 - Gastrointestinal-1 (GI-1s): Oral Aminosalicylates Subclass
 - Pancreatic Enzyme Products (PEPs)
- New Drugs in Previously Reviewed Class
 - Bupropion extended release (Forfivo XL)
 - Desvenlafaxine extended release (Khedezla)
 - Levomilnacipran (Fetzima)
 - Vortioxetine (Brintellix)
- Re-evaluation of NF Agent: Duloxetine (Cymbalta)
- Utilization Management
- Overview of Upcoming Meetings

Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs)

ICS/LABA Drugs and Dosage



Generic Name	Generic Name	Dosage Form /Device	Strength (mcg)	Starting Dose	Indications
Fluticasone/ Salmeterol	Advair Diskus	DPI	100/50 250/50 500/50	1 puff BID	Asthma & COPD
Fluticasone/ Salmeterol	Advair HFA	pMDI	45/21 115/21 230/21	2 puffs BID	Asthma
Budesonide/ Formoterol	Symbicort	pMDI	80/4.5 160/4.5	2 puffs BID	Asthma and COPD
Mometasone / Formoterol	Dulera	pMDI	100/5 200/5	2 puffs BID	Asthma only
Fluticasone/ Vilanterol	Breo Ellipta	DPI	100/25	1 puff QD	COPD only

Indications



Indication	Drug				
	Advair Diskus fluticasone/ salmeterol	Advair HFA fluticasone/ salmeterol	Symbicort HFA budesonide/ salmeterol	Dulera HFA mometasone/ formoterol	Breo Ellipta HFA fluticasone/ vilanterol
COPD					
Maintenance	X		X		X
Decrease Exacerbations	X				X
Asthma	X	X	X	X	
Age range	≥ 4 yrs of age	≥ 12 yrs of age	≥ 12 yrs of age	≥ 12 yrs of age	N/A

Clinical Conclusions....



- Advair Diskus and Symbicort are highly interchangeable for asthma and COPD
- Advair Diskus, Symbicort, and Breo Ellipta are all approved for maintenance txt of COPD.
 - Advair Diskus and Breo Ellipta are approved for decreasing COPD exacerbations.
Symbicort does have observational data showing decreases in COPD exacerbations.
- Dulera is ONLY FDA approved for the treatment of asthma; no head to head studies available with ICS/LABA combinations. Two trials show benefit in improving spirometric endpoints in COPD.
- Breo Ellipta is ONLY FDA approved for the treatment of COPD, only limited data available for asthma.
- Breo Ellipta offers the convenience of once a day dosing. However, long term safety data regarding vilanterol is unknown.
- Advair Diskus is the only drug approved for treatment in children down to the age of 4 years; Advair offers the benefit of an MDI and a DPI for the txt of asthma.
- There does not appear to be significant safety differences between Dulera, Advair, and Symbicort.
- Breo Ellipta has been associated with an increased incidence of pneumonia at a dose higher than what is marketed in the US.

ICS/LABA Formulary Placement



■ Decision:

- BCF & step preferred: Advair Diskus & Advair HFA
- NF behind the step: **Breo Ellipta, Dulera, & Symbicort**
- No grandfathering for step therapy – All users **older than age 12** will hit step

■ Justification

- Insufficient evidence to suggest if one agent is superior to another
- Advair offers benefit of approval for both asthma and COPD; age down to 4 years; availability in both MDI and DPI
- Lowest cost per month of therapy for Advair
- Lowest projected budgetary impact
- Additional cost avoidance due to step therapy & no grandfathering

Gastrointestinal-1 (GI-1s): Oral Aminosalicylates Subclass

Gastrointestinal-1 Drug Class



Drug Class	Generic Name	Brand Name	Generic
Aminosalicylates	Sulfasalazine	Azulfidine Azulfidine EN	Yes
	Balsalazide	Colazal Giazo	Yes No
	Olsalazine	Dipentum	Patent Expired
	Oral Mesalamine	Delzicol, Asacol HD Apriso Lialda Pentasa	No
			No
			No
Rectal Mesalamine	Canasa Rowasa sfRowasa	Patent Expired Yes No	
GI-Steroids	Budesonide	Entocort EC	No
	Hydrocortisone	Cortenema Cortifoam	Yes
Miscellaneous agents	Alosetron	Lotronex	No
	Tegaserod	Zelnorm	Withdrawn from market

