



FLORIDA HEALTH CARE PLAN, INC.

1340 Ridgewood Ave., Holly Hill, FL 32117

POLICY

It is the policy of Florida Health Care Plan, Inc (FHCP) to manage certain high risk or high cost medications through a Prior Authorization program or a Stepped Care Program.

PURPOSE

Prior Authorization and Stepped Care are tools in a process to assist in the proper implementation of medication use.

Process for Prior Authorization Request

- Prior Authorization for a Medication may be requested by the member, or prescribing physician or a member's authorized representative verbally or in writing by contacting the FHCP Central Referrals Department.
- Referral nurses will gather clinical information to be evaluated. A clinical pharmacist with Doctor of Pharmacy degree will perform the preliminary review of the request and recommend a determination. A negative determination is reviewed by a Utilization Management Physician for final determination.
- For standard requests, FHCP notifies the requesting physician, member or members' representative of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 days for commercial members after receipt of the request or 72 hours for Medicare members after receipt of the request.
- For expedited requests, FHCP notifies the requesting physician, member or member's authorized representative' representative of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request and supporting clinical documentation. Should FHCP require additional information or documentation an additional 48 hours will be allowed to obtain the information and evaluate for a determination. Under no circumstances will an expedited request exceed 72 hours.

Medications Requiring Prior Authorizations

FHCP: MCG004

Review/Revision: 22

- FHCP Central Referrals Department notifies the requesting Physician, Member or Member's representative of a favorable or an adverse Prior Authorization determination in writing. All adverse determination notices will include the appropriate instructions on how to file an Appeal.
- When a Request is for a Prior Authorization Medication is denied FHCP will;
 1. Specify reason for the denial in easily understandable language.
 2. Refer to the guideline, protocol, benefit provision or other criterion upon which the decision is based.
 3. Notify the member and requesting physician they may request a copy of any criterion used to make the decision.
 4. Provide member and requesting physician with a description of appeal rights, including the right to submit written comments, documentation or other information relevant to the appeal and the timeframes for deciding appeals
 5. Provide member with a description of the expedited appeal process for urgent pre-service or urgent concurrent denials.

PROCEDURE BY MEDICATION (See Attachment 1)

Please note: Part B Drugs are identified by an asterisk () before the Drug name.*

Please note: Medications that are processed through CVS Caremark are identified by a number symbol/pound sign (#)

Abilify – Prior authorization only applies to existing members who are new starts on the drug.

- Approved when written/ordered by a Psychiatrist or Neurologist through Pharmacy for new starts.

***Abraxane (paclitaxel protein bound)** – This medication is an anti-neoplastic indicated for use in Metastatic Breast Cancer and advanced non-small cell lung cancer

- Off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.

Actimmune – This medication is used to prevent infection in Chronic Granulomatous disease, and also delay the time to progression with severe malignant osteopetrosis.

- Coverage will be based on medical history/status, antibiotic failure for chronic granulomatous disease
- Response to previous treatments, and the consideration of other therapeutic options.
- Limited to specialist trained in management of prescribed condition.

Actos (pioglitazone) – This is a Step Therapy Medication used for treatment of type 2 diabetes mellitus.

- Covered after failure of metformin or a sulfonylurea.

***Adagen** – This enzyme replacement therapy is used for treatment Adenosine deaminase deficiency and severe combined immunodeficiency in children.

- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Aloxi inj (Palonosetron)** – This is an antiemetic used for Chemotherapy induced nausea and Vomiting.

- Coverage of palonosetron for prevention of chemotherapy induced nausea and vomiting will require failure of Ondansetron (J2405) + Dexamethasone (J1111) on Day one and Ondansetron 8mg (ODT or tablets) BID-TID on days 2 and 3 following infusion.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Amitiza (lubiprostone) – This is a medication used for chronic constipation and irritable bowel syndrome

- Coverage is restricted to gastroenterology after failure of lactulose and miralax

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Aldurazyme** – This enzyme replacement therapy is used for treatment of MPS-1 type 1 (Hurler and Hurler– Scheie forms).

- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Anadrol (Oxymethalone) – This is an anabolic steroid used to treat anemia's related to deficient red blood cell production.

- Medical history and information reviewed by referrals. Coverage will be response to previous treatments, and the consideration of other therapeutic options (ESAs, B12/folate, iron).

***Antizol** – This medication is an alcohol dehydrogenase inhibitor used to treat acute ingestion of methanol and polyethylene glycols.

- Coverage will be based on the circumstances and treatment options pertaining to the authorization request.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

#Apokyn – This medication is used to treat poorly controlled off time in patients with Parkinson's disease who have failed conventional therapy.

- Patient must have failed Levodopa/Carbidopa + COMT inhibitor.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

#Arcalyst – This medication is used to treat Cryopyrin Associated Periodic Syndromes (CAPS).

- Coverage will be based on: Diagnosis of CAPS and Documentation of disability due to the condition, failure of 1 other treatment used for this condition such as anakinra, canakinumab, and NSAIDs.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Aranesp/Procrit – This medication is used to treat anemia related to Chronic Kidney Disease, Chemotherapy, Myelodysplastic Syndrome, Antiviral therapy. Prior authorization is required for pharmacy coverage of medication. Procrit/Aranesp administered at a clinic or physician's office

and billed through claims will have a post service determination for compliance with current Medicare guidelines.

