

# P&T Webcast 12 Dec 2013



# DHA Vision

“A joint, integrated, premier system of health, supporting those who serve in the defense of our country.”





# Introduction

- Greetings from the PEB
- 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

- Contracting Corner
  
- Review of Aug 2013 P&T Committee Meeting
  - UF Class Reviews
  - BCF Issues
  - Utilization Management
  
- Overview of Nov 2013 P&T Committee Meeting
  
- Quick Look at February 2014 P&T Committee Meeting
  
- Questions



# **Contracting Corner**

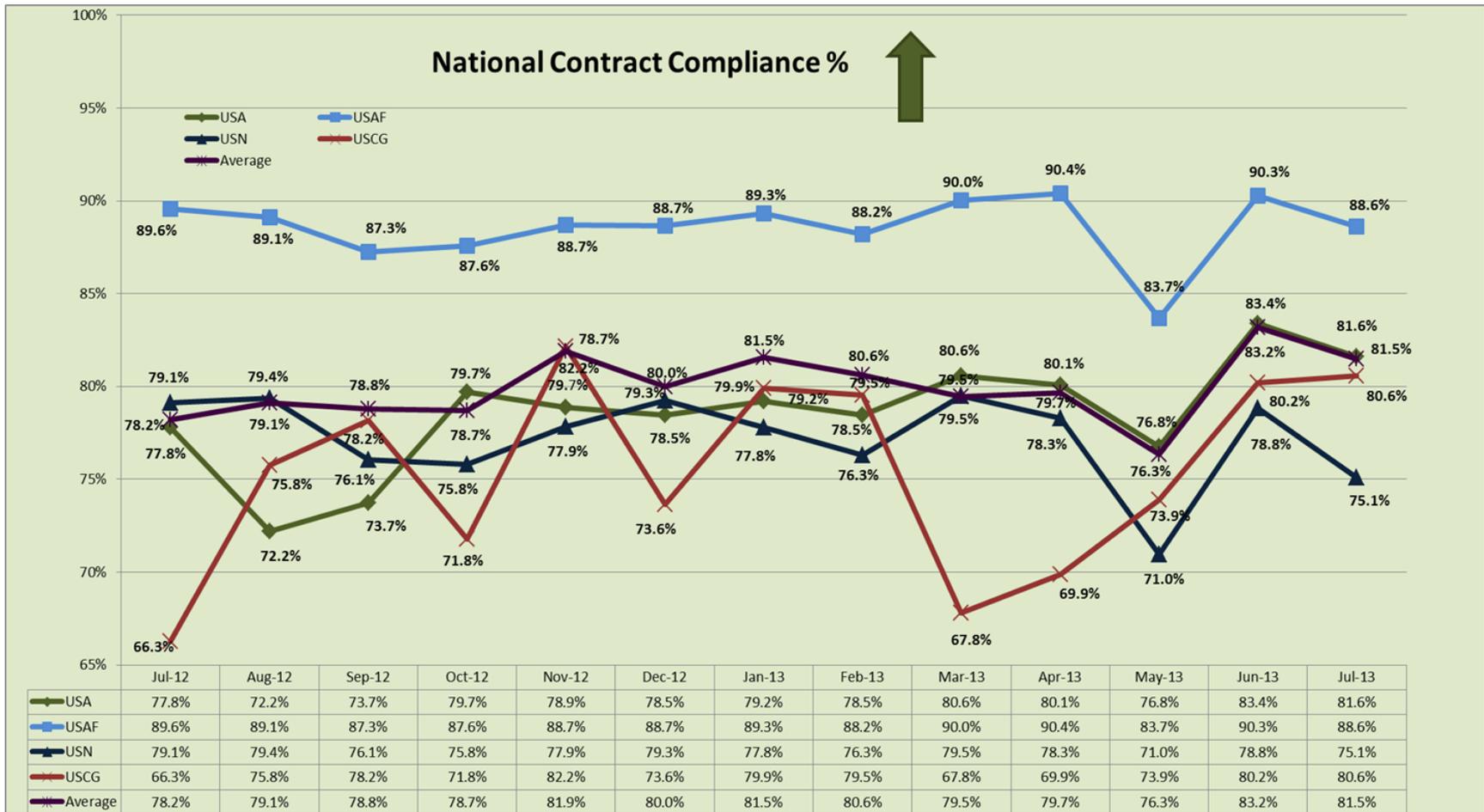
**Jeremy Briggs, PharmD, MBA**  
**Industry Liason**