Aminosalicylates

Overall Clinical Conclusion



- No clinically relevant difference between sulfasalazine and oral 5-ASAs in terms of efficacy for induction of remission of mild to moderately active ulcerative colitis
- For maintenance of remission, sulfasalazine proved superior to the 5-ASAs. This was offset by the increase in AEs.
- Differences in 5-ASA release mechanisms have not been shown to confer additional benefits in terms of clinical response. All 5-ASAs are superior to placebo in treating colonic disease.
- Delzicol is the phthalate-free replacement for Asacol, and has been shown to be bioequivalent to its predecessor; no clinical trials were conducted with Delzicol.
- Giazol has less clinical utility than other 5-ASAs given its restricted indication (males only). It has not been directly compared with any other 5-ASA and offers no compelling advantage to the other commercially available products.

Aminosalicylates

Overall Clinical Conclusion



- Of the mesalamine formulations, Lialda and Delzicol are indicated for both treatment of active disease and maintenance of remission.
- In terms of safety, evidence from systematic reviews show no significant differences among the 5-ASA products. Giaso may result in higher AEs in females (it is not indicated for use in women).
- QD dosing has not been shown to have any clinically relevant benefits in terms of efficacy or safety compared to conventional dosing regimens. Apriso and Lialda are both dosed once daily.
- Ultimately, the choice of oral 5-ASA will depend on patient and provider preference.

Aminosalicylates Formulary Placement



■ Decision:

BCF: sulfasalazine, Lialda

UF :

- (brands): Apriso, and Delzicol (mesalamine agents)
- UF (generics): sulfasalazine, olsalazine, and balsalazide (Colazol 750 mg)

NF: **Asacol HD, Pentasa, and Giazol (balsalazide 1,110 mg)**

■ Justification:

Agents are clinically interchangeable, and will meet the clinical needs of DoD patients

Pancreatic Enzyme Products (PEPs)

Strengths



Product	Lipase (USP units)	Protease (USP units)	Amylase (USP units)
FDA-approved Products—Labeled Content Reflects Actual Amount			
Creon Delayed-Release Capsules (Abbvie)	3,000	9,500	15,000
	6,000	19,000	30,000
	12,000	38,000	60,000
	24,000	76,000	120,000
	36,000	114,000	180,000
Pancreaze Delayed- Release Capsules (Janssen)	4,200	10,000	17,500
	10,500	25,000	43,750
	16,800	40,000	70,000
	21,000	37,000	61,000
Zenpep Delayed- Release Capsules (Aptalis)	3,000	10,000	16,000
	5,000	17,000	27,000
	10,000	34,000	55,000
	15,000	51,000	82,000
	20,000	68,000	109,000
	25,000	85,000	136,000

Strengths Cont.



Product	Lipase (USP units)	Protease (USP units)	Amylase (USP units)
FDA-approved Products—Labeled Content Reflects Actual Amount			
Viokace (Abbvie)	10,440	39,150	39,150
(uncoated tablet; take with PPI)	20,880	78,300	78,300
Ultressa (Janssen)	13,800	27,600	27,600
	20,700	41,400	41,400
	23,000	46,000	46,000
Pertzye (Aptalis)	8,000	28,750	30,250
	16,000	57,500	60,500

Pancreatic Enzyme Products (PEPs)

Overall Clinical Effectiveness Conclusion



- Based on clinical efficacy alone, Creon, Pancreaze, Zenpep, Viokace, Ultresa, and Pertzye are effective at increasing the coefficient of fat absorption (CFA) in patients with exocrine pancreatic insufficiency, compared to placebo
- With regards to safety, the available evidence suggests there are no clinically relevant differences between any of the PEPs
- With regards to other factors such as microsphere size, and storage requirements/stability, there are no clinically relevant differences between the PEPs
- Zenpep and Viokace have information for G-tube administration
- Creon has the most indications and highest MHS utilization
- Zenpep has the most strengths; Not approved for pancreatitis or pancreatectomy (compared to Creon)
- Viokace must be used with a PPI
- Pertzye and Ultresa have limited data; limited strengths
- Creon, Pancreaze, and Zenpep have dosing for infants up to 12 months old

PEP Agents Decision

UF Placement



■ Recommendation:

