

ODJFS P&T Committee Meeting Minutes

June 27, 2012

77 S. High St., Room 1948

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

Xerox (formerly named ACS) staff present: Stephanie Levine, RPh, Clinical Manager, Denise Hefley, PharmD, Clinical Pharmacist, Ed Jingluski, Account Manager

ODJFS staff present: Michael Howcroft, RPh; Jill Griffith, PharmD; Mary Applegate, MD

Approximately 75 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. Steve Jewell, MD
 - b. Deana Couture, PA-C
 - c. Denise Gastayz, NAMI Ohio
 - d. Laura Brown, RN, Ironton City Health Department
 - e. Ms. Valerie VernonThe speakers reported no conflicts of interest

2. Preferred Drug List (PDL) proposal

Mr. Wascovich recognized Dr. Hefley 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 unanimously by the committee.

Analgesics: Opioids

The recommendation for step therapy of short-acting, single entity, CII tablet/capsule products was clarified: Before a claim for codeine sulfate tablets, hydromorphone tablets, meperidine tablets, methadone tablets, morphine sulfate immediate-release tablets, oxycodone immediate-release tablets or capsules, or Nucynta tablets will be approved, the patient must have a one-week trial of at least one opioid combination

product (codeine/acetaminophen, hydrocodone/acetaminophen, oxycodone/acetaminophen, or oxycodone/aspirin), or tramadol.

Blood formation, coagulation, and thrombosis agents: Oral anticoagulants

The committee discussed what constitutes a "failure" on a preferred drug and suggested the state consider "inadequate clinical response to a preferred drug." Mr. Wascovich suggested that Xarelto is superior to Pradaxa. Ms. Eastman agreed, and suggested that Xarelto (all strengths) should be preferred. Dr. Welker agreed that it is confusing to have different criteria for different strengths of the same drug. Ms. Baker asked whether the diagnosis could be included on a claim for Xarelto to ensure it is being used appropriately. Mr. Wascovich noted that the dosing should signify the indication. The committee voted 7 to 1 to move Xarelto (all strengths) to preferred status.

Cardiovascular agents: Antiarrhythmics

Mr. Wascovich noted that Multaq converts to amiodarone and is effective. Dr. Welker suggested that criteria for non-preferred agents be a one-month trial of one agent. The vote was unanimous.

Cardiovascular agents: Pulmonary arterial hypertension

Dr. Hrometz suggested that if patients are newly diagnosed at stage 3 or higher, that epoprostenol should be approved. In addition, the clinical information for Tracleer is comparable to Letairis so if the cost is similar both should be available. Dr. Jacobs noted that the industry representative for Tracleer had mentioned that there are fewer and less severe drug interactions with Tracleer than with Letairis. Dr. Hrometz agreed but said that the drug interactions may not be clinically relevant.

The committee unanimously voted to grandfather patients on existing therapy, and allow inhaled or intravenous drugs to be approved if the patient is at Group 3 or higher.

The committee did not discuss the length or number of preferred drug trials to be completed before non-preferred drugs would be approved.

Central Nervous System (CNS): Alzheimer's agents

Ms. Scott asked the committee whether current patients should be grandfathered on current therapy. The vote was unanimous for grandfathering. Ms. Scott also clarified that there was a typo in the step therapy criteria. Non-preferred drugs would require trials of no less than one month each of at least two preferred generics or brands.

CNS: Antidepressants

Dr. Jacobs said that Cymbalta has SNRI activity at the lowest dose, while venlafaxine does not, so suggested that Cymbalta be moved to preferred status. She also recommended that Viibryd be moved to preferred brand status.

The committee voted 4 to 2 with one abstention to move Viibryd to preferred brand status (requiring a trial of one other drug).

The committee voted 4 to 3 for Cymbalta to be moved to preferred status with no step therapy through a generic drug required.

CNS: Antipsychotics, second generation

Dr. Hefley announced that the department has decided to allow Invega Sustenna, Risperdal Consta, and Zyprexa Relprevv to be payable to the pharmacy, if the pharmacy does not dispense the drug directly to the patient but ensures that it is dispensed to the administering provider office.

Dr. Jacobs said that she is concerned about requiring two trials of two weeks each for a patient to be able to receive a non-preferred drug from a non-psychiatrist prescriber. She also noted that Latuda and clozapine are pregnancy category B.

The committee voted unanimously to allow Latuda or clozapine to be approved for a pregnant patient.

The committee voted 5 to 1 to move Abilify and Seroquel XR to preferred status, meaning that the category would have only preferred and non-preferred drugs without step therapy with preferred generics.

CNS: Attention deficit hyperactivity disorder

Dr. Jacobs recommended that non-stimulants Strattera and Intuniv be available for first-line use, to avoid diversion in accordance with House Bill 93. Mr. Wascovich asked if Strattera would be used for a newly-diagnosed patient. Dr. Huffman said that she does not use Strattera first line, but understands the need to keep an eye on stimulants and respect when the parents don't want stimulants in the house. Dr. Jacobs indicated that although stimulants are a first line choice there are child psychiatrists who use Strattera and Intuniv, particularly when parents prefer not to have their children on stimulants. Forcing patients to use stimulants first seemed to be a contradiction to House Bill 93. Dr. Hrometz agreed that having only controlled options available doesn't make sense.

The committee voted 5 to 1 to move Strattera and Intuniv to preferred status, meaning that the category would have only preferred and non-preferred drugs without step therapy with preferred generics.

CNS: Fibromyalgia agents

Dr. Hrometz said that a drug approved by the FDA for fibromyalgia should be available without prior authorization (PA), and that requiring three drugs before an FDA-approved drug is extreme. The committee also noted concerns about requiring an opioid before a drug approved for fibromyalgia. Ms. Scott clarified that the department does not recommend the use of opioids for fibromyalgia, but if they had been tried they would count toward the PA. Dr. Jacobs said that prior to leaving, Dr. Welker had suggested that Lyrica be available without PA.

The committee voted unanimously that only two agents should be necessary before approval. The committee voted 5 to 1 to move Lyrica to preferred status. Ms. Scott clarified with the committee that they recommended that two agents be tried within 90 days, including Lyrica, before Cymbalta or Savella would be approved.

CNS: Medication-assisted treatment of opioid addiction

Dr. Hefley announced that the department has decided to allow Vivitrol to be payable to the pharmacy, if the pharmacy does not dispense the drug directly to the patient but ensures that it is dispensed to the administering provider office.

Ms. Scott pointed out the proposed change to criteria for Suboxone, limiting the dose to 16mg per day with no patient receiving more than 24mg per day, because studies have shown that receptors are 95% saturated at 16mg. Dr. Jacobs said that while the information Ms. Scott shared is true, this dosing recommendation is contentious among addiction specialists and those she has spoken with would like to allow a higher dose until the Ohio Department of Alcohol and Drug Addiction Services has completed a study that is starting in Jackson County. Currently the lower dose protocol was presented as a guideline. Once the study in Jackson County has been completed and proves successful should the new dosing protocol even be considered. Additionally it must be noted the proposed dosing is different than the FDA recommended dosing. The committee voted 5 to 1 to recommend a dose of 16-24mg per day, with a maximum of 32mg per day.

CNS: Multiple sclerosis

Ms. Eastman recommended that Gilenya be moved to preferred status, she has seen that monitoring is being done after the first dose as recommended.

The committee voted 4 to 2 with one abstention to move Gilenya to preferred status.

CNS: Neuropathic pain

Dr. Jacobs suggested a trial of one preferred generic instead of two, before a preferred brand. Length of authorizations was not discussed by the committee.

CNS: Sedative-hypnotics, non-barbiturate

Dr. Hrometz noted that the half life of flurazepam is 30 hours so is not recommended.

Ms. Scott said that several years ago, triazolam had been removed from the PDL document because the P&T Committee did not recommend its use but the department did not feel that a PA was warranted. The committee agreed to this strategy.

Endocrine agents: Oral hypoglycemics

M. Wascovich tabled discussion regarding the role glyburide plays in diabetes management and potentially moving glyburide products to a non preferred PDL status.

Endocrine agents: Growth hormone

Mr. Howcroft presented the department's recommendations for new PA criteria (included in PDL document attached to these minutes). Dr. Huffman asked why a limit of age 6 was included for chronic renal insufficiency. Mr. Howcroft said that there is no evidence for use in patients over 6 years, and will send the literature to Dr. Huffman. Dr. Huffman recommended only one growth hormone stimulation test, and that obstetricians should be stricken as a specialist able to prescribe for children who are small for gestational age. She recommended that the child should be evaluated by an endocrinologist.

Gastrointestinal agents: Chronic constipation agents

Dr. Hrometz recommended that the trial of preferred drugs be two weeks rather than one month. The committee vote was unanimous.

Gastrointestinal agents: Ulcerative colitis agents

Ms. Eastman noted that the pill burden for Lialda is much lower and is once-daily so may help compliance. She recommended moving to preferred brand status.

The committee voted 3 to 1, with 2 abstentions.

Respiratory agents: Chronic obstructive pulmonary disease

Dr. Hrometz suggested basing approval of Daliresp on history of long-acting beta agonist only, not on diagnosis, to minimize paperwork. Mr. Wascovich said he was in favor of the department-recommended criteria. However, utilization of Daliresp is low so the risk of inappropriate use in patients with a history of long-acting beta agonists is small.

The committee voted 5 to 1 in favor of Daliresp being approved based on a history of long-acting beta agonist alone.

Topical agents: Anti-parasitics

Dr. Hefley announced that a change has been made to the recommendations, moving Ovide to non-preferred status along with its generic malathion. Dr. Huffman said that she has had great luck with Ovide with no parent complaints. She recommended removing lindane from the document.

Topical agents: Corticosteroids

Dr. Huffman said that she does not prescribe longer than 2 weeks of high-potency agents.

Dr. Hefley said that very high potency agents are indicated for no more than 3 weeks.

Mr. Wascovich suggested a PA length of 3 months. Dr. Hrometz suggested no more than two claims per year.

The committee voted unanimously to allow a 3-month authorization for high and very high potency agents, and 1 year for low and medium potency.

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

Notes from ODJFS after the meeting:

The committee recommendations for Xarelto, Strattera, Intuniv, Lyrica for fibromyalgia, Gilenya, and Lialda were accepted. The department also reviewed Letairis and Tracleer and will include both in preferred status, with PA requiring diagnosis.

Committee recommendations on PA criteria and length for antiarrhythmics were accepted.

Committee recommendations on grandfathering current patients for pulmonary arterial hypertension and Alzheimer's agents were accepted.

The committee recommendations on Cymbalta and Viibryd were not accepted. The criteria in the proposed PDL will be implemented.

The committee recommendations on Abilify and Seroquel XR were not accepted. The criteria in the proposed PDL will be implemented. However, Latuda and clozapine may be approved for pregnant patients.

The committee recommendation on dosing of Suboxone was accepted.

Flurazepam will be removed from the PDL document, but will remain available without PA. Lindane will be removed from the PDL document, and will continue to require PA.

The committee recommendation on criteria for growth hormone was accepted.

The committee recommendation on length of trials for chronic constipation agents was accepted.

The committee recommendation for length of authorization for topical corticosteroids was accepted.

The department will implement the following criteria not specifically recommended by the committee:

Pulmonary arterial hypertension – non-preferred drugs may be approved after a trial of one month on one preferred agent.

Neuropathic pain – Lyrica will be preferred, Cymbalta will require a trial of one preferred drug, and Gralise, Horizant, and Lidoderm will require trials of two preferred drugs or Cymbalta. Length of authorization will be 1 year.

The department is reviewing the recommendation on Daliresp.

UPDATE 9/24/12: The minutes reflecting discussion regarding ADHD and Medication Assisted Treatment have been updated after the recording was reviewed.

The department will require PA for Daliresp: Systematic PA will be approved if there is a history of 3 claims for a long-acting beta agonist (LABA) in the previous 6 months. If there is an allergy or life-threatening adverse event to LABAs, Daliresp may be approved if there is a history of 3 claims for inhaled anticholinergics in the previous 6 months.

Ohio Health Plans Fee-For-Service

Pharmacy Benefit Management Program

Preferred Drug List



Effective October 1, 2012

Ohio Department of Job and Family Services

Revised June 13, 2012

Changes from previous version are technical corrections only
No policy changes have been made from the June 6 draft document

DRAFT

For P&T Committee Discussion Only

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Analgesic Agents: Gastroprotective NSAIDs

LENGTH OF AUTHORIZATIONS: 1 year, except as specified in items (2) and (3)
under Additional Information

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

- *Allergy to non-gastroprotective NSAIDs*
- *Contraindication to or drug-to-drug interaction with medications not requiring prior approval. Acceptable contraindications include:*
 - *Concurrent or history of a GI event (perforation, ulcer, bleed)*
 - *Other risks for treatment with non-selective NSAIDs:*
 - *Coagulation disorders (i.e. hemophilia, chronic liver disease), erosive esophagitis*
 - *Documented NSAID-induced ulcer*
 - *Peptic ulcer disease (PUD)*
 - *Patient on anticoagulants (warfarin or heparin)*
 - *Patient on oral corticosteroids*
 - *Patient on methotrexate*
- *History of unacceptable/toxic side effects to medications not requiring prior approval including non-gastroprotective NSAIDs*

ADDITIONAL INFORMATION

1. *Preferred gastroprotective NSAIDs may be approved if there have been therapeutic failures to no less than a one-month trial of at least two non-gastroprotective NSAID medications.*
2. *Preferred gastroprotective NSAIDs may be approved for patients who are undergoing surgical or other medical procedures that may predispose them to potential bleeding complications. Authorization will be for a 2-month period.*
3. *Preferred gastroprotective NSAIDs may be approved for patients who are being treated for *H. pylori*. Authorization will be for a 30-day period.*

CRITERIA FOR SYSTEMATIC PA OF PREFERRED AGENTS

1. *Patient age equal to or over 60 years; or*
2. *Patient has claims history of warfarin, heparin, or heparin-related agents in past 120 days; or*
3. *Patient has claims history of oral corticosteroid in past 120 days; or*
4. *Patient has claims history of methotrexate in past 120 days; or*
5. *Patient has claims history of aspirin in past 120 days; or*
6. *If there have been therapeutic failures to no less than a one-month trial of at least two non-gastroprotective NSAID medications.*

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ANALGESIC AGENTS: GASTROPROTECTIVE NSAIDS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CELEBREX [®] (celecoxib) (no PA required for age 60 or older)	ARTHROTEC [®] (diclofenac/misoprostol) CELEBREX [®] (celecoxib) (PA required for under age 60) DUEXIS [®] (ibuprofen/famotidine) VIMOVO [®] (naproxen/esomeprazole)

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Analgesic Agents: Gout

LENGTH OF AUTHORIZATIONS: 1 year

Is there any reason the patient cannot be changed to an agent 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

ADDITIONAL INFORMATION

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

- Agents to reduce hyperuricemia will be approved after adequate trial of allopurinol, or intolerance/contraindication to allopurinol.
- Analgesic agents will be approved if any one of the following is true:
 - Diagnosis of Familial Mediterranean Fever (FMF) (6 month approval); OR
 - Trial of one of the following:
 - NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
 - Oral corticosteroid

ANALGESIC AGENTS: GOUT – Agents to Reduce Hyperuricemia

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ALLOPURINOL (generic of Zyloprim®) PROBENECID (generic for Benemid) PROBENECID-COLCHICINE	ULORIC® (febuxostat)

ANALGESIC AGENTS: GOUT – Analgesic Agents

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	COLCRYS®* (colchicine)

* Colcris® (colchicine) quantity limit 6 tabs/claim for acute gout, 60 tabs/month for chronic gout after trial on xanthine oxidase inhibitor, 120 tabs/month for FMF

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Analgesic Agents: Opioids

LENGTH OF AUTHORIZATIONS: 6 months

Step Therapy: Long-acting drugs

- 1) ***For a preferred brand, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than one week of at least one preferred generic***
- 2) ***For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one week each of at least two preferred generics or brands***

Step Therapy: Short-acting drugs

- 1) ***Short-acting, single entity, CII tablets/capsules require previous utilization of combination products or tramadol***
- 2) ***For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one week each of at least two preferred generics or brands***

Other approval criteria:

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

Acceptable reasons include:

- Allergy to at least two unrelated 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
- Patient must have failed the generic product (if covered by the state) before brand is authorized, in addition to the above.

ADDITIONAL CRITERIA FOR TRANSMUCOSAL FENTANYL:

- Diagnosis of cancer pain; and
- Prescription is from oncologist or pain specialist; and
- Concurrently taking a long-acting opioid at therapeutic dose (any of the following for ≥ 1 week without adequate pain relief):
 - ≥ 60 mg oral morphine/day, or
 - ≥ 25 mcg/hr transdermal fentanyl, or
 - ≥ 30 mg oral oxycodone/day, or
 - ≥ 8 mg oral hydromorphone/day, or
 - ≥ 25 mg oral oxymorphone/day, or
 - Equianalgesic dose of another opioid; and
- Dose is ≤ 4 units per day

ADDITIONAL CRITERIA FOR TRANSDERMAL BUPRENORPHINE (BUTRANS®):

Butrans® may be approved under the criteria for non-preferred short-acting products

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ANALGESIC AGENTS: OPIOIDS – Long-Acting Oral

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
Extended Release Morphine Products		
MORPHINE SULFATE ER (generic of MS Contin®)	<i>KADIAN®(morphine)</i>	AVINZA® (morphine)
Extended Release Oxycodone Products		
		OXYCONTIN® (oxycodone)
Extended Release Tramadol Products		
		CONZIP® (tramadol) RYZOLT ER® (tramadol) TRAMADOL ER (generic of Ultram ER®)
Extended Release Oxymorphone Products		
		OPANA ER® (oxymorphone)
Extended Release Hydromorphone Products		
		EXALGO® (hydromorphone)
Extended Release Tapentadol Products		
	<i>NUCYNTA ER®</i>	

ANALGESIC AGENTS: OPIOIDS – Long-Acting Transdermal

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
FENTANYL PATCH (generic of Duragesic®)		BUTRANS® PATCH (buprenorphine)

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ANALGESIC AGENTS: OPIOIDS – Short-Acting Oral Single-Entity CII *

* Note: Step therapy required for all Short-Acting Oral Single-Entity CII products; patient must have prior therapy with combination products or tramadol

STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED
Codeine Products	
CODEINE SULFATE TABLETS	
Hydromorphone Products	
HYDROMORPHONE HCL TABLETS (generic of Dilaudid®)	
Levorphanol Products	
	LEVORPHANOL TABLETS (generic of Levo-Dromoran)
Meperidine Products	
MEPERIDINE TABLETS (generic of Demerol®)	
Methadone Products	
METHADONE TABLETS (generic of Dolophine®)	
Morphine Products	
MORPHINE SULFATE: IMMEDIATE-RELEASE TABLETS (generic of MSIR®)	
Oxycodone Products	
ROXICODONE® tablets OXYCODONE HCL capsules, tablets (generic of M-OXY®, OxyIR®)	
Oxymorphone Products	
	OXYMORPHONE HCL tablets (generic of Opana®)
Tapentadol Products	
NUCYNTA® (tapentadol)	

ANALGESIC AGENTS: OPIOIDS – Short-Acting Combination

NO PA REQUIRED “PREFERRED”	PA REQUIRED
Codeine Combinations	
ACETAMINOPHEN w/CODEINE TABLETS (generic of Tylenol® #2, #3, #4)	COCET® (acetaminophen-codeine) COCET PLUS® (acetaminophen-codeine)
Dihydrocodeine Combinations	
	DIHYDROCODEINE/ACETAMINOPHEN/ CAFFEINE (generic of Zerlor®) TREZIX® (acetaminophen/ caffeine/dihydrocodeine)
Hydrocodone Combinations	
HYDROCODONE/ACETAMINOPHEN tablets (generic of Anexsia, Lorcet, Lortab, Maxidone, Norco, Vicodin)	HYDROCODONE/ IBUPROFEN (generic of Vicoprofen®) IBUDONE® (hydrocodone/ibuprofen) MARGESIC H® (hydrocodone/ acetaminophen) REPREXAIN® (hydrocodone/ ibuprofen) XODOL® (hydrocodone/ acetaminophen) ZYDONE® (hydrocodone/ acetaminophen)

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Oxycodone Combinations	
OXYCODONE W/ ACETAMINOPHEN tablets (generic of Percocet®) OXYCODONE W/ ACETAMINOPHEN capsules (generic of Tylox®) OXYCODONE W/ ASPIRIN tablets 4.5mg/325mg (generic of Percodan®)	MAGNACET® (oxycodone/ acetaminophen) OXYCODONE W/ IBUPROFEN (generic of Combunox®) PRIMLEV® (oxycodone/ acetaminophen) ROXICET® 5mg/500mg (oxycodone/ acetaminophen)
Pentazocine Combinations	
<i>Not advocated for use</i>	PENTAZOCINE/NALOXONE (generic of Talwin NX®) PENTAZOCINE HCL/ ACETAMINOPHEN (generic of Talacen®)
Tramadol Combinations	
	TRAMADOL/ACETAMINOPHEN (generic of Ultracet®)

ANALGESIC AGENTS: CENTRAL, WITH OPIOID ACTIVITY

NO PA REQUIRED "PREFERRED"	PA REQUIRED
TRAMADOL (generic of Ultram®)	RYBIX® ODT (tramadol)

ANALGESIC AGENTS: OPIOIDS –Liquids Immediate-Release (Single Entity)

NO PA REQUIRED "PREFERRED"	PA REQUIRED
METHADONE HCL SOLN 5mg/5ml, 10mg/5ml OXYCODONE oral solution 5mg/5ml (generic of Oxydose®) MEPERIDINE HCL SYRUP: 50 mg/5ml (generic of Demerol Oral Syrup®) METHADONE HCL oral concentrate 10mg/ml METHADONE INTENSOL® 10mg/ml MORPHINE SULFATE solution: 10 mg/5ml, 20mg/5ml, 20mg/ml (generic of MSIR Soln® and Roxanol Soln®)	<i>HYDROMORPHONE 1mg/ml liquid (generic of Dilaudid-5®)</i>

ANALGESIC AGENTS: OPIOIDS – Liquids and Oral Syrup Immediate-Release (Combination)

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ACETAMINOPHEN w/CODEINE ORAL SOLN 120mg-12mg/5ml (generic of Tylenol w/Codeine Elixir®) HYDROCODONE BITARTRATE w/ ACETAMINOPHEN ELIXIR 2.5mg- 167mg/5ml (generic of Lortab Elixir®) ROXICET ORAL SOLN® (5mg Oxycodone-325mg APAP/5ml)	CAPITAL w/CODEINE® suspension 12mg codeine- 120mg APAP/5ml HYCET® (hydrocodone/ acetaminophen) HYDROCODONE/ACETAMINOPHEN ORAL SOLUTION 10mg-325mg/15ml (generic of Zamiset®)

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ANALGESIC AGENTS: OPIOIDS – Nasal Inhalers

NO PA REQUIRED “PREFERRED”	PA REQUIRED
BUTORPHANOL TARTRATE NS (generic of Stadol NS [®])	

ANALGESIC AGENTS: OPIOIDS – Transmucosal System *

NO PA REQUIRED “PREFERRED”	PA REQUIRED
	ABSTRAL [®] (fentanyl) FENTANYL CITRATE (generic of Actiq [®]) FENTORA [®] (fentanyl) ONSOLIS [®] (fentanyl) SUBSYS [®] (fentanyl)

* Note: Clinical criteria must be met for transmucosal systems

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For P&T Committee Discussion Only

**Blood Formation, Coagulation, and Thrombosis Agents:
Hematopoietic Agents**

LENGTH OF AUTHORIZATIONS: Dependent on diagnosis

All products in this class require clinical prior authorization:

Approval of epoetin alfa or darbepoetin:

Diagnosis	Hemoglobin Level	Approval Length
Anemia due to chronic renal failure, patient on dialysis	<=11	12 months
Anemia due to chronic renal failure, patient not on dialysis	<=10	12 months
Chemotherapy-induced anemia	<=10	3 months
Anemia in myelodysplastic syndrome	<=11	6 months

Approval of epoetin alfa only (not darbepoetin):

Diagnosis	Hemoglobin Level	Approval Length
Autologous blood donation, patient will require blood transfusions	>10, <=13	1 month
Anemia of prematurity, age <=6 months	N/A	6 weeks
Anemia associated with chronic inflammatory disorders (e.g., rheumatoid arthritis)	<=11	6 months
Anemia associated with ribavirin combination therapy in hepatitis C-infected patient	<=11	6 months
Anemia in zidovudine-treated HIV-infected patients	<=11	6 months

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 all medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
- Has the patient failed therapeutic trials of two weeks with preferred medications?

BLOOD AGENTS: HEMATOPOIETIC AGENTS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ARANESP® (darbepoetin alfa) SYRINGE OR VIAL PROCRIT® (epoetin alfa)	EPOGEN® (epoetin alfa)

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For P&T Committee Discussion Only

**Blood Formation, Coagulation, and Thrombosis Agents:
Heparin-Related Preparations**

LENGTH OF AUTHORIZATIONS: Varies based on criteria below

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 all medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. Has the patient failed therapeutic trials of two weeks with medications not requiring prior approval?

DURATION OF THERAPY LIMIT: 35 days

Guidelines from the American College of Chest Physicians limit duration of therapy in the outpatient setting for most indications to less than five weeks. Patients should be transitioned to oral warfarin as soon as possible.

- Is there any reason the patient cannot be changed to oral warfarin? Acceptable reasons include:
- patients with cancer (approved up to 6 months),
 - pregnant women (approved up to 40 weeks), or
 - patients unable to take warfarin (approved up to 6 months).

BLOOD AGENTS: HEPARIN-RELATED PREPARATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
FRAGMIN [®] SYRINGE (dalteparin)	FONDAPARINUX (generic of Arixtra[®])
FRAGMIN [®] VIAL (dalteparin)	ENOXAPARIN (generic of Lovenox [®])
LOVENOX [®] AMPULE (enoxaparin)	
LOVENOX [®] PREFILLED SYRINGE (enoxaparin)	
LOVENOX [®] VIAL (enoxaparin)	

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For P&T Committee Discussion Only

Blood Formation, Coagulation, and Thrombosis Agents: Oral Anticoagulants

LENGTH OF AUTHORIZATIONS: *1 year*

INDICATIONS:

		<i>Clopidogrel</i>	<i>Dabigatran</i>	<i>Prasugrel</i>	<i>Rivaroxaban</i>	<i>Ticagrelor</i>	<i>Warfarin</i>
	<i>Prophylaxis of DVT in patients undergoing total hip or knee replacement</i>				✓ (10mg)		
<i>Reduction of atherosclerotic events:</i>	<i>After cardiac valve replacement</i>						✓
	<i>In established peripheral arterial disease</i>	✓					
	<i>In non-STEMI ACS</i>	✓		✓		✓	✓
	<i>In non-valvular atrial fibrillation</i>		✓		✓ (15 & 20mg)		✓
	<i>In recent MI or stroke</i>	✓					✓
	<i>In STEMI ACS</i>	✓		✓		✓	✓
	<i>Venous thrombosis, pulmonary embolism</i>						✓

DVT: deep vein thrombosis; STEMI: ST-elevated myocardial infarction; ACS: acute coronary syndrome; MI: myocardial infarction

- 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 all medications not requiring prior approval*
 - History of unacceptable/toxic side effects to medications not requiring prior approval*
- 2. Has the patient failed therapeutic trials of two weeks with medications not requiring prior approval?*

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For P&T Committee Discussion Only

BLOOD AGENTS: ORAL ANTICOAGULANTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CLOPIDOGREL (generic of Plavix [®]) WARFARIN (generic of Coumadin [®]) XARELTO [®] 10mg tablets (rivaroxaban) *	BRILINTA [®] (ticagrelor) <i>EFFIENT[®] (prasugrel)</i> PRADAXA [®] (dabigatran) XARELTO [®] 15mg, 20mg tablets (rivaroxaban)

* Note: Duration limit of 35 days applies to Xarelto 10mg tablets

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For P&T Committee Discussion Only

Cardiovascular Agents: Hypertension & Heart Failure

LENGTH OF AUTHORIZATIONS: 1 year

Angiotensin II Receptor Antagonist (ARB) and ARB Combination Step Therapy:

- 1) ***For a preferred brand, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than one month of at least one preferred generic***
- 2) ***For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one month each of at least two preferred generics or brands***

Other approval criteria:

- 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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
- 2. 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 one-month trial of at least one medication within the same class not requiring prior approval
 - The requested medication’s corresponding generic (if covered by the state) has been attempted and failed or is contraindicated
- 3. If there is a specific indication for a medication requiring prior approval, for which medications not requiring prior approval are not indicated, then may approve the requested medication. This medication should be reviewed for need at each request for reauthorization.

