

ODJFS P&T Committee Meeting Minutes

June 29, 2011

77 S. High St., 31st floor South A&B

Committee members present: Susan Baker, APN; Suzanne Eastman, RPh; Ioanna Giatis, DO; Robert Hunter, DO (chair); Karen Jacobs, DO; Margaret Scott, RPh; Michael Wascovich, RPh; Mary Jo Welker, MD

ACS staff present: Stephanie Levine, RPh, Clinical Manager, Denise Hefley, PharmD, Clinical Pharmacist

Approximately 90 stakeholders were present, most representing pharmaceutical manufacturers and advocacy associations.

Beginning at 9:00 AM, pharmaceutical manufacturers were given the opportunity to present clinical information on their products and respond to questions from the Committee members.

The meeting was called to order at 12:30 PM.

1. Interested party presentations

a. Aaron Boster, MD

Dr. Boster reports relationships as a consultant for Teva Neuroscience, Biogen Idec, and Novartis; lecturer for Teva Neuroscience and Biogen Idec; and clinical trial research with Teva Neuroscience, Biogen Idec, Novartis, Roche, Acorda and Actellion

b. Robert J. Masone, MD

Dr. Masone reports relationships as a speaker for Nucynta (Ortho-McNeil), Cymbalta (Lilly), and Naprelan and Rybix (Victory Pharma)

c. NAMI Ohio, Betsy Johnson

NAMI Ohio reports that in fiscal year 2010, approximately 5% of their funding was received from corporate members including some pharmaceutical companies

d. American Lung Association of Ohio, Shelly Kiser

The American Lung Association of Ohio reports receiving in the past funding from pharmaceutical companies for program and advocacy activities.

e. Ohio Psychiatric Physicians Association, Janet Shaw

OPPA reports no conflicts of interest

f. Ms. Valerie Vernon

Ms. Vernon reports no conflict of interest

2. Preferred Drug List (PDL) proposal

Dr. Hunter recognized Dr. Hefley to present recommendations from ACS, the Medicaid managed care plans, and ODJFS for the preferred drug list (PDL). A copy of the presentation used by ACS showing clinical changes in each drug class, market share, and recommendations, is attached to this document. The minutes reflect only those drug

classes that produced discussion. The recommendations presented for all other drug classes were approved unanimously by the committee.

Analgesic Agents: Gout

The length of prior authorization was discussed. A one-year authorization was approved unanimously.

Analgesic Agents: Opioids

Dr. Jacobs noted that there are many opioids available without prior authorization, and she is sensitive to addiction issues in Ohio.

Dr. Hunter said he is in favor of Nucynta based on the potential for less diversion.

The committee voted 7 to 1 in favor of preferred status for Nucynta.

Blood Formation, Coagulation, and Thrombosis Agents: Platelet Aggregation Inhibitors

Ms. Baker noted that Effient may be needed for patients who are determined to be a non-responder to Plavix based on genetic testing.

Mr. Wascovich said that the doctors who presented information in the morning session classified Effient as superior to Plavix.

Dr. Hunter commented that he generally defers to the interventional cardiologist that performed the procedure.

Dr. Welker noted that the cardiologist is not likely to request a prior authorization.

Mr. Wascovich noted the narrow indication of Effient, and wondered whether it would be prescribed when Plavix is indicated.

Dr. Welker thought that more prescriptions for Effient would be written, in part to avoid drug interactions with Plavix and omeprazole. She said that primary care providers should change from omeprazole to ranitidine to avoid the interaction.

Mr. Wascovich suggested adding Effient to preferred status, with a retrospective drug utilization review (DUR) to be done in 6 months. The committee voted 5 to 3 in favor of preferred status for Effient.

Cardiovascular Agents: Lipotropics

Dr. Hunter noted that Welchol has 53% of the market share for bile acid sequestrants, and that in his practice he is unable to convince patients to take powder cholestyramine. In addition, Welchol is useful in diabetes.

Dr. Hunter and Dr. Welker both said that their patients have gastrointestinal side effects from colestipol.

The committee voted 7 to 1 in favor of preferred status for Welchol.

Dr. Giatis noted the prior authorization requirement for statins for no less than two agents used for a one-month trial, and said that Crestor has great data.

Dr. Welker said that Lovaza is needed as an alternative for patients with lipid profiles.

Mr. Wascovich agreed that there are no other similar drugs, and Dr. Jacobs noted that it also has a specific indication.

The committee voted 6 to 2 in favor of preferred status for Lovaza.

Central Nervous System Agents: Anti-Migraine Agents

The committee voted 7 to 1 in favor of keeping Maxalt and Maxalt MLT in preferred status.

If Maxalt is in preferred status, the prior authorization criteria requiring therapeutic trials of two medications not requiring prior approval is appropriate.

Central Nervous System Agents: Antidepressants

Dr. Welker noted the high market share of Cymbalta but also noted the grandfathering policy. Ms. Scott confirmed that patients stable on an antidepressant must be allowed to continue the drug for both fee-for-service and managed care plans, as required by House Bill (HB) 153 (the state budget bill). Dr. Jacobs said that low doses of venlafaxine ER do not have a norepinephrine effect, only Cymbalta and Pristiq are true serotonin-norepinephrine reuptake inhibitors at any dose and at least one is necessary.

The committee voted 7 to 1 in favor of keeping preferred status for Cymbalta.

Dr. Jacobs also noted that the language in HB 153 only exempts psychiatrists from prior authorization when the prescription is in accordance with FDA-approved indications.

Many antidepressants are not approved for all indications in all age groups, particularly the child and adolescent population. Ms. Scott said that the department worked with the legislature and managed care plans on the bill language to include FDA-approved indications because of the concern of high prescribing of atypical antipsychotics for young children; however Ms. Scott acknowledged that the language does allow prior authorization for off-label indications as well.

Central Nervous System Agents: Antipsychotics, Second Generation, Oral

Dr. Jacobs noted that the discussion regarding HB 153 also applies to the antipsychotics. Many drugs are approved for acute mania, but not for maintenance therapy. Ms. Scott reiterated that patients stable on the drug must be allowed to continue the drug.

Dr. Jacobs also said that she is impressed with Latuda, with few side effects and the convenience of once daily dosing. Dr. Welker said that primary care providers rarely prescribe antipsychotics before a patient has seen a psychiatrist.

The committee voted 7 to 1 to keep Latuda in non-preferred status.

Central Nervous System Agents: Attention Deficit Hyperactivity Disorder Agents

Dr. Jacobs noted that Intuniv and Kapvay are both non-controlled options that should be considered. Ms. Eastman agreed that both drugs should be added to preferred status.

Mr. Wascovich said that the morning speaker for Kapvay said that in Texas, after Kapvay was added to the PDL the number of prescriptions for atypical antipsychotics for children decreased.

Dr. Hunter said that the market share slide for sympatholytic antihypertensives showed high prescribing of clonidine and guanfacine, and wondered how much was for children.

Dr. Jacobs said that the child psychiatrists at her institution have more experience with Intuniv than with Kapvay.

The committee voted 6 to 2 to add Intuniv and Kapvay to preferred status.

The committee also asked the department to look at the age of patients on clonidine and guanfacine, and to do a retrospective DUR in 6 months.

The committee also voted unanimously to change the length of authorizations to 1 year for all medications in the class.

Central Nervous System Agents: Fibromyalgia

Dr. Giatis said that since the state is trying to decrease prescribing of opioids, at least one agent should be preferred.

The committee voted 7 to 1 to move Cymbalta, Lyrica, and Savella to preferred status.

Central Nervous System Agents: Multiple Sclerosis Agents

Dr. Giatis said that Gilenya is used by the Cleveland Clinic Mellen Center for Multiple Sclerosis Treatment and Research as first line therapy. As one speaker noted, "time is brain." Oral therapy will increase compliance, and enable more patients who do not want to take injections to be treated.

The committee voted 7 to 1 to move Gilenya to preferred status.

Central Nervous System Agents: Sedative-Hypnotics

Dr. Jacobs said that she would like to see a non-controlled option. Ms. Scott said that one of the criteria for approval of non-controlled options is a history of addiction.

The committee noted that there is no time frame for therapeutic trials of preferred medications. Ms. Scott and Ms. Levine were not able to recall the protocol used by the ACS call center and will report back to the committee.

Central Nervous System Agents: Smoking Deterrents

Mr. Wascovich asked why the recommendation is to move Chantix to non-preferred status. Ms. Scott said that all of the managed care plans would like to require prior authorization, so the fee-for-service program is trying to align with the plans.

Dr. Welker said that a lot of her patients will not take Chantix because of the side effects.

Dr. Hunter said that he has had remarkable success with Chantix for his patients. Dr. Huffman, the committee pediatrician who was unable to attend the meeting made it known to the committee, she was against placing Chantix on the preferred list.

The committee voted 7 to 1 to keep Chantix in preferred status.

Endocrine Agents: Diabetes Adjunctive Therapy

Dr. Giatis noted that international recommendations for diabetes are to start patients on dual therapy if hemoglobin A1c is greater than 9.

Gastrointestinal Agents: Ulcerative Colitis Agents

Dr. Welker noted the unique mechanism of action of Lialda.

The committee voted 7 to 1 in favor of placing Lialda in preferred status.

Genitourinary Agents: Benign Prostatic Hyperplasia

Dr. Giatis said that Avodart works better than finasteride, but thought that a one-month trial of finasteride is fine.

Genitourinary Agents: Urinary Antispasmodics

Dr. Hunter noted that his nursing home patients do well on Toviaz. Dr. Giatis agreed but noted that the class requires only a one-month trial of a preferred agent so if cognitive side effects manifest the patient can be changed quickly.

Infectious Disease Agents: Antibiotics – Quinolones

Ms. Eastman asked about the new generic levofloxacin. Ms. Scott said that it was just approved and has not yet been reviewed for pricing. This will be brought back to the committee at the October meeting.

Respiratory Agents: Nasal Preparations

Dr. Huffman, the committee pediatrician, was not able to attend the meeting but communicated with Ms. Scott that Nasonex is indicated for ages 2 and over, while fluticasone is indicated for age 4 and over. She recommended an allowance for patients under age 4 for Nasonex. Ms. Scott said that Nasacort AQ, Nasonex and Veramyst are all indicated for ages 2 and over.

Ms. Eastman asked about the new generic Nasacort AQ. Ms. Scott said that similar to the new generic levofloxacin, it was just approved and has not yet been reviewed.

Ms. Baker said that Veramyst has data showing improvement in ocular symptoms. Dr. Hefley noted that other agents have similar data.

Ms. Scott said that if the committee wants to add a third agent, she would recommend Nasacort AQ because of the recent generic availability and indication for age 2 and over. The committee voted unanimously to add Nasacort AQ or its generic to preferred status.

Topical Agents: Anti-Parasitics

Ms. Baker noted that Ulesfia is non-toxic, and that often patients come to her after having purchased products over-the-counter (OTC).