Pharmacy coverage criteria:

- Patient must have adequate iron stores (ferritin \geq 100 ng/ml, transferrin saturation $>$ 20%).
- Hemoglobin for initiation and maintenance must be compliant with current FDA labeling.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Arixtra (Fondaparinux) – This Medication is an injectable Anti-thrombotic. It is a synthetic heparin analog.

- Approval will be based on contraindication to Lovenox, or use for an indication which Lovenox is not FDA approved.
- Approval will cover no more than a ten day supply per co-pay.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Avastin (Bevacizumab)** – This is 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 oncology indications coverage will be authorized for the following conditions:

- Metastatic carcinoma of the colon or rectum when used in combination with intravenous 5-Fluorouracil based chemotherapy for first-line or second-line treatment and the dose is 5 to 10 mg/kg every 2 weeks
- Metastatic human epidermal growth factor receptor 2 (HER2)-negative breast cancer when used in combination with paclitaxel for the treatment of patients who have not received chemotherapy for metastatic HER2-negative breast cancer and the dose is either 10 mg/kg every 2 weeks or 15 mg/kg every 3 weeks
- Nonsquamous non-small cell lung cancer in combination with carboplatin and paclitaxel for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous cell disease and the dose is up to 15 mg/kg every 3 weeks
- Central nervous system (CNS) cancers and the dose is up to 10 mg/kg every 2 weeks
- Renal cell carcinoma (RCC) and the dose is up to 10 mg/kg every 2 weeks.
- Ovarian cancer and the dose is up to 15 mg/kg every 3 weeks
- Cervical cancer and the dose is up to 15 mg/kg every 3 weeks
- Other Off-Label use must be supported by NCCN guidelines with an evidence level of 2a or greater.

Banzel – This medication is indicated for treatment of Lennox Gastaut syndrome. Prior authorization only applies to existing members who are new starts on the drug.

- Approved when written/ordered by a Neurologist for seizures through Pharmacy.

***Blenoxane** – This medication is an antineoplastic, and can be used as a sclerosing agent for malignant pleural effusions.

- Approved when written by oncology.

* **Boniva Infusion (Ibandronate)** – This medication is indicated for treatment of Osteoporosis. It is a parenteral bisphosphonate given by IV infusion every 3 months.

- Patient must have contraindication or intolerance to oral bisphosphonates such as esophageal stricture.
- Not for use in patients with severe renal impairment (Crcl<30 ml/min).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Bosulif (bosutinib) – This medication is indicated for treatment of Ph+ CML after failure of a first line tyrosine kinase inhibitor.

- Restricted to hematology/oncology.
- Patient must fail first line TKI indicated for CML.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Botox/Xeomin** – This medication is approved for medical and cosmetic purposes. FHCP covers this medication only for medically necessary purposes and is approved for:

- Cervical dystonia, not responsive to physical therapy.
- Blepharospasm that interferes significantly with vision.
- Headache not responsive to preventive and acute therapy by Neurology for at least 16 weeks.
- This information is sent to the Referrals Department.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Budesonide EC capsules (generic entocort) – Entocort is an oral steroid capsule that has low bioavailability.

Entocort is indicated for Mild to Moderate Active Crohn's disease involving the ileum and/or the ascending colon and the maintenance of clinical remission in mild-to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months.

Approval will be based on the following

- Written by a gastroenterologist
- Used in Mild to Moderate Crohn's disease

Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician. Approved referrals will be for a maximum of 3 months

***Buphenyl** – The medication is used to treat hyperammonemia in patients with urea cycle disorders.

- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy

Bydureon/Byetta (Exenatide) – This is an injectable anti-diabetic agent used to treat Type 2 Diabetes. Byetta is indicated for adjunctive use with a sulfonylurea and/or metformin. Coverage will be based on the following:

- Patient must be on maximal doses of Sulfonylurea and Metformin, or have intolerance/contraindication.
- Not for use in patients with severe renal impairment (Crcl<30 ml/min) or Gastroparesis.
- Coverage will initially be allowed for six months of coverage (Non-Medicare). For continued coverage patients must demonstrate an improvement in Ha1c (reduction >0.4%).
- Off label use of Byetta will cancel coverage on previously approved members (Non-Medicare).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Cerezyme** – This is a medication used for the treatment of specific enzyme deficiency.

- Indicated for the treatment of a patient with Type 1 Gaucher's disease with anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly.
- This information is sent to Referrals Department.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Chantix – This is a medication indicated for smoking cessation.

- Coverage will be based on failure of bupropion SR or enrollment/failure in Quitsmart smoking cessation program.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Clotrimazole Troche – This is a medication indicated for oral candidiasis.

- Coverage will be based on failure of fluconazole and nystatin
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

#Cometriq – This is a medication indicated for treatment of metastatic medullary thyroid cancer

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.
- Prescriber must be a Hematologist/Oncologist.

***Cubicin** – This medication is an IV antibiotic that is used for the treatment of resistant gram positive bacterial infections. FHCP will participate in a program to reduce the risk of further development of drug resistant strains of bacteria by encouraging appropriate and limited use of.

