

ODJFS P&T Committee Meeting Minutes

July 7, 2010

77 S. High St., Room 1948

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

ACS staff present: Stephanie Levine, PharmD, 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 1:00 PM.

1. Interested party presentations

- a. NAMI-Ohio
- b. Ohio Psychiatric Physicians Association
- c. The Ohio Council of Behavioral Health & Family Services Providers
- d. Pauline Z. Bryant, RN, BSN, Founder of Preventative HealthCare Services, Inc. and Executive Director of The Ohio Black Nurses Coalition
- e. Dr. Paraja Thakuria, Columbus Area, Inc.

2. Preferred Drug List (PDL) proposal

Dr. Hunter recognized Dr. Hefley to present recommendations from ACS 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.

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

Dr. Jacobs asked whether Effient should be made available without prior authorization (PA) to interventional cardiologists. Drs. Hunter and Welker said no. If the drug is used in the hospital, it does not require prior authorization. If it is used outpatient, it is the primary care provider that will need to request the PA.

Cardiovascular Agents: Hypertension & Heart Failure – Beta Blockers

Dr. Jacobs asked if there is any advantage to the vasodilation effects of Bystolic vs. any other beta blocker. Dr. Hunter shared that he changed some of his nursing facility patients to Bystolic because of the once daily dosing and because the patients had experienced hypotension with other beta blockers. Mr. Wascovich noted that the beta-one selectivity would be advantageous for patients with asthma, and there may be an advantage for obese patients. Dr. Welker said she has not seen cardiologists use Bystolic first line.

On the question of whether to add Bystolic as preferred, the question was defeated 5-3.

Cardiovascular Agents: Lipotropics – Statins

Ms. Baker noted that Crestor has a unique indication for adolescents (indicated in pediatric patients 10 to 17 years of age with heterozygous familial hypercholesterolemia to reduce elevated total-C, LDL-C and ApoB after failing an adequate trial of diet therapy). Dr. Hunter also noted its indication for primary prevention (indicated for risk reduction of MI, stroke, and arterial revascularization procedures in patients without clinically evident CHD, but with multiple risk factors). Mr. Wascovich suggested that the adolescent indication be added to the prior authorization criteria. Ms. Scott noted that in other categories, there is approval criteria for specific products that have unique indications. The department can consider adding this language for the lipotropics.

Cardiovascular Agents: Lipotropics – Omega-3 Polyunsaturated Fatty Acids

Dr. Welker noted that there are no products in this category available. Ms. Scott explained that the federal Centers for Medicare and Medicaid Services limits pharmacy coverage to drugs that are approved by the FDA. Most omega-3 supplements are nutritional products rather than drugs. Ms. Scott will investigate whether any omega-3 supplements are available for coverage. Mr. Wascovich recommended a change to preferred status for Lovaza, because of non-FDA approved indications such as those mentioned by the speaker in the morning session. Drs. Welker, Hunter, and Jacobs agreed. Mr. Wascovich said this could be monitored over the next 12 to 18 months. Ms. Scott shared that she has only received one phone call about Lovaza, and it was a request for a 16-year-old patient with triglycerides of about 300, who had not tried any other therapy. The committee did not vote on Lovaza.

Central Nervous System Agents: Anti-Migraine Agents

Dr. Hunter noted that Treximet is the only combination drug for migraine, and it is recommended for non-preferred status. Ms. Scott said that the generic of Imitrex in combination with naproxen in separate tablets is much less expensive than Treximet, which was not true before generic Imitrex was covered.

Central Nervous System Agents: Antidepressants – Selective Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)

Dr. Jacobs said that the morning speaker, a family practice physician, made some good points about general practitioners' use of SNRIs, including dosing Effexor XR at low doses that work more like a SSRI and do not give the noradrenergic effects. Dr. Jacobs also noted a potential conflict of interest that she speaks on behalf of Pfizer (manufacturer of Pristiq). She said that Cymbalta and Pristiq have true SNRI effects, and that dosing is easier with these drugs, while withdrawal from Effexor XR is harder. She recommends having "true" SNRIs available. Dr. Welker said that the committee needs to keep Cymbalta due to the cardiac side effects with Effexor, and the indication for fibromyalgia since there is often comorbid depression. Dr. Hunter shared that a family member had a good experience with Cymbalta for pain and neuropathy. Dr. Jacobs said that to differentiate Pristiq and Cymbalta, Pristiq does not use the 2D6 metabolic pathway so there is less concern about drug-drug interactions. She recommended moving venlafaxine, Venlafaxine ER tablets, and Effexor XR to non-preferred. Dr. Huffman asked why Effexor should be moved to non-preferred. Dr. Jacobs responded that it would depend on the prescribing pattern, whether patients are receiving high enough doses to get the SNRI effects. Dr. Hunter recommended moving Cymbalta to preferred status. Mr. Wascovich said that keeping Cymbalta preferred would cause less disruption.

On the question of whether to move the venlafaxine products to non-preferred, the committee voted unanimously to keep them preferred.

On the question of whether to move Cymbalta to preferred, the question was approved 6-2.

On the question of whether to move Pristiq to preferred, the question was defeated 7-1.

Central Nervous System Agents: Second Generation Antipsychotics

Dr. Jacobs asked why Seroquel XR is recommended for non-preferred status. Ms. Scott said that this is due to a combination of low market share and a provision in the federal health care reform bill that ties the rebate of line extensions to the parent drug, and the entire additional rebate will be kept by the federal government. Dr. Jacobs noted that Seroquel immediate release is sometime misused because it may have a "buzz" factor. Ms. Scott said that different payers have taken different approaches. On one end, the Ohio Department of Rehabilitation and Corrections only allows Seroquel XR in the prison system, while several private insurers only allow the immediate release. Dr. Welker asked about inmates released from prison who are eligible for Medicaid. If they are stable on the Seroquel XR, would PA be allowed? Ms. Scott said that it would require a prescriber request, but it would be approved. Dr. Jacobs confirmed that patients would still be grandfathered, and that psychiatrists are exempt from PA.

Central Nervous System Agents: Attention Deficit Hyperactivity Disorder Agents

Dr. Jacobs said that Vyvanse is a long-acting prodrug with a good safety profile and 13 hour duration in adolescents and 14 hour duration in adults. 91% of adults treated with Vyvanse do not need a second drug. There is less diversion and abuse compared with Adderall, and there are consistent blood levels throughout the day. She recommends preferred status. Dr. Huffman has concerns that the drug was made preferred when it was new, when the PA criteria are more liberal than private insurance. Dr. Jacobs also noted that the effect is not dependent of food, so it is good for adolescents who may not have a consistent eating pattern.

On the question of whether to move Vyvanse to preferred status, the question was approved 5-3.

Dr. Jacobs also noted that Strattera is a noncontrolled drug with less abuse potential.

On the question of whether to move Strattera to preferred status, the question was approved 5-3.

Dr. Jacobs said that Intuniv is another non-stimulant option with a unique mechanism of action. She recommends preferred status.

On the question of whether to move Intuniv to preferred status, the question was defeated 6-2.

Dr. Welker asked if the recommendation from the January meeting to exempt psychiatrists from PA of ADHD drugs should be revisited. Dr. Jacobs recommends an exemption for psychiatrists. Dr. Huffman noted that with the changes to Vyvanse and Strattera, there are few non-preferred drugs. Dr. Hunter noted that extending PA exemptions is a slippery slope, with recent discussions about exempting certain drugs for interventional cardiologists or ophthalmologists. Dr. Huffman agreed, noting that she does not like the exemption since most drugs are preferred and it is not difficult to get PA.

On the question of whether to exempt psychiatrists from PA on ADHD drugs, the question was defeated 7-1.

Dr. Jacobs noted that up to 40% of emergency department visits have a psychiatric component.

Dr. Hunter said that as an emergency doctor and new member of the Implement Medicaid Programs for the Reduction of Avoidable Visits to the Emergency Department (IMPROVE) collaborative, he knows that this situation is being researched.

Central Nervous System Agents: Sedative-Hypnotics, Non-Barbiturate

Dr. Jacobs asked why the recommendation was to move Rozerem to non-preferred status. Dr. Hefley responded that it was a combination of the drug not having a clinical benefit vs. other drugs and the low market share. Ms. Scott added that cost was a consideration. Dr. Jacobs and Dr. Hunter noted that it is the only non-controlled option.

Central Nervous System Agents: Smoking Deterrents

Mr. Wascovich asked if the drug utilization review program was looking at this therapy. Ms. Scott responded that it is on the list of topics to consider, but has not been made a priority.

Endocrine Agents: Diabetes – Oral Hypoglycemics

Dr. Hunter asked if the recommendation to move Avandia to non-preferred status was due to the recent studies and publicity. Dr. Hefley responded that the recent publicity was part of the reason, along with the change to the American Diabetes Association algorithm to remove Avandia. Dr. Jacobs asked if the information provided by the manufacturer in the morning session changed anyone's opinion. Dr. Hunter said that the studies were overhyped, he has never had an issue with Avandia and recommends keeping the drug preferred.

On the question of whether to keep Avandia in preferred status, the question was tied 3-3 with one abstention (Dr. Welker had left the meeting).

Mr. Wascovich said that this should be a financial decision. Dr. Hunter recommended that Ms. Scott ask Dr. Welker for her vote.

Genitourinary Agents: Urinary Antispasmodics

Dr. Jacobs asked if Detrol or Toviaz work differently than the drugs recommended preferred. Dr. Hunter and Mr. Wascovich said that the agents recommended preferred were sufficient.

Respiratory Agents: Nasal Preparations

Ms. Baker noted that the morning speaker for Veramyst cited studies showing that the drug reduced both nasal and ocular symptoms of allergy, possibly negating the need for both an ophthalmic antihistamine and a nasal spray. Dr. Hunter recommended that Veramyst be moved to preferred status. Mr. Wascovich also noted that Veramyst may reduce the need for oral antihistamines.

