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# Ohio Medicaid

Pharmacy Benefit Management Program

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Department of  
Medicaid

## Preferred Drug Lists

### Fee-for-Service Preferred Drug List

Effective July 1, 2019

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## Analgesic Agents: NSAIDs

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

NSAID Type	Approval Criteria	Approval Length
Non-Gastroprotective NSAIDs	no less than a <u>one-month</u> trial of at least <u>two</u> non-gastroprotective NSAID medications	1 year
Gastroprotective	no less than a <u>one-month</u> trial of at least <u>two</u> non-gastroprotective NSAID medications.	1 year
Gastroprotective	patient is undergoing surgical or other medical procedures that may predispose them to potential bleeding complications.	2 months
Gastroprotective	patient is being treated for H. pylori.	30 days
Transdermal/Topical	diclofenac solution: no less than a <u>one-month</u> trial of at least <u>one</u> preferred topical NSAID medications within the past 6 months	3 months

**PDL CRITERIA:**

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

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval. Acceptable contraindications for GASTROPROTECTIVE NSAIDs include:
  - Concurrent or history of a GI event (perforation, ulcer, bleed)
  - Other risks for treatment with NON-GASTROPROTECTIVE 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

**ADDITIONAL INFORMATION**

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

1. The medication is prescribed for an approved indication
2. There has been a therapeutic failure as defined as:
  - NON-GASTROPROTECTIVE NSAIDS:
    - no less than a one-month trial of at least two non-gastroprotective NSAID medications
  - GASTROPROTECTIVE NSAIDS:
    - no less than a one-month trial of at least two non-gastroprotective NSAID medications.

- OR
  - patient is undergoing surgical or other medical procedures that may predispose them to potential bleeding complications.
- OR
  - patient is being treated for H. pylori.
- TRANSDERMAL/TOPICAL:
  - no less than a one-month trial of at least one preferred topical NSAID medications within the past 6 months

**ANALGESIC AGENTS: NON-GASTROPROTECTIVE NSAIDS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DICLOFENAC SODIUM (generic of Voltaren®) DICLOFENAC POTASSIUM (generic of Cataflam®) ETODOLAC (generic of Lodine, Lodine XL) FENOPROFEN IBUPROFEN (generic of Motrin®) INDOMETHACIN (generic of Indocin®) KETOPROFEN KETOROLAC MECLOFENAMATE SODIUM MEFENAMIC ACID (generic of Ponstel®) MELOXICAM (generic of Mobic®) NABUMETONE NAPROXEN OXAPROZIN (generic of Daypro®) PIROXICAM (generic of Feldene®) SULINDAC TOLMETIN	TIVORBEX® (indomethacin) VIVLODEX™ (meloxicam) ZORVOLEX® (diclofenac)

**ANALGESIC AGENTS: GASTROPROTECTIVE NSAIDS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CELECOXIB (generic for Celebrex®) (no PA required for age 60 or older)	CELECOXIB (generic for Celebrex®) (PA required for under age 60) DICLOFENAC/MISOPROSTOL (generic of Arthrotec®) DUEXIS® (ibuprofen/famotidine) VIMOVO® (naproxen/esomeprazole)

**ANALGESIC AGENTS: NSAIDS TRANSDERMAL/TOPICAL**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
FLECTOR® patch (diclofenac epolamine) VOLTAREN® gel (diclofenac sodium)	DICLOFENAC 1.5% topical solution (generic of Pennsaid®) PENNSAID® 2% solution (diclofenac sodium)

## 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 30-day trial of allopurinol, or intolerance/contraindication to allopurinol.
- Lesinurad will be approved when target serum uric acid levels (<6mg/dL) are not achieved on appropriate dose of xanthine oxidase inhibitor alone for at least 90 days and the treatment plan includes ongoing use of an appropriate dose of xanthine oxidase inhibitor

- Appropriate dose of xanthine oxidase inhibitors:

- Allopurinol: 300mg daily (200mg daily in patients with eCrCl <60mL/min)
- Febuxostat: 80mg daily

Use of the combination pill of lesinurad and allopurinol will be limited to those cases where lesinurad has already demonstrated that the member has reached their target serum uric acid levels

- 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 within the last 30 days:
    - NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
    - Oral corticosteroid

### **ANALGESIC AGENTS: GOUT – Agents to Reduce Hyperuricemia**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALLOPURINOL (generic of Zyloprim®) PROBENECID (generic for Benemid®) PROBENECID-COLCHICINE	DUZALLO® (lesinurad and allopurinol) ULORIC® (febuxostat) ZURAMPIC® (lesinurad)

### **ANALGESIC AGENTS: GOUT – Analgesic Agents\***

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
COLCHICINE capsules (generic of Mitigare®)	COLCHICINE tablets (generic of Colcrys®)

- \* Colchicine quantity limit 6/claim for acute gout, 60/month for chronic gout after trial on xanthine oxidase inhibitor, 120/month for FMF

## Analgesic Agents: Opioids

**LENGTH OF AUTHORIZATIONS:** For the course of therapy, up to 6 months

- There must have been inadequate clinical response to preferred alternatives, including a trial of no less than one week each of at least one preferred product.

**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 EXCEEDING SHORT-ACTING OPIOID NEW START CRITERIA**

- System will define “new start” as having less than a 1-day supply of opioids in the previous 90 days
- Exemptions for certain conditions: active cancer treatment, palliative care, and end-of-life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, major orthopedic surgery
- Attestation that patient is not opioid naïve
  - For example, if patient is newly eligible for Medicaid and there is no prior claims data
  - For example, if patient was on a higher dose in the hospital
- Non-pharmacologic treatments and/or non-opioid analgesics ineffective or contraindicated
- Diagnosis code required: should be for somatic type pain
- Benefits and risks of opioid therapy have been discussed with patient (attestation)
- Prescriber has checked OARRS (attestation)
- Length of authorization: UP TO 90 days, depending on the indication (could be more restrictive)

**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  $\geq 1$  week without adequate pain relief):
  - $\geq 60$  mg oral morphine/day, or
  - $\geq 25$  mcg/hr transdermal fentanyl, or
  - $\geq 30$  mg oral oxycodone/day, or
  - $\geq 8$  mg oral hydromorphone/day, or
  - $\geq 25$  mg oral oxymorphone/day, or
  - Equianalgesic dose of another opioid; and
- Dose is  $\leq 4$  units per day

**ALL LONG-ACTING OPIOIDS REQUIRE PRIOR AUTHORIZATION:**

- Initial request (90 day approval)
  - Catastrophic injury or cancer pain does not require additional documentation
  - All other causes of pain:
    - Documented treatment plan including risk assessment, substance abuse history, concurrent therapies
    - OARRS checked within 7 days prior to initiating long-acting therapy
    - Documentation of pain and function scores at each visit
    - Baseline urine drug test and plan for random urine screens
    - Opioid contract required
    - Documented failure of both non-opioid pharmacologic and non-pharmacologic treatments
    - History of short-acting opioids for  $\geq 60$  days
    - Cumulative dose  $\leq 80$  MED
- Renewal requests (after initial 90 days then every 180 days)
  - Current treatment plan
  - Demonstrated adherence to treatment plan through progress notes including pain and function scores and random urine screens, no serious adverse outcomes
- Dose escalation requests
  - Prescriber indicates escalation of dose is likely to result in improved function and pain control
  - Cumulative dose  $>100$  MED requires pain specialist or anesthesiologist consultation



**ANALGESIC AGENTS: OPIOIDS – Long-Acting Oral**

**ALL LONG-ACTING OPIOIDS REQUIRE CLINICAL PRIOR AUTHORIZATION**

<b>CLINICAL PA REQUIRED “PREFERRED”</b>	<b>PA REQUIRED “NON-PREFERRED”</b>
<b>Extended Release Buprenorphine Products</b>	
	BELBUCA™ (Buprenorphine buccal film)
<b>Extended Release Hydrocodone Products</b>	
	HYSINGLA ER® (hydrocodone) ZOHYDRO ER® (hydrocodone)
<b>Extended Release Morphine Products</b>	
EMBEDA® (morphine sulfate/ naltrexone) MORPHINE SULFATE ER tablet (generic of MS Contin®)	ARYMO™ (morphine ER) MORPHABOND™ ER (morphine ER) MORPHINE SULFATE ER capsule (generic of Avinza®, Kadian®)
<b>Extended Release Oxycodone Products</b>	
	OXYCODONE ER (generic of Oxycontin®) OXYCONTIN® (oxycodone) XARTEMIS XR® (oxycodone/ acetaminophen) XTAMPZA® ER (oxycodone)
<b>Extended Release Tramadol Products</b>	
	CONZIP® (tramadol) TRAMADOL ER (generic of Ryzolt ER®, Ultram ER®)
<b>Extended Release Oxymorphone Products</b>	
	OPANA® ER tablets (oxymorphone abuse-deterrent) OXYMORPHONE HCL ER tablets (generic of Opana® ER non-abuse-deterrent)
<b>Extended Release Hydromorphone Products</b>	
	HYDROMORPHONE ER (generic of Exalgo® ER)
<b>Extended Release Tapentadol Products</b>	
	NUCYNTA® ER (tapentadol)
<b>Methadone Products</b>	
	METHADONE tablet (generic of Dolophine®) METHADONE HCL oral concentrate 10mg/ml METHADONE HCL SOLN 5mg/5ml, 10mg/5ml METHADONE INTENSOL® 10mg/ml

**ANALGESIC AGENTS: OPIOIDS – Long-Acting Transdermal**

<b>NO PA REQUIRED “PREFERRED”</b>	<b>PA REQUIRED “NON-PREFERRED”</b>
Trial of oral Long-acting	BUTRANS® patch (buprenorphine) FENTANYL PATCH (generic of Duragesic®) FENTANYL patch 37.5mg/hr, 62.5mg/hr, 87.5mg/hr

**ANALGESIC AGENTS: OPIOIDS – SHORT-ACTING ORAL SINGLE-ENTITY CII \***

Note: Effective July 1, 2018, patients with short acting opioid therapy will be limited to 30 MED per prescription and a maximum of 7 days per prescription. Prior authorization will be required to exceed these limits\*

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
<b>Codeine Products</b>	
CODEINE SULFATE tablet	
<b>Hydromorphone Products</b>	
HYDROMORPHONE HCL tablet (generic of Dilaudid®)	
<b>Levorphanol Products</b>	
	LEVORPHANOL TABLETS (generic of Levo-Dromoran)
<b>Meperidine Products</b>	
	MEPERIDINE tablet (generic of Demerol®)
<b>Morphine Products</b>	
MORPHINE SULFATE: immediate-release tablets (generic of MSIR®)	
<b>Oxycodone Products</b>	
ROXICODONE® tablets (oxycodone) OXYCODONE HCL capsules, tablets (generic of M-Oxy®, OxyIR®)	OXECTA® (oxycodone)
<b>Oxymorphone Products</b>	
	OXYMORPHONE HCL tablets (generic of Opana®)
<b>Tapentadol Products</b>	
	NUCYNTA® (tapentadol)

### ANALGESIC AGENTS: OPIOIDS – Short-Acting Combination and tramadol

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

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

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

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

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ACETAMINOPHEN w/CODEINE ORAL SOLN 120mg-12mg/5ml (generic of Tylenol w/Codeine Elixir®) HYDROCODONE BITARTRATE w/ ACETAMINOPHEN ELIXIR 2.5mg-167mg/5ml, 2.5mg-108mg/5ml (generic of Hycet®, Lortab Elixir®) LORTAB® 10mg-300mg/15ml (hydrocodone/acetaminophen) ROXICET® ORAL SOLN (5mg Oxycodone-325mg APAP/5ml)	CAPITAL w/CODEINE® suspension 12mg codeine-120mg APAP/5ml ZAMICET® 10mg-325mg/15ml (hydrocodone/acetaminophen)

**ANALGESIC AGENTS: OPIOIDS – Nasal Inhalers**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BUTORPHANOL TARTRATE NS (generic of Stadol NS®)	

**ANALGESIC AGENTS: OPIOIDS – Transmucosal System \***

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	ABSTRAL® (fentanyl) FENTANYL CITRATE (generic of Actiq®) FENTORA® (fentanyl) SUBSYS® (fentanyl)

\* Note: Clinical criteria must be met for transmucosal systems

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

**LENGTH OF AUTHORIZATIONS:**                      Dependent on diagnosis

**ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:**

Approval of epoetin alfa or darbepoetin:

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

Approval of epoetin alfa only (not darbepoetin):

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

**PDL CRITERIA:**

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

**BLOOD AGENTS: HEMATOPOIETIC AGENTS**

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

## Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors

**LENGTH OF AUTHORIZATIONS:**                      Dependent on diagnosis

**ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:**

Approval based upon diagnosis:

<b>Diagnosis</b>	<b>Approval Length</b>
Acute Myeloid Leukemia (AML)	14 days or duration of chemotherapy regimen
Malignancy at risk for febrile neutropenia or undergoing myeloablative chemotherapy prior to allogeneic or autologous bone marrow transplantation	14 days or duration of chemotherapy regimen
Myeloid Engraftment for bone marrow transplant (BMT)	1 month
Severe, chronic neutropenia with absolute neutrophil count (ANC) of less than 500/mm <sup>3</sup> and have symptoms associated with neutropenia (e.g. fever, infections, oropharyngeal ulcers).	1 month
Hematopoietic radiation injury syndrome	1 month

**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-COLONY STIMULATING FACTORS**

<b>CLINICAL PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
GRANIX® (tbo-filgrastim) NEUPOGEN® (filgrastim)	FULPHILA™ (pegfilgrastim-jmdb) LEUKINE® (sargramostim) NEULASTA® (pegfilgrastim) NIVESTYM™ (filgrastim) ZARXIO® (filgrastim-sndz)

## Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors

**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 previously, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

**ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:**

Approval based upon diagnosis and dosage appropriate to weight, patient pharmacokinetic factors, and presence of inhibitors.

