Uniform Formulary Beneficiary Advisory Panel Handout
February 2006

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 Class Review.

Table 1: UNIFORM FORMULARY RECOMMENDATIONS FOR THE OVERACTIVE BLADDER DRUGS (OABs), MISCELLANEOUS ANTI-HYPERTENSIVE DRUGS, AND GABA ANALOG DRUGS (GABAs)

Overactive Bladder Drugs (OABs)	
Uniform Formulary	Tolterodine sustained release (Detrol LA)
	Oxybutynin sustained release (Ditropan XL)
	Oxybutynin immediate release (generics)
	Solifenacin (Vesicare)
	Darifenacin (Enablex)
Non-Formulary	Tolterodine immediate release (Detrol)
	Oxybutynin transdermal patch (Oxytrol)
	Trospium (Sanctura)
Miscellaneous Anti-hypertensive Drugs	
Uniform Formulary	Amlodipine / benazepril (Lotrel)
	Clonidine (generics)
	Clonidine transdermal patch (Catapress-TTS)
	Hydralazine (generics)
	Minoxidil (generics)
	Methyldopa (generics)
	Guanabenz, guanfacine, prazosin, reserpine, guanadrel, guanethidine, mecamylamine (all available generically)
Non-Formulary	Felodipine / enalapril (Lexxel)
	Verapamil sustained release / trandolapril (Tarka)
GABA Analog Drugs (GABAs)	
Uniform Formulary	Gabapentin (generics)
	Tiagabine (Gabitril)
Non-Formulary	Pregabalin (Lyrica)

Note: Drugs with a trade name listed in parentheses are not available in generic formulations
These classes do not have prior authorization criteria or quantity limits that apply.

OVERACTIVE BLADDER DRUGS (OAB)

Table 2: Overactive Bladder Drugs generic and trade names

Note: All are approved for treating symptoms of overactive bladder, including urge incontinence

Generic Name	Brand Name (Manufacturer)	Generics available	Strengths & formulations	FDA approval date
Oxybutynin immediate release	generics	Yes	5 mg tabs; 5 mg/mL syrup	1975
Oxybutynin sustained release	Ditropan XL	No	5 mg, 10 mg, 15 mg ER tabs	1999
Oxybutynin transdermal patch	Oxytrol	No	3.9 mg/day patch	2003
Tolterodine immediate release	Detrol	No	1mg, 2 mg tabs	1998
Tolterodine sustained release	Detrol LA	No	2 mg, 4 mg caps	2000
Trospium	Sanctura	No	20 mg tabs	2004 (May)
Solifenacin	Vesicare	No	5 mg, 10 mg tabs	2004 (Nov)
Darifenacin	Enablex	No	7.5, 15 mg ER tabs	2004 (Dec)

