Ohio Medicaid

Pharmacy Benefit Management Program

DRAFT

Preferred Drug List

Unified Preferred Drug List

Effective January 1, 2020

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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 30 day trial of at least two non-gastroprotective NSAID medications	365 days
Gastroprotective	no less than a 30 day trial of at least two non-gastroprotective NSAID medications.	365 days
Gastroprotective	patient is undergoing surgical or other medical procedures that may predispose them to potential bleeding complications.	60 days
Gastroprotective	patient is being treated for H. pylori.	30 days
Transdermal/Topical	diclofenac solution: no less than a 30 day trial of at least one preferred topical NSAID medications within the past 180 days	90 days

PDL CRITERIA:

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-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 30 day trial of at least two non-gastroprotective NSAID medications
- GASTROPROTECTIVE NSAIDS:
  - no less than a 30 day trial of at least two non-gastroprotective NSAID medications. **OR**

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- 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 30 day trial of at least one preferred topical NSAID medications within the past 180 days

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) IBUPROFEN Tablets and Susp (generic of Motrin®) INDOMETHACIN (generic of Indocin®) KETOROLAC MECLOFENAMATE SODIUM MEFENAMIC ACID (generic of Ponstel®) MELOXICAM (generic of Mobic®) NABUMETONE NAPROXEN NAPROXEN SUSP (no PA age <12) OXAPROZIN (generic of Daypro®) PIROXICAM (generic of Feldene®) SULINDAC	FENOPROFEN KETOPROFEN NAPRELAN (naproxen) NAPROXEN CR, DR NAPROXEN SUSP (PA required age ≥12) QMIIZ ODT™ (meloxicam) TIVORBEX® (indomethacin) TOLMETIN 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"
DICLOFENAC 1% (generic of VOLTAREN® gel)	DICLOFENAC 1.5% topical solution (generic of Pennsaid®) FLECTOR® patch (diclofenac epolamine) PENNSAID® 2% solution (diclofenac sodium)

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Analgesic Agents: Gout

LENGTH OF AUTHORIZATIONS: 365 days

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 maximum allopurinol dose, or intolerance/contraindication to allopurinol.
- Lesinurad will be approved when target serum uric acid levels (<6mg/dL) are not achieved on appropriate dose of xanithine 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 tablet 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) (180 day 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 tablets (generic of Colcrys®)	COLCHICINE capsules (generic of Mitigare®)

* Colchicine quantity limit 6/claim for acute gout, 60/30 days for chronic gout after trial on xanthine oxidase inhibitor, 120/30 days for FMF

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Analgesic Agents: Opioids

LENGTH OF AUTHORIZATIONS: For the course of therapy, up to 180 days

- There must have been inadequate clinical response to preferred alternatives, including a trial of no less than 7 days 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
- Patients receiving short-acting opioids for certain conditions are exempt from these requirements: 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 will exempt patients from these requirements, for example:
    - If patient is newly eligible for Medicaid and there is no prior claims data
    - If patient was on a higher dose in the hospital
- To exceed acute opioid limits patient must have:
    - Trialed and failed non-pharmacologic treatments and/or non-opioid analgesics ineffective or contraindicated
    - Diagnosis code must be submitted and should be for somatic type pain
    - Benefits and risks of opioid therapy have been discussed with patient (attestation documented on prior authorization form)
    - Prescriber has checked OARRS (attestation documented on prior authorization form)
    - Length of authorization: UP TO 90 days, depending on the indication, previous member utilization, and requested length of therapy (could be more restrictive)

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ADDITIONAL CRITERIA FOR TRANSMUCOSAL FENTANYL:

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

ALL LONG-ACTING OPIOIDS REQUIRE PRIOR AUTHORIZATION:

- Initial request (90 day approval)
  - Catastrophic injury or cancer pain does not require additional documentation (documentation should be provided as part of prior authorization form)
  - 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 submitted and treatment plan includes requirements for random urine screens
    - Opioid contract required to be in place and should be submitted with prior authorization form
    - Documented failure of both non-opioid pharmacologic and non-pharmacologic treatments
    - History of short-acting opioids for >/= 60 days
    - Cumulative dose </= 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 results reviewed and concerns addressed, no serious adverse outcomes observed
- 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

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ANALGESIC AGENTS: OPIOIDS – Long-Acting Oral
ALL LONG-ACTING OPIOIDS REQUIRE CLINICAL PRIOR AUTHORIZATION

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Extended Release Buprenorphine Products	
	BELBUCA™ (Buprenorphine buccal film)
Extended Release Hydrocodone Products	
	HYSINGLA ER® (hydrocodone) ZOHYDRO ER® (hydrocodone)
Extended Release Morphine Products	
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®)
Extended Release Oxycodone Products	
	OXYCODONE ER (generic of Oxycontin®) OXYCONTIN® (oxycodone) XARTEMIS XR® (oxycodone/ acetaminophen) XTAMPZA® ER (oxycodone)
Extended Release Tramadol Products	
	CONZIP® (tramadol) TRAMADOL ER (generic of Ryzolt ER®, Ultram ER®)
Extended Release Oxymorphone Products	
	OPANA® ER tablets (oxymorphone abuse-deterrent) OXYMORPHONE HCL ER tablets (generic of Opana® ER non-abuse-deterrent)
Extended Release Hydromorphone Products	
	HYDROMORPHONE ER (generic of Exalgo® ER)
Extended Release Tapentadol Products	
	NUCYNTA® ER (tapentadol)
Methadone Products	
	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

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BUPRENORPHINE patch (generic for Butrans®)	FENTANYL PATCH (generic of Duragesic®) FENTANYL patch 37.5mg/hr, 62.5mg/hr, 87.5mg/hr

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

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*

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

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ANALGESIC AGENTS: OPIOIDS – Short-Acting Combination and tramadol

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

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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

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Blood Formation, Coagulation, and Thrombosis Agents: Hematopoietic Agents

LENGTH OF AUTHORIZATIONS: Dependent on diagnosis

ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:

Approval of epoetin alfa or darbepoetin:

Diagnosis	Hemoglobin Level	Approval Length
Anemia due to chronic renal failure, patient on dialysis	<=11	365 days
Anemia due to chronic renal failure, patient not on dialysis	<=10	365 days
Chemotherapy-induced anemia	<=10	90 days
Anemia in myelodysplastic syndrome	<=11	180 days

Approval of epoetin alfa only (not darbepoetin):

Diagnosis	Hemoglobin Level	Approval Length
Autologous blood donation, patient will require blood transfusions	>10, <=13	30 days
Anemia of prematurity, age <=6 months	N/A	42 days
Anemia associated with chronic inflammatory disorders (e.g., rheumatoid arthritis)	<=11	180 days
Anemia associated with ribavirin combination therapy in hepatitis C-infected patient	<=11	180 days
Anemia in zidovudine-treated HIV-infected patients	<=11	180 days

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 14 days with preferred medications?

BLOOD AGENTS: HEMATOPOIETIC AGENTS

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

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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:

Diagnosis	Approval Length
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)	30 days
Severe, chronic neutropenia with absolute neutrophil count (ANC) of less than 500/mm^3 and have symptoms associated with neutropenia (e.g. fever, infections, oropharyngeal ulcers).	30 days
Hematopoietic radiation injury syndrome	30 days

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 14 days with preferred medications?

