Uniform Formulary Beneficiary Advisory Panel Handout
December 2005

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 ALZHEIMER'S DRUGS, NASAL STEROIDS, ANTIDEPRESSANTS (PART 1), AND MACROLIDE /KETOLIDE ANTIBIOTICS

Alzheimer's drugs	
Uniform Formulary	Donepezil (Aricept)
	Rivastigmine (Exelon)
	Galantamine (Razadyne, Reminyl)
	Memantine (Namenda)
Non-Formulary	Tacrine (Cognex)
Nasal Steroids	
Uniform Formulary	Flunisolide (Nasarel)
	Fluticasone propionate (Flonase)
	Mometasone furoate (Nasonex)
Non-Formulary	Beclomethasone dipropionate (Beclovent AQ, Vancenase AQ/DS)
	Budesonide (Rhinocort AQ)
	Triamcinolone acetonide (Nasacort AQ)
Antidepressants (Part 1)	
Formulary	**Selective Serotonin Reuptake Inhibitors (SSRI)**
	Fluoxetine (excludes Prozac Weekly, Sarafem)
	Citalopram
	Paroxetine HCl immediate release, paroxetine mesylate
	Sertraline (Zoloft)
	Fluvoxamine
	Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)
	Venlafaxine (Effexor, Effexor XR)
	Serotonin-Antagonist/Reuptake Inhibitors (SARIs)
	Nefazodone
	Trazodone
	Norepinephrine and Dopamine Reuptake Inhibitors (NDRIs)
	Bupropion immediate release, bupropion sustained release
	Alpa-2 Receptor Antagonists
	Mirtazapine
Non-Formulary	**Selective Serotonin Reuptake Inhibitors (SSRI)**
	Fluoxetine weekly (Prozac Weekly)
	Fluoxetine in special packaging for premenstrual dysphoric disorder (Sarafem)
	Escitalopram (Lexapro)
	Paroxetine HCl Controlled release (Paxil CR)
	Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)
	Duloxetine (Cymbalta)
	Norepinephrine and Dopamine Reuptake Inhibitors (NDRIs)
	Bupropion extended release (Wellbutrin XL)
Macrolides/Ketolide Antibiotics	
Uniform Formulary	Azithromycin (Excludes Zmax)
	Clarithromycin (all formulations; IR, SR)
	Erythromycin (all oral salts and bases)
Non-Formulary	Azithromycin 2 gm extended release suspension (Zmax)
	Telithromycin (Ketek)

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.**

ANTIDEPRESSANTS (PART 1)

Table 2: ANTIDEPRESSANTS I – GENERIC AND BRAND NAMES

Generic Name	Brand Name (Manufacturer)	Generics Available	Initial FDA approval date
Selective Serotonin Reuptake Inhibitors (SSRIs)			
Citalopram	Celexa	yes	17 July 98
Escitalopram	Lexapro (Forest)	no	14 Aug 02
Fluoxetine	Prozac (Lilly)	yes	29 Dec 87
Fluoxetine 90 mg caps (weekly regimen)	Prozac Weekly (Lilly)	no	26 Feb 01
Fluoxetine (special packaging)	Sarafem (Lilly)	no	6 Jul 00
Fluvoxamine	Generics only*	yes	5 Dec 94
Paroxetine HCl	Paxil (GSK)	yes	29 Dec 92
Paroxetine HCl controlled release	Paxil CR (GSK)	no	16 Feb 99 (02 launch)
Paroxetine mesylate	Pexeva (Synthon)	no	11 Mar 02
Sertraline	Zoloft (Pfizer)	no	30 Dec 91
Serotonin – Norepinephrine Reuptake Inhibitors (SNRIs)			
Duloxetine	Cymbalta (Lilly)	no	3 Aug 04
Venlafaxine immediate release	Effexor (Wyeth)	yes	28 Dec 93
Venlafaxine extended release	Effexor XR (Wyeth)	no	20 Oct 97
Serotonin-2 Antagonist/Reuptake Inhibitors (SARIs)			
Nefazodone	Generics only*	no	22 Dec 94
Trazodone	Desyrel	yes	24 Dec 81
Norepinephrine and Dopamine Reuptake Inhibitors (NDRIs)			
Bupropion	Wellbutrin	yes	30 Dec 85
Bupropion sustained release	Wellbutrin SR	yes	4 Oct 96
Bupropion extended release	Wellbutrin XL	no	28 Aug 03
Alpha-2 Receptor Antagonists			
Mirtazapine tablets	Remeron	yes	14 Jun 96
Mirtazapine ODT	Remeron SolTab,	yes	12 Jan 01