**PDL CRITERIA:**

1. Is there any reason the patient cannot use 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 had a demonstrated trial of one preferred medication?
3. For extended half-life factors, prescribing physician attests that patient is not a suitable candidate for treatment with shorter-acting half-life product.
4. If Rebinyn<sup>®</sup> is requested, confirmation that it is not being used for routine prophylaxis

**BLOOD AGENTS: FACTOR VII CONCENTRATE**

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
NOVOSEVEN (factor VIIa recombinant)	

**BLOOD AGENTS: FACTOR VIII**

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ADVATE <sup>®</sup> (factor VIII recombinant)	ADYNOVATE <sup>®</sup> (factor VIII recombinant) †
HEMOFIL M <sup>®</sup> (factor VIII human)	AFSTYLA <sup>®</sup> (factor VIII recombinant)
KOATE <sup>®</sup> (factor VIII human)	ELOCTATE <sup>®</sup> (factor VIII recombinant, fc fusion protein) †
KOGENATE FS <sup>®</sup> (factor VIII recombinant)	JIVI <sup>®</sup> (factor VIII recombinant, pegylated-aucl) †
MONOCLATE-P <sup>®</sup> (factor VIII human)	KOVALTRY <sup>®</sup> (factor VIII recombinant)
NOVOEIGHT <sup>®</sup> (factor VIII recombinant)	OBIZUR <sup>®</sup> (factor VIII recombinant, porcine sequence)
NUWIQ <sup>®</sup> (factor VIII recombinant)	
RECOMBINATE <sup>®</sup> (factor VIII recombinant)	
XYNTHA <sup>®</sup> (factor VIII recombinant)	

†Denotes long half-life factor

### BLOOD AGENTS: FACTOR IX

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALPHANINE SD <sup>®</sup> (factor IX human) ALPROLIX <sup>®</sup> (factor IX recombinant) † BENEFIX <sup>®</sup> (factor IX recombinant) IXINITY <sup>®</sup> (factor IX recombinant) MONONINE <sup>®</sup> (factor IX human) PROFILNINE <sup>®</sup> (factor IX complex human) RIXUBIS <sup>®</sup> (factor IX recombinant)	BEBULIN <sup>®</sup> (factor IX complex human) IDELVION <sup>®</sup> (factor IX recombinant)† REBINYN <sup>®</sup> (factor IX recombinant)†

†Denotes long half-life factor

### BLOOD AGENTS: ANTI-INHIBITOR COAGULATION COMPLEX

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
FEIBA <sup>®</sup> (anti-inhibitor coagulant complex)	

### BLOOD AGENTS: VON WILLEBRAND FACTOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
WILATE <sup>®</sup> (factor VIII/Von Willebrand factor human)	VONVENDI <sup>®</sup> (Von Willebrand factor recombinant)

### BLOOD AGENTS: VON WILLEBRAND FACTOR/FACTOR VIII

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALPHANATE <sup>®</sup> (factor VIII/Von Willebrand factor human) HUMATE-P <sup>®</sup> (factor VIII/Von Willebrand factor human)	

### ADDITIONAL CRITERIA FOR EMICIZUMAB-KXWH (HEMLIBRA<sup>®</sup>)

- Indicated for hemophilia A (factor VIII deficiency):
  - Patient has factor VIII inhibitors
  - Patient will not use concurrently with activated prothrombin complex concentrate (aPCC)
  - Dose does not exceed 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks, followed by 1.5 mg/kg once weekly.

### MONOCLONAL MODIFIED IMMUNOGLOBULIN G4 ANTIBODY\*

CLINICAL PA REQUIRED "PREFERRED"	REQUIRED "NON-PREFERRED"
HEMLIBRA <sup>®</sup> (emicizumab-kxwh)	

\* Note: Clinical criteria must be met



# 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 "NON-PREFERRED"
ENOXAPARIN (generic of Lovenox®)	FONDAPARINUX (generic of Arixtra®) FRAGMIN® (dalteparin)

## Blood Formation, Coagulation, and Thrombosis Agents: Oral Anticoagulants

**LENGTH OF AUTHORIZATIONS:** 1 year

**INDICATIONS:**

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

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

**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 in the same class not requiring prior approval?

**BLOOD AGENTS: ORAL ANTICOAGULANTS**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
ELIQUIS® (apixaban) PRADAXA® (dabigatran) WARFARIN (generic of Coumadin®) XARELTO® (rivaroxaban) *	SAVAYSA® (edoxaban)

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

**BLOOD AGENTS: PLATELET AGGREGATION INHIBITORS**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
ASPIRIN BRILINTA® (ticagrelor) CLOPIDOGREL (generic of Plavix®) PRASUGREL (generic of Effient®)	YOSPRALA™ (aspirin/omeprazole) ZONTIVITY® (vorapaxar sulfate)

## Cardiovascular Agents: Angina, Hypertension & Heart Failure

**LENGTH OF AUTHORIZATIONS:** 1 year

**CHRONIC STABLE ANGINA STEP THERAPY:**

Ranolazine (Ranexa<sup>®</sup>) may be approved if there has been a therapeutic failure to no less than a one-month trial of a beta blocker, a diltiazem product, AND a nitrate (excluding sublingual nitroglycerin), or contraindications to these agents exist.

**HYPERPOLARIZATION-ACTIVATED CYCLE NUCLEOTIDE-GATED CHANNEL INHIBITOR CLINICAL PRIOR AUTHORIZATION CRITERIA:**

Ivabradine (Corlanor<sup>®</sup>) may be approved if all of the following are met:

1. Diagnosis of stable, symptomatic heart failure, and
2. Left ventricular ejection fraction less than or equal to 35%, and
3. Resting heart rate 70 bpm or higher, and
4. Patient in sinus rhythm, and
5. Heart failure symptoms persisting with maximally tolerated doses of beta blockers, or patient has a contraindication to beta blocker therapy.

**ARB/ NEPRILYSIN INHIBITOR COMBINATION CLINICAL PRIOR AUTHORIZATION CRITERIA:**

Valsartan/sacubitril (Entresto<sup>™</sup>) may be approved if all of the following are met:

1. Diagnosis of chronic heart failure (NYHA Class II-IV), and
2. Age greater than or equal to 18 years, and
3. Left ventricular ejection fraction less than or equal to 40%

### **OTHER APPROVAL CRITERIA:**

1. Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include:
  - Allergy to medications not requiring prior approval
  - Contraindication to or drug interaction with preferred medications
  - History of unacceptable/toxic side effects to preferred medications
2. The requested medication may be approved if both of the following are true:
  - If there has been a therapeutic failure to no less than a one-month trial of at least one medication within the same class not requiring prior approval
  - The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated
3. If there is a specific indication for a medication requiring prior approval, for which medications not requiring prior approval are not indicated, then may approve the requested medication. This medication should be reviewed for need at each request for reauthorization.

### **CHRONIC STABLE ANGINA**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
Generic beta blockers Generic calcium channel blockers Generic nitrates	RANEXA <sup>®</sup> (ranolazine)

### **ACE INHIBITORS**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
BENAZEPRIL (generic of Lotensin <sup>®</sup> ) CAPTOPRIL (generic of Capoten <sup>®</sup> ) ENALAPRIL (generic of Vasotec <sup>®</sup> ) EPANED <sup>®</sup> (enalapril oral solution) FOSINOPRIL (generic of Monopril <sup>®</sup> ) LISINOPRIL (generic of Zestril <sup>®</sup> , Prinivil <sup>®</sup> ) MOEXIPRIL (generic of Univasc <sup>®</sup> ) PERINDOPRIL ERBUMINE (generic of Aceon <sup>®</sup> ) QUINAPRIL (generic of Accupril <sup>®</sup> ) RAMIPRIL (generic of Altace <sup>®</sup> ) TRANDOLAPRIL (generic of Mavik <sup>®</sup> )	QBRELIS <sup>™</sup> (lisinopril oral solution)

### **ACE INHIBITORS/CCB COMBINATION**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
AMLODIPINE/BENAZEPRIL (generic of Lotrel <sup>®</sup> ) VERAPAMIL/TRANDOLAPRIL (generic of Tarka <sup>®</sup> )	PRESTALIA <sup>®</sup> (perindopril-amlodipine tablet)

### **ACE INHIBITORS/DIURETIC COMBINATION**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
BENAZEPRIL/HCTZ (generic of Lotensin HCT <sup>®</sup> ) CAPTOPRIL/HCTZ (generic of Capozide <sup>®</sup> ) ENALAPRIL/HCTZ (generic of Vasoretic <sup>®</sup> ) FOSINOPRIL/HCTZ (generic of Monopril HCT <sup>®</sup> ) LISINOPRIL/HCTZ (generic of Zestoretic <sup>®</sup> , Prinzide <sup>®</sup> ) MOEXIPRIL/HCTZ (generic of Uniretic <sup>®</sup> ) QUINAPRIL/HCTZ (generic of Accuretic <sup>®</sup> )	

**ALDOSTERONE ANTAGONIST**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SPIRONOLACTONE (generic of Aldactone®)	CAROSPIR® SUSP (spironolactone)

**ALPHA-BETA BLOCKERS**

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

**ANGIOTENSIN II RECEPTOR ANTAGONISTS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
IRBESARTAN (generic of Avapro®)	CANDESARTAN (generic of Atacand®)
LOSARTAN (generic of Cozaar®)	EDARBI® (azilsartan)
VALSARTAN (generic of Diovan®)	EPROSARTAN (generic of Teveten®)
	OLMESARTAN (generic of Benicar®)
	TELMISARTAN (generic of Micardis®)

**ANGIOTENSIN II RECEPTOR ANTAGONISTS/ DIURETIC COMBINATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
IRBESARTAN-HCTZ (generic of Avalide®)	CANDESARTAN/HCTZ (generic of Atacand HCT®)
LOSARTAN-HCTZ (generic of Hyzaar®)	EDARBYCLOR™ (azilsartan/ chlorthalidone)
VALSARTAN/HCTZ (generic of Diovan HCT®)	OLMESARTAN/HCTZ (generic of Benicar HCT®)
	TELMISARTAN/HCTZ (generic of Micardis HCT®)
	TEVETEN HCT® (eprosartan/HCTZ)

**ANGIOTENSIN II RECEPTOR ANTAGONISTS/ BETA BLOCKERS COMBINATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Trial of Preferred Beta blocker and a preferred angiotensin II receptor antagonist	BYVALSON™ (nebivolol/valsartan)

**ANGIOTENSIN II RECEPTOR ANTAGONISTS/ CALCIUM CHANNEL BLOCKER COMBINATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AMLODIPINE/OLMESARTAN (generic of Azor®)	
AMLODIPINE/ TELMISARTAN (generic of Twynsta®)	
AMLODIPINE/VALSARTAN (generic of Exforge®)	

**ANGIOTENSIN II RECEPTOR ANTAGONISTS/ CALCIUM CHANNEL BLOCKER/DIURETIC COMBINATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AMLODIPINE/ VALSARTAN /HCTZ (generic of Exforge® HCT)	OLMESARTAN/AMLODIPINE/ HCTZ (generic of Tribenzor®)

**ANGIOTENSIN II RECEPTOR ANTAGONIST/ NEPRILYSIN INHIBITOR COMBINATION\***

CLINICAL PA REQUIRED "PREFERRED"	NO PA REQUIRED "NON-PREFERRED"
ENTRESTO™ (valsartan/sacubitril)	

\* Note: Clinical criteria must be met

## BETA BLOCKERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ACEBUTOLOL (generic of Sectral®)	BYSTOLIC® (nebivolol)
ATENOLOL (generic of Tenormin®)	INNOPRAN XL® (propranolol)
BETAXOLOL (generic of Kerlone®)	KAPSPARGO SPRINKLE™ (metoprolol succinate)
BISOPROLOL FUMARATE (generic of Zebeta®)	LEVATOL® (penbutolol)
METOPROLOL SUCCINATE (generic of Toprol XL®)	SOTYLIZE® oral solution (sotalol)
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®)	

## BETA-BLOCKERS/DIURETIC COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
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 "NON-PREFERRED"
AMLODIPINE (generic of Norvasc®)	ISRADIPINE (generic of Dynacirc®)
FELODIPINE (generic of Plendil®)	NIMODIPINE (generic of Nimotop®)*
NICARDIPINE (generic of Cardene®)	NYMALIZE oral solution (nimodipine) *
NIFEDIPINE ER (generic of Procardia XL®, Adalat CC®)	NISOLDIPINE (generic of Sular®)
NIFEDIPINE IMMEDIATE RELEASE (generic of Procardia®)	

\* 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 "NON-PREFERRED"
DILTIAZEM (generic of Cardizem®)	DILTIAZEM 24H ER tablet (generic of Cardizem LA®)
DILTIAZEM ER (generic of Cardizem CD® q24h, Tiazac®)	VERAPAMIL ER PM (generic of Verelan PM®)
DILTIAZEM SR (generic of Cardizem SR® q12h)	
VERAPAMIL (Generic of Calan®)	
VERAPAMIL SR/ER (Generic of Calan SR®, Isoptin SR®, Verelan®)	

## DIRECT RENIN INHIBITORS\* and combinations

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Trial of any one preferred anti-hypertensive agent	TEKTURNA® (aliskiren)
	TEKTURNA HCT® (aliskiren/HCTZ)

## HYPERPOLARIZATION-ACTIVATED CYCLE NUCLEOTIDE-GATED CHANNEL INHIBITOR\*

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	CORLANOR® (ivabradine)

\* Note: Clinical criteria must be met

## 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 "NON-PREFERRED"
AMIODARONE (generic of Cordarone®) 200mg DISOPYRAMIDE PHOSPHATE IR (generic of Norpace®) DISOPYRAMIDE PHOSPHATE ER (generic of Norpace® CR) FLECAINIDE (generic of Tambocor®) MEXILITINE PROPAFENONE (generic of Rythmol®) PROPAFENONE ER (generic of Rythmol SR®) QUINIDINE GLUCONATE ER QUINIDINE SULFATE QUINIDINE SULFATE ER TIKOSYN® (dofetilide)	AMIODARONE 100mg, 400mg MULTAQ® (dronedarone)





Baseline lab results are required, and approvals will be limited to 12 weeks initially and then annually thereafter. Subsequent approvals will require additional levels being done to assess changes.