# 5 Drugs to go Generic

- Adderall XR
- Levaquin
- Lotrel
- Lovenox
- Provigil



# National Contract Compliance Rate



## Quick Notes from DLA

- New Niaspan UF BPA
- Newly awarded joint national contract for escitalopram
- Joint national contracts should be awarded soon
  - Pioglitazone
  - Valacyclovir
- DLA working on 8 more national contracts
  - Should see more joint contracts in the next 2-3 months
- Gold Coast Pen Needles
  - Potential cost savings



# **Review of Aug 2013 P&T Committee Meeting**

**Dave Meade, PharmD, BCPS  
Clinops Director**

# Aug 2013

## DoD P&T Committee Meeting



- **Uniform Formulary Class Reviews**
  - Corticosteroid Immune Modulators (Topical Steroids)
  - Self-Monitoring Blood Glucose System (SMBGS) Test Strips
  
- **Utilization Management**
  
- **BCF Update**
  - Emergency Contraceptives



# Topical Steroid Agents

# Drugs in the Topical Steroid Class: High Potency



High Potency (Class 1, 2 Steroids)			
Generic Name	Strength/Formulation	Availability	Patent Expiration
Amcinonide	0.1% Ointment	Brand: none Generic: multisource	--
Betamethasone Dipropionate (augmented base)	0.05% Cream, Ointment, Lotion, Gel	Brand: none Generic: multisource	--
Clobetasol Propionate	0.05% Cream	Brand: Temovate, Temovate E Generic: Cormax, Embeline E, multisource	--
	0.05% Ointment, Gel, Solution	Brand: Temovate Generic: Embeline, multisource	
	0.05% Lotion, Shampoo	Brand: Clobex Generic: multisource	
	0.05% Foam	Brand: Olux, Olux E Generic: One single source for each	
	0.05% Shampoo	Brand: Temovate Generic: Embeline, multisource	
	0.05% Spray	Brand: Clobex Generic: single source	
	Desoximetasone	0.25% Cream	Brand: none Generic: Topicort, multisource
0.05% Ointment		Brand: Topicort Generic: NO	
0.25% Ointment, 0.05% Gel		Brand: none Generic: Topicort, single source	
0.25% Spray		Brand: Topicort Generic: NO	
Diflorasone Diacetate	0.05% Cream, Ointment	Brand: none Generic: two sources for each	
Fluocinonide	0.1% Cream	Brand: Vanos Generic: 4 Tentative Approvals	
	0.05% Cream	Brand: No Brand Name, but NDA Generic: multisource	
	0.05% Ointment, Gel, Solution	Brand: none Generic: multisource for each	
Flurandrenolide	0.004 mg/cm <sup>2</sup> Tape	Brand: Cordran Generic: NO	
Halobetasol Propionate	0.05% Cream, Ointment	Brand: Ultravate Generic: multisource for each	
Halcinonide	0.1% Cream, Ointment	Brand: Halog Generic: NO for either vehicle	

# Drugs in the Class: Medium Potency



Medium Potency			
(Class 3, 4, 5 Steroids)			
Generic Name	Strength/Formulation	Availability	Patent Expiration
Amcinonide	0.1% Cream, Lotion	Brand: none	--
		Generic: multisource	
Betamethasone Dipropionate (non-augmented base)	0.05% Cream, Ointment	Brand: No Brand Name, but NDAs	--
		Generic: multisource	
	0.05% Lotion	Brand: none	--
		Generic: multisource	
Betamethasone Valerate	0.1% Cream	Brand: Beta-Val, betamethasone valerate	--
		Generic: Dermabet, Valnac, multisource	
	0.1% Ointment	Brand: No Brand Name, but NDAs	--
		Generic: multisource	
	0.1% Lotion	Brand: No Brand Name, but NDAs	--
		Generic: Beta-Val, multisource	
	0.12% Foam	Brand: Luxiq	Mar 2016 - May 2017
		Generic: single source	
Clocortolone Pivalate	0.1% Cream	Brand: Cloderm	--
		Generic: NO	
Desonide	0.05% Ointment	Brand: No Brand Name, but NDA	--
		Generic: Desowen, multisource	
Desoximetasone	0.05% Cream	Brand: none	--
		Generic: Topicort	
Fluocinolone Acetonide	0.025% Cream, Ointment	Brand: Synalar	--
		Generic: multisource	



