

**'Beneficiary Advisory Panel Handout
Uniform Formulary Decisions
14 Jan 2010**

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 Nov 2009 DoD P&T Committee Meeting

UF Status / Implementation Period	Brand Name (Generic)
Phosphodiesterase Type 5 Inhibitors (PDE-5 inhibitors) for Pulmonary Arterial Hypertension	
Formulary	Revatio (sildenafil)
Non-Formulary	Adcirca (tadalafil) – recommended for NF November 2009
Recommended implementation period	60 days

Figure 1: PDE5 Inhibitors for Pulmonary Arterial Hypertension

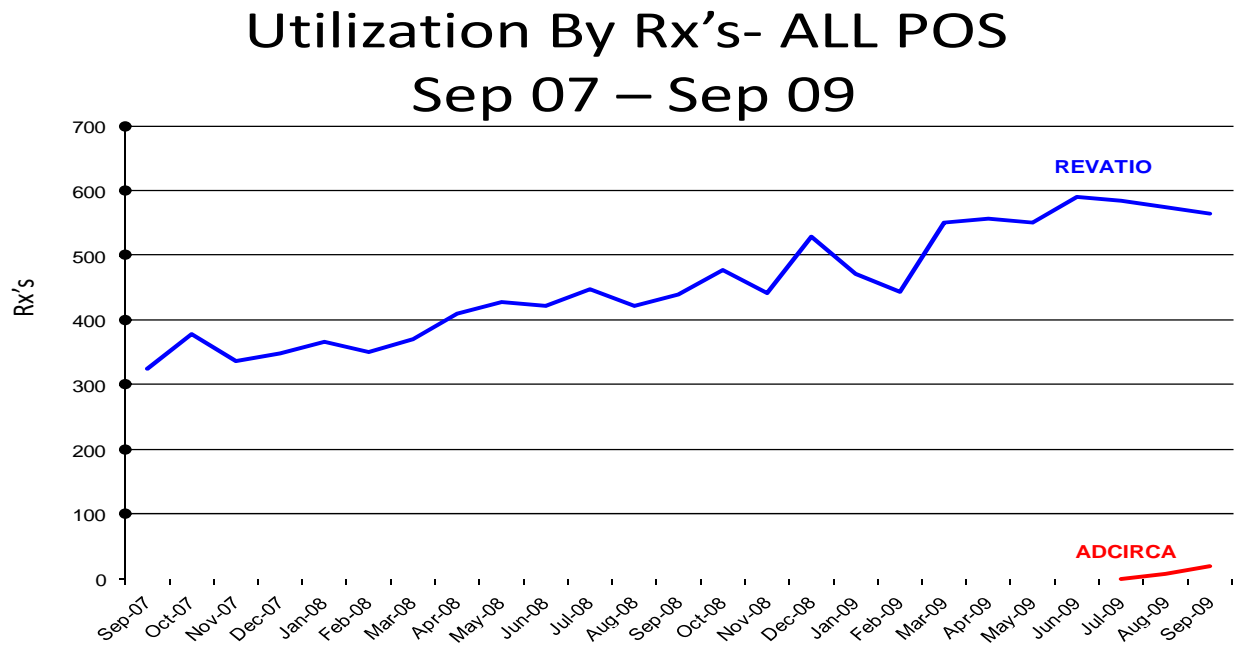


Table 2: Interferon beta 1b (Extavia): Uniform Formulary Recommendations from Nov 2009 for the Multiple Sclerosis - Disease Modulating Drugs (MS-DMDs)

Multiple Sclerosis - Disease Modulating Drugs (MS-DMDs)			
UF Status / Implementation Period	Generic Name (Brand)	Formulations	Generics Available?
Uniform Formulary	IFN beta- 1a (Avonex)	Injection	No
	IFN beta- 1a (Rebif)	Injection	No
	IFN beta- 1b (Betaseron)	Injection	No
	Glatiramer acetate (Copaxone)	Injection	No
Non-Formulary	Interferon beta 1b (Extavia) – recommended for NF November 2009	Injection	No
Recommended implementation period	60 days for Extavia		

