

ODJFS P&T Committee Meeting Minutes

July 8, 2009

77 S. High St., Room 1948

Committee members present: Susan K. Baker, APN; Suzanne Eastman, RPh; Ioanna Giatis, DO; Cheryl Huffman, MD; Robert L. Hunter, DO (chair); Karen Jacobs, DO; Margaret Scott, RPh; Michael P. Wascovich, RPh; Mary Jo Welker, 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; Ed Jingluski, Account Manager

JFS staff present: Jill Griffith, PharmD, DUR Director

Approximately 100 stakeholders were present, most representing pharmaceutical manufacturers and advocacy groups.

The meeting was called to order at 9:05 AM by Ms. Scott (Dr. Hunter, Chair, was not yet present). Ms. Scott noted that the Committee had adopted a conflict of interest statement at the April meeting, and that statements had been signed by all members present.

Ms. Scott 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.

Hematopoietic Agents: Mr. Wascovich asked if utilization in this class has decreased due to the changes to product labeling including increased warnings. Dr. Hefley and Ms. Scott did not have the answer, but will research the question and report back to the committee at a future meeting.

Antidepressants: Dr. Jacobs expressed concern that Venlafaxine ER tablets may not be equivalent to Effexor XR capsules, and that the FDA-approved indications are different. She recommended more options in the SNRI class. Dr. Hunter agreed with this statement, and also suggested that the PA criteria be changed to require a one-month trial of only one preferred antidepressant. Dr. Huffman questioned whether one month was long enough to show improvement. Dr. Jacobs replied that onset of action should occur in nine to 12 days at therapeutic dose, and expressed concern that a patient not adequately treated for depression for two months might need to be hospitalized. Dr. Welker asked if a prescriber would change from a preferred generic SSRI to a non-preferred SNRI, without trying a preferred SNRI first. Dr. Giatis said that if a patient is not doing well she will refer them to a psychiatrist. Mr. Wascovich suggested having all SNRIs

available and asking the DUR program to look at non-specialist use. Dr. Griffith and Ms. Scott were not confident that the data supplied by pharmacies on the prescription claim would be sufficient to complete this analysis. Dr. Hunter expressed concern that non-psychiatrists were limited in therapeutic options. Dr. Welker said she was comfortable with two one-month trials of preferred agents, and Drs. Huffman and Giatis agreed. Dr. Welker also does not support having all SNRIs preferred. Dr. Giatis asked Dr. Jacobs which SNRIs should be available without PA. Dr. Jacobs said that Pristiq is the active metabolite of venlafaxine, and that Cymbalta is completely different. Dr. Hunter suggested that Effexor XR and Cymbalta should be preferred, with Pristiq non-preferred. The Committee consensus was to leave the PA criteria the same (two one-month trials of preferred agents), and move all SNRIs except Pristiq to preferred status. Dr. Welker suggested that the Committee should follow up on the market share in six months.

Dr. Jacobs said that she would like the PA exemption for psychiatrists to be extended to advance practice nurses with a specialty in psychiatric mental health nursing. Dr. Huffman said she is vehemently against this, and that it would be insulting for her as a graduate of medical school to need a PA when an APN does not; it would be a slippery slope to begin an exemption for APNs. Dr. Hunter agreed with Dr. Huffman, and said that the Ohio Osteopathic Association shares the opinion. Dr. Welker said that the APN should have their collaborating psychiatrist prescribe the non-preferred drug, and Dr. Huffman said that the APN can request PA. Dr. Jacobs said that if the patient leaves the office before this is done there is a lower chance that the patients will get the drug. The other physicians disagreed with this statement, and said that they have the same issue in their practices. Mr. Wascovich said that in his experience, APNs follow guidelines better than other practitioners. Ms. Scott shared data on SmartPA automated PA transaction results. 66.23% of non-preferred antidepressant claims are approved automatically by the computer without the prescriber needing to request PA. Within that percentage, a large number are bupropion XL prescriptions that ODJFS would prefer be filled with the brand Wellbutrin XL. Ms. Scott further explained that these percentages represent transactions, not actual prescriptions, so if a denied claim were re-submitted and denied again, it would be counted as two transactions. Dr. Jacobs asked if the same information was available for antipsychotics. Ms. Scott reported that 76.98% of non-preferred antipsychotic transactions were automatically approved, with the majority of the rejections for Zyprexa and Zyprexa Zydis.

Second Generation Antipsychotics: Dr. Jacobs asked why Zyprexa had been recommended non-preferred in 2008. Ms. Scott responded that ODJFS and ACS were concerned about higher prevalence of metabolic effects with Zyprexa than with Abilify, Geodon, Risperdal, and Seroquel. Dr. Jacobs pointed out that only Abilify and Geodon have labels claiming to cause less metabolic effects. Dr. Welker said that there is increased incidence of metabolic effects with Zyprexa than with the alternatives. Dr. Jacobs asked if the increased incidence of metabolic effects was seen in Medicaid data. Ms. Scott responded that only published reports were used, not specifically data on Medicaid outcomes. Mr. Wascovich asked Dr. Jacobs what the benefits of Zyprexa are. Dr. Jacobs said that she has found that Zyprexa works faster in hospitalized patients, and

that the efficacy is superb. Dr. Hunter said that only a 14-day trial of another agent is needed before Zyprexa can be used, and that psychiatrists are exempt from PA.

Attention Deficit Hyperactivity Disorder: Dr. Huffman does not understand why Vyvanse is recommended for first-line use. If there is a cost differential, she would not recommend it to be used first. Because agents in this class produce their effect quickly, it is easy to tell whether patients will respond.

Smoking Cessation: Mr. Wascovich asked if there are any quantity or time limits on use of smoking cessation products. Ms. Scott said there are not, but that the DUR program has looked at this and found several patients receiving prescriptions for nicotine replacement for a year or more. Mr. Wascovich said that the recommended duration of therapy for nicotine replacement is only eight weeks, and for Chantix is up to a year. Dr. Welker pointed out that Chantix is much more expensive. Dr. Huffman asked how many times we should allow a patient to use Chantix. Ms. Scott said that it is hard to balance a limit on smoking cessation products with the health risks of a patient continuing to smoke. Dr. Giatis said that at some point, the patient should bear some responsibility for quitting. Dr. Hunter would like to see data on length of therapy for Medicaid patients.

Diabetes – Insulins: Dr. Giatis mentioned that recent reports indicate a link between Lantus and cancer; since this is the only preferred long-acting insulin, she is concerned that her patients will refuse to use it after hearing news reports. Dr. Welker said that the same thing happens with other drugs. Ms. Scott said that a representative from Sanofi-Aventis was available to address any questions. Dr. Hunter recognized the representative to give additional information. The Sanofi-Aventis representative said that the cancer association came from a retrospective trial, but that a prospective study shows no difference in malignancy. She will provide a copy of the study to Ms. Scott to distribute to the Committee.

Growth Hormones: Mr. Wascovich asked if patients on Norditropin would be grandfathered if it is moved to non-preferred status. Ms. Scott said that grandfathering was not part of the recommendations because all the products are somatropin. Dr. Huffman said that a change should be fine for the patient, and verified that idiopathic short stature is not an approvable indication for growth hormone.

Osteoporosis: Mr. Wascovich asked if patients would be asked to switch from Boniva or Actonel to alendronate, and expressed concern due to the large market share. Dr. Hunter suggested that there should be an option available with monthly dosing, and other committee members agreed. Dr. Hunter suggested that since Actonel has several dosing options, it should be preferred. Dr. Giatis agreed, but said that Actonel with Calcium should remain non-preferred. The committee agreed that a non-preferred agent could be approved after a one-month trial of a preferred agent.