- Patient is identified as having an infection caused by VRE (Vancomycin Resistant Enterococcus) or VRSA (Vancomycin Resistant Staph Aureus) by culture and sensitivity; and Oral Zyvox is not a therapeutic option OR
- Patient has a skin or soft tissue infection caused by cMRSA and resistant/PT allergic to other generically available oral agents or combinations which may be used to treat cMRSA (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.
- This information is sent to the Referrals or Case management Department.

Duragesic patch (Fentanyl) – This is a medication used for pain management.

- Approved when written/ordered by an Oncologist or Pain Management through Pharmacy.

***Elaprase** – This medication is used to treat Hunter's Syndrome a lysosomal storage disorder.

- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.
- Limited to specialist trained in management of prescribed condition.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Eliquis (apixaban) – This medication is an oral anti-coagulant used for non-valvular Atrial fibrillation.

- Step therapy medication requiring trial of warfarin and restricted to cardiology.

***Elitek** – This enzyme therapy is used to treat/prevent hyperuricemia due to chemotherapy.

- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Elmiron – This medication is used to treat interstitial cystitis.

- Restricted to urology, covered with diagnosis of interstitial cystitis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Emend (Aprepitant) capsules or injection – This Medication 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.

- Medication will be approved through pharmacy when written by Oncology.
- 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.

Emsam – This medication is used for treatment of major depression.

- Medication is written by a psychiatrist, patient has failed a 6 week trial of two or more formulary antidepressants.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Enbrel – Enbrel is a biologic disease modifying agent, used for treatment of RA, JRA, PSA, Plaque psoriasis, Crohn's Disease, Ulcerative colitis (see [Guidelines for Enbrel](#) (Attachment 2))

- Must be written by Rheumatology, Dermatology or Specialist trained in management of prescribed condition.
- For RA Patient must fail adequate trial of MTX in combination with a DMARD If MTX contraindicated, must try combination of 2-nonbiologic DMARDS.
- For Ankylosing Spondylitis PT must fail 2 NSAIDS within past 6 months.
- For Plaque Psoriasis patient must fail MTX or Soriatane and topical therapy.

- For Psoriatic Arthritis Patient must fail adequate trial of MTX or LEF in past 6 months.

***Euflexxa, Hyalgan or Synvisc** – This medication is indicated for the treatment of osteoarthritis of the knee and is approved according to [Referral Form for Synvisc, Hyalgen or Euflexxa](#) (Attachment 3).

#Exjade (Deferasirox) – This is an oral medication used to treat iron overload typically on patients receive chronic RBC transfusions.

- Patient has failed or intolerant to Deferoxamine.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Fabrazyme** – This medication is used for treatment of Fabry’s disease.

- Patient is diagnosed with Fabry’s Disease with significant cardiac or renal manifestations of disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Fanapt – Prior authorization only applies to existing members who are new starts on the drug.

- Approved when written/ordered by a Psychiatrist or Neurologist through Pharmacy for new starts.

Fentanyl Lozenge – This medication is used to treat breakthrough cancer pain in patients taking long acting opioids. Quantity is limited to 30 lozenges per dispensing

- Prescribing restricted to oncology or pain management.
- Patient must be on a long acting opioid
- patient must have failure of two short acting opioids (morphine elixir, oxycodone, hydromorphone)

Forteo – This medication is used to treat osteoporosis (see [Forteo Patient Consent form](#) (Attachment 7)).

- Patient is diagnosed with osteoporosis with a BMD less than -2.5.
- Patient fails treatment with oral bisphosphonate, and IV bisphosphonate.
- Exclusions – children, adolescents, Paget’s patients with Paget ’s disease or hypercalcemia, or patients with a history of primary or metastatic bone cancer.
- Limitations of treatment – 2 years of treatment.
- For Patients with Calculated GFR or CRcl < 60ml/min Referral must include recent iPTH and Vitamin D (25 OH, 1,25 OH) labs. Must be within normal limits.

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Fosrenol – This medication is used to manage hyperphosphatemia in ESRD.

- Patient has ESRD.
- Patient has elevated calcium on phosphate binders, or not a candidate for Phosphate binders based on KDOQI guidelines.
- Nephrology orders this medication.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Gammagard** – This product is used for immunodeficiency disorders as well as certain autoimmune conditions, including: Hypogammaglobinemia, Kawasaki disease, ITP.

- Approval will be based on compliance with most current Medicare NCD or LCD coverage criteria for IVIG.
- This information is sent to the Referrals Department.

Geodon – Prior authorization only applies to existing members who are new starts on the drug.

- Approved when written/ordered by a Psychiatrist or Neurologist through Pharmacy for new starts.

Growth Hormones other than omnitrope (Genotropin, Humatrope, Norditropin, Nutropin, Saizen, Tevtropin) – Growth Hormone is a pituitary hormone.

