# FLORIDA HEALTH CARE PLAN, INC.

2450 Mason Avenue, Daytona Beach, FL 32114

POLICY/PROCEDURE NO.: MCG004 REVISION: 74

**SUBJECT:** Medications Requiring Prior Authorizations or Step

Therapy

**APPLICABLE PRODUCT TYPE:** 

| Federal Health Exchange Marketplace

☐ ERISA

☐ Medicare

**EFFECTIVE DATE:** June 12, 2024 **REVIEW/REVISION DATE:** June 12, 2024

ATTACHMENT (S): (4)

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Services

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**LEADERSHIP APPROVAL:** [Approved version maintained within PolicyTech.]

Steven Blumberg, President/Chief Executive Officer

#### **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 Step Therapy.

#### **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.

FHCP Central Referral Department will gather clinical information to be evaluated. A clinical pharmacist with Doctor of Pharmacy degree will perform the final determination. Appeals are reviewed by a Utilization Management Physician for final determination.

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> 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.

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- Medications which are provided and administered by a health care professional incident to a visit are generally part B (unless self-administered greater than fifty percent of the time). If a medication is provided by a pharmacy and administered by a physician, it may be Part D. Further clarification can be found at https://www.cms.gov/Outreachand-Education/Outreach/Partnerships/Downloads/determine.pdf
- 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.
- Approved prior authorizations must be renewed by the member, or prescribing physician or a member's authorized representative verbally or in writing through the FHCP Central Referrals Department prior to expiration date for continued coverage.
- 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.
- All non-formulary medications are not covered. A prior authorization is required for any exceptions.
- 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.

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 Provide member with a description of the expedited appeal process for urgent preservice or urgent concurrent denials. Once a prior authorization request has been approved, coverage will be authorized for up to 12 months for most medications.

However, certain generic medications may be covered indefinitely at discretion of the clinical reviewer. An enrollee is not required to re-request an approval to continue using the prescription drug, as long as all of the following conditions are met:

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- o The member's prescribing physician continues to prescribe the drug.
- The drug continues to be considered safe and effective for treating the member's disease or medical condition.
- The member continues to remain eligible under the plan.

#### SUMMARY OF CHANGES FROM PREVIOUS VERSION

Update Adcetris, Ampyra, Dificid Entyvio, strensiq, Xolair,

Delete Azilect, Amitiza, Leukine, Livalo, denavir, quinine, rapaflo, riluzole, risidronate, saphris

PROCEDURE BY MEDICATION (See Attachment 1)

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# Abilify Maintena (Aripiprazole injection) J0401

Exchange Pharmacy	Х	Medical Commercial	Х
Commercial Pharmacy	X	Medical Exchange	Х
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Aripiprazole is a psychotropic medication.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- FDA approved indications
- Failure of oral aripiprazole and lurasidone
- Approved when written/ordered by a Psychiatrist or Neurologist through referrals for new starts.

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# Abraxane (paclitaxel protein bound)-J9264

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Abraxane is an anti-neoplastic agent indicated to treat metastatic breast cancer, advanced non-small cell lung cancer, and metastatic pancreatic adenocarcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

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# Actemra (tocilizumab)-J3262

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	X
Step Therapy		Limited Distribution	
		Quantity Limit	

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

- FDA approved indications must be prescribed by a rheumatologist.
- Must fail Kevzara, Adalimumab, Enbrel, Renflexis for overlapping indications

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Actimmune (interferon gamma-1b)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

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- Actimmune is indicated to prevent infection in Chronic Granulomatous disease, and also delay the time to progression with severe malignant osteopetrosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Coverage will be based on medical history/status, antibiotic failure for chronic granulomatous disease.
- Limited to specialist trained in management of prescribed condition.

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## Adcetris (brentuximab vedotin)-J9042

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- ADCETRIS is an antibody-drug conjugate FDA indicated to treat Hodgkin lymphoma and systemic anaplastic large cell lymphoma
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

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**Adcirca-Generic Only (tadalafil)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

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- Adcirca is indicated for treatment of pulmonary arterial hypertension (WHO group 1).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Pulmonary hypertension must be diagnosed by right 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.

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Adempas (riociguat)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Adempas is indicated to treat Pulmonary Arterial Hypertension (PAH) and Chronic Thromboembolic Pulmonary Hypertension (CTPH).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- FDA approved indications
- Failure of tadalafil and ambrisentan
- Prescriber must be a cardiologist or pulmonologist
- Diagnosis of PAH supported by right heart catheterization.
- Failure of sildenafil and bosentan.

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# **Afinitor Generic Only (Everolimus)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

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- Afinitor is an oral tyrosine kinase inhibitor indicated to treat several malignancies.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# Criteria for coverage as follows:

• Prescribing restricted to oncology.

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Aimovig (erenumab) injection

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

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Aimovig is an anti-CGRP antibody indicated for prophylaxis of Episodic and Chronic Migraines

### **Episodic Migraines**

Aimovig will be approved based upon all of the following criteria:

- (1) Diagnosis of episodic migraines with **both** of the following:
  - (a) Less than 15 headache days per month
  - (b) Patient has 4 to 14 migraine days per month
  - -AND-
- (2) Recent trial and failure (trial of at least three months) of two generic medications FDA indicated for migraine prophylaxis (topiramate/divalproex). If either or both are contraindicated or not tolerated the medications below could be used:
  - (a) Amitriptyline
  - (b) atenolol, metoprolol, nadolol, propranolol, or timolol
  - I Venlafaxine (Effexor/Effexor XR)

#### AND

(3) Medication will not be used in combination with an oral CGRP antagonist or inhibitor **Authorization will be issued for 6 months.** 

#### 2. Reauthorization

- a. **Aimovig** will be approved based on **all** of the following criteria:
- (1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity
  - -AND-
- (2) Medication will not be used in combination with an oral CGRP Antagonist.

Authorization will be issued for 12 months.

#### **B. Chronic Migraines**

### 1. Initial Therapy

**Aimovig** will be approved based upon **all** of the following criteria:

- (1) Diagnosis of chronic migraines with **both** of the following:
  - (a) Greater than or equal to 15 headache days per month continued.
  - (b) Greater than or equal to 8 migraine days per month

-AND-

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Recent trial and failure (trial of at least three months) of two generic medications FDA indicated for migraine prophylaxis (topiramate/divalproex). If either or both are contraindicated or not tolerated the medications below could be used:

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- (a) Amitriptyline
- (b) atenolol, metoprolol, nadolol, propranolol, or timoll(e) Venlafaxine (Effexor/Effexor XR)

#### -AND-

(3) Medication will not be used in combination with an oral CGRP antagonist **Authorization will be issued for 6 months.** 

#### 2. Reauthorization

- a. **Aimovig** will be approved based on **all** of the following criteria:
- (1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

#### -AND-

(2) Medication will not be used in combination with an oral CGRP Antagonist.

Authorization will be issued for 12 months.

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# <u>Akynzeo (netupitant-palonosetron) tablet</u>

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Akynzeo is indicated for chemotherapy induced nausea and vomiting
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must have failed generic ondansetron, generic granisetron (oral/IV), aprepitant, Aloxi, and low-dose olanzapine (when supported by NCCN guidelines)

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Alecensa (alectinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Alecensa is indicated to treat patients with ALK+ metastatic Non-Small cell lung cancer.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater
- Prescriber must be an oncologist

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## Alimta (pemetrexed) J9305

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Alimta is indicated to treat metastatic or locally advanced non-squamous NSCLC and Mesothelioma
- Medical history and studies are reviewed in Referrals and if approved will notify the physician

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater
- Prescriber must be an oncologist

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## Ampyra GENERIC ONLY (dalfampridine)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	х
		Quantity Limit	

• Ampyra is indicated to treat patients with multiple sclerosis who have walking disability.

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

### Criteria for coverage as follows:

## Diagnosis of multiple sclerosis AND patient is ambulatory Anadrol (Oxymetholone)

- Anadrol is an anabolic steroid indicated to treat various types of anemia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

### Criteria for coverage as follows:

FDA approved indications

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).

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## **Aptiom (eslicarbazepine)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Aptiom is an anti-convulsant indicated for adjunctive treatment of partial seizures.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- FDA approved indications
- Must be written by neurology for adjunctive treatment of seizures.
- Failure of Oxcarbazepine and carbamazepine.

FHCP: MCG004 Review/Revision: 74

#### Retacrit

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- ESAs are used to treat anemia related to Chronic Kidney Disease, Chemotherapy, Myelodysplastic Syndrome, Antiviral therapy. Prior authorization is required for pharmacy coverage of medication.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

## Pharmacy coverage criteria as follows:

- FDA approved indications
- ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure.
- Patient must have adequate iron stores (ferritin ≥ 100 ng/ml, transferrin saturation >20%).
- Hemoglobin for initiation and maintenance must be compliant with current FDA labeling.

FHCP: MCG004 Review/Revision: 74

**Arcalyst (rilonacept)** 

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Arcalyst is indicated to treat Cryopyrin Associated Periodic Syndromes (CAPS).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- Diagnosis of CAPS and Documentation of disability due to the condition, failure of anakinra, and nsaids.
- Prescribing limited to immunologist.

FHCP: MCG004 Review/Revision: 74

## Arzerra (ofatumumab) J9303

Exchange Pharmacy	Medical Commercial	X
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Arzerra is indicated to treat chronic lymphocytic leukemia (CLL)
- Medical history and studies are reviewed in Referrals and if approved will notify the physician

- 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 rituximab
- Prescriber must be an oncologist

FHCP: MCG004 Review/Revision: 74

## Augmentation therapy for Alpha-1 Antitrypsin Deficiency (Aralast/Prolastin) J0256

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- This is an infusion therapy for patients with severe obstructive disease due to Alpha-1 Antitrypsin deficiency.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- FDA approved indications.
- 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.)
- Documented progressive COPD.
- FEV<sub>1</sub> between 35%-65% predicted.
- Currently using Long acting bronchodilator and Oral or inhaled corticosteroids.

FHCP: MCG004 Review/Revision: 74

<u>Zirabev</u>	<u>(Bevacizumab-bvzr)</u>	Q5	<u> 5118</u>	

Exchange Pharmacy	Medical Commercial	X
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- 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.

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.

FHCP: MCG004 Review/Revision: 74

**Avonex (Interferon Beta-1a)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Avonex is an interferon indicated to treat multiple sclerosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# Criteria for coverage as follows:

• Failure of glatiramer and Dimethyl Fumarate for new starts

FHCP: MCG004 Review/Revision: 74

# Axert (almotriptan)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Axert is a 5-ht agonist indicated for treatment of migraine headaches.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- FDA approved indications
- This medication requires failure of rizatriptan and sumatriptan prior to coverage.

FHCP: MCG004 Review/Revision: 74

## **Banzel (rufinamide)-Generic Only**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Banzel is indicated for treatment of Lennox Gastaut syndrome. 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.

- FDA approved indications
- Approved when written/ordered by a Neurologist for seizures through referrals.

FHCP: MCG004 Review/Revision: 74

## Baqsimi (glucagon) nasal powder

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Baqsimi is indicated for severe hypoglycemia where patient is unable to eat, drink or follow commands.
- Baqsimi is intranasal but does not need to be inhaled, patient does not need to be conscious for Baqsimi to be administered.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- Ordered by an endocrinologist.
- Limit of 1 device per dispensing, two per year.

FHCP: MCG004
Review/Revision: 74

## Bavencio (Avelumab) J9023

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- BAVENCIO is a programmed death ligand-1 (PD-L1) blocking antibody indicated treatment of advanced or metastatic cancers
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

### Berinert [C1 Esterase Inhibitor (Human)] J0597

Exchange Pharmacy	Х	Medical Exchange	
Commercial Pharmacy	Х	Limited Distribution	
Step Therapy		Quantity Limit	

Effective Date: June 12, 2024

- BERINERT is a plasma-derived C1 Esterase Inhibitor (Human) indicated for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adult and pediatric patients
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be prescribed by an immunologist, allergist or hematologist
- Must have C1INH deficiency demonstrated by labs (C1INH and C4 labs)
- Must not be taking medications that can exacerbate the frequency and/or severity of hereditary angioedema (HAE) attacks including estrogens and ACE inhibitors.

