

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

June 11, 2014

77 S. High St, 31st Floor, Columbus, OH

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

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

ODM staff present: Patricia Nussle, RPh; Jill Griffith, PharmD; Anam Khan

Approximately 70 stakeholders were present, most representing pharmaceutical manufacturers and advocacy associations.

Beginning at 9:30 AM, pharmaceutical manufacturers were given the opportunity to present clinical information on their products and respond to questions from the committee members. Jennifer Hanrahan, DO, was not able to attend the afternoon interested party session so presented remarks to the committee at 9:30 AM.

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

1. Interested party presentations

- a. Jeanette Moleski, DO
- b. Matt Wovrosh, Ohio AIDS Coalition
- c. Kathy Schrag, Epilepsy Foundation of Greater Cincinnati and Columbus
- d. Emily Klatter, MD, Epilepsy Foundation of Greater Cincinnati and Columbus
- e. Amy Detrick, CPhT, Epilepsy Foundation of Greater Cincinnati and Columbus

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 Xerox showing clinical changes in each drug class, market share, and recommendations, is attached to this document. The minutes reflect only those drug classes that produced discussion. The recommendations presented for all other drug classes were approved by the committee unanimously.

Analgesics: Long-Acting Opiates

Mr. Wascovich asked if patients taking Kadian would be grandfathered or notified of the change. Dr. Hunton pointed out that less than 1% of the market share is Kadian. The committee voted unanimously to accept the recommendations.

Blood Agents: Oral Antiplatelets

Ms. Baker noted that most prescriptions for Effient are started by an interventional cardiologist and suggested allowing specialists to prescribe. Dr. Jacobs noted that Effient had been in

preferred status for the previous year. Dr. Hunter said that his hospital uses Effient, while Mr. Wascovich said that his hospital uses more Brilinta. Dr. Hauler said the cardiologist should make the choice. Dr. Jacobs suggested retaining Effient preferred and watching utilization. Ms. Baker suggested limiting to cardiologists.

Dr. Hunter asked for a vote on retaining Effient in preferred status and asking the retrospective drug utilization review (DUR) program to watch utilization. The vote was 7 to 1, with Ms. Scott dissenting.

Blood Agents: Oral Anticoagulants

Mr. Wascovich suggested adding Eliquis to preferred status based on the comments of the cardiologist speaker in the morning session.

Dr. Hunter asked for a vote on adding Eliquis to preferred status. The vote was 4 in favor, 1 opposed (Scott), and 3 abstaining (Baker, Jacobs, Jefferis).

Cardiovascular Agents: Chronic Stable Angina

Mr. Wascovich noted that the speaker for Ranexa in the morning suggesting changing the criteria for Ranexa to be a trial of one beta blocker or calcium channel blocker, rather than two.

Dr. Hunter asked for a vote on changing the approval criteria for Ranexa to a trial on one agent. The vote was 7 to 0, with Ms. Scott abstaining.

Central Nervous System Agents: Alzheimer's Agents

Dr. Hunter noted that immediate-release Namenda would be discontinued in August 2014 so recommended moving Namenda XR to Preferred Brand status. Ms. Scott noted that generic Namenda is expected to be available in early 2015.

Dr. Hunter asked for a vote on moving Namenda XR to Preferred Brand status. The vote was 6-1, with Ms. Scott dissenting. Mr. Wascovich had stepped out of the room.

Central Nervous System Agents: Anticonvulsants

Dr. Jacobs brought up the recommendation from the epilepsy community speakers requesting a change in criteria to a trial of only one preferred product. Ms. Scott said that most patients have already tried two generic products before a third, non-preferred product is added, and that it is difficult to tell whether the drugs are being used for seizures or other disorders. Dr. Jacobs said that her colleagues have noted difficulties in receiving authorization for their patients whose therapy was started in the hospital.

Dr. Hunter called for a vote on a trial of one preferred product before a non-preferred product is approved. The vote was 7 to 1, with Ms. Scott dissenting.

Ms. Baker suggested an expedited approval for neurologists. Mr. Wascovich suggested a trial on one preferred product for all prescribers except neurologists. Ms. Scott said that the data would be reviewed and ODM will work with Xerox to determine how to expedite approval for patients with seizures.

Central Nervous System Agents: Antidepressants

Dr. Jacobs suggested that the system use a longer lookback period or find another way to account for trials of preferred products that had occurred more than 120 days prior. She asked how difficult the prior authorization process is for primary care providers. Dr. Jefferis said that it was not different than other insurance plans. Mr. Wascovich asked Dr. Jacobs about the newest

product, Brintellix. Dr. Jacobs responded that she does not yet consider it to be a first-line drug, but it is nice to have a drug with unique mechanism of action. She noted that she has a conflict of interest because she has done speaking engagements for the manufacturer. She also noted that the speaker in the morning session had mis-stated the lack of withdrawal from Brintellix, as this has been seen with the 20mg dose. Mr. Wascovich asked if it is adequate for primary care providers to use two preferred drugs first, or go to Brintellix as second line. Dr. Jacobs said that both Brintellix and Pristiq are good drugs to use second line, and asked for a change to one, one-month trial of a preferred drug, noting a concern for patients who are discharged from the hospital and suicidal patients.

Dr. Hunter asked for a vote on changing the criteria to one trial of a preferred drug. The vote was 7 to 1, with Ms. Scott dissenting.

Central Nervous System Agents: Antipsychotics, Second Generation

Dr. Jacobs suggesting moving Latuda to Preferred Brand status because it has a new indication for bipolar disorder and she has not seen the same amount of weight gain as with other drugs.

Dr. Hunter asked for a vote to move Latuda to Preferred Brand status. The vote was 7 to 1, with Ms. Scott dissenting.

Central Nervous System Agents: Attention Deficit Hyperactivity Disorder Agents

Dr. Jacobs noted that the speaker for Quillivant XR had recommended allowing it to be prescribed first-line to children under age 12, since it is a liquid. Ms. Scott said ODM and Xerox have discussed this with the manufacturer, but found that many children required larger doses that resulted in the need for two bottles per month, greatly increasing the cost. In addition, Ms. Scott has found in her practice most children with ADHD are able to swallow pills.

Central Nervous System Agents: Medication Assisted Treatment of Opioid Addiction

Dr. Jacobs said that she has spoken with addiction psychiatrists who are working with Representatives Smith and Sprague on the opiate problem in Ohio. Her colleagues have said that there are not enough addiction psychiatrists or addictionologists to refer patients to if they need greater than 16mg buprenorphine daily. This is especially a problem for re-authorizations, since some people will need a lifetime of therapy. She also recommended that Zubsolv be moved to Preferred status. Dr. Hunter said a maximum dose of 16mg is appropriate, because a dose above 16mg is probably a signal of diversion. Mr. Wascovich noted that the compromise is to require a specialist consultation. Members of the committee were not aware whether there is a definition of addictionologist, and recommended further discussion of the dose reduction at the next meeting.

Dr. Hunter asked for a vote on moving Zubsolv to Preferred status. The vote was 7 to 1, with Ms. Scott dissenting.

Endocrine Agents: Oral Hypoglycemics

Mr. Wascovich asked if the change in status of Janumet XR should be communicated to patients and prescribers. Dr. Levine said that there were 26 patients who used Janumet XR.

Infectious Disease Agents: Antivirals – HIV

Mr. Wascovich said that the data for Stribild are compelling. The infectious disease pharmacists at his institution are starting patients on Stribild.

Dr. Hunter asked for a vote on retaining Stribild in Preferred status. The vote was 7 to 1, with Ms. Scott dissenting.

The meeting was adjourned with a reminder that the next meeting is scheduled for Wednesday, October 8.

Notes from ODM after the meeting:

6/18/14

ODM is reviewing the recommendations of the P&T Committee:

- Retain Effient in preferred status
- Add Eliquis to preferred status
- Changing the approval criteria for Ranexa to a trial on one agent
- Move Namenda XR to Preferred Brand status
- In the anticonvulsant class, ensure expedited approval of prescriptions from neurologists for seizures
- Changing the criteria for Non-Preferred Antidepressants to one trial of one preferred antidepressant
- Move Latuda to Preferred Brand status
- Move Zubsolv to Preferred status
- Retain Stribild in Preferred status

7/18/14:

The following decisions were made in response to the P&T Committee's recommendations:

- Retain Effient in preferred status – ODM agrees, will remain preferred.
- Add Eliquis to preferred status – ODM disagrees, will remain non-preferred.
- Changing the approval criteria for Ranexa to a trial on one agent – ODM agrees, criteria changed as follows:
 - 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).
- Move Namenda XR to Preferred Brand status – ODM disagrees, Namenda XR will remain non-preferred. However, once Namenda IR is no longer available, patients taking Namenda IR will be able to receive Namenda XR through the automated PA process (no prescriber request necessary).
- In the anticonvulsant class, ensure expedited approval of prescriptions from neurologists for seizures. ODM agrees, criteria changed as follows:
 - 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.

- Changing the criteria for Non-Preferred Antidepressants to one trial of one preferred antidepressant – ODM disagrees, will retain a requirement for trials of two preferred products.
- Move Latuda to Preferred Brand status – ODM agrees.
- Move Zubsolv to Preferred status – ODM agrees.
- Retain Stribild in Preferred status – ODM disagrees, Stribild will move to non-preferred status with the existing grandfathering provision.

DRAFT

Ohio Medicaid Fee-For-Service
Pharmacy Benefit Management Program



Preferred Drug List

Effective October 1, 2014

Revised June 4, 2014

DRAFT for P&T Committee Discussion Only

DRAFT
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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.

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ANALGESIC AGENTS: GASTROPROTECTIVE NSAIDS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CELEBREX [®] (celecoxib) (no PA required for age 60 or older)	CELEBREX [®] (celecoxib) (PA required for under age 60) DICLOFENAC/MISOPROSTOL (generic of Arthrotec [®]) DUEXIS [®] (ibuprofen/famotidine) VIMOVO [®] (naproxen/esomeprazole)

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
	COLCRYS® * (colchicine)

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

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®)		KADIAN® (morphine) MORPHINE SULFATE ER capsule (generic of Avinza®, Kadian®)
Extended Release Oxycodone Products		
		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		
		EXALGO® ER (hydromorphone)
Extended Release Tapentadol Products		
	NUCYNTA ER®	

ANALGESIC AGENTS: OPIOIDS – Long-Acting Transdermal

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

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

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

STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED
Codeine Products	
CODEINE SULFATE TABLETS	
Hydromorphone Products	
HYDROMORPHONE HCL TABLETS (generic of Dilaudid®)	
Levorphanol Products	
	LEVORPHANOL TABLETS (generic of Levo-Dromoran)
Meperidine Products	
MEPERIDINE TABLETS (generic of Demerol®)	
Methadone Products	
METHADONE TABLETS (generic of Dolophine®)	
Morphine Products	
MORPHINE SULFATE: immediate-release tablets (generic of MSIR®)	
Oxycodone Products	
ROXICODONE® tablets OXYCODONE HCL capsules, tablets (generic of M-Oxy®, OxyIR®)	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	
	SYNALGOS-DC® (dihydrocodeine/aspirin/caffeine)
Hydrocodone Combinations	
HYDROCODONE/ACETAMINOPHEN tablets <i>containing 325mg acetaminophen</i> (generic of Lorcet, Lortab, Norco)	HYDROCODONE/ IBUPROFEN (generic of Vicoprofen®) HYDROCODONE/ACETAMINOPHEN <i>tablets containing 300mg acetaminophen</i> (generic of Vicodin®, Xodol®) IBUDONE® (hydrocodone/ibuprofen)
Oxycodone Combinations	
OXYCODONE W/ ACETAMINOPHEN tablets (generic of Percocet®)	OXYCODONE W/ IBUPROFEN (generic of Combunox®) PRIMLEV® (oxycodone/ acetaminophen)
Pentazocine Combinations	
<i>Not advocated for use</i>	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®) 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 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®)	

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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 [®]) <i>LORTAB[®] 10mg-300mg/15ml (hydrocodone/ acetaminophen)</i> 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)

DRAFT

**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®)
LOVENOX® (enoxaparin)	FONDAPARINUX (generic of Arixtra®)

DRAFT

Blood Formation, Coagulation, and Thrombosis Agents: Oral Anticoagulants

LENGTH OF AUTHORIZATIONS: 1 year

INDICATIONS:

		Apixaban	Clopidogrel	Dabigatran	Prasugrel	Rivaroxaban	Ticagrelor	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		✓					✓
	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)		✓ (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)

* 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 [®]) WARFARIN (generic of Coumadin [®])	<i>EFFIENT[®] (prasugrel)</i>

DRAFT

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:

Ranexa® may be approved if there has been a therapeutic failure to no less than a one-month trial of at least two beta blockers and/or calcium channel blockers

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.

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CHRONIC STABLE ANGINA

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

ACE INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
BENAZEPRIL (generic of Lotensin [®]) CAPTOPRIL (generic of Capoten [®]) ENALAPRIL (generic of Vasotec [®]) EPANED (<i>enalapril oral solution</i>) 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)	

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 [®])	BENICAR [®] (olmesartan) DIOVAN [®] (valsartan)	CANDESARTAN (generic of Atacand [®]) EDARBI [®] (azilsartan) EPROSARTAN (generic of Teveten [®]) TELMISARTAN (<i>generic of Micardis[®]</i>)

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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 [®]) EPROSARTAN/HCTZ (generic of Teveten HCT [®]) EDARBYCLOR [™] (azilsartan/chlorthalidone) <i>TELMISARTAN/HCTZ (generic of Micardis HCT[®])</i>

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)	<i>AMLODIPINE/ TELMISARTAN (generic of Twynsta[®])</i>

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)	

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)

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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 [®])	CARDENE SR [®] (nicardipine) ISRADIPINE (generic of Dynacirc [®]) NIMODIPINE (generic of Nimotop [®])* <i>NYMALIZE oral solution (nimodipine) *</i> NISOLDIPINE (generic of Sular [®])

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

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.

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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.

