Beneficiary Advisory Panel Handout Uniform Formulary Decisions 26 Mar 2009

PURPOSE: The purpose of this handout is to provide BAP Committee members with a reference document for the relative clinical effectiveness presentations for each Uniform Formulary (UF) Class review.

Table 1: Uniform Formulary Recommendations from the February 2009 DoD P&TCommittee Meeting: Inhaled Corticosteroids (ICS), Long-Acting Beta Agonists, (LABAs),and Inhaled Corticosteroids/Long-Acting Beta Agonists Combinations (ICS/LABAs)

UF Status / Implementation Period	Brand Name (Generic)							
	Inhaled Corticosteroids (ICS)							
	Asmanex (mometasone dry powder inhaler)							
Formulary	Pulmicort Respules, generic (budesonide inhalation solution)							
T Officially	Flovent HFA (fluticasone metered-dose inhaler)							
	Flovent Diskus (fluticasone dry powder inhaler)							
	Aerobid (flunisolide metered-dose inhaler)*							
	Aerobid M (flunisolide with menthol metered-dose inhaler)*							
Non-Formulary	Alvesco (ciclesonide metered-dose inhaler)							
Non-i ormalary	Azmacort (triamcinolone metered-dose inhaler)*							
	Pulmicort Flexhaler (budesonide dry powder inhaler)							
	QVAR (beclomethasone metered-dose inhaler)							
Recommended implementation period	120 days							
	Long-Acting Beta Agonists (LABA)							
	Serevent (salmeterol dry powder inhaler)							
Formulary	Foradil (formoterol dry poweder inhaler)							
	Brovana (arformoterol inhalation solution)							
Non-Formulary	Perforomist (formoterol inhalation solution)							
Recommended implementation period	120 days							
Inhaled Corticos	steroid/Long-Acting Beta Agonist Combinations (ICS/LABA)							
	Advair Diskus (fluticasone/salmeterol dry powder inhaler)							
Formulary	Advair HFA (fluticasone/salmeterol metered-dose inhaler)							
	Symbicort (budesonide/formoterol metered-dose inhaler)							
Non-Formulary	None							
Recommended implementation period	120 days							

*: Contains chlorofluorocarbon (CFC) propellant

Table 2: TRUEtest strip - Uniform Formulary Recommendations from for the Self-Monitored Blood Glucose Systems (SMBGS) Test Strips

UF Status / Implementation Period	Test Strip (SMBGS meter)
	TRUEtest (for TRUEresult and TRUE2go meters) recommended for UF February 2009
Formulary	Accu-chek Aviva (for Accu-chek Aviva meter)
i officiary	Ascensia Contour (for Ascensia Contour meter)
	Freestyle Lite (for Freestyle Lite and Freestyle Freedom Lite meters)
	Precision Xtra (for Precision Xtra meter)
	One Touch (for One Touch Ultra 2, One Touch Ultra Mini, One Touch Ultra Smart meters)
	TrueTrack (for TrueTrack meter)
	Accu-chek Comfort Curve (for Accu-chek Advantage meter)
	Accu-chek Compact Plus drum (for Accu-check Compact Plus meter)
	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)
Non-Formulary	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
	Plus all other store/private label brand strips not included on Uniform Formulary
Recommended implementation period	N/A for TRUEtest SMBGS test strip

Figure 1:

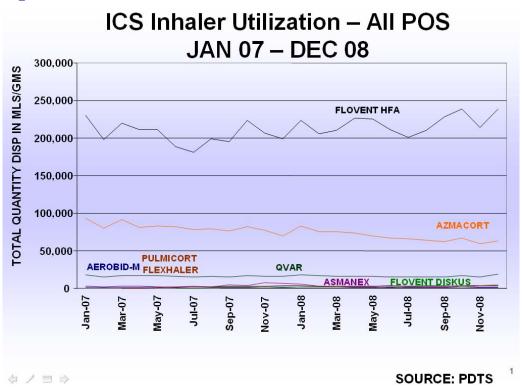
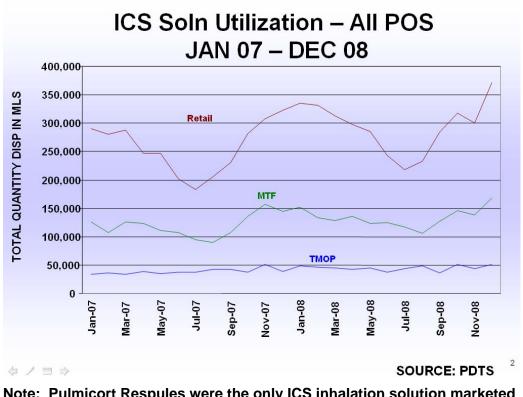


Figure 2:



Note: Pulmicort Resputes were the only ICS inhalation solution marketed during this time period.

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Figure 3:

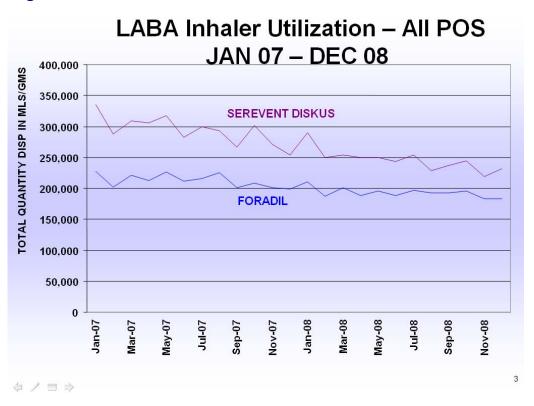
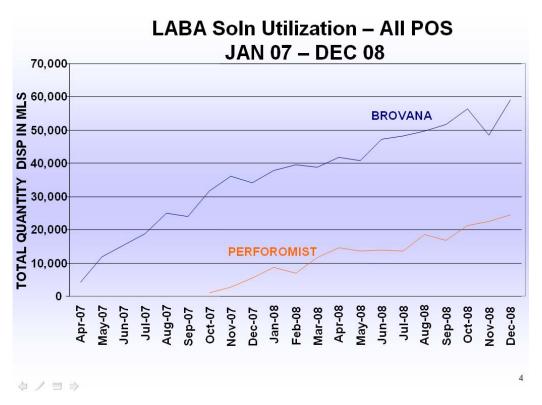
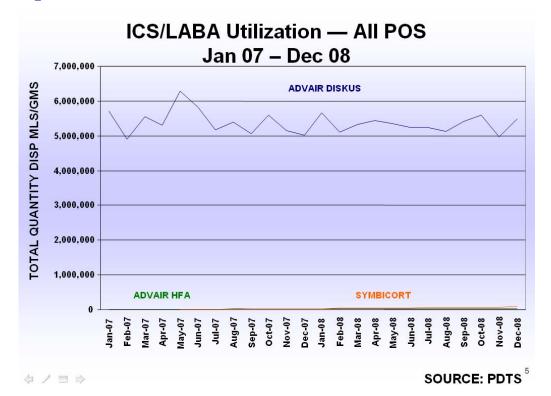


Figure 4:



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Figure 5:



Maating	Drug	Non-Formulary Medications	Total Beneficiaries Affected	Benefic	iaries Affe POS	cted by	Implementation Plan	Justification	Step
Meeting	Class	Class Non-Formulary Medications	(# of patients affected)	Retail	Mail Order	First Wednesday X days after the decision date	JUSTICATION	Therapy	
Feb 09	Inhaled Corticosteroids	 Beclomethasone HFA MDI (Qvar) Budesonide DPI (Pulmicort Flexhaler) Ciclesonide HFA MDI (Alvesco) Flunisolide CFC MDI (Aerobid) Flunisolide CFC MDI with Menthol (Aerobid M) Triamcinolone CFC MDI (Azmacort) 	13,489	3,556	7,831	2,102	120	Lag time to allow implementation of drug classes from Aug 08 and Nov 08	No
Feb 09	Long-Acting Beta Agonists	 Formoterol inhalation solution (Perforomist) 	109	2	44	63	120	Lag time to allow implementation of drug classes from Aug 08 and Nov 08	No
Feb 09	Inhaled Corticosteroids / Long-Acting Beta Agonist Combinations	(no drugs made non-formulary)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Nov 08	Inhaled Short Acting Beta Agonist	 Metaproterenol inhaled solution Pirbuterol CFC MDI (Maxair) 	1,278	44	1,002	232	60 (8 Apr 09)	Small number of beneficiaries affected	No
Nov 08	Nasal Allergy Drugs	 Beclomethasone (Beconase AQ) Budesonide (Rhinocort AQ) Ciclesonide (Omnaris) Fluticasone Furoate (Veramyst) Triamcinolone (Nasacort AQ) Olopatadine (Patanase) 	34,271	440	27,017	6,814	60 (8 Apr 09)	Nasal corticosteroids reviewed Nov 05, no changes to UF other than Patanase and Omnaris made non-formulary (1,794 users)	No
Aug 08	Self-Monitoring Blood Glucose System Test Strips	 One Touch (for One Touch Ultra 2, Ultra Mini, and Ultra Smart meters) TrueTrack strips (for TrueTrack meter) Accu-chek Comfort Curve strips (for Accu-chek Advantage meter) 	58,142	12,271	33,658	12,231	120	Allow time for patients to receive new meters	No

Table 3: Uniform Formulary Implementation Plan Summary – 2006 to present

Meeting	Drug	Non-Formulary Medications	Total Beneficiaries Affected	Benefic	iaries Affe POS	cted	Implementation Plan	Justification	Step Therapy
Meeting	Class		(# of patients affected)	MTF	Retail	Mail Order	First Wednesday X days after the decision date	Justification	
		 Accu-chek Compact Plus drum (for Accu-check Compact Plus meter) 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 Plus all other store/private label brand strips not included on Uniform Formulary (see the BCF/ECF column) 							
Aug 08	Overactive Bladder Drugs	Tolterodine IR (Detrol)Trospium IR (Sanctura)	4,215	235	1,210	2,770	90	Typical 90-day implementation period	No
Aug 08	Antidepressant – 1s	 Desvenlafaxine (Pristiq) 	745	0	694	51	60	New drug in already reviewed class; low utilization	No

Meeting	Drug	Non-Formulary Medications	Total Beneficiaries Affected	Benefic	iaries Affeo POS	cted	Implementation Plan	less (16) and any	Step Therapy
meeting	Class		(# of patients affected)	MTF	Retail	Mail Order	First Wednesday X days after the decision date	bustineation	
		 Original Meeting Nov 05 paroxetine HCI CR (Paxil) fluoxetine 90 mg for weekly administration (Prozac Weekly) fluoxetine in special packaging for PMDD (Sarafem) escitalopram (Lexapro) duloxetine (Cymbalta) bupropion extended release (Wellbutrin XL) 	See previous meetings below in table				See previous meetings below in table	See previous meetings below in table	No
		 Nisoldipine geomatrix (Sular geomatrix) 	2,027	56	1,188	783	60	New drug in already reviewed class; low utilization	No
Aug 08	Calcium Channel Blockers	 Original Meeting Aug 05 amlodipine (Norvasc) Nov 07: removed from NF status isradipine IR (Dynacirc) isradipine ER (Dynacirc CR) nicardipine IR (Cardene, generics) nicardipine SR (Cardene SR) verapamil ER (Verelan) verapamil ER for bedtime dosing (Verelan PM, Covera HS) diltiazem ER for bedtime dosing (Cardizem LA) 	See previous meetings below in table				See previous meetings below in table	See previous meetings below in table	No
Jun 08	Triptans	 Almotriptan (Axert) Frovatriptan (Frova) Naratriptan (Amerge) 	3,763	208	3,212	343	(26 Nov 2008) 90 days	Typical 90-day implementation period	No

