Ohio Department of Medicaid (ODM) P&T Committee Meeting Minutes

June 10, 2015
30 E. Broad St., Lobby Hearing Room, Columbus, OH

Committee members present: Susan Baker, CNP; Suzanne Eastman, PharmD; Michael Howcroft, RPh; Cheryl Huffman, MD; Robert Hunter, DO; Karen Jacobs, DO; Melissa Jefferis, MD; Margaret Scott, RPh; Michael Wascovich, PharmD.

Xerox staff present: Stephanie Levine, RPh, Clinical Manager, Kimberly Hunton, PharmD, Clinical Pharmacist

ODM staff present: Jill Griffith, PharmD; Anam Khan

Approximately 80 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. Interested party presentations began at noon, with committee discussion following.

1. Interested party presentations
    a. Bruce Trapnell, MD
    b. Betsy Johnson, NAMI-Ohio
    c. Jeanette Moleski, DO
    d. Megan Hart, MS, RD, LD
    e. Jackie Taylor, RD, CSP, LD
    f. Brian Beesley, DO
    g. Charles Noble, MD

2. Preferred Drug List (PDL) proposal

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

Analgesic Agents: Long-Acting Opioids

Dr. Jacobs asked if there were any thought to adding a preferred agent with an abuse-deterrent formulation. Ms. Scott gave some context to the recommendations to move fentanyl patches and methadone products to non-preferred status, and tramadol/acetaminophen to preferred status, by discussing the state's work to reduce the morphine equivalent dosing that is prescribed, and recommending lower-potency opioids. ODM's recommendation for generic MS Contin to be first-line long-acting therapy, with Nucynta ER second-line, supports this initiative. Nucynta ER is difficult to crush, so may reduce the incidence of abuse. The committee voted on the recommendation from Xerox and ODM, and the recommendation was accepted unanimously.

Blood Agents: Oral Anticoagulants
Dr. Jacobs noted that the interested party presentation made a compelling case for Eliquis. Dr. Hunter agreed, and said he has seen an uptake of Eliquis in the emergency department; he also noted that both Eliquis and Xarelto have good data. Dr. Wascovich asked if the proposal is to add Eliquis to Xarelto, or to replace Xarelto. Drs. Jacobs and Hunter both said they would advocate for both to be preferred. The committee vote was 7 in favor, with ODM staff abstaining.

Cardiovascular Agents: Pulmonary Arterial Hypertension
Dr. Huffman suggested that Revatio oral solution should be available for children who are unable to swallow pills. Ms. Scott said that ODM will add an age limit for Revatio oral suspension to be available for children first-line.

Central Nervous System Agents: Medication Assisted Treatment of Opioid Addiction
The committee discussed prior authorization criteria for buprenorphine products. Dr. Jacobs reported that she has consulted with colleagues who specialize in addiction treatment. Her colleagues suggested that individual counseling for addiction may not be useful, and that 12-step program attendance three times per week is more useful. In addition, aftercare following inpatient treatment is necessary. Dr. Jefferis asked how ODM will identify addictionologists. Ms. Scott said that we will rely on the medical board specialty listings and the American Board of Medical Specialties. Dr. Huffman asked about documentation for 12-step program attendance. Dr. Hunter said that physician attestation is sufficient, and if necessary an audit can be performed. Dr. Jacobs asked about the requirement for a dose reduction on re-authorization. Ms. Scott said that the goal is for patients to be able to wean off buprenorphine, so ODM will ask for a discussion of dose reduction to happen every six months. The same dose may be continued if the physician and patient agree that a dose reduction is not appropriate.
Dr. Huffman noted the abuse potential of Suboxone and said she does not agree with keeping it as a preferred drug. Dr. Jacobs noted that there are 16,000 deaths per year from opioid overdoses and only 600 for Suboxone, so the risk of death is lower. Dr. Hunter said he would like to see Bunavail or Zubsolv as preferred agents, substituting for Suboxone. Dr. Jacobs suggested that Zubsolv remain preferred. Dr. Jefferis asked for the rationale for the recommendation to move it to non-preferred status. Dr. Hunton said that Xerox and ODM look first at clinical factors, then to market share and financial considerations. In this case, the market share of Zubsolv was low after moving to preferred status. Dr. Hunter said that low market share of Zubsolv is not an issue and that it should be included as an option because it is not as likely to be diverted. The vote to retain Zubsolv in preferred status was 7 in favor, with ODM staff abstaining.

Endocrine Agents: Diabetes Adjunctive Therapy
Dr. Hunter asked about the market share for Victoza. Dr. Levine said that the market share was 83% in the first quarter of 2015. Dr. Hunter noted that it will be tough to move so many patients to other agents. Dr. Eastman noted that Bydureon requires additional patient intervention to prepare the syringe. Ms. Baker noted that the American Diabetes Association recommends these drugs as an add-on to metformin after 3 months, and perhaps allowing endocrinologists to prescribe non-preferred drugs is a compromise. Dr. Hunter noted that primary care also treats diabetes and recommended keeping Victoza in preferred status. Dr. Huffman agreed with the

proposal to require continued use of oral hypoglycemics and/or insulin. The vote to retain Victoza in preferred status was 7 in favor, with ODM staff abstaining.

Endocrine Agents: Diabetes – Insulin
Dr. Jacobs noted that Levemir is pregnancy category B so should be available for pregnant women. Dr. Hunton said that all insulin except Lantus, Apidra and Toujeo are pregnancy category B. Dr. Jefferis suggested that clinical criteria should be added to allow patients needing higher doses of insulin to be able to access Toujeo.
Ms. Scott agreed that ODM will consider changes to the prior authorization criteria to allow pregnant women to receive Levemir and patients needing high doses of insulin to receive Toujeo.

Endocrine Agents: Diabetes – Oral Hypoglycemics
Dr. Wascovich noted that the newest guidelines include sodium-glucose cotransporter-2 inhibitors (SGLT2) as second line therapy, and asked if ODM should add a preferred agent in this category. Ms. Scott said that ODM did not find SGLT2s better than other agents either clinically or financially. Dr. Wascovich noted that they improve weight loss and lower blood pressure. Dr. Hunton noted that SGLT2s also increase LDL. Dr. Hunter said that there should be additional information from FDA soon, so this can be discussed at the October meeting.

Gastrointestinal Agents: Chronic Constipation Agents
Dr. Eastman asked why ODM chose 12 weeks for the opioid-induced constipation criteria. Ms. Scott responded that this is consistent with the state's guidelines for treatment of chronic pain, as approved by the professional licensing boards.

Gastrointestinal Agents: Pancreatic Enzymes
Dr. Jacobs said that the earlier presentations from dietitians about cystic fibrosis patients was compelling, and she would love to see all products available. Dr. Wascovich said that he struggles with that suggestion because he doesn't know what medication should be chosen to start, and that perhaps shorter trials are a better idea. Ms. Baker asked about the market share in this class. Dr. Levine said that Creon is the leader with 86% of the market. Dr. Huffman said that two months of trials is too long, and suggested two products for two weeks each, or one product for two weeks. Dr. Wascovich suggested one agent for one month. Ms. Baker said that one month is too long, and agreed with one agent for two weeks. Dr. Hunter asked for a vote on a trial of one agent for two weeks. The vote was 7 in favor, with ODM staff abstaining.

Immunomodulator Agents for Systemic Inflammatory Disease
Dr. Jacobs asked if it makes sense to have an oral agent available in this class. Ms. Scott noted that Otezla is indicated only for psoriasis, and Dr. Hunton said that Xeljanz is indicated only for rheumatoid arthritis. Enbrel and Humira cover all indications.

Infectious Disease Agents: Antibiotics – Inhaled
Dr. Jacobs noted that TOBI Podhaler is convenient. Dr. Huffman said that the amount of time that cystic fibrosis patients and their families have to take to treat daily is long, and that to keep children out of the hospital ODM should try to keep treatment times low. Dr. Levine said that only 12 clients had used the TOBI Podhaler in the first quarter of 2015, and that 80% of

utilization is for the nebulizer solutions. Dr. Wascovich asked if there is an advantage to the nebulizer besides cost, and suggested that Kitabis and TOBI Podhaler be preferred. Dr. Hunter asked for a vote on Kitabis, Bethkis, and TOBI Podhaler being put into preferred status. The vote was 7 in favor with ODM staff abstaining.

Infectious Disease Agents: Antivirals – HIV
Dr. Wascovich asked if Vitekta and Tybost are part of combination therapies. Dr. Hunton said that they are.

Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Short Acting
Dr. Huffman said that it is important to be sure that an option with a dose counter is available.

Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Long Acting
Ms. Scott noted that there is a mistake on the draft PDL, Symbicort should not have been moved to non-preferred status. The recommendation is for Dulera and Symbicort to be preferred. Dr. Wascovich asked about the market share for Advair, since the recommendation is to move to non-preferred. Dr. Levine responded that the market share is 46% for Advair Diskus. The committee discussed moving market share and notifying clients about the change. Dr. Hunter asked for a vote on retaining Advair Diskus in preferred status. The vote was 7 in favor, with ODM staff abstaining.

Respiratory Agents: Epinephrine Auto-Injectors
Dr. Huffman asked ODM to encourage the managed care plans to cover Auvi-Q, because it talks the user through the injection process.

Respiratory Agents: Nasal Preparations
Dr. Jefferis noted that budesonide is the only nasal steroid in pregnancy category B. Dr. Hunton responded that Atrovent is also category B.

Dr. Hunter recognized Mike Wascovich for his service to the committee, and said that he will be missed as he moves out of state to take a new position.

The meeting was adjourned with a reminder that the next meeting is scheduled for Wednesday, October 14.

Notes from ODM after the meeting:

6/15/14
ODM is reviewing the recommendations of the P&T Committee:

- Add Eliquis to preferred status
- Add an age limit for Revatio oral suspension to be available for children first-line
- Prior authorization criteria for Medication Assisted Treatment to include:
    - Initial dosing may be higher than 16mg Suboxone equivalent if one of the exceptions in the Ohio Administrative Code has been met

    - Counseling at minimum may be attendance at a twelve-step program three times weekly, with the physician collecting attendance slips and attesting to attendance.
- Retain Zubsolv in preferred status
- Retain Victoza in preferred status
- Add prior authorization criteria to allow pregnant women to receive Levemir and patients needing high doses of insulin to receive Toujeo
- Change prior authorization criteria for non-preferred pancreatic enzymes to a trial of one preferred agent for two weeks
- Add TOBI Podhaler to preferred status
- Retain Advair Diskus in preferred status

7/8/15
ODM will implement all recommendations except adding prior authorization criteria for patients using high doses of Lantus to receive Toujeo.

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Ohio Medicaid Fee-For-Service

Pharmacy Benefit Management Program

Ohio Department of Medicaid

John R. Kasich, Governor

John B. McCarthy, Director

Preferred Drug List

Effective October 1, 2015

Draft May 29, 2015

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Analgesic Agents: Gastroprotective NSAIDs

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

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 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

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 from the same prescriber.

ANALGESIC AGENTS: GASTROPROTECTIVE NSAIDS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CELECOXIB (generic for Celebrex®) (no PA required for age 60 or older)	CELECOXIB (generic for Celebrex®) (PA required for under age 60) DICLOFENAC/MISOPROSTOL (generic of Arthrotec®) 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:

- Febuxostat will be approved after adequate trial of allopurinol, or intolerance/contraindication to allopurinol.
- Colchicine 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
	COLCHICINE (generic of Colcrys®, Mitigare®)*

* 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: NSAIDs Transdermal/Topical

LENGTH OF AUTHORIZATIONS: ***Dependent on medication request***

All products in this class require clinical prior authorization:

- ***Requests for diclofenac patches require a diagnosis of acute pain due to minor strains, sprains, and contusions***
- ***Requests for diclofenac pump or solution require a diagnosis of osteoarthritis of the knee(s)***
- ***Requests for diclofenac gel require a diagnosis of osteoarthritis of the hand(s) or knee(s)***
- ***Approvals for diclofenac solution and gel require history of a 30-day trial each of two different oral NSAIDs within the past 6 months; the approval length will be 3 months***
- ***Approvals for diclofenac patch require history of at least a 7-day trial on one oral NSAID; the approval length will be 14 days with a quantity limit of 2 patches/day***

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 14-day trial of at least one preferred medication***

ANALGESIC AGENTS: NSAIDS TRANSDERMAL/TOPICAL

CLINICAL PA REQUIRED "PREFERRED"	*PA REQUIRED*
VOLTAREN® gel (diclofenac sodium)	*DICLOFENAC 1.5% topical solution (generic of Pennsaid®)* *FLECTOR® patch (diclofenac epolamine)* *PENNSAID® 2% solution (diclofenac sodium)*

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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 at least one combination product or tramadol, for no less than one week
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 agents

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 or non-preferred long-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 Hydrocodone Products		
		ZOHYDRO ER® (hydrocodone)
Extended Release Morphine Products		
MORPHINE SULFATE ER tablet (generic of MS Contin®)		EMBEDA® (morphine sulfate/ naltrexone) MORPHINE SULFATE ER capsule (generic of Avinza®, Kadian®)
Extended Release Oxycodone Products		
		HYSINGLA ER® (oxycodone) OXYCODONE ER (generic of Oxycontin®) OXYCONTIN® (oxycodone) XARTEMIS XR® (oxycodone/ acetaminophen)
Extended Release Tramadol Products		
		CONZIP® (tramadol) TRAMADOL ER (generic of Ryzolt ER®, Ultram ER®)
Extended Release Oxymorphone Products		
		OPANA ER tablets (oxymorphone abuse-deterrent) OXYMORPHONE HCL ER tablets (generic of Opana® ER non-abuse-deterrent)
Extended Release Hydromorphone Products		
		HYDROMORPHONE ER (generic of Exalgo® ER)
Extended Release Tapentadol Products		
	NUCYNTA ER® (tapentadol)	

ANALGESIC AGENTS: OPIOIDS – Long-Acting Transdermal

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
		BUTRANS® patch (buprenorphine) ***FENTANYL PATCH (generic of Duragesic®)*** ***FENTANYL patch 37.5mg/hr, 62.5mg/hr, 87.5mg/hr***

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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 tablet	
Hydromorphone Products	
HYDROMORPHONE HCL tablet (generic of Dilaudid®)	
Levorphanol Products	
	LEVORPHANOL TABLETS (generic of Levo-Dromoran)
Meperidine Products	
	MEPERIDINE tablet (generic of Demerol®)
Methadone Products	
	METHADONE tablet (generic of Dolophine®)
Morphine Products	
MORPHINE SULFATE: immediate-release tablets (generic of MSIR®)	
Oxycodone Products	
ROXICODONE® tablets (oxycodone) OXYCODONE HCL capsules, tablets (generic of M-Oxy®, OxyIR®)	OXECTA® (oxycodone)
Oxymorphone Products	
	OXYMORPHONE HCL tablets (generic of Opana®)
Tapentadol Products	
NUCYNTA® (tapentadol)	

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ANALGESIC AGENTS: OPIOIDS – Short-Acting Combination

NO PA REQUIRED "PREFERRED"	PA REQUIRED
Codeine Combinations	
ACETAMINOPHEN w/CODEINE TABLETS (generic of Tylenol® #2, #3, #4)	
Dihydrocodeine Combinations	
	DIHYDROCODEINE/ASPIRIN/CAFFEINE (generic of Synalgos-DC®)
Hydrocodone Combinations	
HYDROCODONE/ACETAMINOPHEN tablets containing 325mg acetaminophen (generic of Lorcet, Lortab, Norco)	HYDROCODONE/ IBUPROFEN (generic of Ibudone®, Vicoprofen®) HYDROCODONE/ACETAMINOPHEN tablets containing 300mg acetaminophen (generic of Vicodin®, Xodol®)
Oxycodone Combinations	
OXYCODONE W/ ACETAMINOPHEN tablets (generic of Percocet®)	OXYCODONE W/ IBUPROFEN (generic of Combunox®) PRIMLEV® (oxycodone/ acetaminophen)
Pentazocine Combinations	
Not advocated for use	PENTAZOCINE/NALOXONE (generic of Talwin NX®)
Tramadol Combinations	
TRAMADOL/ACETAMINOPHEN (generic of Ultracet®)	
Carisoprodol Combinations	
	CARISOPRODOL/ASPIRIN/CODEINE (generic of Soma Compound w/Codeine®)

ANALGESIC AGENTS: CENTRAL, WITH OPIOID ACTIVITY

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

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

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

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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, 2.5mg-108mg/5ml (generic of Hycet®, Lortab Elixir®) LORTAB® 10mg-300mg/15ml (hydrocodone/ acetaminophen) ROXICET ORAL SOLN® (5mg Oxycodone-325mg APAP/5ml)	CAPITAL w/CODEINE® suspension 12mg codeine-120mg APAP/5ml ZAMICET 10mg-325mg/15ml

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) SUBSYS® (fentanyl)

* Note: Clinical criteria must be met for transmucosal systems

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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:

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 preferred medications?

BLOOD AGENTS: HEMATOPOIETIC AGENTS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ARANESP® (darbepoetin alfa) PROCRIT® (epoetin alfa)	EPOGEN® (epoetin alfa) ***MIRCERA® (methoxy polyethylene glycol-epoetin beta)***

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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® (dalteparin) ENOXAPARIN (generic of Lovenox®)	FONDAPARINUX (generic of Arixtra®)

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Blood Formation, Coagulation, and Thrombosis Agents: Oral Anticoagulants

LENGTH OF AUTHORIZATIONS: 1 year

INDICATIONS:

		Apixaban	Clopidogrel	Dabigatran	Edoxaban	Prasugrel	Rivaroxaban	Ticagrelor	Voraxapar	Warfarin
Reduction of atherosclerotic events:	After cardiac valve replacement									✓
	In established peripheral arterial disease		✓						✓	
	In non-STEMI ACS		✓			✓		✓		✓
	In non-valvular atrial fibrillation	✓		✓	✓		✓ (15 & 20mg)			✓
	In recent MI or stroke		✓						✓ (MI only)	✓
	In STEMI ACS		✓			✓		✓		✓
Thrombosis Risk and Treatment	Treatment of venous thrombosis, pulmonary embolism	✓		✓ (in patients who have been treated with a parenteral anticoagulant for 5-10 days)	✓ (in patients who have been treated with a parenteral anticoagulant for 5-10 days)		✓ (15 & 20mg)			✓
	Prophylaxis of DVT in patients undergoing total hip or knee replacement	✓					✓ (10mg)			
	Reduce risk of recurrence of DVT and PE in patients who have been previously treated	✓		✓			✓ (20mg)			

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

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

BLOOD AGENTS: ORAL ANTICOAGULANTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
WARFARIN (generic of Coumadin®) XARELTO® (rivaroxaban) *	ELIQUIS® (apixaban) PRADAXA® (dabigatran) SAVAYSA® (edoxaban)

* Note: Duration limit of 35 days applies to Xarelto 10mg tablets, see Heparin-Related Preparations for details

BLOOD AGENTS: PLATELET AGGREGATION INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BRILINTA® (ticagrelor) CLOPIDOGREL (generic of Plavix®) EFFIENT® (prasugrel) WARFARIN (generic of Coumadin®)	ZONTIVITY® (vorapaxar sulfate)

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Cardiovascular Agents: Angina, 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
3. For ARB/calcium channel blocker combinations, the preferred generic trial may be a calcium channel blocker or ARB

CHRONIC STABLE ANGINA STEP THERAPY:

Ranolazine (Ranexa®) may be approved if there has been a therapeutic failure to no less than a one-month trial of at least one beta blocker, calcium channel blocker, or nitrate (excluding sublingual nitroglycerin).

OTHER APPROVAL CRITERIA:

1. Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with preferred medications
   - History of unacceptable/toxic side effects to preferred medications
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.

CHRONIC STABLE ANGINA

NO PA REQUIRED "PREFERRED"	PA REQUIRED
Generic beta blockers Generic calcium channel blockers Generic nitrates	RANEXA® (ranolazine)

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ACE INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BENAZEPRIL (generic of Lotensin®) CAPTOPRIL (generic of Capoten®) ENALAPRIL (generic of Vasotec®) EPANED® (enalapril oral solution) 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®)	

ACE INHIBITORS/CCB COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AMLODIPINE/BENAZEPRIL (generic of Lotrel®) TARKA® (verapamil/trandolapril)	VERAPAMIL/TRANDOLAPRIL (generic of Tarka®)

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 Vaseretic®) FOSINOPRIL/HCTZ (generic of Monopril HCT®) LISINOPRIL/HCTZ (generic of Zestoretic®, Prinzide®) MOEXIPRIL/HCTZ (generic of Uniretic®) QUINAPRIL/HCTZ (generic of Accuretic®)	

ALPHA-BETA BLOCKERS

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

ANGIOTENSIN II RECEPTOR ANTAGONISTS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
IRBESARTAN (generic of Avapro®) LOSARTAN (generic of Cozaar®) ***VALSARTAN (generic of Diovan®)***	BENICAR® (olmesartan)	CANDESARTAN (generic of Atacand®) EDARBI® (azilsartan) EPROSARTAN (generic of Teveten®) TELMISARTAN (generic of Micardis®)

ANGIOTENSIN II RECEPTOR ANTAGONISTS/ DIURETIC COMBINATION

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
IRBESARTAN-HCTZ (generic of Avalide®) LOSARTAN-HCTZ (generic of Hyzaar®) VALSARTAN/HCTZ (generic of Diovan HCT®)	BENICAR HCT® (olmesartan/hctz)	CANDESARTAN/HCTZ (generic of Atacand HCT®) EDARBYCLOR™ (azilsartan/ chlorthalidone) TELMISARTAN/HCTZ (generic of Micardis HCT®) TEVETEN HCT® (eprosartan/HCTZ)

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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)	AMLODIPINE/ TELMISARTAN (generic of Twynsta®) AMLODIPINE/ VALSARTAN (generic of Exforge®)

ANGIOTENSIN II RECEPTOR ANTAGONISTS/ CALCIUM CHANNEL BLOCKER/DIURETIC COMBINATION

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
	EXFORGE HCT® (amlodipine/ valsartan/hctz) TRIBENZOR® (olmesartan/ amlodipine/hctz)	AMLODIPINE/ VALSARTAN /HCTZ (generic of Exforge® HCT)

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®) TIMOLOL (generic of Blocadren®)	BYSTOLIC® (nebivolol) INNOPRAN XL® (propranolol) LEVATOL® (penbutolol) ***SOTILYZE® oral solution (sotalol)***

BETA-BLOCKERS/DIURETIC COMBINATION

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

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®)	ISRADIPINE (generic of Dynacirc®) NIMODIPINE (generic of Nimotop®)* NYMALIZE oral solution (nimodipine) * NISOLDIPINE (generic of Sular®)

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

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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®)	DILTIAZEM 24H ER tablet (generic of Cardizem LA®) VERAPAMIL ER PM (generic of Verelan PM®)

DIRECT RENIN INHIBITORS*

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
TEKTURNA® (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.

DIRECT RENIN INHIBITOR/DIURETIC Combination*

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
TEKTURNA 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.

DIRECT RENIN INHIBITOR/CALCIUM CHANNEL BLOCKER COMBINATION*

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
TEKAMLO® (aliskiren/amlodipine)	

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

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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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
2. Has the patient failed a therapeutic trial of one month with one medication not requiring prior approval?

CARDIOVASCULAR AGENTS: ANTIARRHYTHMICS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AMIODARONE (generic of Cordarone®) 200mg DISOPYRAMIDE PHOSPHATE IR (generic of Norpace®) DISOPYRAMIDE PHOSPHATE ER (generic of 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)	AMIODARONE 100mg, 400mg MULTAQ® (dronedarone)

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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 AND ICOSAPENT ETHYL (LOVAZA®, VASCEPA®):

Prescription-only omega-3 polyunsaturated fatty acid and icosapent ethyl are approvable only for adult patients with triglyceride levels equal to or greater than 500 mg/dL 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®) TABLETS:

- Colesevelam tablets 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

ADDITIONAL CRITERIA FOR EZETIMIBE (ZETIA®) TABLETS:

- Ezetimibe tablets may be approved after a therapeutic trial of one month on one HMG-CoA Reductase Inhibitor

CARDIOVASCULAR AGENTS: LIPOTROPICS – BILE ACID SEQUESTRANTS

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

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CARDIOVASCULAR AGENTS: LIPOTROPICS - STATINS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ATORVASTATIN (generic of Lipitor®) LOVASTATIN (generic of Mevacor®) PRAVASTATIN (generic of Pravachol®) SIMVASTATIN (generic of Zocor®)	ALTOPREV® (lovastatin) CRESTOR® (rosuvastatin) FLUVASTATIN (generic of Lescol®) LESCOL XL® (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
GEMFIBROZIL (generic of Lopid®) FENOFIBRATE (generic of Tricor®) FENOFIBRIC ACID (generic of Trilipix®)	ANTARA® (fenofibrate) LIPOFEN® (fenofibrate) LOFIBRA® (fenofibrate) TRIGLIDE® (fenofibrate)

CARDIOVASCULAR AGENTS: LIPOTROPICS - NICOTINIC ACID DERIVATIVES

NO PA REQUIRED PREFERRED"	PA REQUIRED
NIACIN NIASPAN® (niacin)	NIACIN ER (generic of Niaspan®)

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	OMEGA 3-ACID ETHYL ESTERS (generic of Lovaza®) VASCEPA® (icosapent ethyl)

CARDIOVASCULAR AGENTS: LIPOTROPICS - SELECTIVE CHOLESTEROL ABSORPTION INHIBITORS *

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
ZETIA® (ezetimibe)	

* Note: Step therapy required – must have therapeutic trial of one preferred statin.

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

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
	LIPTRUZET® (atorvastatin/ezitimibe) 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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Cardiovascular Agents: Pulmonary Arterial Hypertension

LENGTH OF AUTHORIZATIONS: 1 year
All products in this class require clinical prior authorization: Diagnosis of pulmonary arterial hypertension

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

1. Patients diagnosed as World Health Organization Group 3 or more severe may be approved for inhalation or intravenous agents
2. Riociguat (Adempas®) may be approved for patients with persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) who have had surgical treatment or have inoperable CTEPH.
3. 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 a therapeutic trial of at least one month with at least two medications, one of which is a Phosphodiesterase-5 Inhibitor, not requiring prior approval?

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION, Phosphodiesterase-5 Inhibitor, Oral*

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
ADCIRCA® (tadalafil) SILDENAFIL (generic of Revatio®)	REVATIO® oral solution (sildenafil)

*Patients on current regimens will be grandfathered.

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION, Endothelin Receptor Antagonist, Oral*

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
LETAIRIS® (ambrisentan) TRACLEER® (bosentan)	OPSUMIT® (macitentan)

*Patients on current regimens will be grandfathered.

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION, Prostacyclin Analog, Oral*

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	ORENITRAM® (treprostinil diolamine)

*Patients on current regimens will be grandfathered.

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION, Guanylate Cyclase Stimulators, Oral*

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	ADEMPAS® (riociguat)

*Patients on current regimens will be grandfathered.

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION, Prostacyclin Analog, Inhaled *

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	TYVASO® (treprostinil) VENTAVIS® (iloprost)

*Patients on current regimens will be grandfathered.

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION Prostacyclin Analog, Intravenous *

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	EPOPROSTENOL (generic of Flolan®) REMODULIN® (treprostinil sodium) VELETRI® (epoprostenol)

*Patients on current regimens will be grandfathered.

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

LENGTH OF AUTHORIZATIONS: 1 year

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

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:
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 a patient who is unable to swallow.

