Beneficiary Advisory Panel Handout
Uniform Formulary Decisions
June 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 (UF) Class review.

Table 1: Antiemetics and Contraceptives Uf Recommendations

Note: Drugs with a trade name listed in parentheses are not available in generic formulations.

Antiemetics		
Uniform Formulary	Newer Antiemetics	Granisetron (Kytril)
		Ondansetron (Zofran)
		Aprepitant (Emend)
	Older Antiemetics	Dronabinol (Marinol)
		Meclizine (generics)
		Promethazine (generics)
		Prochlorperazine (generics)
		Thiethylperazine (Torecan)
		Transdermal scopolamine (Transderm Scop)
		Trimethobenzamide (generics)
Non-Formulary		Dolasetron (Anzemet)

Contraceptives		
Uniform Formulary	Monophasic OCs with 20 mcg EE	EE 20 mcg; 0.1 mg levonorgestrel
		EE 20 mcg; 1.0 mg norethindrone
		EE 20 mcg; 1.0 mg norethindrone; ferrous fumarate
		EE 20 mcg; 3 mg drospirenone (Yaz)
	Monophasic OCs with 30 mcg EE	EE 30 mcg; 0.15 mg levonorgestrel (excluding Seasonale)
		EE 30 mcg; 0.3 mg norgestrel
		EE 30 mcg; 0.15 mg desogestrel
		EE 30 mcg; 1.5 mg norethindrone
		EE 30 mcg; 1.5 mg norethindrone; ferrous fumarate
		EE 30 mcg; 3 mg drospirenone (Yasmin)
	Monophasic OCs with 35 mcg EE	EE 35 mcg; 0.5 mg norethindrone
		EE 35 mcg; 0.25 mg norgestimate
		EE 35 mcg; 1.0 mg norethindrone
		EE 35 mcg; 1.0 mg ethynodiol diacetate
	Monophasic OCs with 50 mcg EE or mestranol	Mestranol 50 mcg; 1 mg norethindrone
		EE 50 mcg; 1 mg ethynodiol diacetate
		EE 50 mcg; 0.5 mg norgestrel
	Biphasic OCs	EE 35 mcg; 0.5/1.0 mg norethindrone
		EE 20/10 mcg; 0.15 mg desogestrel
	Triphasic OCs	EE 25 mcg; 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen Lo)
		EE 35 mcg; 0.18/0.215/0.25 mg norgestimate
		EE 30/40/30 mcg; 0.05/0.075/0.125 mg levonorgestrel
		EE 35 mcg; 0.5/1/0.5 mg norethindrone
		EE 35 mcg; 0.5/0.75/1 mg norethindrone
		EE 25 mcg; 0.1/0.125/0.15 mg desogestrel
	Progestogen-only OCs	0.35 mg norethindrone
	Patch	EE; norelgestromin (Ortho-Evra)
	Vaginal ring	EE; etonorgestrel (Nuvaring)
	Injectable	104 mg/ 0.65mL depot medroxyprogesterone acetate (Depo-subq Provera 104)
		150 mg/mL depot medroxyprogesterone acetate
	Emergency contraceptives	0.75 mg levonorgestrel (Plan B)
Non-Formulary	EE 30 mcg; levonorgestrel 0.15 mg in special packaging for extended use (Seasonale)	
	EE 35 mcg; 0.4 mg norethindrone (Ovcon 35)	
	EE 50 mcg; 1 mg norethindrone (Ovcon 50)	
	EE 20/30/35 mcg; norethindrone 1 mg (Estrostep Fe)	

EE = ethinyl estradiol; OC = oral contraceptive.