Meeting	Drug	Non-Formulary Medications	Total Beneficiaries Affected	Benefic	iaries Affeo POS	cted	Implementation Plan	Justification	Step
mooting	Class	Non't officially moulouiono	(# of patients affected)	MTF	Retail	Mail Order	First Wednesday X days after the decision date	Custinication	Therapy
Jun 08	Osteoporosis Agents	 Salmon-calcitonin (Miacalcin) 	2,914	945	1,948	1,021	(26 Nov 2008) 90 days	Typical 90-day implementation period	No
	Newer Antihistamines (NAs) (new drug in	 Levocetirizine (Xyzal) 	19,254	0	19,254	0	(29 Oct 2008) 60 days	New drug in already reviewed class	No
Jun 08	previously reviewed class); Original decision Aug 07	Original Meeting Aug 07 • desloratadine (Clarinex) • desloratadine/pseudoephed. (Clarinex D)	27,396	60	20,102	7,234	See previous meetings below in table	Typical 90-day implementation period	No
Jun 08	Leukotriene Modifiers (LMs (new drug in previously reviewed class);	 Zileuton extended release (Zyflo CR) 	288	0	288	0	(29 Oct 2008) 60 days	New drug in already reviewed class; low utilization	No
	Original decision Aug 07	Original Meeting Aug 07 • zileuton (Zyflo)	144	4	110	31	See previous meetings below in table	Typical 90-day implementation period	No
	Beta Adrenergic Receptor Blockers (ABAs) (new drug in	 Nebivolol (Bystolic) 	2,462	0	2,462	0	(29 Oct 2008) 60 days	New drug in already reviewed class; low utilization	No
Jun 08	previously reviewed class); Original decision Nov 07	<i>Original Meeting Nov 0</i> 7 (No drugs designated non formulary)	0	0	0	0	See previous meetings below in table	No meds moved to non-formulary status	No
Jun 08	Renin Antihypertensive Agents (RAAs) (new drug in previously	ARB/CCB combos (Jun 08) • Olmesartan / amlodipine (Azor)	2,641	0	2,641	0	(29 Oct 2008) 60 days	New drug in already reviewed class with current low utilization	No

Meeting	Drug	Non-Formulary Medications	Total Beneficiaries Affected	Benefic	iaries Affe POS	cted	Implementation Plan	Justification	Step
Meeting	Class	Non-i officially medications	(# of patients affected)	MTF	Retail	Mail Order	First Wednesday X days after the decision date	Justineation	Therapy
	reviewed class);	ARB/CCB combos (Nov 07) • valsartan / amlodipine (Exforge)	2,376	0	2,376	0	(16 Apr 2008) 60 days	New drug in already reviewed class with current low utilization	No
		ARBs – (May 07 meeting) eprosartan (Teveten) eprosartan HCTZ (Teveten HCT) irbesartan (Avapro) irbesartan HCTZ (Avalide) olmesartan (Benicar) olmesartan HCTZ (Benicar HCT) valsartan (Diovan) valsartan HCTZ (Diovan HCT) ACE/CCB combos – Feb 06 meeting felodipine/enalapril (Lexxel) verapamil/trandolapril (Tarka) ACE Inhibitors (Aug 05 meeting) moexipril (Univasc), moexipril / HCTZ (Uniretic) perindopril (Accupril) quinapril (Accupril) quinapril (Altace)	See previous meetings for affected beneficiaries for each subclass				See previous meetings below in table	See previous meetings below in table	
Nov 07	Benign Prostatic Hypertension (BPH) Alpha Blockers (ABs)	 tamsulosin (Flomax) 	64,783	1,426	40,161	23,196	(16 Apr 2008) 60-days	3 rd class for Step Therapy	Yes
Nov 07	Targeted Immuno- modulatory Biologics (TIBs)	 etanercept (Enbrel) anakinra (Kineret) 	7,397	1,939	4,149	1,309	(18 Jun 2008) 90-days	Typical 90-day implementation period	No