# Drugs in the Class: Medium Potency (cont)



Defense Health Agency

Medium Potency (Class 3, 4, 5 Steroids)			
Generic Name	Strength/Formulation	Availability	Patent Expiration
Flurandrenolide	0.05% Cream, Lotion	Brand: Cordran SP, Cordran Generic: NO	--
	0.025% Cream	Brand: Cordran SP Generic: NO	--
Fluticasone Propionate	0.05% Cream, Lotion	Brand: Cutivate Generic: multisource	Lotion: Oct 2019
	0.005% Ointment	Brand: Cutivate Generic: multisource	--
Hydrocortisone Butyrate	0.1% Cream	Brand: Locoid, Locoid Lipocream Generic: single source	Lipocream: Jun 2014
	0.1% Ointment, Solution	Brand: Locoid Generic: single source	--
	0.1% Lotion	Brand: Locoid Generic: NO	Jan 2025 - Dec 2026
Hydrocortisone Probutate	0.1% Cream	Brand: Pandel Generic: NO	--
Hydrocortisone Valerate	0.2% Cream	Brand: none Generic: multisource	--
	0.2% Ointment	Brand: none Generic: single source	--
Mometasone Furoate	0.1% Cream, Ointment, Lo	Brand: Elocon Generic: multisource	--
Prednicarbate	0.1% Cream	Brand: Dermatop E Generic: single source	--
	0.1% Ointment	Brand: Dermatop Generic: single source	--
Triamcinolone Acetonide	0.147mg/g Spray	Brand: Kenalog Generic: NO	--
	0.5% Cream	Brand: none Generic: multisource	--
	0.1% Cream	Brand: none Generic: Triderm, multisource	--
	0.025% Cream	Brand: none Generic: multisource	--
	0.5%, 0.1%, 0.025% Ointm	Brand: none Generic: multisource	--
	0.1%, 0.025% Lotion	Brand: none Generic: multisource	--



# Drugs in the Topical Steroid Class: Low Potency



**Low Potency** Defense Health Agency

(Class 6, 7 Steroids)

Generic Name	Strength/Formulation	Availability	Patent Expiration
Alclometasone Dipropionate	0.05% Cream, Ointment	Brand: Aclovate	--
		Generic: multisource for each	
Desonide	0.05% Cream	Brand: Desowen	--
		Generic: single source	
	0.05% Lotion	Brand: none	--
		Generic: Desowen, single source	
	0.05% Gel	Brand: Desonate	Aug 2020
0.05% Foam	Brand: Verdeso	Sep 2019	
Fluocinolone Acetonide	0.01% Shampoo	Brand: Capex	--
		Generic: NO	
	0.01% Solution	Brand: Synalar	--
		Generic: multisource	
	0.01% Oil	Brand: Dermasmooth FS (2 ND)	--
0.01% Cream	Brand: Synalar	--	
Hydrocortisone	2.5% Solution	Brand: none	--
		Generic: Texacort	
	2.5% Lotion	Brand: none	--
		Generic: Nutracort, Stie-Cort, multisource	
	2.5% Cream	Brand: none	--
		Generic: Micort-HC, Synacort, multisource	
	2.5% Ointment	Brand: none	--
		Generic: multisource	
	2% Lotion	Brand: none	--
		Generic: Ala-Scalp	
	2% Cream	Brand: none	--
		Generic: Micort-HC	
	1% Cream	Brand: none	--
		Generic: Ala-cort, Synacort, multisource	
	1% Lotion	Brand: none	--
Generic: Ala-Cort, Nutracort			
1% Ointment	Brand: none	--	
	Generic: multisource		

# Clinical Conclusion



All agents:

- All agents are FDA approved
  - There is very limited generalizable data
  - Heterogeneity of the data precludes direct and indirect comparisons
- A “hair friendly” product from each class is desirable

# Clinical Conclusion



## High Potency:

- None of high potency agents offer unique advantages in terms of efficacy or safety over other agents in the High Potency subclass
  - ❑ Clobetasol is offered in more vehicles; is more extensively studied and cited
  - ❑ Fluocinonide was frequently advocated in our provider survey
  - ❑ Flurandrenolide tape has several relatively unique therapeutic uses
  - ❑ Desoximetasone is a High Potency Coopman Class C agent
  - ❑ Clobetasol, halobetasol, augmented betamethasone dipropionate, and fluocinonide 1% cream products have package-labeled weekly exposure limits