BLOOD AGENTS: HEMATOPOIETIC AGENTS-COLONY STIMULATING FACTORS

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

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Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors

LENGTH OF AUTHORIZATIONS: 365 days

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 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® 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® (factor VIII recombinant)	ADYNOVATE® (factor VIII recombinant) †
HEMOFIL M® (factor VIII human)	AFSTYLA® (factor VIII recombinant)
KOATE® (factor VIII human)	ELOCTATE® (factor VIII recombinant, fc fusion protein) †
KOGENATE FS® (factor VIII recombinant)	JIVI® (factor VIII recombinant, pegylated-aucl) †
MONOCLATE-P® (factor VIII human)	KOVALTRY® (factor VIII recombinant)
NOVOEIGHT® (factor VIII recombinant)	OBIZUR® (factor VIII recombinant, porcine sequence)
NUWIQ® (factor VIII recombinant)	
RECOMBINATE® (factor VIII recombinant)	
XYNTHA® (factor VIII recombinant)	

†Denotes long half-life factor

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BLOOD AGENTS: FACTOR IX

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

†Denotes long half-life factor

BLOOD AGENTS: ANTI-INHIBITOR COAGULATION COMPLEX

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
FEIBA® (anti-inhibitor coagulant complex)	

BLOOD AGENTS: VON WILLEBRAND FACTOR

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

BLOOD AGENTS: VON WILLEBRAND FACTOR/FACTOR VIII

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

ADDITIONAL CRITERIA FOR EMICIZUMAB-KXWH (HEMLIBRA®)

- Indicated for hemophilia A (factor VIII deficiency):
  - Patient has factor VIII inhibitors or hemophilia A without inhibitors with documented failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level previous history of inhibitors) after a trial of prophylactic factor VIII replacement products.
  - 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® (emicizumab-kxwh)	

* Note: Clinical criteria must be met

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

LENGTH OF AUTHORIZATIONS: Varies based on criteria below

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

DURATION OF THERAPY LIMIT: 35 days

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

Is there any reason the patient cannot be changed to oral warfarin? Acceptable reasons include:

- patients with cancer (approved up to 180 days),
- pregnant women (approved up to 280 days), or
- patients unable to take warfarin (approved up to 180 days).

BLOOD AGENTS: HEPARIN-RELATED PREPARATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ENOXAPARIN (generic of Lovenox®)	FONDAPARINUX (generic of Arixtra®) FRAGMIN® (dalteparin)

DRAFT

Blood Formation, Coagulation, and Thrombosis Agents: Oral Anticoagulants

LENGTH OF AUTHORIZATIONS: 365 days

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

DRAFT

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 14 days with one medication in the same class not requiring prior approval?

BLOOD AGENTS: ORAL ANTICOAGULANTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
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; XARELTO® 2.5mg requires concurrent use of aspirin via a point-of-sale check

BLOOD AGENTS: PLATELET AGGREGATION INHIBITORS

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

DRAFT

Cardiovascular Agents: Angina, Hypertension & Heart Failure

LENGTH OF AUTHORIZATIONS: 365 days

CHRONIC STABLE ANGINA STEP THERAPY:
Ranolazine (Ranexa®) may be approved if there has been a therapeutic failure to no less than a 30 day 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®) 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™) 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%

DRAFT

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 30 day trial of at least two medication within the same class not requiring prior approval
   - The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated
3. If there is a specific indication for a medication requiring prior approval, for which medications not requiring prior approval are not indicated, then may approve the requested medication. This medication should be reviewed for need at each request for reauthorization.

CHRONIC STABLE ANGINA

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "NON-PREFERRED"
Generic beta blockers Generic calcium channel blockers Generic nitrates	RANOLAZINE (generic of Ranexa®)

ACE INHIBITORS

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

ACE INHIBITORS/CCB COMBINATION

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

ACE INHIBITORS/DIURETIC COMBINATION

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

DRAFT

ALDOSTERONE ANTAGONIST

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

ALPHA-BETA BLOCKERS

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

ANGIOTENSIN II RECEPTOR ANTAGONISTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
IRBESARTAN (generic of Avapro®) LOSARTAN (generic of Cozaar®) VALSARTAN (generic of Diovan®)	CANDESARTAN (generic of Atacand®) EDARBI® (azilsartan) 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®) LOSARTAN-HCTZ (generic of Hyzaar®) VALSARTAN/HCTZ (generic of Diovan HCT®)	CANDESARTAN/HCTZ (generic of Atacand HCT®) EDARBYCLOR™ (azilsartan/ chlorthalidone) 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 angiotesnsin 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)	OLMESARAN/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

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BETA BLOCKERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ACEBUTOLOL (generic of Sectral®) ATENOLOL (generic of Tenormin®) BETAXOLOL (generic of Kerlone®) BISOPROLOL FUMARATE (generic of Zebeta®) METOPROLOL SUCCINATE (generic of Toprol XL®) METOPROLOL TARTRATE (generic of Lopressor®) NADOLOL (generic of Corgard®) PINDOLOL (generic of Visken®) PROPRANOLOL (generic of Inderal®) PROPRANOLOL ER (generic of Inderal LA®) SOTALOL (generic of Betapace®) SOTALOL AF (generic of Betapace AF®) TIMOLOL (generic of Blocadren®)	BYSTOLIC® (nebivolol) INNOPRAN XL® (propranolol) KAPSPARGO SPRINKLE™ (metoprolol succinate) LEVATOL® (penbutolol) SOTYLIZE® oral solution (sotalol solution)

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®) FELODIPINE (generic of Plendil®) NICARDIPINE (generic of Cardene®) NIFEDIPINE ER (generic of Procardia XL®, Adalat CC®) NIFEDIPINE IMMEDIATE RELEASE (generic of Procardia®)	ISRADIPINE (generic of Dynacirc®) NIMODIPINE (generic of Nimotop®)* NYMALIZE oral solution (nimodipine solution) * NISOLDIPINE (generic of Sular®)

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

CALCIUM CHANNEL BLOCKERS- NON-DIHYDROPYRIDINE

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

DIRECT RENIN INHIBITORS* 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 INBITOR*

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

* Note: Clinical criteria must be met

DRAFT

Cardiovascular Agents: Antiarrhythmics

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to 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 30 days 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)

DRAFT

Cardiovascular Agents: Lipotropics

LENGTH OF AUTHORIZATIONS: 365 days all Lipotropics except Omega-3 Fatty Acid
60 days for Omega-3 Polyunsaturated Fatty Acid

Trial period	30 days for HMG-CoA Reductase Inhibitors, Niacin derivatives, 90 days for Fibrates
Number of non-PA agents	1 medication – The assumption is that the medication must be in the same class of the medication requested, if available, except for HMG-CoA reductase inhibitors- see specific criteria

GENERAL GUIDELINES:

- Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
  - Allergy to medications not requiring prior approval
  - Contraindication to or drug-to-drug interaction with medications not requiring prior approval (pravastatin is the only HMG-CoA not metabolized by the cytochrome P450 liver enzyme system)
  - History of unacceptable/toxic side effects to medications not requiring prior approval
- If there has been a therapeutic failure to no less than two of the HMG-CoA preferred products for a 30 day trial, then a non-preferred HMG-CoA agent will be authorized.

ADDITIONAL CRITERIA FOR OMEGA-3 POLYUNSATURATED FATTY ACID AND ICOSAPENT ETHYL (LOVAZA®, VASCEPA®):

- Prescription-only omega-3 polyunsaturated fatty acid and icosapent ethyl are approvable only for adult patients with triglyceride levels equal to or greater than 500 mg/dL who have been unable to lower triglyceride levels with lifestyle changes including diet and exercise.
- Medications known to increase triglycerides (beta blockers, thiazides, and estrogens) must be discontinued or changed, if clinically appropriate, before the drug is approved. Initial approval will be for 60 days, with evidence of reduced triglycerides required for re-approval.

ADDITIONAL CRITERIA FOR COLESEVELAM (WELCHOL®):

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

ADDITIONAL CRITERIA FOR PCSK9 INHIBITORS:

- All products in this class require clinical prior authorization:
  - Age ≥18 years or Age ≥ 13 years and Homozygous Familial Hypercholesterolemia (HoFH)
  - Documented adherence to prescribed lipid lowering medications for previous 90 days

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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 3rd 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 1st or 2nd 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®) 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®) CHOLESTYRAMINE POWDER (generic of Questran®) COLESTIPOL tablets (generic of Colestid® tablets) PREVALITE® POWDER (cholestyramine)	COLESTIPOL granules (generic of Colestid® granules) WELCHOL® packets (colesevelam) WELCHOL® tablets (colesevelam)

CARDIOVASCULAR AGENTS: LIPOTROPICS - STATINS

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

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CARDIOVASCULAR AGENTS: LIPOTROPICS - FIBRIC ACID DERIVATIVES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
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

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

CARDIOVASCULAR AGENTS: LIPOTROPICS - OMEGA-3 POLYUNSATURATED FATTY ACIDS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
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

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

CARDIOVASCULAR AGENTS: LIPOTROPIC/HYPERTENSION COMBINATION

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

CARDIOVASCULAR AGENTS: LIPOTROPICS PCSK9 INHIBITORS*

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	PRALUENT® (alirocumab) REPATHA™ (evolocumab)

* Note: Clinical criteria must be met

DRAFT

Cardiovascular Agents: Pulmonary Arterial Hypertension

LENGTH OF AUTHORIZATIONS: 365 days

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.

