

P&T Webcast 13 March 2014



- 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

- Contracting Corner
- Protest Update: Test Strips
- Review of Nov 2013 P&T Committee Meeting
 - UF Class Reviews
 - New Drugs in Previously Reviews Class
 - Utilization Management
- Overview of Feb 2014 P&T Committee Meeting
- Quick Look at May 2014 P&T Committee Meeting
- Questions

Contracting Corner

- DLA Troop Support provides baseline utilization to Prime vendors for all newly awarded National Contracts
 - Prior 12 month purchase history
 - Ex: 12 bottles/12 months = 1 bottle per month
 - (Caveat: If you bought all 12 bottles in the last month, still calculated at 1 bottle per month)
- Usage changes need to be communicated with your local Distribution Center

National Contract Product Shortages



DRUG	MFR	STRENGTH	EST. GET WELL DATE	ALTERNATE PRODUCT CONSIDERATIONS
Atorvastatin*	Ranbaxy	10mg, 20mg, 40mg, & 80mg	Unknown; Pending FDA manufacturing investigation	10mg: 59762-0155-01, 42291-0143-90, 60429-0323-90 20mg: 59762-0156-01, 42291-0144-90, 60429-0324-90 40mg: 59762-0157-01, 42291-0145-90, 60429-0325-90 80mg: 59762-0158-01, 42291-0146-90, 60429-0326-90
Donepezil **	Ranbaxy	5mg & 10mg	Unknown; Pending FDA manufacturing investigation	5mg: 59762-0245-04 10mg: 59762-0246-04
Famotidine**	Mylan	20mg & 40mg	Mar-14	20mg: 00904-5780-51 40mg: Multiple Items on RDAPA
Meloxicam **	Mylan	7.5mg & 15mg	May-14	7.5mg: 4306-30452-90, 50268-0525-15 15mg: 5528-90376-90, 50268-0526-15
Bumetanide*	Sandoz	0.5mg, 1mg, & 2mg	Unknown	Nationwide shortage http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1073 Consider therapeutic alternatives
*Reimbursement form available—Contact CPOC@dla.mil				

Reimbursement Timelines



Famotidine 20mg
NDC: 0378-3020-01 10/18/13 – TBD

Famotidine 40mg
NDC: 0378-3040-01 10/25/13 – TBD

Meloxicam 7.5mg
NDC: 0378-1066-01 11/27/13 – TBD
NDC: 0378-1066-05 10/22/13 – TBD

Meloxicam 15mg
NDC: 0378-1089-01 1/31/14 – TBD
NDC: 0378-1089-05 12/16/13 – TBD

Donepezil
All Ranbaxy NDCs Jan 2014 - 6/14/14

Atorvastatin
All Ranbaxy NDC's Jan 2014 – 4/30/214

Bumetanide
NDC: 00185-0128-01 Feb 2014 – TBD
NDC: 00185-0129-01 Feb 2014 – TBD
NDC: 00185-0130-01 Feb 2014 – TBD

For questions, email DLA at CPOC@dla.mil



<https://www.medical.dla.mil/Portal/Pharmaceutical/CPOC.aspx>

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

SMBG Test Strips Background



- SMBG test strips
 - FDA classifies as a medical device
 - Part of TRICARE pharmacy benefit
 - Available from MTFs, Mail Order, Retail Network
- SMBG meters
 - FDA classifies as a medical device
 - Not part of TRICARE pharmacy benefit
 - Available from MTFs and Retail
- Formulary decision required for SMBG test strips
 - Mfg will supply 1 no-cost meter to DoD beneficiaries
- Does not include following diabetic supplies
 - Lancets, lancet devices, syringes, insulin pumps or EtOH swabs

SMBGS Overall Clinical Conclusion



- The Committee concluded that any of the 10 final SMBGS test strip candidates were acceptable for inclusion on the UF. There are no clinically relevant differences between the 10 SMBGS test strips meeting the final technical and U.S. Federal Government contracting requirements set forth by the P&T Committee