ANTIEMETICS

Table 2: Antiemetic Drugs: Generic and Trade Names

Generic	Brand (Manufacturer)	Generics	FDA Approval date
Newer Antiemetics			
Serotonin 3 (5-HT3) antagonists			
Ondansetron	Zofran (GSK)	No	Jan 1991
Granisetron	Kytril (Roche)	No	Dec 1993
Dolasetron	Anzemet (Sanofi-Aventis)	No	Sep 1997
Neurokinin (NK1) antagonists			
Aprepitant	Emend (Merck)	No	Mar 2003
Older Antiemetics			
Cannabinoids			
Dronabinol	Marinol (Unimed)	No	May 1985
Antihistamines			
Meclizine	Antivert (Pfizer)	multiple generics	Feb 1957
Promethazine	Phenergan (Wyeth)	multiple brands and generics	Mar 1951
Phenothiazines			
Prochlorperazine	Compazine (GSK)	multiple generics	Oct 1956
Thiethylperazine	Torecan (Novartis)	No	July 1961
Anticholinergics			
Trimethobenzamide	Tigan (King)	multiple generics	Jul 1974
Transdermal Scopolamine	Transderm Scop (Novartis)	No	Dec 1979

Table 3: FDA-Approved Indications for the Newer Antiemetics

Generic Name (Subclass)	Brand (Manufacturer)	FDA Approved Indications for the prevention of nausea and vomiting (oral formulations)
Serotonin 3 (5-HT3) antagonists		
Ondansetron	Zofran (GSK)	Chemotherapy-induced nausea and vomiting (CINV) Post-Operative-induced nausea and vomiting (PONV) Radiation-inducted nausea and vomiting (RINV) Note: Evidence supports use in nausea and vomiting in pregnancy
Granisetron	Kytril (Roche)	Chemotherapy-induced nausea and vomiting (CINV) Radiation-inducted nausea and vomiting (RINV) Note: Evidence supports use in post-operative nausea and vomiting (PONV)
Dolasetron	Anzemet (Sanofi-Aventis)	Chemotherapy-induced nausea and vomiting (CINV) Post-Operative-induced nausea and vomiting (PONV) Note: Evidence supports use in Radiation-inducted nausea and vomiting (RINV)
Neurokinin (NK1) antagonists		
Aprepitant	Emend (Merck)	Chemotherapy-induced nausea and vomiting (CINV) added on to ondansetron

Figure 1: Military Health System (MHS) Utilization of the Newer Antiemetics: Feb 05 to Jan 06

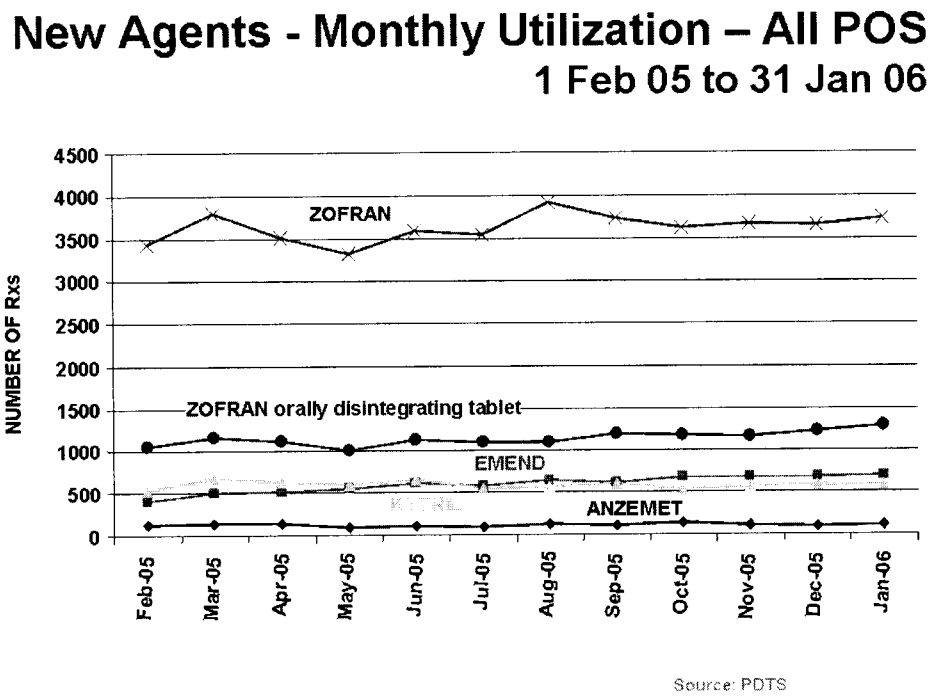
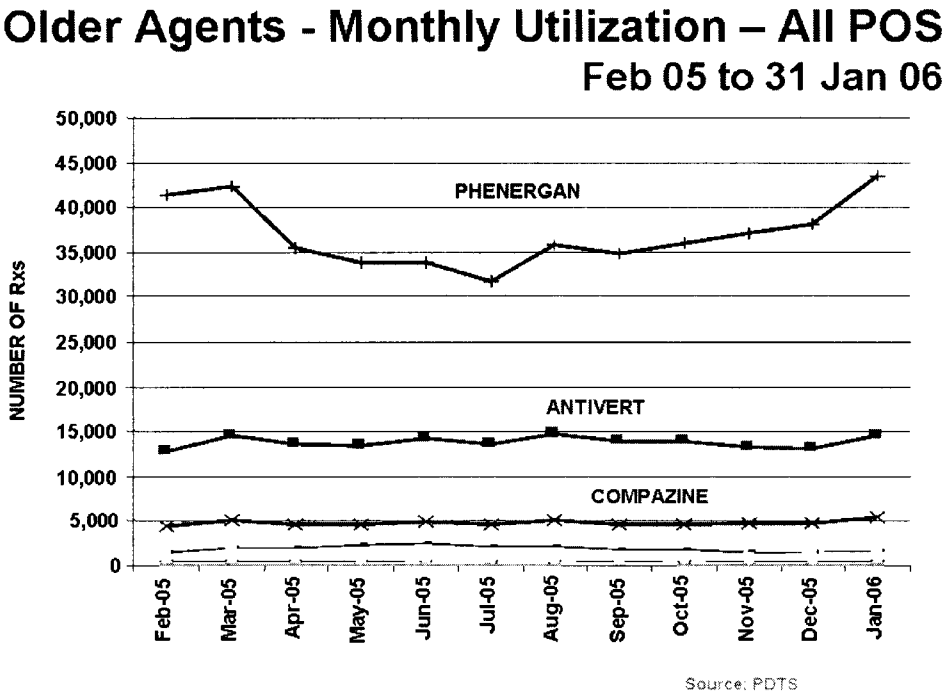