CNS AGENTS: ALZHEIMER'S AGENTS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
DONEPEZIL 5mg, 10mg (generic of Aricept®) DONEPEZIL ODT (generic of Aricept® ODT) GALANTAMINE (generic of Razadyne™) GALANTAMINE ER (generic of Razadyne™ ER) GALANTAMINE 4mg/ml solution (generic of Razadyne™) RIVASTIGMINE capsules (generic of Exelon®)	EXELON® patch (rivastigmine) NAMENDA® (memantine) NAMENDA® 10mg/5ml solution (memantine)	DONEPEZIL 23mg (generic of Aricept® 23mg) NAMENDA XR® ***NAMZARIC® (memantine ER/donepezil)***

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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 preferred medications
  - Contraindication to all preferred medications
  - History of unacceptable/toxic side effects to at least two preferred medications

CLINICAL CONSIDERATIONS:

Prior Authorization will not be given for prophylaxis 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"	PA REQUIRED
IMITREX® INJECTION (sumatriptan) IMITREX® NASAL SPRAY (sumatriptan) RIZATRIPTAN tablets (generic of Maxalt®) RIZATRIPTAN ODT (generic of Maxalt-MLT®) SUMATRIPTAN TABLETS (generic of Imitrex®)	AXERT® (almotriptan) RELPAX® (eletriptan) SUMATRIPTAN injection (generic of Imitrex®) SUMATRIPTAN nasal spray (generic of Imitrex®) SUMAVEL DOSEPRO® (sumatriptan) ZOLMITRIPTAN (generic of Zomig®) ZOLMITRIPTAN ODT (generic of Zomig ZMT®) ZOMIG® NASAL SPRAY (zolmitriptan)

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®)	FROVA® (frovatriptan)	

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

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	TREXIMET® (sumatriptan/naproxen)

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Central Nervous System (CNS) Agents: Anticonvulsants

LENGTH OF AUTHORIZATIONS: **1 year**

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

OTHER APPROVAL CRITERIA:

1. Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include:
   - Allergy to two preferred medications
   - Contraindication to or drug interaction with two preferred medications
   - History of unacceptable/toxic side effects to two preferred medications
   - The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.
2. If there has been a therapeutic failure to no less than two preferred products for a one-month trial each. Prescriptions submitted with the prescriber NPI of a physician who has registered a neurology specialty with Ohio Medicaid, for products that are used only for seizures, require a trial of one preferred product for one month. This provision applies only to the standard tablet/capsule dosage form, and does not apply to brand products with available generic alternatives.

ANTICONVULSANTS: CARBAMAZEPINE DERIVATIVES

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CARBAMAZEPINE IR tablet, chewable, oral suspension (generic of Tegretol®) CARBATROL® (carbamazepine 12-hour ER) OXCARBAZEPINE tablet, suspension (generic of Trileptal®) TEGRETOL XR® tablet (carbamazepine 12-hour ER) TRILEPTAL® suspension	CARBAMAZEPINE 12-hour ER capsule, tablet (generic of Carbatrol®, Tegretol XR®) OXTELLAR XR (oxcarbazepine)

ANTICONVULSANTS: FIRST GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CLONAZEPAM tablet (generic of Klonopin®) DIASTAT® rectal gel (diazepam) DIVALPROEX (generic of Depakote®) DIVALPROEX ER (generic of Depakote® ER) ETHOSUXAMIDE (generic of Zarontin®) PHENOBARBITAL PHENYTOIN (generic of Dilantin®) PRIMIDONE (generic of Mysoline®) VALPROIC ACID (generic of Depakene®)	CELONTIN® (methsuximide) CLONAZEPAM ODT (generic of Klonopin® wafer) DIAZEPAM rectal gel (generic of Diastat®) ONFI® (clobazam) PEGANONE® (ethotoin) STAVZOR (valproic acid delayed-release)

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ANTICONVULSANTS: SECOND GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
GABAPENTIN (generic of Neurontin®) LAMOTRIGINE IR tablet, chewable tablet (generic of Lamictal®) LEVETIRACETAM IR tablet, solution (generic of Keppra®) SABRIL® powder (no PA for age < 2) TOPIRAMATE tablet (generic of Topamax®) ZONISAMIDE (generic of Zonegran®)	BANZEL® (rufinamide) FELBAMATE (generic of Felbatol®) FYCOMPA® (perampanel) LAMICTAL®ODT LAMOTRIGINE ER tablet(generic of Lamictal® XR) LEVETIRACETAM ER tablet (generic of Keppra® XR) LYRICA® (pregabalin) QUDEXY XR® (topiramate ER) SABRIL® powder (PA required for age > 2) SABRIL® tablet (vigabatrin) TIAGABINE (generic of Gabitril®) TOPIRAMATE ER TOPIRAMATE sprinkle cap (generic of Topamax® sprinkle cap) TROKENDI XR® (topiramate)

ANTICONVULSANTS: THIRD GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	APTIOM® (esliscarbazepine acetate) POTIGA® (ezogabine) VIMPAT® (lacosamide)

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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 Medicaid 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

1. If there has been a therapeutic failure to no less than two preferred products for a one-month trial each.
2) Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include:
   - Allergy to preferred medications
   - Contraindication to or drug interaction with preferred medications
   - History of unacceptable/toxic side effects to preferred medications
   - 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.

ANTIDEPRESSANTS: SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRI)*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CITALOPRAM solution (generic of Celexa®) CITALOPRAM tablets (generic of Celexa®) ESCITALOPRAM (generic of Lexapro®) FLUOXETINE HCL capsules, tablets (generic of Prozac®) FLUOXETINE HCL solution (generic of Prozac®) FLUVOXAMINE MALEATE (generic of Luvox®) PAROXETINE HCL (generic of Paxil®) SERTRALINE (generic of Zoloft®) SERTRALINE oral concentrate (generic of Zoloft®)	BRISDELLE® (paroxetine mesylate) FLUOXETINE ER (generic of Prozac Weekly®) FLUVOXAMINE ER (generic of Luvox CR®) PAROXETINE ER (generic of Paxil CR®) PEXEVA® (paroxetine mesylate)

*Patients on current regimens will be grandfathered.

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ANTIDEPRESSANTS: SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRI)*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
DULOXETINE (generic of Cymbalta®) VENLAFAXINE (generic of Effexor®) VENLAFAXINE ER capsule (generic of Effexor XR®)	DESVENLAFAXINE ER tablet DESVENLAFAXINE FUMARATE FETZIMA® (levomilnacipran) KHEDEZLA ER® (desvenlafaxine) PRISTIQ® (desvenlafaxine) VENLAFAXINE ER tablet

*Patients on current regimens will be grandfathered.

ANTIDEPRESSANTS: NOREPINEPHRINE AND DOPAMINE REUPTAKE INHIBITORS (NDRI)*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BUPROPION HCL (generic of Wellbutrin®) BUPROPION SR (generic of Wellbutrin SR®) BUPROPION XL (generic of Wellbutrin XL®)	APLENZIN™ (bupropion) FORFIVO XL® (bupropion)

*Patients on current regimens will be grandfathered.

ANTIDEPRESSANTS: ALPHA-2 RECEPTOR ANTAGONISTS*

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

*Patients on current regimens will be grandfathered.

ANTIDEPRESSANTS: MONOAMINE OXIDASE INHIBITORS (MAOI)*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	EMSAM® patches (selegiline) MARPLAN® (isocarboxazid) NARDIL® (phenelzine) TRANYLCYPROMINE (generic of Parnate®)

*Patients on current regimens will be grandfathered.

ANTIDEPRESSANTS: Serotonin-2 Antagonist/Reuptake Inhibitors (SARI)*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
NEFAZODONE TRAZODONE 50mg, 100mg, 150mg	OLEPTRO ER® (trazodone) TRAZODONE 300mg

*Patients on current regimens will be grandfathered.

ANTIDEPRESSANTS: SSRI - SEROTONIN PARTIAL AGONIST*

NO PA REQUIRED "PREFERRED GENERIC"	PA REQUIRED
	BRINTELLIX® (vortioxetine) VIIBRYD® (vilazodone)

*Patients on current regimens will be grandfathered.

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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 Medicaid 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 preferred medication? Acceptable reasons include:

- Allergy to preferred medications
- Contraindication to or drug interaction with preferred medications
- History of unacceptable/toxic side effects to preferred medications
- 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.
- Clozapine or lurasidone (pregnancy category B) may be approved if a patient is pregnant

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ANTIPSYCHOTICS, SECOND GENERATION *

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
QUETIAPINE (generic of Seroquel®) RISPERIDONE (generic of Risperdal®) ZIPRASIDONE (generic of Geodon®)	ABILIFY® solution (aripiprazole) ABILIFY® tablet (aripiprazole) LATUDA® (lurasidone) SEROQUEL XR® (quetiapine)	ARIPIPRAZOLE tablet (generic of Abilify®) ABILIFY DISCMELT® (aripiprazole) CLOZAPINE (generic of Clozaril®) FANAPT® (iloperidone) FAZACLO® (clozapine) INVEGA® (paliperidone) OLANZAPINE (generic of Zyprexa®) OLANZAPINE ODT (generic of Zyprexa® Zydis) SAPHRIS® (asenapine) VERSACLOZ® (clozapine oral suspension)

*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
		FLUOXETINE/OLANZAPINE (generic of Symbyax®)

*Patients on current regimens will be grandfathered.

ANTIPSYCHOTICS, SECOND GENERATION LONG-ACTING INJECTABLES * +

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ABILIFY MAINTENA® (aripiprazole) INVEGA SUSTENNA® (paliperidone) RISPERDAL CONSTA® (risperidone) ZYPREXA RELPREVV® (olanzapine)	

*Patients on current regimens will be grandfathered.

+ Long-Acting Injectable Antipsychotics may be billed by the pharmacy if they are not dispensed directly to the patient. The drug must be released only to the administering provider or administering provider's staff, following all regulations for a Prescription Pick-Up Station as described by the Ohio Board of Pharmacy.

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

LENGTH OF AUTHORIZATIONS: 1 year

Short Acting considered separately from Long Acting products

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
   - Daytrana® or Quillivant XR® may be approved if the patient is unable to swallow pills.

CNS AGENTS: ATTENTION DEFICIT HYPERACTIVITY DISORDER AGENTS – Short Acting

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AMPHETAMINE SALTS (generic of Adderall®) DEXMETHYLPHENIDATE (generic of Focalin®) DEXTROAMPHETAMINE (generic of Dexedrine®) DEXTROSTAT® (dextroamphetamine) FOCALIN® (dexmethylphenidate) ***METHYLIN® chewable tablets (methylphenidate)*** METHYLPHENIDATE tablets (generic of Ritalin®)	DEXTROAMPHETAMINE solution (generic of Procentra®) ***EVEKEO® (amphetamine sulfate)*** METHAMPHETAMINE (generic of Desoxyn®) ***METHYLPHENIDATE solution,*** chewable tablets (generic of Methylin®) ZENZEDI® (dextroamphetamine)

CNS AGENTS: ATTENTION DEFICIT HYPERACTIVITY DISORDER AGENTS – Long Acting

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ADDERALL XR® (amphetamine/dextroamphetamine) DEXTROAMPHETAMINE SA (generic of Dexedrine® spansule) FOCALIN® XR (dexmethylphenidate) INTUNIV® (guanfacine) METADATE® CD (methylphenidate) METADATE® ER (methylphenidate) METHYLIN® ER (methylphenidate) METHYLPHENIDATE ER (generic of Concerta®) METHYLPHENIDATE ER (generic of Ritalin SR®) STRATTERA® (atomexetine) VYVANSE™ (lisdexamfetamine)	CLONIDINE ER (generic of Kapvay®) DAYTRANA® (methylphenidate) DEXMETHYLPHENIDATE ER (generic of Focalin XR®) DEXTROAMPHETAMINE-AMPHETAMINE (generic of Adderall XR®) METHYLPHENIDATE LA (generic of Metadate® CD, Ritalin® LA) QUILLIVANT XR® suspension (methylphenidate)

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Central Nervous System (CNS) Agents: Fibromyalgia Agents

LENGTH OF AUTHORIZATIONS: 1 year

Non-preferred medications will be approved for fibromyalgia after trial of agents from no less than 2 of the following drug classes in the past 90 days (guidelines suggest use of multiple agents concurrently to manage the signs of fibromyalgia):

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

**** The P&T Committee does not recommend the use of opioids for treatment of fibromyalgia**

CNS AGENTS: FIBROMYALGIA AGENTS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
LYRICA® (pregabalin) *	SAVELLA® (milnacipran)

* Clinical PA required for Lyrica®, may be approved for diagnosis of fibromyalgia.

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

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

*****P&T COMMITTEE TO DISCUSS LENGTH OF AUTHORIZATION AND THE AMOUNT OF INFORMATION THAT IS APPROPRIATE FOR MEDICAID TO REQUIRE VS. WHAT IS IN THE OAC*****

Prescribing for buprenorphine products must follow the requirements of Ohio Administrative Code rule 4731-11-12, Office based opioid treatment.

BUPRENORPHINE INITIAL AUTHORIZATION CRITERIA:

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 to counseling for addiction treatment ~~(re-authorizations should indicate how often the patient is receiving counseling)~~
4. Maximum dose ~~24mg per day, (16mg is target, no patient should receive more than 32mg)~~ ***16mg Suboxone equivalent (11.4mg Zubsolv or 8.4mg Bunavail) per day***
5. Prescriber has reviewed Ohio Automated Rx Reporting System (OARRS) for opioid prescription use, ***within 7 days prior to requesting the PA.***
6. ~~Periodic drug screens are addressed in treatment plan (will be performed by prescriber or by counseling team)~~
7. ~~For re-authorizations – 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~~

BUPRENORPHINE SUBSEQUENT AUTHORIZATION CRITERIA:

1. ***Patient has been personally seen by the physician:***
   - ***For the first year of therapy, at least monthly***
   - ***In subsequent years, at least every 3 months***
2. ***Patient is actively participating in counseling: P&T COMMITTEE INPUT NEEDED.***
   - ***HOW OFTEN?***
   - ***WHO SHOULD PERFORM COUNSLING?***
   - ***ARE 12-STEP PROGRAMS SUFFICIENT?***
3. ***The physician has reviewed OARRS within 7 days prior to the PA request. If the patient has received controlled substances since the previous authorization:***
   - ***The physician has coordinated with all other prescribers of controlled substances and has determined that the patient should continue treatment; and***
   - ***If the patient has received other controlled substances for 12 or more continuous weeks, the physician has consulted with a board-certified addictionologist or addiction psychiatrist who has recommended the patient receive substance abuse treatment (consultation not necessary if the prescriber is a board-certified additionologist or addiction psychiatrist).***
4. ***The dose is no more than 16mg/day Suboxone-equivalent, unless:***
   - ***The higher dose was started prior to January 31, 2015, or***

- ***The physician is a board certified addictionologist or addiction psychiatrist and has determined that a dosage greater than 16 milligrams is required for the patient, and has documented patient-specific reasons for the need for a dosage greater than 16 milligrams in the patient's record, or***
- ***The physician has consulted with a board certified addictionologist or addiction psychiatrist who has recommended a dosage greater than 16 milligrams and that fact is documented in the patient's medical record.***

5. ***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.***
6. ***The prescriber has provided toxicology results showing the presence of buprenorphine and its metabolites, and the absence of other opioids, at least twice in the previous 6 months. If the toxicology report is not as expected, the physician must document actions taken.***

For buprenorphine only ***(without naloxone)***:

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

ADDITIONAL INFORMATION

A non-preferred medication may be approved if the following is true:

- ***The patient experiences a relapse that the physician suspects may be due to non-adherence with treatment***
- ***The patient is allergic to ingredients other than buprenorphine***
- ***The patient experiences adverse events that are attributable to ingredients other than buprenorphine***

CENTRAL NERVOUS SYSTEM AGENTS: MEDICATION ASSISTED TREATMENT OF OPIOID ADDICTION

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SUBOXONE® SL film (buprenorphine/naloxone)	***BUNAVAIL® buccal film (buprenorphine/naloxone)*** BUPRENORPHINE SL tablets (generic of Subutex®) BUPRENORPHINE/NALOXONE SL tablets ***ZUBSOLV® SL tablets (buprenorphine/naloxone)***

CENTRAL NERVOUS SYSTEM AGENTS: MEDICATION ASSISTED TREATMENT OF OPIOID ADDICTION LONG-ACTING INJECTABLES +

NO PA REQUIRED "PREFERRED"	PA REQUIRED
VIVITROL® (naltrexone)	

+ Vivitrol may be billed by the pharmacy if it is not dispensed directly to the patient. The drug must be released only to the administering provider or administering provider's staff, following all regulations for a Prescription Pick-Up Station as described by the Ohio Board of Pharmacy.

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Central Nervous System (CNS) Agents: Multiple Sclerosis

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, INJECTABLE *

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AVONEX® (interferon beta-1a) BETASERON® (interferon beta-1b) COPAXONE® (glatiramer) ***20MG*** REBIF® (interferon beta-1a)	***COPAXONE® (glatiramer) 40MG*** EXTAVIA® (interferon beta-1b) ***PLEGRIDY® (peginterferon beta-1a)***

*Patients on current regimens will be grandfathered.

CNS AGENTS: MULTIPLE SCLEROSIS DISEASE MODIFYING AGENTS, ORAL *

NO PA REQUIRED "PREFERRED"	PA REQUIRED
GILENYA® (fingolimod)	AUBAGIO® (teriflunomide) ***TECFIDERA® (dimethyl fumarate)***

*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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Central Nervous System (CNS) Agents: Neuropathic Pain

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 authorization

Lidocaine patch (Lidoderm®) will only be approved for treatment of neuropathic pain (e.g., diabetic peripheral neuropathy, post-herpetic neuralgia).

CNS AGENTS: NEUROPATHIC PAIN

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AMITRIPTYLINE (generic of Elavil®)	GRALISE® (gabapentin)
CARBAMAZEPINE (generic of Tegretol®)	HORIZANT® (gabapentin enacarbil)
CLOMIPRAMINE (generic of Anafranil®)	LIDOCAINE patch (generic of Lidoderm®)
DESIPRAMINE (generic of Norpramin®)	LYRICA® (pregabalin)
DOXEPIN (generic of Sinequan®)	
DULOXETINE (generic of Cymbalta®)	
GABAPENTIN (generic of Neurontin®)	
IMIPRAMINE (generic of Tofranil®)	
NORTRIPTYLINE (generic of Pamelor®)	
OXCARBAZEPINE (generic of Trileptal®)	

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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:

1) If there has been a therapeutic failure to no less than a one-month trial of at least one medication not requiring prior approval
2) The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.
3) Neupro® may be approved if the patient is unable to swallow.

PARKINSON'S AGENTS – COMT INHIBITOR

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ENTACAPONE (generic of Comtan®)	TASMAR® (tolcapone) TOLCAPONE (generic of Tasmar®)

PARKINSON'S AGENTS – DOPAMINE RECEPTOR AGONISTS, NON-ERGOT, INJECTABLE

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

PARKINSON'S AGENTS – DOPAMINE RECEPTOR AGONISTS, NON-ERGOT, ORAL

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

PARKINSON'S AGENTS – DOPAMINERGIC AGENTS, ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CARBIDOPA/LEVODOPA (generic of Sinemet®) CARBIDOPA/LEVODOPA CR (generic of Sinemet® CR) SELEGILINE (generic of Eldepryl®)	AZILECT® (rasagiline) CARBIDOPA/LEVODOPA dispersible tablets (generic of Parcopa®) CARBIDOPA/LEVODOPA/ENTACAPONE (generic of Stalevo®) NEUPRO® patch (rotigotine) ***RYTARY® (carbidopa/levodopa ER)*** ZELAPAR® ODT (selegiline)

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®)	HORIZANT® (gabapentin enacarbil)
ROPINIROLE (generic of Requip®)	NEUPRO® patch (rotigotine)

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

LENGTH OF AUTHORIZATIONS: 6 months

1. The requested medication may be approved if there has been a therapeutic failure to no less than a ten-day trial of at least two medications not requiring prior approval
2. 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
3. If the prescriber indicates the patient has a history of addiction, then may approve a requested non-controlled medication.
4. The P&T Committee does not recommend use of flurazepam (Dalmane®) or triazolam (Halcion®)

CNS AGENTS: SEDATIVE-HYPNOTICS, NON-BARBITURATE

NO PA REQUIRED "PREFERRED GENERIC"	PA REQUIRED
ESTAZOLAM (generic of Prosom®) TEMAZEPAM 15mg, 30mg (generic of Restoril®) ZALEPLON (generic of Sonata®) ZOLPIDEM (generic of Ambien®)	BELSOMRA® (suvorexant) EDLUAR® SL (zolpidem) ESZOPICLONE (generic of Lunesta®) INTERMEZZO® SL (zolpidem) ROZEREM® (ramelteon) SILENOR® (doxepin) TEMAZEPAM 7.5mg, 22.5mg (generic of Restoril®) ZOLPIDEM ER (generic of Ambien® CR) ZOLPIMIST® (zolpidem)

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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®) CHLORZOXAZONE (generic of Parafon Forte®) CYCLOBENZAPRINE (generic of Flexeril®) DANTROLENE (generic of Dantrium®) METHOCARBAMOL (generic of Robaxin®) TIZANIDINE tablets (generic of Zanaflex®)	CARISOPRODOL (generic of Soma®) * CARISOPRODOL COMPOUND (generic of Soma Compound®) * CARISOPRODOL COMPOUND W/CODEINE (generic of Soma Compound w/Codeine®) * CYCLOBENZAPRINE ER (generic of Amrix®) FEXMID® (cyclobenzaprine) LORZONE® (chlorzoxazone) METAXALONE (generic of Skelaxin®) ORPHENADRINE (generic of Norflex®) ORPHENADRINE COMPOUND (generic of Norgesic®) ORPHENADRINE COMPOUND FORTE (generic of Norgesic Forte®) TIZANIDINE capsules (generic of Zanaflex®)

* 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.

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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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Endocrine Agents: Diabetes Adjunctive Therapy

LENGTH OF AUTHORIZATIONS: ~~1 year~~ ***6 months***

All drugs in this class require step therapy: Patient must have a claim for an oral hypoglycemic or insulin in the previous 120 days. ***Refills require continued use of oral hypoglycemics and/or insulin.***

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)	***TANZEUM™ (albiglutide)*** ***TRULICITY® (dulaglutide)*** ***VICTOZA® (liraglutide)***

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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.

ADDITIONAL CLINICAL CRITERIA FOR INHALED INSULIN:

- ***Patient has a claim for a long-acting insulin in the previous 120 days, or patient has type 2 diabetes; and***
- ***Patient has not been diagnosed with asthma or COPD; and***
- ***Spirometry shows FEV1 > / = 70% predicted; and***
- ***Patient has not smoked for at least 6 months;***

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)	***AFREZZA® inhalation powder (insulin 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)	

* 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) ***TOUJEO® (insulin glargine)***

* Patients on current insulin regimens will be grandfathered.

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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

DIABETES – ORAL HYPOGLYCEMICS, ALPHA-GLUCOSIDASE INHIBITORS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
ACARBOSE (generic of Precose®)	GLYSET® (miglitol)	

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®)		METFORMIN ER (generic of Fortamet®) RIOMET® 500mg/5ml (Metformin)

DIABETES – ORAL HYPOGLYCEMICS, BIGUANIDE/SULFONYLUREA COMBO

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

DIABETES – DIPEPTIDYL PEPTIDASE-4 INHIBITOR

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
	JANUVIA® (sitagliptin) TRADJENTA™(linagliptin)	NESINA® (alogliptin) ONGLYZA® (saxagliptin)

DIABETES – DIPEPTIDYL PEPTIDASE-4 INHIBITOR COMBINATIONS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
	JANUMET™ (sitagliptin/metformin) JENTADUETO™ (linagliptin/ metformin)	JANUMET XR™ (sitagliptin/ metformin) KAZANO® (alogliptin/ metformin) KOMBIGLYZE XR® (saxagliptin/metformin)

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DIABETES – ORAL HYPOGLYCEMICS, MEGLITINIDES

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
NATEGLINIDE (generic of Starlix®)		REPAGLINIDE (generic of Prandin®)

DIABETES – ORAL HYPOGLYCEMICS, MEGLITINIDE/BIGUANIDE COMBO

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
		PRANDIMET® (repaglinide/ metformin)

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 Glynase PressTabs®)		

DIABETES – ORAL HYPOGLYCEMICS, THIAZOLIDINEDIONES

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
PIOGLITAZONE (generic of Actos®)		AVANDIA® (rosiglitazone)

DIABETES – ORAL HYPOGLYCEMICS, TZD/SULFONYLUREAS COMBO

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
		AVANDARYL® (glimepiride/ rosiglitazone) GLIMEPIRIDE/PIOGLITAZONE (generic of Duetact®)

DIABETES – ORAL HYPOGLYCEMICS, TZD / DPP-4 COMBINATION

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
		OSENI® (pioglitazone/alogliptin)

DIABETES – ORAL HYPOGLYCEMICS, TZD / BIGUANIDE COMBO

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
PIOGLITAZONE/METFORMIN (generic of ActoPlus Met®)	ACTOPLUS MET XR® (pioglitazone/metformin)	AVANDAMET® (rosiglitazone/ metformin)

DIABETES – ORAL HYPOGLYCEMICS, SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR *AND COMBINATIONS*

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
		FARXIGA® (dapagliflozin) ***GLYXAMBI® (empagliflozin/ linagliptin)*** ***INVOKAMET® (canagliflozin/ metformin)*** INVOKANA® (canagliflozin) JARDIANCE® (empagliflozin) ***XIGDUO XR® (dapagliflozin/ metformin)***

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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

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)

ESTROGENS – ORAL ESTROGEN/PROGESTERONE COMB

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

ESTROGENS & ESTROGEN AGONIST/ANTAGONIST COMB

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	DUAVEE (conjugated estrogens/bazedoxifene)

ENDOCRINE AGENTS: ESTROGENS – TRANSDERMAL ESTROGENS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ALORA® patch (estradiol) ESTRADIOL patch (generic of Climara®, Vivelle-Dot®)	DIVIGEL® transdermal gel (estradiol) ELESTRIN® transdermal gel (estradiol) ESTRASORB® transdermal emulsion (estradiol) EVAMIST® transdermal solution (estradiol) MENOSTAR® patch (estradiol) MINIVELLE® patch (estradiol)

ESTROGENS – TRANSDERMAL ESTROGEN/ PROGESTERONE COMB

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CLIMARA PRO® (estradiol/levonorgestrel oral) COMBIPATCH® (estradiol/norethindrone)	

ESTROGENS – VAGINAL ESTROGENS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ESTRING® vaginal ring (estradiol) PREMARIN® vaginal cream (estrogens conjugated)	ESTRACE® vaginal cream (estradiol) FEMRING® vaginal ring (estradiol) VAGIFEM® vaginal tablet (estradiol)

Endocrine Agents: Growth Hormone

LENGTH OF AUTHORIZATIONS: varies as listed below.

