

Beneficiary Advisory Panel Handout Uniform Formulary Decisions December 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: Uniform Formulary Recommendations from the Nov 06 DoD P&T Committee Meeting

| Drug Class | Generic Name (Brand) | Formulations | Generics Available? |
|---------------------------------------------------------------------|-----------------------------------------------------|-------------------------------|------------------------------------|
| Attention Deficit Hyperactivity (ADHD) and Narcolepsy Agents | | | |
| Uniform Formulary | ADHD Agents | | |
| | Non-Stimulants | | |
| | Atomoxetine (Strattera) | caps | No |
| | Stimulants | | |
| | Once daily use products | | |
| | Methylphenidate OROS (Concerta) | tabs | No |
| | Methylphenidate 30% IR/70% ER (Metadate CD) | caps | No |
| | Methylphenidate SODAS (Ritalin LA) | caps | No |
| | Mixed amphetamine salts ER (Adderall XR) | caps | No |
| | Multiple daily use products | | |
| | Methylphenidate SR (Ritalin SR) | tabs | Yes |
| | Methylphenidate IR (Ritalin, generics) | tabs, chew tab, oral solution | Yes (except solution and chew tab) |
| | Mixed Amphetamine salts (Adderall, generics) | tabs | Yes |
| | Dexamphetamine IR (Dexedrine, Dextrostat, generics) | tabs | Yes |
| | Methamphetamine IR (Deosyn, generics) | tabs | Yes |
| | Narcolepsy Agents | | |
| Modafinil (Provigil) | tabs | No | |
| Sodium Oxybate (Xyrem) | oral solution | No | |
| Non-Formulary | Methylphenidate transdermal system (Daytrana) | patch | No |
| | Dexmethylphenidate IR (Focalin) | caps | No |
| | Dexmethylphenidate SODAS (Focalin XR) | caps | No |
| Recommended implementation period | 90 days | | |
| Older Sedative Hypnotics | | | |
| Uniform Formulary | Benzodiazepines | | |
| | Estazolam (Prosom, generics) | caps | Yes |
| | Flurazepam (Dalmane, generics) | caps | Yes |
| | Quazepam (Doral) | caps | No |
| | Temazepam (Restoril, generics) | caps | Yes |
| | Triazolam (Halcion, generics) | caps | Yes |
| | Barbiturates | | |
| | Butabarbital (Butisol) | tabs | No |
| | Secobarbital (Seconal, generics) | tabs | Yes |
| | Other | | |
| Chloral hydrate (Noctec, generics)) | oral solution | Yes | |
| Non-Formulary | No medications moved to non-formulary status | | |
| Recommended implementation period | Not applicable | | |

cap = capsule; ER = extended release; IR = immediate release;
 OROS = osmotically controlled-release delivery system
 SODAS = spheroidal oral drug absorption system
 SR = sustained release; tab = tablet;

Table 2: Uniform Formulary Recommendations from the Nov 06 DoD P&T Committee Meeting for New Drugs in Classes Previously Reviewed for UF Status