Ms. Scott noted that if patients have tried OTC products, the prescriber can submit a prior authorization stating this and the non-preferred agent can be approved.

Dr. Huffman had communicated that lindane is toxic so should be removed from the PDL if possible, or at least include a note that it should not be used in patients under the age of two.

Topical Agents: Pleuromutilin Derivatives

Ms. Scott noted that the smaller tubes of Altabax have been discontinued. ODJFS had originally approved only the 5g and 10g sized, because the manufacturer had said that patients should not need larger tubes. However, very few prescriptions were written for the smaller tube sizes so the manufacturer discontinued those and continued to market only the larger tubes. The larger tubes are much more expensive. The criteria do not include a length of trial or number of other medications to be tried because the smaller tubes were available. The committee asked that this be brought back in October with recommendations about prior therapy.

The meeting was adjourned with a reminder that the next meeting is Wednesday, October 12 at 10 AM.

Notes from ODJFS after the meeting:

The current prior authorization criteria for sedative-hypnotics used by the ACS call center is a history of a claim for a preferred product filled at least 10 days, but not more than 45 days, prior to the prior authorization request.

Committee recommendations regarding length of prior authorizations and addition of Nasacort AQ or its generic will be implemented by the department. The department will also add indicated ages for Second Generation Antihistamines, Nasal Preparations, and Anti-Parasitics and generic names for all drugs to the PDL document as requested by committee members.

The department is reviewing the recommendations for Nucynta, Effient, Welchol, Lovaza, Maxalt, Maxalt MLT, Cymbalta for depression, Intuniv, Kapvay, Cymbalta for fibromyalgia, Lyrica, Savella, Gilenya, Chantix, and Lialda.

Update 7/26/11:

The department has not accepted the recommendations for Nucynta or Lovaza. These agents will remain on prior authorization.

The department has accepted the recommendations for Effient, Welchol, Maxalt, Maxalt MLT, Cymbalta for depression, Intuniv, Kapvay, Cymbalta for fibromyalgia, Lyrica, Savella, Gilenya, Chantix, and Lialda. In addition, ODJFS will retain Nicotrol inhaler and nasal sprays in preferred status. Utilization and outcomes with Effient, Intuniv, and Kapvay will be monitored closely with a report to the P&T Committee to be presented at the April 11, 2012, meeting.

The P&T Committee will meet the second Wednesday of January, April, and October, and the last Wednesday in June. Upcoming meetings are scheduled for:

October 12, 2011

January 11, 2012

April 11, 2012

June 27, 2012



Ohio Health Plans Pharmacy Benefit Management Program Preferred Drug List Recommendations

Denise Hefley, PharmD
ACS Clinical Information Pharmacist

Page 1



COX-2 Inhibitors: Clinical Highlights

- Celebrex®
 - Familial Adenomatous Polyposis (FAP) indication removed from product labeling

Page 2

July 5, 2011



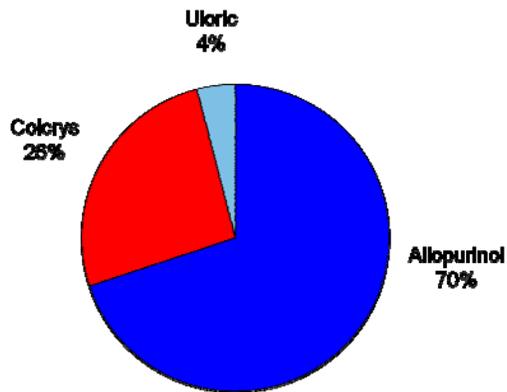
NSAID-PPI Combination: Clinical Highlights

- New class for inclusion on the PDL
- Agent reviewed in this class:
 - Vimovo™ (esomeprazole/naproxen)

Gout Agents: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class are:
 - Allopurinol (Zyloprim®)
 - Colchicine (Colcrys™)
 - Febuxostat (Uloric™)
 - Probenecid
 - Probenecid/Colchicine

Gout Agents: Market Share



Gout Agents: Recommendations

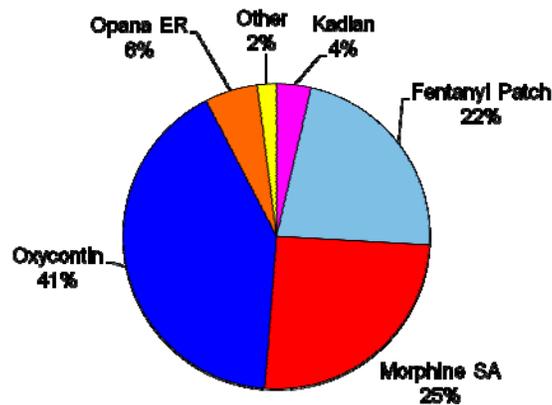
- Add to Preferred:
 - Allopurinol
 - Probenecid
 - Probenecid/Colchicine

- Add to Non-Preferred
 - Zyloprim®
 - Colcrys™ w/SmartPA
 - Uloric™ w/SmartPA

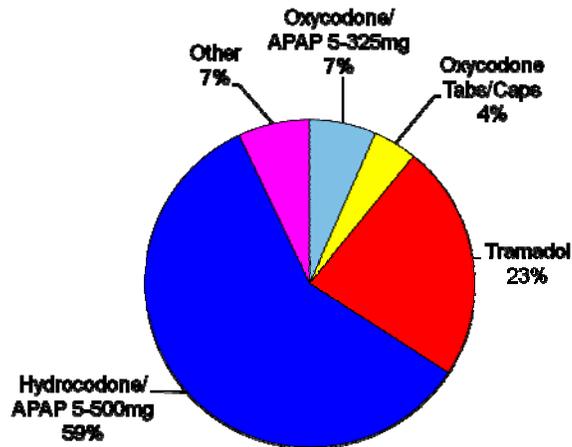
Opioids: Clinical Highlights

- FDA approvals:
 - Abstral™ (fentanyl sublingual)
 - Butrans™ (buprenorphine transdermal)
- Propoxyphene withdrawn from market
- APAP limit for combination products
- Long Acting Opioids REMS program

Long-Acting Opioids: Market Share



Short-Acting Opioids: Market Share



Opioids: Recommendations

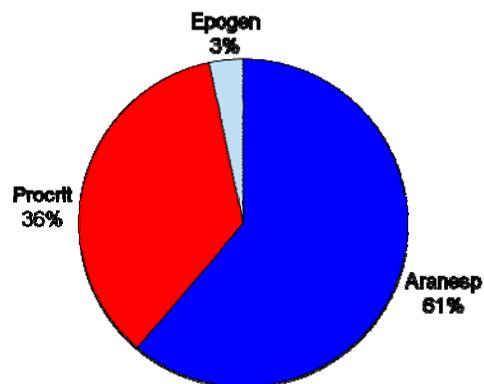
- Move to Non-Preferred:
 - Generic oxycodone ER
 - Kadian®
 - Oxycontin®
 - Trezix™

- Transmucosal Fentanyl Products
 - Enhance PA criteria

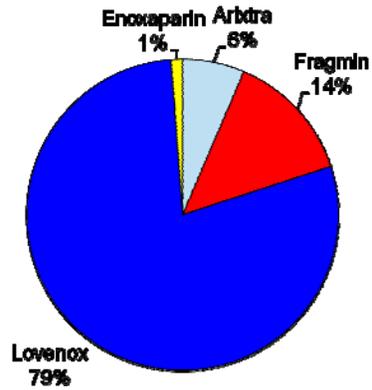
Blood Agents: Clinical Highlights

- FDA approval:
 - Generic enoxaparin
 - A rated to Lovenox®

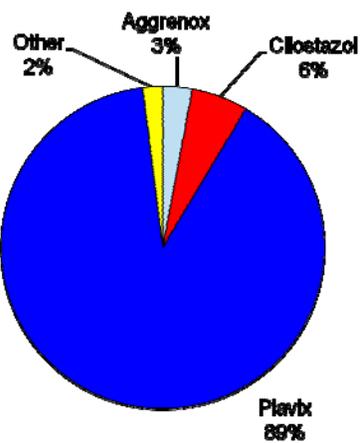
Hematopoietic Agents: Market Share



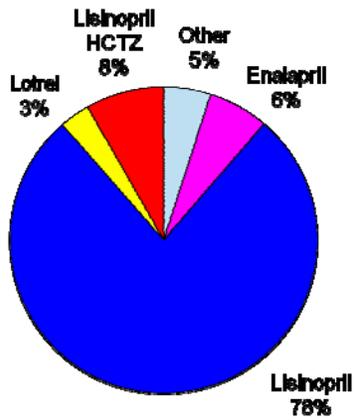
Heparin-Related Preparations: Market Share



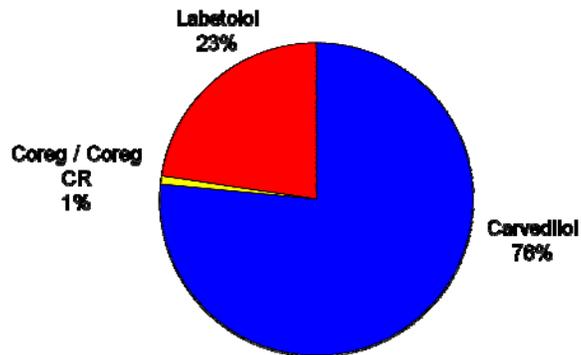
Platelet Aggregation Inhibitors: Market Share



Angiotensin Converting Enzyme Inhibitors: Market Share



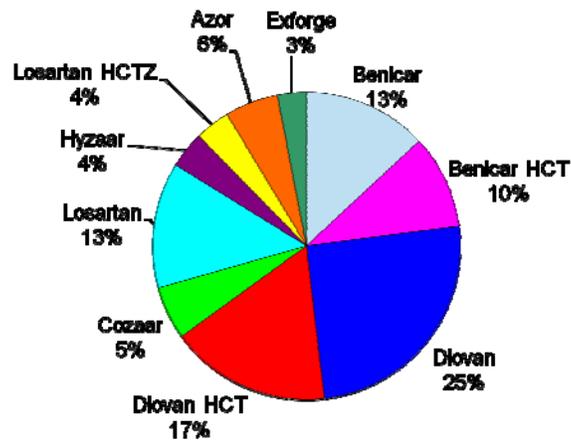
Alpha-Beta Adrenergic Blockers: Market Share



Angiotensin Receptor Blockers: Clinical Highlights

- FDA approvals:
 - Edarbi™ (azilsartan)
 - Tribenzor™ (olmesartan/amlodipine/hctz)

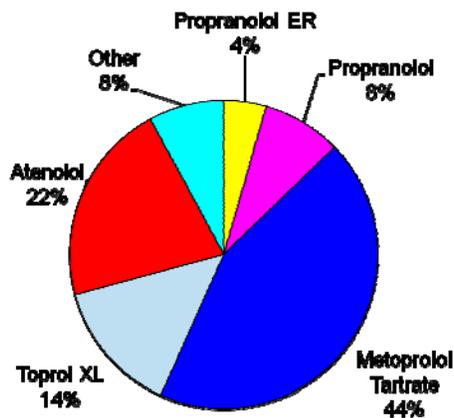
Angiotensin Receptor Blockers: Market Share