FHCP: MCG004 Review/Revision: 74

## **Betaseron (Interferon Beta-1b)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Betaseron is an interferon indicated to treat multiple sclerosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• Failure of Dimethyl Fumarate and glatiramer or fingolimod for new starts

FHCP: MCG004 Review/Revision: 74

## Blenoxane (Bleomycin) J9040

Exchange Pharmacy	Medical Commercial	X
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Blenoxane is an antineoplastic and can be used as a sclerosing agent for malignant pleural effusions.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications.
- Must be prescribed by oncologist.

FHCP: MCG004 Review/Revision: 74

## Blincyto (Blinatumomab) J9039

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Blincyto is a Bispecific monoclonal antibody targeting CD-19, it is FDA indicated for second-line treatment for Philadelphia chromosome-negative relapsed or refractory acute lymphoblastic leukemia
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

### Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

## **Boniva Infusion (Ibandronate) J1740**

Exchange Pharmacy	M	edical Commercial	
Commercial Pharmacy	M	edical Exchange	Х
Step Therapy	Lir	mited Distribution	
	Qı	uantity Limit	

Effective Date: June 12, 2024

- Boniva IV is indicated for treatment of Osteoporosis. It is a parenteral bisphosphonate given by IV infusion every 3 months.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- FDA approved indications
- Failure of zoledronic acid.
- Not for use in patients with severe renal impairment (Crcl<30 ml/min).

FHCP: MCG004 Review/Revision: 74

**Bosulif (bosutinib)** 

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Bosolif is indicated for treatment of Ph+ CML after failure of a first line tyrosine kinase inhibitor.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Restricted to hematology/oncology.
- Failure of imatinib.

FHCP: MCG004 Review/Revision: 74

### Botox/Xeomin (botulinum toxin) J0585 J0588

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Botulinum toxin is approved for medical and cosmetic purposes. FHCP covers this medication <u>only</u> for medically necessary purposes and is approved for:
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- 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.

FHCP: MCG004 Review/Revision: 74

**Budesonide EC capsules 3mg (generic entocort)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Entocort is an oral steroid capsule that has low bioavailability. Entocort is indicated for mild to moderately 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.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Written by a gastroenterologist
- Approved referrals will be for a maximum of 6 months.

FHCP: MCG004 Review/Revision: 74

## Bydureon/BCISE/Byetta (Exenatide) Step Therapy Drug - Not Prior Authorization

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Byetta/Bydureon are injectable anti-diabetic agent used to treat Type 2 Diabetes.
   Bydureon/ Byetta are indicated for adjunctive use with a sulfonylurea and/or metformin.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

• Step therapy after trial of metformin.

FHCP: MCG004
Review/Revision: 74

Caprelsa (vandetanib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Caprelsa 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.

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Prescriber must be a Hematologist/Oncologist.

FHCP: MCG004 Review/Revision: 74

Carbaglu (carglumic acid)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	х
		Quantity Limit	

Effective Date: June 12, 2024

- Carbaglu is indicated to treat NAGS deficiency.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

• FDA approved indications.

FHCP: MCG004 Review/Revision: 74

## **Cayston (aztreonam for inhalation)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Cayston is indicated for treatment of pulmonary pseudomonas in cystic fibrosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- FDA approved indications.
- Failure or intolerance to Tobramycin nebulized solution

FHCP: MCG004 Review/Revision: 74

Cerezyme (imiglucerase)

Exchange Pharmacy	Medical Commercial	х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Cerezyme is indicated for the treatment of Gaucher's disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• Indicated for the treatment of a patient with Type 1 Gaucher's disease with anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly.

FHCP: MCG004 Review/Revision: 74

Cesamet (nabilone)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Cesamet is a cannabinoid indicated to prevent nausea and vomiting related to chemotherapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

• Failure of ondansetron AND palonosetron AND aprepitant

FHCP: MCG004 Review/Revision: 74

Cometriq (cabozantinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	х
		Quantity Limit	

Effective Date: June 12, 2024

- Cometriq is 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.

- FDA approved indications.
- Prescriber must be a Hematologist/Oncologist.
- Combination use with other tyrosine kinase inhibitors is excluded.

FHCP: MCG004
Review/Revision: 74

## **Cotellic (cobimetinib)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Cotellic is indicated for treatment of BRAF+ metastatic or unresectable melanoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Must be prescribed by Oncologist.
- Must be used in combination with Zelboraf.

FHCP: MCG004 Review/Revision: 74

### **Cubicin GENERIC only (Daptomycin) J0878**

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Cubicin is an IV antibiotic indicated 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 use.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- 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 cMRSA and resistant/PT allergic to other generically availably 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

FHCP: MCG004 Review/Revision: 74

## **Cuprimine(Penicillamine) Generic**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Cuprimine is indicated for treatment of Rheumatoid arthritis, Wilsons Disease and cystinuria.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Written by a Rheumatologist, or Neurologist, or Urologist or Hepatologist.
- Coverage for Rheumatoid Arthritis requires failure of a TNF Agent, and A JAK inhibitor or Abatacept.

FHCP: MCG004 Review/Revision: 74

## Cyramza (ramucirumab) J9308

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Cyramza is a VEGF-2 antagonist indicated for treatment of NSCLC, Gastric and GE junction adenocarcinoma, and metastatic colorectal cancer.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Prescribed by a hematologists/oncologist.

FHCP: MCG004 Review/Revision: 74

**Daraprim (pyrimethamine)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Daraprim is used to treat toxoplasmosis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Toxoplasmosis.
- Patient must have failed recent trial of combination of inhaled corticosteroids AND long acting beta Agonist AND inhaled anti-cholinergic.

FHCP: MCG004 Review/Revision: 74

#### Darzalex (daratumumab) j9145

Exchange Pharmacy	Medical Commercial	X
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

DARZALEX is a CD38-directed cytolytic antibody 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
- 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
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

#### Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

**Diabetic Test strips (other than Ascensia Products)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

• Test strips other than Ascensia products are covered only when incompatible with an insulin pump, or if patient has a severe visual impairment.

FHCP: MCG004 Review/Revision: 74

## **Dibenzyline (phenoxybenzamine)**

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Dibenzyline is used to treat pheochromocytoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• Diagnosis of Pheochromocytoma.

FHCP: MCG004 Review/Revision: 74

# <u>Diclofenac Topical 3% (Generic Solaraze)</u>

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- This medication is a topical NSAID indicated for treatment of Actinic Keratosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Diagnosis of actinic keratosis.
- Prescribed by a dermatologist.

FHCP: MCG004 Review/Revision: 74

**Dificid (fidaxomicin)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Dificid is an oral antibiotic indicated to treat clostridium difficile related diarrhea.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications.
- Failure of vancomycin 6 week taper dose (unless fulminant C-Difficile).

FHCP: MCG004 Review/Revision: 74

**Dimethyl Fumarate (Generic Tecfidera)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Dimethyl fumarate is an oral DMT (disease modifying treatment) indicated to treat relapsing remitting multiple sclerosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• FDA approved indications.

FHCP: MCG004 Review/Revision: 74

**Doxepin topical (generic Zonalon)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	х

Effective Date: June 12, 2024

• This medication is a topical tricyclic for indicated for short term treatment of pruritus in patients with atopic dermatitis.

- Failure of topical steroids and hydroxyzine.
- FDA approved indication.
- Approved only for short term use.
- Prescribed by a dermatologist.

FHCP: MCG004 Review/Revision: 74

Doxil/Lipodox (Doxorubicin liposomal) Q2050

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

DOXIL is an anthracycline topoisomerase II inhibitor indicated for:

Ovarian cancer
 After failure of platinum-based chemotherapy.

- AIDS-related Kaposi Sacoma
   After failure of prior systemic chemotherapy or intolerance to such therapy.
- Multiple Myeloma
   In combination with bortezomib in patients who have not previously received bortezomib and have received at least one prior therapy
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

### Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

## **Dronabinol (generic marinol)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Dronabinol is indicated to treat HIV/Cancer related Cachexia and chemotherapy induced nausea and vomiting.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

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

FHCP: MCG004 Review/Revision: 74

## Elaprase (idursulfase) J1743

Exchange Pharmacy	Medical Commercial	
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Elaprase is an enzyme replacement therapy indicated to treat Hunter's Syndrome.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- 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.

FHCP: MCG004 Review/Revision: 74

### Elitek (rasburicase)J2783

Exchange Pharmacy	Medical Commercial	
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

• Elitek is an enzyme replacement therapy indicated to treat/prevent hyperuricemia due to chemotherapy.

Effective Date: June 12, 2024

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

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

FHCP: MCG004 Review/Revision: 74

## **Emend (Aprepitant) capsules**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- 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.

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

FHCP: MCG004 Review/Revision: 74

**Emgality (galcanezumab) injection** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

Emgality is an anti-CGRP antibody indicated for prophylaxis of Episodic and Chronic Migraines, and Cluster Headaches

#### **Episodic Migraines**

**Emgality 120 mg** will be approved based upon **all** of the following criteria:

- (1) Diagnosis of episodic migraines with **both** of the following:
  - (a) Less than 15 headache days per month
  - (b) Patient has 4 to 14 migraine days per month
  - -AND-
- (2) Recent trial and failure (trial of at least three months) of two generic medications FDA indicated for migraine prophylaxis (topiramate/divalproex). If either or both are contraindicated or not tolerated the medications below could be used:
  - (a) Amitriptyline
  - (b) atenolol, metoprolol, nadolol, propranolol, or tilol
  - (e) Venlafaxine (Effexor/Effexor XR)

#### AND

(3) Medication will not be used in combination with an oral CGRP antagonist or inhibitor **Authorization will be issued for 6 months.** 

#### 2. Reauthorization

- a. **Emgality 120 mg** will be approved based on **all** of the following criteria:
- (1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity
  - -AND-
- (2) Medication will not be used in combination with an oral CGRP Antagonist.

Authorization will be issued for 12 months.

#### **B. Chronic Migraines**

#### 1. Initial Therapy

**Emgality 120 mg** will be approved based upon **all** of the following criteria:

- (1) Diagnosis of chronic migraines with **both** of the following:
  - (a) Greater than or equal to 15 headache days per month continued.
  - (b) Greater than or equal to 8 migraine days per month

#### -AND-

FHCP: MCG004
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Recent trial and failure (trial of at least three months) of two generic medications FDA indicated for migraine prophylaxis (topiramate/divalproex). If either or both are contraindicated or not tolerated the medications below could be used:

Effective Date: June 12, 2024

- (a) Amitriptyline
- (b) atenolol, metoprolol, nadolol, propranolol, orimolol
- (e) Venlafaxine (Effexor/Effexor XR)

#### -AND-

(3) Medication will not be used in combination with an oral CGRP antagonist **Authorization will be issued for 6 months.** 

#### 2. Reauthorization

a. **Emgality 120 mg** will be approved based on **all** of the following criteria:

(1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

#### -AND-

(2) Medication will not be used in combination with an oral CGRP Antagonist.

Authorization will be issued for 12 months.

#### C. Episodic Cluster Headache

- 1. Initial Therapy
- a. **Emgality 100 mg** will be approved based upon **all** of the following criteria:
- (1) Diagnosis of episodic cluster headache

#### -AND

(2) Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.

#### -AND

(3) Medication will not be used in combination with an oral CGRP antagonist.

Authorization will be issued for 6 months.

#### 2. Reauthorization

- a. **Emgality 100 mg** will be approved based on **all** of the following criteria:
- (1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

#### -AND-

(2) Medication will not be used in combination with an oral CGRP antagonist

#### Authorization will be issued for 12 months

FHCP: MCG004 Review/Revision: 74

### Empliciti (elotuzumab) J9176

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

EMPLICITI is a SLAMF7-directed immunostimulatory antibody indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies

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

### Criteria for coverage as follows:

• FDA approved indications; off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

**Enbrel (etanercept)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Enbrel is a biologic disease modifying agent, indicated for treatment of RA, JRA, PSA, Plaque psoriasis (see <u>Guidelines for Enbrel</u> (Attachment 3)
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- 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 (3 month trial in past 6 months).
- For Ankylosing Spondylitis PT must fail MTX or sulfasalazine and 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.

