

Prior Authorization Guidelines

GENERIC: ACARBOSE

BRAND: PRECOSE[®]

INDICATION:

- (1) Type 2 diabetes mellitus

Criteria:

- (a) Failure of maximal doses of *one* oral sulfonylurea (e.g., glyburide 20mg daily or equivalent). Failure is defined as Hemoglobin A1c > 7.0.

GENERIC: ACLIDINIUM BROMIDE AEROSOL POWDER

BRAND: TUDORZA PRESSAIR[®]

INDICATION:

- (1) Long-term maintenance treatment of bronchospasm associated with COPD (including bronchitis and emphysema)

Criteria:

- (a) Diagnosis of COPD **and**
- (b) Must be greater than 18 years of age **and**
- (c) Documented inadequate response or intolerance to Spiriva

GENERIC: ACYCLOVIR TOPICAL OINTMENT/SUSPENSION

BRAND: ZOVIRAX[®] 5%

INDICATIONS:

- (1) Herpes genitalis
- (2) Oral herpes infection

Criteria:

- (a) Herpes genitalis – for initial episode only; **or**
- (b) Oral herpes infection – for immunocompromised patients *only*.

Additional Criteria for Suspension:

- (c) Patient is <17 years of age; **or**
- (d) Unable to ingest solid dosage form (e.g. capsules) due to dysphagia

GENERIC: ADALIMUMAB

BRAND: HUMIRA[®]

INDICATIONS:

- (1) Moderate to severely active rheumatoid arthritis (RA)
- (2) Moderately to severely Active Polyarticular Juvenile Idiopathic Arthritis (JIA)
- (3) Psoriatic arthritis (PsA)
- (4) Ankylosing spondylitis (AS)
- (5) Moderate to severely active Crohn's disease (CD)
- (6) Moderately to Severely Active Ulcerative Colitis (UC)
- (7) Moderately to Severely Active Plaque Psoriasis (Ps)
- (8) Moderately to Severely Active Hidradenitis Suppurativa (HS)
- (9) Uveitis

Criteria:

- (a) The patient had a NEGATIVE tuberculin skin test, or if positive, has received treatment for latent TB prior to Humira therapy; **and**
- (b) The patient does not have a clinically important active infection

Additional Criteria for RA, JIA, and PsA:

- (c) The patient has failed or is intolerant to one formulary NSAID **and**

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(d) The patient has failed or is intolerant to one formulary DMARD

Additional Criteria for AS:

(c) Physician documents that patient failed treatment with at least two NSAIDs for at least three months, except if NSAIDs are contraindicated or if patient has presented toxicity or intolerance.

Additional Criteria for CD and UC:

- (c) The patient has failed or is intolerant to infliximab; or
- (d) The patient has failed or is intolerant to mesalamine or sulfasalazine; and
- (e) The patient has failed or is intolerant to corticosteroids; and
- (f) The patient has failed or is intolerant to an immunomodulator (e.g., methotrexate, 6-mercaptopurine or azathioprine)

Additional Criteria for Ps

(c) Document that the patient has an incomplete response or intolerance or contraindicated to one appropriate systemic agent (ex: MTX, cyclosporine, acitretin) or phototherapy or biologic agents.

Additional Criteria for Hs

(c) Documentation of evidence failure with the previous treatment including antibiotics, hormonal therapies or oral retinoid at least for 90 days.

GENERIC: ANTIHEMOPHILIC FACTORS

BRAND: KOATE-DVI[®], FEIBA VH[®], RECOMBINATE[®], THROMBATE III[®]

INDICATION:

(1) Hemophilia A

Criteria:

(a) Diagnosis of Hemophilia A

GENERIC: APREPITANT

BRAND: EMEND[®]

INDICATION:

(1) Nausea and vomiting

Criteria:

- (a) For the prevention of post-operative nausea and vomiting; **or**
- (b) For the prevention of chemotherapy-induced nausea and vomiting

GENERIC: AZELASTINE NASAL SPRAY

BRAND: ASTELIN[®]

INDICATIONS:

- (1) Perennial allergic rhinitis
- (2) Seasonal allergic rhinitis

Criteria:

- (a) Patient is ≥ 5 years of age with one of the above diagnoses; **and**
- (b) Failure of at least one formulary nasal steroid after a period of at least two months on the maximum dose appropriate and tolerated by the patient

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GENERIC: AZELASTINE 0.05% Eye Drops

INDICATION:

- (1) Allergic conjunctivitis

Criteria:

- (a) Patient is ≥ 3 years of age with the above diagnosis
- (b) Failure of Ketotifen and any various store brands OTC shelf

GENERIC: BRIMONIDINE

BRAND: ALPHAGAN 0.2%[®], ALPHAGAN P 0.15%[®]

INDICATION:

- (1) Glaucoma

Criteria:

- (a) Failure of formulary ophthalmic beta blocker (betaxolol, timolol, dorzolamide/timolol)

GENERIC: BUDESONIDE/FORMOTEROL

BRAND: SYMBICORT[®]

INDICATION:

- (1) Maintenance treatment of asthma in patients 12 years of age and older
- (2) Maintenance Treatment of Chronic Obstructive Pulmonary Disease

Criteria:

Criteria for Asthma:

- (a) Currently on, but not controlled by an inhaled corticosteroid for more than sixty (60) days; **and**
- (b) The patient must be reevaluated after 6 months

Criteria for COPD:

- (a) Currently on, but not controlled by a LAMA for more than sixty (60) days; **and**
- (b) The patient must be reevaluated after 6 months

* For members currently with an approved prior authorization for Symbicort, claims will process as long as the member has filled Symbicort within the last 4 months. No yearly renewal will be needed for compliant members. Prior authorization will be required for members new to the plan, new to Symbicort therapy or with no claims history of Symbicort within the last 4 months. Once approved, 90- day supplies are allowed.

GENERIC: CALCITONIN-SALMON

BRAND: MIACALCIN[®]

INDICATIONS:

- (1) Mild to moderate Paget's disease of bone
- (2) Osteoporosis

Criteria:

- (a) Failure, contraindication or intolerance to adequate trial of oral bisphosphonate; **and**
- (b) One of the following:
 - (1) Bone density measurement ≥ 2.5 standard deviations below the mean for normal, young adults of same gender (T-score ≤ -2.5); **or**
 - (2) History of an osteoporotic vertebral fracture; **or**
 - (3) Postmenopausal woman with low bone mineral density defined by T-score between -2.0 and -2.5 AND one of the following risk factors for fracture:
 - (a) Thinness or low body mass index defined by weight < 127 lb (57.7 kg) or BMI < 21 kg/m²
 - (b) History of fragility fracture since menopause
 - (c) History of hip fracture in a parent
- (4) Diagnosis of Paget's disease of bone

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- (c) Patients receiving glucocorticoids in daily dosages of >7.5mg prednisone daily (see table) AND who have bone density measurement > 1 standard deviations below the mean for normal, young adults of same gender (T-score < -1.0)

Glucocorticoid Potency Equivalencies			
Glucocorticoid	Approximate equivalent dose (mg)	Relative anti-inflammatory (glucocorticoid) potency	Relative mineralocorticoid potency
<i>Short-acting</i>			
Cortisone	25	0.8	2
Hydrocortisone	20	1	2
<i>Intermediate-acting</i>			
Prednisone	5	4	1
Prednisolone	5	4	1
Triamcinolone	4	5	0
Methylprednisolone	4	5	0
<i>Long-acting</i>			
Dexamethasone	0.75	20-30	0
Betamethasone	0.6-0.75	20-30	0

Table adapted from Facts and Comparisons® 1999:122

* For injectable medications administered by a healthcare professional, please refer to the “Specialty Medication Guidelines” in the beginning of this formulary.