- Lipid profile required at week 8 for HeFH or ASCVD
- Lipid profile required after 3<sup>rd</sup> dose for HoFH

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH): must meet both:

1. Total Cholesterol > 290 mg/dL or LDL-C > 190 mg/dL and one of the following:
  - Presence of tendon xanthomas or 1<sup>st</sup> or 2<sup>nd</sup> degree relative with documented tendon xanthomas, MI at age ≤ 60 years or TC > 290 mg/dL **OR**
  - Confirmation of diagnosis by gene or receptor testing
2. Unable to reach goal LDL-C with maximally tolerated dose of statin
  - A trial of 2 or more statins, at least one must be atorvastatin

Diagnosis of Clinical Atherosclerotic Cardiovascular Disease: must meet both:

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA or PVD of atherosclerotic origin and
2. Unable to reach goal LDL-C with maximally tolerated dose of statin
  - A trial of 2 or more statins, at least one must be atorvastatin

Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH): must meet all:

1. Total cholesterol and LDL-C >600 mg/dL and TG within reference range or confirmation of diagnosis by gene or receptor testing
2. Unable to reach goal LDL-C with maximally tolerated dose of statin plus ezetimibe (Zetia<sup>®</sup>) 10 mg daily with at least 1 other concurrently administered lipid lowering agent
3. Age ≥ 13 years old

#### CARDIOVASCULAR AGENTS: LIPOTROPICS – BILE ACID SEQUESTRANTS

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

#### CARDIOVASCULAR AGENTS: LIPOTROPICS - STATINS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATORVASTATIN (generic of Lipitor <sup>®</sup> ) LOVASTATIN (generic of Mevacor <sup>®</sup> ) PRAVASTATIN (generic of Pravachol <sup>®</sup> ) ROSUVASTATIN (generic of Crestor <sup>®</sup> ) SIMVASTATIN (generic of Zocor <sup>®</sup> )	ALTOPREV <sup>®</sup> (lovastatin) FLUVASTATIN (generic of Lescol <sup>®</sup> , Lescol XL <sup>®</sup> ) LIVALO <sup>®</sup> (pitavastatin) ZYPITAMAG <sup>™</sup> (pitavastatin)

**CARDIOVASCULAR AGENTS: LIPOTROPICS - FIBRIC ACID DERIVATIVES**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
GEMFIBROZIL (generic of Lopid®) FENOFIBRATE TABLETS (generic of Tricor®)	ANTARA® (fenofibrate) FENOFIBRATE CAPSULES (generic of Lipofen®) FENOFIBRIC ACID (generic of Trilipix®) LOFIBRA® (fenofibrate) TRIGLIDE® (fenofibrate)

**CARDIOVASCULAR AGENTS: LIPOTROPICS - NICOTINIC ACID DERIVATIVES**

<b>NO PA REQUIRED PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
NIACIN NIASPAN® (niacin)	NIACIN ER (generic of Niaspan®)

**CARDIOVASCULAR AGENTS: LIPOTROPICS - OMEGA-3 POLYUNSATURATED FATTY ACIDS**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
OTC FISH OIL 340-1000, 360-1200, 435-880, 500-1000	OMEGA 3-ACID ETHYL ESTERS (generic of Lovaza®) VASCEPA® (icosapent ethyl)

**CARDIOVASCULAR AGENTS: LIPOTROPICS - SELECTIVE CHOLESTEROL ABSORPTION INHIBITORS**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
	EZETIMIBE (generic of ZETIA®) VYTORIN® (simvastatin/ezetimibe)

**CARDIOVASCULAR AGENTS: LIPOTROPIC/HYPERTENSION COMBINATION**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
Inability to utilize agents separately	AMLODIPINE/ATORVASTATIN (generic of Caduet®)

**CARDIOVASCULAR AGENTS: LIPOTROPICS PCSK9 INHIBITORS\***

<b>CLINICAL PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
	PRALUENT® (alirocumab) REPATHA™ (evolocumab)

\* Note: Clinical criteria must be met

## 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 (e.g. new to Medicaid), will be approved for PA after prescriber contact.

1. Patients diagnosed as World Health Organization Group 3 or more severe may be approved for inhalation or intravenous agents
2. Riociguat (Adempas®) may be approved for patients with persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) who have had surgical treatment or have inoperable CTEPH.
3. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
  - Allergy to medications not requiring prior approval
  - Contraindication to all medications not requiring prior approval
  - History of unacceptable/toxic side effects to medications not requiring prior approval
4. Has the patient failed a therapeutic trial of at least one month with at least two medications, one of which is a Phosphodiesterase-5 Inhibitor, not requiring prior approval?

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

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ADCIRCA® (tadalafil) REVATIO® oral solution (sildenafil) (no PA for age under 6) SILDENAFIL (generic of Revatio®)	REVATIO® oral solution (sildenafil) (PA required for age over 6)

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

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

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

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

### **CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION, Prostacyclin Receptor Agonist, Oral**

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	UPTRAVI® (selexipag)

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

<b>CLINICAL PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
	ADEMPAS <sup>®</sup> (riociguat)

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

<b>CLINICAL PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
	TYVASO <sup>®</sup> (treprostinil) VENTAVIS <sup>®</sup> (iloprost)

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

<b>CLINICAL PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
	EPOPROSTENOL (generic of Flolan <sup>®</sup> ) REMODULIN <sup>®</sup> (treprostinil sodium) VELETRI <sup>®</sup> (epoprostenol)

## 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 (e.g. new to Medicaid), will be approved for PA after prescriber contact.

**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
- Has the patient failed a therapeutic trial of at least one month with at least two 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”	PA REQUIRED “NON-PREFERRED”
DONEPEZIL 5mg, 10mg (generic of Aricept®) DONEPEZIL ODT (generic of Aricept® ODT) EXELON® patch (rivastigmine) GALANTAMINE (generic of Razadyne™) GALANTAMINE ER (generic of Razadyne™ ER) MEMANTINE tablets (generic of Namenda®) RIVASTIGMINE capsules (generic of Exelon®)	DONEPEZIL 23mg (generic of Aricept® 23mg) GALANTAMINE 4mg/ml solution (generic of Razadyne™) MEMANTINE 10mg/5ml solution (generic of Namenda®) NAMENDA XR® (memantine ER) NAMZARIC® (memantine ER/donepezil) RIVASTIGMINE patch (generic of Exelon® patch)

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

**LENGTH OF AUTHORIZATIONS:** 6 months

**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
  - Has the patient failed a therapeutic trial of at least two weeks with at least two medications not requiring prior approval

**CLINICAL CONSIDERATIONS FOR PROPHYLAXIS:**

Prior Authorization will not be given for prophylaxis unless the patient has exhausted or has contraindications to at least three other “controller” migraine medications (i.e., beta-blockers, neuroleptics, tricyclic antidepressants, and/or serotonin-norepinephrine)

**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 – CALCITONIN GENE-RELATED PEPTIDE RECEPTOR ANTAGONIST**

CLINICAL PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
	AIMOVIG™ (erenumab-aooe)† AJOVY™ (fremanezumab-vfrm)* EMGALITY™ (galcanezumab)

†Initial Dose is limited to 70mg once monthly; may request dose increase if 70mg fails to provide adequate relief over two consecutive months.

\* 675mg doses (quarterly administration) will not be authorized until patient has demonstrated efficacy of medication for at least 90 days

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

**Onset**

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
RIZATRIPTAN tablets (generic of Maxalt®) RIZATRIPTAN ODT (generic of Maxalt-MLT®) SUMATRIPTAN tablets, nasal spray, injection (generic of Imitrex®)	ALMOTRIPTAN (generic of Axert®) ONZETRA™ XSAIL™ (sumatriptan) ELETRIPTAN (generic of Relpax®) SUMAVEL DOSEPRO® (sumatriptan) ZOLMITRIPTAN (generic of Zomig®) ZOLMITRIPTAN ODT (generic of Zomig ZMT®) ZOMIG® NASAL SPRAY (zolmitriptan) ZECUITY® (sumatriptan)

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

**Onset**

NO PA REQUIRED “NON-PREFERRED”	PA REQUIRED “NON-PREFERRED”
NARATRIPTAN (generic of Amerge®)	FROVA® (frovatriptan)

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

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
	TREXIMET® (sumatriptan/naproxen)



## 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 (e.g. new to Medicaid), will be approved for PA after prescriber contact.

**OTHER APPROVAL CRITERIA:**

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

**ANTICONVULSANTS: CARBAMAZEPINE DERIVATIVES**

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

**ANTICONVULSANTS: FIRST GENERATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
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) SYMPAZAN™ (clobazam film)

## ANTICONVULSANTS: SECOND GENERATION

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

## ANTICONVULSANTS: THIRD GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
VIMPAT® (lacosamide)	APTIOM® (eslicarbazepine acetate)

## ADDITIONAL CRITERIA FOR CANNABINOID

### LENGTH OF AUTHORIZATIONS:

Initial Authorization 6 months  
Subsequent Authorizations 1 year

- Patient has a diagnosis of Lennox-Gastaut syndrome or Dravet syndrome
- Patient has trialed and failed (inadequate seizure control or intolerance) 3 prior anticonvulsant therapies for one month each (**Note:** not required to be met for a diagnosis of Dravet Syndrome)
- Prescriber has obtained serum transaminases (ALT and AST) and total bilirubin levels prior to starting therapy
- Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)

## ANTICONVULSANTS: CANNABINOID

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
EPIDIOLEX® (cannabidiol)†	

†Excluded from Grandfathering. Re-authorization requires documented reduction in average number of seizure days per month (measured monthly or quarterly).

## 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 (e.g. new to Medicaid), 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 "NON-PREFERRED"
CITALOPRAM solution (generic of Celexa®) CITALOPRAM tablets (generic of Celexa®) ESCITALOPRAM (generic of Lexapro®) FLUOXETINE HCL capsules, tablets (generic of Prozac®) FLUOXETINE HCL solution (generic of Prozac®) FLUVOXAMINE MALEATE (generic of Luvox®) PAROXETINE HCL (generic of Paxil®) SERTRALINE (generic of Zoloft®) SERTRALINE oral concentrate (generic of Zoloft®)	BRISDELLE® (paroxetine mesylate) FLUOXETINE ER (generic of Prozac Weekly®) FLUVOXAMINE ER (generic of Luvox CR®) PAROXETINE ER (generic of Paxil CR®) PEXEVA® (paroxetine mesylate)

**ANTIDEPRESSANTS: SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRI)\***

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DULOXETINE 20mg, 30mg, 60mg (generic of Cymbalta®) VENLAFAXINE (generic of Effexor®) VENLAFAXINE ER capsule (generic of Effexor XR®)	DESVENLAFAXINE ER (generic of Khedezla ER®) DESVENLAFAXINE ER tablet DESVENLAFAXINE FUMARATE DULOXETINE 40mg (generic of Irenka®) FETZIMA® (levomilnacipran) PRISTIQ® (desvenlafaxine) VENLAFAXINE ER tablet

**ANTIDEPRESSANTS: NOREPINEPHRINE AND DOPAMINE REUPTAKE INHIBITORS (NDRI)\***

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

**ANTIDEPRESSANTS: ALPHA-2 RECEPTOR ANTAGONISTS\***

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

**ANTIDEPRESSANTS: MONOAMINE OXIDASE INHIBITORS (MAOI)\***

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	EMSAM® patches (selegiline) MARPLAN® (isocarboxazid) PHENELZINE (generic of NARDIL®) TRANLYCYPROMINE (generic of Parnate®)

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

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

**ANTIDEPRESSANTS: SSRI - SEROTONIN PARTIAL AGONIST\***

NO PA REQUIRED "PREFERRED GENERIC"	PA REQUIRED "NON-PREFERRED"
	TRINTELLIX® (vortioxetine) VIIBRYD® (vilazodone)

## Central Nervous System (CNS) Agents: Atypical Antipsychotics

### **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 (e.g. new to Medicaid), will be approved for PA after prescriber contact.

### **PSYCHIATRIST EXEMPTION:**

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

**LENGTH OF AUTHORIZATIONS:** 1 year

### **STEP THERAPY:** all agents listed

1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than fourteen days of at least one preferred product
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 or step therapy products

### **ADDITIONAL CRITERIA FOR AGENTS FOR PARKINSON'S DISEASE PSYCHOSIS (NUPLAZID™):**

Pimavanserin (Nuplazid™) may be approved if all of the following are met:

1. Patient is diagnosed with Parkinson's disease and has psychotic symptoms (hallucinations and/or delusions) that started after Parkinson's diagnosis
2. These psychotic symptoms are severe and frequent enough to warrant treatment with an antipsychotic AND are not related to dementia or delirium
3. The patient's other medications for Parkinson's Disease have been reduce or adjusted and psychotic symptoms remain OR patient is unable to tolerate adjustment of these other medications
4. There has been inadequate clinical response to a trial of no less than fourteen days of either quetiapine or clozapine OR these therapies cannot be utilized
5. An exemption to the criteria will be granted for prescribing doctors with a neurology specialty to a patient with a history of an anti-Parkinson's agent

**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
- Abilify Mycite® will be restricted to prescribing by a psychiatrist following an aripiprazole serum blood level draw indicating need for further investigation of adherence.

