ODJFS P&T Committee Meeting Minutes

June 12, 2013
30 E. Broad Street, Columbus, OH, Lobby Hearing Room

Committee members present: Susan Baker, CNP; Jennifer Hauler, DO; Michael Howcroft, RPh; Robert Hunter, DO; Karen Jacobs, DO; Margaret Scott, RPh; Michael Wascovich, RPh. Comments on the proposal were received via email from Cheryl Huffman, MD.

Xerox staff present: Stephanie Levine, RPh, Clinical Manager, Kimberly Hunton, PharmD, Clinical Pharmacist, Randy Charles, RPh, Educational Outreach; Corey Less, RPh, Educational Outreach

Approximately 105 stakeholders were present, most representing pharmaceutical manufacturers and advocacy associations.

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

The meeting was called to order at 1:00 PM.

1. Interested party presentations
    a. Aaron Boster, MD
    b. Betsy Johnson, Coalition for Healthy Communities
    c. Valerie Vernon
    d. Cheryl Baxter, RN, MS
    e. Edward Hamilton, ADAP Educational Initiative
    f. Tyler Andrew TerMeer, MS, Director, Ohio AIDS Coalition, a Division of AIDS Resource Center Ohio
    g. Kathy Schrag, Executive Director, Epilepsy Foundation of Greater Cincinnati and Columbus
    h. Channing Seideman, Epilepsy Foundation of Greater Cincinnati and Columbus
    i. Katie West, Epilepsy Foundation of Greater Cincinnati and Columbus
    j. Parkash Kotagal, MD, Cleveland Clinic, Epilepsy Foundation of Greater Cincinnati and Columbus

2. Preferred Drug List (PDL) proposal

Dr. Hunter recognized Dr. Hunton to present recommendations from Xerox and ODJFS for the preferred drug list (PDL). A copy of the proposed PDL as well as the presentation used by Xerox showing clinical changes in each drug class, market share, and recommendations, is attached to this document. The minutes reflect only those drug classes that produced discussion. The recommendations presented for all other drug classes were approved by the committee unanimously.

Blood Agents: Oral Anticoagulants

Dr. Jacobs noted that Eliquis has been shown to be superior to warfarin. Ms. Scott said that Xarelto has been shown to be non-inferior to warfarin. Dr. Jacobs asked if there are comparisons between Xarelto and Eliquis, and Dr. Hunton responded that there have been no head-to-head studies. Ms. Baker asked if a two-week trial of preferred medications is too long; Dr. Hunter responded that it would be about right for blood levels to be tested and Mr. Wascovich agreed that two weeks is appropriate.
Mr. Wascovich said that Brilinta and Effient are superior to clopidogrel and believes one should be preferred; he recommended Brilinta to be moved to preferred status.
The committee vote was 5 to 1 in favor of moving Brilinta to preferred status, with Ms. Scott dissenting.

Central Nervous System Agents: Alzheimer's Agents
Dr. Hunter suggested that Namenda XR is better than immediate-release Namenda and recommended moving Namenda IR to PA required (third tier) status and Namenda XR to Step Therapy Required (Preferred Brand) status.
The vote was 5 to 1 in favor of moving Namenda XR to preferred brand status and Namenda IR to PA, with Ms. Scott dissenting.

Central Nervous System Agents: Anti-Migraine Agents
Dr. Huffman communicated via email that several managed care plans would not allow triptans to patients under age 12 and asked that the committee make a recommendation that these drugs be used in children under age 12. The committee discussed that none of the products are approved by FDA for under age 12 so declined to make a statement.

Central Nervous System Agents: Anticonvulsants
Dr. Jacobs commented that the prior authorization criteria requiring a trial of two preferred products for one month each may be too long, and noted that Dr. Kotagal had expressed concern that patients may be changed from one manufacturer to another at the pharmacy without notification to the patient or prescriber.
Dr. Hunter said that the P&T committee may not be the proper setting for mandating that a pharmacy notify patients or prescribers of manufacturer changes. Mr. Wascovich agreed that this would be difficult for the PBM to identify this change, but agreed that the communication should take place. Ms. Scott also said that this subject has been raised in the legislature but no bills have been passed; Medicaid has opposed these bills because of the possibility of costs increasing if patients remain on branded drugs rather than generics.
Mr. Wascovich raised the issue of the length of trial of preferred products. Dr. Hunter said that four weeks is probably appropriate because the patient is not likely to return to the prescriber office in that time.
Mr. Wascovich noted that patients are grandfathered but asked about the prior authorization request time for patients new to Medicaid and stable on therapy. Ms. Scott responded that PA requested by fax is usually turned around in 4 to 5 hours while PA requested by phone receives an immediate answer.
The committee vote in favor of the ODJFS/Xerox proposal was unanimous.

Central Nervous System Agents: Antidepressants

Dr. Jacobs recommended that Pristiq be moved to step therapy (preferred brand) status with Cymbalta, because of the decreased interactions with the 2D6 pathway and ease of dosing since the starting dose is the maintenance dose. An alternative would be to have only preferred and non-preferred drugs without step therapy.
The committee vote to move Pristiq to step therapy (preferred brand) status was 5 to 1, with Ms. Scott dissenting.
Dr. Hunter mentioned the issue raised by Betsy Johnson on behalf of the Coalition for Healthy Communities that while psychiatrist physicians are exempt from prior authorization, this is not extended to nurse practitioners and physician assistants practicing in psychiatry. Dr. Jacobs noted that many community mental health centers do not have psychiatrists on site at all times.
Dr. Hunter asked for a vote on asking ODJFS to investigate adding allied health professionals to the prior authorization exemption. The committee vote was 5 to 1 in favor, with Ms. Scott dissenting.

Central Nervous System Agents: Antipsychotics, Second Generation
Dr. Jacobs said she is thrilled that the long-acting injectable drugs do not require prior authorization. She recommended collapsing this category to preferred and non-preferred drugs without step therapy because there are no preferred drugs that are appropriate in pregnancy or that are truly weight neutral.
Mr. Wascovich noted that the PDL is geared toward non-psychiatrists and asked Dr. Jacobs if she recommends specific drugs to be used by non-psychiatrists. Dr. Jacobs noted that Latuda is easy to use, and she also recommends Saphris and Invega. Clozapine should remain non-preferred because it should not be used by non-psychiatrists.
The committee vote to move Latuda and Saphris to step therapy (preferred brand) status was 5 to 1, with Ms. Scott dissenting.

Central Nervous System Agents: Attention Deficit Hyperactivity Disorder Agents
Dr. Jacobs is happy to have Strattera and Intuniv recommended preferred.
Ms. Baker asked about the committee's recommendation at the April meeting to allow approval for Quillivant XR for patients who cannot swallow. Dr. Levine said that Xerox is implementing criteria for Quillivant XR and Daytrana for patients who are unable to swallow pills.

Central Nervous System Agents: Fibromyalgia
Dr. Hauler said that it is important to keep Lyrica because there are no other options and the committee does not want to steer prescribers toward opioids. Mr. Wascovich agreed that Lyrica is the best drug for fibromyalgia and suggested making Lyrica approvable with a prescriber-initiated PA for a diagnosis of fibromyalgia.
The committee vote to allow Lyrica with a prescriber-requested PA with diagnosis of fibromyalgia was unanimous.

Central Nervous System Agents: Multiple Sclerosis
Mr. Wascovich said that there should be a preferred oral option. Dr. Hunter agreed and mentioned that Gilenya has been in preferred status with only 10% market share. Mr. Wascovich noted that patients may not be compliant with injectable drugs.
The committee vote to retain Gilenya on preferred status was 5 to 1, with Ms. Scott dissenting.

Central Nervous System Agents: Parkinson's Agents
Dr. Jacobs noted that Neupro is the only non-oral product for Parkinson's and recommended that patients unable to swallow or with poor gastrointestinal absorption should be approved for Neupro.
The committee vote to allow Neupro for patients unable to swallow or with poor gastrointestinal absorption was unanimous.

Endocrine Agents: Growth Hormone
Ms. Baker noted that the speaker for Tev-Tropin had mentioned that the product has a needle-free injection device and suggested that a needle-free product might be needed.
Dr. Hunter asked Ms. Scott to consult with Dr. Huffman on this question.

Gastrointestinal Agents: Irritable Bowel Syndrome / Chronic Constipation Agents
Dr. Hauler said she is interested in ensuring proper use of these products but does not use them enough to know what is appropriate. Dr. Hunter said that most patients have probably tried over-the-counter options before visiting the doctor and recommended moving Linzess to preferred status because of its efficacy on pain.
The committee vote on moving Linzess to preferred status was 5 to 1, with Ms. Scott dissenting.

Genitourinary Agents: Urinary Antispasmodics
Dr. Jacobs noted Ms. Baxter's presentation to the committee that after oxybutynin ER, Detrol LA and Gelnique are the best option for children.
The committee vote to allow Detrol LA and Gelnique for children after a trial on preferred generic drugs was unanimous.

Immunomodulator Agents for Systemic Inflammatory Disease
Dr. Hunton noted new indications for products in this class for ulcerative colitis. Ms. Scott said that ODJFS and Xerox have not investigated this indication. The committee asked that a recommendation be brought to the committee at a future meeting.

Infectious Disease Agents: Antivirals – HIV
Dr. Jacobs noted that several interested parties had mentioned the high cost of Stribild, and that it is non-preferred on many commercial plans. Ms. Scott responded that the cost is not an issue for Medicaid.
Mr. Wascovich said that as the committee begins to review more drugs that are specific to virus phenotype for hepatitis C and HIV, it may be helpful to engage consultants in infectious disease.

Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Short Acting
Ms. Baker noted that Ventolin HFA has a dose counter, which is nice for patients. Ms. Scott said that ProAir has added a dose counter within the last year. Dr. Hunter reported that he has had patients complain that ProAir does not work. Ms. Baker said that she has not had a problem with Ventolin. Dr. Hunter agreed and suggested keeping Ventolin preferred.
The committee vote to retain Ventolin HFA on preferred status was 5 to 1, with Ms. Scott dissenting.

Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Long Acting
Dr. Huffman had commented via email that many patients use Advair, and that while she does not prescribe it she is concerned about the number of patients that would need to change. Ms. Baker agreed that Advair is needed. Dr. Hunter also recommended keeping Advair preferred. The committee vote to retain Advair on preferred status was 4 to 2, with Ms. Scott and Mr. Wascovich dissenting.

Respiratory Agents: Chronic Obstructive Pulmonary Disease
Dr. Hunter noted that Daliresp is the only oral product. Mr. Wascovich said that the treatment guidelines recommend it as third-line therapy.

Respiratory Agents: Nasal Preparations
Ms. Baker asked if ODJFS has done research on whether patients using Veramyst are less likely to also need an ophthalmic antihistamine. Ms. Scott said that this has been looked at, but the results not reported to the committee. This will be brought to a future meeting.

Topical Agents: Anti-Parasitics
Dr. Jacobs was surprised to see Natroba moved to non-preferred status since it has very little systemic absorption and is in pregnancy category B. Dr. Hunter also noted that Natroba is recommended in the Red Book and suggested both Natroba and Sklice should be preferred. The committee vote to retain Natroba on preferred status was 5 to 1, with Ms. Scott dissenting.

The meeting was adjourned with a reminder that the next meeting is scheduled for Wednesday, October 9.

Notes from ODJFS after the meeting:

The committee recommendation to move Brilinta to preferred status is under review.

The committee recommendation to move Namenda XR to preferred brand status and Namenda IR to PA is under review.

The committee recommendation to move Pristiq to step therapy (preferred brand) is under review.

The committee recommendation to investigate adding allied health professionals specializing in psychiatry to the prior authorization exemption is under review.

The committee recommendation to move Latuda and Saphris to step therapy (preferred brand) status is under review.

The committee recommendation to allow Lyrica with a clinical prior authorization request giving a diagnosis of fibromyalgia will be implemented, with Lyrica moving to prior authorization status for all indications effective October 1 (with grandfathering). The PDL criteria for neuropathic pain and anticonvulsants will be implemented.

The committee recommendation to retain Gilenya on preferred status is under review.

The committee recommendation to allow Neupro for patients unable to swallow or with poor gastrointestinal absorption will be implemented.

Ms. Scott researched growth hormone products and found that both Tev-Tropin and Saizen have needle-free devices. There are approximately 375 patients on growth hormone, about 275 on the recommended preferred products Genotropin and Norditropin, 25 patients on Tev-Tropin (unknown how many using the needle-free device) and 4 patients using the needle-free device for Saizen. Based on this data, Dr. Huffman and the other committee members agreed that a needle-free device is not necessary.

The committee recommendation to move Linzess to preferred status is under review.

The committee recommendation to allow Detrol LA and Gelnique for children after a trial on preferred generic drugs will be implemented.

The committee recommendation to retain Ventolin HFA on preferred status was accepted.

The committee recommendation to retain Advair on preferred status was accepted.

The committee recommendation to retain Natroba on preferred status is under review.

Ohio Health Plans

Pharmacy Benefit Management Program

Preferred Drug List

Recommendations

Kimberly Hunton, PharmD, MBA, MSHA
Clinical Information Pharmacist
Xerox State Healthcare, LLC

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Analgesic: Gastroprotective NSAIDs

Clinical Highlights

- New Generics:
  - diclofenac/misoprostol (generic of Arthrotec®) tablets

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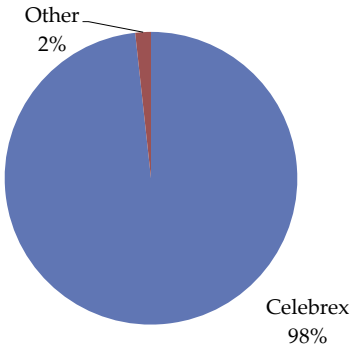
Analgesic: Gastroprotective NSAIDs

Market Share



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Analgesic: Gout Agents

Clinical Highlights

- Uloric® label recently revised to acknowledge postmarketing reports of fatal and non-fatal hepatic failure

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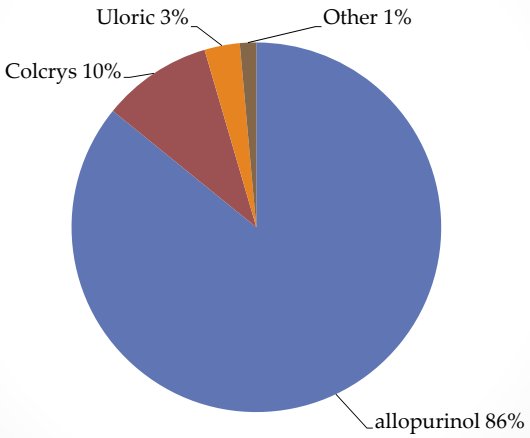
Analgesic: Gout Agents

Market Share



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Analgesic: Opioids

Clinical Highlights

- Codeine Sulfate Oral Solution approved in a 30mg/5mL concentration
- Exalgo approved in a new 32 mg strength
- Nucynta ER received a new indication for the management of neuropathic pain associated with diabetic peripheral neuropathy
- Oxymorphone ER tablets available in five additional generic strengths: 5-, 10-, 20-, 30-, and 40-mg (A-rated to older Opana ER formulation)

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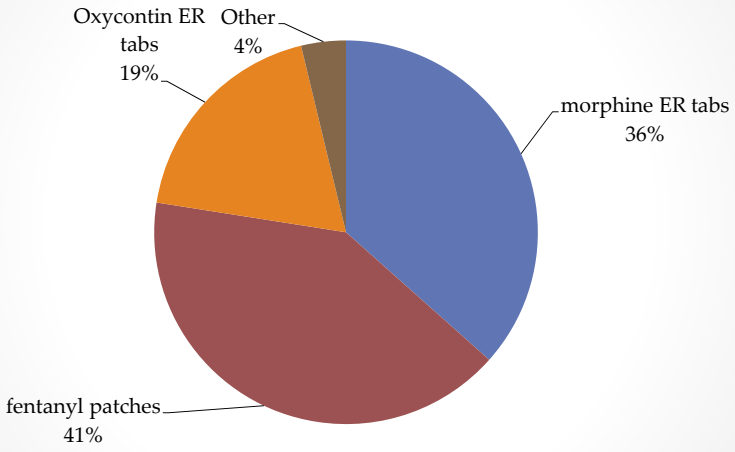
Analgesic: Opioids

Market Share



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Blood: Hematopoietic Agents

Clinical Highlights

- During February 2013, Omontys was voluntarily recalled due to reports of serious hypersensitivity reactions, including life-threatening and fatal events.

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Blood: Oral Anticoagulants

Clinical Highlights

- Eliquis: New Direct Factor Xa Inhibitor indicated to reduce the risk of stroke and systemic embolism in patients with NVAF
- Xarelto: Recently approved for <u>treatment</u> of VTE; therefore, now approved for prevention and treatment of VTE as well as reduction of stroke risk and systemic embolism in patients with NVAF

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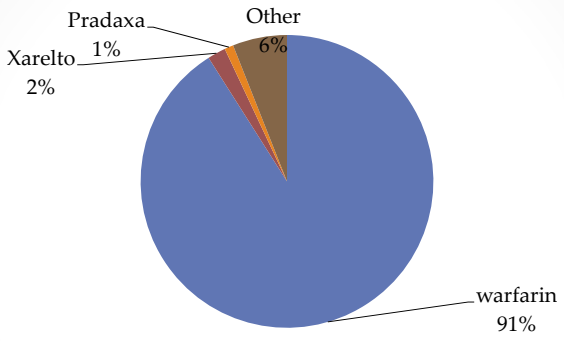
Blood: Oral Anticoagulants

Market Share



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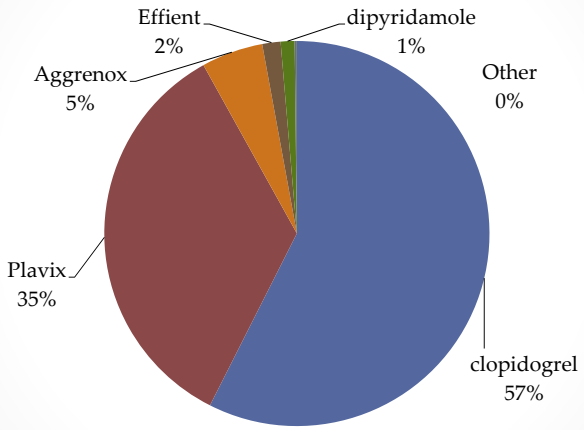
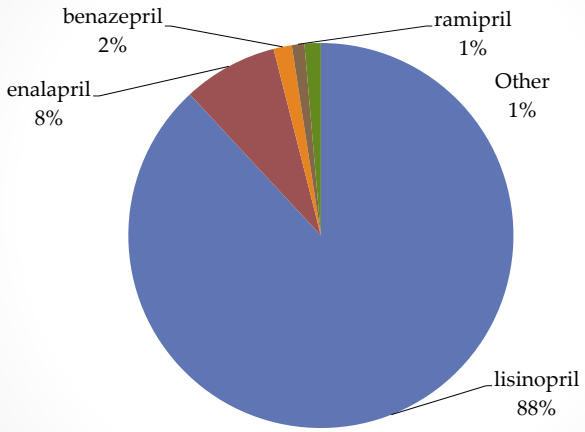
Blood: Oral Anticoagulants Market Share