ODT = Orally disintegrating tablets; MDD = Major Depressive Disorder, GAD = Generalized Anxiety Disorder, OCD = Obsessive Compulsive Disorder, PD = Panic Disorder, PTSD = Posttraumatic Stress Disorder, PMDD = Premenstrual Dysphoric Disorder; SAD = Social Anxiety Disorder; DPNP = Diabetic Peripheral Neuropathic Pain

*Name brand nefazodone (Serzone) and fluvoxamine (Luvox) have been withdrawn from the U.S. market. Generic versions remain available.

TABLE 3: ANTIDEPRESSANTS 1 – FDA-APPROVED INDICATIONS (AS OF JULY 2005) AND CLINICAL EVIDENCE SUPPORTING EFFICACY

	MDD	GAD	OCD	PD	PMDD	PTSD	SAD	Bulimia	DPNP
Citalopram	X		*	*	*				
Escitalopram	X	X		*			*		
Fluoxetine	X Ped		X Ped	X	X**	*		X	
Fluvoxamine			X Ped				*	*	
Paroxetine	X	X	X	X	X	X	X		
Sertraline	X	*	X Ped	X	X	X	X		
Duloxetine	X								X
Venlafaxine	X	X		*	*		X		
Nefazodone	X								
Trazodone	X								
Bupropion	X								
Mirtazapine	X								

* Not FDA-indicated, but fair to good clinical evidence supports efficacy
** as Sarafem
Ped = pediatric labeling
MDD = Major Depressive Disorder, GAD = Generalized Anxiety Disorder, OCD = Obsessive Compulsive Disorder, PD = Panic Disorder, PTSD = Posttraumatic Stress Disorder, PMDD = Premenstrual Dysphoric Disorder; SAD = Social Anxiety Disorder; DPNP = Diabetic Peripheral Neuropathic Pain

Table 4: TOTAL NUMBER OF AD1 PRESCRIPTIONS DISPENSED AT MHS POINTS OF SERVICE, FY05

	Mail Order	MTF	Retail	Total
Citalopram	16,056	155,105	127,843	**299,004**
Escitalopram (Lexapro)	38,536	166,846	426,557	**631,939**
Fluoxetine IR	24,417	198,496	222,406	**445,319**
Fluoxetine 90-mg caps (Prozac Weekly)	636	197	7,336	**8,169**
Fluoxetine special packaging (Sarafem)	381	5	5,584	**5,970**
Fluvoxamine	567	1,259	9,896	**11,722**
Paroxetine HCl IR	20,917	160,085	204,408	**385,410**
Paroxetine mesylate IR	124		1,398	**1,522**
Paroxetine HCl CR (Paxil CR)	6,733	12,002	75,685	**94,420**
Sertraline (Zoloft)	47,083	369,132	407,714	**823,929**
Duloxetine (Cymbalta)	7,236	9,458	104,568	**121,262**
Venlafaxine IR (Effexor)	1,758	10,104	20,355	**32,217**
Venlafaxine ER (Effexor XR)	24,111	167,165	246,019	**437,295**
Nefazodone	1,134	2,904	8,697	**12,735**
Trazodone	17,783	141,107	186,096	**344,986**
Bupropion IR and SR	11,432	154,828	113,059	**279,319**
Bupropion ER (Wellbutrin XL)	14,524	60,258	187,550	**262,332**
Mirtazapine	7,944	19,971	113,055	**140,970**
Total	241,372	1,628,922	2,468,226	**4,338,520**