* If documentation of osteoporosis is available, please submit with PA request.

GENERIC: CELECOXIB

BRAND: CELEBREX®

INDICATIONS:

- (1) Relief of signs and symptoms of rheumatoid arthritis (RA) in adults
- (2) Relief of signs and symptoms of osteoarthritis (OA)
- (3) Relief of signs and symptoms of ankylosing spondylitis
- (4) Management of acute pain in adults
- (5) Treatment of primary dysmenorrhea
- (6) To reduce the number of adenomatous polyps in familial adenomatous polyposis, as an adjunct to usual care

Criteria:

- (a) Failure, intolerance, or contraindication to at least 2 formulary NSAIDs; **and**
- (b) One of the following:
 - (1) Age greater than 65; **or**
 - (2) Concomitant use of warfarin or other antiplatelet therapy; **or**
 - (3) Concomitant use of chronic systemic corticosteroid therapy; **or**
 - (4) Documented history of ulcer disease or GI bleed; **or**
 - (5) Documented history of significant GI disease requiring therapy with an H2 antagonist or PPI; **or**
 - (6) Documented history of nonselective NSAID-induced GI adverse effects; **and**
- (c) For OA, therapeutic failure (≥21-day trial), intolerance of, or contraindication to at least 1 of the following: acetaminophen or opioid analgesics or topical analgesics (capsaicin, etc.)

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GENERIC: CLOXACILLIN SODIUM

INDICATION:

(1) Treatment of infections due to penicillinase-producing staphylococci

Criteria:

- (a) Diagnosis of staphylococcal infection; **and**
- (b) Failure of dicloxacillin sodium.

GENERIC: CYANOCOBALAMIN (HYDROXOCOBALAMIN)

BRAND: VITAMIN B-12[®]

INDICATION:

(1) Vitamin B-12 deficiency

Criteria:

- (a) Patients who lack intrinsic factor; **or**
- (b) Patients who are on long-term PPI therapy; **or**
- (c) Patients with a partial or complete gastrectomy.

** For injectable medications administered by a healthcare professional, please refer to the "Specialty Medication Guidelines" in the beginning of this formulary.*

GENERIC: CYCLOSPORINE OPHTHALMIC EMULSION 0.05%

BRAND: RESTASIS

INDICATION:

(1) Increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca

Criteria:

- (a) Failure of, intolerance to, contraindication, or previous use to artificial tears, or equivalent

GENERIC: DABIGATRAN ETEXILATE MESYLATE

BRAND: PRADAXA[®]

INDICATION:

(1) Reduce the risk of stroke and systemic embolism in patients with non-vascular atrial fibrillation.

Criteria:

- (a) Diagnosis of non-vascular atrial fibrillation; **and**
- (b) Must have recent CrCl levels or Scr and current patient weight; **and**
- (c) No active pathological bleeding; **and**
- (d) Must have tried and failed or intolerant to Warfarin

NOTE: Conversion to Pradaxa:

- (a) From Warfarin: discontinue warfarin and start Pradaxa when INR<2.0
- (b) From Parenteral Anticoagulants: start Pradaxa 0-2 hrs prior to next scheduled dose of parenteral anticoagulant, or at the time of discontinuation of continuous parenteral drug (e.g. heparin)

GENERIC: DALFAMPRIDINE

BRAND: AMPYRA[®]

INDICATION:

(1) Improved walking speed in patients with multiple sclerosis

Criteria:

- (a) Diagnosis of multiple sclerosis; **and**
- (b) Prescribed by a neurologist; **and**

Prior Authorization Guidelines

- (c) Currently taking a disease modifying drug for multiple sclerosis (Avonex, Aubagio, Betaseron, Copaxone, Extavia, Gilenya, Rebif, Tecfidera or Tysabri)

* *Renewals will require documented improvement in walking speed (demonstrated improvement in timed 25-foot walk)*

GENERIC: DANTROLENE

BRAND: DANTRIUM[®]

INDICATION:

- (1) Spasticity resulting from upper motor neuron disorders

Criteria:

- (a) Demonstrated failure of, or intolerance to, Baclofen (Lioresal[®]).

GENERIC: DAPAGLIFLOZIN

BRAND: FARXIGA[®]

INDICATION:

- (1) Type 2 diabetes mellitus
(2) To reduce the risk of hospitalization and/or death for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors or heart failure with reduced ejection fraction (NYHA class II-IV).
(3) To reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

Criteria for Type 2 diabetes mellitus:

- (a) Diagnosis of Type 2 diabetes mellitus
(b) Has not achieved adequate glycemic control on the following:
(1) Metformin (alone or in combination)

Criteria for heart failure:

- (a) Diagnosis of heart failure with reduced ejection fraction.
(b) Has not achieved adequate symptom control with the following:
(1) ACE/ARB or ARNI, and
(2) Beta Blocker

Criteria for Chronic Kidney Disease:

- (a) Diagnosis of Chronic Kidney Disease
(b) Has not achieved adequate symptom control with the following:
(1) ACE/ARB,
(c) NOT on dialysis

GENERIC: DARBEOETIN ALFA

BRAND: ARANESP[®]

INDICATIONS:

- (1) Anemia with cancer chemotherapy (nonmyeloid)
(2) Anemia due to chronic renal failure

Criteria:

- (a) Ensure patient's iron stores are adequate (Ferritin \geq 100 ng/mL and/or Transferrin saturation \geq 20%) or patient is being treated with iron; **and**
(b) Adequate blood pressure control; **and**

Chronic kidney disease patients:

- (a) Initiate treatment when hemoglobin is $<$ 10g/dL; **or**

Anemia due to chemotherapy in cancer:

- (a) Initiate treatment only if hemoglobin is $<$ 10g/dL; **and**

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(b) Anticipated duration of myelosuppressive chemotherapy is ≥ 2 months

For renewals:

(a) **Chronic kidney disease patients:**

(1) With dialysis Hbg < 11 ; **or**

(2) Without dialysis Hbg < 10

(b) **Anemia due to chemotherapy in cancer patients:**

(1) Hbg < 11

GENERIC: DARIFENACIN

BRAND: ENABLEX[®]

INDICATION:

(1) Overactive bladder

Criteria:

(a) Failure of Oxybutynin

GENERIC: DESMOPRESSIN

BRAND: DDAVP[®]

INDICATIONS:

(1) Central cranial diabetes insipidus (CCDI)

(2) Primary nocturnal enuresis

Criteria:

(a) Diagnosis of CCDI; **or**

(b) For the treatment of enuresis, age 6 to 18 years; **and**

(c) Failure of behavior modification for 6 months (e.g., alarms, no beverages after 5pm, special diapers, etc.)

** Renewals for the indication of nocturnal enuresis will require the documentation of a retrial of behavior modification.*

GENERIC: DIMETHYL FUMERATE

BRAND: TECFIDERA[®]

INDICATION:

(1) Diagnosis of a relapsing form of Multiple Sclerosis;

Criteria:

(a) Prescribed by neurologist, and

(b) Not requesting combination of any 2 agents together: Copaxone, Betaseron, Avonex, Tysabri, Gilenya, Aubagio or Tecfidera.