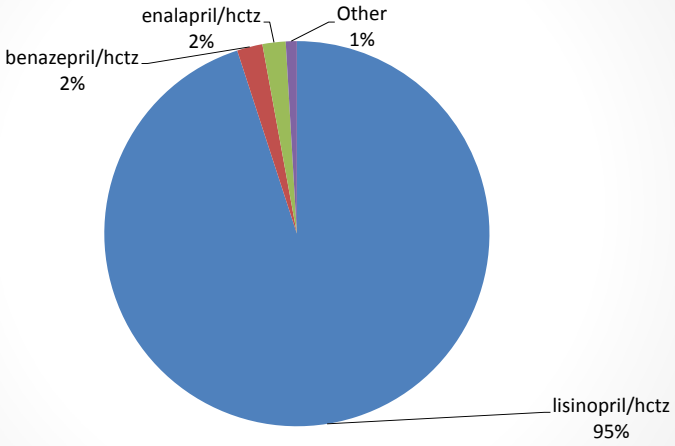
Blood Agent Recommendations

- No changes: Hematopoietic Agents, Heparin-Related Preparations, and Oral Anticoagulants

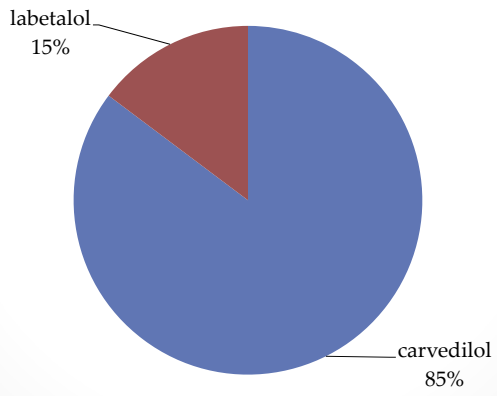
Cardiovascular: ACE Inhibitors Market Share



Cardiovascular: ACE with Diuretics Market Share



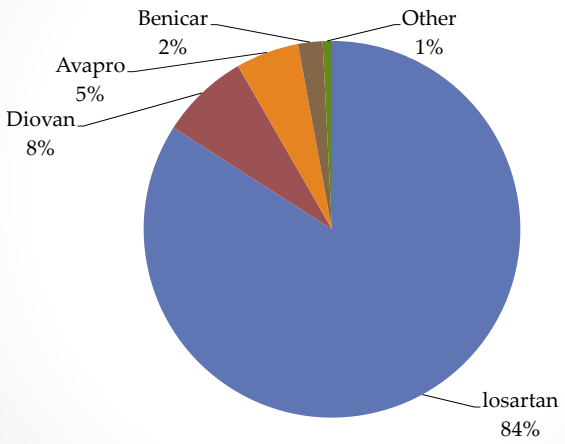
Cardiovascular: Alpha-Beta Blockers Market Share



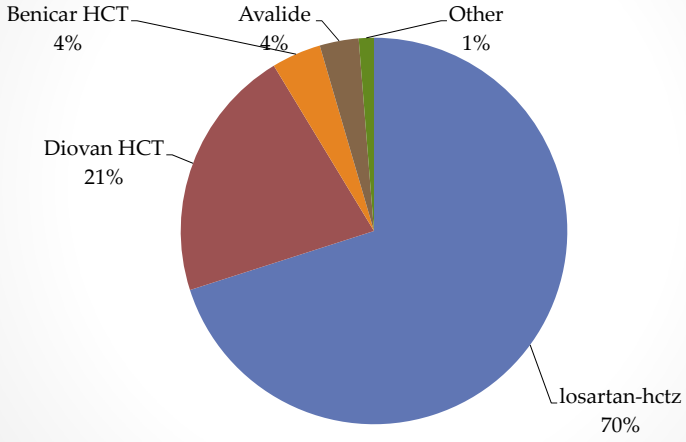
Cardiovascular: ARBs Clinical Highlights

- New Generics:
  - candesartan/hctz (generic of Atacand HCT®)
  - valsartan/hctz (generic of Diovan HCT®)

Cardiovascular: ARBs Market Share



Cardiovascular: ARBs with Diuretics Market Share



Cardiovascular: ARBs Recommendations

- Add candesartan/hctz to Non-Preferred
- Move irbesartan and irbesartan/hctz to Preferred
- Move Avapro® and Avalide® to Non-Preferred

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Cardiovascular: Antianginal Agents Clinical Highlights

- New class for inclusion on the PDL
- Beta-Blockers considered 1st line
- CCBs may be substituted or added if patients do not respond to Beta-Blockers
- Nitrates may also be added or substituted

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Cardiovascular: Antianginal Agents

Clinical Highlights

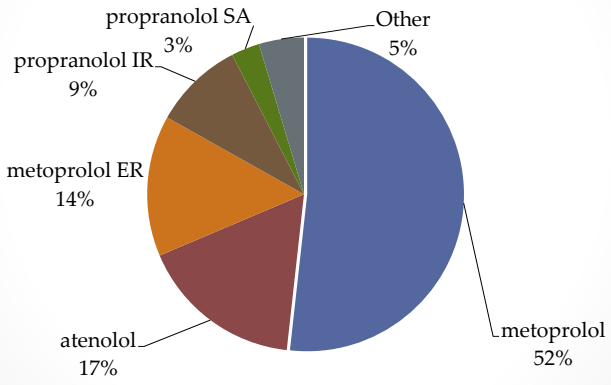
- Ranexa®
  - Indicated for chronic angina
  - May be used in combination with several drug classes including beta-blockers, calcium channel blockers, and nitrates
  - American College of Cardiology recommends Ranexa® when beta-blockers, calcium-channel blockers, and nitrates are not effective or well-tolerated

Cardiovascular: Antianginal Agents

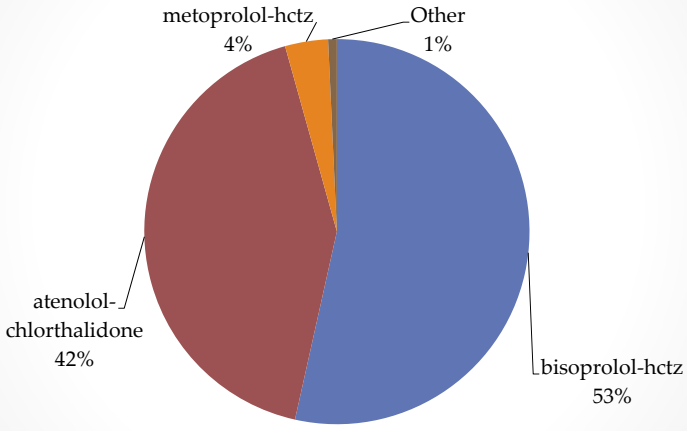
Recommendations

- Preferred:
  - Generic beta-blockers and CCBs
- Non-Preferred:
  - Ranexa®

Cardiovascular: Beta-Blockers Market Share

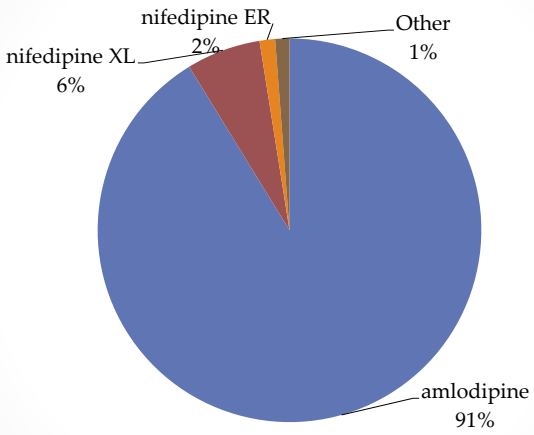


Cardiovascular: BB-Diuretics Market Share



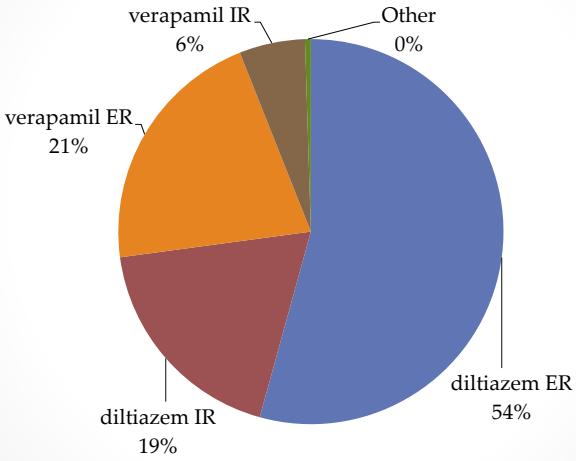
Cardiovascular: CCBs (DHP)

Market Share

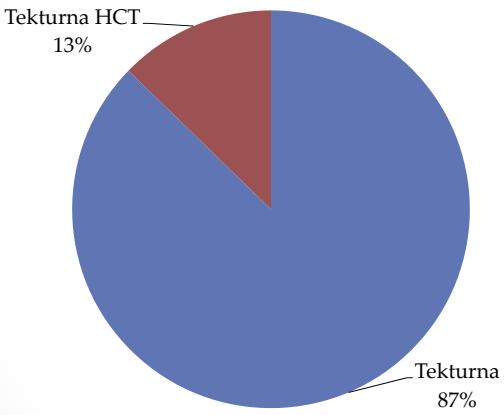


Cardiovascular: CCBs (non-DHP)