Figure 1: Military Health System (MHS) All OAB Rxs, Jan 04 – Dec 05

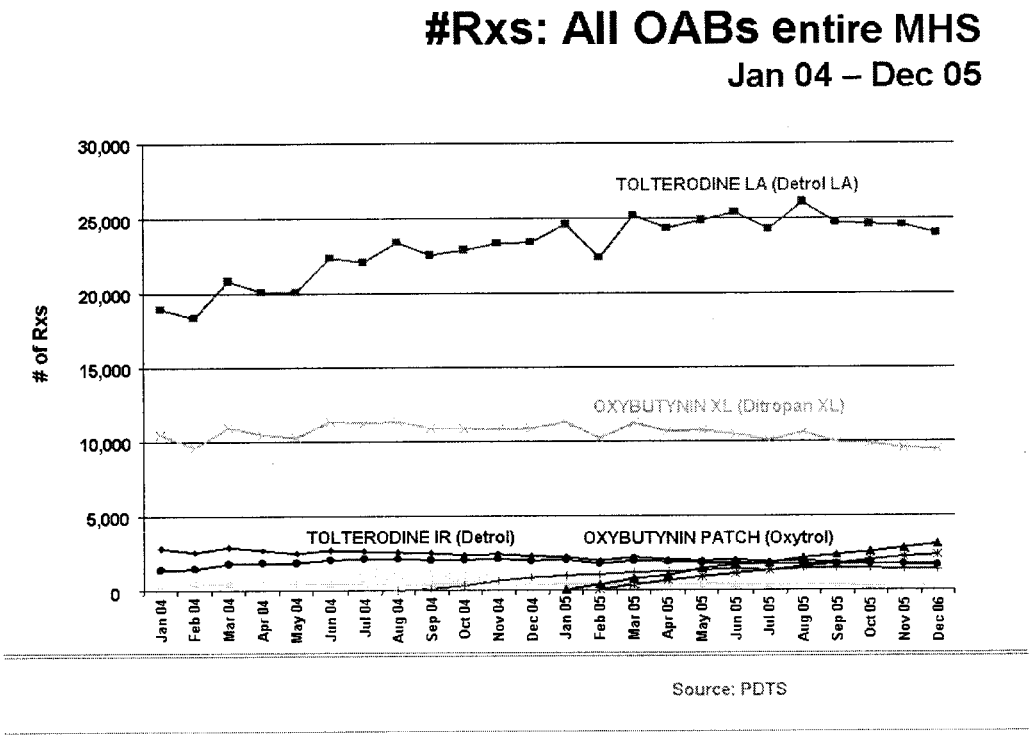
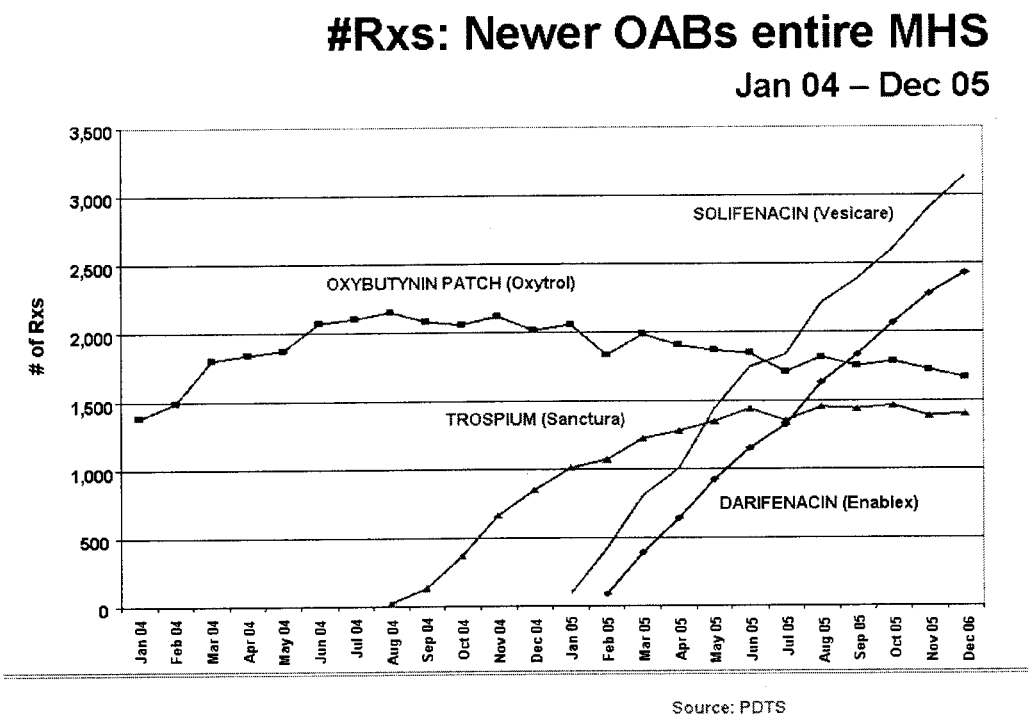