CARDIOVASCULAR AGENTS: ACE INHIBITORS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
BENAZEPRIL (generic of Lotensin®)	
CAPTOPRIL (generic of Capoten®)	
ENALAPRIL (generic of Vasotec®)	
FOSINOPRIL (generic of Monopril®)	
LISINOPRIL (generic of Zestril®, Prinivil®)	
MOEXIPRIL (generic of Univasc®)	
PERINDOPRIL ERBUMINE (generic of Aceon®)	
QUINAPRIL (generic of Accupril®)	
RAMIPRIL (generic of Altace®)	
TRANDOLAPRIL (generic of Mavik®)	

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For P&T Committee Discussion Only

CARDIOVASCULAR AGENTS: ACE INHIBITORS/CCB Combination

NO PA REQUIRED "PREFERRED"	PA REQUIRED
LOTREL [®] (Amlodipine/Benazepril) TARKA [®] (Verapamil/Trandolapril)	AMLODIPINE/BENAZEPRIL (generic of Lotrel [®]) TRANOLAPRIL/VERAPAMIL (generic of Tarka [®])

CARDIOVASCULAR AGENTS: ACE INHIBITORS/DIURETIC Combination

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BENAZEPRIL/HCTZ (generic of Lotensin HCT [®]) CAPTOPRIL/HCTZ (generic of Capozide [®]) ENALAPRIL/HCTZ (generic of Vaserecic [®]) FOSINOPRIL/HCTZ (generic of Monopril HCT [®]) LISINOPRIL/HCTZ (generic of Zestoretic [®] , Prinzide [®]) MOEXIPRIL/HCTZ (generic of Uniretic [®]) QUINAPRIL/HCTZ (generic of Accuretic [®])	

CARDIOVASCULAR AGENTS: ALPHA-BETA BLOCKERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CARVEDILOL (generic of Coreg [®]) LABETALOL (generic of Trandate [®])	COREG CR [™] (carvedilol)

CARDIOVASCULAR AGENTS: ANGIOTENSIN II RECEPTOR ANTAGONISTS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
AVAPRO [®] (irbesartan) LOSARTAN (generic of Cozaar [®])	BENICAR[®] (olmesartan) MICARDIS[®] (telmisartan) DIOVAN[®] (valsartan)	ATACAND [®] (candesartan) EDARBI [®] (azilsartan) TEVETEN [®] (eprosartan)

* Note: Step therapy required for Angiotensin Receptor Antagonists—patient must have a claim for an ACE Inhibitor or combination within the last 120 days.

CARDIOVASCULAR AGENTS: ANGIOTENSIN II RECEPTOR ANTAGONISTS/DIURETIC Combination

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
AVALIDE [®] (irbesartan/hctz) LOSARTAN-HCTZ (generic of Hyzaar [®])	BENICAR HCT[®] (olmesartan/hctz) MICARDIS HCT[®] (telmisartan/hctz) DIOVAN HCT[®] (valsartan/hctz)	ATACAND HCT [®] (candesartan/hctz) TEVETEN HCT [®] (eprosartan/hctz) EDARBYCLOR (azilsartan/ chlorthalidone)

* Note: Step therapy required for Angiotensin Receptor Antagonists—patient must have a claim for an ACE Inhibitor or combination within the last 120 days.

CARDIOVASCULAR AGENTS: ANGIOTENSIN II RECEPTOR ANTAGONISTS/CALCIUM CHANNEL BLOCKER Combination

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
	AZOR [®] (Amlodipine/ Olmesartan)	EXFORGE[®] (Amlodipine/ Valsartan) TWYNSTA [®] (Amlodipine/ Telmisartan)

* Note: Step therapy required for Angiotensin Receptor Antagonists—patient must have a claim for an ACE Inhibitor or combination within the last 120 days.

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For P&T Committee Discussion Only

CARDIOVASCULAR AGENTS: ANGIOTENSIN II RECEPTOR ANTAGONISTS/ CALCIUM CHANNEL BLOCKER/DIURETIC Combination

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
	TRIBENZOR [®] (olmesartan/amlodipine/hctz)	<i>EXFORGE HCT[®] (amlodipine/ valsartan/hctz)</i>

* Note: Step therapy required for Angiotensin Receptor Antagonists – patient must have a claim for an ACE Inhibitor or combination within the last 120 days.

CARDIOVASCULAR AGENTS: BETA-BLOCKERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ACEBUTOLOL (generic of Sectral [®]) ATENOLOL (generic of Tenormin [®]) BETAXOLOL (generic of Kerlone [®]) BISOPROLOL FUMARATE (generic of Zebeta [®]) METOPROLOL SUCCINATE (generic of Toprol XL [®]) METOPROLOL TARTRATE (generic of Lopressor [®]) NADOLOL (generic of Corgard [®]) PINDOLOL (generic of Visken [®]) PROPRANOLOL (generic of Inderal [®]) PROPRANOLOL ER (generic of Inderal LA [®]) SOTALOL (generic of Betapace [®]) SOTALOL AF (generic of Betapace AF [®]) TIMOLOLOL (generic of Blocadren [®])	BYSTOLIC [®] (nebivolol) INNOPRAN XL [®] (propranolol) LEVATOL [®] (penbutolol)

CARDIOVASCULAR AGENTS: BETA-BLOCKERS/DIURETIC COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ATENOLOL/CHLORTHALIDONE (generic of Tenoretic [®]) BISOPROLOL/HCTZ (generic of Ziac [®]) METOPROLOL/HCTZ (generic of Lopressor HCT [®]) NADOLOL/BENDROFLUMETHIAZIDE (generic of Corzide [®]) PROPRANOLOL/HCTZ (generic of Inderide [®]) <i>DUTOPROL[®] (metoprolol succinate/HCTZ)</i>	

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For P&T Committee Discussion Only

**CARDIOVASCULAR AGENTS: CALCIUM CHANNEL BLOCKERS-
DIHYDROPYRIDINE**

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AMLODIPINE (generic of Norvasc [®]) FELODIPINE (generic of Plendil [®]) NICARDIPINE (generic of Cardene [®]) NIFEDIPINE ER (generic of Procardia XL [®] , Adalat CC [®]) NIFEDIPINE IMMEDIATE RELEASE (generic of Procardia [®])	CARDENE SR [®] (nicardipine) DYNACIRC CR [®] (isradipine) ISRADIPINE (generic of Dynacirc [®]) NIMODIPINE (generic of Nimotop [®])* NISOLDIPINE (generic of Sular [®]) SULAR [®] (nisoldipine)

* Note: Clinical criteria required for nimodipine, only approvable for 21 days after subarachnoid hemorrhage.

**CARDIOVASCULAR AGENTS: CALCIUM CHANNEL BLOCKERS- NON-
DIHYDROPYRIDINE**

NO PA REQUIRED "PREFERRED"	PA REQUIRED
DILTIAZEM (generic of Cardizem [®]) DILTIAZEM ER (generic of Cardizem CD [®] q24h, Tiazac [®]) DILTIAZEM SR (generic of Cardizem SR [®] q12h) VERAPAMIL (Generic of Calan [®]) VERAPAMIL SR/ER (Generic of Calan SR [®] , Isoptin SR [®] , Verelan [®])	COVERA HS [®] (verapamil) DILTIAZEM 24H ER tablet (generic of Cardizem LA [®]) VERAPAMIL ER PM (generic of Verelan PM [®])

CARDIOVASCULAR AGENTS: DIRECT RENIN INHIBITORS*

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
TEKURNA [®] (aliskiren)	

* Note: Step therapy required for direct renin inhibitors – patient must have a claim for an alternative anti-hypertensive agent within the last 120 days.

**CARDIOVASCULAR AGENTS: DIRECT RENIN INHIBITOR/DIURETIC
COMBINATION***

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
TEKURNA HCT [®] (aliskiren/HCTZ)	

* Note: Step therapy required for direct renin inhibitors – patient must have a claim for an alternative anti-hypertensive agent within the last 120 days.

**CARDIOVASCULAR AGENTS: DIRECT RENIN INHIBITOR/ANGIOTENSIN
RECEPTOR BLOCKER COMBINATION***

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
VALTURNA [®] (Aliskiren/Valsartan)	

* Note: Step therapy required for direct renin inhibitors – patient must have a claim for an alternative anti-hypertensive agent within the last 120 days.

*To be discontinued July 2012

**CARDIOVASCULAR AGENTS: DIRECT RENIN INHIBITOR/CALCIUM CHANNEL
BLOCKER COMBINATION***

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
TEKAMLO [®] (Aliskiren/Amlodipine)	

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* Note: Step therapy required for direct renin inhibitors – patient must have a claim for an alternative anti-hypertensive agent within the last 120 days.

CARDIOVASCULAR AGENTS: DIRECT RENIN INHIBITOR/CALCIUM CHANNEL BLOCKER/DIURETIC COMBINATION*

STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED
AMTURNIDE® (Aliskiren/Amlodipine/HCTZ)	

* Note: Step therapy required for direct renin inhibitors – patient must have a claim for an alternative anti-hypertensive agent within the last 120 days.

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For P&T Committee Discussion Only

Cardiovascular Agents: Antiarrhythmics

LENGTH OF AUTHORIZATIONS: *1 year*

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 all medications not requiring prior approval*
 - *History of unacceptable/toxic side effects to medications not requiring prior approval*

3. *Has the patient failed therapeutic trials of [to be discussed by P&T Committee] with [number of medications to be discussed by P&T Committee] not requiring prior approval?*

CARDIOVASCULAR AGENTS: ANTIARRHYTHMICS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AMIODARONE (generic of Cordarone®)	<i>MULTAQ® (dronedarone)</i>
DISOPYRAMIDE PHOSPHATE (generic of Norpace®)	
NORPACE CR®	
FLECAINIDE (generic of Tambocor®)	
MEXILITINE	
PROPAFENONE (generic of Rythmol®)	
PROPAFENONE ER (generic of Rythmol SR®)	
QUINIDINE GLUCONATE ER	
QUINIDINE SULFATE	
QUINIDINE SULFATE ER	
TIKOSYN® (dofetilide)	

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For P&T Committee Discussion Only

Cardiovascular Agents: Pulmonary Arterial Hypertension

LENGTH OF AUTHORIZATIONS: *1 year*

All products in this class require clinical prior authorization: Diagnosis of pulmonary arterial hypertension

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 all medications not requiring prior approval*
 - *History of unacceptable/toxic side effects to medications not requiring prior approval*
2. *Has the patient failed therapeutic trials of [to be discussed by P&T Committee] with [number of medications to be discussed by P&T Committee] not requiring prior approval?*

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION ORAL

<i>CLINICAL PA REQUIRED "PREFERRED"</i>	<i>PA REQUIRED</i>
<i>ADCIRCA[®] (tadalafil)</i> <i>REVATIO[®] (sildenafil)</i> <i>LETAIRIS[®] (ambrisentan)</i>	<i>TRACLEER[®] (bosentan)</i>

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION INHALATION

<i>CLINICAL PA REQUIRED "PREFERRED"</i>	<i>PA REQUIRED</i>
	<i>TYVASO[®] (treprostinil)</i> <i>VENTAVIS[®] (iloprost)</i>

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION INTRAVENOUS

<i>CLINICAL PA REQUIRED "PREFERRED"</i>	<i>PA REQUIRED</i>
	<i>EPOPROSTENOL (generic of Flolan[®])</i> <i>REMODULIN[®] (treprostinil)</i> <i>VELETRI[®] (epoprostenol)</i>

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For P&T Committee Discussion Only

Cardiovascular Agents: Lipotropics

LENGTH OF AUTHORIZATIONS: 1 year all Lipotropics except Omega-3 Fatty Acid
2 months for Omega-3 Polyunsaturated Fatty Acid

Trial period	1 month (30 days) for HMG-CoA Reductase Inhibitors, Niacin derivatives, 3 months for Fibrates
Number of non-PA agents	1 medication – The assumption is that the medication must be in the same class of the medication requested, if available, except for HMG-CoA reductase inhibitors- see specific criteria

General Guidelines:

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 (pravastatin is the only HMG-CoA not metabolized by the cytochrome P450 liver enzyme system)
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to no less than two of the HMG-CoA preferred products for a one-month trial, then a non-preferred HMG-CoA agent will be authorized.

ADDITIONAL CRITERIA FOR OMEGA-3 POLYUNSATURATED FATTY ACID (LOVAZA®):

Prescription-only Omega-3 Polyunsaturated Fatty Acid is approvable only for adults with triglyceride levels equal to or greater than 500 mg/dL in patients who have been unable to lower triglyceride levels with lifestyle changes including diet and exercise. Medications known to increase triglycerides (beta blockers, thiazides, and estrogens) must be discontinued or changed, if clinically appropriate, before the drug is approved. Initial approval will be for 2 months, with evidence of reduced triglycerides required for re-approval.

ADDITIONAL CRITERIA FOR COLESEVELAM (WELCHOL®):

- *Colesevelam may be approved as first-line therapy if there is a diagnosis of diabetes*
- *Will be approved through systematic PA if there is a history of an oral hypoglycemic or insulin in the previous 120 days*

CARDIOVASCULAR AGENTS: LIPOTROPICS – BILE ACID SEQUESTRANTS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CHOLESTYRAMINE LIGHT POWDER (generic of Questran Light®)	COLESTIPOL granules (generic of Colestid® granules)
CHOLESTYRAMINE POWDER (generic of Questran®)	WELCHOL® packets (colesevelam)
COLESTIPOL tablets (generic of Colestid® tablets)	WELCHOL® tablets (colesevelam)
PREVALITE® POWDER (cholestyramine)	

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For P&T Committee Discussion Only

CARDIOVASCULAR AGENTS: LIPOTROPICS - STATINS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
LIPITOR [®] (atorvastatin) LOVASTATIN (generic of Mevacor [®]) PRAVASTATIN (generic of Pravachol [®]) SIMVASTATIN (generic of Zocor [®])	ALTOPREV [®] (lovastatin) ATORVASTATIN (generic of Lipitor [®]) CRESTOR [®] (rosuvastatin) LESCOL XL [®] (fluvastatin) LESCOL [®] (fluvastatin) LIVALO [®] (pitavastatin)

CARDIOVASCULAR AGENTS: LIPOTROPICS – STATIN/NIACIN COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
SIMCOR [®] (Simvastatin/Niacin)	ADVICOR [®] (Lovastatin/Niacin)

CARDIOVASCULAR AGENTS: LIPOTROPICS - FIBRIC ACID DERIVATIVES

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ANTARA [®] (fenofibrate) GEMFIBROZIL (generic of Lopid [®]) TRICOR [®] (fenofibrate) TRILIPIX [®] (fenofibrate)	FENOFIBRATE FENOFIBRIC ACID (generic of Fibracor [®]) LIPOFEN [®] (fenofibrate) LOFIBRA [®] (fenofibrate) TRIGLIDE [®] (fenofibrate)

CARDIOVASCULAR AGENTS: LIPOTROPICS - NICOTINIC ACID DERIVATIVES

NO PA REQUIRED PREFERRED	PA REQUIRED
NIACIN NIASPAN [®] (niacin)	

CARDIOVASCULAR AGENTS: LIPOTROPICS - OMEGA-3 POLYUNSATURATED FATTY ACIDS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
OTC FISH OIL 340-1000, 360-1200, 435-880, 500-1000	LOVAZA [®] (omega 3 fatty acids)

CARDIOVASCULAR AGENTS: LIPOTROPICS - SELECTIVE CHOLESTEROL ABSORPTION INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	ZETIA[®] (ezetimibe)

CARDIOVASCULAR AGENTS: LIPOTROPICS – STATIN / SELECTIVE CHOLESTEROL ABSORPTION INHIBITOR COMBINATIONS

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
VYTORIN[®] (Simvastatin/Ezetimibe) *	

* Note: *Step therapy required – must have therapeutic trial of two preferred statins.*

CARDIOVASCULAR AGENTS: LIPOTROPIC/HYPERTENSION COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	AMLODIPINE/ATORVASTATIN (generic of Caduet [®])

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For P&T Committee Discussion Only

CARDIOVASCULAR AGENTS: LIPOTROPIC/DPP-4 COMBINATION

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
JUVISYNC [®] (sitagliptin/simvastatin) *	

* Note: Step therapy required for DPP-4 Inhibitors – patient must have a claim for an alternate oral hypoglycemic or insulin within the previous 120 days.

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For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Alzheimer’s Agents

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy:

- 1) ***For a preferred brand, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than one month of at least one preferred generic***
- 2) ***For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one week each of at least two preferred generics or brands***

Other approval 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

ADDITIONAL CRITERIA FOR RIVASTIGMINE PATCH (EXELON®):

May be approved first-line for patient who is unable to swallow.

CNS AGENTS: ALZHEIMER’S AGENTS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
DONEPEZIL (generic of Aricept®) DONEPEZIL ODT (generic of Aricept® ODT) RIVASTIGMINE (generic of Exelon®) GALANTAMINE (generic of Razadyne™) GALANTAMINE ER (generic of Razadyne™ ER) GALANTAMINE 4mg/ml solution (generic of Razadyne™)	<i>EXELON® patch (rivastigmine)</i> <i>NAMENDA® (memantine)</i> <i>NAMENDA® 10mg/5ml solution (memantine)</i> <i>COGNEX® (tacrine)</i>	ARICEPT® 23mg EXELON® 2mg/ml solution (rivastigmine)

DRAFT

For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Anti-Migraine Agents

LENGTH OF AUTHORIZATIONS: 6 months

Step Therapy: All anti-migraine agents listed

- 1) *For a preferred brand, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than two weeks of at least one preferred generic*
- 2) *For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than two weeks each of at least two preferred generics or brands*

Other approval criteria:

- Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to ***at least two*** medications not requiring prior approval
 - Contraindication to all medications not requiring prior approval
 - History of unacceptable/toxic side effects to at least ***two preferred*** medications ~~not requiring prior approval~~

CLINICAL CONSIDERATIONS:

Prior Authorization will not be given for prophylactic therapy of migraine headache unless the patient has exhausted or has contraindications to all other “controller” migraine medications (i.e., beta-blockers, neuroleptics, calcium channel blockers, etc.)

ADDITIONAL INFORMATION

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per month is restricted based on the manufacturer’s package insert.

CNS AGENTS: ANTI-MIGRAINE AGENTS – SEROTONIN 5-HT1 RECEPTOR AGONISTS – “Fast” Onset

NO PA REQUIRED PREFERRED GENERIC”	STEP THERAPY REQUIRED "PREFERRED BRAND”	PA REQUIRED
IMITREX® INJECTION (sumatriptan) SUMATRIPTAN TABLETS (generic of Imitrex®)	<i>IMITREX® NASAL SPRAY (sumatriptan) MAXALT® (rizatriptan) MAXALT-MLT® (rizatriptan)</i>	AXERT® (almotriptan) RELPAK® (eletriptan) SUMATRIPTAN INJECTION (generic of Imitrex®) SUMATRIPTAN NASAL SPRAY (generic of Imitrex®) SUMAVEL DOSEPRO® (sumatriptan) ZOMIG® (zolmitriptan) ZOMIG ZMT® (zolmitriptan) ZOMIG® NASAL SPRAY (zolmitriptan)

DRAFT

For P&T Committee Discussion Only

CNS AGENTS: ANTI-MIGRAINE AGENTS – SEROTONIN 5-HT1 RECEPTOR AGONISTS - “Slow” Onset

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
NARATRIPTAN (generic of Amerge®)	<i>FROVA® (frovatriptan)</i>	

CNS AGENTS: ANTI-MIGRAINE AGENTS – SEROTONIN 5-HT1 RECEPTOR AGONIST/NSAID COMBINATION

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
		TREXIMET® (Sumatriptan/ Naproxen)

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For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Antidepressants

GRANDFATHERING:

Patients who have a claim for a non-preferred drug, **or drug requiring step therapy**, in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (new to Medicaid, samples, etc.), will be approved for PA after prescriber contact.

PSYCHIATRIST EXEMPTION:

Physicians who are registered with Ohio Health Plans as having a specialty in psychiatry are exempt from prior authorization of any non-preferred antidepressant, **or step therapy of any preferred brand**, in the standard tablet/capsule dosage forms. Other dosage forms may still require prior authorization by a psychiatrist. The exemption will be processed by the claims system when the pharmacy has submitted the prescriber on the claim using the individual national provider identifier (NPI) for the psychiatrist.

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy: All antidepressants listed

- 1) For a preferred brand, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than one month of at least one preferred generic***
- 2) For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one month each of at least two preferred generics or brands***

Other approval 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 interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
- For orally disintegrating tablet dosage forms, the patient is unable or unwilling to swallow the standard tablet/capsule dosage form.
- The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

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For P&T Committee Discussion Only

ANTIDEPRESSANTS: SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRI)*

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
CITALOPRAM solution (generic of Celexa®) CITALOPRAM tablets (generic of Celexa®) FLUOXETINE HCL 10mg, 20mg (generic of Prozac®) FLUOXETINE HCL solution (generic of Prozac®) FLUVOXAMINE MALEATE (generic of Luvox®) LEXAPRO® solution (escitalopram) LEXAPRO® tablet (escitalopram) PAROXETINE HCL (generic of Paxil®) PAROXETINE HCL solution (generic of Paxil®) SERTRALINE (generic of Zoloft®) SERTRALINE oral concentrate (generic of Zoloft®)		ESCITALOPRAM (generic of Lexapro®) FLUOXETINE ER (generic of Prozac Weekly®) FLUOXETINE HCL 40mg (generic of Prozac®) LUVOX CR® (fluvoxamine) PAROXETINE ER (generic of Paxil CR®) PEXEVA® (paroxetine mesylate)

*Patients on current regimens will be grandfathered.

ANTIDEPRESSANTS: SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRI)*

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
VENLAFAXINE (generic of Effexor®) VENLAFAXINE ER capsule (generic of Effexor XR®)	CYMBALTA® (duloxetine)	PRISTIQ® (desvenlafaxine) VENLAFAXINE ER tablet

*Patients on current regimens will be grandfathered.

ANTIDEPRESSANTS: NOREPINEPHRINE AND DOPAMINE REUPTAKE INHIBITORS (NDRI)*

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
BUPROPION HCL (generic of Wellbutrin®) BUPROPION SR (generic of Wellbutrin SR®) BUPROPION XL (generic of Wellbutrin XL®)		APLENZIN™ (bupropion)

*Patients on current regimens will be grandfathered.

ANTIDEPRESSANTS: ALPHA-2 RECEPTOR ANTAGONISTS*

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
MIRTAZAPINE (generic of Remeron®) MIRTAZAPINE rapid dissolve (generic of Remeron® Sol-Tab)		

*Patients on current regimens will be grandfathered.

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For P&T Committee Discussion Only

ANTIDEPRESSANTS: MONOAMINE OXIDASE INHIBITORS (MAOI)*

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
		PA REQUIRED
		EMSAM [®] patches (selegiline) MARPLAN [®] (isocarboxazid) NARDIL [®] (phenelzine) TRANLYCPROMINE (generic of Parnate [®])

*Patients on current regimens will be grandfathered.

ANTIDEPRESSANTS: SEROTONIN-2 ANTAGONIST/REUPTAKE INHIBITORS (SARI)*

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
NEFAZODONE TRAZODONE		OLEPTRO ER [®] (trazodone)

*Patients on current regimens will be grandfathered.

ANTIDEPRESSANTS: SSRI - SEROTONIN PARTIAL AGONIST*

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
		VIIBRYD [®] (vilazodone)

*Patients on current regimens will be grandfathered.

DRAFT

For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Antipsychotics, Second Generation, Oral

GRANDFATHERING:

Patients who have a claim for a non-preferred drug, *or drug requiring step therapy*, in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (new to Medicaid, samples, etc.), will be approved for PA after prescriber contact.

PSYCHIATRIST EXEMPTION:

Physicians who are registered with Ohio Health Plans as having a specialty in psychiatry are exempt from prior authorization of any non-preferred second generation antipsychotic, *or step therapy of any preferred brand*, in the standard tablet/capsule dosage forms. Other dosage forms may still require prior authorization by a psychiatrist. The exemption will be processed by the claims system when the pharmacy has submitted the prescriber on the claim using the individual identifier for the psychiatrist.

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy: All agents listed

- 1) ***For a preferred brand, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than fourteen days of at least one preferred generic***
- 2) ***For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than fourteen days each of at least two preferred generics or brands***

Other approval 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 interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval
- For orally disintegrating tablet dosage forms, the patient is unable or unwilling to swallow the standard tablet/capsule dosage form.
- The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

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For P&T Committee Discussion Only

ANTIPSYCHOTICS, SECOND GENERATION *

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
GEODON [®] (ziprasidone) RISPERIDONE solution (generic of Risperdal [®]) RISPERIDONE tablet (generic of Risperdal [®]) RISPERIDONE M-TAB (generic of Risperdal M-tab [®]) SEROQUEL [®] (quetiapine)	<i>ABILIFY[®] (aripiprazole)</i> <i>ABILIFY[®] solution (aripiprazole)</i> <i>SEROQUEL XR[®] (quetiapine)</i>	ABILIFY DISCMELT [®] (aripiprazole) CLOZAPINE (generic of Clozaril [®]) CLOZARIL [®] (clozapine) FANAPT [®] (iloperidone) FAZACLO [®] (clozapine) INVEGA [®] (paliperidone) LATUDA [®] (lurasidone) OLANZAPINE (generic of Zyprexa [®]) OLANZAPINE ODT (generic of Zyprexa [®] Zydis) QUETIAPINE (generic of Seroquel [®]) <i>SAPHRIS[®] (asenapine)</i> ZIPRASIDONE (generic of Geodon [®])

*Patients on current regimens will be grandfathered.

ANTIPSYCHOTICS, SECOND GENERATION and SSRI COMBINATION *

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
		<i>SYMBYAX[®] (fluoxetine/olanzapine)</i>

*Patients on current regimens will be grandfathered.