| New Drugs in Classes Previously Reviewed for UF Status | | |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Contraceptives | | |
| Recommendation at Nov 2006 meeting | | |
| Monophasic OCs with 20 mcg EE | UF | No new monophasic OCs with 20 mcg EE recommended for UF status |
| | Non-Formulary | 20 mcg EE / 1 mg norethindrone acetate 24 day regimen (Loestrin 24 Fe) |
| Monophasic OCs with 30 mcg EE | UF | No new monophasic OCs with 30 mcg EE recommended for UF status |
| | Non-Formulary | 30/10 mcg EE / 0.15 mg levonorgestrel in special packaging for extended use (Seasonique) |
| Recommended implementation period | 60-days | |
| Existing UF Status of Contraceptives (May 2006) & Nov 2006 recommendations | | |
| Monophasic OCs with 20 mcg EE | UF | EE 20 mcg; 0.1 mg levonorgestrel (Alesse, Levlite, generics) |
| | | EE 20 mcg; 1.0 mg norethindrone; ferrous fumarate (Loestrin 1/20, generics) |
| | | EE 20 mcg; 1.0 mg norethindrone (Loestrin Fe 1/20, generics) |
| | | EE 20 mcg; 3 mg drospirenone (Yaz) |
| | Nov 06 - Recommended for NF | EE 20 mcg; 1.0 mg norethindrone – 24-day regimen (Loestrin 24 Fe) |
| Monophasic OCs with 30 mcg EE | UF | EE 30 mcg; 0.15 mg levonorgestrel (Nordette, generics; excluding Seasonale) |
| | | EE 30 mcg; 0.3 mg norgestrel (Lo-Ovral, generics) |
| | | EE 30 mcg; 0.15 mg desogestrel (Ortho-Cept, Desogen, generics) |
| | | EE 30 mcg; 1.5 mg norethindrone (Loestrin 1.5/30, generics) |
| | | EE 30 mcg; 3 mg drospirenone (Yasmin) |
| | Non-formulary | EE 30 mcg; 0.15 mg levonorgestrel in special packaging for extended use (Seasonale, generics) |
| Nov 06 - Recommended for NF | EE 30/10 mcg; 0.15 mg levonorgestrel for extended use (Seasonique) | |
| Monophasic OCs with 35 mcg EE | UF | EE 35 mcg; 0.5 mg norethindrone (Modicon, generics) |
| | | EE 35 mcg; 0.25 mg norgestimate (Ortho-Cyclen, generics) |
| | | EE 35 mcg; 1.0 mg norethindrone (Ortho-Novum 1/35, generics) |
| | | EE 35 mcg; 1.0 mg ethynodiol diacetate (Demulen 1/35, generics) |
| | Non-formulary | EE 35 mcg; 0.4 mg norethindrone (Ovcon 35) |
| Monophasic OCs with 50 mcg EE or mestranol | UF | Mestranol 50 mcg; 1 mg norethindrone (Ortho-Novum 1.50, generics) |
| | | EE 50 mcg; 1 mg ethynodiol diacetate (Demulen 1/50, generics) |
| | Non-formulary | EE 50 mcg; 0.5 mg norgestrel (Ovral, generics) |
| | | EE 50 mcg; 1 mg norethindrone (Ovcon 50) |
| Biphasic OCs | | EE 35 mcg; 0.5/1.0 mg norethindrone (Ortho-Novum 10/11, generics) |
| | | EE 20/10 mcg; 0.15 mg desogestrel (Mircett, generics) |
| Triphasic OCs | UF | EE 25 mcg; 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen Lo, generics) |
| | | EE 35 mcg; 0.18/0.215/0.25 mg norgestimate (Ortho-Cyclen, generics) |
| | | EE 30/40/30 mcg; 0.05/0.075/0.125 mg levonorgestrel Triphasil, generics) |
| | | EE 35 mcg; 0.5/1/0.5 mg norethindrone (Tri-Norinyl, generics) |
| | | EE 25 mcg; 0.1/0.125/0.15 mg desogestrel (Cyclessa, generics) |
| | Non-formulary | EE 20/30/35 mcg; norethindrone 1 mg (Estrostep Fe) |
| Progestogen-only OCs | | 0.35 mg norethindrone (OrthoMicronor, generics) |
| 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 | |