Figure 1: MHS AD1 Rxs by Subclass, Oct 02 – Oct 05

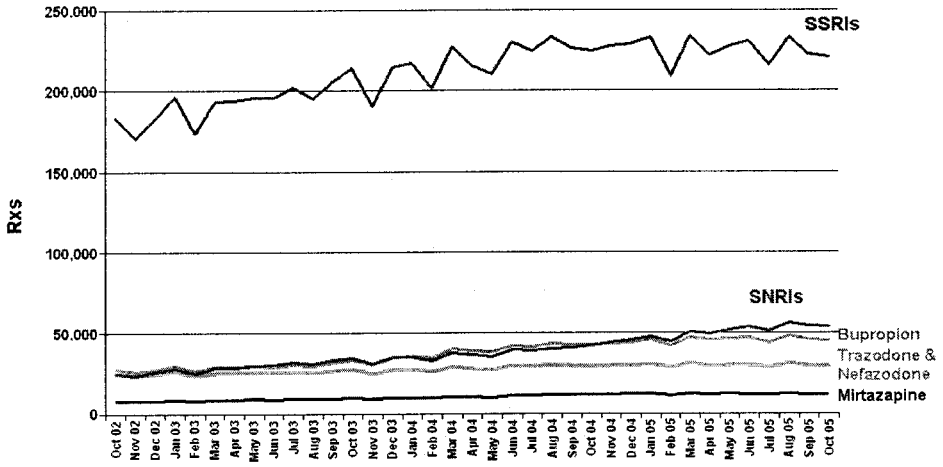


Figure 2: MHS SSRI Rxs by Medication, Oct 02 – Oct 05

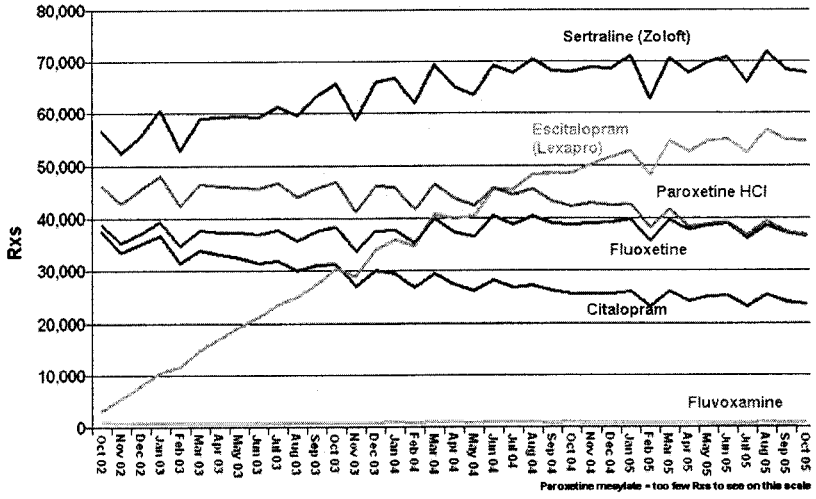


Figure 3: MHS SNRI Rxs by Medication, Oct 02 – Oct 05

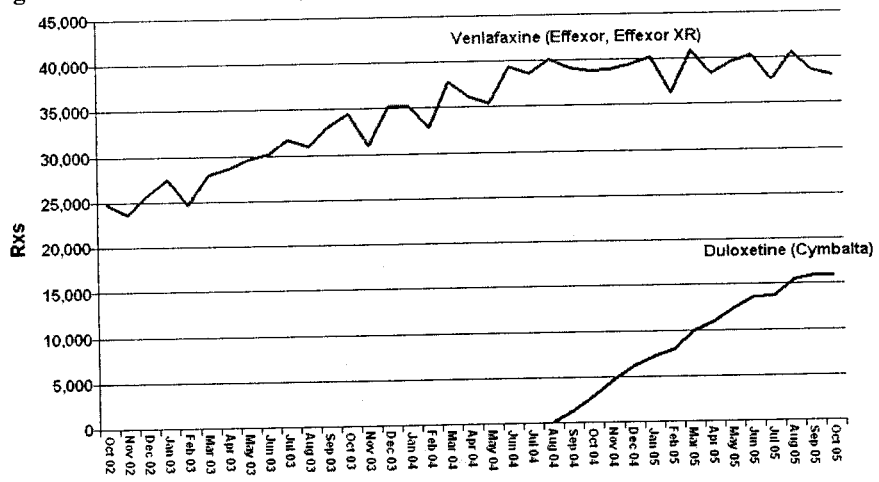


Figure 4: MHS Paroxetine Rxs by Formulation, Oct 02 – Oct 05

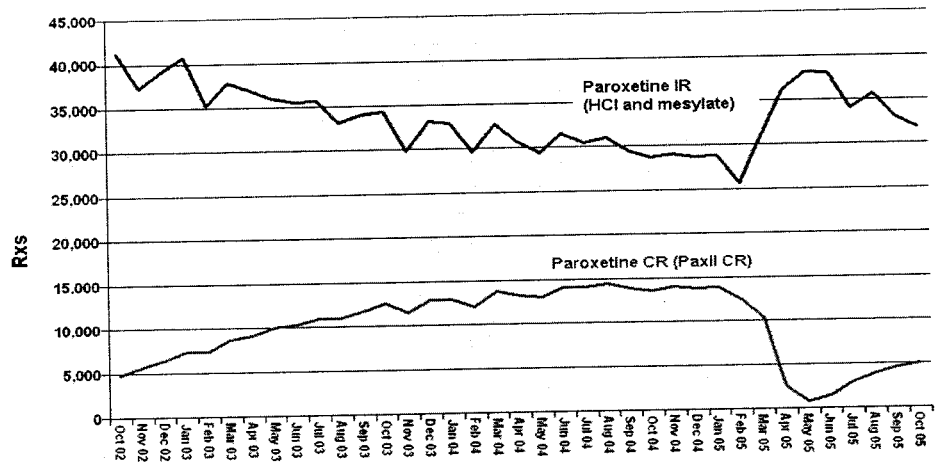


Figure 5: MHS Fluoxetine Rxs by Formulation, Oct 02 – Oct 05

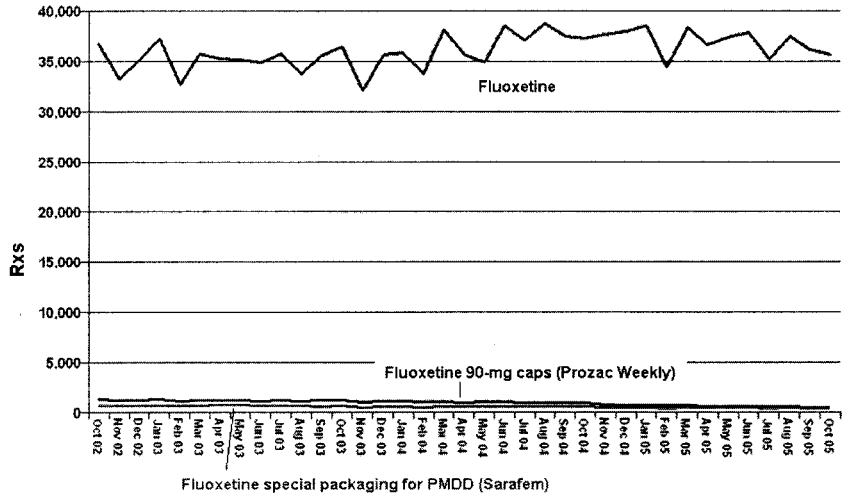


Figure 6: MHS Bupropion Rxs by Formulation, Oct 02 – Oct 05