Figure 2: MS-DMDs

Utilization By Rx's- ALL POS Sep 07 – Sep 09

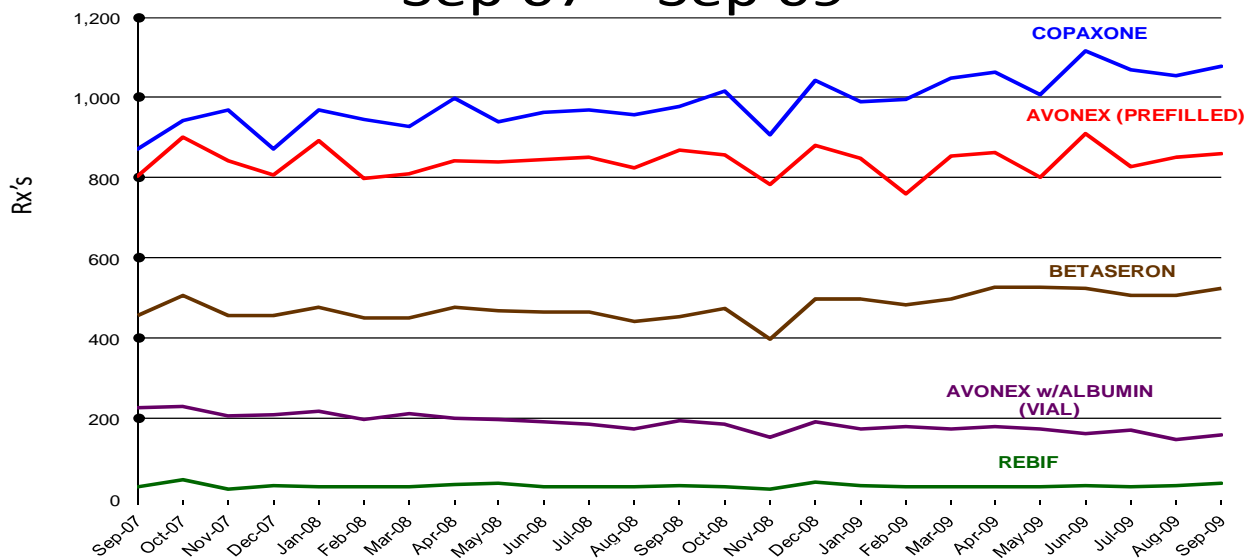
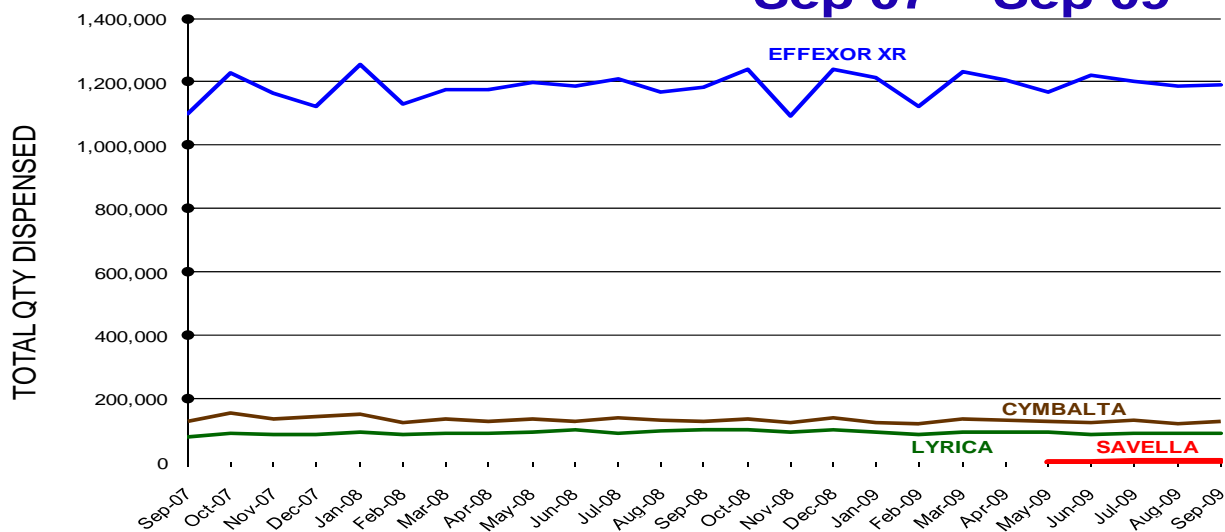


Table 3: Milnacipran tablets (Savella), Bupropion hydrobromide extended release tablets (Aplenzin), and Bupropion hydrochloride extended release tablets (Wellbutrin XL): UF Recommendations from Nov 2009 for the Antidepressant 1 (AD-1) Drugs

UF Status / Implementation Period	Generic Name (Brand)	Formulations	Generics Available?
Antidepressant 1 (AD-1s)			
Formulary	Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)		
	Venlafaxine IR (Effexor)	tabs	Yes
	Venlafaxine ER (Effexor XR)	caps	No
	Venlafaxine extended release tablets (VERT)	Tabs	No
	Selective Reuptake Inhibitors (SSRI)		
	Fluoxetine (excludes Prozac Weekly, Sarafem)	caps, syrup	Yes
	Citalopram	tabs	Yes
	Paroxetine HCl IR	tabs	Yes
	Paroxetine mesylate (Pexeva)	tabs	No
	Sertraline (Zoloft)	tabs	Yes
	Fluvoxamine (Luvox brand discontinued)	tabs	Yes
	Serotonin-Antagonist/Reuptake Inhibitors (SARIs)		
	Nefazodone	tabs	Yes
	Trazodone	tabs	Yes
	Norepinephrine and Dopamine Reuptake Inhibitors (NDRIs)		
	Bupropion immediate release (Wellbutrin)	tabs	Yes
	Bupropion sustained release (Wellbutrin SR)	tabs	Yes
	Bupropion extended release (Wellbutrin XL) recommended to move from NF to UF November 2009	tabs	Yes
	Alpa-2 Receptor Antagonists		
	Mirtazapine (Remeron)	Tabs,	Yes
Non-Formulary	Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)		
	Milnacipran (Savella) recommended for NF November 2009	tabs	No
	Desvenlafaxine (Pristiq)	tab	No
	Duloxetine (Cymbalta)	caps	No
	Norepinephrine and Dopamine Reuptake Inhibitors (NDRIs)		
	Bupropion hydrobromide ER tablets (Aplenzin) recommended for NF Nov 2009	tabs	No
	Selective Reuptake Inhibitors (SSRIs)		
	Fluoxetine weekly (Prozac Weekly)	caps	No
	Fluoxetine in special packaging for premenstrual dysphoric disorder (Sarafem)	caps, tabs	Yes
	Escitalopram (Lexapro)	tabs	No
Paroxetine ER (Paxil CR)	Tabs	No	
Recommended implementation period	60 days for Savella 60 days for Aplenzin Immediate upon signing of the minutes for Bupropion XL (Wellbutrin XL, generics)		

