

ODJFS P&T Committee Meeting Minutes

July 16, 2008

77 S. High St., Room 1948

Committee members present: Susan K. Baker, APN; Suzanne Eastman, RPh; Cheryl Huffman, MD; Robert L. Hunter, DO; Robert P. Reid, RPh (chair); Michael P. Wascovich, RPh; Mary Jo Welker, MD

ODJFS staff present: Margaret Scott, RPh, BHPP pharmacist; Elise Geig, Legislative Liaison, Trudy Rammon, Legislative Liaison.

Ohio Department of Mental Health staff present: Mark Hurst, MD; Howard Sokolov, MD

ACS staff present: Denise Hefley, PharmD, Clinical Information Pharmacist; Kimberly Hunton, PharmD, Clinical Information Pharmacist; Stephanie Levine, RPh, Clinical Manager; Randy Charles, RPh, Educational Outreach Professional; Corey Less, RPh, Educational Outreach Professional; Ed Jingluski, Account Manager

Approximately 95 stakeholders were present, representing pharmaceutical manufacturers, professional medical organizations, and advocacy groups. Michael Unger, MD, psychiatrist, was available for questions.

The meeting was called to order at 9:02 AM by Mr. Reid, chair. Mr. Reid noted that psychiatrists from the Ohio Department of Mental Health and a psychiatrist in the community mental health system were available if the committee members had questions.

Mr. Reid recognized Dr. Hefley and Dr. Hunton 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.

Lipotropics: Mr. Wascovich asked if Zetia and Vytorin should be moved to non-preferred status based on a study (ENHANCE) that lacked a true outcome. Dr. Huffman suggested that the literature should be reviewed again in another six months. Mr. Wascovich suggested keeping Zetia and Vytorin preferred and revisiting this drug class in six months. Dr. Welker noted that some patients are not responsive to or cannot take statins so another option should be available.

Antidepressants: Dr. Welker noted that many managed care plans require a trial on two preferred medications. Mr. Wascovich believes that 60 days of treatment may be needed to show treatment failure and asked for comments from the psychiatrists in attendance. Dr. Unger agreed that a response should be seen in 6 to 8 weeks, but in the community

mental health setting he would be more aggressive in finding the best medication due to the high incidence of comorbidities. In addition, Dr. Unger noted that a trial of two agents for two months each may be four months before a patient is prescribed the most appropriate medication. Dr. Hurst noted that research bears out that it may take two months for a full response to be seen, but that a lack of response after one month indicates a need for a medication change.

Dr. Huffman noted that many drugs show significant market share so she is uncomfortable with requiring prior authorization (PA) for some of these drugs. Dr. Welker noted that existing patients would be grandfathered. Mr. Wascovich agreed that a trial on two drugs is not asking too much and that with the exemption from PA for psychiatrists and grandfathering of existing patients the impact should be minimal. Dr. Huffman suggested that a trial of two agents for one month each may be more reasonable. Dr. Welker asked about prescriptions for Cymbalta for an indication other than depression. Ms. Baker asked if a trial on two preferred agents would be required if the Cymbalta is not for depression. Ms. Scott mentioned that in other drug classes, PA criteria include use of a drug for a unique indication, and this could be included for the antidepressants. Mr. Wascovich suggested a SmartPA for patients taking a drug that might indicate diabetic peripheral neuropathy. Ms. Scott will explore this possibility with ACS.

Dr. Huffman asked if PA of liquids was necessary, since these are needed for pediatric patients. Ms. Eastman noted that geriatric patients may need liquids, and asked if there is inappropriate use. Mr. Wascovich suggested that the liquids be preferred drugs and the drug utilization review (DUR) program can explore whether there is inappropriate use. Mr. Wascovich asked if it was important to include a long-acting SSRI on the preferred list. Dr. Hefley responded that the long-acting products have specific indications. Paroxetine ER (Paxil CR) is indicated for premenstrual dysphoric disorder (PMDD), which is also an indication for sertraline, and Luvox CR is indicated for Social Anxiety Disorder (SAD), which is also an indication for sertraline and paroxetine immediate release. Mr. Wascovich asked about the market share of paroxetine ER. Dr. Hunton reported that the market share was 1.6%.

Ms. Baker noted that the letter that the committee received from the Ohio Council of Behavioral Healthcare Providers requested that the PA exemption for psychiatrists be extended to clinical nurse specialists with a specialty in psychiatry, particularly in rural areas where psychiatrists are not as accessible. Dr. Welker said that the nurse must have a collaborating physician, presumably a psychiatrist who would be exempt from PA. Ms. Baker responded that the collaborating physician is probably not at the same practice site. Dr. Huffman expressed concern that if PA exemption is extended to mid-level prescribers, but not all physicians, it may be a slippery slope. She noted that these medications can be phoned in by the collaborating physician. Dr. Welker agreed. Mr. Wascovich suggested that the committee should stay finely tuned to advance practice nurse prescribing and revisit the issue in six months.

Antipsychotics, Second Generation, Oral: Dr. Hefley asked for discussion about the number of preferred drugs that should be tried before a non-preferred drug and the length of therapy that should be required. Dr. Welker said that she does not start patients on

these drugs often enough to know what is appropriate. Dr. Hunter said that psychiatrists are often not the original prescribers of these drugs. He pointed to the letters sent by two organizations that he represents, the Ohio Osteopathic Association and Ohio Academy of Family Physicians, who are concerned that it is hard to get a patient an appointment to see a psychiatrist. This can result in emergency department visits and hospitalization. Since the hospital or primary care physician may be the first prescriber of an antipsychotic, he recommends a PA exemption for all physicians. In addition, he has success with patients using Zyprexa Zydis, both in the emergency department and in long-term care patients, due to its rapid-dissolve property. Dr. Welker noted that the primary care physician can continue a non-preferred medication that has previously been prescribed due to the grandfathering policy. Dr. Huffman also noted that not requiring PA for primary care providers for antipsychotics but requiring PA for antidepressants doesn't make sense since more primary care providers prescribe antidepressants. Dr. Welker suggested that if the primary care provider has tried a preferred medication and the patient is not controlled, the patient should be referred to a psychiatrist. Dr. Hunter expressed concern that there is not easy access to psychiatrists. He suggested either an open formulary or removing the psychiatrist PA exemption.

Mr. Wascovich noted that the market share shows that most patients are taking the products that have been recommended preferred.

Dr. Unger said that a noticeable improvement should be seen in three to five days. Complete symptom remission will not occur in this time frame, but it is long enough to see improvement. After titrating the dose for 10 to 15 days without seeing an improvement, he would change the medication. Mr. Wascovich asked Dr. Unger where Zyprexa fits into therapy. Dr. Unger believes that Zyprexa is very effective but because so many metabolic effects are seen, it is probably underutilized by psychiatrists because they are less able to handle the metabolic side effects than a primary care physician. Dr. Unger also likes to use the orally disintegrating tablets (ODT) for patients who "don't like pills" because they don't see the ODT formulation as a "pill". He is very calculating in choosing which drug to use for a particular patient based on symptoms, and has clear reasons for choosing each drug. As far as safety, Dr. Unger believes that Invega is the safest drug because it is not metabolized in the liver so there are fewer drug interactions. This is useful in patients with comorbid conditions who may have interactions due to the cytochrome p450 metabolic pathway.

Dr. Hurst noted that adherence is required for any response, and that any barriers to obtaining the medication will make adherence more difficult. In addition, a patient with psychosis may feel better about taking a drug that is a specific color or has a specific name. He also noted that more family physicians are treating bipolar disorder and psychosis.

Dr. Welker noted that based on the discussion a one-month trial may be too long and suggested 14 days. Dr. Hunter suggested a trial on one preferred drug. Mr. Wascovich asked about the status of Invega. Ms. Scott noted that the recommendation to keep Invega on PA is clinical, because it is a metabolite of Risperdal and there is no literature to suggest that Invega will be more effective than Risperdal. Because there is no hepatic metabolism, Invega may be a better choice for a patient with a potential for drug interactions. The controlled release dosage form may also be an advantage for a patient

who experiences side effects due to the peaks and troughs of Risperdal dosing. Since Risperdal is now available generically, the price of Invega was also a consideration. At the moment, brand Risperdal will be the preferred risperidone formulation because it is cheaper than the generic after rebate. Dr. Welker suggested revisiting Invega's status in another six months to see if there is new clinical information and to review the pricing of generic Risperdal.

Dr. Hunter said that he prefers Zyprexa Zydis, and would like to see one ODT formulation available without PA. The other committee members did not express support for this position.

Parkinson's Disease: Several committee members asked about Requip XL, which is a new formulation. Dr. Hefley said that the drug was not part of this review because it is too new. It will be discussed at the next meeting.

Dr. Hefley invited discussion about the number of preferred agents to try, and the length of the trial. Mr. Wascovich suggested a trial of 30 days. Ms. Eastman suggested one medication.