Formulary Status – Test Strips



- FreeStyle Lite (Abbott) is BCF
- Precision Xtra (Abbott) is UF
- FreeStyle InsuLinx (Abbott) is UF
- All other test strips are NF and non-step preferred
- All current and future users require a trial of Abbott test strips
- Prior Authorization criteria applies
- Quantity Limits exist
 - 150 strips/30 day supply at Retail
 - 450 strips/90-day supply at Mail
- Justification: Cost-effectiveness

- DO NOT need to convert from Precision Xtra
- How to convert is a local decision
 - Clinic vs. pharmacy
- No BCF meter selected, but encouraged to use FreeStyle Freedom Lite meter as the “workhorse” meter
- Abbott support from local and national levels
 - Abbott Logistics support: 1-800-401-1183 and Press “2”
 - Carole Hamm, Sr. National Account Manager, Government
 - 858-776-5245 Carole.hamm@abbott.com
 - Tom Tveit, Senior Account Manager, Government
 - 949-244-7348 Tom.tveit@abbott.com

Review of Nov 2013 P&T Committee Meeting

Dave Meade, PharmD, BCPS

Nov 2013

DoD P&T Committee Meeting



- Uniform Formulary Class Reviews
 - Short Acting Beta Agonists (SABAs) Metered Dose Inhalers
 - Benign Prostatic Hyperplasia Agents - 5 Alpha Reductase Inhibitors
 - Anti-Lipidemic-1s (Interim Meeting)
- New Drugs in Previously Reviewed Class
 - DPP-4 Inhibitors
 - Alogliptin (Nesina); Alogliptin/Metformin (Kazano); Alogliptin/Pioglitazone (Oseni)
 - Bisphosphonates: Effervescent Alendronate (Binosto)
- Utilization Management
- Overview of Upcoming Meetings

Short Acting Beta Agonists

Overall Clinical Effectiveness Conclusion



■ Asthma

- In children, the evidence for comparative efficacy is mixed and inconclusive for albuterol vs. levalbuterol
- There are no studies comparing efficacy of albuterol vs. Xopenex MDIs

■ Exercise Induced Bronchospasm

- 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. There is insufficient evidence to compare the agents

Overall Clinical Effectiveness Conclusion



- Although there is a lack of comparative safety data between levalbuterol and albuterol MDIs, there is no evidence to suggest clinically relevant differences in safety between both stereoisomers
- Adverse events and drug interactions are similar across the SABAs
- In terms of other factors, there are some differences among the SABA HFA MDIs
 - Proventil and Xopenex do NOT have a dose counter
 - ProAir and Ventolin DO have a dose counter

■ Formulary Decision:

- ProAir HFA as BCF
- Ventolin HFA, Proventil HFA and Xopenex HFA agents NF

■ Justification:

- Agents are clinically highly interchangeable
- Availability of ProAir HFA will meet the clinical needs of DoD patients
- ProAir HFA is the most cost-effective SABA agent

Benign Prostatic Hyperplasia Agents

5 Alpha Reductase Inhibitors

- Both finasteride and dutasteride (Avodart):
 - Reduce symptoms of BPH compared to baseline/placebo
 - However, absolute difference compared to placebo is less than clinically noticeable
 - Effect dependent on baseline prostate volume
 - Delay progression of BPH
 - Reduce risk of prostate cancer
 - Absolute reduction greater with smaller baseline prostate volume/PSA
 - Not reduce 15-year mortality
 - Not cost effective for unselected population of men with BPH
 - May prevent development of BPH in asymptomatic men > 65 years