- All products in this class require clinical prior authorization
- Must be treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist or gastroenterologist (as appropriate for diagnosis)

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

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 preferred medication

CLINICAL CRITERIA

Children - initial approval for the following diagnoses:

1. Growth Hormone Deficiency (GHD) – 6 month approval:
    a. Acquired GHD due to cranial irradiation, panhypopituitarism, central nervous system tumors, trauma, radiation, or pituitary damage; OR
    b. GHD with all the following:
        i. Must be evaluated, therapy prescribed and monitored by a pediatric endocrinologist; and
        ii. Must not have attained epiphyseal closure (documented by X-ray); and
        iii. Must have failed to respond to TWO standard GH stimulation tests (with insulin, levodopa, arginine, propranolol, clonidine, or glucagon; may be done in the same session) defined as a peak measure GH level of less than 10ng/ml after stimulation; and
        iv. Height at initiation of therapy must be > 2 standard deviations below population normal mean height for age and sex; and
        v. Bone age is ≥ 2 years behind chronological age
2. Genetic diagnosis – 1 year approval:
    a. Krause-Kivlin Syndrome; or
    b. Turner Syndrome; or
    c. Prader-Willi Syndrome; or
    d. Noonan Syndrome
3. Short stature associated with Chronic Renal Insufficiency PRIOR to kidney transplant – 6 month approval (AACE does not recommend GH for post-transplantation).
4. SHOX – Short Stature Homeobox Gene deficiency
    a. Diagnosis documented by chromosome analysis; and
    b. Must not have attained epiphyseal closure (documented by X-ray); and
    c. Height at initiation of therapy must be > 2 standard deviations below population normal mean height for age and sex; and
    d. Bone age is ≥ 2 years behind chronological age

5. Small for gestational age (intrauterine growth restriction) – 1 year approval:
    a. Birth weight or length is ≥ 2 SD below the mean for gestational age; and
    b. Child fails to manifest catch-up growth by age of 2 years, defined as a height ≥ 2 SD below the mean for age and sex; and
    c. Age is no less than 24 months and no more than 48 months
6. Reauthorization– 1 year approval:
    a. Acquired GHD or genetic syndrome diagnosis; or
    b. Growth Hormone Deficiency, Small for Gestational Age and SHOX
        i. Must not have attained epiphyseal closure (documented by X-ray)
        ii. Increase in growth double the annualized pre-treatment growth rate within first six months, then at least 3cm per year thereafter

Adults - initial approval for the following diagnoses:

1. AIDS-related wasting or cachexia – 6 month approval
    a. Diagnosis; and
    b. Involuntary weight loss of >10% from baseline or BMI < 20; and
    c. Patient has not responded to high-calorie diet; and
    d. Patient is being treated with antiretroviral drugs
2. Short bowel syndrome – 6 month approval
    a. Diagnosis by gastroenterologist; and
    b. Patient receiving intravenous nutritional support
3. Pituitary damage – 1 year approval
    a. Acquired GHD due to cranial irradiation, panhypopituitarism, central nervous system tumors, trauma, radiation, or pituitary damage; OR
    b. Must have failed to respond to TWO standard GH stimulation tests (with insulin, levodopa, arginine, propranolol, clonidine, or glucagon; may be done in the same session) defined as a peak measure GH level of less than 5 ng/ml after stimulation
4. Reauthorization: The patient health status has improved since last approval (weight gain, improved body composition)
    a. AIDS-related wasting or cachexia or short bowel syndrome – 6 months
    b. Pituitary damage or genetic syndrome – 1 year

GROWTH HORMONES

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
GENOTROPIN® cartridge, miniquick (somatropin) NORDITROPIN® cartridge, FlexPro, NordiFlex, vial (somatropin)	HUMATROPE® cartridge, vial (somatropin) NUTROPIN AQ® cartridge, Nuspin, vial (somatropin) NUTROPIN® vial (somatropin) OMNITROPE® cartridge, vial (somatropin) SAIZEN® cartridge, vial (somatropin) SEROSTIM® vial (somatropin) TEV-TROPIN® vial (somatropin) ZORBTIVE® vial (somatropin)

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

CRITICAL INFORMATION

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

ENDOCRINE AGENTS: OSTEOPOROSIS - BONE OSSIFICATION ENHANCERS - ORAL BISPHOSPHONATES

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ALENDRONATE tablets (generic of Fosamax®)	ACTONEL® (risedronate) ALENDRONATE ORAL SOLN 70mg/75ml (generic of Fosamax®) ATELVIA® (risedronate) BINOSTO® (alendronate sodium effervescent tablet) ETIDRONATE (generic of Didronel®) FOSAMAX PLUS D™ (alendronate/cholecalciferol) FOSAMAX® ORAL SOLN 70mg/75ml (alendronate) IBANDRONATE (generic of Boniva®) RISEDRONATE (generic of Actonel®)

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

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

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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
2. The requested medication may be approved if there has been a therapeutic failure to no less than a seven-day trial on at least one medication not requiring prior approval.

GASTROINTESTINAL AGENTS: ANTI-EMETIC AGENTS

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

GASTROINTESTINAL AGENTS: ANTI-EMETIC AGENTS: non-5-HT3 receptor antagonists

NO PA REQUIRED "PREFERRED"	PA REQUIRED
DIMENHYDRINATE tablets DIPHENHYDRAMINE tablets, capsules, solution MECLIZINE tablets (generic of Antivert®) METOCLOPRAMIDE tablets (generic of Reglan®) PHOSPHORATED CARBOHYDRATE SOLUTION (generic of Emetrol®) PROCHLORPERAZINE tablets, suppositories (generic of Compazine®) PROMETHAZINE tablets, suppositories (generic of Phenergan®) TRANSDERM-SCOP® patch (scopolamine) TRIMETHOBENZAMIDE capsules (generic of Tigan®)	DICLEGIS® (doxylamine and pyridoxine) METOCLOPRAMIDE ODT (generic of Metozolv® ODT)

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Gastrointestinal Agents: Chronic Constipation Agents

LENGTH OF AUTHORIZATIONS: 1 year

~~STEP THERAPY:~~

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 two-week trial of at least two medications not requiring prior approval

ADDITIONAL INFORMATION:

1. ***Patient must be 18 years or older***
2. ***Approval for opioid-induced constipation agents requires a history of chronic pain requiring continuous opioid therapy for 12 weeks or longer. Electronic PA will approve with a history of 90 days of opioid therapy in the previous 90 days, in addition to trials of preferred products.***

GASTROINTESTINAL AGENTS: *IRRITABLE BOWEL SYNDROME WITH* CHRONIC CONSTIPATION *& CHRONIC IDIOPATHIC 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®)	AMITIZA® capsule (lubiprostone) LINZESS™ capsule (linaclotide)

GASTROINTESTINAL AGENTS: OPIOID-INDUCED 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®)	AMITIZA® capsules (lubiprostone) ***MOVANTIK® tablets (naloxegol)*** ***RELISTOR® subcutaneous injection (methylnaltrexone bromide)***

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 two medications not requiring prior approval

GASTROINTESTINAL AGENTS: PANCREATIC ENZYMES

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CREON® (pancrelipase) PANCRELIPASE 5000 ZENPEP® (pancrelipase)	PANCREAZE® (pancrelipase) PERTZYE® (pancrelipase) ULTRESA® (pancrelipase) VIOKACE® (pancrelipase)

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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 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

NO PA REQUIRED "PREFERRED"	PA REQUIRED
LANSOPRAZOLE capsules (generic of Prevacid®)	ACIPHEX® sprinkle capsule (rabeprazole)
NEXIUM 24HR® (esomeprazole)	DEXILANT® (dexlansoprazole)
OMEPRAZOLE capsules (generic of Prilosec®)	ESOMEPRAZOLE STRONTIUM
OMEPRAZOLE tablets (generic of Prilosec OTC®)	ESOMEPRAZOLE capsules (generic of NEXIUM®)
PANTOPRAZOLE (generic of Protonix®)	NEXIUM® packets (esomeprazole)
PREVACID 24 HR® (lansoprazole)	OMEPRAZOLE/SODIUM BICARBONATE
PREVACID SOLUTAB® (lansoprazole ODT) (No PA required for age 6 or under)	PREVACID SOLUTAB® (lansoprazole ODT) (PA required for age over 6)
PRILOSEC OTC® tablets (omeprazole)	PRILOSEC® suspension (omeprazole)
ZEGERID OTC® (omeprazole/sodium bicarbonate)	PROTONIX® suspension
	RABEPRAZOLE (generic of Aciphex®)

DRAFT for P&T Committee Discussion Only

Gastrointestinal Agents: Ulcerative Colitis Agents

LENGTH OF AUTHORIZATIONS: 6 months

~~STEP THERAPY:~~ ~~Oral agents only~~
~~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~~
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~~ ***products***.

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

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 rectal 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®)~~	~~DELZICOL® (mesalamine)~~ ~~LIALDA® (mesalamine)~~ ~~PENTASA® (mesalamine)~~	~~APRISO® (mesalamine)~~ ~~ASACOL HD® (mesalamine)~~ ~~DIPENTUM® (olsalazine)~~ ~~GIAZO® (balsalazide disodium)~~

GASTROINTESTINAL AGENTS: ULCERATIVE COLITIS AGENTS - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
APRISO® (mesalamine) ***DELZICOL® (mesalamine)*** ***PENTASA® (mesalamine)*** SULFASALAZINE (generic of Azulfidine®) SULFASALAZINE EC (generic of Azulfidine Entab®)	ASACOL HD® (mesalamine) ***BALSALAZIDE DISODIUM (generic of Colazal®)*** DIPENTUM® (olsalazine) GIAZO® (balsalazide disodium) ***LIALDA® (mesalamine)***

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) ***UCERIS® foam (budesonide)***

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

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)

BENIGN PROSTATIC HYPERPLASIA AGENTS – 5-ALPHA REDUCTASE INHIBITORS

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

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

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	JALYN® (dutasteride/tamsulosin)

BENIGN PROSTATIC HYPERPLASIA AGENTS – PHOSPHODIESTERASE TYPE 5 INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	CIALIS® (tadalafil) 2.5mg, 5mg only *

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

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Genitourinary Agents: Electrolyte Depleter 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 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

CLINICAL INFORMATION

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

ELECTROLYTE DEPLETERS FOR HYPERPHOSPHATEMIA

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
CALCIUM ACETATE (generic of PhosLo® gelcap) CALCIUM CARBONATE	MAGNEBIND® (calcium carbonate/ magnesium carbonate/folic acid) RENAGEL® (sevelamer)	AURYXIA® (ferric citrate) tablets ELIPHOS® (calcium acetate) FOSRENOL® (lanthanum carbonate) PHOSLO® (calcium acetate) PHOSLYRA® solution (calcium acetate) RENVELA® (sevelamer) VELPHORO® (sucroferric oxyhydroxide)

Genitourinary Agents: Urinary Antispasmodics

LENGTH OF AUTHORIZATIONS: 1 year

- Patients under age 18 may be approved for tolterodine SR or Gelnique® if there was inadequate clinical response to a trial of no less than one month of oxybutynin (IR or ER).
- The requested medication may be approved if there has been a therapeutic failure to a trial of no less than two weeks of at least two medications not requiring prior approval
- 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"	PA REQUIRED
ENABLEX® (darifenacin) OXYBUTYNIN ER (generic of Ditropan® XL) OXYBUTYNIN syrup (generic of Ditropan®) OXYBUTYNIN tablets (generic of Ditropan®) OXYTROL® FOR WOMEN OTC patch (oxybutynin) VESICARE® (solifenacin)	GELNIQUE® (oxybutynin) MYRBETRIQ® (mirabegron) TOLTERODINE (generic of Detrol®) TOLTERODINE SR (generic of Detrol® LA) TOVIAZ® (fesoterodine) TROSPIUM (generic of Sanctura®) TROSPIUM ER (generic of Sanctura® XR)

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Immunomodulator Agents for Systemic Inflammatory Disease

LENGTH OF AUTHORIZATIONS: Dependent on indication

All products in this class require clinical prior authorization:

- No current infection; and
- Prior first-generation therapy appropriate for diagnosis; and
- Diagnosis of one of the following: 1-year approval
  - Rheumatoid Arthritis
  - Psoriatic Arthritis
  - Polyarticular Juvenile Idiopathic Arthritis
  - Crohn's Disease
  - Ankylosing Spondylitis
  - Psoriasis
- Diagnosis of Moderate to Severe Ulcerative Colitis (UC) (Humira and Simponi only): initial approval 8 weeks, reapprovals 1 year
  Humira may be approved if there is an inadequate clinical response to at least three months of therapy with both 5-ASA and immunosuppresants.
  Initial approval for Humira will be for 8 weeks. If clinical response is not seen in 8 weeks, further therapy with TNF inhibitors will not be approved. If there is an initial clinical response to Humira after 8 weeks of therapy, but no improvement in the progression of ulcerative colitis symptoms after 6 months, Simponi may be approved.
  - Quantity limits for UC diagnosis:
    Humira – 7 pens/syringes during month one, then 2 pens/syringes per month
    Simponi – 3 pens/syringes during month one, then 1 pen/syringe per month

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 preferred medication

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ANTI-INFLAMMATORY TUMOR NECROSIS FACTOR INHIBITOR

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

ANTI-INFLAMMATORY INTERLEUKIN ~~-1~~ RECEPTOR ANTAGONIST

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	ACTEMRA® syringe (tocilizumab) ***COSENTYX™ (secukinumab)*** KINERET® syringe (anakinra)

~~ANTI-INFLAMMATORY INTERLEUKIN-6 RECEPTOR ANTAGONIST~~

~~CLINICAL PA REQUIRED "PREFERRED"~~	~~PA REQUIRED~~
	~~ACTEMRA® syringe (tocilizumab)~~

JANUS KINASE INHIBITOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	XELJANZ® tablet (tofacitinib citrate)

PHOSPHODIESTERASE-4 INHIBITOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	OTEZLA® tablet (apremilast)

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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.

CEPHALOSPORINS, FIRST GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CEFADROXIL capsules, suspension (generic of Duricef®) CEPHALEXIN 250mg, 500 mg capsules, suspension (generic of Keflex®)	CEPHALEXIN 750mg (generic of Keflex®)

CEPHALOSPORINS, SECOND GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CEFACLOR (generic of Ceclor®) CEFACLOR ER (generic of Ceclor CD®) CEFACLOR suspension (no PA required for age 12 or under) (generic of Ceclor®) CEFPROZIL (generic of Cefzil®) CEFPROZIL suspension (generic of Cefzil®) (no PA required for age 12 or under) CEFTIN® suspension (no PA required for age 12 or under) (cefuroxime) CEFUROXIME (generic of Ceftin®)	CEFACLOR suspension (PA required for age over 12) (generic of Ceclor®) CEFTIN® suspension (PA required for age over 12) (cefuroxime) CEFPROZIL suspension (generic of Cefzil®) (PA required for age over 12)

CEPHALOSPORINS, THIRD GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CEFDINIR capsules, suspension (generic of Omnicef®)	CEFTIBUTEN capsules, suspension (generic of Cedax®) CEFDITOREN PIVOXIL (generic of Spectracef®) CEFPODOXIME tablets, suspension (generic of Vantin®) SUPRAX® capsules, chew tabs, suspension (cefixime)

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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®) CLARITHROMYCIN ER (generic of Biaxin XL®) 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*** PCE® (erythromycin base) ZMAX™ (azithromycin ER) for oral suspension

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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, 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®)	CIPROFLOXACIN suspension (PA required for age over 12) (generic of Cipro®) CIPROFLOXACIN ER (generic of Cipro®XR) NOROXIN® (norfloxacin)

INFECTIOUS DISEASE AGENTS: QUINOLONES, THIRD GENERATION - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
LEVOFLOXACIN (generic of Levaquin®)	MOXIFLOXACIN (generic of Avelox®)

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Infectious Disease Agents: Antibiotics – Inhaled

LENGTH OF AUTHORIZATIONS: ***28 days, reauthorized through electronic PA if history of product in previous 120 days***

All products in this class require clinical prior authorization:

- ***Diagnosis of cystic fibrosis with pseudomonas-related infection***
- ***Age limit of 6 and older for tobramycin products***
- ***Age limit of 7 and older for aztreonam***
- ***"Pulse" dosing cycles of 28 days on drug, followed by 28 days off drug***

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 28-day trial of at least one preferred medication***

INFECTIOUS DISEASE AGENTS: QUINOLONES, THIRD GENERATION - ORAL

CLINICAL PA REQUIRED "PREFERRED"	*PA REQUIRED*
BETHKIS® inhalation solution (tobramycin) ***KITABIS® PAK (tobramycin inhalation solution with nebulizer)***	***CAYSTON® inhalation solution (aztreonam)*** ***TOBI™ Podhaler™ (tobramycin inhalation powder)*** ***TOBRAMYCIN inhalation solution (generic of TOBI™)***

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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) ONMEL® (itraconazole) 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)

Infectious Disease Agents: Antivirals – Hepatitis C Agents

LENGTH OF AUTHORIZATIONS: 1 year except simeprevir and direct acting antivirals (DAAs), see below

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 CRITERIA FOR DAAs:

All HCV DAAs require clinical prior authorization. Only regimens recommended by the American Association for the Study of Liver Diseases (AASLD) will be approved. Patients must meet all criteria below.

Step 1: Patient Readiness Evaluated

- Patient must be 18 years or older.
- Female patient must have a negative pregnancy test within the last 30 days and must not be lactating.
- Patient must be free for 6 months from alcohol use, controlled drug abuse, and illicit drug use before consideration of therapy.
- If patient is a recovering substance abuser/alcoholic and in a prescribed medication assisted therapy program, must continue counseling during HCV treatment and maintain sobriety.
- Patient's psychiatric status has been stable for 6 months documented in medical record. If patient has mental health conditions that are not currently being treated, then a mental health professional must be consulted to assess for patient readiness before HCV treatment can begin.
- ***Patient Tested for HIV and, if positive, treated appropriately***
- Patient vaccinated against Hepatitis A and Hepatitis B.
- Patient must not have severe renal impairment (eGFR < 30 mL/min/1.73m^2) or end stage renal disease requiring hemodialysis.
- Patient must not be concomitantly taking drugs that have significant clinical interaction as described in the prescribing information for each agent.
- Patient must agree in writing to being adherent with office visits, lab testing, imaging, procedures and, if deemed a candidate, the HCV medication regimen. Prescribers may use the form below or a similar form that covers all four points. Patient signature is required. This statement and patient signature must be included as part of the prior authorization request.

Hepatitis C Patient Readiness:

_____ (print name) agrees to the following:

1. I have not abused alcohol, injectable drugs, or other controlled substances for at least 6 months prior to starting Hepatitis C treatment, and I will not use these substances while being treated for Hepatitis C. If I am involved in a support group or counseling for addiction, I will continue therapy to encourage successful abstinence.

2. I have been reasonably adherent with all my current medications for all conditions and will take my Hepati- tis C treatment daily as prescribed.

3. I have a history of showing up for scheduled appointments and labs, and will continue to show up for all appointments and lab tests while taking Hepatitis C treatment.

4. If I have mental health conditions, I have been and will continue to adhere to my prescribed mental health medications and/or psychotherapy.

Patient signature: _____ Date: _____

Step 2: Clinical Assessment of Disease

- Confirmation of chronic hepatitis C (CHC):
  - Hepatitis C Virus (HCV) antibody test reactive
  - Provide HCV RNA load measured within 90 days prior to starting DAA therapy
  - Specify the Genotype
- Document progression of disease:
  - Document the degree of liver fibrosis:
    - Metavir score (scale of 1-4) must be F3 (bridging fibrosis) or F4 (cirrhosis); or
    - Ishak score (scale of 1-6) is F4-F5 (bridging cirrhosis) or F6 (cirrhosis)
    - If cirrhosis is present, indicate whether cirrhosis is compensated or decompensated and provide the Child-Turcotte-Pugh (CTP) score. Patients with decompensated cirrhosis ***(CTP score 7 or higher)*** will be approved for therapy only after consultation with a physician in a liver transplant center.
  - Document any HCV-related extra hepatic manifestations: e.g., lymphoma, symptomatic cryoglobulinemia, membranoproliferative glomerulonephritis
- Indicate any relevant co-infection, e.g., HIV or Hepatitis B
- Document that patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions
- Document any previously tried Hepatitis C treatments, dates treated, and response/outcome (patient will not be approved if any other HCV treatments have been used in the last 6 months)

Step 3: Direct Acting Antivirals (DAA) conditions for coverage

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist
- Initial approval: 8 week period
- HCV RNA testing is required every 4 weeks; treatment beyond the initial 8 weeks of therapy require confirmation of lowered viral load; refills will NOT be granted unless a greater than or equal to a 2 log reduction in the HCV RNA or the HCV RNA is less than 25 IU/mL
- HIV/HCV-coinfected persons should be treated and retreated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications
- No lost or stolen medication will be replaced
- Only regimens listed as recommended or alternative in the current AASLD guidance (http://hcvguidelines.org) will be approved. Regimens listed as not recommended will not be approved.

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
- Simeprevir: Patient has genotype 1 disease, and if genotype 1a does not have the Q80k polymorphism. Initial approval for 4 weeks, then must report viral load and follow response-guided therapy outlined in the prescribing information. Simeprevir should not be used in patients who have previously failed therapy with boceprevir or telepravir.

INFECTIOUS DISEASE AGENTS: HEPATITIS C – DIRECT-ACTING ANTIVIRAL

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
HARVONI® (ledipasvir/sofosbuvir) tablets VIEKIRA PAK™ (ombitasvir/paritaprevir and ritonavir tablets/dasabuvir tablets)	SOVALDI® (sofosbuvir)

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)	

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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

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	OLYSIO® (simeprevir)

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®) VALACYCLOVIR (generic of Valtrex®)	FAMCICLOVIR (generic of Famvir®) ***SITAVIG® buccal tablets (acyclovir)***

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Infectious Disease Agents: Antivirals – HIV

LENGTH OF AUTHORIZATIONS: 1 year

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

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 all medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. Has the patient failed a therapeutic trial of at least one month with at least one medication not requiring prior approval?

HIV PROTEASE INHIBITORS *AND COMBINATIONS*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CRIXIVAN® (indinavir sulfate) INVIRASE® (saquinavir mesylate) KALETRA® (lopinavir/ritonavir) LEXIVA® (fosamprenavir calcium) ~~NORVIR® (ritonavir)~~ REYATAZ® capsules, oral powder (atazanavir sulfate) VIRACEPT® (nelfinavir mesylate)	EVOTAZ® (atazanavir/cobicistat)

HIV NON-PEPTIDIC PROTEASE INHIBITORS *AND COMBINATIONS*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
PREZISTA® (darunavir ethanolate)	APTIVUS® (tipranavir; tipranavir/vitamin E) PREZCOBIX® (darunavir/cobicistat)

HIV REVERSE TRANSCRIPTASE INHIBITORS, NUCLEOSIDE ANALOGS *AND COMBINATIONS*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ABACAVIR SULFATE tablet (generic of Ziagen®) DIDANOSINE capsule (generic of Videx®) EMTRIVA® (emtricitabine) EPIVIR® solution EPZICOM® (abacavir/lamivudine) LAMIVUDINE solution, tablet (generic of Epivir®) LAMIVUDINE/ZIDOVUDINE (generic of Combivir®) STAVUDINE (generic of Zerit®) TRIZIVIR® (abacavir/lamivudine/zidovudine) VIDEX® solution (didanosine) ZIAGEN® solution (abacavir sulfate) ZIDOVUDINE (generic of Retrovir®)	

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HIV REVERSE TRANSCRIPTASE INHIBITORS, NUCLEOTIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
VIREAD® (tenofovir disoproxil fumarate)	

HIV REVERSE TRANSCRIPTASE INHIBITORS, NON-NUCLEOSIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
NEVIRAPINE ER (generic of Viramune® XR) NEVIRAPINE IR (generic of Viramune®) SUSTIVA® (efavirenz) VIRAMUNE® XR (nevirapine)	EDURANT® (rilpivirine) INTELENCE® (etravirine) RESCRIPTOR® (delavirdine mesylate)

HIV INTEGRASE STRAND TRANSFER INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ISENTRESS® tablets, chewable tablet, powder packets (raltegravir potassium) TIVICAY® (dolutegravir sodium)	***VITECTA® (elvitegravir)***

HIV CCR5 CO-RECEPTOR ANTAGONISTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	SELZENTRY® (maraviroc)

HIV FUSION INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	FUZEON® (enfuvirtide)

HIV RTI, NUCLEOSIDE-NUCLEOTIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
TRUVADA® (emtricitabine/tenofovir)	

HIV RTI, NUCLEOSIDE, NUCLEOTIDE, & NON-NUCLEOSIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ATRIPLA® (emtricitabine/efavirenz/tenofovir) COMPLERA® (emtricitabine/rilpivirine/tenofovir)	

HIV INTEGRASE INHIBITOR & RTI COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
TRIUMEQ® (dolutegravir/abacavir/lamivudine)	STRIBILD® (elvitegravir/cobicistat/emtricitabine/ tenofovir)

HIV PHARMACOKINETIC ENHANCERS (CYP3A INHIBITORS)

NO PA REQUIRED "PREFERRED"	*PA REQUIRED*
NORVIR® (ritonavir)	***TYBOST® (cobicistat)***

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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 quinolones only 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 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. 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®)	CILOXAN® ointment (ciprofloxacin) VIGAMOX® drops (moxifloxacin)	BESIVANCE® drops (besifloxacin) LEVOFLOXACIN drops (generic of Quixin®) MOXEZA® drops (moxifloxacin) GATIFLOXACIN drops (generic of Zymaxid®)

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OPHTHALMIC AGENTS: ANTIBACTERIAL – NON-QUINOLONE

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

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®) SULFACETAMIDE/ PREDNISOLONE drops (generic of Vasocidin®) TOBRADEX® drops (dexamethasone/tobramycin)	BLEPHAMIDE® drops (prednisolone/sulfacetamide) BLEPHAMIDE® ointment (prednisolone/ sulfacetamide) 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)

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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: MAST CELL STABILIZERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CROMOLYN (generic of Crolom®)	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®) PATADAY™ (olopatadine) ZADITOR® OTC (ketotifen)	AZELASTINE (generic of Optivar®) EPINASTINE (generic of Elestat®) EMADINE® (emedastine) LASTACAFT® (alcaftadine) PATANOL® (olopatadine) ***PAZEO® (olopatadine)***

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Ophthalmic Agents: Glaucoma Agents

LENGTH OF AUTHORIZATIONS: 1 year

STEP THERAPY: ACROSS ALL AGENTS

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

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)

GLAUCOMA AGENTS – PROSTAGLANDIN INHIBITORS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
LATANAPROST (generic of Xalatan®)	TRAVATAN®Z (travoprost)	BIMATOPROST 0.03% LUMIGAN™ 0.01% (bimatoprost) RESCULA® (unoprostone isopropyl) TRAVAPROST ZIOPTAN® (tafluprost)

GLAUCOMA AGENTS – ALPHA ADRENERGIC AGONISTS/SYMPATHOMIMETICS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
BRIMONIDINE 0.2% ALPHAGAN®P (brimonidine 0.15%)	ALPHAGAN®P (brimonidine 0.1%)	APRACLONIDINE 0.5% (generic of Iopidine®) BRIMONIDINE 0.15% (generic of Alphagan® P) IOPIDINE® 1% (apraclonidine)

GLAUCOMA AGENTS – CARBONIC ANHYDRASE INHIBITORS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
DORZOLAMIDE (generic of Trusopt®)	AZOPT® (brinzolamide)	

GLAUCOMA AGENTS – COMBO BETA BLOCKER & ALPHA ADRENERGIC AGONIST

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
	COMBIGAN® (brimonidine/ timolol)	

GLAUCOMA AGENTS – COMBO BETA BLOCKER & CARBONIC ANHYDRASE INHIBITORS

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

COMBO ALPHA-ADRENERGIC AGONIST AND CARBONIC ANHYDRASE INHIBITORS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
		SIMBRINZA™ (brinzolamide/ brimonidine)

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:

1) If there has been a therapeutic failure to no less than a three-day trial of at least one medication not requiring prior approval
2) 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) BROMFENAC (generic of Bromday®, Xibrom®) ILEVRO® (nepafenac) NEVANAC® (nepafenac) PROLENSA® (bromfenac)

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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) NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE solution (generic of Cortisporin® solution) NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE suspension (generic of Cortisporin® suspension)	CIPRO HC® suspension (ciprofloxacin with hydrocortisone) COLY-MYCIN-S® suspension (neomycin and colistin with hydrocortisone) CORTISPORIN-TC® suspension (neomycin and colistin with hydrocortisone)

OTIC AGENTS: ANTIBACTERIAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
OFLOXACIN drops (generic of Floxin Otic®)	CIPROFLOXACIN (generic of Cetraxal®)

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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
- Cetirizine and desloratadine 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) CETIRIZINE syrup (generic of Zyrtec®) (no PA required for age 6 or under) CETIRIZINE tablets (generic of Zyrtec®) CLARITIN® chewable (loratadine) LORATADINE rapid dissolve (generic of Claritin® Redi-tabs) LORATADINE syrup (generic of Claritin® Syrup) LORATADINE tablets (generic of Claritin®)	ALAVERT® rapid dissolve (loratadine) ALAVERT® tablets (loratadine) ALLEGRA® ODT (fexofenadrine) ALLEGRA® suspension (fexofenadrine) CETIRIZINE chewable (generic of Zyrtec®) (PA required for over age 6) CETIRIZINE syrup (generic of Zyrtec®) (PA required for over age 6) CLARINEX REDI-TABS® (desloratadine) CLARINEX® syrup (desloratadine) CLARITIN REDITABS® 5mg (loratadine) DESLORATADINE ODT (generic of Clarinex®) DESLORATADINE tablets (generic of Clarinex®) FEXOFENADINE tablets, suspension (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®) LORATADINE-D (generic of Claritin-D®)	ALAVERT D-12HR® (loratadine/pseudoephedrine) 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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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)	***PROAIR RESPICLICK® (albuterol)*** ***VENTOLIN HFA® (albuterol)*** XOPENEX HFA® (levalbuterol)

RESPIRATORY AGENTS: BETA-ADRENERGIC, SHORT-ACTING NEBULIZERS

NO PA REQUIRED " PREFERRED"	PA REQUIRED
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)	ALBUTEROL 0.42mg/ml, 0.63mg/ml (generic of Accuneb®) (PA required for over age 12) LEVALBUTEROL (generic of Xopenex®)

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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	6 months
Patient scored <= 19 on Asthma Control Test™	6 months

RESPIRATORY AGENTS: BETA-ADRENERGIC, LONG-ACTING INHALERS

STEP THERAPY REQUIRED " PREFERRED"	PA REQUIRED
FORADIL® (formoterol) STRIVERDI RESPIMAT® (olodaterol)	ARCAPTA NEOHALER® (indacaterol) SEREVENT DISKUS®(salmeterol)

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

STEP THERAPY REQUIRED " PREFERRED"	PA REQUIRED
	BROVANA™ (arformoterol) PERFOROMIST® (formoterol)

RESPIRATORY AGENTS: BETA-ADRENERGIC COMBINATIONS

STEP THERAPY REQUIRED " PREFERRED"	PA REQUIRED
DULERA® (formoterol/mometasone)	***ADVAIR DISKUS® (salmeterol/fluticasone)*** ***ADVAIR HFA (salmeterol/fluticasone)*** ANORO ELLIPTA (umeclidinium/vilanterol) BREO ELLIPTA (fluticasone/vilanterol) ***SYMBICORT® (formoterol/budesonide)***

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Respiratory Agents: Chronic Obstructive Pulmonary Disease

LENGTH OF AUTHORIZATIONS: 1 year for inhaled therapy
Daliresp evaluated with each refill

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®):
Patient must be adherent to concurrent therapy with long-acting beta agonist

RESPIRATORY AGENTS: COPD ANTICHOLINERGICS

NO PA REQUIRED " PREFERRED"	PA REQUIRED
ATROVENT HFA® (ipratropium) IPRATROPIUM nebulizer solution IPRATROPIUM/ALBUTEROL nebulizer solution (generic of Duoneb®) SPIRIVA® (tiotropium)	COMBIVENT Respimat® (ipratropium/albuterol) ***INCRUSE ELLIPTA® (umeclidinium)*** TUDORZA® (aclidinium bromide)

RESPIRATORY AGENTS: PHOSPHODISTERASE-4 INHIBITORS *

NO PA REQUIRED " PREFERRED"	PA REQUIRED
	DALIRESP® (roflumilast)

* Note: Concurrent therapy with long-acting beta agonist required

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Respiratory Agents: Epinephrine Auto-Injectors

LENGTH OF AUTHORIZATIONS: 1 year

The requested medication may be approved if there has been therapeutic failure using the product(s) not requiring prior approval.