**ANTIPSYCHOTICS, SECOND GENERATION, ORAL**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
ARIPIPRAZOLE tablet (generic of Abilify®) OLANZAPINE (generic of Zyprexa®) QUETIAPINE (generic of Seroquel®) RISPERIDONE (generic of Risperdal®) ZIPRASIDONE (generic of Geodon®)	LATUDA® (lurasidone) QUETIAPINE ER (generic of Seroquel XR®)	ABILIFY DISCMELT® (aripiprazole) ABILIFY MYCITE® (aripiprazole with IEM) ARIPIPRAZOLE solution (generic of Abilify®) CLOZAPINE (generic of Clozaril®) FANAPT® (iloperidone) FAZACLO® (clozapine) OLANZAPINE ODT (generic of Zyprexa® Zydis) PALIPERIDONE (generic of INVEGA®) REXULTI® (brexpiprazole) SAPHRIS® (asenapine) VERSACLOZ® (clozapine oral suspension) VRAYLAR™ (cariprazine capsule)

**ANTIPSYCHOTICS, SECOND GENERATION, AGENTS FOR PARKISON’S PSYCHOSIS\***

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
		NUPLAZID™ (pimavanserin)

\* Note: Clinical criteria must be met

**ANTIPSYCHOTICS, SECOND GENERATION and SSRI COMBINATION**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
	A trial of no less than fourteen days each of at least two preferred second generation oral antipsychotics or step therapy products	FLUOXETINE/OLANZAPINE (generic of Symbyax®)

**ANTIPSYCHOTICS, SECOND GENERATION, LONG-ACTING INJECTABLES +**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
ABILIFY MAINTENA® (aripiprazole) ARISTADA™ (aripiprazole lauroxil) ARISTADA™ Initio (aripiprazole lauroxil) INVEGA SUSTENNA® (paliperidone) INVEGA TRINZA® (paliperidone) PERSERIS™ (risperidone) RISPERDAL CONSTA® (risperidone) ZYPREXA RELPREVV® (olanzapine)	

+ Long-Acting Injectable Antipsychotics may be billed by the pharmacy if they are not dispensed directly to the patient. If not administered by the pharmacist, 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.

## 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
  - Preferred long-acting non-solid dosage forms may be approved for a patient over age 12 if the patient is unable to swallow pills
  - Has the patient failed a therapeutic trial of at least two weeks with at least two medications not requiring prior approval

### CNS AGENTS: ATTENTION DEFICIT HYPERACTIVITY DISORDER AGENTS – SHORT ACTING

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

### CNS AGENTS: ATTENTION DEFICIT HYPERACTIVITY DISORDER AGENTS – LONG ACTING, SOLID DOSAGE FORMS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATOMOXETINE (generic of Strattera®) APTENSIO XR™ (methylphenidate) CONCERTA® (methylphenidate ER) DEXTROAMPHETAMINE-AMPHETAMINE XR (generic of Adderall XR®) DEXTROAMPHETAMINE SA (generic of Dexedrine® spansule) FOCALIN® XR (dexmethylphenidate) GUANFACINE ER (generic of Intuniv®) VYVANSE® (lisdexamfetamine)	CLONIDINE ER (generic of Kapvay®) DEXMETHYLPHENIDATE ER (generic of Focalin XR®) METHYLPHENIDATE ER (generic of Metadate® ER, Methylin® ER, Ritalin SR®) METHYLPHENIDATE ER (generic of Concerta®)† METHYLPHENIDATE LA (generic of Metadate® CD, Ritalin® LA) MYDAYIS™ (amphetamine-dextroamphetamine ER)

†Members on METHYLPHENIDATE ER (generic of Concerta®) will be grandfathered on therapy through June 30th, 2019



**CNS AGENTS: ATTENTION DEFICIT HYPERACTIVITY DISORDER AGENTS – LONG ACTING, NON-SOLID DOSAGE FORMS**

<b>CLINICAL PA REQUIRED “PREFERRED”</b>	<b>PA REQUIRED “NON-PREFERRED”</b>
<p>QUILLICHEW™ ER (methylphenidate tablet, chewable, extended release) (no PA for age 12 or under)</p> <p>QUILLIVANT XR® suspension (methylphenidate) (no PA for age 12 or under)</p> <p>VYVANSE® chewable (lisdexamfetamine)</p>	<p>ADZENYS™ XR-ODT, Susp (amphetamine tablet, ODT)</p> <p>COTEMPLA XR-ODT™ (methylphenidate, ODT)</p> <p>DAYTRANA® (methylphenidate)</p> <p>DYANAVEL™ XR (amphetamine ER oral suspension)</p> <p>QUILLICHEW™ ER (methylphenidate tablet, chewable, extended release) (PA required for age over 12)</p> <p>QUILLIVANT XR® suspension (methylphenidate) (PA required for age over 12)</p>

## Central Nervous System (CNS) Agents: Fibromyalgia Agents

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

### CNS AGENTS: FIBROMYALGIA AGENTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
LYRICA® (pregabalin) SAVELLA® (milnacipran)	

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

**LENGTH OF AUTHORIZATIONS:**

No PA required for short-acting, buprenorphine containing, oral agents  
 30 days for initial authorization of injectable  
 Not to exceed 6 months for subsequent authorizations of injectable; length depending upon patient status and compliance to treatment plan

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

**BUPRENORPHINE SAFETY EDITS AND DRUG UTILIZATION REVIEW CRITERIA:**

In favor of eliminating prior authorization for all forms of oral short acting buprenorphine-containing products, ODM and the Managed Care Plans will implement safety edits and a retrospective drug utilization review process for all brand and generic forms of oral short acting buprenorphine-containing products.

**CENTRAL NERVOUS SYSTEM AGENTS: MEDICATION ASSISTED TREATMENT OF OPIOID ADDICTION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BUNAVAIL® buccal film (buprenorphine/naloxone) BUPRENORPHINE SL tablets (generic of Subutex®) BUPRENORPHINE/NALOXONE SL tablets SUBOXONE® SL film (buprenorphine/naloxone) ZUSOLV® SL tablets (buprenorphine/naloxone)	

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

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

+ Vivitrol may be billed by the pharmacy if it is not dispensed directly to the patient. If not administered by the pharmacist, 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.

**Criteria for SUBCUTANEOUS BUPRENORPHINE INJECTION (SUBLOCADE™)**

- Indicated for opioid dependence:
  - Patient ≥18 years
  - Currently established on a dose of at least 8mg of oral buprenorphine for at least 7 days
  - Medical justification supports inability to continue to use oral formulation
  - Urine drug screen result obtained within the last 7 days with no illicit substances or non-prescribed therapies detected (initially). Subsequent authorization dependent upon UDS results indicating compliance to treatment plan.
  - Patient is actively participating in counseling. Prescriber should retain documentation of meeting attendance and submit with PA request.
  - The physician has reviewed OARRS within 7 days prior to the PA request. If the patient has received controlled substances since the previous authorization:
    - The physician has coordinated with all other prescribers of controlled substances and has determined that the patient should continue treatment; and
    - If the patient has received other controlled substances for 12 or more continuous weeks, the physician has consulted with a board-certified addictionologist or addiction psychiatrist who has recommended the patient receive substance abuse treatment (consultation not necessary if the prescriber is a board-certified addictionologist or addiction psychiatrist).
  - Dose does not exceed 300mg per month in the first two months and 100mg thereafter. Providers may request a maintenance dose increase beyond 100mg by submitting additional clinical documentation supporting the need for a higher dose
- Re-authorization requires adherence to specified treatment plan inclusive of adherence to counseling, OARRS and urine drug screening requirements

**SUBCUTANEOUS BUPRENORPHINE INJECTION \* +**

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SUBLOCADE™ (buprenorphine)	

\* Note: Clinical criteria must be met

+ Sublocade™ may be billed by the pharmacy if it is not dispensed directly to the patient. If not administered at the pharmacy, the drug must be released only to the administering provider or administering provider's staff, following all applicable regulations.

# Central Nervous System (CNS) Agents: Multiple Sclerosis

## DISEASE MODIFYING AGENTS

**LENGTH OF AUTHORIZATIONS:** 1 year

**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 (e.g. new to Medicaid), will be approved for PA after prescriber contact.

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 "NON-PREFERRED"
AVONEX® (interferon beta-1a) BETASERON® (interferon beta-1b) COPAXONE® (glatiramer) REBIF® (interferon beta-1a)	EXTAVIA® (interferon beta-1b) GLATOPA™ (glatiramer) PLEGRIDY® (peginterferon beta-1a)

**CNS AGENTS: MULTIPLE SCLEROSIS DISEASE MODIFYING AGENTS, ORAL**

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

## 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 "PREFERRED"
	AMPYRA® (dalfampridine)

\* Note: Clinical criteria must be met

# 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 two medications not requiring prior authorization

**CNS AGENTS: NEUROPATHIC PAIN**

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

## 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 "NON-PREFERRED"
ENTACAPONE (generic of Comtan®)	TASMAR® (tolcapone) TOLCAPONE (generic of Tasmar®)

### **PARKINSON'S AGENTS – DOPAMINERGIC AGENTS, ORAL**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AMANTADINE	GOCOVRI™ (amantadine er) OSMOLEX ER™ (amantadine er)

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

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

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

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

### **PARKINSON'S AGENTS – DOPAMINERGIC AGENTS, ORAL**

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

## Central Nervous System (CNS) Agents: Restless Legs Syndrome

**LENGTH OF AUTHORIZATIONS:** 1 year

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

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

### **ADDITIONAL INFORMATION**

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

### **CNS AGENTS: RESTLESS LEGS SYNDROME AGENTS**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
PRAMIPEXOLE (generic of Mirapex®)	HORIZANT® (gabapentin enacarbil)
ROPINIROLE (generic of Requip®)	NEUPRO® patch (rotigotine)



## 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<sup>®</sup>) or triazolam (Halcion<sup>®</sup>)

### CNS AGENTS: SEDATIVE-HYPNOTICS, NON-BARBITURATE

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

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

\* Note: Clinical criteria must be met for Soma<sup>®</sup>/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.

## Central Nervous System (CNS) Agents: Smoking Deterrents

### CNS AGENTS: SMOKING DETERRENTS – NICOTINE REPLACEMENT

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

## Endocrine Agents: Androgens

**LENGTH OF AUTHORIZATIONS:** 1 year

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

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

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

### **ADDITIONAL INFORMATION**

Limited to males >/= 18 years

### **ORAL AGENTS: ANDROGENS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	ANDROXY® (fluoxymesterone) METHYLTESTOSTERONE (generic of Android®, Methitest®, Testred®) STRIANT (testosterone)

### **INJECTABLE AGENTS: ANDROGENS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DEPO-TESTOSTERONE (testosterone cypionate) TESTOSTERONE CYPIONATE (generic of Depo-Testosterone) TESTOSTERONE ENANTHATE (generic of Delatestryl)	XYOSTED™ (testosterone enanthate)

### **TOPICAL AGENTS: ANDROGENS**

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

## 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. A therapeutic failure is the inability to reach A1C goal after at least 120 days of current regimen with documented adherence and appropriate dose escalation.

### **ADDITIONAL CLINICAL CRITERIA FOR INHALED INSULIN:**

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

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

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
HUMALOG <sup>®</sup> vial and pen (insulin lispro)	AFREZZA <sup>®</sup> inhalation powder (insulin human)
HUMULIN R <sup>®</sup> (insulin regular human)	ADMELOG <sup>®</sup> (insulin lispro) <sup>†</sup>
HUMULIN R 500-U <sup>®</sup> vial and pen (insulin regular human)	APIDRA <sup>®</sup> vial and pen (insulin glulisine)
NOVOLIN R <sup>®</sup> (insulin regular human)	FIASP <sup>®</sup> (insulin aspart)
NOVOLOG <sup>®</sup> vial and pen (insulin aspart)	

<sup>†</sup>Due to the nature of the drug, allergy or therapeutic failure to Humalog is insufficient to justify use

### **ENDOCRINE AGENTS: DIABETES - INSULINS - Intermediate Acting**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
HUMALOG MIX 50/50, 75/25 <sup>®</sup> vial and pen (insulin lispro protamine/insulin lispro)	
HUMULIN 70/30 <sup>®</sup> vial and pen (insulin NPH/regular)	
HUMULIN N <sup>®</sup> vial and pen (insulin NPH)	
NOVOLIN 70/30 <sup>®</sup> (insulin NPH/regular)	
NOVOLIN N <sup>®</sup> (insulin NPH)	
NOVOLOG MIX 70/30 <sup>®</sup> vial and pen (insulin aspart protamine/ insulin aspart)	

### **ENDOCRINE AGENTS: DIABETES - INSULINS - Long Acting**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
LANTUS <sup>®</sup> vial and pen (insulin glargine)	BASAGLAR <sup>®</sup> (insulin glargine) <sup>†</sup>
LEVEMIR <sup>®</sup> vial and pen (insulin detemir)	TOUJEO <sup>®</sup> (insulin glargine)
	TRESIBA FLEXTOUCH <sup>®</sup> (insulin degludec)

<sup>†</sup>Due to the nature of the drug, allergy or therapeutic failure to Lantus is insufficient to justify use

## Endocrine Agents: Diabetes – Non-Insulin

**LENGTH OF AUTHORIZATIONS:** 1 year

**STEP THERAPY:**

1. For a drug requiring step therapy, there must have been inadequate clinical response to metformin products (either single-ingredient or in a sulfonylurea/ metformin or TZD/metformin combination), including a trial of no less than three months of at least one preferred metformin product
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including metformin and a trial of no less than three months of at least one preferred or step therapy product

Note: Inadequate clinical response is the inability to reach A1C goal after at least 90 days of recommended therapeutic dose with documented adherence to the regimen.

