# 2021 Prior Authorization Criteria For FHCP's Medical Pharmacy Formulary

# abatacept (Orencia)

### **Products Affected**

Orencia Intravenous

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Must fail Kevzara, Simponi Aria, Renflexis, Enbrel and Xeljanz.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Must be prescribed by a rheumatologist
Coverage Duration	Up to 12 months
Other Criteria	Orencia is indicated to treat rheumatoid arthritis. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# ado-trastuzumab emtansine (Kadcyla)

### **Products Affected**

Kadcyla

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncology
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	Coverage will be based on failure of prior taxane and Herceptin (trastuzumab).

# aflibercept (Zaltrap)

# **Products Affected**

Zaltrap

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncologist/Hematologist.
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	Coverage will be based on failure or intolerance of Avastin.

# alpha 1-antitrypsin (Prolastin)

### **Products Affected**

 Prolastin-C Intravenous Solution Reconstituted 1000 MG

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	FDA labeled contraindications.
Required Medical Information	Medical notes, previous treatment history, and associated studies. Patient must have documented progressive COPD.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months
Other Criteria	Patient must be a non-smoker. Serum Concentration of Alpha-1 Antitrypsin must be less than 11micromoles/L. Must have a high-risk AAT deficiency phenotype (PiZZ, PiZ (null) or Pi (null)(null) or other phenotypes associated with serum AAT concentrations of less than 11 uM/L.). FEV1 between 35%-65% predicted. Must currently be using long acting bronchodilator AND oral or inhaled corticosteroids.

# aminolevulinate (Levulan)

### **Products Affected**

Levulan Kerastick

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Dermatologist or Plastic Surgeon
Coverage Duration	12 Months
Other Criteria	

# aminolevulinic acid (Ameluz)

### **Products Affected**

Ameluz

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

# aprepitant (Emend)

# **Products Affected**

Aprepitant

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Patient must have failed Zofran. A pre-packaged three-day course of this medication will be approved per each co-pay incidental to a chemotherapy treatment cycle.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Medication will be approved through referrals when written by Oncology
Coverage Duration	12 months
Other Criteria	Emend is used as part of a three day regimen for chemotherapy induced nausea and vomiting (CINV) of moderate to highly emetogenic Chemotherapy treatments, and Post-Operative Nausea and Vomiting. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# aripiprazole (Abilify)

### **Products Affected**

• Abilify Maintena Intramuscular Suspension Reconstituted ER

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Failure of oral aripiprazole.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Approved when written/ordered by a Psychiatrist or Neurologist through referrals for new starts.
Coverage Duration	12 months
Other Criteria	Aripiprazole is a psychotropic medication. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

# arsenic trioxide (Trisenox)

### **Products Affected**

 Trisenox Intravenous Solution 10 MG/10ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

# atezolizumab (Tecentriq)

### **Products Affected**

 Tecentriq Intravenous Solution 1200 MG/20ML

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications, progression on PD-1/PDL-1 in previous line of treatment
Required Medical Information	Medical notes, previous treatment history, and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncologist/Hematologist.
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

# avelumab (Bavencio)

### **Products Affected**

### Bavencio

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Adults and pediatric patients 12 years and older
Prescriber Restrictions	
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	BAVENCIO is a programmed death ligand-1 (PD-L1) blocking antibody indicated for the treatment of advanced or metastatic cancers. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# belatacept (Nulojix)

# **Products Affected**

Nulojix

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes and previous treatment history.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Nephrologist or Transplant specialist.
Coverage Duration	12 months
Other Criteria	Requires failure or intolerance to a calcineurin inhibitor.

# belimumab (Benlysta)

### **Products Affected**

• Benlysta Intravenous

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

# bevacizumab-bvzr (Zirabev)

### **Products Affected**

Zirabev

PA Criteria	Criteria Details
Covered Uses	Criteria for coverage (for oncology indications) as follows:FDA Approved Uses. Off-Label indications will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months or until disease progression
Other Criteria	Zirabev an anti-VEGF monoclonal antibody used to treat metastatic, recurrent, or locally advanced cancers.  Ophthalmic uses such as wet AMD and macular edema will be covered without clinical review for Zirabev or Avastin.