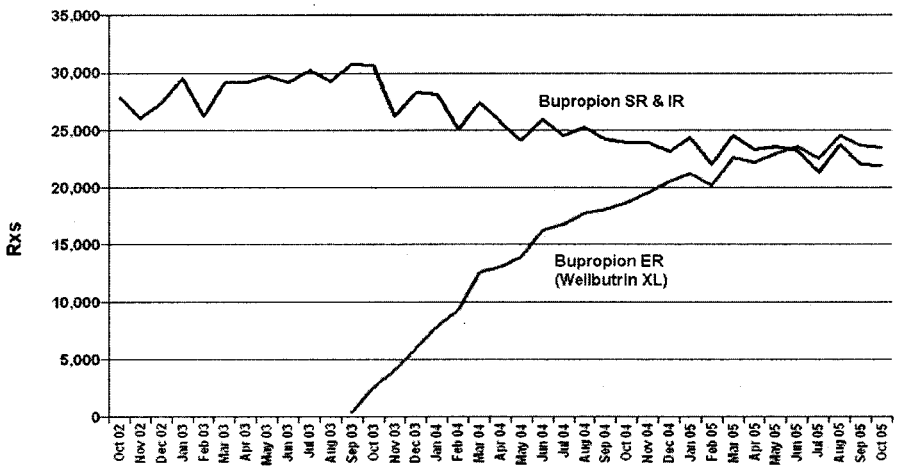


Figure 7: MHS Macrolide/Ketolide Antibiotic Utilization

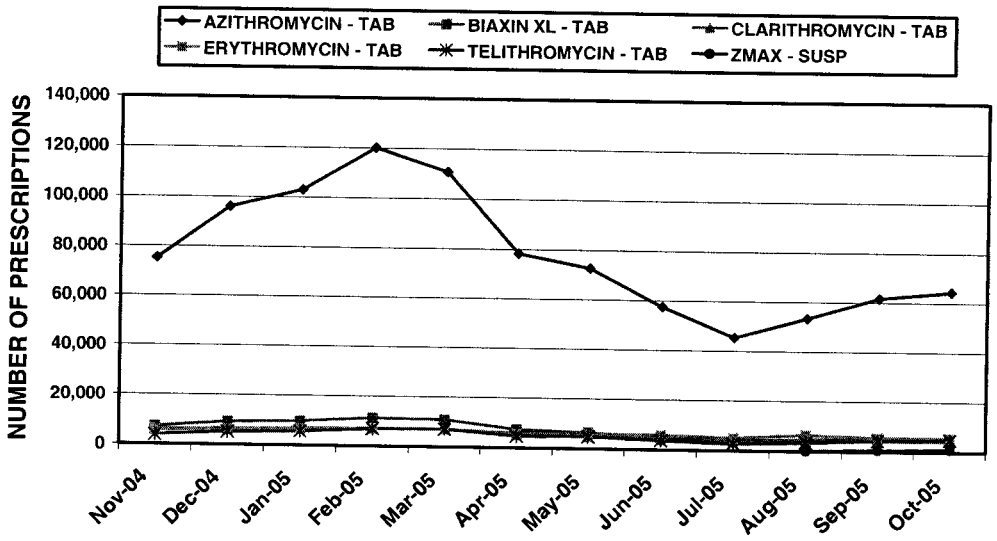


Table 5: Macrolides/Ketolide Antibiotics Available In the U.S.

Generic	Brand (Manufacture)	Generics Available	Strengths & Formulations
Azithromycin	Zithromax; (Pfizer, generics)	Yes (tablets only)	Tablets: 250 mg, 500 mg; 600 mg Suspension: 100 mg/5 ml, 200 mg/5 ml; 1 gm/packet
Azithromycin	Zmax, (Pfizer)	No	Suspension: 2gm XL (extended release suspension) one-time dose
Clarithromycin	Biaxin; (Abbott, generics)	Yes	Tablets: 250 mg, 500 mg Suspension: 125 mg/5 ml, 250 mg/5 ml
Clarithromycin	Biaxin XL, (Abbott)	No	Tablet: 500 mg
Erythromycin[a]	ERYC, PCE, E-MYCIN, ERY-TAB, E-BASE, E.E.S, E.E.S 200, E.E.S 400, Pediamycin, Pediamycin 400, ERYPED, Erythrocin stearate, Pediazole[b] (Abbott, generics)	Yes	Tablets: 250 mg, 333 mg; 400 mg, 500 mg Suspensions: 125 mg/5 ml, 200 mg/5 ml; 250 mg/5 ml, 400 mg/5 ml 200 mg/5 ml;600 mg/5 ml
Telithromycin	Ketek (Sanofi-Aventis)	No	400mg tablet