- BCF: Creon
- UF: Pancreaze, and Zenpep
- NF: **Viokace, Ultresa, and Pertzye**
- The PEPs were previously an Extended Formulary Class (ECF), but now BCF (Pancreaze no longer ECF)

■ Justification:

- Recommended UF agents managed 99% of existing MHS use and are more cost effective
- Availability of recommended PEP products will meet the clinical needs of DoD patients

New Drugs in Previously Reviewed Class Antidepressants

Bupropion 450 mg extended release (Forfivo XL)

Bupropion 450 mg ER (Forfivo XL)



Parameter	Forfivo XL
Pharmacologic Class	Norepinephrine Dopamine Reuptake Inhibitors (NDRIs)
Approval Type	Approved via 505(b)2 process using data from Wellbutrin XL
Mechanism of Action	<ul style="list-style-type: none">• Weakly inhibits neuronal uptake of dopamine and norepinephrine• Does not inhibit MAO or reuptake of serotonin
Strength and Formulation	450mg extended release tablet
FDA label indication	Major depressive disorder in adults
Dosing	Once daily

Bupropion Drugs in NDRI Subclass



Active Ingredient	Brand Name	Strengths (mg)	Dosing Frequency	Generic available	Label Indication(s)
Bupropion HBr, ER	Aplenzin	174, 348, 522	QD		MDD, SAD
Bupropion HCl, ER (12 HR)	Budeprion SR	100,150	BID	X	MDD, SAD
Bupropion HCl, ER	Budeprion XL	100, 150, 200	QD	X	MDD, SAD
Bupropion HCl	Wellbutrin	75, 100	BID - TID	X	MDD, SAD
Bupropion HCl, ER (12 HR)	Wellbutrin SR	100, 150, 200	BID	X	MDD, SAD
Bupropion HCl, ER (24 HR)	Wellbutrin XL	150, 300	QD	X	MDD, SAD
Bupropion HCl, ER	Zyban Buproban	150	BID		Smoking cessation
Bupropion HCl, ER	Forfivo XL	450	QD		MDD

MDD = major depressive disorder

SAD = seasonal affective disorder

Overall Clinical Conclusion



- Forfivo XL offers a one tablet once daily dosing schedule for patients requiring a high dose of bupropion
- Forfivo XL is therapeutically interchangeable with 3 tablets of bupropion 150mg extended-release
- Cannot initiate therapy or titrate doses with this formulation
- Cannot be dose-adjusted in renal or hepatic impairment
- Similar efficacy, safety and tolerability profile as other bupropion agents
- Food may increase drug absorption by 7 hours & AUC by 25%
- **Forfivo XL offers no clinically compelling advantages over existing UF bupropion agents**

Bupropion XL (Forfivo XL) Formulary Decision



- The DoD P&T Committee decided that Bupropion XL (Forfivo XL) be classified as **non-formulary** under the UF
- Implementation: August 6, 2014

Desvenlafaxine extended release (Khedeza)

Levomilnacipran (Fetzima)

Vortioxetine (Brintellix)

Dosing & Pharmacology



Generic Name	Brand Name	Indication	Strengths	Dosing	MOA	Approval Type
Desvenlafaxine ER	Khedeza	MDD	50 & 100 mg ER tabs	50mg QD	SNRI	505(b)2
Levomilnacipran	Fetzima	MDD	20, 40, 80, 120 mg ER caps	40 - 120mg QD	SNRI	New Drug Application
Vortioxetine	Brintellix	MDD	5, 10, 15, 20 mg tabs	10 mg QD	SSRI, 5HT3 antagonist, 5HT1A agonist	New Drug application

Overall Clinical Conclusion



- Khedezla is a SNRI that is an ER form of desvenlafaxine (Pristiq) indicated for the treatment of major depressive disorder (MDD)
 - Khedezla has shown bioequivalence to Pristiq in three studies
 - Generic desvenlafaxine is now available
- Levomilnacipran (Fetzima) is an extended-release stereoisomer of milnacipran (Savella). Fetzima is indicated for MDD whereas Savella is indicated for fibromyalgia
 - No head to head studies exists of levomilnacipran with other antidepressants
 - All doses produced a statistically significant change from baseline in MADRS score compared to placebo. In one study, the response rate was only statistically significant at the 120mg dose
 - Response rate was significant (90%) in one flex-dose study where all doses were pooled compared to placebo (63%)
 - There was no difference from placebo in remission rate at any dose