Figure 2: Military Health System (MHS) Newer OAB Rxs, Jan 04 – Dec 05



Source: PDTS

MISCELLANEOUS ANTI-HYPERTENSIVE DRUGS

Table 3: Miscellaneous anti-hypertensive drugs generic and brand names

Note: All are approved for treating high blood pressure

Generic	Brand (Manufacturer)	Generics available	FDA approval date
ACE inhibitor / Calcium Channel Blocker Combinations			
Amlodipine + benazepril	**Lotrel**	No	1995
Felodipine + enalapril	**Lexxel**	No	1996
Verapamil sustained release + trandolapril	**Tarka**	No	1996
Vasodilators (direct acting)			
Hydralazine	Apresoline	Yes	1951
Minoxidil	Loniten	Yes	1979
Centrally acting α-2 agonists			
Clonidine tablets **Clonidine transdermal patch**	**Catapress** **Catapres TTS**	Yes No	1960s 1984
Methyldopa	Aldomet	Yes	1962
Guanabenz	Wytensin	Yes	1982
Guanfacine	Tenex	Yes	1986
Peripheral α-1 antagonists			
Prazosin	Minipress	Yes	1976
Adrenergic antagonists			
Reserpine	N/A	Yes	1949
Guanadrel	Hylorel	Yes	1982
Guanethidine	N/A	Yes	1959
Ganglionic Blockers			
Mecamylamine	Inversine	No	1950s, 2002

Figure 3: MHS Miscellaneous Anti-Hypertensive Drugs ACE inhibitor / Calcium Channel Blocker subclass Rxs, Feb 05 – Jan 06