Proton Pump Inhibitors: Mr. Wascovich asked how much BID dosing is seen. Ms. Scott said that since there is a PA required for BID dosing, not much is seen. Mr. Wascovich

asked why there was no PA recommended for BID dosing of omeprazole 10mg and 20mg capsules. Dr. Giatis said that there is a 40mg dose of omeprazole. Ms. Scott said that there is a big price difference between one 40mg capsule and two 20mg capsules.

Urinary Antispasmodics: Dr. Giatis asked where Gelnique is applied. Dr. Hunton said it is comparable to Oxytrol patches and is usually applied to the arm or shoulder. Dr. Jacobs asked how the recommendations were made. Dr. Hunton replied that all recommendations are based on clinical and financial information. An audience member asked if the market share information presented was correct. Dr. Hunton said that it was correct.

Oral Quinolones: Dr. Giatis said that for a patient with a combined urinary tract infection and pneumonia, Levaquin would be the best choice because it has coverage for both infections while Avelox is better for pneumonia and ciprofloxacin is better for urinary infections. Dr. Welker said that Levaquin is overutilized and there is higher resistance.

Injectable Anti-Rheumatic Agents: The Committee discussed the PA criteria. Mr. Wascovich suggested a three-month trial. Dr. Hunter recommended only one preferred agent must be tried. Dr. Welker asked Mr. Wascovich why he recommended three months. Mr. Wascovich said that based on his knowledge of the mechanism of action, a patient may not see benefit in the first two months. Dr. Welker asked Ms. Scott if the department could check with rheumatologists to see if three months is reasonable. Ms. Scott agreed, and said that the department would take the recommendation of the rheumatology expert.

Ophthalmology – Glaucoma: Mr. Wascovich asked why Lumigan was recommended to be moved to preferred. Dr. Hunton said that all the recommendations are based on clinical and financial data. Mr. Wascovich asked if there are any specific clinical benefits to Lumigan. Dr. Hunton did not cite any specific benefits.

Otic Antibiotics: The Committee was in agreement that quinolones are necessary, and accepted the updated recommendations that are attached to the minutes. The committee did not discuss a length of trial or number of preferred agents to use before a non-preferred agent is approved.

Topical Agents – Acne: Dr. Huffman said that retinoids are first-line therapy. The Committee accepted the updated recommendations that are attached to the minutes. Dr. Huffman said that a trial of a preferred agent should be in the same drug class, and recommended a one-month trial of one preferred agent. Since Aczone and Finacea are not part of any class, the Committee recommended a one-month trial of any preferred agent.

Topical Agents – Anti-parasitics: Dr. Huffman said that the proposal was generous in its choices, but asked if it is possible not to allow lindane products at all. Ms. Scott said that

under federal law all drugs must be covered. Dr. Hunter suggested a one-month trial of one preferred agent before a non-preferred agent is approved.

Other: Dr. Giatis asked what the FDA is planning to do with acetaminophen products. Ms. Eastman said that most likely the over-the-counter dosages would be reduced. Ms. Scott said that if there are any FDA changes that affect the Medicaid PDL, the opioids class would be revisited at a quarterly Committee meeting.

Meeting dates for October and January will be published soon.

Dr. Hunter adjourned the meeting at 12:00.

Following the meeting, changes were made to the PDL:

- Antidepressants: Effexor XR and Cymbalta added to preferred status
- Osteoporosis: Actonel and Boniva added to preferred status
- Proton Pump Inhibitors: Change wording under additional information to “No PA needed for up to 40mg daily of omeprazole capsules”
- Injectable anti-rheumatic agents: criteria for approval of non-preferred agents is trial of one preferred agent for three months
- Otic Antibiotics: Cipro HC, Ciprodex, and ofloxacin drops added to preferred status; criteria for approval of non-preferred agent is a trial on one preferred agent for one week.
- Topical Agents – Acne: Differin cream and gell, Tazorac cream and gel, Retin-A cream and gel, Retin-A Micro gel, Ziana gel added to preferred status

In addition, the market share of the Urinary Antispasmodics class was checked again. The market share presented to the Committee was incorrect. A corrected graph is attached to the minutes. The correct market share was used when ACS and the department made their recommendations to the Committee.

DRAFT

For P&T Committee Discussion Only

Otic Agents: Antibacterial and Antibacterial/Steroid Combination Drops

LENGTH OF AUTHORIZATIONS:

for the date of service only; no refills for acute infection. Refills for up to 6 months may be authorized for ofloxacin only for patients with chronic suppurative otitis media and perforated tympanic membrane.

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval?
Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug-to-drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
 - Note diagnosis and any culture and sensitivity reports

The requested medication may be approved if both of the following are true:

- If there has been a therapeutic failure to no less than a [length of trial to be discussed] trial of at least [number of medications to be discussed] medications not requiring prior approval
- The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

Document clinically compelling information

OTIC AGENTS: ANTIBACTERIAL – STERIOD COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CIPRO HC [®] suspension (ciprofloxacin with hydrocortisone)	<i>CORTISPORIN-TC[®] suspension (neomycin and colistin with hydrocortisone)</i>
CIPRODEX [®] suspension (ciprofloxacin with dexamethasone)	<i>PEDIOTIC[®] suspension (neomycin and polymyxin B with hydrocortisone)</i>
COLY-MYCIN-S [®] suspension (neomycin and colistin with hydrocortisone)	
NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE solution (generic of Cortisporin [®] solution)	
NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE suspension (generic of Cortisporin [®] suspension)	

OTIC AGENTS: ANTIBACTERIAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
OFLOXACIN drops (generic of Floxin Otic [®])	<i>FLOXIN[®] singles</i>

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For P&T Committee Discussion Only

Topical Agents: Acne Preparations

LENGTH OF AUTHORIZATIONS: 1 year

CLINICAL CRITERIA:

All topical retinoids require prior authorization for patients over age 23:

- Patient diagnosis psoriasis – may approve tazarotene (Tazorac[®])
- Patient diagnosis acne vulgaris – may approve retinoid if the patient has a history of at least 30 days of therapy with alternative therapy (benzoyl peroxide, sodium sulfacetamide or antibiotic) in the previous 90 days

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- If there has been a therapeutic failure to no less than a ***[length of trial to be discussed]*** trial of at least ***[number of medications to be discussed]*** medication not requiring prior approval

OTHER DISCUSSION POINTS FOR P&T COMMITTEE TO CONSIDER

Should a patient be required to try a benzoyl peroxide, antibiotic, and/or sodium sulfacetamide product prior to a retinoid?