| New Drugs in Classes Previously Reviewed for UF Status | | |
|---------------------------------------------------------------------------------------------------|---------------------------------------------------|-----------------------------------------------------------------------------|
| Existing UF Status of Contraceptives (May 2006) & Nov 2006 recommendations (continued) | | |
| Emergency contraceptives | 0.75 mg levonorgestrel (Plan B) | |
| Antiemetics | | |
| Recommendation at Nov 2006 meeting | | |
| Older Antiemetics | UF | Nabilone (Cesamet) |
| | Non-formulary | No older antiemetics recommended for NF status |
| Recommended implementation period | Not applicable | |
| Existing UF Status of Antiemetics (Feb 2006) & Nov 2006 recommendations | | |
| Newer Antiemetics | UF | Granisetron (Kytril) |
| | | Ondansetron (Zofran) |
| | | Aprepitant (Emend) |
| | Non-formulary | Dolasetron (Anzemet) |
| Older Antiemetic | Nov 06 - Recommended for Uniform Formulary | Nabilone (Cesamet) |
| | UF | Dronabinol (Marinol) |
| | | Meclizine (generics) |
| | | Promethazine (generics) |
| | | Prochlorperazine (generics) |
| | | Thiethylperazine (Torecan) |
| | | Transdermal scopolamine (Transderm Scop) |
| Trimethobenzamide (generics) | | |
| Antifungals | | |
| Recommendation at Nov 2006 meeting | | |
| Azoles | UF | No new azoles recommended for UF status |
| | Non-formulary | 0.25% miconazole / 15% zinc oxide / 81.35% white petrolatum (Vusion) |
| Recommended implementation period | 60 days | |
| Existing UF Status of Antiemetics (May 2005) & Nov 2006 recommendations | | |
| Azoles | UF | Clotrimazole (Lotrimin, generics) |
| | | Miconazole (Monistat Derm, generics) |
| | | Ketoconazole (Nixoral, generics) |
| | Non-formulary | Econazole (Spectazole, generics) |
| | | Oxiconazole (Oxistat) |
| | | Sertaconazole (Ertaczo) |
| | | Sulconazole (Exelderm) |
| | Nov 06 - Recommended for NF | 0.25% miconazole, 15% zinc oxide, 81.35% white petrolatum (Vusion) |
| Allylamine | UF | Butenafine (Mentax) |
| | | Naftifine (Naftin) |
| Others | UF | Nystatin (Mycostatin, generics) |
| | Non-formulary | Ciclopirox (Loprox, generics) |

Figure 1:

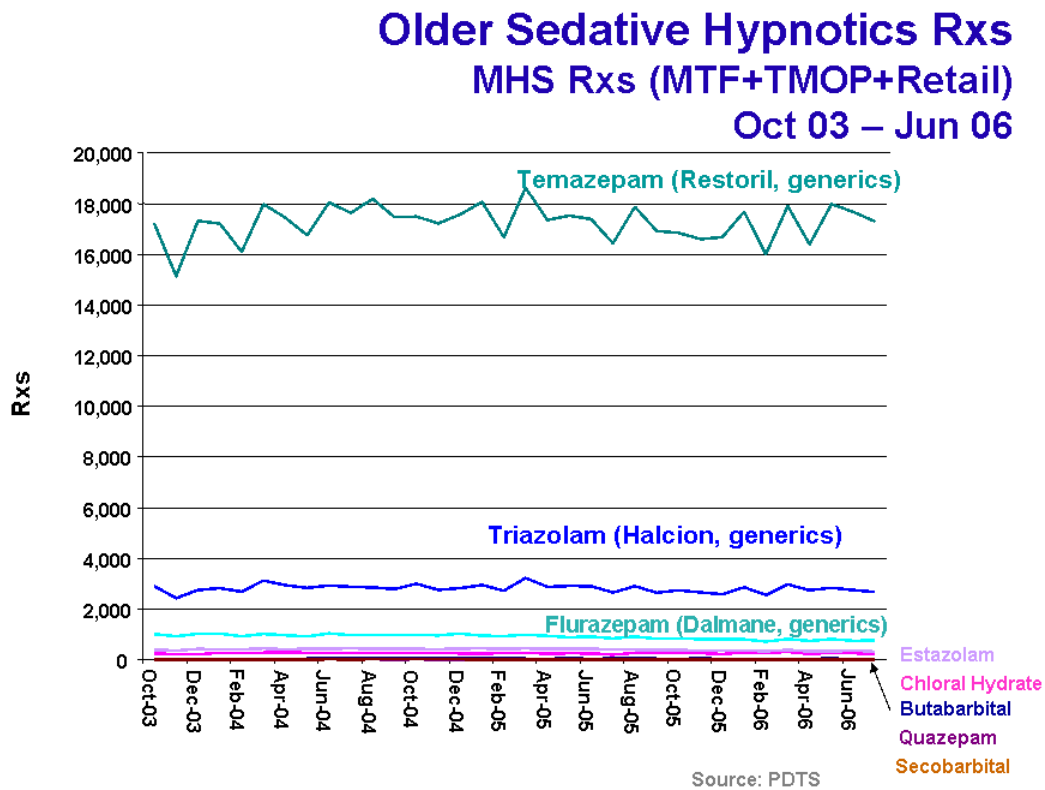


Figure 2:

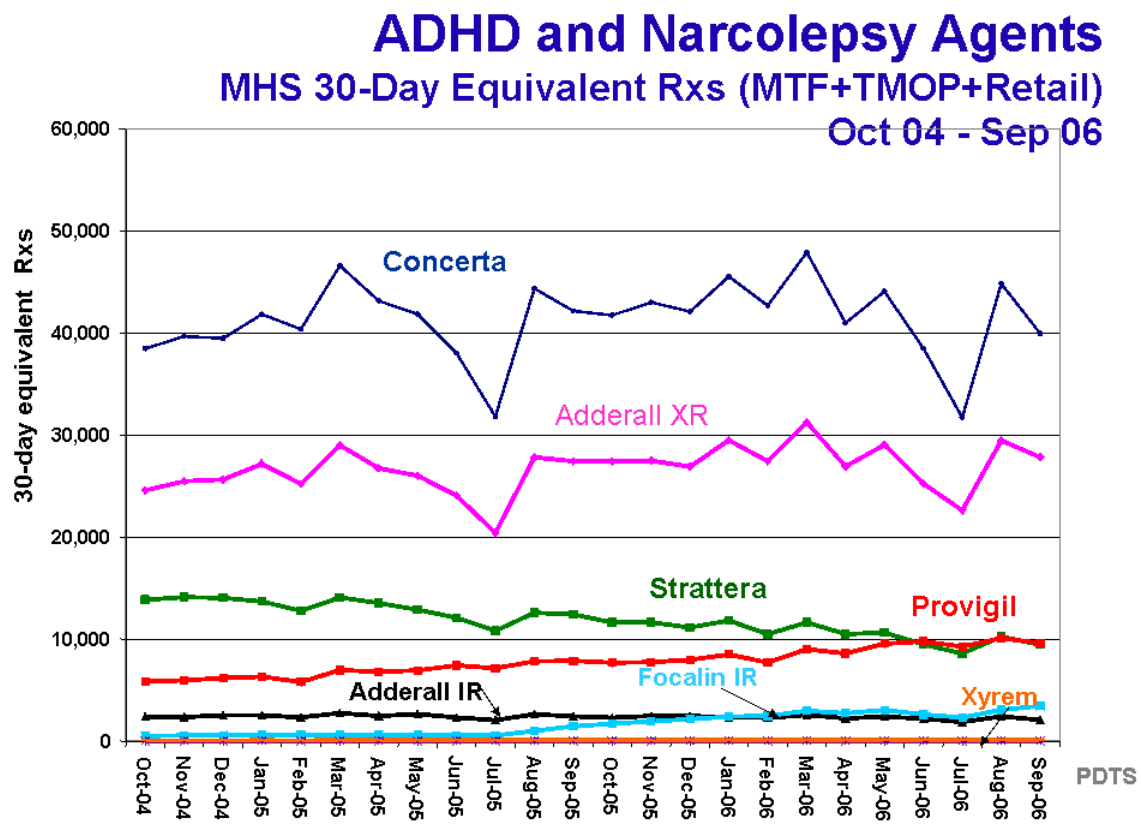


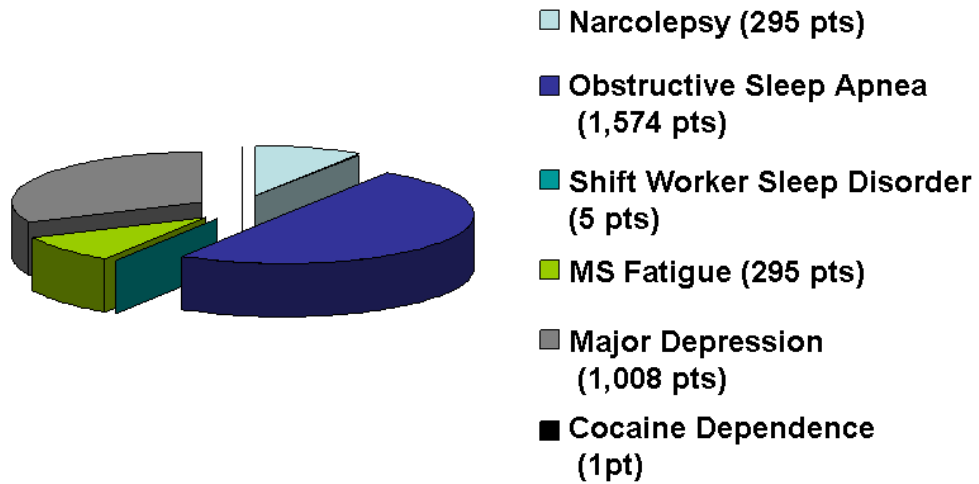
Table 3: Provigil (Modafinil) Supportable Uses

| Supportable Uses of Provigil |
|-----------------------------------------|
| FDA – Approved Indications |
| Narcolepsy |
| Obstructive Sleep Apnea Syndrome (OSAS) |
| Shift Worker Sleep Disorder (SWSD) |
| Non- FDA Approved Indications |
| Major Depressive Disorder |
| Multiple Sclerosis Fatigue |
| Cocaine Dependence |
| Myotonic Dystrophy |
| Idiopathic Hypersomnia |

Figure 3:

Modafinil (Provigil) Supportable Uses

3,178 patients (56%) supportable uses



2,528 patients (44%) other uses

Sources: M2, PDTS

Table 4: 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 |
|---------|---------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|-------------------------------|--------|------------|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| | | | | 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 | 90 days (proposed) | Small number of beneficiaries affected |
| Nov 06 | Older Sedative Hypnotics | - | 0 | 0 | 0 | 0 | Not applicable | No medications moved to non-formulary status |
| Aug 06 | TZDs | - | 0 | 0 | 0 | 0 | Not applicable | No medications moved to non-formulary status |
| Aug 06 | H2 Antagonists / GI protectants | - | 0 | 0 | 0 | 0 | Not applicable | No medications moved to non-formulary status |
| 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 |
| 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) |

| 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 |
|---------------------------------------|-----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|-------------------------------|---------|------------|-----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| | | | | 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 |
| | | <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 leonorgestrel for extended use (Seasonique) | Seasonique 161 (from Apr 06-Oct 06) | 0 Rxs | 112 Rxs | 4 Rxs | 60 days (proposed) | Small number of beneficiaries affected |
| | Loestrin 24 Fe: 2,227 (from Apr 06-Oct 06) | 22 Rxs | 3,417 Rxs | 64 Rxs | | | | |
| 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 |
| 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 |
| 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 |