Sedative-Hypnotics: Ms. Eastman stated that Rozerem is the only non-controlled option in this category. Dr. Welker noted that none of the preferred recommendations are indicated for long-term use. Mr. Wascovich questioned if we should be treating insomnia long-term without referring to a specialist. Dr. Hunter said that long-term care facility patients require long-term use of sedative-hypnotics. He suggested keeping Rozerem and Lunesta as preferred drugs. There is data about long-term use of Lunesta. Ms. Eastman suggested keeping Rozerem preferred because it is non-controlled. Dr. Welker suggested that Halcion should be non-preferred. Ms. Scott said that most use is by dentists, and because there is very little utilization PA may not be appropriate. However, it can be removed as a preferred option on the PDL documents that are distributed to providers, and it is not listed as a preferred drug suggestion in the point-of-sale messaging when pharmacy claims for a non-preferred drug are denied. Mr. Wascovich suggested keeping Rozerem preferred and asking the DUR program to review long-term use of sedative-hypnotics.

Smoking cessation: Mr. Wascovich was concerned about the length of authorization of one year when smoking cessation products should be used short-term to quit smoking. Dr. Welker agreed that a six month approval was more appropriate.

Diabetes – Insulins: Ms. Eastman asked if the Novolog/Humalog decision was financial, considering that Humalog has additional mix ratios available. Ms. Scott responded that a clinical difference was not seen between the agents, but that patients who refill their non-preferred prescription at least once every 120 days are grandfathered. Mr. Wascovich noted the grandfathering, but asked about patients new to Medicaid. Ms. Scott responded that if the prescriber indicates previous use, the PA request would be approved. Dr. Hunter asked about the market share of Apidra. Dr. Hunton reported 0.22% market share.

Growth hormones: Dr. Hefley asked for discussion about the number of preferred agents to try and the length of the trial. Dr. Hunter and Ms. Eastman suggested one agent. Dr. Huffman said that two months was reasonable and possibly not long enough. Dr. Welker suggested three months. Dr. Huffman agreed that one product should be tried for three months since the endocrinologist would probably not see the patient again for at least three months. She also expressed concern that idiopathic short stature was recommended to be included as an approvable indication. She believes that this will increase claims and is not warranted. The other committee members agreed that this indication should not be added.

Proton Pump Inhibitors: Mr. Wascovich suggested that the DUR program review PPIs for length of therapy and dosing. Ms. Scott reminded the committee that there is a PA requirement for patients to receive more than one dose per day.

Anti-fungals for onychomycosis and systemic infections: Mr. Wascovich asked if a SmartPA could be implemented for transplant patients to approve itraconazole if there is a history of cyclosporine. Ms. Scott will explore this suggestion.

Ophthalmic antibiotics: Mr. Wascovich expressed concern that Vigamox may be inappropriately overused. Dr. Huffman noted that she has never seen a failure on Polytrim and does not prescribe quinolones. The committee requested that the DUR program review use of ophthalmic quinolones for review at a future meeting. The suggestion is that prior authorization may be warranted for all ophthalmic quinolones, requiring a failure on another drug and/or culture reports, possibly with an exemption for ophthalmologists.

Short-Acting Beta Adrenergic Agents: Mr. Wascovich suggested that Xopenex should be non-preferred. Dr. Huffman agreed, saying that Xopenex should only be used for patients who have side effects when using albuterol. Ms. Scott said that since patients are moving to the HFA albuterol products, there is no price difference between the Xopenex MDI and HFA inhalers. Dr. Welker suggested a PA for the nebulizer formulation.

Long-Acting Beta Adrenergic Agents: Dr. Huffman disagreed with the recommendation to move Advair to non-preferred. It has the highest market share and is available in three strengths. Symbicort is approved only for patients age 12 and older. Dr. Welker and Ms. Eastman agreed.

Inhaled corticosteroids: Dr. Huffman asked if there is an age limit on the Pulmicort respules. Ms. Scott responded that there is not but based on the high market share a limit may be warranted. Dr. Huffman said that some pulmonologists are starting patients as young as 2 on inhalers. She would recommend something higher. The committee agreed that an age limit of 8 on Pulmicort respules would be appropriate.

Leukotriene modifiers: Mr. Wascovich asked if a diagnosis should be required for these drugs to limit to use in asthma. Dr. Huffman said that many commercial plans require a

trial on a nasal steroid, which she is not in favor of for pediatric patients. She would agree with a trial on other medications. Dr. Welker said that it would be hard to differentiate a prescription for asthma vs. allergies. Dr. Huffman said that other plans will approve automatically if there are claims for other asthma medications. Ms. Scott indicated that this could be done through SmartPA, since the asthma guidelines do indicate that inhaled corticosteroids are the first-line medication. Dr. Welker agreed with implementing a SmartPA for asthma. Ms. Scott suggested that she can research this in the same way that the department reviewed claims before recommending step therapy for the long-acting beta adrenergic products. She will report at a future meeting.

Nasal preparations: Ms. Eastman asked if the relief of ocular allergy symptoms and the unique delivery device of Veramyst were considered in making the recommendations. Dr. Hunton responded that they were. Dr. Hunter agreed that Veramyst does help ocular symptoms and he is aware of some allergists who use Veramyst as their primary choice.

Topical agents, post-herpetic neuralgia (PHN): Dr. Welker noted that many pain management specialists use Lidoderm for chronic pain that is unrelated to PHN. Dr. Hunter agreed that this off-label use is reasonable because it can decrease the use of narcotics. Mr. Wascovich agreed, but said that the drug should still require PA because it is not a first-line agent. There should be additional criteria beyond PHN. Dr. Welker suggested that the department work with pain management specialists to determine appropriate use. Dr. Huffman agreed that it is not a first-line agent and that therapy and other agents should be tried first.


Following the discussion of the PDL, Mr. Reid moved to the next agenda item, election of a new chair since he is retiring. Dr. Welker asked about this process since Mr. Reid is an ODJFS employee. Discussion followed about the duties of the chair and whether the position should be filled by an ODJFS employee. Dr. Hunter indicated his interest in the position. Ms. Eastman seconded the nomination. The vote was unanimous.

Mr. Reid adjourned the meeting.

Following the meeting, changes were made to the PDL:


- Lipotropics
 - Zetia and Vytorin were restored to preferred status.
- Antidepressants
 - The trial of preferred agents was set to 2 agents for 30 days each.
 - If there is a specific indication for a medication requiring prior approval, for which medications not requiring prior approval are not indicated, then may approve the requested medication (e.g., Cymbalta may be authorized for diabetic peripheral neuropathic pain or fibromyalgia). This medication should be reviewed for need at each request for reauthorization.

- The automated SmartPA system will automatically approve Cymbalta for patients who have a claims history for both an antidiabetic agent and a medication used for diabetic peripheral neuropathic pain (tricyclic antidepressant, gabapentin, or Lyrica) in the previous 3 months.
 - Liquid SSRIs were moved to preferred status.
- Antipsychotics, Second Generation
 - The trial of preferred agents was set to one agent for 14 days.
 - Generic risperidone was moved to non-preferred status, with brand Risperdal kept on preferred status.
- Parkinson's Disease
 - The trial of preferred agents was set to one agent for 30 days.
- Sedative-Hypnotics
 - Rozerem was restored to preferred status.
 - Triazolam was removed from the PDL document.
- Smoking Cessation
 - Generic nicotine patches were moved to preferred status.
- Diabetes – Insulins
 - Humulin and Humalog products were moved to preferred status.
- Growth Hormones
 - The trial of preferred agents was set to one agent for 3 months.
 - Idiopathic short stature is not an approvable diagnosis.
 - Nutropin, Nutropin AQ, and Tev-Tropin were moved to preferred status.
- Antifungals for Onychomycosis and Systemic Infections
 - The automated SmartPA system will automatically approve itraconazole if there is a claims history of an immunosuppressive agent in the previous 60 days.
- Long-Acting Beta-Adrenergic Agents
 - Advair was restored to preferred status.
- Topical Agents, PHN
 - Lidoderm was moved to preferred status.



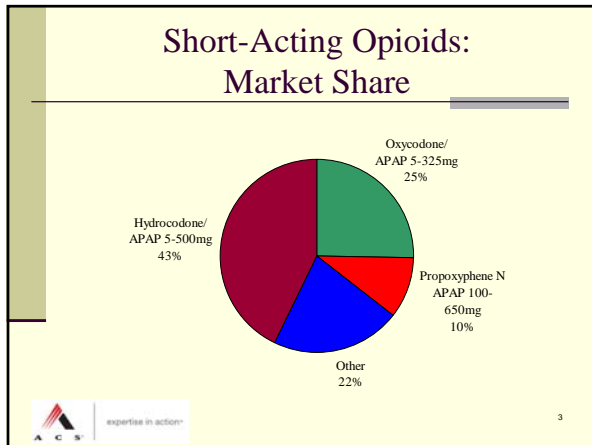
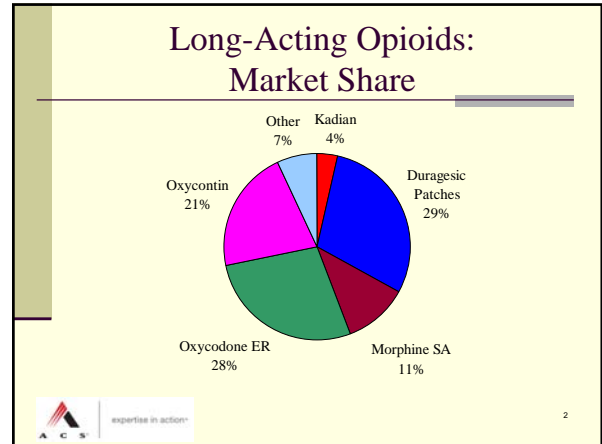
**Ohio Health Plans Fee-For-Service
Pharmacy Benefit Management Program
Preferred Drug List
Recommendations**