ANTIBIOTIC PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CLINDAMYCIN gel (generic of Cleocin T [®] , Clindamax [®])	AKNE-MYCIN [®] ointment
CLINDAMYCIN lotion (generic of Cleocin T [®] , Clindamax [®])	<i>CLINDAGEL[®]</i>
CLINDAMYCIN pledgets (generic of Cleocin T [®])	<i>ERY PADS[®]</i>
CLINDAMYCIN solution (generic of Cleocin T [®])	EVOCLIN [®] foam
ERYTHROMYCIN gel (generic of Erygel [®])	
ERYTHROMYCIN solution (generic of A/T/S [®] , Akne-Mycin [®])	

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BENZOYL PEROXIDE AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BENZACLIN [®] gel (benzoyl peroxide and clindamycin)	<i>BENZAMYCINPAK[®] gel (benzoyl peroxide and erythromycin)</i>
BENZOYL PEROXIDE cleanser (generic of Oscion [®] , Triaz [®])	<i>BENZOYL PEROXIDE pads (generic of Oscion[®], Triaz[®])</i>
BENZOYL PEROXIDE gel (generic of Benzac AC [®] , Benzagel [®] , Desquam-X [®])	<i>BENZOYL PEROXIDE MICROSPHERES cream (generic of Neobenz Micro[®])</i>
BENZOYL PEROXIDE lotion (generic of Zaclir [®])	<i>BENZOYL PEROXIDE-UREA cleanser (generic of Zoderm[®])</i>
BENZOYL PEROXIDE wash (generic of Benzac AC [®] , Benzac W [®] , Brevoxyl [®] , Desquam-X [®])	<i>BENZOYL PEROXIDE-UREA cream (generic of Zoderm[®])</i>
ERYTHROMYCIN-BENZOYL PEROXIDE gel (generic of Benzamycin [®])	<i>BENZOYL PEROXIDE-UREA gel (generic of Zoderm[®])</i>
NEOBENZ MICRO [®] cream	<i>BENZOYL PEROXIDE-UREA pads (generic of Zoderm[®] redi-pads)</i>
ZACLIR [®] lotion	<i>BENZOYL PEROXIDE-UREA wash (generic of Zoderm[®] hydrating wash)</i>
ZODERM [®] cream	<i>DUAC CS[®] kit (benzoyl peroxide and clindamycin)</i>
	<i>DUAC[®] gel (benzoyl peroxide and clindamycin)</i>
	NEOBENZ MICRO [®] wash
	NEOBENZ MICRO SD [®] cream

OTHER PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AZELEX [®] cream	ACZONE [®] gel (dapsone)
	FINACEA [®] gel

RETINOID AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
DIFFERIN [®] cream	ATRALIN [®] gel
DIFFERIN [®] gel	<i>EPIDUO[®] gel (adapalene and benzoyl peroxide)</i>
TAZORAC [®] cream	TRETINOIN cream (generic of Retin-A [®])
TAZORAC [®] gel	TRETINOIN gel (generic of Retin-A [®])
RETIN-A [®] cream	
RETIN-A [®] gel	
RETIN-A MICRO [®] gel	
ZIANA [®] gel (clindamycin and tretinoin)	

DRAFT

For P&T Committee Discussion Only

SODIUM SULFACETAMIDE AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
<p><i>KLARON[®] lotion</i></p>	<p>AVAR[®] gel <i>SODIUM SULFACETAMIDE cream (generic of Ovace[®])</i> <i>SODIUM SULFACETAMIDE gel (generic of Ovace[®])</i> <i>SODIUM SULFACETAMIDE lotion (generic of Klaron[®])</i> <i>SODIUM SULFACETAMIDE wash (generic of Ovace[®])</i> <i>SODIUM SULFACETAMIDE cream (generic of Avar-E[®])</i> <i>SODIUM SULFACETAMIDE-SULFUR cleanser kit</i> <i>SODIUM SULFACETAMIDE-SULFUR lotion (generic of Sulfacet-R[®])</i> <i>SODIUM SULFACETAMIDE-SULFUR pads (generic of Plexion[®] cleansing cloths)</i> <i>SODIUM SULFACETAMIDE-SULFUR suspension (generic of Plexion[®] TS)</i> <i>SODIUM SULFACETAMIDE-SULFUR wash (generic of Avar[®] cleanser, Plexion[®] cleanser, Rosac[®] wash)</i> <i>SODIUM SULFACETAMIDE-SULFUR-AVOBENZONE cream (generic of Rosac[®] cream)</i> <i>SODIUM SULFACETAMIDE-SULFUR-UREA cleanser (generic of Rosula[®] cleanser)</i> <i>SODIUM SULFACETAMIDE-SULFUR-UREA gel (generic of Rosula[®] aqueous gel)</i> <i>SODIUM SULFACETAMIDE-SULFUR-UREA wash (generic of Rosula[®] clarifying wash)</i> <i>SODIUM SULFACETAMIDE-SULFUR-UREA WITH SUNSCREEN kit (generic of Rosula[®] CLK)</i> <i>SODIUM SULFACETAMIDE-SULFUR-WITCH HAZEL cream (generic of Plexion[®] SCT cream)</i> <i>SODIUM SULFACETAMIDE-UREA pads (generic of Rosula[®] NS medicated pads)</i></p>



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



Cox-2 Inhibitors: Clinical Highlights

- Celebrex® new dosage regimen
 - Treatment should be initiated at half the lowest recommended dose in patients who are known or suspected poor CYP2C9 metabolizers
 - Alternative management in JRA patients who are poor metabolizers should be considered

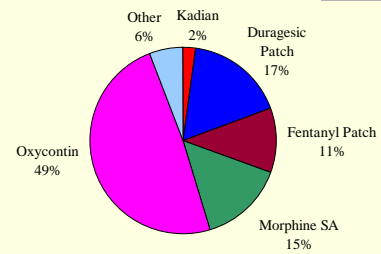


Opioids: Clinical Highlights

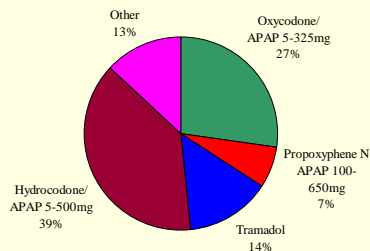
- Ryzolt™ received FDA approval
 - 100mg, 200mg, 300mg extended release tablets
- Zamicet™ Oral Solution received FDA approval
 - Relief of moderate to moderately severe pain
 - 10/325mg per 15mL solution
- Duragesic® shortage
 - All 5 strengths now being manufactured
- Opioid shortage
 - IR hydromorphone, morphine, oxycodone



Long-Acting Opioids: Market Share



Short-Acting Opioids: Market Share

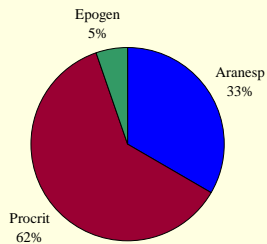


Opioids: Recommendations

- Ryzolt™ to non-preferred status

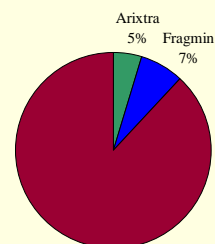


Hematopoietic Agents: Market Share



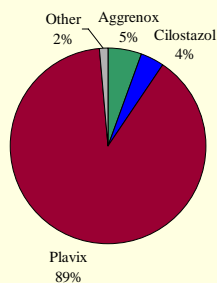
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Heparin-Related Preparations: Market Share



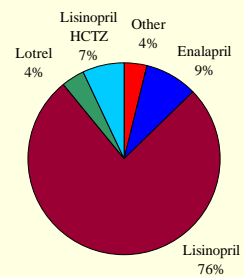
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Platelet Aggregation Inhibitors: Market Share



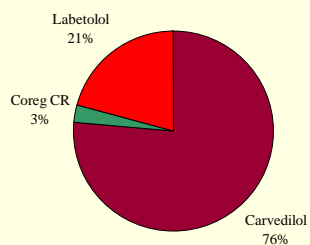
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Angiotensin Converting Enzyme Inhibitors: Market Share



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Alpha-Beta Adrenergic Blockers: Market Share



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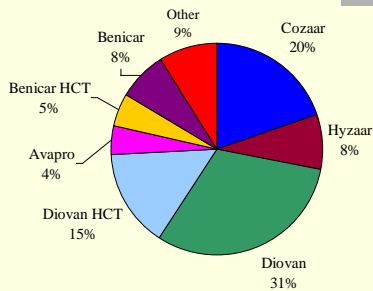
Angiotensin Receptor Blockers: Clinical Highlights