**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, BIGUANIDES**

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
METFORMIN (generic of Glucophage®) METFORMIN ER (generic of Glucophage XR®)		GLUCOPHAGE®, GLUCOPHAGE® XR (metformin) METFORMIN ER (generic of Fortamet®) METFORMIN SOLUTION (generic of Riomet®)

**DIABETES – ORAL HYPOGLYCEMICS, BIGUANIDE/SULFONYLUREA COMBO**

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
GLIPIZIDE/METFORMIN (generic of Metaglip®) GLYBURIDE/METFORMIN (generic of Glucovance®)		METAGLIP® (glipizide/metformin) GLUCOVANCE® (glyburide/metformin)

**DIABETES – ORAL HYPOGLYCEMICS, TZD / BIGUANIDE COMBO**

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PIOGLITAZONE/ METFORMIN (generic of ActoPlus Met®)	ACTOPLUS MET XR® (pioglitazone/metformin)	

**DIABETES – DIPEPTIDYL PEPTIDASE-4 INHIBITOR**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
	JANUVIA® (sitagliptin) TRADJENTA™ (linagliptin)	ALOGLIPTIN (generic of Nesina®) NESINA® (alogliptin) ONGLYZA® (saxagliptin)

**DIABETES – DIPEPTIDYL PEPTIDASE-4 INHIBITOR COMBINATIONS**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
	JANUMET™ (sitagliptin/ metformin) JANUMET XR™ (sitagliptin/ metformin) JENTADUETO™ (linagliptin/ metformin)	JENTADUETO® XR (linagliptin/ metformin) ALOGLIPTIN/METFORMIN (generic of Kazano®) KAZANO® (alogliptin/metformin) KOMBIGLYZE XR® (saxagliptin/metformin)

**DIABETES – ORAL HYPOGLYCEMICS, TZD / DPP-4 COMBINATION**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
		PIOGLITAZONE/ALOGLIPTIN (generic of Oseni®) OSENI® (pioglitazone/alogliptin)

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

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
	FARXIGA® (dapagliflozin) JARDIANCE® (empagliflozin)	INVOKANA® (canagliflozin) STEGLATRO™ (ertugliflozin)

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

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
	SYNJARDY® (empagliflozin and metformin) SYNJARDY® XR (empagliflozin and metformin)	GLYXAMBI® (empagliflozin/ linagliptin) INVOKAMET® (canagliflozin/ metformin) INVOKAMET® XR (canagliflozin/ metformin) SEGLUROMET™ (ertugliflozin/metformin) XIGDUO XR® (dapagliflozin/ metformin)

**DIABETES – ORAL HYPOGLYCEMICS, SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR AND DPP-4 COMBINATIONS**

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
No less than <u>three months</u> of at least <u>one</u> preferred DPP-4 and SGLT product	QTERN® (dapagliflozin-saxagliptin) STEGLUJAN™ (ertugliflozin/sitagliptin)

**DIABETES – ORAL HYPOGLYCEMICS, ALPHA-GLUCOSIDASE INHIBITORS**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
ACARBOSE (generic of Precose®)	GLYSET® (miglitol)	MIGLITOL (generic of Glyset®) PRECOSE® (acarbose)

**DIABETES – ORAL HYPOGLYCEMICS, MEGLITINIDES**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
NATEGLINIDE (generic of Starlix®) REPAGLINIDE (generic of Prandin®)		STARLIX® (nateglinide) PRANDIN® (repaglinide)

**DIABETES – ORAL HYPOGLYCEMICS, MEGLITINIDE/BIGUANIDE COMBO**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
REPAGLINIDE/ METFORMIN (generic of Prandimet®)		PRANDIMET® (repaglinide/ metformin)

**DIABETES – ORAL HYPOGLYCEMICS, SULFONYLUREAS SECOND GENERATION**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
GLIMEPIRIDE (generic of Amaryl®) GLIPIZIDE (generic of Glucotrol®) GLIPIZIDE ER (generic of Glucotrol XL®) GLYBURIDE (generic of Diabeta®, Micronase®) GLYBURIDE MICRONIZED (generic of Glynase PresTabs®)		AMARYL® (glimepiride) DIABETA® (glyburide) GLUCOTROL®, GLUCOTROL XL® (glipizide) GLYNASE PRESTABS® (glyburide micronized)

**DIABETES – ORAL HYPOGLYCEMICS, THIAZOLIDINEDIONES**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
PIOGLITAZONE (generic of Actos®)		ACTOS® (pioglitazone) AVANDIA® (rosiglitazone)

**DIABETES – ORAL HYPOGLYCEMICS, TZD/SULFONYLUREAS COMBO**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
		DUETACT® (glimepiride/pioglitazone) GLIMEPIRIDE/PIOGLITAZONE (generic of Duetact®)

**ENDOCRINE AGENTS: DIABETES – AMYLIN ANALOGS**

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
No less than <u>three months</u> of at least <u>one</u> preferred insulin product	SYMLIN® (pramlintide)	



**ENDOCRINE AGENTS: DIABETES –GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS**

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	BYDUREON® (exenatide) VICTOZA® (liraglutide)	ADLYXIN™ (lixisenatide) BYDUREON® BCISE (exenatide) BYETTA™ (exenatide) OZEMPIC® (semaglutide) TRULICITY® (dulaglutide)

**ENDOCRINE AGENTS: DIABETES – GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS & INSULIN COMBINATIONS**

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
		SOLIQUA™ 100/33 (insulin glargine/lixisenatide)† XULTOPHY® 100/3.6 (insulin degludec and liraglutide)†

† Request must address inability to use the individual components.

## Endocrine Agents: Estrogenic Agents

**LENGTH OF AUTHORIZATIONS:** 1 year

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

### ESTROGENS – ORAL ESTROGENS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ESTRADIOL (generic of Estrace®) ESTROPIPATE MENEST® (esterified estrogens) PREMARIN® (conjugated estrogens)	FEMTRACE® (estradiol)

### ESTROGENS – ORAL ESTROGEN/PROGESTERONE COMB

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

### ESTROGENS & ESTROGEN AGONIST/ANTAGONIST COMB

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

### ENDOCRINE AGENTS: ESTROGENS – TRANSDERMAL ESTROGENS

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

### ESTROGENS – TRANSDERMAL ESTROGEN/ PROGESTERONE COMB

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

### ESTROGENS – VAGINAL ESTROGENS

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

## Endocrine Agents: Progestin Agents

**LENGTH OF AUTHORIZATIONS:** 1 year

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 or drug interaction with medications not requiring prior approval
  - History of unacceptable/toxic side effects to medications not requiring prior approval
4. 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

### PROGESTIN – ORAL PROGESTINS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
MEDROXYPROGESTERONE ACETATE TABLET NORETHINDRONE ACETATE MEGESTROL ACETATE SUSP (generic of Megace®) PROGESTERONE	

### PROGESTIN – INJECTABLE PROGESTINS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
HYDROXYPROGESTERONE CAPROATE (generic of Delalutin®) HYDROXYPROGESTERONE CAPROATE (generic of Makena®) MAKENA® (hydroxyprogesterone caproate)	PROGESTERONE IN OIL

## 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 (AAACE does not recommend GH for post-transplantation).
4. SHOX – Short Stature Homeobox Gene deficiency – 1 year approval:
  - 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
- Small for gestational age (intrauterine growth restriction) – 1 year approval:
- a. Birth weight or length is  $\geq 2$  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  $\geq 2$  SD below the mean for age and sex; and
  - c. Age is no less than 24 months and no more than 48 months
5. 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 approval
  - b. Pituitary damage or genetic syndrome – 1 year approval

**GROWTH HORMONES**

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
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) ZOMACTON® vial (somatropin)

## Endocrine Agents: Osteoporosis – Bone Ossification Enhancers

**LENGTH OF AUTHORIZATIONS:** 1 year

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

### **CRITICAL INFORMATION**

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

### **ADDITIONAL CRITERIA FOR ABALOPARATIDE (TYMLOS™)**

Abaloparatide is indicated in postmenopausal women with osteoporosis at high risk for fracture.

1. Patient is female and postmenopausal
2. Diagnosis of osteoporosis
3. Trial of bisphosphonates for greater than 12 months or if bisphosphonates are contraindicated, trial of calcitonin-salmon for greater than 24 months
4. Total lifetime therapy of parathyroid hormone analogs does not exceed 2 years

### **ENDOCRINE AGENTS: OSTEOPOROSIS - BONE OSSIFICATION ENHANCERS - ORAL BIPHOSPHONATES**

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

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

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Therapeutic failure to bisphosphonate and not continuing with bisphosphonate agent	CALCITONIN-SALMON (generic of Miacalcin®) FORTICAL® (calcitonin salmon)

**ENDOCRINE AGENTS: OSTEOPOROSIS – PARATHYROID HORMONE RELATED PEPTIDE ANALOG\***

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
	TYMLOS™ (abaloparatide)

\* Note: Clinical criteria must be met

## Gastrointestinal Agents: Anti-Emetics

**LENGTH OF AUTHORIZATIONS:** 1 year

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

### GASTROINTESTINAL AGENTS: ANTI-EMETIC AGENTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
EMEND <sup>®</sup> tablets, trifold, suspension (aprepitant) ONDANSETRON tablets, solution, ODT (generic of Zofran <sup>®</sup> )	ANZEMET <sup>®</sup> (dolasetron) GRANISETRON tablet, solution (generic of Kytril <sup>®</sup> ) SANCUSO <sup>®</sup> patch (granisetron) VARUBI <sup>™</sup> (rolapitant) ZUPLENZ <sup>®</sup> film (ondansetron)

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

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



## Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) / Selected GI

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

**STEP THERAPY:** all agents listed

1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than two-week trial of at least two medications not requiring prior approval
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than two-week trial of at least two step therapy products

**ADDITIONAL INFORMATION:**

1. Patient must be 18 years or older
2. NUTRESTORE™, ZORBTIVE®, and GATTEX® require a diagnosis of short bowel syndrome (SBS) and evidence of specialized nutritional support
  - a. NUTRESTORE™ requires evidence of concurrent use of recombinant growth hormone
  - b. GATTEX® requires evidence of parenteral nutrition support at least three times per week and appropriate colonoscopy and lab assessment (bilirubin, alkaline phosphatase, lipase, and amylase) 6 months prior to initiation
  - c. Re-authorization of these therapies requires evidence of improved condition (i.e. as measured by total volume, total calories, or decreased frequency of specialized nutrition support)
3. MYTESI™ requires a diagnosis of non-infectious diarrhea and evidence of concurrent HIV antiviral therapy
  - a. MYTESI™ will be limited to no more than 2 tablets per day

### IBS WITH CONSTIPATION & CHRONIC IDIOPATHIC CONSTIPATION AGENTS

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BISACODYL (generic of Dulcolax®) CASANTHRANOL/DOCUSATE SODIUM (generic of Peri-Colace®) LACTULOSE (generic of Chronulac®) POLYETHYLENE GLYCOL (generic of Miralax®) PSYLLIUM FIBER (e.g. Konsyl®) SENNA (generic of Senokot®)	AMITIZA® capsule (lubiprostone) LINZESS™ capsule (linaclotide)	TRULANCE™ (plecanatide)

### IBS WITH DIARRHEA AGENTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DICYCLOMINE (generic of Bentyl®) DIPHENOXYLATE/ATROPINE (generic of Lomotil®) LOPERAMIDE (Maximum of 16mg per day)	ALOSETRON (generic of Lotronex®) VIBERZI™ (eluxadoline tablet) XIFAXAN® (rifaximin)

### SHORT BOWEL SYNDROME AGENTS\*

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	NUTRESTORE™ (l-glutamine) ZORBTIVE® (somatropin) GATTEX® (teduglutide)

\* Note: Clinical criteria must be met

### NON-INFECTIOUS DIARRHEA AGENTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DIPHENOXYLATE/ATROPINE (generic of Lomotil®) LOPERAMIDE (Maximum of 16mg per day)	MYTESI™ (crofelemer)

## Gastrointestinal Agents: Opioid-Induced Constipation

**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. **Step Therapy: ALL AGENTS LISTED**
  1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than two-week trial of at least two medications not requiring prior approval
  2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than two-week trial of at least two step therapy products

**ADDITIONAL INFORMATION:**

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

**GASTROINTESTINAL AGENTS: OPIOID-INDUCED CONSTIPATION AGENTS**

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BISACODYL (generic of Dulcolax®) CASANTHRANOL/DOCUSATE SODIUM (generic of Peri-Colace®) POLYETHYLENE GLYCOL (generic of Miralax®) PSYLLIUM FIBER (e.g. Konsyl®) SENNA (generic of Senokot®)	AMITIZA® capsule (lubiprostone) MOVANTIK® tablets (naloxegol)	RELISTOR® tablets and subcutaneous injection (methylnaltrexone bromide) SYMPROIC® (naldemedine)

## 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 two-week trial of at least one medication not requiring prior approval

### **GASTROINTESTINAL AGENTS: PANCREATIC ENZYMES**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CREON® (pancrelipase) ZENPEP® (pancrelipase)	PANCREAZE® (pancrelipase) PERTZYE® (pancrelipase) ULTRESA® (pancrelipase) VIOKACE® (pancrelipase)

## 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
  - Presence of a gastrostomy and/or jejunostomy tube (G-, GJ-, J-tube)
  - 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 "NON-PREFERRED"
DEXILANT <sup>®</sup> (dexlansoprazole) OMEPRAZOLE capsules (generic of Prilosec <sup>®</sup> ) NEXIUM <sup>®</sup> packets (esomeprazole) PANTOPRAZOLE (generic of Protonix <sup>®</sup> ) PROTONIX <sup>®</sup> suspension (No PA required for age 6 or under)	ACIPHEX <sup>®</sup> sprinkle capsule (rabeprazole) ESOMEPRAZOLE STRONTIUM ESOMEPRAZOLE capsules (generic of Nexium <sup>®</sup> ) LANSOPRAZOLE capsules (generic of Prevacid <sup>®</sup> ) OMEPRAZOLE tablets (generic of Prilosec OTC <sup>®</sup> ) OMEPRAZOLE/SODIUM BICARBONATE PREVACID SOLUTAB <sup>®</sup> (lansoprazole ODT) PRILOSEC <sup>®</sup> suspension (omeprazole) PROTONIX <sup>®</sup> suspension (PA required for age over 6) RABEPRAZOLE (generic of Aciphex <sup>®</sup> )

## Gastrointestinal Agents: Ulcerative Colitis Agents

**LENGTH OF AUTHORIZATIONS:**      12 months

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 products.

**OTHER APPROVAL CRITERIA:**

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

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

**ADDITIONAL INFORMATION**

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

**GASTROINTESTINAL AGENTS: ULCERATIVE COLITIS AGENTS - ORAL**

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

**GASTROINTESTINAL AGENTS: ULCERATIVE COLITIS AGENTS - RECTAL**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CANASA® suppositories (mesalamine) MESALAMINE enema (generic of Rowasa® and SRowasa®)	MESALAMINE enema kit (generic for Rowasa® kit) UCERIS® foam (budesonide)

## 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 and have a therapeutic failure to no less than a one-month trial on at least one alpha-1 adrenergic blocker and a three-month trial of finasteride.

