Support Materials for the 27 June 2005 Beneficiary Advisory Panel Meeting

Prepared by the DoD Pharmacoeconomic Center

Summary of DoD P&T Committee Uniform Formulary Status Recommendations by Drug Class: May 2005

Drug Class	Formulary on UF	Non-Formulary on UF
PDE-5 Inhibitors	vardenafil	sildenafil, tadalafil
Topical Antifungals	clotrimazole, ketoconazole, miconazole, butenafine, naftifine, nystatin	econazole, sulconazole, oxiconazole, sertaconazole, ciclopirox
Multiple Sclerosis Disease Modifying Drugs	IFN beta-1a (Avonex), INF beta-1a (Rebif), IFN beta-1b (Betaseron), Glatiramer (Copaxone)	

Phosphodiesterase Type 5 Inhibitors (PDE5s)

PDE5-Inhibitors: Initial FDA Approval Dates & Patent Expirations

Generic Name	Brand (Manufacturer)	Strength & Formulation	FDA approval date, earliest (patent expiration)
Sildenafil	Viagra® (Pfizer)	25, 50, 100 mg tablets	March 1998 (March 2012)
Vardenafil	Levitra® (Bayer)	2.5, 5, 10, 20 mg tablets	Aug 2003 (Aug 2008)
Tadalafil	Cialis® (Lilly, ICOS)	5,10, 20 mg tablets	Nov 2003 (Nov 2008)

DoD PDE5-Inhibitors: Unique Utilizers

1 Feb 2004 – 31 Jan 2005

	MTFs	Retail	Mail Order	Total
Sildenafil	53,676	36,727	19,066	109,469
Vardenafil	2,876	8,706	2,744	14,326
Tadalafil	1,485	13,123	3,930	18,538
Total	58,037	58,556	25,740	142,333

PDE5 Inhibitor Implementation Plan

- **DoD P&T Committee recommended an effective date no later than the first Wednesday following a 90 day implementation period.**
  - **Due to the substantial number of patients currently receiving either sildenafil or tadalafil**
    - **128,007 patients (90%) of all PDE-5 Inhibitor Unique Utilizers**