- Azor™, Exforge® new indication
 - Initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals
- Exforge HCT® received FDA approval
 - Treatment of HTN
 - 5/160/12.5mg, 10/160/12.5mg, 5/160/25mg, 10/160/25mg, and 10/320/25mg tablets



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Angiotensin Receptor Blockers: Market Share



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Antiotensin Receptor Blockers: Recommendations

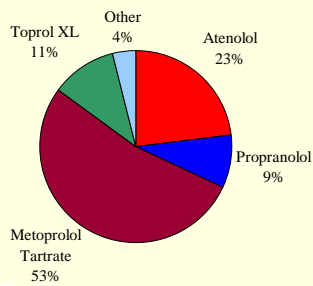
- Azor™ to preferred status
- Exforge HCT® to preferred status



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Beta-Blockers: Market Share



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Calcium Channel Blockers: Clinical Highlights

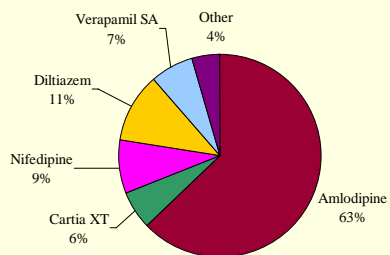
- Generic nifedipine injection received FDA approval
 - Short-term treatment of HTN when oral therapy is not feasible
 - 2.5 mg/mL solution
 - AP rated to Cardene®



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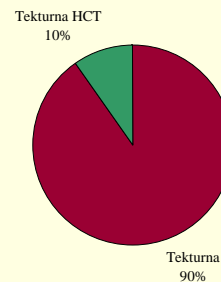
Calcium Channel Blockers: Market Share



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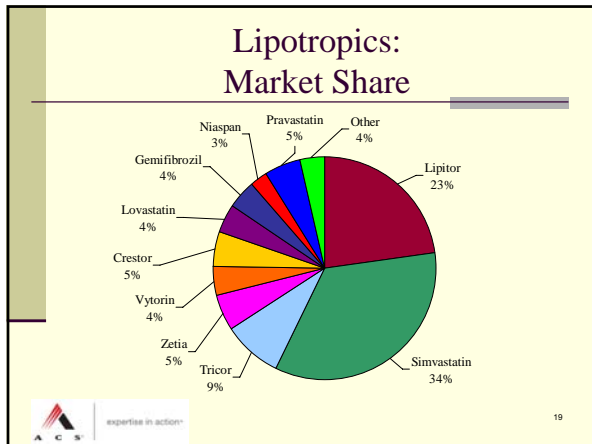
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Direct Renin Inhibitors: Market Share



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Lipotropics: Recommendations

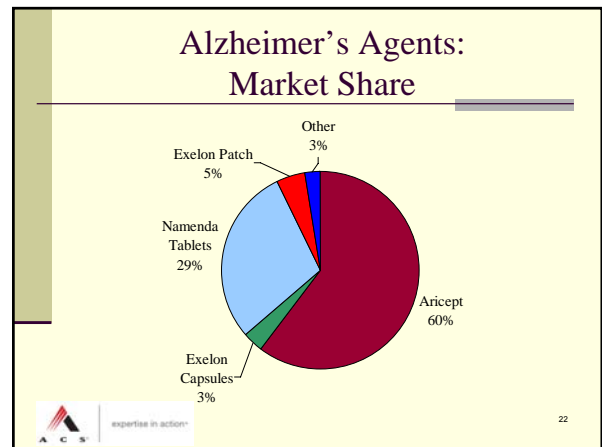
- Crestor® to non-preferred status

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Alzheimer's Agents: Clinical Highlights

- Generic galantamine IR received FDA approval
 - 4mg, 8mg, and 12mg tablets
 - AB rated to Razadyne™
- Generic galantamine ER received FDA approval
 - 8mg, 16mg, and 24mg ER capsules
 - AB rated to Razadyne™ ER

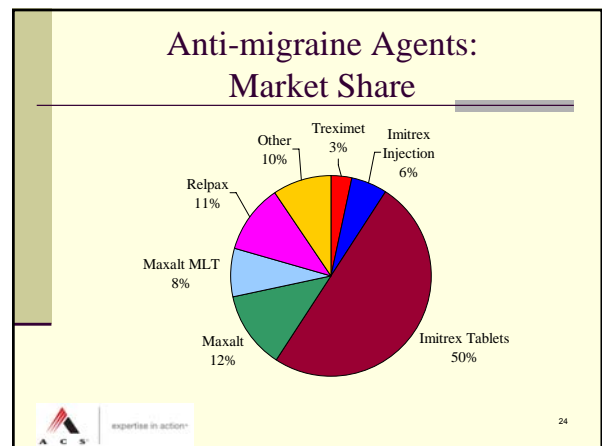
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Anti-migraine Agents: Clinical Highlights

- Axert® new indication
 - Acute treatment of migraine in adolescents age 12 to 17 years
 - Dose same as adult (6.25mg to 12.5mg)
- Generic sumatriptan received FDA approval
 - 25mg, 50mg, 100mg Tablets; AB rated to Imitrex®
 - 6mg/0.5mL Injection; AB rated to Imitrex®
 - 5mg, 20mg Nasal Spray; not rated

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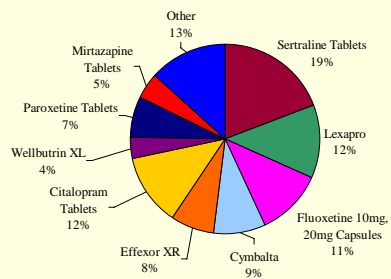
Antidepressants: Clinical Highlights

- Aplenzin™ (bupropion hydrobromide) received FDA approval
 - Indicated for MDD
 - 174mg, 348mg, and 522mg tablets
- Lexapro® new indication
 - Acute and maintenance treatment of adolescent MDD
- Venlafaxine ER received FDA approval
 - 37.5mg, 75mg, 150mg, and 225mg tablets
 - Therapeutically equivalent to Effexor XR®



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Antidepressants: Market Share



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Antidepressants: Recommendations

- Venlafaxine ER tablets to preferred status
- Aplenzin™ to non-preferred status
- Effexor XR® to non-preferred status



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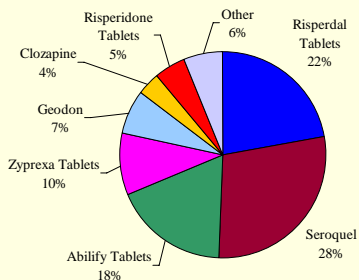
Second Generation Antipsychotics: Clinical Highlights

- Generic risperidone received FDA approval
 - 1mg/1mL oral solution
 - 0.25mg, 0.5mg, 1mg, 2mg, 3mg, and 4mg tablets
- Seroquel XR® new strength
 - 150mg tablet
- Symbyax® new indication
 - Treatment resistant depression in adults



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Second Generation Antipsychotics: Market Share



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Second Generation Antipsychotics: Recommendations

- Risperdal® tablets to non-preferred status

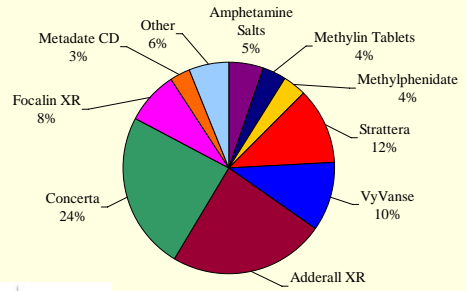


30

Attention Deficit Hyperactivity Disorder Agents: Clinical Highlights

- Concerta® new indication
 - Treatment of ADHD in adults
- Generic amphetamine salts extended release received FDA approval
 - 5mg, 10mg, 15mg, 20mg, 25mg, 30mg capsules
 - Therapeutically equivalent to Adderall XR®