Figures 3 and 4: AD-1s

Utilization - ALL POS Sep 07 – Sep 09



Utilization XL'S - ALL POS Sep 07 – Sep 09

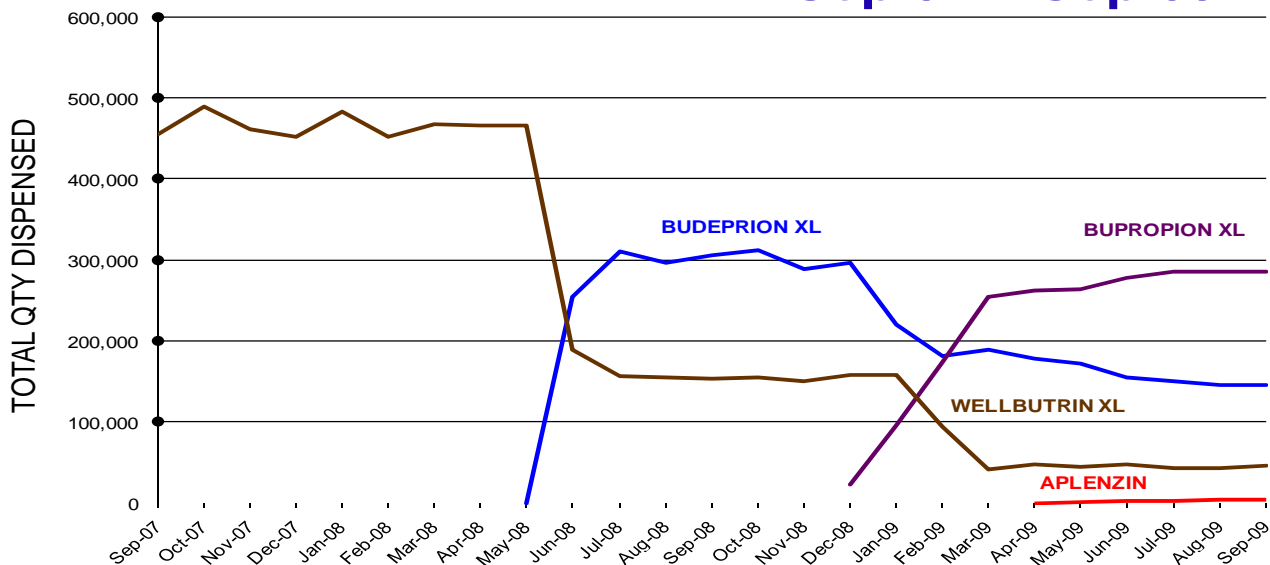


Table 4: Oxybutynin 10% topical Gel (Gelnique): Uniform Formulary Recommendations from Nov 2009 for the Overactive Bladder (OAB) Drugs

Overactive Bladder Drugs			
UF Status / Implementation Period	Generic Name (Brand)	Formulations	Generics Available?
Formulary	Darifenacin (Enablex)	tabs	No
	Oxybutynin IR (Ditropan)	tabs, syrup	Yes
	Oxybutynin ER (Ditropan XL)	tabs	Yes
	Oxybutynin transdermal (Oxytrol)	patch	No
	Solifenacin (Vesicare)	tabs	No
	Tolterodine ER (Detrol LA)	caps	No
	Trospium ER (Sanctura XR)	caps	No
Non-Formulary	Oxybutynin 10 % gel (Gelnique) recommended for NF November 2009	topical gel	No
	Fesoterodine ER (Toviaz)	tabs	No
	Tolterodine IR (Detrol)	tabs	No
	Sanctura IR (Trospium IR)	tabs	No
Recommended implementation period	60 days for Gelnique		