FHCP: MCG004 Review/Revision: 74

**Entresto (Sacubitril/valsartan)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

- Entresto is a medication used for treatment of Heart Failure
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

Criteria for coverage as follows:

- For Heart Failure with reduced ejection fraction (≤ 40%)
  - For initiation
    - eGFR ≥30ml/min and K+<5.0 meg/l for initiation</p>
    - Patient has NYHA Class II-IV symptoms
    - Approve for 3 months initially
  - For continuation
    - Member is at target dose approve for 12 months
    - Member is below Entresto target dose THEN
      - Approve for 3 months if member is tolerating dose but has not had a titration attempt and SBP >100

Effective Date: June 12, 2024

OR

Approve for 12 months if member has failed titration attempt or SBP<100

- For Heart Failure with preserved ejection fraction
  - For initiation
    - Patient has an ejection fraction ≤55%
    - NYHA Class II-IV symptoms
    - Currently taking an SGLT-2 inhibitor
    - eGFR >30 ml/min
    - Approve for 3 months initially
  - For continuation
    - Member is at target dose approve for 12 months
    - Member is below Entresto target dose THEN
      - Approve for 3 months if member is tolerating dose but has not had a titration attempt and SBP >100

OR

 Approve for 12 months if member has failed titration attempt or SBP<100</li>

FHCP: MCG004 Review/Revision: 74

#### **Enspryng (satralizumab)**

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Enspryng is a monoclonal antibody indicated to treat neuromyelitis optica spectrum disorder
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

- a. Member meets **ALL** of th– following documentation must be provided:
- i. Anti-aquaporin-4 (AQP4) antibody positive disease
- ii. **ONE** of the following:
  - 1. Member has a history of at least 2 relapses in the past 12 months
  - 2. Member has a history of at least 3 relapses in the past 24 months with at least 1 relapse in the previous 12 months
- iii. Member has an Expanded Disability Status Scale (EDSS) score less than or equal to 7
- iv. Member had an inadequate response or contraindication to corticosteroids IV

#### AND

- a. **ONE** of the following:
  - 1. Member had an inadequate response to an adequate trial of **ONE** or more of the following:
    - a. azathioprine
    - b. mycophenolate mofetil
    - c. methotrexate

#### AND

b. Member had an inadequate response to rituximab

#### **AND**

c. Treatment is prescribed by or in consultation with a neurologist

**INITIAL** Approval duration: 60 days for all indications, continuation based on clinical improvement.

FHCP: MCG004 Review/Revision: 74

#### Entyvio (vedolizumab) J3380

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Entyvio is indicated for the treatment of Crohn's disease, ulcerative colitis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

#### Criteria for coverage as follows:

 Must be written by a gastroenterologist and had recent failure of an immunosuppressant (Azathioprine, 6-mp or Methotrexate) and an anti-inflammatory (5asa, sulfasalazine, balsalazide, mesalamine) And Renflexis and Adalimumab (if TNF naive or previous TNF responder). Requires a 3 month trial in past 6 months

FHCP: MCG004 Review/Revision: 74

**Generic flolan (epoprostinil)** 

Exchange Pharmacy	Medical Commercial	
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	Х
	Quantity Limit	

Effective Date: June 12, 2024

- 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.

- FDA approved indications
- 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 combination ambrisentan and tadalafil.

FHCP: MCG004 Review/Revision: 74

#### Erbitux (cetuximab) J9055

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

Erbitux is indicated for squamous cell carcinoma of the head and neck and K-Ras wild type EGFR-expressing metastatic colorectal cancer

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

Criteria for coverage as follows:

• FDA approved indications; off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

**Ergomar (ergotamine tablets)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Ergomar is indicted for treatment of vascular headaches.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Failure of two formulary 5HT- antagonists (triptans).
- Must be prescribed by Neurologist

FHCP: MCG004 Review/Revision: 74

### **Erivedge (vismodegib capsules)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Erivedge is indicated for treatment of metastatic or locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery and are not candidates for radiation.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Prescriber is a hematologist/oncologist.
- Patient has Metastatic basal cell cancer, or recurrent basal cell cancer, or who are not candidates for surgery and not candidates for radiation.

FHCP: MCG004 Review/Revision: 74

**Eucrisa (crisaborole)- STEP THERAPY DRUG- NOT PRIOR AUTHORIZATION** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy	Х	Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

• Eucrisa is a Step Therapy Medication indicated for treatment of mild to moderate atopic dermatitis.

## Criteria for coverage as follows:

• Covered after failure of topical steroid when clinically appropriate.

FHCP: MCG004 Review/Revision: 74

### **Exelderm (sulconazole nitrate)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Exelderm is a topical antifungal indicated for tinea pedis tinea corporis, and tinea versicolor.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Patient has failed 2 generically available topical anti-fungals in past 6 months.
- Approved by referrals based on pharmacy history.

FHCP: MCG004 Review/Revision: 74

# **Exjade (Deferasirox) Generic Only**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	х
		Quantity Limit	

Effective Date: June 12, 2024

- Exjade is an oral medication used to treat iron overload typically in patients receiving chronic RBC transfusions.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• FDA approved indications

FHCP: MCG004 Review/Revision: 74

# Fanapt (Iloperidone)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Fanapt is indicated to treat schizophrenia.
- 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.

- FDA approved indications
- Failure of aripiprazole, or lurasidone

FHCP: MCG004 Review/Revision: 74

#### Fentanyl patch (generic Duragesic)/ Fentanyl Citrate Lozenge (Generic Actiq)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Fentanyl patch is a long acting opioid analgesic indicated for moderate to severe chronic pain.
- Fentanyl Citrate Lozenge is a short acting opioid indicated for cancer breakthrough pain
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Fentanyl citrate lozenges approved after failure of hydromophone IR and morphine IR and oxycodone IR
- Approved when written/ordered by an Oncologist or Pain Management through referrals.

FHCP: MCG004
Review/Revision: 74

## Ferriprox (deferiprone)-Generic Only

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Ferriprox is indicated to treat iron overload secondary to transfusion dependence. This medication is only on the Medicare and Exchange formularies.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Prescriber restricted to Oncologist/hematologist.
- Failure of deferasirox
- Failure of Desferal.

FHCP: MCG004 Review/Revision: 74

Fetzima (levomilnacipran)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

• Fetzima is an antidepressant (enantiomer of milnacipran) used to treat major depressive disorder.

Effective Date: June 12, 2024

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

- FDA approved indications
- Failure or intolerance to two generically available anti-depressants in past 6 months.

FHCP: MCG004 Review/Revision: 74

Finacea (Azelaic Acid)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Fincea is indicated to treat mild to moderate rosacea.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Coverage will be based on failure of metronidazole and an oral tetracycline.

FHCP: MCG004 Review/Revision: 74

# Firazyr (icatibant)-Generic

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Firazyr is indicated to treat acute attacks of Hereditary Angioedema
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician. Limited to two per month.

## Criteria for coverage as follows:

• FDA approved indications

FHCP: MCG004 Review/Revision: 74

Firmagon (degarelix)

Exchange Pharmacy	Х	Medical Commercial	Х
Commercial Pharmacy		Medical Exchange	Х
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Firmagon is indicated to treat advanced prostate cancer
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician. Limited to two per month.

- FDA approved indications
- Written by oncology or urology

FHCP: MCG004 Review/Revision: 74

### Fosrenol-Generic (lanthanum carbonate)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Fosrenol is a non-calcium based, chewable, phosphate binder indicated to manage hyperphosphatemia in ESRD.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Patient has ESRD.
- Patient has elevated calcium on phosphate binders, or not a candidate for calcium based phosphate binders based on KDOQI guidelines.
- Prescribed by a nephrologist
- Not covered in combination with other non-calcium based phosphate binders.

FHCP: MCG004 Review/Revision: 74

# Frova (frovatriptan)-Generic Only

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Frova is a 5-ht agonist indicated for treatment of migraine headaches.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- This medication requires failure of rizatriptan and sumatriptan prior to coverage.

FHCP: MCG004
Review/Revision: 74

#### Fusilev (levoleucovorin) J0641

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Fusilev is a folate analog indicated for: use in combination with fluorouracil-based regimens, high-dose methotrexate rescue, impaired methotrexate elimination and folic acid antagonist overdose.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Leucovorin must be unavailable in the United States

FHCP: MCG004 Review/Revision: 74

Fycompa (perampanel)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Fycompa is an anti-convulsant indicated for adjunctive treatment of partial seizures.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Written by a neurologist for treatment of seizures.
- Failure of Levetiracetam, topiramate, and lamotrigine

FHCP: MCG004
Review/Revision: 74

Gammagard (IVIG) J1569

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- This product is used for immunodeficiency disorders as well as certain autoimmune conditions, Including: Hypogammaglobinemia, Kawasaki disease, ITP.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

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

FHCP: MCG004 Review/Revision: 74

## Gazyva (Obinutuzumab) J9301

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Gazyva is indicated to treat follicular lymphoma and chronic lymphocytic leukemia
- Medical history and studies are reviewed in Referrals and if approved will notify the physician

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater
- Prescriber must be an oncologist

FHCP: MCG004 Review/Revision: 74

#### **Geodon injection (ziprasidone) J3486**

Exchange Pharmacy	Medical Commercial	X
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- 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.

- FDA approved indications
- Approved when written/ordered by a Psychiatrist or Neurologist through referrals for new starts.

FHCP: MCG004 Review/Revision: 74

# **Gilenya (Fingolimod) Generic Only**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Gilenya is an oral medication indicated for treatment of relapsing remitting multiple sclerosis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Must be written by a neurologist
- Covered for patients who have failed a trial of glatiramer and Dimethyl Fumarate

FHCP: MCG004 Review/Revision: 74

## **Gilotrif (Afatinib)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Gilotrif is an oral tyrosine kinase inhibitor indicated to treat NCSLC with the genetic tumor markers of exon 19 deletion and exon 21 substitution.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

#### Criteria for coverage as follows:

Prescribing restricted to oncology.

Patient must have NSCLC mutations consistent with FDA label.

Test for T790M mutation if previously on a TKI inhibitor

FHCP: MCG004 Review/Revision: 74

## Halaven (eribulin mesylate) J9179

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

• HALAVEN is a microtubule inhibitor indicated for the treatment of patients with metastatic breast cancer Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• FDA approved indications; off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

# Halog cream (Halcinonide)-Generic Only

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Halog is a topical high potency steroid
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Coverage will be based on failure of Diflorasone and Betamethasone.

FHCP: MCG004 Review/Revision: 74

**Hepatitis C Direct Acting Antivirals Mavyret** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

Mavyret is the exclusive and preferred DAA for treatment of HCV in chronically infected non-cirrhotic and compensated cirrhotic patients for genotypes 1-6. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Mavyret is the preferred DAA for all genotypes, other DAAs will be covered on a case by case basis if Mavyret use is not supported by current FDA indication or HCV guidelines based on patient specific characteristics

FHCP: MCG004 Review/Revision: 74

**HADLIMA Biosimilar Humira (adalimumab)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	X

Effective Date: June 12, 2024

- Adalimumab is indicated for the treatment of confirmed rheumatoid arthritis (RA),
  plaque psoriasis (PP), Psoriatic Arthritis (PSA) Crohn's disease (CD), ulcerative colitis
  (UC), Hydradenitis suppurativa, uveitis. This is non-preferred for commercial, ACA, and
  Exchange.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Must be written by Rheumatology, Dermatology or Specialist trained in management of prescribed condition.
- Dosing for indication is the FDA approved dose, off label dosing for an indication is not covered.
- For RA Patient must fail adequate trial of MTX in combination with a DMARD If MTX contraindicated, must try combination of 2-nonbiologic DMARDS (3 month trial in past 6 months).
- For Ankylosing Spondylitis PT must fail MTX or sulfasalazine and 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.
- Renflexis, Azathioprine, and 6 Mercaptopurine.
- For hidradenitis suppurativa must have moderate to severe disease and have failed recent trial 8 to 12 week trial in past month of oral clindamycin and rifampin or doxycycline/Minocycline, Infliximab, AND oral retinoid (acitretin or isotretinoin) unless contraindicated in the past 6 months.
- For Uveitis patient must fail 8-12 week trial of methotrexate

FHCP: MCG004 Review/Revision: 74

## Humulin U-500 (insulin)

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Humulin U 500 is used to treat insulin resistant diabetes mellitus.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Initiation restricted to endocrinology.
- Insulin requirements of >200 units/day

FHCP: MCG004 Review/Revision: 74

**Ibrance (palbociclib)** 

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Ibrance is a CDK 4/6 inhibitor indicated for first-line/second line treatment of metastatic ER+/HER- breast cancer used in combination with an aromatase inhibitor
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be prescribed by Hematologist/oncologist.
- Diagnosis Metastatic ER+ HER- Breast cancer.