Antiotensin Receptor Blockers: Recommendations

- Move to Preferred:
 - Generic losartan
 - Generic losartan/HCTZ
- Move to Non-Preferred:
 - Cozaar[®]
 - Hyzaar[®]
- Add step therapy
 - All ARBs and combination agents
 - ACE or combination agent previous 120 days

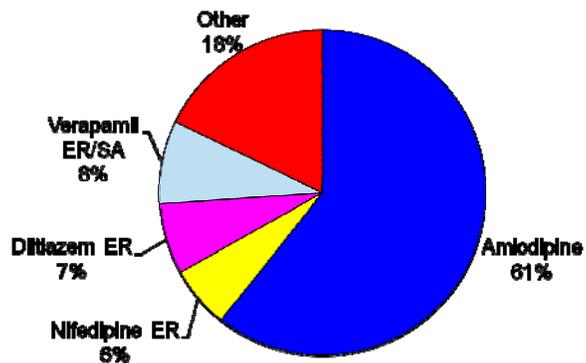
Beta-Blockers: Market Share



Beta Blockers: Recommendations

- Move to Preferred:
 - Generic metoprolol succinate ER
 - Generic metoprolol HCT

Calcium Channel Blockers: Market Share



Calcium Channel Blockers: Recommendations

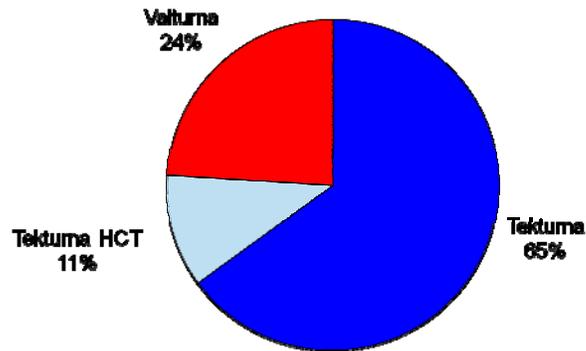
- Move to Preferred:
 - Generic nifedipine IR

- Move to Non-Preferred
 - Dynacirc CR®

Direct Renin Inhibitors: Clinical Highlights

- FDA approvals:
 - Amturnide® (aliskiren/valsartan/hctz)
 - Tekamlo™ (aliskiren/amlodipine)

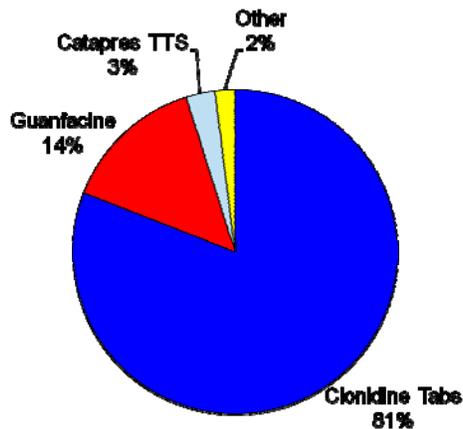
Direct Renin Inhibitors: Market Share



Sympatholytic Antihypertensives: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class are:
 - Clonidine IR (Catapres®)
 - Clonidine ER (Nexiclon™ XR)
 - Clonidine Transdermal (Catapres®)
 - Guanfacine (Tenex®)
 - Methyldopa
 - Methyldopa/HCTZ
 - Reserpine

Sympatholytic Antihypertensives: Market Share



Sympatholytic Antihypertensives: Recommendations

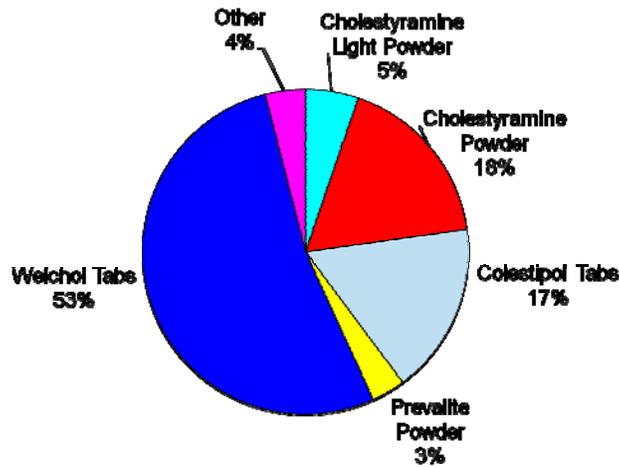
■ Add to Preferred:

- Catapres TTS®
- Clonidine Tablet
- Guanfacine
- Methyldopa
- Methyldopa/HCTZ

■ Add to Non-Preferred:

- Catapres® Tablet
- Clonidine Patch
- Nexiclon™ XR Tablet
- Nexiclon™ XR Susp
- Reserpine
- Tenex®

Bile Acid Sequestrants: Market Share



Bile Acid Sequestrants: Recommendations

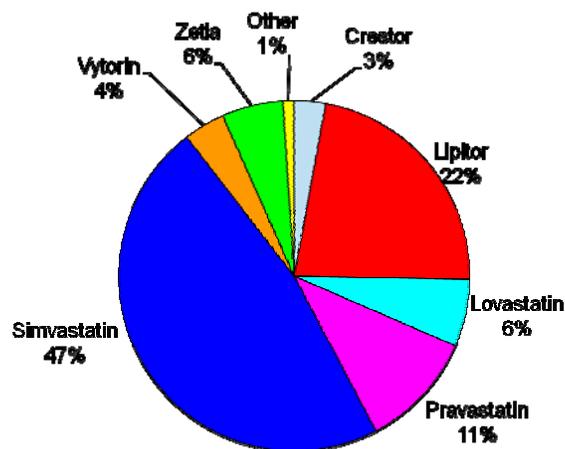
- Move to Preferred:
 - Generic cholestyramine Packets
 - Generic cholestyramine Light Packets
 - Prevalite® Packets

- Move to Non-Preferred:
 - Welchol™ Tablets

Statins: Clinical Highlights

- New safety warning
 - High dose simvastatin (80mg)
 - Increased risk of myopathy

Statins: Market Share

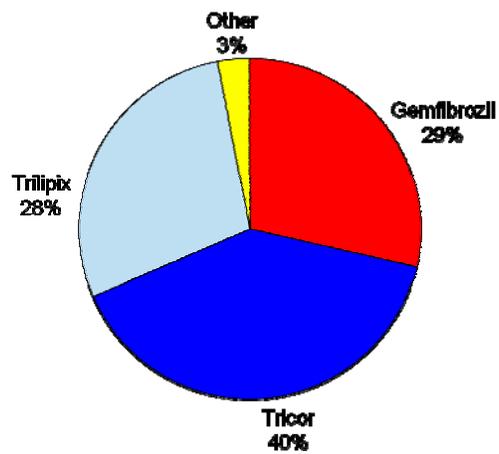


Statins: Recommendations

■ Move to Non-Preferred:

- Lescol®
- Lescol® XL

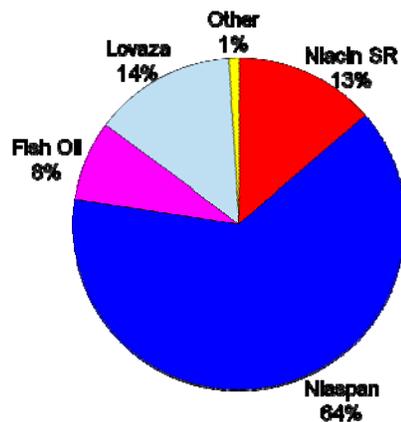
Fibric Acid Derivatives: Market Share



Other Lipotropics: Clinical Highlights

- New dosage strengths:
 - Simcor® (simvastatin/niacin ER)
 - 500mg/40mg
 - 1000mg/40mg

Other Lipotropics: Market Share



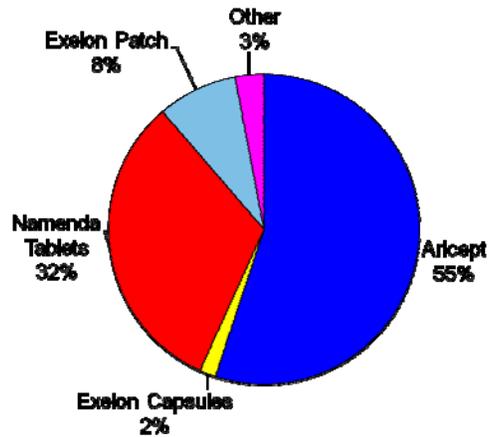
Lipotropic / HTN Combination: Recommendations

- Move to Non-Preferred:
 - Caduet®

Alzheimer's Agents: Clinical Highlights

- FDA approvals:
 - Aricept® 23mg
 - Moderate to severe Alzheimer's
 - Generic donepezil
 - A rated to Aricept®
 - Generic rivastagmine
 - A rated to Exelon®

Alzheimer's Agents: Market Share



Alzheimer's Agents: Recommendations

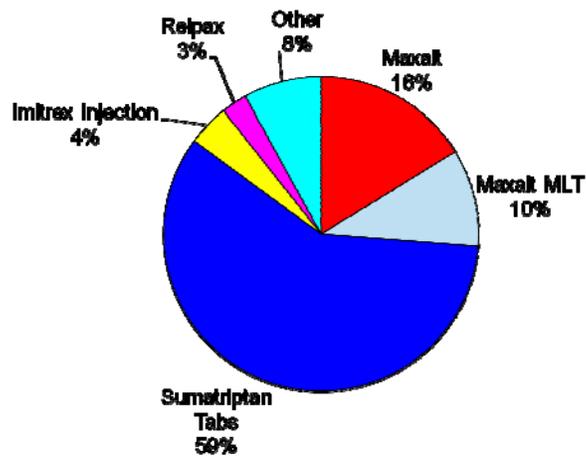
- Move to Preferred:
 - Generic galantamine IR
 - Generic galantamine ER

- Move to Non-Preferred:
 - Razadyne® IR
 - Razadyne® ER

Anti-Migraine Agents: Clinical Highlights

- FDA approval:
 - Generic naratriptan
 - A rated to Ammerge®

Anti-Migraine Agents: Market Share



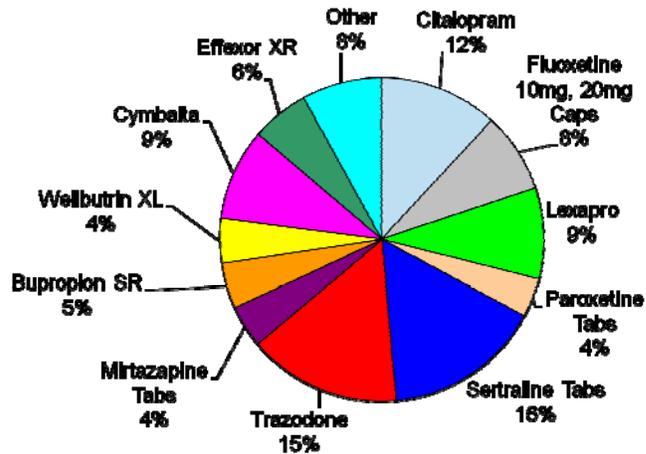
Anti-Migraine Agents: Recommendations

- Move to Preferred:
 - Generic naratriptan
- Move to Non-preferred:
 - Amerge®
 - Frova®
 - Maxalt®
 - Maxalt MLT®
 - Sumavel® Dosepro™