DRAFT

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 NORPACE CR [®] (disopyramide) PROPAFENONE (generic of Rythmol [®]) PROPAFENONE ER (generic of Rythmol SR [®]) QUINIDINE GLUCONATE ER QUINIDINE SULFATE QUINIDINE SULFATE ER RYTHMOL SR [®] (propafenone) 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

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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)

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 [®]) <i>FENOFIBRATE</i> (generic of Tricor [®]) <i>FENOFIBRIC ACID</i> (generic of Trilipix [®])	<i>ANTARA</i> [®] (<i>fenofibrate</i>) 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	LOVAZA [®] (omega 3 fatty acids) 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/ezetimibe) VYTORIN [®] (simvastatin/ezetimibe)

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

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CARDIOVASCULAR AGENTS: LIPOTROPIC/HYPERTENSION COMBINATION

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

DRAFT

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 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*

Table with 2 columns: CLINICAL PA REQUIRED "PREFERRED" and PA REQUIRED. Rows include ADCIRCA (tadalafil) and SILDENAFIL (generic of Revatio).

*Patients on current regimens will be grandfathered.

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

Table with 2 columns: CLINICAL PA REQUIRED "PREFERRED" and PA REQUIRED. Rows include LETAIRIS (ambrisentan) and TRACLEER (bosentan), with OPSUMIT (macitentan) listed under PA REQUIRED.

*Patients on current regimens will be grandfathered.

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

Table with 2 columns: CLINICAL PA REQUIRED "PREFERRED" and PA REQUIRED. Row includes ORENITRAM (treprostinil diolamine) under PA REQUIRED.

*Patients on current regimens will be grandfathered.

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

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	ADEMPAS® (<i>riociguat</i>)

*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.

DRAFT

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®)	EXELON® patch (rivastigmine)	DONEPEZIL 23mg (generic of Aricept® 23mg)
DONEPEZIL ODT (generic of Aricept® ODT)	NAMENDA® (memantine)	EXELON® 2mg/ml solution (rivastigmine)
GALANTAMINE (generic of Razadyne™)	NAMENDA® 10mg/5ml solution (memantine)	NAMENDA XR®
GALANTAMINE ER (generic of Razadyne™ ER)		
GALANTAMINE 4mg/ml solution (generic of Razadyne™)		
RIVASTIGMINE capsules (generic of Exelon®)		

DRAFT

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) <i>ZOLMITRIPTAN (generic of Zomig[®])</i> <i>ZOLMITRIPTAN ODT (generic of Zomig ZMT[®])</i> 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)	

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

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

DRAFT

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.

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)

DRAFT

ANTICONVULSANTS: SECOND GENERATION

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

ANTICONVULSANTS: *THIRD GENERATION*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	<i>APTIOM[®] (eslicarbazepine acetate)</i>
	POTIGA [®] (ezogabine)
	VIMPAT [®] (lacosamide)

DRAFT

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®)	BRISDELLE® (paroxetine mesylate)
CITALOPRAM tablets (generic of Celexa®)	FLUOXETINE ER (generic of Prozac Weekly®)
ESCITALOPRAM (generic of Lexapro®)	FLUVOXAMINE ER (generic of Luvox CR®)
FLUOXETINE HCL capsules, tablets (generic of Prozac®)	PAROXETINE ER (generic of Paxil CR®)
FLUOXETINE HCL solution (generic of Prozac®)	PEXEVA® (paroxetine mesylate)
FLUVOXAMINE MALEATE (generic of Luvox®)	
PAROXETINE HCL (generic of Paxil®)	
SERTRALINE (generic of Zoloft®)	
SERTRALINE oral concentrate (generic of Zoloft®)	

*Patients on current regimens will be grandfathered.

DRAFT

ANTIDEPRESSANTS: SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRI)*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
DULOXETINE (generic of <i>Cymbalta</i> [®]) VENLAFAXINE (generic of Effexor [®]) VENLAFAXINE ER capsule (generic of Effexor XR [®])	DESVENLAFAXINE ER tablet DESVENLAFAXINE FUMARATE FETZIMA [®] (levomilnacipran) KHEDEZLA ER [®] 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 TM (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) TRANLYCPROMINE (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.

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

GRANDFATHERING:

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

PSYCHIATRIST EXEMPTION:

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

LENGTH OF AUTHORIZATIONS: 1 year

STEP THERAPY: all agents listed

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

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a 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

DRAFT

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 [®] (aripiprazole) ABILIFY [®] solution (aripiprazole) SEROQUEL XR [®] (quetiapine)	ABILIFY DISCMELT [®] (aripiprazole) CLOZAPINE (generic of Clozaril [®]) FANAPT [®] (iloperidone) FAZACLO [®] (clozapine) INVEGA [®] (paliperidone) LATUDA [®] (lurasidone) OLANZAPINE (generic of Zyprexa [®]) OLANZAPINE ODT (generic of Zyprexa [®] Zydis) SAPHRIS [®] (asenapine) <i>VERSACLOZ[®] (clozapine oral suspension)</i>

*Patients on current regimens will be grandfathered.

ANTIPSYCHOTICS, SECOND GENERATION and SSRI COMBINATION *

NO PA REQUIRED "PREFERRED GENERIC"	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.

DRAFT

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®)	METHAMPHETAMINE (generic of Desoxyn®)
DEXMETHYLPHENIDATE (generic of Focalin®)	METHYLIN® chewable tablets
DEXTROAMPHETAMINE (generic of Dexedrine®)	PROCENTRA® solution(dextroamphetamine)
DEXTROSTAT® (dextroamphetamine)	ZENZEDI® (dextroamphetamine)
FOCALIN® (dexmethylphenidate)	
METHYLIN® tablets (methylphenidate)	
METHYLIN® solution (methylphenidate)	
METHYLPHENIDATE solution (generic of Methylin®)	
METHYLPHENIDATE tablets (generic of Ritalin®)	

CNS AGENTS: ATTENTION DEFICIT HYPERACTIVITY DISORDER AGENTS – Long Acting

NO PA REQUIRED “PREFERRED”	PA REQUIRED
ADDERALL XR® (amphetamine/dextroamphetamine)	DAYTRANA® (methylphenidate)
DEXTROAMPHETAMINE SA (generic of Dexedrine® spansule)	<i>DEXMETHYLPHENIDATE ER (generic of Focalin XR®)</i>
FOCALIN® XR (dexmethylphenidate)	DEXTROAMPHETAMINE-AMPHETAMINE (generic of Adderall XR®)
INTUNIV® (guanfacine)	KAPVAY® (clonidine)
METADATE® CD (methylphenidate)	METHYLPHENIDATE LA (generic of Metadate® CD, Ritalin® LA)
METADATE® ER (methylphenidate)	QUILLIVANT XR® suspension (methylphenidate)
METHYLIN® ER (methylphenidate)	
METHYLPHENIDATE ER (generic of Concerta®)	
METHYLPHENIDATE ER (generic of Ritalin SR®)	
STRATTERA® (atomoxetine)	
VYVANSE™ (lisdexamfetamine)	

DRAFT

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.

DRAFT

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

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

SUBLINGUAL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:

1. Patient has diagnosis of opioid addiction (NOT approvable for pain)
2. Prescribing physician has a DATA 2000 waiver ID ("X-DEA" number)
3. Patient has been referred counseling for addiction treatment (re-authorizations should indicate how often the patient is receiving counseling)
4. Maximum dose ***16mg per day, doses above 16mg require a consult with an addiction psychiatrist or addictionologist*** (no patient should receive more than 32mg)
5. Prescriber has reviewed Ohio Automated Rx Reporting System (OARRS) for opioid prescription use
6. Periodic drug screens are addressed in treatment plan (will be performed by prescriber or by counseling team)
7. For 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

For buprenorphine only:

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

CENTRAL NERVOUS SYSTEM AGENTS: MEDICATION ASSISTED TREATMENT OF OPIOID ADDICTION

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SUBOXONE® SL film (buprenorphine/naloxone)	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.

DRAFT

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) REBIF [®] (interferon beta-1a)	EXTAVIA [®] (interferon beta-1b)

*Patients on current regimens will be grandfathered.

CNS AGENTS: MULTIPLE SCLEROSIS DISEASE MODIFYING AGENTS, ORAL *

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

*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)

DRAFT

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®) CARBAMAZEPINE (generic of Tegretol®) CLOMIPRAMINE (generic of Anafranil®) DESIPRAMINE (generic of Norpramin®) DOXEPIN (generic of Sinequan®) DULOXETINE (generic of Cymbalta®) GABAPENTIN (generic of Neurontin®) IMIPRAMINE (generic of Tofranil®) NORTRIPTYLINE (generic of Pamelor®) OXCARBAZEPINE (generic of Trileptal®)	GRALISE® (gabapentin) HORIZANT® (gabapentin enacarbil) LIDOCAINE patch (generic of Lidoderm®) LYRICA® (pregabalin)

DRAFT

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)

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) ZELAPAR® ODT (selegiline)

DRAFT

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)

DRAFT

**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 [®])	DORAL [®] (quazepam) EDLUAR [®] SL (zolpidem) <i>ESZOPICLONE (generic of Lunesta[®])</i> INTERMEZZO [®] SL (zolpidem) ROZEREM [®] (ramelteon) SILENOR [®] (doxepin) TEMAZEPAM 7.5mg, 22.5mg (generic of Restoril [®]) ZOLPIDEM ER (generic of Ambien [®] CR) ZOLPIMIST [®] (zolpidem)

DRAFT

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

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to an agent not requiring prior approval, then may approve the requested medication.

CNS AGENTS: SKELETAL MUSCLE RELAXANTS - ORAL

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

DRAFT

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)	

DRAFT

Endocrine Agents: Diabetes Adjunctive Therapy

LENGTH OF AUTHORIZATIONS: 1 year

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

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
 - Condition is difficult to control (i.e. prone to ketoacidosis, hypoglycemia)
2. The requested medication may be approved if there has been a therapeutic failure to at least one medication within the same class not requiring prior authorization.

ENDOCRINE AGENTS: DIABETES – AMYLIN ANALOGS

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

ENDOCRINE AGENTS: DIABETES – INCRETIN MIMETICS

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

DRAFT

Endocrine Agents: Diabetes – Insulin

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
 - Condition is difficult to control (i.e. prone to ketoacidosis, hypoglycemia)
2. The requested medication may be approved if there has been a therapeutic failure to at least one medication within the same class not requiring prior authorization.

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

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

* Patients on current insulin regimens will be grandfathered.

ENDOCRINE AGENTS: DIABETES - INSULINS - Intermediate Acting*

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

* Patients on current insulin regimens will be grandfathered.

ENDOCRINE AGENTS: DIABETES - INSULINS - Long Acting*

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

* Patients on current insulin regimens will be grandfathered.

DRAFT

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 COMBINATION

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)

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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/ <i>metformin</i>) KAZANO® (alogliptin/ metformin) KOMBIGLYZE XR® (saxagliptin/metformin)

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 COMBINATION

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, THIAZOLIDINEDIONES / SULFONYLUREAS COMBINATION

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

DRAFT

DIABETES – ORAL HYPOGLYCEMICS, THIAZOLIDINEDIONES / DPP-4 COMBINATION

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
		OSENI [®] (pioglitazone/alogliptin)

DIABETES – ORAL HYPOGLYCEMICS, THIAZOLIDINEDIONES / BIGUANIDE COMBINATION

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

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
		FARXIGA [®] (dapagliflozin) INVOKANA [®] (canagliflozin)

DRAFT

Endocrine Agents: Estrogenic Agents

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to at least two trials of thirty days each with medications not requiring prior approval

ENDOCRINE AGENTS: ESTROGENS – ORAL ESTROGENS

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

ENDOCRINE AGENTS: ESTROGENS – ORAL ESTROGEN/PROGESTERONE COMBINATIONS

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

ENDOCRINE AGENTS: ESTROGENS AND ESTROGEN AGONIST/ANTAGONIST COMBINATION

NO PA REQUIRED “PREFERRED”	PA REQUIRED
	<i>DUAVEE (conjugated estrogens/bazedoxifene)</i>

ENDOCRINE AGENTS: ESTROGENS – TRANSDERMAL ESTROGENS

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

DRAFT

ENDOCRINE AGENTS: ESTROGENS – TRANSDERMAL ESTROGEN/ PROGESTERONE COMBINATIONS

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

ENDOCRINE AGENTS: 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 \geq 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 \geq 2 years behind chronological age

DRAFT

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)

DRAFT

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®)

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

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

DRAFT

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

Table with 2 columns: NO PA REQUIRED 'PREFERRED' and PA REQUIRED. Lists medications like EMEND, ONDANSETRON, ANZEMET, GRANISETRON, SANCUSO, and ZUPLENZ.

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

Table with 2 columns: NO PA REQUIRED 'PREFERRED' and PA REQUIRED. Lists medications like DIMENHYDRINATE, DIPHENHYDRAMINE, MECLIZINE, METOCLOPRAMIDE, PHOSPHORATED CARBOHYDRATE SOLUTION, PROCHLORPERAZINE, PROMETHAZINE, TRANSDERM-SCOP, and TRIMETHOBENZAMIDE.

DRAFT

Gastrointestinal Agents: Irritable Bowel Syndrome / 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

GASTROINTESTINAL AGENTS: CHRONIC CONSTIPATION AGENTS

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

DRAFT

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)

DRAFT

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

DRAFT

Gastrointestinal Agents: Ulcerative Colitis Agents

LENGTH OF AUTHORIZATIONS: 6 months

STEP THERAPY: Oral agents only

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

OTHER 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)	<i>APRISO[®] (mesalamine)</i> ASACOL HD [®] (mesalamine) DIPENTUM [®] (olsalazine) GIAZO [®] (balsalazide disodium)

GASTROINTESTINAL AGENTS: ULCERATIVE COLITIS AGENTS - RECTAL

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

DRAFT

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.

DRAFT

Genitourinary Agents: Electrolyte Depletter 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)	<i>CALPHRON[®] (calcium acetate)</i> <i>ELIPHOS[®] (calcium acetate)</i> FOSRENOL [®] (lanthanum carbonate) <i>PHOSLO[®] (calcium acetate)</i> PHOSLYRA [®] solution (calcium acetate) RENVELA [®] (sevelamer) <i>VELPHORO[®] (sucroferric oxyhydroxide)</i>

DRAFT

Genitourinary Agents: Urinary Antispasmodics

LENGTH OF AUTHORIZATIONS: 1 year

STEP THERAPY:

- For a preferred brand agent, there must have been inadequate clinical response to preferred generic alternatives, including a trial of no less than one month of at least one preferred generic
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
Patients under age 18 may be approved for Detrol LA or Gelnique if there was inadequate clinical response to a trial of no less than one month of oxybutynin (IR or ER).