On the question of whether to move Veramyst to preferred status, the question was approved 5-2.

The meeting was adjourned at 3:07 PM.

Following the meeting, ODJFS followed the Committee's recommendations to retain Cymbalta, Strattera and Vyvanse in preferred status.

The current prior authorization criteria for the lipotropics-statins allows approval for a non-preferred drug if the prescriber is requesting the product due to a unique indication or if the professional literature indicates superiority of a non-preferred product for a particular patient. Existing criteria would allow approval of Crestor for its unique indications.

Ms. Scott contacted Dr. Welker about Avandia, Avandaryl, and Avandamet to break the tie vote. Dr. Welker agreed with the recommendations of the department and ACS to move these drugs to non-preferred status.

The department is reviewing the recommendations for Lovaza and other omega-3 polyunsaturated agents, and for Veramyst.

8/17/10 – Updates

The department decided to keep Seroquel XR preferred, and leave Lovaza and Veramyst non-preferred. The department has responded to the P&T Committee's request for omega-3 fatty acids by adding coverage of over-the-counter fish oil products in the following strengths: 340-1000mg, 360-1200mg, 435-880mg, 500-1000mg.

In addition, ODJFS decided that all generic ACE inhibitors and ACE inhibitor-hydrochlorothiazide combinations will be preferred, and that cefuroxime suspension will be preferred for children age 12 and under.



Ohio Health Plans
Pharmacy Benefit Management Program
Preferred Drug List
Recommendations

Denise Hefley, PharmD
ACS Clinical Information Pharmacist



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1

Opioids: Clinical Highlights

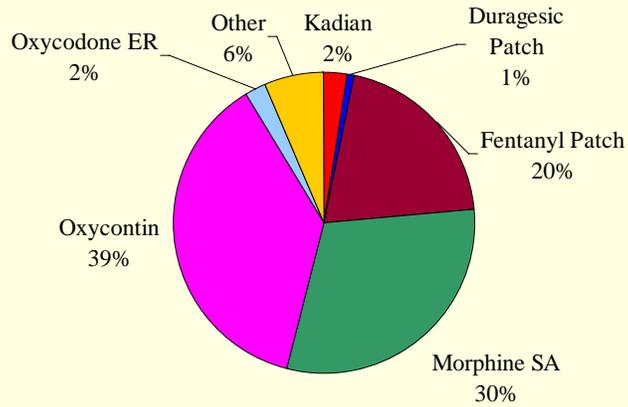
- FDA approvals
 - Embeda™ (morphine/naltrexone)
 - Exalgo™ (hydromorphone ER)
 - Nucynta™ (tapentadol)
 - Rybix™ ODT (tramadol)
 - Onsolis™ (fentanyl buccal)
- Oxycontin® new formulation
 - 10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg tablets only



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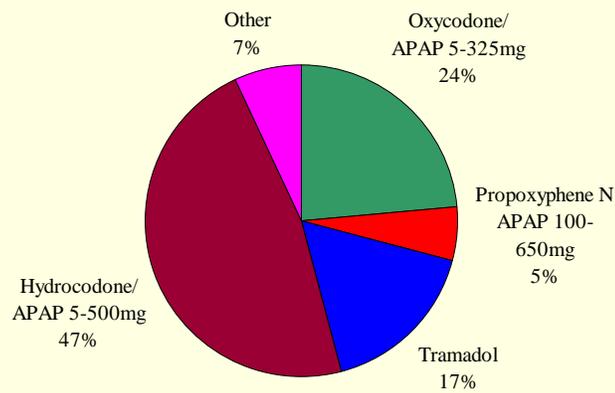
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Long-Acting Opioids: Market Share



3

Short-Acting Opioids: Market Share



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Opioids: Recommendations

- Exalgo™ to non-preferred
- Rybix™ ODT to non-preferred



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Blood Agents: Clinical Highlights

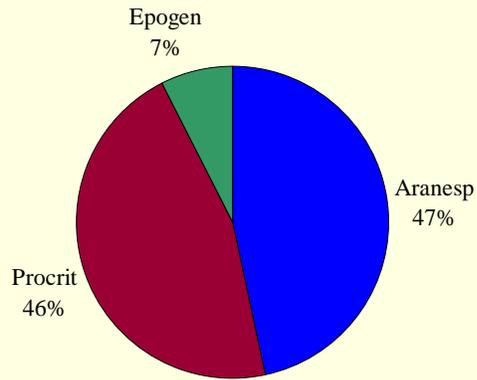
- FDA approval of Effient™ (prasugrel)
 - For reduction of thrombotic CV in patients with acute coronary syndrome who are to be managed with PCI
- Plavix® Labeling Revision
 - Significant drug interaction with omeprazole
- Erythropoiesis Stimulating Agents
 - New risk management program



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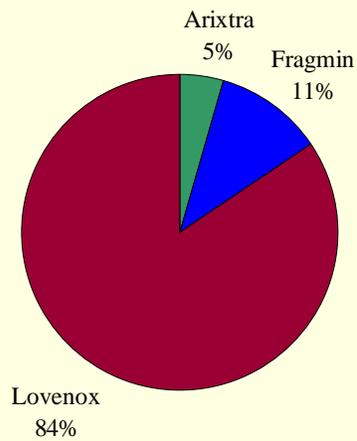
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Hematopoietic Agents: Market Share



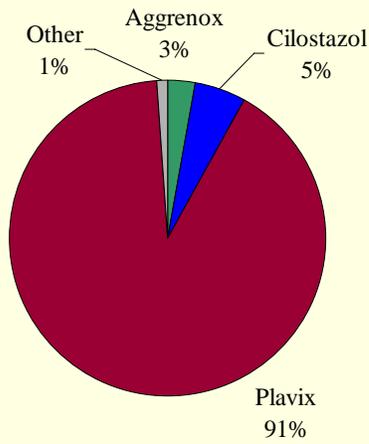
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Heparin-Related Preparations: Market Share



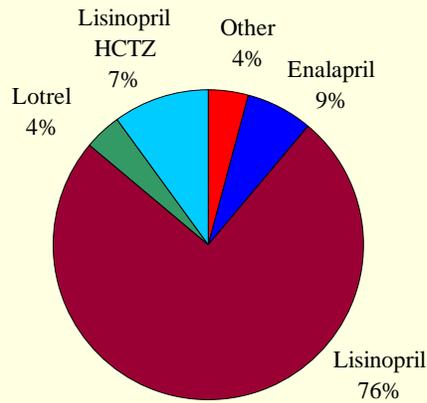
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Platelet Aggregation Inhibitors: Market Share



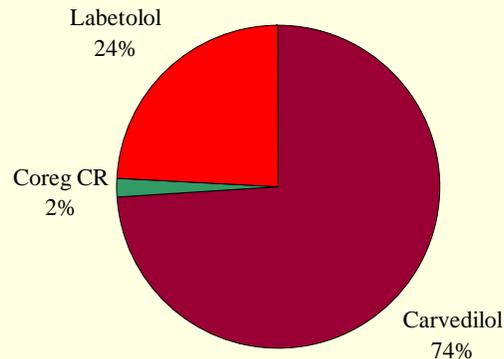
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Angiotensin Converting Enzyme Inhibitors: Market Share



10

Alpha-Beta Adrenergic Blockers: Market Share



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Angiotensin Receptor Blockers: Clinical Highlights

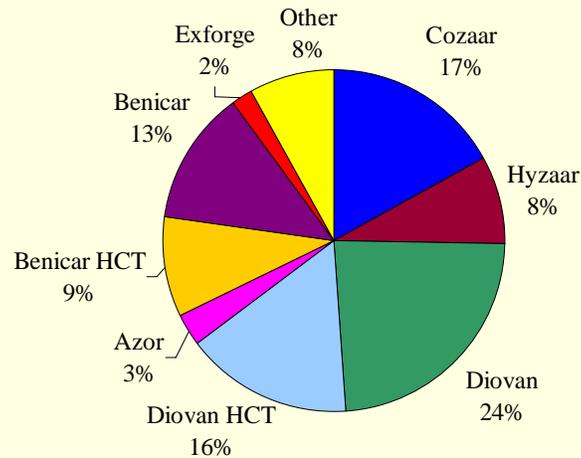
- Atacand® new indication
 - HTN in children 1 to < 17 yrs
- Benicar® new indication
 - HTN in pediatric patients 6-16 yrs
- Micardis® new indication
 - Reduction of risk of MI, stroke, or death from CV causes in patients ≥ 55 yrs
- FDA approval of Twynsta® (telmisartan/amlodipine)
 - 5/40mg, 10/40mg, 5/80mg, 10/80mg tablets
- FDA approval of generic losartan (Cozaar) and losartan/HCTZ (Hyzaar)



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Angiotensin Receptor Blockers: Market Share



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Antiotensin Receptor Blockers: Recommendations

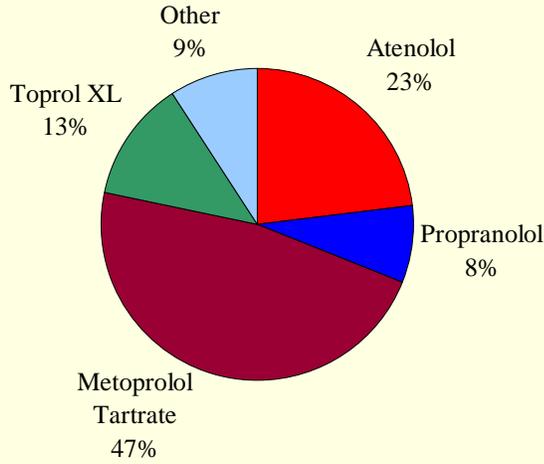
- Generic losartan to non-preferred status
- Generic losartan/HCTZ to non-preferred status