Denise Hefley, PharmD
and
Kimberly Hunton, PharmD
ACS Clinical Information Pharmacists

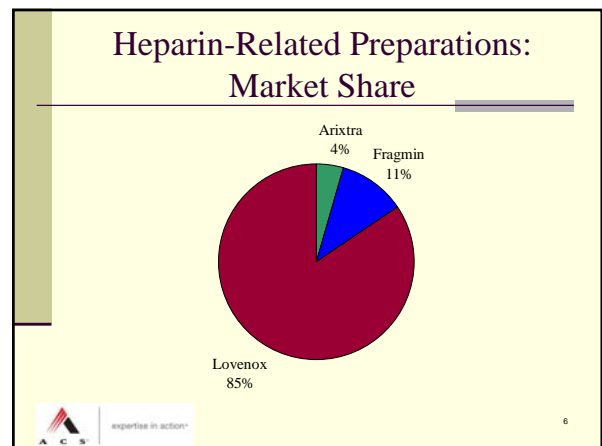
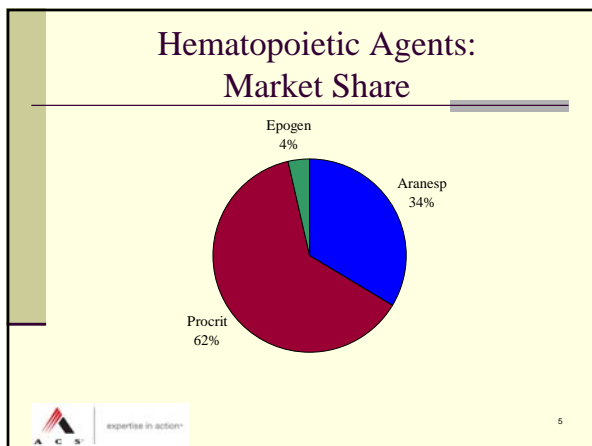


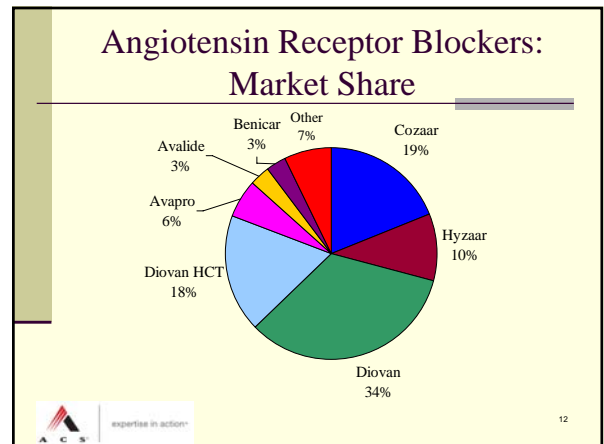
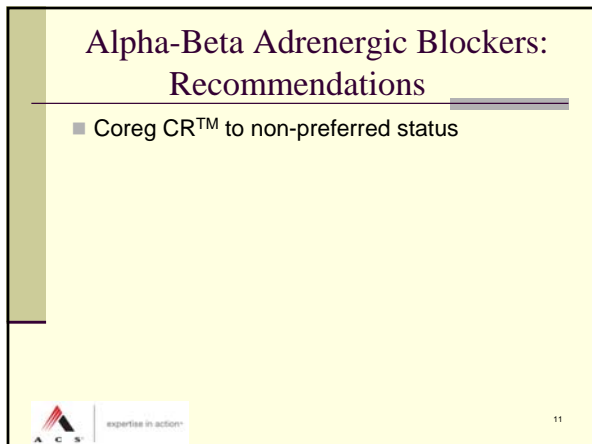
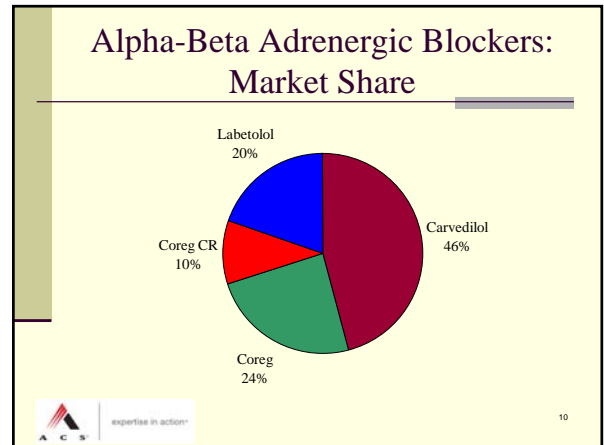
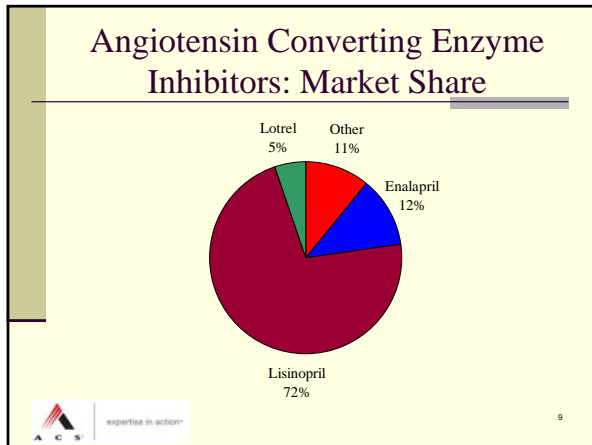
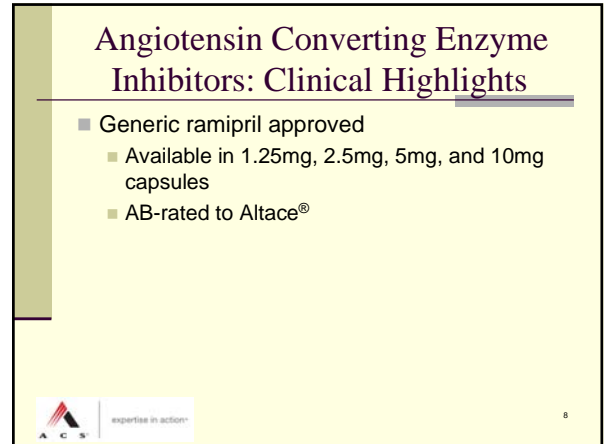
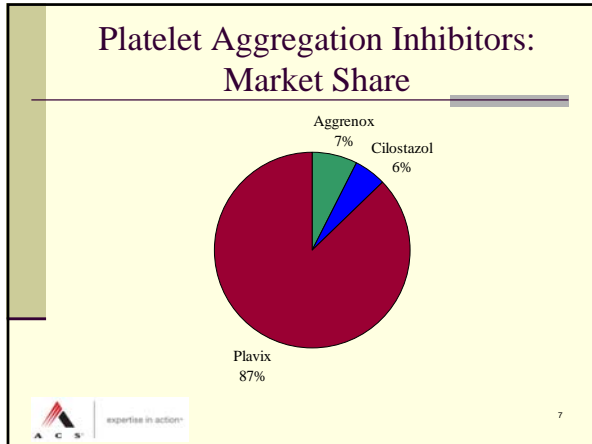
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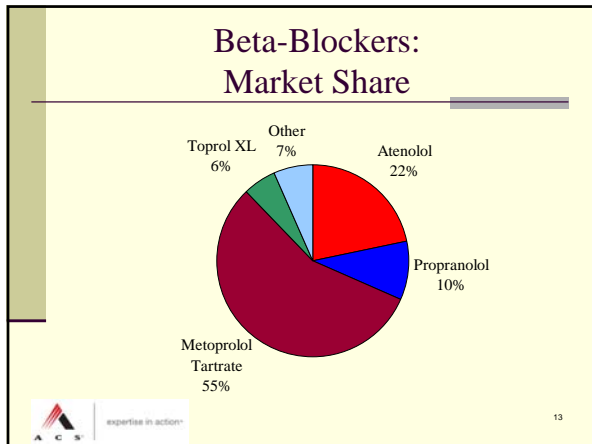
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- ### Opioids: Recommendations
- Oramorph® SR to preferred status
 - Hydrocodone/Acetaminophen 7.5/650mg, 7.5/750mg, 10/650mg, and 10/660mg to preferred status
 - Oxycodone/Acetaminophen all strengths to preferred status
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Beta-Blocker: Recommendations

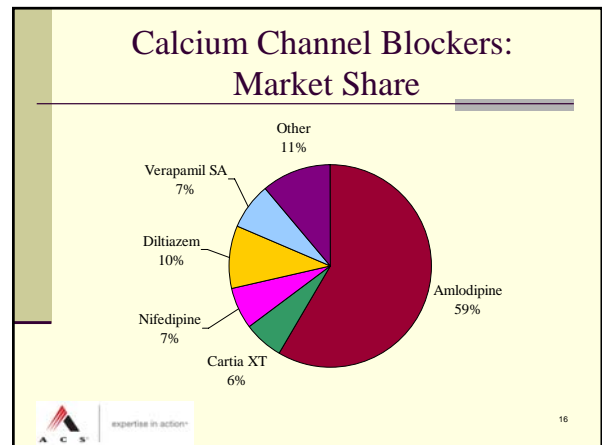
- Inderal LA® to non-preferred status

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Calcium Channel Blockers: Clinical Highlights

- Sular® tablets reformulated
 - 10mg, 20mg, 30mg, and 40mg tablets have been reformulated, and are now available as 8.5mg, 17mg, 25.5mg, and 34mg tablets
 - New lower strength tablets bioequivalent to previously available higher strength tablets

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Calcium Channel Blockers: Recommendations

- Sular® to non-preferred status

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Direct Renin Inhibitors: Clinical Highlights

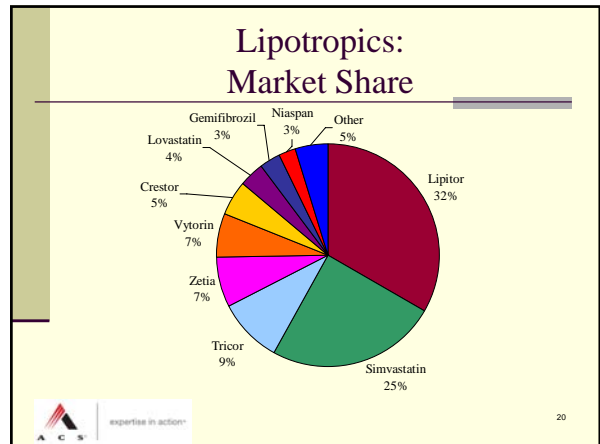
- Tekturna HCT® tablets approved
 - For the treatment of hypertension as add-on therapy or as replacement therapy for the titrated individual components.