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

GENITOURINARY AGENTS: URINARY ANTISPASMODICS

Table with 2 columns: NO PA REQUIRED 'PREFERRED GENERIC' and PA REQUIRED. Lists various medications like ENABLEX, OXYBUTYNIN, SANCTURA, VESICARE, GELNIQUE, MYRBETRIQ, TOLTERODINE, TOVIAZ, and TROSPIUM.

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 immunosuppressants.
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

DRAFT

ANTI-INFLAMMATORY TUMOR NECROSIS FACTOR INHIBITOR

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

ANTI-INFLAMMATORY INTERLEUKIN-1 RECEPTOR ANTAGONIST

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	KINERET [®] syringe (anakinra)

ANTI-INFLAMMATORY INTERLEUKIN-6 RECEPTOR ANTAGONIST

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	<i>ACTEMRA[®] syringe (tocilizumab)</i>

JANUS KINASE INHIBITOR

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

PHOSPHODIESTERASE-4 INHIBITOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	<i>Otezla[®] tablet (apremilast)</i>

DRAFT

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 – CAPSULES AND TABLETS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CEFADROXIL (generic of Duricef®) CEPHALEXIN 250mg, 500 mg (generic of Keflex®)	CEPHALEXIN 750mg (generic of Keflex®)

CEPHALOSPORINS, FIRST GENERATION – SUSPENSIONS AND LIQUIDS

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

CEPHALOSPORINS, SECOND GENERATION – CAPSULES AND TABLETS

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

CEPHALOSPORINS, SECOND GENERATION – SUSPENSIONS AND LIQUIDS

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

DRAFT

CEPHALOSPORINS, THIRD GENERATION – CAPSULES AND TABLETS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CEFDINIR (generic of Omnicef®)	<i>CEFTIBUTEN</i> (generic of Cedax®) CEFDITOREN PIVOXIL (generic of Spectracef®) CEFPODOXIME (generic of Vantin®) SUPRAX® (cefixime)

CEPHALOSPORINS, THIRD GENERATION – SUSPENSIONS AND LIQUIDS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
CEFDINIR suspension (generic of Omnicef®)	<i>CEFTIBUTEN suspension</i> (generic of Cedax®) SUPRAX® suspension (cefixime) CEFPODOXIME suspension (generic of Vantin®)

DRAFT

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

DRAFT

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 (PA required for age over 12)
CIPRO [®] suspension (no PA required for age 12 or under) (ciprofloxacin)	(ciprofloxacin)
OFLOXACIN (generic of Floxin [®])	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 [®])	<i>MOXIFLOXACIN (generic of Avelox[®])</i>

DRAFT

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)

DRAFT

Infectious Disease Agents: Antivirals – Hepatitis C Agents

LENGTH OF AUTHORIZATIONS: 1 year *except simeprevir and sofosbuvir, 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 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 1b 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.

ADDITIONAL CRITERIA FOR SOFOSBUVIR:

LENGTH OF INITIAL APPROVAL 12 weeks – 24 weeks (genotype 3, genotype 4 post liver transplant)

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist; AND
- Patient must be 18 years of age or older; AND
- ***Female patient must have a negative pregnancy test within the last 30 days; AND***
- Dose not to exceed Sovaldi 400 mg once a day; AND
- Patient readiness assessed to insure compliance with treatment regimen; AND
- Discussion of deferred therapy (more effective / less toxic treatments); AND
- Vaccinate against Hepatitis A and Hepatitis B; AND
- Baseline viral load: AND
- ***Screening for and maintenance of sobriety (alcohol/controlled drugs/IV drug use) before and during treatment; AND***
- Tests to confirm a diagnosis of chronic hepatitis C (CHC) and laboratory monitoring;
 - Hepatitis C Virus (HCV) antibody test reactive
 - HCV RNA detected
 - Specify the Genotype
 - Patient must not have severe renal impairment (GFR < 30 ml/min/1.73m²) or end stage renal disease requiring hemodialysis

DRAFT

- Advanced liver fibrosis
 - *Metavir score (scale of 1-4): F3 (bridging fibrosis) or F4 (cirrhosis) or*
 - *Ishak score (scale of 1-6): F4-F5 (bridging cirrhosis) or F6 (cirrhosis)*
 - Documented diagnosis of HIV antibody and evidence of hepatitis B surface antigen
 - Any evidence of HCV-related extra hepatic manifestations: Lymphoma, symptomatic cryoglobulinemia, membranoproliferative glomerulonephritis
- Recommended initial regimen and treatment duration for Sovaldi combination therapy in HCV mono-infected and HCV/HIV-1 co-infected patients:

Genotype	Treatment	Duration
1 or 4	Sovaldi 400 mg + IFN + RBV	12 weeks
1 –IFN ineligible, IFN non-responder, advanced liver disease, low WBC, low platelets, post liver transplant	Sovaldi 400 mg + Olysio 150 mg With or without RBV or Sovaldi 400 mg + RBV	12 weeks 24 weeks
2	Sovaldi 400 mg + RBV	12 weeks 24 weeks in post liver transplant
3	Sovaldi 400 mg + RBV	24 weeks
3 (cirrhotic, previous non-responder)	Sovaldi 400 mg + IFN + ribavirin	12 weeks
4 – IFN ineligible, IFN non-responder, advanced liver disease, low WBC, low platelets, post liver transplant	Sovaldi 400 mg + RBV	24 weeks
Hepatocellular carcinoma waiting for liver transplant	Sovaldi 400 mg + RBV	Up to 48 weeks or until liver transplantation
5 and 6	Sovaldi 400 mg + IFN + RBV	12 weeks

DRAFT

INFECTIOUS DISEASE AGENTS: HEPATITIS C - PEGYLATED INTERFERONS

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

INFECTIOUS DISEASE AGENTS: HEPATITIS C - RIBAVIRINS

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

INFECTIOUS DISEASE AGENTS: HEPATITIS C – PROTEASE INHIBITORS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
INCIVEK [®] (telaprevir) OLYSIO [®] (simeprevir) VICTRELIS [®] (boceprevir)	

INFECTIOUS DISEASE AGENTS: HEPATITIS C – DIRECT-ACTING ANTIVIRAL

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
SOVALDI [®] (sofosbuvir)	

DRAFT

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®)

DRAFT

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

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CRIXIVAN [®] (indinavir sulfate) INVIRASE [®] (saquinavir mesylate) KALETRA [®] (lopinavir/ritonavir) LEXIVA [®] (fosamprenavir calcium) NORVIR [®] (ritonavir) REYATAZ [®] (atazanavir sulfate) VIRACEPT [®] (nelfinavir mesylate)	

HIV NON-PEPTIDIC PROTEASE INHIBITORS

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

HIV REVERSE TRANSCRIPTASE INHIBITORS, NUCLEOSIDE ANALOGS

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 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 [®])	

DRAFT

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 [®] (raltegravir potassium) TIVICAY [®] (dolutegravir sodium)	

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
	STRIBILD [®] (elvitegravir/cobicistat/emtricitabine/tenofovir)

DRAFT

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 Ocuflax®)	CILOXAN® ointment (ciprofloxacin) VIGAMOX® drops (moxifloxacin)	BESIVANCE® drops (besifloxacin) LEVOFLOXACIN drops (generic of Quixin®) MOXEZA® drops (moxifloxacin) <i>GATIFLOXACIN drops (generic of Zymaxid®)</i>

DRAFT

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)

DRAFT

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 [®])	ALAMAST [®] (pemirolast) ALOCRIL [®] (nedocromil) ALOMIDE [®] (lodoxamide)

OPHTHALMIC AGENTS: ANTIHISTAMINE/MAST CELL STABILIZERS

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

DRAFT

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

OPHTHALMIC AGENTS: GLAUCOMA AGENTS – BETA BLOCKERS

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

OPHTHALMIC AGENTS: GLAUCOMA AGENTS – PROSTAGLANDIN INHIBITORS

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
LATANAPROST (generic of Xalatan®)	TRAVATAN®Z (travoprost)	LUMIGAN™ (bimatoprost) RESCULA® (unoprostone isopropyl) TRAVAPROST ZIOPTAN® (tafluprost)

OPHTHALMIC AGENTS: GLAUCOMA AGENTS – ALPHA ADRENERGIC AGONISTS/SYPATHOMIMETICS

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
BRIMONIDINE 0.2% ALPHAGAN®P (brimonidine 0.15%)	ALPHAGAN®P (brimonidine 0.1%)	APRACLONIDINE (generic of Iopidine®) BRIMONIDINE 0.15% (generic of Alphagan® P)

DRAFT

OPHTHALMIC AGENTS: GLAUCOMA AGENTS – CARBONIC ANHYDRASE INHIBITORS

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

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

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

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

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

OPHTHALMIC AGENTS: GLAUCOMA AGENTS – COMBINATION ALPHA-ADRENERGIC AGONIST AND CARBONIC ANHYDRASE INHIBITORS

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

DRAFT

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) BROMDAY [®] (bromfenac) BROMFENAC (generic of Xibrom [®]) ILEVRO [®] (nepafenac) NEVANAC [®] (nepafenac) PROLENSA [®] (bromfenac)

DRAFT

Otic Agents: Antibacterial and Antibacterial/Steroid Combinations

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

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

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

- If there has been a therapeutic failure to no less than a one-week trial of at least one medication not requiring prior approval
- The requested medication’s corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

OTIC AGENTS: ANTIBACTERIAL – STERIOD COMBINATION

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

OTIC AGENTS: ANTIBACTERIAL

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

DRAFT

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

RESPIRATORY AGENTS: ANTIHISTAMINE/DECONGESTANT COMBO: SECOND GENERATION

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

DRAFT

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

LENGTH OF AUTHORIZATIONS: 1 year

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

RESPIRATORY AGENTS: BETA-ADRENERGIC, SHORT-ACTING

Metered Dose Inhalers or Other Devices

NO PA REQUIRED “PREFERRED”	PA REQUIRED
PROAIR [®] HFA (albuterol) PROVENTIL HFA [®] (albuterol) VENTOLIN HFA [®] (albuterol)	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 [®])

DRAFT

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

LENGTH OF AUTHORIZATIONS: 1 year

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

STEP THERAPY REQUIRED for all long-acting beta agonists and combinations:

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

RESPIRATORY AGENTS: BETA-ADRENERGIC, LONG-ACTING INHALERS

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

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

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

RESPIRATORY AGENTS: BETA-ADRENERGIC COMBINATIONS

STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED
ADVAIR DISKUS® and HFA (salmeterol/fluticasone) DULERA® (formoterol/mometasone) SYMBICORT® (formoterol/budesonide)	<i>ANORO ELLIPTA (umeclidinium/vilanterol)</i> <i>BREO ELLIPTA (fluticasone/vilanterol)</i>

DRAFT

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.

GRANDFATHERING (COMBIVENT®):

Patients who have a claim for Combivent MDI or Combivent Respimat in the previous 90 days will be approved for Combivent Respimat.

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) TUDORZA® (aclidinium bromide)

RESPIRATORY AGENTS: PHOSPHODIESTERASE-4 INHIBITORS *

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

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

DRAFT

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
EPINEPHRINE EPIPEN [®] (epinephrine) EPIPEN JR [®] (epinephrine)	<i>AUVI-Q[™] (epinephrine)</i>

DRAFT

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
<i>AEROSPAN[®] HFA (flunisolide)</i> FLOVENT DISKUS [®] and HFA (fluticasone) <i>PULMICORT FLEXHALER[®] (budesonide)</i> QVAR [®] (beclomethasone)	ALVESCO [®] (ciclesonide) <i>ASMANEX[®] (mometasone)</i>

RESPIRATORY AGENTS: GLUCOCORTICOIDS – NEBULIZERS

NO PA REQUIRED “PREFERRED”	PA REQUIRED
PULMICORT [®] nebulizer solution (no PA required for <i>age 4 or under</i>) (budesonide)	BUDESONIDE nebulizer solution (generic of Pulmicort [®]) PULMICORT [®] nebulizer solution (PA required for <i>over age 4</i>) (budesonide)

DRAFT

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®)	ZYFLO® (zileuton)
ZAFIRLUKAST (generic of Accolate®)	ZYFLO CR® (zileuton)

DRAFT

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 FLUTICASONE (generic of Flonase [®])	NASONEX [®] (mometasone)	BECONASE [®] AQ (beclomethasone) <i>BUDESONIDE (generic of Rhinocort Aqua[®])</i> DYMISTA [®] (fluticasone/azelastine) OMNARIS [®] (ciclesonide) QNASL [®] (beclomethasone) <i>TRIAMCINOLONE (generic of Nasacort[®] AQ)</i> VERAMYST [™] (fluticasone furoate) ZETONNA [®] (ciclesonide)

RESPIRATORY AGENTS: NASAL PREPARATIONS - ANTIHISTAMINES

	PA REQUIRED
ASTEPRO [®] (azelastine) PATANASE [®] (olopatadine)	AZELASTINE (generic of Astelin [®] , <i>Astepro[®]</i>)

RESPIRATORY AGENTS: NASAL PREPARATIONS - ANTICHOLINERGICS

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

DRAFT

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
CLINDAGEL [®] (clindamycin) 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) CLINDAMYCIN foam (generic of Evoclin [®]) CLINDAMYCIN pledgets (generic of Cleocin T [®]) ERY PADS [®] (erythromycin)

