

## **XIV. IMPLEMENTATION OF FEDERAL CEILING PRICE REGULATION**

### **P&T Comments**

The committee reviewed drugs that were not included on a Department of Defense Retail Refund Pricing Agreement; these drugs are not compliant with 32 C.F.R. 199.21(q)(2), part of the regulation implementing the FY2008 National Defense Authorization Act, Section 703. The regulation provides that if a drug is not covered by a pricing agreement to comply with Federal Ceiling Prices, the drugs will generally be designated non-formulary (Tier 3) under the Uniform Formulary and will require a pre-authorization prior to use in the retail point of service. These drugs will remain available in the mail order point of service without pre-authorization. Drugs, with and without pricing agreements, were systematically classified based along therapeutic and pharmacologic lines. The classification system was based on the American Hospital Formulary System Classification and First Data Bank classification.

By the August P&T meeting, over 130 manufacturers has submitted executed pricing agreements representing over 90% of the drugs and 94% of the potential FCP-based refunds. Out of the 190 drugs (59 as of 23 September 2009) reviewed that were not covered by pricing agreements, 169 (45 as of 23 September 2009) were recommended by the Committee to move to Tier 3. Ten drugs (6 as of 23 September 2009) were recommended to remain on Tier 2 and eleven drugs (8 as of 23 September 2009) were tabled for the November meeting. At the meeting, all drugs that were on Tier 3 and were covered by a pricing agreement were maintained on Tier 2 (with the exception of three newly approved drugs separately reviewed by the Committee). The Committee considered each drug carefully with the goal of minimizing the impact on beneficiary care. The Committee considered many factors in its recommendations. These included whether a drug was considered “one-of-a-kind,” whether there were other brand name products in the same drug class, and whether multiple generics were available in the class. From these considerations, the Committee’s rationale was to move drug to non-formulary (Tier 3) only if the Committee knew there were appropriate therapeutic substitutions within that drug class. Those without appropriate therapeutic substitutes were not moved and those that the Committee needed additional information on were deferred to the November meeting. Also, the Committee recommended that any drug manufacturer that signs a pricing agreement before 14 October would not have their drug(s) moved to non-formulary (Tier 3). If their drug(s) were already in Tier 3, they would remain in Tier 3 but without an additional pre-authorization.

The DoD P&T Committee recommended the following:

- A. The following drugs, though not on a pricing agreement, should retain their formulary designation on the UF:

<b>DRUG</b>	<b>DRUG CLASSIFICATION</b>	<b>MANUFACTURER</b>	<b>NUMBER OF PATIENTS</b>
ACTIMMUNE	Immunological/Immunomodulators	INTERMUNE	25
INTAL	Pulmonary II Agents	KING (MONARCH)	439
PANRETIN	Topical Antineoplastic & Premalignant Lesion	EISAI	1
RADIOGARDASE	Binders/Chelators/Antidotes/Overdose /Radiation Exposure	HEYLTEX	514
THIOLA	Urinary/Kidney Stone Agents	MISSION	12
VANCOGIN HCL	Anti-Infectives/Antibiotics	VIROPHARMA	1,491

- B. The following drugs should be designated or retain the designation of non-formulary on the UF:

<b>DRUG</b>	<b>DRUG CLASSIFICATION</b>	<b>MANUFACTURER</b>	<b>NUMBER OF PATIENTS</b>
ACHIPHEX	Immunological Agents	INTERMUNE	25,129
ACLOVATE	Topical Corticosteroids/Immune Modulators	PHARMADERM	1
AGRYLIN	Hematological Agents	SHIRE	8
ALTACE	Renin-Angiotensin Antihypertensives (RAAs)	KING (MONARCH)	69
APTIVUS	HIV Antivirals	BOEHRINGER INGELHEIM	6
ATROVENT	Respiratory/Nasal Anticholinergics	BOEHRINGER INGELHEIM	11
ATROVENT HFA	Pulmonary II Agents	BOEHRINGER INGELHEIM	3,565
BUPHENYL	GI Agents/Ammonia Inhibitors	MEDICIS	7
CARBATROL	Anticonvulsants/Antimania	SHIRE	1,311
CARNITOR	Metabolic Replacement Agents	SIGMA-TAU	15
CARNITOR SF	Metabolic Replacement Agents	SIGMA-TAU	2
CATAPRES	Antihypertensives/Sympatholytics	BOEHRINGER INGELHEIM	19
CETROTIDE	FSH/LH Fertility Agents	EMD SERONO	34
CORGARD	Beta Blockers/HCTZ Combos	KING (MONARCH)	42
CORTISPORIN	Topical Antibiotics & Combos	KING (MONARCH)	3
CUTIVATE	Topical Corticosteroids/Immune Modulators	PHARMADERM	1,355
CYTOMEL	Thyroid Replacements	KING (MONARCH)	2,955