ER: extended release
IR: immediate release

Figure 5: OABs

Utilization - ALL POS Sep 08 – Sep 09

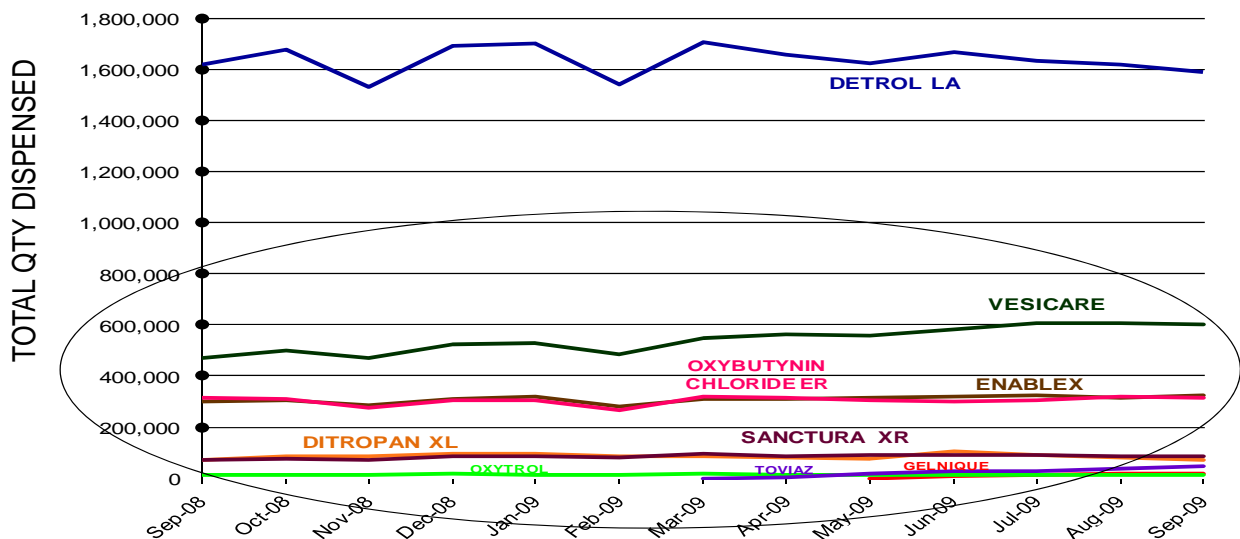


Figure 6: OABs

Con't Utilization - ALL POS Sep 08 – Sep 09

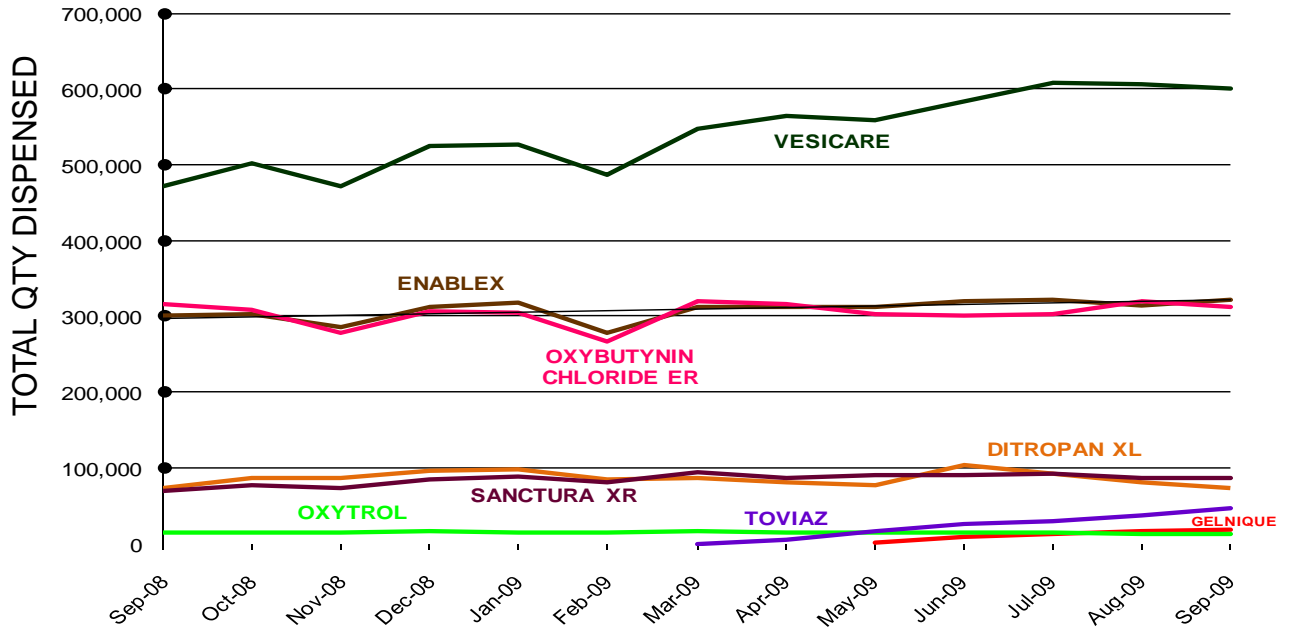


Table 5: Tapendatol (Nucynta) and Tramadol ER (Ryzolt): Uniform Formulary Recommendations from Nov 2009 for the Narcotic Analgesics