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

- Allergy to medication(s) not requiring prior approval
- Contraindication to or drug interaction with medication(s) not requiring prior approval
- History of unacceptable/toxic side effects to medication(s) not requiring prior approval

RESPIRATORY AGENTS: EPINEPHRINE AUTO-INJECTORS

NO PA REQUIRED " PREFERRED"	PA REQUIRED
AUVI-Q™ (epinephrine) ***EPINEPHRINE (generic of Adrenaclick®)*** EPIPEN JR® (epinephrine) EPIPEN® (epinephrine)	

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

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
AEROSPAN® HFA (flunisolide) FLOVENT DISKUS® and HFA (fluticasone) PULMICORT FLEXHALER® (budesonide) QVAR® (beclomethasone)	ALVESCO® (ciclesonide) ***ARNUITY ELLIPTA® (fluticasone furoate)*** ASMANEX® HFA, Twisthaler (mometasone)

RESPIRATORY AGENTS: GLUCOCORTICOIDS – NEBULIZERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BUDESONIDE nebulizer solution (generic of Pulmicort®) (no PA required for age 4 or under)	BUDESONIDE nebulizer solution (generic of Pulmicort®) (PA required for over age 4)

Respiratory Agents: Hereditary Angioedema

LENGTH OF AUTHORIZATIONS: ***6 months***

All products in this class require clinical prior authorization:

- ***Diagnosis of hereditary angioedema***
- ***History of recurrent angioedema (without urticaria) within the past 6 months***
- ***History of recurrent episodes of abdominal pain and vomiting within the past 6 months***
- ***History of laryngeal edema within the past 6 months***
- ***Positive family history of angioedema***

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 one episode of angioedema during use of a preferred medication***

RESPIRATORY AGENTS: HEREDITARY ANGIOEDEMA

CLINICAL PA REQUIRED "PREFERRED"	*PA REQUIRED*
CINRYZE® (C1 esterase inhibitor) *RUCONEST® (C1 esterase inhibitor, recombinant)*	*BERINERT® (C1 esterase inhibitor)* *FIRAZYR® (icatibant acetate)* *KALBITOR® (ecallantide)*

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
MONTELUKAST tablets, chewable tablets, granules (generic of Singulair®) ZAFIRLUKAST (generic of Accolate®)	ZYFLO® (zileuton) ZYFLO CR® (zileuton)

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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, 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

RESPIRATORY AGENTS: NASAL PREPARATIONS - GLUCOCORTICOIDS

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
FLUNISOLIDE ***FLONASE OTC® (fluticasone)*** FLUTICASONE (generic of Flonase®)	NASONEX® (mometasone***)***	BECONASE®AQ (beclomethasone) BUDESONIDE (generic of Rhinocort Aqua®) DYMISTA® (fluticasone/azelastine) OMNARIS® (ciclesonide) QNASL® (beclomethasone) TRIAMCINOLONE (generic of Nasacort® AQ) VERAMYST™ (fluticasone furoate) ZETONNA® (ciclesonide)

RESPIRATORY AGENTS: NASAL PREPARATIONS - ANTIHISTAMINES

	PA REQUIRED
ASTEPRO® (azelastine) PATANASE® (olopatadine)	AZELASTINE (generic of Astelin®, Astepro®) OLOPATADINE (generic of Patanase®)

RESPIRATORY AGENTS: NASAL PREPARATIONS - ANTICHOLINERGICS

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

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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

ANTIBIOTIC PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CLINDAMYCIN gel (generic of Cleocin T®, Clindamax®) CLINDAMYCIN lotion (generic of Cleocin T®, Clindamax®) CLINDAMYCIN solution (generic of Cleocin T®) ERYTHROMYCIN gel ERYTHROMYCIN solution (generic of A/T/S®, Akne-Mycin®)	AKNE-MYCIN® ointment (erythromycin) CLINDACIN® Pak (clindamycin/skin cleanser kit) ***CLINDAGEL® (clindamycin)*** CLINDAMYCIN foam (generic of Evoclin®) CLINDAMYCIN pledgets (generic of Cleocin T®) ERYTHROMYCIN pads (generic of Ery Pads®)

ACNE PREPARATIONS – OTHER PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AZELEX® cream (azelaic acid)	ACZONE® gel (dapsone) FINACEA® gel (azelaic acid)

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BENZOYL PEROXIDE AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CLINDAMYCIN-BENZOYL PEROXIDE gel (generic of Benzaclin®, Duac®) BENZOYL PEROXIDE cleanser (generic of Oscion®, Triaz®) BENZOYL PEROXIDE gel (generic of Benzac AC®, Brevoxyl®, Desquam-X®, Panoxyl®) BENZOYL PEROXIDE wash (generic of Benzac AC ®, Benzac W®, Brevoxyl®, Desquam-X®, Pacnex®) ERYTHROMYCIN-BENZOYL PEROXIDE gel (generic of Benzamycin®) PANOXYL® 10% foam, wash (benzoyl peroxide)	ACANYA® (clindamycin-benzoyl peroxide) BENZAMYCINPAK® gel (benzoyl peroxide and erythromycin) BENZEFOAM® BENZOYL PEROXIDE MICROSPHERES wash (generic of Neobenz Micro®) BENZOYL PEROXIDE pads (generic of Oscion®, Triaz®) BENZOYL PEROXIDE-ALOE VERA wash (generic of Benziq® wash) DUAC CS® gel (benzoyl peroxide and clindamycin) INOVA EASY PAD® (benzoyl peroxide) ***NEUAC® gel (clindamycin-benzoyl peroxide)*** ***ONEXTON™ gel (clindamycin-benzoyl peroxide)*** PACNEX HP® (benzoyl peroxide) PACNEX LP® (benzoyl peroxide) PACNEX MX® (benzoyl peroxide)

RETINOID AND COMBINATION PRODUCTS

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

SODIUM SULFACETAMIDE AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
KLARON® lotion (sulfacetamide) SODIUM SULFACETAMIDE-SULFUR wash (generic of Avar® cleanser, Clenia® foaming wash, Plexion® cleanser, Rosac® wash)	CLARIFOAM EF® emollient foam CLENIA emollient cream ***OVACE PLUS® (sodium sulfaetamide)*** ***ROSULA® wash (sodium sulfacetamide-sulfur)*** SODIUM SULFACETAMIDE lotion (generic of Klaron®) SODIUM SULFACETAMIDE-SULFUR pads (generic of Plexion® cleansing cloths) SODIUM SULFACETAMIDE-SULFUR-UREA cleanser (generic of Rosula® cleanser) SODIUM SULFACETAMIDE-SULFUR-UREA wash (generic of Rosula® clarifying wash) SODIUM SULFACETAMIDE-SULFUR-WITCH HAZEL cream (generic of Plexion® SCT cream) SULFACETAMIDE SODIUM-SULFUR topical suspension (generic of Sumaxin TS®)

Topical Agents: Androgens

LENGTH OF AUTHORIZATIONS: 1 year
The requested medication may be approved if there has been a therapeutic failure to no less than a three-month trial of all medications not requiring prior approval.

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

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

ADDITIONAL INFORMATION
Limited to males >/= 18 years

TOPICAL AGENTS: ANDROGENS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ANDRODERM® patch (testosterone) ANDROGEL® (testosterone)	AXIRON® gel (testosterone) ***NATESTO® nasal gel (testosterone)*** ***TESTOSTERONE gel (generic of Androgel® 1%, Fortesta®, Testim®)*** ***VOGELXO™ gel (testeosterone)***

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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, gel, topical suspension, shampoo (generic of Loprox®)	CICLOPIROX kit (generic of CNL® Nail lacquer kit)
CICLOPIROX solution (generic of Penlac®)	ERTACZO® (sertaconazole)
CLOTRIMAZOLE (generic of Lotrimin®)	EXELDERM® (sulconazole)
CLOTRIMAZOLE/BETAMETHASONE (generic of Lotrisone®)	***JUBLIA® solution (efinaconazole)***
ECONAZOLE (generic of Spectazole®)	***KERYDIN® solution (tavaborole)***
KETOCONAZOLE Cream & Shampoo (generic of Kuric®, Nizoral®)	KETOCONAZOLE foam(generic of Extina®)
MICONAZOLE	LUZU® (luliconazole)
NYSTATIN	MENTAX® (butenafine)
NYSTATIN/TRIAMCINOLONE	NAFTIN® (naftifine)
TERBINAFINE (generic of Lamisil®)	OXISTAT® (oxiconazole)
TOLNAFTATE (generic of Tinactin®)	PEDIADERM AF® cream (nystatin)
	VUSION® ointment (miconazole/zinc)

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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
- Ivermectin is indicated for age 6 months and older
- Lindane lotion and shampoo are indicated only in patients who cannot tolerate or who have failed other treatments. **The P&T Committee does not recommend use of lindane.**
- 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~~ ***6 months*** of age and older
- Package labeling does not list age for permethrin or piperonyl butoxode-pyrethrins

ANTI-PARASITICS, TREATMENT OF SCABIES

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

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) SKLICE® lotion (ivermectin)	MALATHION lotion (generic of Ovide®) SPINOSAD (generic of Natroba®) ULESFIA® lotion (benzyl alcohol)

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Topical Agents: Corticosteroids

LENGTH OF AUTHORIZATIONS: 1 year for low and medium potency
3 months for high and very high potency

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
DESONIDE cream, ointment (generic of Desowen®) FLUOCINOLONE ACETONIDE 0.01% cream, solution (generic of Synalar®) FLUOCINOLONE body oil, scalp oil (generic of Derma-Smoothe/ FS®) HYDROCORTISONE cream, lotion, ointment	ALCLOMETASONE cream, ointment (generic of Aclovate®) CAPEX® shampoo (fluocinolone acetonide) DESONATE®gel (desonide) DESONIDE lotion (generic of Desowen®) HYDROCORTISONE ACETATE WITH ALOE gel HYDROCORTISONE WITH UREA cream (generic of Carmol HC®) PANDEL® cream (hydrocortisone probutate) PEDIADERM HC® kit VERDESO® foam (desonide)

TOPICAL AGENTS: CORTICOSTEROIDS – MEDIUM POTENCY

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BETAMETHASONE VALERATE cream, lotion (generic of Valisone®) FLUOCINOLONE ACETONIDE 0.025% cream, ointment (generic of Synalar®) FLUTICASONE PROPIONATE cream, ointment (generic of Cutivate®) HYDROCORTISONE BUTYRATE solution (generic of Locoid®) MOMETASONE FUROATE cream, lotion, ointment (generic of Elocon®) TRIAMCINOLONE ACETONIDE cream, ointment (generic of Aristocort®, Kenalog®)	BETAMETHASONE DIPROPIONATE lotion (generic of Diprolene®) CLOCORTOLONE PIVALATE (generic of Cloderm®) CORDRAN® tape (flurandrenolide) DESOXIMETASONE cream, gel, ointment (generic of Topicort®) FLUTICASONE PROPIONATE lotion (generic of Cutivate®) HYDROCORTISONE BUTYRATE cream, ointment (generic of Locoid®) HYDROCORTISONE VALERATE cream, ointment (generic of Westcort®) LUXIQ® (betamethasone valerate foam) MOMEXIN® combo pack (mometasone/ammonium lactate) PREDNICARBATE cream, ointment (generic of Dermatop®) TRIAMCINOLONE ACETONIDE lotion (generic of Kenalog®)

TOPICAL AGENTS: CORTICOSTEROIDS – HIGH POTENCY

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AMCINONIDE ointment, cream, lotion BETAMETHASONE VALERATE ointment (generic of Valisone®) DIFLORASONE DIACETATE cream, ointment (generic of Florone®) FLUOCINONIDE cream, gel, ointment, solution (generic of Lidex®, Lidex-E®)	APEXICON-E® (diflorasone diacetate emollient base) cream BETAMETHASONE DIPROPIONATE cream, ointment (generic of Diprolene®) FLUOCINONIDE (generic of Vanos® cream) HALOG® cream, ointment (halcinonide) KENALOG® aerosol spray (triamcinolone acetonide)

TOPICAL AGENTS: CORTICOSTEROIDS – VERY HIGH POTENCY

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	BETAMETHASONE DIPROPIONATE AUGMENTED cream, ointment, lotion, gel (generic of Diprolene AF®) CLOBETASOL PROPIONATE cream, emollient base cream, foam, gel, lotion, ointment, shampoo, solution, ***spray*** (generic of ***Clobex®***, Olux®, Temovate®) CLOBEX® lotion, shampoo,(clobetasol propionate) ***CLODAN® shampoo, kit (clobetasol propionate)*** HALOBETASOL PROPIONATE cream, ointment (generic of Ultravate®) OLUX-E® foam (clobetasol propionate)

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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 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

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

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
ELIDEL® * (pimecrolimus)	TACROLIMUS (generic of PROTOPIC®) *

* Pimecrolimus and tacrolimus have age restriction of 2 years or older

Ohio Department of Medicaid

Pharmacy Benefit Management Program

Preferred Drug List

Recommendations

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

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Analgesic: Gastroprotective NSAIDs

Clinical Highlights

- New generics: celecoxib (Celebrex®) 50 mg, 100 mg, 200 mg, and 400 mg capsules

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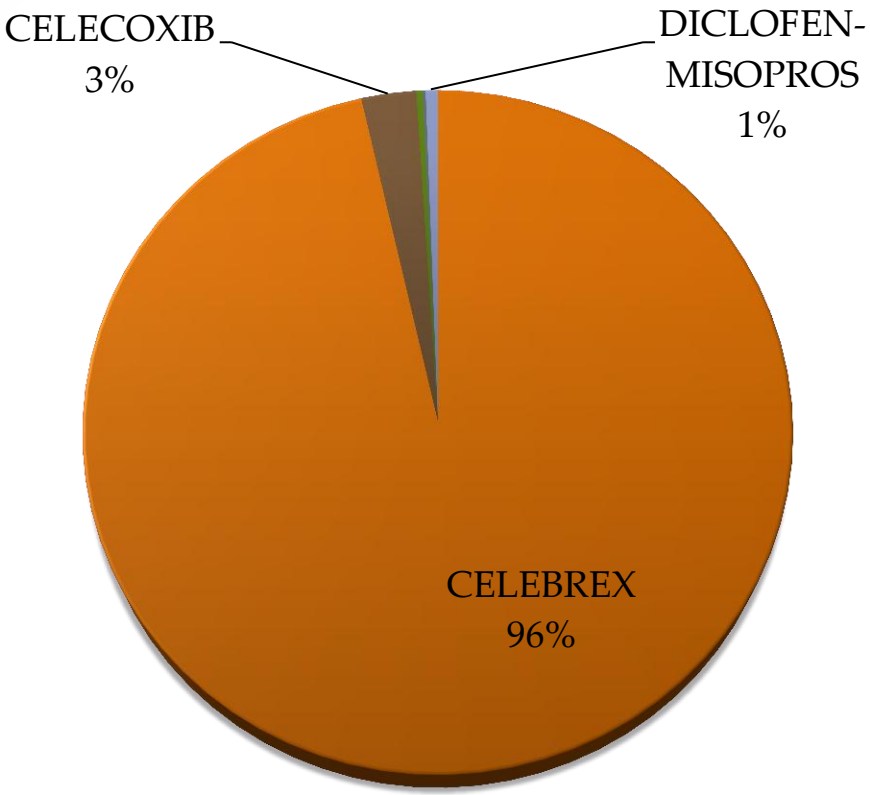
Analgesic: Gastroprotective NSAIDs

Market Share



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Analgesic: Gastroprotective NSAIDs Recommendation(s)

- Patients ≥ 60 years of age: add generic celecoxib as Preferred
- Patients < 60 years of age: Non-Preferred
- Maintain current criteria

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Analgesic: Gout Agents

Clinical Highlights

- New generics: colchicine capsules and tablets (Colcrys®, Mitigare®)

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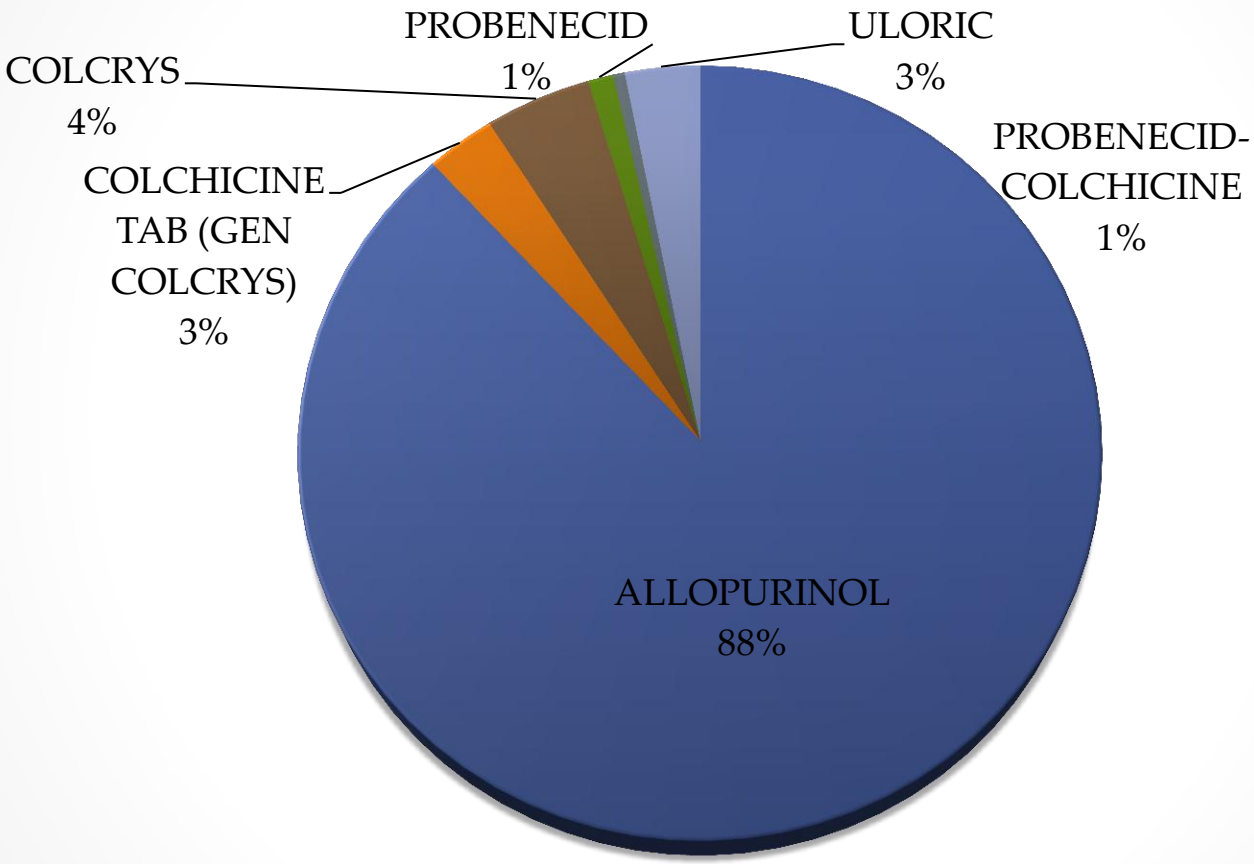
Analgesic: Gout Agents Market Share



Analgesic: Gout

Recommendation(s)

- Add colchicine capsules and tablets as Non-Preferred; maintain current criteria

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Analgesic: Topical

Clinical Highlights

- New class:
  - Agents in review are diclofenac epolamine (Flector®)and diclofenac sodium (Pennsaid®, Voltaren®)
  - Flector® Patch is approved for acute pain due to minor strains, sprains and contusions
  - Pennsaid® Solution and Voltaren® Gel are approved for OA of the hands and knees

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Analgesic: Topical

Recommendation(s)

- Criteria:
  - Diagnosis required
  - Approvals for diclofenac solution/gel require history of 30-day trial each on two different oral NSAIDs within the past 6 months; approval lengths will be 3 months
  - Approvals for diclofenac patch require history of 7-day trial of an oral NSAID; approval length will be 14 days with limit of 2 patches/day

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Analgesic: Topical

Recommendation(s)

- Add as Preferred: Voltaren® Gel
- Add as Non-Preferred:
  - diclofenac 1.5% topical solution
  - Pennsaid® 2% solution
  - Flector® Patch
- 14-day trial of a Preferred medication required prior to receiving a Non-Preferred medication

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Analgesic: Long-Acting Opioids

Clinical Highlights

- Butrans® (buprenorphine):
  - new 7.5 mcg strength patch
  - recent change in indication: now approved for management of pain severe enough to require daily, around-the-clock long-term opioid treatment for which alternative treatment options are inadequate
  - previously approved for moderate to severe pain in patients requiring an opioid analgesic for an extended period of time

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Analgesic: Long-Acting Opioids

Clinical Highlights

- Embeda ER® (morphine/naltrexone): recently re-launched in an abuse-deterrent formulation
- Hysingla ER® (hydrocodone bitartrate): new opioid agonist approved for management of severe pain
- Zohydro ER® (hydrocodone bitartrate): now available in an abuse-deterrent formulation

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Analgesic: Short-Acting Opioids

Clinical Highlights

- Trezix® (dihydrocodeine/apap/caffeine): approved for moderate to moderately severe pain; available in 16-320.5-30 mg capsule strength

- Verdrocet® (hydrocodone/apap): new 2.5-325 mg tablet formulation

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Analgesic: Opioids

Clinical Highlights

- New generics: fentanyl 37.5 mcg, 62.5 mcg, and 87.5 mcg patches; hydromorphone ER tablets (Exalgo ER®)

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Analgesic: Opioids

Recommendation(s)

- Add as Non-Preferred:
  - new fentanyl patch strengths
  - Embeda ER®
  - hydromorphone ER
  - Hysingla ER ®
  - Trezix®
  - Verdrocet ®
- Move to Preferred: tramadol/apap (Ultracet ®)

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Analgesic: Opioids

Recommendation(s)

- Move to Non-Preferred:
  - older fentanyl patch strengths
  - meperidine and methadone formulations

- Butrans®: approve under criteria for Non-Preferred long-acting products

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Blood: Hematopoietic Agents

Clinical Highlights

- Mircera®:
  - anemia associated with chronic kidney disease
  - initially administered once every 2 weeks
  - once monthly when hemoglobin stabilized

- Aranesp®:
  - available in a new 10 mcg/0.4 mL strength intended to facilitate lower doses

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Blood: Hematopoietic Agents Recommendation(s)