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For P&T Committee Discussion Only

**Central Nervous System (CNS) Agents: Attention Deficit
Hyperactivity Disorder Agents**

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy: Short Acting considered separately from Long Acting products

- 1) *For a preferred brand, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than fourteen days of at least one preferred generic*
- 2) *For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than fourteen days each of at least two preferred generics or brands*

Other approval criteria:

- Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to at least two medications not requiring prior approval
 - Contraindication to all medications not requiring prior approval
 - History of unacceptable/toxic side effects to at least two medications not requiring prior approval

**CNS AGENTS: ATTENTION DEFICIT HYPERACTIVITY DISORDER AGENTS –
Short Acting**

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
AMPHETAMINE SALTS (generic of Adderall®) DEXTROAMPHETAMINE (generic of Dexedrine®) DEXTROSTAT®* (dextroamphetamine) FOCALIN® (dexamethylphenidate) METHYLIN® tablets (methylphenidate) METHYLIN® solution (methylphenidate) METHYLPHENIDATE solution (generic of Methylin®) METHYLPHENIDATE tablets (generic of Ritalin®)	<i>METHYLIN® chewable tablets</i>	DEXMETHYLPHENIDATE (generic of Focalin®) METHAMPHETAMINE (generic of Desoxyn®) PROCENTRA® solution* (dextroamphetamine)

* Dextroamphetamine/methamphetamine products require clinical PA for age 18 and over

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For P&T Committee Discussion Only

CNS AGENTS: ATTENTION DEFICIT HYPERACTIVITY DISORDER AGENTS – Long Acting

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
ADDERALL XR [®] (amphetamine/dextroamphetamine) METHYLPHENIDATE ER (generic of Concerta [®]) DEXTROAMPHETAMINE SA (generic of Dexedrine [®] spansule) METHYLPHENIDATE ER (generic of Ritalin SR [®])	<i>FOCALIN[®] XR</i> <i>(dexmethylphenidate)</i> <i>INTUNIV[®] (guanfacine)</i> <i>METADATE[®] CD</i> <i>(methylphenidate)</i> <i>METADATE[®] ER</i> <i>(methylphenidate)</i> <i>METHYLIN[®] ER</i> <i>(methylphenidate)</i> <i>STRATTERA[®] (atomoxetine)</i> <i>VYVANSE[™] (lisdexamfetamine)</i>	DAYTRANA [®] (methylphenidate) DEXTROAMPHETAMINE-AMPHETAMINE (generic of Adderall XR [®]) <i>KAPVAY[®] (clonidine)</i> RITALIN [®] LA (methylphenidate)

* Dextroamphetamine/methamphetamine products require clinical PA for age 18 and over

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For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Fibromyalgia Agents

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy:

Agents FDA-approved for fibromyalgia will be approved after trial of agents from no less than 3 of the following drug classes in the past 90 days (guidelines suggest use of multiple agents concurrently to manage the signs of fibromyalgia):

- ***Tricyclic antidepressants***
- ***SSRIs***
- ***SNRIs***
- ***Short- and/or long-acting opioids***
- ***Skeletal muscle relaxants***
- ***Tramadol***
- ***Trazodone***
- ***Gabapentin***

ADDITIONAL CRITERIA FOR APPROVAL OF PREGABALIN (LYRICA®)

Pregabalin will be approved for seizure disorders if there is a history of any of the following anticonvulsants in the previous 120 days:

- | | | |
|-----------------------------------|-----------------------------|-----------------------------|
| <i>Diazepam rectal gel</i> | <i>Lacosamide</i> | <i>Primidone</i> |
| <i>Divalproex</i> | <i>Lamotrigine</i> | <i>Topiramate</i> |
| <i>Ethosuximide</i> | <i>Levetiracetam</i> | <i>Valproic acid</i> |
| <i>Felbamate</i> | <i>Methsuxamide</i> | <i>Zonisamide</i> |
| <i>Fosphenytoin</i> | <i>Phenytoin</i> | |

CNS AGENTS: FIBROMYALGIA AGENTS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"
	<i>CYMBALTA® (duloxetine)</i> <i>LYRICA® (pregabalin)</i> <i>SAVELLA® (milnacipran)</i>

DRAFT

For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction

LENGTH OF AUTHORIZATIONS: 30 days for initial authorization
6 months for subsequent authorizations

All products in this class require clinical prior authorization:

1. Patient has diagnosis of opioid addiction (NOT approvable for pain)
2. Prescribing physician has a DATA 2000 waiver ID ("X-DEA" number)
3. Patient has been referred counseling for addiction treatment (re-authorizations should indicate how often the patient is receiving counseling)
4. ***Maximum dose 16mg per day (no patient should receive more than 24mg)***
5. Prescriber has reviewed Ohio Automated Rx Reporting System (OARRS) for opioid prescription use
6. Periodic drug screens are addressed in treatment plan (will be performed by prescriber or by counseling team)
7. For reauthorizations – the dose has been reduced in the previous 6 months, or the patient has been evaluated for a dose reduction and the prescriber and patient agree that a dose reduction would not be beneficial/may be harmful

For buprenorphine only:

1. Patient is pregnant or breast-feeding a methadone-dependent baby
2. Patient has documented allergy to naloxone (very rare)

CENTRAL NERVOUS SYSTEM AGENTS: MEDICATION ASSISTED TREATMENT OF OPIOID ADDICTION

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SUBOXONE [®] SL film (buprenorphine/naloxone) SUBOXONE [®] SL tablets (buprenorphine/naloxone)	BUPRENORPHINE SL tablets (generic of Subutex [®])

DRAFT

For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Multiple Sclerosis Agents

DISEASE MODIFYING AGENTS

LENGTH OF AUTHORIZATIONS: 1 year

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to no less than a one-month trial on at least one medication not requiring prior approval.

CNS AGENTS: MULTIPLE SCLEROSIS DISEASE MODIFYING AGENTS *

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AVONEX® (interferon beta 1a) BETASERON® (interferon beta 1b) COPAXONE® (glatiramer) REBIF® syringe (interferon beta 1a) REBIF® titration pack (interferon beta 1a)	EXTAVIA® (interferon beta 1b) GILENYA® (fingolimod)

*Patients on current regimens will be grandfathered.

POTASSIUM CHANNEL BLOCKERS

LENGTH OF AUTHORIZATIONS: *Initial authorization 180 days,*
Subsequent authorizations 1 year

1. Clinical criteria for initial authorization:
 - Diagnosis of multiple sclerosis; and
 - Prescription written by physician specializing in neurology
2. Criteria for subsequent authorizations
 - Improvement in function

CNS AGENTS: MULTIPLE SCLEROSIS POTASSIUM CHANNEL BLOCKERS

NO PA REQUIRED "PREFERRED"	CLINICAL PA REQUIRED
	AMPYRA® (dalfampridine)

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For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Neuropathic Pain

LENGTH OF AUTHORIZATIONS: **[to be discussed by P&T Committee]**

Step Therapy:

- 1) For a preferred brand, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than fourteen days of at least one preferred generic***
- 2) For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than fourteen days each of at least two preferred generics or brands***

Other approval criteria:

ADDITIONAL CRITERIA FOR APPROVAL OF PREGABALIN (LYRICA®)

Pregabalin will be approved for seizure disorders if there is a history of any of the following anticonvulsants in the previous 120 days:

<i>Diazepam rectal gel</i>	<i>Lacosamide</i>	<i>Primidone</i>
<i>Divalproex</i>	<i>Lamotrigine</i>	<i>Topiramate</i>
<i>Ethosuximide</i>	<i>Levetiracetam</i>	<i>Valproic acid</i>
<i>Felbamate</i>	<i>Methsuxamide</i>	<i>Zonisamide</i>
<i>Fosphenytoin</i>	<i>Phenytoin</i>	

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 interaction with medications not requiring prior approval***
- History of unacceptable/toxic side effects to medications not requiring prior approval***

ADDITIONAL INFORMATION

The requested medication may be approved if there has been a therapeutic failure to no less than a one-month trial of at least two oral medications used for neuropathic pain:

<i>Amitriptyline</i>	<i>Desipramine</i>	<i>Nortriptyline</i>
<i>Amoxapine</i>	<i>Doxepin</i>	<i>Oxcarbazepine</i>
<i>Carbamazepine</i>	<i>Gabapentin</i>	<i>Protriptyline</i>
<i>Clomipramine</i>	<i>Imipramine</i>	<i>Trimipramine</i>

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For P&T Committee Discussion Only

CNS AGENTS: NEUROPATHIC PAIN

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
AMITRIPTYLINE (generic of Elavil®) AMOXAPINE CARBAMAZEPINE (generic of Tegretol®) CLOMIPRAMINE (generic of Anafranil®) DESIPRAMINE (generic of Norpramin®) DOXEPIN (generic of Sinequan®) GABAPENTIN (generic of Neurontin®) IMIPRAMINE (generic of Tofranil®) NORTRIPTYLINE (generic of Pamelor®) OXCARBAZEPINE (generic of Trileptal®) PROTRIPTYLINE (generic of Vivactil®) TRIMIPRAMINE (generic of Surmontil®)	<i>CYMBALTA® (Duloxetine)</i> <i>LYRICA® (Pregabalin)</i>	GRALISE® (gabapentin) HORIZANT® (gabapentin enacarbil) LIDODERM® (lidocaine patch)

DRAFT

For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Parkinson's Agents

LENGTH OF AUTHORIZATIONS: 1 year

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

ADDITIONAL INFORMATION

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 one-month trial of at least one medication not requiring prior approval
- The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

CNS AGENTS: PARKINSON'S AGENTS – COMT Inhibitor

NO PA REQUIRED "PREFERRED"	PA REQUIRED
COMTAN [®] (entacapone)	TASMAR [®] (tolcapone)

CNS AGENTS: PARKINSON'S AGENTS – Dopamine Receptor Agonists, Non-Ergot, Injectable

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	APOKYN [®] (apomorphine)

CNS AGENTS: PARKINSON'S AGENTS – Dopamine Receptor Agonists, Non-Ergot, Oral

NO PA REQUIRED "PREFERRED"	PA REQUIRED
PRAMIPEXOLE (generic of Mirapex [®])	MIRAPEX ER [®] (pramipexole)
ROPINIROLE (generic of Requip [®])	REQUIP XL [®] (ropinirole)

CNS AGENTS: PARKINSON'S AGENTS – Dopaminergic Agents, Oral

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CARBIDOPA/LEVODOPA (generic of Sinemet [®])	AZILECT [®] (rasagiline)
CARBIDOPA/LEVODOPA CR (generic of Sinemet [®] CR)	CARBIDOPA/LEVODOPA DISPERSIBLE TABLETS (generic of Parcopa [®])
SELEGILINE (generic of Eldepryl [®])	STALEVO [®] (Carbidopa/Levodopa/Entacapone)
	ZELAPAR [®] ODT (selegiline)

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For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Restless Legs Syndrome

LENGTH OF AUTHORIZATIONS: *1 year*

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 interaction with medications not requiring prior approval*
- *History of unacceptable/toxic side effects to medications not requiring prior approval*

ADDITIONAL INFORMATION

The requested medication may be approved if there has been a therapeutic failure to no less than a one-month trial of at least one medication not requiring prior approval

CNS AGENTS: RESTLESS LEGS SYNDROME AGENTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
PRAMIPEXOLE (generic of Mirapex [®]) ROPINIROLE (generic of Requip [®])	HORIZANT [®] (Gabapentin Enacarbil)

DRAFT

For P&T Committee Discussion Only

**Central Nervous System (CNS) Agents: Sedative-Hypnotics,
Non-Barbiturate**

LENGTH OF AUTHORIZATIONS: 6 months

Step Therapy:

- 1) For a preferred brand, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than ten days each of at least two preferred generics***
- 2) For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than ten days each of at least three preferred generics or brands***

Other approval 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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
- If the prescriber indicates the patient has a history of addiction, then may approve a requested non-controlled medication.

CNS AGENTS: SEDATIVE-HYPNOTICS, NON-BARBITURATE

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
ESTAZOLAM (generic of Prosom [®]) FLURAZEPAM (generic of Dalmane [®]) TEMAZEPAM 15mg, 30mg (generic of Restoril [®]) ZALEPLON (generic of Sonata [®]) ZOLPIDEM (generic of Ambien [®])	<i>LUNESTA[®] (eszopiclone)</i>	DORAL [®] (quazepam) EDLUAR [®] SL (zolpidem) INTERMEZZO [®] SL (zolpidem) ROZEREM [®] (ramelteon) SILENOR [®] (doxepin) TEMAZEPAM 7.5mg, 22.5mg (generic of Restoril [®]) ZOLPIDEM ER (generic of Abmien [®] CR) ZOLPIMIST [®] (zolpidem)

DRAFT

For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Skeletal Muscle Relaxants, Non-Benzodiazepine

LENGTH OF AUTHORIZATIONS: 1 year

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to an agent not requiring prior approval, then may approve the requested medication.

CNS AGENTS: SKELETAL MUSCLE RELAXANTS - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BACLOFEN (generic of Lioresal [®])	CARISOPRODOL (generic of Soma [®]) *
CHLORZOXAZONE (generic of Parafon Forte [®])	CARISOPRODOL COMPOUND (generic of Soma Compound [®]) *
CYCLOBENZAPRINE (generic of Flexeril [®])	CARISOPRODOL COMPOUND W/CODEINE (generic of Soma Compound w/Codeine [®]) *
DANTROLENE (generic of Dantrium [®])	CYCLOBENZAPRINE ER (generic of Amrix [®])
METHOCARBAMOL (generic of Robaxin [®])	FEXMID [®] (cyclobenzaprine)
TIZANIDINE tablets (generic of Zanaflex [®])	METAXOLONE (generic of Skelaxin [®])
	ORPHENADRINE (generic of Norflex [®])
	ORPHENADRINE COMPOUND (generic of Norgesic [®])
	ORPHENADRINE COMPOUND FORTE (generic of Norgesic Forte [®])
	SOMA [®] * (carisoprodol)
	ZANAFLEX [®] capsules (tizanidine)

* Note: Clinical criteria must be met for Soma[®]/Carisoprodol products– approvable only if no other muscle relaxant or agent to treat fibromyalgia, or any musculoskeletal condition, would serve the clinical needs of the patient.

DRAFT

For P&T Committee Discussion Only

Central Nervous System (CNS) Agents: Smoking Deterrents

LENGTH OF AUTHORIZATIONS: 1 year

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to an agent not requiring prior approval, then may approve the requested medication.

CNS AGENTS: SMOKING DETERRENTS – NICOTINE REPLACEMENT

NO PA REQUIRED "PREFERRED"	PA REQUIRED
COMMIT™ lozenge (nicotine) NICODERM®CQ patch (nicotine) NICORETTE® gum (nicotine) NICOTINE gum (generic of Nicorette®) NICOTINE lozenge (generic of Commit™) NICOTINE patch (generics) NICOTROL® inhaler (nicotine) NICOTROL® nasal spray(nicotine)	

CNS AGENTS: SMOKING DETERRENTS – NON-NICOTINE PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BUPROPION (generic of Zyban®) CHANTIX®(varenicline)	

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For P&T Committee Discussion Only

Endocrine Agents: Diabetes Adjunctive Therapy

LENGTH OF AUTHORIZATIONS: 1 year

All drugs in this class require step therapy: Patient must have a claim for an oral hypoglycemic or insulin in the previous 120 days.

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
 - Condition is difficult to control (i.e. prone to ketoacidosis, hypoglycemia)
2. The requested medication may be approved if there has been a therapeutic failure to at least one medication within the same class not requiring prior authorization.

ENDOCRINE AGENTS: DIABETES – AMYLIN ANALOGS

STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED
SYMLIN [®] (pramlintide)	

ENDOCRINE AGENTS: DIABETES – INCRETIN MIMETICS

STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED
BYDUREON [®] (exenatide)	
BYETTA [™] (exenatide)	
VICTOZA [®] (liraglutide)	

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For P&T Committee Discussion Only

Endocrine Agents: Diabetes – Insulin

LENGTH OF AUTHORIZATIONS: 1 year

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
 - Condition is difficult to control (i.e. prone to ketoacidosis, hypoglycemia)
2. The requested medication may be approved if there has been a therapeutic failure to at least one medication within the same class not requiring prior authorization.

ENDOCRINE AGENTS: DIABETES - INSULINS - Rapid and Short Acting*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
HUMALOG [®] (insulin lispro) HUMULIN R [®] (insulin regular human) HUMULIN R 500-U [®] (insulin regular human) NOVOLIN R [®] (insulin regular human) NOVOLOG [®] (insulin aspart) RELION R [®] (insulin regular human)	APIDRA [®] (insulin glulisine)

* Patients on current insulin regimens will be grandfathered.

ENDOCRINE AGENTS: DIABETES - INSULINS - Intermediate Acting*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
HUMALOG MIX 50/50, 75/25 [®] (insulin lispro protamine/insulin lispro) HUMULIN 50/50 [®] (insulin NPH/regular) HUMULIN 70/30 [®] (insulin NPH/regular) HUMULIN N [®] (insulin NPH) NOVOLIN 70/30 [®] (insulin NPH/regular) NOVOLIN N [®] (insulin NPH) NOVOLOG MIX 70/30 [®] (insulin aspart protamine/insulin aspart) RELION 70/30 [®] RELION N [®] (insulin NPH)	

* Patients on current insulin regimens will be grandfathered.

ENDOCRINE AGENTS: DIABETES - INSULINS - Long Acting*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
LANTUS [®] (insulin glargine)	LEVEMIR [®] (insulin detemir)

* Patients on current insulin regimens will be grandfathered.

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For P&T Committee Discussion Only

Endocrine Agents: Diabetes – Oral Hypoglycemics

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy: All oral hypoglycemics

- 1) *For a preferred brand, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than one month of at least one preferred generic*
- 2) *For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one month each of at least two preferred generics or brands*

Other approval criteria:

Is there any reason the patient cannot be changed to a medication within the same class not requiring prior approval? Acceptable reasons include:

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

ENDOCRINE AGENTS: DIABETES – ORAL HYPOGLYCEMICS, ALPHA-GLUCOSIDASE INHIBITORS

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
ACARBOSE (generic of Precose®)	<i>GLYSET® (miglitol)</i>	

ENDOCRINE AGENTS: DIABETES – ORAL HYPOGLYCEMICS, BIGUANIDES

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
METFORMIN (generic of Glucophage®) METFORMIN ER (generic of Glucophage XR®)		FORTAMET® (metformin) GLUMETZA™ (metformin) RIOMET® 500mg/5ml (Metformin)

ENDOCRINE AGENTS: DIABETES – ORAL HYPOGLYCEMICS, BIGUANIDE/SULFONYLUREA COMBINATION

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
GLIPIZIDE/METFORMIN (generic of Metaglip®) GLYBURIDE/METFORMIN (generic of Glucovance®)		

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For P&T Committee Discussion Only

ENDOCRINE AGENTS: DIABETES – DIPEPTIDYL PEPTIDASE-4 INHIBITOR

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
	JANUVIA [®] (sitagliptin) ONGLYZA [®] (saxagliptin) TRADJENTA [™] (linagliptin)	

ENDOCRINE AGENTS: DIABETES – DIPEPTIDYL PEPTIDASE-4 INHIBITOR COMBINATIONS

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
	JANUMET XR [™] (sitagliptin/ metformin) JANUMET [™] (sitagliptin/metformin) JENTADUETO [™] (linagliptin/ metformin) KOMBIGLYZE XR [®] (saxagliptin/ metformin)	

ENDOCRINE AGENTS: DIABETES – ORAL HYPOGLYCEMICS, MEGLITINIDES

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
STARLIX [®] (nateglinide)		NATEGLINIDE (generic of Starlix [®]) PRANDIN [®] (repaglinide)

ENDOCRINE AGENTS: DIABETES – ORAL HYPOGLYCEMICS, MEGLITINIDE/BIGUANIDE COMBINATION

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
		PRANDIMET [®] (repaglinide/ metformin)

ENDOCRINE AGENTS: DIABETES – ORAL HYPOGLYCEMICS, SULFONYLUREAS SECOND GENERATION

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
GLIMEPIRIDE (generic of Amaryl [®]) GLIPIZIDE (generic of Glucotrol [®]) GLIPIZIDE ER (generic of Glucotrol XL [®]) GLYBURIDE (generic of Diabeta [®] , Micronase [®]) GLYBURIDE MICRONIZED (generic of GlynasePressTabs [®])		

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**ENDOCRINE AGENTS: DIABETES – ORAL HYPOGLYCEMICS,
THIAZOLIDINEDIONES**

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
	<i>ACTOS[®] (pioglitazone)</i>	AVANDIA [®] (rosiglitazone)

**ENDOCRINE AGENTS: DIABETES – ORAL HYPOGLYCEMICS,
THIAZOLIDINEDIONES / SULFONYLUREAS COMBINATION**

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
	<i>DUETACT[®] (glimepiride/pioglitazone)</i>	AVANDARYL [®] (glimepiride/ rosiglitazone)

**ENDOCRINE AGENTS: DIABETES – ORAL HYPOGLYCEMICS,
THIAZOLIDINEDIONES / BIGUANIDE COMBINATION**

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
	<i>ACTOPLUS MET[®] (pioglitazone/ metformin) ACTOPLUS MET XR[®] (pioglitazone/metformin)</i>	AVANDAMET [®] (rosiglitazone/ metformin)

**ENDOCRINE AGENTS: DIABETES – ORAL HYPOGLYCEMICS, LIPOTROPIC/DPP-4
COMBINATION**

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
	JUVISYNC [®] (sitagliptin/simvastatin)	

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For P&T Committee Discussion Only

Endocrine Agents: Estrogenic Agents

LENGTH OF AUTHORIZATIONS: 1 year

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to at least two trials of thirty days each with medications not requiring prior approval

ENDOCRINE AGENTS: ESTROGENS – ORAL ESTROGENS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CENESTIN [®] (synthetic conjugated estrogens) ENJUVIA [®] (synthetic conjugated estrogens) ESTRADIOL (generic of Estrace [®]) ESTROPIPATE MENEST [®] (esterified estrogens) PREMARIN [®] (conjugated estrogens)	FEMTRACE [®] (estradiol)

ENDOCRINE AGENTS: ESTROGENS – ORAL ESTROGEN/PROGESTERONE COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ETHINYL ESTRADIOL/NORETHINDRONE ACETATE (generic of FemHRT [®]) FEMHRT [®] (norethindrone/ethinylestradiol) PREMPHASE [®] (medroxyprogesterone/estrogens conjugated) PREMPRO [®] (medroxyprogesterone/estrogens conjugated)	ANGELIQ [®] (drospirenone/estradiol) ESTRADIOL/NORETHINDRONE ACETATE tablets (generic of Activella [®]) PREFEST [®] (estradiol/norgestimate)

ENDOCRINE AGENTS: ESTROGENS – TRANSDERMAL ESTROGENS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ALORA [®] patch (estradiol) ESTRADIOL patch (generic of Climara [®])	DIVIGEL [®] transdermal gel (estradiol) ELESTRIN [®] transdermal gel (estradiol) ESTRASORB [®] transdermal emulsion (estradiol) EVAMIST [®] transdermal solution (estradiol) MENOSTAR [®] patch (estradiol) VIVELLE-DOT [®] patch (estradiol)

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**ENDOCRINE AGENTS: ESTROGENS – TRANSDERMAL
ESTROGEN/PROGESTERONE COMBINATIONS**

NO PA REQUIRED “PREFERRED”	PA REQUIRED
COMBIPATCH [®] (estradiol/norethindrone)	CLIMARA PRO [®] (estradiol/levonorgestrel oral)

ENDOCRINE AGENTS: ESTROGENS – VAGINAL ESTROGENS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
ESTRING [®] vaginal ring (estradiol)	ESTRACE [®] vaginal cream (estradiol)
PREMARIN [®] vaginal cream (estrogens conjugated)	FEMRING [®] vaginal ring (estradiol)
	VAGIFEM [®] vaginal tablet (estradiol)

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For P&T Committee Discussion Only

Endocrine Agents: Growth Hormone

LENGTH OF AUTHORIZATIONS: varies as listed below.

All products in this class require clinical prior authorization:

1. Initial Authorization For Children:

Must have one of the following diagnoses from an endocrinologist or gastroenterologist, nephrologist or obstetrician:

- a. *Growth deficiency associated with a specific genetic syndrome – 1-year approval*
 - i. *Krause-Kivlin Syndrome, or*
 - ii. *Noonan Syndrome, or*
 - iii. *Prader-Willi Syndrome, or*
 - iv. *Turner Syndrome*
- b. *Growth failure due to chronic renal insufficiency in pediatric kidney transplant or dialysis patients less than 6 years of age – 6-month approval;*
- c. *Fetal growth restriction – 1- year approval*
 - i. *Intrauterine growth restriction with ultrasound biometry*
 - ii. *Small for Gestational Age (inadequate catch up in first 2 years)*
 1. *Birth weight and or length is/was less than the 3rd percentile for gestational age*
 2. *Height less than 2 SD below the mean for age*
- d. *Growth Hormone deficiency – 6-month approval*
 - i. *Rule out other causes (hypothyroidism, IGF-1, ILGFB protein-3); and*
 - ii. *Must not have attained epiphyseal closure as determined by X-ray; and*
 - iii. *Failed to respond to at least two growth hormone stimulation tests, measured GH level of less than 10ng/ml after stimulation*
 1. *Arginine*
 2. *Clonidine*
 3. *Glucagon*
 4. *Insulin*
 5. *Levodopa*
 6. *Propranolol; and*
 - iv. *One of the following:*
 1. *Height is more than 2 SD below the average for the population mean height for age and sex or gestational age AND*
 2. *Height velocity measured over one year is more than 1 SD below the mean for chronological age or,*
 3. *For children over 2 years old, there is a decrease in height greater than 0.5 SD over one year, or*
 4. *Bone age obtained within the least year assessed through x-ray indicating a greater than or equal to 2 SD below the mean when compared to chronological age*

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For P&T Committee Discussion Only

2. **Reauthorization for Children – 1-year approval:**
 - a. **Specific genetic syndrome and chronic renal insufficiency - Diagnosis**
 - b. **Fetal growth restriction, SGA and Growth Hormone Deficiency**
 - i. **Must not have attained epiphyseal closure as determined by X-ray**
 - ii. **Increase in growth at least 3cm per year**
3. **Authorization and reauthorization for adults – 1- year approval:**

Must have one of the following diagnoses by a gastroenterologist or endocrinologist

 - a. **Short bowel syndrome and dependent on parenteral nutrition – 4-week approval**
 - b. **Wasting or cachexia associated with HIV – 3-month initial approval**
 - i. **Involuntary weight loss of >10% from baseline or BMI < 20, and**
 - ii. **Patient has not responded to high-calorie diet**
 - c. **Acquired growth hormone deficiency – 1-year approval**
 - i. **Congenital absence of pituitary**
 - ii. **Pituitary gland removal**
 - iii. **Pituitary insufficiency due to trauma, tumor, or radiation treatments, and patient has not responded to growth hormone stimulation test, measured GH level of less than 5 ng/ml after stimulation**
 - d. **Childhood Onset: Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes – 1-year approval**

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

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 three-month trial of at least one medication not requiring prior approval

GROWTH HORMONES

CLINICAL PA REQUIRED “PREFERRED”	PA REQUIRED
GENOTROPIN [®] CARTRIDGE (somatropin)	HUMATROPE [®] CARTRIDGE (somatropin)
GENOTROPIN [®] MINIQUICK (somatropin)	HUMATROPE [®] VIAL (somatropin)
NORDITROPIN [®] CARTRIDGE (somatropin)	NUTROPIN AQ [®] NUSPIN (somatropin)
NORDITROPIN [®] FLEXPLO (somatropin)	NUTROPIN AQ [®] PEN CARTRIDGE (somatropin)
NORDITROPIN [®] NORDIFLEX (somatropin)	NUTROPIN AQ [®] VIAL (somatropin)
NORDITROPIN [®] VIAL (somatropin)	NUTROPIN [®] VIAL (somatropin)
OMNITROPE [®] CARTRIDGE (somatropin)	SAIZEN [®] CARTRIDGE (somatropin)
OMNITROPE [®] VIAL (somatropin)	SAIZEN [®] VIAL (somatropin)
TEV-TROPIN [®] VIAL (somatropin)	SEROSTIM [®] VIAL (somatropin)
	ZORBTIVE [®] VIAL (somatropin)

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For P&T Committee Discussion Only

Endocrine Agents: Osteoporosis – Bone Ossification Enhancers

LENGTH OF AUTHORIZATIONS: 1 year

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. There are two (2) classes of drugs in this category of Ossification Enhancers
 - a. Bisphosphonates
 - b. Calcitonin-Salmon

CRITICAL INFORMATION

Patients should only be on ONE of the above therapeutic classes (bisphosphonates, calcitonin-salmon).