Meeting	Drug	Non-Formulary Medications	Total Beneficiaries Affected	Benefic	iaries Affeo POS	cted	Implementation Plan	Justification	Step
Meeting	Class	Non Formulary medications	(# of patients affected)	MTF	Retail	Mail Order	First Wednesday X days after the decision date	oustineation	Therapy
Nov 07	Attention Deficit Hyperactivity Disorder (ADHD) / Narcolepsy agents (new drug in previously reviewed	 lisdexamfetamine (Vyvanse) 	2,200 Rxs	0	2,200 Rxs	0	(16 Apr 2008) 60 days	New drug in already reviewed class with current low utilization	No
	class); Previous decision Nov 06	 Original decision Nov 06 Dexmethylphenidate IR (Focalin) Dexmethylphenidate SODAS (Focalin XR) Methylphenidate transdermal patch (Daytrana) 	3,078 (1.7% of patients receiving an ADHD drug)	62	2,965	51	18 Apr 07 (90 days)	Small number of beneficiaries affected	
Nov 07	Contraceptive Agents (new drug in previously reviewed class); Previous decisions May 06, Nov 06	 EE 20 mcg / levonorgestrel 0.09 mg (Lybrel) 	290 Rxs	2 Rxs	263 Rxs	25 Rxs	(16 Apr 2008) 60 days	New drug in already reviewed class with current low utilization	No
		 Previous meetings May 06 & Nov 06 EE 30 mcg / levonorgestrel 0.15 mg in special packaging for extended use (Seasonale) EE 25 mcg / norethindrone 0.4 mg (Ovcon 35) EE 50 mcg / norethindrone 1 mg (Ovcon 	23,221 (4% of patients receiving a contraceptive)	3,128	19,249	844	24 Jan 07 (180 days)	Seasonale, packaged as a 3- month supply; Loestrin 24 FE and Seasonique to coincide with Seasonale decision	
		 EE 30 mcg / norethindrone 1 mg (Ovcon 50) EE 20/30/35 mcg / norethindrone 1 mg (Estrostep Fe) EE 20 mcg/1 mg norethindrone- 24 day regimen (Loestrin 24 Fe) EE 30/10 mcg/ 0.15 mg levonorgestrel for 	Seasonique: 161 (from Apr 06-Oct 06)	0 Rxs	112 Rxs	4 Rxs			

Meeting	Drug	Non-Formulary Medications	Total Beneficiaries Affected	Benefic	iaries Affeo POS	cted	Implementation Plan	Justification	Step
meeting	Class		(# of patients affected)	MTF	Retail	Mail Order	First Wednesday X days after the decision date	Ustinoution	Therapy
		extended use (Seasonique)	Loestrin 24 Fe: 2,227 (from Apr 06-Oct 06)	22 Rxs	3,417 Rxs	64 Rxs			
Aug 07	Nasal Corticosteroid Agents (new drug in previously reviewed class);	fluticasone furoate (Veramyst)	650	0	650	0	TMOP & TRRx: 60- days for current users; \$22 co-pay in effect immediately for new users MTF: No later than 60 days	New drug in already reviewed class with current low utilization	No
	Original décision Nov 05	 Original Decision: Nov 05 beclomethasone dipropionate (Beconase AQ, Vancenase AQ) budesonide (Rhinocort Aqua) triamcinolone (Nasacort AQ) 					19 Jan 06 (90 days)	Substantial number of beneficiaries	
Aug 07	Growth Stimulating Agents (GSAs)	 somatropin (Genotropin, Genotropin Miniquick) somatropin (Humatrope) somatropin (Omnitrope) somatropin (Saizen) 	653	77	310	266	TMOP & TRRx: 60- days for current users; MTF: No later than 60 days	Low number of affected beneficiaries affected	No
May 07	Antilipidemic II Agents (LIP-2s)	 fenofibrate nanocrystallized (Tricor) fenofibrate micronized (Antara) omega-3 fatty acids (Omacor) colesevelam (Welchol) 	83,612	18,849	44,402	20,361	24 Oct 07 (90 days)	Typical 90-day implementation period	No
May 07	5-Alpha Reductase Inhibitors (5-ARIs)	 dutasteride (Avodart) 	20,917	1,087	12,830	7,000	24 Oct 07 (90 days)	Typical 90-day implementation period	No
May 07 (Update from Feb 05)	PPIs	 lansoprazole (Prevacid) omeprazole/sodium bicarbonate (Zegerid) pantoprazole (Protonix) rabeprazole (Aciphex) 	453,525	212,130	178,120	63,275	24 Oct 07 (90 days)	Typical 90-day implementation period	Yes