GENERAL GUIDELINES:

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 30 days 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®) TADALAFIL (generic for Adcirca®)	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"
AMBRISENTAN (generic for Letairis®) TRACLEER® (bosentan)	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

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

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION, Prostacyclin Analog, Inhaled

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

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION Prostacyclin Analog, Intravenous

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

DRAFT

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

LENGTH OF AUTHORIZATIONS: 365 days

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 30 days with at least two medications not requiring prior approval?

ADDITIONAL CRITERIA FOR DONEPEZIL ODT (ARICEPT®) & 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®) GALANTAMINE (generic of Razadyne™) GALANTAMINE ER (generic of Razadyne™ ER) MEMANTINE tablets (generic of Namenda®) RIVASTIGMINE capsules (generic of Exelon®)	DONEPEZIL ODT (generic of Aricept® ODT) 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)

DRAFT

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

LENGTH OF AUTHORIZATIONS: 180 days

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 OF CHRONIC AND/OR EPISODIC MIGRAINES:

1. Patient must have a diagnosis of chronic or episodic migraine with the following frequencies of migraine:
   - 15 or more headaches per 30 days measured over 90 consecutive days and headache duration of longer than 4 hours per day or longer during an attack on average.
2. Prior Authorization will not be given for prophylaxis unless the patient has exhausted or has contraindications to at least three other "controller" migraine medications for at least 30 days within the last 120 days (i.e., beta-blockers, neuroleptics, tricyclic antidepressants, and/or serotonin-norepinephrine)
3. Medication must be initiated by a neurologist
4. Initial authorization will be limited to 180 days. Re-authorization for 365 days will be allowed based upon evidence of improved headache control. Re-authorization requests may be managed in consultation with a specialist.

CLINICAL CONSIDERATIONS FOR EPISODIC CLUSTER HEADACHE

1. At least 5 attacks within 30 days
2. Attacks characterized by severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes when untreated; during part (but less than half) of the time-course of cluster headache, attacks may be less severe and/or of shorter or longer duration
3. Either or both of the following:
   - A. At least one of the following symptoms or signs ipsilateral to the headache:
     - I. Conjunctival injection and/or lacrimation
     - II. Nasal congestion and/or rhinorrhea
     - III. Eyelid edema
     - IV. Forehead and facial sweating
     - V. Miosis and/or ptosis
   - B. A sense of restlessness or agitation
4. Attacks have a frequency between one every other day and eight per day; during part (but less than half) of the active time-course of cluster headache, attacks may be less frequent
5. Not better accounted for by another ICD-3 diagnosis
6. In addition, to be considered episodic cluster headaches (emgality is not yet approved for chronic cluster ha)

A. Attacks fulfilling criteria for cluster headache (above) and occurring in bouts (cluster periods)
B. At least two cluster periods lasting from seven days to one year (when untreated) and separated by pain-free remission periods of 90 days or more

And

Failure or intolerance of the following preventative therapies:

1. Verapamil titrated at least to a dose of 480 mg daily(may need to be combined with glucocorticoids as adjunctive therapy for more rapid relief until verapamil is titrated)

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

NO PA REQUIRED "PREFERRED" (Trails of at least 3 controller medications)	PA REQUIRED "NON-PREFERRED"
Cardiovasular Agents: Beta-blockers CNS Agents: Anticonvulsant CNS Agents: Tricyclic antidepressants CNS Agents: Serotonin-norepinephrine	AIMOVIG™ (erenumab-aooe)† EMGALITY™ (galcanezumab) AJOVY™ (fremanezumab-vfrm)*

†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

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

DRAFT

Central Nervous System (CNS) Agents: Anticonvulsants

LENGTH OF AUTHORIZATIONS: 365 days

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 30 days 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 30 days. 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)

DRAFT

ANTICONVULSANTS: SECOND GENERATION

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
GABAPENTIN (generic of Neurontin®) LAMOTRIGINE IR tablet, chewable tablet (generic of Lamictal®) LEVETIRACETAM IR tablet, solution (generic of Keppra®) SABRIL® powder (no PA for age < 2) TOPIRAMATE tablet (generic of Topamax®) ZONISAMIDE (generic of Zonegran®)	FYCOMPA® (perampanel) PREGABALIN (generic for Lyrica®)	BANZEL® (rufinamide) BRIVIACT® (brivaracetam) FELBAMATE (generic of Felbatol®) LAMICTAL® ODT (lamotrigine) LAMOTRIGINE ER tablet (generic of Lamictal® XR) LEVETIRACETAM ER tablet (generic of Keppra® XR) QUDEXY XR® (topiramate ER) 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"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Alternative Anticonvulsant	VIMPAT® (lacosamide)	APTIOM® (esliscarbazepine acetate)

ADDITIONAL CRITERIA FOR CANNABINOID

LENGTH OF AUTHORIZATIONS: Initial Authorization 180 days
Subsequent Authorizations 365 days

- 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 30 days 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)
    - Maximum daily dose (QL) not to exceed 20 mg/kg/day (titration based on response/tolerability)

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).

ADDITIONAL CRITERIA FOR STIRIPENTOL

LENGTH OF AUTHORIZATIONS: Initial Authorization 180 days
Subsequent Authorizations 365 days

- Medication is prescribed by a neurologist or in consultation with a neurologist
- Patient has Dravet Syndrome
- Patient has baseline hematologic testing (CBC)
  - Prescribers must include management plans for patients with neutrophil counts <1500 cells/mm3 or platelet count less than 150,000/µL
- Address any co-morbid conditions
  - Patients with phenylketonuria (PKU) will not be authorized for suspension dosage form without evidence of total daily amount of phenylalanine
- Patient must be concurrently managed with clobazam.
- Dose will be restricted based upon patient weight to 50 mg/kg/day. Requested dose not to exceed 3,000mg/day
- Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)

ANTICONVULSANTS: STIRIPENTOL

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DIACOMIT® (stiripentol)	

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

DRAFT

Central Nervous System (CNS) Agents: Antidepressants

GRANDFATHERING:
Patients who have a claim for a non-preferred drug, or drug requiring step therapy, in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (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: 365 days

1. If there has been a therapeutic failure to no less than two preferred products for a 30 day 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®)	BRISDELLE® (paroxetine mesylate)
CITALOPRAM tablets (generic of Celexa®)	FLUOXETINE ER (generic of Prozac Weekly®)
ESCITALOPRAM (generic of Lexapro®)	FLUVOXAMINE ER (generic of Luvox CR®)
FLUOXETINE HCL capsules, tablets (generic of Prozac®)	PAROXETINE ER (generic of Paxil CR®)
FLUOXETINE HCL solution (generic of Prozac®)	PEXEVA® (paroxetine mesylate)
FLUVOXAMINE MALEATE (generic of Luvox®)	
PAROXETINE HCL (generic of Paxil®)	
SERTRALINE (generic of Zoloft®)	
SERTRALINE oral concentrate (generic of Zoloft®)	

DRAFT

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®) TRANYLCYPROMINE (generic of Parnate®)

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

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

ANTIDEPRESSANTS: SSRI - SEROTONIN PARTIAL AGONIST*

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

DRAFT

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: 365 days

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 thirty 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 thirty 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 thirty 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

DRAFT

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®) CLOZAPINE (generic of Clozaril®) QUETIAPINE (generic of Seroquel®) RISPERIDONE (generic of Risperdal®) ZIPRASIDONE (generic of Geodon®)	LATUDA® (lurasidone) QUETIAPINE ER (generic of Seroquel XR®) FANAPT® (iloperidone) SAPHRIS® (asenapine)	ABILIFY DISCMELT® (aripiprazole) ABILIFY MYCITE® (aripiprazole with IEM) ARIPIPRAZOLE solution (generic of Abilify®) CLOZAPINE RAPID DIS(generic of Clozaril®) FAZACLO® (clozapine) OLANZAPINE ODT (generic of Zyprexa® Zydis) PALIPERIDONE (generic of INVEGA®) REXULTI® (brexpiprazole) 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 +

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
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.

DRAFT

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

LENGTH OF AUTHORIZATIONS: 365 days

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 14 days with at least two medications not requiring prior approval
2. Note: Members on non-preferred therapies are not required to obtain prior authorization for the use of their product until after June 30th, 2020. Providers may obtain prior authorization before June 30th, 2020.