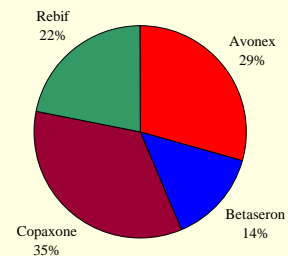
Attention Deficit Hyperactivity Disorder Agents: Market Share



Multiple Sclerosis (MS) Agents: Clinical Highlights

- Copaxone® indication expanded
 - Patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis

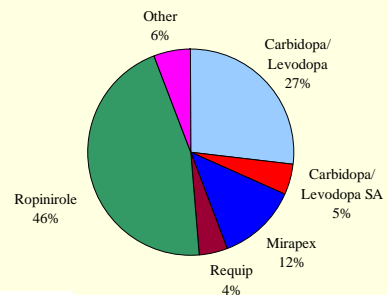
Multiple Sclerosis (MS) Agents: Market Share



Parkinson's Agents: Clinical Highlights

- Generic carbidopa/levodopa ODT received FDA approval
 - 10/100mg, 25/100mg, and 5/250mg tablets
 - AB rated to Parcopa™
- Requip® XL™ received FDA approval
 - 2mg, 3mg, 4mg, and 8mg tablets
- Class labeling
 - Reports of intense urges to gamble, increased sexual urges, and other intense urges
 - Higher risk (2- to approximately 6-fold higher) of developing melanoma

Parkinson's Agents: Market Share



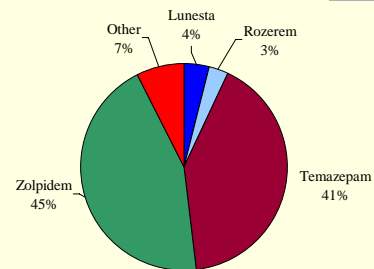
Sedative Hypnotics, Non-Barbiturate: Clinical Highlights

- Generic zaleplon received FDA approval
 - 5mg and 10mg capsules
 - AB rated to Sonata®



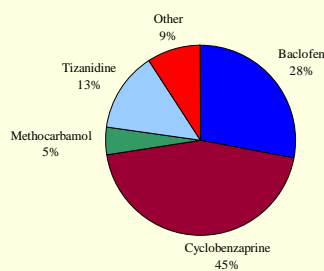
37

Sedative Hypnotics, Non-Barbiturate: Market Share



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Skeletal Muscle Relaxants, Non-Benzodiazepine: Market Share



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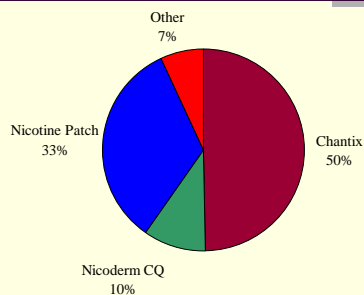
Skeletal Muscle Relaxants, Non-Benzodiazepine: Recommendations

- Orphenadrine, Orphenadrine Compound, Orphenadrine Compound Forte to non-preferred status



40

Smoking Deterrents: Market Share



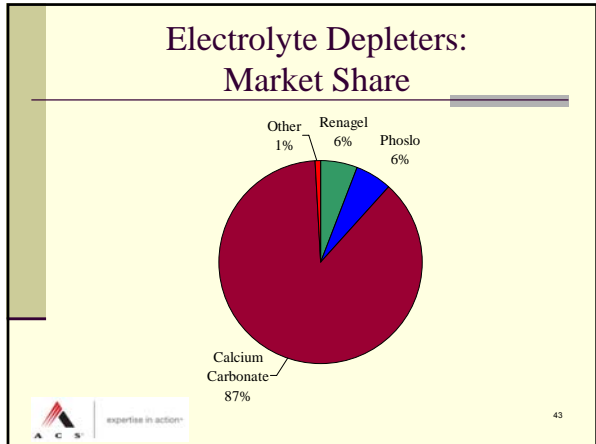
41

Electrolyte Depleters: Clinical Highlights

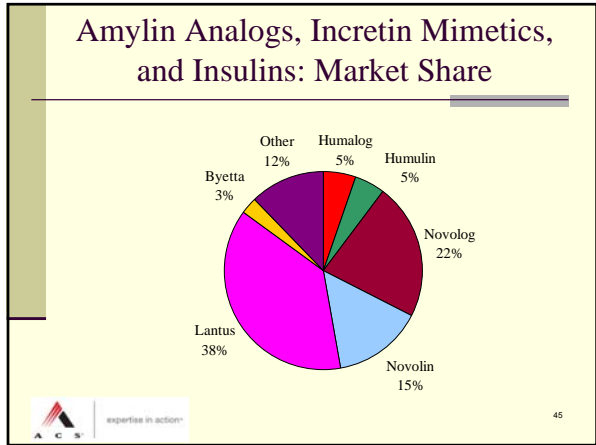
- Generic calcium acetate received FDA approval
 - 667mg capsule
 - AB rated to Phoslo® Gelcaps
- Eliphos™ (calcium acetate) received FDA approval
 - Control of hyperphosphatemia in ESRD
 - 667mg tablet
- Renage® production will end September 30, 2009



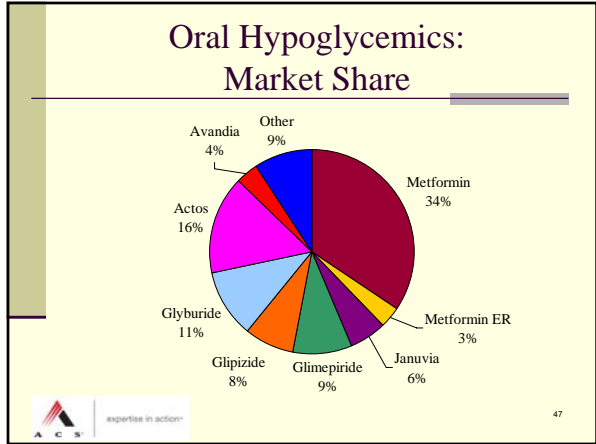
42



- ### Amylin Analogs, Incretin Mimetics, and Insulins: Clinical Highlights
- Apidra® SoloStar® received FDA approval
 - Improvement of glycemic control in adults and children ≥ 4 years with diabetes
 - Prefilled disposable pen
 - Eliminates the need for patients to change cartridges
- AC S expertise in action™ 44



- ### Oral Hypoglycemics: Clinical Highlights
- Generic acarbose received FDA approval
 - 25mg, 50mg, and 100-mg tablets
 - AB rated to Precose™
 - Prandimet™ received FDA approval
 - Adults with type 2 diabetes who are already treated with a meglitinide and metformin, or who have inadequate glycemic control on a meglitinide alone or metformin alone
 - 1 mg/500 mg and 2 mg/500 mg tablets
- AC S expertise in action™ 46

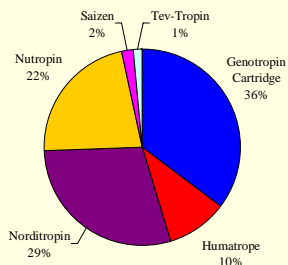


- ### Oral Hypoglycemics: Recommendations
- Prandimet™ to non-preferred status
- AC S expertise in action™ 48