CYTOXAN	Oral Oncological/Alkylating Agents	BRISTOL-MYERS-SQUIBB	0
DEPAKENE	Anticonvulsants/Antimania	ABBOTT	12
ELESTRIN	Estrogens	AZUR	26
ELIGARD	LHRH Agonists	SANOFI	20
ENDOMETRIN	Gynecological/Pregnancy Facilitating/Maintaining Agent	FERRING	350
EURAX	Topical Anti-Infectives	RANBAXY	54
FLOMAX	Alpha Blockers for BPH	BOEHRINGER INGELHEIM	29,039
FOSRENOL	Electrolyte Depleting/Phosphate Binders	SHIRE	635
GYNAZOLE-1	Vaginal Anti-Infectives/Antiseptics	THER-RX	908
HALOG	Topical Corticosteroids/Immune Modulators	RANBAXY	261
KADIAN	Narcotic Analgesics & Combos	ALPHARMA	1,512
KAON-CL 10	Electrolyte/Mineral/Trace Element/Potassium Replacement	SAVAGE	35
KINERET	Targeted Immunomodulatory Biologics	BIOVITRUM	27
LAC-HYDRIN	Emollients	RANBAXY	25
LEVULAN	Acne	DUSA	0
LIMBITROL	TCAs & Combos	VALEANT	0
LITHOSTAT	GI Agents/Ammonia Inhibitors	MISSION	1
LOCOID	Topical Corticosteroids/Immune Modulators	TRIAx	0
LUVERIS	FSH/LH Fertility Agents	EMD SERONO	17
MICRO-K	Electrolyte/Mineral/Trace Element/Potassium Replacement	THER-RX	55
MINOCIN	Tetracyclines	TRIAx	0
MIRAPEX	Parkinsons Medications	BOEHRINGER INGELHEIM	8,405
MOBIC	NSAIDs	BOEHRINGER INGELHEIM	18
MONODOX	Tetracyclines	AQUA	2
MS CONTIN	Narcotic Analgesics & Combos	PURDUE	18
NIRAVAM	Antianxiety/Anxiolytics	AZUR	181
OMNICEF	Beta-Lactams	ABBOTT	7
OXISTAT	Topical Antifungals	PHARMADERM	2,460
PAMINE FORTE	Anticholinergics/Antispasmodics	KENWOOD LABS	4
PAMINE FQ	Anticholinergics/Antispasmodics	KENWOOD LABS	1
PERSANTINE	Antiplatelet/Hemorrhologic Agents	BOEHRINGER INGELHEIM	4

PHOSLO	Electrolyte Depleting Medications	FRESENIUS	24
PLETAL	Antiplatelet/Hemorrhologic Agents	OTSUKA AMERICA	9
PROAMATINE	Cardiovascular/Adrenergic Vasopressors	SHIRE	4
RHEMATREX	Antirheumatics	DAVA	10
RIOMET	Oral Anitdiabetics I/Biguanides	RANBAXY	105
SAIZEN	Growth Stimulating Agents/Growth Hormone	EMD SERONO	31
SALAGEN	Neurological/Parasympathetic Agents	EISAI	10
SEPTRA	Sulfonamides/Folate Antagonists	KING (MONARCH)	
SEPTRA DS	Sulfonamides/Folate Antagonists	KING (MONARCH)	3
SEROSTIM	Growth Stimulating Agents/Growth Hormones	EMD SERONO	3
SILVADENE	Topical Anti-infectives/Sulfonamides	KING (MONARCH)	7
SONATA	Sedative/Hypnotics I	KING (MONARCH)	282
TAPAZOLE	Thyroid Medications	KING (MONARCH)	6
TEMOVATE	Topical Corticosteroid/Immune Modulators	PHARMADERM	4
TEMOVATE EMOLLIENT	Topical Corticosteroid/Immune Modulators	PHARMADERM	2
THALITONE	Diuretics/Thiazide	KING (MONARCH)	29
TIGAN	Antiemetic/Antivertigo Agents	KING (MONARCH)	2
TINDAMAX	Anti-infectives/Antiprotozoal	MISSION	691
TRANSDERM-SCOP	Antiemetic/Antivertigo Agents	BAXTER	974
TRETIN-X	Acne Medications	TRIAx	94
ULTRAVATE	Topical Corticosteroid/Immune Modulators	PHARMADERM	8
ULTRAVATE PAC	Topical Corticosteroid/Immune Modulators	RANBAXY	144
VIRAMUNE	HIV Antivirals	BOEHRINGER INGELHEIM	52
VIROPTIC	Ophthalmic/Antivirals	KING (MONARCH)	5
VYVANSE	ADHD/Narcolespy Agents	SHIRE	14,885
WESTCORT	Topical Corticosteroid/Immune Modulators	RANBAXY	0
ZONEGRAN	Anticonvulsants/Antimania	EISAI	85
ZORBTIVE	Growth Stimulating/Growth Hormone	EMD SERONO	0

Pre-authorization will be determined at the November P&T Committee meeting.

C. The following drugs require more information prior to determination of a formulary status:

<b>DRUG</b>	<b>DRUG CLASSIFICATION</b>	<b>MANUFACTURER</b>
FARESTON	Oral Onocological Agents	GTX
GLUCAGEN	Binders/Chelators/Antidotes/Overdose/Hyperglycemics	BEDFORD LABS
GONAL-F	FSH/LH Agents	EMD SERONO
GONAL-F RFF	FSH/LH Agents	EMD SERONO
PAREMYD	Ophthalmics/Mydriatics	AKORN
REBIF	MS-DMDs	EMD SERONO
SYNTHROID	Thyroid	ABBOTT
UROCIT-K	Urinary Ph Agents	MISSION