**BENIGN PROSTATIC HYPERPLASIA AGENTS – ALPHA-1 ADRENERGIC BLOCKERS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
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 "NON-PREFERRED"
FINASTERIDE (generic of Proscar®)	DUTASTERIDE (generic of AVODART®)

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

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	DUTASTERIDE/TAMSULOSIN (generic of JALYN®)

**BENIGN PROSTATIC HYPERPLASIA AGENTS – PHOSPHODIESTERASE TYPE 5 INHIBITORS**

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

\* Note: Clinical PA required for Cialis®. Patient must have diagnosis of benign prostatic hyperplasia and demonstrate trials of preferred products.

## Genitourinary Agents: Electrolyte Depletter Agents

**LENGTH OF AUTHORIZATIONS:** 1 year

**STEP THERAPY:**

1. For a step therapy required agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one week of at least one preferred product
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 or step therapy products

**OTHER APPROVAL CRITERIA:**

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

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

**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"	STEP THERAPY REQUIRED "PREFERRED"	NON-PREFERRED "NON-PREFERRED"
CALCIUM ACETATE (generic of PhosLo® gelcap) CALCIUM CARBONATE PHOSLYRA® solution (calcium acetate)	MAGNEBIND® (calcium carbonate/magnesium carbonate/folic acid) RENAGEL® (sevelamer)	AURYXIA® (ferric citrate) tablets ELIPHOS® (calcium acetate) LANTHANUM CARBONATE (generic of Fosrenol®) RENVELA® (sevelamer) VELPHORO® (sucroferric oxyhydroxide)



## Genitourinary Agents: Urinary Antispasmodics

**LENGTH OF AUTHORIZATIONS:** 1 year

1. Patients under age 18 may be approved for tolterodine SR or Gelnique® if there was inadequate clinical response to a trial of no less than one month of oxybutynin (IR or ER).
2. The requested medication may be approved if there has been a therapeutic failure to a trial of no less than two weeks of at least two medications not requiring prior approval
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
  - Contraindications to or drug interaction with medications not requiring prior approval
  - History of unacceptable/toxic side effects to medications not requiring prior approval

### GENITOURINARY AGENTS: URINARY ANTISPASMODICS

NO PA REQUIRED "PREFERRED GENERIC"	PA REQUIRED "NON-PREFERRED"
OXYBUTYNIN ER (generic of Ditropan® XL)	ENABLEX® (darifenacin)
OXYBUTYNIN syrup (generic of Ditropan®)	GELNIQUE® (oxybutynin)
OXYBUTYNIN tablets (generic of Ditropan®)	MYRBETRIQ® (mirabegron)
OXYTROL® FOR WOMEN OTC patch (oxybutynin)	TOLTERODINE (generic of Detrol®)
TOVIAZ® (fesoterodine)	TOLTERODINE SR (generic of Detrol® LA)
VESICARE® (solifenacin)	TROSPIUM (generic of Sanctura®)
	TROSPIUM ER (generic of Sanctura® XR)

## Immunomodulator Agents for Systemic Inflammatory Disease

**LENGTH OF AUTHORIZATIONS:**

Dependent on indication

**INDICATIONS:**

	Adalimumab	Etanercept	Abatacept	Anakinra	Apremilast	Baricitinib	Brodalumab	Certolizumab	Golimumab	Guselkumab	Ixekizumab	Sarilumab	Secukinumab	Tildrakizumab-asmn	Tocilizumab	Tofacitinib
Rheumatoid Arthritis	✓	✓	✓	✓		✓		✓	✓			✓			✓	✓
Juvenile Idiopathic Arthritis	✓	✓	✓												✓	
Psoriatic Arthritis	✓	✓	✓		✓			✓	✓		✓		✓			✓
Ankylosing Spondylitis	✓	✓						✓	✓				✓			
Crohn's Disease	✓							✓								
Ulcerative Colitis	✓								✓							✓
Plaque Psoriasis	✓	✓			✓		✓	✓		✓	✓		✓	✓		
Uveitis	✓															
Cryopyrin-Associated Periodic Syndrome				✓												
Cytokine Release Syndrome															✓	
Giant Cell Arteritis															✓	
Hidradenitis Suppurativa	✓															
Non-radiographic axial spondyloarthritis								✓								

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
  - Plaque Psoriasis
  - Psoriatic Arthritis
  - Polyarticular Juvenile Idiopathic Arthritis
  - Crohn's Disease
  - Ankylosing Spondylitis
  - Psoriasis
  - Uveitis
  - Cryopyrin-Associated Periodic Syndrome
  - Giant Cell Arteritis
  - Hidradenitis Suppurativa
- Diagnosis of Moderate to Severe Ulcerative Colitis (UC) (Humira, Simponi, and Xeljanz 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 or Xeljanz 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  
Xeljanz – 60 pills 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
- Step therapy: secukinumab (Cosentyx®) may be approved for labeled indications after a trial of adalimumab (Humira®) or etanercept (Enbrel®)

- For patients with a diagnosis of moderate to severe plaque psoriasis receiving phototherapy, initial authorization for Humira® or Enbrel® will only be approved if there is inadequate clinical response to at least 3 months of phototherapy.

**ANTI-INFLAMMATORY TUMOR NECROSIS FACTOR INHIBITOR**

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

**ANTI-INFLAMMATORY INTERLEUKIN RECEPTOR ANTAGONIST**

CLINICAL PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	COSENTYX™ (secukinumab)	ACTEMRA® syringe (tocilizumab) ILUMYA™ (tildrakizumab-asmn) KEVZARA® (sarilumab) KINERET® syringe (anakinra) SILIQ™ (brodalumab) TALTZ™ (ixekizumab injection) TREMFYA™ (guselkumab)

**JANUS KINASE INHIBITOR**

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	OLUMIANT® (baricitinib) XELJANZ® tablet (tofacitinib citrate) XELJANZ® XR (tofacitinib tablet, extended release)

**PHOSPHODIESTERASE-4 INHIBITOR**

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

## Infectious Disease Agents: Antibiotics – Cephalosporins

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

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
  - Allergy to medications not requiring prior approval
  - Contraindication to or drug interaction with medications not requiring prior approval
  - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
  - Note diagnosis and any culture and sensitivity reports
3. If there have been therapeutic failures to no less than a three-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

### **ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION**

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

### **CEPHALOSPORINS, FIRST GENERATION**

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

### **CEPHALOSPORINS, SECOND GENERATION**

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

### **CEPHALOSPORINS, THIRD GENERATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CEFDINIR capsules, suspension (generic of Omnicef®)	CEFTIBUTEN capsules, suspension (generic of Cedax®) CEFPODOXIME tablets, suspension (generic of Vantin®) CEFIXIME SUSP (generic for SUPRAX®) SUPRAX® (cefixime)

## 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 "NON-PREFERRED"
AZITHROMYCIN tablets and suspension (generic of Zithromax®)	ERYPED® (erythromycin ethylsuccinate)
CLARITHROMYCIN ER (generic of Biaxin XL®)	ERY-TAB® (erythromycin base)
CLARITHROMYCIN tablets and suspension (generic of Biaxin®)	ERYTHROCIN STEARATE® (erythromycin stearate)
	ERYTHROMYCIN BASE
	ERYTHROMYCIN ETHYLSUCCINATE
	ZMAX™ (azithromycin ER) for oral suspension

## 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 "NON-PREFERRED"
CIPROFLOXACIN (generic of Cipro®) CIPRO® suspension (no PA required for age 12 or under) (ciprofloxacin)	CIPROFLOXACIN suspension (PA required for age over 12) (generic of Cipro®) CIPROFLOXACIN ER (generic of Cipro®XR)

**INFECTIOUS DISEASE AGENTS: QUINOLONES, THIRD GENERATION - ORAL**

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

**INFECTIOUS DISEASE AGENTS: QUINOLONES, OTHER - ORAL**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	BAXDELA™ (delafloxacin)

## Infectious Disease Agents: Antibiotics – Inhaled

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

All products in this class require clinical prior authorization:

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

**PDL CRITERIA:**

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

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

**ADDITIONAL INFORMATION**

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

- If there has been no less than a 28-day trial of at least one preferred medication

**INFECTIOUS DISEASE AGENTS: ANTIBIOTICS - INHALED**

CLINICAL PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
BETHKIS® inhalation solution (tobramycin) KITABIS® PAK (tobramycin inhalation solution with nebulizer) TOBRAMYCIN inhalation solution-Labeler 00093 (generic of TOBI™)	TOBI™ Podhaler™ (tobramycin inhalation powder)	CAYSTON® inhalation solution (aztreonam) TOBRAMYCIN inhalation solution (generic of TOBI™)



## 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 "NON-PREFERRED"
GRIFULVIN®V tablets (griseofulvin, microsize)	ITRACONAZOLE (generic of Sporanox®)
GRISEOFULVIN suspension (generic of Grifulvin®V)	LAMISIL Granules (terbinafine)
GRIS-PEG® (griseofulvin, ultramicrosize)	ONMEL® (itraconazole)
TERBINAFINE (generic of Lamisil®)	SPORANOX® 100mg/10ml oral solution (itraconazole)

### **INFECTIOUS DISEASE AGENTS: AGENTS FOR SYSTEMIC INFECTIONS**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
FLUCONAZOLE (generic of Diflucan®)	CRESEMBA® (isavuconazonium)
FLUCONAZOLE suspension (generic of Diflucan®)	ITRACONAZOLE capsules (generic of Sporanox®)
FLUCYTOSINE (generic of Ancobon®)	NOXAFIL® (posaconazole)
KETOCONAZOLE (generic of Nizoral®)	ORAVIG® (miconazole)
	SPORANOX® 100mg/10ml oral solution (itraconazole)
	VORICONAZOLE (generic of Vfend®)
	TOLSURA (itraconazole)

## Infectious Disease Agents: Antivirals – Hepatitis C Agents

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

Is there any reason the patient cannot be changed to a medication within the same class that 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
- Member established on current therapy with prior payer (i.e. Commercial, Fee-for-Service, Managed Care Plan, etc).

### **ADDITIONAL CRITERIA FOR DAAs:**

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

#### **Step 1: Patient Readiness Evaluated**

- Patient must meet labeled age requirements for product.
- Patient must be free for 6 months from alcohol use, controlled drug abuse, and illicit drug use before consideration of therapy.
- Patient must meet kidney function as indicated in package labeling for product.
- Patient must not be concomitantly taking drugs that have significant clinical interaction as described in the prescribing information for each agent.
- Patient must agree to be adherent with office visits, lab testing, imaging, procedures and, if deemed a candidate, the HCV medication regimen. Prescribers must submit documentation demonstrating the patient attests to meet these requirements (Office notes documenting this are sufficient to meet this criteria).

## **Step 2: Clinical Assessment of Disease**

- Confirmation of chronic hepatitis C (CHC):
  - Hepatitis C Virus (HCV) antibody test reactive
  - Provide HCV RNA load measured within 90 days prior to starting DAA therapy
  - Specify the Genotype
- Document progression of disease:
  - Document the degree of liver fibrosis:
    - Liver biopsy; or
    - One radiological and one serological test
    - If cirrhosis is present, indicate whether cirrhosis is compensated or decompensated and provide the Child-Turcotte-Pugh (CTP) score.
    - Patients with decompensated cirrhosis (CTP score 7 or higher) will be approved for therapy only after consultation with a physician in a liver transplant center.
- Document that patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions
- Document any previously tried Hepatitis C treatments, dates treated, and response/outcome (patient will not be approved if any other HCV treatments have been used in the last 6 months)

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

- Must be prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist
- HCV RNA testing is required every 4 weeks
- Providers of HIV/HCV-coinfected persons should recognize and manage interactions with other antiretroviral medications (e.g. DAAs)
- Only regimens listed as recommended or alternative in the current AASLD guidance (<http://hcvguidelines.org>) will be approved with duration of approval based upon guidelines. Regimens listed as not recommended will not be approved.

## **ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION**

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

**INFECTIOUS DISEASE AGENTS: HEPATITIS C – DIRECT-ACTING ANTIVIRAL**

<b>CLINICAL PA REQUIRED “PREFERRED”†</b>	<b>PA REQUIRED “NON-PREFERRED”</b>
EPCLUSA® (sofosbuvir/velpatasvir) MAVYRET® (glecaprevir and pibrentasvir) ZEPATIER™ (elbasvir and grazoprevir tablet)	DAKLINZA™ (daclatasvir) HARVONI® (ledipasvir/sofosbuvir) tablets SOVALDI® (sofosbuvir) VOSEVI™ (sofosbuvir, velpatasvir, voxilaprevir)

†Selection of regimen will be based upon guidelines; refer to PA form for guidance.

**INFECTIOUS DISEASE AGENTS: HEPATITIS C - PEGYLATED INTERFERONS**

<b>NO PA REQUIRED “PREFERRED”</b>	<b>PA REQUIRED “NON-PREFERRED”</b>
PEGASYS® (peginterferon alfa-2a) PEG-INTRON® (peginterferon alfa-2b)	

**INFECTIOUS DISEASE AGENTS: HEPATITIS C - RIBAVIRINS**

<b>NO PA REQUIRED “PREFERRED”</b>	<b>PA REQUIRED “NON-PREFERRED”</b>
RIBAVIRIN (generic of Rebetol®)	COPEGUS® (ribavirin) MODERIBA PAK® (ribavirin) REBETOL® (ribavirin) RIBAPAK® (ribavirin) RIBASPHERE® (ribavirin) 400mg, 600mg

## 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
- 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.

### INFECTIOUS DISEASE AGENTS: ANTIVIRALS - HERPES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ACYCLOVIR (generic of Zovirax®)	FAMCICLOVIR (generic of Famvir®)
VALACYCLOVIR (generic of Valtrex®)	SITAVIG® buccal tablets (acyclovir)

## 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 (e.g. new to Medicaid), will be approved for PA after prescriber contact.