ACNE PREPARATIONS – OTHER PRODUCTS

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

DRAFT

BENZOYL PEROXIDE AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CLINDAMYCIN-BENZOYL PEROXIDE gel (generic of Benzaclin [®] , <i>Duac</i> [®])	ACANYA [®] (clindamycin-benzoyl peroxide)
BENZOYL PEROXIDE cleanser (generic of Oscion [®] , Triaz [®])	BENZAMYCINPAK [®] gel (benzoyl peroxide and erythromycin)
BENZOYL PEROXIDE gel (generic of Benzac AC [®] , Brevoxyl [®] , Desquam-X [®] , Panoxyl [®])	BENZEFOAM [®]
BENZOYL PEROXIDE wash (generic of Benzac AC [®] , Benzac W [®] , Brevoxyl [®] , Desquam-X [®] , Pacnex [®])	BENZOYL PEROXIDE MICROSPHERES wash (generic of Neobenz Micro [®])
ERYTHROMYCIN-BENZOYL PEROXIDE gel (generic of Benzamycin [®])	BENZOYL PEROXIDE pads (generic of Oscion [®] , Triaz [®])
PANOXYL [®] 10% foam, wash (benzoyl peroxide)	BENZOYL PEROXIDE-ALOE VERA wash (generic of Benziq [®] wash)
	DUAC CS [®] gel (benzoyl peroxide and clindamycin)
	INOVA EASY PAD [®] (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)	ADAPALENE cream, gel (generic of Differin [®])
RETIN-A MICRO [®] gel (tretinoin)	ATRALIN [®] gel (tretinoin)
TAZORAC [®] cream, gel (tazarotene)	EPIDUO [®] gel (adapalene/benzoyl peroxide)
TRETINOIN cream, gel (generic of Retin-A [®])	<i>FABIOR[®] foam (adapalene)</i>
	VELTIN [®] gel (clindamycin/tretinoin)
	ZIANA [®] gel (clindamycin/tretinoin)

SODIUM SULFACETAMIDE AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
KLARON [®] lotion (sulfacetamide)	CLARIFOAM EF [®] emollient foam
SODIUM SULFACETAMIDE-SULFUR wash (generic of Avar [®] cleanser, Clenia [®] foaming wash, Plexion [®] cleanser, Rosac [®] wash)	CLENIA emollient cream
	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 [®])

DRAFT

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 \geq 18 years

TOPICAL AGENTS: ANDROGENS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ANDRODERM [®] patch (testosterone) ANDROGEL [®] (testosterone)	AXIRON [®] gel (testosterone) FORTESTA [®] gel (testosterone) TESTIM [®] gel (testosterone)

DRAFT

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 [®])	<i>ECOZA foam (econazole)</i>
CLOTRIMAZOLE (generic of Lotrimin [®])	ERTACZO [®] (sertaconazole)
CLOTRIMAZOLE/BETAMETHASONE (generic of Lotrisone [®])	EXELDERM [®] (sulconazole)
ECONAZOLE (generic of Spectazole [®])	KETOCONAZOLE foam (generic of Extina [®])
KETOCONAZOLE Cream & Shampoo (generic of Kuric [®] , Nizoral [®])	<i>LUZU[®] (luliconazole)</i>
MICONAZOLE	MENTAX [®] (butenafine)
NYSTATIN	NAFTIN [®] (naftifine)
NYSTATIN/TRIAMCINOLONE	OXISTAT [®] (oxiconazole)
TERBINAFINE (generic of Lamisil [®])	PEDI-DRI [®] powder (nystatin)
TOLNAFTATE (generic of Tinactin [®])	PEDIADERM AF [®] cream (nystatin)
	VUSION [®] ointment (miconazole/zinc)
	XOLEGEL [™] (ketoconazole)

DRAFT

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
• Crothamiton 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 of age and older
• Package labeling does not list age for permethrin or piperonyl butoxide-pyrethrins

ANTI-PARASITICS, TREATMENT OF SCABIES

Table with 2 columns: NO PA REQUIRED 'PREFERRED' and PA REQUIRED. Row 1: PERMETHRIN cream (generic of Elimite) vs EURAX cream, lotion (crothamiton)

ANTI-PARASITICS, TREATMENT OF LICE

Table with 2 columns: NO PA REQUIRED 'PREFERRED' and PA REQUIRED. Row 1: LICE kit [piperonyl butoxide-pyrethrins shampoo, comb, permethrin home spray] (generic of Rid complete kit) vs MALATHION lotion (generic of Ovide), SPINOSAD (generic of Natroba), ULESFIA lotion (benzyl alcohol). Other rows list NATROBA, PERMETHRIN, PIPERONYL BUTOXIDE-PYRETHRINS, and SKLICE.

DRAFT

TOPICAL AGENTS: CORTICOSTEROIDS – HIGH POTENCY

NO PA REQUIRED “PREFERRED”	PA REQUIRED
AMCINONIDE ointment, cream, lotion	APEXICON-E [®] (diflorasone diacetate emollient base) cream
BETAMETHASONE VALERATE ointment (generic of Valisone [®])	BETAMETHASONE DIPROPIONATE cream, ointment (generic of Diprolene [®])
DIFLORASONE DIACETATE cream, ointment (generic of Florone [®])	<i>FLUOCINONIDE (generic of Vanos[®] cream)</i>
FLUOCINONIDE cream, gel, ointment, solution (generic of Lidex [®] , Lidex-E [®])	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 (generic of Olux [®] , Temovate [®])
	CLOBEX [®] lotion, shampoo, spray (clobetasol propionate)
	HALOBETASOL PROPIONATE cream, ointment (generic of Ultravate [®])
	OLUX-E [®] foam (clobetasol propionate)

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)	PROTOPIC [®] * (tacrolimus)

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



Ohio Medicaid
Pharmacy Benefit Management Program
Preferred Drug List
Recommendations

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



Analgesic: Gastroprotective NSAIDs

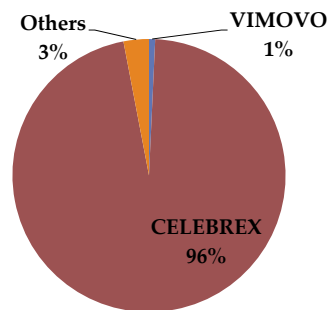
Clinical Highlights

- Generics for Vimovo[®] tablets and Celebrex[®] capsules recently approved:
 - Not available as of the clinical submission deadline



Analgesic: Gastroprotective NSAIDs

Market Share



Analgesic: Opioids

Clinical Highlights

- Xartemis® XR
 - Approved for management of acute pain severe enough to require opioid treatment
 - 1st oxycodone/apap ER product (7.5/325 mg)
 - Used when alternative treatment options are inadequate
 - Dosed as 2 tablets every 12 hours

Analgesic: Opioids

Clinical Highlights

- Zohydro[®] ER
 - Approved for management of pain severe enough to require daily, long-term opioid treatment
 - 1st single-entity and extended-release hydrocodone product
 - Used when alternative treatment options are inadequate
 - Dosed every 12 hours
 - Available in following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg

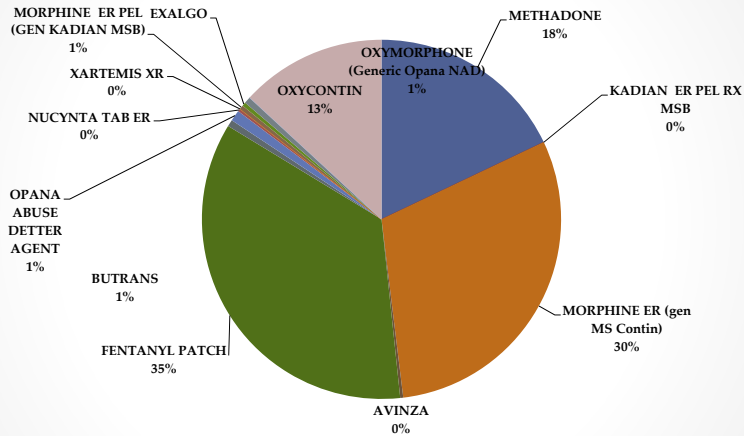
Analgesic: Opioids

Clinical Highlights

- New strengths/formulations
 - Butrans[®] patch – new 15 mcg/hr strength available
 - Hydrocodone/apap oral solutions – new 2.5-108 mg/5 mL and 5-217 mg/10 mL concentrations available

Analgesic: Opioids

Market Share



Analgesic: Opioids

Recommendation(s)

- Add Zohydro[®] ER and Xartemis[®] XR as Non-Preferred
- Move Kadian[®] to Non-Preferred

Analgesic: Opioids

Recommendation(s)

- Add hydrocodone/apap formulations containing 325 mg apap (e.g., Lorcet[®]) as Preferred
- Add hydrocodone/apap formulations containing 300 mg apap (e.g., Vicodin) as Non-Preferred
- Add Lortab[®] 10-300 mg/15 mL hydrocodone-apap solution as Preferred

Other Analgesic

Recommendation(s)

- No changes: Gout Agents

Blood: Oral Anticoagulant & PAI

Clinical Highlights

- Eliquis®:
 - New indication for prophylaxis of DVT in patients who have undergone hip or knee replacement surgery
 - Previously indicated to reduce the risk of stroke and systemic embolism in patients with NVAF only

Blood: Oral Anticoagulant & PAI

Clinical Highlights

- Pradaxa®:
 - New indication for treatment of DVT and PE in patients who have been treated with a parenteral anticoagulant for 5 to 10 days
 - Also, new indication to reduce risk of recurrence of DVT and PE in patients who have been previously treated
 - Previously indicated for NVAF only

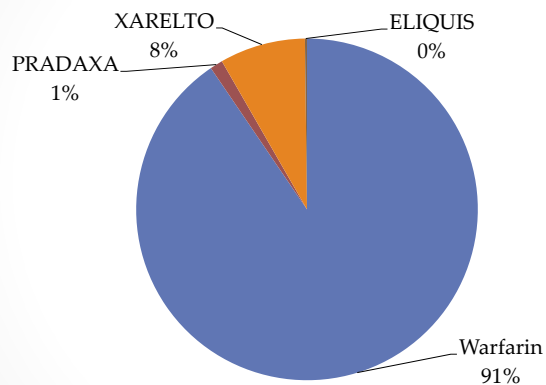
Blood: Oral Anticoagulant & PAI

Clinical Highlights

- Zontivity®:
 - New PAI indicated to reduce thrombotic CV events in patients with a history of MI or with PAD
 - Used in combination with ASA and/or clopidogrel
 - Not available as of the clinical submission deadline

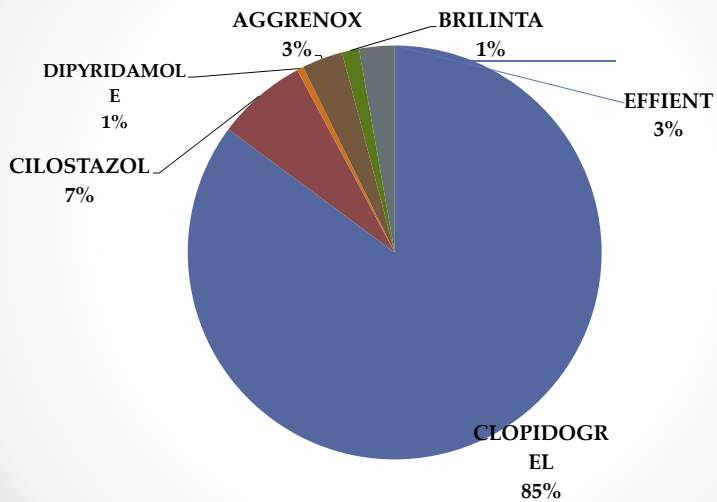
Blood: Oral Anticoagulants

Market Share



Blood: Oral PAI

Market Share



Blood: Oral Anticoagulant & PAI

Recommendation(s)

- Move Effient® to Non-Preferred

Other Blood Agent Recommendation(s)

- No changes: Hematopoietic Agents and Heparin-Related Preparations

Cardiovascular: ACE Inhibitors Clinical Highlights

- ADA now recommends blood pressure goal <140/80 mmHg
- JNC 8 and ASH guidelines recommend blood pressure goal of <140/90 for diabetic patients
- Current guidelines also recommend starting blood pressure therapy with an ACE, ARB, CCB, or thiazide for most patients

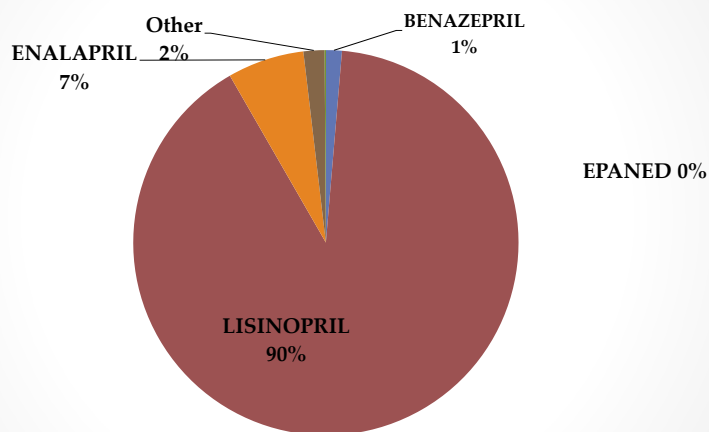
Cardiovascular: ACE Inhibitors

Clinical Highlights

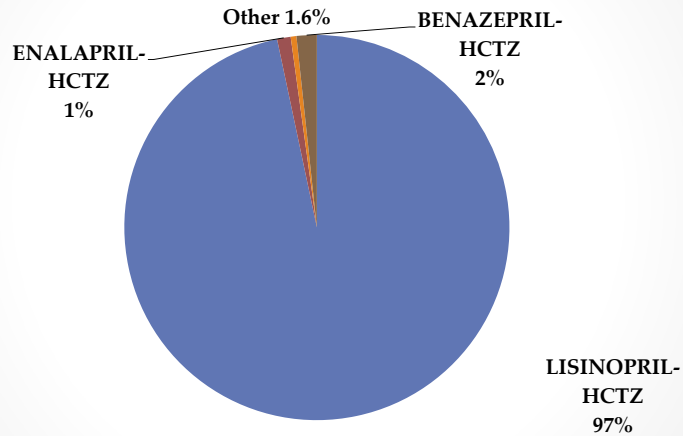
- Epaned[®]:
 - Enalapril oral solution recently approved for treatment of hypertension in adults and children older than one month
 - Recommended starting dose in pediatric patients is 0.08 mg/kg (up to 5 mg), and 5 mg once daily in adult patients
 - Available in 1mg/mL concentration

Cardiovascular: ACE Inhibitors

Market Share



Cardiovascular: ACE with Diuretics Market Share



Cardiovascular: ACE Inhibitors Recommendation(s)