# bleomycin (Blenoxane)

### **Products Affected**

• Bleomycin Sulfate Injection Solution Reconstituted 30 UNIT

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncologist
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

# blinatumomab (Blincyto)

### **Products Affected**

Blincyto

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

# bortezomib (Velcade)

### **Products Affected**

Velcade Injection

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

# brentuximab vedotin (Adcetris)

### **Products Affected**

### Adcetris

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

# C1 esterase inhibitor (Cinryze)

### **Products Affected**

Cinryze

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months
Other Criteria	Patient must have two or more angioedema attacks per month and must have failed danazol

# cabazitaxel (Jevtana)

### **Products Affected**

Jevtana

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncology
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

# carfilzomib (Kyprolis)

### **Products Affected**

 Kyprolis Intravenous Solution Reconstituted 30 MG, 60 MG

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

# cetuximab (Erbitux)

### **Products Affected**

• Erbitux

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncology
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

# daptomycin (Cubicin)

### **Products Affected**

• DAPTOmycin Intravenous Solution Reconstituted 500 MG

PA Criteria	Criteria Details
Covered Uses	Daptomycin is an IV antibiotic indicated for the treatment of resistant gram + bacterial infections.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months
Other Criteria	Patient is identified as having an infection caused by VRE (Vancomycin Resistant Enterococcus) or VRSA (Vancomycin Resistant Staph Aureus) by culture and sensitivity; and Linezolid is not a therapeutic option OR patient has a skin or soft tissue infection caused by MRSA and resistant/allergic to other generically availably oral agents or combinations which may be used to treat MRSA (Sulfamethoxazole/TMP,?Rifampin, Clindamycin, Doxycycline) and patient is allergic to Vancomycin and Zyvox. OR patient has MRSA (non-skin/soft tissue) and is allergic to Vancomycin and oral Zyvox is not a therapeutic option.

# daratumumab (Darzalex)

### **Products Affected**

### Darzalex

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	Indicated in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. Indicated in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double refractory.

# denosumab (Prolia)

### **Products Affected**

Prolia Subcutaneous Solution

PA Criteria	Criteria Details
Covered Uses	FDA approved indications Intolerance or contraindication to injectable bisphosphonate required for coverage of Prolia.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Prolia is a RANK-L ligand antagonist indicated for treatment of osteoporosis and prevention of osteoporosis for patients taking aromatase inhibitors. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# denosumab (Xgeva)

# **Products Affected**

Xgeva

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Must have failed or a contraindication to an intravenous bisphosphonate.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescriber must be an oncologist or endocrinologist
Coverage Duration	12 months
Other Criteria	Xgeva is a RANKL ligand antagonist indicated to treat osteolytic cancers. Medical history and studies are reviewed in Referrals and if approved will notify the physician.

# diabetic test strips (other than Ascensia products)

### **Products Affected**

- Accu-Chek Aviva Plus In Vitro
- FreeStyle Lite Test
- FreeStyle Test
- Nova Max Glucose Test
- OneTouch Ultra Blue
- OneTouch Verio In Vitro Strip
- Prodigy No Coding Blood Gluc In Vitro

PA Criteria	Criteria Details
Covered Uses	Test strips other than Ascensia products are covered only when incompatible with an insulin pump, or if patient has a severe visual impairment.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

# doxorubicin (Doxil/Lipodox)

### **Products Affected**

• DOXOrubicin HCl Liposomal

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

# durvalumab (Imfinzi)

### **Products Affected**

• Imfinzi

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications, progression on PD-1/PDL-1 in previous line of treatment
Required Medical Information	Medical notes, previous treatment history and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Hematology/Oncology
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

# edaravone (Radicava)

### **Products Affected**

### Radicava

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

# elaprase (Elaprase)

# **Products Affected**

Elaprase

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Limited to specialist trained in management of prescribed condition.
Coverage Duration	Up to 12 months
Other Criteria	Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.

# elotuzumab (Empliciti)

# **Products Affected**

• Empliciti

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

# epoprostenol (Flolan)

# **Products Affected**

• Epoprostenol Sodium

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Pulmonary hypertension must be diagnosed by heart catheterization, Evaluation, EKG, diffusion studies, catheterization results and an objective test of exercise ability (6 minute walk) must be submitted with referral. Patient must be a WHO class III or IV and fail combination ambrisentan and tadalafil.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Must be written by a pulmonologist or cardiologist.
Coverage Duration	12 Months
Other Criteria	epoprostinil is a prostacyclin analog indicated to treat primary pulmonary arterial hypertension. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# eribulin (Halaven)

### **Products Affected**

Halaven

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncologist
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.