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) EVEKEO ODT™ (amphetamine sulfate ODT) 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) DEXMETHYLPHENIDATE ER (generic of Focalin XR®)† DEXTROAMPHETAMINE-AMPHETAMINE XR (generic of Adderall XR®) DEXTROAMPHETAMINE SA (generic of Dexedrine® spansule) GUANFACINE ER (generic of Intuniv®) METHYLPHENIDATE ER (generic of Metadate® ER, Methylin® ER, Ritalin SR®) METHYLPHENIDATE ER (generic of Concerta®) [Labeler 10147] METHYLPHENIDATE LA (generic of Metadate® CD, Ritalin® LA) VYVANSE® (lisdexamfetamine)	CLONIDINE ER (generic of Kapvay®) JORNAY PM™ (methylphenidate ER) METHYLPHENIDATE ER (generic of Concerta®) [All other Labelers] MYDAYIS™ (amphetamine-dextroamphetamine ER)

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

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
QUILLICHEW™ ER (methylphenidate tablet, chewable, extended release) (no PA for age 12 or under) VYVANSE® chewable (lisdexamfetamine) †	ADZENYS™ XR-ODT, Susp (amphetamine tablet, ODT) COTEMPLA XR-ODT™ (methylphenidate, ODT) DAYTRANA® (methylphenidate) DYANAVEL™ XR (amphetamine ER oral suspension) QUILLICHEW™ ER (methylphenidate tablet, chewable, extended release) (PA required for age over 12) QUILLIVANT XR® suspension (methylphenidate) ~~(PA required for age over 12)~~ †

†Members will be grandfathered on therapy through June 30th , 2020

DRAFT

Central Nervous System (CNS) Agents: Fibromyalgia Agents

LENGTH OF AUTHORIZATIONS: 365 days

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 in different classes (see below) not requiring prior approval
   - Contraindication to all medications not requiring prior approval
   - History of unacceptable/toxic side effects to at least two medications in different classes (see below) not requiring prior approval
2. Non-preferred medications will be approved for fibromyalgia after trial of agents from no less than 2 of the following drug classes for at least 14 days each in the past 90 days (guidelines suggest use of multiple agents concurrently to manage the signs of fibromyalgia):
   - Gabapentin
   - ~~Pregabalin~~
   - Short- and/or long-acting opioids**
   - Skeletal muscle relaxants
   - SNRIs
   - SSRIs
   - Trazodone
   - Tricyclic antidepressants

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

CNS AGENTS: FIBROMYALGIA AGENTS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PREGABALIN (generic for Lyrica®)	SAVELLA® (milnacipran)

DRAFT

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 180 days 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/NALOXONE SL tablets and films SUBOXONE® SL film (buprenorphine/naloxone) ZUBSOLV® SL tablets (buprenorphine/naloxone)	BUPRENORPHINE SL tablets (generic of Subutex®)†

†Restricted to women of childbearing agent unless patient has an allergy to preferred products

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.

DRAFT

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.

DRAFT

Central Nervous System (CNS) Agents: Multiple Sclerosis

DISEASE MODIFYING AGENTS

LENGTH OF AUTHORIZATIONS: 365 days

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 30 day 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) MAVENCLAD® (cladribine) MAYZENT® (siponimod)† TECFIDERA® (dimethyl fumarate)

†Must review liver function tests (LFTS) complete blood count (CBC), ophthalmic examination, varicella zoster virus antibodies, and electrocardiogram (ECG) prior to initiation. Must confirm member is not CYP2C9*3*3 genotype. Dose limited to 2mg/day.

CNS AGENTS: MULTIPLE SCLEROSIS POTASSIUM CHANNEL BLOCKERS*

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

DRAFT

Central Nervous System (CNS) Agents: Neuropathic Pain

LENGTH OF AUTHORIZATIONS: 365 days

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 30 day trial of at least two medications in separate pharmacologic classes not requiring prior authorization

CNS AGENTS: NEUROPATHIC PAIN

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

DRAFT

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

LENGTH OF AUTHORIZATIONS: 365 days

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 30 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.
3. Neupro® or Inbrija™ 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

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

†Use not recommended as monotherapy; edit may ensure used concomitantly

Central Nervous System (CNS) Agents: Restless Legs Syndrome

LENGTH OF AUTHORIZATIONS: 365 days

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 30 day trial of at least one medication not requiring prior approval

CNS AGENTS: RESTLESS LEGS SYNDROME AGENTS

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

DRAFT

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

LENGTH OF AUTHORIZATIONS: 180 days

1. The requested medication may be approved if there has been a therapeutic failure to no less than a 10 day trial of at least two medications not requiring prior approval
2. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
3. If the prescriber indicates the patient has a history of addiction, then may approve a requested non-controlled medication.
4. The P&T Committee does not recommend use of flurazepam (Dalmane®) or triazolam (Halcion®)

CNS AGENTS: SEDATIVE-HYPNOTICS, NON-BARBITURATE

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

DRAFT

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

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to a 30 day trial 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®) CHLORZOXAZONE (generic of Parafon Forte®) CYCLOBENZAPRINE (generic of Flexeril®) DANTROLENE (generic of Dantrium®) METHOCARBAMOL (generic of Robaxin®) TIZANIDINE tablets (generic of Zanaflex®)	CARISOPRODOL (generic of Soma®) * CARISOPRODOL COMPOUND (generic of Soma Compound®) * CARISOPRODOL COMPOUND W/CODEINE (generic of Soma Compound w/Codeine®) * CYCLOBENZAPRINE ER (generic of Amrix®) FEXMID® (cyclobenzaprine) LORZONE® (chlorzoxazone) METAXALONE (generic of Skelaxin®) ORPHENADRINE (generic of Norflex®) ORPHENADRINE COMPOUND (generic of Norgesic®) ORPHENADRINE COMPOUND FORTE (generic of Norgesic Forte®) TIZANIDINE capsules (generic of Zanaflex®)

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

DRAFT

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)	

DRAFT

Endocrine Agents: Androgens

LENGTH OF AUTHORIZATIONS: 365 days

All products within this category require submission of lab work to support the need for testosterone supplementation

The requested medication may be approved if there has been a therapeutic failure to no less than a 90 day 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

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	ANDROXY® (fluoxymesterone) METHYLTESTOSTERONE (generic of Android®, Methitest®, Testred®) STRIANT (testosterone)

INJECTABLE AGENTS: ANDROGENS

CLINICAL 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

CLINICAL 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)

DRAFT

Endocrine Agents: Diabetes – Insulin

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
   - Condition is difficult to control (i.e. prone to ketoacidosis, hypoglycemia)
2. The requested medication may be approved if there has been a therapeutic failure to at least one medication within the same class not requiring prior authorization. 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 180 days

ENDOCRINE AGENTS: DIABETES - INSULINS - Rapid and Short Acting

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
HUMALOG® vial and pen (insulin lispro) HUMULIN R® (insulin regular human) HUMULIN R 500-U® vial and pen(insulin regular human) INSULIN ASPART vial and pen (authorized generic of Novolog®) INSULIN LISPRO vial and pen (authorized generic of Humalog®) NOVOLIN R® (insulin regular human) NOVOLOG® vial and pen (insulin aspart)	ADMELOG® (insulin lispro)† AFREZZA® inhalation powder (insulin human) APIDRA® vial and pen (insulin glulisine) FIASP® (insulin aspart)

†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® vial and pen (insulin lispro protamine/insulin lispro) HUMULIN 70/30® vial and pen (insulin NPH/regular) NOVOLIN 70/30® (insulin NPH/regular) NOVOLOG MIX 70/30® vial and pen (insulin aspart protamine/ insulin aspart)	HUMULIN N® vial and pen (insulin NPH) NOVOLIN N® (insulin NPH)

ENDOCRINE AGENTS: DIABETES - INSULINS - Long Acting

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"

LANTUS® vial and pen (insulin glargine) LEVEMIR® vial and pen (insulin detemir)	TRESIBA FLEXTOUCH® (insulin degludec)	BASAGLAR® (insulin glargine)† TOUJEO® (insulin glargine)

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

DRAFT

Endocrine Agents: Diabetes – Non-Insulin

LENGTH OF AUTHORIZATIONS: 365 days

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 90 days 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 90 days 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)	

DRAFT

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®) 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®) 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®)

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

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	JARDIANCE® (empagliflozin)	FARXIGA® (dapagliflozin) 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)	GLYXAMBI® (empagliflozin/ linagliptin) INVOKAMET® (canagliflozin/ metformin) INVOKAMET® XR (canagliflozin/ metformin) SEGLUROMET™ (ertugliflozin/metformin) SYNJARDY® XR (empagliflozin and 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 90 days of at least one preferred DPP-4 and SGLT product	QTERN® (dapaglifozin-saxagliptin) STEGLUJAN™ (ertugliflozin/sitagliptin)

DRAFT

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®)

DIABETES – ORAL HYPOGLYCEMICS, MEGLITINIDES

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

DIABETES – ORAL HYPOGLYCEMICS, MEGLITINIDE/BIGUANIDE COMBO

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
REPAGLINIDE/ METFORMIN (generic of Prandimet®)		

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®)		

DIABETES – ORAL HYPOGLYCEMICS, THIAZOLIDINEDIONES

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

DIABETES – ORAL HYPOGLYCEMICS, TZD/SULFONYLUREAS COMBO

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
		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 90 days of at least one preferred insulin product	SYMLIN® (pramlintide)	

DRAFT

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

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

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.