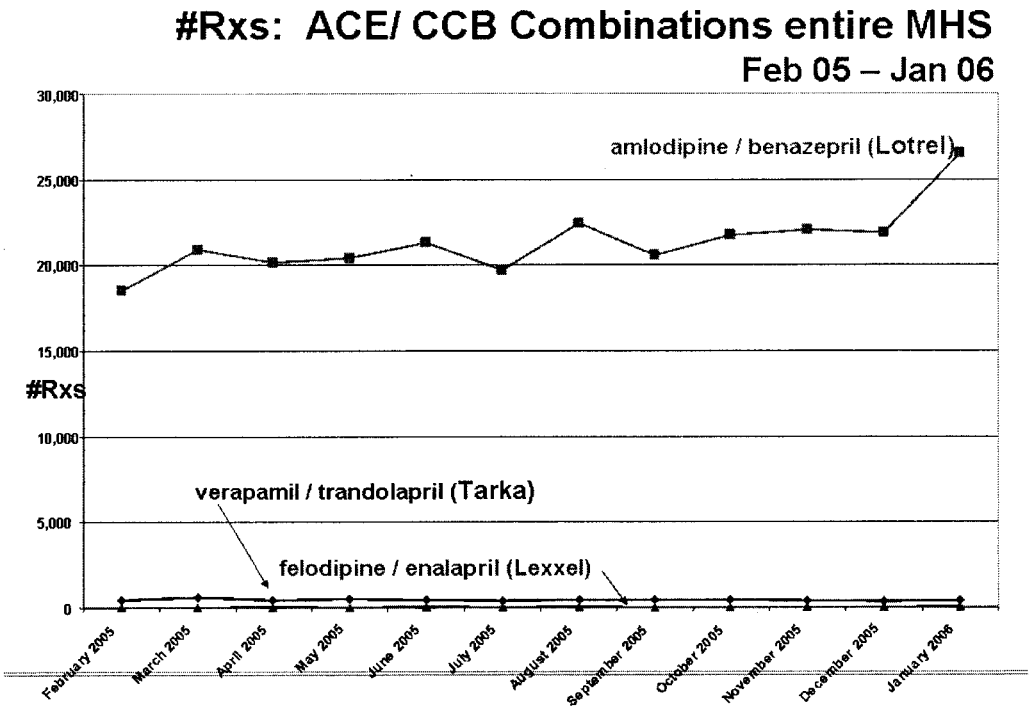


Figure 4: MHS Miscellaneous Anti-Hypertensive Agents Rxs, Nov 04 – Oct 05

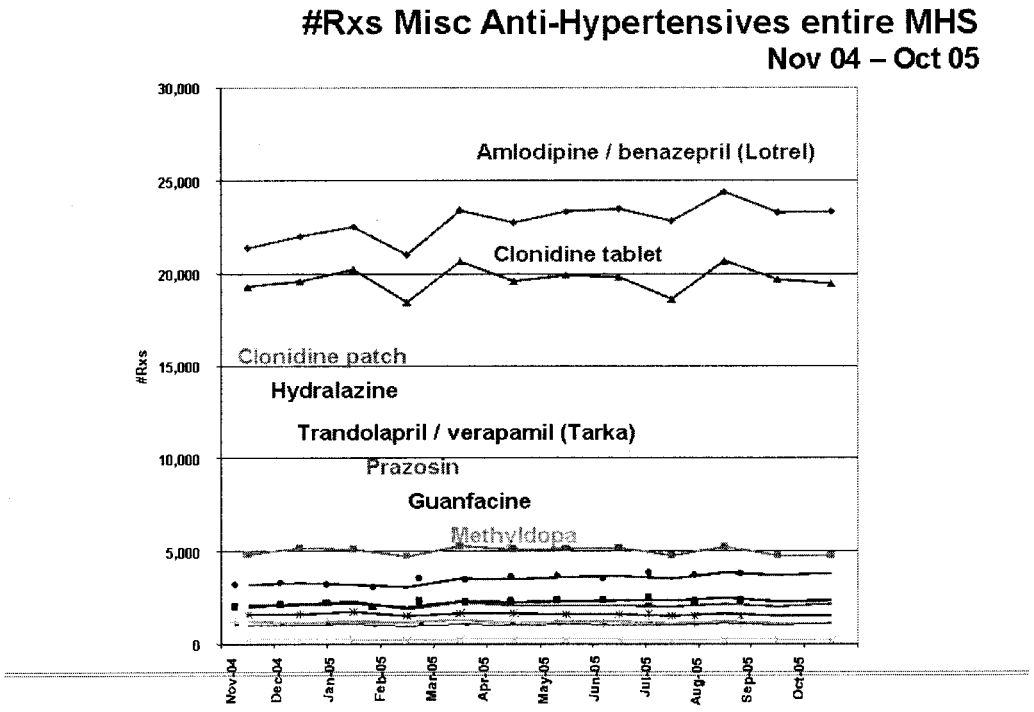


Figure 5: Evaluation of drugs based on both cost and effectiveness

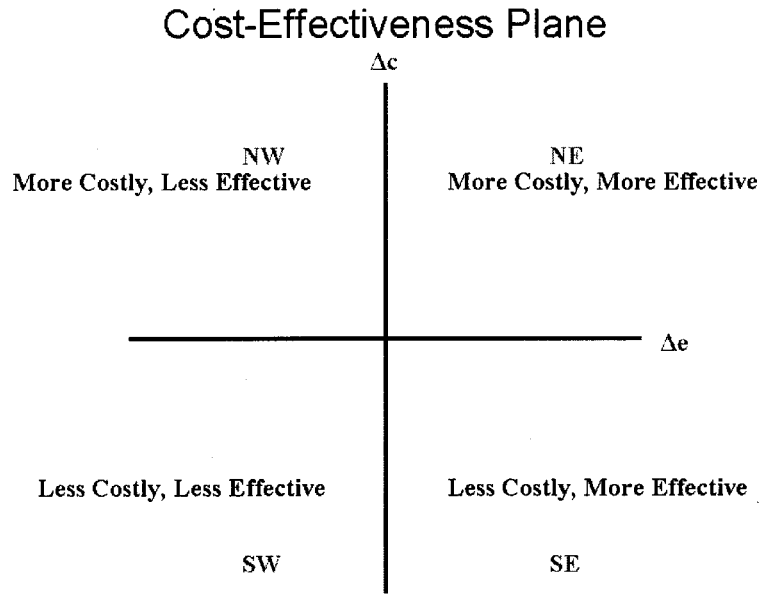
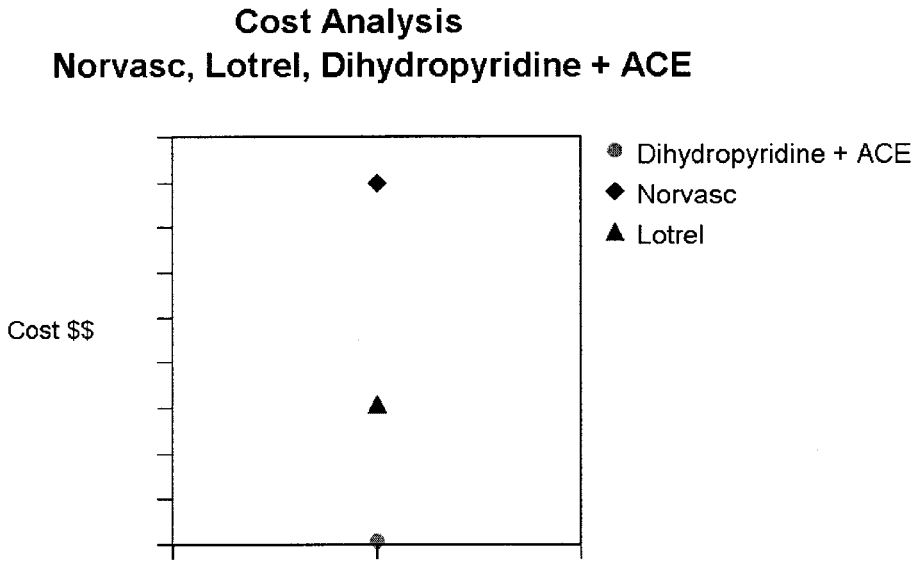


