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-BWWD, ADALIMUMAB-ADAZ
BRAND: HADLIMA®, HYRIMOZ® (UNBRANDED)

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 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**

(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: ALOGLIPTIN

Step Therapy Criteria:

Recent trial of metformin or sulfonylurea or thiazolidinedione - Cumulative days' supply for more than sixty (60) days within the last one-hundred and eighty (180) days with at least one (1) cumulative fill.

GENERIC: AMBRISENTAN

INDICATION:

(1) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1)

Criteria:

(a) Documentation of pulmonary arterial hypertension (PAH) (WHO Group 1)

GENERIC: ANTIHEMOPHILIC FACTORS
BRAND: KOATE-DVI®, FEIBA VH®, RECOMBINATE®, THROMBATE III®

INDICATION:

(2) 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

Prior Authorization Guidelines

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

GENERIC: BUDESONIDE/FORMOTEROL
BRAND: SYMBICORT®

INDICATION:
(1) Maintenance treatment of asthma in patients 6 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/m^2
    (b) History of fragility fracture since menopause
    (c) History of hip fracture in a parent
  (4) Diagnosis of Paget's disease of bone
(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**
Short-acting			
Cortisone	25	0.8	2
Hydrocortisone	20	1	2
Intermediate-acting			
Prednisone	5	4	1
Prednisolone	5	4	1
Triamcinolone	4	5	0
Methylprednisolone	4	5	0
Long-acting			
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®

Step Therapy Criteria:
Single trial of at least 7 days of NSAIDs in the past 30 days

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: 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**

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: DARBEPOETIN 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**

(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

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 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: DUPILUMAB
BRAND: DUPIXENT®

INDICATION:

(1) Treatment of pediatric patients 6 months and older, who have had an inadequate response or intolerance to topical drug products, with active atopic dermatitis (AD).

(2) Treatment of pediatric patients 6 years and older, characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma, with moderate-to-severe asthma.

(3) Treatment of adult patients, as an add-on maintenance treatment, chronic rhinosinusitis with nasal polyposis (CRSwNP).

(4) Treatment of pediatric patients 12 years and older with eosinophilic esophagitis (EoE).

(5) Treatment of adult patients with prurigo nodularis (PN).

Criteria:

(a) For pediatric patients 6 months and older with AD and PN
   i. Previous treatment, or intolerance of, with TCS for more than sixty (60) days; and
   ii. Previous treatment, or intolerance of, with TCI for more than sixty (60) days

(b) For pediatric and adult patients 6 years and older with asthma
   i. Previous treatment, or intolerance of, with Xolair for more than sixty (60) days; and
   ii. Patients must be reevaluated after 6 months

(c) For adult patients with CRSwNP
   i. Previous treatment, or intolerance of, with Xolair for more than sixty (60) days; and
   ii. Previous treatment, or intolerance of, with oral corticosteroid

(d) For pediatric patients 12 years and older with EoE
   i. Confirmed diagnosis with endoscopic esophageal biopsy showing the presence of eosinophils (≥15 eosinophils per high-power field); and
   ii. Previous treatment with proton-pump inhibitor (PPI) for more than sixty (60) days; and
   iii. Previous treatment with oral corticosteroid; and
   iv. Attestation of dietary modifications (e.g., avoidance of food allergen triggers)

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 MC-Rx 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 hearth 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.

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 ≥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, Allogeneic;
Prophylaxis:
(c) Patient's pre-operative Hgb >10 to ≤13 g/dL (14-day approval)

For renewals:
Chronic kidney disease patients:
(a) With dialysis Hbg <11
(b) Without dialysis Hbg <10
Anemia due to chemotherapy in cancer patients:
(a) Hbg <11
Anemia due to zidovudine in HIV-infected patients:
(a) Hbg <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**
(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 ≥ 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: FENOFIBRIC ACID 35MG, 105MG, 45MG, AND 135 MG

Step Therapy Criteria:

Recent trial of formulary product generic Fenofibrate - Cumulative days supply for more than sixty (60) days within the last one-hundred and eighty (180) days with at least one (1) cumulative fill

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/

GENERIC: FESOTERODINE FUMARATE

Step Therapy Criteria:

Recent trial of formulary product generic Oxybutynin - Cumulative days' supply for more than sixty (60) days within the last one-hundred and eighty (180) days with at least one (1) cumulative fill

GENERIC: FILGRASTIM-AYOW
BRAND: RELEUKO®

INDICATIONS:

(1) Prevention of neutropenia in patients receiving myelosuppressive chemotherapy for nonmyeloid 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: FLASH GLUCOSE SENSOR
BRAND: FREESTYLE LIBRE®

INDICATIONS:

(1) Treatment of patients indicated for the management of diabetes in persons aged 4 years and older.

