Prescription drug policies and coverage criteria

MercyCare Health Plans™

mercycarehealthplans.com

12/1/2021

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Introduction

MercyCare Health Plans (MCHP) maintains a drug formulary as a guide for providers to prescribe ambulatory medications. Medications are listed under the 2-Tier Formulary, 3-Tier Formulary, and 4-Tier Formulary. The MercyCare Pharmacy and Therapeutics (P&T) Committee of physicians and pharmacists endorse the agents listed based on product selection criteria. There may be occasions when an unlisted drug is desired for medical management of a specific patient. In those infrequent instances the unlisted medication may be requested through the Drug Exception process. MercyCare reserves the right to change the formulary at any time without notice. For complete benefit explanation please review your certificate of coverage and your drug rider or summary plan description.

Contact information

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Prior authorization and exception forms should be faxed to:

Quality Health Management Department
MercyCare Health Plans
Fax: (608) 758-7726

MercyCare will honor all requests for paper copies of any and all material on our website; however, we cannot take responsibility for notifying you when those paper copies have become outdated. Generally our formulary is updated monthly.

Formulary Options

MercyCare Health Plans (MCHP) offers different formulary options to its members, based on the number of tiers, which are identified on the front of the member's insurance card. The member's drug plan depends on the benefit selected by the employer or individual. If you have questions about which formulary is available for a member's drug plan, please call customer service at (800) 895-2421. MCHP's formulary options are as follows:

Two Tier

- Tier 1 is for preferred generic drugs and has the lower co-payment.
- Tier 2 covers selected generic drugs, brand name drugs, and clinically-appropriate noncovered drugs by approval and has the higher co-payment.

Three Tier

- Tier 1 is for preferred generic drugs and has the lowest co-payment.
- Tier 2 covers selected generic drugs and brand name drugs, and has the second lowest copayment.
- Tier 3 represents all non-preferred drugs and clinically-appropriate non-covered drugs by approval, and has the highest co-payment.

Four Tier

- Tier 1 is for preferred generic drugs and has the lowest co-payment.
- Tier 2 covers selected generic drugs and brand name drugs, and has the second lowest copayment.
- Tier 3 represents all non-preferred drugs and clinically-appropriate non-covered non-specialty drugs by approval, except specialty drugs, and has the third lowest co-payment.
- Tier 4 covers only selected generic drugs, selected brand name drugs, specialty drugs, and clinically-appropriate non-covered drugs by approval, and has the highest co-payment.

Formulary Key

The formulary is divided by Alphabetical Index and then Category/Class.
The back of the formulary also has specific sections:

- Prior Authorization Drug List
- Over-the-Counter (OTC) Medications
- Mandatory Specialty Pharmacy (MSP) Medications
- Smoking Cessation Agents
- Quantity Limit (QL) Medications

In drug classes where there are several products on the market, only certain products within that class may be on the formulary. By limiting the products available, it is possible to reduce drug costs through the use of generic drugs and cost-effective choices. The key below demonstrates the meaning of the symbols in the formulary.

OTC	Over-the-Counter. Specific OTC products are covered with a prescription.
SP	Available through Specialty Pharmacy Program. SP drugs may be available and required to be filled at a Mercy Pharmacy, depending on your plan.
MSP	Mandatory Specialty Pharmacy Program. Specialty Pharmacy will be used to dispense selected medications. Members will select a Mercy Pharmacy to obtain the prescribed medication. A different Network Specialty Pharmacy may be designated,depending on the drug and/or plan.
PA	Prior Authorization. PA criteria established. The P&T Committee has decided that PA drugs be used only in specific circumstances. Prescribers must follow the PA procedure to request coverage. Please see the Prior Authorization Procedure section for more detail. Prescriber must follow PA procedure to request coverage for PA drug. If denied or if PA was not submitted by the prescriber, the member pays 100% of the medication cost.
QL	Quantity limits are established to promote safe and appropriate cost-effective use ofspecific classes of medications for both formulary and non-formulary agents. All members may receive a maximum of 30 days supply unless otherwise specified by drug rider or summary plan description or by quantity limits listed in the formulary.
NC	Not Covered. Check the formulary for alternative medications that are covered. Drug Exception Procedure: Please see the Drug Exception section for more detail. If the physician believes that a drug not covered or not found on MercyCare formulary is necessary for the patient, then he or she must apply for the drug exception. Prescriber's office must fax a completed Non-Formulary request form to MercyCare Health Plans at (608) 758-7726. Forms are available at www.mercycarehealthplans.com.