# Clinical Conclusion



## Mid Potency:

- Triamcinolone is offered in more vehicles; is more extensively studied; and was more frequently advocated in provider survey than other Mid Potency agents. It has modest risk of skin atrophy.
  - Kenalog Spray is the only spray product in the Mid Potency sub-class
  - The Pediderm TA combination product of triamcinolone and an emollient base and there is no compelling evidence that it provides a clinical advantage
- Clocortolone and desoximetasone are Coopman Class C agents. There is weak evidence that clocortolone may have less risk of HPA axis suppression than other agents in the Mid-Potency sub-class.
- Hydrocortisone butyrate and fluticasone propionate are the only Mid-Potency agents labeled down to 3 months of age
- Fluticasone propionate, mometasone, and prednicarbate have the most favorable Therapeutic Indices among the Mid Potency sub-class agents
- Desonide ointment and lotion, betamethasone valerate, and hydrocortisone valerate were frequently advocated in our provider survey

# Clinical Conclusion



## Low Potency:

- None of the agents in this sub-class have evidence to support clinically meaningful differences in efficacy or safety over other agents in the sub-class.
- Hydrocortisone was more frequently advocated in our provider survey than the other Low Potency agents.
  - The PEDIADERM HC combination product of hydrocortisone and an emollient base and there is no compelling evidence that it provides a clinical advantage
- Dermasmoothe FS, a fluocinolone acetonide shampoo product, has the theoretical risk of inducing a peanut allergy.
- Desonate Gel, Verdeso Foam, and Capex Shampoo products all remain uniquely branded. There is no evidence to suggest a clinical advantage in terms of efficacy or safety for any of these products over other Low Potency sub-class agents.

# Clinical Conclusion



- Issues of safety are considered class effects. No particular agent, within a potency sub-class, demonstrates compelling advantage or disadvantage in safety compared to the other members of the sub-class.
  - ❑ Systemic absorption is likely with High Potency agents, but is possible with Mid- and Low Potency agents, as well. Variables that may influence systemic absorption are: occlusive dressing, body surface area involved, duration of therapy, use in children (and possibly geriatric populations), and application over non-intact integument.
  - ❑ Local effects are uncommon, tend to be mild-to-moderate, and do not differ substantially between agents within each sub-class. Atrophic scarring, hypopigmentation, and many telangiectasias are not reversible. Burning and stinging, pruritis, pain, irritation are common and tend to vary directly with the potency of the agent and vehicle,
  - ❑ Allergies to topical steroids may present as failure-to-heal rather than exacerbation of the target lesion. The Coopman Classification system is useful for predicting which agents will cross-react. Cross-reactivity is high within Coopman Classes and between Classes, particularly between A and D<sub>1</sub>, but not with Class C.
  - ❑ For use in children, use of higher potency agents over a shorter duration may mitigate systemic adverse events seen with lower potency agents used over a longer duration.
  - ❑ All Spray and (Aerosol) Foam products are flammable.

# Topical Steroid Agents – High Potency Formulary Status



Drug	Strength	Forms	Recommendation
Betamethasone	0.05%	Cream, Oint, Gel, Lotn	UF
Clobetasol	0.05%	Cream, Oint, Soln, Foam, Gel, Shampoo, Lotn, Spray	UF
Desoximetasone	0.05%, 0.25%	Cream, Oint, Gel, Spray	UF
Fluocinonide	0.05%	Cream, Oint, Soln, Gel	UF
Flurandrenolide	4mcg/cm <sup>2</sup>	Tape	UF
Halobetasol	0.05%	Cream, Oint, Lotion	UF
Amcinonide	0.1%	Oint	NF
Diflorasone	0.05%	Cream, Oint	NF
Fluocinonide	0.1%	Cream	NF
Halcinonide	0.1%	Cream, Oint	NF

# Topical Steroid Agents – Medium Potency Formulary Status



Drug	Strength	Forms	Recommendation
Betamethasone Dipro	0.05%	Cream, Lotion	<b>UF</b>
Betamethasone Val	0.05%	Cream, Oint, Lotn	<b>UF</b>
Fluticasone	0.01%, 0.05%	Cream, Oint, Lotn	<b>UF</b>
Hydrocortisone Butyrate	0.1%	Oint, Soln	<b>UF</b>
Hydrocortisone Val	0.2%	Cream, Oint	<b>UF</b>
Mometasone	0.1%	Cream, Oint, Soln	<b>UF</b>
Prednicarbate	0.1%	Cream, Oint	<b>UF</b>
Triamcinolone	0.025%, 0.5%, 0.1%, 0.5%	Cream, Oint, Lotn	<b>UF</b>
Triamcinolone Spray	0.015%	Spray	<b>UF</b>
Desoximetasone	0.05%	Cream	<b>UF</b>
Fluocinolone	0.025%	Cream, Oint	<b>UF</b>
Amcinonide	0.1%	Cream, Lotion	<b>NF</b>
Betamethasone Val	0.12%	Foam	<b>NF</b>
Desonide	0.05%	Lotion	<b>NF</b>
Clocortolone	0.1%	Cream	<b>NF</b>
HC Probutate	0.1%	Cream	<b>NF</b>
Hydrocortisone Butyrate	0.1%	Cream, Lotion	<b>NF</b>
Triamcinolone w/Emoll	0.1%	Cream Kit	<b>NF</b>