Figure 6: Miscellaneous antihypertensive agents cost analysis: comparison of the ACE inhibitor / calcium channel blocker combination products with Norvasc (Amlodipine)



GABA ANALOG DRUGS (GABAs)

Table 4: GABA analog drugs generic and trade names

Generic Name	Trade Name	Available in generics	Strength and Formulation	FDA Approval Date
Gabapentin	generics	Yes (except for syrup)	100, 300, 400 mg capsules 600, 800 mg tablets 250 mg /5 mL oral solution	December 1993 Generics available Oct 2004
Pregabalin	Lyrica	No	25, 50, 75, 100, 150, 200, 225, 300 mg capsules	December 2004
Tiagabine	Gabitril	No	2, 4, 12, 16 mg capsules 2 mg/mL oral solution	April 1999

Table 5: GABA analogs FDA-approved indications and clinical evidence supporting efficacy

Generic Name / Trade Name	Shingles (Post herpetic neuralgia)	Diabetic Nerve Pain (Diabetic Neuropathy)	Other types of neuropathic (nerve) pain	Partial Seizures in Adults	Partial Seizures in Children**
Gabapentin (generics)	√	Evidence*	Evidence*	√	√
Pregabalin (Lyrica)	√	√	No published studies	√	No published studies in children
Tiagabine (Gabitril)	No published studies	No published studies	Anecdotal evidence	√	√

√: FDA-approved

* Not approved by the FDA, but clinical evidence supports efficacy

** Gabapentin is approved for seizures in children 3 years of age and older; tiagabine is approved for seizures in children older than 12 years of age