a: includes all esters/salts: base, estolate, stearate, ethylsuccinate
b: 200 mg/5 ml;500 mg/5 ml: erythromycin ethylsuccinate and sulfisoxazole acetyl

Table 6: Clinical Comparisons of Macrolides/Ketolide Antiobotics

Clinical Characteristic	Azithromycin	Zmax	Cl IR	Cl ER	Erythromycin	Telithromycin
Indications						
CAP	Yes	Yes	Yes	Yes	Yes[a]	Yes[b]
ABECB	Yes	No[c]	Yes	Yes	Yes[a]	Yes
ABS	Yes	Yes	Yes	Yes	Yes[a]	Yes
Acute Pharyngitis	Yes	No	Yes	Yes	Yes[a]	No[c]
AOM	Yes	No	Yes	No	Yes[a]	No
H. pylori	No[c]	No	Yes	No	No	No
MAC	Yes	No	Yes	No	No	No
Dosing	Daily	Once	Twice daily	Daily	Twice to Four times daily	Daily
Days of treatment	3-5	1	7-14	7-14	7-21	5-10
Pregnancy	B	B	C	C	B	C
Pediatrics	Yes	No	Yes	No	Yes	No
Gastrointestinal Adverse Effects	+	++	+	+	+++	++
Drug Interactions	+	+	+++	+++	+++	+++

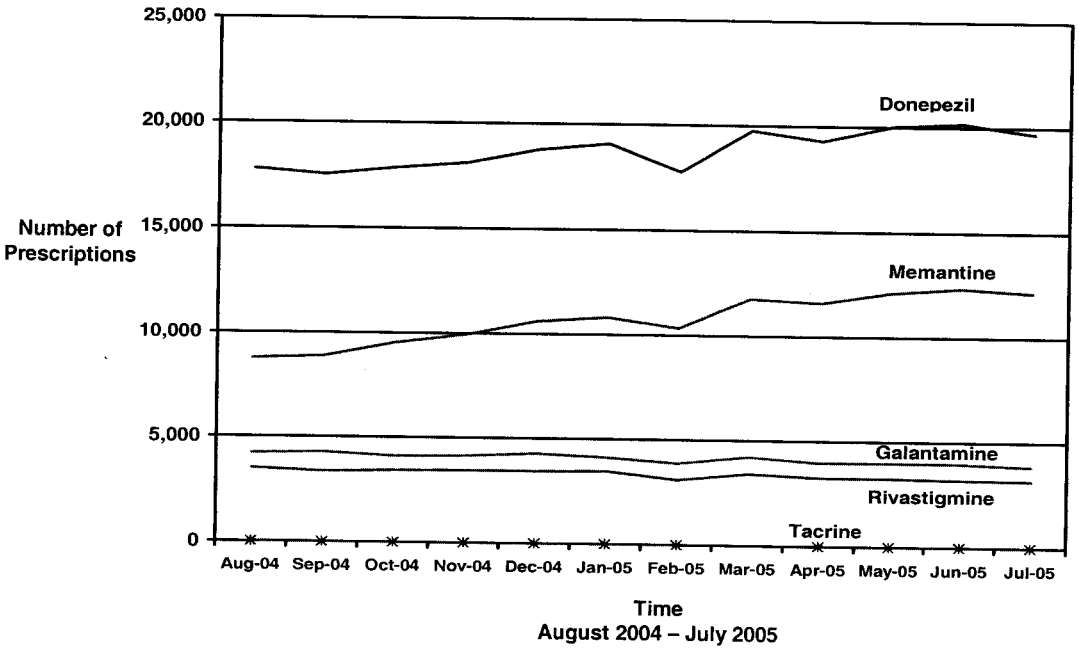
Az: azithromycin, Cl IR: clarithromycin immediate release, Cl ER: clarithromycin extended release, E: erythromycin, Tel: Telithromycin, CAP: community acquired pneumonia, ABECB: acute bacterial exacerbation of chronic bronchitis, ABS: acute bacterial sinusitis, AOM: acute otitis media, MAC: *Mycobacterium avium* complex
+: low
++: moderate
+++: high
a: official indication: upper and lower respiratory tract infections
b: indicated for multi-drug resistant *Streptococcus pneumoniae*
c: has been evaluated and shown to be efficacious