- Must fail or have allergy or contraindication to Omnitrope.
- Covered in adults for patients who are growth hormone deficient.
- This information with the lab attached is sent to the Referrals Department.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Hepsera – This medication is used for the treatment of Hepatitis B and is approved when:

- Patient has a confirmed diagnosis of Hepatitis B.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

High Risk Medications in Patients >65 years (Medicare Only) – These medications are only covered for beneficiaries < 65 years old due to for increased potential for adverse effects

- Clorazepate, Cyclobenzaprine, Diazepam, Nitrofurantoin, Phenobarbital.

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Humira – This medication is indicated for the treatment of confirmed rheumatoid arthritis and is approved when:

- Patient is under the care of a Rheumatologist.
- Patient has failed treatment Enbrel for RA, PSA, AS, Plaque psoriasis.
- Must fail Remicade for Crohn's or ulcerative colitis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

***Hyalgan, Synvisc or Euflexxa** – This medication is indicated for the treatment of osteoarthritis of the knee and is approved according to [Referral Form for Synvisc, Hyalgen or Euflexxa](#) (Attachment 3).

#Iclusig (ponatanib) – This medication is a tyrosine Kinase inhibitor used to treat Chronic Myelogenous Leukemia

- Coverage will be based on failure of first or second line TKI for CML or presence of T350I mutation.
- Must be prescribed by Hematologist/oncologist

Increlex – This medication is used to treat short stature in patient with primary Insulin like Growth Factor deficiency, and Patients with neutralizing antibodies to HGH.

- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.
- Must be prescribed by a Pediatric Endocrinologist

Intuniv (guanfacine ER) – This medication is used to treat ADHD.

- Coverage will be require failure of guanfacine IR
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Jakafi – This medication is a JAK inhibitor indicated for treatment of intermediate to high risk myelofibrosis including primary myelofibrosis, polycythemia vera myelofibrosis, and essential thrombocythemia myelofibrosis:

- Not used in combination with lenolidamide/thalidomide, other JAK or TKI inhibitors
- Prescriber is a hematologist/oncologist.

- Continuation in therapy will require 50% reduction in baseline spleen size, or 35% reduction in spleen volume, or a 50% reduction in baseline Myelofibrosis symptom score.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Januvia (Sitagliptin) – This is an oral anti-diabetic agent used to treat Type 2 Diabetes (DPP-IV inhibitor). Januvia coverage will be based on the following:

- Patient must be on maximal doses of Metformin and Sulfonylurea or other combination therapy if metformin contraindicated for at least 6 months, or have intolerance/contraindication.
- Coverage will initially be allowed for six months of coverage (Non-Medicare). For continued coverage patients must demonstrate an improvement in Ha1c (reduction >0.4%).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Kadcyla** – Kadcyla is a Antibody Drug Conjugate (ADC) indicated for second line treatment of HER+ metastatic breast cancer.

- Coverage will be based on failure of prior taxane and Herceptin (Trastuzumab)
- Medical history and studies are reviewed in Referrals and will notify provider after coverage determination.

Kineret – This is a biologic agent used for treatment of rheumatoid arthritis.

- Patient must fail two anti-TNF biologics.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Kuvan – This medication is used to treat Phenylketonuria (PKU).

- Coverage will be based on medical history/status, response to previous treatments, Dietary compliance, and the consideration of other therapeutic options.
- Prescribing limited to specialist trained in management of PKU.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Latuda – Prior authorization only applies to existing members who are new starts on the drug.

- Approved when written/ordered by a Psychiatrist or Neurologist through Pharmacy for new starts.

***Levulan** – This medication is approved to treat actinic keratosis of the scalp or face.

- Patient is identified as having actinic keratosis by biopsy.
- Patient fails cryotherapy.
- Patient fails Efudex or Aldara.
- Limitations – This can be performed by Dermatology or Plastic Surgery only.
- This information is sent to the Referrals Department.
- CMO or designee reviews the information and approves the request if the above are met.
- The Referrals Department notifies Pharmacy.

Lidoderm – This is a transdermal formulation of lidocaine indicated for treatment of post-herpetic neuralgia.

- Coverage will be based on failure or contraindications of other therapies including failure of Gabapentin.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Linzess (linaclotide) – This is a medication used for chronic constipation and irritable bowel syndrome.

- Coverage is restricted to gastroenterology after failure of lactulose and miralax
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Lotronex – This medication is used to refractory IBS with severe diarrhea.

- Prescribing limited to gastroenterology and registration with monitoring program for Lotrenox, prescription is reviewed in the pharmacy department.

Lyrica – This medication is indicated for the treatment of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia and as an adjunct for partial seizures and is covered when: (Prior authorization only applies to existing members who are new starts on the drug)

- Patient has failed gabapentin and one other medication used for Diabetic peripheral neuropathy.
- Patient has failed Gabapentin for postherpetic neuralgia.
- Written by Neurology for seizures.

For the indication of Fibromyalgia. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Patient has failed or intolerant to Gabapentin and has tried one other medication used for treatment of Fibromyalgia, patient must have tried therapy for minimum of 1 month to be considered failure. Not restricted by prescriber type for this indication.

- Fluoxetine
- Cymbalta
- Tramadol
- Amitriptyline
- Cyclobenzaprine
- NSAID

Marinol (dronabinol) – This medication is used to treat HIV/Cancer related Cachexia and chemotherapy induced nausea and vomiting.