Narcotic Analgesics			
Uniform Formulary	High-potency single analgesic agents		
	Long-acting agents (≥ 12 hour duration)		
	Fentanyl transdermal system (Duragesic)	patch	Yes
	Morphine sulfate ER 24 hr (Kadian, Avinza)	cap	No
	Morphine sulfate ER 12 hr (MS Contin, Oramorph)	tab, soln, supp, inj	Yes
	Oxycodone ER (Oxycontin)	tabs	No
	Oxymorphone (Opana ER)	tabs	No
	Short acting agents (<12 hour duration)		
	Codeine	tabs, soln, inj	Yes
	Fentanyl citrate buccal (Fentora)	tabs	No
	Fentanyl citrate transmucosal (Actiq)	lozenges	Yes
	Hydromorphone (Dilaudid)	tab, inj, liquid	Yes, except for 1 mg tab
	Levorphanol (Levo-Dromoran)	tab, inj	Yes
	Meperidine (Demerol)	tab, soln, inj	Yes
	Meperidine / promethazine (Mepergan Fortis)	caps	Yes
	Methadone (Dolophine)	tab, oral conc, soln, inj	Yes
	Morphine sulfate IR	tabs	Yes
	Opium	tincture	Yes
	Opium / belladonna alkaloids	supp	Yes
	Oxycodone IR	caps, oral conc, soln	Yes
	Oxymorphone IR (Opana)	tabs	No
	High-potency combination agents		
	Oxycodone /APAP (e.g., Percocet, Tylox, others)	tab, cap, soln	Yes
	Oxycodone / ASA (Percodan)	tabs	Yes
	Low potency single analgesic agents		
	Buprenorphine (Buprenex)	inj (excludes SL tabs)	Yes
	Butorphanol (Stadol)	nasal spray, inj	Yes
	Pentazocine / naloxone (Talwin NX)	tabs	Yes
	Propoxyphene (Darvon)	caps, tabs	Yes
	Nalbuphine (Nubain) not a controlled substance)	Inj	Yes
	Tramadol IR(Ultram) not a controlled substance	tab	Yes
	Low potency combination agents		
	Codeine / APAP (Tylenol with codeine)	tabs, elixir, oral susp	Yes
Codeine / ASA	tabs	Yes	
Codeine / ASA / carisoprodol (Soma)	tabs	Yes	
Codeine / caffeine / butalbital / APAP (Fioricet with codeine)	caps	Yes	
Codeine / caffeine / butalbital / ASA (Fiorinal with caffeine)	caps, tabs	Yes	
Dihydrocodeine / caffeine / APAP e.g., Panlor DC, Panlor SS)	caps, tabs	Yes	
Dihydrocodeine / caffeine / ASA (Synalgos-DC)	caps	Yes	
Hydrocodone / APAP (Lortab, Lorcet, Vicodin)	caps	Yes	

	Pentazocine / APAP (Talacen)	tabs	Yes
	Propoxyphene / APAP (Darvocet)	tabs	Yes
	Propoxyphene / ASA / caffeine (Darvon Compound 65)	caps	Yes
	Tramadol/APAP (Ultracet) not a controlled substance	tab	Yes
Non-Formulary	Low potency single analgesic agents		
	Tramadol extended release (Ultram ER)	tab	No
	Tramadol extended release (Ryzolt) Recommended for NF Nov 2009	tab	No
	High potency single analgesic agents; short-acting agents (<12 hours duration)		
	Tapentadol (Nucynta) Recommended for NF Nov 2009	tab	No
Recommended implementation period	60 days for Nucynta 60 days for Ryzolt		