DRUGS FOR ALZHEIMER'S DISEASE (AZ)

Table 7: Cholinesterase† and (N-methyl D-aspartate) NMDA§ inhibitors available in the U.S, and their FDA-Indications

Generic Name	Brand (Manufacturer)	Strengths & formulations	FDA approval date	FDA Indications
Tacrine†	Cognex (First Horizon)	10mg, 20mg, 30 mg 40 mg capsules	09/09/1993	Mild to Moderate AD
Donepezil†	Aricept (Pfizer/Eisai)	5mg, 10mg tablets 5mg, 10 mg ODT 5mg/5ml oral solution	11/25/1996	Mild to Moderate AD
Rivastigmine†	Exelon (Novartis)	1.5mg, 3mg, 4.5mg 6mg capsules 2mg/ml oral solution	4/21/2000	Mild to Moderate AD
Galantamine†	Reminyl / Razadyne, Razadyne ER (Janssen)	4mg, 8mg, 12mg tablets 4mg/ml oral solution 8mg, 16mg, 24mg extended release tablets	2/28/2001	Mild to Moderate AD
Memantine§	Namenda (Forest)	5mg, 10mg 15mg 20mg tablets 2mg/ml oral solution	10/16/2003	Moderate to Severe AD

Figure 8: MHS Alzheimer's Disease Drugs Utilization, Prescriptions Filled



NASAL CORTICOSTEROIDS

Table 8: NASAL CORTICOSTEROIDS GENERIC AND BRAND NAMES

Generic	Brand (Manufacturer)	Generics available	FDA approval date
Beclomethasone dipropionate	Beconase AQ (GlaxoSmithKline)	No	July 1987
	Vancenase AQ Vancenase AQ DS (Schering-Plough)	No No	March 1995 June 1996
Budesonide	Rhinocort AQ (AstraZeneca)	No	October 1999
Flunisolide	Nasarel (Ivax)	Yes	March 1992
Fluticasone propionate	Flonase (GlaxoSmithKline)	No	October 1994
Mometasone furoate	Nasonex (Schering-Plough)	No	October 1997
Triamcinolone acetonide	Nasacort AQ (Sanofi-Aventis)	No	May 1996

Figure9: MHS Nasal Corticosteroids Utilization, Prescriptions Filled Aug 04-Jul 05