# **Filgrastim**

# **Products Affected**

Nivestym

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Off label use must be supported by NCCN category 2a or greater

## imiglucerase (Cerezyme)

### **Products Affected**

 Cerezyme Intravenous Solution Reconstituted 400 UNIT

PA Criteria	Criteria Details
Covered Uses	Indicated for the treatment of a patient with Type 1 Gaucher?s disease with anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months
Other Criteria	

## immunoglobulin G (Gammagard)

### **Products Affected**

Gammagard

PA Criteria	Criteria Details
Covered Uses	Approval will be based on compliance with most current Medicare NCD or LCD coverage criteria for IVIG.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months
Other Criteria	

## immunoglobulin G (Gamunex)

### **Products Affected**

Gamunex-C

PA Criteria	Criteria Details
Covered Uses	FDA approved indications
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months
Other Criteria	Approval will be based on compliance with most current Medicare NCD or LCD coverage criteria for IVIG.

## incobotulinumtoxinA (Xeomin)

### **Products Affected**

Xeomin

PA Criteria	Criteria Details
Covered Uses	FHCP covers this medication only for medically necessary purposes, like cervical dystonia, not responsive to physical therapy, blepharospasm that interferes significantly with vision, and headache not responsive to preventive and acute therapy by Neurology for at least 16 weeks.
Exclusion Criteria	FDA labeled contraindications OR cosmetic conditions
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

## infliximab (Remicade)

### **Products Affected**

Renflexis

PA Criteria	Criteria Details
Covered Uses	Renflexis is indicated for the treatment of Crohn's Disease and Rheumatoid Arthritis, Ulcerative Colitis, Ankylosing Spondylitis, Psoriatic Arthritis, Plaque Psoriasis. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician. Criteria for coverage as follows: For use in RA must fail adequate trial of MTX in combination with a DMARD If MTX contraindicated, must try combination of 2-nonbiologic DMARDS (3month trial in past 6 months). For use in Ankylosing Spondylitis PT must fail MTX or sulfasalazine and 2 NSAIDS within past 6 months. For use in Plaque Psoriasis must fail MTX or Soriatane and topical therapy. For Psoriatic Arthritis must fail adequate trial of MTX or LEF in past 6 months. For with Crohn's disease and ulcerative colitis must be written by a gastroenterologist and had recent failure of an immunosuppressant (Azathioprine, 6-mp or Methotrexate) and an anti-inflammatory (5-asa, sulfasalazine, balsalazide, mesalamine)
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	see covered uses

PA Criteria	Criteria Details
Coverage Duration	Up to 12 months
Other Criteria	

## ipilimumab (Yervoy)

### **Products Affected**

Yervoy

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications, and not covered in combinations unsupported by the NCCN evidence 2a or greater (i.e. Vemurafenib).
Required Medical Information	Medical notes, previous treatment history, and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Hematology/Oncology
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	Doses exceeding 3 mg/kg will only be approved in adjuvant treatment setting.

## isavuconazonium (Cresemba)

### **Products Affected**

#### Cresemba Intravenous

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Infectious Disease or Pulmonology Specialist
Coverage Duration	Up to 12 months
Other Criteria	For treatment of Invasive aspergillosis patient must have failed or have contraindication to voriconazole. For treatment of invasive mucormycosis patient must have failed or have contraindication to amphotericin B.

## ixabepilone (Ixempra)

### **Products Affected**

Ixempra Kit

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncology
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

## lanreotide (Somatuline)

### **Products Affected**

Somatuline Depot

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Failure of octreotide.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Prescriber must be an endocrinologist.
Coverage Duration	12 months
Other Criteria	This medication is used to treat Acromegaly. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# natalizumab (Tysabri)

### **Products Affected**

Tysabri

PA Criteria	Criteria Details
Covered Uses	FDA approved indications
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Neurologist/Gastroenterologist
Coverage Duration	Up to 12 months
Other Criteria	Requires failure of a TNF-antagonist for Crohns disease. Requires failure of a first line DMARD for multiple sclerosis

## nivolumab (Opdivo)

#### **Products Affected**

 Opdivo Intravenous Solution 100 MG/10ML, 40 MG/4ML

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications, progression on PD-1/PDL-1 in previous line of treatment
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncologist/Hematologist.
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