FHCP: MCG004 Review/Revision: 74

## **Iclusig (ponatanib)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	х
		Quantity Limit	

Effective Date: June 12, 2024

- Iclusig is a tyrosine Kinase inhibitor indicated to treat Chronic Myelogenous Leukemia. Coverage will be based on failure of first or second line TKI for CML or presence of T350I mutation.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be prescribed by Hematologist/oncologist.

FHCP: MCG004 Review/Revision: 74

#### Idhifa (enasidenib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Idhifa is indicated for treatment of relapsed or refractory AML in patients with an IDH2 mutation as detected by an approved test
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Prescriber must be a Hematologist/Oncologist

FHCP: MCG004 Review/Revision: 74

Imbruvica (ibrutinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Imbruvica is a BTK inhibitor used to treat B cell lymphomas. It is indicated for relapsed refractory chronic lymphocytic leukemia and Mantle Cell Lymphoma, and first line CLL.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Must be prescribed by Hematologist/oncologist.
- FDA approved indications
- NCCN supported use with evidence rating 2a or greater

FHCP: MCG004 Review/Revision: 74

#### Imfinzi (durvalumab) J9173

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Imfinzi is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for urothelial carcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.

FHCP: MCG004 Review/Revision: 74

**Imlygic (talimogene laherparepvec)** 

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

IMLYGIC is a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

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

### Criteria for coverage as follows:

• FDA approved indications; off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

**Increlex (mecasermin)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Increlex is indicated to treat short stature in patient with primary Insulin like Growth Factor deficiency, and patients with neutralizing antibodies to HGH.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

### Criteria for coverage as follows:

- FDA approved indications
- 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.

FHCP: MCG004 Review/Revision: 74

## Inlyta (axitinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Inlyta is an oral tyrosine kinase inhibitor indicated for advanced renal cell carcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• Prescribing restricted to oncology.

FHCP: MCG004 Review/Revision: 74

Invega Sustenna (Paliperidone injection) J2426

Exchange Pharmacy	Х	Medical Commercial	Х
Commercial Pharmacy	Х	Medical Exchange	Х
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Invega Sustenna is a psychotropic medication.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- FDA approved indications
- Failure of oral aripiprazole, paliperidone and risperidone
- Approved when written/ordered by a Psychiatrist or Neurologist through referrals.

FHCP: MCG004 Review/Revision: 74

### Iressa (gefitinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	х
		Quantity Limit	

Effective Date: June 12, 2024

- Iressa is indicated to treat non-small cell lung cancer with EGFR mutation exon 19 deletion or Exon 21 substitution mutations.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Must be prescribed by Oncologist
- T790 mutation testing when indicated i.e. previously treated with a TKI inhibitor

FHCP: MCG004 Review/Revision: 74

### IVIG- Gammagard, Privigen, Octogam, Flebogam, Gammunex, Gammar, Gammaplex

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

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

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

### Criteria for coverage as follows:

• 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.

FHCP: MCG004 Review/Revision: 74

### Ixempra (ixabepilone) J9207

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

Ixempra, a microtubule inhibitor, in combination with capecitabine is indicated for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane.

Ixempra as monotherapy is indicated for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline, a taxane, and capecitabine

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

#### Criteria for coverage as follows:

• FDA approved indications; off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

### Jakafi (ruxolitinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	х
		Quantity Limit	

Effective Date: June 12, 2024

- Jakafi is an oral JAK inhibitor indicated for treatment of intermediate to high risk myelofibrosis including primary myelofibrosis, polycythemia vera, myelofibrosis, and essential thrombocythemia myelofibrosis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Not used in combination with lenalidomide/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.

FHCP: MCG004 Review/Revision: 74

Januvia (Sitagliptin)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Januvia is an oral anti-diabetic agent used to treat Type 2 Diabetes (DPP-IV inhibitor).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- 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.
- Failure of Onglyza.

FHCP: MCG004 Review/Revision: 74

## Jevtana (cabazitaxel) J9043

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

Jevtana is a microtubule inhibitor indicated for treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment

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

### Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

## Kadcyla (ado-trastuzumab) J9354

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Kadcyla is an Antibody Drug Conjugate (ADC) indicated for second line treatment of HER+ metastatic breast cancer.
- Medical history and studies are reviewed in Referrals and will notify provider after coverage determination.

- FDA approved indications
- Coverage will be based on failure of prior taxane and Herceptin (Trastuzumab).

FHCP: MCG004 Review/Revision: 74

Kalydeco (ivacaftor)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Kalydeco is an oral medication indicated to treat Cystic fibrosis patients with specific genetic mutations in the CFTR gene.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Patient must have an FDA approved mutation.
- Must be prescribed by a Pulmonologist

FHCP: MCG004 Review/Revision: 74

Kevzara (sarilumab)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Kevzara is an injectible II-6 antagonist indicated for rheumatoid arthritis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Coverage is limited to Rheumatoid arthritis
- Must fail a preferred specialty agent (Enbrel, Xeljanz, Hadlima)
- Most have clear documentation of moderate to severe rheumatoid arthritis

FHCP: MCG004
Review/Revision: 74

## Keytruda (pembrolizumab) J9271

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Keytruda is a PD-1 inhibitor indicated treatment of several cancer types.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.

FHCP: MCG004 Review/Revision: 74

## Kineret (anakinra)

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Kineret is a biologic agent indicated for treatment of rheumatoid arthritis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Patient must fail two anti-TNF biologics and Xeljanz

FHCP: MCG004
Review/Revision: 74

## Kuvan (sapropterin)-Generic Only

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Kuvan is indicated to treat Phenylketonuria (PKU).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Coverage will be based on medical history/status, response to previous treatments, Dietary compliance, and the consideration of other therapeutic options.
- PKU level above 6mg/dl (360 micromoles/L).
- Prescribing limited to specialist trained in management of PKU.

FHCP: MCG004
Review/Revision: 74

Kynamro (mipomersen)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	х
		Quantity Limit	

Effective Date: June 12, 2024

- Kynamro is indicated to treat Homozygous Familial hypercholesterolemia
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Genetic confirmation that patient is HoFH.
- Failure of Statin, Ezetimibe, and PCSK-9 therapy.
- Continuation of Kynamro after 3 month trial based on LDL reduction of at least 25% while on therapy.

FHCP: MCG004 Review/Revision: 74

### Kyprolis (carfilzomib) J9047

Exchange Pharmacy	Medical Commercial	X
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

Kyprolis is a proteasome inhibitor that is indicated:

- in combination with dexamethasone or with lenalidomide plus deamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy one of which containing bortezomib
- as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

#### Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater and failure of bortezomib.

FHCP: MCG004 Review/Revision: 74

Lenvima (lenvatinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	х
		Quantity Limit	

Effective Date: June 12, 2024

- Lenvima is a tyrosine kinase inhibitor indicated for several cancers
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be written by an oncologist/hematologist.

FHCP: MCG004 Review/Revision: 74

**Letairis Generic Only (ambrisentan)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Letairis is an endothelin receptor antagonist used to treat WHO group 1 pulmonary arterial hypertension.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Pulmonary hypertension must be diagnosed by heart catheterization.
- Patient must have failed or have contraindication to sildenafil.
- 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,

FHCP: MCG004 Review/Revision: 74

Levulan (aminolevulinic acid)

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Levulan is indicated for actinic keratosis of the scalp or face.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

- FDA Approved indications
- by Dermatology or Plastic Surgery only.
- This information is sent to the Referrals Department.

FHCP: MCG004 Review/Revision: 74

## **Lidocaine patches (generic Lidoderm)**

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- This is a transdermal formulation of lidocaine indicated for treatment of post-herpetic neuralgia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

### Criteria for coverage as follows:

• Coverage will be based on failure or contraindications of other therapies including failure of Gabapentin.

FHCP: MCG004 Review/Revision: 74

Linzess (linaclotide)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Linzess is indicated for chronic constipation and irritable bowel syndrome.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- failure of lubiprostone

FHCP: MCG004 Review/Revision: 74

## Lokelma (Sodium zirconium cyclosilicate)

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Lokelma is indicated to treat hyperkalemia
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• Hyperkalemia after discontinuation trial of potassium sparring medications, trial of a loop diuretic if clinically indicated.

FHCP: MCG004
Review/Revision: 74

## **Lonsurf (trifluridine and tipiracil)**

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Lonsurf is indicated to treat patients with metastatic colorectal cancer who have progressed on two to three lines of treatment
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

### Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

## Lynparza (olaparib)

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Lynparza is used to treat BRCA+ ovarian or breast cancers
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• Restricted to Hematology/Oncology.

FHCP: MCG004 Review/Revision: 74

## Mekinist (trametinib)

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Mekinist is a MEK inhibitor indicated to treat BRAF+ V600e/k mutation Stage IIIc-IV metastatic Melanoma and NSCLC
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Patient must have BRAF V600E/K mutation.
- Must be written by an oncologist.

FHCP: MCG004 Review/Revision: 74

## **Movantik (Naloxegol)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Movantik is a Peripherally Acting Mu Opioid Antagonist (PAMORA) indicated for opioid induced constipation
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Requires failure of lactulose and Miralax.

FHCP: MCG004 Review/Revision: 74

### Mozobil (plerixafor) J2562

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

Mozobil, a hematopoietic stem cell mobilizer, is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma and multiple.

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

### Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

## Multaq (dronedarone)

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Multaq is indicated for treatment of atrial fibrillation.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must have previously failed or have contraindication to both sotalol and amiodarone.

FHCP: MCG004 Review/Revision: 74

## Myrbetriq (mirabegron)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- This medication is used to treat overactive bladder.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Failure of solifenacin, trospium, and Toviaz.

FHCP: MCG004 Review/Revision: 74

**Omnipod/ Omnipod Dash** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

Omnipod and Omnipod Dash are covered for Type 1 diabetics who meet MCG (Milliman Coverage Guideline) criteria

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

FHCP: MCG004 Review/Revision: 74

# Nebupent (nebulized pentamidine)-Generic

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Nebupent is an inhaled solution used to treat PCP pneumonia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• Failure of topical ketoconazole, econazole, clotrimazole betamethasone, nystatin triamcinolone.

FHCP: MCG004 Review/Revision: 74

### Nerlynx (neratinib)

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Nerlynx is indicated for extended adjuvant treatment of early stage HER2 breast cancer
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Prescriber must be a Hematologist/Oncologist

FHCP: MCG004 Review/Revision: 74

Neupro (rotigotine)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Neupro is a transdermal dopamine agonist indicated for treatment of Parkinson's disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Failure of Ropinirole and Pramipexole.

FHCP: MCG004 Review/Revision: 74

## **Nexavar Generic only(sorafenib)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Nexavar is an oral tyrosine kinase inhibitor indicated to treat Renal cell carcinoma, Hepatocellular carcinoma, and thyroid carcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• Prescribing restricted to oncology.

FHCP: MCG004 Review/Revision: 74

**Nicotrol (Nicotine replacement)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Indicated for smoking cessation therapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Must have previously failed or have contraindication to Bupropion.
- Coverage is approved for 24 weeks of treatment.
- Copayment will be applied per package.

FHCP: MCG004 Review/Revision: 74

Ninlaro (ixazomib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Ninlaro is an oral proteasome inhibitor indicated to treat relapsed or refractory multiple myeloma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Must be prescribed by Oncology
- Must have failed bortezomib

FHCP: MCG004 Review/Revision: 74

Nisoldipine (generic Sular)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Nisoldipine is an oral calcium channel blocker used for treatment of hypertension
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Failure of Amlodipine and Diltiazem required for coverage of Nisoldipine, approved by referrals.

FHCP: MCG004 Review/Revision: 74

# Noxafil (Ge137osaconazoleposaconazole)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Noxafil is an anti-fungal indicated for aspergillus and Candida in immunocompromised patients.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Organism must be resistant to itraconazole, voriconazole, and fluconazole.