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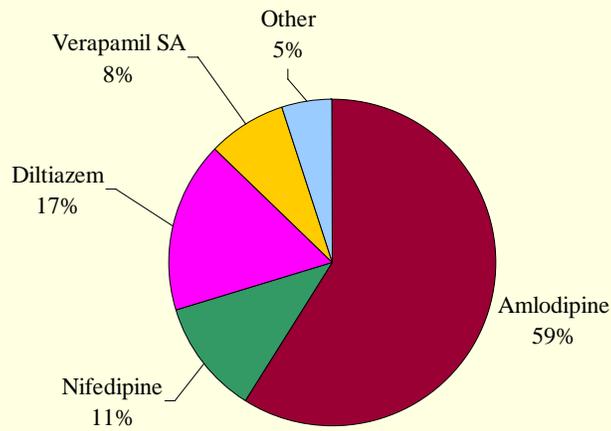
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Beta-Blockers: Market Share



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Calcium Channel Blockers: Market Share



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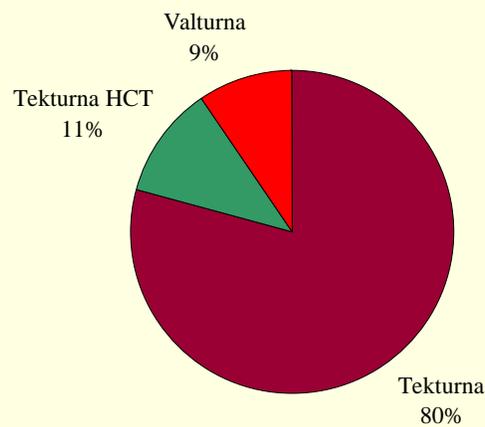
Direct Renin Inhibitors: Clinical Highlights

- FDA approval of Valturna® (aliskiren/valsartan)
 - Treatment of HTN
 - 150/160mg and 300/320mg tablets



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Direct Renin Inhibitors: Market Share



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Lipotropics: Clinical Highlights

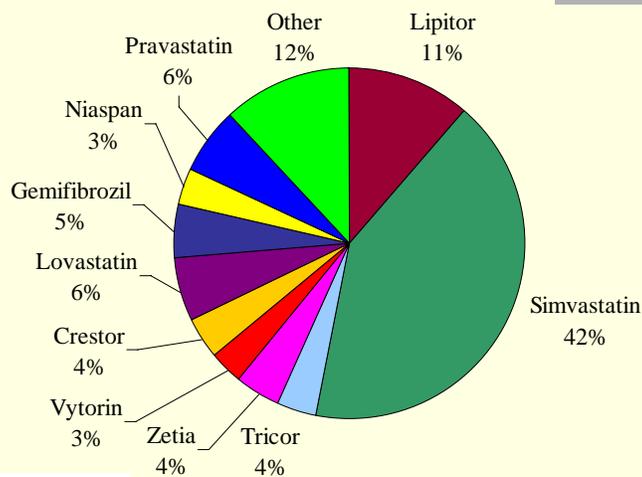
- Bile Acid Sequestrants
 - New class for inclusion on the PDL
- Crestor® new indications
 - Treatment of heterozygous familial hypercholesterolemia in adolescent boys and postmenarchal girls, ages 10-17 yrs
 - Primary prevention of CV disease, reduce risk of stroke, MI, and arterial revascularization
- FDA approvals
 - Fibracor® (fenofibric acid)
 - Livalo® (pitavastatin)



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Lipotropics: Market Share



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Lipotropics: Recommendations

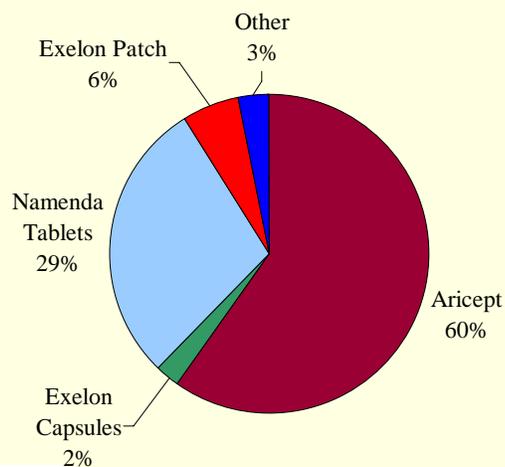
- BAS to preferred status:
 - Cholestyramine powder (can), cholestyramine light powder (can), colestipol tablets, Prevalite® powder (can), Welchol® tablets
- BAS to non-preferred status:
 - Cholestyramine powder (packet), cholestyramine light powder (packet), Colestid® granules, Colestid® tablets, colestipol granules, Prevalite® packets, Questran® products, Welchol® packets
- Livalo® to non-preferred status



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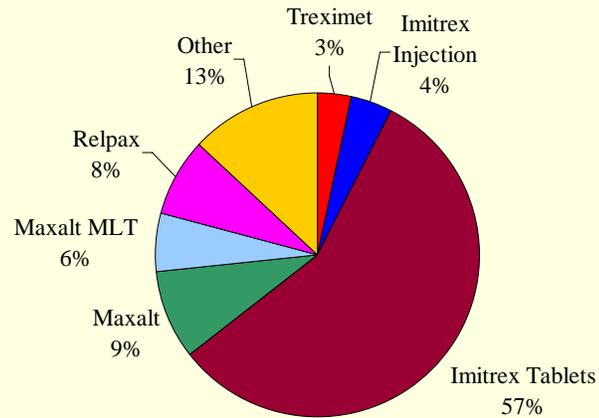
Alzheimer's Agents: Market Share



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Anti-migraine Agents: Market Share



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Anti-migraine Agents: Recommendations

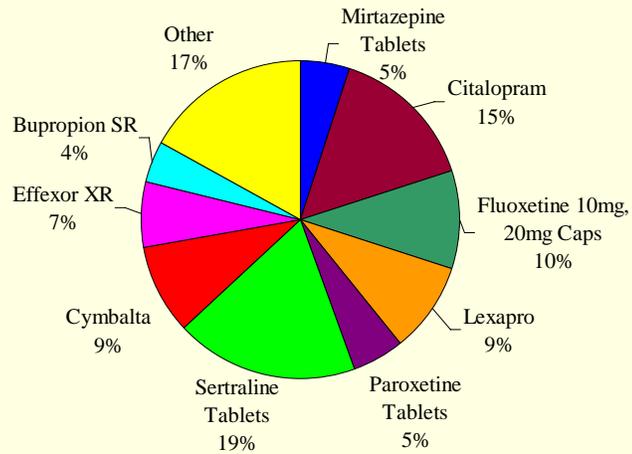
- To non-preferred status:
 - Axert®
 - Imitrex® Tablets
 - Relpax®
 - Treximet®



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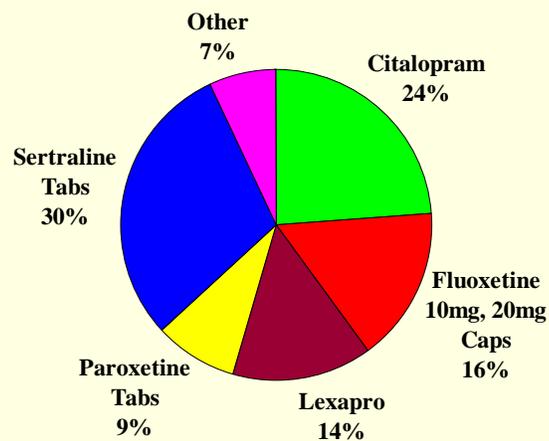
24

Antidepressants: Total Market Share



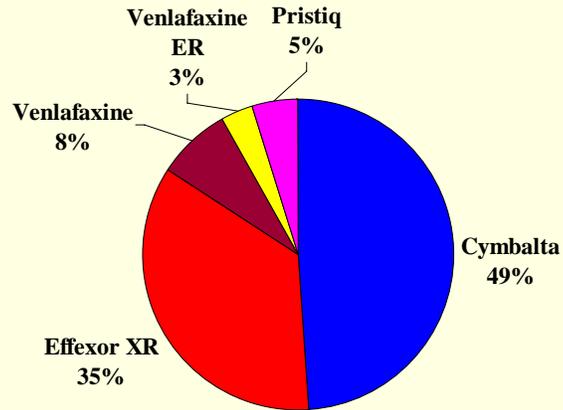
25

Antidepressants: SSRI Market Share



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Antidepressants: SNRI Market Share



Antidepressants: Recommendations

- Cymbalta® to non-preferred status



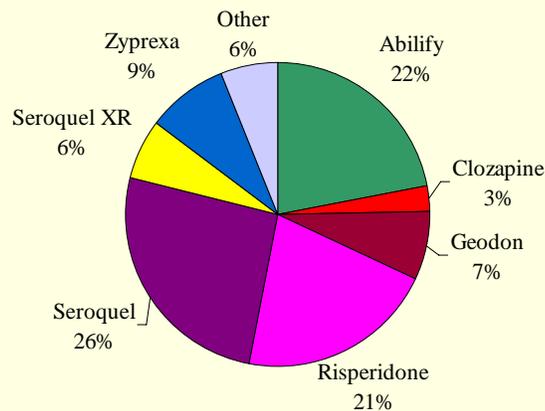
Second Generation Antipsychotics: Clinical Highlights

- New Indications:
 - Abilify®
 - Invega®
 - Geodon®
 - Seroquel XR®
- FDA approvals
 - Fanapt® (iloperidone)
 - Saphris® (asenaphine)



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Second Generation Antipsychotics: Market Share