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Lipotropics: Clinical Highlights

- Results of the ENHANCE trial published
 - Multicenter, randomized, double-blind, comparator trial evaluating simvastatin 80mg alone versus simvastatin 80mg plus ezetimibe 10mg (Vytorin®)
 - Change in the carotid-artery intima-media thickness (CIMT) was not statistically different between the two treatment groups (primary endpoint)
 - Significantly greater reductions in mean LDL-C, triglycerides, and C-reactive protein were seen in the simvastatin/ezetimibe group (secondary endpoints)

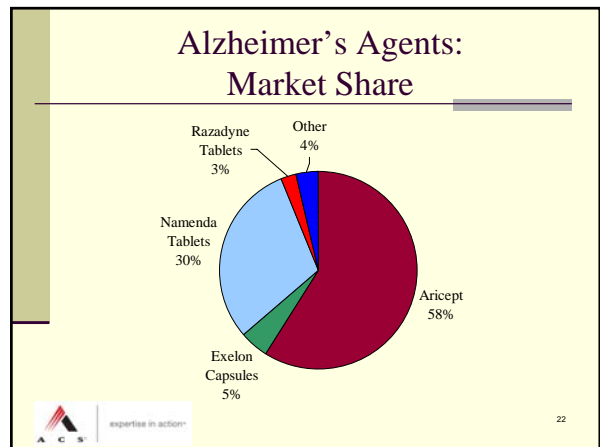
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Lipotropics: Recommendations

- Zetia® and Vytorin® to non-preferred status

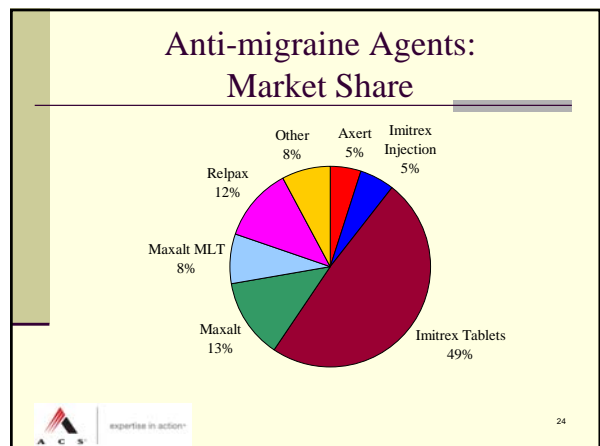
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Anti-migraine Agents: Clinical Highlights


- Treximet® (sumatriptan/naproxen) has received FDA approval
 - Indicated for the acute treatment of migraine attacks with or without aura in adults
 - Available as an 85/500mg tablet

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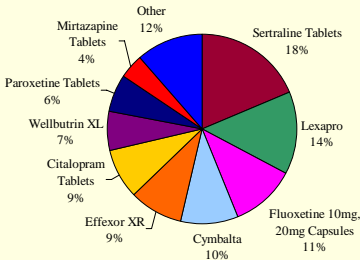


Antidepressants: Clinical Highlights


- New class for inclusion on the PDL
- Cymbalta® is the only antidepressant that is FDA approved for use in diabetic peripheral neuropathy and fibromyalgia


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Antidepressants: Market Share




Drug	Market Share (%)
Sertraline Tablets	18%
Lexapro	14%
Fluoxetine 10mg, 20mg Capsules	11%
Cymbalta	10%
Effexor XR	9%
Citalopram Tablets	9%
Wellbutrin XL	7%
Paroxetine Tablets	6%
Mirtazapine Tablets	4%
Other	12%


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Antidepressants: Additional Information

- Grandfathering
 - Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history will be approved for PA after prescriber contact
- Psychiatrist exemption
 - Physicians who are registered with Ohio Health Plans as having a specialty in psychiatry are exempt from prior authorization of any non-preferred antidepressant in the standard tablet/capsule dosage forms. Other dosage forms may still require PA by a psychiatrist.


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Antidepressants: Recommendations

- Antidepressants
 - Alpha-2 Receptor Antagonists
 - Mirtazapine and mirtazapine rapid dissolve to preferred status
 - Serotonin-Norepinephrine Reuptake Inhibitors
 - Effexor XR® and venlafaxine to preferred status
 - Cymbalta® and Pristiq® to non-preferred status
 - Monoamine Oxidase Inhibitors
 - Emsam®, Marplan®, Nardil®, and Parnate® to non-preferred status


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Antidepressants: Recommendations (Continued)

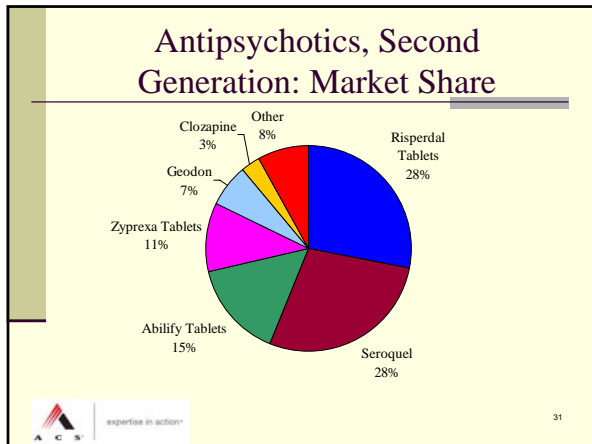
- Antidepressants
 - Norepinephrine and Dopamine Reuptake Inhibitors
 - Bupropion, bupropion SR, Wellbutrin XL® to preferred status
 - Bupropion XL to non-preferred status
 - Selective Serotonin Reuptake Inhibitors
 - Citalopram tablets, fluoxetine 10mg, 20mg, fluoxetine solution, fluvoxamine, Lexapro® tablets, paroxetine tablets, and sertraline tablets to preferred status
 - Citalopram solution, fluoxetine 40mg, Lexapro® solution, Luvox CR®, paroxetine ER, paroxetine solution, Peveva®, Prozac Weekly®, Selfemra®, and sertraline concentrate to non-preferred status


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Antipsychotics, Second Generation: Clinical Highlights

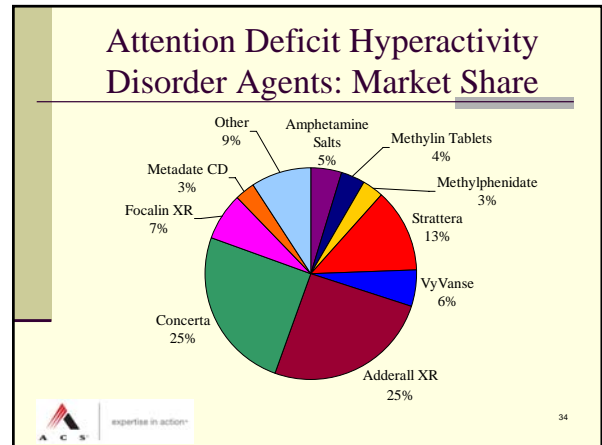
- New class for inclusion on the PDL
- Generic risperidone approved
 - Available in 0.25mg, 0.5mg, 1mg, 2mg, 3mg, and 4mg tablets
- Risperdal® is the only second generation antipsychotic FDA approved for irritability associated with Autistic disorder in children and adolescents over 5 years of age
- Abilify® is the only second generation antipsychotic FDA approved as adjunctive treatment to antidepressants in MDD


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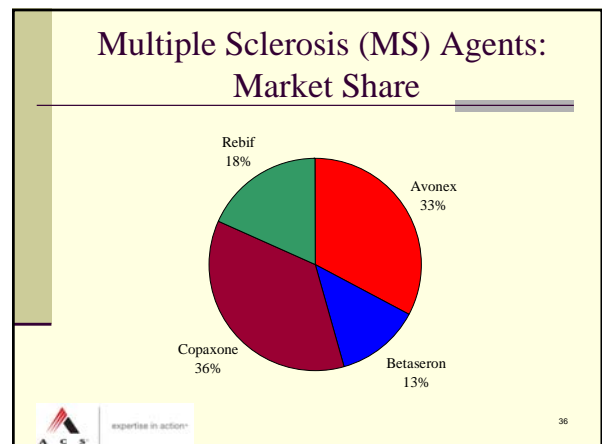


- ### Antipsychotics, Second Generation: Additional Information
- Grandfathering
 - Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history will be approved for PA after prescriber contact
 - Psychiatrist exemption
 - Physicians who are registered with Ohio Health Plans as having a specialty in psychiatry are exempt from prior authorization of any non-preferred antipsychotic in the standard tablet/capsule dosage forms. Other dosage forms may still require PA by a psychiatrist.