FHCP: MCG004 Review/Revision: 74

#### Nucala (mepolizumab)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Nucala is an interleukin 5 antagonist indicated for eosinophilic asthma and eosinophilic granulomatosis with polyangiitis and nasal polyps
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.
- Nasal Polyp indication is covered only by exception and will be based on all available treatment options including nebulized sinus treatments and devices

The following criteria must be met for coverage for severe eosinophilic asthma:

- Prescriber must be a pulmonologist or allergist.
- Two or more severe exacerbations in the past 12 months
- Patient must fail 3 months of therapy on maximal indicated doses of Trelegy and Montelukast

FHCP: MCG004 Review/Revision: 74

**Nucynta ER (tapentadol)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Nucynta is an opioid analgesic indicated for chronic pain or severe diabetic peripheral neuropathy (DPN).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- For Chronic pain, failure of morphine sulfate, tramadol, and fentanyl patch.
- For DPN must fail an oral opioid and duloxetine.

FHCP: MCG004 Review/Revision: 74

Nuedexta (Dextromethorphan/quinidine)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Nuedexta is indicated to treat pseudobulbar affect.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications (Not covered for off-label use)
- Prescriber must be a neurologist.

FHCP: MCG004 Review/Revision: 74

### Nulojix (belatacept) J0485

Exchange Pharmacy	Medical Commercial	
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Nulojix is a biologic immunosuppressive anti-rejection agent for kidney transplant.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Prescriber must be a nephrologist or transplant specialist.
- Patient must have failure or intolerance to a calcineurin inhibitor.

FHCP: MCG004
Review/Revision: 74

### Ocrevus (ocrelizumab) J2350

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- 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.

- FDA approved indications
- Must be prescribed by a neurologist
- For Relapsing Remitting Multiple Sclerosis must have failed Dimethyl Fumarate or Glatiramer

FHCP: MCG004 Review/Revision: 74

Odomzo (sonidegib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Odomzo is an oral oncology agent indicated to treat locally advanced basal cell carcinoma which has recurred following radiation or surgery.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be prescribed by Oncology

FHCP: MCG004 Review/Revision: 74

Omnitrope (somatotropin)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Growth Hormone is a pituitary hormone used for endogenous HGH deficiencies
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician

- FDA approved indications
- This information with the lab attached is sent to the Referrals Department.

FHCP: MCG004 Review/Revision: 74

### Onfi (clobazam) -Generic Only

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Onfi is a benzodiazepine indicated to treat seizures.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Failure of levetiracetam, topiramate, and clonazepam
- Approved when written/ordered by a Neurologist through referrals for new starts.

FHCP: MCG004 Review/Revision: 74

Onglyza (Saxagliptin) Kombiglyze (Saxagliptin/Metformin)- Step Therapy

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	X

Effective Date: June 12, 2024

- Onglyza is an oral anti-diabetic agent (DPP-IV inhibitor) indicated to treat Type 2 Diabetes.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

• Trial of Metformin

FHCP: MCG004 Review/Revision: 74

### **Opsumit (macitentan)**

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Opsumit is indicated for treatment Pulmonary arterial Hypertension (PAH).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Failure of ambrisentan and sildenafil/tadalafil.
- Pulmonary hypertension diagnosed by right heart catheterization.

FHCP: MCG004 Review/Revision: 74

Opdivo (nivolumab) J9299

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Opdivo is a PD-1 inhibitor used for treatment of several tumor types.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.

FHCP: MCG004 Review/Revision: 74

### Orencia (Abatacept) J0129

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy		Medical Exchange	X
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Orencia is indicated to treat rheumatoid arthritis, JIA, and Psoriatic arthritis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be prescribed by a rheumatologist.
- Must fail Kevzara, Simponi Aria, Renflexis, adalimumab, and Enbrel for shared indications.

FHCP: MCG004 Review/Revision: 74

Orenitram (treptostinil)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Orenitram is indicated to treat Pulmonary Arterial Hypertension.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Group 1 PAH
- Must be prescribed by a Pulmonologist or Cardiologist.
- Right Heart catheterization to diagnose PAH
- Failure of combination ERA+PDE5 inhibitor, failure of remodulin

FHCP: MCG004 Review/Revision: 74

## Orfandin (nitisinone)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Orfandin is indicated for hereditary tyrosinemia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be prescribed by a specialist experienced in treatment of this disorder.
- Failure of dietary modification

FHCP: MCG004 Review/Revision: 74

### Orilissa/Oriahnn (elagolix, elagolix +estradiol/norethindrone)

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Orilissa is indicated for moderate to severe pain due to endometriosis
- Oraihnn is indicated for treatment of heavy menstrual bleeding due to uterine fibroids
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Failure of an NSAID and oral contraceptive/progestin for endometriosis

FHCP: MCG004 Review/Revision: 74

Oxandrin (Oxandrolone)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Oxandrin is an anabolic steroid indicated for weight gain in cachexia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Approved when written by Oncology, through referrals.

FHCP: MCG004
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## Oxymorphone ER (generic Opana ER)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Oxymorphone is an opioid analgesic indicated for moderate too severe chronic pain.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- For Chronic pain, failure of morphine sulfate ER, Methadone, and fentanyl patch.
- QTY limit of 93/month

FHCP: MCG004 Review/Revision: 74

Panretin (alitretinion)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Panretin is a retinoid indicated for Karposi sarcoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Failure of vinblastine

FHCP: MCG004 Review/Revision: 74

### Perjeta (pertuzumab) J9306

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Perjeta is a monoclonal antibody indicated for first and second line treatment of HER+ metastatic breast cancer.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by Oncology

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Pirfenidone

<u>mremdone</u>			
Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Pirfenidone is indicated for idiopathic pulmonary fibrosis.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

- Confirmed diagnosis of IPF by high resolution CT or surgical biopsy.
- Prescribed by a pulmonologist

FHCP: MCG004 Review/Revision: 74

Pomalyst (pomalidomide)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	х
		Quantity Limit	

Effective Date: June 12, 2024

- Pomalyst is thalidomide analog used to treat refractory Multiple Myeloma
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, Off label use must be supported by NCCN with evidence rating of 2a or greater
- Restricted to Hematology/Oncology.
- Coverage requires failure of Revlimid and Velcade

FHCP: MCG004 Review/Revision: 74

### Prolia (Denosumab) J0897

Exchange Pharmacy	Medical Commercial	X
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- 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.

- FDA approved indications
- Intolerance or contraindication to injectable bisphosphonate required for coverage of Prolia.

FHCP: MCG004
Review/Revision: 74

Promacta (eltrombopag)

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Promacta is indicated to treat ITP and thrombocytopenia secondary to HCV treatment.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Patient must have chronic ITP and bleed risk, with platelet count less than 30,000, and refractory to IVIG, corticosteroids or splenectomy.

FHCP: MCG004
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### **Pulmicort Respules (Budesonide) Generic Only**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- This medication is a respiratory steroid indicated for treatment of asthma in pediatric patient's ages 6 months—8 years old.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

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

FHCP: MCG004 Review/Revision: 74

Pulmozyme (Dornase Alfa)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Pulmozyme is indicated to reduce pulmonary exacerbation in patients with cystic fibrosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be written by a pulmonologist.
- Patient must have an FVC ≥ 40% of predicted value and recurrent pulmonary infections.

FHCP: MCG004 Review/Revision: 74

QTERN (Saxagliptin/Dapagliflozin)- Step Therapy

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- QTERN is an oral anti-diabetic agent (DPP-IV inhibitor +SGLT-2) indicated to treat Type 2 Diabetes.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

• Trial of Metformin

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**QVAR (beclomethasone) inhaler** 

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- QVAR is an inhaled corticosteroid indicated for asthma
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must have failed Arnuity and Flovent for overlapping indications.

FHCP: MCG004 Review/Revision: 74

Radicava (edaravone) J1301

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- This medication is indicated for amyotrophic lateral sclerosis
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

• FDA approved indications

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Rebif (Interferon Beta-1a)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Rebif is an interferon indicated to treat multiple sclerosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

## Criteria for coverage as follows:

• Failure of glatiramer and Dimethyl Fumarate for new starts

FHCP: MCG004 Review/Revision: 74

Repatha (evolocumab)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Repatha is a PCSK-9 inhibitor used to treat hypercholesterolemia. Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

#### Criteria for coverage as follows:

Failure of rosuvastatin 40mg or atorvastatin 80 and ezetimibe 10mg in combination.
 Diagnosis of HeFH must be supported by Dutch Lipid Clinic Network criteria. Statin intolerant patients must have had a hydrophilic statin such as rosuvastatin, pravastatin, fluvastatin in the absence of fibrates or other combinations which can increase risk of myopathy or myalgia.

FHCP: MCG004 Review/Revision: 74

**Generic Remodulin (treprostinil)** 

Exchange Pharmacy	Medical Commercial	
Commercial Pharmacy	Medical Exchange	X
Step Therapy	Limited Distribution	Х
	Quantity Limit	

Effective Date: June 12, 2024

- 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.

- FDA approved indications
- 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 combination ambrisentan and tadalafil.

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#### Renflexis (infliximab-abda) Q5104

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	X
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- 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.

- 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 acitretin(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) for maintenance of remission or failure of corticosteroids for induction of remission.

FHCP: MCG004 Review/Revision: 74

## **Revlimid (Lenalidomide) - Generic Only**

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	Х

Effective Date: June 12, 2024

- Revlimid is indicated for treatment of Multiple Myeloma, Myelodysplastic syndrome anemia that is transfusion dependent and has 5q deletion karyotype, mantle cell lymphoma
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Prescriber is a hematologist/oncologist.
- Patient must have failed Aranesp & Procrit for MDS anemia.
- Mantle cell Lymphoma requires failure of two prior treatment regimens one of which being bortezomib.

FHCP: MCG004 Review/Revision: 74

# Risperdal Consta (Risperidone injection) J2794

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	Х
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Risperdal Consta is a psychotropic medication.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- FDA approved indications
- Failure of oral aripiprazole and risperidone
- Approved when written/ordered by a Psychiatrist or Neurologist through referrals.

FHCP: MCG004 Review/Revision: 74

Ruxience (rituximab) Q5119

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	X
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- 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.

FHCP: MCG004 Review/Revision: 74

Rozlytrek (entrectinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Rozyltrek is a kinase inhibitor indicated for solid tumors with NTRK-Fusions and ROS-1 mutated Non-Small Cell lung cancer
- Medical history, studies, and appropriate confirmatory tests are reviewed in Referrals and if approved will notify pharmacy and the physician.

# Criteria for coverage as follows:

• FDA approved indications

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# Rydapt (midostaurin)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Rydapt is a kinase inhibitor indicated to treat AML, MCL, and systemic mastocytosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.

FHCP: MCG004 Review/Revision: 74

Samsca (tolvaptan) Generic Only

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Samsca is indicated to treat hyponatremia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Symptomatic hyponatremia (serum sodium <125 mEq/L).
- Failure of demeclocycline and fluid restriction.
- Removal of medications which are associated with hyponatremia if clinically possible.
- Prescribed by nephrology.
- Limited to 30 days of use.
- Initiated under hospital observation.

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# **Sandostatin LAR (Octreotide)**

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	X
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Sandostatin is indicated for acromegaly and severe diarrhea associated carcinoid syndrome or VIP secreting tumors
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# Criteria for coverage as follows:

• Failure of recent 2 month trial of octreotide (non LAR) in past 3 months

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## Sensipar (cinacalcet) -Generic Only

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Sensipar is indicated to treat hyperparathyroidism that is secondary to renal insufficiency or hypercalcemia secondary to parathyroid carcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- 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.
- Medicare Part B is patient is ESRD.

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### Sildenafil citrate 20mg (generic Revatio)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Revatio is indicated for the treatment of Primary pulmonary hypertension or pulmonary hypertension related to connective tissue disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- 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.