Market Share



Cardiovascular: Direct Renin Inhibitors Market Share



Cardiovascular: Antiarrhythmic Agents Recommendation

- No changes; maintain current status of all agents

Cardiovascular: PAH Agents
Clinical Highlights

- New Generics:
  - sildenafil (generic of Revatio®) tablets

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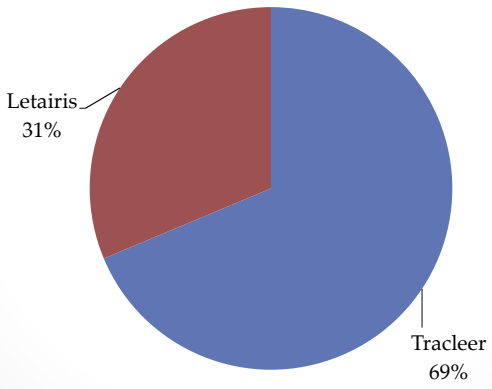
Cardiovascular: PAH Agents
Market Share



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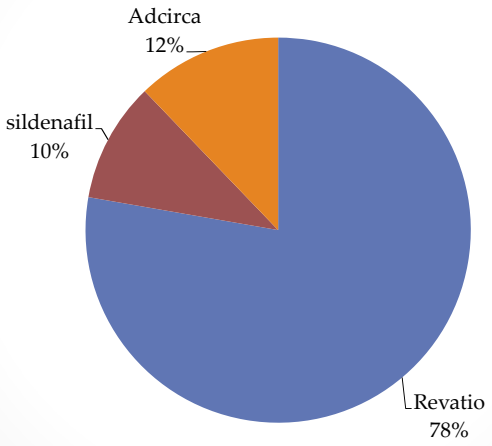
Cardiovascular: PAH Agents

Market Share



Cardiovascular: PAH Agents

Recommendations

- Add sildenafil as Preferred
- Move Revatio® to Non-Preferred

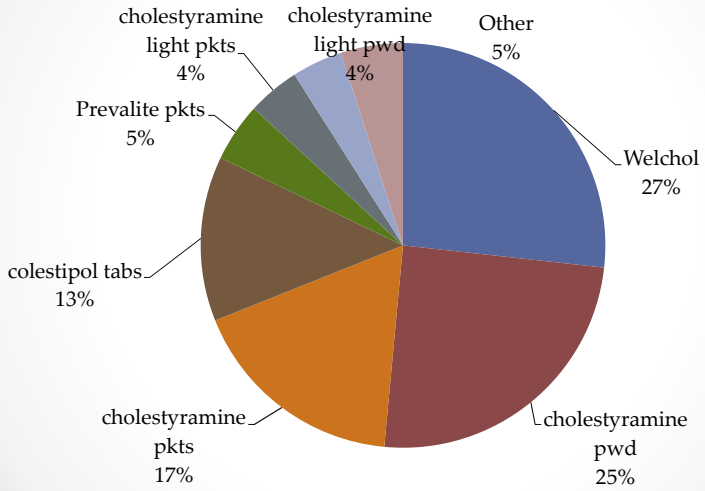
Cardiovascular: Bile Acid Sequestrants

Clinical Highlights

- Welchol® label recently updated to warn of potentail drug interactions when colesevelam is administered with glimepiride or metformin ER

Cardiovascular: Bile Acid Sequestrants

Market Share



Cardiovascular: Statins and Combinations

Clinical Highlights

- Liptruzet® (atorvastatin/ezetimibe) recently approved as an adjunct to diet to
  - reduce elevated total-C, LDL-C, Apo-B, TG, and non-HDL, and to increase HDL-C in patients with primary or mixed hyperlipidemia
  - reduce elevated total-C and LDL-C in patients with hypercholesterolemia, as an adjunct to other lipid-lowering treatment

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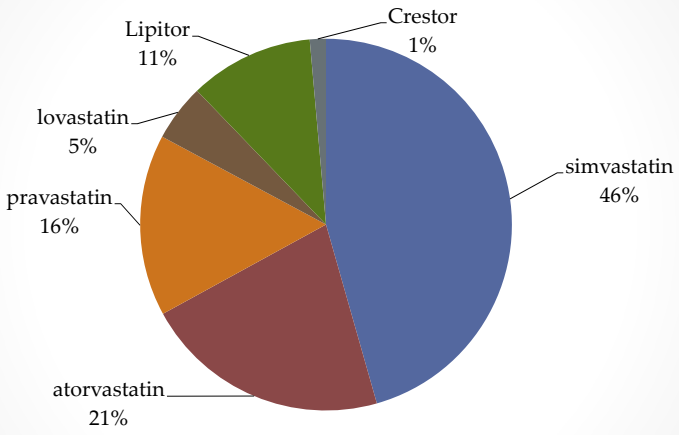
Cardiovascular: Statins

Market Share



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Cardiovascular: Statin and Combinations

Recommendations

- Add Liptruzet® to Non-Preferred with step edit requiring trial of two preferred statins
- Move Vytorin® to Non-Preferred and maintain step edit requiring trial of two preferred statins

Cardiovascular: FADs

Clinical Highlights

- Therapeutic equivalents of Tricor®, fenofibrate 48 mg and 145 mg tablets, became available late last year
- Fenofibrate 43 mg and 130 mg capsules, A-rated to Antara®, also recently became available

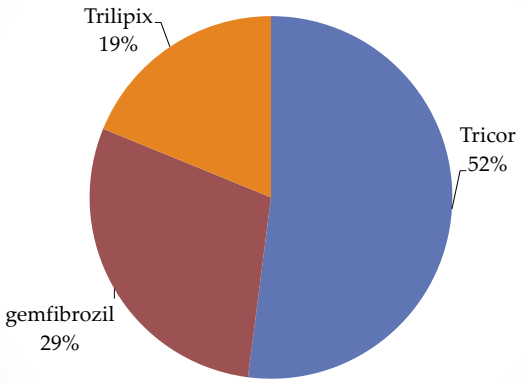
Cardiovascular: FADs

Clinical Highlights

- Postmarketing reports of severe decreases in HDL levels, as low as 2 mg/dL, in patients initiated on fibrate therapy
- HDL decrease reported to occur within two weeks to years after initiation of therapy; levels remain depressed until fibrate therapy withdrawn

Cardiovascular: FADs

Market Share



Cardiovascular: FADs Recommendation

- Add fenofibrate 43 mg and 130 mg capsules to Non-Preferred with other fenofibrate dosage forms

Cardiovascular: Other Lipotropics Clinical Highlights

- Vascepa® (icosapent ethyl) capsules recently approved as adjunct to diet to reduce triglyceride levels in adults with severe hypertriglyceridemia

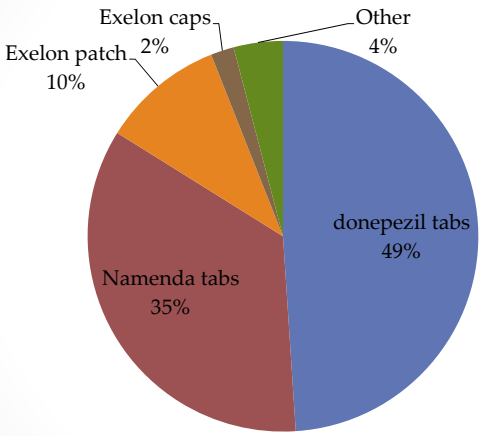
Cardiovascular: Other Lipotropics Recommendation

- Add Vascepa® to Non-Preferred with same approval criteria as Lovaza®: initial approval would be for two months, with evidence of reduced triglycerides required for re-approval

CNS: Alzheimer's Agents Clinical Highlights

- Exelon® Patch approved in a new 13.3 mg/24hr strength; therefore, now available in three different strengths: 4.6 mg/24hr, 9.5 mg/24hr, and 13.3 mg/24hr
- Namenda® XR tablets recently became available; indicated for moderate to severe dementia and dosed once daily

CNS: Alzheimer's Agents Market Share



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CNS: Alzheimer's Agents Recommendation

- Add Namenda® XR tablets to Non-Preferred with step therapy currently in place for Non-Preferred agents

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CNS: Antimigraine Agents

Clinical Highlights

- New Generics:
  - rizatriptan tablets and rizatriptan ODT (generics of Maxalt® and Maxalt MLT)

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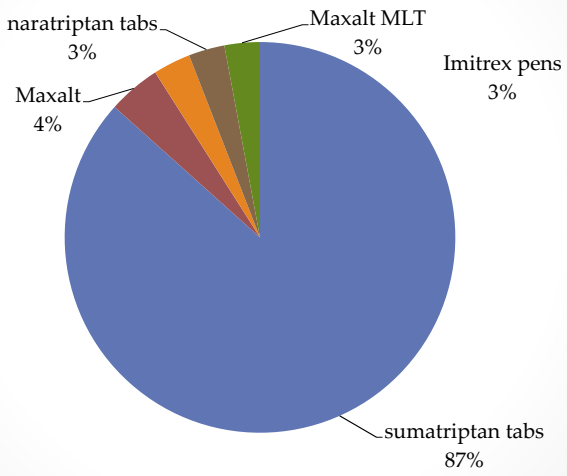
CNS: Antimigraine Agents

Market Share



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CNS: Antimigraine Agents

Recommendations

- Add rizatriptan tablets to Preferred
- Add rizatriptan ODT to Non-Preferred
- Move Maxalt® MLT to Preferred
- Move Maxalt® to Non-Preferred

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CNS: Anticonvulsants

Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed include:
  - carbamazepine (Carbatrol®ER, Epitol™, Equetro®, Tegretol®, Tegretol®XR)
  - clobazam (Onfi®)
  - clonazepam (Klonopin®, Klonopin® ODT)
  - diazepam (Diastat® Acudial, Diastat® Pedi System)
  - divalproex (Depakote®, Depakote® ER)

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CNS: Anticonvulsants

Clinical Highlights

- Anticonvulsants reviewed (cont.):
  - ethosuximide (Zarontin®)
  - ethotoin (Peganone®)
  - ezogabine (Potiga®)
  - felbamate (Felbatol®)
  - gabapentin (Neurontin®)
  - lacosamide (Vimpat®)
  - lamotrigine (Lamictal®, Lamictal® CD, Lamictal® ODT, Lamictal® XR)