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Second Generation Antipsychotics: Recommendations

- Seroquel XR[®] to non-preferred status



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Attention Deficit Hyperactivity Disorder Agents: Clinical Highlights

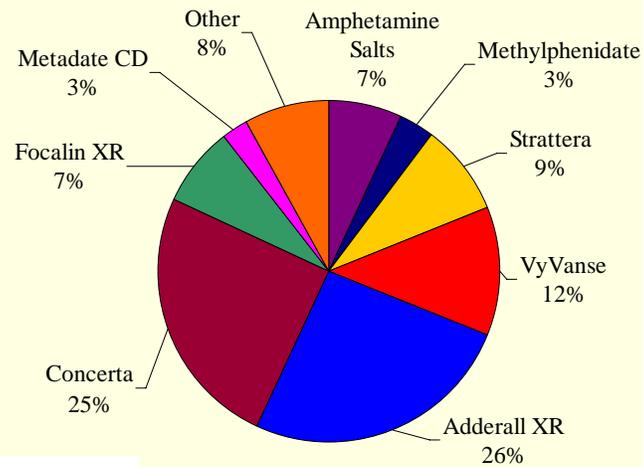
- FDA approvals
 - Intuniv[™] (guanfacine)
 - 1mg, 2mg, 3mg, 4mg ER tablets
 - Generic methamphetamine
 - 5mg tablet
 - A rated to Desoxyn[®]



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Attention Deficit Hyperactivity Disorder Agents: Market Share



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Attention Deficit Hyperactivity Disorder Agents: Recommendations

- To preferred status
 - Generic dextroamphetamine-amphetamine ER
- To non-preferred status
 - Desoxyn®
 - Generic methamphetamine
 - Strattera®
 - Vyvanse®



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Multiple Sclerosis (MS) Agents: Clinical Highlights

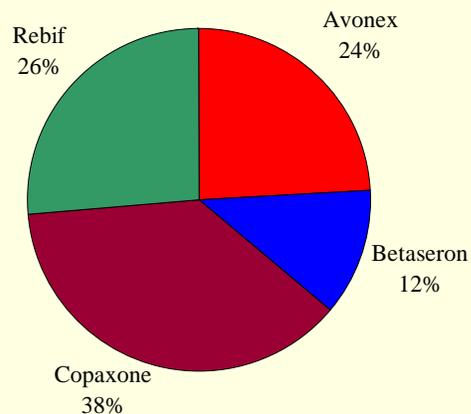
- FDA approvals
 - Ampyra™ (dalfampridine)
 - Increases walking speed
 - 10mg ER tablets
 - Extavia® (interferon beta 1-b)
 - Indicated for Relapsing forms of MS
 - Lyophilized powder for SQ injection



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Multiple Sclerosis (MS) Agents: Market Share



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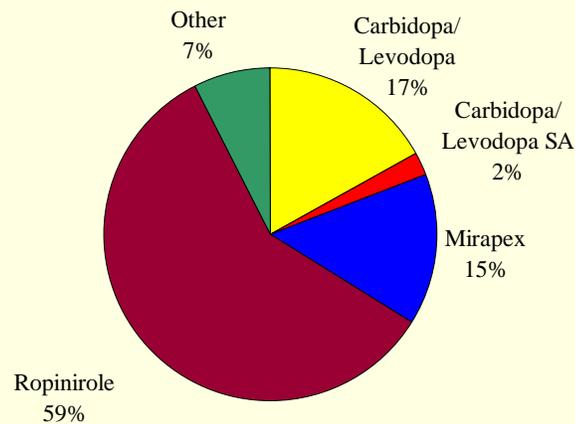
Parkinson's Agents: Clinical Highlights

- FDA approval of Mirapex ER® (pramipexole)
 - Signs/symptoms of early idiopathic PD
 - 0.375mg, 0.75mg, 1.5mg, 3mg, 4.5mg tablets



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Parkinson's Agents: Market Share



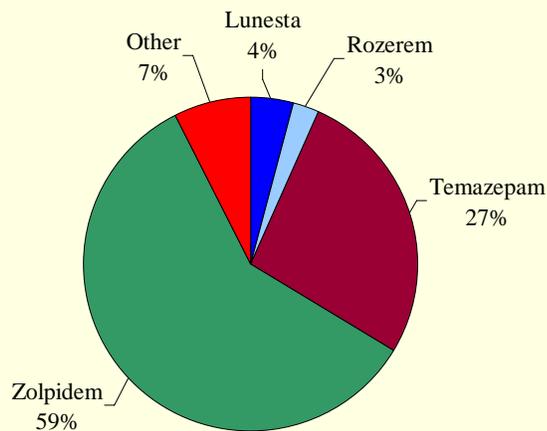
38

Sedative Hypnotics, Non-Barbiturate: Clinical Highlights

- FDA approval of Edluar™ (zolpidem)
 - Short term treatment of insomnia
 - 5mg and 10mg sublingual tablets



Sedative Hypnotics, Non-Barbiturate: Market Share



Sedative Hypnotics, Non-Barbiturate: Recommendations

- Rozerem[®] to non-preferred status



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Skeletal Muscle Relaxants, Non-Benzodiazepine: Clinical Highlights

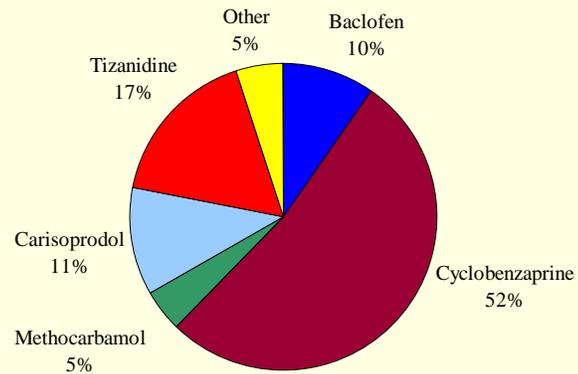
- FDA approval of generic metaxalone
 - 800mg tablets
 - A rated to Skelaxin[®]



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Skeletal Muscle Relaxants, Non-Benzodiazepine: Market Share



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Skeletal Muscle Relaxants, Non-Benzodiazepine: Recommendations

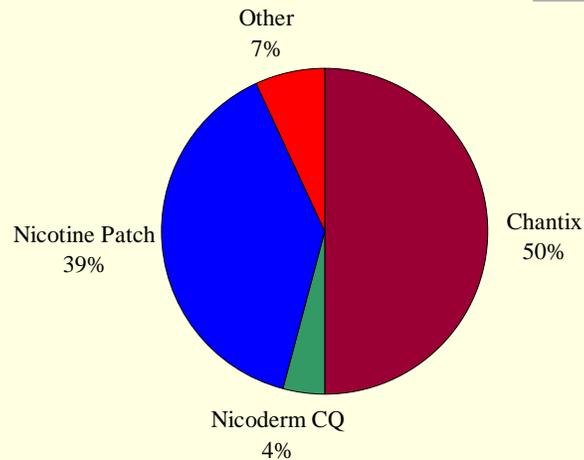
- Generic metaxalone to non-preferred status



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Smoking Deterrents: Market Share



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Electrolyte Depleters: Clinical Highlights

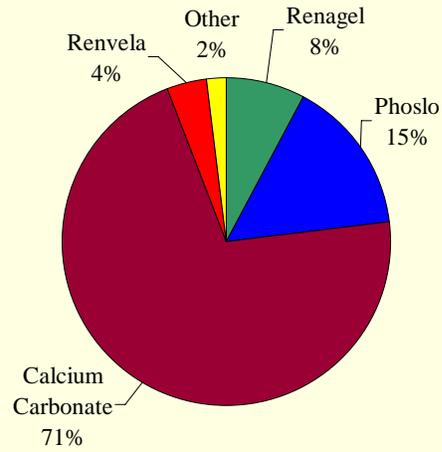
- FDA approval of new Renvela® dosage form
 - 0.8mg and 2.4mg powder packets



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Electrolyte Depleters: Market Share



Electrolyte Depleters: Recommendations

- Renvela® packets to non-preferred status



Amylin Analogs, Incretin Mimetics, and Insulins: Clinical Highlights

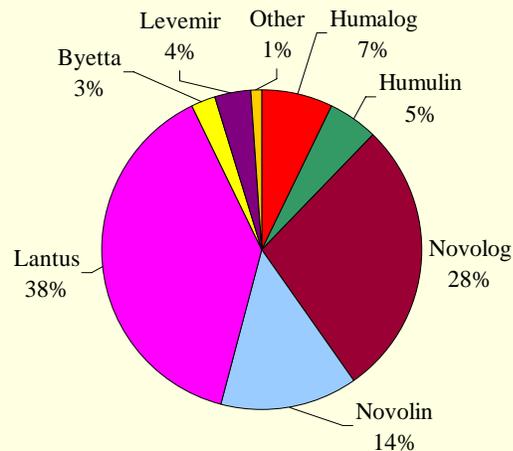
- FDA approvals
 - NovoPen® 4
 - Use with Penfill cartridges
 - Victoza® (liraglutide)
 - Once daily SQ injection
- Byetta® modified indication
 - Not required for patients to be taking metformin, a sulfonylurea, a thiazolidinedione, or combination of those



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Amylin Analogs, Incretin Mimetics, and Insulins: Market Share



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Amylin Analogs, Incretin Mimetics, and Insulins: Recommendations

- To preferred status
 - Relion Novolin® R
 - Relion Novolin® 70-30
 - Relion Novolin® N



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Oral Hypoglycemics: Clinical Highlights