- ### Antipsychotics, Second Generation: Recommendations
- Second Generation Antipsychotics
 - Abilify® solution, Abilify® tablets, Geodon®, Risperdal® solution, Risperdal® tablets, risperidone tablets, Seroquel®, and Seroquel XR® to preferred status
 - Abilify Discmelt®, clozapine, Clozaril®, Fazaclo®, Invega®, Risperdal M-Tab®, Zyprexa®, and Zyprexa Zydys® to non-preferred status
 - Second Generation Antipsychotic / SSRI Combination
 - Symbyax® to non-preferred status




- ### Attention Deficit Hyperactivity Disorder: Recommendations
- Amphetamine Salts all strengths to preferred status
 - Adderall® to non-preferred status

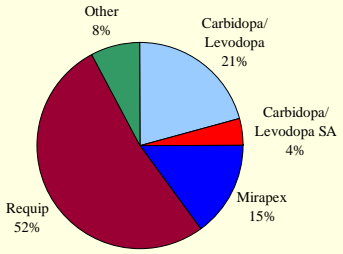


Anti-parkinson Agents: Clinical Highlights


- New class for inclusion on the PDL
- Ropinirole (generic Requip®) recently approved
- Neupro® (rotigotine transdermal system) discontinued at the end of April 2008

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Anti-parkinson Agents: Market Share




Agent	Market Share
Requip	52%
Carbidopa/Levodopa	21%
Mirapex	15%
Carbidopa/Levodopa SA	4%
Other	8%

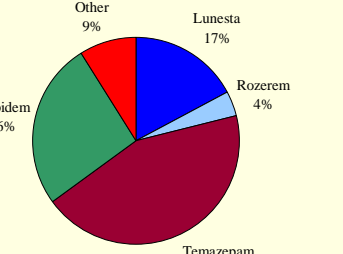
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Anti-parkinson Agents: Recommendations


- Carbidopa/levodopa, carbidopa/levodopa CR, Comtan®, ropinirole, selegiline, and Stalevo® to preferred status
- Apokyn®, Azilect®, Mirapex®, Parcopa®, Tasmal®, and Zelapar® ODT, to non-preferred status

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Sedative Hypnotics, Non-Barbiturate: Market Share




Agent	Market Share
Temazepam	44%
Zolpidem	26%
Lunesta	17%
Other	9%
Rozerem	4%

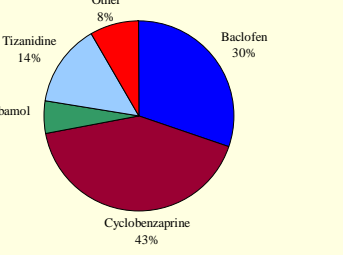
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Sedative Hypnotics, Non-Barbiturate: Recommendations


- Rozerem® and Lunesta® to non-preferred status

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Skeletal Muscle Relaxants, Non-Benzodiazepine: Market Share




Agent	Market Share
Cyclobenzaprine	43%
Baclofen	30%
Tizanidine	14%
Other	8%
Methocarbamol	5%

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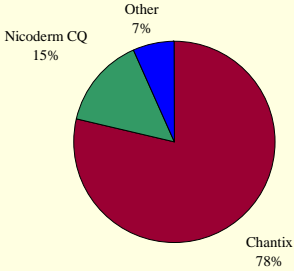
Smoking Deterrents: Clinical Highlights

- Department of Health and Human Services
 - Smoking Cessation Guidelines updated in 2008 to include nicotine lozenges and varenicline (Chantix®) as recommended first line agents
 - Combinations of first-line medications have been shown to be effective smoking cessation treatments
- Postmarketing reports of serious neuropsychiatric symptoms including depressed mood, agitation, changes in behavior, suicidal ideation and suicide in patients attempting to quit smoking while taking Chantix®.




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Smoking Deterrents: Market Share




Product	Market Share
Chantix	78%
Nicoderm CQ	15%
Other	7%



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Smoking Deterrents: Recommendations


- Zyban® to non-preferred status



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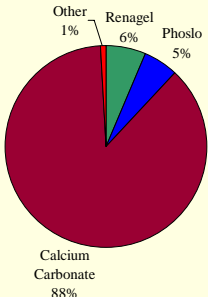
Electrolyte Depleters: Clinical Highlights

- Renvela® (sevelamer carbonate) has received FDA approval
 - Control of serum phosphorus in patients with chronic kidney disease on dialysis
 - Available in 800mg tablets




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Electrolyte Depleters: Market Share

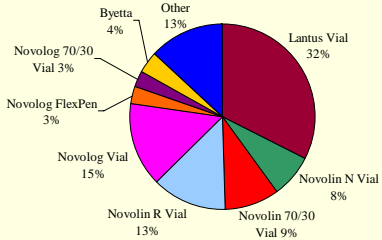


Product	Market Share
Calcium Carbonate	88%
Renagel	6%
Phoslo	5%
Other	1%




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Amylin Analogs, Incretin Mimetics, and Insulins: Market Share




Product	Market Share
Lantus Vial	32%
Novolog Vial	15%
Novolin R Vial	13%
Novolin 70/30 Vial	9%
Novolin N Vial	8%
Other	13%
Byetta	4%
Novolog FlexPen	3%
Novolog 70/30 Vial	3%



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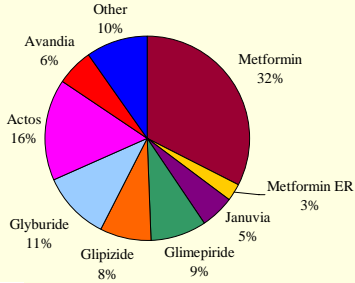
Oral Hypoglycemics: Clinical Highlights

- Generic acarbose approved
 - Available as 25mg, 50mg, and 100mg tablets
 - AB-rated to Precose®




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Oral Hypoglycemics: Market Share




Drug	Market Share (%)
Metformin	32%
Actos	16%
Glyburide	11%
Glipizide	8%
Glimepiride	9%
Januvia	5%
Metformin ER	3%
Avandia	6%
Other	10%



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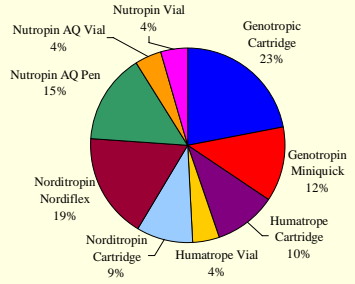
Growth Hormones: Clinical Highlights

- New class for inclusion on the PDL
- All agents contain somatropin
 - Many delivery devices available for administration
 - Saizen® is the only agent delivered via a hidden needle or needle-free device
 - No generic equivalents




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Growth Hormones: Market Share




Drug	Market Share (%)
Genotropin Cartridge	23%
Norditropin Nordiflex	19%
Nutropin AQ Pen	15%
Humatrope Cartridge	10%
Genotropin Miniquick	12%
Norditropin Cartridge	9%
Humatrope Vial	4%
Nutropin AQ Vial	4%
Nutropin Vial	4%



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Growth Hormones: Recommendations


- Genotropin® Cartridge, Genotropin® Miniquick, Norditropin Nordiflex®, Norditropin® Cartridge, and Norditropin® Vial to preferred status
- Humatrope® Cartridge, Humatrope® Vial, Nutropin® AQ Pen Cartridge, Nutropin® AQ Vial, Nutropin® Vial, Omnitrope® Vial, Saizen® Vial, Serastim® Vial, Tev-Tropin® Vial, and Zorbtive® Vial to non-preferred status



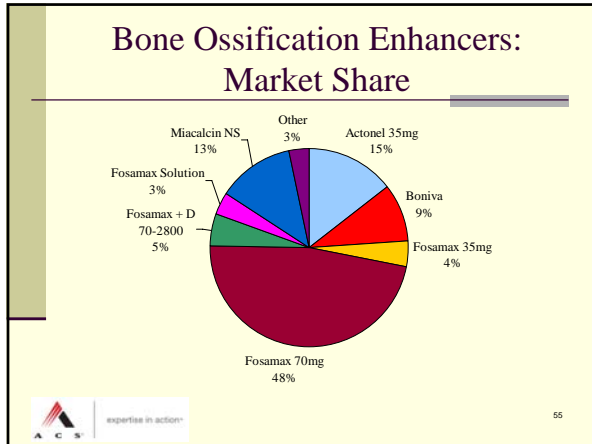
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Bone Ossification Enhancers: Clinical Highlights