Overall Clinical Conclusion



- Vortioxetine (Brintellix) is a new antidepressant with serotonergic effects indicated for the treatment of MDD
- There have been no head to head studies between vortioxetine and other antidepressants
- In 4 of 7 placebo controlled studies, vortioxetine was superior to placebo in improving MADRS or HAM-D scores from baseline
- In active comparator studies using duloxetine or venlafaxine, vortioxetine showed similar clinical results in the endpoints of MADRS, HAM-D, response, or remission
- Vortioxetine has fewer known ADRs and warnings compared to desvenlafaxine and levomilnacipran, although this antidepressant is the newest to market and presence of additional ADRs may increase during post-marketing surveillance
- Although vortioxetine offers additional serotonergic effects in its mechanism of action and has fewer ADRs overall, this has not translated into greater efficacy in treating depression
- Khedezla, Fetzima, and Brintellix offer no clinically compelling advantages over existing UF agents

Formulary Decision



- The DoD P&T Committee concluded:
 - Khedezla be classified as **NF** behind the step
 - Must try venlafaxine first
 - Fetzima be classified as **NF** behind the step
 - Must try at least one of the following first:
SSRIs, duloxetine, SNRIs (except milnacipran), TCAs, mirtazapine, bupropion, SARIs, MAOIs
 - Brintellix be classified as **NF** behind the step
 - Must try at least one of the following first:
SSRIs, duloxetine, SNRIs (except milnacipran), TCAs, mirtazapine, bupropion, SARIs, MAOIs.

Re-Evaluation of NF Agent: Duloxetine (Cymbalta)

Duloxetine (Cymbalta) Background



■ Nov 2011

- Drugs for Depression/Non-Opioid Pain reviewed
- Cymbalta continued as NF
- Step therapy implemented; must try another generic antidepressant drug 1st before using Cymbalta

■ Dec 2013 – Duloxetine generics approved with no company having exclusivity; 10 companies making duloxetine, price has decreased

- Cymbalta still non-formulary
- PEC Branch will continue to monitor price; as soon as cost-effective, will designate formulary and remove step therapy requirements; field will be notified

Utilization Management

Utilization Management: Prior Authorizations



■ Overactive Bladder Medications

- ❑ Mirabegron (Myrbetriq) requires a trial of a generic OAB drug or Detrol LA
 - Implemented on June 11

■ Phosphodiesterase-5 (PDE-5 Inhibitor)

- ❑ Avanafil (Stendra) requires a trial of Viagra
 - Same Prior Authorization criteria as Viagra and the other PDE-5s

Utilization Management: Quantity Limits



■ Hepatitis C Drugs

- Sofosbuvir (Sovaldi) limited to 28 tablets a fill at all POS

■ Phosphodiesterase-5 (PDE-5 Inhibitor)

- Avanafil (Stendra) limited to 6 tabs in 30 days or 18 tablets in 90 days

May 2014 P&T Committee Meeting



■ UF Class reviews

- Nasal Allergy Drugs
- Inhaled Corticosteroids
- Osteoporosis - bisphosphonates

■ New drugs

- Oral DM drugs, SGLT-2 inhibitors GLP1-RAs: dapagliflozin (Farxiga)
- Hep C drugs: sofosbuvir (Sovaldi)
- Anticoagulants: apixaban (Eliquis)
- GI-1, steroids: budesonide ER caps (UCeris)
- LABA: indacaterol (Arcapta)
- OAB: mirabegron (Mybetriq)
- NSAID: low dose diclofenac (Zorvolex)

Upcoming P&T Committee Meetings



■ August 2014

UF Class reviews

- Multiple Sclerosis Agents – oral and injectables
- Targeted Immunomodulatory Biologics – oral and injectables

New drugs

- GLP1-RAs: albiglutide (Tanzeum)
- ADHD: methylphenidate ER suspension (Quillivant XR)

■ November 2014

UF Class reviews

- Oncological Agents
- Pulmonary Arterial Hypertension Agents

55 New drugs - To be determined

Miscellaneous items



Next webcast will be held on September 11th 2014 at 0900
& 1700 EST

Pharmacy Operations Div. webcast coming soon. Watch
for information.

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!

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Thank you!