Growth Hormones: Clinical Highlights

- Genotropin® new indication
 - Idiopathic short stature in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means
- Humatrope®, Norditropin® new indication
 - Short stature in pediatric patients small for gestational age who do not manifest catch up growth by age 2 to 4 years

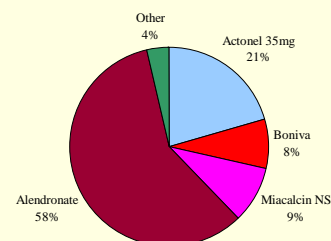
Growth Hormones: Market Share



Growth Hormones: Recommendations

- Saizen® vial, Saizen® cartridge to preferred status
- Norditropin® Nordiflex®, Norditropin® vial, Norditropin® cartridge to non-preferred status

Bone Ossification Enhancers: Market Share



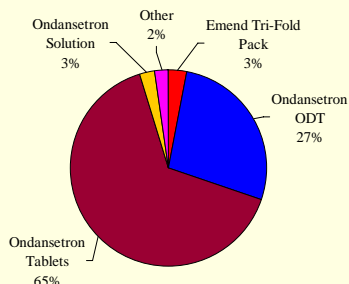
Bone Ossification Enhancers: Recommendations

- Actonel® to non-preferred status
- Boniva® to non-preferred status
- Etidronate to non-preferred status
- Fosamax® Oral Solution to non-preferred status

Anti-emetic Agents: Clinical Highlights

- Sancuso® received FDA approval
 - Prevention of N/V in patients receiving moderately and/or highly emetogenic chemotherapy regimens of up to 5 consecutive days duration
 - 3.1mg transdermal patch

Anti-emetic Agents: Market Share



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Pancreatic Enzymes: Clinical Highlights

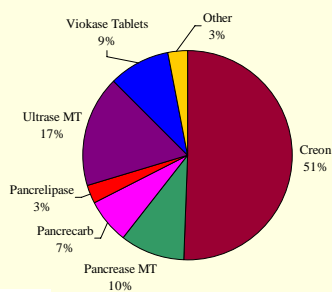
- Creon® Delayed Release Capsules received FDA approval
 - First PEP approved under new guidelines
 - Current formulation available until late 2009 when new formulation becomes commercially available



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Pancreatic Enzymes: Market Share



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Pancreatic Enzymes: Recommendations

- Remove Dygase®, Lipram, Lipram PN, Pangestyme CN, Pangestyme EC, Pangestyme MT, Pangestyme UL, and Plaretase from PDL



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Proton Pump Inhibitors (PPIs): Clinical Highlights

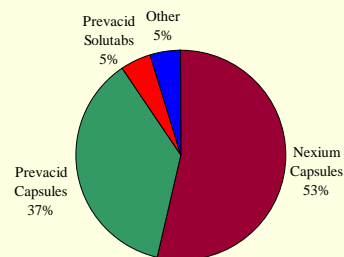
- Kapidex™ received FDA approval
 - Erosive esophagitis; heartburn associated with non-erosive GERD
 - 30mg and 60mg delayed release capsules
- Nexium® Oral Suspension received FDA approval
 - 10mg delayed release packets
- Prilosec® Oral Suspension received FDA approval
 - 2.5mg and 10mg delayed release packets



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Proton Pump Inhibitors (PPIs): Market Share



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Proton Pump Inhibitors (PPIs): Recommendations

- Omeprazole 10mg and 20mg capsules to preferred status
 - No PA for BID dosing of 20mg caps
- Kapidex™ to non-preferred status
- Prevacid® Capsules to non-preferred status



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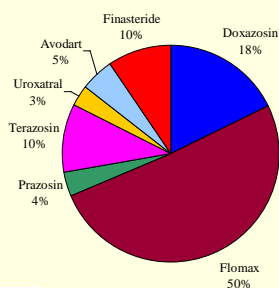
Benign Prostatic Hypertrophy Agents: Clinical Highlights

- Avodart® new indication
 - In combination with tamsulosin for treatment of symptomatic BPH in men with an enlarged prostate
- Rapaflo™ received FDA approval
 - Treatment of the signs and symptoms of BPH
 - 4mg and 8mg capsules



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Benign Prostatic Hypertrophy Agents: Market Share



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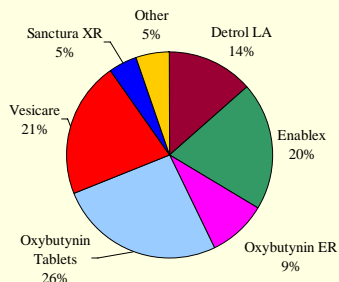
Urinary Antispasmodics: Clinical Highlights

- Gelnique™ (oxybutinin chloride) Topical Gel received FDA approval
 - Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency
 - 10% formulation
- Toviaz™ (fesoterodine fumarate) received FDA approval
 - Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency
 - 4mg and 8mg extended-release tablets



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Urinary Antispasmodics: Market Share



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Urinary Antispasmodics: Recommendations

- Sanctura®, Sanctura XR™ to preferred status
- Detrol® LA to non-preferred status
- Gelnique™ to non-preferred status
- Toviaz™ to non-preferred status



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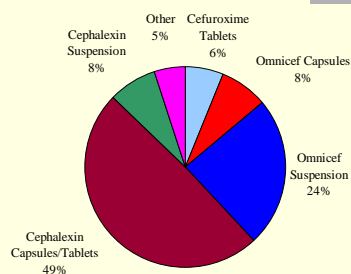
Oral Cephalosporins: Clinical Highlights

- Spectracef® new strength
 - 400mg tablet
- Suprax® new strength
 - 400mg tablet available after being discontinued > 6 years ago
 - Only one-dose oral treatment recommended by the CDC for uncomplicated gonorrhea



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Oral Cephalosporins: Market Share



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Oral Cephalosporins: Recommendations

- Cefdinir® capsules, Cefdinir® oral suspension to preferred status
- Omnicef® to non-preferred status



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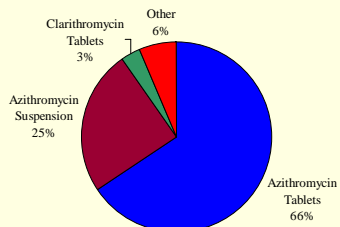
Oral Macrolides: Clinical Highlights

- Zmax® new indication
 - Use in pediatric patients ≥ 6 months of age for community acquired pneumonia



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Oral Macrolides: Market Share



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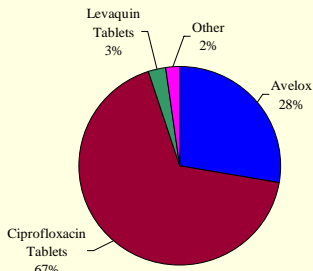
Oral Quinolones: Clinical Highlights

- Levaquin® new indication
 - Use in pediatric patients ≥ 6 months of age for inhalational anthrax (post-exposure)



72

Oral Quinolones: Market Share



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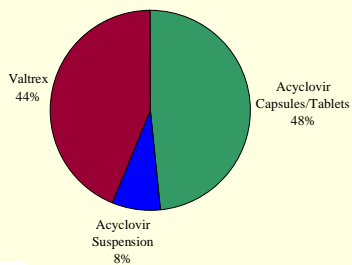
Anti-virals Herpes: Clinical Highlights

- Valtrex® new indication
 - Treatment of chickenpox in children 2 to <18 years of age



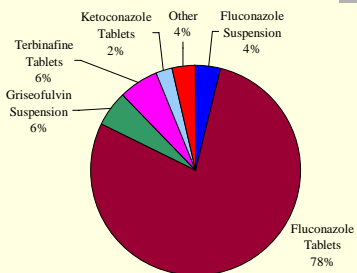
74

Anti-virals Herpes: Market Share



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Agents for Onychomycosis & Systemic Infections: Market Share