Figure 2: Military Health System (MHS) Utilization of the Older Antiemetics: Feb 05 to Jan 06



CONTRACEPTIVES

Table 4: Contraceptives: Generic and Trade Names, and Numbers of Prescriptions in the MHS

Note: FDA approval dates listed in Table 4 are for the originator product (first FDA approval) in each "generic product" group. In most cases, the other products in each group represent generic equivalents to the originator product (for example, Microgestin Fe 1/20 is generically equivalent to Loestrin Fe 1/20). Generic contraceptive products typically have their own "brand" or "trade" names.

Subgroup (Oral contraceptives = OC; Ethinyl estradiol = EE)	**Generic Product Description** (Ethinyl estradiol = EE; progestogen)	**Brand Name**	**FDA Approval** (originator product)	**Cost Assessment Groups**	**MHS Rxs** Jan-Dec 05
Monophasic OCs with 20 mcg EE (M20)	EE 20 mcg; 0.1 mg levonorgestrel	Alesse	Mar 97	Generically available OCs	86,569
		Aviane			
		Lutera			
		Lessina			
		Levlite			
	EE 20 mcg; 1.0 mg norethindrone	Junel 1/20	Oct 76	Generically available OCs	2,038
		Loestrin-21 1/20			
		Microgestin 1/20			
	EE 20 mcg; 1.0 mg norethindrone; ferrous fumarate	Junel Fe 1/20	Apr 73	Generically available OCs	18,356
		Loestrin Fe 1/20			
		Microgestin Fe 1/20			
	EE 20 mcg; 3 mg drospirenone	Yaz[1]	Mar 06	Brand-name only OCs	-
Monophasic OCs with 30 mcg EE (M30)	EE 30 mcg; 0.15 mg levonorgestrel	Levlen 28	Jul 82	Generically available OCs	25,092
		Levora 0.15/30-28			
		Nordette-28			
		Portia-28			
	EE 30 mcg; 0.15 mg levonorgestrel	Seasonale[2]	Sep 03	Brand-name only OCs	20,153
	EE 30 mcg; 0.3 mg norgestrel	Cryselle	Mar 75	Generically available OCs	123,501
		Lo/Ovral			
		Low-Ogestrel			
	EE 30 mcg; 0.15 mg desogestrel	Apri	Dec 92	Generically available OCs	59,086
		Desogen			
		Ortho-Cept			
		Reclipsen			
		Solia			
	EE 30 mcg; 1.5 mg norethindrone acetate	Junel 1.5/30	Oct 76	Generically available OCs	1,048
		Loestrin-21 1.5/30			
		Microgestin 1.5/30			
	EE 30 mcg; 1.5 mg norethindrone; ferrous fumarate	Junel Fe 1/5/30	Apr 73	Generically available OCs	19,472
		Loestrin-FE 1.5/30			
		Microgestin Fe 1.5/30			
	EE 30 mcg; 3 mg drospirenone	Yasmin	May 01	Brand-name only OCs	125,965