Figure 7: MHS GABA Analog drugs Unique Utilizers, Feb 05 – Dec 05

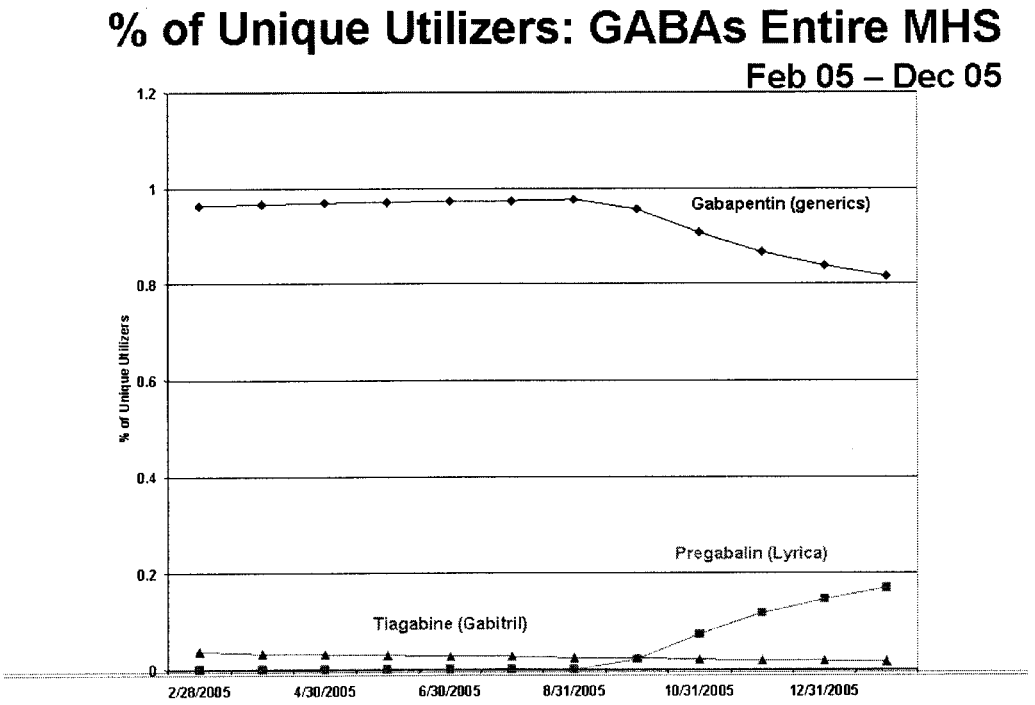
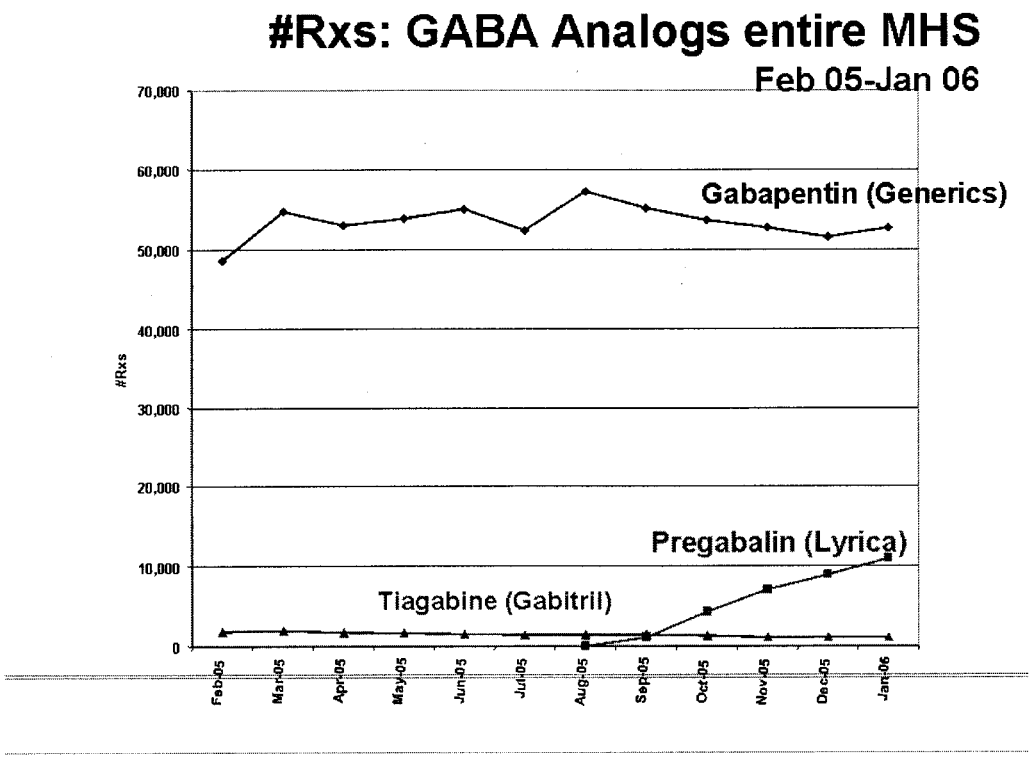