# Topical Steroid Agents – Low Potency Formulary Status



Drug	Strength	Forms	Recommendation
Hydrocortisone	1%, 2%	Cream, Oint, Lotn	<b>UF</b>
Alclometasone	0.05%	Cream, Oint	<b>UF</b>
Fluocinolone oil	0.01%	Oil	<b>UF</b>
Fluocinolone w/shower cap	0.01%	Oil	<b>UF</b>
Desonide	0.05%	Cream, Oint	<b>UF</b>
Fluocinolone	0.01%	Cream, Soln	<b>NF</b>
Desonide	0.05%	Foam	<b>NF</b>
Fluocinolone	0.01%	Shampoo	<b>NF</b>
Hydrocortisone w/Emoll #45	2%	Kit Lotion	<b>NF</b>
Desonide	0.05%	Gel	<b>NF</b>

# Topical Steroid Agents

## BCF Status



### ■ Remaining BCF:

- fluocinonide 0.05% cream
- triamcinolone 0.1% cream on the BCF and

### ■ Added to the BCF:

- clobetasol 0.05% cream and ointment
- fluocinonide 0.05% ointment
- triamcinolone 0.1% ointment

Clobetasol	0.05%	Cream and Ointment	High Potency
Fluocinonide	0.05%	Cream and Ointment	High Potency
Triamcinolone	0.1%	Cream and Ointment	Medium Potency



# 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

# Current Formulary Status

SMBGs Test Strips	
BCF	<ul style="list-style-type: none"> <li>Precision Xtra (Precision Xtra meter)</li> </ul>
UF	<ul style="list-style-type: none"> <li>Accu-chek Aviva (Aviva meter)</li> <li>Contour (Ascensia Contour meter)</li> <li>Freestyle Lite (Freestyle Lite &amp; Freestyle Freedom Lite meters)</li> <li>True Test (True Result &amp; True 2 Go meters) - Aug 2009</li> <li>Glucocard 01 (Glucocard 01, Mini) &amp; Glucocard Vital (Vital) – Feb 2011</li> <li>Embrace (Embrace meter) – Feb 2011</li> </ul>
NF*	<ul style="list-style-type: none"> <li>One Touch Ultra (One Touch Ultra 2, Mini &amp; One Touch Ultra Smart)</li> <li>True Track (True Track meter)</li> <li>Compact Plus (Accu-chek Compact Plus meter)</li> <li>Comfort Curve (Accu-chek Advantage meter)</li> <li>Nova Max (Nova Max Plus and Nova Max Link) - Feb 2011</li> </ul>

\***Aug 2008:** Accu-chek Simplicity, Ascensia Autodisk, Ascensia Breeze 2, Ascensia Elite, Assure, Assure 3, Assure II, Assure Pro, BD Test Strips, Chemstrip Bg, Control AST, Dextrostix Reagent, Easygluco, Easypro, Fast Take, Freestyle test strips (other than Freestyle Lite), Glucofilm, Glucolab, Glucometer Dex, Glucometer Elite, Glucose Test Strip, Glucostix, Optium, Precision PCX, Precision PCX Plus, Precision Q-I-D, Precision Sof-Tact, Prestige Smart System, Prodigy, Quicktek, Sidekick, Sof-Tact, Surestep, Surestep Pro, Test Strip, Relion Ultima, Uni-Check **Feb 2011:** Advocate Redi-code, Blood Sugar Diagnostic, EasyMax, EZ Smart Plus, Fifty50, Liberty, Microdot, Rightest GS100, Rightest GS300, Ultratrak Ultimate, Wavesense Jazz, and Wavesense Presto