- Add Epaned[®] as Preferred

Cardiovascular: ARBs

Clinical Highlights

- Olmesartan:
 - FDA recently issued drug safety communication warning olmesartan can cause intestinal problems known as sprue-like enteropathy
 - FDA evaluating safety of olmesartan-containing products and will communicate any new information

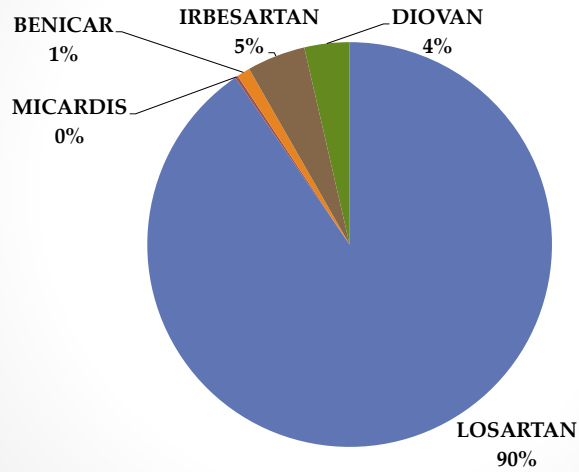
Cardiovascular: ARBs

Clinical Highlights

- New Generics:
 - Telmisartan, Telmisartan/hctz, and Telmisartan/amlodipine (generics of Micardis[®], Micarids HCT[®], and Twynsta[®])

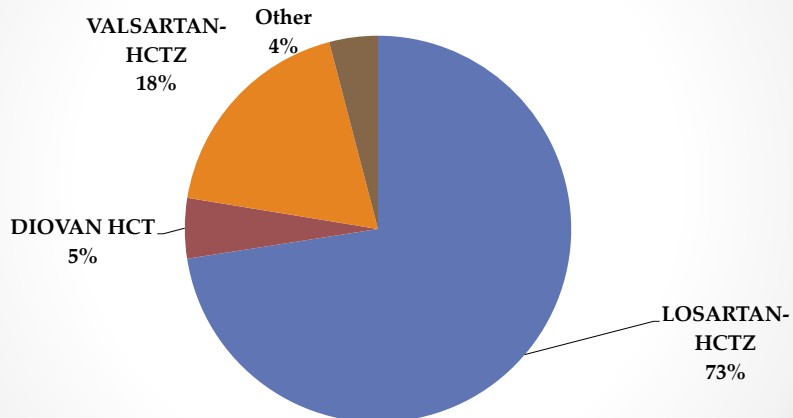
Cardiovascular: ARBs

Market Share



Cardiovascular: ARBs with Diuretics

Market Share



Cardiovascular: ARBs

Recommendation(s)

- Add Telmisartan, Telmisartan/hctz, and Telmisartan/amlodipine as Non-Preferred
- Move Micardis[®] and Micardis[®] HCT to Non-Preferred

Cardiovascular: CCBs

Clinical Highlights

- Nymalize[®]:
 - Nimodipine oral solution recently approved to treat patients with symptoms of subarachnoid hemorrhage (e.g., sudden intense headaches, neck pain, nausea or vomiting)
 - Available in 60 mg/20 mL concentration

Cardiovascular: CCBs Recommendation(s)

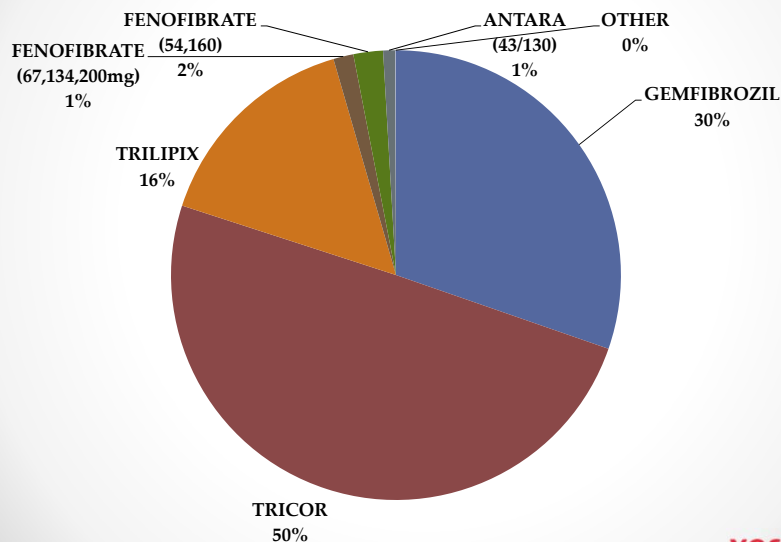
- Add Nymalize[®] as Non-Preferred

Cardiovascular: Lipotropic – FADs Clinical Highlights

- Antara[®] recently available in two new strengths: 30 mg and 90 mg capsules
- Generic fenofibric acid 45 mg and 135 mg delayed-release capsules also available; therapeutic equivalents of Trilipix[®]

Cardiovascular: Lipotropic – FADs

Market Share



Cardiovascular: Lipotropic – FADs

Recommendation(s)

- Add fenofibrate capsules and tablets, and fenofibric acid capsules as Preferred
- Move Antara[®], Tricor[®], and Trilipix[®] to Non-Preferred

CV: Statin & Other Lipotropics

Clinical Highlights

- AHA/ACC now recommend specific statin doses shown to improve cardiovascular outcomes
- According to the guidelines:
 - Most patients with CV disease should use high-intensity statins (e.g., atorvastatin 40 to 80 mg or rosuvastatin 20 to 40 mg)
 - High-intensity therapy also recommended for patients with LDL \geq 190 mg/dL
 - Moderate intensity therapy can be used if needed to limit side effects
 - Non-statin therapy should not be routinely recommended; should be alternatives for patients unable to tolerate statins

CV: Statin & Other Lipotropic

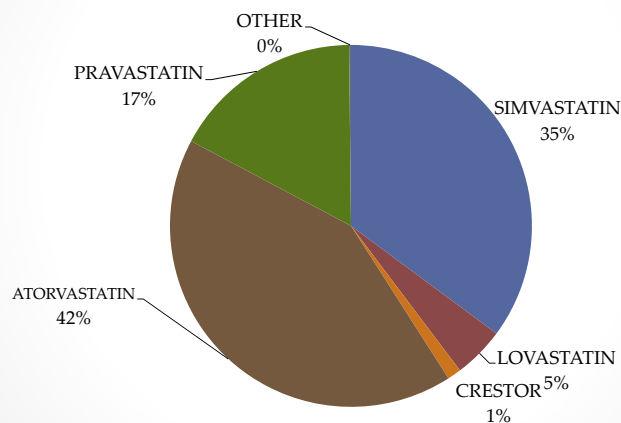
Clinical Highlights

- Juvisync[®]:
 - Recently discontinued; products available in the U.S. will expire by October 2014
 - Simvastatin and sitagliptin components will remain available

CV: Statin & Other Lipotropic Clinical Highlights

- Epanova[®]:
 - Recently approved as adjunct to diet to reduce TGs
 - Dosed as 2 or 4 capsules once daily
 - Not yet available as of clinical submission deadline

Cardiovascular: Statins Market Share



CV: Statin & Other Lipotropics

Recommendation(s)

- Move Zetia[®] to Preferred; add step therapy requiring therapeutic trial of one preferred statin
- Remove Juvisync[®] from PDL

Cardiovascular: PAH Agents

Clinical Highlights

- Adempas[®]:
 - Recently approved for treatment of PAH (WHO Group 1) to improve exercise capacity and delay clinical worsening
 - Also approved to treat adults with persistent, recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH, WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity

Cardiovascular: PAH Agents

Clinical Highlights

- **Adempas[®]:**
 - Dosed as 1 tablet three times daily
 - Available in following strengths: 0.5 mg, 1 mg, 1.5 mg, 2 mg, and 2.5 mg

Cardiovascular: PAH Agents

Clinical Highlights

- **Opsumit[®]:**
 - Recently approved for treatment of PAH to delay disease progression
 - Dosed as one tablet once daily
 - Available in 10 mg strength only

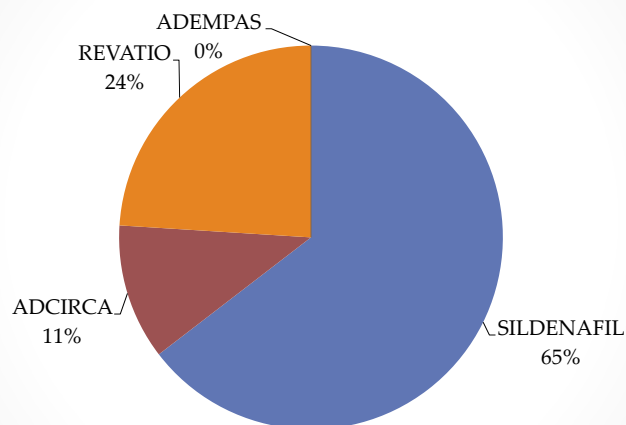
Cardiovascular: PAH Agents

Clinical Highlights

- Orenitram ER®:
 - Recently approved for treatment of PAH to improve exercise capacity
 - Dosed as one tablet twice daily
 - Available in following strengths: 0.125 mg, 0.25 mg, 1 mg, and 2.5 mg

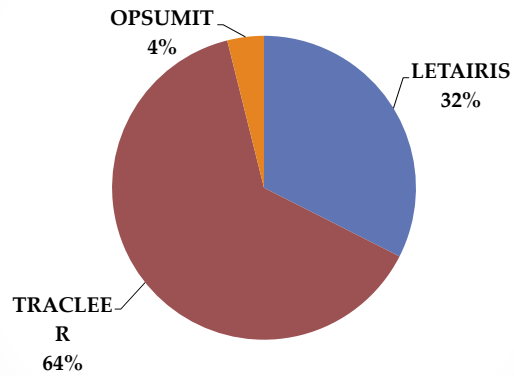
Cardiovascular: PAH Agents

Market Share



Cardiovascular: PAH Agents (ERA)

Market Share



Cardiovascular: PAH Agents

Recommendation(s)

- Add Adempas[®], Opsumit[®], and Orenitram ER[®] as Non-Preferred

Other Cardiovascular Recommendation(s)

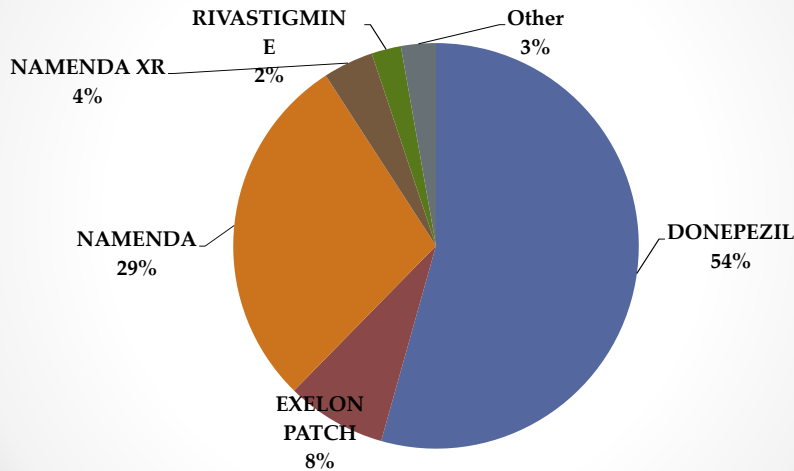
- No changes: Antianginal Agents, Antiarrhythmic Agents, Beta-Blockers, Direct Renin Inhibitors, Bile Acid Sequestrants, & Ethyl Esters

CNS: Alzheimer's Agents Clinical Highlights

- Exelon[®] Patch recently received approval for severe dementia; now approved for mild, moderate, and severe dementia
- Generic donepezil 23 mg tablets (Aricept[®]) available

CNS: Alzheimer's Agents

Market Share



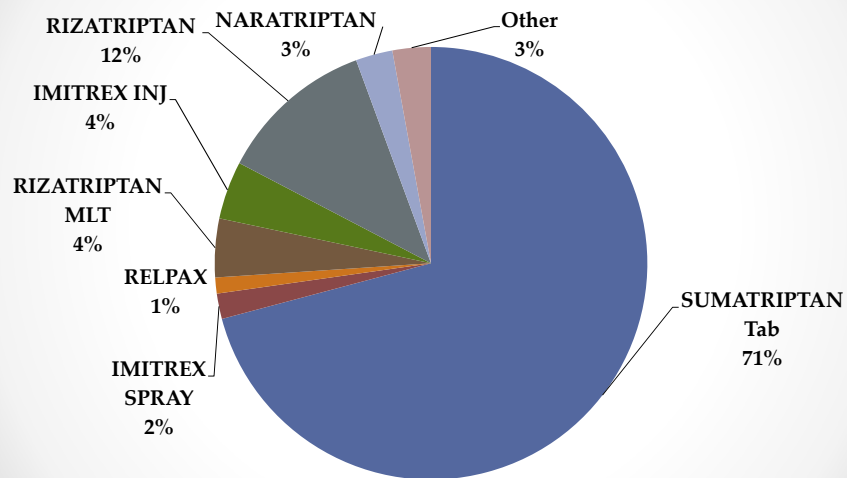
CNS: Antimigraine Agents

Clinical Highlights

- Generic zolmitriptan tablets and zolmitriptan ODT available (generics of Zomig[®] and Zomig-ZMT[®])
- Zomig[®] Nasal Spray available in new 2.5 mg strength

CNS: Antimigraine Agents

Market Share



CNS: Antimigraine Agents

Recommendation(s)

- Add zolmitriptan tablets and zolmitriptan ODT as Non-Preferred

CNS: Anticonvulsants

Clinical Highlights

- Aptiom[®]:
 - Recently approved as adjunctive therapy for partial-onset seizures
 - Dose range 400 mg to 1200 mg once daily
 - Available in following tablet strengths: 200 mg, 400 mg, 600 mg, and 800 mg

CNS: Anticonvulsants

Clinical Highlights

- Fycompa[®]:
 - Recently approved as adjunctive therapy for partial-onset seizures
 - Dose range 2 mg to 12 mg once daily at bedtime
 - Available in following tablet strengths: 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg

CNS: Anticonvulsants

Clinical Highlights

- Trokendi XR[®]:
 - Topiramate formulation recently approved for monotherapy in patients 10 & older with partial-onset or primary generalized tonic-clonic seizures
 - Also approved as adjunctive therapy in patients 6 & older with partial-onset or primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome

CNS: Anticonvulsants

Clinical Highlights

- Trokendi XR[®] available in following capsule strengths: 25 mg, 50 mg, 100 mg, and 200 mg

CNS: Anticonvulsants

Clinical Highlights

- Onfi®:
 - Available in a new 2.5 mg/mL suspension
 - FDA recently issued drug safety communication warning clobazam can cause rare, but serious skin reactions that could result in permanent harm and death; reactions can occur at any time during treatment

CNS: Anticonvulsants

Clinical Highlights

- Sabril®:
 - Now approved for use as adjunctive therapy in patients ≥ 10 years of age with refractory complex partial seizures; previously approved for use in adults only

CNS: Anticonvulsants

Clinical Highlights

- Topamax[®] /Topamax Sprinkles[®] - recently approved for prophylaxis of migraine headache in patients 12 and older; previously approved for migraine prevention in adults only

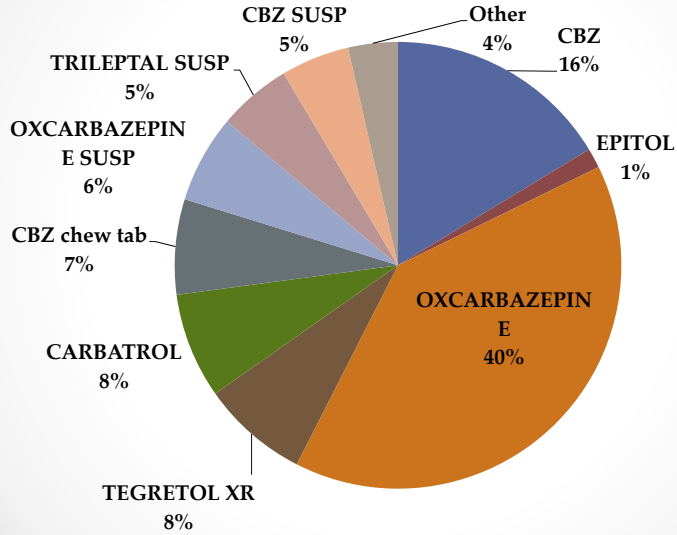
CNS: Anticonvulsants

Clinical Highlights

- Qudexy XR[®]:
 - Topiramate extended-release capsule recently approved to treat partial-onset seizures, primary generalized tonic-clonic seizures, and Lennox-Gastaut Syndrome
 - Not yet available as of clinical submission deadline

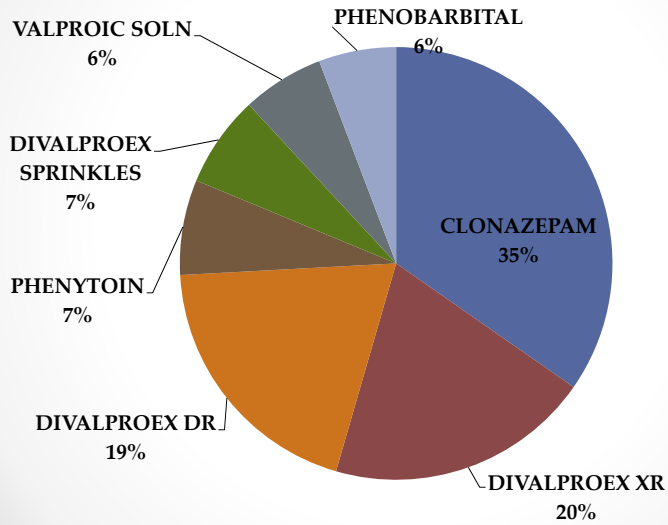
CNS: Anticonvulsants

Market Share



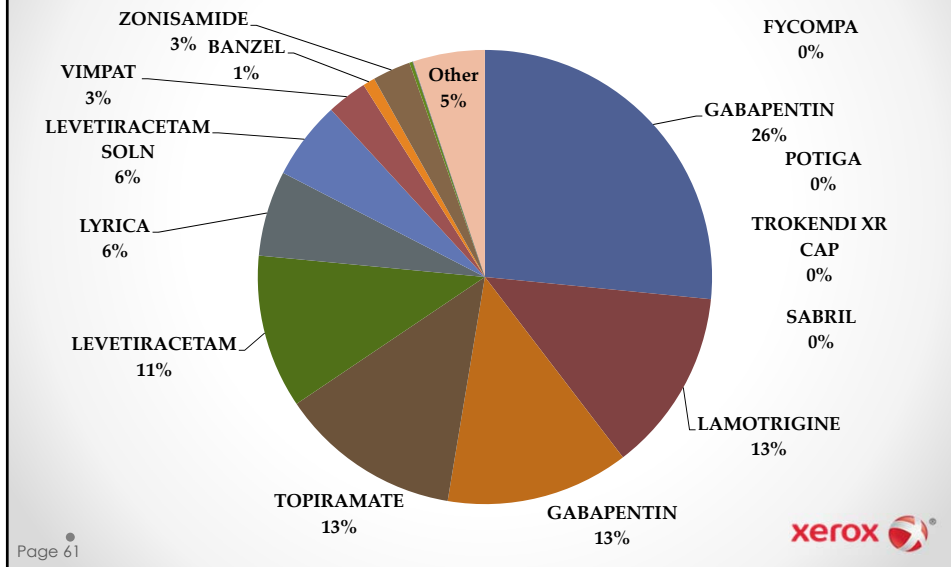
CNS: Anticonvulsants

Market Share



CNS: Anticonvulsants

Market Share



CNS: Anticonvulsants

Recommendation(s)

- Add Aptiom® as Non-Preferred

CNS: Antidepressants

Clinical Highlights

- Brintellix[®] tablets:
 - Recently approved for MDD
 - Available in following strengths: 5 mg, 10 mg, 15 mg, and 20 mg
- Brisdelle[®] capsules:
 - 7.5 mg paroxetine formulation approved for moderate to severe vasomotor symptoms associated with menopause

CNS: Antidepressants

Clinical Highlights

- Desvenlafaxine fumarate – new ER salt formulation available in 50 mg and 100 mg tablet strengths
- Khedezla – additional desvenlafaxine ER formulation available in 50 mg and 100 mg tablet strengths

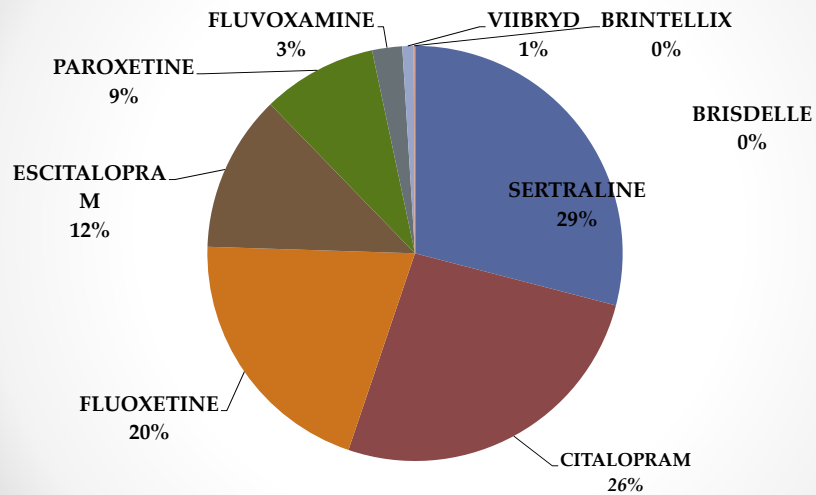
CNS: Antidepressants

Clinical Highlights

- Duloxetine capsules (Cymbalta®) recently approved and available

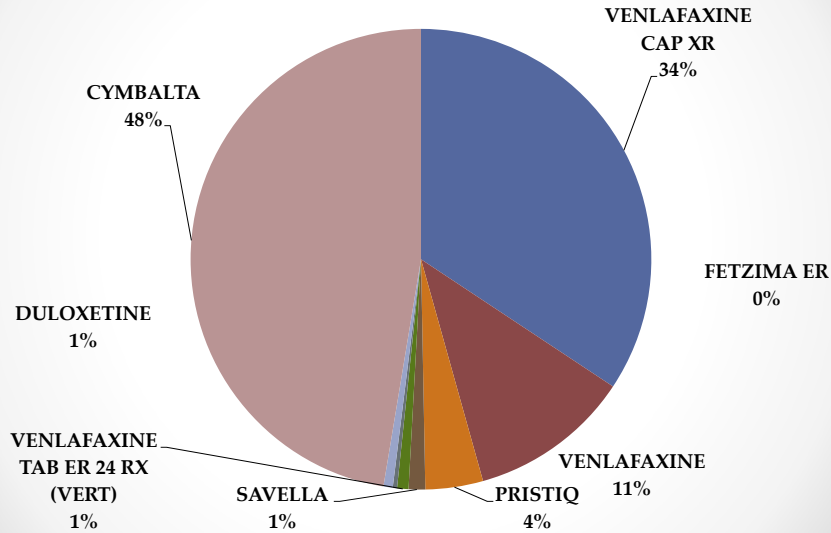
CNS: SSRIs

Market Share



CNS: SNRIs

Market Share



CNS: Antidepressants

Recommendation(s)

- Add duloxetine as Preferred; move Cymbalta® to Non-Preferred
- Add Brintellix® and desvenlafaxine fumarate as Non-Preferred
- All Non-Preferred agents require one-month trial each of two different Preferred products

CNS: 2nd Generation Antipsychotics

Clinical Highlights

■ Latuda[®]:

- Recently approved for treatment of depressive episodes associated with Bipolar I Disorder, both as monotherapy and adjunctive therapy with lithium or valproate
- Available in a new 60 mg tablet strength; other available strengths include 20 mg, 40 mg, 80 mg, and 120 mg

CNS: 2nd Generation Antipsychotics

Clinical Highlights

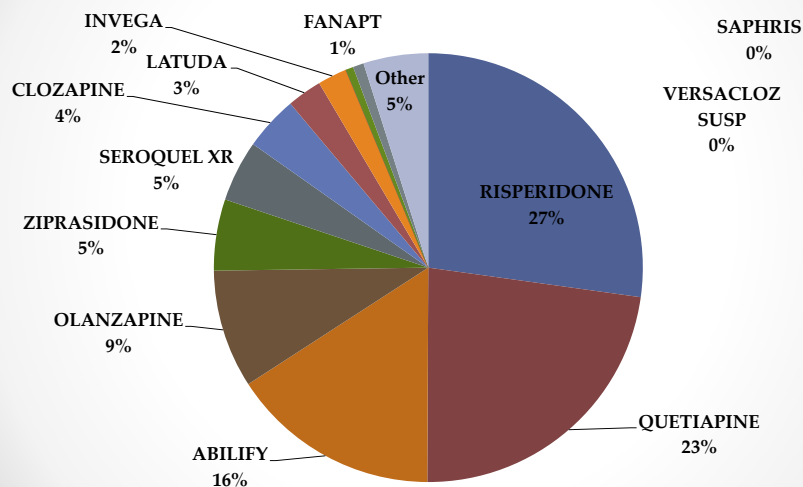
■ Versacloz[®]:

- New clozapine 50 mg/mL oral suspension approved for treatment-resistant schizophrenia and for reducing suicidal behavior in patients with schizophrenia or schizoaffective disorder

CNS: 2nd Generation Antipsychotics Clinical Highlights

- Risperidone
 - Available as a syringe in 1 mg/1mL, 2 mg/mL, and 3 mg/mL concentrations

CNS: 2nd Generation Antipsychotics Market Share



CNS: 2nd Generation Antipsychotics Recommendation(s)

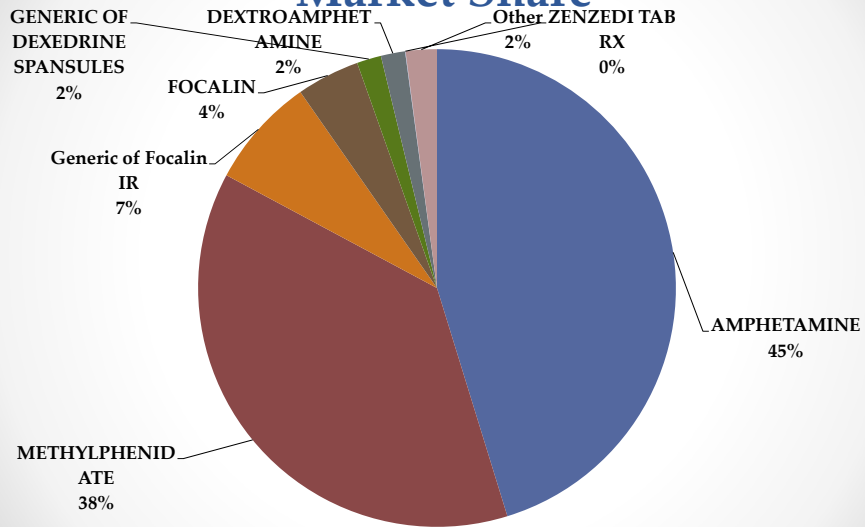
- Add Versacloz[®] as Non-Preferred

CNS: ADHD Agents Clinical Highlights

- Zenedi[®]
 - New dextroamphetamine product approved in following tablet strengths: 2.5 mg, 5 mg, 7.5 mg, and 10 mg
- Generic dexamethylphenidate ER (Focalin XR[®]) approved in 15 mg, 30 mg, and 40 mg strengths

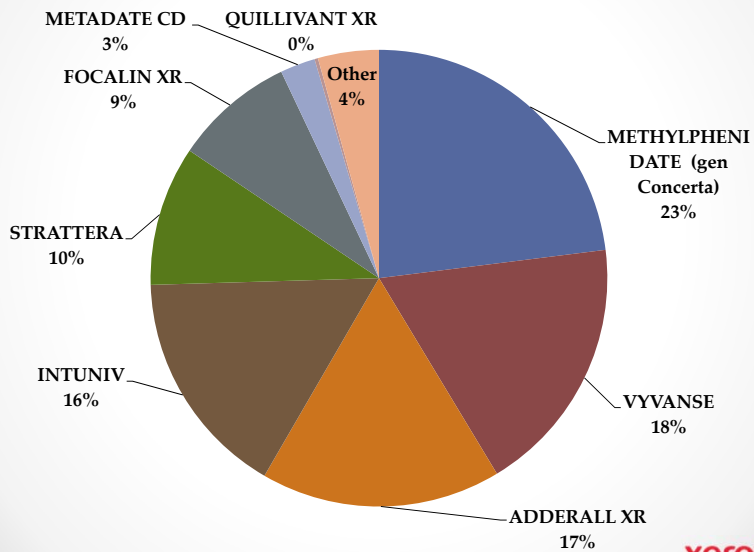
CNS: ADHD Agents

Market Share



CNS: ADHD Agents (LA)