ENDOCRINE AGENTS: OSTEOPOROSIS - BONE OSSIFICATION ENHANCERS - ORAL BISPHOSPHONATES

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ALENDRONATE (generic of Fosamax [®])	ACTONEL [®] (risedronate) ATELVIA [®] (risedronate) BONIVA [®] (ibandronate) ETIDRONATE (generic of Didronel [®]) FOSAMAX [®] ORAL SOLN 70mg/75ml (alendronate) FOSAMAX PLUS D [™] (alendronate/cholecalciferol) SKELID [®] (tiludronate)

ENDOCRINE AGENTS: OSTEOPOROSIS - BONE OSSIFICATION ENHANCERS - CALCITONIN-SALMON

NO PA REQUIRED "PREFERRED"	PA REQUIRED
FORTICAL [®] (calcitonin salmon) MIACALCIN [®] (calcitonin salmon)	CALCITONIN-SALMON (generic of Miacalcin [®])

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For P&T Committee Discussion Only

Gastrointestinal Agents: Anti-Emetics

LENGTH OF AUTHORIZATIONS: 1 year

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

GASTROINTESTINAL AGENTS: ANTI-EMETIC AGENTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
EMEND [®] (aprepitant)	ANZEMET [®] (dolasetron)
EMEND [®] TRIFOLD (aprepitant)	GRANISETRON solution (generic of Kytril [®])
ONDANSETRON ODT (generic of Zofran [®])	GRANISETRON tablet (generic of Kytril [®])
ONDANSETRON oral solution (generic of Zofran [®])	SANCUSO [®] patch (granisetron)
ONDANSETRON tablets (generic of Zofran [®])	ZUPLENZ [®] soluble film (ondansetron)

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For P&T Committee Discussion Only

Gastrointestinal Agents: Chronic Constipation Agents

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy:

There must have been inadequate clinical response to over-the-counter alternatives, including a trial of no less than one month each of at least two of the preferred products.

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if the following is true:
 - ***If there has been a therapeutic failure to no less than a one-month trial of at least two medications not requiring prior approval***

GASTROINTESTINAL AGENTS: CHRONIC CONSTIPATION AGENTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
POLYETHYLENE GLYCOL (generic of Miralax [®]) BISACODYL(generic of Dulcolax [®]) SENNA (generic of Senokot [®]) CASANTHRANOL/DOCUSATE SODIUM (generic of Peri-Colace [®])	<i>AMITIZA[®] (lubiprostone)</i>

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For P&T Committee Discussion Only

Gastrointestinal Agents: H. Pylori Packages

LENGTH OF AUTHORIZATIONS: 1 course of treatment

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

Also consider whether components are appropriate vs. package

GASTROINTESTINAL AGENTS: H. PYLORI PACKAGES

NO PA REQUIRED "PREFERRED"	PA REQUIRED
HELIDAC [®] (metronidazole/tetracycline/bismuth subsalicylate)	OMECLAMOX-PAK [®] (omeprazole/clarithromycin/amoxicillin) PREVPAC [®] (lansoprazole/amoxicillin/clarithromycin) PYLERA [®] (metronidazole/tetracycline/bismuth subsalicylate)

DRAFT

For P&T Committee Discussion Only

Gastrointestinal Agents: Pancreatic Enzymes

LENGTH OF AUTHORIZATIONS: 1 year

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

ADDITIONAL INFORMATION

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 one-month trial of at least [number to be discussed by P&T Committee if any non-preferred drugs are added] medications not requiring prior approval

GASTROINTESTINAL AGENTS: PANCREATIC ENZYMES

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CREON [®] (pancrelipase) PANCREAZE [®] (pancrelipase) PANCRELIPASE 5000 ZENPEP [®] (pancrelipase)	

DRAFT

For P&T Committee Discussion Only

Gastrointestinal Agents: Proton Pump Inhibitors

LENGTH OF AUTHORIZATIONS: 6 months, except as listed under clinical criteria

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to no less than a one-month trial of at least one medication in the same class not requiring prior approval, then may approve the requested medication.
3. If a medication requiring prior approval was initiated in the hospital for the treatment of a condition such as a GI bleed, may approve the requested medication.

ADDITIONAL INFORMATION

- No PA needed for preferred PPI at once-daily dosing
- No PA needed for preferred PPI at any dose for age under 21
- Must have therapeutic failure on preferred agent before PA of non-preferred

CLINICAL CRITERIA FOR PPI DOSES GREATER THAN ONCE DAILY

1. For diagnosis of H. Pylori, BID dosing may be authorized for 1 month
2. For diagnosis of COPD, Dyspepsia, Gastritis, Gastroparesis, Symptomatic Uncomplicated Barrett’s Esophagus, Carcinoma of GI tract, Crest Syndrome, Esophageal Varices, Scleroderma, Systemic Mastocytosis, Zollinger Ellison Syndrome:
 - Length of authorization: 1 year
 - Criteria for approval: Must have failed QD dosing

GASTROINTESTINAL AGENTS: PPIs

<u>NO PA REQUIRED “PREFERRED”</u>	<u>PA REQUIRED</u>
LANSOPRAZOLE capsules (generic of Prevacid®)	ACIPHEX® (rabeprazole)
LANSOPRAZOLE ODT (generic of Prevacid SoluTab®) (No PA required for age 6 or under)	DEXILANT® (dexlansoprazole)
OMEPRAZOLE capsules (generic of Prilosec®)	LANSOPRAZOLE ODT (generic of Prevacid SoluTab®) (PA required for age over 6)
OMEPRAZOLE tablets (generic of Prilosec OTC®)	NEXIUM® capsules (esomeprazole)
PANTOPRAZOLE (generic of Protonix®)	NEXIUM® packets (esomeprazole)
PREVACID 24 HOUR® (OTC) (lansoprazole)	OMEPRAZOLE/SOCIUM BICARBONATE
PRILOSEC OTC® tablets (omeprazole)	PRILOSEC® suspension (omeprazole)
ZEGERID OTC® (omeprazole/sodium bicarbonate)	PROTONIX® suspension

DRAFT

For P&T Committee Discussion Only

Gastrointestinal Agents: Ulcerative Colitis Agents

LENGTH OF AUTHORIZATIONS: 6 months

Step Therapy: Oral agents only

- 1) *For a preferred brand oral agent, there must have been inadequate clinical response to preferred generic oral alternatives, including a trial of no less than one month of at least one preferred generic*
- 2) *For a non-preferred oral agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one month each of at least two preferred generics or brands*

Other 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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

- 1. Ulcerative Colitis Agents are available in both oral (IR, ER) and rectal (enema, suppository) formulations. Patients with mild or moderate disease may be treated with either topical or oral agents.
- 2. The efficacy among the different 5-ASA derivatives appears to be comparable.

GASTROINTESTINAL AGENTS: ULCERATIVE COLITIS AGENTS - ORAL

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
BALSALAZIDE DISODIUM (generic of Colazal [®]) SULFASALAZINE (generic of Azulfidine [®]) SULFASALAZINE EC (generic of Azulfidine Entab [®])	<i>APRISO[®] (mesalamine)</i> <i>ASACOL[®] (mesalamine)</i>	DIPENTUM [®] (olsalazine) PENTASA [®] (mesalamine) <i>ASACOL HD[®] (mesalamine)</i> <i>LIALDA[®] (mesalamine)</i>

GASTROINTESTINAL AGENTS: ULCERATIVE COLITIS AGENTS - RECTAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CANASA [®] suppositories (mesalamine) MESALAMINE enema (generic of Rowasa [®] and SFRowasa [®])	MESALAMINE enema kit (generic for Rowasa [®] kit)

DRAFT

For P&T Committee Discussion Only

Genitourinary Agents: Benign Prostatic Hyperplasia

LENGTH OF AUTHORIZATIONS: 1 year

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
 - Contraindications to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. Patient must have a therapeutic failure to no less than a one-month trial on at least one medication not requiring prior approval.

ADDITIONAL CRITERIA FOR APPROVAL OF TADALAFIL (CIALIS®):

Patient must have diagnosis of benign prostatic hyperplasia

GENITOURINARY AGENTS: BENIGN PROSTATIC HYPERPLASIA AGENTS – ALPHA-1 ADRENERGIC BLOCKERS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
DOXAZOSIN (generic of Cardura®) PRAZOSIN (generic of Minipress®) TAMSULOSIN (generic of Flomax®) TERAZOSIN (generic of Hytrin®)	ALFUZOSIN (generic of Uroxatral®) CARDURA® XL (doxazosin) RAPAFLO® (silodosin)

GENITOURINARY AGENTS: BENIGN PROSTATIC HYPERPLASIA AGENTS – 5-ALPHA REDUCTASE INHIBITORS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
FINASTERIDE (generic of Proscar®)	AVODART® (dutasteride)

GENITOURINARY AGENTS: BENIGN PROSTATIC HYPERPLASIA AGENTS – COMBINATION 5-ALPHA REDUCTASE INHIBITOR/ALPHA-1 ADRENERGIC BLOCKER

NO PA REQUIRED “PREFERRED”	PA REQUIRED
	JALYN® (dutasteride/tamsulosin)

GENITOURINARY AGENTS: PHOSPHODIESTERASE TYPE 5 INHIBITORS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
	CIALIS® (tadalafil) *

* Note: Clinical PA required for Cialis®. Patient must have diagnosis of benign prostatic hyperplasia.

DRAFT

For P&T Committee Discussion Only

Genitourinary Agents: Electrolyte Depletor Agents

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy:

- 1) *For a preferred brand agent, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than one week of at least one preferred generic*
- 2) *For a non-preferred agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one week each of at least two preferred generics or brands*

Other 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 interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

CLINICAL INFORMATION

Calcium acetate products may lead to hypercalcemia. This agent is recommended in patients with normal serum calcium levels.

GENITOURINARY AGENTS: ELECTROLYTE DEPLETERS FOR HYPERPHOSPHATEMIA

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
CALCIUM ACETATE (generic of PhosLo [®] gelcap) CALCIUM CARBONATE CALPHRON [®] (calcium acetate) ELIPHOS [®] (calcium acetate) PHOSLO [®] (calcium acetate)	MAGNEBIND [®] (calcium carbonate/magnesium carbonate/folic acid) RENAGEL [®] (sevelamer)	REVELA [®] (sevelamer) FOSRENOL [®] (lanthanum carbonate) PHOSLYRA [®] solution (calcium acetate)

DRAFT

For P&T Committee Discussion Only

Genitourinary Agents: Urinary Antispasmodics

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy:

- 1) *For a preferred brand agent, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than one month of at least one preferred generic*
- 2) *For a non-preferred agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one month each of at least two preferred generics or brands*

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

GENITOURINARY AGENTS: URINARY ANTISPASMODICS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
OXYBUTYNIN ER (generic of Ditropan [®] XL) OXYBUTYNIN syrup (generic of Ditropan [®]) OXYBUTYNIN tablets (generic of Ditropan [®]) SANCTURA [®] (trospium)	<i>ENABLEX[®] (darifenacin)</i> <i>OXYTROL[®] patch (oxybutynin)</i> <i>SANCTURA XR[®] (trospium)</i> <i>VESICARE[®] (solifenacin)</i>	DETROL [®] (tolterodine) DETROL [®] LA (tolterodine) GELNIQUE [®] (oxybutynin) TOVIAZ [®] (fesoterodine) TROSPIUM (generic of Sanctura [®])

DRAFT

For P&T Committee Discussion Only

Infectious Disease Agents: Antibiotics – Cephalosporins

LENGTH OF AUTHORIZATIONS: for the date of service only; no refills

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 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
3. If there have been therapeutic failures to no less than a three-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

**INFECTIOUS DISEASE AGENTS: CEPHALOSPORINS, FIRST GENERATION –
Capsules and Tablets**

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CEFADROXIL (generic of Duricef®) CEPHALEXIN (generic of Keflex®)	KEFLEX 750mg capsule (cephalexin)

**INFECTIOUS DISEASE AGENTS: CEPHALOSPORINS, FIRST GENERATION –
Suspensions and Liquids**

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CEFADROXIL suspension (generic of Duricef®) CEPHALEXIN suspension (generic of Keflex® Suspension)	

**INFECTIOUS DISEASE AGENTS: CEPHALOSPORINS, SECOND GENERATION –
Capsules and Tablets**

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CEFACLOR (generic of Ceclor®) CEFACLOR ER (generic of Ceclor CD®) CEFPROZIL (generic of Cefzil®) CEFUROXIME (generic of Cefitin®)	

DRAFT

For P&T Committee Discussion Only

**INFECTIOUS DISEASE AGENTS: CEPHALOSPORINS, SECOND GENERATION –
Suspensions and Liquids**

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CEFACLOR suspension (generic of Ceclor [®])	CEFTIN [®] suspension (PA required for age over 12) (cefuroxime)
CEFTIN [®] suspension (no PA required for age 12 or under) (cefuroxime)	CEFUROXIME suspension (generic of Ceftin [®]) (PA required for age over 12)
CEFUROXIME suspension (generic of Ceftin [®]) (no PA required for age 12 or under)	CEFPROZIL suspension (generic of Cefzil [®]) (PA required for age over 12)
CEFPROZIL suspension (generic of Cefzil [®]) (no PA required for age 12 or under)	

**INFECTIOUS DISEASE AGENTS: CEPHALOSPORINS, THIRD GENERATION –
Capsules and Tablets**

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CEFDINIR (generic of Omnicef [®])	CEDAX [®] (ceftibuten)
	CEFDITOREN PIVOXIL (generic of Spectracef [®])
	CEFPODOXIME (generic of Vantin [®])
	SUPRAX [®] (cefixime)

**INFECTIOUS DISEASE AGENTS: CEPHALOSPORINS, THIRD GENERATION –
Suspensions and Liquids**

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CEFDINIR suspension (generic of Omnicef [®])	CEDAX [®] suspension (ceftibuten)
	SUPRAX [®] suspension (cefixime)
	CEFPODOXIME suspension (generic of Vantin [®])

DRAFT

For P&T Committee Discussion Only

Infectious Disease Agents: Antibiotics – Macrolides

LENGTH OF AUTHORIZATIONS: for the date of service only; no refills

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 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
3. If there has been a therapeutic failure to no less than a three-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

INFECTIOUS DISEASE AGENTS: MACROLIDES - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AZITHROMYCIN tablets and suspension (generic of Zithromax [®])	PCE [®] (erythromycin base)
CLARITHROMYCIN ER (generic of Biaxin XL [®])	ZMAX [™] (Azithromycin ER) for oral suspension
CLARITHROMYCIN tablets and suspension (generic of Biaxin [®])	
ERYPED [®] (erythromycin ethylsuccinate)	
ERY-TAB [®] (erythromycin base)	
ERYTHROCIN STEARATE [®] (erythromycin stearate)	
ERYTHROMYCIN BASE	
ERYTHROMYCIN ETHYLSUCCINATE	
ERYTHROMYCIN W/SULFISOXAZOLE	

DRAFT

For P&T Committee Discussion Only

Infectious Disease Agents: Antibiotics – Quinolones

LENGTH OF AUTHORIZATIONS: for the date of service only; no refills

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 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
3. If there has been a therapeutic failure to at least a three-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

1. If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.
2. If the prescriber expresses concern over safety issues of a preferred agent (~~e.g., cardiotoxicity associated with Avelox[®]~~), a non-preferred agent may be approved.

INFECTIOUS DISEASE AGENTS: QUINOLONES, SECOND GENERATION - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CIPROFLOXACIN (generic of Cipro [®]) CIPRO [®] suspension (no PA required for age 12 or under) (ciprofloxacin) OFLOXACIN (generic of Floxin [®])	CIPRO [®] suspension (PA required for age over 12) (ciprofloxacin) CIPROFLOXACIN ER (generic of Cipro [®] XR) NOROXIN [®] (norfloxacin) PROQUIN [®] XR (ciprofloxacin)

INFECTIOUS DISEASE AGENTS: QUINOLONES, THIRD GENERATION - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
LEVOFLOXACIN (generic of Levaquin [®])	AVELOX[®] (moxifloxacin) AVELOX ABC PACK[®] (moxifloxacin)

INFECTIOUS DISEASE AGENTS: QUINOLONES, FOURTH GENERATION - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	FACTIVE[®] (gemifloxacin)

DRAFT

For P&T Committee Discussion Only

Infectious Disease Agents: Antifungals for Onychomycosis & Systemic Infections

LENGTH OF AUTHORIZATIONS: For the duration of the prescription (up to 6 months)

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:
Drug interactions (inhibition of CYP450 system)
Ketoconazole > Itraconazole > Voriconazole > Fluconazole
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the patient has a serious illness that causes them to be immunocompromised [i.e. AIDS, cancer, organ (solid or non-solid) transplant] then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

1. If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital or other similar location, or if the patient has just become Medicaid eligible and is already on a course of treatment with a medication requiring prior approval, then may approve the requested medication.
2. If the request is for a diagnosis other than fungal infection, please refer the case to a pharmacist. An off label use may be approvable for a medication such as Nizoral® for advanced prostate cancer or for Cushing’s Syndrome when standard treatments have failed.

INFECTIOUS DISEASE AGENTS: AGENTS FOR ONYCHOMYCOSIS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
GRIFULVIN®V tablets (griseofulvin, microsize) GRISEOFULVIN suspension (generic of Grifulvin®V) GRIS-PEG® (griseofulvin, ultramicrosize) TERBINAFINE (generic of Lamisil®)	ITRACONAZOLE (generic of Sporanox®) LAMISIL Granules (terbinafine) SPORANOX® 100mg/10ml oral solution (itraconazole)

INFECTIOUS DISEASE AGENTS: AGENTS FOR SYSTEMIC INFECTIONS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
FLUCONAZOLE (generic of Diflucan®) FLUCONAZOLE suspension (generic of Diflucan®) KETOCONAZOLE (generic of Nizoral®)	ITRACONAZOLE CAPSULES (generic of Sporanox®) NOXAFIL® (posaconazole) SPORANOX® 100mg/10ml oral solution (itraconazole)

DRAFT

For P&T Committee Discussion Only

Infectious Disease Agents: Antivirals – Hepatitis C Agents

LENGTH OF AUTHORIZATIONS: 1 year

Is there any reason the patient cannot be changed to a medication within the same class which does not require prior approval? Acceptable reasons include:

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

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- Pegylated Interferons have a Black Box Warning which indicates that a patient should be monitored closely with periodic clinical and laboratory evaluations.
- Ribavirins are contraindicated in women who are pregnant and in their male partner(s). At least two reliable forms of contraception must be used during therapy.

ADDITIONAL CRITERIA FOR PROTEASE INHIBITORS:

Patient is receiving prior/concurrent interferon and ribavirin as recommended in the FDA-approved package labeling

INFECTIOUS DISEASE AGENTS: HEPATITIS C - PEGYLATED INTERFERONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
PEGASYS [®] (peginterferon alfa 2a) PEGASYS CONVENIENCE PACK [®] (peginterferon alfa 2a) PEG-INTRON [®] (peginterferon alfa 2b) PEG-INTRON REDIPEN [®] (peginterferon alfa 2b)	

INFECTIOUS DISEASE AGENTS: HEPATITIS C - RIBAVIRINS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
RIBAVIRIN (generic of Rebetol [®])	COPEGUS [®] (ribavirin) REBETOL [®] (ribavirin) RIBAPAK [®] (ribavirin) RIBASPHERE[®] (ribavirin) 400mg, 600mg

INFECTIOUS DISEASE AGENTS: HEPATITIS C – PROTEASE INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
INCIVEK [®] (telaprevir) VICTRELIS [®] (boceprevir)	

DRAFT

For P&T Committee Discussion Only

Infectious Disease Agents: Antivirals – Herpes

LENGTH OF AUTHORIZATIONS: For the duration of the prescription (up to 6 months)

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

INFECTIOUS DISEASE AGENTS: ANTIVIRALS - HERPES

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ACYCLOVIR (generic of Zovirax®)	FAMCICLOVIR (generic of Famvir®)
ACYCLOVIR suspension (generic of Zovirax®)	VALACYCLOVIR (generic of Valtrex®)
VALTREX® (valacyclovir)	

DRAFT

For P&T Committee Discussion Only

Injectable Antirheumatic Agents

LENGTH OF AUTHORIZATIONS: 1 year

All products in this class require clinical prior authorization:

- No current infection; and
- Prior non-biologic therapy appropriate for diagnosis; and
- Diagnosis of one of the following:
 - Rheumatoid Arthritis
 - Psoriatic Arthritis
 - Polyarticular Juvenile Idiopathic Arthritis
 - Crohn's Disease
 - Ankylosing Spondylitis
 - Psoriasis

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

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 three-month trial of at least two medications not requiring prior approval

ANTI-INFLAMMATORY TUMOR NECROSIS FACTOR INHIBITOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
CIMZIA [®] syringe (certolizumab pegol)	SIMPONI [™] pen (golimumab)
ENBREL [®] kit (etanercept)	SIMPONI [™] syringe (golimumab)
ENBREL SURECLIK [®] syringe (etanercept)	ORENCIA [®] syringe (abatacept)
ENBREL [®] syringe (etanercept)	
HUMIRA [®] pen (adalimumab)	
HUMIRA [®] starter packs (adalimumab)	
HUMIRA [®] syringe (adalimumab)	

ANTI-INFLAMMATORY INTERLEUKIN-1 RECEPTOR ANTAGONIST

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	<i>KINERET[®] syringe (anakinra)</i>

DRAFT

For P&T Committee Discussion Only

Ophthalmic Agents: Antibiotic and Antibiotic-Steroid Combination Drops and Ointments

LENGTH OF AUTHORIZATIONS: for the date of service only; no refills for acute infection. Refills for up to 14 days may be authorized for patients undergoing surgery.

Step Therapy:

- 1) ***For a preferred brand agent, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than three days of at least one preferred generic***
- 2) ***For a non-preferred agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than three days each of at least two preferred generics or brands***

Other Criteria:

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 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

OPHTHALMIC AGENTS: ANTIBACTERIAL - QUINOLONES

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
CIPROFLOXACIN drops (generic of Ciloxan®) OFLOXACIN drops (generic of Ocuflox®)	<i>CILOXAN® ointment (ciprofloxacin)</i> <i>VIGAMOX® drops (moxifloxacin)</i>	BESIVANCE® drops (besifloxacin) IQUIX® drops (levofloxacin) LEVOFLOXACIN drops (generic of Quixin®) MOXEZA® drops (moxifloxacin) ZYMAR® drops (gatifloxacin) ZYMAXID® drops (gatifloxacin)

DRAFT

For P&T Committee Discussion Only

OPHTHALMIC AGENTS: ANTIBACTERIAL – NON-QUINOLONE

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
BACITRACIN ointment BACITRACIN-POLYMYXIN ointment ERYTHROMYCIN ointment GENTAMICIN drops GENTAMICIN ointment NEOMYCIN/POLYMYXIN/BACITRACIN ointment NEOMYCIN/POLYMYXIN/GRAMICIDIN drops (generic of Neosporin®) POLYMYXIN/TRIMETHOPRIM drops (generic of Polytrim®) TOBRAMYCIN drops (generic of Tobrex®)	TOBREX® ointment (tobramycin)	AZASITE® drops (azithromycin)

OPHTHALMIC AGENTS: ANTIBACTERIAL – STEROID COMBINATIONS

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
NEOMYCIN/POLYMYXIN/ BACITRACIN/ HYDROCORTISONE ointment NEOMYCIN/POLYMYXIN/ DEXAMETHASONE drops (generic of Maxitrol®) NEOMYCIN/POLYMYXIN/ DEXAMETHASONE ointment (generic of Maxitrol®) TOBRADEX® drops (dexamethasone/tobramycin)	BLEPHAMIDE® drops (prednisolone/sulfacetamide) BLEPHAMIDE® ointment (prednisolone/ sulfacetamide) POLY-PRED® drops PRED-G® drops (prednisolone/gentamicin) PRED-G® ointment (prednisolone/gentamicin) TOBRADEX® ointment (dexamethasone/tobramycin)	NEOMYCIN/POLYMYXIN/ HYDROCORTISONE drops (generic of Cortisporin®) TOBRADEX ST® (dexamethasone/tobramycin) TOBRAMYCIN/ DEXAMETHASONE drops (generic of TobraDex®) ZYLET® drops (tobramycin/loteprednol)

DRAFT

For P&T Committee Discussion Only

Ophthalmic Agents: Antihistamines & Mast Cell Stabilizers

LENGTH OF AUTHORIZATIONS: 1 year

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
 - Contraindications to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. Patient must have a therapeutic failure to at least one of the preferred agents.

OPHTHALMIC AGENTS: ANTIHISTAMINES

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	ALAMAST [®] (pemirolast) ALOCRIL [®] (nedocromil) ALOMIDE [®] (lodoxamide)

OPHTHALMIC AGENTS: ANTIHISTAMINE/MAST CELL STABILIZERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ALAWAY [®] (ketotifen) BEPREVE [®] (bepotastine) KETOTIFEN (generic of Alaway [®] , Zaditor [®]) OPTIVAR [®] (azelastine) PATADAY [™] (olopatadine) ZADITOR [®] OTC (ketotifen)	AZELASTINE (generic of Optivar [®]) EPINASTINE (generic of Elestat [®]) EMADINE [®] (emedastine) LASTACAFT [®] (alcaftadine) PATANOL [®] (olopatadine)

DRAFT

For P&T Committee Discussion Only

Ophthalmic Agents: Glaucoma Agents

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy: across all agents

- 1) *For a preferred brand agent, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than one month of at least one preferred generic*
- 2) *For a non-preferred agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one month each of at least two preferred generics or brands*

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

OPHTHALMIC AGENTS: GLAUCOMA AGENTS – BETA BLOCKERS

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
BETAXOLOL CARTEOLOL LEVOBUNOLOL (generic of Betagan®) METIPRANOLOL (generic of Optipranolol®) TIMOLOL gel solution (generic of Timoptic-XE®) TIMOLOL solution (generic of Timoptic®)	BETIMOL® (timolol)	BETOPTIC®S (betaxolol) ISTALOL™ (timolol)

OPHTHALMIC AGENTS: GLAUCOMA AGENTS – PROSTAGLANDIN INHIBITORS

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
LATANAPROST (generic of Xalatan®)	TRAVATAN®Z (travoprost)	LUMIGAN™ (bimatoprost)

OPHTHALMIC AGENTS: GLAUCOMA AGENTS – ALPHA ADRENERGIC AGONISTS/SYPATHOMIMETICS

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
BRIMONIDINE 0.2% ALPHAGAN®P (brimonidine 0.15%)		APRACLONIDINE (generic of Iopidine®) BRIMONIDINE 0.15% (generic of Alphagan® P)

DRAFT

For P&T Committee Discussion Only

OPHTHALMIC AGENTS: GLAUCOMA AGENTS – CARBONIC ANHYDRASE INHIBITORS

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
TRUSOPT® (dorzolamide)	AZOPT® (brinzolamide)	DORZOLAMIDE (generic of Trusopt®)

OPHTHALMIC AGENTS: GLAUCOMA AGENTS – COMBINATION BETA BLOCKER AND ALPHA ADRENERGIC AGONIST

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
	COMBIGAN® (Brimonidine/ Timolol)	

OPHTHALMIC AGENTS: GLAUCOMA AGENTS – COMBINATION BETA BLOCKER AND CARBONIC ANHYDRASE INHIBITORS

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
COSOPT® (Dorzolamide/Timolol)		COSOPT® PF (dorzolamide/timolol) DORZOLAMIDE/TIMOLOL (generic of Cosopt®)

DRAFT

For P&T Committee Discussion Only

Ophthalmic Agents: NSAIDs

LENGTH OF AUTHORIZATIONS: for the date of service only; no refills for acute use. Refills for up to 14 days may be authorized for patients undergoing surgery.

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

ADDITIONAL INFORMATION

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 three-day trial of at least one medication not requiring prior approval
- The requested medication’s corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

OPHTHALMIC NSAIDs

NO PA REQUIRED “PREFERRED”	PA REQUIRED
DICLOFENAC (generic of Voltaren [®]) FLURBIPROFEN (generic of Ocufen [®]) KETOROLAC (generic of Acular [®] , Acular LS [®])	ACUVAIL [®] (ketorolac) <i>BROMDAY[®] (bromfenac)</i> BROMFENAC (generic of Xibrom [®]) NEVANAC [®] (nepafenac)

DRAFT

For P&T Committee Discussion Only

Otic Agents: Antibacterial and Antibacterial/Steroid Combinations

LENGTH OF AUTHORIZATIONS: for the date of service only; no refills for acute infection.