CNS: Anticonvulsants

Clinical Highlights

- Anticonvulsants reviewed (cont.):
  - levetiracetam (Keppra®, Keppra® XR)
  - methsuximide (Celontin®)
  - oxcarbazepine (Trileptal®, Oxtellar™XR)
  - phenobarbital (n/a)
  - phenytoin (Dilantin®)
  - pregabalin (Lyrica®)
  - primidone (Mysoline®)
  - rufinamide (Banzel®)

CNS: Anticonvulsants

Clinical Highlights

- Anticonvulsants reviewed (cont.):
  - tiagabine (Gabitril®)
  - topiramate (Topamax®, Topamax® Sprinkles)
  - valproic acid (Depakene®, Stavzor®)
  - vigabatrin (Sabril®)
  - zonisamide (Zonegran®)

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CNS: Anticonvulsants

Clinical Highlights

- Grandfathering:
  - Patients with a claim for a Non-Preferred medication within the past 120 days
  - Patients with no claims history who have taken a Non-Preferred medication within the past 120 days

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CNS: Anticonvulsants

Clinical Highlights

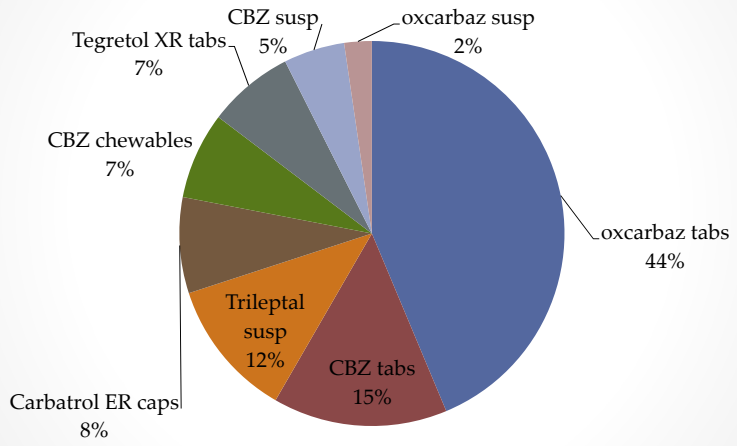
- Acceptable reasons for not being able to use a preferred medication:
  - Allergy to two preferred agents
  - Contraindication to or drug interaction with two preferred agents
  - Side effects to two preferred agents
  - Failure or contraindication related to preferred corresponding generic

CNS: Anticonvulsants

Clinical Highlights

- Additional approval criteria:
  - Must have been therapeutic failure to no less than two preferred products for one month trial each
  - Requests for Banzel® and Onfi® will require diagnosis of Lennox-Gastaut Syndrome (LGS)
  - Requests for Sabril® will require diagnosis of "infantile spasms"

CNS: Anticonvulsants Market Share



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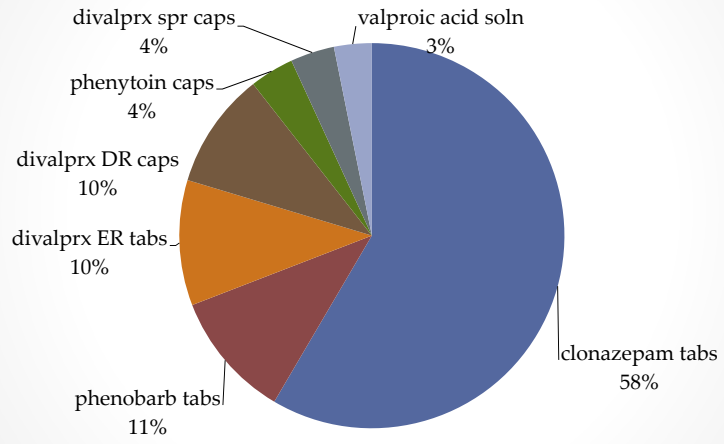
CNS: Anticonvulsants Market Share



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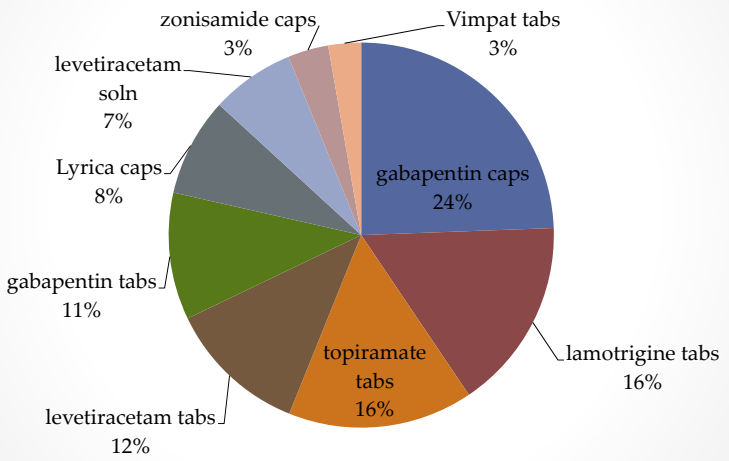
CNS: Anticonvulsants

Market Share



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CNS: Anticonvulsants

Recommendations

- Preferred CBZ derivatives:
  - carbamazepine IR tabs, chewables, & susp; Carbatrol® ER caps; oxcarbazepine tabs & susp; Tegretol® XR tabs; Trileptal® susp
- Non-Preferred CBZ derivatives:
  - carbamazepine ER caps & tabs; Oxtellar® XR tabs

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CNS: Anticonvulsants

Recommendations

- Preferred 1st generation agents:
  - clonazepam tabs; Diastat® rectal gel; divalproex; divalproex ER; ethosuximide; phenobarbital; phenobarbital; phenytoin; primidone; valproic acid
- Non-Preferred 1st generation agents:
  - Celontin®; clonazepam ODT; diazepam rectal gel; Onfi®; Peganone®; Stavzor®
- LGS diagnosis required for all 1st generation requests

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CNS: Anticonvulsants

Recommendations

- Preferred 2nd generation agents:
  - gabapentin; lamotrigine IR tabs & chewable tabs; levetiracetam IR tabs & solution; topiramate tabs; zonisamide
- Non-Preferred 2nd generation agents:
  - Banzel®; felbamate; Lamictal® ODT; lamotrigine ER tabs; levetiracetam ER tabs; Lyrica®; Potiga®; Sabril®; tiagabine; topiramate sprinkle caps; Vimpat®
- Requests for Banzel® require LGS diagnosis; requests for Sabril® require diagnosis of infantile spasms

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CNS: Antidepressants

Clinical Highlights

- Aplenzin® (bupropion hydrobromide) label updated to include SAD as a new indication
- Desvenlafaxine 50 mg and 100 mg extended-release tablets now available
  - Indicated for MDD
  - Not equivalent to Pristiq®
- Forfivo® XL (bupropion ER) 450 mg tablets recently approved for MDD

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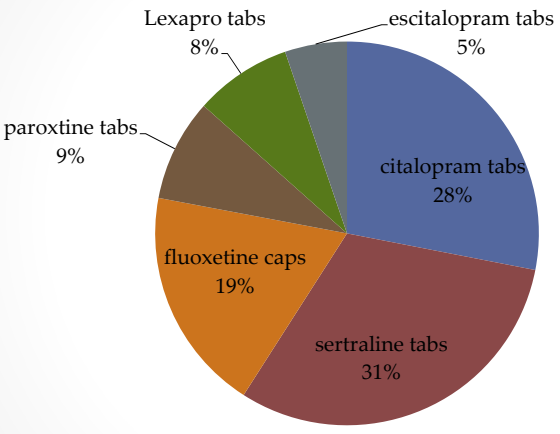
CNS: SSRIs

Market Share



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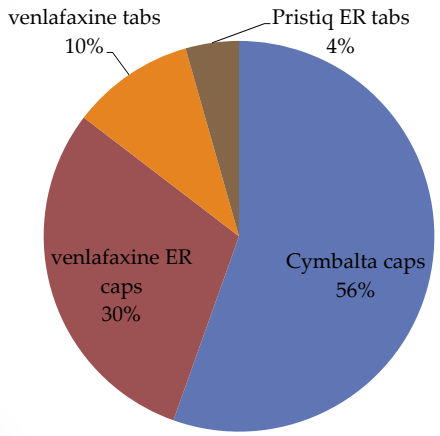
CNS: SNRIs

Market Share



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CNS: Antidepressants

Recommendation

- Add desvenlafaxine ER tablets to Non-Preferred

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CNS: 2nd Generation Antipsychotics Clinical Highlights

- Abilify® Maintena (aripiprazole) recently approved for schizophrenia
- olanzapine/fluoxetine (generic of Symbyax®)capsules recently approved

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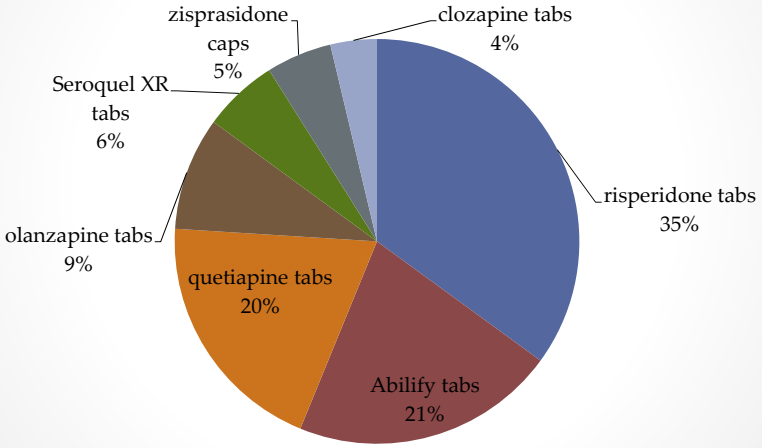
CNS: 2nd Generation Antipsychotics Market Share