- In terms of efficacy, agents are highly interchangeable

Efficacy Conclusions Combination



- Paucity of new data
- Compared to monotherapy with A1B
 - Unselected: Addition of 5-ARI adds little to symptom improvement
 - Large baseline prostate: Addition of 5-ARI shows greater symptom improvement
 - However, absolute difference is less than that expected to be clinically noticeable
 - Delays disease progression
- Compared to monotherapy with 5-ARI
 - Addition of A1B shows greater symptom improvement than 5-ARI monotherapy
 - However, absolute difference is less than that expected to be clinically noticeable
 - Delays disease progression
- Duration of combination therapy unclear

Efficacy Conclusions Combination



- Most studies assess finasteride + A1B
 - Variety of A1Bs assessed
- Single study assess dutasteride (CombAT)
 - A1B tamsulosin

- As 5-ARI are highly interchangeable, it likely makes little difference which 5-ARI is used in combination with A1B

■ Formulary Decision:

- Finasteride is BCF (preferred)
- Avodart and Jalyn are NF and non-preferred
 - Avodart: Prior Authorization – must try generic finasteride 1st unless contraindicated or adverse events
 - Jalyn: Prior Authorization
 - ▷ Existing patients are grandfathered
 - ▷ New patients must try generic finasteride and need combination therapy; unless adverse events
- Justification: Agents are clinically highly interchangeable

Antilipidemic 1s

(Interim Meeting 17 Dec 2013)

- New guidelines from ACC/AHA released Nov 12 2013; interim meeting held Dec 19 2013
 - New Cost model
 - Survey to MTF/civilian providers re: new guidelines
- Major changes/ highlights of the new guidelines
 - Four patient groups where statins are recommended
 - Existing clinical atherosclerotic heart disease (ASCVD)
 - LDL \geq 190 mg/dL
 - T2DM pts age 40-75 without ASCVD and with LDL b/w 70-189 mg/dL
 - Patients age 40-75 with 10-year CV risk \geq 7.5% with LDL b/w 70-189 mg/dL
 - New CV risk tool replaces Framingham risk score
 - Controversial – potentially over-estimates risk

- Major changes/ highlights of the new guidelines
 - ❑ Only trials with clinical outcomes showing reduced risk of ASCVD evaluated
 - ❑ No more treating to target based on LDL; % LDL reduction from baseline used
 - ❑ No more titrating dose based on LDL; check fasting lipid panels to assess adherence
 - ❑ No difference b/w primary and secondary prevention
 - ❑ Non-statin therapies (ezetimibe, niacin, fenofibrates, bile acid salts) not recommended due to lack of evidence to reduce CV risk or risk of AEs
 - Use non-statin if AEs with statins; less than anticipated responses; statin tolerability issues; or those with drug interactions
 - ❑ Statins divided into 3 groups, based on LDL lowering.
- P&T Committee recognized controversy with the new guidelines, but also recognized they are endorsed by ACC/AHA.

Antilipidemics-1 – Statins and intensity



High intensity	Moderate Intensity	Low Intensity
↓ LDL by ~ ≥50%	↓ LDL by ~ 30% to <50%;	↓ LDL by <30%
Atorvastatin (40†) 80 mg Rosuvastatin 20 (40) mg	Atorvastatin 10 (20) mg Rosuvastatin (5) 10 mg Simvastatin 20-40 mg†† Pravastatin 40 (80) mg Lovastatin 40 mg Fluvastatin XL 80 mg Fluvastatin 40 mg BID Pitavastatin 2-4 mg	Simvastatin 10 mg Pravastatin 10–20 mg Lovastatin 20 mg Fluvastatin 20–40 mg Pitavastatin 1 mg

New guidelines don't give preference for one drug over another in the intensity groups

†: evidence from one RCT only (IDEAL) ; atorva 40 mg used if unable to tolerate atorva 80 mg

††: Although simvastatin 80 mg was evaluated in RCTs, not recommended by FDA due to risk of myopathy, including rhabdomyolysis