### **NIH RECOMMENDED REGIMENS – TREATMENT NAIVE PATIENTS**

#### **Integrase Strand Transfer Inhibitor-Based Regimens:**

ODM Preferred:

- Dolutegravir (Tivicay<sup>®</sup>) plus tenofovir disoproxil fumarate/emtricitabine (AI) (Truvada<sup>®</sup>)
- Elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine (AI) (Genvoya<sup>®</sup>)
- Raltegravir (Isentress<sup>®</sup>) plus tenofovir disoproxil fumarate/emtricitabine (AI) (Truvada<sup>®</sup>)
- Dolutegravir (Tivicay<sup>®</sup>) plus tenofovir alafenamide/emtricitabine (AI) (Descovy<sup>®</sup>)
- Raltegravir (Isentress<sup>®</sup>) plus tenofovir alafenamide/emtricitabine (AI) (Descovy<sup>®</sup>)
- Bictegravir/emtricitabine/tenofovir (Biktarvy<sup>®</sup>)†

†Recommended Initial Regimen based upon March 27, 2018 NIH News Release

ODM Non-Preferred/PA Required

- Dolutegravir/abacavir/lamivudine (only for patients who are HLA-B\*5701 negative) (AI) (Triumeq<sup>®</sup>)
- Elvitegravir/cobicistat/tenofovir disoproxil fumarate/emtricitabine (AI) (Stribild<sup>®</sup>)

### **OTHER APPROVAL CRITERIA:**

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

1. Allergy to medications not requiring prior approval
2. Contraindication to recommended regimens not requiring prior approval
3. History of unacceptable/toxic side effects to medications not requiring prior approval
4. Has the patient had a therapeutic trial of at least one month with at least one medication not requiring prior approval? If applicable, the request must address the inability to use the individual components.

## HIV PROTEASE INHIBITORS AND COMBINATIONS

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

## HIV NON-PEPTIDIC PROTEASE INHIBITORS AND COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PREZCOBIX <sup>®</sup> (darunavir/cobicistat) PREZISTA <sup>®</sup> (darunavir ethanolate)	APTIVUS <sup>®</sup> (tipranavir; tipranavir/vitamin E) SYMTUZA <sup>™</sup> (darunavir, cobicistat, emtricitabine, tenofovir alafenamide) †

† Request must address use of the individual components PREZCOBIX and DESCOVY

## HIV REVERSE TRANSCRIPTASE INHIBITORS, NUCLEOSIDE ANALOGS AND COMBINATIONS

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

## HIV REVERSE TRANSCRIPTASE INHIBITORS, NUCLEOTIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
VIREAD <sup>®</sup> (tenofovir disoproxil fumarate)	

## HIV REVERSE TRANSCRIPTASE INHIBITORS, NON-NUCLEOSIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SUSTIVA <sup>®</sup> (efavirenz)	EDURANT <sup>®</sup> (rilpivirine) INTELENCE <sup>®</sup> (etravirine) NEVIRAPINE ER (generic of Viramune <sup>®</sup> XR) NEVIRAPINE IR (generic of Viramune <sup>®</sup> ) PIFELTRO <sup>™</sup> (doravirine) RESCRIPTOR <sup>®</sup> (delavirdine mesylate)

## HIV INTEGRASE STRAND TRANSFER INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ISENTRISS <sup>®</sup> tablets, chewable tablet, powder packets (raltegravir potassium) TIVICAY <sup>®</sup> (dolutegravir sodium)	

## HIV CCR5 CO-RECEPTOR ANTAGONISTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	SELZENTRY <sup>®</sup> (maraviroc)

## HIV FUSION INHIBITORS

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

## HIV RTI, NUCLEOSIDE-NUCLEOTIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DESCOVI® (emtricitabine/ tenofovir alafenamide) CIMDUO™ (lamivudine/tenofovir) TRUVADA® (emtricitabine/tenofovir)	

## HIV RTI, NUCLEOSIDE-NUCLEOTIDE ANALOGS AND COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SYMFI & SYMFI LO™ (efavirenz/lamivudine/tenofovir)	DELSTRIGO™ (doravirine, lamivudine, and tenofovir disoproxil)

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

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATRIPLA® (emtricitabine/efavirenz/tenofovir) COMPLERA® (emtricitabine/rilpivirine/tenofovir) ODEFSEY® (emtricitabine/rilpivirine/tenofovir alafenamide)	

## HIV INTEGRASE INHIBITOR & RTI COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
GENVOYA® (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide)	STRIBILD® (elvitegravir/cobicistat/emtricitabine/tenofovir) TRIUMEQ® (dolutegravir/abacavir/lamivudine)†

† Request must address use of the individual components TIVICAY and EPZICOM.

## HIV INTEGRASE INHIBITOR & NUCLEOSIDE ANALOG COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BIKTARVY® (bictegravir/emtricitabine/tenofovir)	

## HIV INTEGRASE INHIBITOR & NON-NUCLEOSIDE COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	JULUCA (dolutegravir/rilpivirine)

## HIV PHARMACOKINETIC ENHANCERS (CYP3A INHIBITORS)

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



# 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.

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 products

**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"	NON-PREFERRED "NON-PREFERRED"
CILOXAN <sup>®</sup> ointment (ciprofloxacin)	BESIVANCE <sup>®</sup> drops (besifloxacin)
CIPROFLOXACIN drops (generic of Ciloxan <sup>®</sup> )	LEVOFLOXACIN drops (generic of Quixin <sup>®</sup> )
MOXEZA <sup>®</sup> (moxifloxacin)	MOXIFLOXACIN (generic of Moxeza <sup>®</sup> , Vigamox <sup>®</sup> drops)
OFLOXACIN drops (generic of Ocuflox <sup>®</sup> )	GATIFLOXACIN drops (generic of Zymaxid <sup>®</sup> )

**OPHTHALMIC AGENTS: ANTIBACTERIAL – NON-QUINOLONE**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
BACITRACIN-POLYMYXIN ointment	AZASITE <sup>®</sup> drops (azithromycin)
ERYTHROMYCIN ointment (generic of Ilotycin <sup>®</sup> )	BACITRACIN ointment
GENTAMICIN drops	GENTAMICIN ointment
NEOMYCIN/POLYMYXIN/ BACITRACIN ointment (generic of Neosporin <sup>®</sup> )	SULFACETAMIDE ointment
NEOMYCIN/POLYMYXIN/ GRAMICIDIN drops (generic of Neosporin <sup>®</sup> )	
POLYMYXIN/TRIMETHOPRIM drops (generic of Polytrim <sup>®</sup> )	
SULFACETAMIDE drops	
TOBRAMYCIN drops (generic of Tobrex <sup>®</sup> )	
TOBREX <sup>®</sup> ointment (tobramycin)	

**OPHTHALMIC AGENTS: ANTIBACTERIAL – STEROID COMBINATIONS**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
NEOMYCIN/POLYMYXIN/ BACITRACIN/ HYDROCORTISONE ointment	BLEPHAMIDE <sup>®</sup> drops, ointment (prednisolone/sulfacetamide)
NEOMYCIN/POLYMYXIN/ DEXAMETHASONE drops (generic of Maxitrol <sup>®</sup> )	NEOMYCIN/POLYMYXIN/ HYDROCORTISONE drops (generic of Cortisporin <sup>®</sup> )
NEOMYCIN/POLYMYXIN/ DEXAMETHASONE ointment (generic of Maxitrol <sup>®</sup> )	PRED-G <sup>®</sup> drops, ointment (prednisolone/ gentamicin)
SULFACETAMIDE/ PREDNISOLONE drops (generic of Vasocidin <sup>®</sup> )	TOBRADEX ST <sup>®</sup> (dexamethasone/ tobramycin)
TOBRADEX <sup>®</sup> drops, ointment (dexamethasone/tobramycin)	TOBRAMYCIN/ DEXAMETHASONE drops (generic of TobraDex <sup>®</sup> )
	ZYLET <sup>®</sup> drops (tobramycin/ loteprednol)

## 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 "NON-PREFERRED"
CROMOLYN (generic of Crolom <sup>®</sup> )	ALOCRIL <sup>®</sup> (nedocromil) ALOMIDE <sup>®</sup> (lodoxamide)

### OPHTHALMIC AGENTS: ANTIHISTAMINE/MAST CELL STABILIZERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AZELASTINE (generic of Optivar <sup>®</sup> ) KETOTIFEN (generic of Alaway <sup>®</sup> , Zaditor <sup>®</sup> ) LASTACAFT <sup>®</sup> (alcaftadine) PAZEO <sup>®</sup> (olopatadine)	BEPREVE <sup>®</sup> (bepotastine) EPINASTINE (generic of Elestat <sup>®</sup> ) EMADINE <sup>®</sup> (emedastine) OLOPATADINE (generic of Patanol <sup>®</sup> ) PATADAY <sup>™</sup> (olopatadine)

## Ophthalmic Agents: Dry Eye Treatments

**LENGTH OF AUTHORIZATIONS:** 1 year

All drugs in this class require step therapy: Patient must have a claim for an artificial tear or OTC dry eye drop 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
  - 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: Dry Eye Treatments

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
RESTASIS® trays (cyclosporine)	CEQUA™ (CYCLOSPORINE) RESTASIS® multi-dose (cyclosporine) XIIDRA™ (lifitegrast)

## Ophthalmic Agents: Glaucoma Agents

**LENGTH OF AUTHORIZATIONS:** 1 year

### **STEP THERAPY: ACROSS ALL AGENTS**

1. For a product requiring step therapy, there must have been inadequate clinical response to preferred alternatives for glaucoma, including a trial of no less than one month of at least one preferred product
2. For a non-preferred agent for glaucoma, 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 or step therapy products

### **OTHER APPROVAL CRITERIA:**

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

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

### **GLAUCOMA AGENTS – BETA BLOCKERS**

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

### **GLAUCOMA AGENTS – PROSTAGLANDIN INHIBITORS**

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	NON-PREFERRED "NON-PREFERRED"
LATANAPROST (generic of Xalatan®)	TRAVATAN®Z (travoprost)	BIMATOPROST 0.03% LUMIGAN™ 0.01% (bimatoprost) TRAVAPROST VYZULTA™ (latanoprostene bunod) XELPROS™ (LATANOPROST) ZIOPTAN® (tafluprost)

### **GLAUCOMA AGENTS – ALPHA ADRENERGIC AGONISTS/SYPATHOMIMETICS**

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

**GLAUCOMA AGENTS – CARBONIC ANHYDRASE INHIBITORS**

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

**GLAUCOMA AGENTS – COMBO BETA BLOCKER & ALPHA ADRENERGIC AGONIST**

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	NON-PREFERRED "NON-PREFERRED"
	COMBIGAN® (brimonidine/timolol)	

**GLAUCOMA AGENTS – COMBO BETA BLOCKER & CARBONIC ANHYDRASE INHIBITORS**

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

**COMBO ALPHA-ADRENERGIC AGONIST AND CARBONIC ANHYDRASE INHIBITORS**

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	NON-PREFERRED "NON-PREFERRED"
SIMBRINZA™ (brinzolamide/brimonidine)		

**GLAUCOMA AGENTS – RHO KINASE INHIBITORS**

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	NON-PREFERRED "NON-PREFERRED"
RHOPRESSA® (netarsudil)		

## 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 “NON-PREFERRED”
DICLOFENAC (generic of Voltaren®) FLURBIPROFEN (generic of Ocufen®) KETOROLAC (generic of Acular®, Acular LS®) ILEVRO® (nepafenac) NEVANAC® (nepafenac)	ACUVAIL® (ketorolac) BROMFENAC (generic of Bromday®, Xibrom®) BROMSITE™ (bromfenac) PROLENSA® (bromfenac)

## 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 "NON-PREFERRED"
CIPRO HC <sup>®</sup> suspension (ciprofloxacin with hydrocortisone)	COLY-MYCIN-S <sup>®</sup> suspension (neomycin and colistin with hydrocortisone)
CIPRODEX <sup>®</sup> suspension (ciprofloxacin with dexamethasone)	CORTISPORIN-TC <sup>®</sup> suspension (neomycin and colistin with hydrocortisone)
NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE solution (generic of Cortisporin <sup>®</sup> solution)	OTOVEL <sup>®</sup> (ciprofloxacin with fluocinolone)
NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE suspension (generic of Cortisporin <sup>®</sup> suspension)	

### OTIC AGENTS: ANTIBACTERIAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
OFLOXACIN drops (generic of Floxin Otic <sup>®</sup> )	CIPROFLOXACIN (generic of Cetraxal <sup>®</sup> )



## 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 "NON-PREFERRED"
CETIRIZINE chewable (generic of Zyrtec®) (no PA required for age 6 or under)	CETIRIZINE syrup (generic of Zyrtec®) (PA required for over age 6)
CETIRIZINE syrup (generic of Zyrtec®) (no PA required for age 6 or under)	CLARINEX® syrup (desloratadine)
CETIRIZINE tablets (generic of Zyrtec®)	CLARITIN REDITABS® 5mg (loratadine)
LORATADINE rapid dissolve (generic of Claritin® Reditabs)	DESLORATADINE ODT (generic of Clarinex®)
LORATADINE syrup (generic of Claritin® Syrup)	DESLORATADINE tablets, ODT (generic of Clarinex®)
LORATADINE tablets (generic of Claritin®)	FEXOFENADINE tablets, suspension
	LEVOCETIRIZINE (generic of Xyzal®)

### **RESPIRATORY AGENTS: ANTIHISTAMINE/DECONGESTANT COMBO: SECOND GENERATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CETIRIZINE/PSEUDOEPHEDRINE (generic of Zyrtec- D®)	CLARINEX-D 12, 24 HOUR® (desloratadine/pseudoephedrine)
LORATADINE-D (generic of Claritin-D®)	

## 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 "NON-PREFERRED"
PROAIR <sup>®</sup> HFA (albuterol) PROAIR RESPICLICK <sup>®</sup> (albuterol) PROVENTIL HFA <sup>®</sup> (albuterol) VENTOLIN HFA <sup>®</sup> (albuterol)	XOPENEX HFA <sup>®</sup> (levalbuterol)

### RESPIRATORY AGENTS: BETA-ADRENERGIC, SHORT-ACTING NEBULIZERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALBUTEROL (generic of Proventil <sup>®</sup> , Ventolin <sup>®</sup> ) 0.083% Premixed nebulizers, 0.5% Concentrated Solution) ALBUTEROL 0.42mg/ml, 0.63mg/ml (generic of Accuneb <sup>®</sup> ) (no PA required for ages 12 and under)	ALBUTEROL 0.42mg/ml, 0.63mg/ml (generic of Accuneb <sup>®</sup> ) (PA required for over age 12) LEVALBUTEROL (generic of Xopenex <sup>®</sup> )