| 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 |

| 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 |
|---------|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|-------------------------------|---------|------------|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| | | | | MTF | Retail | Mail Order | | |
| 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 |
| 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 |
| 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 |
| 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 |
| 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 |

| 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 |
|------------------------------------|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|-------------------------------|---------|------------|-----------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| | | | | MTF | Retail | Mail Order | | |
| 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 |
| 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 |
| 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 |
| | | <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 | 60 days (proposed) | Small numbers of beneficiaries affected |
| May 05 | MS-DMDs | - | 0 | 0 | 0 | 0 | Not applicable | No medications moved to non-formulary status |
| 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 |
| 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 |

| 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 |
|---------|------------|---------------------------|-------------------------------------------------------|-------------------------------|--------|------------|-----------------------------------------------------------------------|---------------|
| | | | | MTF | Retail | Mail Order | | |

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

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; GI = gastrointestinal; GABA = gamma-aminobutyric acid; H2 = Histamine-2 receptor; HCTZ = hydrochlorothiazide; MS-DMDs = Multiple Sclerosis Disease-Modifying Drugs; OABs = Overactive Bladder Medications; PDE-5 Inhibitors = Phosphodiesterase-5 inhibitors; PMDD = Premenstrual Dysmorphic Disorder; PPIs = Proton Pump Inhibitors; 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])