GENERIC: DONEPEZIL

BRAND: ARICEPT[®]

INDICATION:

(1) Alzheimer's disease: for the treatment of dementia.

Criteria:

(a) Dementia must be confirmed by clinical evaluation

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GENERIC: DULAGLUTIDE

BRAND: TRULICITY[®]

INDICATION:

- (1) Adjunct to diet and exercise to improve glycemic control in patients with type II diabetes mellitus
- (2) To reduce the risk of major adverse cardiovascular events in adults with type II diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors

Criteria:

- (a) Diagnosis of type II diabetes mellitus; **and**
- (b) Must be under the care of a healthcare provider skilled with the use of insulin and supported by diabetes educator
- (c) Must have tried at least 2 antidiabetic agents such as metformin, sulfonylureas, thiazolidinedione or insulin and not achieved adequate glycemic control despite treatment or intolerant to other antidiabetic medications

GENERIC: ELBASVIR-GRAZOPREVIR

BRAND: ZEPATIER[®]

INDICATION:

- (1) Chronic Hepatitis C

Criteria:

- (a) Preferred for genotypes 1 and 4
- (b) Must follow the clinical criteria as set by the Maryland Department of Health
- (c) Special Hepatitis C PA request forms, treatment plan template, preferred status information, and full criteria can be obtained at <http://www.jaimedicalsystems.com/providers/pharmacy/> or by contacting ProCare at 1-800-555-8513

GENERIC: EMPAGLIFLOZIN

BRAND: JARDIANCE[®]

INDICATION:

- (1) Type II Diabetes Mellitus
- (2) To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure
- (3) To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.

Criteria for Type 2 diabetes mellitus:

- (a) Failure of metformin, a sulfonylurea, or pioglitazone

Criteria for heart failure:

- (a) Diagnosis of heart failure
- (b) Has not achieved adequate symptom control with the following:
 - (1) ACE/ARB or ARNI, and
 - (2) Beta Blocker

GENERIC: EMPAGLIFLOZIN-LINAGLIPTIN

BRAND: GLYXAMBI[®]

INDICATION:

- (1) Type II Diabetes Mellitus

Criteria:

- (a) For use when an SGLT2 and a DPP-4 Inhibitor is appropriate.

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GENERIC: ENTACAPONE

BRAND: COMTAN[®]

INDICATION:

(1) As an adjunct to levodopa/carbidopa to treat patients with idiopathic Parkinson's disease

Criteria:

- (a) Diagnosis of idiopathic Parkinson's disease; **and**
- (b) Patient is receiving concomitant levodopa/carbidopa therapy.

GENERIC: EPOETIN ALFA

BRAND: EPOGEN[®]

INDICATIONS:

- (1) Anemia with cancer chemotherapy (nonmyeloid)
- (2) Anemia due to chronic renal failure
- (3) Anemia of HIV infection associated with zidovudine
- (4) Reduction of allogenic blood transfusion for elective, noncardiac, nonvascular surgery

Criteria:

- (a) Patient's iron stores are adequate (Ferritin ≥ 100 mcg/mL and/or Transferrin saturation $\geq 20\%$) or patient is being treated with iron; **and**
- (b) Adequate blood pressure control

Chronic kidney disease patients:

- (c) Initiate treatment when hemoglobin is < 10 g/dL (3-month approval)

Anemia due to chemotherapy in cancer patients:

- (c) Initiate treatment only if hemoglobin < 10 g/dL and anticipated duration of myelosuppressive chemotherapy is ≥ 2 months

Anemia due to zidovudine in HIV-infected patients:

- (c) Initiate treatment when hemoglobin is < 10 g/dL

Surgical procedure - Transfusion of blood product, Allogenic;

Prophylaxis:

- (c) Patient's pre-operative Hgb > 10 to ≤ 13 g/dL (14-day approval)

For renewals:

Chronic kidney disease patients:

- (a) With dialysis Hgb < 11
- (b) Without dialysis Hgb < 10

Anemia due to chemotherapy in cancer patients:

- (a) Hgb < 11

Anemia due to zidovudine in HIV-infected patients:

- (a) Hgb < 11

GENERIC: ETANERCEPT

BRAND: ENBREL[®]

INDICATIONS:

- (1) Moderate to severely active rheumatoid arthritis
- (2) Moderate to severely active polyarticular juvenile rheumatoid arthritis
- (3) Psoriatic spondylitis
- (4) Ankylosing spondylitis
- (5) Plaque psoriasis

Criteria:

- (a) The patient had a NEGATIVE tuberculin skin test, or if positive, has received treatment for latent TB prior to Enbrel therapy; **and**

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(b) The patient does not have a clinically important active infection

Additional Criteria for RA:

(c) The patient has failed or is intolerant to one formulary NSAID **and**

(d) The patient has failed or is intolerant to one formulary DMARD

Additional Criteria for Plaque Psoriasis:

(c) Involvement of $\geq 10\%$ body surface area (BSA)

GENERIC: EVOLOCUMAB

BRAND: REPATHA[®]

INDICATION:

(1) Primary hyperlipidemia

(2) High cholesterol in the blood

(3) Heterozygous familial hypercholesterolemia (HeFH)

(4) Reduce the risk of heart attack, stroke, and certain types of heart surgery in patients.

(5) Atherosclerotic cardiovascular disease (ASCVD)

(6) Homozygous familial hypercholesterolemia

Criteria:

(a) Documentation of positive clinical response

(b) Comprehensive counseling regarding diet

(c) Not used in combination with another type 9 (PCSK9) INHIBITOR

GENERIC: EXENATIDE

BRAND: BYDUREON[®]

INDICATION:

(1) Adjunctive therapy of type 2 diabetes mellitus

Criteria:

(a) Diagnosis of type 2 diabetes; **and**

(b) Failure or intolerance to sulfonylureas and/or metformin at optimal dosing. Failure defined as Hemoglobin A1c ≥ 7.0 ; **and**

(c) Patient ≥ 10 years of age

GENERIC: EZETIMIBE

BRAND: ZETIA[®]

INDICATIONS:

(1) Hypercholesterolemia

(2) Sitosterolemia

Criteria:

(a) Diagnosis of Sitosterolemia; **or**

(b) For the diagnosis of hypercholesterolemia, failure of optimal dosing/duration or intolerance/contraindication to 2 formulary anti-lipid agents (with at least one agent being a statin)

GENERIC: EZETIMIBE/SIMVASTATIN

BRAND: VYTORIN[®]

INDICATION:

(1) Hypercholesterolemia

Criteria:

(a) Failure of optimal dosing/duration or intolerance/contraindication to 2 formulary anti-lipid agents (with at least one agent being a statin)

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GENERIC: FENOFIBRATE

BRAND: LIPOFEN[®], TRIGLIDE[®]

INDICATION:

- (1) Hypercholesterolemia, Hypertriglyceridemia

Criteria:

- (a) Failure of generic fenofibrate 48, 54, 154, or 160 mg after a period of at least two months on the maximum dose appropriate and tolerated by the patient.

GENERIC: FENOFIBRIC ACID

BRAND: TRILIPIX[®]

INDICATION:

- (1) Hypercholesterolemia, Hypertriglyceridemia

Criteria:

- (a) Failure of generic fenofibrate 48, 54, 154 or 160 mg after a period of at least two months on the maximum dose appropriate and tolerated by the patient.

GENERIC: FENOFIBRATE MICRONIZED

BRAND: ANTARA[®]

INDICATION:

- (1) Hypercholesterolemia, Hypertriglyceridemia

Criteria:

- (a) Failure of generic fenofibrate 54 or 160 mg after a period of at least two months on the maximum dose appropriate and tolerated by the patient.