Figure 7: Narcotics

Narcotics Utilization By Rx's - ALL POS Sep 07 – Sep 09

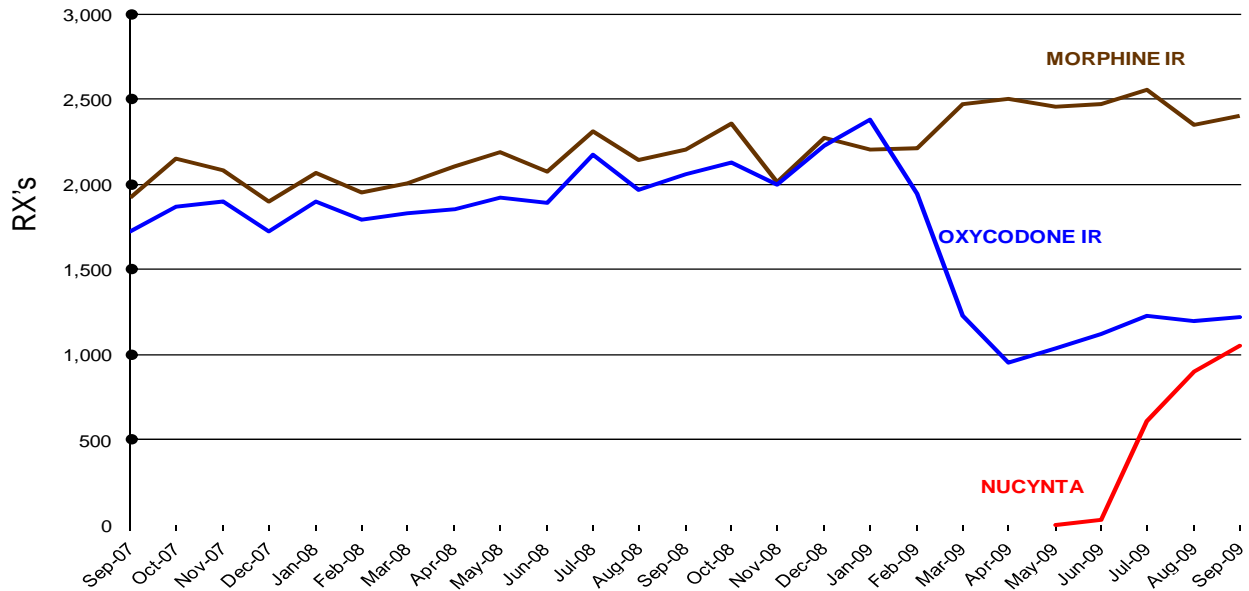


Figure 8: Narcotics

Narcotics Utilization - All POS Sep 07 – Sep 09

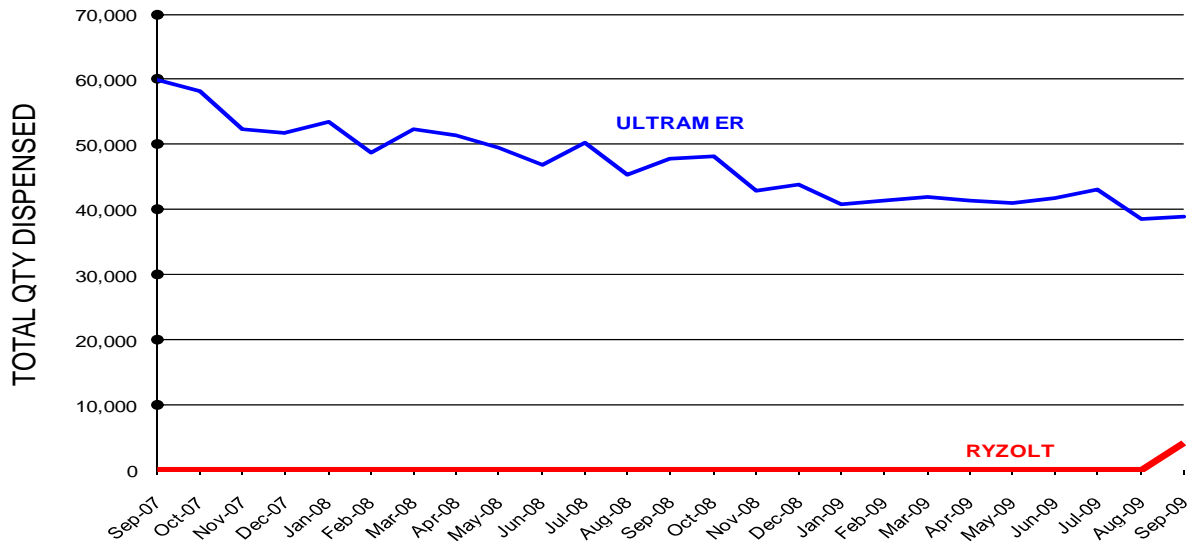


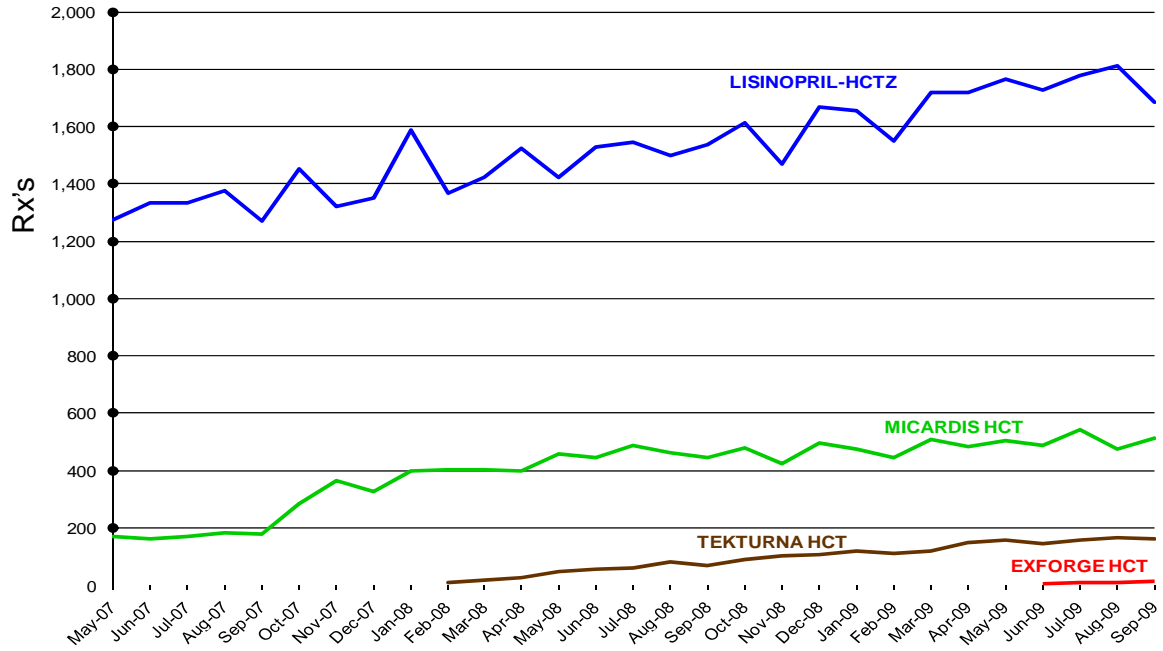
Table 6: Valsartan / Amlodipine / Hydrochlorothiazide (Exforge HCT) Uniform Formulary Recommendations from Nov 2009 for the Renin Angiotensin Antihypertensives (RAAs)