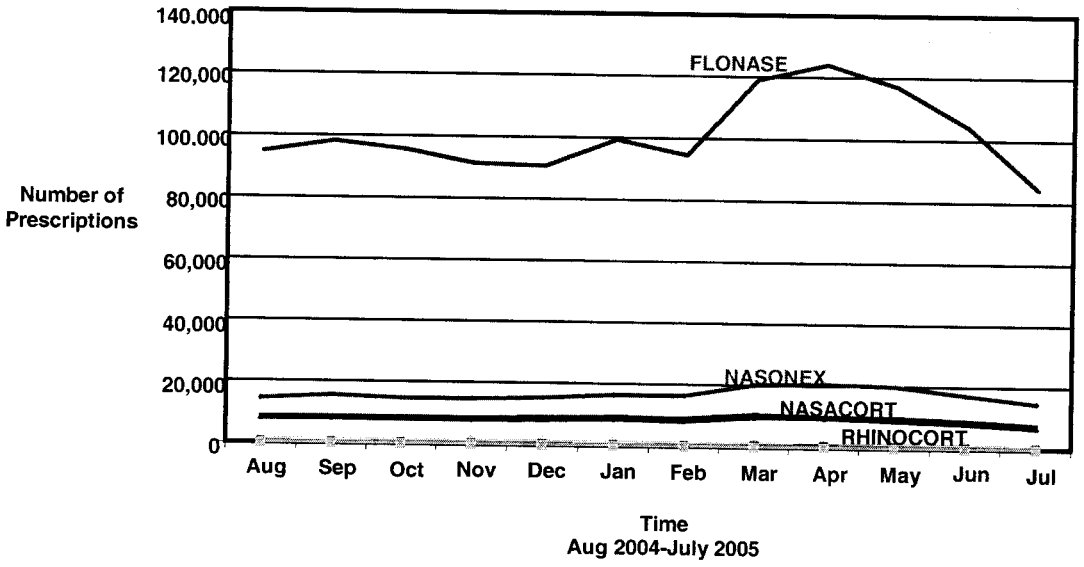


Table 9: Nasal Corticosteroid FDA Approved Indications

	FDA Approved Indications					
Indication	**Beclomethasone dipropionate**	**Budesonide**	**Flunisolide**	**Fluticasone propionate**	**Mometasone furoate**	**Triamcinolone acetonide**
SAR	Yes	Yes	Yes	Yes	Yes	Yes
PAR	Yes	Yes	Yes	Yes	Yes	Yes
Pediatric SAR/PAR	Yes 6-12 years	Yes 6-12 years	Yes 6-14 years	Yes 4-12 years	Yes 2-11 years	Yes 6-12 years
Rhinitis, Non-allergic	Yes	No	No	Yes	No	No
Prophylaxis of AR	No	No	No	No	Yes >12 years	No
Nasal Polyps	prevention/ recurrence of nasal polyps post-surgery > 5 years old	No	No	No	Treatment of nasal polyps >18 years old	No
Pregnancy	C	B	C	C	C	C

AR: Allergic Rhinitis; SAR: Seasonal Allergic rhinitis; PAR: Perennial allergic Rhinitis

UNIFORM FORMULARY IMPLEMENTATION PLAN SUMMARY

Table 10: 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	
Proton Pump Inhibitors	138,739 (13% of patients receiving PPIs)	MTF: 6,691 Retail: 117,520 Mail: 14,528	90-Days	17 Jul 05	Basec numt
Angiotensin Receptor Blockers	2,184 (0.5% of patients receiving ARB)	MTF: 13 Retail: 1,644 Mail: 527	90-Days	17 Jul 05	Recc implemer day B/
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	Basec numt
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	Medicati (rather th not like
Multiple Sclerosis Disease Modifying Drugs	0	MTF: 0 Retail: 0 Mail: 0	N/A	14 Jul 05	No medi non-for
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	Basec numt
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	Basec numt
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	Basec numt

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	
Alzheimer's Disease Drugs	5	MTF: 0 Retail: 3 Mail: 2	90-Days	*	
Nasal Corticosteroids	96,999	MTF: 13,556 Retail: 73,381 Mail: 10,062	90-Days	*	Basec numt
Antidepressants (Part 1)	182,916 (21.34% of patients receiving an anti-depressant)	MTF: 52,624 Retail: 118,582 Mail: 11,710	180-Days	*	Basec numt
Macrolide/Ketolide Antibiotics	**	**	60-Days	*	Based (benefici acute c cl

*: Implementation dates unknown, as final Nov 2005 DoD P&T Meeting minutes have not been signed as of 5 Dec 2005

**: # of Beneficiaries not provided, as macrolides/ketolide antibiotics are used to treat acute infections, not chronic diseases. 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