- For cachexia, patient must fail megestrol acetate.
- For nausea and vomiting patient must fail Ondansetron and Emend

Mekinist – This medication is a MEK inhibitor used to treat BRAF+ V600e/k mutation Stage IIIc-IV metastatic Melanoma.

- Patient must have BRAF V600E/K mutation
- Must be written by an oncologist
- Not covered for combination use unless supported by NCCN guidelines.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Menest- This medication is only covered for palliative treatment of breast cancer.

- Must be written by an oncologist
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Naglazyme** – This enzyme replacement therapy is used for treatment Maroteaux-Lamy syndrome.

- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Neutrexin** – This is an anti-metabolite used to treat moderate to severe PCP pneumonia resistant to SMX/TMP.

- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Nicotrol (Nicotine replacement) – Indicated for smoking cessation therapy.

- Must have previously failed or have contraindication to Bupropion.
- Patient must be actively enrolled in a Smoking Cessation Program.
- Coverage is approved for 24 weeks of treatment.
- Copayment will be applied per package.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy

***Nulojix (belatacept)** – This medication is an immunosuppressive anti-rejection agent for kidney transplant.

- Prescriber must be a nephrologist or transplant specialist.
- Patient must have failure or intolerance to a calcineurin inhibitor.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Omnitrope – (Human Growth Hormone) Growth Hormone is a pituitary hormone.

- Covered in adults for patients who are growth hormone deficient.
- Covered in pediatric patients with growth hormone deficiency.
- This information with the lab attached is sent to the Referrals Department.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Onfi (clobazam) – This is a benzodiazepine indicated to treat seizures.

- Approved when written/ordered by a Neurologist through Pharmacy for new starts.

Onglyza (Saxagliptin) – This is an oral anti-diabetic agent used to treat Type 2 Diabetes (DPP-IV inhibitor). Onglyza coverage will be based on the following:

- Patient must be on maximal doses of Metformin and Sulfonylurea or other combination therapy if metformin contraindicated for at least 6 months, or have intolerance/contraindication.

- Coverage will initially be allowed for six months of coverage (Non-Medicare). For continued coverage patients must demonstrate an improvement in Ha1c (reduction >0.4%).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Ontak** – This Medication is indicated for treatment of Cutaneous T cell Lymphoma (CTCL).

- Coverage will be based on medical history, response to previous treatments, and the consideration of other therapeutic options.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Orencia – This is a biologic agent used for treatment of rheumatoid arthritis.

- Patient must fail Anti-TNF agent.
- For patients where anti-tnf agents are contraindicated must fail 3 month trial of combination DMARD therapy in the past 6 months.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Orfadin – This medication is a treatment for Type I Tyrosinemia.

- Coverage will be based on medical history/status, response to previous treatments, appropriate trials of dietary changes, and the consideration of other therapeutic options.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Oxandrin (Oxalandrone) – This is an anabolic steroid used to promote weight gain.

- Approved when written by Oncology, through pharmacy.

Pegasys – This is a Pegylated interferon used to treat hepatitis B and Hepatitis C.

- Hepatitis C only covered if patient is a candidate for Peg-Intron coverage by FHCP criteria, and has an allergy or contraindication to Peg Intron.
- Covered for treatment of HBV in accordance to FDA labeled dose and duration of therapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy

Peg Intron – [\(See Attachments 4 \(Referral Form for Patient with Hep C\)\)](#)

***Perjeta** – Perjeta is a monoclonal antibody indicated for second line treatment of HER+ metastatic breast cancer

- Coverage will be based on failure of prior taxane and Herceptin (Trastuzumab)
- Medical history and studies are reviewed in Referrals and will notify provider after coverage determination.

#Pomalyst – This medication is thalidomide analog used to treat refractory Multiple Myeloma

- Restricted to Hematology/Oncology.
- Coverage requires failure of Revlimid

Pradaxa – This medication is an oral anti-coagulant used for non-valvular Atrial fibrillation.

- Restricted to cardiology.
- Coverage requires failure on warfarin such as unstable INR, non-GI related bleeding, Stroke while in therapeutic range.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy

#Promacta – This medication is used to treat chronic idiopathic thrombocytopenic purpura.

- Patient must have chronic ITP with platelet count less than 50,000, and refractory to IVIG, corticosteroids or splenectomy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Provigil (Modafinil) – This medication is for the treatment of narcolepsy, shift work sleep disorder and obstructive sleep apnea/hypopnea syndrome. Quantity limited to 31 tablets per month.

- These disorders are diagnosed by history, overnight polysomnography, and multiple sleep latency studies.
- Medical and pharmacy history are reviewed through Referrals and if approved will notify pharmacy and the physician.
- Approval for MS related Fatigue will require amantadine failure.

***Pulmicort Respules (Budesonide)** – This medication is a respiratory steroid indicated for treatment of asthma in pediatric patient's ages 6 months– 8 years old.

- Approved when written for patients ages 6 months to 8 years through pharmacy.

***Pulmozyme (dornase Alfa)** – This medication is used to reduce exacerbation in patients with cystic fibrosis.

- Must be written by a pulmonologist
- Patient must have an FVC \geq 40% of predicted value and recurrent pulmonary infections.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Ranexa (Ranolazine) – This medication is indicated for chronic angina in combination with amlodipine, nitrates or beta blockers.