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 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 one-week trial of at least one medication not requiring prior approval
- The requested medication’s corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

OTIC AGENTS: ANTIBACTERIAL – STERIOD COMBINATION

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

OTIC AGENTS: ANTIBACTERIAL

NO PA REQUIRED “PREFERRED”	PA REQUIRED
OFLOXACIN drops (generic of Floxin Otic [®])	CETRAXAL [®] solution (ciprofloxacin)
	FLOXIN [®] singles (ofloxacin)

DRAFT

For P&T Committee Discussion Only

Respiratory Agents: Antihistamines – Second Generation

LENGTH OF AUTHORIZATIONS: 1 year

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there have been therapeutic failures after courses of treatment (e.g., one month for allergic rhinitis) with medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION

- Fexofenadine is indicated for patients 6 years of age and older
- Loratadine is indicated for patients 2 years of age and older
- Clarinex® and cetirizine are indicated for patients 6 months of age and older

RESPIRATORY AGENTS: ANTIHISTAMINES: SECOND GENERATION

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CETIRIZINE chewable (generic of Zyrtec®) (no PA required for age 6 or under)	ALAVERT® rapid dissolve (loratadine)
CETIRIZINE syrup (generic of Zyrtec®) (no PA required for age 6 or under)	ALAVERT® tablets (loratadine)
CETIRIZINE tablets (generic of Zyrtec®)	ALLEGRA® ODT (fexofenadrine)
LORATADINE rapid dissolve (generic of Claritin® Redi-tabs)	ALLEGRA® suspension (fexofenadrine)
LORATADINE syrup (generic of Claritin® Syrup)	CETIRIZINE chewable (generic of Zyrtec®) (PA required for over age 6)
LORATADINE tablets (generic of Claritin®)	CETIRIZINE syrup (generic of Zyrtec®) (PA required for over age 6)
	CLARINEX REDI-TABS® (desloratadine)
	CLARINEX® tablets (desloratadine)
	CLARINEX® syrup (desloratadine)
	CLARITIN REDITABS® 5mg (loratadine)
	CLARITIN® chewable (loratadine)
	FEXOFENADINE (generic of Allegra®)
	LEVOCETIRIZINE (generic of Xyzal®)

RESPIRATORY AGENTS: ANTIHISTAMINE/DECONGESTANT COMBO: SECOND GENERATION

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CETIRIZINE/PSEUDOEPHEDRINE (generic of Zyrtec-D®)	ALAVERT D-12HR® (loratadine/pseudoephedrine)
LORATADINE-D (generic of Claritin-D®)	ALLEGRA-D 24 HOUR® (fexofenadrine/pseudoephedrine)
	CLARINEX-D 12, 24 HOUR® (desloratadine/pseudoephedrine)
	FEXOFENADINE/PSEUDOEPHEDRINE (generic of Allegra-D 12 Hour®)

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For P&T Committee Discussion Only

Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Short Acting

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to no less than a two-week trial of at least one medication not requiring prior approval within the same class and formulation. (i.e., nebulizers for nebulizers).

RESPIRATORY AGENTS: BETA-ADRENERGIC, SHORT-ACTING

Metered Dose Inhalers or Other Devices

NO PA REQUIRED “PREFERRED”	PA REQUIRED
PROAIR [®] HFA (albuterol) PROVENTIL HFA [®] (albuterol) VENTOLIN HFA [®] (albuterol)	MAXAIR AUTOHALER [®] (pirbuterol) XOPENEX HFA [®] (levalbuterol)

RESPIRATORY AGENTS: BETA-ADRENERGIC, SHORT-ACTING NEBULIZERS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
ACCUNEB [®] (Albuterol – pediatric dosing of premixed nebs) (no PA required for ages 12 and under) ALBUTEROL (generic of Proventil [®] , Ventolin [®]) 0.083% Premixed nebulizers, 0.5% Concentrated Solution) ALBUTEROL 0.42mg/ml, 0.63mg/ml (generic of Accuneb [®]) (no PA required for ages 12 and under)	ACCUNEB [®] (Albuterol – pediatric dosing of premixed nebs) (PA required for over age 12) ALBUTEROL 0.42mg/ml, 0.63mg/ml (generic of Accuneb [®]) (PA required for over age 12) LEVALBUTEROL (generic of Xopenex [®]) XOPENEX [®] (levalbuterol)

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For P&T Committee Discussion Only

Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Long Acting

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to no less than a two-week trial of at least one medication not requiring prior approval within the same class and formulation. (i.e., nebulizers for nebulizers).

Step therapy required for all long-acting beta agonists and combinations:

Criteria	Approval Length
>= 3 claims for LABA (formoterol or salmeterol alone or in combination with steroid) in previous 6 months	6 months
>= 1 claim for anticholinergic (ipratropium, tiotropium, ipratropium/albuterol) in previous 6 months	12 months
>= 3 claims for inhaled corticosteroid (beclomethasone, budesonide, flunisolide, fluticasone, mometasone, triamcinolone) in previous 12 months	6 months
>= 3 claims for leukotriene modifier (montelukast, zafirlukast, zileuton) in previous 12 months	6 months
>= 3 claims for theophylline in previous 12 months	6 months
>= 3 claims for oral corticosteroid in previous 4 months	6 months
Diagnosis is COPD or exercise-induced bronchospasm	12 months
Diagnosis is moderate persistent or severe persistent asthma, or partly controlled or uncontrolled asthma (see classification below)	6 months
Patient scored <= 19 on Asthma Control Test TM	6 months

RESPIRATORY AGENTS: BETA-ADRENERGIC, LONG-ACTING INHALERS

STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED
FORADIL [®] (formoterol)	ARCAPTA NEOHALER [®] (indacaterol) SEREVENT DISKUS [®] (salmeterol)

RESPIRATORY AGENTS: BETA-ADRENERGIC, LONG-ACTING NEBULIZER SOLUTION

STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED
	BROVANA [™] (arformoterol) PERFOROMIST [®] (formoterol)

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For P&T Committee Discussion Only

RESPIRATORY AGENTS: BETA-ADRENERGIC COMBINATIONS

STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED
ADVAIR DISKUS [®] and HFA (Salmeterol/Fluticasone) DULERA [®] (Formoterol/Mometasone) SYMBICORT [®] (Formoterol/Budesonide)	

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For P&T Committee Discussion Only

Respiratory Agents: Chronic Obstructive Pulmonary Disease

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to no less than a two-week trial of at least one medication not requiring prior approval.

ADDITIONAL CRITERIA FOR ROFLUMILAST (DALIRESP®):

Diagnosis of chronic bronchitis and inadequately controlled on long-acting beta agonist

RESPIRATORY AGENTS: COPD ANTICHOLINERGICS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
ATROVENT HFA® (ipratropium) COMBIVENT MDI® (ipratropium/albuterol) IPRATROPIUM nebulizer solution IPRATROPIUM/ALBUTEROL nebulizer solution (generic of Duoneb®) SPIRIVA® (tiotropium)	

RESPIRATORY AGENTS: PHOSPHODIESTERASE-4 INHIBITORS *

NO PA REQUIRED “PREFERRED”	PA REQUIRED
	<i>DALIRESP® (roflumilast)</i>

** Note: Clinical criteria required for roflumilast*

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For P&T Committee Discussion Only

Respiratory Agents: Glucocorticoid Agents – Inhaled

LENGTH OF AUTHORIZATIONS: 1 year

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
 - Patient’s condition is clinically unstable--patient has had an ER visit or at least two hospitalizations for asthma in the past thirty days--changing to a medication not requiring prior approval might cause deterioration of the patient’s condition.
2. If there have been therapeutic failures to no less than one-month trials of at least two medications not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

1. If a medication requiring prior approval was initiated in the hospital, may approve the requested medication.

If the patient is a child under 13 years old or a patient with a significant disability, and unable to use an inhaler which does not require prior approval, or is non-compliant on an inhaler not requiring prior approval because of taste, dry mouth, infection; then may approve the requested medication.

RESPIRATORY AGENTS: GLUCOCORTICOIDS – Inhaled

NO PA REQUIRED “PREFERRED”	PA REQUIRED
ASMANEX® (mometasone) FLOVENT DISKUS® and HFA (fluticasone) QVAR® (beclomethasone)	ALVESCO® (ciclesonide) PULMICORT FLEXHALER® (budesonide)

RESPIRATORY AGENTS: GLUCOCORTICOIDS – Nebulizers [‡]

NO PA REQUIRED “PREFERRED”	PA REQUIRED
PULMICORT® nebulizer solution (no PA required for age 8 or under) (budesonide)	BUDESONIDE nebulizer solution (generic of Pulmicort®) PULMICORT® nebulizer solution (PA required for over age 8) (budesonide)

‡Patients on current regimens will be grandfathered.

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For P&T Committee Discussion Only

Respiratory Agents: Leukotriene Receptor Modifiers and Inhibitors

LENGTH OF AUTHORIZATIONS: 1 year

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to the agent not requiring prior approval, then may approve the requested medication.

RESPIRATORY AGENTS: LEUKOTRIENE RECEPTOR ANTAGONISTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ACCOLATE [®] (zafirlukast)	ZYFLO [®] (zileuton)
SINGULAIR [®] CHEWABLE TABLETS (montelukast)	ZYFLO CR [®] (zileuton)
SINGULAIR [®] ORAL GRANULES (montelukast)	
SINGULAIR [®] TABLETS (montelukast)	
ZAFIRLUKAST (generic of Accolate [®])	

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For P&T Committee Discussion Only

Respiratory Agents: Nasal Preparations

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy: Glucocorticoids only

- 1) *For a preferred brand, there must have been inadequate clinical response to preferred generic alternatives, with the same long-acting or short-acting classification, including a trial of no less than one month of at least one preferred generic*
- 2) *For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one month each of at least two preferred generics or brands*

Other Criteria:

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 interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there have been therapeutic failures to no less than one-month trials of at least two medications not requiring prior approval, then may approve the requested medication.

RESPIRATORY AGENTS: NASAL PREPARATIONS - GLUCOCORTICOIDS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
FLUNISOLIDE FLUTICASONE (generic of Flonase®) NASACORT® AQ (triamcinolone)	NASONEX® (mometasone)	BECONASE® AQ (beclomethasone) OMNARIS® (ciclesonide) QNASL® (beclomethasone) RHINOCORT AQUA® (budesonide) TRIMCINOLONE (generic of Nasacort® AQ) VERAMYST™ (fluticasone furoate)

RESPIRATORY AGENTS: NASAL PREPARATIONS - ANTIHISTAMINES

	PA REQUIRED
ASTELIN® (azelastine) ASTEPRO® (azelastine) PATANASE® (olopatadine)	AZELASTINE (generic of Astelin®)

RESPIRATORY AGENTS: NASAL PREPARATIONS - ANTICHOLINERGICS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
IPRATROPIUM (generic of Atrovent®)	

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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
- Patient diagnosis skin cancer – may approve retinoid

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

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 one-month trial of at least one medication in the same class not requiring prior approval

TOPICAL AGENTS: ACNE PREPARATIONS – ANTIBIOTIC PRODUCTS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CLINDAMYCIN gel (generic of Cleocin T®, Clindamax®)	AKNE-MYCIN® ointment (erythromycin)
CLINDAMYCIN lotion (generic of Cleocin T®, Clindamax®)	CLINDAGEL® (clindamycin)
CLINDAMYCIN solution (generic of Cleocin T®)	CLINDAMYCIN foam (generic of Evoclin®)
ERYTHROMYCIN gel	CLINDAMYCIN pledgets (generic of Cleocin T®)
ERYTHROMYCIN solution (generic of A/T/S®, Akne-Mycin®)	ERY PADS® (erythromycin)

TOPICAL AGENTS: ACNE PREPARATIONS – OTHER PRODUCTS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
AZELEX® cream (azelaic acid)	ACZONE® gel (dapsone)
	FINACEA® gel (azelaic acid)
	FINACEA PLUS® kit (azelaic acid)

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For P&T Committee Discussion Only

TOPICAL AGENTS: ACNE PREPARATIONS – BENZOYL PEROXIDE AND COMBINATION PRODUCTS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
BENZACLIN [®] gel (benzoyl peroxide and clindamycin)	ACANYA [®] (Clindamycin-Benzoyl Peroxide)
BENZOYL PEROXIDE cleanser (generic of Oscion [®] , Triaz [®])	BENZACLIN CAREKIT [®] (clindamycin/benzoyl peroxide)
BENZOYL PEROXIDE gel (generic of Benzac AC [®] , Benzagel [®] , Brevoxyl [®] , Desquam-X [®])	BENZAMYCINPAK [®] gel (benzoyl peroxide and erythromycin)
BENZOYL PEROXIDE lotion (generic of Zaclir [®])	BENZASHAVE [®] cream
BENZOYL PEROXIDE wash (generic of Benzac AC [®] , Benzac W [®] , Brevoxyl [®] , Desquam-X [®] , Pacnex [®])	BENZEFOAM [®]
ERYTHROMYCIN-BENZOYL PEROXIDE gel (generic of Benzamycin [®])	BENZOYL PEROXIDE Complete Pack (generic of Brevoxyl Complete Pack [®])
PANOXYL [®] 10% foam (benzoyl peroxide)	BENZOYL PEROXIDE MICROSPHERES cream, wash (generic of Neobenz Micro [®])
ZODERM [®] cream	BENZOYL PEROXIDE foaming cloths (generic of Triaz [®])
	BENZOYL PEROXIDE pads (generic of Oscion [®] , Triaz [®])
	BENZOYL PEROXIDE-ALOE VERA gel (generic of Benziq [®] gel)
	BENZOYL PEROXIDE-ALOE VERA wash (generic of Benziq [®] wash)
	BENZOYL PEROXIDE-SULFUR gel (generic of Nuox [®] gel)
	BENZOYL PEROXIDE-UREA cleanser (generic of Zoderm [®])
	BENZOYL PEROXIDE-UREA cream (generic of Zoderm [®])
	BENZOYL PEROXIDE-UREA gel (generic of Zoderm [®])
	BENZOYL PEROXIDE-UREA pads (generic of Zoderm [®] redi-pads)
	BENZOYL PEROXIDE-UREA wash (generic of Zoderm [®] hydrating wash)
	CLINDAMYCIN-BENZOYL PEROXIDE gel (generic of Benzaclin [®])
	DUAC CS [®] kit (benzoyl peroxide and clindamycin)
	DUAC [®] gel (benzoyl peroxide and clindamycin)
	INOVA EASY PAD [®]
	PACNEX HP [®]
	PACNEX LP [®]

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For P&T Committee Discussion Only

TOPICAL AGENTS: ACNE PREPARATIONS – RETINOID AND COMBINATION PRODUCTS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
RETIN-A MICRO [®] gel (tretinoin) RETIN-A [®] cream (tretinoin) RETIN-A [®] gel (tretinoin) TAZORAC [®] cream (tazarotene) TAZORAC [®] gel (tazarotene)	ADAPALENE cream, gel (generic of Differin [®]) ATRALIN [®] gel (tretinoin) DIFFERIN [®] gel (adapalene) DIFFERIN [®] lotion (adapalene) EPIDUO [®] gel (adapalene/benzoyl peroxide) TRETINOIN cream (generic of Retin-A [®]) TRETINOIN gel (generic of Retin-A [®]) VELTIN [®] gel (clindamycin/tretinoin) ZIANA [®] gel (clindamycin/tretinoin)

TOPICAL AGENTS: ACNE PREPARATIONS – SODIUM SULFACETAMIDE AND COMBINATION PRODUCTS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
KLARON [®] lotion (sulfacetamide) SODIUM SULFACETAMIDE-SULFUR lotion (generic of Novacet [®] , Sulfacet-R [®]) SODIUM SULFACETAMIDE-SULFUR suspension (generic of Plexion [®] TS) SODIUM SULFACETAMIDE-SULFUR wash (generic of Avar [®] cleanser, Clenia [®] foaming wash, Plexion [®] cleanser, Rosac [®] wash)	AVAR [®] gel (sodium sulfacetamide-sulfur) CLARIFOAM EF [®] emollient foam OVACE PLUS [®] cream (sodium sulfacetamide) OVACE PLUS [®] wash (sodium sulfacetamide) OVACE [®] foam (sodium sulfacetamide) ROSULA [®] foam (sodium sulfacetamide/sulfur) SODIUM SULFACETAMIDE cream (generic of Ovace [®]) SODIUM SULFACETAMIDE gel (generic of Ovace [®]) SODIUM SULFACETAMIDE lotion (generic of Klaron [®]) SODIUM SULFACETAMIDE wash (generic of Ovace [®]) SODIUM SULFACETAMIDE-SULFUR cleanser kit SODIUM SULFACETAMIDE-SULFUR cream (generic of Avar-E [®]) SODIUM SULFACETAMIDE-SULFUR pads (generic of Plexion [®] cleansing cloths) SODIUM SULFACETAMIDE-SULFUR-AVOBENZONE cream (generic of Rosac [®] cream) SODIUM SULFACETAMIDE-SULFUR-UREA cleanser (generic of Rosula [®] cleanser) SODIUM SULFACETAMIDE-SULFUR-UREA gel (generic of Rosula [®] aqueous gel) SODIUM SULFACETAMIDE-SULFUR-UREA wash (generic of Rosula [®] clarifying wash) SODIUM SULFACETAMIDE-SULFUR-UREA WITH SUNSCREEN kit (generic of Rosula [®] CLK) SODIUM SULFACETAMIDE-SULFUR-WITCH HAZEL cream (generic of Plexion [®] SCT cream) SODIUM SULFACETAMIDE-UREA pads (generic of Rosula [®] NS medicated pads) SUMAXIN TS [®]

DRAFT

For P&T Committee Discussion Only

Topical Agents: Anti-Fungals

LENGTH OF AUTHORIZATIONS: Duration of the prescription (up to 6 months)

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to at least two medications not requiring prior approval
 - Contraindication to all medications not requiring prior approval
 - History of unacceptable/toxic side effects to at least two medications not requiring prior approval
2. Is the infection caused or presumed to be caused by an organism resistant to medications not requiring prior approval?
3. Has the patient failed therapeutic trials of two weeks with two medications not requiring prior approval?

TOPICAL AGENTS: ANTI-FUNGALS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CICLOPIROX cream, topical suspension, shampoo (generic of Loprox [®])	CICLOPIROX gel (generic of Loprox [®])
CICLOPIROX solution (generic of Penlac [®])	CICLOPIROX kit (generic of CNL [®] Nail lacquer kit)
CLOTRIMAZOLE (generic of Lotrimin [®])	ERTACZO [®] (sertaconazole)
CLOTRIMAZOLE/BETAMETHASONE (generic of Lotrisone [®])	EXELDERM [®] (sulconazole)
ECONAZOLE (generic of Spectazole [®])	EXTINA [®] foam (ketoconazole)
KETOCONAZOLE Cream & Shampoo (generic of Kuric [®] , Nizoral [®])	MENTAX [®] (butenafine)
LOPROX [®] gel (ciclopirox)	NAFTIN [®] (naftifine)
MICONAZOLE	OXISTAT [®] (oxiconazole)
NYSTATIN	PEDI-DRI [®] powder (nystatin)
NYSTATIN W/TRIAMCINOLONE	PEDIADERM AF [®] cream (nystatin)
TERBINAFINE (generic of Lamisil [®])	VUSION [®] ointment (miconazole/zinc)
TOLNAFTATE (generic of Tinactin [®])	XOLEGEL [™] (ketoconazole)

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For P&T Committee Discussion Only

Topical Agents: Anti-Parasitics

LENGTH OF AUTHORIZATIONS: 2 weeks

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

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 one-month trial of at least one medication not requiring prior approval
- The requested medication’s corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

INDICATIONS AS APPROVED BY FDA

- Benzyl alcohol lotion is indicated for patients 6 months of age and older
- Crotamiton is indicated for adults
- Lindane lotion and shampoo are indicated only in patients who cannot tolerate or who have failed other treatments
- Malathion is indicated for patients 6 years of age and older
- Permethrin cream and lotion are indicated for patients 2 months of age and older
- Spinosad is indicated for patients 4 years of age and older
- Package labeling does not list age for permethrin or piperonyl butoxide-pyrethrins

ANTI-PARASITICS, TREATMENT OF SCABIES

NO PA REQUIRED “PREFERRED”	PA REQUIRED
PERMETHRIN cream (generic of Elimite®)	EURAX® cream, lotion (crotamiton) LINDANE lotion

ANTI-PARASITICS, TREATMENT OF LICE

NO PA REQUIRED “PREFERRED”	PA REQUIRED
LICE kit [piperonyl butoxide-pyrethrins shampoo, comb, permethrin home spray] (generic of Rid® complete kit) NATROBA® (spinosad) PERMETHRIN lotion (generic of Nix® cream rinse) PIPERONYL BUTOXIDE-PYRETHRINS lotion PIPERONYL BUTOXIDE-PYRETHRINS shampoo (generic of Rid® shampoo)	LINDANE shampoo MALATHION lotion (generic of Ovide®) <i>OVIDE® lotion (malathion)</i> ULESFIA® lotion (benzyl alcohol)

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For P&T Committee Discussion Only

Topical Agents: Corticosteroids

LENGTH OF AUTHORIZATIONS: *Duration of the prescription [maximum length to be discussed by P&T Committee]*

1. *Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:*
 - *Allergy to at least two medications not requiring prior approval*
 - *Contraindication to all medications not requiring prior approval*
 - *History of unacceptable/toxic side effects to at least two medications not requiring prior approval*
2. *Has the patient failed therapeutic trials of two weeks with two medications not requiring prior approval?*

TOPICAL AGENTS: CORTICOSTEROIDS – LOW POTENCY

NO PA REQUIRED “PREFERRED”	PA REQUIRED
DERMA-SMOOTH/ FS [®] body oil, scalp oil	<i>ALCLOMETASONE cream, ointment (generic of Aclovate[®])</i>
DESONIDE cream, ointment (generic of Desowen [®])	<i>CAPEX[®] shampoo (fluocinolone acetonide)</i>
FLUOCINOLONE ACETONIDE 0.01% cream, solution (generic of Synalar [®])	<i>DESONATE[®] gel (desonide)</i>
FLUOCINOLONE body oil, scalp oil (generic of Derma-Smooth/ FS [®])	<i>DESONIDE lotion (generic of Desowen[®])</i>
HYDROCORTISONE cream, lotion, ointment, solution	<i>HYDROCORTISONE WITH UREA cream (generic of Carmol HC[®])</i>
	<i>PANDEL[®] cream (Hydrocortisone Probutate)</i>
	<i>PEDIADERM HC[®] kit</i>

TOPICAL AGENTS: CORTICOSTEROIDS – MEDIUM POTENCY

NO PA REQUIRED “PREFERRED”	PA REQUIRED
BETAMETHASONE VALERATE cream, lotion (generic of Valisone [®])	<i>BETAMETHASONE DIPROPIONATE lotion (generic of Diprolene[®])</i>
FLUOCINOLONE ACETONIDE 0.025% cream, ointment (generic of Synalar [®])	<i>CLODERM[®] (Clocortolone Pivalate)</i>
FLUTICASONE PROPIONATE cream, ointment (generic of Cutivate [®])	<i>CORDRAN[®] tape (Flurandrenolide)</i>
MOMETASONE FUROATE cream/lotion/ointment (generic of Elocon [®])	<i>DESOXIMETASONE cream, gel, ointment (generic of Topicort[®])</i>
TRIAMCINOLONE ACETONIDE cream, ointment (generic of Aristocort [®] , Kenalog [®])	<i>FLUTICASONE PROPIONATE lotion (generic of Cutivate[®])</i>
	<i>HYDROCORTISONE BUTYRATE cream, ointment (generic of Locoid[®])</i>
	<i>HYDROCORTISONE VALERATE cream, ointment (generic of Westcort[®])</i>
	<i>LUXIQ[®] (Betamethasone Valerate foam)</i>
	<i>PREDNICARBATE cream, ointment (generic of Dermatop[®])</i>
	<i>TRIAMCINOLONE ACETONIDE lotion (generic of Kenalog[®])</i>

DRAFT

For P&T Committee Discussion Only

TOPICAL AGENTS: CORTICOSTEROIDS – HIGH POTENCY

NO PA REQUIRED “PREFERRED”	PA REQUIRED
AMCINONIDE ointment, cream, lotion DIFLORASONE DIACETATE cream, ointment (generic of Florone [®]) FLUOCINONIDE cream, gel, ointment, solution (generic of Lidex [®] , Lidex-E [®])	<i>APEXICON-E[®] (Diflorasone Diacetate emollient base) cream</i> <i>BETAMETHASONE DIPROPIONATE cream, ointment (generic of Diprolene[®])</i> <i>HALOG[®] cream, ointment (Halcinonide)</i> <i>KENALOG[®] aerosol spray (Triamcinolone Acetonide)</i> <i>VANOS[®] cream (Fluocinonide)</i>

TOPICAL AGENTS: CORTICOSTEROIDS – VERT HIGH POTENCY

NO PA REQUIRED “PREFERRED”	PA REQUIRED
	<i>BETAMETHASONE DIPROPIONATE AUGMENTED cream/ointment/lotion/gel (generic of Diprolene AF[®])</i> <i>CLOBETASOL PROPIONATE cream, emollient base cream, foam, gel, lotion, ointment, shampoo (generic of Olux[®], Temovate[®])</i> <i>CLOBEX[®] lotion, shampoo, spray (Clobetasol Propionate)</i> <i>HALOBETASOL PROPIONATE cream/ointment (generic of Ultravate[®])</i> <i>OLUX-E[®] foam (Clobetasol Propionate)</i>

DRAFT

For P&T Committee Discussion Only

Topical Agents: Immunomodulators

LENGTH OF AUTHORIZATIONS: 1 year

Step Therapy:

- 1) *For a preferred brand, there must have been inadequate clinical response to no less than two one-month trials of topical corticosteroids*
- 2) *For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one month of the preferred brand*

Other 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 interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

CLINICAL INFORMATION

- Indicated for short-term and intermittent long-term treatment of atopic dermatitis if:
 - Alternative, conventional therapies (such as topical corticosteroids) are deemed inadvisable because of potential risks, or
 - There has been inadequate response or intolerance to alternative, conventional therapies (such as topical corticosteroids)
- Elidel[®] and Protopic[®] 0.03% are indicated in patients 2 years old or older. Protopic[®] 0.1% is indicated in adults only

TOPICAL IMMUNOMODULATORS

<i>STEP THERAPY REQUIRED "PREFERRED"</i>	<i>PA REQUIRED</i>
<i>ELIDEL[®] * (pimecrolimus)</i>	<i>PROTOPIC[®] * (tacrolimus)</i>

* Elidel[®] & Protopic[®] have age restriction of 2 years or older



Ohio Health Plans Pharmacy Benefit Management Program Preferred Drug List Recommendations

Denise Hefley, PharmD
Clinical Information Pharmacist
Xerox State Healthcare, LLC

Page 1



Gastroprotective NSAIDs: Clinical Highlights

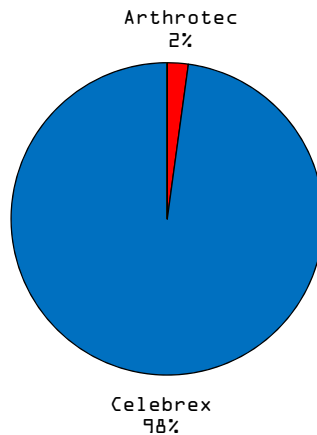
- New class for inclusion on the PDL
- Agent reviewed in this class:
 - Arthrotec[®] (diclofenac/misoprostol)
 - Celebrex[®] (celecoxib)
 - Duexis[®] (ibuprofen/famotidine)
 - Vimovo[®] (esomeprazole/naproxen)