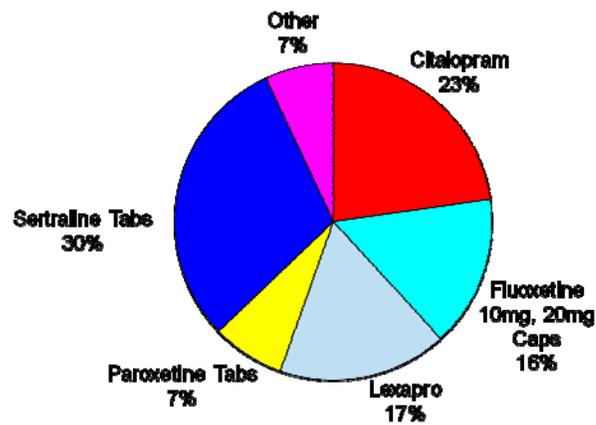
Antidepressants: Clinical Highlights

- FDA approvals:
 - Generic phenelzine
 - A rated to Nardil®
 - Oleptro™ (trazodone ER)
 - Treatment of MDD
- New Indication:
 - Cymbalta®
 - Chronic musculoskeletal pain

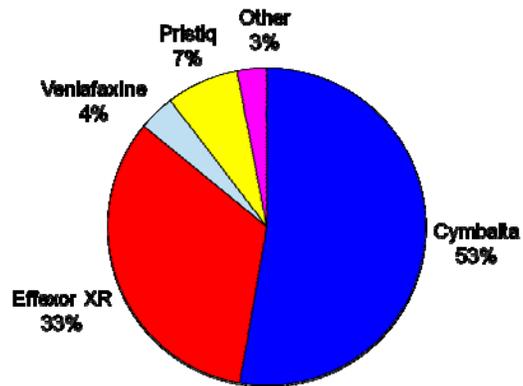
Antidepressants: Total Market Share



Antidepressants: SSRI Market Share



Antidepressants: SNRI Market Share



Antidepressants: Recommendations

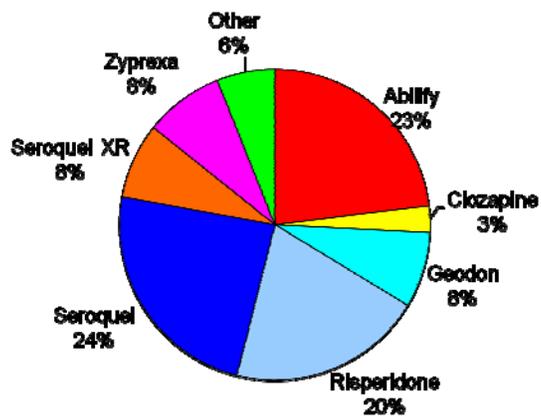
- Move to Preferred:
 - Generic venlafaxine ER

- Move to Non-Preferred:
 - Cymbalta[®]
 - Effexor XR[®]
 - Venlafaxine ER Tablets
 - Wellbutrin XL[®]

Second Generation Antipsychotics: Clinical Highlights

- FDA approval:
 - Latuda® (lurasidone)
 - Treatment of schizophrenia
- New dosage strengths:
 - Fazaclo® ODT
 - 150mg, 200mg
- New indications:
 - Abilify®
 - Bipolar I Disorder - adjunct to lithium or valproate
 - Invega®
 - Schizophrenia in adolescents 12-17yrs

Second Generation Antipsychotics: Market Share



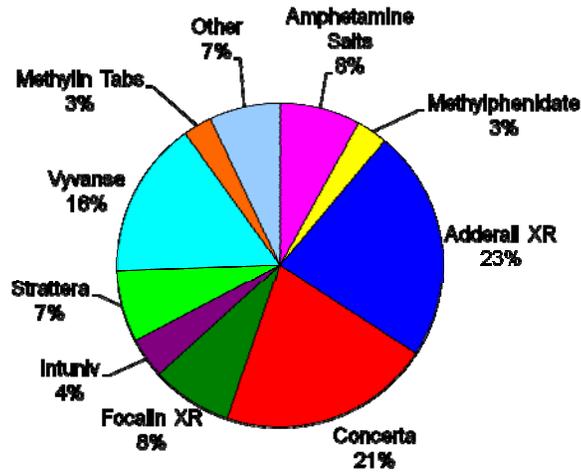
Second Generation Antipsychotics: Recommendations

- Move to Preferred:
 - Generic risperidone M-Tab

Attention Deficit Hyperactivity Disorder Agents: Clinical Highlights

- FDA approval:
 - Kapvay™ (clonidine ER)
 - Monotherapy or adjunctive therapy
- Generic methylphenidate oral solution
 - A rated to Methylin®
- New Indications:
 - Daytrana® (methylphenidate)
 - Use in adolescents 13-17yrs
 - Intuniv™ (guanfacine)
 - Adjunctive Treatment w/LA psychostimulants
 - Vyvanse® (lisdexamfetamine)
 - Use in adolescents 13-17yrs

Attention Deficit Hyperactivity Disorder Agents: Market Share



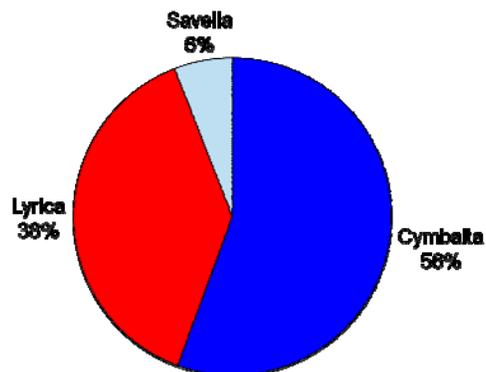
Attention Deficit Hyperactivity Disorder Agents: Recommendations

- Move to Non-Preferred:
 - Dexedrine®

Fibromyalgia Agents: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class are:
 - Cymbalta®
 - Lyrica®
 - Savella®

Fibromyalgia Agents: Market Share



Fibromyalgia Agents: Recommendations

- Add to Non-Preferred:

- Cymbalta®

- Lyrica®

- Savella®

Medication Assisted Treatment Agents: Clinical Highlights

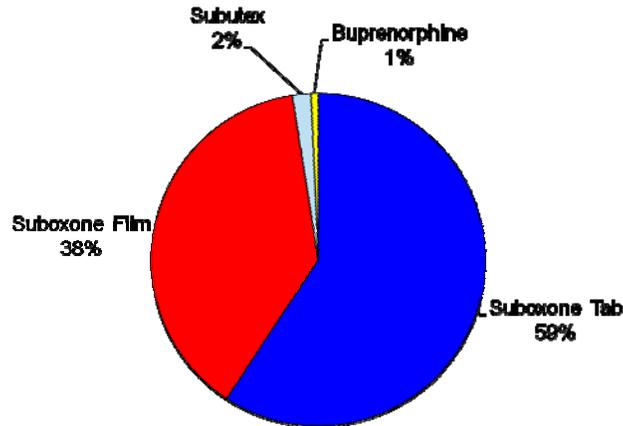
- New class for inclusion on the PDL

- Agents reviewed in this class are:

- Buprenorphine (Subutex®)

- Suboxone®

Medication Assisted Treatment Agents: Market Share



Medication Assisted Treatment Agents: Recommendations

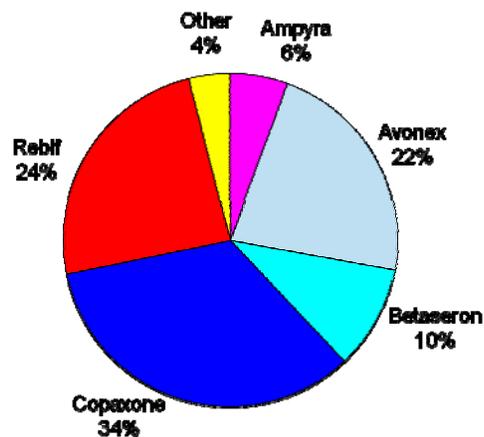
- Add to Preferred:
 - Generic buprenorphine
 - Suboxone[®] Film
 - Suboxone[®] Tablets

- Add to Non-Preferred:
 - Subutex[®]

Multiple Sclerosis Agents: Clinical Highlights

- FDA approval:
 - Gilenya™ (fingolimod)
 - 0.5mg oral tablet formulation
 - Treatment of relapsing forms of MS

Multiple Sclerosis Agents: Market Share



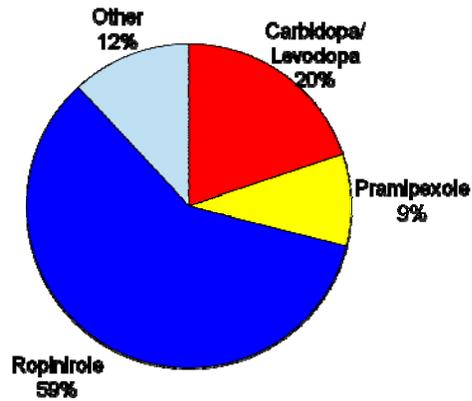
Multiple Sclerosis Agents: Recommendations

- Ampyra®
 - Change initial authorization period from 60 days to 90 days

Parkinson's Agents: Clinical Highlights

- FDA approval:
 - Generic pramipexole
 - A rated to Mirapex®

Parkinson's Agents: Market Share



Parkinson's Agents: Recommendations

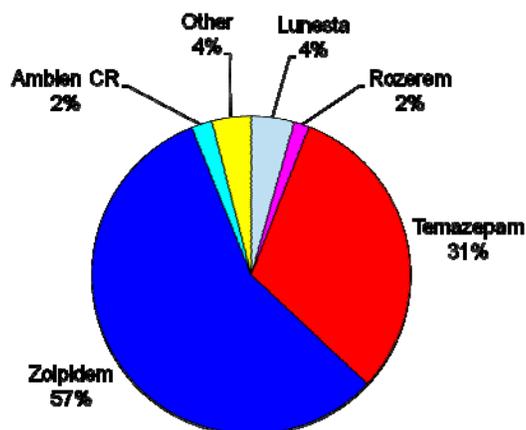
- Move to Preferred:
 - Generic pramipexole

