

**Beneficiary Advisory Panel Handout
Uniform Formulary Decisions
18 September 2007**

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 Aug 07 DoD P&T Committee Meeting

UF Status / Implementation Period	Generic Name (Brand)	Formulations	Generics Available?
Newer Antihistamines (NAs)			
Formulary	Fexofenadine (Allegra)	tab; ODT; suspension	Yes
	Fexofenadine / pseudoephedrine (Allegra D)	tab	No
	Cetirizine (Zyrtec)	tab, chew tab, syrup	No
	Cetirizine / pseudoephedrine (Zyrtec -D)	tab	No
	Acrivastine / pseudoephedrine (Semprex-D)	capsule	No
	Loratadine (Claritin) *OTC	tab, ODT, chew tab, syrup	Yes
	Loratadine/ pseudoephedrine (Claritin D) *OTC	tab	Yes
Non-Formulary	Desloratadine (Clarinex)	tab, RDT, syrup	No
	Desloratadine / pseudoephedrine (Clarinex D)	tab	No
Recommended implementation period	90 days		
Leukotriene Modifiers (LMs)			
Formulary	Montelukast (Singulair)	tab, chew tab, granule	No
	Zafirlukast (Accolate)	tab	No
Non-Formulary	Zileuton (Zyflo)	Tab	No
Recommended implementation period	90 days		
Growth Stimulating Agents (GSAs)			
Formulary	Somatropin (Norditropin, Norditropin Nordiflex)	injection	No
	Somatropin (Nutropin, Nutropin AQ)	injection	No
	Somatropin (Serostim)	injection	No
	Somatropin (Tev-Tropin)	injection	No
	Somatropin (Zorbtive)	injection	No
	Mecasermin (Increlex)	injection	No
Non-Formulary	Somatropin (Genotropin, Genotropin Miniquick)	injection	No
	Somatropin (Humatrope)	injection	No
	Somatropin (Omnitrope)	injection	No
	Somatropin (Saizen)	injection	No
Recommended implementation period	60 days		

cap: capsule; chew tab: chewable tablet; ODT: orally disintegrating tablet; OTC: over-the-counter; RDT: rapidly disintegrating tablet; tab: tablet

*Added to the UF as part of the TRICARE OTC Pilot Program

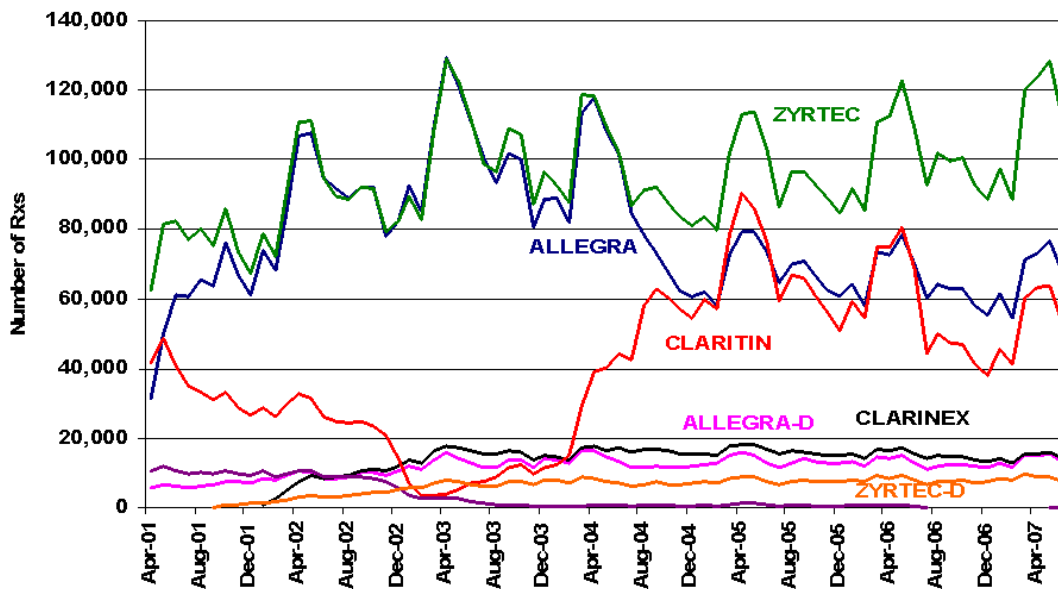
Table 2: Uniform Formulary Recommendations from the Aug 07 DoD P&T Committee Meeting for New Drugs in Classes Previously Reviewed for UF Status