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CNS: 2nd Generation Antipsychotics Recommendation

- Add Abilify® Maintena to Preferred:
  - As with other long-acting injectables, will be payable through pharmacy only if delivered to physician's office

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CNS: ADHD Agents Clinical Highlights

- Quillivant® XR (methylphenidate extended-release)oral suspension recently approved
- Generic methylphenidate ER capsules (A-rated to Metadate® CD) also approved

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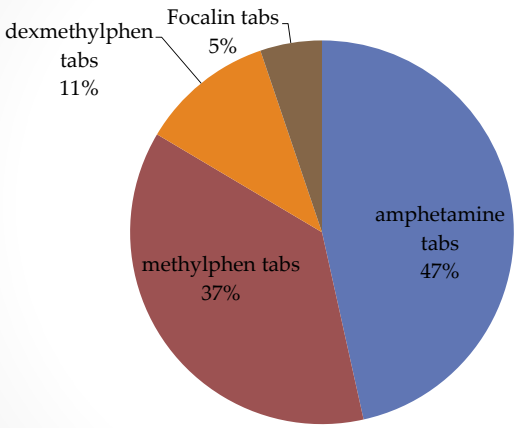
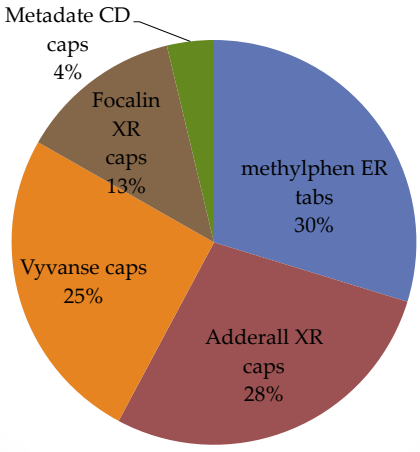
CNS: ADHD Agents
Market Share



CNS: ADHD Agents
Market Share



CNS: Fibromyalgia Agents
Clinical Highlights

- Lyrica® recently approved for management of neuropathic pain associated with spinal cord injury

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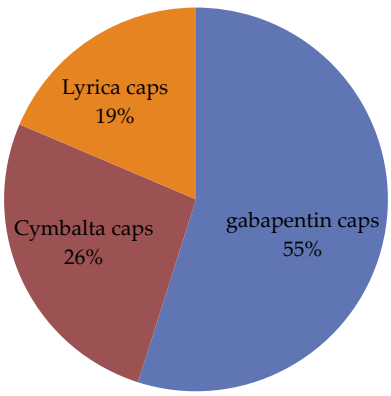
CNS: Fibromyalgia Agents
Market Share



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CNS: Fibromyalgia Agents Recommendation

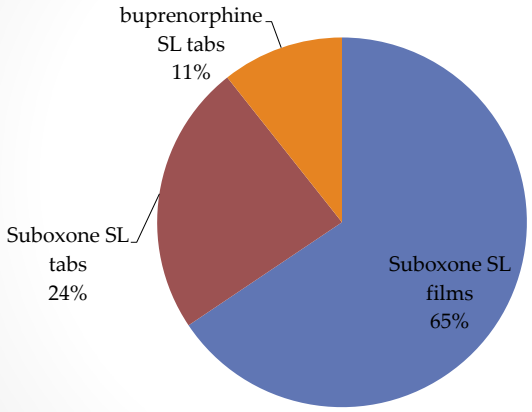
- Move Lyrica® to Non-Preferred

CNS: Medication Assisted Treatment Agents Clinical Highlights

- Buprenorphine/naloxone sublingual tablets (generic of Suboxone®) are now available. Brand Suboxone® SL tablets have been discontinued.

CNS: Medication Assisted Treatment Agents

Market Share



CNS: Medication Assisted Treatment Agents

Recommendations

- Add buprenorphine/naloxone SL tablets to Non-Preferred

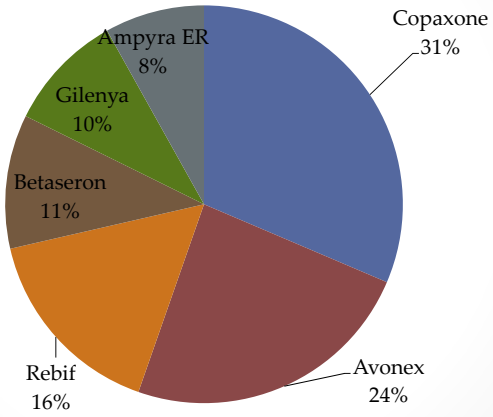
CNS: Multiple Sclerosis Agents
Clinical Highlights

- Rebif® Rebidose (interferon-beta 1a), a new single-use auto-injector, recently approved
- Aubagio® and Tecfidera® both recently approved for relapsing forms of MS

CNS: Multiple Sclerosis Agents
Clinical Highlights

- Gilenya®
  - Recent reports of death after first dose could not be linked to Gilenya®
  - Cardiovascular events associated with Gilenya® use remain a concern

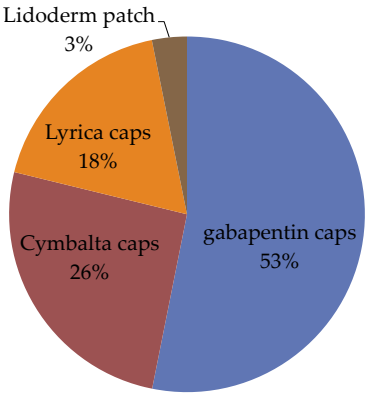
CNS: Multiple Sclerosis Agents Market Share



CNS: Multiple Sclerosis Agents Recommendation

- Add Tecfidera® to Non-Preferred

CNS: Neuropathic Pain Agents Market Share



CNS: Neuropathic Pain Agents Recommendation

- Move Lyrica® to Non-Preferred

CNS: Parkinson's Agents
Clinical Highlights

- New Generics:
  - entacapone (generic of Comtan®) tablets

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CNS: Restless Legs Syndrome Agents
Clinical Highlights

- Neupro® recently approved for treatment of RLS

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CNS: Sedative Hypnotics
Clinical Highlights

- zolpidem-containing products
  - FDA now recommends that bedtime doses be lowered due to potential impairment the morning after use

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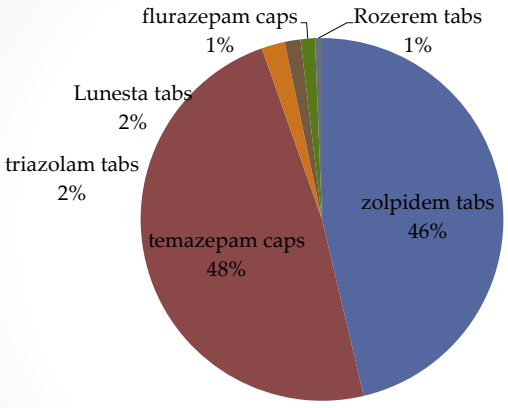
CNS: Sedative Hypnotics
Market Share



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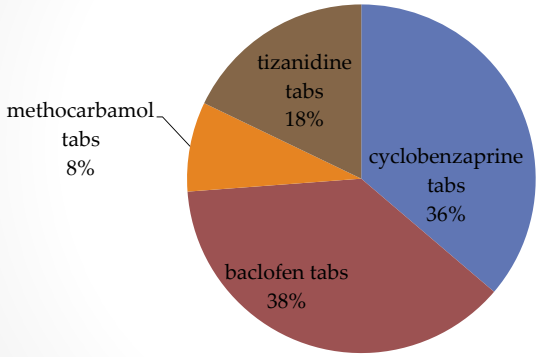
CNS: Skeletal Muscle Relaxants Market Share



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CNS: Smoking Deterrents Clinical Highlights

- Safety communication regarding Chantix® and risk of cardiovascular adverse events

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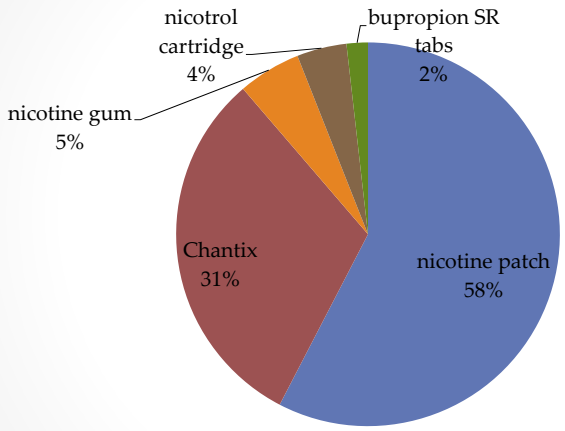
CNS: Smoking Deterrents Market Share



Endocrine: Amylin Analogs, Incretin Mimetics, and Insulin Clinical Highlights

- "Early Communication" regarding incretin mimetics:
  - FDA is evaluating data suggesting an increased risk of pancreatitis and precancerous cellular changes in patients with type 2 diabetes treated with incretin mimetics

Endocrine: Oral Hypoglycemics Clinical Highlights

- Invokana®, Nesina®, Kazano®, and Oseni® all recently approved as adjuncts to diet and exercise to improve glycemic control in adults with type 2 diabetes
- New Generics:
  - pioglitazone (generic of Actos®) and pioglitazone/metformin (generic of Actoplus Met®) tablets

Endocrine: Oral Hypoglycemics Recommendations

- Add Invokana® to Non-Preferred
- Move Onglyza® and Kombiglyze® XR to Non-Preferred
- Move pioglitazone to Preferred and Actos® to Non-Preferred