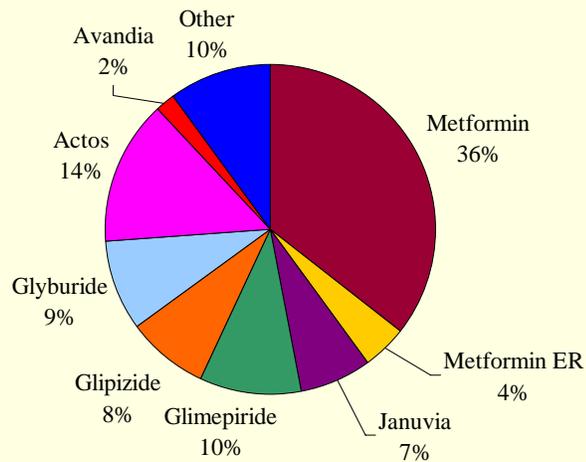
- FDA approvals
 - Generic nateglinide
 - A rated to Starlix®
 - 60mg and 120mg tablets
 - Onglyza™
 - DPP4 Inhibitor
 - 2.5mg and 5mg tablets



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Oral Hypoglycemics: Market Share



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Oral Hypoglycemics: Recommendations

- To non-preferred status
 - Actoplusmet® XR
 - Avandia®
 - Avandamet®
 - Avandaryl®



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Growth Hormones: Clinical Highlights

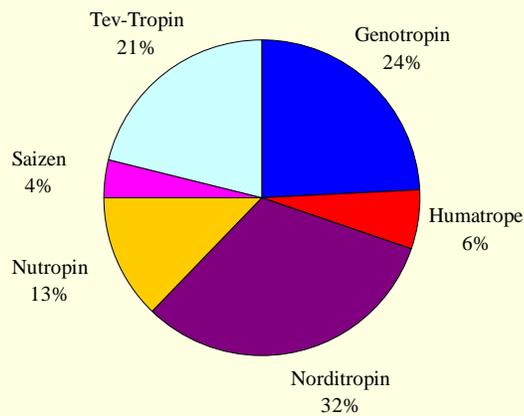
- FDA approvals
 - Norditropin Nordiflex® 30mg/3mL strength
 - Nutropin® AQ 5mg/2mL strength
 - Tev-tropin® Tjet needle free device
- Genotropin® strength change
 - 5.8mg and 13.8mg cartridges now 5mg and 12mg respectively
- Omnitrope® new indications
 - Prader-Willi Syndrome
 - Small for Gestational Age



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Growth Hormones: Market Share



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Growth Hormones: Recommendations

- To preferred status
 - Norditropin®
 - Omnitrope®
- To non-preferred status
 - Nutropin®
 - Saizen®



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Bone Ossification Enhancers: Clinical Highlights

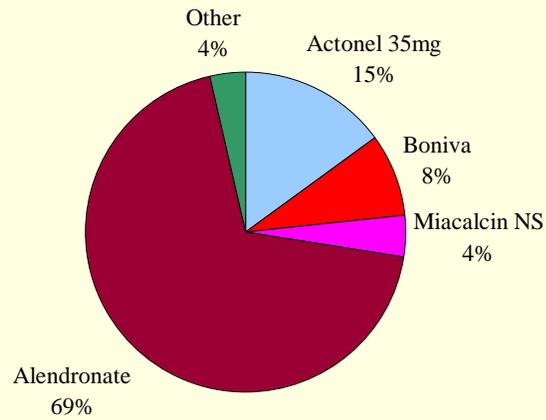
- FDA approvals
 - Generic calcitonin-salmon nasal spray
 - A rated to Miacalcin®



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58

Bone Ossification Enhancers: Market Share



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Bone Ossification Enhancers: Recommendations

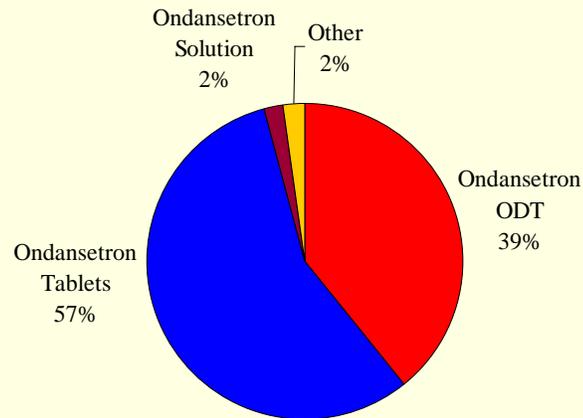
- Boniva® tablets to non-preferred status



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60

Anti-emetic Agents: Market Share



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61

Pancreatic Enzymes: Clinical Highlights

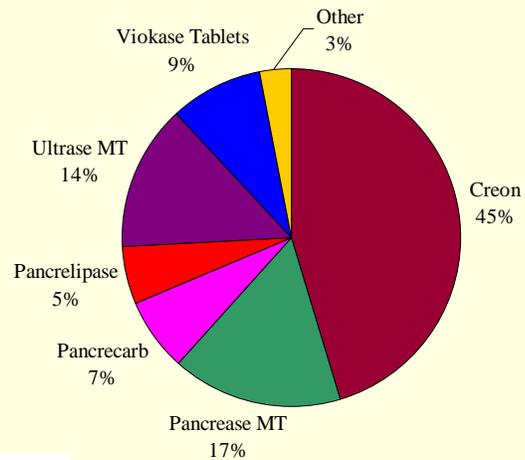
- FDA approvals
 - Creon® new formulations
 - Zenpep®
- Products no longer covered by CMS
 - Pancrease MT®
 - Pancrecarb® MS
 - Ultrase®
 - Ultrase® MT
 - Viokase®



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Pancreatic Enzymes: Market Share



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Pancreatic Enzymes: Recommendations

- Remove from the PDL
 - Pancrease MT®
 - Pancrecarb® MS
 - Ultrase®
 - Ultrase® MT
 - Viokase®



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Proton Pump Inhibitors (PPIs): Clinical Highlights

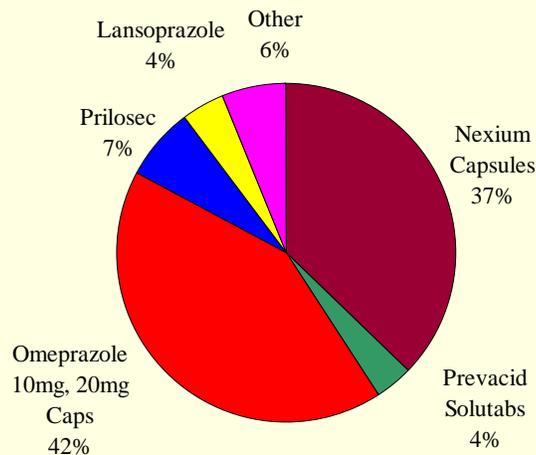
- FDA approvals
 - Generic lansoprazole
 - Prevacid® 24 HR (lansoprazole)
 - Vimovo™ (esomeprazole/naproxen)
 - Zegerid OTC™ (omeprazole/sodium bicarbonate)
- Kapidex™ name change to Dexilant™
 - Same appearance, new NDCs
- Prevacid® NapraPAC discontinued



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Proton Pump Inhibitors (PPIs): Market Share



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Proton Pump Inhibitors (PPIs): Recommendations

- To preferred status
 - Generic lansoprazole
 - Generic omeprazole tablets (OTC)
 - PrilosecOTC[®]
 - Zegerid OTC[™]
- To non-preferred status
 - Nexium[®]
 - Vimovo[™]



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67

Benign Prostatic Hypertrophy Agents: Clinical Highlights

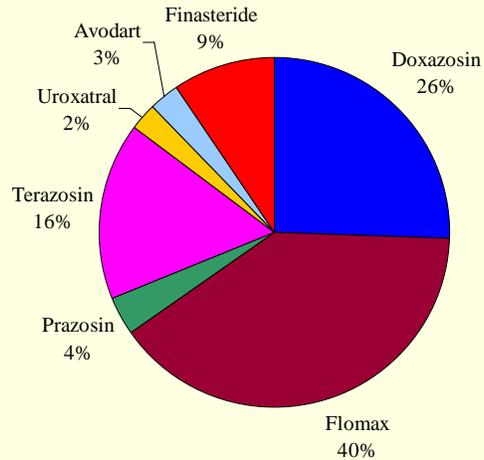
- FDA approval of generic tamsulosin
 - A rated to Flomax[®]
 - 0.4mg capsule



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68

Benign Prostatic Hypertrophy Agents: Market Share



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Benign Prostatic Hypertrophy Agents: Recommendations

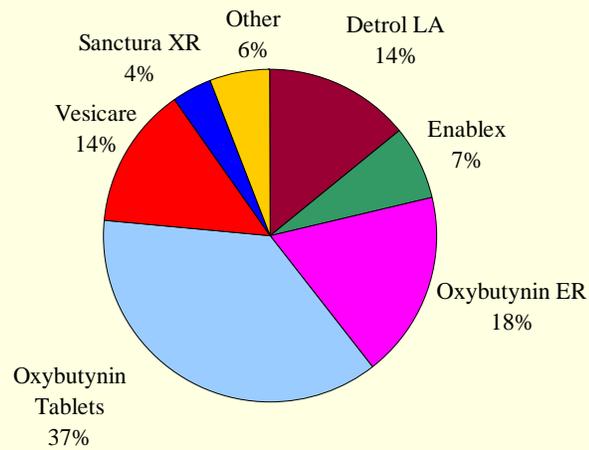
- To preferred status
 - Generic tamsulosin
- To non-preferred status
 - Flomax®
 - Uroxatral®