GENERIC: FENOFIBRIC ACID TAB

BRAND: FIBRICOR[®]

INDICATIONS:

- (1) Hypercholesterolemia
(2) Hypertriglyceridemia

Criteria:

- (a) Failure of generic Fenofibrates

GENERIC: FENTANYL TRANSDERMAL PATCH

BRAND: DURAGESIC[®]

INDICATION:

- (1) Persistent, moderate to severe chronic pain OR cancer-related pain that requires continuous, around-the-clock opioid (narcotic) administration for an extended period of time

Criteria:

- (a) Diagnosis of persistent, moderate to severe chronic or cancer-related pain requiring continuous, around-the-clock opioid administration for an extended period of time; **and**
(b) Patient unable to take medications by mouth; **or**
(c) Failure of or intolerance/contraindication to a long-acting oral opiate (narcotic) medication (controlled-release morphine, oxycodone, or oxymorphone)
(d) Completion of Opioid Prior Authorization/Attestation Form required, available at <http://www.jaimedicalsystems.com/providers/pharmacy/>

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GENERIC: FESOTERODINE

BRAND: TOVIAZ[®]

INDICATION:

- (1) Overactive bladder

Criteria:

- (a) Failure of Oxybutynin

GENERIC: FILGRASTIM

BRAND: NEUPOGEN[®]

INDICATIONS:

- (1) Prevention of neutropenia in patients receiving myelosuppressive chemotherapy for non-myeloid malignancies
- (2) Patients undergoing peripheral blood progenitor cell collection and therapy
- (3) Patients with severe chronic neutropenia

Criteria:

- (a) The patient is undergoing peripheral blood progenitor cell collection and therapy; **or**
- (b) Diagnosis of severe chronic neutropenia with an absolute neutrophil count (ANC) < 1,000; **or**
- (c) ANC nadir of < 1,000 neutrophils to previous chemotherapy. Once this has been documented, approval will be given for prophylaxis for all future chemo cycles.

** For injectable medications administered by a healthcare professional, please refer to the "Specialty Medication Guidelines" in the beginning of this formulary.*

** Please indicate estimated duration of therapy.*

GENERIC: FLUCONAZOLE

BRAND: DIFLUCAN[®]

(PA required after 150mg x2 tablet dispensed)

INDICATIONS:

- (1) Vaginal candidiasis
- (2) Cryptococcal meningitis
- (3) Serious systemic Candida infections
- (4) Oropharyngeal and esophageal candidiasis

Criteria:

- (a) Any of the above diagnoses; **except**
- (b) For the diagnosis of oropharyngeal candidiasis, failure of nystatin therapy; **and**
- (c) For the diagnosis of vaginal candidiasis, patients who are immunocompromised and/or have recurrent or refractory infections.

GENERIC: FLUTICASONE/UMECLINDIUM/VILANTEROL

BRAND: TRELEGY[®]

INDICATION:

- (1) Maintenance treatment of asthma in patients 18 years of age and older
- (2) Maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)

Criteria for Asthma:

- (a) Currently on, but not adequately controlled by an two (2) or more inhaled medium to high dose LABA+ICS for more than sixty (60) days; and
- (b) Patients must be reevaluated after 6 months

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Criteria for COPD:

- (a) Currently on, but not adequately controlled by an two (2) or more inhaled medium to high dose LABA+ICS for more than sixty (60) days; and
- (b) Currently on, but not adequately controlled by an inhaled LAMA or LAMA+LABA for more than sixty (60) days
- (c) Patients must be reevaluated after 6 months

GENERIC: GALANTAMINE HYDROBROMIDE

BRAND: RAZADYNE[®], RAZADYNE ER[®]

INDICATION:

- (1) Alzheimer's disease: for the treatment of dementia

Criteria:

- (a) Confirmation by clinical evaluation

GENERIC: GATIFLOXACIN

BRAND: ZYMAXID[®]

INDICATION:

- (1) Bacterial conjunctivitis

Criteria:

- (a) Failure of, contraindication to, or intolerance to ciprofloxacin ophthalmic formulation.

GENERIC: GLATIRAMER ACETATE

BRAND: COPAXONE[®]

INDICATIONS:

- (1) Relapsing-remitting Multiple Sclerosis
- (2) To prevent or slow the development of clinically definite Multiple Sclerosis in patients who have experienced a first clinical episode and have MRI features consistent with Multiple Sclerosis

Criteria:

- (a) Prescribed by neurologist; and
- (b) Not requesting combination therapy of any 2 agents together: Copaxone, Betaseron, Avonex, Tysabri, Rebif, Gilenya, Aubagio, or Tecfidera

GENERIC: GLECAPREVIR-PIBRENTASVIR

BRAND: MAVYRET[®]

INDICATION:

- (1) Chronic Hepatitis C

Criteria:

- (a) Preferred for genotypes 1, 2, 3, 4, 5 and 6
- (b) Must follow the clinical criteria as set by the Maryland Department of Health
- (c) Special Hepatitis C PA request forms, treatment plan template, preferred status information, and full criteria can be obtained at <http://www.jaimedicalsystems.com/providers/pharmacy/> or by contacting ProCare at 1-800-555-8513

GENERIC: HYDROXOCOBALAMIN

BRAND: HYDROXOCOBALAMIN

INDICATION:

- (1) Vitamin B-12 deficiency

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Criteria:

- (a) Patients who lack intrinsic factor; **or**
- (b) Patients who are on long-term PPI therapy; **or**
- (c) Patients with a partial or complete gastrectomy.

GENERIC: INTERFERON ALFA

BRAND: ROFERON-A[®], INTRON-A[®], and ALFERON N[®]

INDICATIONS:

- (1) Hairy cell leukemia
- (2) AIDS-related Kaposi's sarcoma
- (3) Chronic Hepatitis B or C
- (4) Malignant melanoma

Criteria:

- (a) Any of the above diagnoses.

** For injectable medications administered by a healthcare professional, please refer to the "Specialty Medication Guidelines" in the beginning of this formulary.*

GENERIC: INTERFERON BETA

BRAND: AVONEX[®], BETASERON[®], REBIF[®]

INDICATIONS:

- (1) Diagnosis of a relapsing form of Multiple Sclerosis; **or**
- (2) First clinical demyelinating event with MRI evidence consistent with Multiple Sclerosis

Criteria:

- (a) Prescribed by neurologist; **and**
- (b) If patient has a history of or is currently being treated for severe psychiatric disorders, suicidal ideation or severe depression, this condition is well controlled; **and**
- (c) Not requesting combination of any 2 agents together: Copaxone, Betaseron, Avonex, Tysabri, Rebif, Gilenya, Aubagio, or Tecfidera

** For injectable medications administered by a healthcare professional, please refer to the "Specialty Medication Guidelines" in the beginning of this formulary.*

GENERIC: ISOSORBIDE MONONITRATE

BRAND: IMDUR[®]

INDICATION:

- (1) Prevention of angina pectoris

Criteria:

- (a) Failure of formulary nitrates.

GENERIC: ITRACONAZOLE

BRAND: SPORANOX[®]

INDICATIONS:

- (1) Histoplasmosis infections
- (2) Aspergillosis infections
- (3) Blastomycosis

Criteria:

- (a) Any of the above diagnoses.