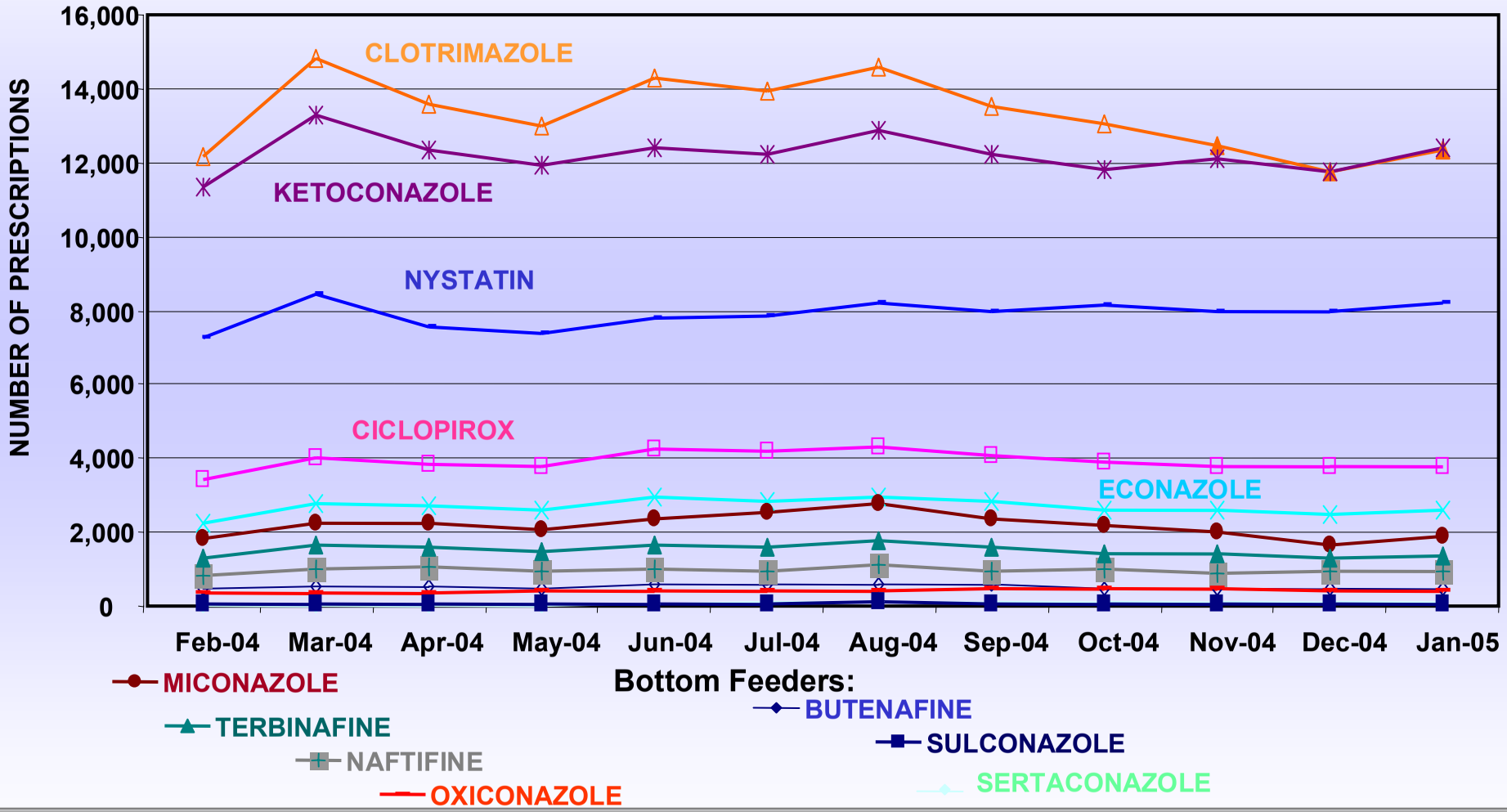
Topical Antifungals

Topical Antifungals

Drug	Brand	OTC	Formulations
"Azoles"			
1) Clotrimazole	Generics; Lotrimin	Yes	Cream, lotion, solution
2) Econazole	Generics; Spectazole		Cream
3) Ketoconazole	Generics; Nizoral		Cream, shampoo
4) Miconazole	Generics; Monistat Derm	Yes	Cream, oint, soln, spray, powder
5) Oxiconazole	Oxistat		Cream, lotion
6) Sertaconazole	Ertaczo		Cream
7) Sulconazole	Exelderm		Cream, solution
"Allylamines"			
8) Butenafine	Mentax	Yes	Cream
9) Naftifine	Naftin		Cream, gel
Terbinafine OTC	Lamisil	Yes	Cream, gel
10) Ciclopirox	Loprox; generic cream		Cream, gel, lotion, shampoo
11) Nystatin	generics		Cream, oint, powder