Nasal Steroids		
Recommendation at August 2007 meeting		
UF	No change from Nov 2005 meeting	
Non-formulary	Fluticasone furoate (Veramyst)	
Recommended implementation period	TMOP & TRRx: 60-days for current users; \$22 co-pay in effect immediately for new users, if technically feasible MTF: No later than 60 days	
Existing UF Status of Nasal Steroids (November 2005) & August 2007 recommendations		
UF	Flunisolide (Nasarel)	
	Fluticasone propionate (Flonase)	
	Mometasone furoate (Nasonex)	
Non-formulary	Fluticasone furoate (Veramyst) (recommended for NF August 2007)	
	Beclomethasone dipropionate (Beconase AQ, Vancenase AQ/DS)	
	Budesonide (Rhinocort AQ)	
	Triamcinolone acetonide (Nasacort AQ)	
Renin Angiotensin Antihypertensives (RAAs)		
Recommendation at August 2007 meeting		
Direct Renin Inhibitor	UF	Aliskiren (Tekturna) (recommended for UF August 2007)
	Non-formulary	No change from previous meetings
Recommended implementation period	Not applicable	
Existing UF Status of RAAs (previous meetings) & August 2007 recommendations		
Direct Renin Inhibitors	UF	Aliskiren (Tekturna) (recommended for UF August 2007)
ARBs	UF	Candesartan (Atacand)
		Candesartan /HCTZ (Atacand HCT)
		Losartan (Cozaar)
		Losartan/HCTZ (Hyzaar)
		Telmisartan (Micardis)
		Telmisartan/HCTZ (Micardis HCT)
		Candesartan (Atacand)
	Non-formulary	Eprosartan (Teveten)
		Eprosartan/HCTZ (Teveten HCT)
		Irbesartan (Avapro)
		Irbesartan/HCTZ (Avalide)
		Olmesartan (Benicar)
		Olmesartan/HCTZ (Benicar HCT)
		Valsartan (Diovan)
Valsartan/HCTZ (Diovan)		
ACE Inhibitors	UF	Benazepril and combo with HCTZ
		Captopril and combo with HCTZ
		Enalapril and combo with HCTZ
		Fosinopril and combo with HCTZ
		Lisinopril and combo with HCTZ

		Trandolapril (Mavik)
	NF	Moexipril (Univasc) and combo with HCTZ
		Perindopril (Aceon)
		Quinapril (Accupril) and combo with HCTZ
		Ramipril (Altace)
ACE/CCB Combinations	UF	Amlodipine / benazepril (Lotrel)
	Non-formulary	Felodipine / enalapril (Lexxel)
		Verapamil sustained release / trandolapril (Tarka)

Figure 1:

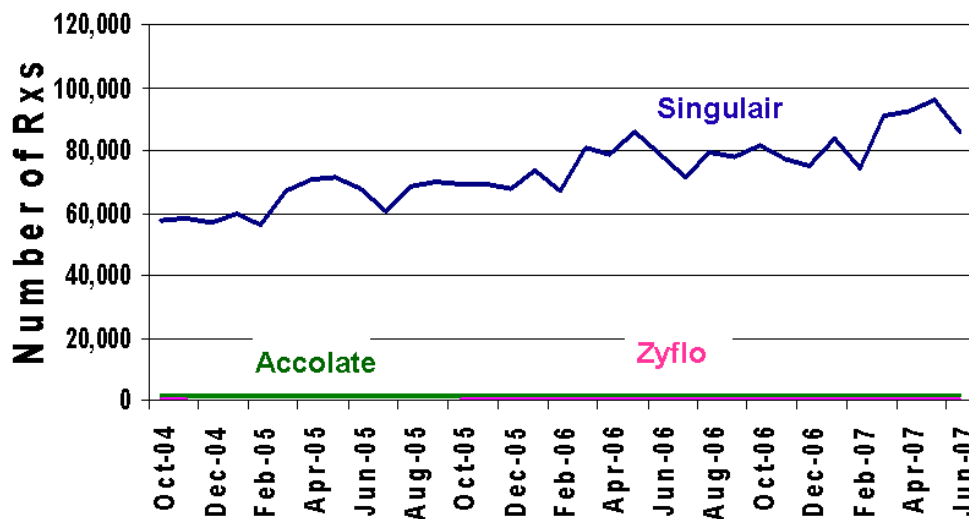
MHS Rx's for Newer Antihistamines By Agent, Apr 01 – Jun 07



Source: PDTS

Figure 2:

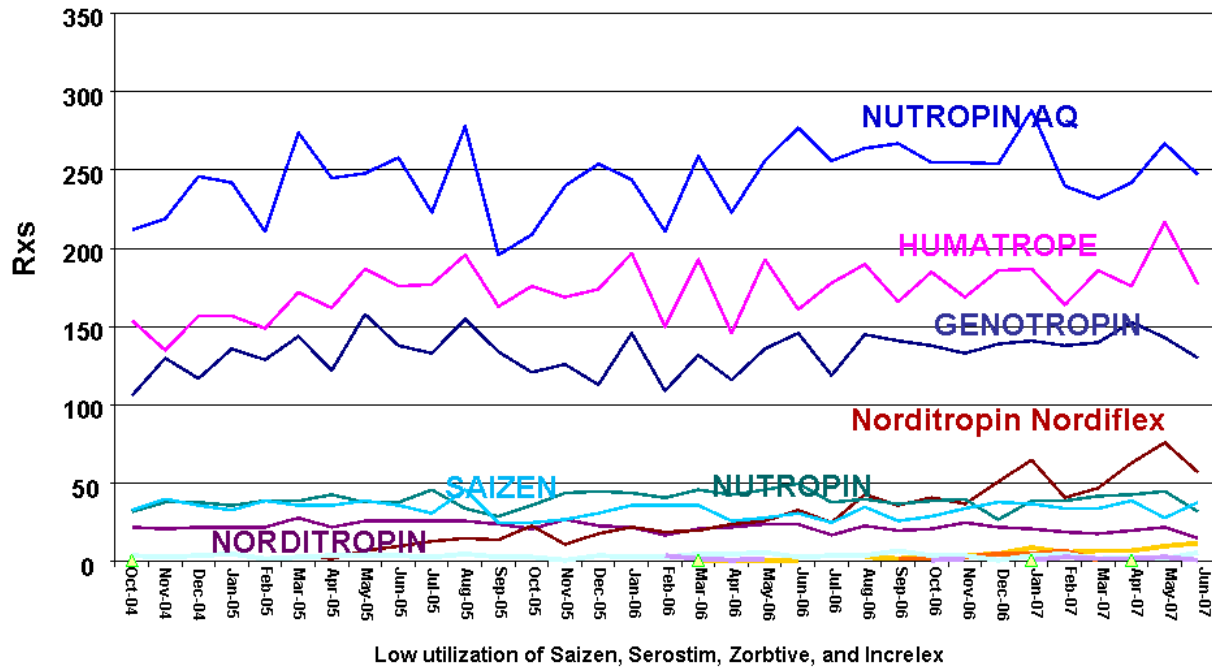
MHS Rx's for Leukotrienes By Agent, Oct 04 - Jun 07



Source: PDTS

Figure 3:

MHS Growth Stimulating Agent Rx's By Agent, Oct 04 – Jun 07



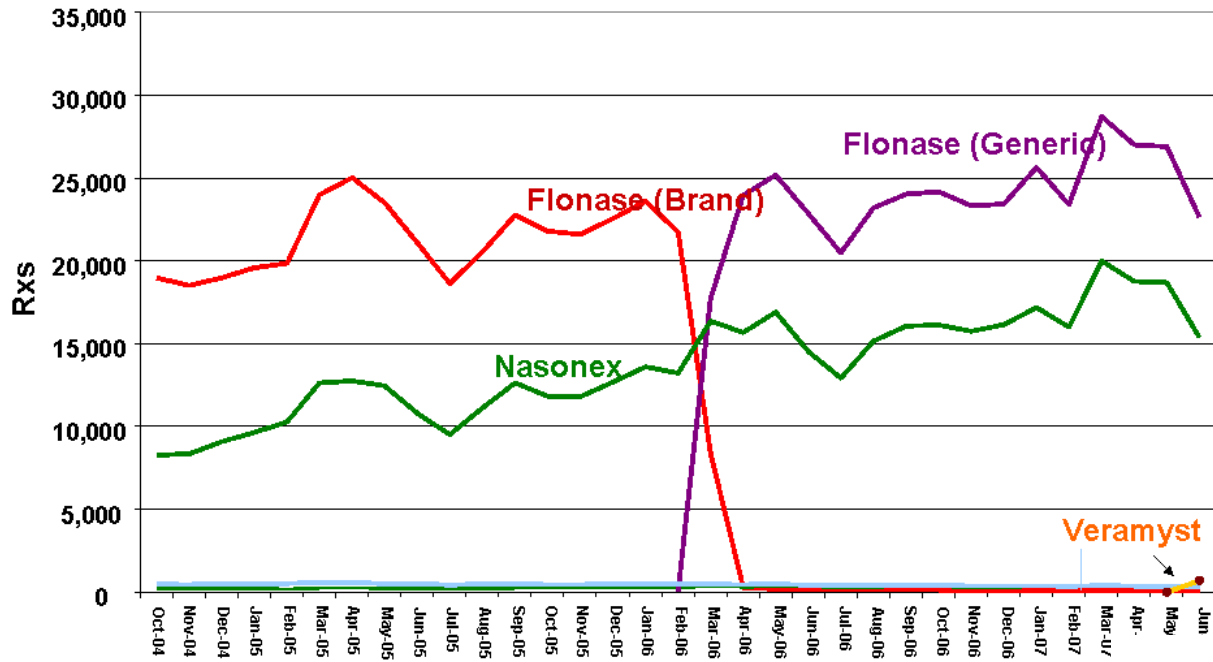
Source: PDTs

Table 2: Somatropin Products – Other Considerations

Drugs	Preservative-free	Delivery Device			Storage		1-800 number
		Vial	Pen Device	Dose calculation to use pen	Ready to use	Room Temperature Storage	
Genotropin	yes		yes	Not required	Miniquick syringe only (single-dose)	Before initial use: Miniquick syringe	yes
Humatrope		yes	yes	Required			yes
Norditropin			yes	Not required	yes	After initial use: (21 days for Nordiflex 5 & 10 mg pens)	yes
Nutropin & Nutropin AQ		yes	yes	Required	yes		yes
Omnitrope	yes	yes		-			yes
Saizen		yes	yes, pen & needle-free pen	Required		Before initial use	yes
Serostim	yes	yes	yes, needle-free pen	Required		Before initial use	yes
Tev-Tropin		yes	*	-			yes
Zorbtive		yes		-			yes

Figure 4:

Retail Nasal Corticosteroid Rx's By Agent, Oct 04 – Jun 07



Source: PDTS

Table 3: Uniform Formulary Implementation Plan Summary

Meeting	Drug Class	Non-Formulary Medications	Total Beneficiaries Affected (# of patients affected)	Beneficiaries Affected by POS			Implementation Plan First Wednesday X days after the decision date	Justification	Step Therapy
				MTF	Retail	Mail Order			
Aug 07	Nasal Corticosteroid Agents (New Drug in Previously Reviewed Class); Original decision Nov 05	<ul style="list-style-type: none"> 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
		<i>Original Decision: Nov 05</i> <ul style="list-style-type: none"> beclomethasone dipropionate (Beconase AQ, Vancenase AQ) budesonide (Rhinocort Aqua) triamcinolone (Nasacort AQ) 					19 Jan 06 (90 days)	Substantial number of beneficiaries	
Aug 07	Renin Antihypertensive Agents (RAAs) (RAAs new class comprised of direct renin inhibitors (aliskerin; Tekturna, ARBs, ACE/CCB combos, ACEs)	<ul style="list-style-type: none"> Not applicable; as Direct Renin Inhibitor aliskiren (Tekturna) was not placed non-formulary 	N/A	N/A	N/A	N/A	Not applicable	Aliskiren (Tekturna) not moved to non-formulary status	No
	<i>ARBs – (May 07 meeting)</i> <ul style="list-style-type: none"> eprosartan (Teveten) eprosartan HCTZ (Teveten HCT) irbesartan (Avapro) irbesartan HCTZ (Avalide) olmesartan (Benicar) olmesartan HCTZ (Benicar HCT) valsartan (Diovan) valsartan HCTZ (Diovan HCT) 								

Meeting	Drug Class	Non-Formulary Medications	Total Beneficiaries Affected (# of patients affected)	Beneficiaries Affected by POS			Implementation Plan First Wednesday X days after the decision date	Justification	Step Therapy
				MTF	Retail	Mail Order			
		<p><i>ACE/CCB combos – Feb 06 meeting</i></p> <ul style="list-style-type: none"> ▪ felodipine/enalapril (Lexxel) ▪ verapamil/trandolapril (Tarka) <p><i>ACE Inhibitors (Aug 05 meeting)</i></p> <ul style="list-style-type: none"> ▪ moexipril (Univasc), ▪ moexipril / HCTZ (Uniretic) ▪ perindopril (Aceon) ▪ quinapril (Accupril) ▪ quinapril / HCTZ (Accuretic) ▪ ramipril (Altace) 							
Aug 07	Newer Antihistamines (NAs)	<ul style="list-style-type: none"> ▪ desloratadine (Clarinet) ▪ desloratadine / pseudoephedrine (Clarinet D) 	27,396	60	20,102	7,234	<p>TMOP & TRRx: 90-days</p> <p>MTF: No later than 90 days</p>	Typical 90-day implementation period	No
Aug 07	Leukotriene Modifiers (LMs)	<ul style="list-style-type: none"> ▪ zileuton (Zyflo) 	144	4	110	31	<p>TMOP & TRRx: 90-days</p> <p>MTF: No later than 90 days</p>	Typical 90-day implementation period	No
Aug 07	Growth Stimulating Agents (GSAs)	<ul style="list-style-type: none"> ▪ somatropin (Genotropin, Genotropin Miniquick) ▪ somatropin (Humatrope) ▪ somatropin (Omnitrope) ▪ somatropin (Saizen) 	653	77	310	266	<p>TMOP & TRRx: 60-days for current users;</p> <p>MTF: No later than 60 days</p>	Low number of affected beneficiaries affected	No
May 07	Antilipidemic II Agents (LIP-2s)	<ul style="list-style-type: none"> ▪ fenofibrate nanocrystallized (Tricor) ▪ fenofibrate micronized (Antara) ▪ omega-3 fatty acids (Omacor) ▪ colessevelam (Welchol) 	83,612	18,849	44,402	20,361	24 Oct 07 (90 days)	Typical 90-day implementation period	No

Meeting	Drug Class	Non-Formulary Medications	Total Beneficiaries Affected (# of patients affected)	Beneficiaries Affected by POS			Implementation Plan First Wednesday X days after the decision date	Justification	Step Therapy
				MTF	Retail	Mail Order			
May 07	5-Alpha Reductase Inhibitors (5-ARIs)	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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
May 07 (Update from Feb 05)	ARBs	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Selegiline transdermal system (Emsam) 	168	0	157	11	1 Aug 07 (90 days)	Small number of beneficiaries affected	No