Prior Authorization Guidelines

GENERIC: LANSOPRAZOLE

BRAND: PREVACID SOLU-TAB[®]

INDICATION:

(1) Gastroesophageal reflux disease (GERD), heartburn, gastric ulcer, and duodenal ulcer.

Criteria:

- (a) Unable to ingest a solid dosage form (e.g. oral tablet or capsule) due to one of the following:
- (1) Age
 - (2) Oral/motor difficulties
 - (3) Dysphagia
 - (4) Patient utilizes a feeding tube for medication administration

GENERIC: LEDIPASVIR-SOFOSBUVIR

BRAND: HARVONI[®]

INDICATION:

(1) Chronic Hepatitis C

Criteria:

- (a) Generic tablet only
- (b) Must follow the clinical criteria as set by the Maryland Department of Health
- (c) Special Hepatitis C PA request forms, treatment plan template, preferred status information, and full criteria can be obtained at <http://www.jaimedicalsystems.com/providers/pharmacy/> or by contacting ProCare at 1-800-555-8513

GENERIC: LEUPROLIDE

BRAND: LUPRON[®]

INDICATIONS:

- (1) Advanced prostate cancer
- (2) Central precocious puberty
- (3) Endometriosis
- (4) Uterine leiomyomata (fibroids)

Criteria:

- (a) Diagnosis of advanced prostate cancer, precocious puberty or fibroids; **or**
- (b) For the diagnosis of endometriosis, failure of NSAIDS **and** oral contraceptives **or** endometriosis diagnosed by laparoscopy.

** Note: This agent is ordinarily administered at the physician's office. For injectable medications administered by a healthcare professional, please refer to the "Specialty Medication Guidelines" in the beginning of this formulary.*

GENERIC: LIDOCAINE PATCH 5%

BRAND: LIDODERM PATCH 5%[®]

INDICATION:

(1) Relief of pain associated with post-herpetic neuralgia.

Criteria:

- (a) Skin application site is intact, and
- (b) For the relief of pain associated with post-herpetic neuralgia;
- and**
- (c) Failure, adverse reaction, or contraindication to two prescription analgesics, including formulary lidocaine topical cream or gel.

Prior Authorization Guidelines

GENERIC: LIRAGLUTIDE

BRAND: VICTOZA®

INDICATION:

- (1) Adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type II diabetes mellitus
- (2) To reduce the risk of major adverse cardiovascular events in adults with type II diabetes mellitus and established cardiovascular disease.

Criteria:

- (a) Diagnosis of type II diabetes mellitus; **and**
- (b) Must be under the care of a healthcare provider skilled with the use of insulin and supported by a diabetes educator; **and**
- (c) Must have tried at least 2 antidiabetic agents such as metformin, sulfonylureas, thiazolidinedione, or insulin and not achieved adequate glycemic control despite treatment or intolerant to other antidiabetic medications; **and**
- (d) Must have tried and failed or intolerant to treatment with Bydureon or Byetta; **and**
- (e) NO personal or family history of medullary thyroid carcinoma

GENERIC: LODOXAMIDE TROMETHAMINE OPHTH SOLN 0.1%

BRAND: ALOMIDE®

INDICATION:

- (1) Allergic conjunctivitis

Criteria:

- (a) Failure or contraindication of Ketotifen

GENERIC: LUBIPROSTONE

BRAND: AMITIZA®

INDICATION:

- (1) Chronic idiopathic constipation
- (2) Irritable bowel syndrome
- (3) Opioid-induced constipation

Criteria:

- (a) Must have a diagnosis of either chronic idiopathic constipation, irritable bowel syndrome, or opioid-induced constipation; and
- (b) Failure of Miralax, Senna-S, and/or lactulose

GENERIC: MEMANTINE

BRAND: NAMENDA®

INDICATION:

- (1) Alzheimer's disease: for treatment of moderate-to-severe cases of dementia

Criteria:

- (a) Dementia must be confirmed by clinical evaluation; **and**
- (b) Documented dementia is either moderate or severe

GENERIC: MEPHYTON

BRAND: VITAMIN K

INDICATION:

- (1) Anticoagulant-induced prothrombin deficiency

Criteria:

- (a) Diagnosis of anticoagulant-induced prothrombin deficiency caused by coumadin or indandione derivatives

Prior Authorization Guidelines

GENERIC: METHADONE

BRAND: METHADONE

INDICATION:

- (1) Persistent, moderate to severe chronic pain that requires around-the-clock opioid (narcotic) administration for an extended period of time; not intended as an as-needed analgesic.

Criteria:

- (a) Completion of Opioid Prior Authorization/Attestation Form required, available at <http://www.jaimedicalsystems.com/providers/pharmacy/>

GENERIC: METRONIDAZOLE VAGINAL GEL

BRAND: METROGEL[®]

INDICATION:

- (1) Bacterial vaginosis

Criteria:

- (a) Pregnancy; **or**
- (b) Intolerance to oral metronidazole

GENERIC: MILNACIPRAN

BRAND: SAVELLA[®]

INDICATION:

- (1) Moderate to severe fibromyalgia

Criteria:

- (a) Diagnosis of fibromyalgia; **and**
- (b) Documented failure or contraindication to:
 - (1) Pain relievers (e.g. Tramadol); **or**
 - (2) Muscle Relaxants (e.g. cyclobenzaprine, Baclofen)

GENERIC: MIRABEGRON

BRAND: MYRBETRIQ[®]

INDICATION:

- (1) Overactive bladder
- (2) Neurogenic detrusor over-activity (NDO) in pediatric patients

Criteria:

- (a) Failure of Oxybutynin
- (b) Age 3 years and older and weighing 35kg or more (NDO)

GENERIC: MORPHINE SULFATE SUSTAINED-RELEASE

BRAND: MS CONTIN[®]

INDICATION:

- (1) Persistent, moderate to severe chronic pain OR cancer-related pain that requires continuous, around-the-clock opioid (narcotic) administration for an extended period of time; not intended as an as needed analgesic

Criteria:

- (a) Completion of Opioid Prior Authorization/Attestation Form required, available at <http://www.jaimedicalsystems.com/providers/pharmacy/>

Prior Authorization Guidelines

GENERIC: MOXIFLOXACIN

BRAND: AVELOX®

INDICATIONS:

- (1) Acute bacterial sinusitis
- (2) Acute bacterial exacerbations of chronic bronchitis
- (3) Mild to moderate pelvic inflammatory disease
- (4) Complicated/Uncomplicated skin and skin structure infections
- (5) Community-acquired pneumonia
- (6) Complicated intra-abdominal infections

Criteria:

In patients ≥ 18 years of age with any of the above listed indications when:

- (a) Cultures show sensitivity to Avelox® only; **or**
- (b) Patient discharged on Avelox® from the hospital and needs to complete regimen on an outpatient basis

GENERIC: NAFARELIN

BRAND: SYNAREL®

INDICATIONS:

- (1) Central precocious puberty
- (2) Endometriosis

Criteria:

- (a) Diagnosis of central precocious puberty; **or**
- (b) For the diagnosis of endometriosis in patients ≥ 18 years of age, failure of NSAIDs **and** oral contraceptives, **or** endometriosis diagnosed by laparoscopy.

GENERIC: NUTRITIONAL SUPPLEMENTS

BRAND: ENSURE®, PEDIASURE®, BOOST®, VIVONEX®

INDICATION:

- (1) Nutritional supplementation

Criteria:

- (a) Patient must have enteral access via one of the following: nasogastric (NG) tube, nasoduodenal (ND) tube, nasojejunal (NJ) tube, percutaneous endoscopic gastrostomy (PEG) or percutaneous endoscopic jejunostomy (PEJ).