- Move to Non-Preferred:
 - Requip[®] XL[™]
 - Stalevo[®]

Sedative Hypnotics, Non-Barbiturate: Clinical Highlights

- FDA approvals:
 - Generic zolpidem ER
 - A rated to Ambien CR®
 - Silenor® (doxepin) Tablets
 - Treatment of insomnia (sleep maintenance)
 - Zolpimist™ (zolpidem tartrate) Spray
 - Short-term treatment of insomnia (sleep initiation)

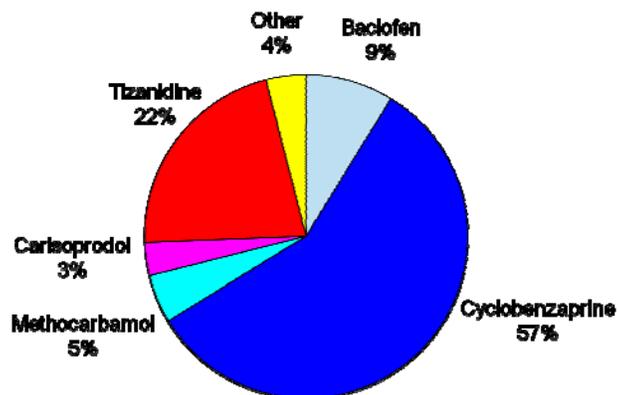
Sedative Hypnotics, Non-Barbiturate: Market Share



Sedative Hypnotics, Non-Barbiturate: Recommendations

- Move to Preferred:
 - Generic zaleplon

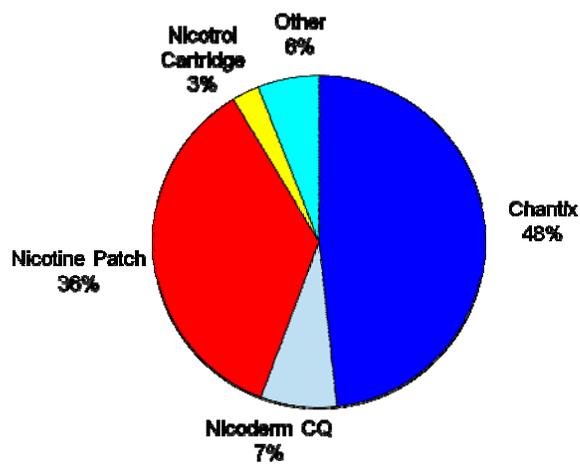
Skeletal Muscle Relaxants, Non- Benzodiazepine: Market Share



Skeletal Muscle Relaxants, Non-Benzodiazepine: Recommendations

- Add to Preferred:
 - Generic dantrolene

Smoking Deterrents: Market Share

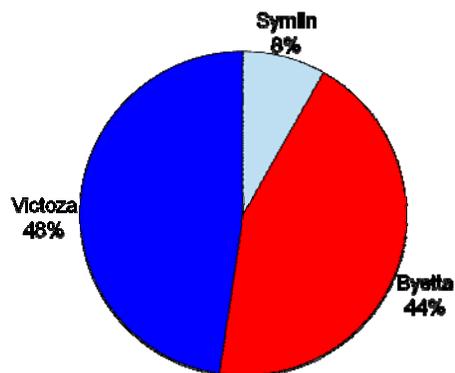


Smoking Deterrents: Recommendations

■ Add to Non-Preferred:

- Chantix®
- Nicotrol® Inhaler
- Nicotrol® NS

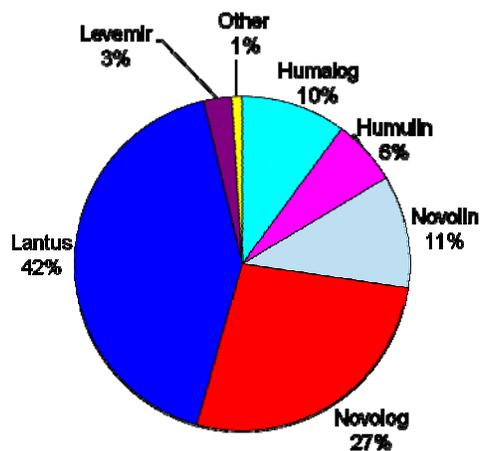
Amylin Analogs and Incretin Mimetics: Market Share



Amylin Analogs and Incretin Mimetics: Recommendations

- Add step edit:
 - Must have a claim for an oral hypoglycemic agent or insulin within the last 120 days

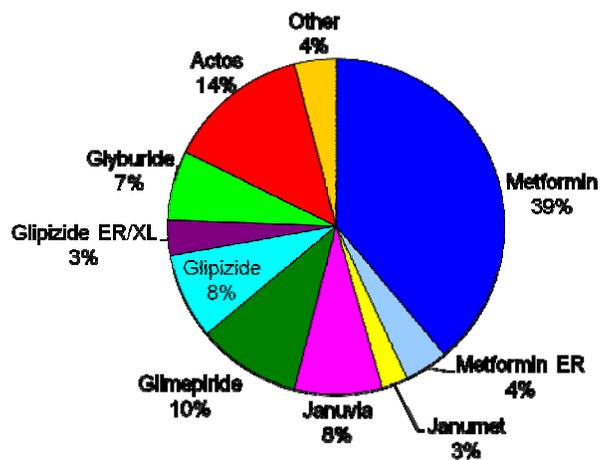
Insulins: Market Share



Oral Hypoglycemics: Clinical Highlights

- FDA approvals
 - Actoplus Met® XR (metform/pioglitazone)
 - Inadequate control on pioglitazone or metformin alone
 - Kombiglyze™ XR (metformin/saxagliptin)
 - Tradjenta™ (linagliptin)
- FDA restriction of Avandia®
 - Elevated risk of CV events
 - Use only if uncontrolled on other therapies

Oral Hypoglycemics: Market Share



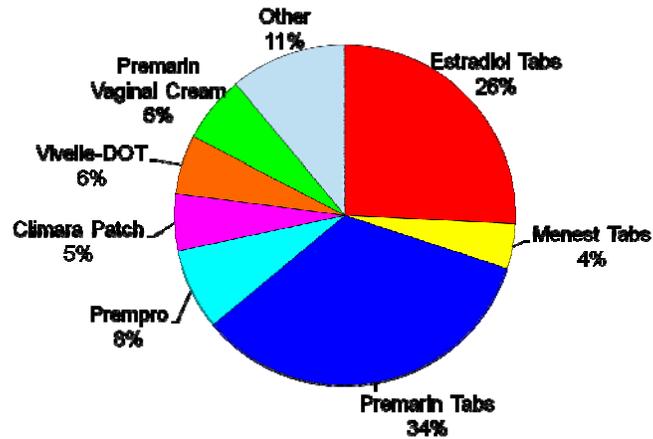
Oral Hypoglycemics: Recommendations

- Move to Preferred:
 - Generic glipizide/metformin
 - Tradjenta™

Estrogenic Agents: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class are:
 - Conjugated estrogens
 - Conjugated estrogens /medroxyprogesterone
 - Esterified estrogens
 - Estradiol
 - Estradiol/drospirenone
 - Estradiol/levonorgestrel
 - Estradiol/norethindrone
 - Estradiol/norgestimate
 - Estropipate
 - Ethinyl estradiol/norethindrone acetate

Estrogenic Agents: Market Share



Estrogenic Agents: Recommendations

■ Add to Preferred:

Oral:

- Cenestin®
- Enjuvia®
- Estradiol
- Estropipate
- Menest®
- Premarin®
- FemHRT®
- PremPhase®
- PremPro®

Topical:

- Alora®
- Combipatch®
- Estradiol

Vaginal:

- Estring®
- Premarin®

Estrogenic Agents: Recommendations (cont'd)

■ Add to Non-Preferred:

Oral:

- Activella®
- Angeliq®
- Jinteli
- Mimvey®
- Prefest®

Topical:

- Climara Pro®
- Divigel®
- Elestrin®
- Estraderm®
- Estrasorb®
- Evamist®
- Menostar®
- Vivelle-Dot®

Vaginal:

- Estrace®
- Femring®
- Vagifem®

Growth Hormones: Clinical Highlights

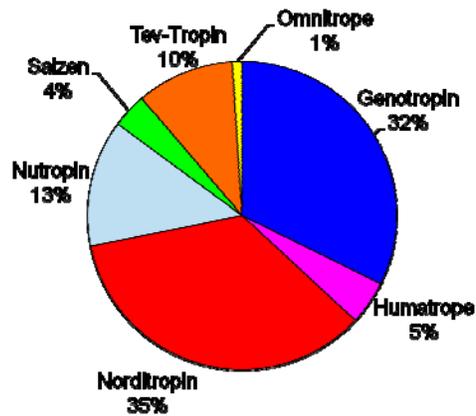
■ New Indications:

- Omnitrope®
 - Treatment of idiopathic short stature (ISS)

■ Case reports of pancreatitis

- Both adults and children
- Possible greater risk in children; girls with Turner Syndrome

Growth Hormones: Market Share

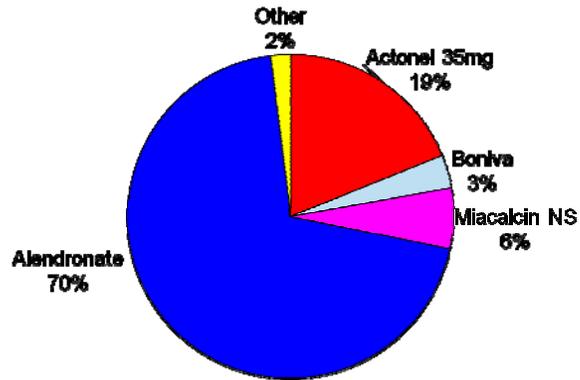


Bone Ossification Enhancers: Clinical Highlights

- FDA approval:
 - Atelvia® (alendronate delayed-release)
 - Treatment of osteoporosis
 - Taken after breakfast

- Discontinued product:
 - Actonel® and Calcium (risedronate/calcium)

Bone Ossification Enhancers: Market Share



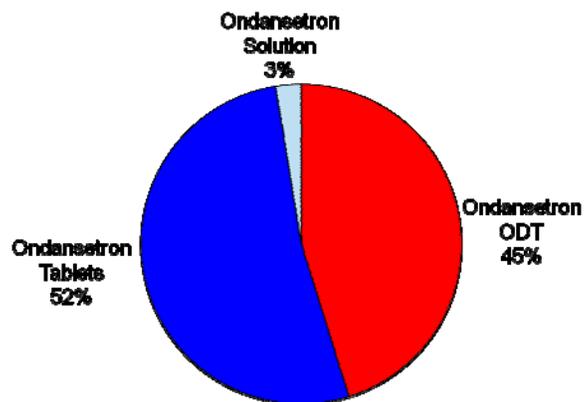
Bone Ossification Enhancers: Recommendations