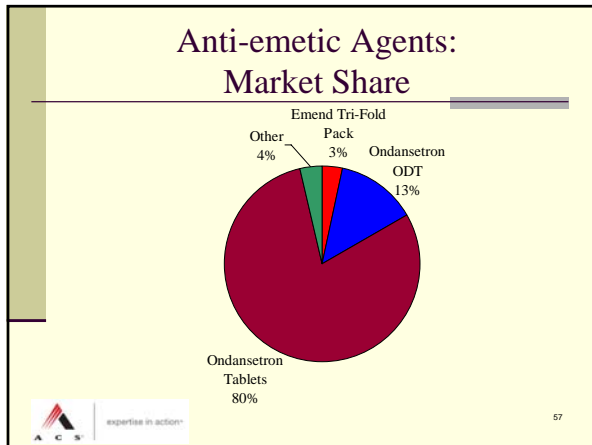
- Actonel® (risedronate)
 - A new 150mg strength available and approved for the prevention and treatment of postmenopausal osteoporosis
 - The dosage regimen for this new strength is 150mg one day per month
- Generic alendronate approved
 - Available as 5mg, 10mg, 35mg, 40mg, and 70mg tablets



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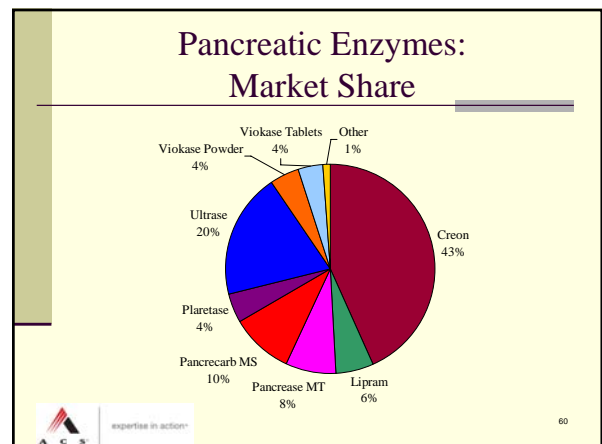


- ### Bone Ossification Enhancers: Recommendations
- Generic alendronate to preferred status
 - Fosamax® and Fosamax Plus D™ to non-preferred status




- ### Chronic Constipation: Clinical Highlights
- Amitiza® (lubiprostone) has a new FDA-approved indication
 - Treatment of Irritable Bowel Syndrome with Constipation (IBS-C) in women 18 years of age and older
 - Dose is 8mcg twice daily
 - 8mcg capsule approved and available

- ### Pancreatic Enzymes: Clinical Highlights
- New class for inclusion on the PDL
 - All agents contain varying amounts of lipase, protease, and amylase
 - In April 2004, the FDA notified manufacturers of pancreatic enzyme products that they must have approval via the submission of an NDA within the next four years in order to remain on the US market
 - Deadline extended to April 2010

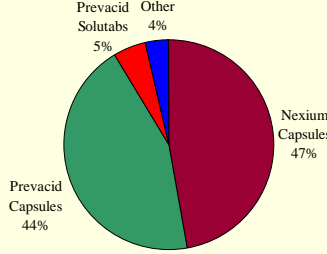


Pancreatic Enzymes: Recommendations


- Creon®, Dygase®, Lipram®, Lipram PN®, Pancrease MT®, Pancrearb MS®, Pancrelipase®, Pangestyme®, Pangestyme EC®, Pangestyme CN®, Pangestyme MT®, Pangestyme UL®, Plaretase®, Ultrase®, Ultrase MT®, Viokase® to preferred status


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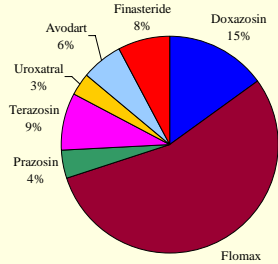
Proton Pump Inhibitors (PPIs): Market Share




Product	Market Share
Nexium Capsules	47%
Prevacid Capsules	44%
Prevacid Solutabs	5%
Other	4%


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Benign Prostatic Hypertrophy Agents: Market Share




Product	Market Share
Flomax	55%
Doxazosin	15%
Terazosin	9%
Finasteride	8%
Avodart	6%
Prazosin	4%
Uroxatral	3%

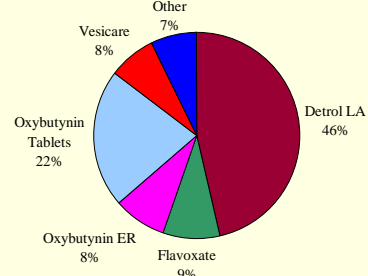

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Benign Prostatic Hypertrophy: Recommendations


- Uroxatral® to preferred status


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Urinary Antispasmodics: Market Share




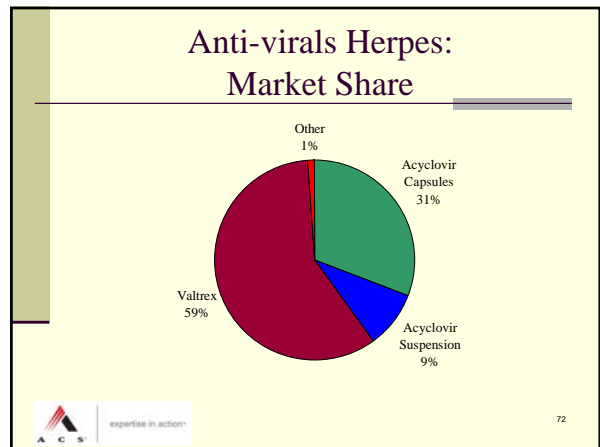
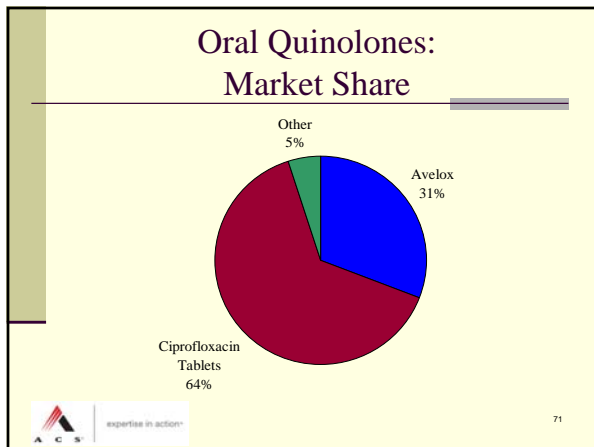
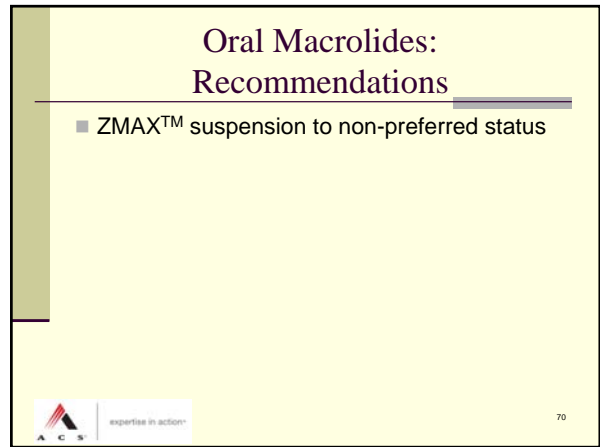
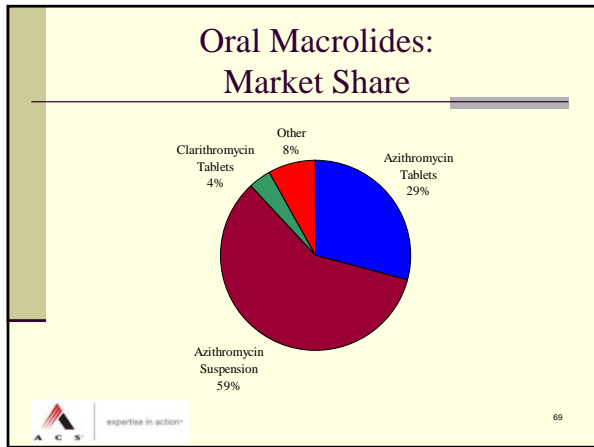
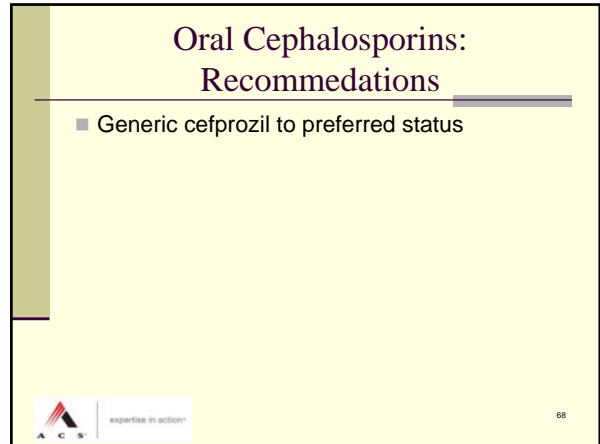
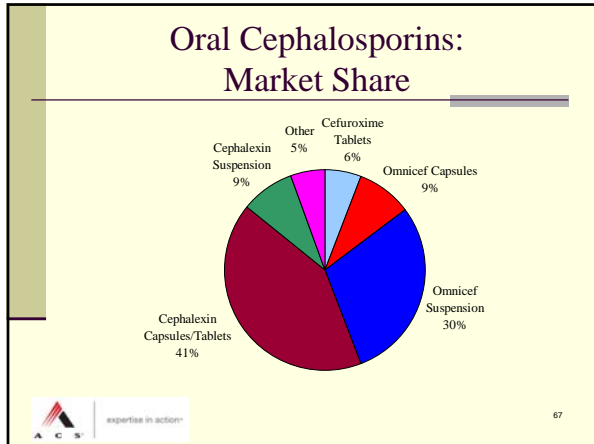
Product	Market Share
Detrol LA	46%
Oxybutynin Tablets	22%
Flavoxate	9%
Oxybutynin ER	8%
Vesicare	8%
Other	7%


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Oral Cephalosporins: Clinical Highlights

- Generic cefuroxime oral suspension approved
 - Available in 125mg/5 mL and 250mg/5 mL formulations
 - AB-rated to Ceftin®
- Suprax® 400mg tablets re-launched in U.S.