## obinutuzumab (Gazyva)

### **Products Affected**

• Gazyva

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

## ocrelizumab (Ocrevus)

### **Products Affected**

Ocrevus

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. For Relapsing Remitting Multiple Sclerosis - must have failed rituximab AND Dimethyl Fumerate or Glatiramer
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Must be prescribed by a neurologist.
Coverage Duration	12 months
Other Criteria	Ocrevus is a CD20-directed cytolytic antibody indicated for the treatment of relapsing remitting or primary progressive forms of multiple sclerosis. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## octreotide (Sandostatin)

### **Products Affected**

• SandoSTATIN LAR Depot

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Requires failure of recent 2 month trial of octreotide (non LAR) in past 3 months

## ofatumumab (Arzerra)

### **Products Affected**

#### Arzerra

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater. Failure of rituxumab.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncologist
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

## omalizumab (Xolair)

#### **Products Affected**

 Xolair Subcutaneous Solution Reconstituted

PA Criteria	Criteria Details
Covered Uses	The following criteria must be met for coverage for severe asthma:Prescriber must be a pulmonologist or allergist.Patient must have baseline IGE levels within indicated range for Xolair labeling.Patient must test positive to an aeroallergen (either skin test or blood test).Patient must fail 3 months of therapy on maximal indicated doses of Trelegy.Patient must have failed leukotriene receptor antagonist Failed Nucala if eosophillic asthma.The following criteria must be met for coverage for chronic idiopathic urticaria:Prescribed by an allergist, immunologist, or dermatologistPatient must have a diagnosis of chronic idiopathic urticaria (at least a 6 week history)Patient must have tried, for a minimum of 2 weeks and failed 2 of the following antihistamines at maximal doses used to treat CIU: cetirizine(40mg/day), levocetirizine (20mg/day), desloratadine(20mg/day), fexofenadine (540mg/day), loratadine (40mg/day)and montelukast
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	For coverage for severe asthma, prescriber must be a pulmonologist or allergist. For coverage for chronic idiopathic urticaria, prescribed by an allergist, immunologist, or dermatologist.

PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Xolair is an anti-IgE monoclonal antibody indicated for patients 12 years and older with moderate to severe persistent asthma who have a positive skin test or in-vitro reactivity to an aeroallergen and chronic idiopathic urticaria. Xolair was not studied in patients who smoke. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## onabotulinumtoxinA (Botox)

### **Products Affected**

Botox

PA Criteria	Criteria Details
Covered Uses	Non-Cosmetic FDA approved indications
Exclusion Criteria	FDA labeled contraindications, and excluded for cosmetic conditions
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	FHCP covers this medication only for medically necessary purposes, like cervical dystonia, not responsive to physical therapy, blepharospasm that interferes significantly with vision, and headache not responsive to preventive and acute therapy by Neurology for at least 16 weeks

## paclitaxel (Abraxane)

### **Products Affected**

#### Abraxane

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

## palivizumab (Synagis)

### **Products Affected**

Synagis

PA Criteria	Criteria Details
Covered Uses	FDA approved indications
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Based on current AAP guidelines.
Other Criteria	Coverage will be based on current AAP guidelines for use of Palivizumab (Synagis). Physician must complete Synagis request form from the referrals department.

## panitumumab (Vectibix)

### **Products Affected**

Vectibix

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

## **PegFilgrastim**

### **Products Affected**

- Fulphila
- Udenyca

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	All FDA approved uses, Off-Label uses must be NCCN supported with a grade 2a recommendation or greater.

## pembrolizumab (Keytruda)

### **Products Affected**

Keytruda

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications, progression on PD-1/PDL-1 in previous line of treatment
Required Medical Information	Medical notes, previous treatment history and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncologist/Hematologist.
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

## pemetrexed (Alimta)

### **Products Affected**

Alimta

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

## pertuzumab (Perjeta)

### **Products Affected**

Perjeta

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncology
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

## plerixafor (Mozobil)

### **Products Affected**

Mozobil

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

## radium-223 (Xofigo)

### **Products Affected**

Xofigo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

## ramucirumab (Cyramza)

### **Products Affected**

Cyramza

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Hematologists/Oncologist.
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

## rituximab-pvvr (Ruxience)

### **Products Affected**

Ruxience

PA Criteria	Criteria Details
Covered Uses	Ruxience is a CD-20 targeted B-cell depleting biologic. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.Rituxan Hycela is not covered. Criteria for coverage (for treatment of malignancies) as follows:FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.Criteria for coverage (for treatment of Rheumatoid Arthritis) as follows:Patient has failed 2 or more Anti-TNF agents. Coverage will be for 1000mg x 2 treatments separated by 2 weeks. Retreatment will not be covered sooner than 24 weeks post initial infusion. Patient must be on Methotrexate.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