- Add Mircera® as Non-Preferred

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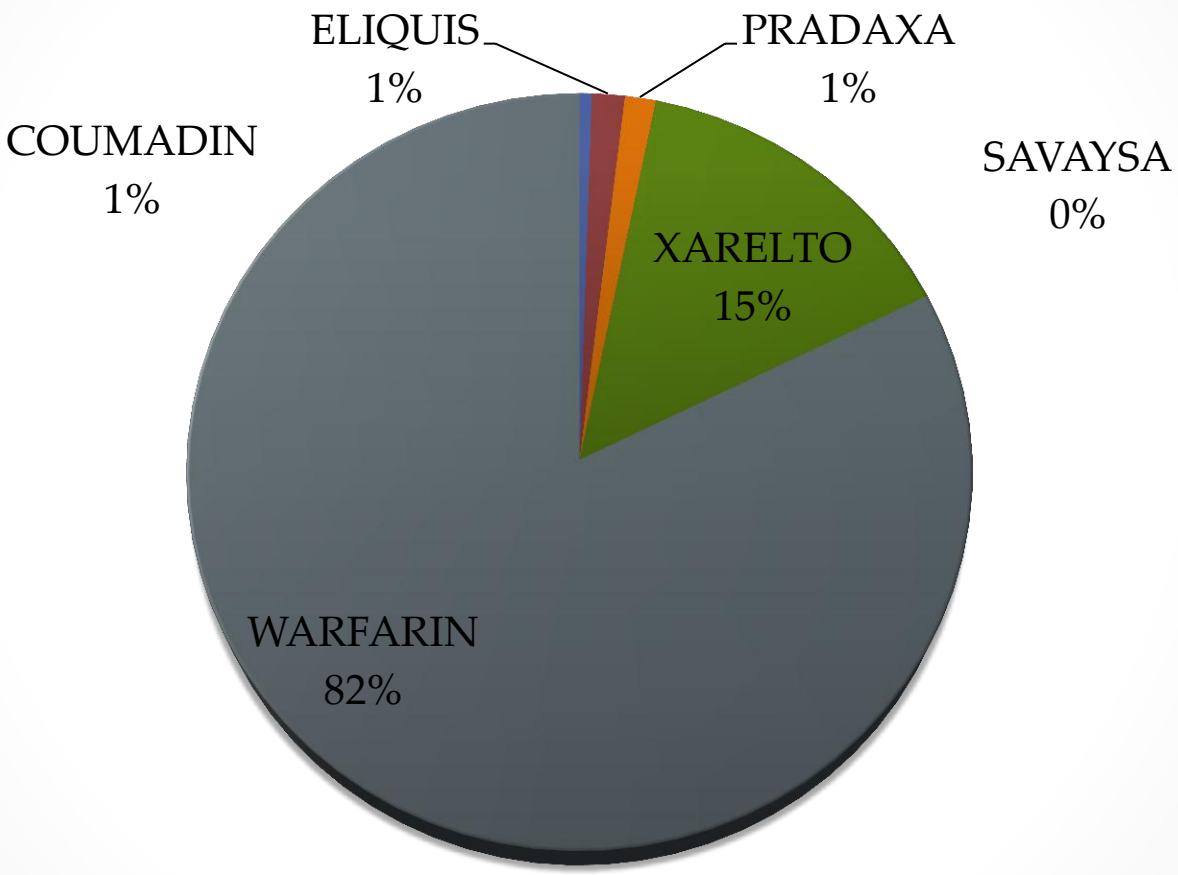
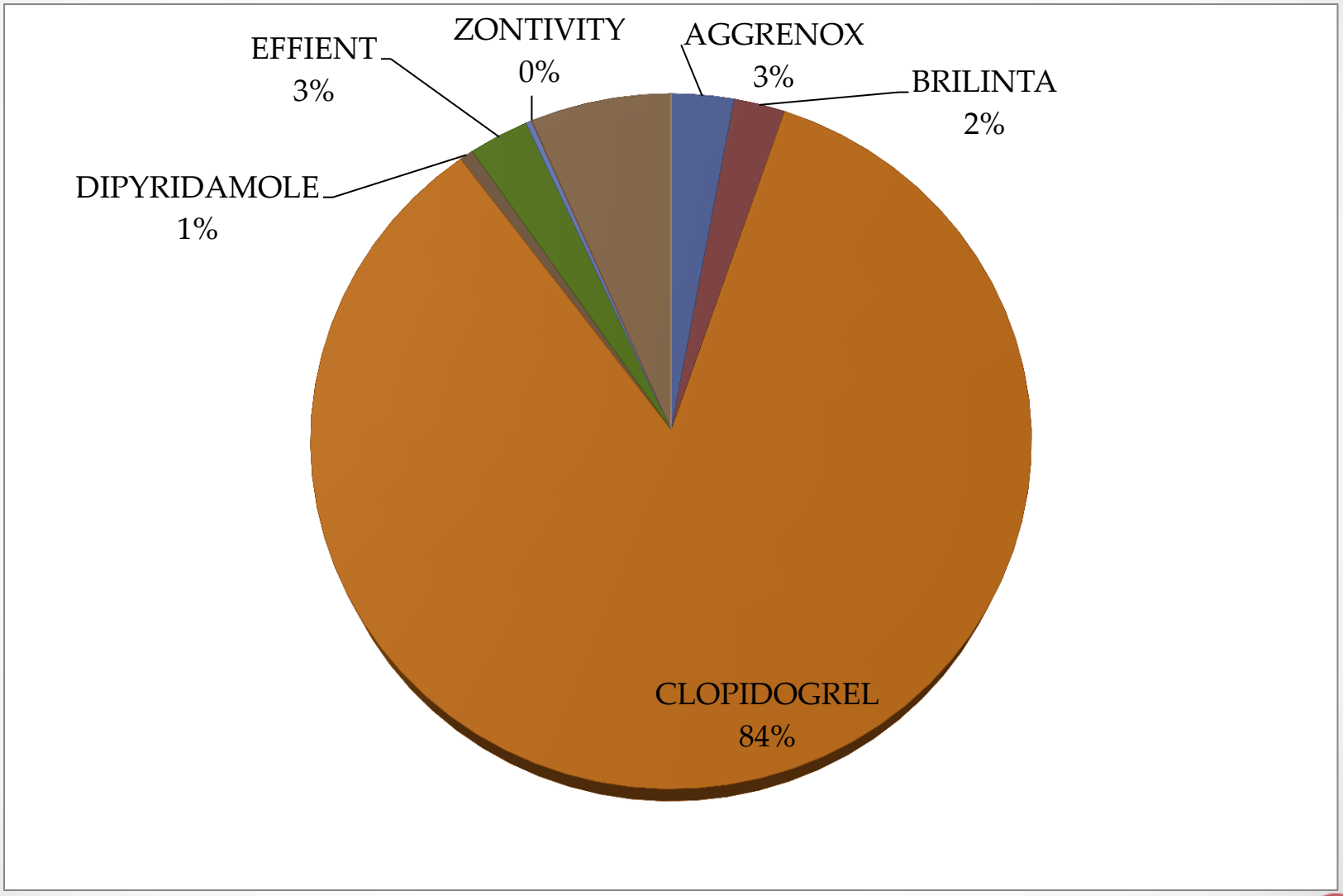
Blood: Oral Anticoagulants

Market Share

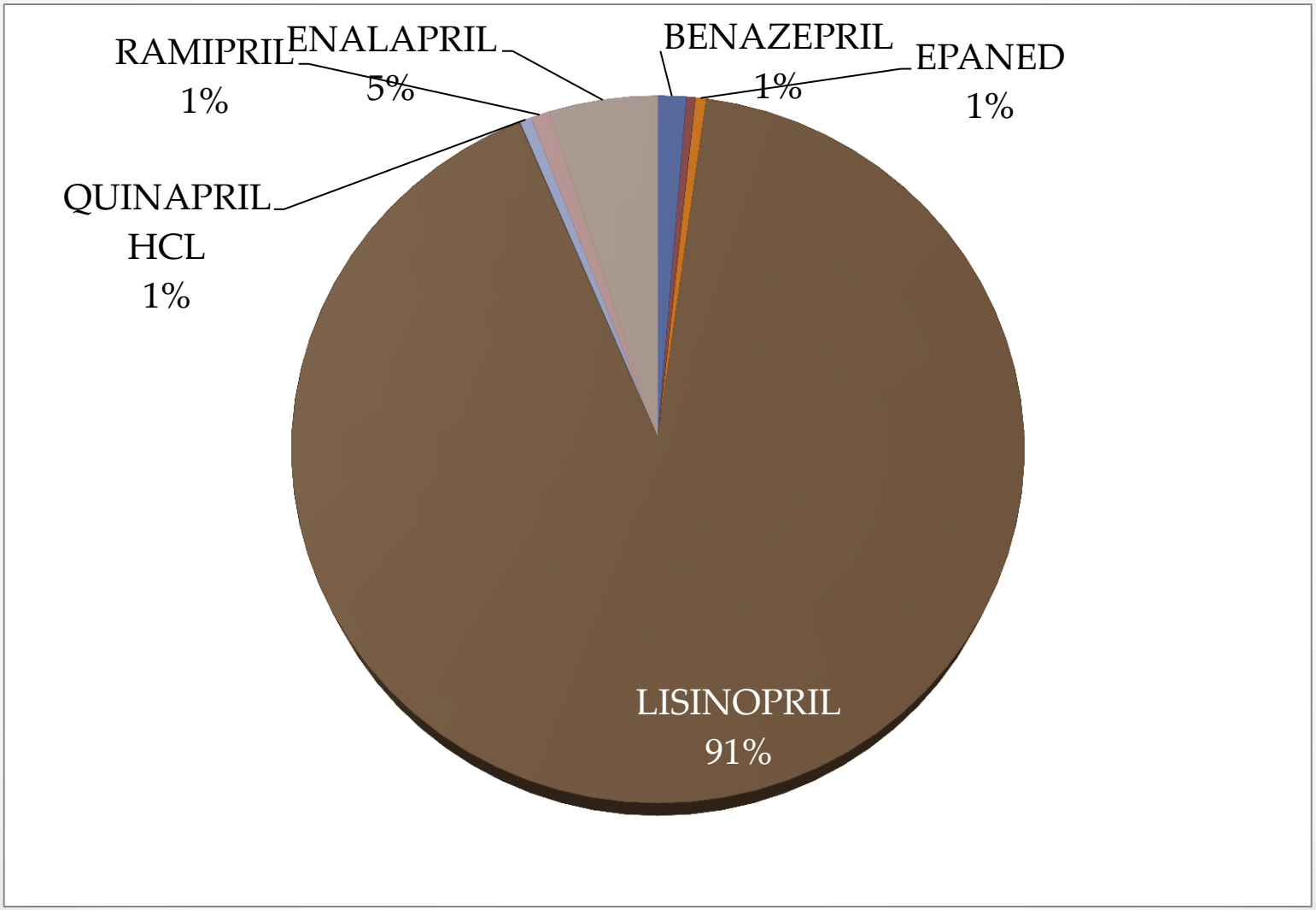


Blood: Oral PAIs

Market Share

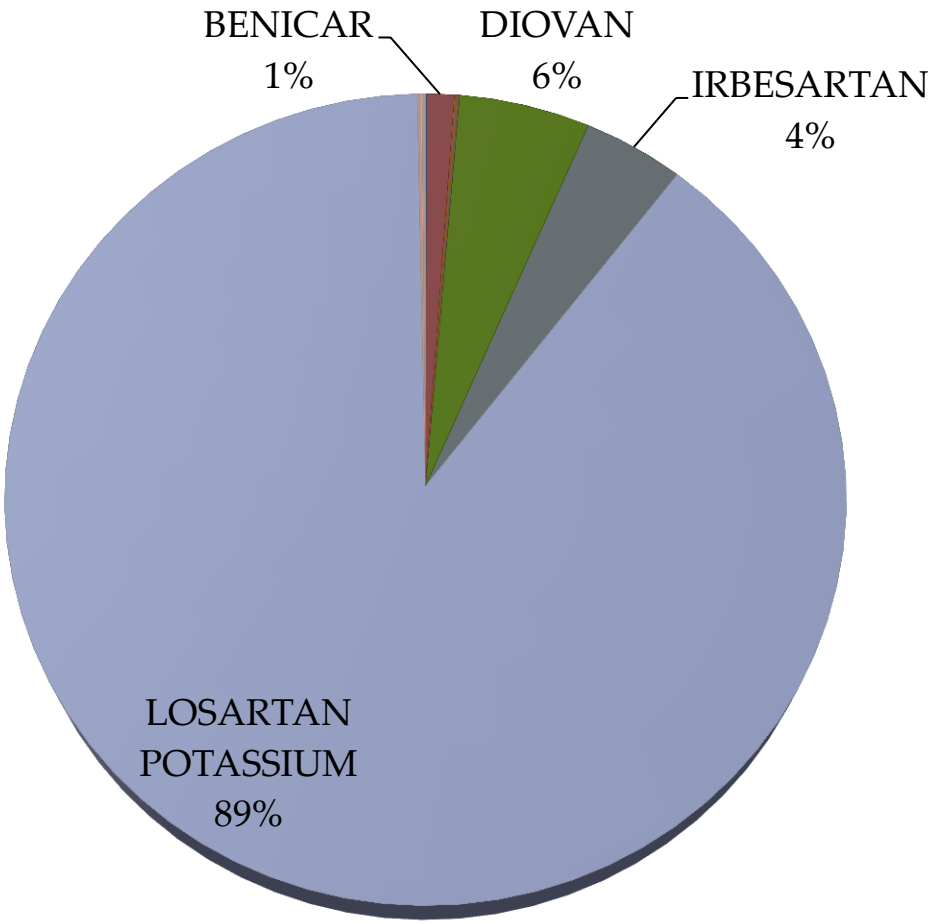


Cardiovascular: ACE Inhibitors Market Share



Cardiovascular: ARBs

Market Share



Cardiovascular: ARBs Recommendation(s)

- Preferred: valsartan (new generic, Diovan®)

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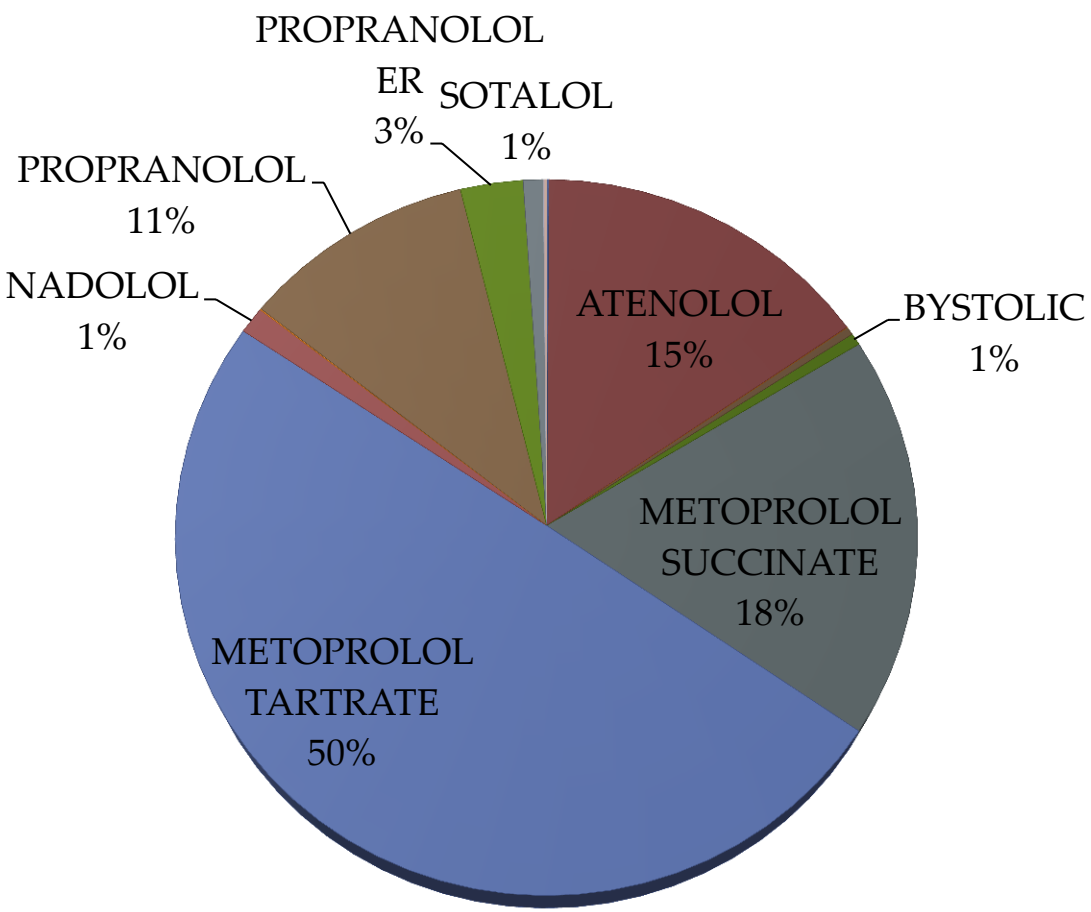
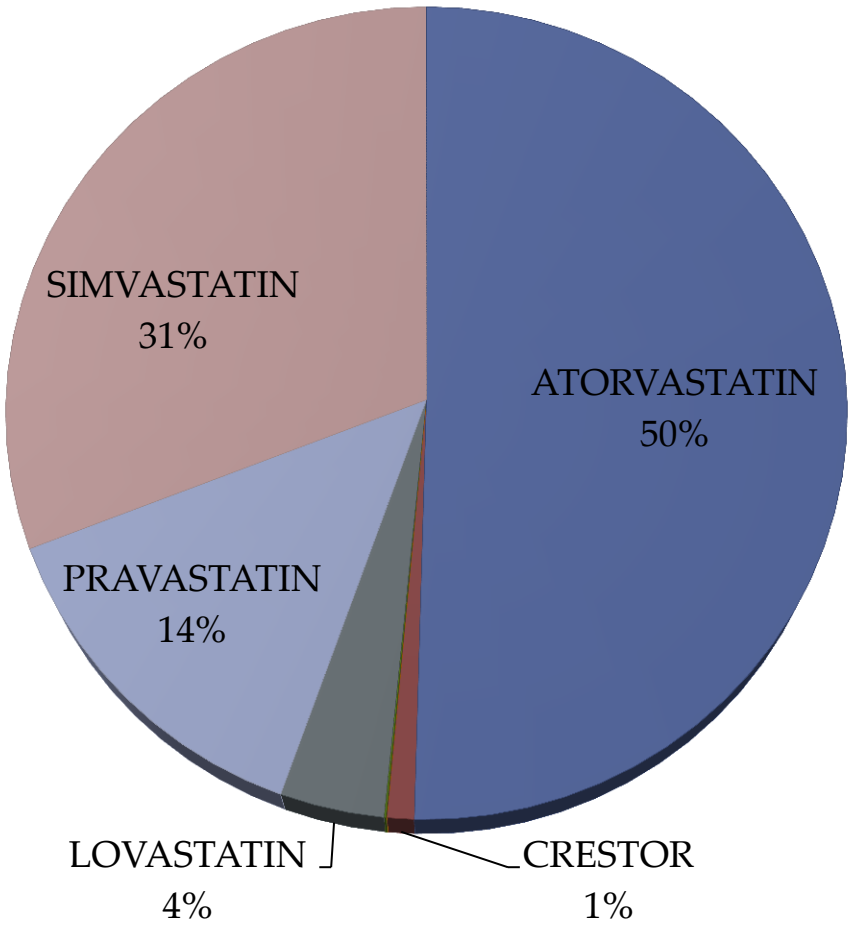
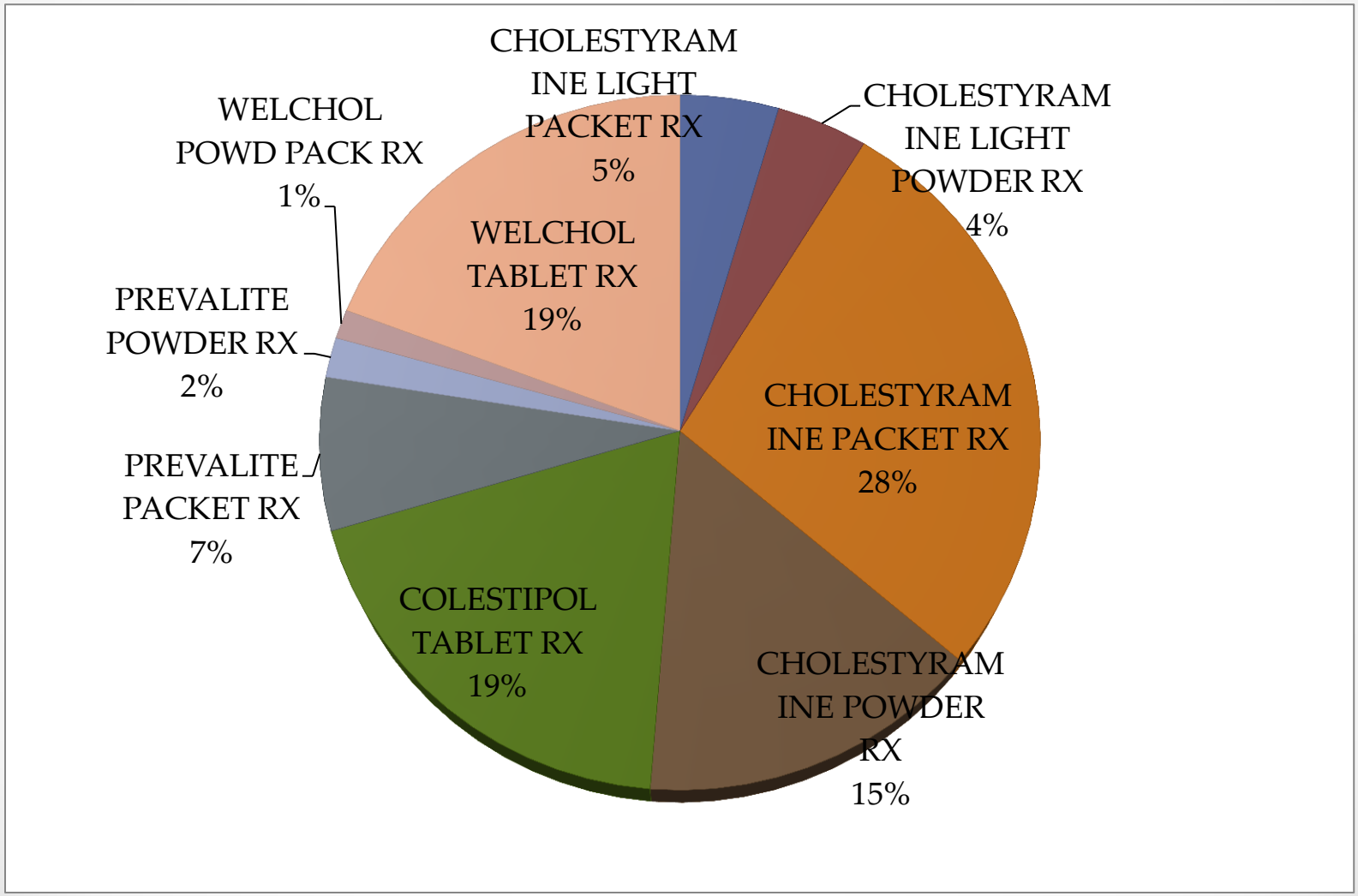
Cardiovascular: BBs Market Share



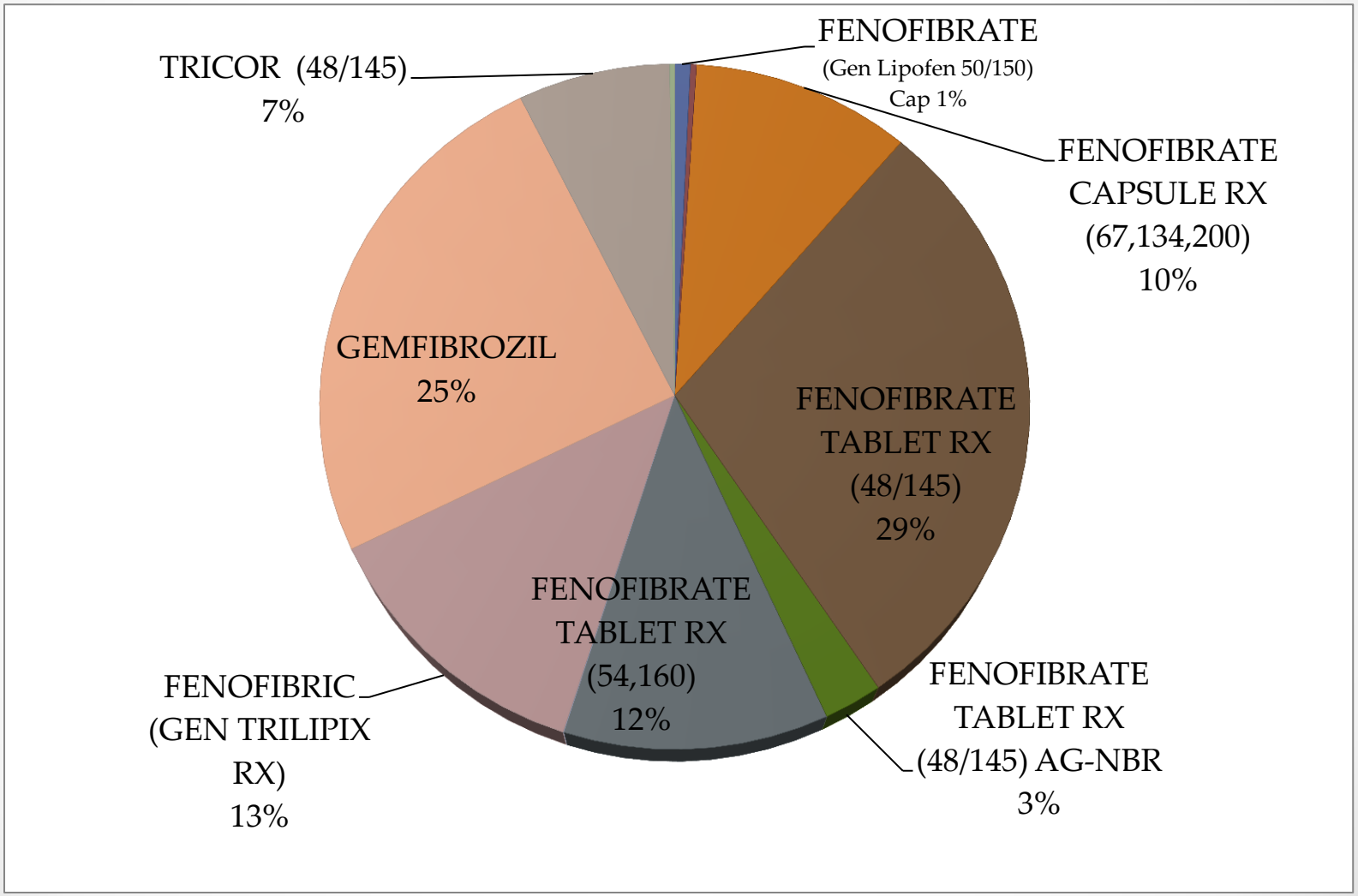
Cardiovascular: Statins Market Share



Cardiovascular: Bile Acids Market Share



CV: Lipotropics, FADs Market Share



Cardiovascular: PAH Agents Clinical Highlights

- Revatio® (sildenafil):
  - Available in a new 10 mg/mL oral suspension
  - Also available as a 20 mg tablet and 10 mg/2.5 mL single-use vial
  - Dosage for both the suspension and tablet is 5 or 20 mg three times a day

xerox

Cardiovascular: PAH Agents Recommendation(s)

- Add Revatio® oral suspension as Non-Preferred

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Other Cardiovascular Recommendation(s)

- No changes: Alpha-Beta Blockers, Antianginal Agents, CCBs, DRIs, and Other Lipotropics/Combos

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CNS: Alzheimer's Agents

Clinical Highlights

- Namzaric® (memantine/donepezil):
  - Extended-release capsules approved for treatment of moderate to severe dementia
  - Taken once daily in the evening

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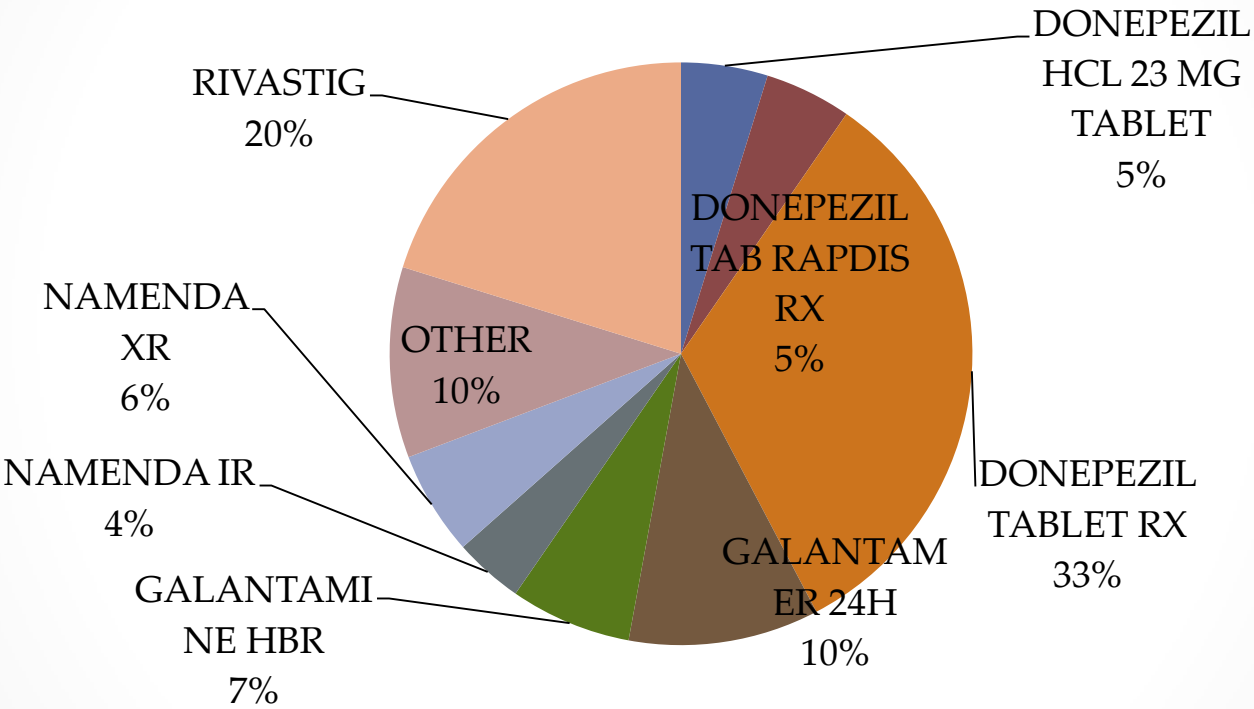
CNS: Alzheimer's Agents Market Share