Antilipidemics-1

BCF	<ul style="list-style-type: none"> • Atorvastatin • Pravastatin • Simvastatin 10, 20, 40 mg • Niaspan (no change from previous)
UF	<p><u>Preferred</u></p> <ul style="list-style-type: none"> • Atorvastatin/amlodipine • Fluvastatin • Lovastatin • Simvastatin 80 mg <p><u>Non-preferred</u> (must try a generic at appropriate LDL intensity 1st)</p> <ul style="list-style-type: none"> • Rosuvastatin (Crestor) – reserve for patients meeting clinical criteria • Ezetimibe (no change from previous)
NF	<p><u>Non-preferred</u></p> <ul style="list-style-type: none"> • Simvastatin/ezetimibe (Vytorin) • Atorvastatin/ezetimibe (Liptruzet) • Pitavastatin (Livalo) • Fluvastatin ER (Lescol XL); lovastatin ER (Altoprev) • Simvastatin/niacin (Simcor); lovastatin/niacin (Advicor)



Antilipidemic-1s Utilization #Rxs



	Crestor	Vytorin	All other Non-preferred
MTF	18,037	34,695	221
Retail	50,849	20,443	9,163
Mail	46,117	14,801	7,688

☐ Justification for UF Recommendations

- Both clinical and cost effectiveness
- Non-statins no longer recommended in the guidelines
- Within the intensity lowering groups, no preference stated in the guidelines for one drug over another
- Inclusion of Crestor on the UF based on moving Rx's from Retail to the Mail Order and MTFs points of service

□ Vytorin

- Vytorin price now \$2.85 (10/20 mg dose)
- MTFs highly encouraged to switch patients currently on Vytorin to monotherapy with atorvastatin or simvastatin at appropriate intensity
- The pt may or may not need to continue additional ezetimibe
- Reserve Vytorin for patients who can't tolerate atorvastatin 40 mg and 80 mg
- Don't switch Vytorin patients to Crestor – can't have overall MHS Crestor use increase

Crestor

- Existing patients are grandfathered
- New Crestor 5/10 mg Rxs: Prior Authorization – must try generic simvastatin ≥ 20 mg , atorvastatin ≥ 10 mg and pravastatin ≥ 40 mg 1st, unless drug interaction or AEs
- New Crestor 20/40 mg Rxs: reserve for patients unable to tolerate atorvastatin ≥ 40 mg

Niaspan

- No change – remains BCF (not part of the solicitation)

Ezetimibe

- No change – remains UF, but non-preferred (not part of the solicitation)

New Drugs in Previously Reviewed Class

DPP-4 Inhibitors
Nesina (Alogliptin)
Kazano (Alogliptin/Metformin)
Oseni (Alogliptin/Pioglitazone)

Overall Clinical Conclusion

- Alogliptin is the 4th DPP-4 inhibitor and is indicated as adjunct to diet and exercise to improve glycemic control in T2DM
- Alogliptin is approved in fixed-dose combinations with metformin (Kazano) and pioglitazone (Oseni)
- All DPP-4 inhibitors exhibit similar A1c-lowering effects compared to the other DPP-4 inhibitors
- Dual therapy with alogliptin provided greater decreases in A1c from baseline in treatment naïve patients (1.22% to 1.71%) compared to previous therapy (0.39% to 0.6%)
- Triple therapy with alogliptin resulted in A1c changes from baseline ranging from 0.63% to 1.4%

Overall Clinical Conclusion



- Alogliptin, similar to the other DPP-4 inhibitors, is lipid and weight neutral and has minimal effects on blood pressure
- DPP-4 inhibitors, including alogliptin, are generally safe and well tolerated; most common SE include nasopharyngitis, HA, URTI
- Low hypoglycemia risk (1.5%) – concomitant use with a SU or insulin did not significantly increase the incidence
- Although Oseni is the first fixed dose combination with a TZD, it offers no additional clinical advantage; additionally the requirements for renal dosing and availability of 6 Oseni strengths limits use