## siltuximab (Sylvant)

### **Products Affected**

Sylvant

PA Criteria	Criteria Details
Covered Uses	FDA approved indications
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Oncologist
Coverage Duration	Up to 12 months
Other Criteria	

## talimogene laherparepvec (Imlygic)

### **Products Affected**

Imlygic

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	Up to 12 months or until disease progression or toxicity
Other Criteria	

## thyrotropin (Thyrogen)

### **Products Affected**

Thyrogen

PA Criteria	Criteria Details
Covered Uses	FDA approved indications
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Approved when written by Oncology or Endocrinology.
Coverage Duration	12 Months
Other Criteria	Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## tocilizumab (Actemra)

### **Products Affected**

Actemra Intravenous

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Rheumatologist
Coverage Duration	Up to 12 months
Other Criteria	Must fail Simponi, Kevzara, Enbrel, Remicade, and Xeljanz.

## treprostinil (Remodulin)

### **Products Affected**

• Treprostinil Sodium

PA Criteria	Criteria Details
Covered Uses	Pulmonary hypertension must be diagnosed by heart catheterization, Evaluation, EKG, diffusion studies, catheterization results and an objective test of exercise ability (6 minute walk) must be submitted with referral.Patient must be a WHO class III or IV and fail combination ambrisentan and tadalafil.
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies.
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Pulmonologist/Cardiologist
Coverage Duration	12 months
Other Criteria	Remodulin is a prostacyclin analog indicated to treat primary pulmonary arterial hypertension. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

### ustekinumab (Stelara)

#### **Products Affected**

- Stelara Subcutaneous Solution 45 MG/0.5ML
- Stelara Subcutaneous Solution Prefilled Syringe

PA Criteria	Criteria Details
Covered Uses	FDA approved indications. Only covered as a medical benefit. Notes supporting moderate to severe Plaque psoriasis or Psoriatic arthritis For Plaque Psoriasis, recent failure (in past 6 months) of Renflexis, and Enbrel in combination with topical treatment following conventional therapy. For Psoriatric Arthritis failure of Renflexis, Enbrel, Xeljanz, and Simponi. For Crohns Disease must fail conventional agents AND Renflexis, Entyvio, Humira, AND TNF in combination with a conventional immunosuppressant (when clinical appropriate) with 5-ASA anti-inflammatory. For Ulcerative Colitis must fail conventional agents AND Renflexis/Simponi, Entyvio, Xeljanz, AND TNF in combination with a conventional immunosuppressant (when clinical appropriate) with 5-ASA anti-inflammatory.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescribed by a dermatologist or Rheumatologist.
Coverage Duration	Up to 12 months

PA Criteria	Criteria Details
Other Criteria	Stelara is indicated for treatment of moderate to severe plaque psoriasis and psoriatic arthritis and Crohns disease Medical history and studies are reviewed in Referrals and if approved will notify the physician.

## vedolizumab (Entyvio)

### **Products Affected**

Entyvio

PA Criteria	Criteria Details
Covered Uses	FDA approved indications
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	Gastroenterologist
Coverage Duration	Up to 12 months
Other Criteria	Must have had recent failure of an immunosuppressant (Azathioprine, 6-mp or Methotrexate) and an anti-inflammatory (5-asa, sulfasalazine, balsalazide, mesalamine) and Remicade. Requires a 3 month trial in past 6 months.

## verteporfin (Visudyne)

### **Products Affected**

Visudyne

PA Criteria	Criteria Details
Covered Uses	FDA approved indications
Exclusion Criteria	FDA labeled contraindications
Required Medical Information	Medical notes, previous treatment history, and associated studies
Age Restrictions	Ages approved in FDA labeling/compendia
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

## ziprasidone (Geodon) injection

### **Products Affected**

Geodon Intramuscular

PA Criteria	Criteria Details
Covered Uses	FDA approved indications.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Approved when written/ordered by a Psychiatrist or Neurologist through referrals for new starts.
Coverage Duration	12 months
Other Criteria	Geodon is a psychotropic medication. Prior authorization only applies to existing members who are new starts on the drug. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

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#### Florida Health Care Plans:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified Interpreters
  - Information written in other languages

If you need these services, contact:

Florida Health Care Plans: 1-877-615-4022

If you believe that Florida Health Care Plans has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Florida Health Care Plans Civil Rights Coordinator 1340 Ridgewood Avenue, Holly Hill, FL 32117. Phone: 1-844-219-6137,

TTY: 1-800-955-8770 Fax: 386-676-7149, Email: rights@fhcp.com.