Meeting	Drug Class	Non-Formulary Medications	Total Beneficiaries Affected (# of patients affected)	Beneficiaries Affected by POS			Implementation Plan First Wednesday X days after the decision date	Justification	Step Therapy
				MTF	Retail	Mail Order			
Nov 06	ADHD	<ul style="list-style-type: none"> 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	No
Nov 06	Older Sedative Hypnotics	-	0	0	0	0	18 Apr 07 (90 days)	No medications moved to non-formulary status	No
Aug 06	TZDs	-	0	0	0	0	Not applicable	No medications moved to non-formulary status	No
Aug 06	H2 Antagonists / GI protectants	-	0	0	0	0	Not applicable	No medications moved to non-formulary status	No
Aug 06	Antilipidemic I Agents	<ul style="list-style-type: none"> Rosuvastatin (Crestor) Atorvastatin / amlodipine (Caduet) 	44,078	851	36,133	6,921	1 Feb 07 (90 days)	Small number of beneficiaries affected	No
May 06	Antiemetics	<ul style="list-style-type: none"> Dolasetron (Anzemet) 	852	14	668	170	27 Sept 06 (60 days)	Small number of beneficiaries affected, and acute nature of treatment (e.g., chemotherapy)	No

Meeting	Drug Class	Non-Formulary Medications	Total Beneficiaries Affected (# of patients affected)	Beneficiaries Affected by POS			Implementation Plan First Wednesday X days after the decision date	Justification	Step Therapy
				MTF	Retail	Mail Order			
May 06 update for new drugs Nov 06	Contraceptive Agents	<ul style="list-style-type: none"> 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 50) EE 20/30/35 mcg / norethindrone 1 mg (Estrostep Fe) 	23,221 (4% of patients receiving a contraceptive)	3,128	19,249	844	24 Jan 07 (180 days)	Relatively low number of beneficiaries affected, but a high proportion are receiving Seasonale, which is packaged as a 3-month supply	No
		<ul style="list-style-type: none"> EE 20 mcg/1 mg norethindrone-24 day regimen (Loestrin 24 Fe) EE 30/10 mcg/ 0.15 mg levonorgestrel for extended use (Seasonique) 	Seasonique 161 (from Apr 06-Oct 06)	0 Rxs	112 Rxs	4 Rxs	Jan 24 07 (60 days; to coincide with Seasonal)	Small number of beneficiaries affected	No
		Loestrin 24 Fe: 2,227 (from Apr 06-Oct 06)	22 Rxs	3,417 Rxs	64 Rxs	Jan 24 07 (60 days; to coincide with Seasonal)			
Feb 06	OABs	<ul style="list-style-type: none"> tolterodine IR (Detrol) oxybutynin patch (Oxytrol) tropium (Sanctura) 	19,118	2,596	13,471	3,051	26 July 06 (90 days)	Recommended 60-day implementation overturned; 90-day BAP recommendation accepted	No
Feb 06	Misc Anti-hypertensive Agents	<ul style="list-style-type: none"> felodipine/enalapril (Lexxel) verapamil/trandolapril (Tarka) 	5,946	336	4,472	1,138	26 July 06 (90 days)	Recommended 60-day implementation overturned; 90-day BAP recommendation accepted	No