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70

Urinary Antispasmodics: Market Share



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71

Urinary Antispasmodics: Recommendations

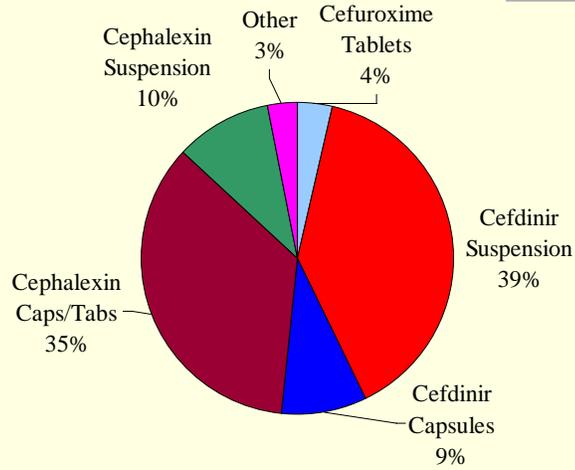
- To non-preferred status
 - Sanctura®
 - Sanctura XR®



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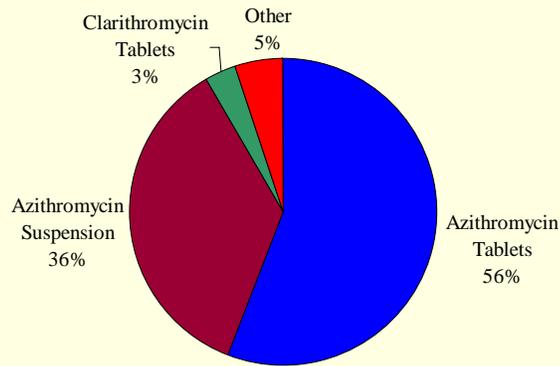
72

Oral Cephalosporins: Market Share



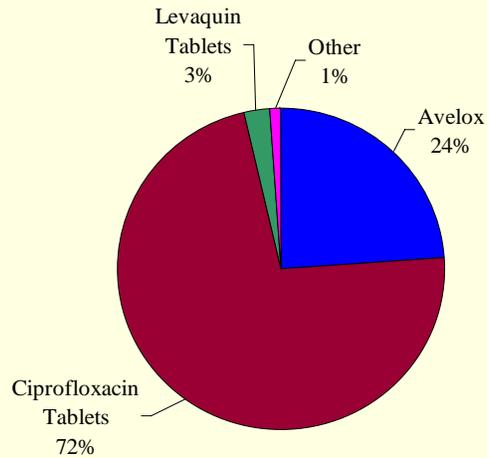
73

Oral Macrolides: Market Share



74

Oral Quinolones: Market Share



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75

Anti-virals Herpes: Clinical Highlights

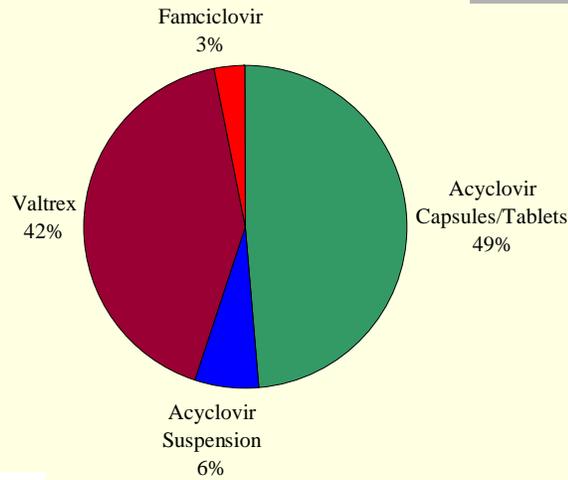
- FDA approval of generic valacyclovir
 - A rated to Valtrex®
 - 500mg and 1g tablets



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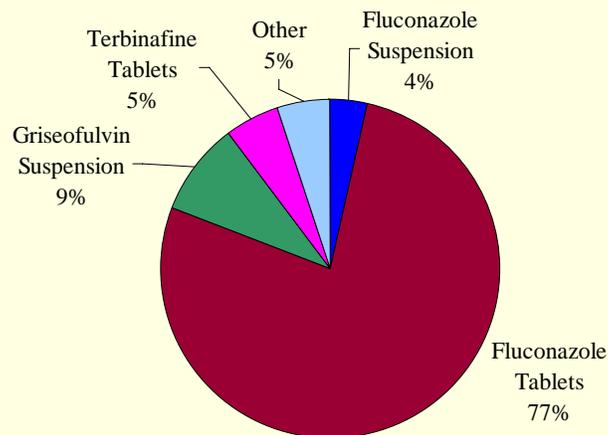
76

Anti-virals Herpes: Market Share



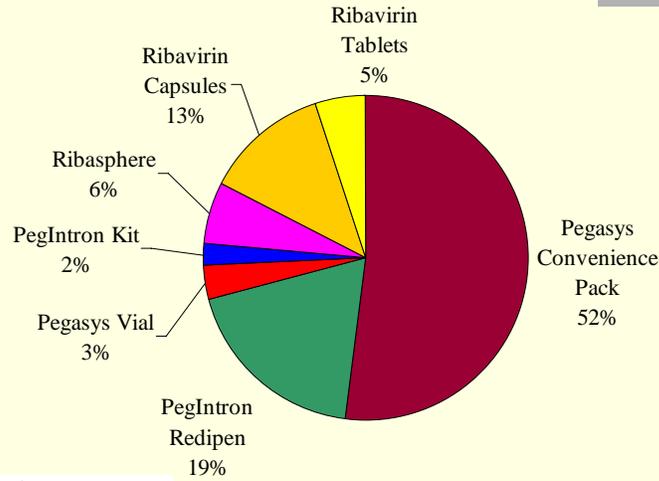
77

Agents for Onychomycosis & Systemic Infections: Market Share



78

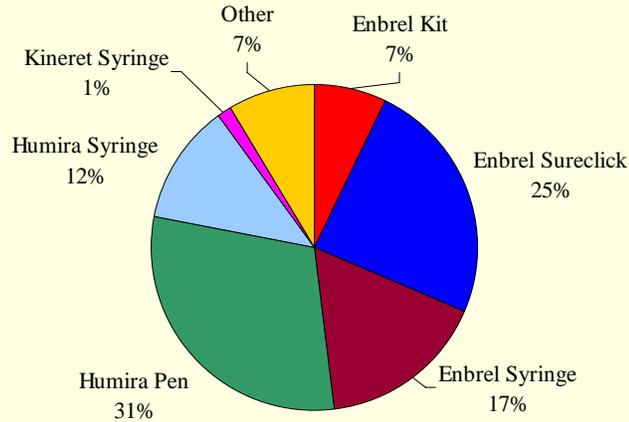
Hepatitis C-Pegylated Interferons & Ribavirins: Market Share



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79

Injectable Anti-Rheumatic Agents: Market Share



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80

Ophthalmic Antibiotic Drops and Ointments: Clinical Highlights

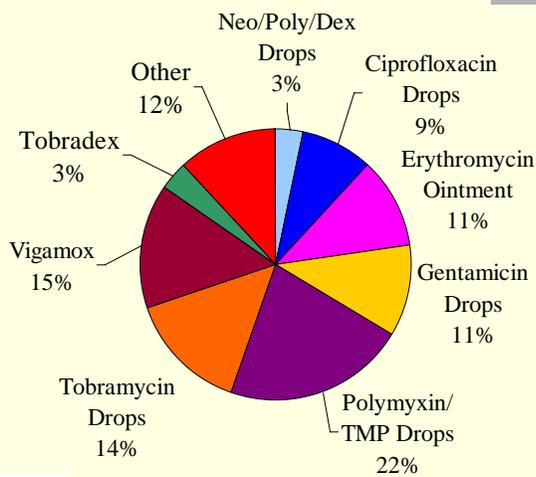
- Antibiotic/Steroid combination agents
 - New class for inclusion on the PDL

- FDA approval of Zymaxid™ (gatifloxacin)
 - Treatment of bacterial conjunctivitis



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Ophthalmic Antibiotic Drops and Ointments: Market Share



82

Ophthalmic Antibiotic Drops and Ointments: Recommendations

- Add to preferred status
 - Blephamide® ointment and suspension
 - Neomycin/polymyxin/bacitracin/hydrocortisone
 - Neomycin/polymyxin/dexamethasone
 - Pred-G®
 - Poly-Pred®
 - Tobradex® ointment and suspension
 - Zylet®
- Add to non-preferred status
 - Tobramycin/dexamethasone suspension
 - Zymaxid™



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Antihistamine/Mast Cell Stabilizers: Clinical Highlights

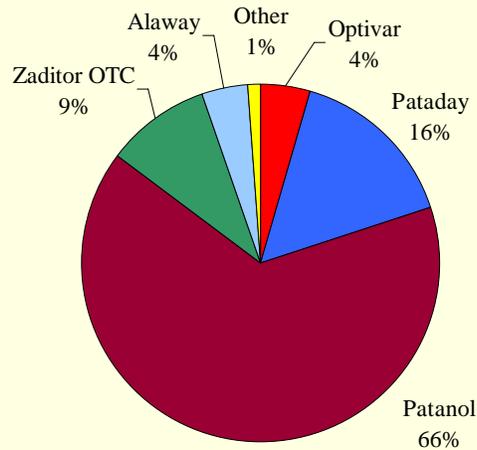
- FDA approvals
 - Bepreve™ (bepotastine)
 - Generic azelastine 0.5%
 - A rated to Optivar®



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Antihistamine/Mast Cell Stabilizers: Market Share



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Antihistamine/Mast Cell Stabilizers: Recommendations

- To preferred status
 - Generic ketotifen
- To non-preferred status
 - Bepreve™



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Glaucoma Agents: Clinical Highlights