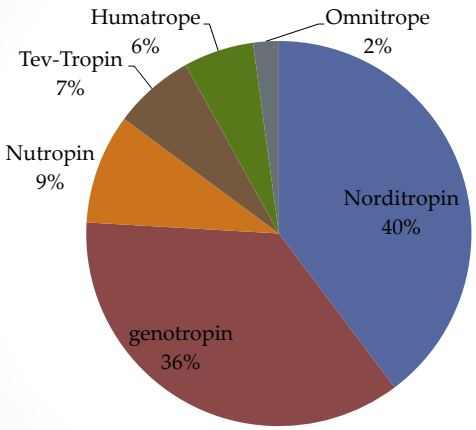
Endocrine: Estrogenic Agents
Clinical Highlights

- Minivelle® recently approved for moderate to severe vasomotor symptoms due to menopause
- Angeliq® was recently approved in a new 0.25mg/0.5mg strength

Endocrine: Estrogenic Agents
Recommendation

- Add Minivelle® Patch to Non-Preferred

Endocrine: Growth Hormone Market Share



Endocrine: Growth Hormone Recommendations

- Move Omnitrope® cartridges and vials to Non-Preferred
- Move Tev-Tropin® vials to Non-Preferred

Endocrine: Bone Ossification Enhancers

Clinical Highlights

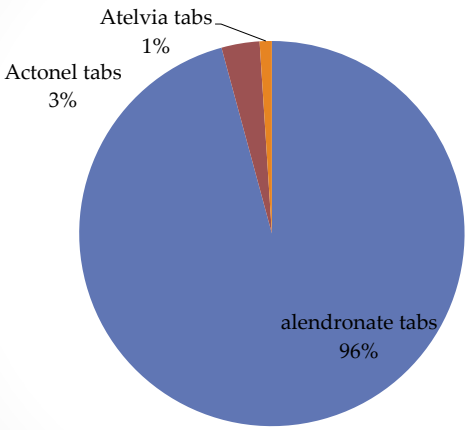
- Binosto® (alendronate) 70 mg effervescent tablets approved
- New generics:
  - alendronate 70 mg/75 mL oral solution (generic of Fosamax®)
  - ibandronate 150 mg tablets (generic of Boniva) ®

Endocrine: Bone Ossification Enhancers

Clinical Highlights

- Miacalcin®
  - No longer recommended as a treatment option for osteoporosis in postmenopausal women

Endocrine: Bone Ossification Enhancers Market Share



Endocrine: Bone Ossification Enhancers Recommendations

- Move both Miacalcin® and Fortical® nasal sprays to Non-Preferred

GI: Anti-Emetic Agents
Clinical Highlights

- Zofran® 32 mg single IV dose discontinued due to serious cardiac risks

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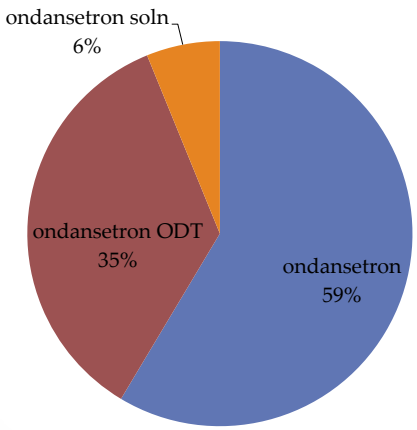
GI: Anti-Emetic Agents
Market Share



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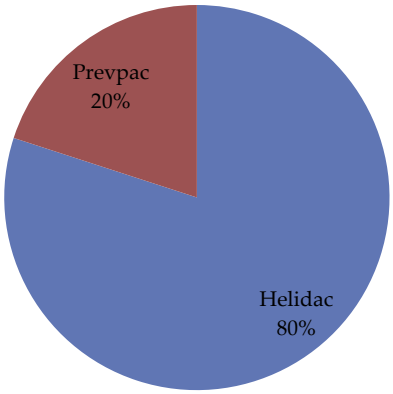
GI: Chronic Constipation Agents
Clinical Highlights

- Linzess® recently approved for chronic idiopathic constipation and irritable bowel syndrome with constipation

GI: H. Pylori Agents
Clinical Highlights

- Omeclamox Pak® recently approved for eradication of H. Pylori

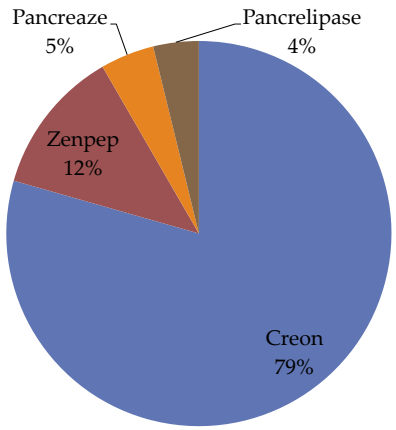
GI: H. Pylori Agents
Market Share



GI: Pancreatic Enzymes
Clinical Highlights

- Pertzye®, Viokace®, and Ultresa® all recently approved for treatment of exocrine pancreatic insufficiency

GI: Pancreatic Enzymes Market Share



GI: Pancreatic Enzymes Recommendation

- Move Pancreaze® to Non-Preferred

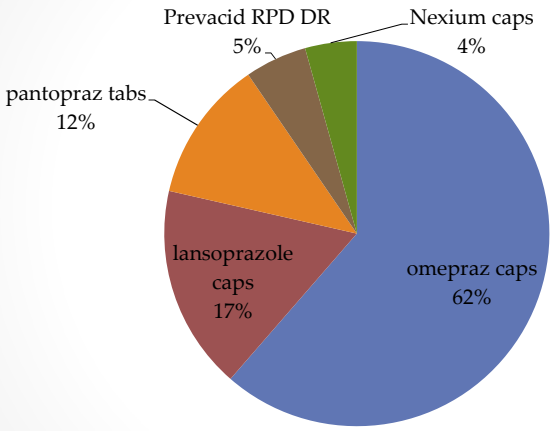
GI: PPI

Clinical Highlights

- PPI labels updated to warn of a potential drug interaction when PPIs are coadministered with methotrexate

GI: PPI

Market Share



GI: Ulcerative Colitis Agents
Clinical Highlights

- Delzicol® delayed-release capsules recently approved for ulcerative colitis; available in a 400 mg strength
- Giazo® tablets also recently approved for ulcerative colitis; available in 1.1gram tablets

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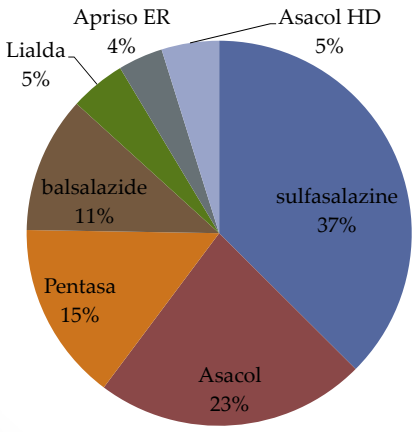
GI: Ulcerative Colitis Agents
Market Share



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GI: Ulcerative Colitis Agents

Recommendations

- Add Giazo® to Non-Preferred
- Move Pentasa® from Non-Preferred to Preferred Brand category

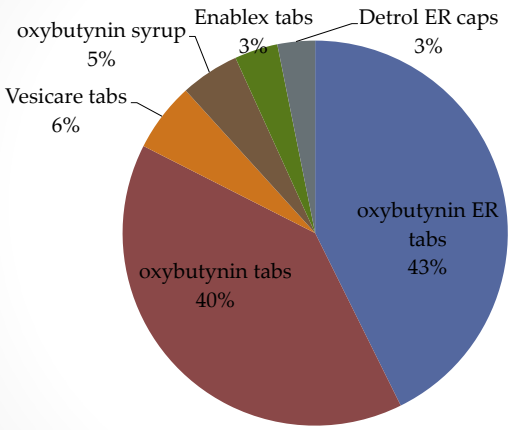
GU: UTAs

Clinical Highlights

- Myrbetriq® recently approved for overactive bladder
- Generic trospium ER capsules recently became available (generic of Sanctura® XR)
- "Oxytrol for Women" recently approved for over-the-counter treatment of OAB in women ages 18 and older

GU: UTA

Market Share



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GU: UTAs

Recommendations

- Add trospium ER to Non-Preferred
- Move Sanctura® XR to Preferred

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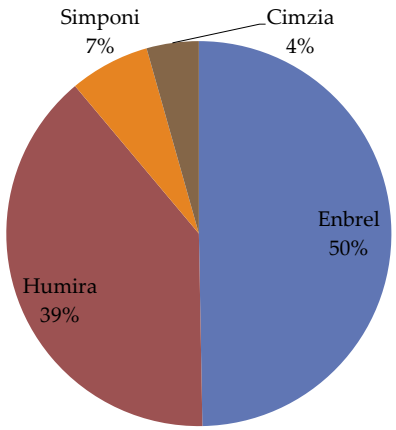
Immunomodulator Agents for Systemic Inflammatory Disease

- Humira® received a new indication for ulcerative colitis
- Kineret® received a new indication for Neonatal Onset Multi-system Inflammatory Disease (NOMID)
- Xeljanz® recently approved for treatment of moderately to severely active RA in patients who cannot take methotrexate

Immunomodulator Agents for Systemic Inflammatory Disease Market Share



Infectious Disease: Cephalosporin Clinical Highlights

- Suprax® 100 mg and 200 mg chewable tablets, and 500 mg/5 ml suspension recently approved

Infectious Disease: Cephalosporin Recommendation

- Make cefaclor suspension Preferred for patients 12 years of age and under
- Move cefaclor suspension to Non-Preferred for patients over 12 years of age