CNS: Alzheimer's Agents Recommendation(s)

- Add Namzaric® as Non-Preferred

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CNS: Anticonvulsants

Clinical Highlights

- Qudexy XR®(topiramate):
  - Newer topiramate formulation approved for partial onset seizures, primary generalized tonic-clonic seizures, and Lennox-Gastaut syndrome (LGS)
  - Available in five capsule strengths: 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg

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CNS: Anticonvulsants

Clinical Highlights

- New generics: lamotrigine ODT (Lamictal ODT®) and topiramate ER (Qudexy XR®)

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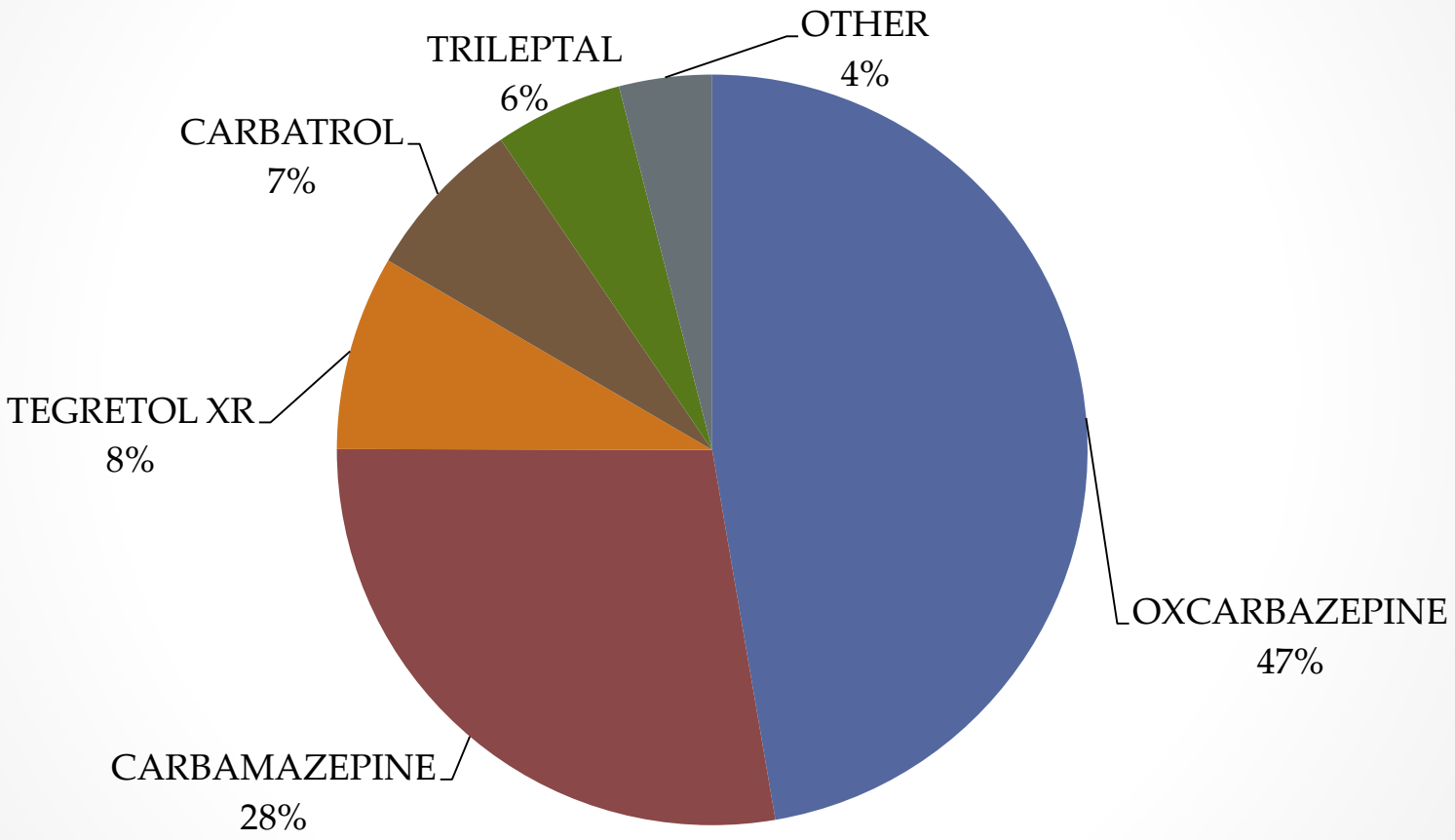
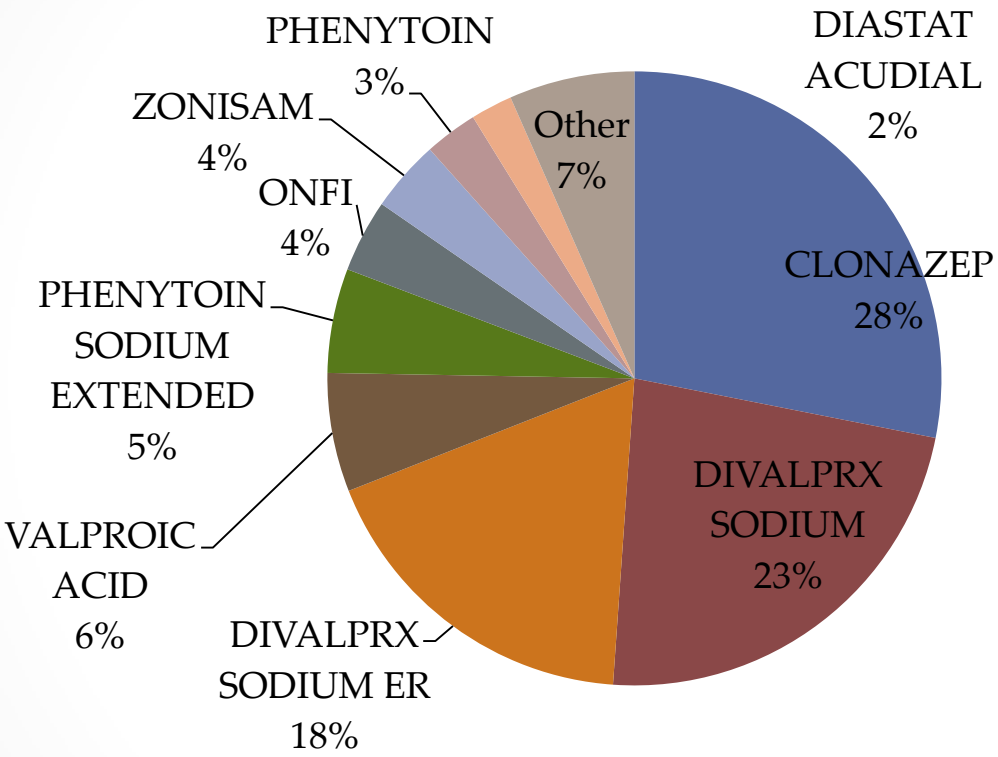
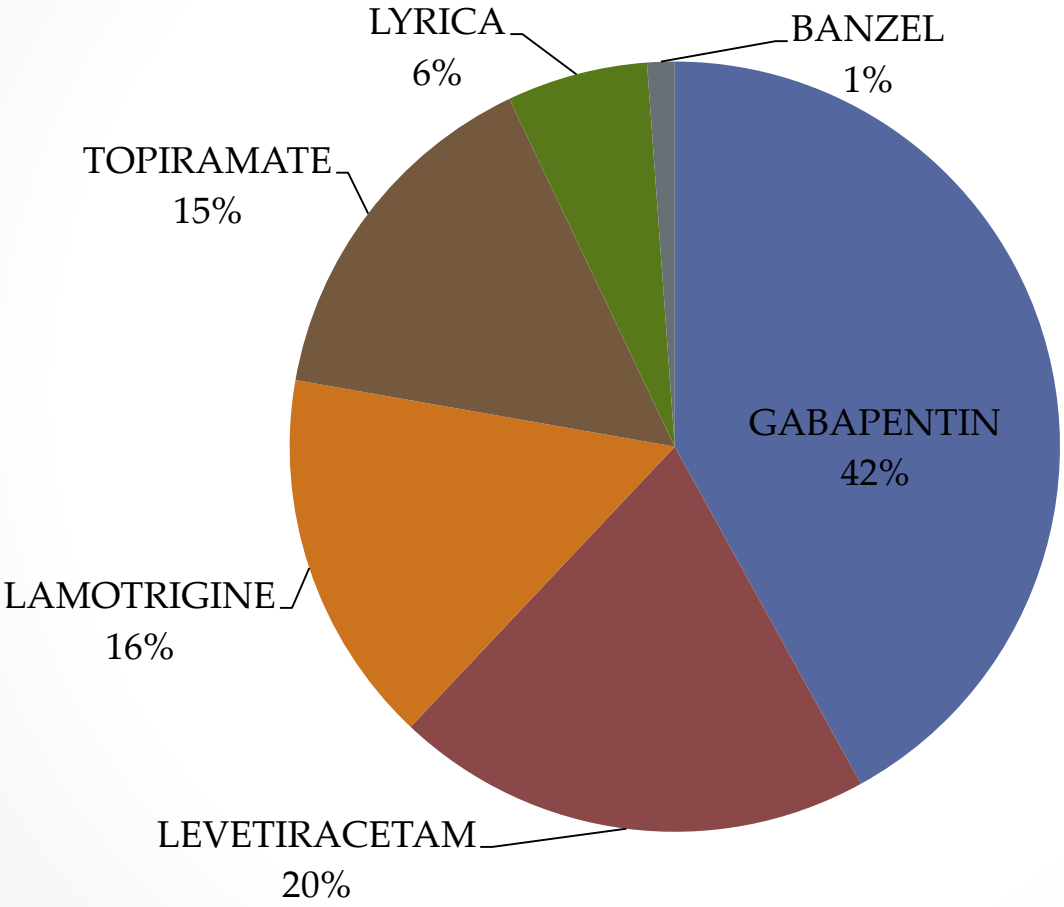
CNS: Anticonvulsants Market Share



CNS: Anticonvulsants Market Share



CNS: Anticonvulsants Market Share



CNS: Anticonvulsants Recommendation(s)

- Add as Non-Preferred:
  - lamotrigine ODT
  - topiramate ER
  - Qudexy XR®

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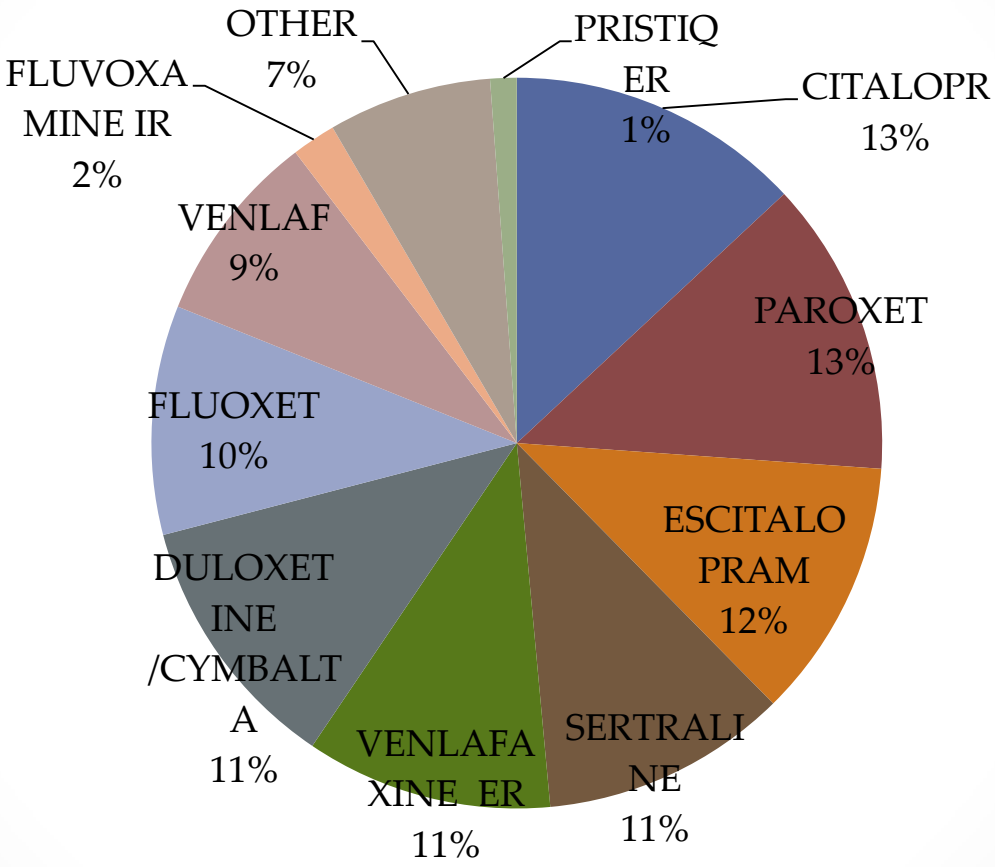
CNS: Antidepressants

Market Share



CNS: 2nd Generation Antipsychotics Clinical Highlights

- Abilify®:
  - New generic
  - New indication; now approved for Tourette's Disorder in pediatric patients
  - Abilify Maintena® available in 300 mg and 400 mg ER syringes; previously available in vials only

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CNS: 2nd Generation Antipsychotics Clinical Highlights

- Invega Sustenna®:
  - now approved for schizoaffective disorder as monotherapy, and for treatment of schizoaffective disorder as an adjunct to mood stabilizers or antidepressants
  - previously indicated for schizophrenia only

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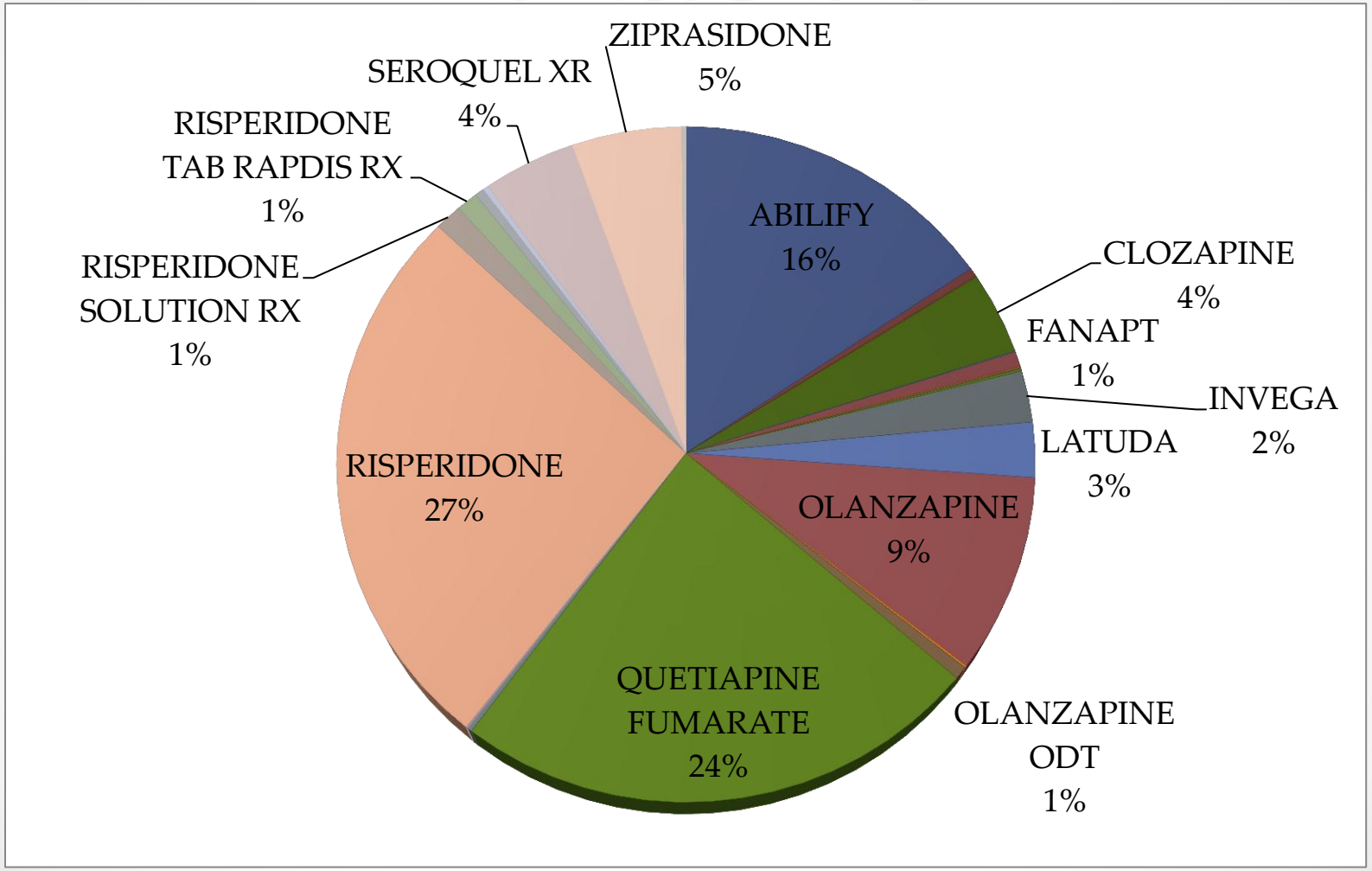
CNS: 2nd Generation Antipsychotics Market Share



CNS: ADHD Agents

Clinical Highlights

- Evekeo® (amphetamine):
  - Approved to treat ADHD, narcolepsy, and exogenous obesity
  - Available in 5 mg and 10 mg tablets

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CNS: ADHD Agents
Clinical Highlights

- New generic: methylphenidate chewable tablets (Methylin®)

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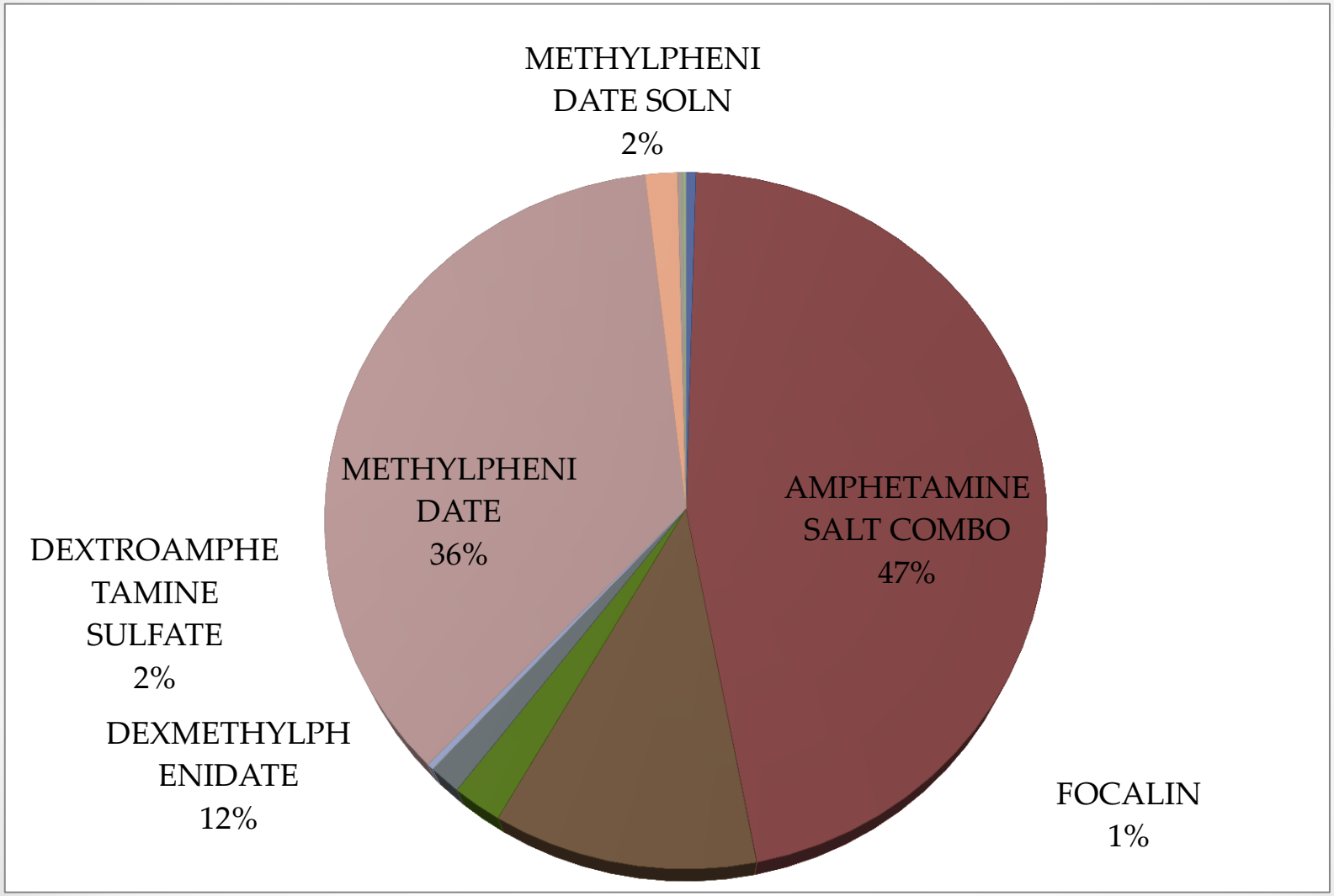
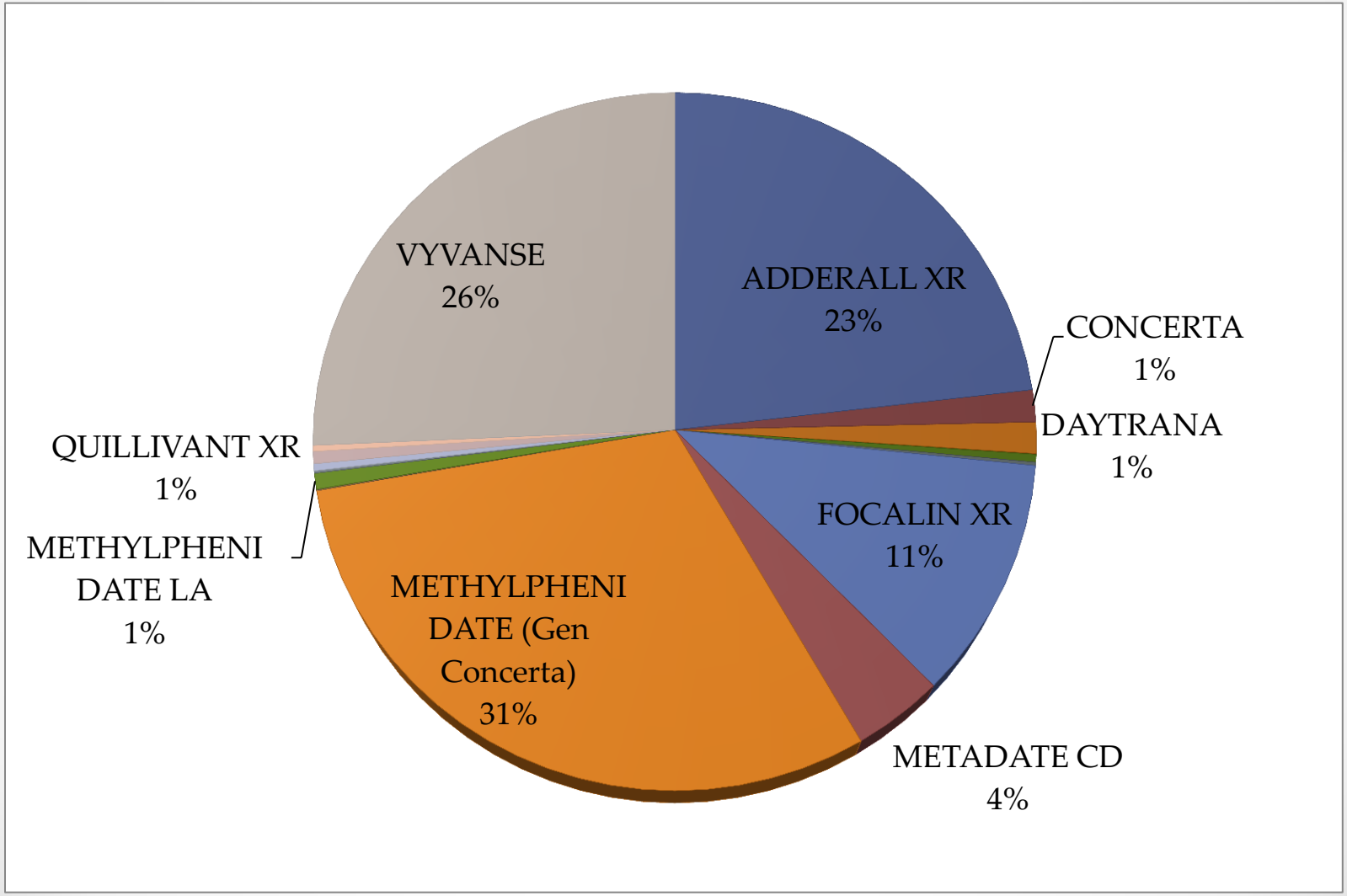
CNS: ADHD Agents (SA) Market Share



CNS: ADHD Agents (LA) Market Share



CNS: ADHD Agents Recommendation(s)

- Add as Non-Preferred:
  - dextroamphetamine solution
  - methylphenidate chewable tablets
  - Evekeo® tablets
- Move to Preferred: Methylin® chewable tablets
- Move to Non-Preferred: methylphenidate solution

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CNS: Medication Assisted Treatment Agents

Clinical Highlights

- Bunavail® (buprenorphine/naloxone):
  - New partial opioid agonist approved for maintenance treatment of opioid dependence
  - Buccal film formulation