Renin Angiotensin Antihypertensives (RAAs)		
ARB / CCB / Diuretic Combinations	UF	Valsartan /amlodipine / hydrochlorothiazide (Exforge HCT) recommended for UF November 2009
ARB /CCB Combinations	Non-Formulary	Olmesartan / amlodipine (Azor)
		Valsartan / amlodipine (Exforge)
Direct Renin Inhibitors & Combinations	UF	Aliskiren hydrochlorothiazide (Tekturna HCT)
		Aliskiren (Tekturna)
ARBs	UF	Candesartan (Atacand)
		Candesartan /HCTZ (Atacand HCT)
		Losartan (Cozaar)
		Losartan/HCTZ (Hyzaar)
		Telmisartan (Micardis)
		Telmisartan/HCTZ (Micardis HCT)
	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 (Lotensin, Lotensin HCT; generics)
		Captopril and combo with HCTZ (Capoten, Capozide; generics)
		Enalapril and combo with HCTZ (Vasotec, Vaseretic; generics)
		Fosinopril and combo with HCTZ (Monopril, Monopril HCT; generics)
		Lisinopril and combo with HCTZ (Prinivil, Zestril, Prinzide, Zestoretic; generics)
		Trandolapril (Mavik)
	NF	Moexipril (Univasc) and combo with HCTZ (generics)
		Perindopril (Aceon)
		Quinapril (Accupril) and combo with HCTZ (generics)
		Ramipril (Altace; generics))
ACE/CCB Combinations	UF	Amlodipine / benazepril (Lotrel; generics)
	Non-formulary	Felodipine / enalapril (Lexxel) – removed from market
		Verapamil sustained release / trandolapril (Tarka)
Recommended implementation period	Not applicable for Exforge HCT (recommended to retain UF status)	

ACE: Angiotensin Converting Enzyme Inhibitor; ARB: Angiotensin Receptor Blocker; CCB: Calcium Channel Blocker; HCTZ: hydrochlorothiazide

Figure 9: RAAS

Utilization By Rx's – TMOP May 07 – Sep 09



Formulary Implementation Plan Summary – 2009 to present

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	Step Therapy
				MTF	Retail	Mail Order		
Nov 09	PDE-5 Inhibitors for Pulmonary Arterial Hypertension	<ul style="list-style-type: none"> tadalafil (Adcirca) 	56	0	52	4	60 days	No; step for the class for erectile dysfunction
Nov 09	Multiple Sclerosis-Disease Modulating Drugs (last reviewed Aug 2005)	<ul style="list-style-type: none"> Interferon Beta-1b injection (Extavia) <p>Aug 2005: No drugs made Non formulary</p>	0	0	0	0	60 days	No
Nov 09	Antidepressants-1 (reviewed in Nov 2005, Aug 08 [Pristiq])	<p>Nov 09</p> <ul style="list-style-type: none"> bupropion hydrobromide extended release Aplenzin 	1488	1	77	1410	60 days	No
		<p>Nov 09</p> <ul style="list-style-type: none"> milnacipran (Savella) 	91	91	6797	522	60 days	No
		<p>Note: Bupropion hydrochloride extended release (Wellbutrin XL, generics) recommended to move from Non formulary to UF</p>	N/A					
		<p>Aug 08</p> <ul style="list-style-type: none"> desvenlafaxine(Pristiq) <p>Original Meeting Nov 05</p> <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) 	See previous BAP meetings					