Market Share



CNS: ADHD Agents

Recommendation(s)

- Add dexamethylphenidate ER as Non-Preferred

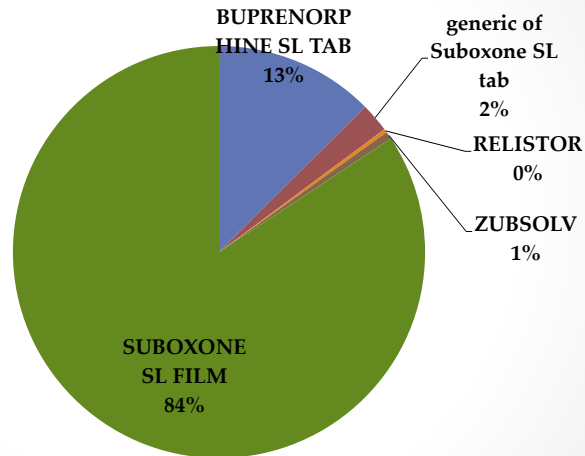
CNS: Medication Assisted Treatment Agents

Clinical Highlights

- Zubsolv[®] (buprenorphine/naloxone) SL tablets approved and available in following strengths:
1.4 mg buprenorphine-0.36 mg naloxone and
5.7 mg buprenorphine-1.4 mg naloxone

CNS: Medication Assisted Treatment Agents

Market Share



CNS: Medication Assisted Treatment Agents

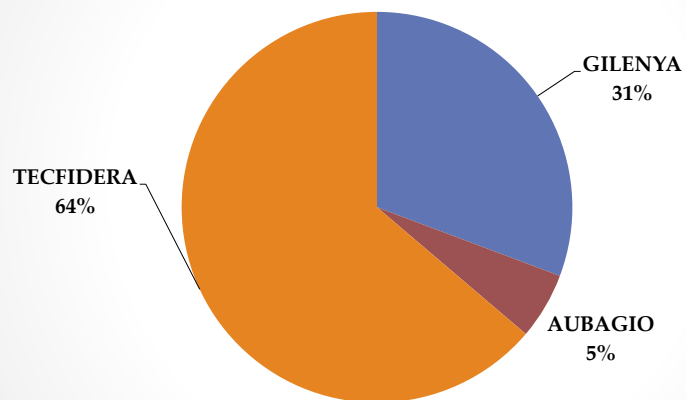
Recommendations

- Maximum dose under SL criteria now 16 mg per day
- Doses above 16 mg would require consult with an addiction psychiatrist or addictionologist

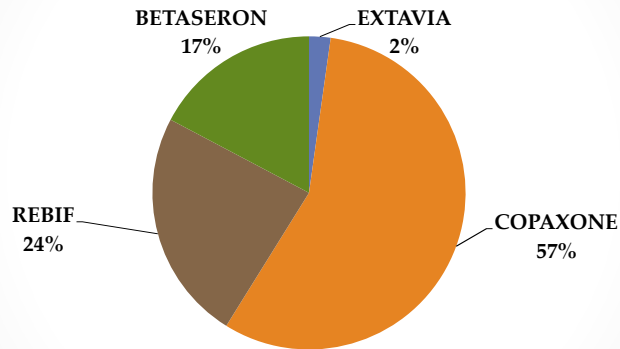
CNS: Multiple Sclerosis Agents Clinical Highlights

- Copaxone®:
 - Available in a new 40 mg/mL strength prefilled syringe
 - 40 mg/mL strength administered SC three times weekly; 20 mg/mL strength administered SC once daily

CNS: Multiple Sclerosis Oral Agents Market Share



CNS: Multiple Sclerosis Inj. Agents Market Share



CNS: Restless Legs Syndrome Agents Clinical Highlights

- Horizant ER[®] available in new 300 mg tablet strength

CNS: Sedative Hypnotics

Clinical Highlights

- Lunesta®:
 - FDA issued drug safety communication warning eszopiclone can cause next-day impairment of activities that require alertness; starting dose decreased from 2 mg to 1 mg at bedtime
 - Generic eszopiclone tablets now available in 1 mg, 2 mg, and 3 mg strengths

CNS: Sedative Hypnotics

Recommendation(s)

- Add eszopiclone as Non-Preferred; move Lunesta® to Non-Preferred
- 10-day trial required each of at least two Preferred medications prior to receiving Non-Preferred agents

Other CNS

Recommendation(s)

- Neuropathic Pain Agents: Add duloxetine as Preferred; maintain Cymbalta® as Non-Preferred
- No changes: Fibromyalgia Agents, Parkinson's Agents, Skeletal Muscle Relaxants, and Smoking Deterrents

Endocrine: Amylin Analog, Incretin Mimetic, and Insulin Clinical Highlights

- Tanzeum®:
 - New GLP-1 receptor agonist approved for type 2 diabetes
 - Dosed SC once weekly
 - Not yet available as of clinical submission deadline

Endocrine: Oral Hypoglycemics

Clinical Highlights

- JNC-8 Guidelines:
 - Now indicate CCBs and thiazides are good alternatives in addition to ACEs and ARBs for diabetic patients with hypertension
 - Patients with CKD should always receive an ACE or ARB since ACEs/ARBs improve outcomes in CKD patients

Endocrine: Oral Hypoglycemics

Clinical Highlights

- Avandia[®]:
 - FDA requiring removal of restrictions on prescribing and use of Avandia based on results from RECORD trial
 - RECORD trial showed no elevation of heart attack risk and death in patients treated with Avandia compared with standard-of-care diabetes drugs

Endocrine: Oral Hypoglycemics Clinical Highlights

- Onglyza[®]:
 - FDA investigating possible association between saxagliptin use and heart failure based on study published in *NEJM*
 - FDA will conduct thorough analysis and report findings once available

Endocrine: Oral Hypoglycemics Clinical Highlights

- Farxiga[®]:
 - New SGLT-2 Inhibitor approved for type 2 diabetes
 - Dose range 5 mg to 10 mg once daily
 - Available in 5 mg and 10 mg tablets

Endocrine: Oral Hypoglycemics Recommendation(s)

- Move Janumet[®] XR to Non-Preferred

Endocrine: Estrogenic Agents Clinical Highlights

- Duavee[®]:
 - New product containing conjugated estrogens with an estrogen agonist-antagonist
 - Indicated to treat moderate to severe vasomotor symptoms associated with menopause; also approved for prevention of postmenopausal osteoporosis
 - Dosed as one tablet (0.45 mg conjugated estrogens-20 mg bazedoxifene) once daily

Endocrine: Estrogenic Agents Recommendation(s)

- Add Duavee® as Non-Preferred
- Move Climara Pro® Patch to Preferred

Other Endocrine Recommendation(s)

- No changes: Growth Hormones and Bone Ossification Enhancers

GI: Anti-Emetic Agents

Clinical Highlights

- Anzemet[®]:
 - No longer indicated for prevention of postoperative nausea and vomiting in adults and children 2 years and older
 - Now only indicated for prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults and children 2 years and older

GI: Anti-Emetic Agents

Clinical Highlights

- Zuplenz[®] label recently updated to warn ECG changes, including QT interval prolongation, have been seen in patients using ondansetron

GI: Anti-Emetic Agents Recommendations

- Add Zuplenz[®] and Metozolv[®] ODT as Non-Preferred

GI: H. Pylori Agents Clinical Highlights

- Helidac[®] recently discontinued
- Generic Prevpac[®] now available
- Recommend no longer reviewing H. Pylori Agents; remove from PDL

GI: PPI

Clinical Highlights

- Aciphex®:
 - Sprinkle delayed-release capsules recently available in 5 mg and 10 mg strengths; indicated for GERD in children 1 to 11 years of age
 - Generic rabeprazole 20 mg delayed-release tablets also available

GI: PPI

Clinical Highlights

- Esomeprazole strontium:
 - New delayed-release capsule available in 24.65 mg and 49.3 mg strengths
 - Lower 24.65 mg strength equivalent to 20 mg of esomeprazole; higher 49.3 mg strength equivalent to 40 mg of esomeprazole

GI: PPI

Clinical Highlights

- Esomeprazole and omeprazole-containing drugs:
 - Labels updated to warn esomeprazole and omeprazole may cause fetal harm based on animal data
 - Pregnancy category of Nexium changed from B to C

GI: PPI

Recommendation(s)

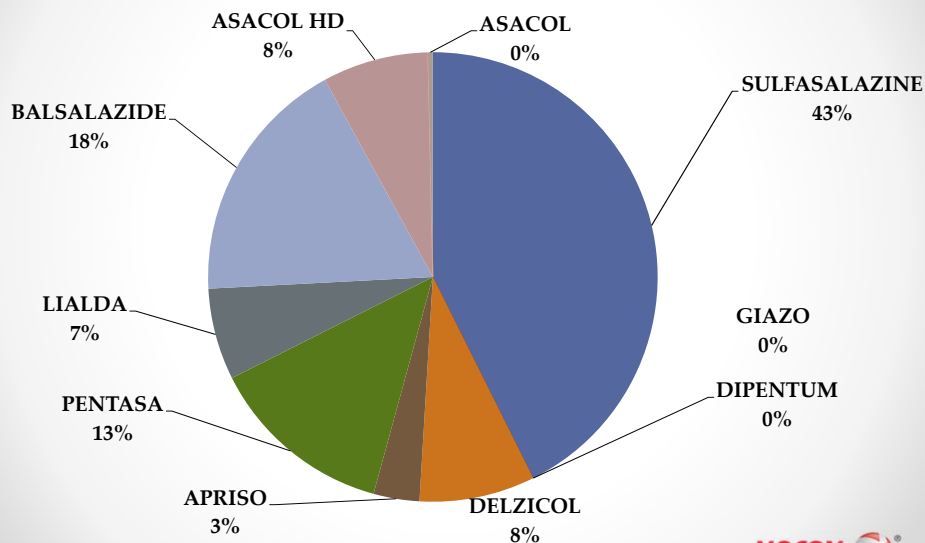
- Add Aciphex sprinkle capsules, esomeprazole strontium capsules, and rabeprazole tablets as Non-Preferred
- Add Prevacid Solutabs as Preferred for children 6 years and under, and Non-Preferred for patients over 6 years of age
- Remove lansoprazole ODT from the PDL

GI: Ulcerative Colitis Clinical Highlights

■ Entyvio®:

- Recently approved for moderately to severely active Ulcerative Colitis, and moderately to severely active Crohn's Disease
- Administered as an IV infusion
- Not yet available as of clinical submission deadline

GI: Ulcerative Colitis Market Share



GI: Ulcerative Colitis Recommendation(s)

- Move Apriso® to Non-Preferred

Other GI Recommendation(s)

- Pancreatic Enzymes: one-month trial required each of two Preferred medications prior to receiving a Non-Preferred medication
- No changes: Chronic Constipation Agents

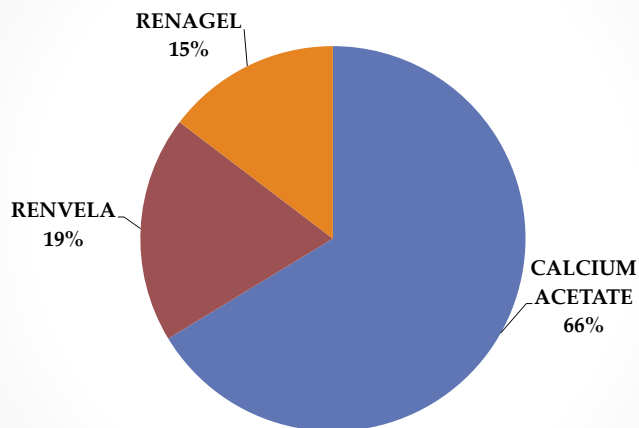
GU: Electrolyte Depleters

Clinical Highlights

- Velphoro[®]:
 - New phosphate binder indicated for control of serum phosphorus levels in CKD patients on dialysis
 - Recommended starting dose 1 tablet three times daily
 - Available as a 500 mg chewable tablet

GU: Electrolyte Depleters

Market Share



GU: Electrolyte Depleters

Recommendation(s)

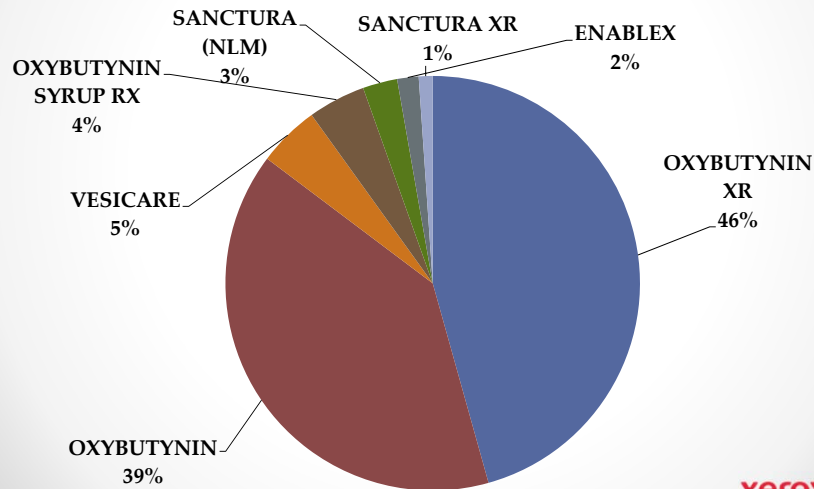
- Add Velphoro[®] as Non-Preferred
- Move Calphron[®], Eliphos[®], and Phoslo[®] to Non-Preferred

GU: UTAs

Clinical Highlights

- Generic tolterodine ER 2 mg and 4 mg capsules available (Detrol LA[®])
- Brand Sanctura[®] XR recently discontinued; generic remains available