Subgroup (Oral contraceptives = OC; Ethinyl estradiol = EE)	Generic Product Description (Ethinyl estradiol = EE; progestogen)	Brand Name	FDA Approval (originator product)	Cost Assessment Groups	MHS Rxs Jan-Dec 05
Monophasic OCs with 35 mcg EE (M35)	EE 35 mcg; 0.5 mg norethindrone	Brevicon	Oct 74	Generically available OCs	772
		Modicon			
		Necon			
		Nortrel 0.5/35			
	EE 35 mcg; 0.4 mg norethindrone	Ovcon-35	Mar 76; Nov 03	Brand-name only OCs	6,681
		Ovcon-35 chewable			
	EE 35 mcg; 0.25 mg norgestimate	Mononessa	Dec 89	Generically available OCs	46,123
		Ortho-Cyclen			
		Previfem			
		Sprintec			
	EE 35 mcg; 1.0 mg norethindrone	Necon	Oct 74	Generically available OCs	92,114
		Norinyl 1+35			
		Nortrel			
		Ortho-Novum 1/35			
	EE 35 mcg; 1.0 mg ethynodiol diacetate	Demulen 1/35	Dec 81	Generically available OCs	17,171
		Kelnor			
		Zovia 1/35E			
Monophasic OCs with 50 mcg EE or mestranol (M50)	Mestranol 50 mcg; 1 mg norethindrone	Necon	May 62	Generically available OCs	3,979
		Norinyl 1+50			
		Ortho-Novum 1/50			
	EE 50 mcg; 1 mg norethindrone	Ovcon-50	Aug 75	Brand-name only OCs	2,061
	EE 50 mcg; 1 mg ethynodiol diacetate	Demulen 1/50	Apr 70	Generically available OCs	1,368
		Zovia 1/50E			
	EE 50 mcg; 0.5 mg norgestrel	Ogestrel	Apr 68	Generically available OCs	2,938
		Ovral-28			
Biphasic OCs (BIP)	EE 35 mcg; 0.5/1.0 mg norethindrone	Necon	Jan 82	Generically available OCs	168
		Ortho-Novum 10/11			
	EE 20/10 mcg; 0.15 mg desogestrel	Kariva	Apr 98	Generically available OCs	22,731
		Mircette			
Triphasic OCs (TRI)	EE 25 mcg; 0.18/0.215/0.25 mg norgestimate	Ortho Tri-Cyclen Lo	Aug 02	Brand-name only OCs	101,349
	EE 35 mcg; 0.18/0.215/0.25 mg norgestimate	Ortho Tri-Cyclen[3]	Jul 92	Generically available OCs	331,429
		Trinessa			
		Tri-Previfem			
		Tri-Sprintec			
	EE 30/40/30 mcg; 0.05/0.075/0.125 mg levonorgestrel	Enpresse	Nov 84	Generically available OCs	76,559
		Tri-levlen			
		Triphasil			
		Trivora			
	EE 35 mcg; 0.5/1/0.5 mg norethindrone	Aranelle	Apr 84	Generically available OCs	1,516
		Leena			
		Tri-Norinyl			
	EE 35 mcg; 0.5/0.75/1 mg norethindrone	Necon 7/7/7	Apr 84	Generically available OCs	59,536
		Nortrel 7/7/7			
		Ortho-Novum 7/7/7			
	EE 25 mcg; 0.1/0.125/0.15 mg desogestrel	Cesia	Dec 00	Generically available OCs	5,648
		Cyclessa			
		Velivet			
	EE 20/30/35 mcg; 1.0 mg norethindrone	Estrostep Fe[3]	Oct 96	Brand-name only OCs	9,916