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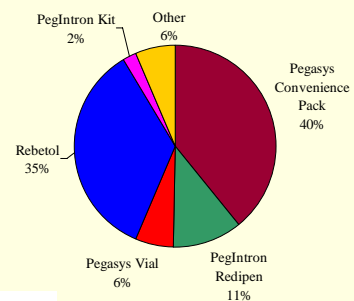
Hepatitis C-Pegylated Interferons & Ribavirins: Clinical Highlights

- PegIntron® new indication
 - Use in pediatric patients 3 to 17 years of age with Chronic Hepatitis C
 - Administer in combination with Ribavirin in this age group



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Hepatitis C-Pegylated Interferons & Ribavirins: Market Share



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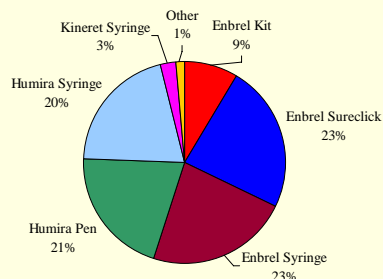
Hepatitis C-Pegylated Interferons & Ribavirins: Recommendations

- Ribasphere® to preferred status
- Ribavirin to preferred status
- Rebetol® to non-preferred status

Injectable Anti-Rheumatic Agents: Clinical Highlights

- Cimzia® new indication
 - Treatment of moderately to severely active RA
 - New 200mg/mL prefilled syringes
- Simponi™ received FDA approval
 - Treatment of moderately to severely active RA in adults in combination with MTX, and for psoriatic arthritis and ankylosing spondylitis
 - 50 mg/0.5 mL pens and syringes

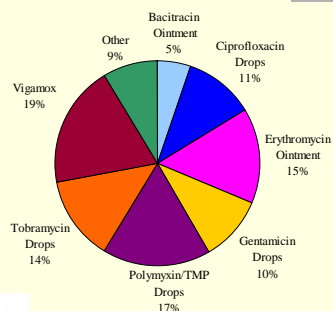
Injectable Anti-Rheumatic Agents: Market Share



Injectable Anti-Rheumatic Agents: Recommendations

- Cimzia® to preferred status
- Simponi™ to non-preferred status

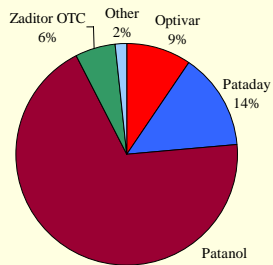
Antibacterial-Antibiotic Drops and Ointments: Market Share



Antibacterial-Antibiotic Drops and Ointments: Recommendations

- Quixin® to non-preferred status

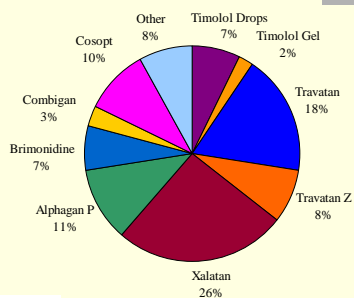
Antihistamine/Mast Cell Stabilizers: Market Share



Glaucoma Agents: Clinical Highlights

- Generic dorzolamide received FDA approval
 - 2% solution
 - AT rated to Trusopt®
- Generic dorzolamide/timolol received FDA approval
 - 2% / 0.5% solution
 - AT rated to Cosopt®

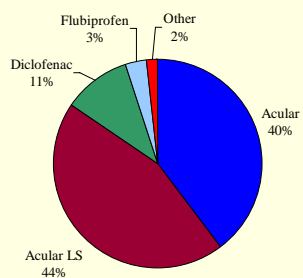
Glaucoma Agents: Market Share



Glaucoma Agents: Recommendations

- Lumigan® to preferred status

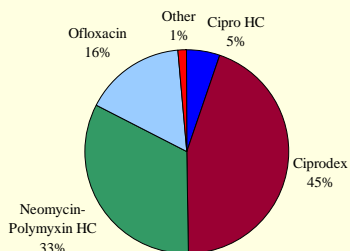
Ophthalmic NSAIDs: Market Share



Otic Antibiotics: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class are Coly-Mycin® S, Neomycin-Polymyxin B w/HC Solution, Neomycin-Polymyxin B w/HC Suspension Cipro® HC, Ciprodex®, Cortisporin® TC, Floxin® Drops, Floxin® Otic Singles, Ofloxacin, and Pediotic®

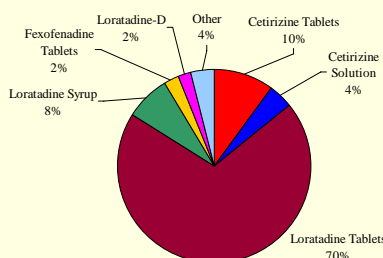
Otic Antibiotics: Market Share



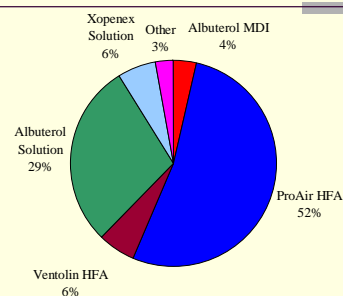
Otic Antibiotics: Recommendations

- Coly-Mycin[®] S, Neomycin-Polymyxin B w/HC Solution, and Neomycin-Polymyxin B w/HC Suspension to preferred status
- Cipro[®] HC, Ciprodex[®], Cortisporin[®] TC, Floxin[®] Drops, Floxin[®] Otic Singles, Ofloxacin, and Pediotic[®] to non-preferred status

Antihistamines, Second Generation: Market Share



Short Acting Beta-adrenergic Agonists-Inhaled: Market Share



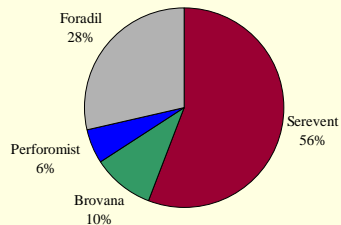
Short Acting Beta-adrenergic Agonists-Inhaled: Recommendations

- Maxair[®] to non-preferred status
- Xopenex[®], Xopenex[®] HFA to non-preferred status

Beta-adrenergic Agonists-Inhaled: Clinical Highlights

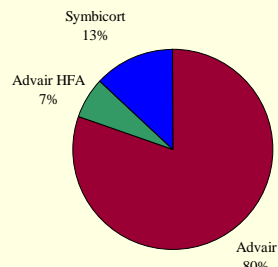
- The FDA Advisory Committee meeting December 2008
 - Benefits of Advair[®] and Symbicort[®] outweigh the risks in asthma patients, and should continue to be used; Serevent[®] and Foradil[®] should be banned from use in the treatment of asthma
- Symbicort[®] new indication
 - Maintenance treatment of airflow obstruction in patients with COPD including chronic bronchitis and emphysema
 - 2 inhalations of the 160/4.5mcg formulation BID

Long Acting Beta-adrenergic Agonists-Inhaled: Market Share



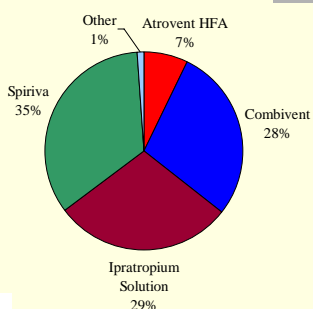
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Long Acting Beta-adrenergic Agonist-Steroid Inhaled: Market Share



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COPD Anticholinergic Agents: Market Share