To obtain nutritional supplements (e.g., Ensure or Pediasure) for members without enteral access, please follow the DME process. For assistance accessing the DME process, please contact Customer Service at 1-888-524-1999.

GENERIC: OCTREOTIDE

BRAND: SANDOSTATIN®

INDICATIONS:

- (1) Symptomatic treatment of severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
- (2) Profuse, watery diarrhea associated with vasoactive intestinal peptide (VIP) secreting tumors
- (3) To reduce the blood levels of growth hormone and IGF-I associated with acromegaly

Criteria:

- (a) Any of the above diagnoses; **and**
- (b) For the diagnosis of acromegaly, the patient has had an inadequate response to, or cannot be treated with surgical resection, pituitary irradiation **and** bromocriptine at maximally tolerated doses.

For injectable medications administered by a healthcare professional, please refer to the "Specialty Medication Guidelines" in the beginning of this formulary.

Prior Authorization Guidelines

GENERIC: OLODATEROL HCL

BRAND: STRIVERDI[®]

INDICATION:

(1) Maintenance Treatment of Chronic Obstructive Pulmonary Disease

Criteria:

- (a) Currently on, but not controlled by a LAMA for more than sixty (60) days; and
- (b) The patient must be reevaluated after 6 months

GENERIC: OLOPATADINE HCL OPHTH SOLN 0.2%

BRAND: PATADAY[®]

INDICATION:

(1) Allergic conjunctivitis

Criteria:

- (a) Failure or contraindication to Ketotifen

GENERIC: OLOPATADINE HCL OPHTH SOLN 0.1%

BRAND: PATANOL[®]

INDICATION:

(1) Allergic conjunctivitis

Criteria:

- (a) Failure or contraindication of Ketotifen

GENERIC: ONDANSETRON SOLUTION

BRAND: ZOFRAN[®]

INDICATIONS:

- (1) Chemotherapy induced nausea and vomiting
- (2) Post-operative nausea and vomiting
- (3) Radiation induced nausea and vomiting

Criteria:

- (a) For patients who have a contraindication or failure of ondansetron tablets

GENERIC: OXYCODONE, CONTROLLED-RELEASE

BRAND: OXYCONTIN[®]

INDICATION:

- (1) Persistent, moderate to severe chronic pain **or** cancer-related pain that requires continuous, around-the-clock opioid (narcotic) administration for an extended period of time; not intended as an as-needed analgesic.

Criteria:

- (a) Persistent, moderate to severe chronic pain **or** cancer-related pain that requires around-the-clock analgesia for an extended period of time; **and**
- (b) For chronic pain, failure, intolerance, or contraindication to at least 2 short-acting formulary narcotic analgesics and controlled-release morphine (MS Contin, others). For cancer pain, failure intolerance, or contraindication to controlled-release morphine (MS Contin, others).
- (c) Completion of Opioid Prior Authorization/Attestation Form required, available at <http://www.jaimedicalsystems.com/providers/pharmacy/>

Prior Authorization Guidelines

GENERIC: PALIVIZUMAB

BRAND: SYNAGIS®

INDICATION:

(1) Prevention of serious lower respiratory disease caused by respiratory syncytial virus (RSV)

Criteria:

- (a) Administration within RSV season (Nov-Apr); **and**
- (b) Pt < 2 years of age at start of RSV season with chronic lung disease that has required treatment (supplemental oxygen, bronchodilator, diuretic, or corticosteroid) within prior 6 months **or**
- (c) Pt born \leq 28 weeks gestation and is \leq 12 months at the start of the RSV season **or**
- (d) Pt born between 29-32 weeks gestation and is \leq 6 months at the start of the RSV season **or**
- (e) Pt \leq 24 months of age at the start of the RSV season with hemodynamically significant congenital heart disease, including one of the following:
 - (1) Receiving medication to control congestive heart failure; **or**
 - (2) With moderate to severe pulmonary artery hypertension; **or**
 - (3) With cyanotic congenital heart disease; **or**
- (f) Pt born between 32-35 weeks gestation, and is \leq 3 months at the start of the RSV season **and** has one of the following risk factors:
 - (1) Childcare attendance; **or**
 - (2) Siblings less than 5 years and children born between 32-35 weeks receive a maximum of 3 doses; **or**
- (g) Is the patient born before 35 weeks of gestation and has either congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions during the first year of life?

Once the prior authorization is received, please contact your Synagis provider. One such provider is Walgreens Specialty pharmacy:

Phone = 866-230-8102

Fax = 888-325-6544

GENERIC: PEGINTERFERON ALFA-2A

BRAND: PEGASYS®

INDICATIONS:

- (1) Use in combination with ribavirin or ribavirin and other Direct-Acting Antivirals for the treatment of chronic Hepatitis C
- (2) Treatment of chronic Hepatitis C in patients coinfecting with HIV whose HIV is clinically stable.
- (3) Treatment of patients with HBeAg positive and HBeAg negative chronic Hepatitis B

Criteria:

(In combination with ribavirin or ribavirin and other Direct-Acting Antivirals)

- (a) Diagnosis as indicated above including any applicable labs and/or tests
- (b) Clinically documented chronic Hepatitis C with detectable HCV RNA levels > 50 IU/mL
- (c) Age \geq 3 years
- (d) Liver biopsy (unless contraindicated) indicates some fibrosis and inflammatory necrosis
- (e) Intolerant to Peg-Intron
- (f) If HIV positive, patient is clinically stable.

(For chronic Hepatitis B)

- (a) Documented HBeAg positive or negative chronic Hepatitis B
- (b) Compensated liver disease
- (c) Evidence of viral replication
- (d) Evidence of liver inflammation
- (e) Not contraindicated

Prior Authorization Guidelines

GENERIC: PEGINTERFERON ALFA-2B

BRAND: PEG-INTRON[®]

INDICATIONS:

- (1) Use in combination with ribavirin for the treatment of chronic Hepatitis C
- (2) Treatment of chronic Hepatitis C in patients coinfecting with HIV whose HIV is clinically stable.

Criteria:

(In combination with ribavirin or ribavirin and other Direct-Acting Antivirals)

- (a) Diagnosis as indicated above including any applicable labs and/or tests
- (b) Clinically documented chronic Hepatitis C with detectable HCV RNA levels > 50 IU/mL
- (c) Age ≥ 3 years
- (d) Liver biopsy (unless contraindicated) indicates some fibrosis and inflammatory necrosis
- (e) If HIV positive, patient is clinically stable.

GENERIC: PENTOXIFYLLINE

BRAND: TRENTAL[®]

INDICATION:

- (1) Intermittent claudication

Criteria:

- (a) Pain on walking or ABI < 0.8; **or**
- (b) Diabetic foot ulcer; **or**
- (c) Gangrene; **or**
- (d) Risk of, or existing, amputation.

GENERIC: PIMECROLIMUS

BRAND: ELIDEL[®]

INDICATION:

- (1) Second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when treatments are not advisable.

Criteria:

- (a) Documented failure of optimal dosing/adequate duration; **or**
- (b) Intolerance or contraindication to at least one formulary topical corticosteroid; **and**
- (c) Diagnosis of mild to moderate atopic dermatitis; **and**
- (d) Using for short-term and non-continuous treatment.