Subgroup (Oral contraceptives = OC; Ethinyl estradiol = EE)	**Generic Product Description** (Ethinyl estradiol = EE; progestogen)	**Brand Name**	**FDA Approval** (originator product)	**Cost Assessment Groups**	**MHS Rxs** Jan-Dec 05
Progestogen-Only OCs (PRO)	0.35 mg norethindrone	Errin	Jan 73	Generically available OCs	71,003
		Ortho Micronor			
		Jolivette			
		Camila			
		Nora-BE			
		Nor-QD			
Contraceptive patch (PATCH)	EE; norelgestromin ~ 60% higher overall exposure than oral contraceptive with 35 mcg EE, but lower peak concentrations	Ortho Evra[4]	Nov 01	Non-oral contraceptives	268,223
Contraceptive vaginal ring (VAG)	Daily dose: ~ EE 15 mcg; ~0.12 mg etonogestrel	Nuvaring[5]	Oct 01	Non-oral contraceptives	55,415
Injectable Contraceptives (INJ)	104 mg/ 0.65mL depot medroxyprogesterone acetate	Depo-subq Provera 104[6]	Dec 04	Non-oral contraceptives	39
	150 mg/mL depot medroxyprogesterone acetate	Depo Provera (syringe, vial)[7]	Oct 92	Non-oral contraceptives	70843
		Generic (syringe, vial)[7]			
Emergency Contraceptives (EMERG)	0.75 mg levonorgestrel	Plan B[8]	Jul 99	Brand-name only OCs	4,049

1. Yaz – packaging for 24-day regimen (24 days on, 4 days off)
2. Seasonale - special packaging for extended use (84 days on, 7 days off)
3. Ortho Tri-Cyclen, Estrostep Fe - FDA approved for treatment of acne
4. Ortho Evra patch - applied weekly for 3 weeks, followed by a patch-free week
5. Nuvaring - inserted vaginally on a monthly basis, removed after 3 weeks, followed by a ring-free week
6. Depo-subq Provera 104 - given subcutaneously (under the skin) every 12 weeks; FDA-approved for treatment of endometriosis pain
7. Depo Provera, generic - given by intramuscular injection every 12 weeks
8. Plan B – given as 1 dose within 72 hours of unprotected intercourse, with a second dose 12 hours later

FDA approval dates per Drugs@FDA database (www.accessdata.fda.gov/scripts/cder/drugsatfda)

Figure 3: Military Health System (MHS) Prescriptions (Rxs) Dispensed, Oct 03 - Mar 06