MHS Topical Antifungal Rx Fills

Feb 04 – Jan 05



Source: PDTS

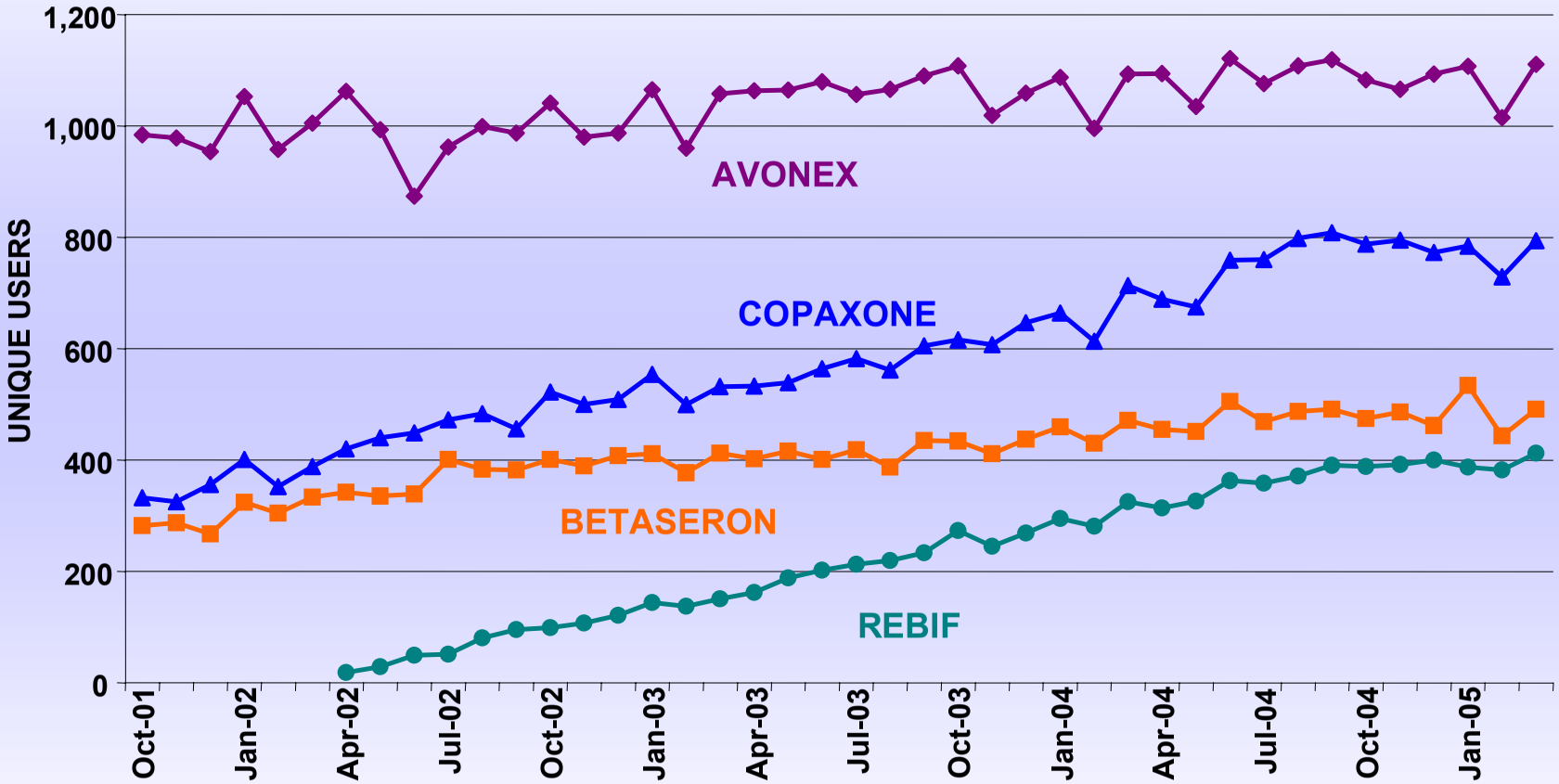
Topical Antifungal Implementation Plan

- **DoD P&T Committee recommended an effective date no later than the first Wednesday following a 30 day implementation period.**
  - **Topical Antifungal products are used to treat acute, rather than chronic infections**
    - **Patients are unlikely to require a change in existing therapy**
    - **49,743 patients = Unique Utilizers Impact**

Multiple Sclerosis Disease Modifying Drug Review

MS
Disease Modifying Drugs

Generic	Brand (manufacturer)	Max dosage	FDA approval
IFN beta-1a	Avonex (Biogen)	30 mcg IM weekly	05/17/1996
IFN beta-1a	Rebif (Serono)	44 mcg SC three times per week	03/07/2002
IFN beta-1b	Betaseron (Berlex)	0.25 mg SC every other day	07/23/1993
Glatiramer acetate	Copaxone (Teva)	20 mg SC daily	12/20/1996

All products selected for formulary status on the Uniform Formulary

MS
DMD Utilization: MHS
Oct 01 – Mar 05