GENERIC: RABEPRAZOLE

BRAND: ACIPHEX[®]

INDICATIONS:

- (1) Gastric hypersecretion, pathological conditions including Zollinger-Ellison Syndrome
- (2) Erosive esophagitis - gastroesophageal reflux disease
- (3) Erosive esophagitis, maintenance therapy - gastroesophageal reflux disease

Criteria:

- (a) Failure, intolerance, or contraindication to 2 formulary PPIs after a period of at least two months on the maximum dose appropriate and tolerated by the patient.

Prior Authorization Guidelines

GENERIC: RALOXIFENE

BRAND: EVISTA[®]

INDICATION:

(1) Treatment and prevention of osteoporosis in postmenopausal women

Criteria:

- (a) Personal or family history of breast cancer; **or**
- (b) Intolerable side effects to at least one formulary estrogen.

GENERIC: REPAGLINIDE

BRAND: PRANDIN

INDICATION:

(1) Type 2 diabetes mellitus

Criteria:

- (a) Diagnosis of Type 2 diabetes mellitus
- (b) Has not achieved adequate glycemic control on at least ONE of the following:
 - (1) Metformin (alone or in combination)
 - (2) A Sulfonylurea (alone or in combination)
 - (3) A preferred DPP-4 inhibitor
- (c) Contraindication to metformin, a sulfonylurea, OR a preferred DPP-4 Inhibitor

GENERIC: RIBAVIRIN

BRAND: REBETOL[®]

INDICATION:

(1) Indicated **only** in combination with a recombinant interferon alfa-2a or alfa-2b product or in combination with other Direct-Acting Antivirals for the treatment of chronic Hepatitis C.

Criteria:

- (a) Diagnosis of chronic Hepatitis C; **and**
- (b) Patient is receiving concomitant recombinant interferon alfa-2a or alfa-2b therapy or other Direct-Acting Antivirals.

GENERIC: RIFAXIMIN 550 MG

BRAND: XIFAXAN[®] 550 MG

INDICATION:

(1) Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults

(2) Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults

Criteria:

- (a) Hepatic encephalopathy
 - Failure of, intolerance to, contraindication, or previous use to lactulose at maximally tolerated doses
- (b) IBS-D
 - Failure of, intolerance to, contraindication, or previous use to loperamide
 - For renewals: the patient has a ten (10) or more week treatment-free period

Prior Authorization Guidelines

GENERIC: RILUZOLE

BRAND: RILUTEK[®]

INDICATION:

(1) Amyotrophic lateral sclerosis (ALS)

Criteria:

(a) Diagnosis of ALS.

GENERIC: RIVASTIGMINE TARTRATE

BRAND: EXELON[®]

INDICATION:

(1) Alzheimer's disease: for the treatment of dementia

Criteria:

(a) Confirmation by clinical evaluation

GENERIC: RIZATRIPTAN

BRAND: MAXALT[®]

INDICATION:

(1) Acute treatment of migraine headache

Criteria:

- (a) Failure of, intolerance to, or contraindication to one traditional formulary agent (NSAID's, ergotamine, or combination analgesic); **or**
- (b) Unsuccessful concurrent or previous use of migraine prophylaxis medications (e.g., beta-blockers, calcium channel blockers, tri-cyclic antidepressants or anticonvulsants); **and**
- (c) Patient is not currently using ergotamine or another 5-HT₁ Receptor Agonist.

GENERIC: ROPINIROLE

BRAND: REQUIP[®]

INDICATIONS:

- (1) For the treatment of signs and symptoms of idiopathic Parkinson's disease.
- (2) Moderate to severe primary Restless Leg Syndrome.

Criteria:

- (a) Diagnosis of idiopathic Parkinson's disease; **or**
- (b) Diagnosis of Restless Leg Syndrome and normal iron stores (serum ferritin and/or iron-binding saturation)

GENERIC: SALMETEROL / FLUTICASONE

BRAND: ADVAIR[®] / ADVAIR HFA[®], WIXELA[®], SALMETEROL / FLUTICASONE

INDICATION:

- (1) Long-term, twice-daily maintenance treatment of asthma in patients 4 years of age and older.
- (2) Maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease.

Criteria for Asthma:

- (a) Currently on, but not controlled by an inhaled corticosteroid for more than sixty (60) days; and
- (b) The patient must be reevaluated after 6 months

Criteria for COPD:

- (a) Currently on, but not controlled by a LAMA for more than sixty (60) days; and
- (b) The patient must be reevaluated after 6 months

Prior Authorization Guidelines

** For members currently with an approved prior authorization for Advair, claims will process as long as the member has filled Advair within the last 4 months. No yearly renewal will be needed for compliant members. Prior authorization will be required for members new to the plan, new to Advair therapy, or with no claim history of Advair within the last 4 months. Once approved, 90-day supplies are allowed.*

GENERIC: SALMETEROL XINAFOATE

BRAND: SEREVENT DISKUS®

INDICATIONS:

- (1) Maintenance treatment of asthma and prevention of bronchospasm in adults and children 4 years of age and older
- (2) Prevention of exercise-induced bronchospasm in patients 4 years of age and older
- (3) Serevent Diskus® is indicated for the maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease

Criteria for Asthma:

- (a) Currently on, but not controlled by an inhaled corticosteroid for more than sixty (60) days; and
- (b) Patients must be reevaluated after 6 months

Criteria for COPD:

- (a) Currently on, but not controlled by a LAMA for more than sixty (60) days; and
- (b) The patient must be reevaluated after 6 months

GENERIC: SILDENAFIL

BRAND: REVATIO®

INDICATION:

- (1) Pulmonary Arterial Hypertension (PAH)

Criteria:

- (a) For the treatment of PAH; **and**
- (b) Current utilization of nitrates is contraindicated; **and**
- (c) Age limit of 2 years and younger for the solution

GENERIC: SIMVASTATIN 80mg

BRAND: ZOCOR®

INDICATIONS:

- (1) Heterozygous or homozygous familial hypercholesterolemia
- (2) Familial type 3 hyperlipoproteinemia
- (3) Hypertriglyceridemia
- (4) Primary hypercholesterolemia, or mixed hyperlipidemia
- (5) Decrease cardiovascular event risk in patients with high coronary event risk
- (6) Cerebrovascular accident prophylaxis

Criteria:

- (a) Age \leq 65 years
- (b) Male gender (female gender predisposed to myopathy including rhabdomyolysis)
- (c) Controlled hypothyroidism
- (d) Normal renal function
- (e) Documentation of all cholesterol lowering agents tried and failed must be provided.