- Alogliptin (Nesina, Kazano, Oseni) all designated NF and non preferred
 - ❑ Must try metformin or a sulfonylurea 1st unless AEs, inadequate response or contraindication
 - ❑ Sitagliptin products (Januvia, Janumet, Janumet XR) are the preferred DPP-4s
- Justification
 - ❑ Offered no clinical advantage over UF agents
 - ❑ Significantly higher cost than UF Agents

Alendronate Effervescent Tablet (Binosto)

Overall Clinical Conclusions



- Binosto is a new dosage form of alendronate approved for treatment of osteoporosis in men and postmenopausal women.
- Binosto effervescent tablet is bioequivalent to Fosamax 70mg oral tablet. There are no clinical trials with Binosto.
- Binosto requires the same dosing and administration concerns as the other bisphosphonates
- Although Binosto might be more convenient for patients by requiring less consumption of water (4 oz. vs. 8 oz.), there is not data that it is better tolerated or safer than other alendronate formulations.
- Compared with other alendronate formulations, Binosto offers no compelling clinical advantages over other alendronate formulations.

- Binosto was designated NF

- Justification
 - Offered no clinical advantage over UF agents
 - Significantly higher cost than UF Agents

Utilization Management

- Multiple Sclerosis Drugs – Dimethyl Fumarate (Tecfidera)
 - ❑ Prior Authorization reflects the package insert indications
 - ❑ Check CBC within 6 months prior to starting therapy due to risk of lymphopenia
 - ❑ Justification: high cost; other MS drugs have PA
- Targeted Immunomodulatory Biologics (TIBS)
 - ❑ Certolizumab (Cimzia) – new indications for ankylosing spondylitis and psoriatic arthritis
 - ❑ Tocilizumab (Actemra) – now SQ for self-injection for RA
 - ❑ Ustekinumab (Stelara) – new indication for psoriatic arthritis

- UF Class reviews
 - Inhaled Corticosteroids/Long Acting Beta Agonists
 - Gastrointestinal-1 Agents – mesalamine products
 - Pancreatic Enzyme Agents
- New drugs
 - Antidepressants
 - Bupropion 450 mg ER (Forfivo XL)
 - Vortioxetine (Brintellix)
 - Levomilnacipran (Fetzima)
 - Desvenlafaxine ER (Khedezla)

May 2014 Meeting

■ UF Class reviews

- Osteoporosis Agents – bisphosphonates subclass
- Nasal Allergy Agents – nasal corticosteroids and nasal antihistamines
- Inhaled Corticosteroids

■ New drugs

- OAB: mirabegron (Myrbetriq)
- Oral anticoagulants: apixaban (Eliquis)
- Hepatitis C: sofosbuvir (Sovaldi)
- Long-acting beta agonist: indacaterol (Arcapta inhaler)
- Non-insulin DM drug SGLT2 inhibitor: dapagliflozin (Farziga)
- GI-1 – steroids: budesonide (Uceris)
- Others: low dose diclofenac (Zorvolex) & methylphenidate ER suspension (Quillivant XR)

Miscellaneous items



Next webcast will be held on June 12th 2014 at 0900 & 1700 EST

Pharmacy Operations Div. webcast 26 Mar 14 1000-1200 Central

DCO URL: <https://connect.dco.dod.mil/r47624589/>

For T-CON:

For calls from CONUS - 1-800-619-7481

For International Calls - 1-312-470-7153

Participant Code: 2599122#

■ BCF review

- Looking for input from the MTFs
- Will look at input in addition to utilization data
- Send input to:

usarmy.jbsa.medcom-ameddcs.list.pecuf2@mail.mil

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-Branch Contact Info



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Pharmacy Operations Center

■ Email Addresses

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○ Website issues

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○ Questions, assistance with PDTS, Business Objects

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○ For other questions, formulary clarification, etc

Do not send patient level information to email addresses listed

Thank you!