# SMBGS Testing Strips Methods



- Mechanism required to streamline UF/BCF candidates
  - Eliminate products failing to meet minimally required specifications
  - All UF/BCF candidates require free meter supplied with strips
  - Strips not making the cuts will be non-formulary
- 1<sup>st</sup> Cut
  - Products with <100 Rxs dispensed in MHS over past 3 years
    - Not all marketed test strips are dispensed in MHS; 99% MHS market share by 5 mfgs
  - Other reasons:
    - Strip D/C'd by mfg
    - Strip upgraded/transitioned to newer version
    - Mfg chose not to offer strip to DoD
- 2<sup>nd</sup> Cut
  - Test strips available at 3 points of service (POS)
  - Eliminates private label brands (e.g., Walgreens, Rite Aid, etc)
- 3<sup>rd</sup> Cut
  - Trade Agreement Act
  - BG strips and meters mfg in USA or TAA-compliant country
- 4<sup>th</sup> Cut
  - Products meeting minimum technical criteria approved at May 2007 P&T Committee meeting, or any new proposed criteria

In addition, surveyed MTFs and MCSC with over 400 responses

# 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

# SMBGS Overall Cost Effectiveness Conclusion



- Abbott test strips (FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra) determined to be the most cost-effective SMBGS products
- Followed by
  - Arkray (GLUCOCARD 01-Sensor, GLUCOCARD Vital)
  - Bayer (CONTOUR NEXT)
  - Nipro (TRUEtest)
  - Roche (ACCU-CHEK Aviva Plus)
  - Prodigy (Prodigy No Coding)
  - Nova (Nova Max) Products

# Formulary Status

- 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
- Formulary decision is being contested



# Utilization Management

# Prior Authorization



- Injectable Corticotropin (HP Acthar Gel) limited to infantile spasms (West Syndrome) for patients < 24 months old
  - Additional uses for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout, and protein-wasting nephropathies may be permitted on appeal
  - Other conditions considered unsupportable and are not covered

# Prior Authorization



- Doxylamine/Pyridoxine (Diclegis)
  - ❑ Contains 10 mg of doxylamine & 10 mg of pyridoxine
  - ❑ FDA approved for treating pregnant women experiencing nausea and vomiting (N/V)
  - ❑ All new users are required to try a nonpharmacologic method for management of N/V during pregnancy AND OTC pyridoxine before receiving Diclegis

# Prior Authorization



## Targeted Immunomodulatory Biologics:

- Ustekinumab (Stelara) indicated for plaque psoriasis
  - PA and quantity limits apply
  
- Golimumab (Simponi)
  - updated PA criteria for new indication of ulcerative colitis
  - also has quantity limits

# Quantity Limits

- SMBG Test Strips
- Ustekinumab (Stelara)
- Golimumab (Simponi)
- Dabrafenib (Tafinlar) - Oral chemotherapy drug
- Trametinib (Mekinist) - Oral chemotherapy drug
- Afatinib (Glotrif) - Oral chemotherapy drug

# Change to May Minutes/BCF



- The Director's decision was that due to over-the-counter availability of levonorgestrel 1.5 mg (Plan B One-Step) without age restrictions, no emergency contraceptives shall be included on the Basic Core Formulary. However, MTFs shall carry Plan B One-Step and provide it at no cost.

# November 2013 Meeting



## ■ UF Class reviews

- Short Acting Beta Agonist Inhalers (SABAs)
- Lip-1 HMGs (guidelines changed day before meeting)
- 5 Alpha Reductase Inhibitors

## ■ New drugs

- Nesina (alogliptin)
- Kazano (alopgliptin/metformin)
- Oseni (alogliptin/pioglitazone)
- Binostro (alendronate effervescent tabs)

# February 2014 Meeting



## ■ UF Class reviews

- Inhaled Corticosteroids/Long Acting Beta Agonists
- Gastro-Intestinal-1 Agents
- Pancreatic Enzymes

## ■ New drugs

- Myrbetriq (Mirabegron)
- Bupropion (Forfivo XL)
- Vortioxetine (Brintellix)
- Levomilnacipran (Fetzima)
- Desvenlafaxine ER (Khedezla)



## Miscellaneous items

### ■ PEC website

- Email questions to [usarmy.jbsa.medcom-ameddcs.mbx.pecweb@mail.mil](mailto:usarmy.jbsa.medcom-ameddcs.mbx.pecweb@mail.mil)

- For other questions, formulary clarification, etc

[usarmy.jbsa.medcom-ameddcs.list.pecuf2@mail.mil](mailto:usarmy.jbsa.medcom-ameddcs.list.pecuf2@mail.mil)

- ### ■ Next webcast will be held on March 13<sup>th</sup> 2014 at 0900 and 1700 EST

# 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!

# PEB Contact Info



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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