- Move to Non-Preferred:
 - Actonel®

Anti-Emetic Agents: Clinical Highlights

- FDA approval:
 - Zuplenz® (ondansetron)
 - Oral Soluble Film
- FDA restriction of Anzemet® Injection
 - Increased risk of torsade de pointes
 - Dose-dependent prolongation of QT, PR, QRS

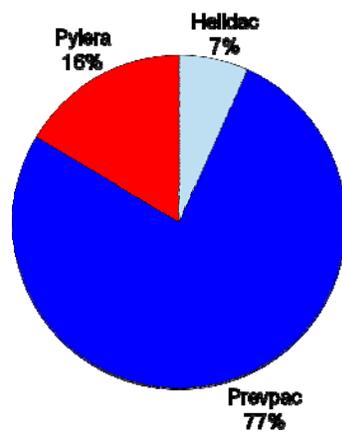
Anti-emetic Agents: Market Share



H. Pylori Agents: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class are:
 - Helidac®
 - Prevpac®
 - Pylera®

H. Pylori Agents: Market Share



H. Pylori Agents: Recommendations

- Add to Preferred:

- Helidac®

- Add to Non-Preferred

- Prevpac®

- Pylera®

Pancreatic Enzymes: Clinical Highlights

- FDA Approval:

- Pancreaze® (lipase/protease/amylase)

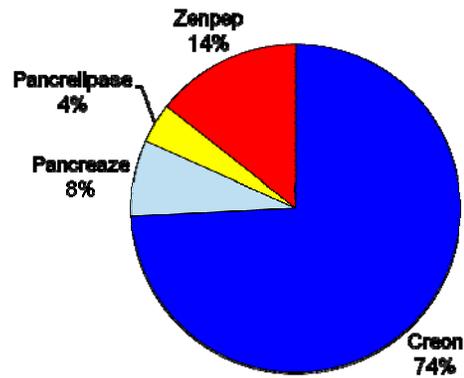
- Available in 3 combinations

- 4,200/10,000/17,500

- 10,500/25,000/43,750

- 16,800/40,000/70,000

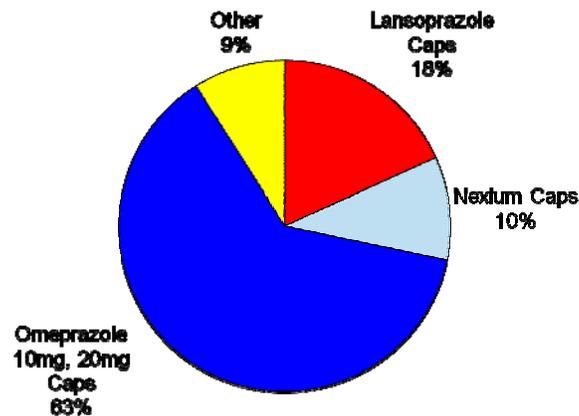
Pancreatic Enzymes: Market Share



Proton Pump Inhibitors (PPIs): Clinical Highlights

- FDA approvals:
 - Generic lansoprazole ODT
 - A rated to Prevacid® Solutab
 - Zegerid OTC® (omeprazole/sodium bicarb)
- All PPIs
 - Hypomagnesemia w/long term use

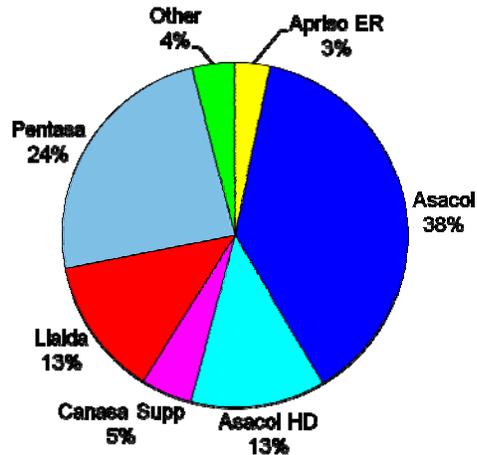
Proton Pump Inhibitors (PPIs): Market Share



Ulcerative Colitis Agents: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class are:
 - Balsalazide
 - Mesalamine
 - Olsalazine
 - Sulfasalazine

Ulcerative Colitis Agents: Market Share



Ulcerative Colitis Agents: Recommendations

■ Add to Preferred:

- Apriso®
- Asacol®
- Asacol® HD
- Balsalazide
- Mesalamine Enema
- Sulfasalazine
- Sulfasalazine EC

■ Add to Non-Preferred:

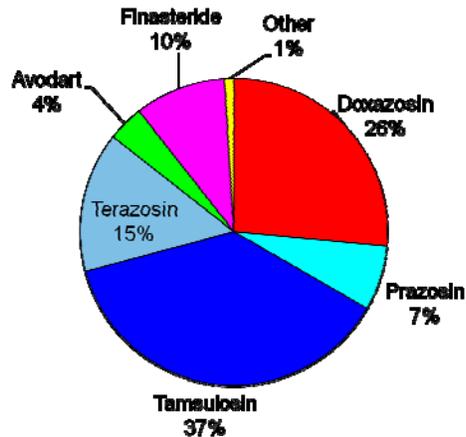
- Azulfidine®
- Azulfidine EN-Tab®
- Canasa®
- Colazal®
- Dipentum®
- Lialda®
- Mesalamine Kit
- Pentasa®
- Rowasa®
- SFRowasa®

Benign Prostatic Hypertrophy Agents: Clinical Highlights

- FDA approval:

- Jalyn™ (dutasteride/tamsulosin)
- Treatment of BPH in men with enlarged prostate

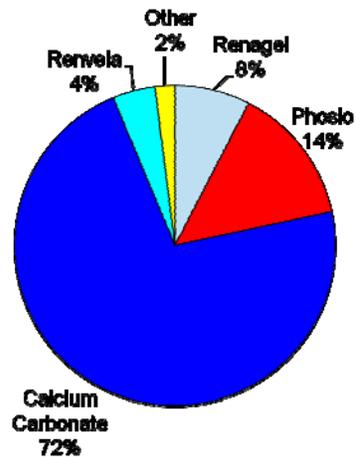
Benign Prostatic Hypertrophy Agents: Market Share



Benign Prostatic Hypertrophy Agents: Recommendations

- Move to Non-Preferred:
 - Avodart®

Electrolyte Depleters: Market Share



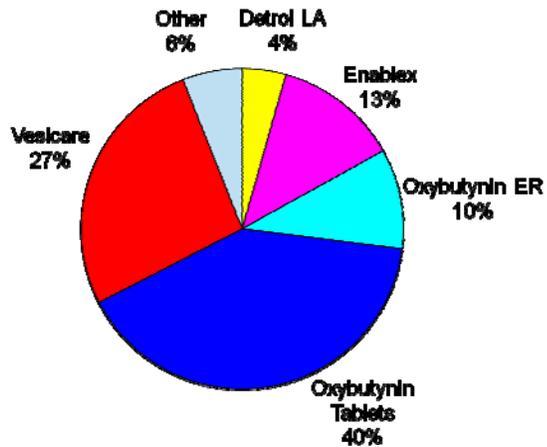
Electrolyte Depleters: Recommendations

- Move to Preferred:
 - Generic calcium acetate
 - Eliphos™

Urinary Antispasmodics: Clinical Highlights

- FDA approval:
 - Generic trospium
 - A rated to Sanctura®

Urinary Antispasmodics: Market Share

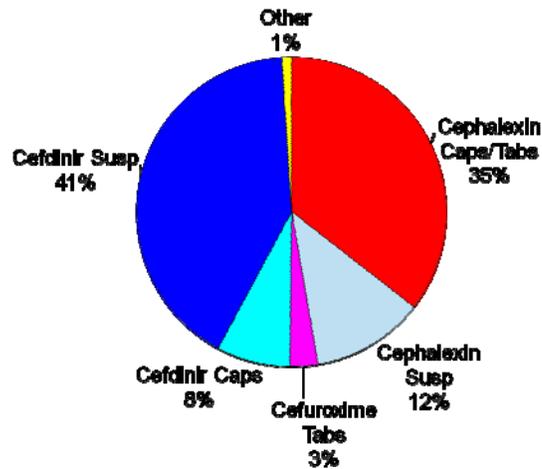


Urinary Antispasmodics: Recommendations

- Move to Preferred:
 - Generic oxybutynin ER
 - Sanctura®
 - Sanctura XR®

- Move to Non-Preferred:
 - Enablex®

Oral Cephalosporins: Market Share

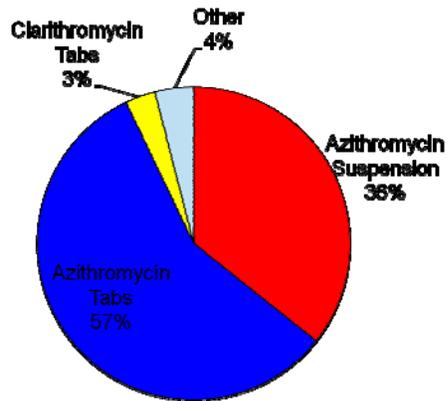


Oral Cephalosporins: Recommendations

- Move to Preferred:
 - Generic cefaclor ER
 - Generic cefadroxil 1gm tablets
 - Generic cefadroxil suspension

- Move to Non-Preferred:
 - Cedax[®] capsules
 - Cedax[®] suspension

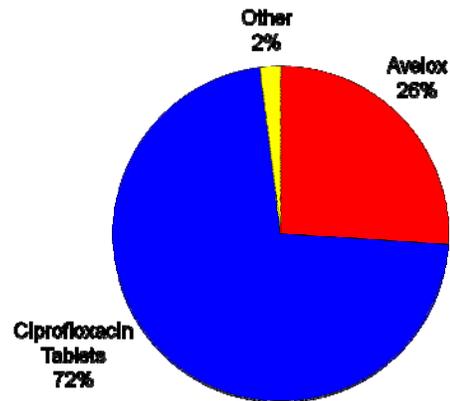
Oral Macrolides: Market Share



Oral Quinolones: Clinical Highlights

- Fluoroquinolone labeling:
 - New Boxed Warning
 - Exacerbation of muscle weakness
 - Avoid in patients w/history of Myasthenia Gravis