DRAFT

Endocrine Agents: Estrogenic Agents

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to at least two trials of 30 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)

DRAFT

Endocrine Agents: Progestin Agents

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
    - Allergy to medications not requiring prior approval
    - Contraindication to or drug interaction with medications not requiring prior approval
    - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to at least two trials of 30 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

DRAFT

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)
- All information and documentation requested on the prior authorization form to justify criteria being met, including height, weight, bone age (children), date of most current x-ray, stimulus test results, IGF-1 levels and a growth chart (children) must be supplied.

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 90 day trial of at least one preferred medication

CLINICAL CRITERIA

Children - initial approval for the following diagnoses:

1. Growth Hormone Deficiency (GHD) – 180 day approval:
   1) Standard deviation of 2.0 or more below mean height for chronological age; AND
   2) No expanding intracranial lesion or tumor diagnosed; AND
   3) Growth rate is:
      1. Below five (5) centimeters per year; OR
      2. Below ten (10) centimeters per year in children under 3 years of age; OR
      3. Below ten (10) centimeters per year during puberty AND
   4) Failure of any two stimuli test to raise the serum growth hormone level above 10 nanograms/milliliter; AND
   5) Epiphyses must be open; AND
   6) Bone age 15-16 years or less in females and 16-17 years or less in males
   7) Females with bone age >16 and males with bone age >17 may be approved for maintenance therapy (approval for 365 days) upon request by an endocrinologist. (Maintenance dose is typically 50% of dose used to improve height)
2. Growth Retardation of Chronic Kidney Disease – 365 day approval:
   1) Standard deviation of 2.0 or more below mean height for chronological age; AND
   2) No expanding intracranial lesion or tumor diagnosed; AND
   3) Growth rate below five (5) centimeters per year; AND
   4) Irreversible renal insufficiency with a glomerular filtration rate less than 75 ml/min per 1.73m2 but pre-renal transplant; AND
   5) Bone age 14-15 years or less in females and 15-16 years or less in males; AND
   6) Epiphyses open.
3. Genetic diagnosis – 365 day approval:

1) One of the following:
   a. Krause-Kivlin Syndrome; or
   b. Turner Syndrome; or
   c. Prader-Willi Syndrome; or
   d. Noonan Syndrome
2) Bone age between 14-15 years; AND
3) Epiphyses open; AND
4) Growth rate below five (5) centimeters per year

4. Neurosecretory Growth Retardation – 180 day approval
   1) Standard deviation of 2.0 or more below mean height for chronological age; AND
   2) No expanding intracranial lesion or tumor diagnosed; AND
   3) Growth rate below five (5) centimeters per year; AND
   4) Bone age 14-15 years or less in females and 15-16 years or less in males; AND
   5) Epiphyses open; AND
   6) Mixed or normal response to any two (2) stimuli test in raising serum growth hormone above 10 nanograms/milliliter.

5. Idiopathic Short Stature – 180 day approval
   1) A standard deviation of 2.25 or more below mean height for chronological age; AND
   2) No expanding intracranial lesion or tumor diagnosed; AND
   3) Growth rate is below five (5) centimeters per year; AND
   4) Bone age is 14-15 years or less in females and 15-16 years or less in males and epiphyses are open; AND
   5) A mixed or normal response to any two stimuli tests in raising serum growth hormone above 10 nanograms/milliliter; AND
   6) The child is proportionally shorter than the predicted rate of growth from the parent's height; AND
   7) Requests must come from a pediatric endocrinologist.

6. Small for Gestational Age (SGA) – 365 day approval
   1) Request must come from a pediatric endocrinologist; AND
   2) Documentation to support diagnosis defined as birth weight or length 2 or more standard deviations below the mean for gestational age.
   3) Child fails to manifest catch up growth before 2 years of age, defined as height 2 or more standard deviations below the mean for age and gender.
   4) Note: Review must include evaluation of growth curves from birth

Adults - initial approval for 180 days:

Adult patients with growth hormone deficiency may be approved for replacement of endogenous growth hormone upon documentation of medical necessity from an endocrinologist. Requests will be reviewed and approved based upon the following conditions:

1) Childhood Onset - Patients who were growth hormone deficient during childhood and who have a continued deficiency which is confirmed by provocative testing.
2) Adult Onset - Patients who have growth hormone deficiency, either alone or with multiple pituitary hormone deficiencies, such as hypopituitarism, as a result of

pituitary disease, surgery, hypothalamic disease, radiation therapy, or trauma.
Criteria for Approval for both conditions listed above:

1) Biochemical diagnosis of growth hormone deficiency by means of a negative response to an appropriate stimulation test ordered by the endocrinologist (Clonidine test is not acceptable for adults.); AND
2) No evidence of malignancy or other contraindication; AND
3) Other hormonal deficiencies addressed with adequate replacement therapy; AND
4) Base-line evaluation of the following clinical indicators
    a. Insulin-like growth factor-1 (IGF-1)-also required following dosage change
    b. Fasting lipid profile
    c. BUN
    d. Fasting glucose
    e. Electrolyte levels
    f. Evaluation of any new osteoarthritis and joint pain
    g. Bone density test

Maximum dose – less than or equal to 0.025mg/kg daily (up to thirty-five (35) years of age)
Maximum dose – less than or equal to 0.0125mg/kg daily (thirty-five 35 years of age or older)

Reauthorization: The patient health status has improved since last approval (weight gain, improved body composition) 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)

DRAFT

Endocrine Agents: Osteoporosis – Bone Ossification Enhancers

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to no less than a 90 day trial of at least one preferred medication

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 365 days or if bisphosphonates are contraindicated, trial of calcitonin-salmon for greater than 730 days (2 years)
4. Total lifetime therapy of parathyroid hormone analogs does not exceed 730 days (2 years)

ENDOCRINE AGENTS: OSTEOPOROSIS - BONE OSSIFICATION ENHANCERS - ORAL BISPHOSPHONATES

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

DRAFT

ENDOCRINE AGENTS: OSTEOPOROSIS – PARATHYROID HORMONE RELATED PEPTIDE ANALOG*

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	TYMLOS™ (abaloparatide)

* Note: Clinical criteria must be met

DRAFT

Gastrointestinal Agents: Anti-Emetics

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to no less than a 7 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® tablets, trifold, suspension (aprepitant) ONDANSETRON tablets, solution, ODT (generic of Zofran®)	ANZEMET® (dolasetron) GRANISETRON tablet, solution (generic of Kytril®) SANCUSO® patch (granisetron) VARUBI™ (rolapitant) ZUPLENZ® film (ondansetron)

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

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

DRAFT

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

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
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 14 day 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 14 day 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 specialize 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) 180 days 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

DRAFT

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™ 145mcg & 290mcg capsule (linaclotide)	LINZESS™ 72mcg capsule (linaclotide) MOTEGRITY™ (prucalopride) TRULANCE™ (plecanatide) ZELNORM™ (tegaserod)†

†Use limited to women less than 65 years of age

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)

DRAFT

Gastrointestinal Agents: Opioid-Induced Constipation

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
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 14 day 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 14 day 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)

DRAFT

Gastrointestinal Agents: Pancreatic Enzymes

LENGTH OF AUTHORIZATIONS: 365 days

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 14 day 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)