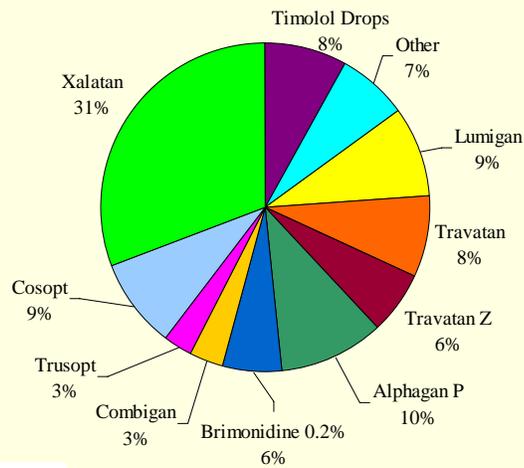
- FDA approvals
 - Generic apraclonidine 0.5%
 - A rated to lopicidine®
 - Generic brimonidine 0.15%
 - A rated to Alphagan® P



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Glaucoma Agents: Market Share



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Ophthalmic NSAIDs: Clinical Highlights

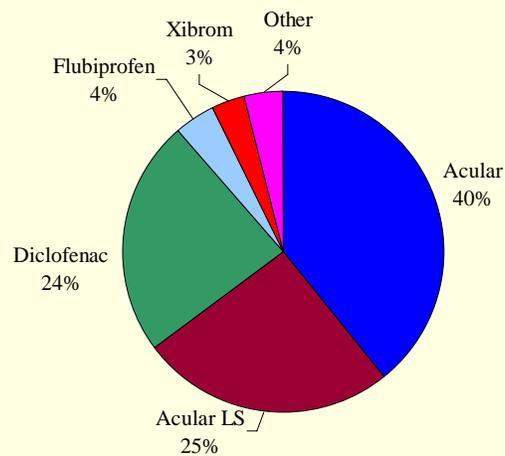
- FDA approvals
 - Acuvail® (ketorolac) 0.45%
 - Generic ketorolac 0.4%
 - A rated to Acular LS®
 - Generic ketorolac 0.5%
 - A rated to Acular®



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Ophthalmic NSAIDs: Market Share



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Ophthalmic NSAIDs: Recommendations

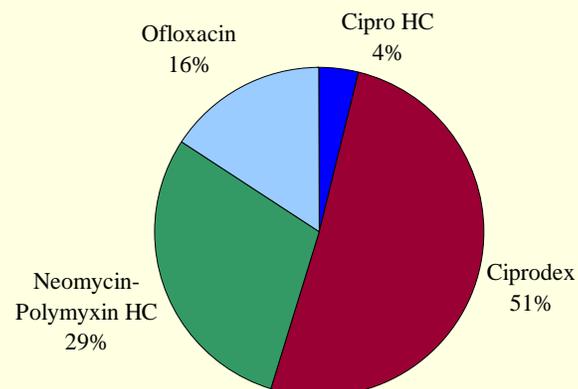
- Xibrom™ to preferred status
- Acular LS® to non-preferred status



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Otic Antibiotics: Market Share



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Otic Antibiotics: Recommendations

- Cipro[®] HC to non-preferred status



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Antihistamines, Second Generation : Clinical Highlights

Xyzal[®] new indications

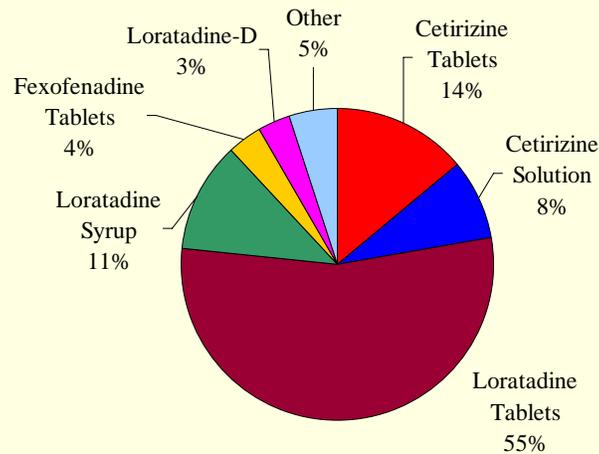
- SAR in children \geq 2 yrs
- PAR in children \geq 6 mo
- Chronic idiopathic urticaria in children \geq 6 mo
- Zyrtec OTC[®] recall
 - Children and Infant liquid products
 - Sugar free/dye free formulations



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Antihistamines, Second Generation: Market Share



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Short Acting Beta-adrenergic Agonists-Inhaled: Clinical Highlights

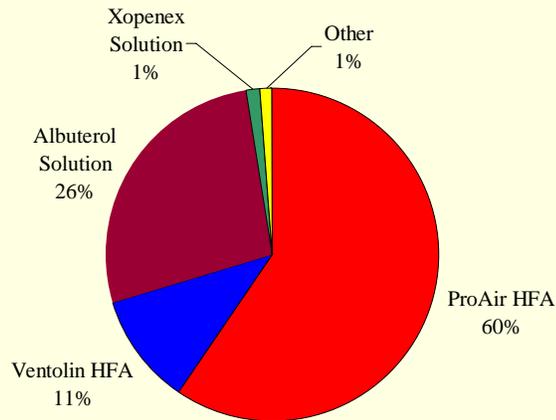
- FDA approvals
 - Levalbuterol inhalation solution 0.25%
 - A rated to Xopenex®
- CFC containing MDIs
 - Montreal Protocol requires market removal
 - Alupent® (metaproterenol) – all products termed
 - Maxair® (pirbuterol) – no CMS term date



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Short Acting Beta-adrenergic Agonists-Inhaled: Market Share



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Short Acting Beta-adrenergic Agonists-Inhaled: Recommendations

- Remove from PDL
 - Alupent® MDI
- To preferred status
 - Foradil®
 - Proventil® HFA



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Long Acting Beta-adrenergic Agonists: Clinical Highlights

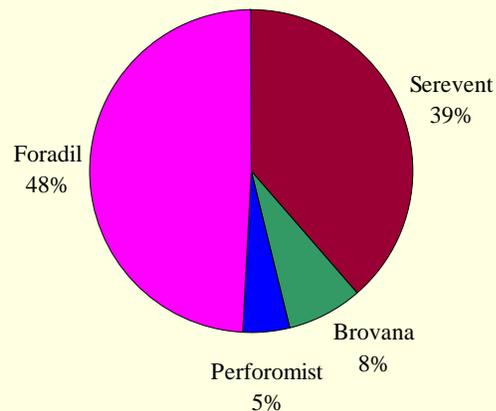
- FDA recommendations
 - Only apply to use in asthma
 - 4 criteria to ensure safe use:
 - Contraindicated without an asthma controller medication (ICS)
 - Long-term use only in patients whose asthma cannot be adequately controlled on asthma controller medications
 - Use for the shortest duration of time required to achieve control of asthma symptoms
 - Pediatric and adolescent patients who require the addition of a LABA to an ICS should use a combination product containing both



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Long Acting Beta-adrenergic Agonists-Inhaled: Market Share



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Long Acting Beta-adrenergic Agonists-Inhaled: Recommendations

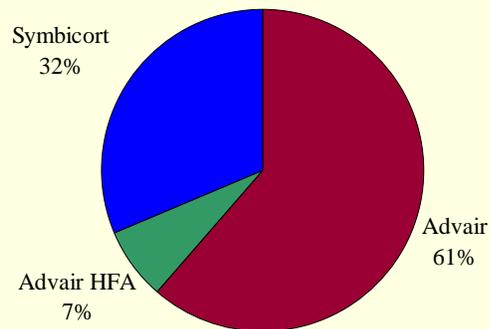
- To preferred status
 - Foradil®



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



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COPD Anticholinergic Agents: Clinical Highlights

- Spiriva® new indication
 - To reduce exacerbations in COPD patients

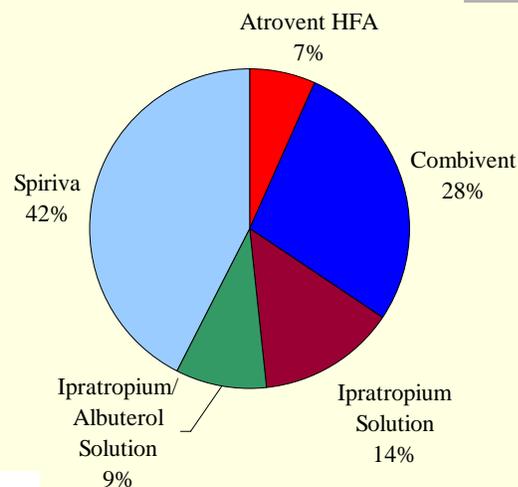
- CFC containing MDIs
 - Montreal Protocol requires market removal
 - Combivent® (albuterol/ipratropium) has been given “essential use” extension through December 31, 2013



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COPD Anticholinergic Agents: Market Share



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Glucocorticoid Agents-Inhaled: Clinical Highlights

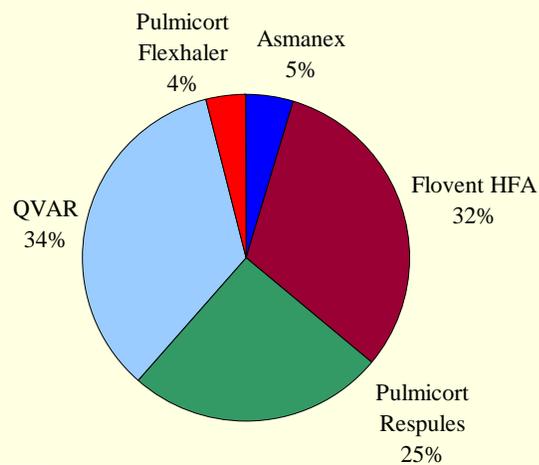
- CFC containing MDIs
 - Montreal Protocol requires market removal
 - Azmacort® (triamcinolone) - discontinued effective December 31, 2009
 - Aerobid® (flunisolide) - no CMS term date