Meeting	Drug Class	Non-Formulary Medications	Total Beneficiaries Affected (# of patients affected)	Beneficiaries Affected by POS			Implementation Plan First Wednesday X days after the decision date	Justification	Step Therapy
				MTF	Retail	Mail Order			
Feb 06	GABA-analogs	<ul style="list-style-type: none"> pregabalin (Lyrica) 	30,649	1,120	27,566	1,963	28 Jun 06 (60 days)	Small number of beneficiaries affected	No
Nov 05	Alzheimer's Drugs	<ul style="list-style-type: none"> tacrine (Cognex) 	5	0	3	2	19 Apr 06 (90 days)	Small number of beneficiaries affected	No
Nov 05	Nasal Corticosteroid Agents	<ul style="list-style-type: none"> beclomethasone dipropionate (Beconase AQ, Vancenase AQ) budesonide (Rhinocort Aqua) triamcinolone (Nasacort AQ) 	96,999	13,556	73,381	10,062	19 Apr 06 (90 days)	Substantial number of beneficiaries affected	No
Nov 05	Macrolide/ Ketolide Antibiotics	<ul style="list-style-type: none"> azithromycin 2 gm (Zmax) telithromycin (Ketek) 	Total number not provided; antibiotics are used to treat acute infections				22 Mar 06 (60 days)	Small number of beneficiaries affected, Medication used to treat acute (not chronic) infections not likely to require therapy change	No
Nov 05	Antidepressants I	<ul style="list-style-type: none"> paroxetine HCl 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) 	182,916	52,624	118,582	11,710	19 Jul 06 (180 days)	Substantial number of beneficiaries affected	No
Aug 05	Alpha Blockers for BPH	<ul style="list-style-type: none"> tamsulosin (Flomax) 	89,926	26,692	47,674	15,560	15 Feb 06 (120 days)	Substantial number of beneficiaries affected	No

Meeting	Drug Class	Non-Formulary Medications	Total Beneficiaries Affected (# of patients affected)	Beneficiaries Affected by POS			Implementation Plan First Wednesday X days after the decision date	Justification	Step Therapy
				MTF	Retail	Mail Order			
Aug 05	CCBs	<ul style="list-style-type: none"> ▪ amlodipine (Norvasc) ▪ 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) 	274,616	133,794	101,345	39,477	15 Mar 06 (150 days)	Substantial number of beneficiaries affected	No
Aug 05	ACE Inhibitors & ACE Inhibitor / HCTZ Combinations	<ul style="list-style-type: none"> ▪ moexipril (Univasc), ▪ moexipril / HCTZ (Uniretic) ▪ perindopril (Aceon) ▪ quinapril (Accupril) ▪ quinapril / HCTZ (Accuretic) ▪ ramipril (Altace) 	158,101	77,159	57,982	22,959	16 Feb 06 (120 days)	Substantial number of beneficiaries affected	No
May 05	PDE-5 Inhibitors	<ul style="list-style-type: none"> ▪ sildenafil (Viagra) ▪ tadalafil (Cialis) 	128,007	55,161	49,850	22,996	12 Oct 05 (90 days)	Substantial number of beneficiaries affected	No
May 05 updated for new drug Nov 06	Topical Antifungals*	<ul style="list-style-type: none"> ▪ econazole ▪ ciclopirox ▪ oxiconazole (Oxistat) ▪ sertaconazole (Ertaczo) ▪ sulconazole (Exelderm) 	49,743	14,266	33,430	2,047	17 Aug 05 (30 days)	Medication used to treat acute (not chronic) infections not likely to require therapy change	No
		<ul style="list-style-type: none"> ▪ miconazole 0.25%, zinc oxide 15%, white petrolatum 82.35% (Vusion) 	581 (Apr 06-Oct 06) (UU not applicable)	7	571	3	21 Feb 07 (60 days)	Small numbers of beneficiaries affected	No

Meeting	Drug Class	Non-Formulary Medications	Total Beneficiaries Affected (# of patients affected)	Beneficiaries Affected by POS			Implementation Plan First Wednesday X days after the decision date	Justification	Step Therapy
				MTF	Retail	Mail Order			
May 05	MS-DMDs	-	0	0	0	0	Not applicable	No medications moved to non-formulary status	No
Feb 05	ARBs	<ul style="list-style-type: none"> ▪ eprosartan (Teveten) ▪ eprosartan/HCTZ (Teveten HCT) 	2,184	13	1,644	527	17 Jul 05 (90 days)	Recommended 30-day implementation overturned; 90-day BAP recommendation accepted	No
Feb 05	PPIs	<ul style="list-style-type: none"> ▪ esomeprazole (Nexium) 	138,739	6,691	117,520	14,528	17 Jul 05 (90 days)	Substantial number of beneficiaries affected	

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])