FHCP: MCG004 Review/Revision: 74

# Silenor 3 mg (doxepin) Generic Only

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Silenor is indicated for the treatment of insomnia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Failure of zolpidem, zaleplon, trazadone, temazepam

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# Simponi (golimumab)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Covered only for Commercial/Exchange Simponi/is a TNF antagonist indicated for Moderate to severe rheumatoid arthritis, ankylosing spondylitis, active psoriatic arthritis, moderate to severe ulcerative colitis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows in Commercial and Exchange only:

• Must fail Hadlima and Renflexis

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#### Soliris (eculizumab) J1300

Exchange Pharmacy	Х	Medical Commercial	X
Commercial Pharmacy	Х	Medical Exchange	X
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- This Soliris is a c5 inhibitor used for paroxysmal nocturnal hemoglobinuria, hemolytic uremic syndrome, anti acetylcholine receptor antibody positive myasthenia gravis, antiaquaporin-4 antibody positive neuromyelitis optica spectrum disorder.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

#### Paroxysmal Nocturnal Hemoglobinuria (PNH)

- a. Flow cytometry to confirm PNH in both red and white blood cells (with at least 5% granulocyte or monocyte clone size) documentation must be provided
- b. Member meets **BOTH** of the following:
  - i. Absolute neutrophil count greater than or equal to 500/mm3
  - ii. Platelets greater than or equal to 30,000/mm3
- c. Member's lactate dehydrogenase (LDH) is elevated (i.e., 1.5 times greater than the upper limit of normal [ULN] as determined by the laboratory performing the test)
- d. **EITHER** of the following:
  - i. Member's disease is transfusion-dependent evidenced by 2 or more transfusions in the 12 months prior to eculizumab initiation
  - ii. Member has a history of a major adverse vascular event (MAVE) from thromboembolism (e.g., myocardial infarction, cerebrovascular accident, deep vein thrombosis)

#### 2. Atypical Hemolytic Uremic Syndrome (aHUS)

- a. Diagnosis is supported by **BOTH** of the following (documentation must be provided):
  - i. No evidence of Shiga toxin-producing E. coli infection all initial and subsequent tests have been negative for the toxin

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ii. ADAMTS-13 level is greater than 5%

- b. **ONE** of the following:
  - i. Member has been vaccinated against meningococcal infection at least 2 weeks prior to therapy initiation

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ii. Member has been vaccinated against meningococcal infection less than 2 weeks prior to therapy initiation and will receive prophylactic antibiotics for at least 2 weeks following vaccination

#### 3. Refractory Generalized Myasthenia Gravis (MG)

- a. Member meets ALL of the following documentation must be provided:
  - i. Anti-acetylcholine receptor (AchR) antibody positive disease
  - ii. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II IV
  - iii. Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 6

#### AND

- 1. Member had an inadequate response to at least one year trial of **TWO** of the following immunosuppressants:
  - a. azathioprine
  - b. cyclosporine
  - c. mycophenolate mofetil
  - d. tacrolimus
  - e. methotrexate
  - f. cyclophosphamide

#### AND

2. Member had an inadequate response to at least one year trial of **ONE** immunosuppressant in combination with either chronic IVIG or plasmapheresis

#### **AND**

3. Member has had a 1 year trial of rituximab

#### AND

4. Treatment is prescribed by or in consultation with a neurologist

#### 4. Neuromyelitis Optica Spectrum Disorder (NMOSD)

a. Member meets **ALL** of the following - documentation must be provided:

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- i. Anti-aquaporin-4 (AQP4) antibody positive disease
- ii. **ONE** of the following:
  - 1. Member has a history of at least 2 relapses in the past 12 months
  - 2. Member has a history of at least 3 relapses in the past 24 months with at least 1 relapse in the previous 12 months

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- iii. Member has an Expanded Disability Status Scale (EDSS) score less than or equal to 7
- iv. Member had an inadequate response or contraindication to corticosteroids IV

#### **AND**

b. Failed Enspryng (satralizumab-mwge)

#### AND

- c. ONE of the following:
  - 1. Member had an inadequate response to an adequate trial of **ONE** or more of the following:
    - a. azathioprine
    - b. mycophenolate mofetil
    - c. methotrexate
    - d. rituximab
  - 2. Member has a contraindication to **ALL** of the following:
    - a. azathioprine
    - b. mycophenolate mofetil
    - c. methotrexate
    - d. rituximab

#### AND

d. Treatment is prescribed by or in consultation with a neurologist

INITIAL Approval duration: 60 days for all indications, continuation based on clinical improvement. Somatuline (lanreotide)

- This medication is used to treat Acromegaly.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

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Criteria for coverage as follows:

• FDA approved indications

- Prescriber must be an endocrinologist
- Failure of octreotide

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**Sprycel (dasatinib)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Sprycel is an oral antineoplastic agent used to treat Philadelphia Chromosome + CML and PH+ ALL
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Covered for treatment failure with imatinib.

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#### Stelara (ustekinumab) J3357

Exchange Pharmacy	Х	Medical Commercial	Х
Commercial Pharmacy	Х	Medical Exchange	Х
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Stelara is indicated for treatment of moderate to severe plaque psoriasis and psoriatic arthritis and Crohn's disease
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

- FDA approved indications only at FDA approved doses
- Prescribed by a dermatologist or Rheumatologist.
- 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 adalimumab, Renflexis, Enbrel, Xeljanz.
- For Crohns Disease must fail conventional agents AND adalimumab, Renflexis, Entyvio, AND TNF in combination with a conventional immunosuppressant (when clinically appropriate) with 5-ASA anti-inflammatory.
- For Ulcerative Colitis must fail conventional agents AND adalimumab, Renflexis, Entyvio, Xeljanz, AND TNF in combination with a conventional immunosuppressant (when clinically appropriate) with 5-ASA anti-inflammatory.

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# Stivarga (Regorafenib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Stivarga is an oral tyrosine kinase inhibitor indicated to treat Colorectal cancer and, Hepatocellular carcinoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# Criteria for coverage as follows:

• Prescribing restricted to oncology.

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**Strensig (Asfotase)** 

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Strensiq is an enzyme replacement therapy indicated for infantile or pediatric onset hypophosphatasia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows: Must meet ALL of the following criteria:

- 1. Member is diagnosed with any of the following:
  - a. Perinatal/infantile-onset hypophosphatasia (HPP)
  - b. Juvenile-onset hypophosphatasia (HPP)

AND

2. Member's diagnosis of HPP is confirmed by or in consultation with an endocrinologist or a bone

and mineral specialist.

AND

3. Member has skeletal abnormalities indicative of HPP – documentation from the medical record  $\,$ 

must be provided.

a. Note: Examples of skeletal abnormalities include chest wall deformities, hypomineralized.

skeleton, rickets, nonhealing fractures.

AND

4. Member has an alkaline phosphatase (ALP) level below age-adjusted lower limit of normal, while off medications which can lower ALP such as anti- resorptives.

AND

5. Member has a pyridoxal-5'-phosphate (PLP) level greater than two times laboratory's upper limit, while off vitamin supplementation (2 week washout)

AND

- 6. Member has an ALPL genetic mutation laboratory documentation must be provided. AND
- 7. Member has an onset of clinical signs and symptoms of HPP prior to 12 years of age documentation from the medical record must be provided.

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STRENSIQ continued...

AND

8. Strensiq is prescribed by or in consultation with an endocrinologist or a bone and mineral specialist.

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AND

9. Dose does not exceed 6 mg/kg/week.

**Initial approval 6 months** 

# <u>Continuation of Strensiq meets definition of Medical Necessity for members when the following criteria are met:</u>

<u>1.</u> Member has demonstrated an objective clinical improvement in symptoms following initiation of asfotase alfa – documentation from the medical record must be provided. This could include improvement in fracture healing, improved 6 minute walk time, improved bone density, reduction in baseline disability.

AND

- 2. Strensiq is prescribed by or in consultation with an endocrinologist or a bone and mineral specialist
- 3. Dose does not exceed:
  - a. Perinatal/infantile-onset HPP: 9 mg/kg/week
- b. Juvenile-onset HPP: 6 mg/kg/week

FHCP: MCG004 Review/Revision: 74

# Sunosi (solriamfetol)

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

• Sunosi is a dopamine and norepinephrine inhibitor indicated for treatment of excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea. Coverage is limited to indication of Narcolepsy

Criteria for coverage as follows:

• Failure of Modafinil and Armodafinil

FHCP: MCG004
Review/Revision: 74

# Sustol (granisetron) extended-release injection J1627

Exchange Pharmacy	Medical Commercial	X
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Sustol is a 5-HT3 receptor antagonist indicated in combination with other antiemetics for chemotherapy induced nausea and vomiting
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must have failed generic ondansetron, generic granisetron (oral/IV), aprepitant, Aloxi, and low-dose olanzapine (when supported by NCCN guidelines)

FHCP: MCG004 Review/Revision: 74

# **Sutent (sunitinib)-Generic**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Sutent is an oral tyrosine kinase inhibitor indicated to treat Renal cell carcinoma, Gastrointestinal Stromal Tumors, and pancreatic neuroendocrine tumors.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# Criteria for coverage as follows:

• Prescribing restricted to oncology.

FHCP: MCG004 Review/Revision: 74

Sylatron (peg-interferon alpha 2b)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Sylatron is an adjuvant treatment for metastatic melanoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- 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.

FHCP: MCG004 Review/Revision: 74

Sylvant (siltuximab) J2860

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Sylvant is a monoclonal antibody indicated to treat multicentric castleman's disease in patients who are HIV negative and HHV-8 negative.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

- FDA approved indications
- Approved when written by an oncologist.

FHCP: MCG004 Review/Revision: 74

**Symlin (Pramlintide)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Symlin is indicated to treat Type 1 and 2 Diabetes. Symlin is indicated for adjunctive treatment of DM with insulin.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Prescriber is an endocrinologist.
- Patient is uncontrolled despite optimal insulin utilization with Ha1c between 7%-9%.
- Not for use in patients with gastroparesis.

FHCP: MCG004 Review/Revision: 74

Synagis (palivizumab)

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Synagis is a monoclonal antibody indicated to prevent Respiratory Syncytial Virus in newborn infants with certain risk factors.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Coverage will be based on current AAP guidelines for use of Palivizumab (Synagis).
- Physician must complete <u>Synagis request form (Attachment 4)</u> and Fax or Mail to the Referrals Department.

FHCP: MCG004 Review/Revision: 74

**Synarel (nafarelin)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Synarel is a GNRH analog (intranasal formulation) indicated to treat precocious puberty in children or endometriosis in adults.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

Criteria for coverage as follows:

• FDA approved indications

Approved when written by an endocrinologist or gynecologist.

FHCP: MCG004 Review/Revision: 74

# Tafinlar (dabrafenib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Tafinlar is a BRAF inhibitor indicated to treat\_BRAF+ V600e/k mutation Stage IIIc-IV metastatic Melanoma and NSCLC
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Patient must have BRAF V600E/K mutation.
- Must be written by an oncologist.

FHCP: MCG004 Review/Revision: 74

# Tagrisso (osimertinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Tagrisso is indicated to treat patients with non-small cell lung cancer who possess an EGFR mutation.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Must possess the t790m mutation if being used after progression on an EGFR tyrosine kinase inhibitor.

FHCP: MCG004 Review/Revision: 74

# **Tarceva (erlotinib)-Generic**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Tarceva is indicated to treat patients with metastatic non-small cell lung cancer who possess an EGFR mutation.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

#### Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

# **Targretin (Bexarotene) Generic Only**

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Targretin is indicated for cutaneous T-cell lymphoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be written by an oncologist.
- Must have failed one prior systemic therapy.

FHCP: MCG004 Review/Revision: 74

Tasigna (nilotinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Tasigna is an oral antineoplastic agent used to treat Philadelphia Chromosome + CML
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Covered for treatment failure with imatinib.

FHCP: MCG004 Review/Revision: 74

# **Generic Tasmar (tolcapone)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Tasmar is indicated for adjunctive treatment of Parkinson's disease when used adjunctively with levo-dopa and carbidopa.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be written by a neurologist.
- Failure of carbidopa/levo depo, entacapone, ropinirole, pramipexole, selegiline and amantadine.

FHCP: MCG004
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# **Tazorac (tazarotene)-Generic Only**

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Tazorac is a topical retinoid indicated to treat Acne or Psoriasis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- For Psoriasis patient must have failed medium to high potency topical corticosteroid.
- For acne patient must have failed adapalene or tretinoin or oral tetracycline class antibiotic.
- Must be written by dermatology.