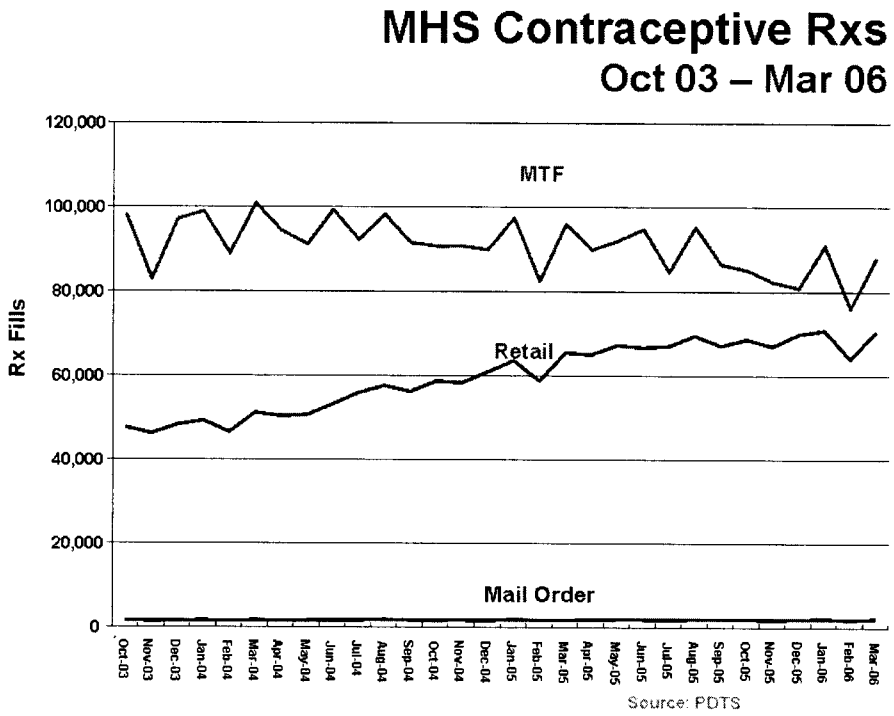


Figure 4: MHS Contraceptive Cycles Dispensed by Subgroup, Jan 06 - Mar 06
(1 cycle = 28-30 days supply)