Meeting	Drug	Non-Formulary Medications	Total Beneficiaries Affected (# of patients affected)	Benefic	iaries Affeo POS	cted	Implementation Plan First Wednesday X days after the decision date	Justification	Step Therapy
	Class			MTF	Retail	Mail Order			
May 07 (Update from Feb 05)	ARBs	 eprosartan (Teveten) eprosartan HCTZ (Teveten HCT) irbesartan (Avapro) irbesartan HCTZ (Avalide) olmesartan (Benicar) olmesartan HCTZ (Benicar HCT) valsartan (Diovan) valsartan HCTZ (Diovan HCT) 	228,581	68,059	109,595	50,930	21 Nov 07 (120 days)	Reservations regarding ESI ability to handle implementation	No
Feb 07	Newer Sedative Hypnotics	 Ramelteon (Rozerem) Zaleplon (Sonata) Zolpidem ER (Ambien CR) 	40,447	5,878	31,550	3,019	1 Aug 07 (90 days)	First time automated PA with step edit	Yes
Feb 07	Narcotic Analgesics	 Tramadol ER (Ultram ER) 	1,088	0	46	1,042	1 Aug 07 (90 days)	Small number of beneficiaries affected	No
Feb 07	Glaucoma Agents	 Travoprost (Travatan, Travatan Z) Timolol maleate (Istalol) Timolol hemihydrate (Betimol) Brinzolamide (Azopt) 	17,139	1,735	12,267	3,117	1 Aug 07 (90 days)	Small number of beneficiaries affected	No
Feb 07	MAOI Antidepressants	 Selegiline transdermal system (Emsam) 	168	0	157	11	1 Aug 07 (90 days)	Small number of beneficiaries affected	No
		•							

BCF = Basic Core Formulary; ECF = Extended Core Formulary; ESI = Express-Scripts, Inc; MN = Medical Necessity; TMOP = TRICARE Mail Order Pharmacy; TRRx = TRICARE Retail Pharmacy program; UF = Uniform Formulary

CR = controlled release; ER = extended release; IR = immediate release; LA = long-acting; SR = sustained release; XL = extended release

5-ARI = 5-Alpha Reductase Inhibitors; ADHD = Attention Deficit Hyperactivity Disorder; ACE Inhibitors = Angiotensin Converting Enzyme Inhibitors; ARBs = Angiotensin Receptor Blockers; BPH = Benign Prostatic Hypertrophy; CCBs = Calcium Channel Blockers; EE = ethinyl estradiol; GSAs = Growth Stimulating Agents; GI = gastrointestinal; GABA = gamma-aminobutyric acid; H2 = Histamine-2 receptor; HCTZ = hydrochlorothiazide; Leukotriene Modifiers = LMs; LIP-1s = Antilipidemic I; LIP-2s = Antilipidemic II; MAOI = Monoamine Oxidase Inhibitor; MS-DMDs = Multiple Sclerosis Disease-Modifying Drugs; NAs = Newer Antihistamines; OABs = Overactive Bladder Medications;

PDE-5 Inhibitors = Phosphodiesterase-5 inhibitors; PMDD = Premenstrual Dysmorphic Disorder; PPIs = Proton Pump Inhibitors; RAAs = Renin Antihypertensive Agents; SODAS = spheroidal oral drug absorption system; TZDs = thiazolidinediones

*The topical antifungal drug class excludes vaginal products and products for onychomycosis (e.g., ciclopirox topical solution [Penlac])