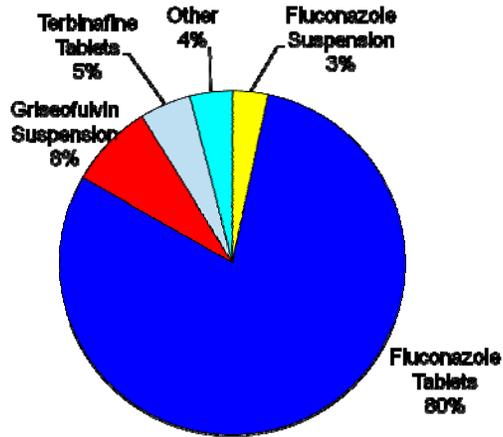
Oral Quinolones: Market Share



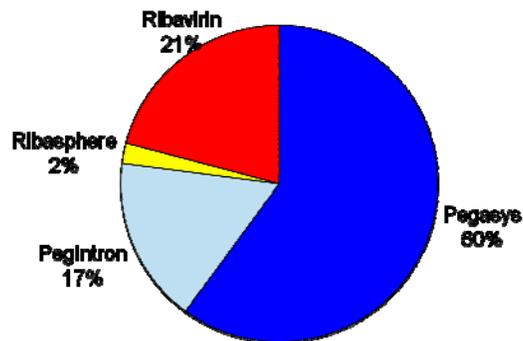
Oral Quinolones: Recommendations

- Move to Preferred:
- Generic ofloxacin

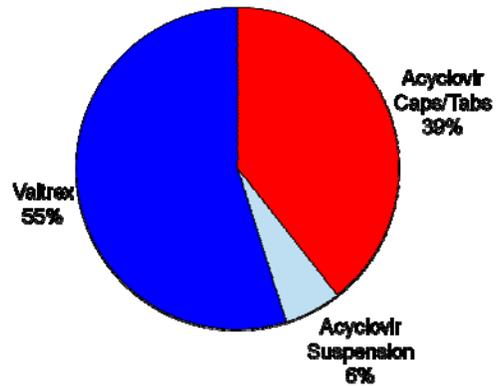
Agents for Onychomycosis & Systemic Infections: Market Share



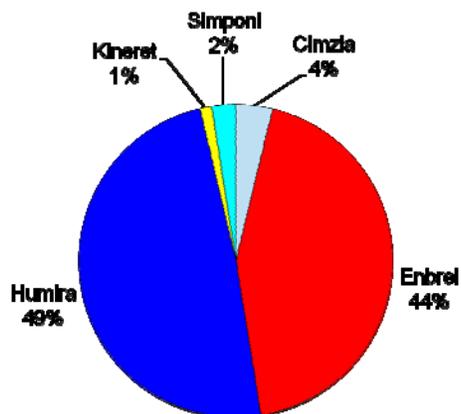
Antivirals - Hepatitis C Agents: Market Share



Antivirals Herpes: Market Share



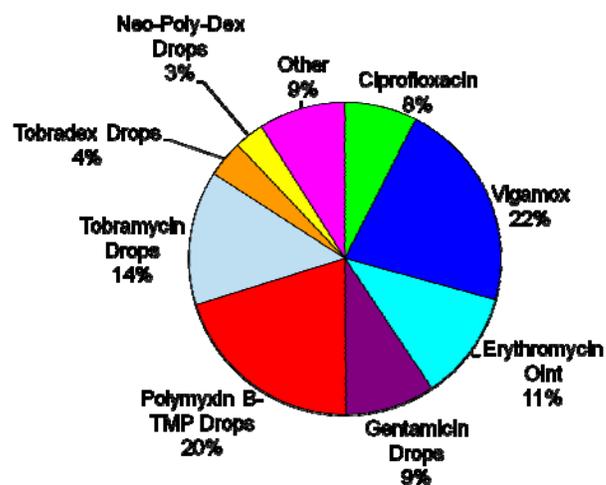
Injectable Anti-Rheumatic Agents: Market Share



Ophthalmic Antibiotic Drops and Ointments: Clinical Highlights

- FDA approvals:
 - Generic levofloxacin
 - Therapeutically equivalent to Quixin®
 - Moxeza™ (moxifloxacin)
 - Treatment of bacterial conjunctivitis

Ophthalmic Antibiotic Drops and Ointments: Market Share



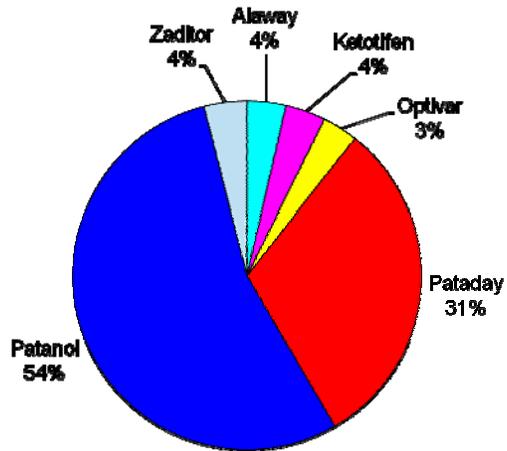
Ophthalmic Antibiotic Drops and Ointments: Recommendations

- Move to Preferred:
 - Ciloxan® Ointment
 - Generic ofloxacin drops

Antihistamine/Mast Cell Stabilizers: Clinical Highlights

- FDA approval:
 - Lastacaft™ (alcaftadine)
 - Prevention of itching associated w/allergic conjunctivitis

Antihistamine/Mast Cell Stabilizers: Market Share



Antihistamine/Mast Cell Stabilizers: Recommendations

■ Move to Preferred:

■ Bepreve™

■ Move to Non-Preferred:

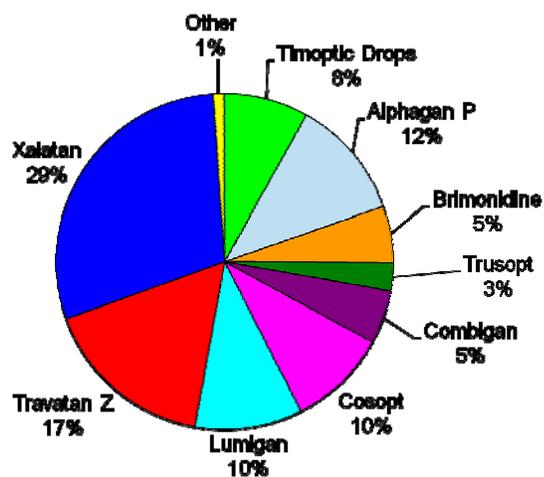
■ Alocril®

■ Alomide®

Glaucoma Agents: Clinical Highlights

- FDA approval:
 - Generic latanoprost
 - A rated to Xalatan®
- New dosage strength
 - Lumigan®
 - 0.01% formulation

Glaucoma Agents: Market Share



Glaucoma Agents: Recommendations

- Move to Preferred:
 - Generic latanoprost

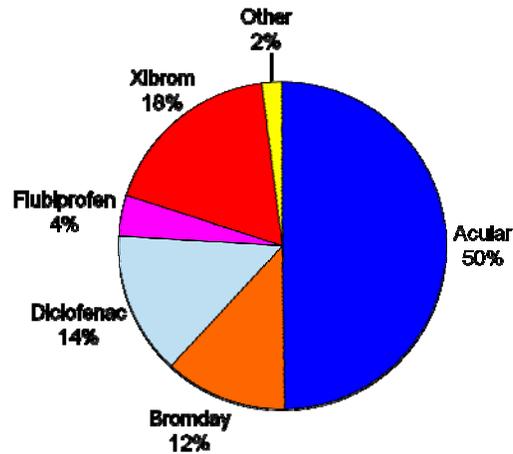
- Move to Non-Preferred:
 - Lumigan®
 - Travatan Z®
 - Xalatan®

Ophthalmic NSAIDs: Clinical Highlights

- FDA approval:
 - Bromday™ (bromfenac)
 - Once daily treatment of post-op inflammation and pain after cataract extraction

- Discontinued product:
 - Acular® PF
 - Xibrom®

Ophthalmic NSAIDs: Market Share



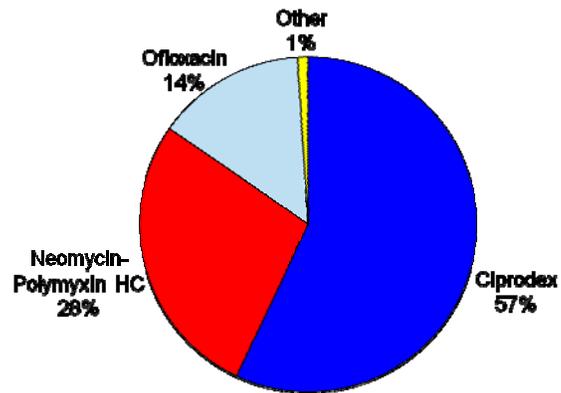
Ophthalmic NSAIDs: Recommendations

- Move to Preferred:
 - Generic ketorolac

- Move to Non-Preferred:
 - Acular®

- Remove from PDL:
 - Xibrom®

Otic Antibiotics: Market Share



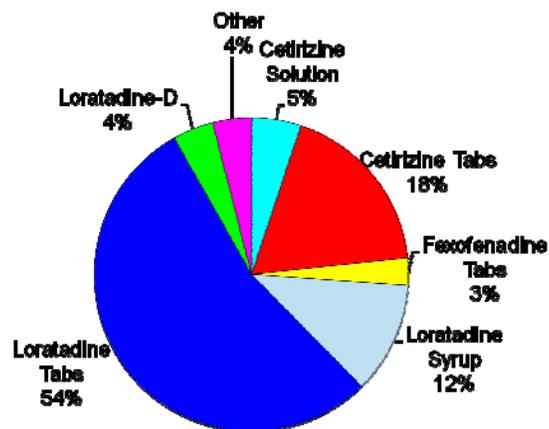
Otic Antibiotics: Recommendations

- Move to Non-Preferred:
 - Coly-Mycin[®] S

Antihistamines, Second Generation : Clinical Highlights

- FDA approval:
 - Generic levocetirizine tablets
 - A rated to Xyzal®

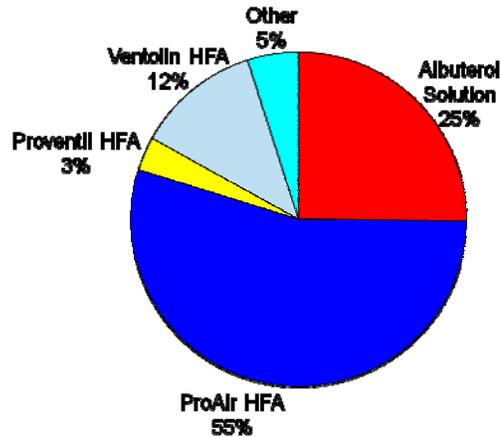
Antihistamines-Second Generation: Market Share



Antihistamines – Second Generation: Recommendations

- Move to Preferred:
 - Generic cetirizine/pseudoephedrine
 - Generic loratadine-D 12 Hour

Short Acting Beta-adrenergic Agonists-Inhaled: Market Share

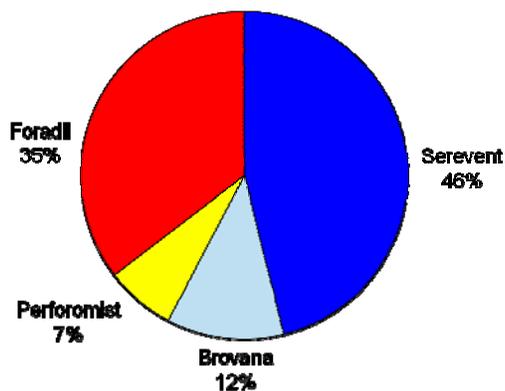


Long Acting Beta-adrenergic Agonists: Clinical Highlights

- Class labeling change:
 - Boxed Warning
 - Risk of asthma related death, intubations, and hospitalization