Figure 8: MHS GABA analog drugs Rxs, Nov 04 – Oct 05



UNIFORM FORMULARY IMPLEMENTATION PLAN SUMMARY

Table 6: Uniform Formulary Implementation Plan Summary

Drug Class	Total Number of Beneficiaries Affected	Beneficiaries Affected by POS	Implementation Plan (First Wednesday after X days after the final decision date)	Implementation Date	Justification
Proton Pump Inhibitors	138,739 (13% of patients receiving PPIs)	MTF: 6,691 Retail: 117,520 Mail: 14,528	90-Days	17 Jul 05	Based on the substantial number of beneficiaries
Angiotensin Receptor Blockers	2,184 (0.5% of patients receiving ARB)	MTF: 13 Retail: 1,644 Mail: 527	90-Days	17 Jul 05	Recommended 30-day implementation overturned; 90-day BAP recommendation accepted
Phosphodiesterase Inhibitors	128,007 (90% of patients receiving a PDE-5 Inhibitor)	MTF: 55,161 Retail: 49,850 Mail: 22,996	90-Days	12 Oct 05	Based on the substantial number of beneficiaries
Topical Antifungals	49,743 (13 % of patients receiving a Topical Antifungal)	MTF: 14,266 Retail: 33,430 Mail: 2,047	30-Days	17 Aug 05	Medication used to treat acute (rather than chronic) infections, not likely to require therapy change
Multiple Sclerosis Disease Modifying Drugs	0	MTF: 0 Retail: 0 Mail: 0	N/A	14 Jul 05	No medications moved to the non-formulary status on UF.
Angiotensin Converting Enzyme Inhibitors	158,101 (21% of patients receiving a ACE Inhibitor)	MTF: 77,159 Retail: 57,982 Mail: 22,959	120-Days	16 Feb 06	Based on the substantial number of beneficiaries
Calcium Channel Blockers	274,616 (73% of patients receiving a CCB)	MTF: 133,794 Retail: 101,345 Mail: 39,477	150-Days	15 Mar 06	Based on the substantial number of beneficiaries
Alpha-Blockers	89,926 (46 % of patients receiving an Alpha-Blocker)	MTF: 26,692 Retail: 47,674 Mail: 15,560	120-Days	15 Feb 06	Based on the substantial number of beneficiaries

Drug Class	Total Number of Beneficiaries Affected	Beneficiaries Affected by POS	Implementation Plan (First Wednesday after X days after the final decision date)	Implementation Date	Justification
Alzheimer's Disease Drugs	5	MTF: 0 Retail: 3 Mail: 2	90-Days	19 Apr 06	Based on low number of beneficiaries
Nasal Corticosteroids	96,999	MTF: 13,556 Retail: 73,381 Mail: 10,062	90-Days	19 Apr 06	Based on the substantial number of beneficiaries
Antidepressants (Part 1)	182,916 (21.34% of patients receiving an anti-depressant)	MTF: 52,624 Retail: 118,582 Mail: 11,710	180-Days	19 Jul 06	Based on the substantial number of beneficiaries
Macrolide/Ketolide Antibiotics	**	**	60-Days	22 Mar 06	Based on the low number of beneficiaries
Overactive Bladder Drugs	19,118	MTF: 2,596 Retail: 13,471 Mail: 3,051	60-days	*	Based on the low number of beneficiaries
Miscellaneous Anti-hypertensive Agents	5,946	MTF: 336 Retail: 4,472 Mail: 1,138	60-Days	*	Based on the low number of beneficiaries
GABA-Analogs	30,649	MTF: 1,120 Retail: 27,566 Mail: 1,963	60-Days	*	Based on the low number of beneficiaries

*: Implementation dates unknown, as final Feb 2006 DoD P&T Meeting minutes have not been signed as of 13 March 06

**: # of Beneficiaries not provided, as macrolides/ketolide antibiotics are used to treat acute infections, not chronic diseases. #Rxs dispensed from Fiscal Year 2005 is provided below:

Zmax: MTF: 93 Rxs; Retail: 47,000 Rxs; Mail: 79 Rxs

Telithromycin: MTF: 0 Rxs; Retail: 2,103 Rxs; Mail: 0 Rxs