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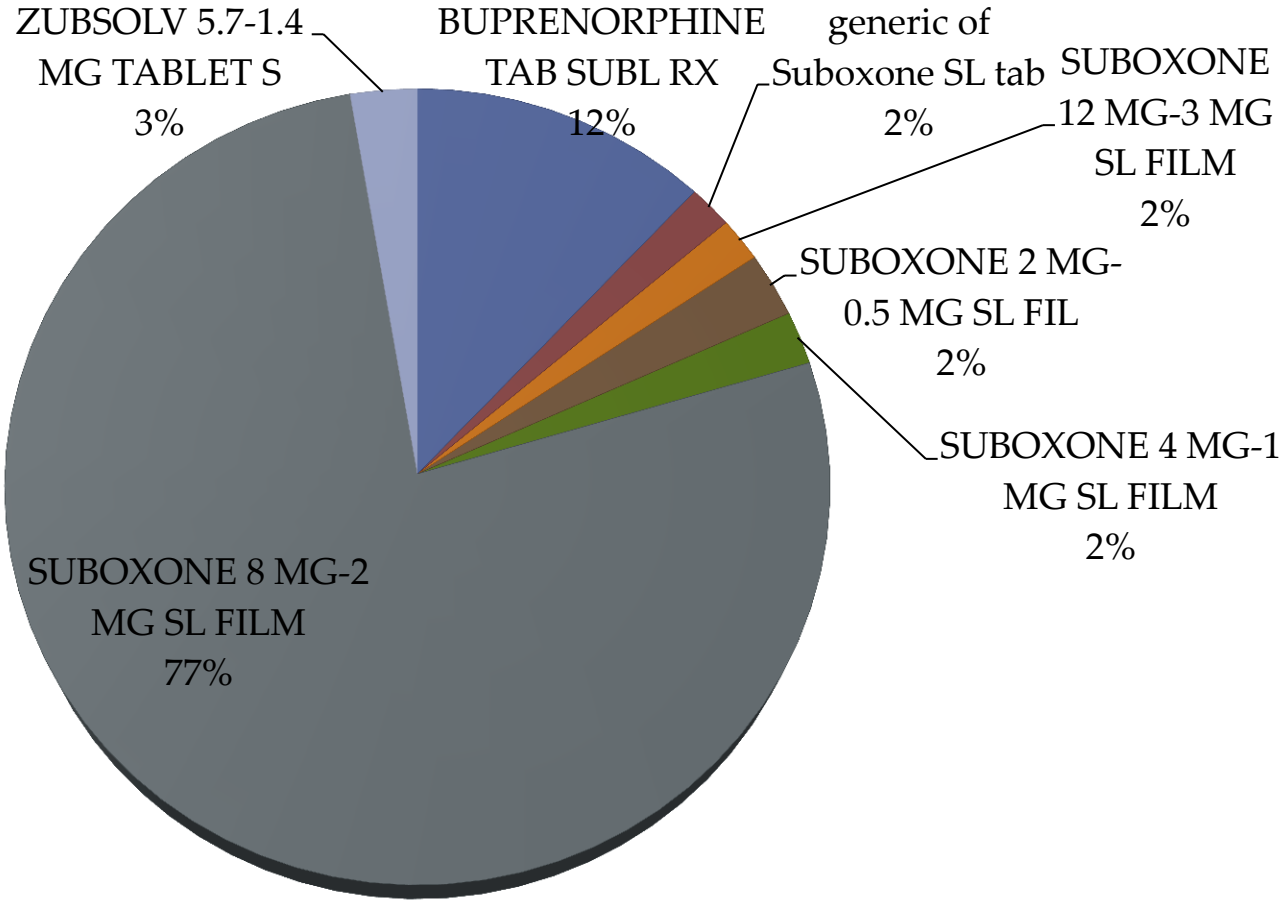
CNS: Medication Assisted Treatment Agents

Market Share



CNS: Medication Assisted Treatment Agents

Clinical Highlights

- Prescribing for buprenorphine products must follow requirements of the Ohio Administrative code rule:
  - Pending discussion among P&T committee

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CNS: Medication Assisted Treatment Agents

Recommendation(s)

- Buprenorphine product quantity limits:
  - Bunavail 2.1-0.3 mg – 4 filmtabs/day
  - Bunavail 4.2-0.7 mg – 2 filmtabs/day
  - Bunavail 6.3-1.0 mg – 1 filmtab/day
  - Suboxone films 2-0.5 mg – 8 filmtabs/day
  - Suboxone films 4-1.0 mg – 4 filmtabs/day
  - Suboxone films 8-2.0 mg – 2 filmtabs/day
  - Suboxone films 12-3.0 mg – 1 filmtab/day

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CNS: Medication Assisted Treatment Agents

Recommendation(s)

- Buprenorphine product quantity limits:
  - Suboxone tabs 2-0.5 mg – 8 tabs/day
  - Suboxone tabs 8-2.0 mg – 2 tabs/day
  - Subutex 2 mg – 8 tabs/day
  - Subutex 8 mg – 2 tabs/day
  - Zubsolv 1.4-0.36 mg – 8 tabs/day
  - Zubsolv 5.7-1.4 mg – 2 tabs/day
  - Zubsolv 8.6-2.1 mg – 1 tab/day

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CNS: Medication Assisted Treatment Agents

Recommendation(s)

- Add as Non-Preferred: Bunavail® buccal films
- Move to Non-Preferred: Zubsolv ® SL tablets

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CNS: Multiple Sclerosis Agents Clinical Highlights

- Tecfidera®:
  - FDA recently issued a warning regarding a patient with MS who, while being treated with Tecfidera®, developed a rare, but serious brain infection called progressive multifocal leukoencephalopathy (PML) and later died. The patient was not taking any other drugs that affect the immune system or any drugs thought to be associated with PML.

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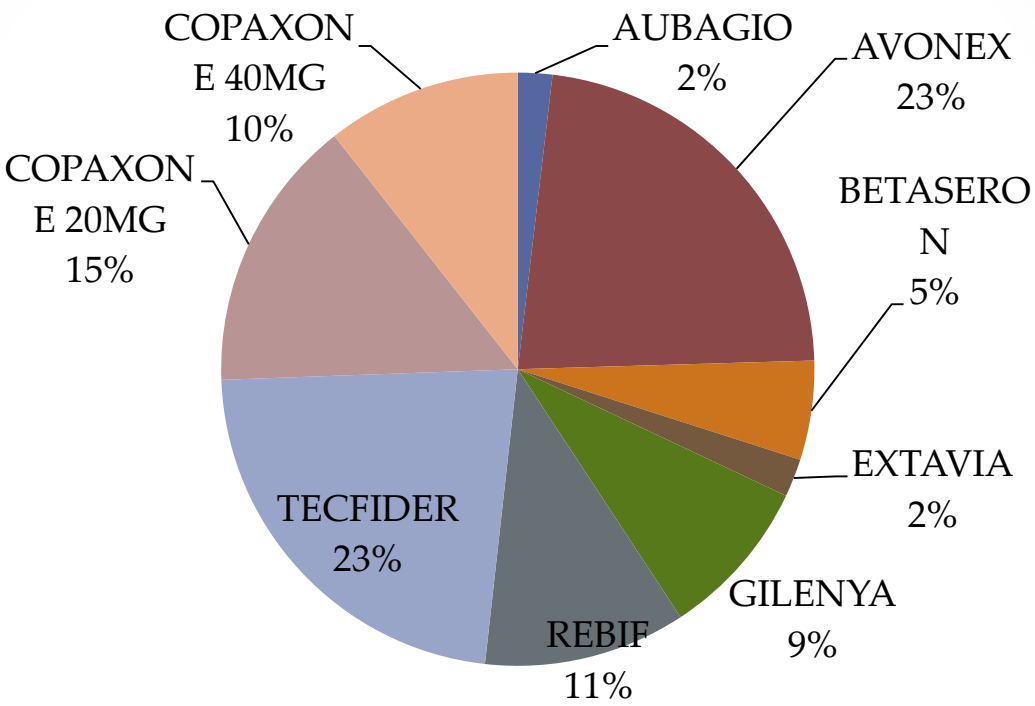
CNS: Multiple Sclerosis Agents Market Share



CNS: Multiple Sclerosis Agents Recommendation(s)

- Move to Non-Preferred:
  - Copaxone® 40 mg/mL syringe
  - Tecfidera®(with grandfathering)

- Maintain Copaxone® 20 mg/mL syringe as Preferred

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CNS: Parkinson's Agents

Clinical Highlights

- Rytary®(carbidopa/levodopa):
  - New extended-release capsules approved for Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism
  - Available strengths: 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, and 61.25 mg/245 mg
  - Dosed three times daily

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CNS: Parkinson's Agents

Clinical Highlights

- New generic: pramipexole ER (Mirapex ER®) 0.375 mg, 0.75 mg, and 1.5 mg tablets

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CNS: Parkinson's Agents Recommendation(s)

- Add Rytary® as Non-Preferred

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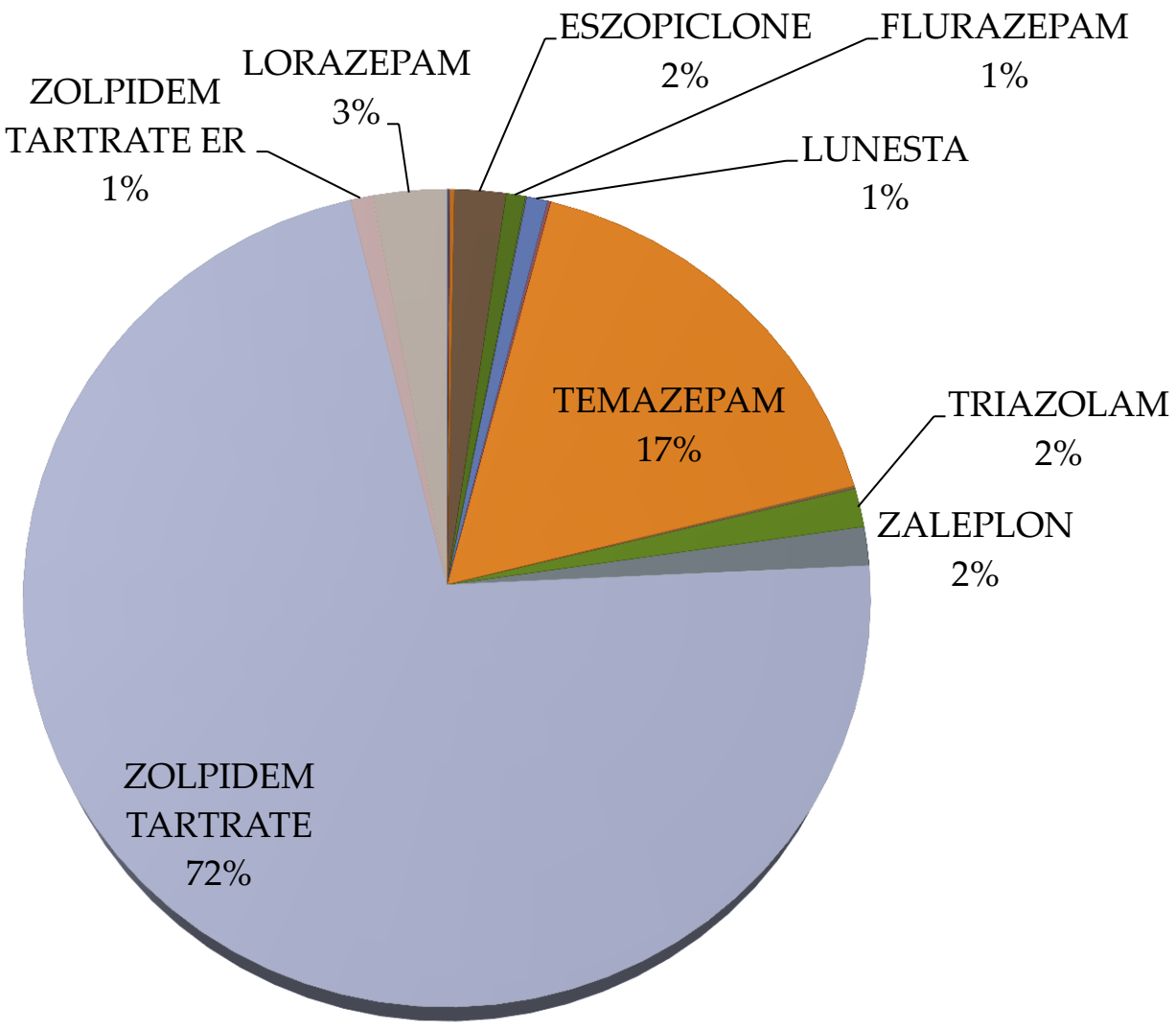
CNS: Sedative Hypnotics Market Share



Other CNS Recommendation(s)

- No changes: Antimigraine, Fibromyalgia Agents, Neuropathic Pain Agents, Restless Legs Syndrome, Skeletal Muscle Relaxants, and Smoking Deterrents

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Endocrine: Diabetes Adjunctive Therapy Recommendation(s)

- Move to Non-Preferred: Victoza®
- Change approval length to 6 months
- Require continued use of oral hypoglycemics and/or insulin for refills

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Endocrine: Diabetes Insulin

Clinical Highlights

- Afrezza® (insulin regular):
  - Rapid-acting inhaled insulin; inhalation powder available as 4 unit and 8 unit single-use cartridges
  - Must be used in combination with a LA insulin in patients with type 1 diabetes
  - Starting dose for insulin naive patients is 4 units at each meal while maintenance doses are individualized

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Endocrine: Diabetes Insulin

Clinical Highlights

- Toujeo® (insulin glargine):
  - New insulin glargine product for glycemic control in adults with diabetes
  - Administered SC once daily at any time of day, at same time every day
  - Available as a SoloStar pen only delivering 80 units per injection
  - Toujeo® concentration 300 units/mL; Lantus® concentration 100 units/mL

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Endocrine: Diabetes Insulin Recommendation(s)

- Add as Non-Preferred:
  - Afrezza®
  - Toujeo®

- Add the following criteria for Afrezza®
  - Type 2 diabetes diagnosis or claim required for LA insulin in the previous 120 days
  - Must not have a diagnosis of asthma or COPD
  - Must not have smoked for at least 6 months
  - Spirometry shows $FEV_1 \geq 70\%$ predicted

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Endocrine: Oral Hypoglycemics

Clinical Highlights

- Recently approved products:
  - Invokamet® (canagliflozin/metformin)
  - Glyxambi® (empagliflozin/linagliptin)
  - Xigduo XR® (dapagliflozin/metformin)
  - Glyxambi® and Xigduo XR® are dosed once daily; Invokamet® is dosed twice daily

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Endocrine: Oral Hypoglycemics Clinical Highlights

- SGLT2 Inhibitors:
  - During May 2015, the FDA sent out an alert warning that SGLT2 inhibitors may lead to ketoacidosis.
  - FDA will continue to investigate this safety issue and determine whether changes are needed in the prescribing of the SGLT2 inhibitors class.

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Endocrine: Oral Hypoglycemics Recommendation(s)

- Add as Non-Preferred
  - Glyxambi®
  - Invokamet®
  - Xigduo XR®

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Endocrine: Estrogenic Agents Clinical Highlights

- New generic:
  - estradiol patch (Vivelle Dot®)

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Endocrine: Estrogenic Agents Recommendation(s)

- Add estradiol patch (generic of Vivelle Dot®) as Preferred

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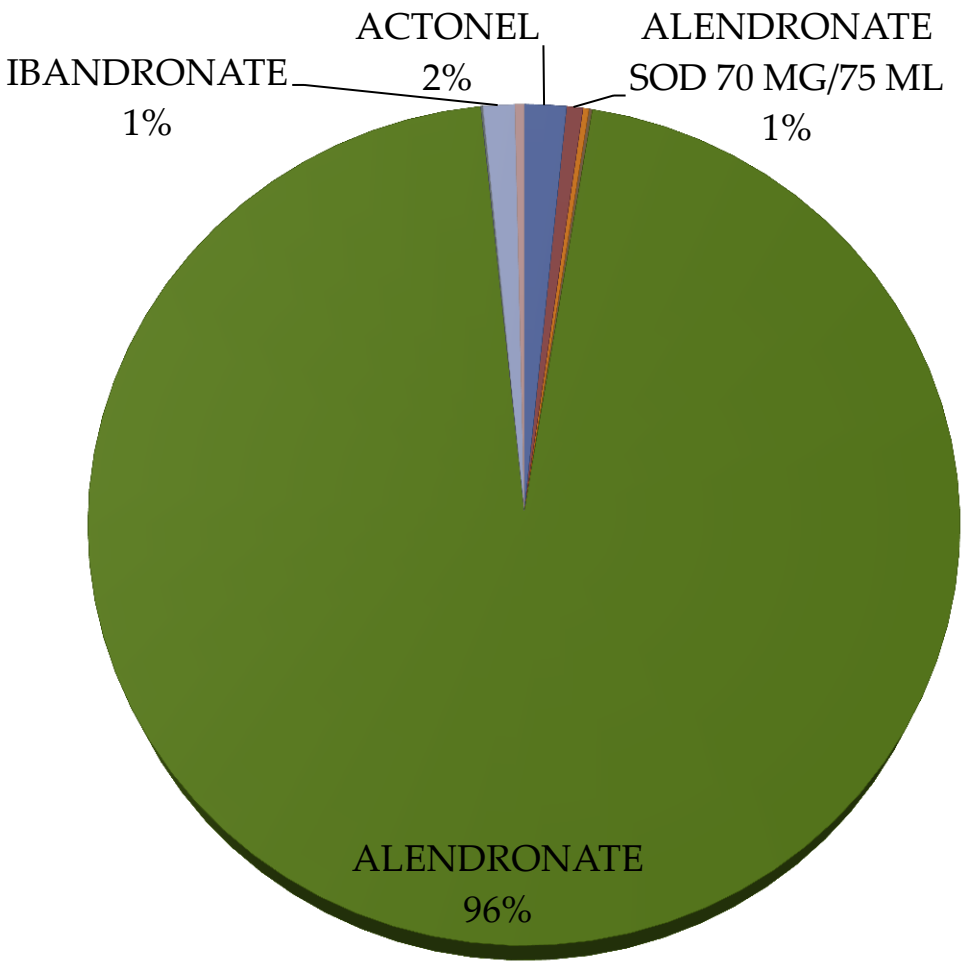
Endocrine: Bone Ossification Enhancers

Market Share



Endocrine: Bone Ossification Enh Clinical Highlights

- New generics: ibandronate 3 mg/3 mL syringes (Boniva®) and risedronate 150 mg tablets (Actonel®)

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GI: IBS/Chronic Constipation

Clinical Highlights

- Movantik® (naloxegol) & Relistor®(methylnaltrexone bromide):
  - Opioid antagonists added to the Chronic Constipation Agents review
  - Both indicated for treatment of opioid-induced constipation (OIC)associated with chronic non-cancer pain
  - Amitiza® also has the OIC indication

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GI: IBS/Chronic Constipation Clinical Highlights

- Relistor® additionally indicated for treatment of OIC in patients with advanced illness who are receiving palliative care

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GI: IBS/Chronic Constipation Recommendation(s)

- Add Movantik® and Relistor® as Non-Preferred
- Include the following OIC criteria for Movantik®, Relistor®, and Amitiza®:
  - Must be 18 years or older
  - Approval for OIC agents requires history of chronic pain requiring continuous opioid therapy for ≥12 weeks
  - Electronic PA will approve with history of 90 days of opioid therapy in the previous 90 days, in addition to trials of preferred products

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GI: PPI

Clinical Highlights

- OTC Nexium® 24hour is available
- New generic: esomeprazole magnesium DR 20 mg and 40 mg capsules (Nexium® Rx)

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GI: PPI

Recommendation(s)

- Add as Preferred: OTC Nexium®
- Add as Non-Preferred: esomeprazole magnesium capsules

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GI: Ulcerative Colitis
Clinical Highlights

- Uceris® (budesonide):
  - Rectal foam approved for induction of remission in patients with active mild to moderate distal ulcerative colitis

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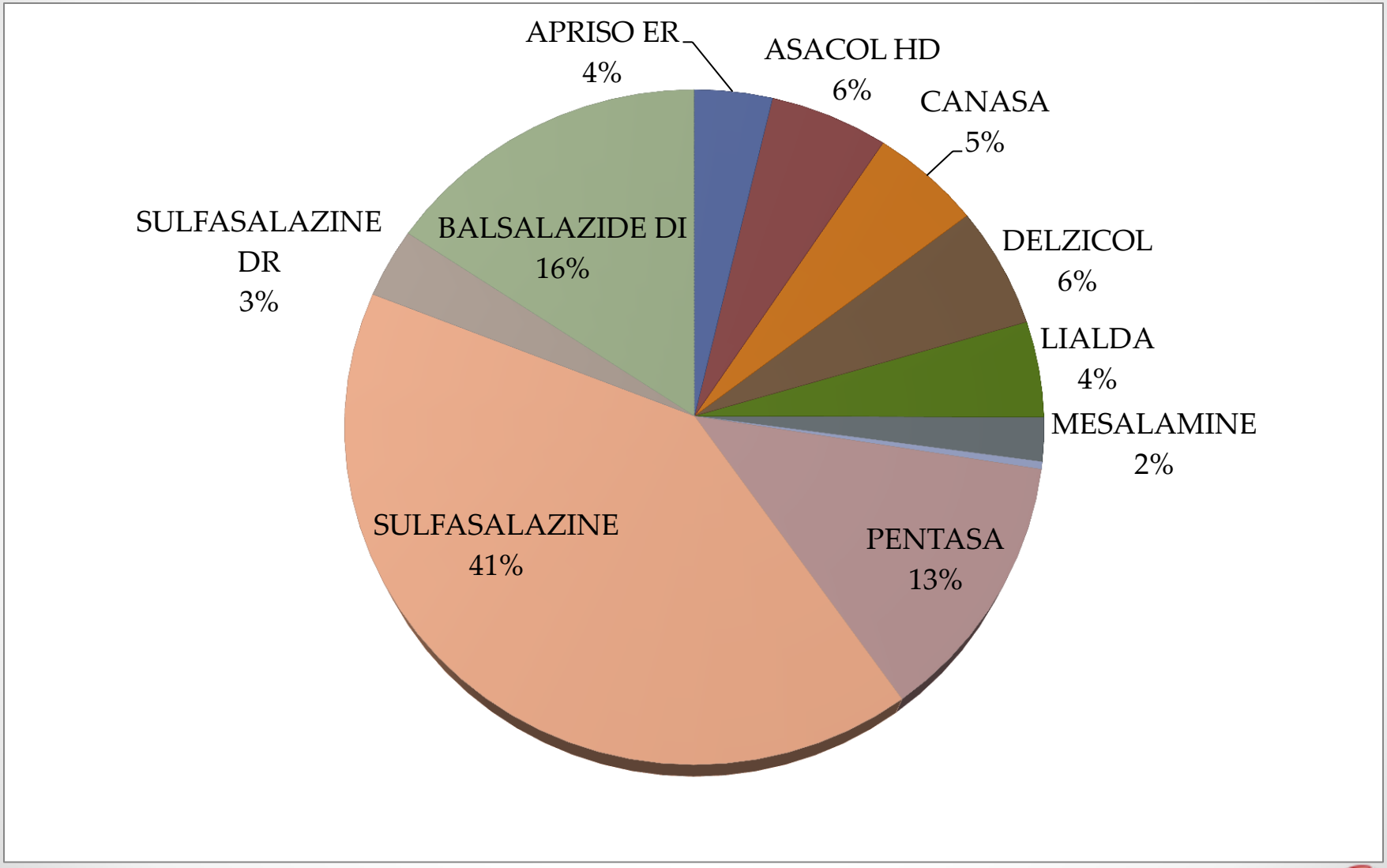
GI: Ulcerative Colitis Agents Market Share



GI: Ulcerative Colitis Recommendation(s)

- Move to Preferred:
  - Apriso®
  - Delzicol®
  - Pentasa®
- Move to Non-Preferred:
  - balsalazide
  - Lialda®
- Add as Non-Preferred: Uceris® rectal foam

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Other GI Recommendation(s)

- No changes: Pancreatic Enzymes

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Other GU Recommendation(s)

- No changes: Electrolyte Depleters, Benign Prostatic Hyperplasia & Urinary Tract Antispasmodics

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Immunomodulator Agents for Systemic Inflammatory Disease

- Cosentyx®:
  - Approved for moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
  - Dosed SC every 4 weeks

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Immunomodulator Agents for Systemic Inflammatory Disease

- Recommendations:
  - Add Cosentyx® as Non-Preferred
  - Move Cimzia® to Non-Preferred

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Inf Disease: Inhaled Antibiotics Clinical Highlights

- New class:
  - Aztreonam (Cayston®) and tobramycin formulations (Bethkis®, Kitabis Pak®, Tobi Solution®, & Tobi Podhaler®) reviewed
  - All drugs approved to treat cystic fibrosis caused by *Pseudomonas aeriginosa*
  - Aztreonam dosed three times daily & tobramycin twice daily
  - All drugs administered 28 days on, followed by 28 days off

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Inf Disease: Inhaled Antibiotics Recommendation(s)

- Add as Preferred:
  - Bethkis®
  - Kitabis Pak®
- Add as Non-Preferred:
  - Cayston®
  - Tobi Podhaler®
  - tobramycin solution
- 28-day trial of at least one Preferred medication required

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Inf Disease: Inhaled Antibiotics Recommendation(s)

- Criteria:
  - Diagnosis of cystic fibrosis with *pseudomonas*-related infection required
  - Age limit of 6 and older for tobramycin products & 7 and older for aztreonam
  - "Pulse" dosing cycles of 28 days on drug followed by 28 days off drug approved
  - 28 days reauthorized through electronic PA if history of product in past 120 days

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Infectious Disease: Hepatitis C Clinical Highlights

- HIV/Hepatitis C Outbreak:
  - The CDC recently issued an advisory regarding a large outbreak of HIV infections in Indiana among people who inject drugs.
  - Many were co-infected with HIV/Hep C
  - Many cases involved people dissolving and injecting Opana ER®

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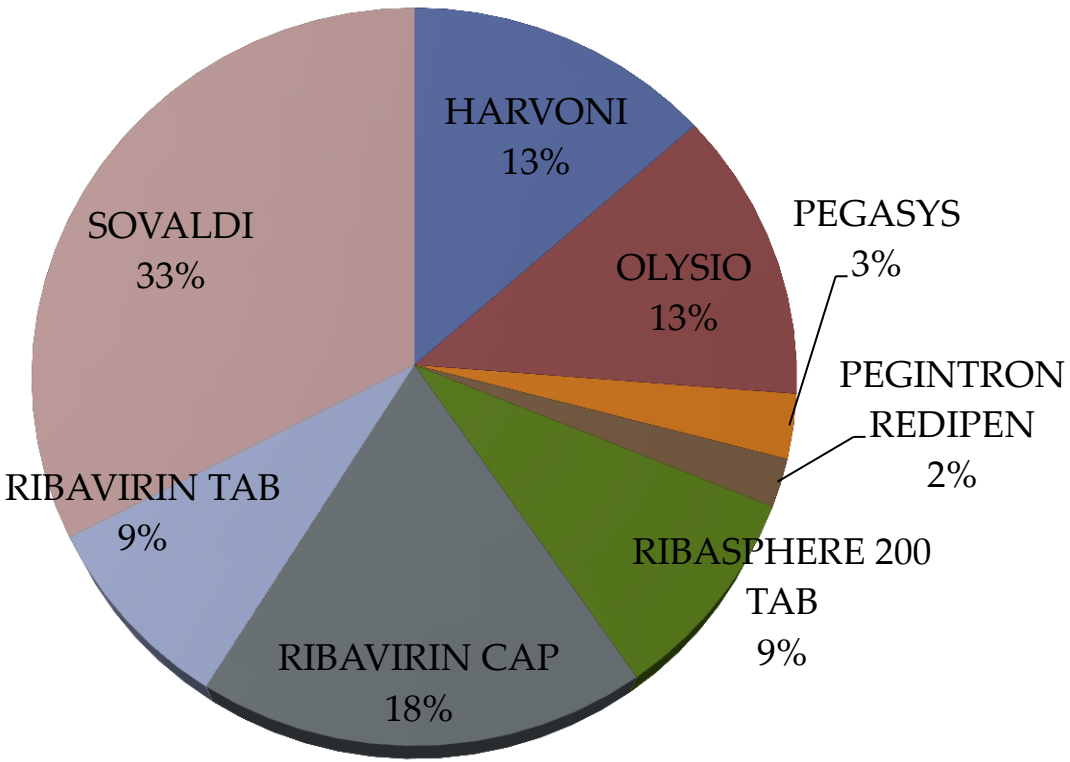
Infectious Disease: Hepatitis C Market Share



Infectious Disease: Hepatitis C Recommendation(s)

- Add as Preferred:
  - Harvoni®
  - Viekira Pak™
- Move to Non-Preferred: Olysio®
- Current criteria apply with the additional requirement that patients who have not be screened for HIV be tested and treated appropriately if positive

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Infectious Disease: HIV Clinical Highlights

- Vitekta® (elvitegravir):
  - New integrase strand transfer inhibitor
  - Approved for use in combination with an HIV PI co-administered with ritonavir and another antiretroviral drug.
  - Vitekta coadministered with PIs and cobicistat is not recommended.