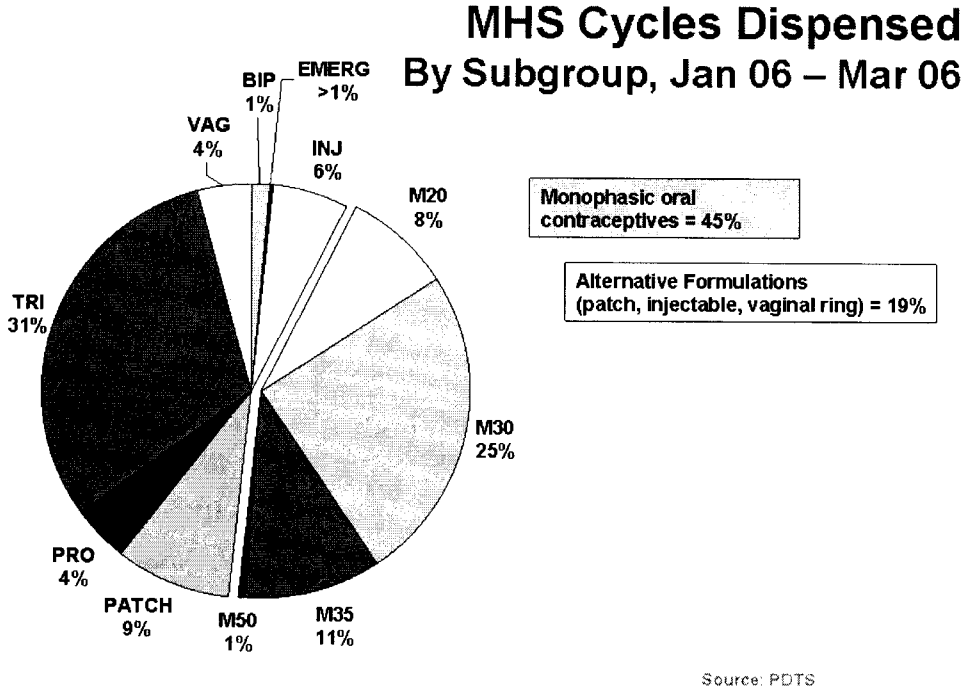


Figure 5: MHS Top 10 Contraceptive Products by Rxs Dispensed, Oct 03 - Mar 06

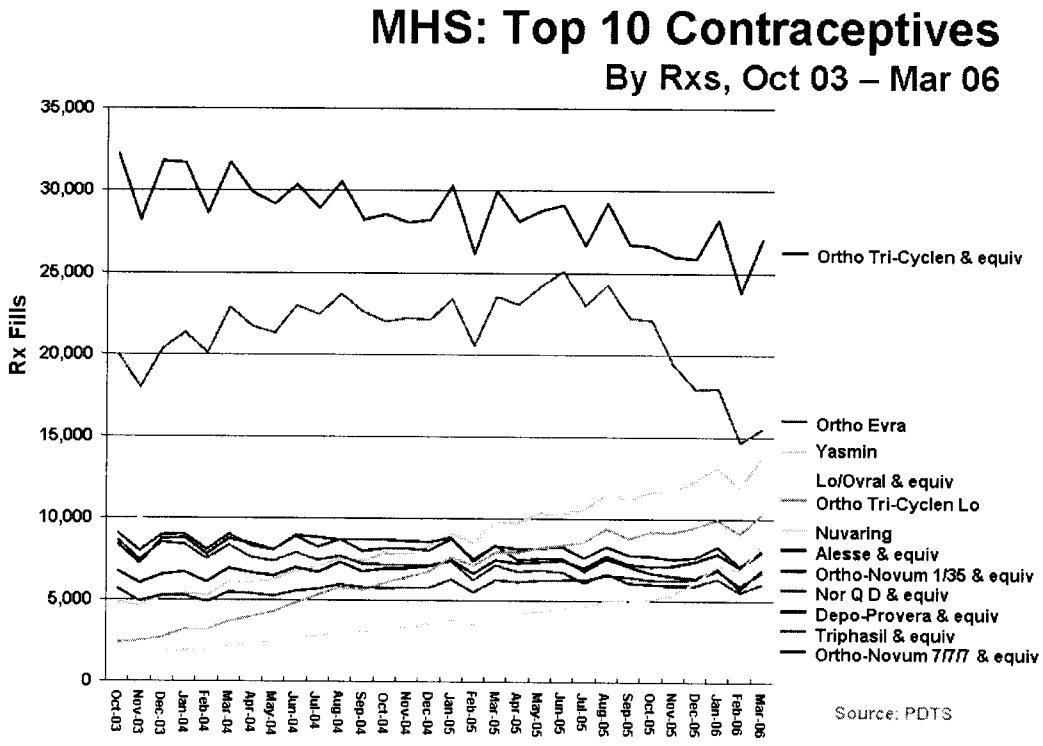


Figure 6: Military Treatment Facility (MTF) Top 16 Contraceptive Products by Rxs Dispensed, Oct 03 - Mar 06