GU: UTA Market Share



GU: UTAs

Recommendation(s)

- Add tolterodine ER as Non-Preferred
- Add OTC Oxytrol[®] Patch for women as Preferred
- Move Enablex[®] and Vesicare[®] to Preferred
- Remove Sanctura[®] XR from PDL

Other GU Recommendation(s)

- No changes: BPH Agents

Immunomodulator Agents for Systemic Inflammatory Disease

- Actemra[®]:
 - Recently available in a SC formulation (162 mg/0.9 mL single-use prefilled syringe)
 - Syringe administered SC every week or every other week depending on patient weight
 - Indicated for RA, PJIA, and SJIA

Immunomodulator Agents for Systemic Inflammatory Disease

- Cimzia®:
 - Recently received new indications for treatment of adult patients with active psoriatic arthritis and treatment of adult patients with active ankylosing spondylitis

Immunomodulator Agents for Systemic Inflammatory Disease

- Otezla®:
 - New PDE-4 Inhibitor indicated for treatment of adult patients with active psoriatic arthritis
 - Recommended maintenance dose 30 mg twice daily
 - Available in following tablet strengths: 10 mg, 20 mg, and 30 mg

Immunomodulator Agents for Systemic Inflammatory Disease

- Simponi®:
 - Received new indication for moderately to severely active ulcerative colitis
 - For use in adults who have demonstrated corticosteroid dependence, or who have had inadequate response to or failed to tolerate aminosalicylates, oral corticosteroids, AZA, or 6-MP

Immunomodulator Agents for Systemic Inflammatory Disease

- Simponi®:
 - Ulcerative colitis dose 200 mg at week 0, 100 mg at week 2, then 100 mg every 4 weeks
 - Also available in a new 100 mg/mL pen and 100 mg/mL syringe

Immunomodulator Agents for Systemic Inflammatory Disease

- Recommendations: Add Actemra[®] syringe and Otezla[®] tablet as Non-Preferred

Infectious Disease: Cephalosporin Clinical Highlights

- Generic ceftibuten 400 mg capsules and 180 mg/5 mL suspension available (Cedax[®])

Infectious Disease: Cephalosporin Recommendation(s)

- Add ceftibuten capsule and suspension as Non-Preferred

Infectious Disease: Quinolones Clinical Highlights

- All fluoroquinolone labels recently updated to better describe peripheral neuropathy side effect
- Generic moxifloxacin tablets (Avelox[®]) now available

Infectious Disease: Quinolones Recommendation(s)

- Add moxifloxacin tablets as Non-Preferred

Infectious Disease: Onychomycosis & Systemic Clinical Highlights

- Nizoral[®]:
 - FDA limiting use of Nizoral[®] oral tablets due to their potential to cause severe liver injury and adrenal gland problems, and lead to harmful drug interactions with other medications

Infectious Disease: Onychomycosis & Systemic Clinical Highlights

■ Nizoral®:

- Nizoral® tablets should not be used 1st line to treat any fungal infection, and should only be used when alternatives are not available or tolerated

Infectious Disease: Hepatitis C Clinical Highlights

■ Olysio®:

- New PI approved for CHC
- Used in combination with peginterferon and ribavirin in genotype 1-infected patients
- Dosed as one capsule (150 mg) once daily
- Recommended treatment duration with peginterferon and ribavirin is 12 weeks followed by 12 or 36 additional weeks of peginterferon and ribavirin depending on prior response

Infectious Disease: Hepatitis C

Clinical Highlights

- Sovaldi®:
 - Polymerase Inhibitor approved for CHC
 - Used in genotype 1, 2, 3, and 4-infected patients, including those with hepatocellular carcinoma awaiting liver transplantation and those with HCV/HIV-1 coinfection
 - Dosed as one tablet (400 mg) once daily

Infectious Disease: Hepatitis C

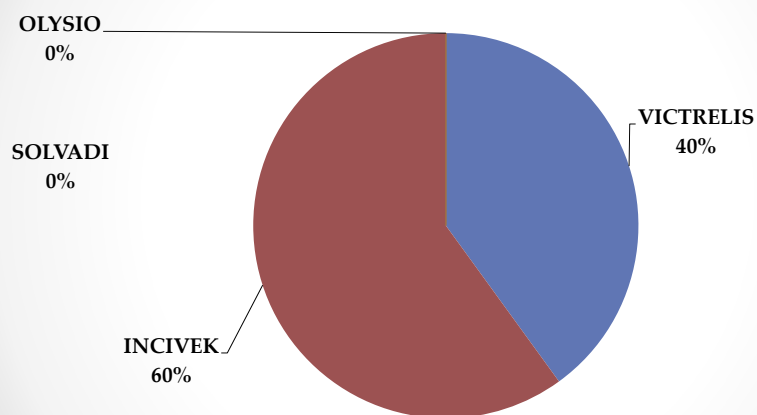
Clinical Highlights

- Sovaldi®:
 - Genotype 1 and 4 infected patients – Sovaldi® + Peg IFN + RBV for 12 weeks
 - Genotype 2 infected patients – Sovaldi® + RBV only for 12 weeks
 - Genotype 3 infected patients – Sovaldi® + RBV only for 24 weeks

Infectious Disease: Hepatitis C Clinical Highlights

- Sovaldi®:
 - Genotype 1 IFN ineligible patients – Sovaldi® + RBV only for 24 weeks
 - Patients with hepatocellular carcinoma awaiting liver transplantation – Sovaldi® + RBV only for up to 48 weeks, or until liver transplantation

Infectious Disease: Hepatitis C Market Share



Infectious Disease: Hepatitis C

Recommendation(s)

- Maintain Olysio® and Sovaldi® as Preferred with PA criteria

Infectious Disease: HIV

Clinical Highlights

- HIV Post-Exposure Prophylaxis Guidelines:
 - Guidelines for healthcare professionals now recommend a 3-drug regimen for 28 days instead of a 2-drug regimen
 - 3-drug regimens are more effective at reducing viral load, more tolerable, and cause less concern for resistance

Infectious Disease: HIV

Clinical Highlights

- Tivicay[®]:
 - New integrase strand transfer inhibitor
 - Approved for use in patients 12 and older weighing at least 40 kg
 - Dosed as 50 mg once or twice daily
- Generic nevirapine ER (Viramune[®] XR) available

Infectious Disease: HIV

Recommendation(s)

- Add nevirapine ER as Preferred
- Move Stribild[®] to Non-Preferred

Other Infectious Disease Recommendation(s)

- No changes: Macrolides and Antiherpetic Agents

Ophthalmic: Antibiotic & Steroid Clinical Highlights

- Generic gatifloxacin 0.5% drops (Zymaxid[®]) available

Ophthalmic: Antibiotic & Steroid Recommendation(s)

- Add gatifloxacin 0.5% drops as Non-Preferred

Other Ophthalmic Recommendations

- No changes: Antihistamine & Mast Cell Stabilizers, Miotics, and NSAIDs
- Also no changes for Otic Agents

Respiratory: Inhaled Beta Adrenergic Agonists, Clinical Highlights

- CFC Inhalers:
 - FDA completed its phase-out of all inhaler medicinal products containing CFCs
 - Combivent® Inhalation Aerosol and Maxair® Autohaler were the last two CFC-containing inhalers to be phased out by the end of 2013

Respiratory: Beta Adrenergic Combination Clinical Highlights

- Anoro Ellipta®
 - New combination anticholinergic (umeclidinium) and long-acting beta agonist (vilanterol) indicated for COPD
 - Dosed as one inhalation once daily
 - Available as an inhalation powder containing two double-foil blister strips: one strip containing 62.5 mcg umeclidinium per blister and one strip containing 25 mcg vilanterol per blister

Respiratory: Beta Adrenergic Combination

Clinical Highlights

- Breo Ellipta[®]
 - New combination product indicated to treat COPD; combination of both fluticasone and the long-acting beta agonist vilanterol
 - Dosed as one inhalation once daily
 - Available as an inhalation powder containing two double-foil blister strips: one strip containing 100 mcg fluticasone furoate per blister and one strip containing 25 mcg vilanterol per blister

Respiratory: Beta Adrenergic Combination

Recommendation(s)

- Add Anoro Ellipta[®] and Breo Ellipta[®] as Non-Preferred

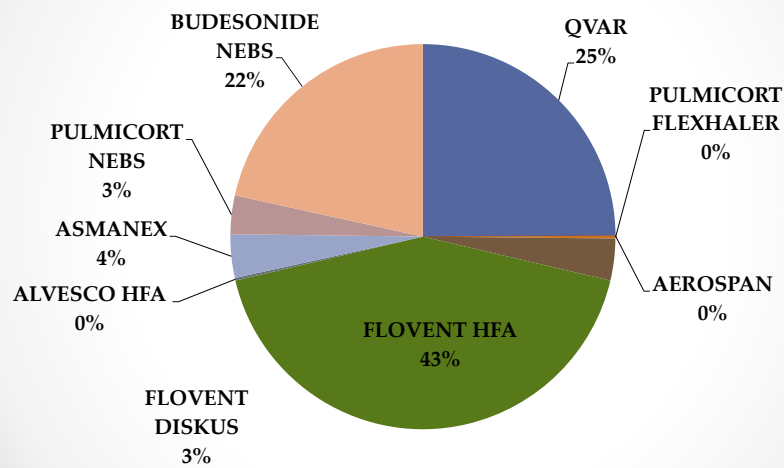
Respiratory: Inhaled Glucocorticoids

Clinical Highlights

- **Aerospan HFA®:**
 - Now available; inhaled corticosteroid for maintenance treatment of asthma in patients 6 years and older
 - Dosed as one inhalation twice daily
 - Includes built-in spacer and delivers 60 or 120 metered 80 mcg doses

Respiratory: Inhaled Glucocorticoids

Market Share



Respiratory: Inhaled Glucocorticoids

Recommendation(s)

- Add Aerospan HFA[®] as Preferred
- Move Pulmicort Flexhaler[®] to Preferred
- Move Asmanex[®] to Non-Preferred
- Change status of Pulmicort[®] nebulizer solution to Preferred for children 4 years and younger, and Non-Preferred for patients over 4 years of age

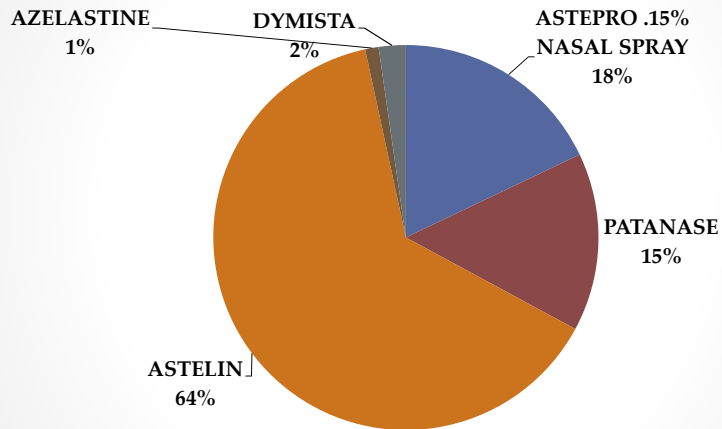
Respiratory: Nasal Preparations

Clinical Highlights

- Astepro[®]:
 - Now approved for use in children 6 years and older
 - Generally dosed as 1 or 2 sprays per nostril once or twice daily depending on patient age
- Brand Astelin[®] 137 mcg NS discontinued; generic remains available
- Nasacort[®] (triamcinolone) NS available OTC
- Generic budesonide NS (Rhinocort Aqua[®]) available

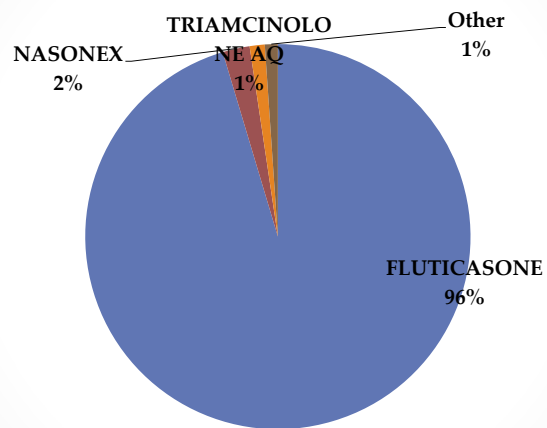
Respiratory: Nasal Preparations

Market Share



Respiratory: Nasal Preparations

Market Share



Respiratory: Nasal Preparations

Recommendation(s)

- Add generic budesonide and triamcinolone nasal sprays as Non-Preferred
- Remove Astelin® from the PDL

Other Respiratory

Recommendation(s)

- Epinephrine Auto-Injectors – Move Auvi-Q® to Non-Preferred
- No changes: 2nd Generation Antihistamines, Inhaled Beta Agonists, COPD Agents, & Leukotriene Receptor Modifiers and Inhibitors

Topical: Acne Preparations

Clinical Highlights

- Generic adapalene 0.3% gel (Differin®) available
- Fabior® (tazarotene) 0.1% foam available; indicated for acne vulgaris in patients 12 and older

Topical: Acne Preparations

Recommendation(s)

- Add Fabior® foam as Non-Preferred
- Move generic clindamycin 1.2%-benzoyl peroxide 5% (Duac®) to Preferred

Topical: Androgens

Clinical Highlights

- FDA investigating whether testosterone products are associated with an increased risk of CV events among groups of men prescribed testosterone therapy
- Agency will communicate findings and recommendations once evaluation complete

Topical: Antifungals

Clinical Highlights

- Ecoza[®] 1% foam approved for treatment of interdigital tinea pedis in patients 12 and older
- Luzu[®] 1% cream approved for treatment of interdigital tinea pedis, tinea cruris, and tinea corporis in patients 18 and older

Topical: Antifungals

Recommendations

- Add Ecoza[®] foam and Luzu[®] cream as Non-Preferred

Topical: Corticosteroids

Clinical Highlights

- Generic fluocinonide 0.1% cream (Vanos[®]) available

Topical: Corticosteroids

Recommendation(s)

- Add fluocinonide cream as Non-Preferred

Other Topical Recommendations

- No changes: Topical Immunomodulators
and Topical Parasitics