Infectious Disease: Onychomycosis & Systemic Clinical Highlights

- Onmel® tablets recently approved for onychomycosis of the toenail

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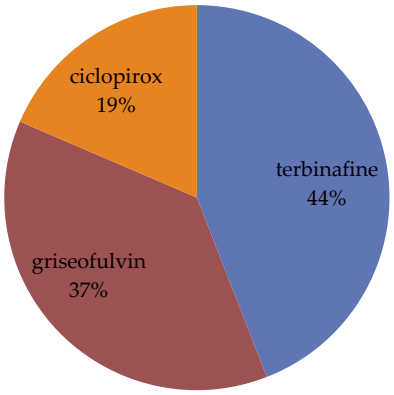
Infectious Disease: Onychomycosis & Systemic Market Share



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Infectious Disease: Onychomycosis & Systemic Recommendation

- Add Onmel® to Non-Preferred

Infectious Disease: HIV Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed include:
  - Reverse Transcriptase Inhibitors - Nucleoside analogs (Ziagen®, Epzicom®, Trizivir®, Videx®, Emtriva®, Epivir®, Zerit®, and Retrovir®); Non-Nucleoside Analogs (Rescriptor®, Sustiva®, Intelence®, Viramune®, and Edurant®)

Infectious Disease: HIV
Clinical Highlights

- HIV agents reviewed (cont.):
  - Reverse Transcriptase Inhibitors - Nucleotide analog (Viread®); Nucleoside-Nucleotide analog (Truvada®); Nucleoside-Nucleotide-Non-Nucleoside analogs (Atripla® and Complera®)

Infectious Disease: HIV
Clinical Highlights

- HIV agents reviewed (cont.):
  - Protease Inhibitors – Reyataz®, Lexiva®, Crixivan®, Kaletra®, Viracept®, Norvir®, Invirase®, Prezista®, and Aptivus®
  - Fusion Inhibitor (Fuzeon®)
  - Integrase Strand Transfer Inhibitor (Isentress®)

Infectious Disease: HIV
Clinical Highlights

- HIV agents reviewed (cont.):
  - Integrase Inhibitor and RTI combination - Stribild®
  - CCR5 Co-Receptor Antagonist (Selzentry®)

Infectious Disease: HIV
Clinical Highlights

- Initial HIV therapy should involve two Nucleoside or Nucleotide RTIs and a potent third agent from another class (e.g., Non-Nucleoside RTI, PI, or Integrase Strand Transfer Inhibitor)

Infectious Disease: HIV
Clinical Highlights

- Tenofovir plus emtricitabine is the recommended RTI combination in initial therapy
- Alternative combinations are abacavir + lamivudine, zidovudine + lamivudine, and tenofovir + abacavir

Infectious Disease: HIV
Clinical Highlights

- Grandfathering:
  - Patients with a claim for a Non-Preferred medication within the past 120 days
  - Patients with no claims history who have taken a Non-Preferred medication within the past 120 days

Infectious Disease: HIV

Clinical Highlights

- Acceptable reasons for not being able to use a preferred medication:
  - Allergy to preferred agents
  - Contraindication to or drug interaction with preferred agents
  - Side effects to two preferred agents
  - Failure or contraindication related to preferred corresponding generic

Infectious Disease: HIV

Recommendations

- All Protease Inhibitors recommended as Preferred, except for Aptivus®: Aptivus® is coadministered with ritonavir and intended for use in treatment-experienced patients infected with HIV strains resistant to more than one protease inhibitor

Infectious Disease: HIV Recommendations

- All Reverse Transcriptase Inhibitors recommended as Preferred, except for the Non-Nucleosides Rescriptor®, Edurant®, and Intelence®
- Fuzeon® and Selzentry® also recommended as Non-Preferred

Ophthalmic: Miotics Clinical Highlights

- Generic travoprost ophthalmic drops were recently approved and are available
- Rescula (unoprostone) 0.15% ophthalmic solution was recently brought back to market. This product is a 1 mg/mL solution administered as one drop in the affected eye twice daily.
- Simbrinza® (brinzolamide/brimonidine)recently approved for reduction of intraocular pressure

Ophthalmic: Miotics

Recommendations

- Add travaprost, Rescula®, and Simbrinza® to Non-Preferred

Ophthalmic: NSAIDs

Clinical Highlights

- Prolensa 0.07% (bromfenac) ophthalmic drops were recently approved
- Ilevro (nepafenac) 0.3% ophthalmic suspension also recently approved

Ophthalmic: NSAIDs

Recommendations

- Add Ilevro® suspension to Non-Preferred

Respiratory: 2nd Generation Antihistamine

Clinical Highlights

- desloratadine 5 mg tablets and ODT 2.5 mg and 5 mg approved (generics of Clarinex® and Clarinex® Reditabs)

Respiratory: Beta Adrenergics and Combinations

Recommendations

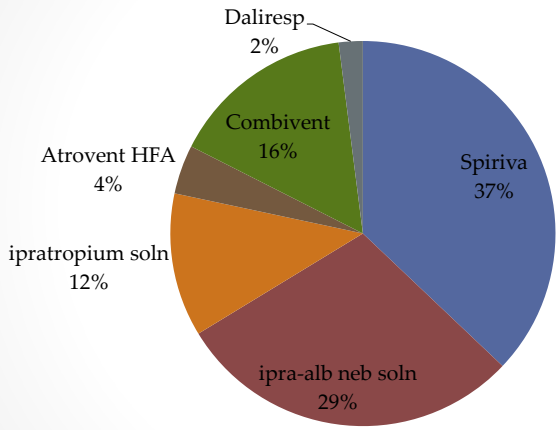
- Move Ventolin® HFA to Non-Preferred
- Move Advair® Diskus and Advair® HFA to Non-Preferred

Respiratory: COPD

Clinical Highlights

- Arcapta® Neohaler recently approved for long-term, once-daily maintenance bronchodilator treatment in patients with COPD
- Combivent® Respimat was recently approved and indicated in patients with COPD on a regular bronchodilator who continue to have evidence of bronshospasm
- Tudorza® Pressair recently approved for long-term maintenace treatment of bronchospasm associated with COPD

Respiratory: COPD Market Share



Respiratory: Leukotriene Receptor Modifiers and Inhibitors

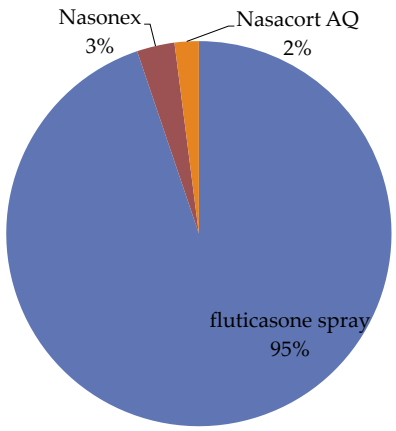
Clinical Highlights

- montelukast recently approved (generic of Singulair®)

Respiratory: Nasal Preparations Clinical Highlights

- Dymista® (azelastine/fluticasone) nasal spray recently approved for relief of symptoms of seasonal allergic rhinitis in patients 12 and older
- Zetonna® (ciclesonide) nasal spray recently approved for relief of symptoms of seasonal and perennial allergic rhinitis in patients 12 and older

Respiratory: Nasal Preparations Market Share



Respiratory: Epinephrine Auto-Injectors

Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed: Auvi-Q®, Epipen®, and Epipen®Jr.

Respiratory: Epinephrine Auto-Injectors

Recommendation

- Majority of market share is for Epipen®
- All agents Preferred
- Approval length 1 year

Topical: Acne Preparations

Clinical Highlights

- Tretinoin 0.04% and 0.1% gels recently approved (generic of Retin-A Micro)

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Topical: Androgens

Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed: Androderm®, Androgel®, Axiron® gel, Fortesta® gel, and Testim® gel

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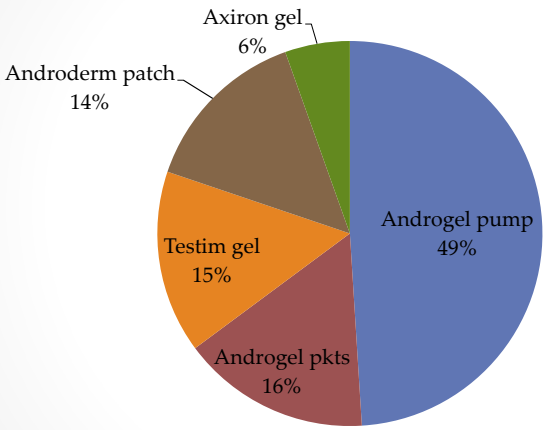
Topical: Androgens

Market Share



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Topical: Androgens

Recommendations

- Preferred: Androgel® and Androderm®
- Non-Preferred: Axiron®, Fortesta®, and Testim®
- Criteria: ≥ 18 years of age; 3 month trial of all preferreds required prior to receiving a non-preferred; approval length x 1 year

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Topical: Androgens

Recommendations

- Acceptable reasons for not being able to use a preferred medication:
  - Allergy to preferred agents
  - Contraindication to or drug interaction with preferred agents
  - Side effects to preferred agents

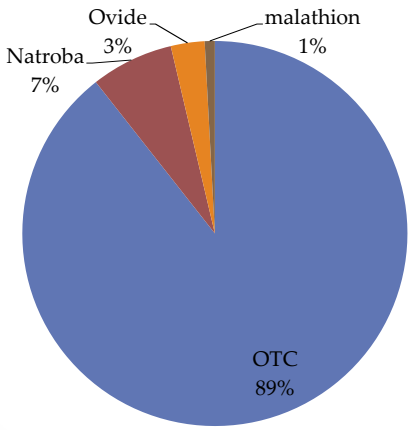
Topical: Parasitics

Clinical Highlights

- Sklice® recently approved for topical treatment of head lice infestations in patients 6 months of age and older

Topical: Parasitics

Market Share



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Topical: Parasitics

Recommendations

- Add Sklice® to Preferred
- Move Natroba® to Non-Preferred

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