- Prescriber is a cardiologist.
- Patient must have failed or has contraindications to other anti-anginal therapies including: beta blockers, calcium channel blockers, long acting nitrates.
- Patient must be using medication in combination with amlodipine, nitrates or betablockers.
- Patient must not have any contraindications to the medication as it has numerous drug/disease interactions.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

*** Reclast (Zoledronic Acid)** – This medication is indicated for treatment of Osteoporosis. It is a parenteral bisphosphonate given by IV infusion every 12 months.

- Patient must have contraindication or intolerance to oral bisphosphonates such as esophageal stricture.
- Not for use in patients with severe renal impairment (CrCl<30 ml/min).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Relistor (Methylnaltrezone) – This medication is used to treat opioid induced constipation.

- Covered for patients with advanced illness receiving palliative opioid treatment who fail Lactulose and metoclopramide at therapeutic doses.
- Prescriber must be a gastroenterologist, Pain management physician, or oncologist.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Remicade** – This medication is indicated for the treatment of Crohn's Disease and Rheumatoid Arthritis, Ulcerative Colitis, Ankylosing Spondylitis, Psoriatic Arthritis and is approved as per [Remicade Order Form](#) (Attachment 6).

***Remodulin (treprostinil)** – This medication is a prostacyclin analog used to treat primary pulmonary arterial hypertension.

- Must be written by a pulmonologist or cardiologist.
- 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 Tracleer.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Retin – A (Tretinoin) – This medication is used to treat moderate to severe acne and diseases of keratinization such as ichthyosis and keratosis follicularis.

- This medication is not covered for wrinkles or photoaging.
- Medical history/photos will be reviewed by Referrals and, if approved, notify pharmacy and physician.

Revatio (Sildenafil) – This medication is for the treatment of Primary pulmonary hypertension or pulmonary hypertension related to connective tissue disease.

- Pulmonary hypertension must be diagnosed by heart catheterization.
- Evaluation, EKG, catheterization results and an objective test of exercise ability (6 minute walk) must be submitted with referral.
- This medication is contraindicated in patients using organic nitrates either regularly or intermittently.
- Approved referrals will initially provide coverage for 12 weeks. Continuation of coverage will be determined by an improvement of an objective test of exercise (6 minute walk) from baseline. Follow-up documentation must be submitted for continuation of coverage.
- Patients who have had an initial positive response based the 12 week follow-up will be approved for an additional 6 months, and reevaluation with documentation will be required every 6 months for continuation of coverage.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

#Revlimid (Lenalidomide) – This medication is a thalidomide analog indicated for treatment of Multiple Myeloma and Myelodysplastic syndrome anemia that is transfusion dependant and has 5q deletion karyotype.

- For Multiple Myeloma, patient must have failed Thalomid therapy.
- Prescriber is a hematologist/oncologist.
- Patient must have failed Arenesp & Procrit for MDS anemia.

Rilutek – This medication is indicated for the treatment of ALS.

- Diagnosis is definite or probable ALS by Neurology.
- Symptoms have been present for less than 5 years.
- Vital Capacity is 60% or more of predicted.
- Patient does not have a tracheostomy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

***Rituxan (for Rheumatoid arthritis)** – Rituxan is a CD-20 targeted B-cell depleting biologic.

Approval for malignancies include all FDA approved indications, off-label use will be reviewed for compliance to NCCN guidelines and have an evidence level of 2a or greater.

Approval for Rheumatoid arthritis is based on the following:

- 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
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.
- Patient must be on Methotrexate.

Sabril – This medication is used to treat infantile spasms or as an adjunct for refractory complex partial seizures.

- Approved when written/ordered by a Neurologist through Pharmacy for new starts.

Saphris – This medication is used for treatment of Bipolar Disorder or Schizophrenia.

- Approved when written/ordered by a Psychiatrist or Neurologist through Pharmacy for new starts.

Sensipar – This medication is used to treat hyperparathyroidism that is secondary to renal insufficiency or hypercalcemia secondary to parathyroid carcinoma.

- Patient is identified as having hypercalcemia associated with parathyroid carcinoma OR
- Patient is identified as having hyperparathyroidism secondary ESRD in patient with elevated PTH. Patient must have failed phosphate binders and active Vitamin-D therapy, iPTH must be >300 in dialysis patients.
- Limitations – This medication must be prescribed by Nephrology or Endocrinology or Oncology.
- Exclusions – Not for use in children, pregnancy, seizure disorder.
- This information is sent to the Referrals Department.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Seroquel XR – This is a psychotropic medication. Approved when written/ordered by a Psychiatrist or Neurologist through Pharmacy. Prior authorization only applies to existing members who are new starts on the drug.

Solaraze (Diclofenac Topical) – This medication is a topical NSAID indicated for treatment of Actinic Keratosis.

- Medication Approval will be through pharmacy when written by a dermatologist with a diagnosis of Actinic Keratosis.

#Somavert – This medication is indicated for the treatment of acromegaly.