FHCP: MCG004
Review/Revision: 74

### Tecentriq (atezolizumab) J9022

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Tecentriq is a PDL-1 antagonist used for second line treatment of metastatic bladder cancer and non small cell lung.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.

FHCP: MCG004

Review/Revision: 74

# **Generic Tekturna (aliskiren) STEP THERAPY- DRUG NOT PRIOR AUTHORIZATION**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy	Х	Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

• Tekturna is a step therapy medication indicated to treat hypertension.

# Criteria for coverage as follows:

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

FHCP: MCG004 Review/Revision: 74

#### **Tepezza** (teprotumumab)

Exchange Pharmacy	х	Medical Commercial	Х
Commercial Pharmacy	Х	Medical Exchange	X
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Tepezza is a medication indicated for Thyroid Eye Disease (TED).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Coverage will be provided for 6 months (max total of 8 infusions) and may not be renewed.
- Patient is at least 18 years old; AND
- Must be prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery or neuro-ophthalmology; AND
- Patient is euthyroid [Note: mild hypo- or hyperthyroidism is permitted which is defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits (every effort should be made to correct the mild hypo- or hyperthyroidism promptly)]; AND
- Patient does not have corneal decompensation that is unresponsive to medical management; AND
- Member has not had a decrease in best corrected visual acuity (BVCA) due to optic neuropathy within the previous six months (i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement)
- Patient does not have poorly controlled diabetes OR inflammatory bowel disease; AND
- Must be used as single agent therapy; AND
- Patient has a clinical diagnosis of active TED that is related to Graves' Disease (i.e., Graves' orbitopathy); AND
- Patient has a baseline clinical activity score (CAS) of at least 4; AND
- Patient has active phase TED that is non-sight threatening but has a significant impact
  on daily living by one or more of the following features- lid retraction ≥ 2 mm, OR
  moderate or severe soft tissue involvement, OR exophthalmos ≥ 3 mm above normal
  for race and gender, OR inconstant or constant diplopia; AND
- Patient's onset of TED symptoms occurred within the previous 9 months; AND
- Patient had an inadequate response or intolerance, to high-dose intravenous glucocorticoids OR Rituxumab AND
- Patient is a non-smoker or has recently stopped smoking for at least 6 months.

FHCP: MCG004 Review/Revision: 74

**Teriflunimide (generic Aubagio)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

• Teriflunimide is indicated to treat Multiple Sclerosis.

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

# Criteria for coverage as follows:

• FDA approved indications

• Prescriber must be a neurologist.

FHCP: MCG004 Review/Revision: 74

**Tetrabenazine (generic xenazine)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Xenazine is indicated to treat chorea associated with Huntington's disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

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

FHCP: MCG004 Review/Revision: 74

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Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

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

- FDA approved indications
- Approved when written by Oncology, Infectious Disease or in HIV through referrals.

FHCP: MCG004 Review/Revision: 74

Thyrogen (Thyrotropin alpha)

<del></del>			
Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

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

- FDA approved indications
- Approved when written by Oncology or Endocrinology.

FHCP: MCG004 Review/Revision: 74

#### <u>Tracleer (bosentan)</u>

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Tracleer is indicated for the treatment of Primary pulmonary arterial hypertension or pulmonary hypertension related to connective tissue disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Pulmonary hypertension must be diagnosed by heart catheterization.
- Patient must have failed or have contraindication to sildenafil, ambrisentan, and tadalafil.
- 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.

FHCP: MCG004 Review/Revision: 74

**Tramadol ER** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

• Tramadol ER is an opioid analgesic

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

# Criteria for coverage as follows:

• FDA approved indications

• Approved after failure of tramadol IR.

FHCP: MCG004

Review/Revision: 74

# <u>Trelegy Ellipta (umeclidinium/fluticasone/vilanterol) - STEP THERAPY DRUG</u>

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy	Х	Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

• Trelegy is used for treatment of moderate to severe COPD and Asthma

## Criteria for coverage as follows:

• Covered after failure of a LAMA or LABA containing agent in the past 180 days.

FHCP: MCG004 Review/Revision: 74

# **Tretinoin (Generic Retin A)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Tretinoin is indicated to treat moderate to severe acne and diseases of keratinization such as ichthyosis and keratosis follicularis.
- Prior authorization only required for patients greater than 30 years of age.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- This medication is not covered for wrinkles or photo aging.

FHCP: MCG004 Review/Revision: 74

**Tretinoin capsules (generic Vesanoid)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Vesanoid is indicated to treat promyelocytic leukemia.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Approved when written by Oncology through referrals.

FHCP: MCG004 Review/Revision: 74

# **Trintellix (vortioxetine)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Trintellix is an antidepressant used to treat major depressive disorder.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Failure or intolerance to two generically available anti-depressants in past 6 months.

FHCP: MCG004 Review/Revision: 74

Trisenox (arsenic trioxide) J9017

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Trisenox is indicated to treat acute promyelocytic leukemia (APL).
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

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

FHCP: MCG004
Review/Revision: 74

# Tykerb (lapatinib) -Generic

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Tykerb is indicated to treat Advanced HER2+ breast cancer in combination with Xeloda.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- 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.

FHCP: MCG004 Review/Revision: 74

Tymlos (abaloparatide)

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	X	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Tymlos is indicated to treat osteoporosis.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Patient is diagnosed with osteoporosis with a BMD less than -2.5.
- Patient fails treatment with IV bisphosphonate and denosumab.
- 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
- Vitamin D (25 OH, 1,25 OH) labs. Must be within normal limits.

FHCP: MCG004 Review/Revision: 74

Tysabri (natalizumab) J2323

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Tysabri a monoclonal antibody indicated to treat refractory relapsed remitting multiple sclerosis and refractory Crohn's disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications Prescriber is a neurologist/gastroenterologist.
- Failure of a TNF-antagonist for Crohn's disease.
- Failure of a first line DMT for multiple sclerosis

FHCP: MCG004 Review/Revision: 74

Tyzeka (Telbivudine)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Tyzeka is indicated for chronic hepatitis B infection.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician

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

FHCP: MCG004
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### Vectibix (Panitumumab) J9303

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

Vectibix is an epidermal growth factor receptor (EGFR) antagonist indicated for the treatment of wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC):

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

### Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004 Review/Revision: 74

# Velcade (bortezomib) J9044

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Bortezomib is indicated to treat multiple myeloma, and mantle cell lymphoma.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

### Criteria for coverage as follows:

• FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.

FHCP: MCG004
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### <u>Velphoro (sucroferric oxyhydroxide)</u>

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Velphoro is a non-calcium based phosphate binder indicated to manage hyperphosphatemia in ESRD.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Patient has ESRD.
- Patient has ecalcium on phosphate binders, or not a candidate for calcium based phosphate binders based on KDOQI guidelines.
- Prescribed by a nephrologist
- Not covered in combination with other non-calcium based phosphate binders

FHCP: MCG004 Review/Revision: 74

# Venclexta (venetoclax)

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Venclexta is a BCL-2 inhibitor indicated for treatment B-cell Lymphomas.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Restricted to Hematology/Oncology.

FHCP: MCG004
Review/Revision: 74

Ventavis (iloprost) nebulized

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Ventavis is a nebulized 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.

- FDA approved indications
- 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 ambrisentan and tadalafil.

FHCP: MCG004 Review/Revision: 74

Victoza (liraglutide)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy	Х	Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

• Victoza is a medication indicated for treatment of type 2 diabetes mellitus.

# Criteria for coverage as follows:

• Covered after failure of metformin AND Bydureon Covered for use in established cardiovascular disease for patients on a Statin who have failed metformin

FHCP: MCG004 Review/Revision: 74

Visudyne (Verteporfin)

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- This medication is a photo-chemotherapy agent for age related wet macular degeneration.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

# Criteria for coverage as follows:

• FDA approved indications

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### Voriconazole (generic Vfend)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Voriconazole is an antifungal medication used to treat aspergillosis and other invasive fungal infections.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Two of the following medications have been tried, unless resistance or contraindication precludes use, Itraconazole, fluconazole, ketoconazole.
- Exclusions to pre-requisite medications are Invasive pulmonary aspergillosis, Scedosporium apiospermum, and fusarium.

FHCP: MCG004 Review/Revision: 74

# Votrient (Pazopanib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Votrient is an oral tyrosine kinase inhibitor indicated to treat Renal cell carcinoma, and soft tissue sarcoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

# Criteria for coverage as follows:

• Prescribing restricted to oncology.

FHCP: MCG004 Review/Revision: 74

### White blood cell colony stimulating factors Granix//Zarzio/Nivastym (filgrastim-aafi), Zarxio-

Effective Date: June 12, 2024

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Filgrastim-sndz, Fulphila, Udenyca, Ziextenzo Leukine- sargramostim)

### Primary Prophylaxis of febrile neutropenia

(Any agent listed)

Consideration should be given to equally effective and safe alternative chemotherapy treatment options that do not require colony stimulating factor (CSF) support, when available.

One white blood cell (WBC) growth factor agent is considered clinically appropriate for primary prophylaxis of chemotherapy-induced febrile neutropenia when **ALL** of the following (1, 2, and 3) are met:

- 1. The individual has a **non-myeloid malignancy** and is **NOT receiving concurrent chemotherapy and radiation**;
- 2. Chemotherapy intent must include one of the following:
  - a. Curative intent (adjuvant treatment for early stage disease, for example),
  - b. Intent is survival prolongation, and the use of a different regimen or dose reduction would reduce the likelihood of reaching the treatment goal
  - c. Intent is symptom management, and the use of a different regimen or dose reduction would reduce the likelihood of reaching the treatment goal
- 3. The individual falls into one of the following risk categories for FN
  - a. High risk of febrile neutropenia (≥20%) based on chemotherapy regimen, OR
  - b. Intermediate risk of FN (≥10% but <20%) based on chemotherapy regimen, and at least ONE of the following significant risk factors:
    - i. Age > 65,
    - ii. Poor performance status (ECOG 3 or 4, but chemotherapy still indicated),
    - iii. Preexisting neutropenia, for example resulting from bone marrow damage or tumor infiltration (ANC <1500mm³),
    - iv. Previous febrile neutropenia episode,
    - v. Liver dysfunction, with bilirubin ≥1.0 or liver enzymes ≥ 2x upper limit of normal,
    - vi. Presence of open wounds or active infections, when chemotherapy cannot be delayed to accommodate recovery,
    - vii. Poor nutritional status (baseline albumin less ≤ 3.5 g/dL or BMI less than 20),

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viii. HIV infection (active),

ix. Advanced cancer,

x. Multiple comorbid conditions.

#### Secondary Prophylaxis of febrile neutropenia

#### (Any agent listed)

**Secondary prophylaxis** of febrile neutropenia is considered clinically appropriate when there has been a previous neutropenic complication (in the absence of primary prophylaxis), and a change to the regimen (including dose reduction, schedule change, or change in therapy) would be expected to compromise patient outcome, particularly in the setting of curative intent.

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### Adjunctive treatment of Febrile Neutropenia (primary prophylaxis not given)

#### (Any agent listed)

**Adjunctive treatment** of febrile neutropenia is considered clinically appropriate when **any** of the following risk factors are present:

- 1. Age > 65
- 2. Neutrophil recovery is expected to be delayed (greater than 10 days)
- 3. Neutropenia is profound (less than 0.1 x 10<sup>9</sup>)
- 4. Active pneumonia
- Sepsis syndrome (hypotension and/or multi-organ damage/dysfunction noted)
- 6. Invasive fungal or opportunistic infection
- 7. Onset of fever during inpatient stay

Note: Febrile neutropenia (FN) is defined as an oral temperature >  $38.3^{\circ}$ C (101.0°F) or 2 consecutive readings of  $38.0^{\circ}$ C (100.4°F) for 1 hour, with an absolute neutrophil count less than 500 cells/microL (0.5 x  $10^{9}$ /L) or less than 1000 cells/microL and expected to fall below 500 cells/microL over the next 48 hours.