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Gastroprotective NSAIDs: Market Share



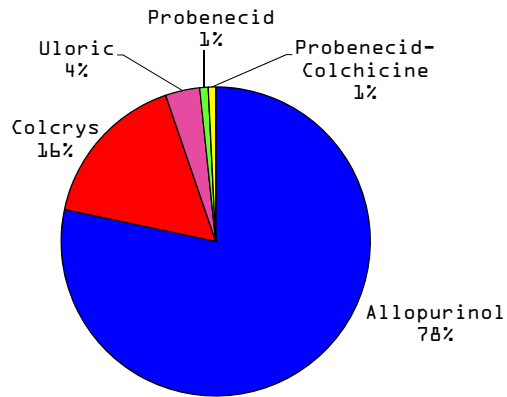
Gastroprotective NSAIDs: Recommendations

- Add to Non-Preferred w/PA criteria:
 - Arthrotec®
 - Duexis®

- Maintain as Non-Preferred w/PA criteria:
 - Vimovo®

- Maintain as Preferred w/PA criteria:
 - Celebrex®

Gout Agents: Market Share



Opioids: Clinical Highlights

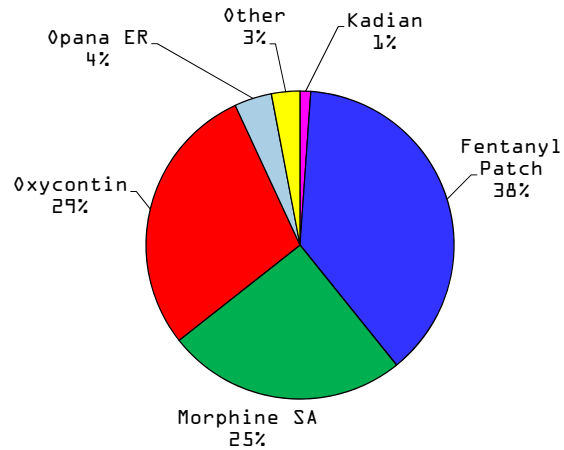
■ FDA approvals:

- Conzip™ (tramadol ER capsules)
- Generic morphine sulf. ER (A rated to Kadian)
- Generic oxymorphone ER (A rated to Opana ER)
- Generic tramadol ER (A rated to Ryzolt)
- Lazanda® (fentanyl nasal spray)
- Nucynta® ER (tapentadol)
- Oxyecta® (oxycodone)
- Subsys™ (fentanyl SL spray)

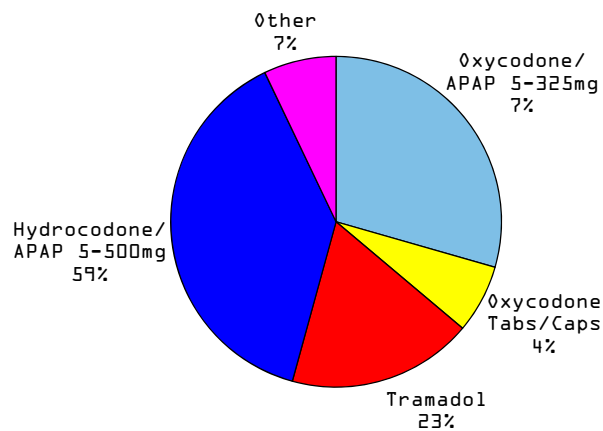
■ New Formulations:

- Opana® ER (oxymorphone)

Long-Acting Opioids: Market Share



Short-Acting Opioids: Market Share



Opioids: Recommendations

■ LA Oral:

- 3-Tiered w/Step Therapy
- Preferred Generics: morphine sulfate ER
- Preferred Brands: Kadian®, Nucynta® ER

■ LA Transdermal:

- 3-Tiered
- Preferred Generics: fentanyl patch
- Preferred Brands: none
- Butrans® additional PA criteria

Opioids: Recommendations (cont'd)

■ SA Oral:

- Step Therapy required
- Add to Preferred: Nucynta®

■ IR Liquids (single entity):

- Add to Non-Preferred: Dilaudid®-5

■ Transmucosal:

- Add to Non-Preferred: Subsys™

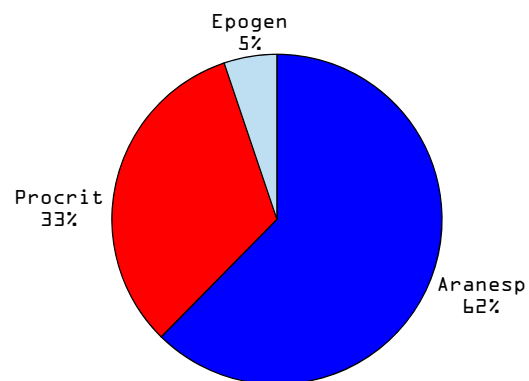
■ Remove from the PDL:

- Oramorph® SR
- Roxicodone® solution & intensol
- Zolvit®

Hematopoietic Agents: Clinical Highlights

- Erythropoiesis Stimulating Agents
 - More conservative dosing guidelines in Anemia with CKD
 - Initiate therapy only when Hg level < 10g/dL

Hematopoietic Agents: Market Share

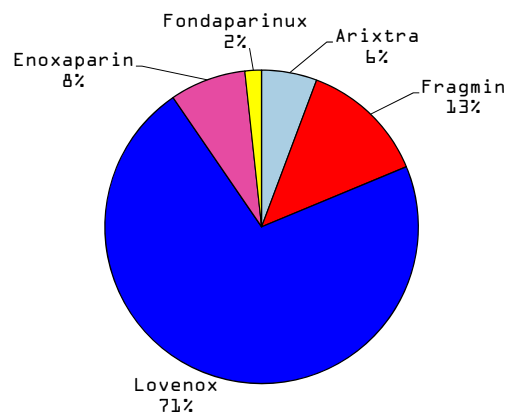


Heparin-Related Preparations: Clinical Highlights

■ FDA Approvals:

- Generic fondaparinux (A rated to Arixtra®)

Heparin-Related Preparations: Market Share



Heparin-Related Preparations: Recommendations

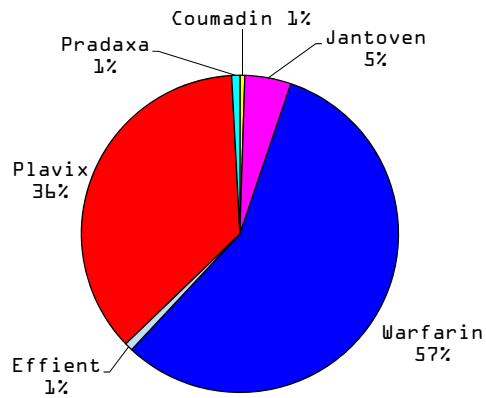
- Move to Non-Preferred:
 - Arixtra®
 - Generic fondaparinux

- Remove from the PDL:
 - Innohep®

Oral Anticoagulants: Clinical Highlights

- New class for inclusion on the PDL
- Agent reviewed in this class:
 - Clopidogrel (Plavix®)
 - Dabigatran (Pradaxa®)
 - Prasugrel (Effient®)
 - Rivaroxaban (Xarelto®)
 - Ticagrelor (Brilinta®)
 - Warfarin (Coumadin®)

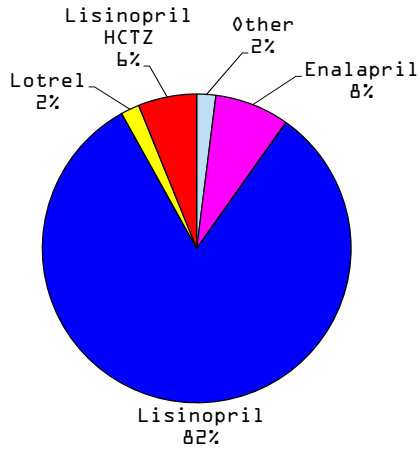
Oral Anticoagulants: Market Share



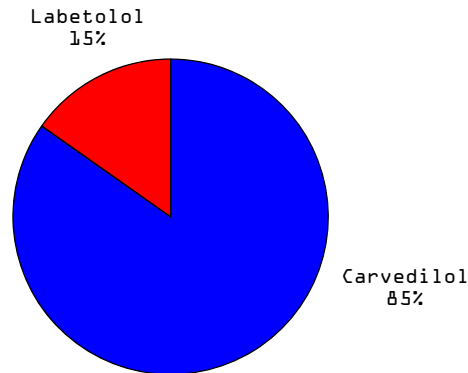
Oral Anticoagulants: Recommendations

- Add to Preferred:
 - Generic clopidogrel
 - Xarelto® 10mg
 - Generic warfarin
- Add to Non-Preferred:
 - Brilinta®
 - Pradaxa®
 - Xarelto® 15mg & 20mg
- Move to Non-Preferred:
 - Effient®
 - Plavix®

Angiotensin Converting Enzyme Inhibitors: Market Share



Alpha-Beta Adrenergic Blockers: Market Share

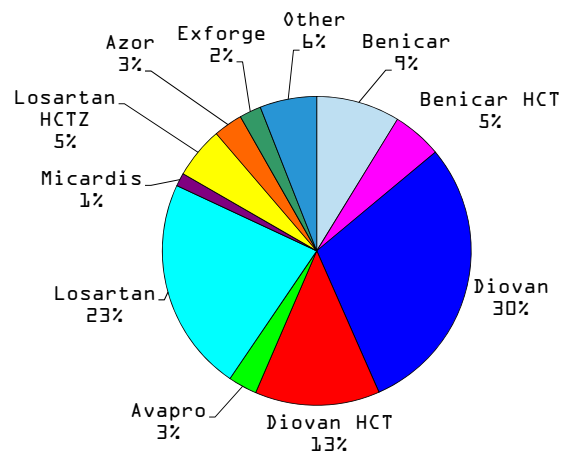


Angiotensin Receptor Blockers: Clinical Highlights

- FDA approvals:

- Generic eprosartan (A rated to Teveten®)

Angiotensin Receptor Blockers: Market Share



Angiotensin Receptor Blockers: Recommendations

■ 3-Tiered Class w/Step Therapy:

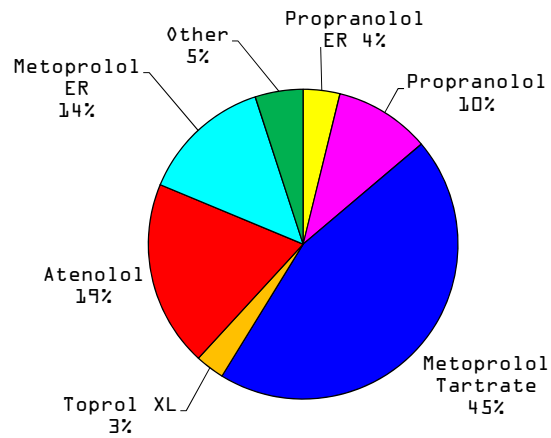
- Preferred Generics: Avapro®, Avalide®, losartan, losartan-HCTZ
- Preferred Brands: Azor®, Benicar®, Benicar HCT®, Diovan®, Diovan HCT®, Micardis®, Micardis HCT®, Tribenzor®

Beta-Blockers: Clinical Highlights

■ FDA Approvals:

- Dutoprol™ (metoprolol succinate ER/HCTZ)

Beta-Blockers: Market Share



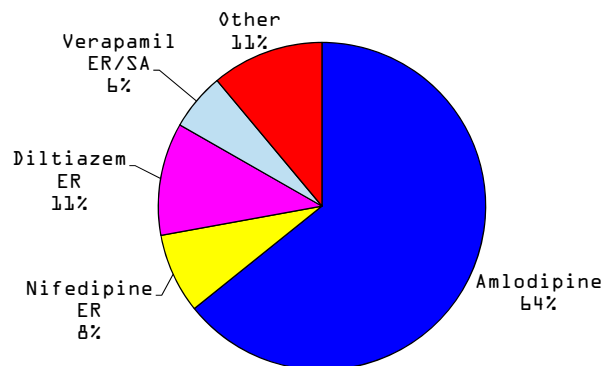
Beta-Blockers: Recommendations

- Add to Preferred:
- Dutoprol™

Calcium Channel Blockers: Clinical Highlights

- Risk of myopathy w/concomitant simvastatin
 - Amlodipine: simva max 20mg/day
 - Verapamil: simva max 10mg/day

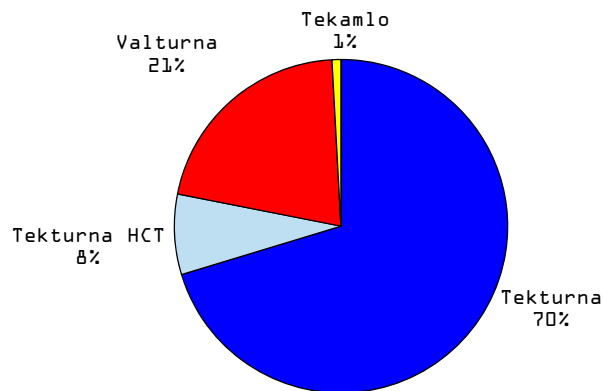
Calcium Channel Blockers: Market Share



Direct Renin Inhibitors: Clinical Highlights

- New Contraindication:
 - Use with ACEIs or ARBs in diabetes
- New Warning:
 - Avoid use with ACEIs or ARBs in moderate-severe renal impairment

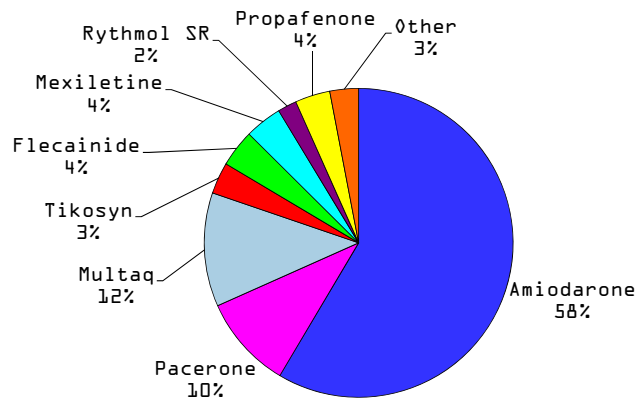
Direct Renin Inhibitors: Market Share



Antiarrhythmics: Clinical Highlights

- New class for inclusion on the PDL
- Agent reviewed in this class:
 - amiodarone (Cordarone®)
 - disopyramide (Norpace®, Norpace CR®)
 - dofetilide (Tikosyn®)
 - dronedarone (Multaq®)
 - flecainide (Tambocor®)
 - mexilitine (Mexitil®)
 - quinidine gluconate
 - quinidine sulfate
 - propafenone (Rythmol®, Rythmol SR®)

Antiarrhythmics: Market Share



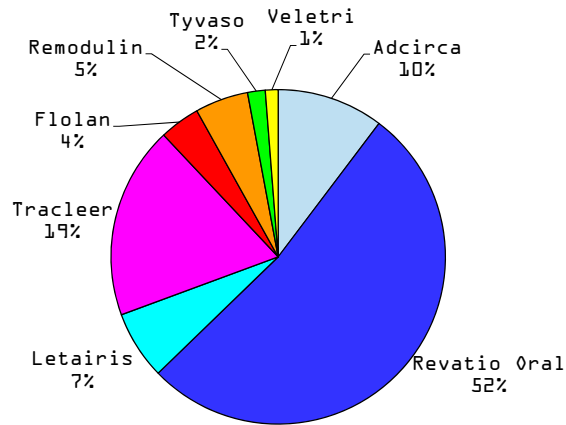
Antiarrhythmics: Recommendations

- Add to Preferred
 - amiodarone
 - disopyramide
 - flecainide
 - mexiletine
 - Norpace CR[®]
 - propafenone IR, ER
 - quinidine gluconate
 - quinidine sulfate
 - Tikosyn[®]
- Add to Non-Preferred
 - Cordarone[®]
 - Multaq[®]
 - Norpace[®]
 - Tambocor[®]
 - Mexitil[®]
 - Rythmol[®]
 - Rythmol SR[®]

Pulmonary Arterial Hypertension Agents: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class are:
 - ambrosentan (Letairis[®])
 - bosentan (Tracleer[®])
 - epoprostenol (Flolan[®], Veletri[®])
 - iloprost (Ventavis[®])
 - sildenafil (Revatio[®])
 - tadalafil (Adcirca[®])
 - treprostenol (Remodulin[®], Tyvaso[®])

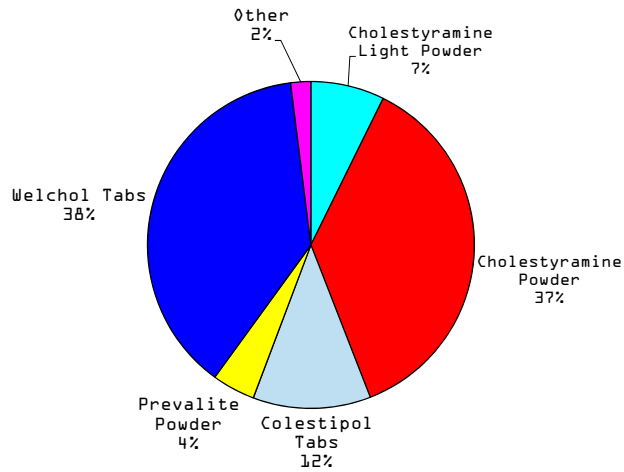
Pulmonary Arterial Hypertension Agents: Market Share



Pulmonary Arterial Hypertension Agents: Recommendations

- Clinical PA required: Diagnosis of PAH
- Add to Preferred:
 - Adcirca®
 - Letairis®
 - Revatio® (oral)
- Add to Non-Preferred:
 - Generic epoprostenol
 - Flolan®
 - Remodulin®
 - Revatio® (inj)
 - Tracleer®
 - Tyvaso®
 - Velettri®
 - Ventavis®

Bile Acid Sequestrants: Market Share



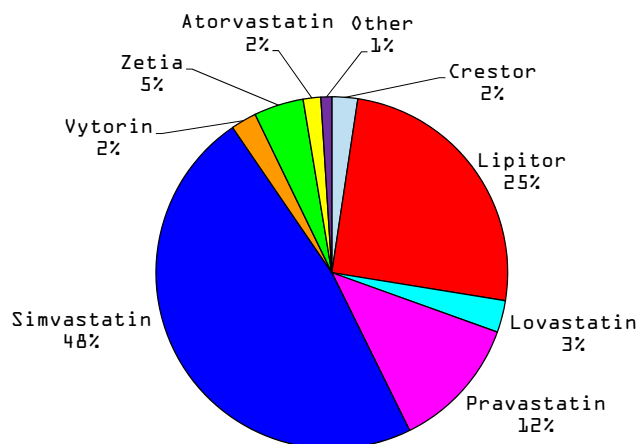
Bile Acid Sequestrants: Recommendations

- Move to Non-Preferred:
 - Welchol® Tablets w/PA criteria

Statins: Clinical Highlights

- FDA Approvals:
 - Generic atorvastatin (A rated to Lipitor®)
 - Generic fluvastatin (A rated to Lescol®)
- Myopathy and dosage limits

Statins: Market Share



Statins: Recommendations

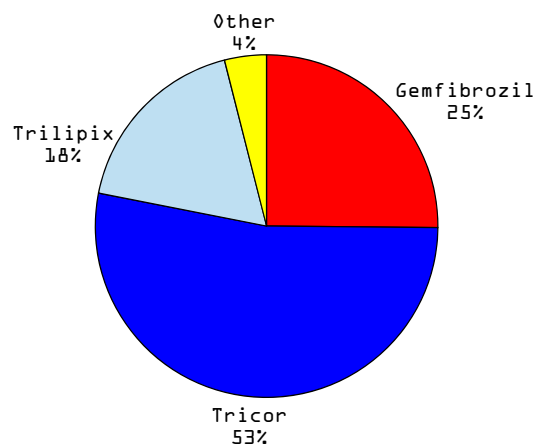
■ Move to Non-Preferred:

■ Zetia®

■ Add Step Therapy:

■ Vytorin®

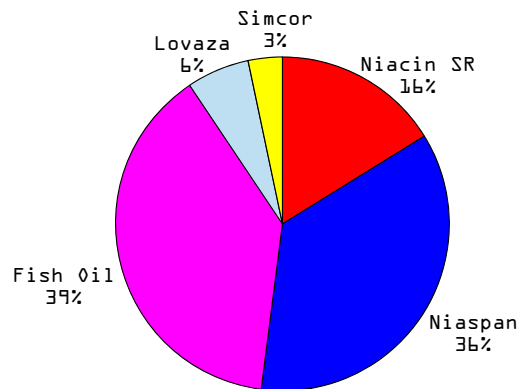
Fibric Acid Derivatives: Market Share



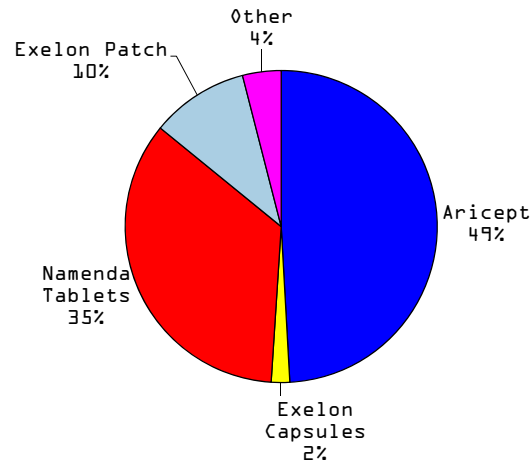
Fibric Acid Derivatives: Recommendations

- Remove from PDL:
 - Fenoglide®

Other Lipotropics: Market Share



Alzheimer's Agents: Market Share



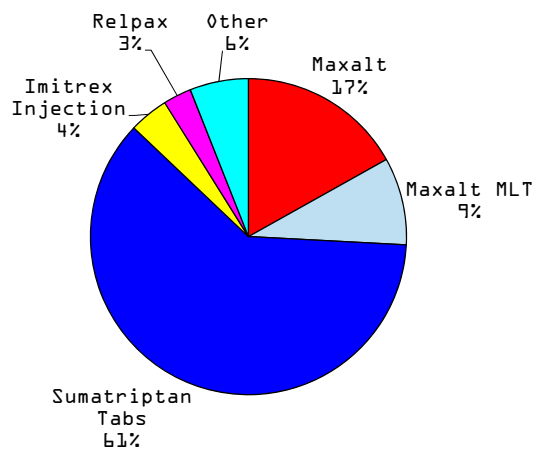
Alzheimer's Agents: Recommendations

- 3-Tiered Class w/Step Therapy:
 - Preferred Generics: donepezil, donepezil ODT, galantamine, galantamine ER, galantamine solution, Exelon capsules
 - Preferred Brands: Cognex®, Exelon® Patch, Namenda®, Namenda® Solution
 - Exelon Patch Additional Criteria

Anti-Migraine Agents: Clinical Highlights

- FDA approval:
 - Generic sumatriptan injection (A rated to Imitrex® Statdose)
- New indications:
 - Maxalt®, Maxalt MLT®
 - Pediatrics - ages 6-17yrs

Anti-Migraine Agents: Market Share



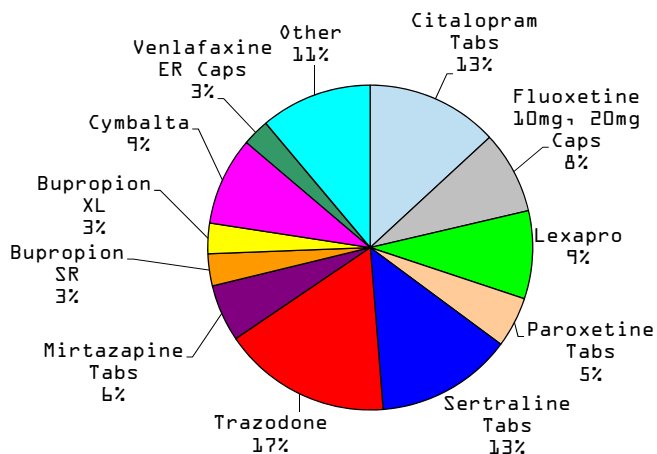
Anti-Migraine Agents: Recommendations

- 3-Tiered Class w/Step Therapy:
 - Preferred Generics: Imitrex[®] injection, naratriptan tablets, sumatriptan tablets
 - Preferred Brands: Imitrex[®] NS, Frova[®], Maxalt[®], Maxalt MLT[®]

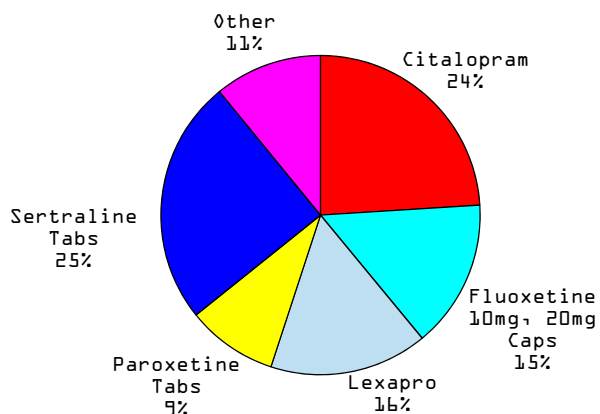
Antidepressants: Clinical Highlights

- FDA approvals:
 - Viibryd[®] (vilazodone)
- New Warnings/Precautions:
 - Celexa[®]
 - Dose dependent QT Prolongation;
max dose 40mg/day
 - Cymbalta[®]
 - Life threatening skin reactions

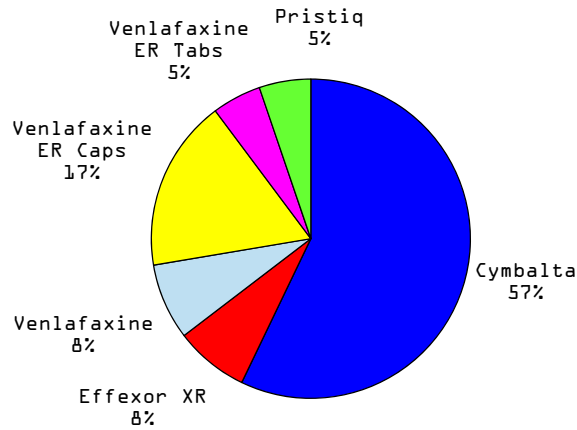
Antidepressants: Total Market Share



Antidepressants: SSRI Market Share



Antidepressants: SNRI Market Share



Antidepressants: Recommendations

■ 3-Tiered Class w/Step Therapy:

- Preferred Generics: bupropion, bupropion SR, bupropion XL, citalopram solution, citalopram tablets, fluoxetine 10mg & 20mg, fluoxetine solution, fluvoxamine tablets, Lexapro® solution, Lexapro® tablets, mirtazepine, mirtazepine RDT, nefazodone, paroxetine solution, paroxetine tablets, sertraline solution, sertraline tablets, trazodone, venlafaxine, venlafaxine ER capsules

- Preferred Brands: Cymbalta®

Second Generation Antipsychotics: Clinical Highlights

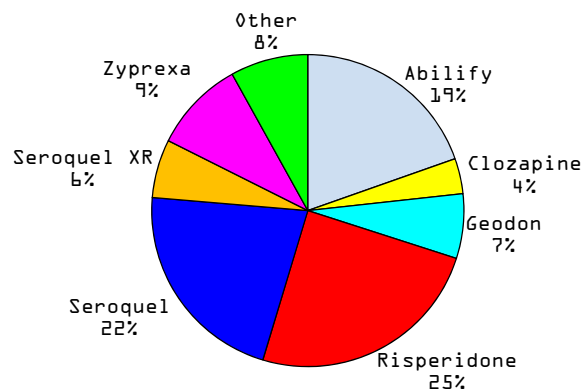
■ FDA approvals:

- Generic olanzapine (A rated to Zyprexa®)
- Generic quetiapine (A rated to Seroquel®)
- Generic ziprasidone (A rated to Geodon®)

■ New Tablet Strengths:

- Latuda® 20mg & 120mg

Second Generation Antipsychotics: Market Share



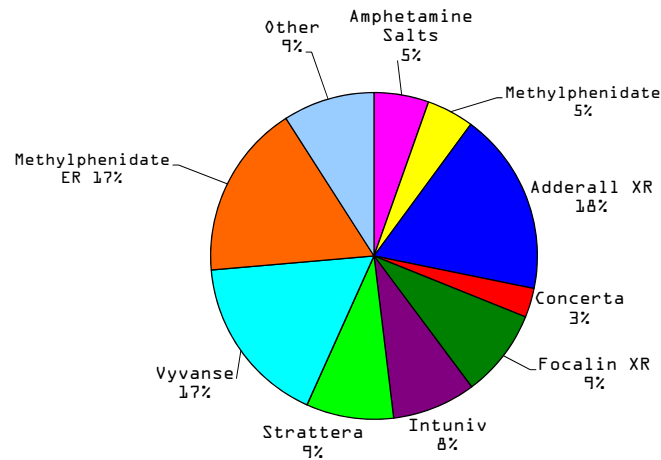
Second Generation Antipsychotics: Recommendations

- 3-Tiered Class w/Step Therapy:
 - Preferred Generics: Geodon[®], risperidone solution, risperidone tablets, risperidone M-tab, Seroquel[®]
 - Preferred Brands: Abilify[®], Abilify[®] solution, Seroquel XR[®]
- Invega Sustenna, Risperdal Consta, Zyprexa Relprevv:
 - Payable through pharmacy if delivered to MD office

Attention Deficit Hyperactivity Disorder Agents: Clinical Highlights

- FDA approvals:
 - Generic methylphenidate ER (A rated to Ritalin LA[®])

Attention Deficit Hyperactivity Disorder Agents: Market Share



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Attention Deficit Hyperactivity Disorder Agents: Recommendations

■ 3-Tiered Class w/Step Therapy:

■ Short Acting:

■ Preferred Generics: amphetamine salts, dextroamphetamine, Dextrostat®, Focalin®, Methylin® tablets & solution, methylphenidate solution, methylphenidate tablets

■ Preferred Brands: Methylin® Chewable

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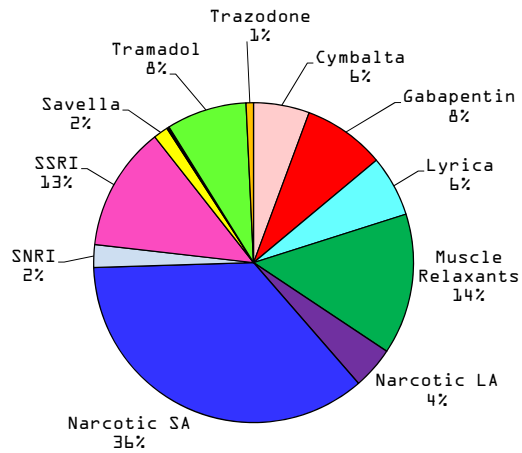
Attention Deficit Hyperactivity Disorder Agents: Recommendations

- 3-Tiered Class w/Step Therapy:
 - Long Acting:
 - Preferred Generics: Adderall XR[®], dextroamphetamine SA, methylphenidate ER (generic of Concerta[®]), methylphenidate ER (generic of Ritalin SR[®])
 - Preferred Brands: Focalin XR[®], Intuniv[®], Metadate[®] CD, Metadate[®] ER, Methylin[®] ER, Strattera[®], Vyvanse[®]

Fibromyalgia Agents: Clinical Highlights

- New Warnings/Precautions:
 - Cymbalta[®]
 - Life threatening skin reactions

Fibromyalgia Agents: Market Share



Fibromyalgia Agents: Recommendations

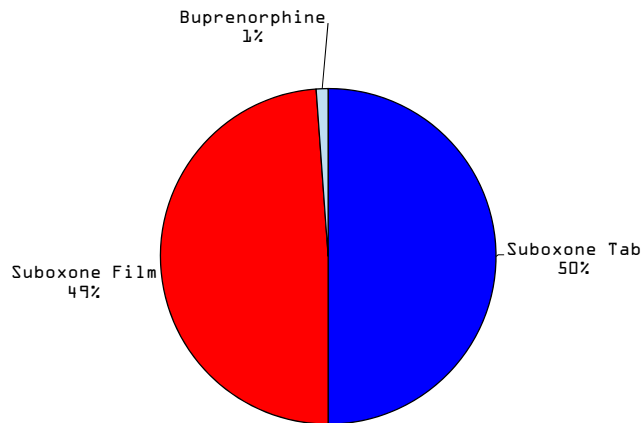
■ Move to Non-Preferred:

- Cymbalta®
- Lyrica®
- Savella®

■ Step Therapy

■ Additional Lyrica® Criteria

Medication Assisted Treatment Agents: Market Share



Medication Assisted Treatment Agents: Recommendations

■ Vivitrol:

- Payable through pharmacy if delivered to MD office

■ Additional PA Criteria:

- Maximum dose 16mg per day (no patient should receive > 24mg)

Multiple Sclerosis Agents: Clinical Highlights

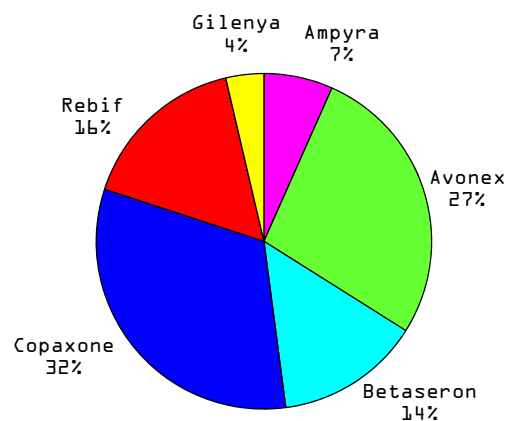
■ FDA approvals:

- Avonex® Pen Pre-filled Autoinjector
- Avostartgrip™ Titration Kit

■ Gilenya®

- Reports of deaths after first dose
- Labeling changes

Multiple Sclerosis Agents: Market Share



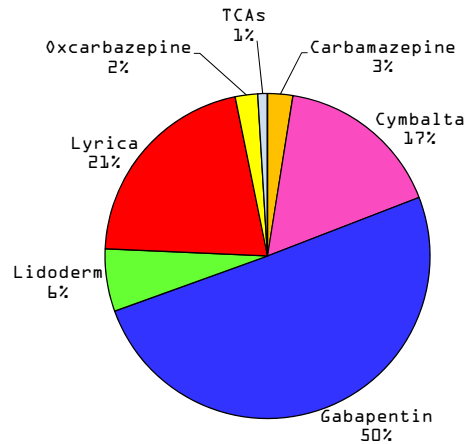
Multiple Sclerosis Agents: Recommendations

- Move to Non-Preferred:
 - Gilenya®

Neuropathic Pain Agents: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class are:
 - amitriptyline
 - carbamazepine
 - clomipramine
 - desipramine
 - doxepin
 - duloxetine
 - gabapentin
 - imipramine
 - lidocaine Patch
 - nortriptyline
 - oxcarbazepine
 - pregabalin

Neuropathic Pain Agents: Total Market Share



Neuropathic Pain Agents: Recommendations

■ 3-Tiered Class w/Step Therapy:

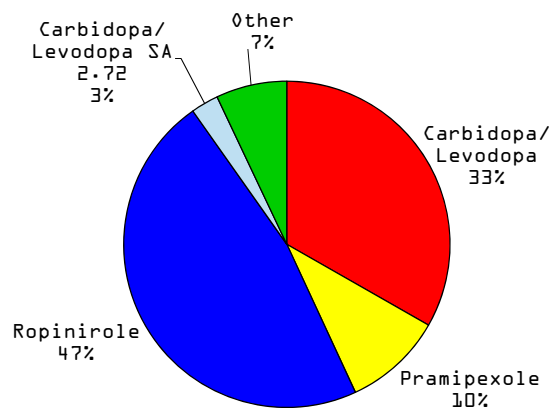
■ Preferred Generics: amitriptyline, amoxapine, carbamazepine, clomipramine, desipramine, doxepin, gabapentin, imipramine, nortriptyline, oxcarbazepine, protriptyline, trimipramine

■ Preferred Brands: Cymbalta®, Lyrica®

Parkinson's Agents: Clinical Highlights

- FDA approvals:
 - Generic carbidopa/levodopa/entacapone (A rated to Stalevo®)
- New Dosage Strengths:
 - Mirapex ER® 2.25mg, 3.75mg

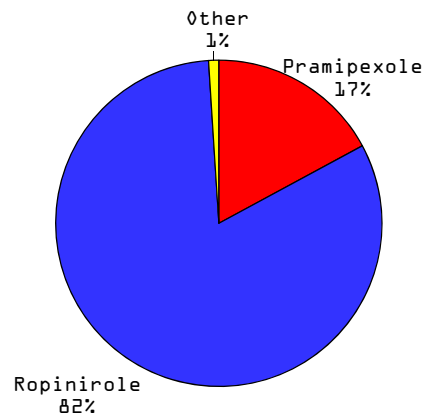
Parkinson's Agents: Market Share



Restless Legs Syndrome Agents: Clinical Highlights

- New class for inclusion on the PDL
- Agents reviewed in this class are:
 - pramipexole (Mirapex®)
 - ropinirole (Requip®)
 - gabapentin enacarbil (Horizant®)

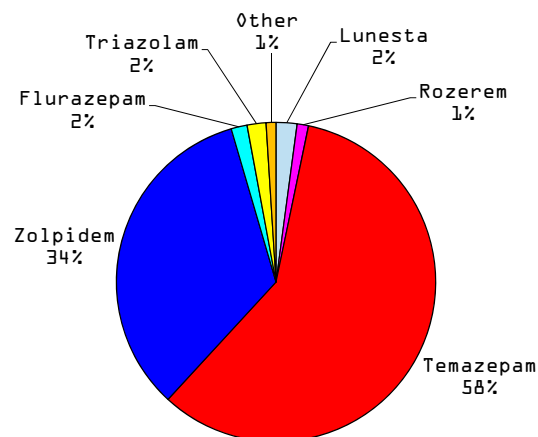
Restless Legs Syndrome Agents: Market Share



Restless Legs Syndrome: Recommendations

- Add to Preferred:
 - Generic pramipexole
 - Generic ropinirole
- Add to Non-Preferred
 - Horizant®

Sedative Hypnotics, Non-Barbiturate: Market Share



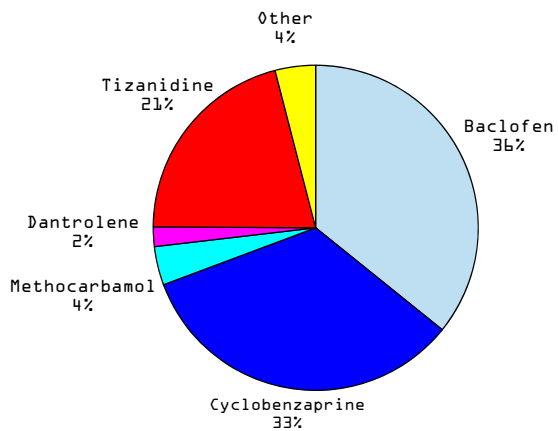
Sedative Hypnotics, Non-Barbiturate : Recommendations

- 3-Tiered Class w/Step Therapy:
 - Preferred Generics: estazolam, flurazepam, temazepam, zaleplon, zolpidem
 - Preferred Brands: Lunesta®

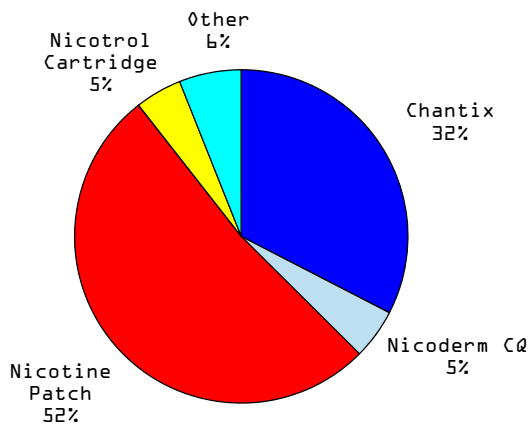
Skeletal Muscle Relaxants, Non-Benzodiazepine: Clinical Highlights

- FDA Approvals:
 - Generic cyclobenzaprine (A rated to Amrix®)
 - Generic tizanidine capsules (A rated to Zanaflex®)
 - Lorzone™ (chlorzoxazone)
- Soma® (carisoprodol):
 - C-IV Controlled Substance all states

Skeletal Muscle Relaxants, Non-Benzodiazepine: Market Share



Smoking Deterrents: Market Share

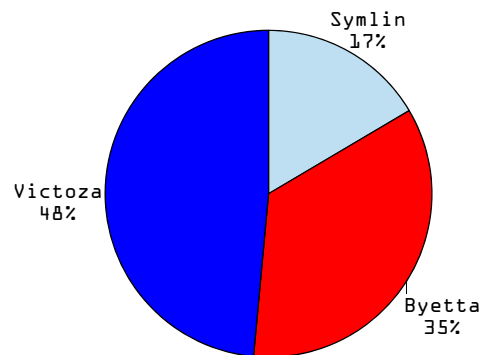


Amylin Analogs and Incretin Mimetics: Clinical Highlights

■ FDA Approvals:

- Bydureon™ (exenatide extended-release)

Amylin Analogs and Incretin Mimetics: Market Share



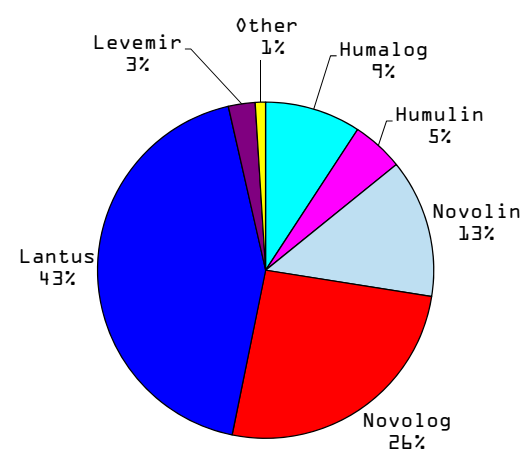
Insulins: Clinical Highlights

■ Levemir®:

- Safety and Efficacy established in children 2-17yrs



Insulins: Market Share

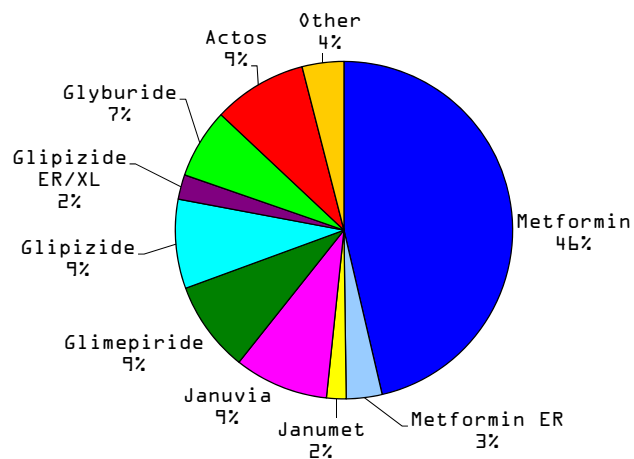


Oral Hypoglycemics: Clinical Highlights

■ FDA approvals:

- Janumet® XR (sitagliptin/metformin)
- Jentadueto™ (linagliptin/metformin)

Oral Hypoglycemics: Market Share



Oral Hypoglycemics: Recommendations

■ 3-Tiered Class w/Step Therapy:

■ Preferred Generics: Acarbose[®], glimepiride, glipizide, glipizide ER, glipizide/metformin, glyburide, glyburide micronized, glyburide/metformin, metformin, metformin ER, Starlix[®]

■ Preferred Brands: Actoplus Met[®], Actoplus Met XR[®], Actos[®], Duetact[®], Glyset[®], Janumet[®], Janumet[®] XR, Januvia[®], Jentadueto[™], Juvisync[™], Kombiglyze[™] XR, Onglyza[®], Tradjenta[®]

Estrogenic Agents: Clinical Highlights

■ FDA Approvals:

■ Jevantique[®] (EE/norethindrone; A rated to FemHRT)

■ New Dosage Strengths:

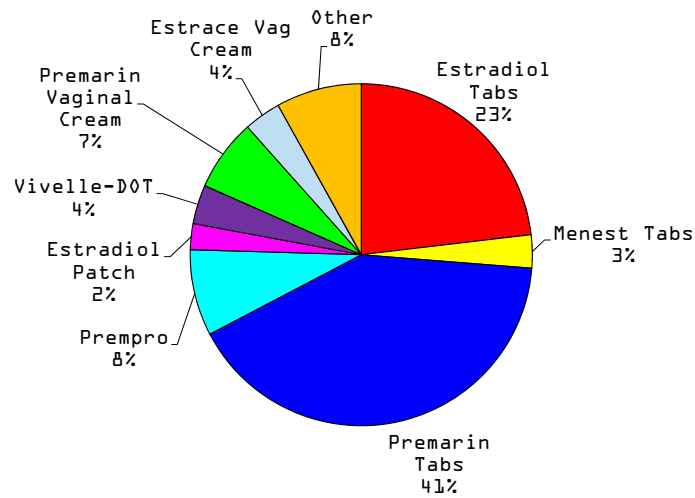
■ Generic EE/norethindrone 0.1mg/0.5mg (A rated to Activella[®])

■ Discontinued products:

■ Estraderm[®] (estradiol) Patch

■ Vagifem[®] 25mcg formulation

Estrogenic Agents: Market Share



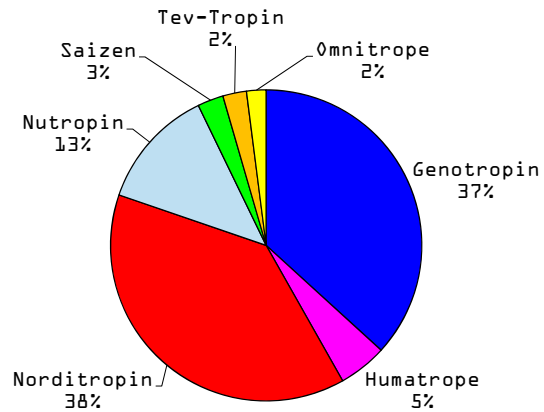
Growth Hormones: Clinical Highlights

■ New Indication:

■ Omnitrope®

- Treatment of pediatric patients with Turner Syndrome

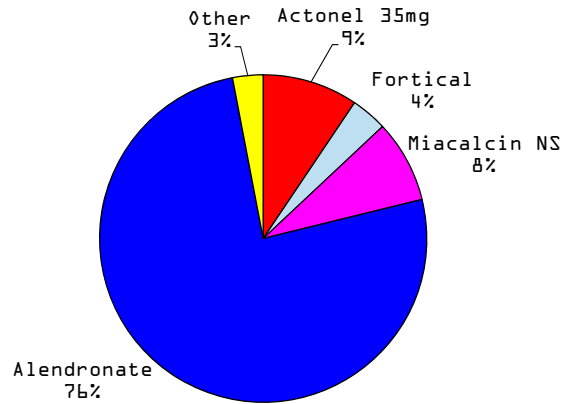
Growth Hormones: Market Share



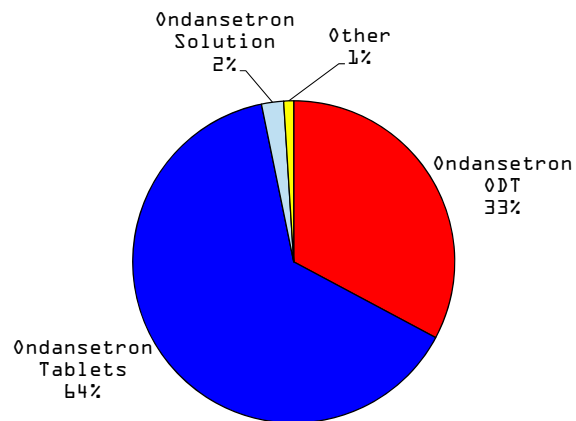
Growth Hormones: Recommendations

- New/Modified PA Criteria:
 - Initial authorization
 - Reauthorization - 1 yr approval

Bone Ossification Enhancers: Market Share



Anti-Emetic Agents: Market Share



Chronic Constipation Agents: Recommendations

- Add to Preferred:

- bisacodyl, casanthranol/docusate sodium, polyethylene glycol, senna

- Move to Non-Preferred:

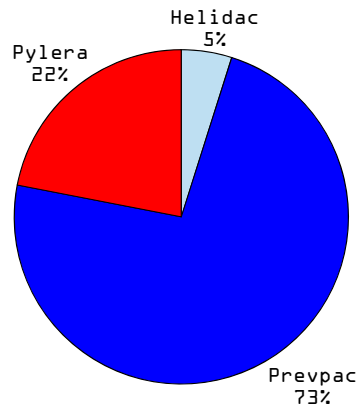
- Amitiza[®] w/Step Therapy

H. Pylori Agents: Clinical Highlights

- FDA Approvals:

- Omeclamox-Pak[®] (omeprazole/
clarithromycin/amoxicillin)

H. Pylori Agents: Market Share



H. Pylori Agents: Recommendations

- Add to Non-Preferred:
 - Omeclamox-Pak®

Pancreatic Enzymes: Clinical Highlights

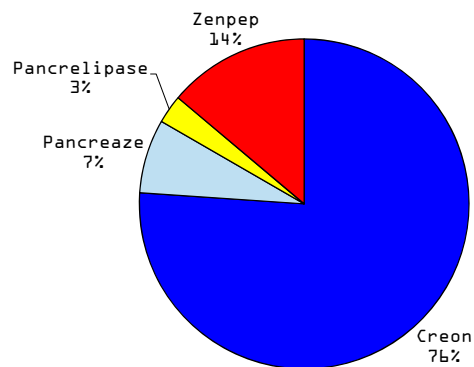
■ New Dosage Strengths:

■ Zenpep® (lipase/protease/amylase)

■ 3,000/10,000/16,000

■ 25,500/85,000/136,000

Pancreatic Enzymes: Market Share

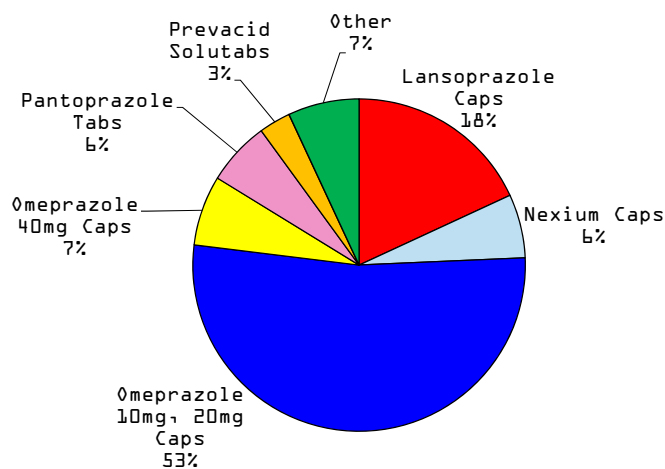


Proton Pump Inhibitors (PPIs): Clinical Highlights

■ New Indication:

- Nexium® - use in EE due to GERD in infants < 1 month to < 1yr

Proton Pump Inhibitors (PPIs): Market Share

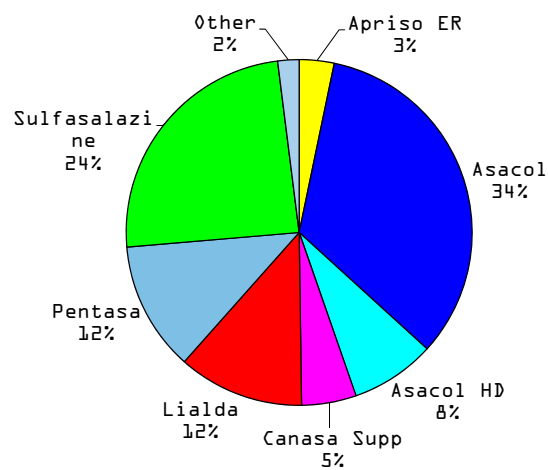


Ulcerative Colitis Agents: Clinical Highlights

■ New Indication:

- Lialda® - maintenance of remission of UC; dose is 2.4gm daily

Ulcerative Colitis Agents: Market Share



Ulcerative Colitis Agents: Recommendations

■ 3-Tiered Class w/Step Therapy (oral only):

■ Preferred Generics: balsalazide, sulfasalazine, sulfasalazine EC

■ Preferred Brands: Apriso[®], Asacol[®]

Benign Prostatic Hypertrophy Agents: Clinical Highlights

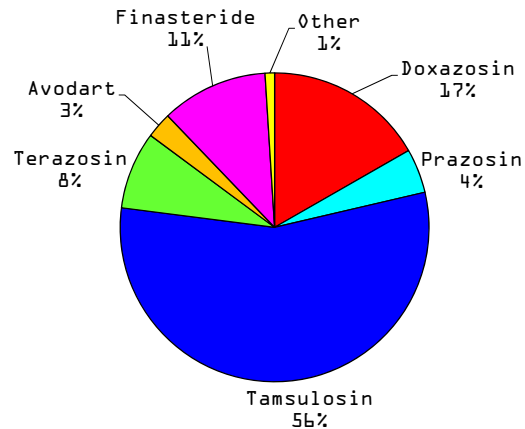
■ FDA approvals:

■ Generic alfuzosin (A rated to Uroxatral[®])

■ Cialis[®] :

■ New indication for BPH

Benign Prostatic Hypertrophy Agents: Market Share



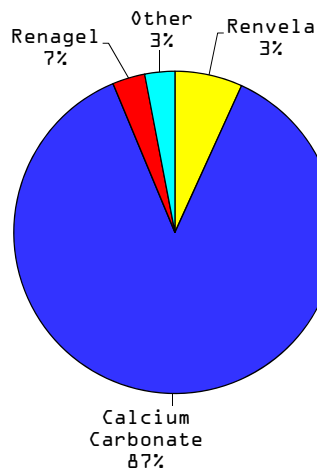
Benign Prostatic Hypertrophy Agents: Recommendations

- Add to Non-Preferred:
 - Cialis® w/PA criteria

Electrolyte Depleters: Clinical Highlights

- FDA approvals:
 - Generic calcium acetate tablets (A rated to Eliphos™)
 - Phoslyra® (calcium acetate) Oral Solution

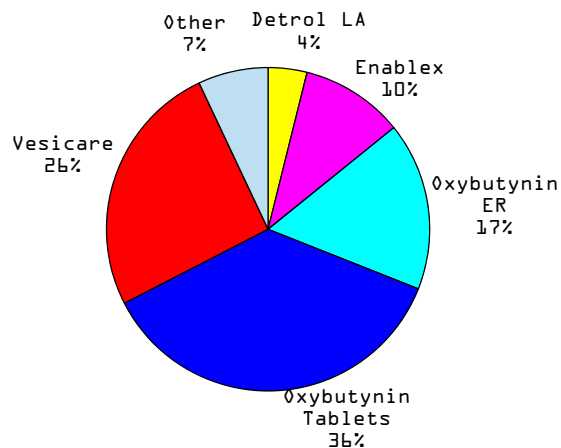
Electrolyte Depleters: Market Share



Electrolyte Depleters: Recommendations

- 3-Tiered Class w/Step Therapy:
 - Preferred Generics: calcium acetate, calcium carbonate, Calphron[®], Eliphos[™], Phoslo[®]
 - Preferred Brands: Magnebind[®], Renagel[®]