Criteria:

(a) Diagnosed with Type I or Type II Diabetes mellitus; and
(b) Actively seeing an Endocrinologist (at least one visit within past 6 months); and
(c) Blood glucose testing at least 4x/day for more than sixty (60) days; and

(d) Insulin injections at least 3x/day; and
(e) The member must have been assessed by the prescriber for ability to adhere to the CGM monitor regimen and any adherence/compliance issues must have been addressed and resolved by the prescriber; and
(f) Frequent adjustments to amount of injected insulin based on glucose testing results; and
(g) Wide variance in blood sugar levels OR unexplained or severe hypoglycemia OR hypoglycemic unawareness

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

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 MC-Rx at 1-800-555-8513

GENERIC: HYDROXOCOBALAMIN

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.

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: ITRACONAZOLE
BRAND: SPORANOX®

INDICATIONS:
(1) Histoplasmosis infections
(2) Aspergillosis infections
(3) Blastomycosis

Criteria:
(a) Any of the above diagnoses.

GENERIC: IXEKIZUMAB
BRAND: TALTZ®

INDICATIONS:
(1) Treatment of pediatric patients aged ≥ 6 years with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
(2) Treatment of adult patients with active psoriatic arthritis
(3) Treatment of adults with active ankylosing spondylitis.
(4) Adults with active non-radiographic axial spondyloarthritis (nrAxSpA) with objective signs of inflammation.

Criteria:
1. First Prescription and every 12 months: The patient had a NEGATIVE tuberculin skin test, or if positive, has received treatment for latent TB prior to treatment.
2. For adult patients with plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and nrAxSpA
   a. Previous treatment, or intolerance of, with Enbrel for more than sixty (60) days; and
   b. Previous treatment, or intolerance of, with formulary Humira biosimilar for more than sixty (60) days

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 MC-Rx 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.

Gender Affirming Treatment:
For all requests for gender affirming care, please refer to the Gender-Affirming Treatment Services Under the Maryland Medicaid Program document (for a copy of the criteria see our website at https://jaimedicalsystems.com/providers/pharmacy/.) Please ensure that all necessary documentation required under the criteria is included to show consent for treatment and medical necessity (documentation requirements may vary depending on patient age, type of treatment requested, and specialty of requesting provider).

** 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.

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

(3) . 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) NO personal or family history of medullary thyroid carcinoma

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: 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 0.75% 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/

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.
Gender Affirming Treatment:
For all requests for gender affirming care, please refer to the Gender-Affirming Treatment Services Under the Maryland Medicaid Program document (for a copy of the criteria see our website at

https://jaimedicalsystems.com/providers/pharmacy/.) Please ensure that all necessary documentation required under the criteria is included to show consent for treatment and medical necessity (documentation requirements may vary depending on patient age, type of treatment requested, and specialty of requesting provider).

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.

GENERIC: OLODATEROL HCL
BRAND: STRIVERDI®

INDCATION:

(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: OMALIZUMAB
BRAND: XOLAIR®

INDCATION:

(1) Treatment of moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.
(2) Treatment of adult patients, as an add-on maintenance treatment, chronic rhinosinusitis with nasal polyposis (CRSwNP).
(3) Treatment of adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment with chronic spontaneous urticaria (CSU).

Criteria:

(a) For pediatric patients 6 years and older with asthma

i. Documentation of baseline (pre-omalizumab treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL
ii. Documentation of positive skin test or in vitro reactivity to a perennial aeroallergen
iii. Previous treatment, or intolerance of, with two (2) or more inhaled medium to high dose LABA+ICS for more than sixty (60) days; and
iv. Patients must be reevaluated after 6 months

(b) For adult patients with asthma
i. Documentation of baseline (pre-omalizumab treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL
ii. Documentation of positive skin test or in vitro reactivity to a perennial aeroallergen
iii. Previous treatment, or intolerance of, with LAMA+LABA+ICS for more than sixty (60) days; and
iv. Patients must be reevaluated after 6 months

(c) For adult patients with CRSwNP
i. Previous treatment, or intolerance of, with two (2) or more intranasal corticosteroid for more than ninety (90) days; and
ii. Previous treatment, or intolerance of, with oral corticosteroid

(d) For pediatric patients 12 years and older with CSU
i. Previous treatment with two (2) H1-antihistamines for more than sixty (60) days within the past ninety (90) days

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/

GENERIC: PEGFILGRASTIM-PBBK
BRAND: FYLNETRA®

INDICATIONS:

(1) Prevention of neutropenia in patients receiving myelosuppressive chemotherapy for nonmyeloid 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: 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 coinfected 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 ≥ 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

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: 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

GENERIC: RILUZOLE
BRAND: RILUTEK®

INDICATION:
(1) Amyotrophic lateral sclerosis (ALS)

Criteria:
(a) Diagnosis of ALS.