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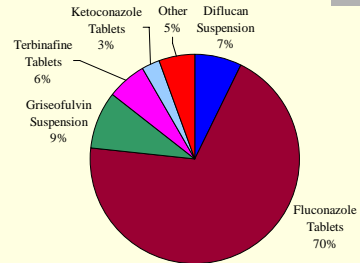
Agents for Onychomycosis & Systemic Infections: Clinical Highlights

- Lamisil® (terbinafine) oral granules approved
 - Indicated for the treatment of tinea capitis in patients 4 years of age and older
 - Available in 125mg and 187.5mg formulations



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Agents for Onychomycosis & Systemic Infections: Market Share



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Agents for Onychomycosis & Systemic Infections: Recommendations

- Fluconazole suspension to preferred status



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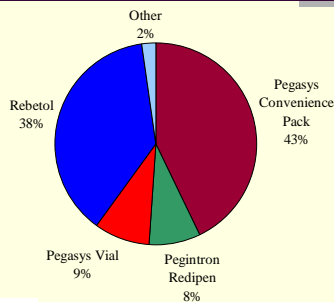
Hepatitis C-Pegylated Interferons & Ribavirins: Clinical Highlights

- Copegus® (ribavirin) postmarketing reports of dehydration
- Generic ribavirin tablets approved
 - Available in 400mg and 600mg tablets



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Hepatitis C-Pegylated Interferons & Ribavirins: Market Share



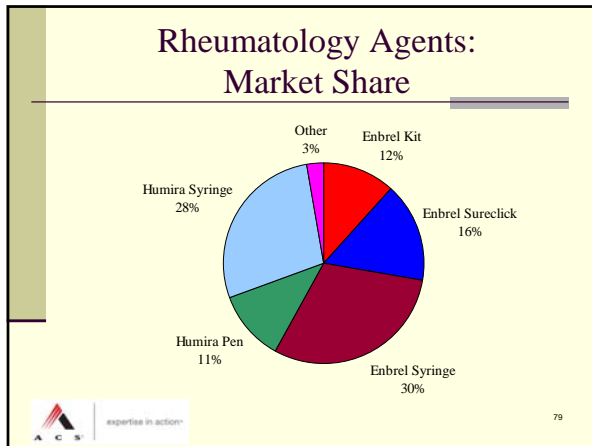
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Rheumatology Agents: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed include Enbrel®, Humira®, and Kineret®

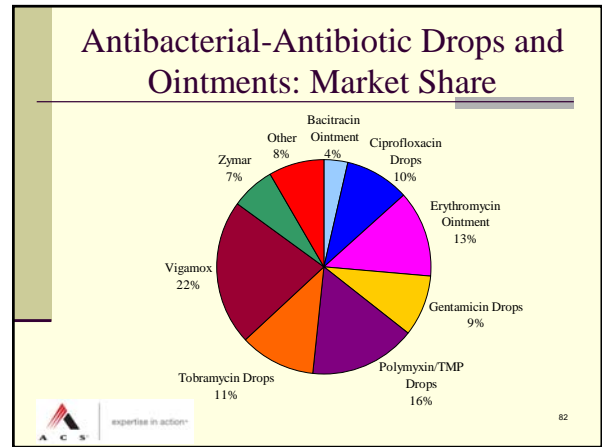


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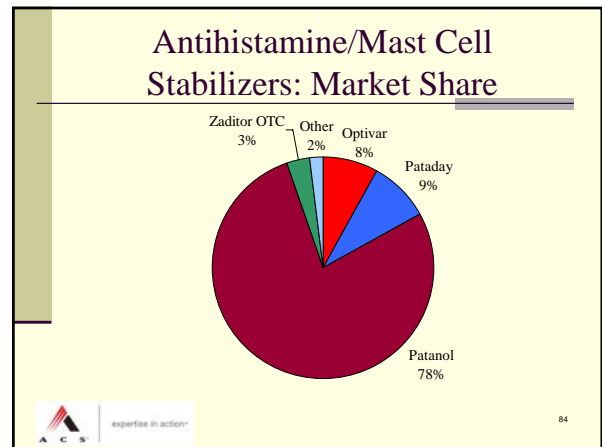


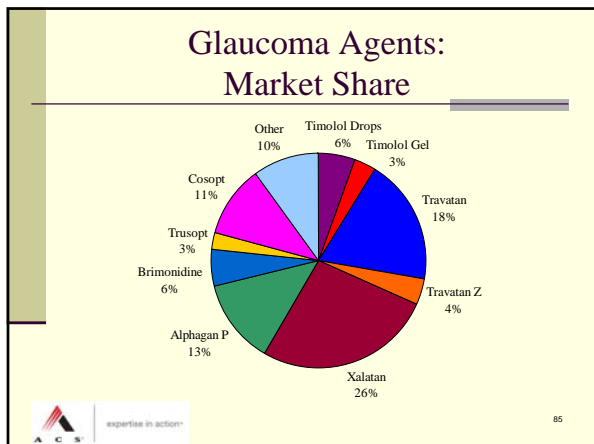
- ### Rheumatology Agents: Recommendations
- Anti-inflammatory Tumor Necrosis Factor Inhibitors
 - Enbrel Kit®, Enbrel Sureclick Syringe®, Enbrel Syringe®, Humira Pen®, Humira Crohn's Starter Pack®, and Humira Syringe® to preferred status
 - Anti-inflammatory Interleukin-1 Receptor Antagonist
 - Kineret® Syringe to preferred status

- ### Antibacterial-Antibiotic Drops and Ointments: Clinical Highlights
- The Ophthalmic Antibiotics class review previously included quinolones only; expanded to include the new macrolide ocular agent, Azasite, as well as other antibacterial agents used in the treatment of ophthalmic infections

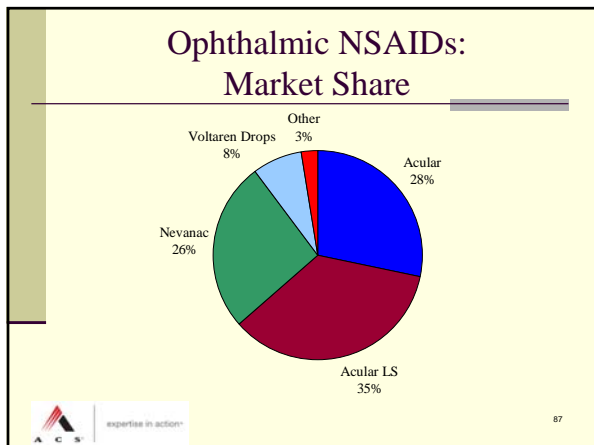


- ### Antibacterial-Antibiotic Drops and Ointments: Recommendations
- Quinolones
 - Quixin® drops to preferred status
 - Ciloxan® ointment, Iquix® drops, and Zymar® drops to non-preferred status
 - Non-Quinolones
 - Bacitracin ointment, Bacitracin-Polymyxin ointment, Erythromycin ointment, Gentamicin drops, Gentamicin ointment, Neomycin/Bacitracin/Polymyxin ointment, Neomycin/Polymyxin/Gramicidin ointment, Neomycin/Polymyxin/Bacitracin drops, Polymyxin/Trimethoprim drops, Tobramycin drops, and Tobrex® ointment to preferred status
 - Azasite® drops to non-preferred status



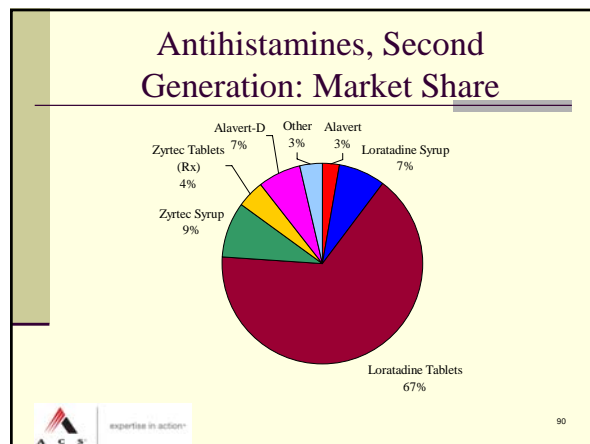


- ### Ophthalmic NSAIDs: Clinical Highlights
- New class for inclusion on the PDL
 - Agents reviewed in this class are bromfenac, diclofenac, flurbiprofen, ketorolac, and nepafenac
 - Flurbiprofen is the only agent indicated for inhibition of intraoperative miosis
 - Ketorolac (Acular®) is the only agent indicated for seasonal allergic conjunctivitis




- ### Ophthalmic NSAIDs: Recommendations
- Acular®, Acular PF®, Acular LS®, diclofenac, and flurbiprofen to preferred status
 - Nevanac® and Xibrom® to non-preferred status