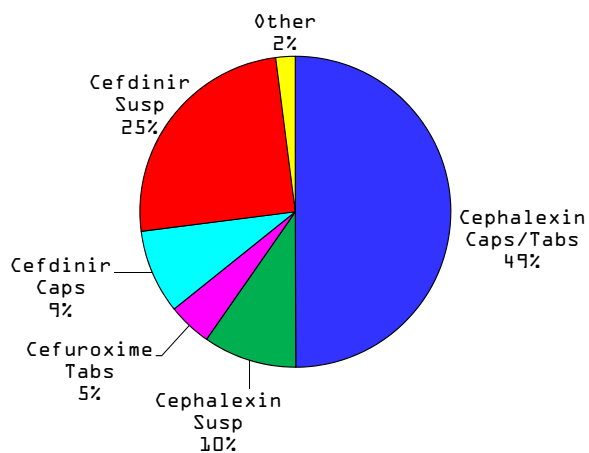
Urinary Antispasmodics: Market Share



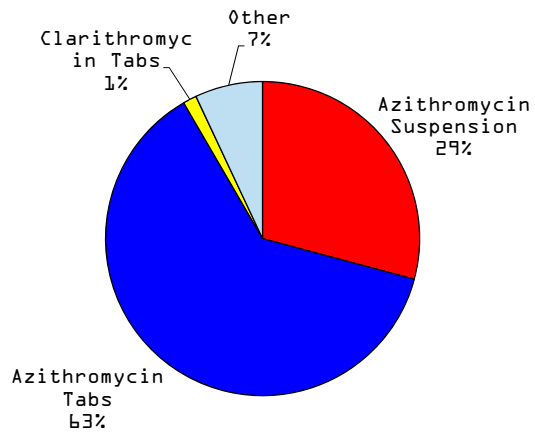
Urinary Antispasmodics: Recommendations

- 3-Tiered Class w/Step Therapy:
 - Preferred Generics: oxybutinin ER, oxybutinin syrup, oxybutinin tablets, Sanctura®
 - Preferred Brands: Enablex®, Oxytrol® Patch, Sanctura XR®, Vesicare®
- Remove from PDL:
 - Urispas® (flavoxate)

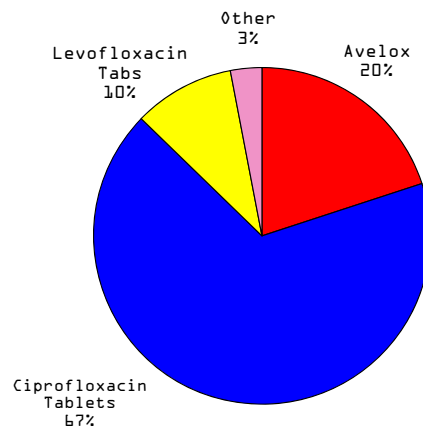
Oral Cephalosporins: Market Share



Oral Macrolides: Market Share



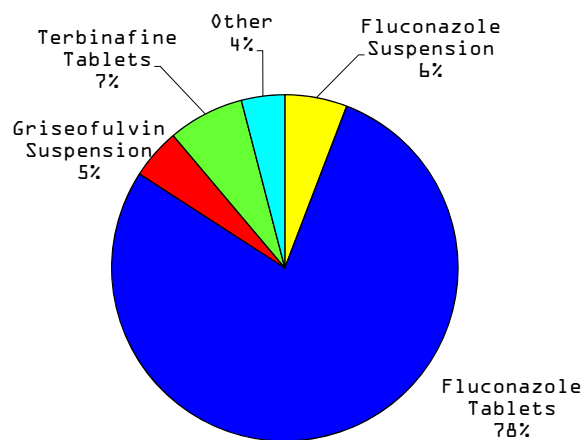
Oral Quinolones: Market Share



Oral Quinolones: Recommendations

- Move to Preferred:
 - Generic levofloxacin
- Move to Non-Preferred:
 - Avelox[®]
 - Avelox[®] ABC Pack

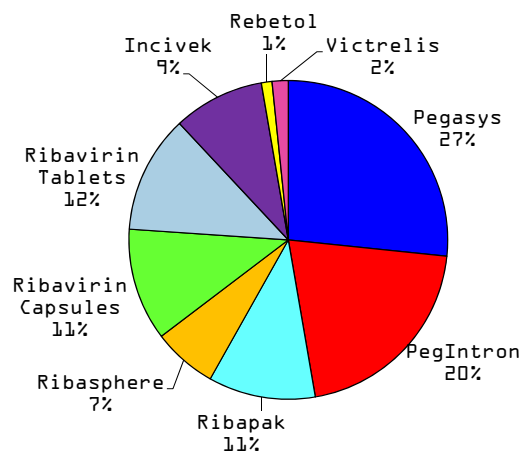
Agents for Onychomycosis & Systemic Infections: Market Share



Antivirals – Hepatitis C Agents: Clinical Highlights

- FDA approvals:
 - Incivek® (teleprevir)
 - Pegasys® Disposable Autoinjectors
125mcg/0.5mL and 180mcg/0.5mL
 - Victrelis® (boceprevir)
- New Indication:
 - Pegasys®
 - Patients 5-17yrs
 - Renal Impairment on chronic HD

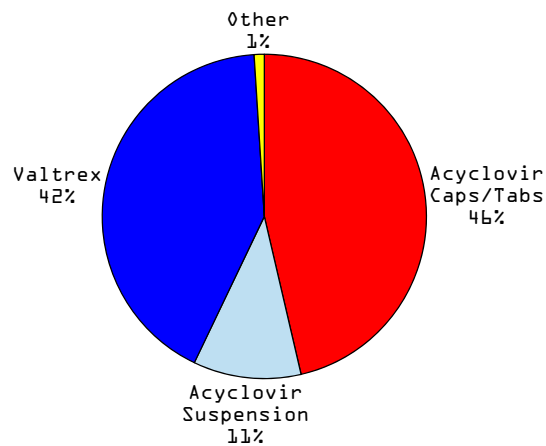
Antivirals - Hepatitis C Agents: Market Share



Antivirals - Hepatitis C Agents: Recommendations

- Move to Non-Preferred:
- Ribasphere®

Antivirals Herpes: Market Share

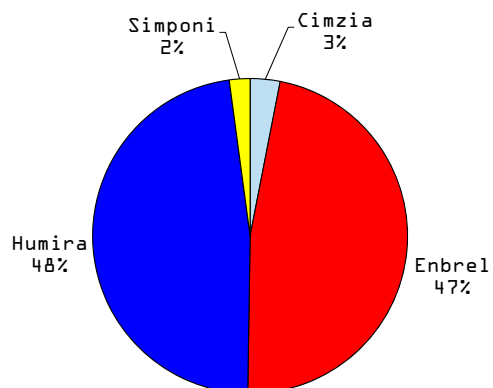


Injectable Antirheumatic Agents: Clinical Highlights

■ FDA approvals:

- Orencia® Syringe 125mcg/mL for SQ use

Injectable Anti-Rheumatic Agents: Market Share



Injectable Antirheumatic Agents: Recommendations

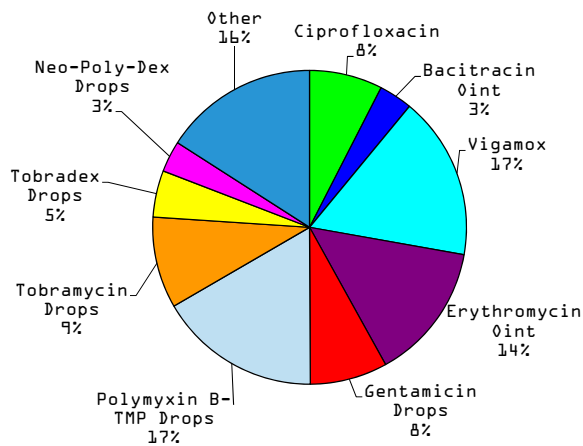
- Add to Non-Preferred:

- Orencia® Syringe

- Move to Non-Preferred:

- Kineret®

Ophthalmic Antibiotic Drops and Ointments: Market Share



Ophthalmic Antibiotic Drops and Ointments: Recommendations

■ 3-Tiered Class w/Step Therapy:

■ Preferred Generics: baci oint, baci/poly oint, ciprofloxacin drops, erythromycin oint, gentamicin drops & oint, neo/poly/baci oint, neo/pol/baci/HC oint, neo/poly/dex drops & oint, neo/poly/grami drops, ofloxacin drops, poly/trimethoprim drops, Tobradex® drops, tobramycin drops

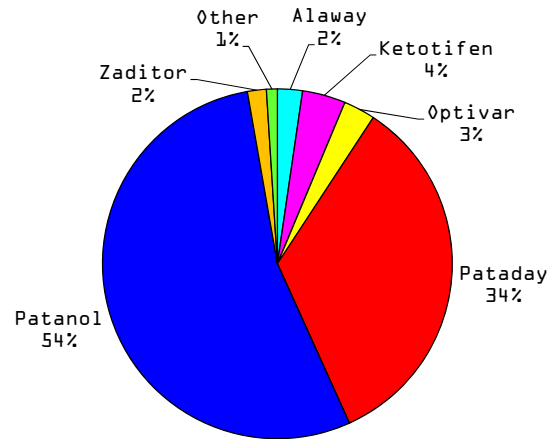
■ Preferred Brands: Blephamide® drops & oint, Ciloxan® ointment, Poly-Pred® drops, Pred-G® drops & oint, Tobradex® oint, Tobrex® oint, Vigamox® drops

Antihistamine/Mast Cell Stabilizers: Clinical Highlights

■ FDA approvals:

■ Generic epinastine 0.05% (A rated to Elestat®)

Antihistamine/Mast Cell Stabilizers: Market Share



Antihistamine/Mast Cell Stabilizers: Recommendations

- Move to Non-Preferred:
 - Patanol®

Glaucoma Agents: Clinical Highlights

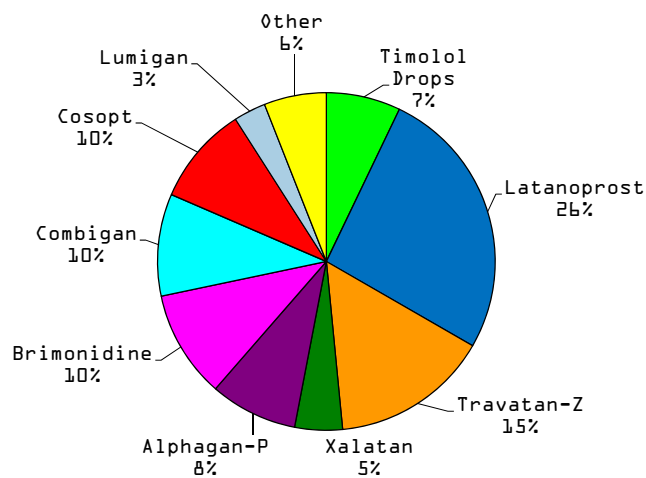
■ FDA approvals:

- Cosopt® PF (dorzolamide/timolol)
- Zioptan® (tafluprost)

■ Discontinued product:

- Travatan®

Glaucoma Agents: Market Share



Glaucoma Agents: Recommendations

■ 3-Tiered Class w/Step Therapy:

■ Preferred Generics: Alphagan[®]-P, betaxolol, brimonidine, carteolol, Cosopt[®], latanoprost, levobunolol, metipranolol, timolol gel, timolol solution, Trusopt[®]

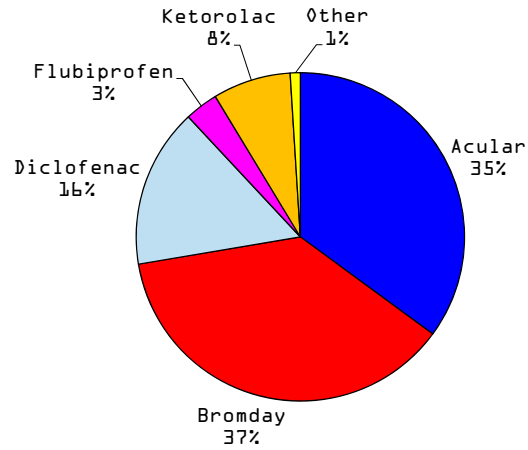
■ Preferred Brands: Azopt[®], Betimol[®], Combigan[®], Travatan-Z[®]

Ophthalmic NSAIDs: Clinical Highlights

■ FDA approvals:

■ Generic bromfenac (A rated to Xibrom[®])

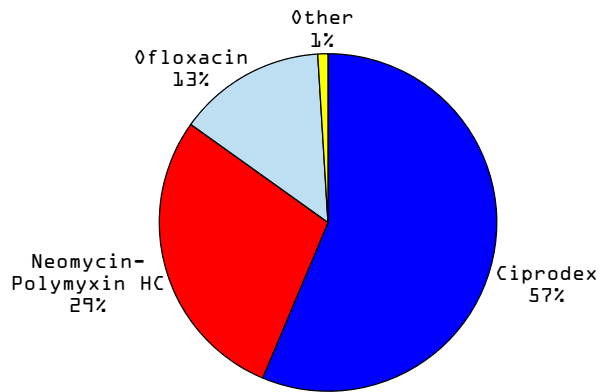
Ophthalmic NSAIDs: Market Share



Ophthalmic NSAIDs: Clinical Highlights

- Move to Non-Preferred:
 - Bromday®

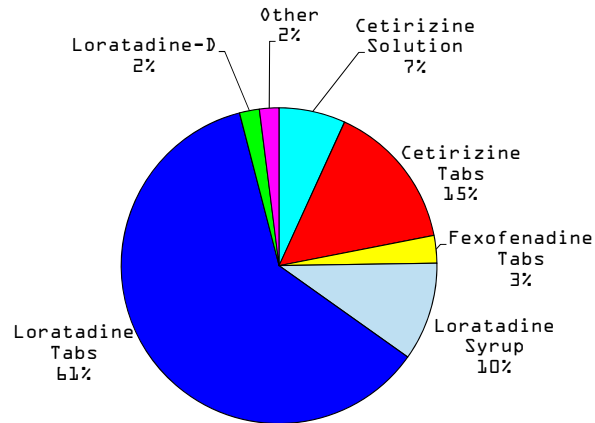
Otic Antibiotics: Market Share



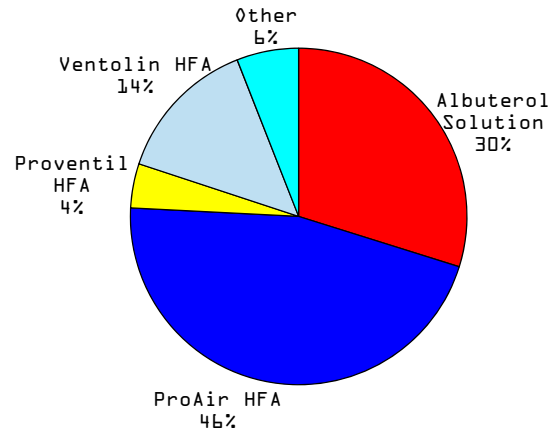
Antihistamines, Second Generation : Clinical Highlights

- FDA approvals:
 - Generic fexofenadine and fexofenadine/PSE Rx to OTC
 - Generic fexofenadine/PSE (A rated to Allegra -D[®])
 - Generic levocetirizine oral solution (A rated to Xyzal[®])

Antihistamines-Second Generation: Market Share



Short Acting Beta-adrenergic Agonists-Inhaled: Market Share

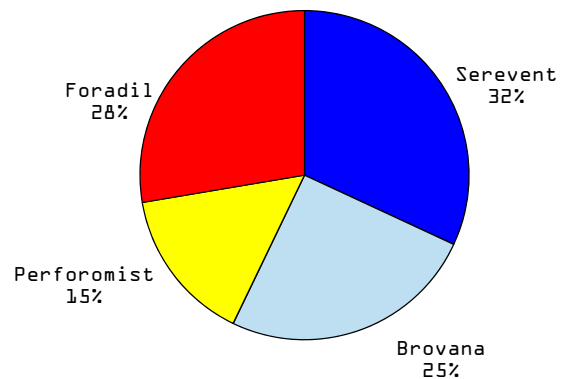


Long Acting Beta-adrenergic Agonists: Clinical Highlights

■ FDA approvals:

■ Arcapta™ Neohaler™ (indacaterol)

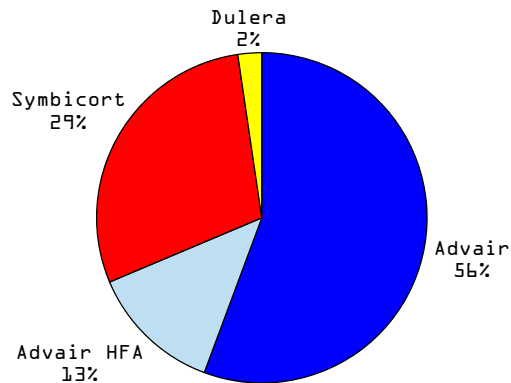
Long Acting Beta-adrenergic Agonists-Inhaled: Market Share



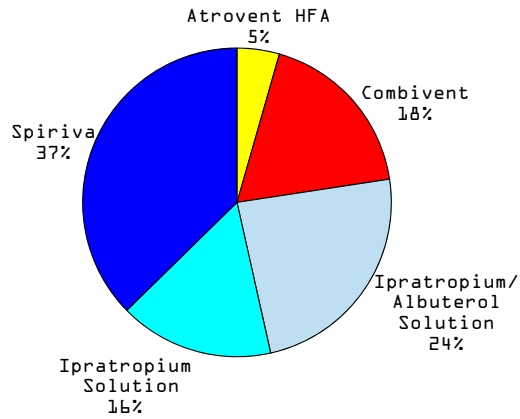
Long Acting Beta-adrenergic Agonists-Inhaled: Recommendations

- Add to Non-Preferred:
 - Arcapta™ Neohaler™

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



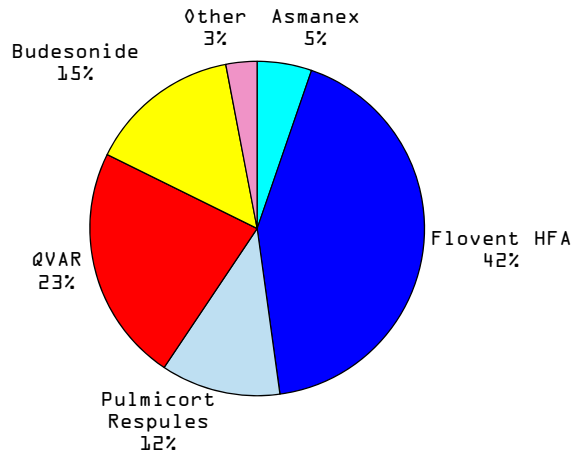
COPD Agents: Market Share



COPD Agents: Recommendations

- Add to Non-Preferred:
 - Daliresp[®] w/PA criteria

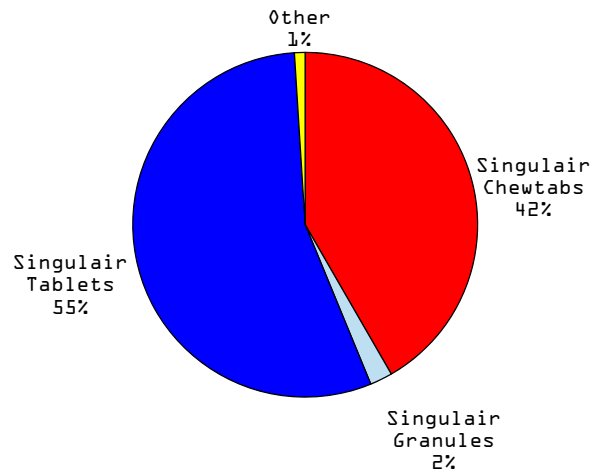
Glucocorticoid Agents-Inhaled: Market Share



Leukotriene Receptor Modifiers and Inhibitors: Clinical Highlights

- New Indication:
 - Singulair®
 - Prevention of EIB in patients \geq 6yrs

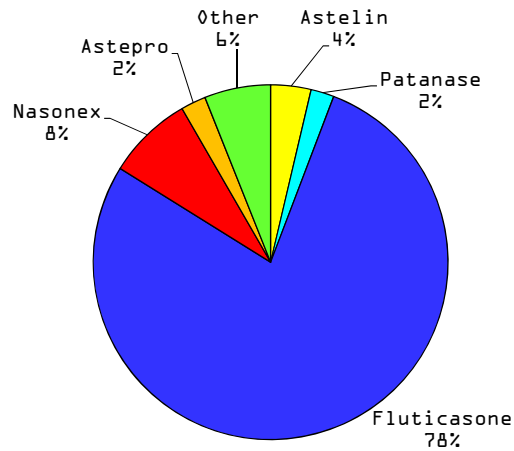
Leukotriene Receptor Modifiers and Inhibitors: Market Share



Nasal Preparations: Clinical Highlights

- FDA approvals:
 - QNASL™ (beclomethasone dipropionate)

Nasal Preparations: Market Share

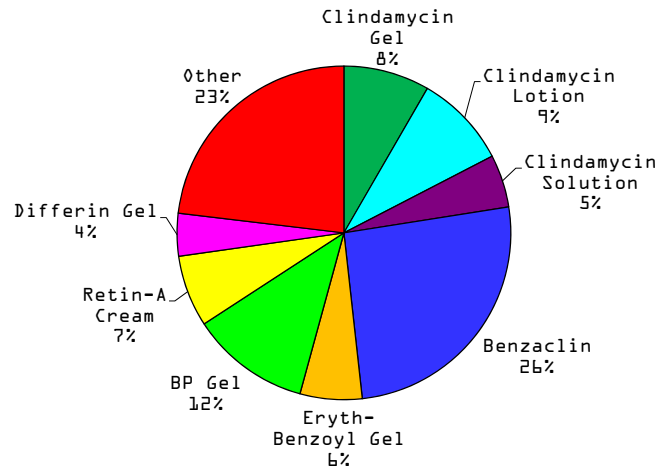


Nasal Preparations: Recommendations

■ 3 Tiered Class w/Step Therapy for Glucocorticoids only:

- Preferred Generics: flunisolide, fluticasone, Nasacort® AQ
- Preferred Brands: Nasonex®

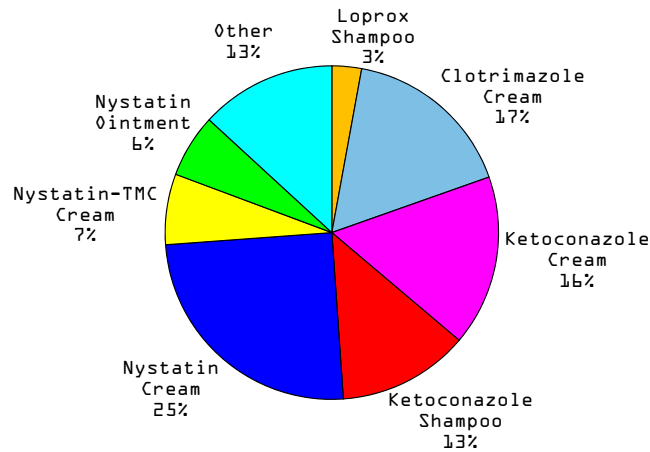
Topical Acne Agents: Market Share



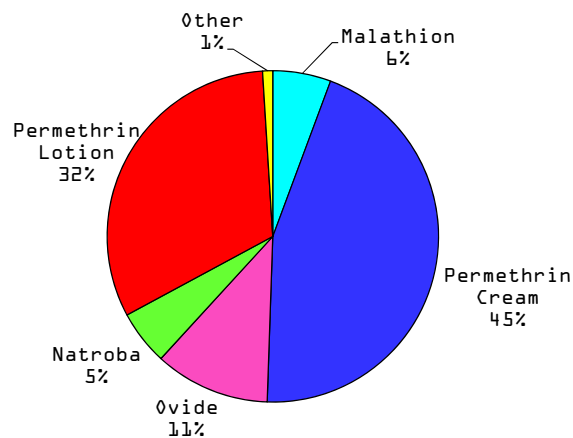
Topical Acne Agents: Recommendations

- Move to Preferred:
- Azelex[®] cream

Topical Anti-Fungals: Market Share



Topical Anti-Parasitic Agents: Market Share



Topical Anti-Parasitic Agents: Recommendations

■ Move to Non-Preferred:

- Ovide®

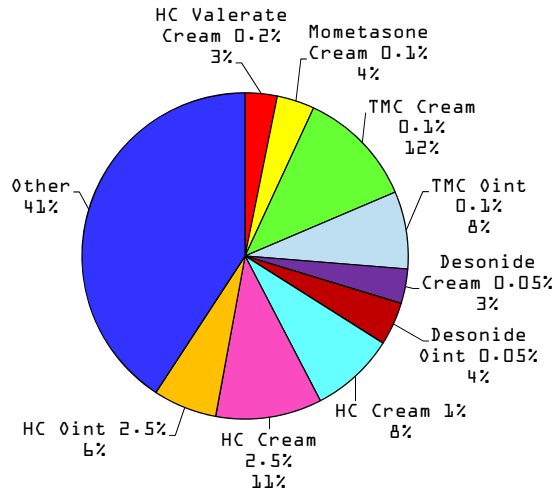
Topical Corticosteroids: Clinical Highlights

■ New class for inclusion on the PDL

■ Agents reviewed in this class are:

- alclometasone
- amcinonide
- betamethasone diprop.
- betamethasone valerate
- clobetasol propionate
- clocortolone pivalate
- desonide
- desoximetasone
- diflorasone diacetate
- fluocinolone acetonide
- fluocinonide
- flurandrenolide
- fluticasone propionate
- halcinonide
- halobetasol propionate
- hydrocortisone
- hydrocortisone acetate
- hydrocortisone butyrate
- hydrocortisone probutate
- hydrocortisone valerate
- mometasone furoate
- prednicarbate
- triamcinolone acetonide

Topical Corticosteroids: Market Share



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Topical Corticosteroids: Recommendations

■ Add to Preferred:

■ Low Potency: DermaSmoothe/FS® body oil & scalp oil, desonide cream & oint, fluocinolone acet. 0.01% cream & solution, fluocinolone body oil & scalp oil, HC cream, lotion, oint, & solution

■ Medium Potency: betamethasone val. cream & lotion, fluocinolone acet. 0.025% cream & oint, fluticasone prop. cream & oint, mometasone furoate cream, lotion, & oint, TMC cream & oint

■ High Potency: amcinonide cream, lotion, & oint, diflorasone diacetate cream & oint, fluocinonide cream, gel, oint, & sol

■ Very High Potency: None

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Topical Corticosteroids: Recommendations (cont'd)

■ Add to Non-Preferred:

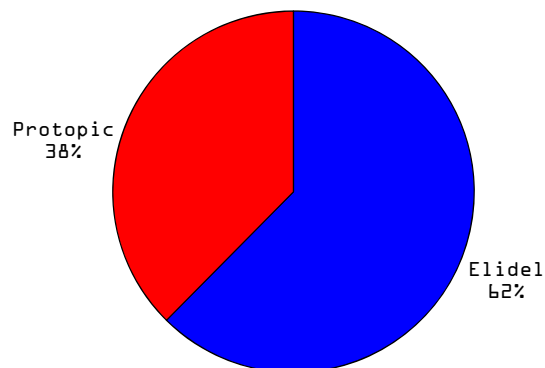
■ Low Potency: alclometasone oint, Capex[®] shampoo, Desonate[®] gel, desonide lotion, HC w/urea cream, Pandel[®] cream, Pediaderm[®] HC kit

■ Medium Potency: betamethasone dip. lotion, Cloderm[®], Cordran[®] tape, desoximetasone cream, gel, & oint, fluticasone prop. lotion, HC butyrate cream & oint, HC valerate cream & oint, Luxiq[®], prednicarbate cream & oint, TMC acetonide lotion

■ High Potency: Apexicon-E[®], beclomethasone dip. cream & oint, Halog[®] cream & oint, Kenalog[®] spray, Vanos[®] cream

■ Very High Potency: betamethasone dip. augmented (all), clobetasol propionate (all), Clobex[®] (all), halobetasol prop. cream & oint, Olux-E[®] foam

Topical Immunomodulators: Market Share



Topical Immunomodulators: Recommendations

- Move to Non-Preferred:

- Protopic®

- Add Step Therapy:

- Trial of topical corticosteroids