GENERIC: RISANKIZUMAB
BRAND: SKYRIZI®

INDICATION:
(1) Treatment of adult patients with moderate-to-severe plaque psoriasis (Ps) who are candidates for systemic therapy or phototherapy.
(2) Treatment of adult patients with active psoriatic arthritis (PsA)
(3) Treatment of adults with moderately to severely active Crohn's disease (CD).

Criteria:

(a) First Prescription and every 12 months: The patient had a NEGATIVE tuberculin skin test, or if positive, has received treatment for latent TB prior to treatment.
(b) For adult patients with Ps and PsA - Previous treatment, or intolerance of, with Taltz for more than sixty (60) days
(c) For adult patients with CD - Previous treatment, or intolerance of, with formulary Humira biosimilar for more than sixty (60) days.

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

* *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 ≤ 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.

GENERIC: SITAGLIPTIN PHOSPHATE
BRAND: JANUVIA®

Step Therapy Criteria:
Recent trial of formulary product Alogliptin - Cumulative days' supply for more than sixty (60) days with at least one (1) fill within the last one-hundred and eighty (180) days.

GENERIC: SOFOSBUVIR-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 MC-Rx at 1-800-555-8513

GENERIC: SOFOSBUVIR-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 MC-Rx at 1-800-555-8513

GENERIC: SOLIFENACIN SUCCINATE

Step Therapy Criteria:
Recent trial of formulary product generic Oxybutynin - Cumulative days' supply for more than sixty (60) days within the last one-hundred and eighty (180) days with at least one (1) cumulative fill

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

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 > 45mcg/dl; **and**
(b) Child is hospitalized; **or**
(c) Child was started on the medication in the hospital and needs to continue upon discharge.

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

Gender Affirming Treatment:

For all requests for gender affirming care, please refer to the Gender-Affirming Treatment Services Under the Maryland Medicaid Program document (for a copy of the criteria see our website at https://jaimedicalsystems.com/providers/pharmacy/.) Please ensure that all necessary documentation required under the criteria is included to show consent for treatment and medical necessity (documentation requirements may vary depending on patient age, type of treatment requested, and specialty of requesting provider).

GENERIC: THROMBIN
BRAND: THROMBIN

INDICATION:
(1) Hemostasis
Criteria:
(a) Diagnosis of a bleeding disorder

GENERIC: TOLTERODINE TARTRATE

Step Therapy Criteria:
Recent trial of formulary product generic Oxybutynin - Cumulative days supply for more than sixty (60) days within the last one-hundred and eighty (180) days with at least one (1) cumulative fill

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 CHLORIDE

Step Therapy Criteria:
Recent trial of formulary product generic Oxybutynin - Cumulative days supply for more than sixty (60) days within the last one-hundred and eighty (180) days with at least one (1) cumulative fill

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: UPADACITINIB
BRAND: RINVOQ®

INDICATIONS:
(1) Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with rheumatoid arthritis (RA).

(2) Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with active psoriatic arthritis (PsA).
(3) Treatment of pediatric patients 12 years and older, who have had an inadequate response or intolerance to other systemic drug products, including biologics, with active atopic dermatitis (AD).
(4) Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with active ulcerative colitis (UC).
(5) Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with active ankylosing spondylitis (AS).
(6) Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with active non-radiographic axial spondyloarthritis (nr-axSpA).

Criteria:

(a) First Prescription and every 12 months:
  i. The patient had a NEGATIVE tuberculin skin test, or if positive, has received treatment for latent TB prior to treatment.
  ii. The patient had a NEGATIVE hepatitis B and C viral screening
(b) For adult patients with RA
  i. Previous treatment, or intolerance of, with Enbrel for more than sixty (60) days; and
  ii. Previous treatment, or intolerance of, with formulary Humira biosimilar for more than sixty (60) days
(c) For adult patients with PsA
  i. Previous treatment, or intolerance of, with Enbrel for more than sixty (60) days; and
  ii. Previous treatment, or intolerance of, with formulary Humira biosimilar for more than sixty (60) days; and
  iii. Previous treatment, or intolerance of, with Taltz for more than sixty (60) days
(d) For pediatric patients 12 years and older with AD
  i. Previous treatment, or intolerance of, with Dupixent, or intolerance of, for more than sixty (60) days
(e) For adult patients with UC
  i. Previous treatment, or intolerance of, with formulary Humira biosimilar for more than sixty (60) days
(f) For adult patients with AS and nr-asSpA
  i. Previous treatment, or intolerance of, with Taltz for more than sixty (60) days

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