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Glucocorticoid Agents-Inhaled: Market Share



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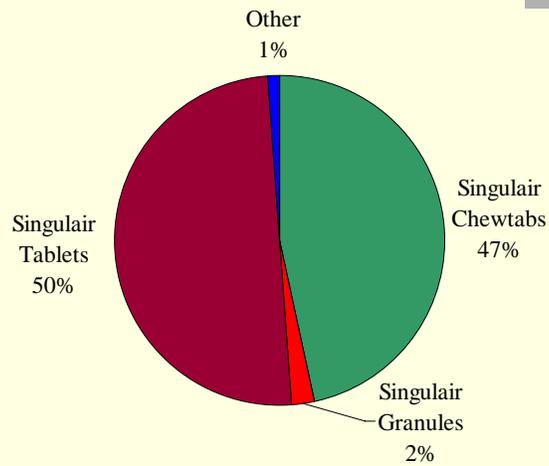
Glucocorticoid Agents-Inhaled: Recommendations

- Remove Azmacort® from PDL



107

Leukotriene Receptor Modifiers and Inhibitors: Market Share



108

Nasal Preparations: Clinical Highlights

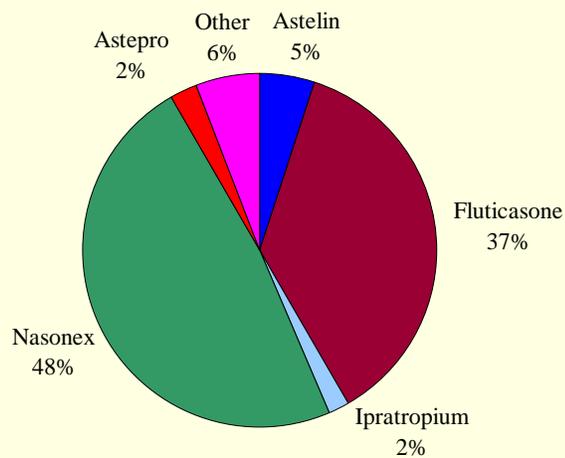
- FDA approval of Astepro 0.15%
 - PAR in patients \geq 12 yrs
- Patanase new indications
 - SAR in adults and children \geq 6 yrs
- Astepro 0.1% to be discontinued



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Nasal Preparations: Market Share



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Topical Acne Agents: Clinical Highlights

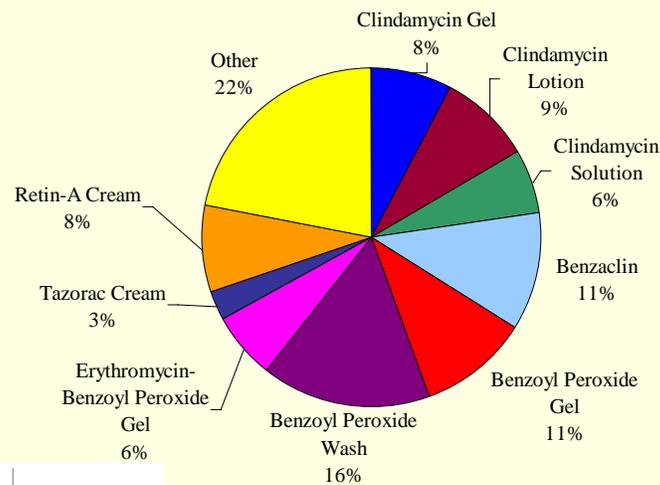
- FDA approvals
 - Generic benzoyl peroxide/clindamycin gel
 - A rated to Benzacilin
 - Generic clindamycin 1% topical foam
 - A rated to Evoclin
 - Differin 0.1% Lotion



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Topical Acne Agents: Market Share



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Topical Acne Agents: Recommendations

- Generic clindamycin foam to non-preferred



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Topical Anti-fungals: Clinical Highlights

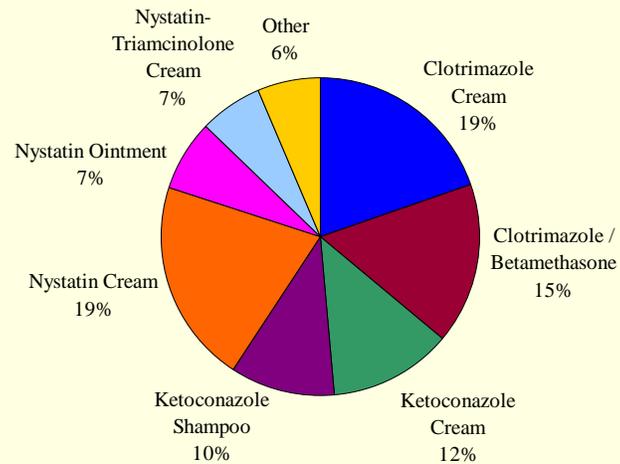
- FDA approval of generic ciclopirox shampoo
 - 0.1% formulation
 - A rated to Loprox



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Topical Anti-fungals: Market Share



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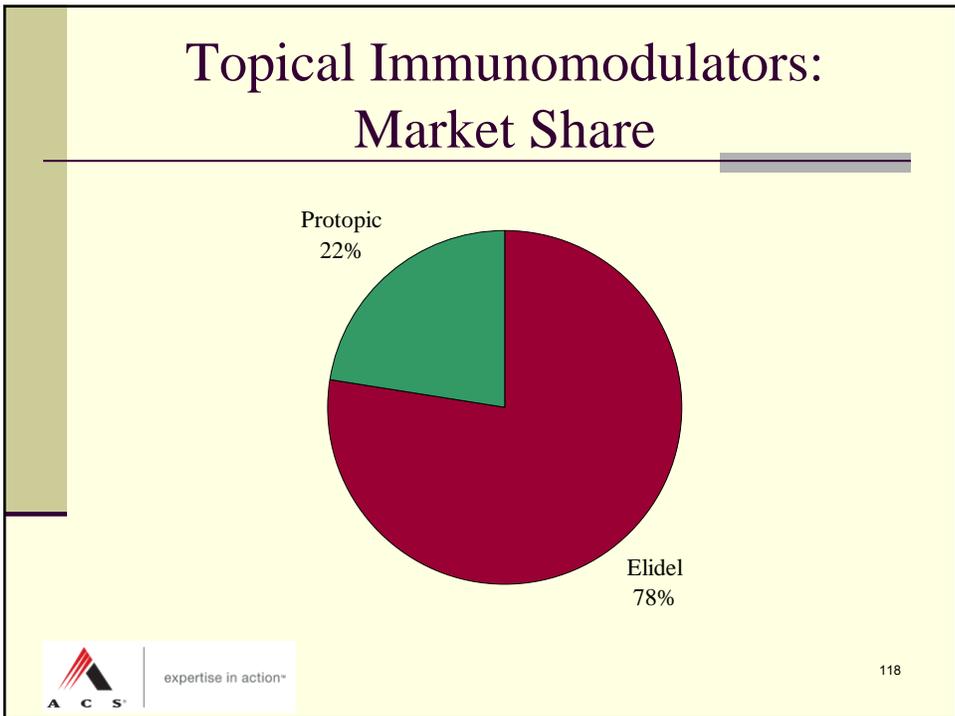
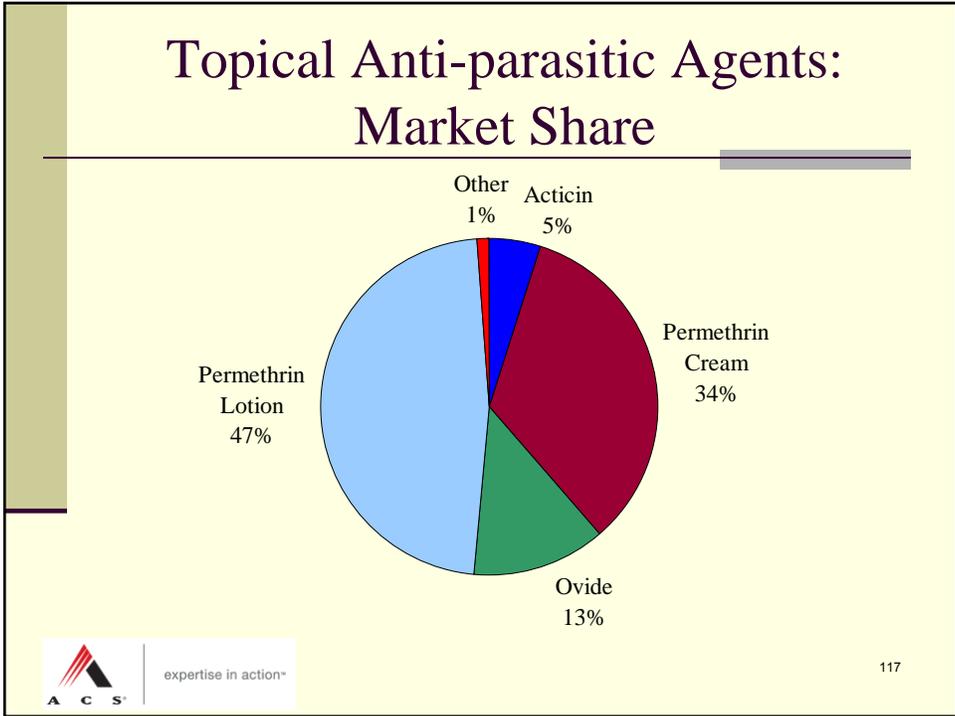
Topical Anti-parasitic Agents: Clinical Highlights

- FDA approval of Ulefsia (benzyl alcohol)
 - Head lice in patients \geq 6 mo
 - 5% lotion



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Topical Pleuromutulin Derivatives: Market Share