- New REMS programs
 - Brovana®
 - Perforomist®

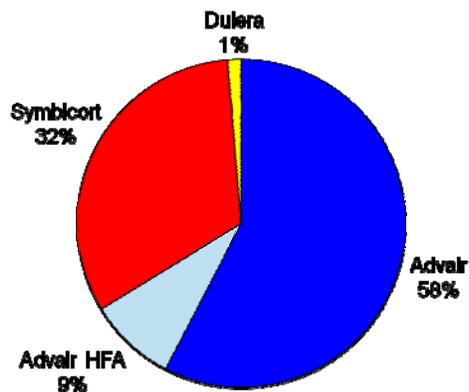
Long Acting Beta-adrenergic Agonists-Inhaled: Market Share



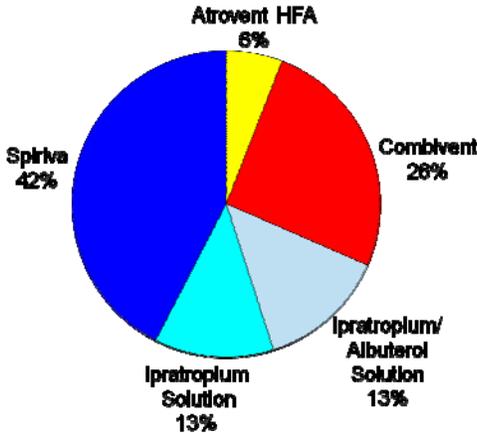
Long Acting Beta-adrenergic Agonists-Inhaled: Recommendations

- Move to Non-Preferred:
- Serevent®

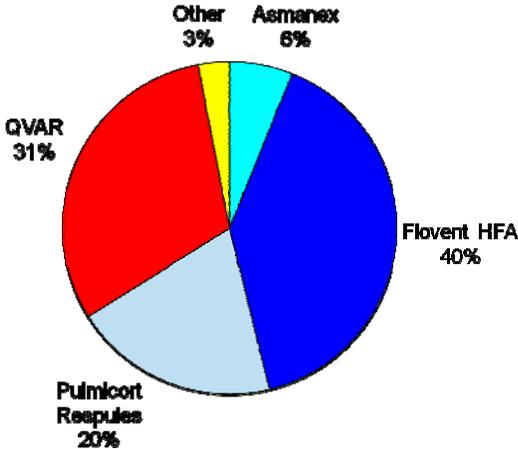
Long Acting Beta-adrenergic Agonist-Steroid Inhaled: Market Share



COPD Anticholinergic Agents: Market Share



Glucocorticoid Agents-Inhaled: Market Share



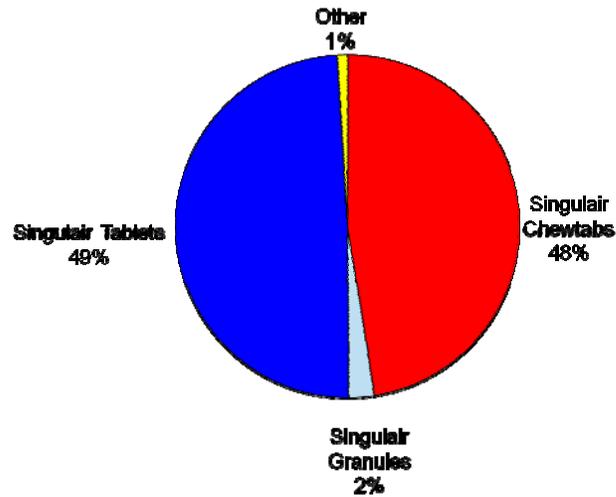
Glucocorticoid Agents-Inhaled: Recommendations

- Remove from PDL
 - Aerobid®

Leukotriene Receptor Modifiers and Inhibitors: Clinical Highlights

- FDA approval:
 - Generic zafirlukast
 - A rated to Accolate®

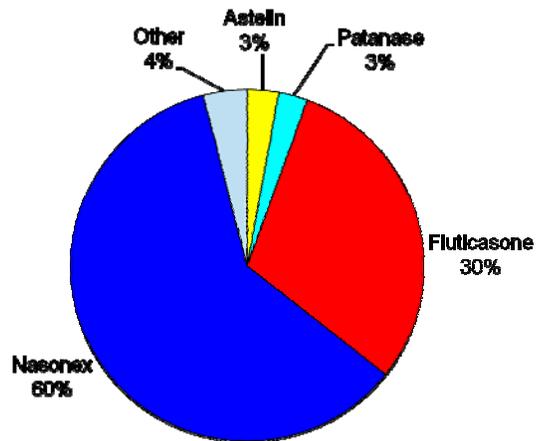
Leukotriene Receptor Modifiers and Inhibitors: Market Share



Nasal Preparations: Clinical Highlights

- New Indication:
 - Nasonex[®]
 - Relief of nasal congestion associated with seasonal allergic rhinitis in adult and pediatric patients ≥ 2 years of age

Nasal Preparations: Market Share



Nasal Preparations: Recommendations

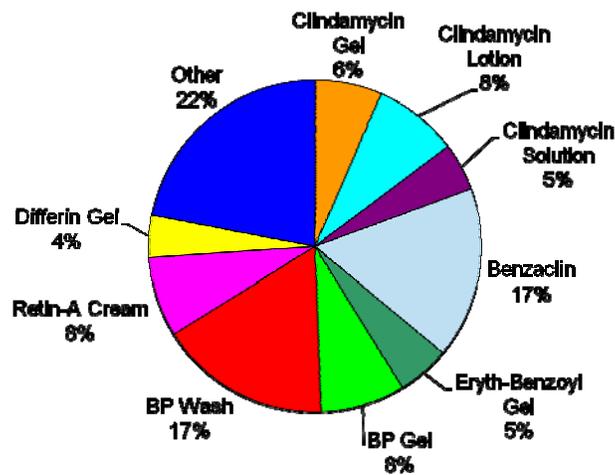
- Move to Preferred:
 - Generic flunisolide

- Move to Non-Preferred:
 - Nasonex®

Topical Acne Agents: Clinical Highlights

- FDA approval:
 - Veltin™ Gel (clindamycin/tretinoin)
 - Treatment of acne in patients ≥ 12 yrs

Topical Acne Agents: Market Share



Topical Acne Agents: Recommendations

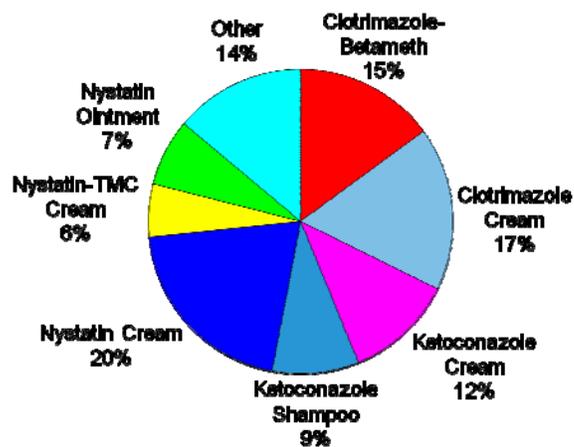
■ Move to Preferred:

- Generic sodium sulfacetamide-sulfur lotion
- Generic sodium sulfacetamide-sulfur suspension
- Generic sodium sulfacetamide-sulfur wash

■ Move to Non-Preferred:

- Azelex®
- Differin® Gel
- Differin® Lotion
- Generic clindamycin pledgets
- Ziana®

Topical Anti-Fungals: Market Share



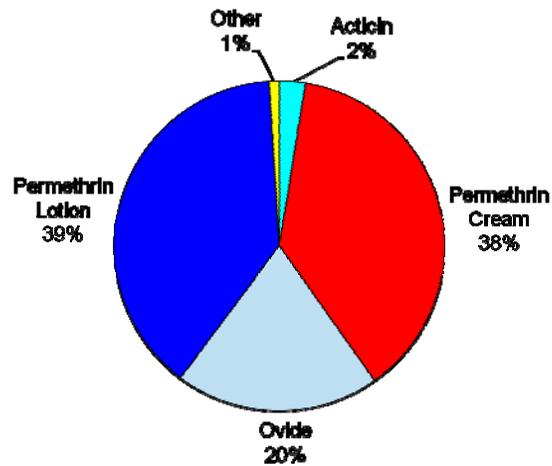
Topical Anti-Fungals: Recommendations

- Move to Preferred:
 - Generic econazole
- Move to Non-Preferred:
 - Loprox[®] Shampoo
 - Naftin[®] Cream
 - Naftin[®] Gel
 - Oxistat[®]
 - Vusion[®]

Topical Anti-Parasitic Agents: Clinical Highlights

- FDA approval:
 - Natroba[™] (spinosad)
 - Treatment of head lice in patients \geq 4 yrs

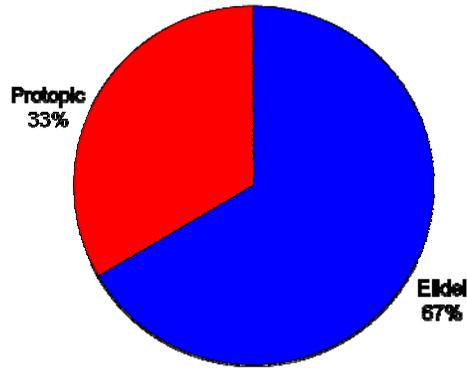
Topical Anti-Parasitic Agents: Market Share



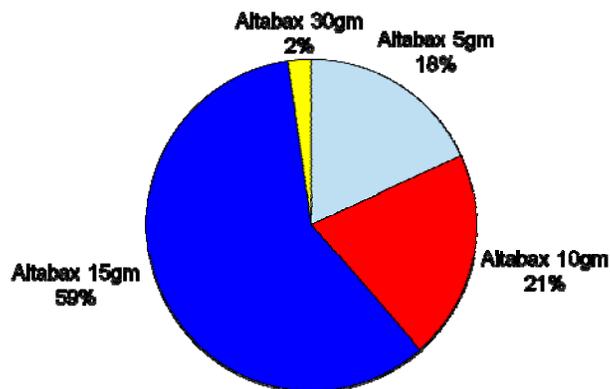
Topical Anti-Parasitics: Recommendations

- Move to Non-Preferred:
 - Eurax[®] Cream

Topical Immunomodulators: Market Share



Topical Pleuromutulin Derivatives: Market Share



Topical Pleuromutulin Derivatives: Recommendations

- Remove from PDL:
 - Altabax[®] 5gm
 - Altabax[®] 10gm

Topical Post-Herpetic Neuralgia Agents: Recommendations

- Move to Non-Preferred:
 - Lidoderm[®]