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Infectious Disease: HIV

Clinical Highlights

- Tybost® (cobicistat):
  - New boosting agent approved
  - CYP3A inhibitor indicated to increase systemic exposure of atazanavir or darunavir in combination with other antiretroviral agents in the treatment of HIV-1 infection.
  - Dosed once daily and only used with once daily atazanavir and darunavir dosing regimens.

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Infectious Disease: HIV Recommendation(s)

- Add as Non-Preferred:
  - Vitekta®
  - Tybost®

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Other Infectious Disease Recommendation(s)

- Antiherpetics: add Sitavig® buccal tablets as Non-Preferred
- Macrolides: move erythromycin formulations to Non-Preferred
- No changes: Cephalosporins, Quinolones and Antifungals for Onychomycosis & Systemic Infections

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Ophthalmic: Antihistamine/MCS Clinical Highlights

- Pazeo® (olopatadine):
  - Approved for treatment of ocular itching associated with allergic conjunctivitis
  - Pazeo (0.7%) solution dosed once daily; Pataday (0.2%) solution dosed once daily; Patanol (0.1%) solution dosed twice daily

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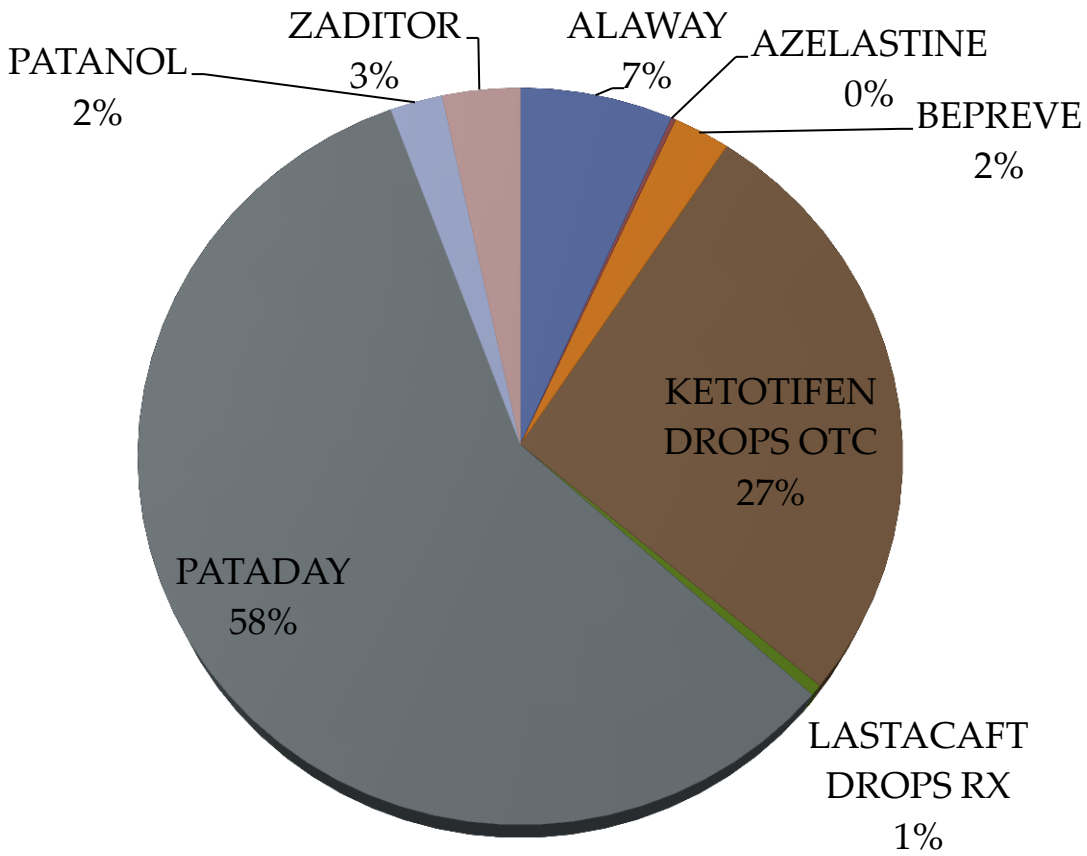
Ophthalmic: Antihistamine/MCS

Market Share



Ophthalmic: Antihistamine/MCS Recommendation(s)

- Add Pazeo® as Non-Preferred

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Other Ophthalmic Recommendations

- No changes: Antibiotics & combinations, Miotics and NSAIDs
- Also no changes for Otic Agents

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Respiratory: Inhaled Beta Adrenergic Agonists, Clinical Highlights

- Proair Respiclick® (albuterol sulfate):
  - Approved for treatment or prevention of bronchospasm in patients ≥ 12 years of age with reversible obstructive airway disease
  - Also approved for prevention of exercise-induced bronchospasm in patients ≥12 years of age

Respiratory: Inhaled Beta Adrenergic Agonists, Recommendation(s)

- Add as Non-Preferred: Proair Respiclick®
- Move to Non-Preferred: Ventolin HFA®

Respiratory: COPD

Clinical Highlights

- Incruse Ellipta® (umeclidinium):
  - New anticholinergic indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD
  - Available as an inhalation powder
  - Recommended dosage is one inhalation once daily

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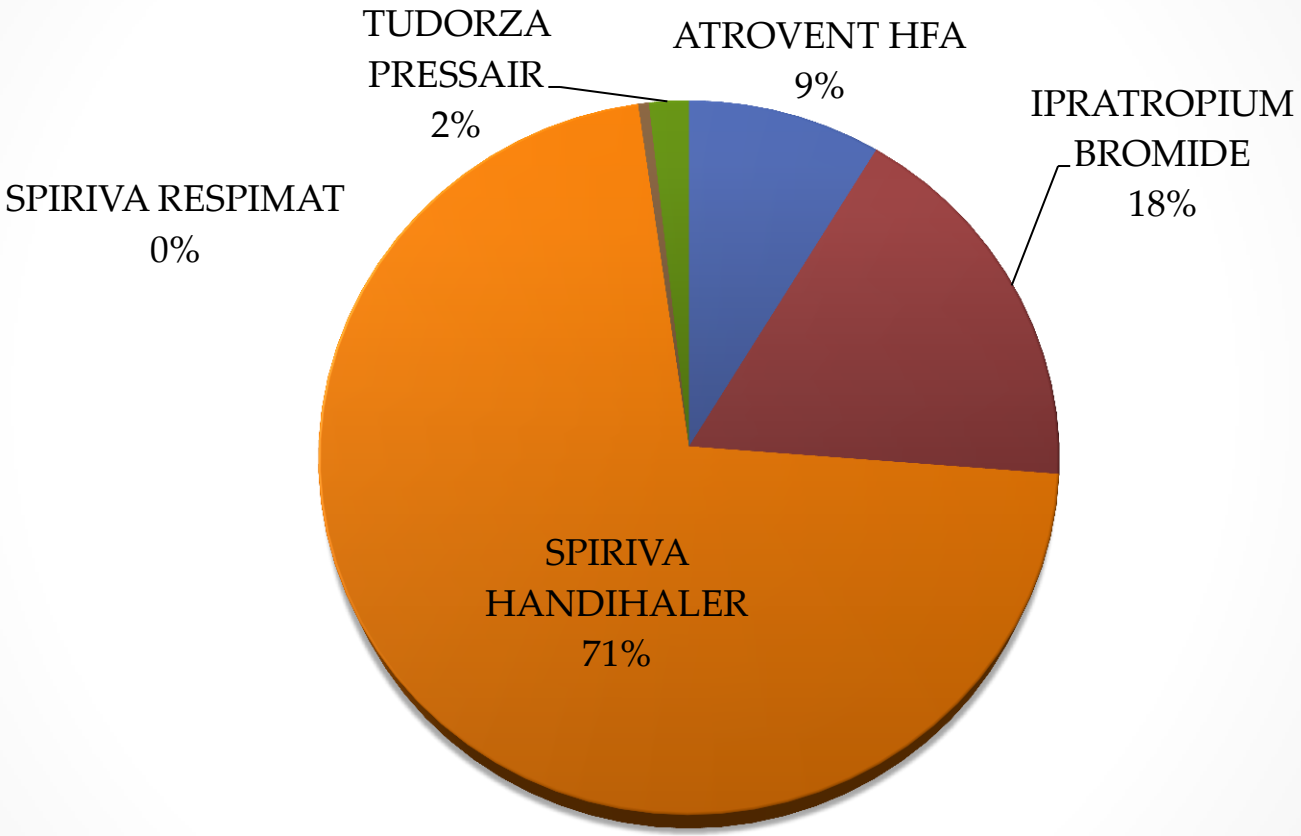
Respiratory: COPD

Market Share



Respiratory: COPD

Recommendation(s)

- Add Incruse Ellipta® as Non-Preferred

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Respiratory: Inhaled Glucocorticoids

Clinical Highlights

- Arnuity Ellipta® (fluticasone furoate):
  - New corticosteroid indicated for once-daily maintenance treatment of asthma as prophylactic therapy in patients ≥12 years of age
  - Available as an inhalation powder; recommended dosage is one 100 mcg or 200 mcg inhalation once daily

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Respiratory: Inhaled Glucocorticoids

Recommendation(s)

- Add Arnuity Ellipta® as Non-Preferred

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Respiratory: Hereditary Angioedema Agents

Clinical Highlights

- New Class:
  - Agents reviewed are C1 Esterase Inhibitor (Berinert®, Cinryze®), C1 Esterase Inhibitor, Recombinant (Ruconest®), Ecallantide (Kalbitor®), and Icatibant Acetate (Firazyr®)
  - HAE causes periodic attacks of non-pruritic, non-pitting edema and swelling
  - Cinryze® is indicated for routine prophylaxis only; all others are indicated to treat acute attacks of HAE in adults, and Kalbitor® is the only agent that cannot be self-administered

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Respiratory: Hereditary Angioedema Agents

Clinical Highlights

- Frequency of HAE attacks is highly variable, ranging from one or fewer per year to one or more per week
- All medications are administered via IV infusion or SC injection

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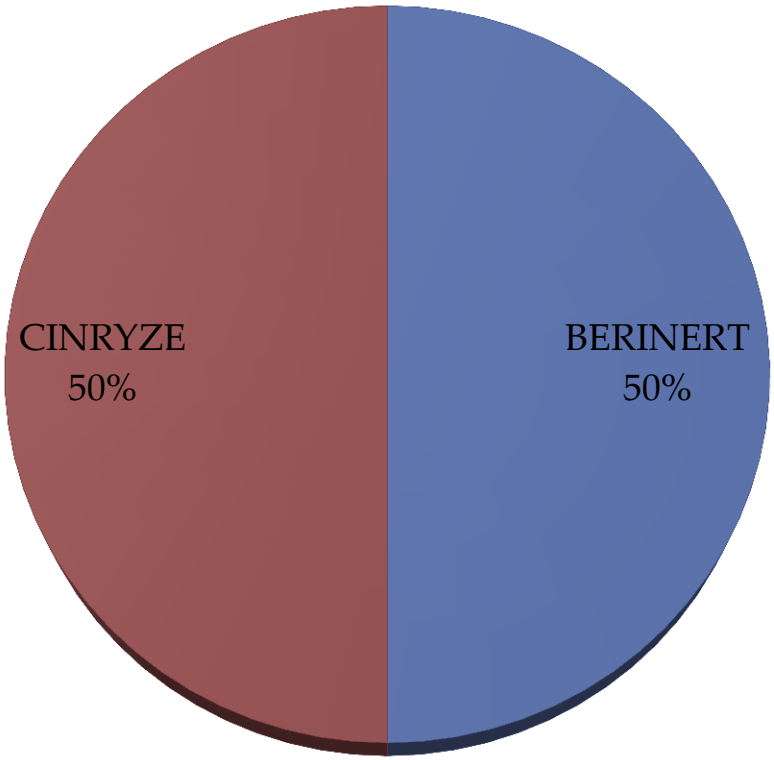
Respiratory: HAE

Market Share



Respiratory: Hereditary Angioedema Agents

Recommendation(s)

- Add as Preferred:
  - Cinryze®
  - Ruconest®
- Add as Non-Preferred:
  - Berinert®
  - Firazyr ®
  - Kalbitor®

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Respiratory: Nasal Preparations

Clinical Highlights

- OTC Flonase® is available
- New generic: olopatadine (Patanase®)

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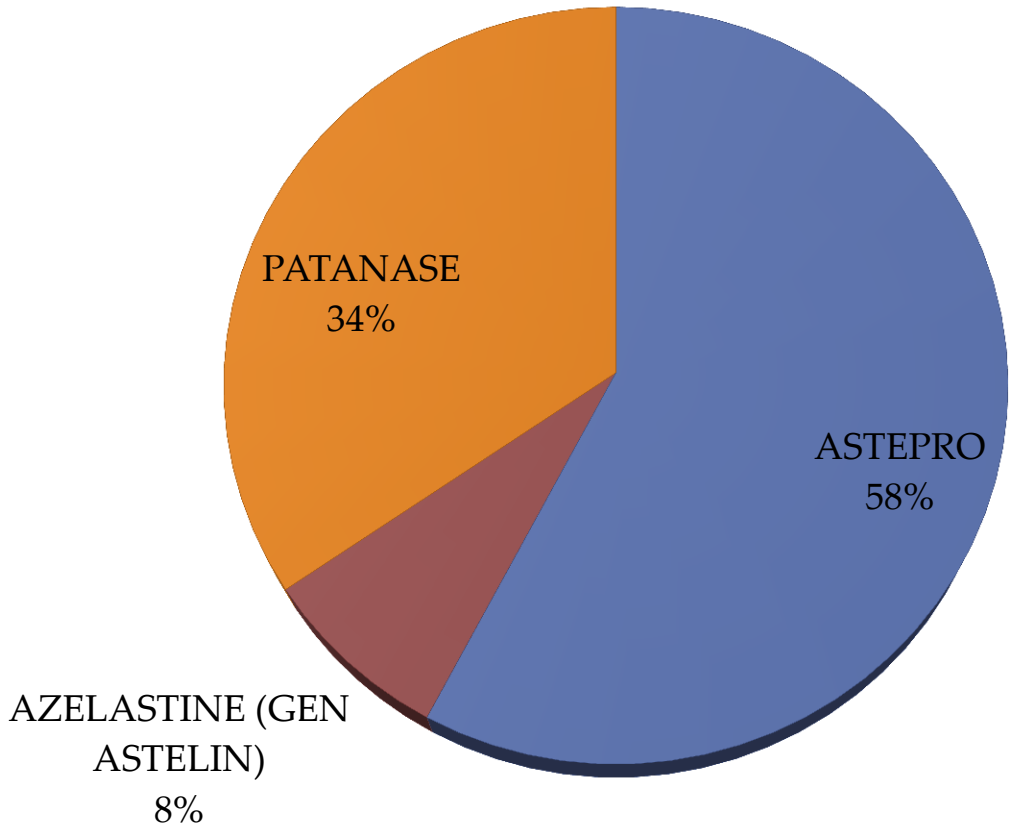
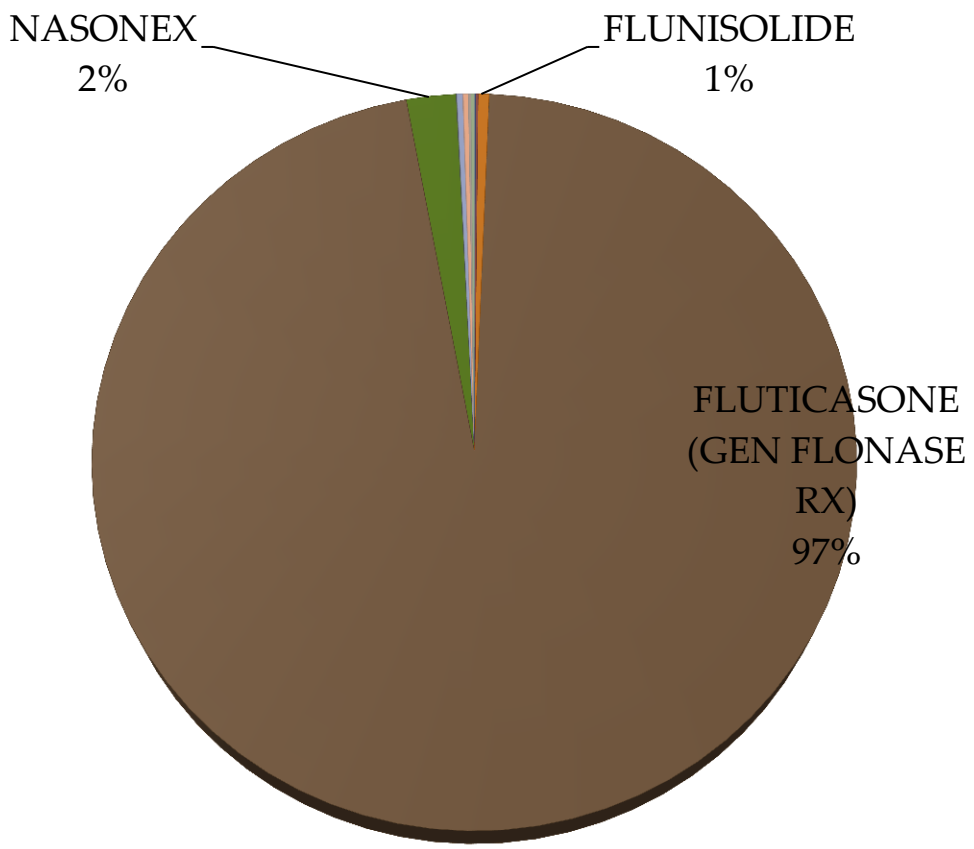
Respiratory: Nasal Antihistamines

Market Share



Respiratory: Nasal Steroids

Market Share



Respiratory: Nasal Preparations

Recommendation(s)

- Add OTC Flonase® as Preferred
- Add olopatadine as Non-Preferred

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Other Respiratory Recommendation(s)

- Epinephrine Auto-Injectors: move Auvi-Q® and epinephrine to Preferred
- 2nd Generation Antihistamines: add fexofenadine suspension (Allegra®) as Non-Preferred
- Beta Adrenergic Combos: Move Advair HFA® and Advair Diskus® to Non-Preferred
- No changes: Leukotriene Receptor Modifiers and Inhibitors

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Topical: Acne Preparations

Clinical Highlights

- Neuac® (clindamycin 1.2%-BPO 5%) and Onexton™ (clindamycin 1.2%-BPO 3.75%) gels are available
- Ovace Plus® (sulfacetamide sodium) 9.8% lotion and Rosula® (sulfacetamide sodium/sulfur) 10%-4.5% wash are available
- Retin-A Micro® Gel is available in a new 0.08% strength

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Topical: Acne Preparations

Recommendation(s)

- Add as Non-Preferred: Neuac® gel, Onexton™ gel, Ovace Plus® lotion, and Rosula® wash
- Move to Non-Preferred: Clindagel®

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Topical: Androgens

Clinical Highlights

- Natesto® (testosterone) gel was recently approved for testosterone deficiency. The new product is applied intranasally three times daily.
- Vogelxo® (testosterone) gel as well as new generics for testosterone (Androgel®, Fortesta®, Testim®) are available.

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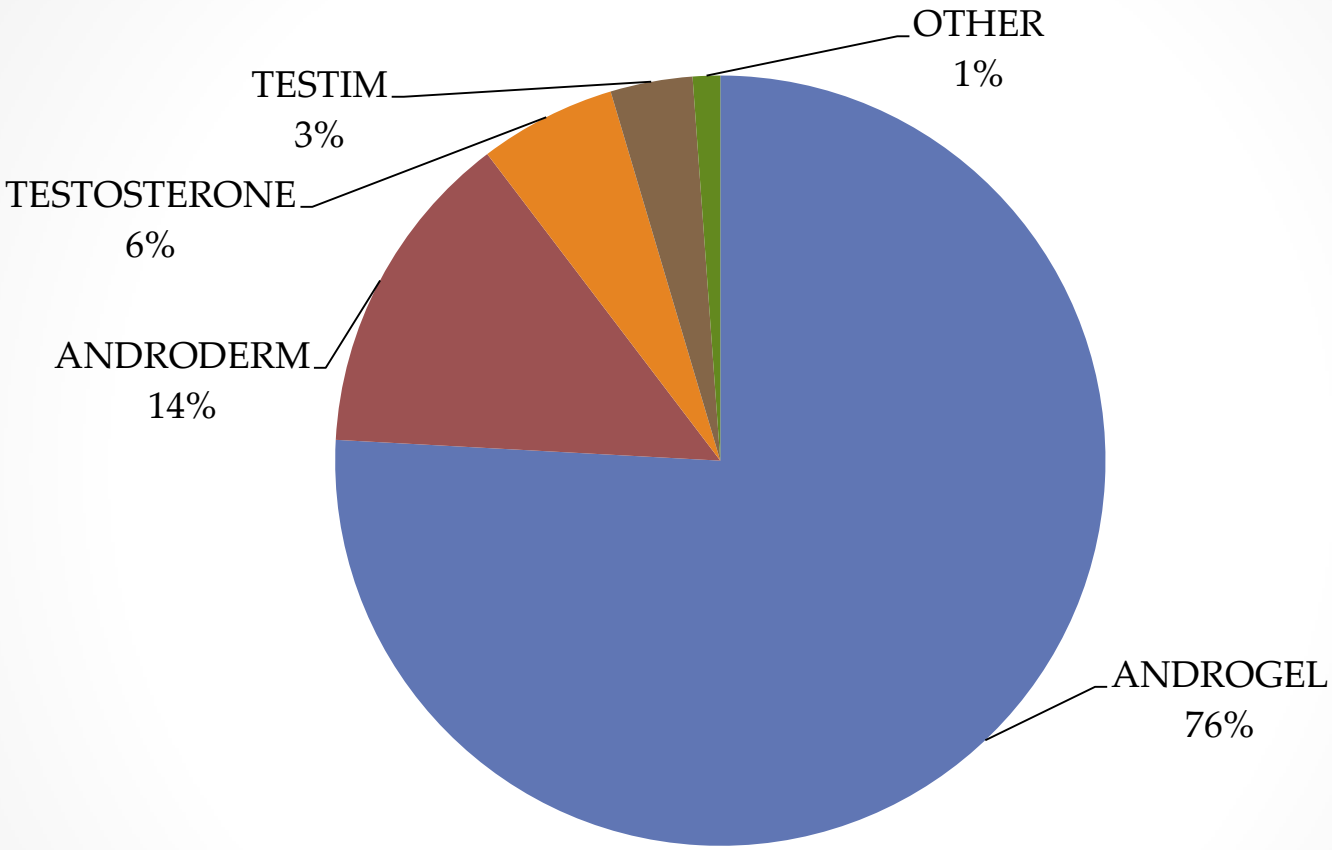
Topical: Androgens

Market Share



Topical: Androgens

Recommendation(s)

- Add Natesto®, testosterone, and Vogelxo® gels as Non-Preferred

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Topical: Antifungals

Clinical Highlights

- Jublia® (efinaconazole) and Kerydin® (tavaborole) were both recently approved for the treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.
- Both are solutions applied to affected toenails once daily for 48 weeks.

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Topical: Antifungals

Recommendations

- Add Jublia® and Kerydin® as Non-Preferred

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Topical: Corticosteroids

Clinical Highlights

- Clodan®, a new clobetasol propionate shampoo and kit, is available.
- Generic clobetasol propionate 0.05% spray (Clobex®) is also available.

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Topical: Corticosteroids

Recommendation(s)

- Add as Non-Preferred: Clodan® shampoo & kit and clobetasol propionate spray

xerox

Topical: Parasitics

Clinical Highlights

- Natroba® (spinosad):
  - Indication recently expanded to acknowledge Natroba® is approved for use in children 6 months of age and older for head lice. Natroba® was previously approved for this indication in children 4 years of age and older.

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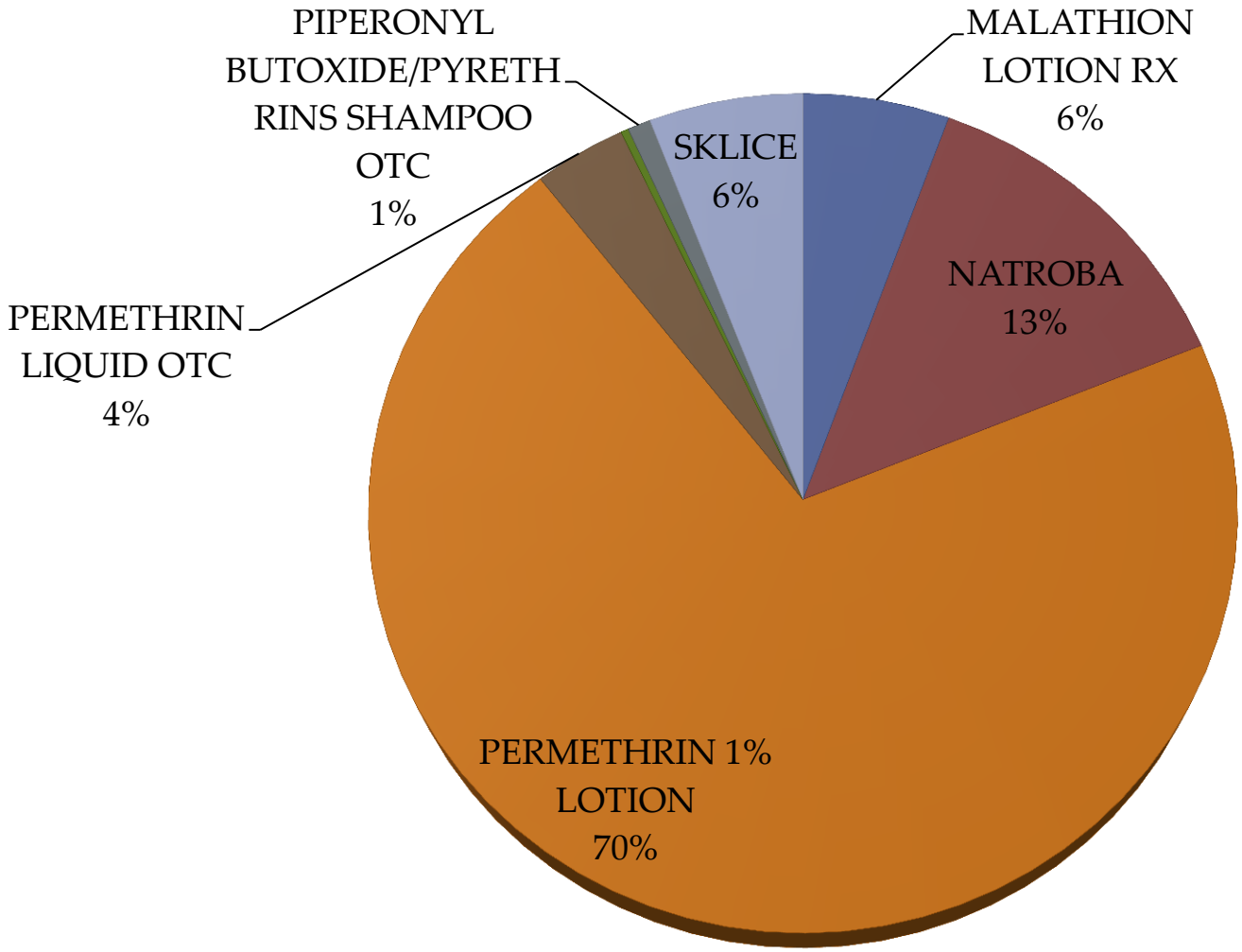
Topical: Parasitics

Market Share



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