- Patient with acromegaly who has had an inadequate response to surgery and/or radiation and other medical therapies.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Sporonox (itraconazole) – This medication is a triazole antifungal medication useful in the treatment of fungal infections including aspergillus, candida, blastomyces, cryptococcus, coccidiomycosis, sporotrichosis and histoplasma and is covered when:

- These pathogens are identified by culture and sensitivity, pathology or stain in a patient with evidence of infection.
- Patient has been treated with fluconazole or ketoconazole or amphotericin first and failed.
- For onychomycosis patient must fail terbinafine
- Medical history and microbiology will be reviewed in Referrals and if approved will notify pharmacy and the physician.

Suboxone/Subutex – This medication is indicated for the treatment of substance abuse/detoxification. This medication is not covered for chronic pain treatment or maintenance treatment in substance abuse.

- Approved when written/ordered by a physician specifically trained and licensed to prescribe this medication through Pharmacy.

Sylatron – (peg-interferon alpha 2b) - This medication is an adjuvant treatment for metastatic melanoma.

- Must be used as adjuvant treatment within 84 days of surgical resection in patients with metastatic melanoma with nodal involvement
- Prescriber must be an oncologist.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Symlin (Pramlintide) -This is an injectable anti-diabetic agent used to treat Type 1 and 2 Diabetes. Symlin is indicated for adjunctive treatment of DM with insulin. Coverage will be based on the following:

- Prescriber is an endocrinologist.
- Patient is uncontrolled despite optimal insulin utilization with Ha1c between 7%-9%.
- Not for use in patients with gastroparesis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.
- Coverage will initially be allowed for six months of coverage (Non-Medicare). For continued coverage patients must demonstrate an improvement in Ha1c (reduction >0.4%)

***Synagis** – This is an antibody used to prevent Respiratory Syncytial Virus in newborn infants with certain risk factors.

- Coverage will be based on current AAP guidelines for use of Pavilizumab (Synagis)
- Physician must complete [Synagis request form](#) (Attachment 8) and Fax or Mail to the Referrals Department

Synarel – This medication is a GNRH analog (intranasal formulation) used to treat precocious puberty in children or endometriosis in adults.

- Approved when written by an endocrinologist or gynecologist.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Synvisc/Hyalgan or Euflexxa** – This medication is indicated for the treatment of osteoarthritis of the knee and is approved according to [Referral Form for Synvisc, Hyalgen or Euflexxa](#) (Attachment 3).

Tafinlar – This medication is a BRAF inhibitor used to treat BRAF+ V600e/k mutation Stage IIIc-IV metastatic Melanoma

- Patient must have BRAF V600E/K mutation
- Must be written by an oncologist
- Not covered for combination use unless supported by NCCN guidelines.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Tasigna – This is an oral antineoplastic agent used to treat Philadelphia Chromosome + CML

- Covered for treatment failure with Gleevac or Sprycel
- Coverage for treatment naïve CML must be Philadelphia chromosome positive
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Tazorac – This medication is a topical retinoid used to treat Acne or Psoriasis.

- For Psoriasis patient must have failed medium to high potency topical corticosteroid
- For acne patient must have failed Tretinoin and oral antibiotic
- Must be written by dermatology
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Tekturna – This is a step therapy medication used to treat hypertension.

- Tekturna is covered after failure of an Angiotensin Receptor Blocker (ARB).

Thalomid – (Thalidomide)

- Approved when written by Oncology, Infectious Disease or in HIV disease through pharmacy.

***Tobi**- (Nebulized Tobramycin)- This medication is used to treat pulmonary infections caused by pseudomonas aeruginosa in patients with Cystic Fibrosis. Safety and efficacy have not been demonstrated in patients under 6 years old or in patients with an FEV-1 <25% or >75% of predicted.

- Must be written by infectious disease specialist or pulmonologist
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

#Tracleer – This medication is for the treatment of Primary pulmonary hypertension or pulmonary hypertension related to connective tissue disease.

- Pulmonary hypertension must be diagnosed by heart catheterization.
- Patient must have failed or have contraindication to Revatio.
- Evaluation, EKG, diffusion studies, catheterization results and an objective test of exercise ability (6 minute walk) must be submitted with referral.
- Approved referrals will initially provide coverage for 12 weeks. Continuation of coverage will be determined by an improvement of an objective test of exercise (6 minute walk) from baseline. Follow-up documentation must be submitted for continuation of coverage.

- Patients who have had an initial positive response based the 12 week follow-up will be approved for an additional 6 months, and re-evaluation with documentation will be required every 6 months for continuation of coverage.
- This medication is contraindicated in pregnancy, those of childbearing ability who are not using contraception, those on glyburide or cyclosporine and in those with active liver disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Tradienta – (Linagliptin) – This is a Step Therapy Medication used for treatment of type 2 diabetes mellitus.

- Covered after failure of metformin and a sulfonylurea.

***Trisenox** – This medication is used to treat Acute Promyelocytic Leukemia (APL).

- Coverage will be based on medical history, response to previous treatments, and the consideration of other therapeutic options.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy

#Tykerb – This is a medication indicated to treat Advanced HER2+ breast cancer in combination with Xeloda. Approval will be based on the following Criteria

- Patient has HER2/neu + breast cancer that has failed treatment/progressed with a regimen including an anthracycline, a taxane and Herceptin.
- Used to treat Metastatic HR+ HER2/neu+ breast cancer in combination with an aromatase inhibitor.
- Prescriber is an oncologist.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Tyzeka – This medication is indicated for hepatitis B infection.

- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Velcade** – This medication is a monoclonal antibody used to treat Multiple Myeloma.

- Coverage will be based on medical history, response to previous treatments, and the consideration of other therapeutic options.

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy

Vesanoid (tretinoin) – This medication is used to treat promyelocytic leukemia.

- Approved when written by Oncology through Pharmacy.

Victrelis – (boceprevir) – This medication is an NS3-4A protease inhibitor used in combination to treat genotype 1 HCV.

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.
- Coverage will be approved based on HCV antiviral policy.

Vimpat – This medication is an adjunct agent used to treat partial onset seizures.

- Approved when written/ordered by a Neurologist for seizures through Pharmacy.

***Visudyne (Verteporfin)** – This medication is a photo-chemotherapy agent for age related wet macular degeneration.

- Medical history and studies are reviewed in Referrals.

Xalkori – (crizotinib) – This is a TKI inhibitor for metastatic NSCLC which is ALK (anaplastic lymphoma kinase) positive.

- Not covered in combination with other tyrosine kinase inhibitors or EGRf inhibitors.
- Must be written by oncologist
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Xarelto (Rivaroxaban) 10mg – This is an oral Factor Xa inhibitor used for DVT prophylaxis following joint replacement therapy it is also indicated for anticoagulation for Atrial Fibrillation. This is only covered for post joint replacement DVT prophylaxis and not atrial fibrillation (20mg dose). Only 10mg dose is covered.

- Only 10mg tablet is covered
- Restricted to use by Orthopedics, Hematology, or Hospitalists, approved by pharmacy.

Xenazine – This medication is used to treat chorea associated with Huntington's disease.

- Patient must have moderate to severe chorea that is refractory to amantadine, neuroleptics or anticonvulsants.
- Prescriber must be a neurologist.

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

***Xolair** – 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 invitro reactivity to an aeroallergen. 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.

The following criteria must be met for coverage:

- 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 ICS +LABA
- Patient must have failed leukotriene receptor antagonist.

#Xtandi (enzalutamide) – This medication is an androgen receptor blocker used for Metastatic Castrate Resistant Prostate Cancer. Covered for 6 months and continuation based on lack of disease progression.

- Coverage will be based on failure of Docetaxol and Abiraterone.
- Must be prescribed by oncologist or urologist.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy

***Yervoy** – This medication is an immunotherapy used for treatment of metastatic melanoma.

- Not covered in combinations unsupported by the NCCN evidence 2a or greater (ie. Vemurafenib)
- Must be prescribed by an oncologist/hematologist.

***Zaltrap** – This medication is an VEGF antagonist used for metastatic colorectal cancer.

- Coverage will be based on failure or intolerance of Avastin
- Must be prescribed by an oncologist/hematologist.

Zavesca – This medication is used for treatment non-neuropathic Gaucher's disease.

- Coverage will be based on medical history/status, response to previous treatments, and the consideration of other therapeutic options.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

#Zelboraf (vemurafenib) – This medication is a BRAF inhibitor used to treat BRAF+ V600e/k

mutation Stage IIIc-IV metastatic Melanoma

- Patient must have BRAF V600E/K mutation
- Must be written by an oncologist
- Not covered for combination use unless supported by NCCN guidelines.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Zemplar (Paricalcitol) – This medication is a late generation synthetic Vitamin D analog used to treat and prevent secondary hyperparathyroidism in CKD. Coverage will be based on the following:

- Prescriber is a Nephrologist or Endocrinologist.
- Patient Has CKD and Hyperparathyroidism.
- Patient is not a candidate for first generation vitamin D analogs (calcitriol) due to hypercalcemia.
- Patient is on a phosphate binder if hyperphosphatemic.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Zolinza (Vorinostat) – Covered for cutaneous manifestations of cutaneous T-cell Lymphoma when the following criterion has been met:

- Failed minimum of two systemic treatments, one of which must be Targretin, unless contraindicated.
- Zolinza is not covered for use in treating conditions not approved by the FDA, as these would be considered investigational.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Zyprexa – This is a psychotropic medication. Prior authorization only applies to existing members who are new starts on the drug.

- Approved when written/ordered by a Psychiatrist or Neurologist through Pharmacy.

#Zytiga – This medication is used to treat castrate resistant metastatic prostate cancer following failure of docetaxol or progression on LHRH treatment. It is taken orally along with prednisone daily.

- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Zyvox – This medication is an antibiotic in a new class that is used for the treatment of resistant bacterial infections. FHCP will participate in a program to reduce the risk of further

development of drug resistant strains of bacteria by encouraging appropriate and limited use of Zyvox.

- Patient is identified as having an infection caused by VRE (Vancomycin Resistant Enterococcus) or VRSA (Vancomycin Resistant Staph Aureus) by culture and sensitivity;
OR
- Patient is identified with MRSA and is allergic to vancomycin.
- This information is sent to the Referrals Department.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.