## 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

### RESPIRATORY AGENTS: BETA-ADRENERGIC, LONG-ACTING (LABA), INHALERS

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
SEREVENT DISKUS®(salmeterol)†	ARCAPTA NEOHALER® (indacaterol)† STRIVERDI RESPIMAT® (olodaterol)

†Denotes breath actuated inhaler

### RESPIRATORY AGENTS: BETA-ADRENERGIC, LONG-ACTING (LABA), NEBULIZER SOLUTION

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
	BROVANA™ (arformoterol) PERFOROMIST® (formoterol)

**RESPIRATORY AGENTS: BETA-ADRENERGIC-STEROID COMBINATIONS (LABA/ICS)**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
ADVAIR DISKUS® (salmeterol/fluticasone)† ADVAIR® HFA (salmeterol/fluticasone) DULERA® (formoterol/mometasone) SYMBICORT® (formoterol/budesonide)	AIRDUO™ RESPICLICK® (fluticasone/salmeterol) † BREO® ELLIPTA® (fluticasone/vilanterol)†

†Denotes breath actuated inhaler

**RESPIRATORY AGENTS: BETA-ADRENERGIC-MUSCARINIC COMBINATIONS (LABA/LAMA)**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
BEVESPI AEROSPHERE™ (glycopyrrolate/ formoterol) †	ANORO™ ELLIPTA (umeclidinium/vilanterol)† STIOLTO™ (tiotropium/olodaterol) UTIBRON™ NEOHALER® (indacaterol and glycopyrrolate)†

†Denotes breath actuated inhaler

## Respiratory Agents: Chronic Obstructive Pulmonary Disease

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

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

**ADDITIONAL CRITERIA FOR ROFLUMILAST (DALIRESP®):**

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

**RESPIRATORY AGENTS: COPD ANTICHOLINERGICS (LAMA)**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATROVENT HFA® (ipratropium) IPRATROPIUM nebulizer solution IPRATROPIUM/ALBUTEROL nebulizer solution (generic of Duoneb®) SPIRIVA® Handihaler® (tiotropium)† TUDORZA® (aclidinium bromide)†	COMBIVENT Respimat® (ipratropium/albuterol) INCRUSE ELLIPTA® (umeclidinium)† LONHALA™ MAGNAIR™ (glycopyrrolate) SEEBRI™ NEOHALER® (glycopyrrolate)† SPIRIVA® Respimat® (tiotropium) YUPELRI™ (revefenacin)

†Denotes breath actuated inhaler

**RESPIRATORY AGENTS: COPD GLUCOCORTICOID-MUSCARINIC-BETA-ADRENERGIC COMBINATION**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	TRELEGY ELLIPTA (fluticasone, umeclidinium and vilanterol) †

†Denotes breath actuated inhaler

**RESPIRATORY AGENTS: PHOSPHODIESTERASE-4 INHIBITORS \***

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

\* Note: Clinical criteria must be met. Concurrent therapy with long-acting beta agonist required

## 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 "NON-PREFERRED"
EPINEPHRINE manufactured by labeler 49502 (authorized generic of EpiPen®)	EPINEPHRINE not manufactured by labeler 49502 (generic of Adrenaclick®, EpiPen®) EPIPEN® (epinephrine) EPIPEN JR® (epinephrine) SYMJEPIT™ (epinephrine)

## Respiratory Agents: Glucocorticoid Agents – Inhaled

**LENGTH OF AUTHORIZATIONS:** 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
  - Allergy to medications not requiring prior approval
  - Contraindication to or drug interaction with medications not requiring prior approval
  - History of unacceptable/toxic side effects to medications not requiring prior approval
  - Patient’s condition is clinically unstable—as defined in current guidelines in terms of oral steroid use or patient’s current symptomatology--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 “NON-PREFERRED”
FLOVENT DISKUS <sup>®†</sup> and HFA (fluticasone) PULMICORT FLEXHALER <sup>®</sup> (budesonide) <sup>†</sup>	AEROSPAN <sup>®</sup> HFA (flunisolide) ALVESCO <sup>®</sup> (ciclesonide) ARMONAIR™ RESPICLICK <sup>®</sup> (fluticasone) † ARNUITY ELLIPTA <sup>®</sup> (fluticasone furoate) <sup>†</sup> ASMANEX <sup>®</sup> HFA, Twisthaler (mometasone) QVAR <sup>®</sup> (beclomethasone)

<sup>†</sup>Denotes breath actuated inhaler

### **RESPIRATORY AGENTS: GLUCOCORTICOIDS – NEBULIZERS**

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
BUDESONIDE nebulizer solution (generic of Pulmicort <sup>®</sup> ) (no PA required for age 6 or under)	BUDESONIDE nebulizer solution (generic of Pulmicort <sup>®</sup> ) (PA required for over age 6)

## Respiratory Agents: Hereditary Angioedema

**LENGTH OF AUTHORIZATIONS:** 12 months

All products in this class require clinical prior authorization:

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

**PDL CRITERIA:**

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

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

**ADDITIONAL INFORMATION**

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

- If there has been one episode of angioedema during use of a preferred medication

**RESPIRATORY AGENTS: HEREDITARY ANGIOEDEMA**

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CINRYZE® (C1 esterase inhibitor, plasma derived) HAEGARDA® (C1 esterase inhibitor, plasma derived)	BERINERT® (C1 esterase inhibitor, plasma derived) FIRAZYR® (icatibant acetate) KALBITOR® (ecallantide) RUCONEST® (C1 esterase inhibitor, recombinant) TAKHZYRO™ (lanadelumab-flyo)



## 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 "NON-PREFERRED"
MONTELUKAST tablets, chewable tablets, granules (generic of Singulair®)	ZILEUTON extended-release (generic of Zyflo CR®)
ZAFIRLUKAST (generic of Accolate®)	ZYFLO® (zileuton)

## Respiratory Agents: Nasal Preparations

**LENGTH OF AUTHORIZATIONS:** 1 year

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 or step therapy products

**OTHER APPROVAL CRITERIA:**

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

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

**RESPIRATORY AGENTS: NASAL PREPARATIONS - GLUCOCORTICOIDS**

NO PA REQUIRED "PREFERRED"	NON-PREFERRED "NON-PREFERRED"
FLUNISOLIDE FLONASE OTC® (fluticasone) FLUTICASONE (generic of Flonase®)	BECONASE®AQ (beclomethasone) BUDESONIDE (generic of Rhinocort Aqua®) DYMISTA® (fluticasone/azelastine) MOMETASONE (generic of Nasonex®) OMNARIS® (ciclesonide) QNASL® (beclomethasone) VERAMYST™ (fluticasone furoate) XHANCE™ (fluticasone) ZETONNA® (ciclesonide)

**RESPIRATORY AGENTS: NASAL PREPARATIONS - ANTIHISTAMINES**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AZELASTINE (generic of Astelin®, Astepro®) OLOPATADINE (generic of Patanase®)	

**RESPIRATORY AGENTS: NASAL PREPARATIONS - ANTICHOLINERGICS**

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

## 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 "NON-PREFERRED"
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®)	CLINDACIN® Pak (clindamycin/skin cleanser kit) CLINDAMYCIN foam (generic of Evoclin®) CLINDAMYCIN pledgets (generic of Cleocin T®) ERYTHROMYCIN pads (generic of Ery Pads®)

**ACNE PREPARATIONS – OTHER PRODUCTS**

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

### BENZOYL PEROXIDE AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CLINDAMYCIN-BENZOYL PEROXIDE gel (generic of Benzaclin <sup>®</sup> , Duac <sup>®</sup> ) BENZOYL PEROXIDE cleanser (generic of Oscion <sup>®</sup> , Triaz <sup>®</sup> ) BENZOYL PEROXIDE gel (generic of Benzac AC <sup>®</sup> , Brevoxyl <sup>®</sup> , Desquam-X <sup>®</sup> , Panoxyl <sup>®</sup> ) BENZOYL PEROXIDE wash (generic of Benzac AC <sup>®</sup> , Benzac W <sup>®</sup> , Brevoxyl <sup>®</sup> , Desquam-X <sup>®</sup> , Pacnex <sup>®</sup> ) ERYTHROMYCIN-BENZOYL PEROXIDE gel (generic of Benzamycin <sup>®</sup> ) NEUAC <sup>®</sup> gel (clindamycin-benzoyl peroxide) PANOXYL <sup>®</sup> 10% foam, wash (benzoyl peroxide)	ACANYA <sup>®</sup> (clindamycin-benzoyl peroxide) BENZOYL PEROXIDE foam (generic of Benzefoam <sup>®</sup> ) ONEXTON <sup>™</sup> gel (clindamycin-benzoyl peroxide)

### RETINOID AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DIFFERIN <sup>®</sup> cream, gel, lotion (adapalene) TAZORAC <sup>®</sup> cream, gel (tazarotene) TRETINOIN cream, gel (generic of Retin-A <sup>®</sup> ) TRETINOIN micro gel (generic of Retin-A <sup>®</sup> micro)	ADAPALENE cream, gel (generic of Differin <sup>®</sup> ) ALTRENO <sup>™</sup> lotion (tretinoin) ATRALIN <sup>®</sup> gel (tretinoin) ADAPALENE/BENZOYL PEROXIDE gel (generic of EPIDUO <sup>®</sup> ) FABIOR <sup>®</sup> foam (adapalene) PLIXDA <sup>™</sup> pad (adapalene) CLINDAMYCIN/TRETINOIN (generic of VELTIN <sup>®</sup> ) ZIANA <sup>®</sup> gel (clindamycin/tretinoin)

### SODIUM SULFACETAMIDE AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SODIUM SULFACETAMIDE lotion (generic of Klaron <sup>®</sup> ) SODIUM SULFACETAMIDE-SULFUR wash (generic of Avar <sup>®</sup> cleanser, Clenia <sup>®</sup> foaming wash, Plexion <sup>®</sup> cleanser, Rosac <sup>®</sup> wash)	SODIUM SULFAETAMIDE pads (generic of AVAR, AVAR LS) OVACE PLUS <sup>®</sup> (sodium sulfacetamide) SODIUM SULFACETAMIDE-SULFUR cream, gel SULFACETAMIDE SODIUM-SULFUR topical suspension

## 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 "NON-PREFERRED"
CICLOPIROX cream, gel, topical suspension, shampoo (generic of Loprox <sup>®</sup> )	CICLOPIROX kit (generic of CNL <sup>®</sup> Nail lacquer kit)
CICLOPIROX solution (generic of Penlac <sup>®</sup> )	ERTACZO <sup>®</sup> (sertaconazole)
CLOTRIMAZOLE (generic of Lotrimin <sup>®</sup> )	EXELDERM <sup>®</sup> (sulconazole)
CLOTRIMAZOLE/BETAMETHASONE (generic of Lotrisone <sup>®</sup> )	JUBLIA <sup>®</sup> solution (efinaconazole)
ECONAZOLE (generic of Spectazole <sup>®</sup> )	KERYDIN <sup>®</sup> solution (tavaborole)
KETOCONAZOLE cream & shampoo (generic of Kuric <sup>®</sup> , Nizoral <sup>®</sup> )	KETOCONAZOLE foam (generic of Extina <sup>®</sup> )
MICONAZOLE	LUZU <sup>®</sup> (luliconazole)
NYSTATIN	MENTAX <sup>®</sup> (butenafine)
NYSTATIN/TRIAMCINOLONE	NAFTIFINE CREAM
TERBINAFINE (generic of Lamisil <sup>®</sup> )	NAFTIN <sup>®</sup> GEL (naftifine)
TOLNAFTATE (generic of Tinactin <sup>®</sup> )	OXICONAZOLE (generic of OXISTAT <sup>®</sup> )
	PEDIADERM AF <sup>®</sup> cream (nystatin)
	VUSION <sup>®</sup> ointment (miconazole/zinc)

## 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 6 months of age and older
- Package labeling does not list age for permethrin or piperonyl butoxide-pyrethrins

### **ANTI-PARASITICS, TREATMENT OF SCABIES**

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
PERMETHRIN cream (generic of Elimite®)	EURAX® cream, lotion (crothamiton)

### **ANTI-PARASITICS, TREATMENT OF LICE**

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
LICE kit [piperonyl butoxide-pyrethrins shampoo, comb, permethrin home spray] (generic of Rid® complete kit) NATROBA® (spinosad) PERMETHRIN lotion (generic of Nix® cream rinse) PIPERONYL BUTOXIDE-PYRETHRINS lotion PIPERONYL BUTOXIDE-PYRETHRINS shampoo (generic of Rid® shampoo) SKLICE® lotion (ivermectin)	MALATHION lotion (generic of Ovide®) SPINOSAD (generic of Natroba®)



**TOPICAL AGENTS: CORTICOSTEROIDS – HIGH POTENCY**

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

**TOPICAL AGENTS: CORTICOSTEROIDS – VERY HIGH POTENCY**

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



## 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% and Dupixent® are indicated in adults only

**TOPICAL IMMUNOMODULATORS**

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ELIDEL® * (pimecrolimus) TACROLIMUS (generic of Protopic®) *	EUCRISA™ (crisaborole)*

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

**ADDITIONAL CRITERIA FOR DUPILUMAB (DUIXENT®)**

- Indicated for moderate to severe atopic dermatitis if:
  - Patient has minimum body surface area (BSA) involvement of at least 10%
  - Prescribed by or in consultation with a dermatologist or allergist/immunologist
  - Patient is 18 years of age or older
  - Patient has had inadequate response or contraindication to two of the following: topical corticosteroids, topical calcineurin inhibitors [e.g. Elidel®], or topical PDE-4 inhibitors [e.g. Eucrisa™]
- Initial authorization is limited to 16 weeks with re-authorization of up to 1 year granted following demonstration of improvement in patient condition with therapy (e.g. reduced BSA affected).

**ANTI-INFLAMMATORY INTERLEUKIN RECEPTOR ANTAGONIST\***

<b>STEP THERAPY REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
	DUPIXENT® (dupilumab)

\* Note: Clinical criteria must be met