DRAFT

Gastrointestinal Agents: Proton Pump Inhibitors

LENGTH OF AUTHORIZATIONS: 180 days, 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 30 days 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 30 days
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: 365 days
   - Criteria for approval: Must have failed QD dosing

GASTROINTESTINAL AGENTS: PPIs

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

DRAFT

Gastrointestinal Agents: Ulcerative Colitis Agents

LENGTH OF AUTHORIZATIONS: 365 days

For a non-preferred agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days 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) BALSALAZIDE DISODIUM (generic of Colazal®) MESALAMINE DR (generic for Delzicol®) PENTASA® (mesalamine) SULFASALAZINE (generic of Azulfidine®) SULFASALAZINE EC (generic of Azulfidine Entab®)	ASACOL HD® (mesalamine) DIPENTUM® (olsalazine) GIAZO® (balsalazide disodium) LIALDA® (mesalamine)

GASTROINTESTINAL AGENTS: ULCERATIVE COLITIS AGENTS - RECTAL

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

DRAFT

Genitourinary Agents: Benign Prostatic Hyperplasia

LENGTH OF AUTHORIZATIONS: 365 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 no less than a 30 day trial on at least two 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 30 day trial on at least one alpha-1 adrenergic blocker and a 90 day trial of finasteride.

BENIGN PROSTATIC HYPERPLASIA AGENTS – ALPHA-1 ADRENERGIC BLOCKERS

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

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.

DRAFT

Genitourinary Agents: Electrolyte Depleter Agents

LENGTH OF AUTHORIZATIONS: 365 days

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 7 days 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 7 days 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)	SEVELAMER (generic for Renagel®, Renvela®)	AURYXIA® (ferric citrate) tablets ELIPHOS® (calcium acetate) LANTHANUM CARBONATE (generic of Fosrenol®) VELPHORO® (sucroferric oxyhydroxide)

DRAFT

Genitourinary Agents: Urinary Antispasmodics

LENGTH OF AUTHORIZATIONS: 365 days

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 30 days of oxybutynin (IR or ER).
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
   - Contraindications to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
3. The requested medication may be approved if there has been a therapeutic failure to a trial of no less than 14 days of at least one medication not requiring prior approval

GENITOURINARY AGENTS: URINARY ANTISPASMODICS

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

DRAFT

Immunomodulator Agents for Systemic Inflammatory Disease

LENGTH OF AUTHORIZATIONS: 365 days

INDICATIONS:

	Adalimumab	Etanercept	Abatacept	Anakinra	Apremilast	Baricitinib	Brodalumab	Certolizumab	Golimumab	Guselkumab	Ixekizumab	Risankizumab-rzaa	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								✓									

DRAFT

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: 365 days 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 56 days, reapprovals 365 days
  Humira may be approved if there is an inadequate clinical response to at least 90 days of therapy with both 5-ASA and immunosuppressants.
  Initial approval for Humira will be for 56 days. If clinical response is not seen in 56 days, further therapy with TNF inhibitors will not be approved. If there is an initial clinical response to Humira after 56 days of therapy, but no improvement in the progression of ulcerative colitis symptoms after 180 days, 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 90 day 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 90 days 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) SKYRIZI™ (risankizumab-rzza) 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)

DRAFT

Infectious Disease Agents: Antibiotics – Cephalosporins

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

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

DRAFT

Infectious Disease Agents: Antibiotics – Macrolides

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

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
   - Note diagnosis and any culture and sensitivity reports
3. If there has been a therapeutic failure to no less than a 3 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®) CLARITHROMYCIN ER (generic of Biaxin XL®) CLARITHROMYCIN tablets and suspension (generic of Biaxin®) ERYTHROCIN STEARATE® (erythromycin stearate) ERYTHROMYCIN BASE ERYTHROMYCIN ETHYLSUCCINATE ERY-TAB® (erythromycin base)	ERYPED® (erythromycin ethylsuccinate) ZMAX™ (azithromycin ER) for oral suspension

DRAFT

Infectious Disease Agents: Antibiotics – Quinolones

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

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
   - Note diagnosis and any culture and sensitivity reports
3. If there has been a therapeutic failure to at least a 3 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)

DRAFT

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

ADDITIONAL CRITERIA FOR AMIKACIN

LENGTH OF AUTHORIZATIONS: Initial authorization 180 days
Subsequent authorizations 365 days

1. Clinical criteria for initial authorization:
   - Diagnosis of *Mycobacterium avium* complex (MAC) lung disease; and
   - Patient has not achieved negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy (e.g. macrolide, rifampin, & ethambutol)
2. Criteria for subsequent authorizations
   - Evidence of culture conversion (negative sputum culture)
3. Dose will be limited to 1 dose per day

INFECTIOUS DISEASE AGENTS: ANTIBIOTICS – INHALED AMIKACIN

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ARIKAYCE® (amikacin)	

DRAFT

Infectious Disease Agents: Antibiotics – Tetracyclines

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

4. 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

5. 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

6. If there have been therapeutic failures to no less than a 3 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.

TETRACYCLINES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Doxycycline tablets, capsules 50mg & 100mg Doxycycline syrup Minocycline capsules Tetracycline capsules	DORYX® (doxycycline) Doxycycline tablets, capsules 20mg, 40mg, 75mg, & 150mg Doxycycline DR Minocycline ER MINOLIRA™ ER (minocycline) SEYSARA™ (sarecycline) SOLODYN® ER (minocycline) XIMINO® (minocycline)

DRAFT

ADDITIONAL CRITERIA FOR OMADACYCLINE

LENGTH OF AUTHORIZATIONS: 14 Days

1. Clinical criteria for initial authorization:
    - Diagnosis of Community-Acquired Bacterial Pneumonia (CABP) with prior failure of other first line agent OR
    - Diagnosis of Acute Bacterial Skin and Skin Structure Infection (ABSSSI) with prior failure of other first line agent

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 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

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.

TETRACYCLINES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	NUZYRA® (omadacycline)

DRAFT

Infectious Disease Agents: Antifungals for Onychomycosis & Systemic Infections

LENGTH OF AUTHORIZATIONS: For the duration of the prescription (up to 180 days)

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug-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.
3. If there have been therapeutic failures to no less than a 7 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 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) GRISEOFULVIN suspension (generic of Grifulvin®V) GRIS-PEG® (griseofulvin, ultramicrosize) TERBINAFINE (generic of Lamisil®)	ITRACONAZOLE (generic of Sporanox®) LAMISIL Granules (terbinafine) ONMEL® (itraconazole) SPORANOX® 100mg/10ml oral solution (itraconazole)

INFECTIOUS DISEASE AGENTS: AGENTS FOR SYSTEMIC INFECTIONS

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

DRAFT

Infectious Disease Agents: Antivirals – Hepatitis C Agents

LENGTH OF AUTHORIZATIONS: 365 days 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 180 days 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).

DRAFT

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 365 days) 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 180 days)

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 28 days
- 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.

DRAFT

INFECTIOUS DISEASE AGENTS: HEPATITIS C – DIRECT-ACTING ANTIVIRAL

CLINICAL PA REQUIRED "PREFERRED"†	PA REQUIRED "NON-PREFERRED"
SOFOSBUVIR/VELPATASVIR (generic of EPCLUSA®) [Labeler 72626] MAVYRET® (glecaprevir and pibrentasvir)	DAKLINZA™ (daclatasvir) LEDIPASVIR/SOFOSBUVIR (generic of HARVONI®) SOVALDI® (sofosbuvir) VOSEVI™ (sofosbuvir, velpatasvir, voxilaprevir) ZEPATIER™ (elbasvir and grazoprevir tablet)

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

INFECTIOUS DISEASE AGENTS: HEPATITIS C - PEGYLATED INTERFERONS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PEGASYS® (peginterferon alfa-2a) PEG-INTRON® (peginterferon alfa-2b)	

INFECTIOUS DISEASE AGENTS: HEPATITIS C - RIBAVIRINS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
RIBAVIRIN (generic of Rebetol®)	COPEGUS® (ribavirin) MODERIBA PAK® (ribavirin) RIBAPAK® (ribavirin) RIBASPHERE® (ribavirin) 400mg, 600mg

DRAFT

Infectious Disease Agents: Antivirals – Herpes

LENGTH OF AUTHORIZATIONS: For the duration of the prescription (up to 180 days)

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

DRAFT

Infectious Disease Agents: Antivirals – HIV

LENGTH OF AUTHORIZATIONS: 365 days

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

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 30 days with at least one medication not requiring prior approval? If applicable, the request must address the inability to use the individual components.