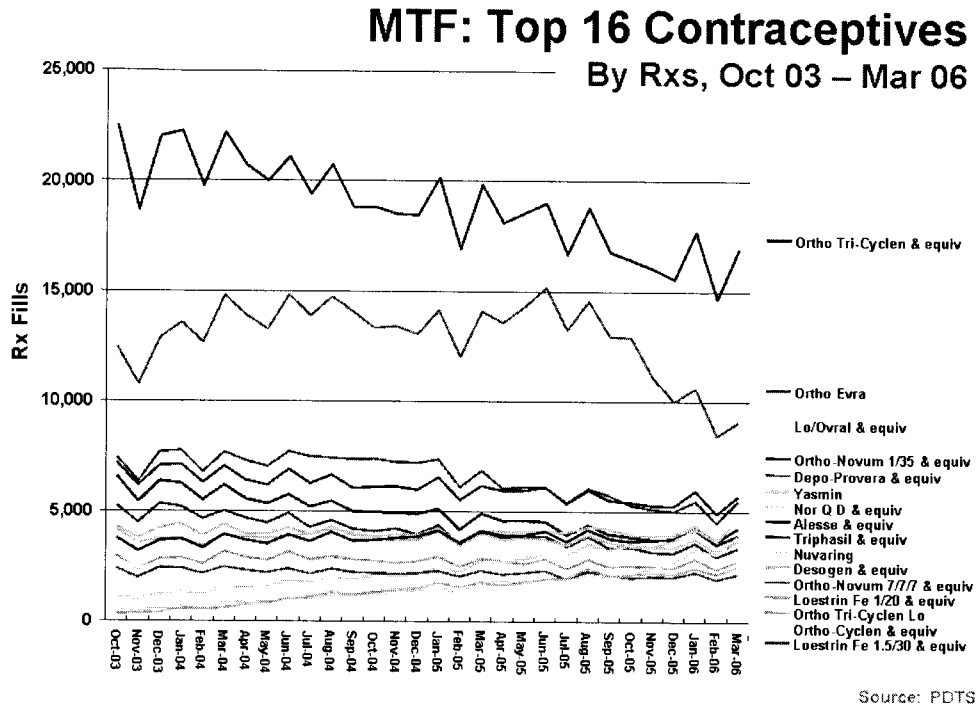
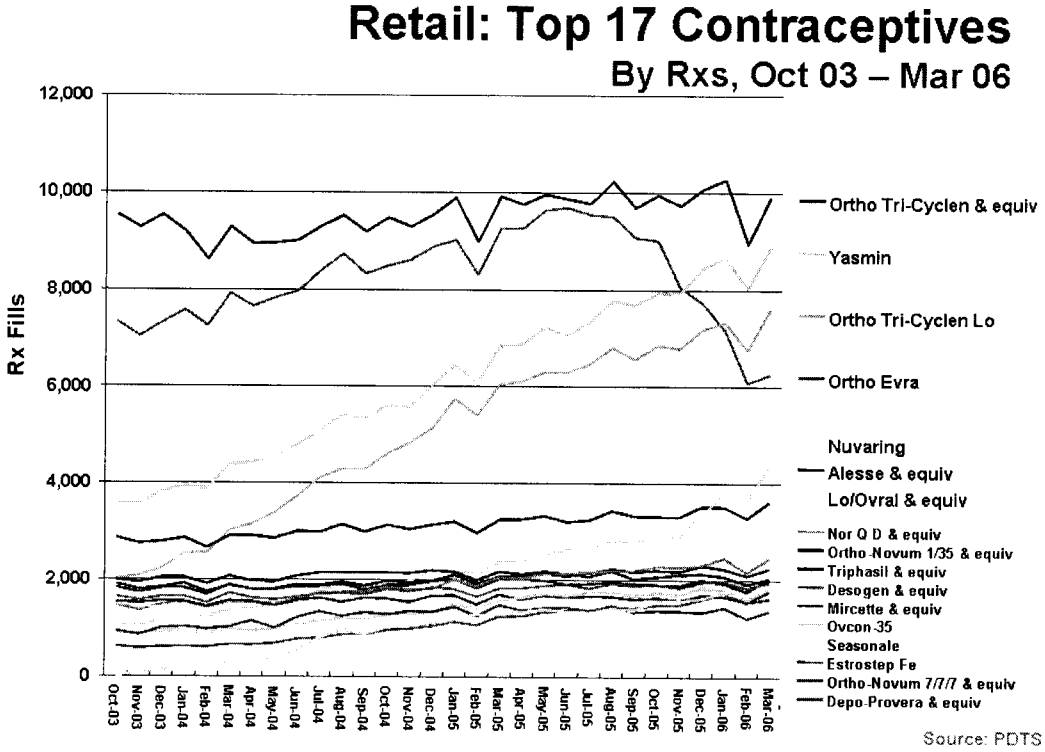


Figure 7: Retail Top 17 Contraceptive Products by Rxs Dispensed, Oct 03 - Mar 06



UNIFORM FORMULARY IMPLEMENTATION PLAN SUMMARY

Table 5: 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
Alzheimer's Disease Drugs	5	MTF: 0 Retail: 3 Mail: 2	90-Days	19 Apr 06	Based on low 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
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	90-days	26 Jul 06	Recommended 60-day implementation overturned; 90-day BAP recommendation accepted
Miscellaneous Anti-hypertensive Agents	5,946	MTF: 336 Retail: 4,472 Mail: 1,138	90-Days	26 Jul 06	Recommended 60-day implementation overturned; 90-day BAP recommendation accepted
GABA-Analogs	30,649	MTF: 1,120 Retail: 27,566 Mail: 1,963	60-Days	28 Jun 06	Based on the low number of beneficiaries
Antiemetics	852	MTF: 14 Retail: 668 Mail: 170	60 days (proposed)	*	Based on the low number of beneficiaries, the acute nature of the treatments (e.g. chemotherapy)
Contraceptives	23,221 (4% of total beneficiaries receiving a contraceptive)	MTF: 3,128 Retail: 19,249 Mail: 844	180 days (proposed)	*	Relatively low number of beneficiaries affected, but a high proportion are receiving Seasonale, which is packaged as a 3-month supply

*: Implementation dates unknown, as final May 2006 DoD P&T Meeting minutes have not been signed as of 15 Jun 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