- ### Antihistamines, Second Generation: Clinical Highlights
- Allegra® (fexofenadine) orally disintegrating tablets approved
 - Available in a 30mg strength
 - Generic cetirizine OTC approved
 - Available in 5mg and 10mg tablets, 5mg and 10mg chewable tablets, and 1mg/mL syrup
 - Cetirizine / Pseudoephedrine ER OTC approved
 - Available as a 5/120mg tablet
 - Xyzal® (levocetirizine) oral solution approved
 - For relief of symptoms associated with SAR and PAR, and for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria
 - Available in a 2.5mg/5mL formulation



Antihistamines, Second Generation: Recommendations

- Cetirizine tablets to preferred status
- Alavert® and Alavert D 12-HR® to non-preferred status




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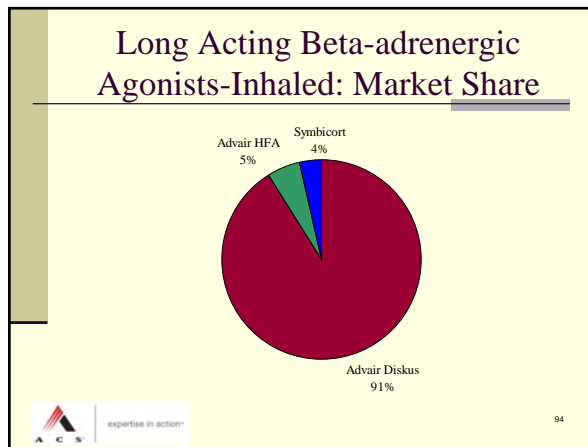
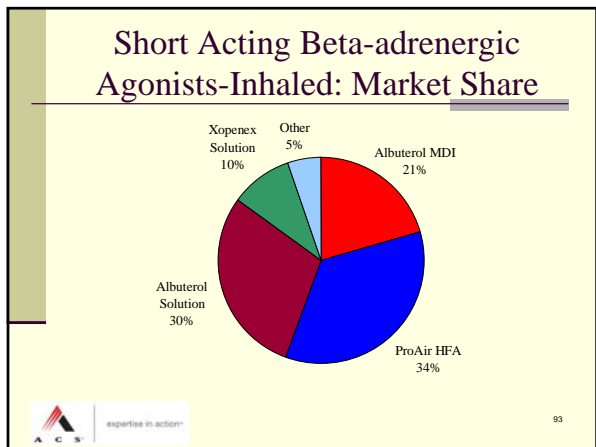
Beta-adrenergic Agonists-Inhaled: Clinical Highlights

- FDA Advisory May 2008
 - Issued to patients, caregivers, and health care professionals to switch to HFA-propelled albuterol inhalers as soon as possible, as CFC-propelled will not be available in the U.S. after December 31, 2008
- Advair Diskus® (fluticasone/salmeterol) 250/50mcg new FDA-approved indication
 - Maintenance treatment of airflow obstruction and reducing exacerbations in patients with COPD including chronic bronchitis and emphysema
 - Dosing for this indication is one inhalation of 250/50mcg twice daily




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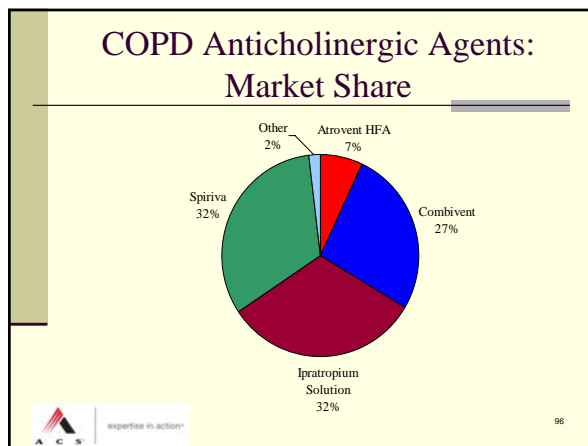
Beta-adrenergic Agonists-Inhaled: Recommendations

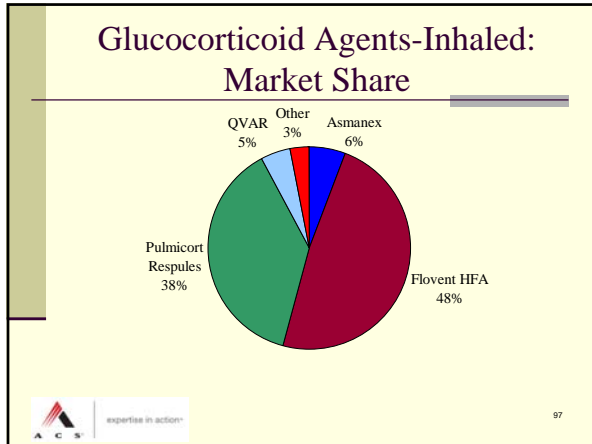
- Advair Diskus® and HFA to non-preferred status



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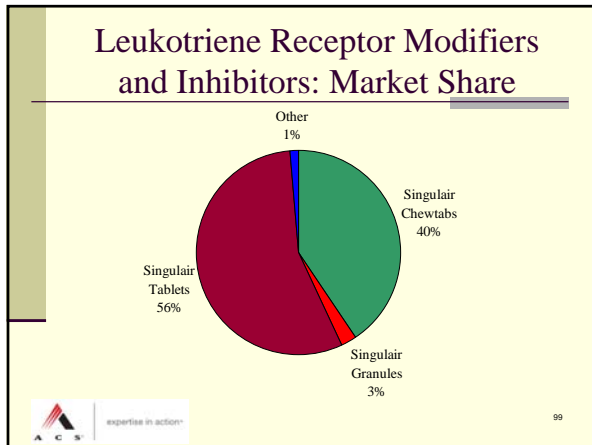




Leukotriene Receptor Modifiers and Inhibitors: Clinical Highlights

- Singulair® (montelukast) postmarketing reports of erythema nodosum and suicidal thinking and behavior
- Zyflo® (zileuton) 600mg IR tablets discontinued by the manufacturer

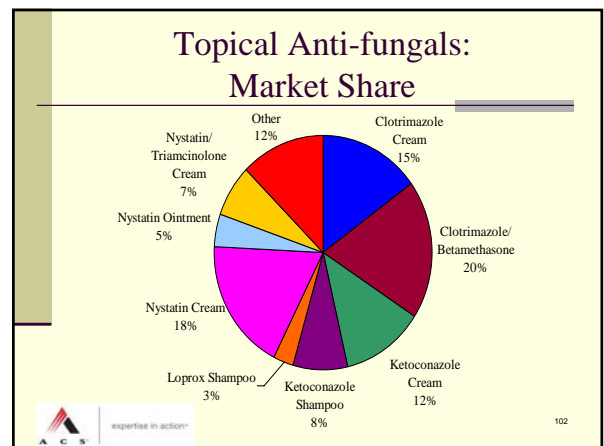
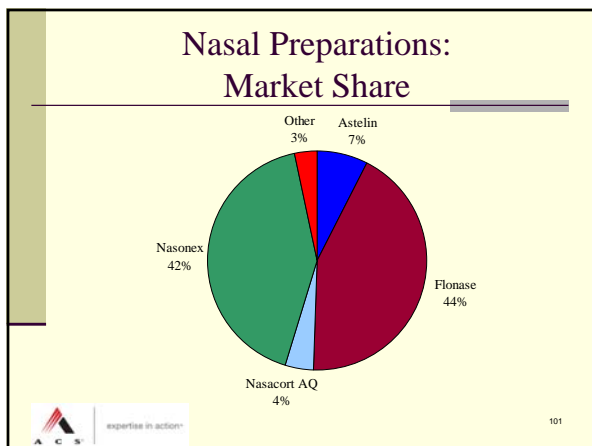
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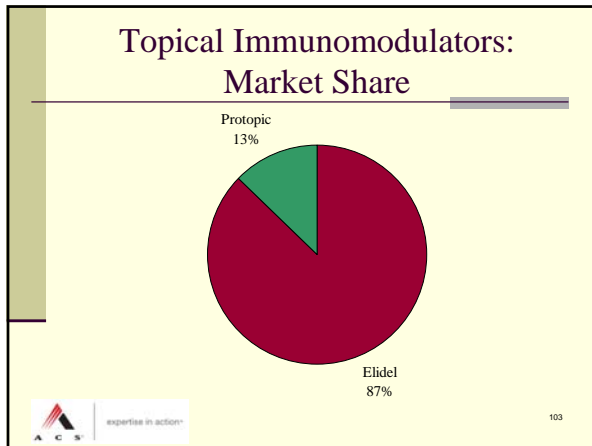



Nasal Preparations: Clinical Highlights


- Omnaris® (ciclesonide) Nasal Spray approved
 - Available in a 50mcg/spray formulation
 - Treatment of SAR and PAR in patients 12 years of age and older
- Patanase® (Olopatadine) Nasal Spray approved
 - Available in a 0.6% formulation
 - Relief of the symptoms of SAR in patients 12 years of age and older

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- ### Topical Post-herpetic Neuralgia Agents: Clinical Highlights
- New class for inclusion on the PDL
 - Lidocaine 5% patch is the only agent currently reviewed in this class
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- ### Topical Post-herpetic Neuralgia Agents: Recommendations
- Lidoderm® to non-preferred status
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