DRAFT

HIV PROTEASE INHIBITORS AND COMBINATIONS

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

HIV NON-PEPTIDIC PROTEASE INHIBITORS AND COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PREZCOBIX® (darunavir/cobicistat) PREZISTA® (darunavir ethanolate)	APTIVUS® (tipranavir; tipranavir/vitamin E) SYMTUZA™ (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®) ABACAVIR/LAMIVUDINE (generic of Epzicom®) EMTRIVA® (emtricitabine) ABACAVIR/LAMIVUDINE/ZIDOVUDINE (generic TRIZIVIR®) ZIDOVUDINE (generic of Retrovir®)	DIDANOSINE capsule (generic of Videx®) LAMIVUDINE solution, tablet (generic of Epivir®) LAMIVUDINE/ZIDOVUDINE (generic of Combivir®) STAVUDINE (generic of Zerit®) VIDEX® solution (didanosine) ZIAGEN® solution (abacavir sulfate)

HIV REVERSE TRANSCRIPTASE INHIBITORS, NUCLEOTIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
VIREAD® 150 mg (tenofovir disoproxil fumarate) TENOFOVIR DISOPROXIL 300mg (generic for VIREAD®)	VIREAD® 250mg & Oral Powder (tenofovir disoproxil fumarate)

HIV REVERSE TRANSCRIPTASE INHIBITORS, NON-NUCLEOSIDE ANALOGS

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

HIV INTEGRASE STRAND TRANSFER INHIBITORS

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

HIV CCR5 CO-RECEPTOR ANTAGONISTS

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

DRAFT

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"
DESCOVY® (emtricitabine/ tenofovir alafenamide) CIMDUO™ (lamivudine/tenofovir) TRUVADA® (emtricitabine/tenofovir)	

HIV RTI, NUCLEOSIDE-NUCLEOTIDE ANALOGS AND COMBINATIONS

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

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)	DOVATO (dolutegravir/lamivudine) † 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"
RITONAVIR (generic for Norvir®) NORVIR® oral Solution (ritonavir)	TYBOST® (cobicistat)

DRAFT

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

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

For a non-preferred agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 3 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® ointment (ciprofloxacin) CIPROFLOXACIN drops (generic of Ciloxan®) MOXIFLOXACIN (generic for Vigamox®) OFLOXACIN drops (generic of Ocuflox®)	BESIVANCE® drops (besifloxacin) GATIFLOXACIN drops (generic of Zymaxid®) LEVOFLOXACIN drops (generic of Quixin®) MOXEZA® drops (moxifloxacin)

DRAFT

OPHTHALMIC AGENTS: ANTIBACTERIAL – NON-QUINOLONE

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

OPHTHALMIC AGENTS: ANTIBACTERIAL – STEROID COMBINATIONS

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

DRAFT

Ophthalmic Agents: Antihistamines & Mast Cell Stabilizers

LENGTH OF AUTHORIZATIONS: 365 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 14 days of one of the preferred agents.

OPHTHALMIC AGENTS: MAST CELL STABILIZERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CROMOLYN (generic of Crolom®)	ALOCRIL® (nedocromil) ALOMIDE® (lodoxamide)

OPHTHALMIC AGENTS: ANTIHISTAMINE/MAST CELL STABILIZERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AZELASTINE (generic of Optivar®) KETOTIFEN (generic of Alaway®, Zaditor®) OLOPATADINE (generic of Patanol®)	BEPREVE® (bepotastine) EPINASTINE (generic of Elestat®) EMADINE® (emedastine) LASTACAFT® (alcaftadine)

DRAFT

Ophthalmic Agents: Dry Eye Treatments

LENGTH OF AUTHORIZATIONS: 365 days

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 30 days of 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)

DRAFT

Ophthalmic Agents: Glaucoma Agents

LENGTH OF AUTHORIZATIONS: 365 days

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 30 days 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 30 days 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/SYMPATHOMIMETICS

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)

DRAFT

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)

GLAUCOMA AGENTS – RHO KINASE AND PROSTAGLANDIN INHIBITORS COMBINATIONS

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	NON-PREFERRED "NON-PREFERRED"
		ROCKLATAN™ (netarsudil and latanoprost)

DRAFT

Ophthalmic Agents: NSAIDs

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

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

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

ADDITIONAL INFORMATION

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

1. If there has been a therapeutic failure to no less than a 3 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®)	ACUVAIL® (ketorolac)
FLURBIPROFEN (generic of Ocufen®)	BROMFENAC (generic of Bromday®, Xibrom®)
KETOROLAC (generic of Acular®, Acular LS®)	BROMSITE™ (bromfenac)
	ILEVRO® (nepafenac)
	NEVANAC® (nepafenac)
	PROLENSA® (bromfenac)

DRAFT

Otic Agents: Antibacterial and Antibacterial/Steroid Combinations

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

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

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

- If there has been a therapeutic failure to no less than a 7 days 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® suspension (ciprofloxacin with hydrocortisone) CIPRODEX® suspension (ciprofloxacin with dexamethasone) NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE solution (generic of Cortisporin® solution) NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE suspension (generic of Cortisporin® suspension)	COLY-MYCIN-S® suspension (neomycin and colistin with hydrocortisone) CORTISPORIN-TC® suspension (neomycin and colistin with hydrocortisone) OTOVEL® (ciprofloxacin with fluocinolone)

OTIC AGENTS: ANTIBACTERIAL

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

DRAFT

Respiratory Agents: Antihistamines – Second Generation

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there have been therapeutic failures after courses of treatment (e.g., 30 days 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®) (no PA required for age 6 or under) CETIRIZINE tablets (generic of Zyrtec®) LORATADINE rapid dissolve (generic of Claritin® Redi-tabs) LORATADINE syrup (generic of Claritin® Syrup) LORATADINE tablets (generic of Claritin®)	CETIRIZINE syrup (generic of Zyrtec®) (PA required for over age 6) CLARINEX® syrup (desloratadine) CLARITIN REDITABS® 5mg (loratadine) DESLORATADINE ODT (generic of Clarinex®) DESLORATADINE tablets, ODT (generic of Clarinex®) 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®) LORATADINE-D (generic of Claritin-D®)	CLARINEX-D 12, 24 HOUR® (desloratadine/ pseudoephedrine)

DRAFT

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

LENGTH OF AUTHORIZATIONS: 365 DAYS

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 14 day 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"
ALBUTEROL HFA (authorized generics Proair®, Proventil®, Ventolin®) PROAIR® HFA (albuterol) PROAIR RESPICLICK® (albuterol) PROVENTIL HFA® (albuterol) VENTOLIN HFA® (albuterol)	XOPENEX HFA® (levalbuterol)

RESPIRATORY AGENTS: BETA-ADRENERGIC, SHORT-ACTING NEBULIZERS

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

DRAFT

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

LENGTH OF AUTHORIZATIONS: 365 days

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 14 day 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)

DRAFT

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

NO PA REQUIRED " PREFERRED"	PA REQUIRED "NON-PREFERRED"
SALMETEROL/FLUTICASONE (generic of Advair Diskus®) † [Labeler 66993] DULERA® (formoterol/mometasone) SYMBICORT® (formoterol/budesonide)	ADVAIR® HFA (salmeterol/fluticasone) AIRDUO™ RESPICLICK® (fluticasone/salmeterol) † BREO® ELLIPTA® (fluticasone/vilanterol)† SALMETEROL/FLUTICASONE (generic of Advair Diskus®) † [All other labelers] WIXELA™ Inhub™ (salmeterol/fluticasone) †

†Denotes breath actuated inhaler

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

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

†Denotes breath actuated inhaler

DRAFT

Respiratory Agents: Chronic Obstructive Pulmonary Disease

LENGTH OF AUTHORIZATIONS: 365 days 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 14 day 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) COMBIVENT Respimat® (ipratropium/albuterol) IPRATROPIUM nebulizer solution IPRATROPIUM/ALBUTEROL nebulizer solution (generic of Duoneb®) SPIRIVA® Handihaler® (tiotropium)† SPIRIVA® Respimat® (tiotropium)	INCRUSE ELLIPTA® (umeclidinium)† LONHALA™ MAGNAIR™ (glycopyrrolate) SEEBRI™ NEOHALER® (glycopyrrolate)† TUDORZA® (aclidinium bromide)† 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: PHOSPHODISTERASE-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