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	Step Therapy
				MTF	Retail	Mail Order		
Nov 09	Overactive Bladder Drugs (1 st reviewed Feb 06, updated Aug 08; May 09-Toviaz;)	Nov 09 <ul style="list-style-type: none"> Oxybutynin 10% topical gel 	1998	0	1654	344	60 days	No
		May 09 <ul style="list-style-type: none"> Fesoterodine ER (Toviaz) Update Aug 08; 1st review Feb 06 <ul style="list-style-type: none"> Tolterodine IR (Detrol) Trospium IR (Sanctura) 	See previous BAP meetings					
Nov 09	Narcotic Analgesics (1 st reviewed Feb 2007)	Nov 09 <ul style="list-style-type: none"> Tapentadol (Nucynta) 	4088	3	4055	30	60 days	No
		Nov 09 <ul style="list-style-type: none"> Tramadol ER (Ryzolt) 	1876	52	1761	63	60 days	No
		<ul style="list-style-type: none"> Feb 07 Tramadol ER (Ultram ER) 	See previous BAP meetings					
Nov 09	Renin Antihypertensive Agents (RAAs)	Nov 09 <ul style="list-style-type: none"> Note: Exforge HCT recommended to remain as UF 	N/A					

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	Step Therapy	
				MTF	Retail	Mail Order			
	(reviewed Feb 95, May 07, Nov 07 [Exforge], Jun 08 [Azor])	<p><i>ARB/CCB combos (Jun 08)</i></p> <ul style="list-style-type: none"> ▪ Olmesartan / amlodipine (Azor) Jun 08 ▪ Valsartan/amlodipine (Exforge) Nov 07 ▪ <p><i>ARBs – (May 07 meeting)</i></p> <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) ▪ <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) ▪ 	See previous BAP meetings						
Aug 09	Phosphodiesterase Type 5 Inhibitors (PDE-5 inhibitors) for Erectile Dysfunction	<ul style="list-style-type: none"> ▪ Aug 09; May 07 ▪ sildenafil (Viagra) ▪ tadalafil (Cialis) <p>note: step therapy requiring trial of vardenafil (Levitra) first</p>	14,524 (new users that will hit step)	0	12,086	2438	60 days (30 Dec 2009)	Yes	
Aug 09	Targeted Immunomodulatory Biologics (TIBs)	<p>Aug 09</p> <ul style="list-style-type: none"> ▪ certolizumab (Cimzia) ▪ golimumab (Simponi) <p>Nov 07</p> <ul style="list-style-type: none"> ▪ etanercept (Enbrel) ▪ anakinra (Kineret) 	See previous meeting below	25	149	37	60 days (30 Dec 2009)	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	Step Therapy
				MTF	Retail	Mail Order		
Aug 09	Alpha-1 blocker BPH Agents	Aug 09 ▪ silodosin (Rapaflo) Nov 07 Tamsulosin (Flomax)	695	2	559	134	60 days (30 Dec 2009)	Yes
May 09	Antilipidemic II Agents (LIP-2s)	May 09 ▪ Fenofibrate acid (Trilipix) <i>Update May 07; 1st review May 07</i> ▪ fenofibrate nanocrystallized (Tricor) ▪ fenofibrate micronized (Antara) ▪ omega-3 fatty acids (Omacor) colesevelam (Welchol)	4,037	4	3,128	885	60 days (28 Oct 09)	No
May 09	Overactive Bladder Drugs	May 09 ▪ Fesoterodine ER (Toviaz) <i>Update Aug 08; 1st review Feb 06</i> ▪ Tolterodine IR (Detrol) Trospium IR (Sanctura)	102	1	86	15	60 days (28 Oct 09)	No
May 09	Nasal Allergy Drugs	<i>May 09</i> ▪ Azelastine with Sucralose (Astepro) <i>Original Meeting Nov 08</i> ▪ Beclomethasone (Beconase AQ) ▪ Budesonide (Rhinocort AQ) ▪ Ciclesonide (Omnaris) ▪ Fluticasone Furoate (Veramyst) ▪ Triamcinolone (Nasacort AQ) ▪ Olopatadine (Patanase)	34,271	440	27,017	6,814	60 days (28 Oct 09) 60 (8 Apr 09)	No
May 09	PPIs	<i>May 09</i> ▪ Dexlansoprazole delayed release tabs (Kapidex) <i>May 07 Update; Feb 05 1st review</i> ▪ lansoprazole (Prevacid)	See previous meeting below				60 days (28 Oct 09)	Yes

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	Step Therapy
				MTF	Retail	Mail Order		
		<ul style="list-style-type: none"> ▪ omeprazole/sodium bicarbonate (Zegerid) ▪ pantoprazole (Protonix) ▪ rabeprazole (Aciphex) 						
May 09	Antiemetics	<i>May 09</i> <ul style="list-style-type: none"> ▪ Granisetron transdermal system (Sancuso) <i>Original Meeting May 06</i> <ul style="list-style-type: none"> ▪ Dolasetron (Anzemet) 	852	14	668	170	60 days (28 Oct 09) 27 Sept 06 (60 days)	No
Feb 09	Inhaled Corticosteroids	<ul style="list-style-type: none"> ▪ 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 (1 Sep 09)	No
Feb 09	Long-Acting Beta Agonists	<ul style="list-style-type: none"> ▪ Formoterol inhalation solution (Perforomist) 	109	2	44	63	120 (1 Sep 09)	No
Feb 09	Inhaled Corticosteroids / Long-Acting Beta Agonist Combinations	<ul style="list-style-type: none"> ▪ (no drugs made non-formulary) 	N/A	N/A	N/A	N/A	N/A	N/A