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COPD Anticholinergic Agents: Recommendations

- Ipratropium/albuterol solution to preferred status



100

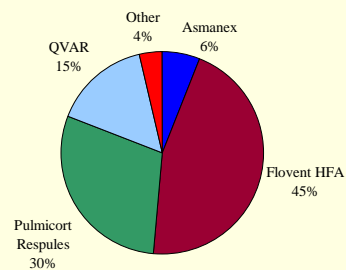
Glucocorticoid Agents-Inhaled: Clinical Highlights

- Alvesco® received FDA approval
 - Indicated for maintenance treatment of asthma as prophylactic therapy in adults and adolescents ≥ 12 years
 - 80mcg and 160mcg MDI
- Budesonide Inhalation Suspension received FDA approval
 - 0.25 mg/2 mL and 0.5 mg/2 mL unit dose vials
 - AB rated to Pulmicort Respules®
 - Not available until December due to patent dispute



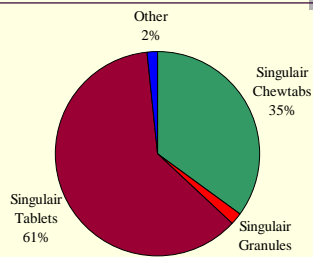
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Glucocorticoid Agents-Inhaled: Market Share



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Leukotriene Receptor Modifiers and Inhibitors: Market Share



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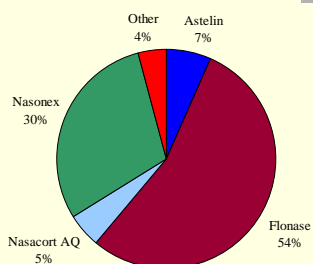
Nasal Preparations: Clinical Highlights

- Astepro™ received FDA approval
 - Indicated for the relief of symptoms of seasonal allergic rhinitis in patients ≥ 12 years
 - 137mcg nasal spray
- Nasacort® AQ new indication
 - Seasonal and perennial allergic rhinitis in patients 2 to 5 years of age



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Nasal Preparations: Market Share



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Nasal Preparations: Recommendations

- Fluticasone to preferred status
- Nasacort® AQ to non-preferred status



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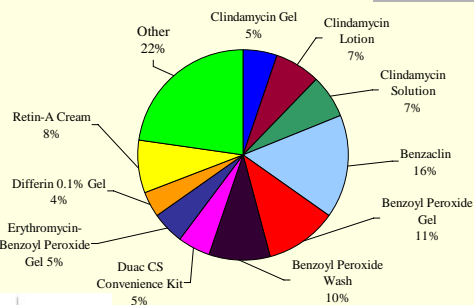
Topical Acne Agents: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class include topical antibiotics, benzoyl peroxides, topical retinoids, sodium sulfacetamides, topical dapsone, and topical azelaic acid



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Topical Acne Agents: Market Share



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Topical Acne Agents: Recommendations

- Antibiotics:
 - Clindamycin gel, Clindamycin lotion, Clindamycin pledgets, Clindamycin solution, Erythromycin gel, and Erythromycin solution to preferred status
 - Akne-Mycin® solution, Clindagel®, Clindamax® gel, Cleocin T® gel, Clindamax® lotion, Cleocin T® lotion, Cleocin T® pledgets, Cleocin T® solution, Erygel®, Ery pads™, and Evoclin® to non-preferred status

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Topical Acne Agents: Recommendations (cont'd)

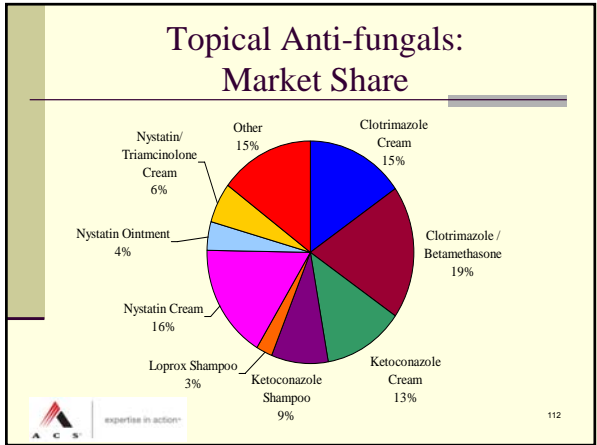
- Benzoyl Peroxides (BP):
 - Benzaclin®, BP cleanser, BP gel, BP lotion, Zaclir™ lotion, BP wash, Neobenz® Micro cream, Zoderm® cream, and Erythromycin-BP gel to preferred status
 - Benzamycin®, Oscion™, Triaz®, Benzac AC®, Benzagel®, Brevoxy®, Desquam-X®, BP pads, BP wash kit, Benzac W®, BP Microspheres cream, BP-Urea, Zoderm® cleanser, Zoderm® gel, Zoderm® Redi-pads, Zoderm® wash, Duac®, Neobenz® Micro wash, and Neobenz® Micro-SD cream to non-preferred status

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Topical Acne Agents: Recommendations (cont'd)

- Other Products:
 - Azelex® cream to preferred status
 - Aczone® gel and Finacea™ gel to non-preferred status
- Retinoids:
 - All agents to non-preferred status
- Sodium Sulfacetamides:
 - All agents to non-preferred status

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Topical Anti-fungals: Recommendations

- Terbinafine cream to preferred status
- Pedi-Dri® to non-preferred status

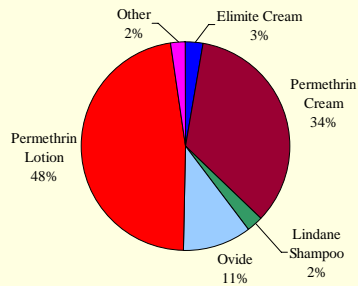
113

Topical Anti-parasitic Agents: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class are Eurax® Cream, Permethrin Cream, Lice Kit, Ovide® Lotion, Permethrin Lotion, Piperonyl Butoxide-Pyrethrins Lotion, and Piperonyl Butoxide-Pyrethrins Shampoo, Elimite® Cream, Eurax® Lotion, Lindane Lotion, Lindane Shampoo, Nix®, Rid®, Malathion

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Topical Anti-parasitic Agents: Market Share



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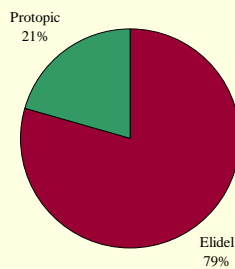
Topical Anti-parasitic Agents: Recommendations

- Eurax[®] Cream, Permethrin Cream, Lice Kit, Ovide[®] Lotion, Permethrin Lotion, Piperonyl Butoxide-Pyrethrins Lotion, and Piperonyl Butoxide-Pyrethrins Shampoo to preferred status
- Elimite[®] Cream, Eurax[®] Lotion, Lindane Lotion, Lindane Shampoo, Nix[®], Rid[®], and Malathion to non-preferred status



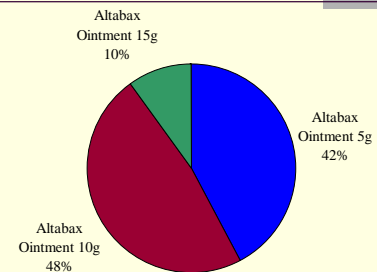
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Topical Immunomodulators: Market Share



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Topical Pleuromutilin Derivatives: Market Share



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Topical Pleuromutilin Derivatives: Recommendations

- Altabax[™] Ointment 5g, 10g to preferred status
- Altabax[™] Ointment 15g to non-preferred status



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Urinary Antispasmodics: Market Share