DRAFT

Respiratory Agents: Epinephrine Auto-Injectors

LENGTH OF AUTHORIZATIONS: 365 days

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)

DRAFT

Respiratory Agents: Glucocorticoid Agents – Inhaled

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
   - 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 30 day trials of at least two medications not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL PA 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"
ASMANEX® Twisthaler (mometasone) FLOVENT DISKUS®† and HFA (fluticasone) PULMICORT FLEXHALER® (budesonide)†	AEROSPAN® HFA (flunisolide) ALVESCO® (ciclesonide) ARMONAIR™ RESPICLICK® (fluticasone) † ARNUITY ELLIPTA® (fluticasone furoate)† ASMANEX® HFA (mometasone) QVAR® (beclomethasone)

†Denotes breath actuated inhaler

RESPIRATORY AGENTS: GLUCOCORTICOIDS – NEBULIZERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BUDESONIDE nebulizer solution (generic of Pulmicort®) (no PA required for age 6 or under)	BUDESONIDE nebulizer solution (generic of Pulmicort®) (PA required for over age 6)

DRAFT

Respiratory Agents: Hereditary Angioedema

LENGTH OF AUTHORIZATIONS: 365 days

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 180 days
- 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"
HAEGARDA® (C1 esterase inhibitor, plasma derived) RUCONEST® (C1 esterase inhibitor, recombinant) TAKHZYRO™ (lanadelumab-flyo)	BERINERT® (C1 esterase inhibitor, plasma derived) CINRYZE® (C1 esterase inhibitor, plasma derived) FIRAZYR® (icatibant acetate) KALBITOR® (ecallantide)

DRAFT

Respiratory Agents: Leukotriene Receptor Modifiers and Inhibitors

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to 90 days of one preferred agents not requiring prior approval, then may approve the requested medication.

RESPIRATORY AGENTS: LEUKOTRIENE RECEPTOR ANTAGONISTS

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
MONTELUKAST tablets, chewable tablets, granules (generic of Singulair®)	ZAFIRLUKAST (generic of Accolate®)	ZILEUTON extended-release (generic of Zyflo CR®) ZYFLO® (zileuton)

DRAFT

Respiratory Agents: Nasal Preparations

LENGTH OF AUTHORIZATIONS: 365 days

For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days 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®)	

DRAFT

Topical Agents: Acne Preparations

LENGTH OF AUTHORIZATIONS: 365 days

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 30 day 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)

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BENZOYL PEROXIDE AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CLINDAMYCIN-BENZOYL PEROXIDE gel (generic of Benzaclin®, Duac®) BENZOYL PEROXIDE cleanser 5%, 6% & 10% BENZOYL PEROXIDE gel 2.5%, 5%, 10% BPO (benzoyl peroxide) Gel 4% & 8% BENZOYL PEROXIDE wash (generic of Benzac AC®, Benzac W®, Brevoxyl®, Desquam-X®, Pacnex®) ERYTHROMYCIN-BENZOYL PEROXIDE gel (generic of Benzamycin®) NEUAC® gel (clindamycin-benzoyl peroxide) PANOXYL® 10% foam, wash (benzoyl peroxide)	ACANYA® (clindamycin-benzoyl peroxide) BENZOYL PEROXIDE foam (generic of Benzefoam®) ONEXTON™ gel (clindamycin-benzoyl peroxide)

RETINOID AND COMBINATION PRODUCTS

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

SODIUM SULFACETAMIDE AND COMBINATION PRODUCTS

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

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Topical Agents: Anti-Fungals

LENGTH OF AUTHORIZATIONS: Duration of the prescription (up to 180 days)

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

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Topical Agents: Anti-Parasitics

LENGTH OF AUTHORIZATIONS: 14 DAYS

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

INDICATIONS AS APPROVED BY FDA

- Benzyl alcohol lotion is indicated for patients 6 months of age and older
- Crotamiton is indicated for adults
- Ivermectin is indicated for age 6 months and older
- Lindane lotion and shampoo are indicated only in patients who cannot tolerate or who have failed other treatments. **The P&T Committee does not recommend use of lindane.**
- Malathion is indicated for patients 6 years of age and older
- Permethrin cream and lotion are indicated for patients 2 months of age and older
- Spinosad is indicated for patients 6 months of age and older
- Package labeling does not list age for permethrin or piperonyl butoxode-pyrethrins

ANTI-PARASITICS, TREATMENT OF SCABIES

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

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

Topical Agents: Corticosteroids

LENGTH OF AUTHORIZATIONS: 365 days for low and medium potency
90 days for high and very high potency

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to at least two medications not requiring prior approval
   - Contraindication to all medications not requiring prior approval
   - History of unacceptable/toxic side effects to at least two medications not requiring prior approval
2. Has the patient failed therapeutic trials of 14 days with two medications not requiring prior approval?

TOPICAL AGENTS: CORTICOSTEROIDS – LOW POTENCY

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DESONIDE cream, ointment (generic of Desowen®) FLUOCINOLONE ACETONIDE 0.01% cream, solution (generic of Synalar®) FLUOCINOLONE body oil, scalp oil (generic of Derma-Smoothe/ FS®) HYDROCORTISONE cream, lotion, ointment	ALCLOMETASONE cream, ointment (generic of Aclovate®) CAPEX® shampoo (fluocinolone acetonide) DESONATE®gel (desonide) DESONIDE lotion (generic of Desowen®) HYDROCORTISONE ACETATE WITH ALOE gel HYDROCORTISONE WITH UREA cream (generic of Carmol HC®) PANDEL® cream (hydrocortisone probutate) PEDIADERM HC® kit

TOPICAL AGENTS: CORTICOSTEROIDS – MEDIUM POTENCY

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

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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"
CLOBETASOL PROPIONATE cream, foam, gel, lotion, ointment, spray, shampoo, solution (generic of Clobex®, Olux®, Temovate®)	BETAMETHASONE DIPROPIONATE AUGMENTED cream, ointment, lotion, gel (generic of Diprolene AF®) BRYHALI™ (halobetasol propionate lotion) CLOBEX® lotion, shampoo,(clobetasol propionate) CLODAN® shampoo, kit (clobetasol propionate) HALOBETASOL PROPIONATE cream, ointment (generic of Ultravate®) LEXETTE™ (halobetasol propionate foam) OLUX-E® foam (clobetasol propionate)

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Topical Agents: Immunomodulators

LENGTH OF AUTHORIZATIONS: 365 days

STEP THERAPY:

1. For a preferred brand, there must have been inadequate clinical response to no less than two 30 day 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 30 days 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"
PIMECROLIMUS (generic of Elidel®) * [Labeler 68682] PROTOPIC (tacrolimus)*	EUCRISA™ (crisaborole)* PIMECROLIMUS (generic of Elidel®) * [All other Labelers] TACROLIMUS (generic of Protopic®) *

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

ADDITIONAL CRITERIA FOR DUPILUMAB (DUPIXENT®)

- 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 12 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™] unless atopic dermatitis is severe and involves greater than 25% of BSA.
  - Initial authorization is limited to 112 days with re-authorization of up to 365 days granted following demonstration of improvement in patient condition with therapy (e.g. reduced BSA affected).

- Indicated for moderate to severe asthma if:
    - Patient is 12 years of age or older
    - Patient has poor symptom control as demonstrated by a validated asthma control questionnaire (i.e. ACQ)
    - Patient has had asthma-related emergency treatments within the last 180 days
    - Patient has eosinophilic phenotype (please include supporting documentation) or with oral corticosteroid dependent asthma.
    - Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 365 days
    - Please identify which asthma-control treatments will continue with dupilumab use
- Indicated for chronic rhinosinusitis with nasal polyposis if:
    - Patient is 18 years of age or older
    - Patient has had an inadequate response, intolerance or contraindication to one medication in each of the following categories:
        - Nasal corticosteroid spray
        - Oral corticosteroid

ANTI-INFLAMMATORY INTERLEUKIN RECEPTOR ANTAGONIST*

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	DUPIXENT® (dupilumab)

* Note: Clinical criteria must be met

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