You can file grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <a href="https://ocrportal.hhs.gov/ocr/portal/lobby.jsf">https://ocrportal.hhs.gov/ocr/portal/lobby.jsf</a>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <a href="http://www.hhs.gov/ocr/office/file/index.html">http://www.hhs.gov/ocr/office/file/index.html</a>.

If you or someone you're helping has questions about Florida Health Care Plans, you have the right to get help and information in your language at no cost. To talk to an interpreter, call 1-877-615-4022. (TTY: TRS Relay 711)

Si usted o alguien a quien ayuda tienen preguntas sobre Florida Health Care Plans, tienen derecho a obtener ayuda e información en su idioma de manera gratuita. Para hablar con un intérprete, llame al 1-877-615-4022. (TTY: TRS Relay 711)

Si ou menm, oswa yon moun w ap ede, gen kesyon sou Florida Health Care Plans, ou gen dwa pou jwenn enfòmasyon nan lang ou gratis. Pou ale ak yon entèprèt, rele 1-877-615-4022. (TTY: TRS Relay 711)

Nếu quý vị, hoặc người nào đó mà quý vị đang giúp đỡ, có các thắc mắc về Florida Health Care Plans, quý vị có quyền được nhận trợ giúp và thông tin bằng ngôn ngữ của quý vị miễn phí. Để trao đổi với phiên dịch, hãy gọi theo số 1-877-615-4022. (TTY: TRS Relay 711)

Se você, ou alguém que estiver a ajudar, tiver dúvidas sobre Florida Health Care Plans, tem o direito de obter ajuda e informações na sua língua, sem nenhumas custas. Para falar com um intérprete, ligue para 1-877-615-4022. (TTY: TRS Relay 711)

如果您或您正協助的某人對Florida Health Care Plans

有疑問,您有權免費以您的語言取得本協助及資訊。如欲與口譯員交談,請致電1-877-615-4022. (TTY: TRS Relay 711)

Si vous ou une personne que vous aidez avez des questions au sujet de Florida Health Care Plans, vous avez le droit d'obtenir gratuitement de l'aide et des informations dans votre langue. Pour parler à un interprète, veuillez appeler le 1-877-615-4022. (TTY: TRS Relay 711)

Kung ikaw, o ang isang taong tinutulungan mo, ay may mga tanong tungkol sa Florida Health Care Plans, mayroon kang karapatang humingi ng tulong at impormasyon sa iyong wika nang walang bayad. Upang makipag-usap sa isang interpreter, tumawag sa 1-877-615-4022. (TTY: TRS Relay 711)

Если у Вас или у кого-то, кому Вы помогаете, есть вопросы о программе Florida Health Care Plans, Вы имеет право бесплатно получить ответы в переводе на Ваш язык. Для того чтобы воспользоваться помощью устного переводчика, позвоните по телефону 1-877-615-4022. (TTY: TRS Relay 711)

ذا كان لديك أو الشخص الذي تساعده استفسارات حول Florida Health Care Plans يحق لك تلقي المساعدة والمعلومات بلغتك مجاناً. تحدث إلى مترجم فوري، اتصل على الرقم [TTY: TRS Relay 711].

se voi, o una persona che state aiutando, avete domande relative al Florida Health Care Plans, avete diritto a ottenere assistenza e informazioni gratuitamente nella vostra lingua. Per parlare con un interprete, chiamare il numero 1-877-615-4022. (TTY: TRS Relay 711)

Falls Sie oder jemand, dem Sie helfen, irgendwelche Fragen über Florida Health Care Plans haben, so haben Sie Anspruch auf kostenlose Unterstützung und Informationen in Ihrer eigenen Sprache. Bitte rufen Sie uns unter der Nummer 1-877-615-4022. (TTY: TRS Relay 711) an, um mit einem Dolmetscher/einer Dolmetscherin zu sprechen.

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หากคุณ หรือคนที่คุณกำลังช่วยเหลืออยู่มีคำถามเกี่ยวกับ Florida Health Care Plans คุณจะได้รับการช่วยเหลือและได้รับข้อมูลในภาษาของคุณโดยที่ไม่มีค่าใช้จ่ายใดๆ หากต้องการพูดคุยกับล่ามแปลภาษา โทร.

1-877-615-4022. (TTY: TRS Relay 711)

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