Prior Authorization Guidelines

GENERIC: SITAGLIPTIN PHOSPHATE

BRAND: JANUVIA[®]

INDICATION:

(1) Type 2 Diabetes Mellitus

Criteria:

- (a) Diagnosis of type 2 diabetes mellitus and
- (b) Must be used adjunct to diet and exercise and
- (c) Failure or contraindication to metformin or
- (d) Failure or contraindication of sulfonylurea or thiazolidinedione

GENERIC: SOFOBUVIR-VELPATASVIR

BRAND: EPCLUSA[®]

INDICATION:

(1) Chronic Hepatitis C

Criteria:

- (a) Generic tablets only
- (b) Preferred for genotypes 1, 2, 3, 4, 5 and 6
- (c) Must follow the clinical criteria as set by the Maryland Department of Health
- (d) Special Hepatitis C PA request forms, treatment plan template, preferred status information, and full criteria can be obtained at <http://www.jaimedicalsystems.com/providers/pharmacy/> or by contacting ProCare at 1-800-555-8513

GENERIC: SOFOBUVIR-VELPATASVIR-VOXILAPREVIR

BRAND: VOSEVI[®]

INDICATION:

(1) Chronic Hepatitis C

Criteria:

- (a) For retreatment only
- (b) Must follow the clinical criteria as set by the Maryland Department of Health
- (c) Special Hepatitis C PA request forms, treatment plan template, preferred status information, and full criteria can be obtained at <http://www.jaimedicalsystems.com/providers/pharmacy/> or by contacting ProCare at 1-800-555-8513

GENERIC: SOLIFENACIN

BRAND: VESICARE[®]

INDICATION:

(1) Overactive bladder

Criteria:

- (a) Failure of Oxybutynin

GENERIC: SOMATROPIN

BRAND: HUMATROPE[®]

INDICATIONS:

- (1) Growth failure in children due to inadequate growth hormone (GH) secretion
- (2) Idiopathic short stature in children defined by height standard deviation (SD) score less than or equal to -2.25 and growth rate not likely to attain normal adult height
- (3) Short stature in children associated with Turner syndrome

Prior Authorization Guidelines

Criteria:

- (a) Patient with open epiphyses (as confirmed by radiograph of wrist and hand) who has not reached final height; **and**
- (b) Medication prescribed by an endocrinologist; **and**
- (c) Patient meets one of the following criteria:
 - (1) Growth Hormone Deficiency (GHD) with diagnosis confirmed by one of the following:
 - i. Severe short stature defined as patient's height at ≥ 2 SD below the population mean
 - ii. Patient's height ≥ 1.5 SD below the midparental height (average of mother's and father's heights)
 - iii. Patient's height ≥ 2 SD below the mean and a 1-year height velocity more than 1 SD below the mean for chronologic age or (in children 2 years of age or older) a 1-year decrease of more than 0.5 SD in height
 - iv. In the absence of short stature, a 1-year height velocity more than 2 SD below the mean or a 2-year height velocity more than 1.5 SD below the mean (may occur in GHD manifesting during infancy or in organic, acquired GHD)
 - v. Signs indicative of an intracranial lesion
 - vi. Signs of multiple pituitary hormone deficiencies
 - vii. Neonatal symptoms and signs of GHD
 - (2) Idiopathic short stature with patient's height at ≥ 2.25 SD below the mean height for normal children of the same age and gender
 - (3) Short stature associated with Turner syndrome and height below the 5th percentile of normal growth curve

* *To continue therapy, requests will be reviewed every six months.*

For injectable medications administered by a healthcare professional, please refer to the "Specialty Medication Guidelines" in the beginning of this formulary.

GENERIC: SUCCIMER

BRAND: CHEMET[®]

INDICATIONS:

- (1) Treatment of lead poisoning in children with blood lead levels > 45 mcg/dl
- (2) Unlabeled uses: Succimer may be beneficial in the treatment of other heavy metal poisonings

Criteria:

- (a) Diagnosis of lead poisoning with blood levels > 45 mcg/dl; **and**
- (b) Child is hospitalized; **or**
- (c) Child was started on the medication in the hospital and needs to continue upon discharge.

GENERIC: SUCRALFATE SUSPENSION

BRAND: CARAFATE[®]

INDICATIONS:

- (1) Gastric ulcers
- (2) Duodenal ulcers
- (3) Gastritis
- (4) GERD

Criteria:

- (a) For patients who have a contraindication or failure of sucralfate tablets

Prior Authorization Guidelines

GENERIC: TACROLIMUS

BRAND: PROTOPIC[®]

INDICATION:

(1) Moderate to severe atopic dermatitis

Criteria:

- (a) Patient must be non-immunocompromised **and**
- (b) Must be at least 2 years of age or older for the 0.03% strength; **or**
- (c) 16 years of age or older for 0.1% strength **and**
- (d) Diagnosis of atopic dermatitis
- (e) Documented failure of 2 different topical corticosteroids of medium to high potency in the past 90 days
- (f) Must be prescribed by a dermatologist, allergist, or for children, a pediatrician

GENERIC: TERIFLUNOMIDE

BRAND: AUBAGIO[®]

INDICATION:

(1) Diagnosis of a relapsing form of Multiple Sclerosis

Criteria:

- (a) Prescribed by neurologist; **and**
- (b) Not requesting combination of any 2 agents together: Copaxone, Betaseron, Avonex, Tysabri, Rebif, Gilenya, Aubagio, or Tecfidera.

GENERIC: TESTOSTERONE

BRAND: ANDROGEL[®], TESTIM[®]

INDICATION:

(1) Hypogonadism

Criteria:

- (a) Must be prescribed by an Endocrinologist or Urologist
- (b) Initial therapy: The patient has documented low testosterone concentration
- (c) Renewal: The patient has documented therapeutic concentration to confirm response

Criteria for transgender members:

- (a) Referral from mental health professional; **and**
- (b) Persistent, well-documented gender dysphoria; **and**
- (c) Capacity to make fully informed decision and to consent for treatment; **and**
- (d) 18 years of age or older

GENERIC: THROMBIN

BRAND: THROMBIN

INDICATION:

(1) Hemostasis

Criteria:

- (a) Diagnosis of a bleeding disorder

GENERIC: TOLTERODINE

BRAND: DETROL[®]/DETROL LA[®]

INDICATION:

(1) Overactive bladder

Criteria:

- (a) Failure of oxybutynin

Prior Authorization Guidelines

GENERIC: TRAMADOL ER

BRAND: ULTRAM ER[®]

INDICATION:

- (1) Pain, chronic (moderate to severe)

Criteria:

- (a) For patients who have a contraindication or failure of tramadol regular release tablets
(b) Completion of Opioid Prior Authorization/Attestation Form required, available at <http://www.jaimedicalsystems.com/providers/pharmacy/>

GENERIC: TROSPIUM

BRAND: SANCTURA[®]

INDICATION:

- (1) Overactive bladder

Criteria:

- (a) Failure of Oxybutynin

GENERIC: UMECLIDINIUM BROMIDE/VILANTEROL RIFENATATE

BRAND: ANORO ELLIPTA[®]

INDICATION:

- (1) Chronic obstructive pulmonary disease (COPD): maintenance of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema.

Criteria:

- (a) Currently on, but not controlled by a LAMA for more than sixty (60) days; and
(b) The patient must be reevaluated after 6 months

GENERIC: VALSARTAN, VALSARTAN-HCTZ

BRAND: DIOVAN[®], DIOVAN-HCT[®]

INDICATION:

- (1) Hypertension

Criteria for Valsartan:

- (a) Failure or contraindication of 2 formulary ARBs (Irbesartan, Losartan)

Criteria for Valsartan-HCTZ:

- (a) Failure or contraindication of 2 formulary ARB-HCTZ combinations (Irbesartan-HCTZ, Losartan-HCTZ)

GENERIC: ZOLMITRIPTAN TABLETS

BRAND: ZOMIG[®]

INDICATION:

- (1) Acute treatment of migraine headache

Criteria:

- (a) Failure of, intolerance to, or contraindication to one traditional formulary agent (NSAID, ergotamine, or combination analgesic); **or**
(b) Unsuccessful concurrent or previous use of migraine prophylaxis medications (e.g., beta-blockers, calcium channel blockers, tri-cyclic antidepressants or anticonvulsants); **and**
(c) Patient is not currently using ergotamine or another 5-HT₁ Receptor Agonist