#### Other oncologic uses for WBC growth factors

The following indications by growth factor type are also considered clinically appropriate if the requirements below are met:

#### Filgrastim/filgrastim-sndz

1. Acute lymphocytic leukemia (ALL):

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- a. after start of induction or first post-remission chemotherapy course
- b. as an alternate or adjunct to donor leukocyte infusions (DLI) for relapsed disease after transplant

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- 2. Acute myeloid leukemia (AML):
  - a. after induction, re-induction, or consolidation OR
  - b. as an alternate or adjunct to donor leukocyte infusions (DLI) for relapsed disease after transplant
- 3. Aplastic anemia moderate or severe
- 4. Hairy cell leukemia to treat severe neutropenia
- 5. Hematopoietic stem cell transplant
  - a. To promote bone marrow myeloid recovery OR
  - b. To treat delayed or failed engraftment OR
  - c. To mobilize stem cells for collection by pheresis
- 6. Myelodysplastic syndrome (MDS)
  - a. to treat recurrent infection OR
  - b. to treat neutrophil count < 500 mm<sup>3</sup>
- 7. Radiation exposure: following radiation therapy in the absence of chemotherapy, if prolonged delays are expected
- 8. Radiation exposure: after accidental or intentional body irradiation of doses greater than 2 Gy, (Hematopoietic Syndrome of Acute Radiation Syndrome)
- 9. Support for dose dense or dose intensive chemotherapy in **at least one of** the following scenarios:
  - a. Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel
  - b. High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer
  - c. Chemotherapy intensification for newly diagnosed, localized Ewing sarcoma.

#### Peg-filgrastim

- 1. Acute lymphocytic leukemia (ALL):
  - a. after start of induction or first post-remission chemotherapy course
- 2. Hematopoietic stem cell transplant
  - a. To promote bone marrow myeloid recovery OR
  - b. To treat delayed or failed engraftment
- 3. Myelodysplastic syndrome (MDS)
  - a. to treat recurrent infection OR
  - b. to treat neutrophil count < 500 mm<sup>3</sup>
- 4. Radiation exposure: after accidental or intentional body irradiation of doses greater than 2 Gy, (Hematopoietic Syndrome of Acute Radiation Syndrome)
- 5. Support for dose dense chemotherapy in the following scenarios:

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a. Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel OR

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- b. High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer OR
  - c. Chemotherapy intensification for newly diagnosed, localized Ewing sarcoma.

#### <u>Sargramostim</u>

- 1. Acute lymphocytic leukemia (ALL):
  - a. after start of induction or first post-remission chemotherapy course
- 2. Acute myeloid leukemia (AML):
  - a. after induction, re-induction, for individuals over 55 years of age
- 3. Hematopoietic stem cell transplant
  - a. To promote bone marrow myeloid recovery OR
  - b. To treat delayed or failed engraftment OR
  - c. To mobilize stem cells for collection by pheresis
- 4. Myelodysplastic syndrome (MDS)
  - a. to treat recurrent infection OR
  - b. to treat neutrophil count < 500 mm<sup>3</sup>
- 5. Radiation exposure: after radiation therapy in the absence of chemotherapy, if prolonged delays are expected
- 6. Radiation exposure: after accidental or intentional body irradiation of doses greater than 2 Gy, (Hematopoietic Syndrome of Acute Radiation Syndrome)
- 7. Support for dose dense chemotherapy in the following scenarios:
  - a. Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel OR
  - b. High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer OR
    - c. Chemotherapy intensification for newly diagnosed, localized Ewing sarcoma.

#### **Tbo-filgrastim**

- 1. Hematopoietic stem cell transplant
  - a. To promote bone marrow myeloid recovery OR
  - b. To treat delayed or failed engraftment OR
  - c. To mobilize stem cells for collection by pheresis

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# Xalkori (crizotinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

Xalkori is a TKI inhibitor for metastatic NSCLC which is ALK (anaplastic lymphoma kinase) positive, or ROS positive.

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

- FDA approved indications
- Not covered in combination with other tyrosine kinase inhibitors or EGRF inhibitors.
- Must be written by oncologist.

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# **Vyvanse (Lisdexamfetamine)**

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

Vyvanse is a stimulant indicated for Binge Eating Disorder or ADHD.

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

# Criteria for coverage as follows:

• FDA approved indications

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# <u>Xartemis (Oxycodone and Acetaminophen) ER Tablets</u>

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Xartemis is an abuse deterrent opioid formulation used for pain.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Medication will be approved through referrals when written by Oncology or pain management.

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#### Xeljanz (tofacitinib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Xeljanz is indicated for treatment of Moderate to severe Rheumatoid arthritis in adults, Psoriatic Arthritis, Ulcerative colitis, JIA
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- For rheumatoid arthritis must be written by Rheumatology, Patient must fail adequate trial of MTX in combination with a DMARD If MTX contraindicated, must try combination of 2-nonbiologic DMARDS (3 month trial in past 6 months) and a preferred TNF.
- For Psoriatic Arthritis Patient must fail adequate trial of MTX or LEF in past 6 months.
- For 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)

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# Xgeva (denosumab) J0897

Exchange Pharmacy	Medical Commercial	X
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- 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.

- FDA approved indications
- Prescriber must be an oncologist or endocrinologist.
- Must have failed or a contraindication to an intravenous bisphosphonate.

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#### Xolair (omalizumab) J2357

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- 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.
- Nasal Polyp indication is covered only by exception and will be based on all available treatment options including nebulized sinus treatments and devices

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

The following criteria must be met for coverage for chronic idiopathic urticaria:

- Prescribed by an allergist, immunologist, or dermatologist
- Patient 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) with MONTELUKAST AND trial Dicyclomine or Hydroxyzine

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#### Xtandi (enzalutamide)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Xtandi is an androgen receptor blocker used for Castrate Resistant Prostate Cancer preand post-chemotherapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Covered for 6 months and continuation based on lack of disease progression.
- Coverage will be based on failure of Abiraterone for overlapping indications (Metastatic Prostate Cancer and Castrate sensitive high risk non-metastatic cancer).
- Must be prescribed by oncologist or urologist.

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#### **Xyrem (Sodium Oxybate) Generic Only**

Exchange Pharmacy	х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- This medication is used for treatment of narcolepsy with cataplexy or excessive daytime sleepiness due to narcolepsy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- Only covered for Narcolepsy with cataplexy.
- Coverage will be based on recent failure of:
  - 1. Modafinil AND Armodafinil AND Amphetamine/Dextroamphetamine And soriamfetol.
  - 2. Tricyclic Antidepressant shown to be effective in cataplexy(Clomipramine/Protriptyline) and Venlafaxine (for cataplexy)
  - 3. Three month discontinuation trials for moderate to highly sedating medications such as benzodiazepines, opioids, anticholinergics, muscle relaxers, atypical antipsychotics, dopamine agonists.
  - 4. Must be prescribed by physician board certified in sleep medicine.

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#### Yervoy (ipilimumab) J9228

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Yervoy is an immunotherapy used for treatment of cancer.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Not covered in combinations unsupported by the NCCN evidence 2a or greater (i.e. Vemurafenib).
- Doses exceeding 3 mg/kg will only be approved in adjuvant treatment setting.
- Must be prescribed by an oncologist/hematologist.

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## Zaltrap (ziv-aflibercept) J9400

Exchange Pharmacy	Medical Commercial	Х
Commercial Pharmacy	Medical Exchange	Х
Step Therapy	Limited Distribution	
	Quantity Limit	

Effective Date: June 12, 2024

- Zaltrap is a VEGF antagonist indicated for metastatic colorectal cancer.
- Medical history and studies are reviewed in Referrals and if approved will notify the physician.

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Coverage will be based on failure or intolerance of Avastin.
- Must be prescribed by an oncologist/hematologist.

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Zavesca (miglustat) Generic Only

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Zavesca is indicated for treatment of non-neuropathic Gaucher's disease.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

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

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## Zejula (niraparib)

Exchange Pharmacy	X	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Zejula is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when used in alignment with NCCN recommendations of class 2A or greater.
- Must be prescribed by an oncologist/hematologist.

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## Zelboraf (vemurafenib)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Zelboraf is a BRAF inhibitor indicated to treat BRAF+ V600e/k mutation Stage IIIc-IV metastatic Melanoma, NSCLC, and Metastatic colorectal cancer
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications, off label use will be covered when there is an NCCN supported indication with a recommendation of class 2A or greater.
- Patient must have BRAF V600E/K mutation.
- Must be written by an oncologist.

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## Zolinza (Vorinostat)

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Zolinza is indicated for cutaneous manifestations of cutaneous T-cell Lymphoma
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Failed minimum of two systemic treatments, one of which must be Targretin, unless contraindicated.

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## **Zortress (everolimus) capsules**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Zortress is an immunosuppressive anti-rejection agent for solid organ transplant.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Prescriber must be a transplant specialist.
- Patient must have failure or intolerance to a calcineurin inhibitor.

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## **Zydelig (idelalisib) Tablets**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Zydelig is a PI3K kinase inhibitor for treatment of relapsed Chronic lymphocytic leukemia, relapsed follicular lymphoma, and small lymphocytic lymphoma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be written by oncologist.

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**Zyflo (zileuton)** 

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	Х

Effective Date: June 12, 2024

- Zyflo is indicates for treatment of asthma.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Must be written by a pulmonologist.
- Uncontrolled Asthma while on maximal doses of long acting bronchodilators and inhaled corticosteroids AND montelukast.
- 6 months of medication compliance with maintenance treatments.

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## Zykadia (ceritinib) capsules

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Zykadia is a TKI inhibitor indicated for metastatic NSCLC which is ALK (anaplastic lymphoma kinase) positive, it is indicated for patients who have failed/progressed on crizotinib (Xalkori)
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy and the physician.

- FDA approved indications
- Not covered in combination with other tyrosine kinase inhibitors or EGRf inhibitors.
- Must be written by oncologist.
- Must have progressed on Xalkori.

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## **Zyprexa Relprevv (Olanzapine injection)**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy		Medical Exchange	
Step Therapy		Limited Distribution	
		Quantity Limit	

Effective Date: June 12, 2024

- Zyprexa Relprevv is a psychotropic medication.
- Medical history and studies are reviewed in Referrals and if approved will notify pharmacy.

- FDA approved indications
- Failure of oral aripiprazole and olanzapine
- Approved when written/ordered by a Psychiatrist or Neurologist through referrals for new starts.

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## **Zytiga (Abiraterone) GENERIC Only**

Exchange Pharmacy	Х	Medical Commercial	
Commercial Pharmacy	Х	Medical Exchange	
Step Therapy		Limited Distribution	Х
		Quantity Limit	

Effective Date: June 12, 2024

- Abiraterone is indicated to treat metastatic prostate cancer. 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.

## Criteria for coverage as follows:

• FDA approved indications

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# **Discrimination is Against the Law**

Florida Health Care Plans complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Florida Health Care Plans does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

#### 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
  - o Information written in other languages

If you need these services, contact Daria Siciliano, RN-BC, CCM.

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:

Daria Siciliano, RN-BC, CCM, Manager of Member Services, 1340 Ridgewood Avenue, Holly Hill, FL 3211. Phone: 1-844-219-6137, TTY: TRS Relay 711, Fax: 386-676-7149,

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, Daria Siciliano, RN-BC, CCM Manager of Member Services 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 http://www.hhs.gov/ocr/office/file/index.html.

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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)

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se voi, o una persona che state aiutando, avete domande relative al Florida Health Care 33Plans, 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.

귀하 또는 귀하가 도와드리고 있는 분이Florida Health Care Plans에 관한 질문이 있을 경우, 귀하에게는 무료로 본인이 구사하는 언어로 도움과 정보를 받을 권리가 있습니다. 통역으로 전화 연결되려면1-877-615-4022. (TTY: TRS Relay 711) 번으로 전화해 주십시오.

Jeśli Ty lub ktoś, komu pomagasz macie pytania dotyczące Florida Health Care Plans, macie prawo uzyskać pomoc i informacje w swoim języku, bez żadnych kosztów. Porozmawiaj z tłumaczem, zadzwoń pod numer 1-877-615-4022. (TTY: TRS Relay 711)

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

หากคุณ หรือคนที่คุณกำลังช่วยเหลืออยู่มีคำถามเกี่ยวกับ Florida Health Care Plans คุณจะได้รับการช่วยเหลือและได้รับข้อมูลในภาษาของคุณโดยที่ไม่มีค่าใช้จ่ายใดๆ หากต้องการพดคยกับล่ามแปลภาษา โทร.

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

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