For complete benefit explanation please review your certificate of coverage and your drug rider or summary plan description. If you are concerned about coverage of a particular drug on a MercyCare Health Plans (MCHP) drug plan, you may call customer service at (800) 895-2421.

Covered Drugs

This prescription drug program provides coverage for drugs that satisfy the following criteria:

- Any prescription drug or insulin in the MercyCare drug formulary, or
- Insulin syringes, or
- Any medication compounded by the participating pharmacy that contains a covered prescription drug.

The medication also must be:

- Medically necessary for patient's medical condition and appropriate given the patient's medical history; and
- Prescribed in a manner consistent with its FDA approval and manufacturer recommendations; and
- Prescribed in its most cost-effective dosing regimen; and
- Used in a manner consistent with any and all guidelines and criteria developed, adopted, or researched by MercyCare.

Prescription drug coverage applies to drugs provided to ambulatory patients and dispensed by the MercyCare network of retail pharmacies. The pharmacy benefit plan is managed internally. Copayment amounts vary, depending on the plan selected by the employer group or individual. Each member's MercyCare identification card indicates the co-payment amount required for each prescription.

Limited additional coverage exists under the medical benefit for drugs administered on an outpatient basis in the physician's office. Drugs administered to hospitalized patients are covered directly in MercyCare's payment to the hospital and are also excluded from the prescription drug coverage.

Drug Coverage for MercyCare

- Most members can receive a supply of medication not exceeding 30 days for one co-pay. Some members have an enhanced benefit allowing them to receive up to a 90-day supply of certain medications. The MercyCare Customer Service Department can verify if the member has the enhanced benefit, and identify the drugs which can be prescribed in the larger supply.
- Covered drugs are only those available on a prescription basis; exclusions include most over-the-counter (OTC) medications. A limited number of OTCs are available and listed in the formulary.
- Insulin, diabetes monitoring products, and associated syringes and needles are covered.
- Generally, there is no coverage for other injectable medications unless it is included under the prior authorization process.

Generic Medications

MercyCare covers and encourages the use of generic medications. Generic medications have the same active ingredient as the brand name and have undergone vigorous scientific comparison studies that are approved by the Federal Food and Drug Administration (FDA). If a brand-name medication is not available in a generic form, members must pay a higher co-pay as outlined in their policy. Co-pay amounts are indicated on the prescription drug rider or summary plan description.

Non-covered Drugs

Prescription drug benefits are not available for the following:*

- Fertility drugs.
- Replacement of any lost, stolen, or destroyed medications.
- Therapeutic devices or appliances, including hypodermic needles or syringes (except for diabetic supplies)
- Any drug or medicine that is administered or delivered by the health care provider to you.
- A brand name drug when it is available as a generic.
- A generic or brand name drug when it is covered as OTC.
- A specialty drug that is not obtained from the designated specialty pharmacy.
- Any drug or medicine which is taken by or administered to you while you are a patient in a licensed hospital, rest home or sanitarium, extended care facility, convalescent hospital, skilled nursing facility or similar institution.
- Any drug labeled "Caution: limited by Federal Law to investigational use" or other wording having similar intent, experimental drugs, FDA approved drugs used for non-FDA approved uses, or FDA approved drugs used in non-FDA approved regimens, even though a charge is made to you, except that coverage shall be provided for any prescription drug which meets the following criteria:
    a. Is prescribed for the treatment of HIV infection or an illness or medical condition arising from or related to HIV infection; AND
    b. Is approved by the Federal Food and Drug Administration, including phase-3 investigational drugs; AND
    c. If the drug is an investigational new drug, is prescribed and administered in accordance with the treatment protocol approved by the Federal Food and Drug Administration for the investigational new drugs.
- Anabolic steroids.
- Anti-obesity and anorexients.
- Growth hormones.
- Any prescription drug for a non-covered procedure or the treatment of a complication from a noncovered procedure/service.
- Any prescription drug for a sickness or bodily injury not covered by the Plan.
- Medication other than prescription drugs or preferred OTC drugs with or without a prescription order.
- Prescription drugs, which the eligible person is entitled to receive without charge under any Worker's Compensation laws or any municipal state or federal program.
- Nutritional supplements.

*For complete benefit explanation please review your certificate of coverage and your drug rider or summary plan description.

Prior Authorization (PA) Procedure

Drugs indicated with a PA are not covered unless they have been prior authorized by MercyCare Health Plans. The physician must apply for prior approval for a specific patient and a specific drug and dose. The request must fulfill PA criteria. This procedure ensures that these drugs are used in a manner consistent with all of the criteria cited in the section COVERED DRUGS.

The following information will be needed when requesting prior approval:

1. Patient name, member number, and date of birth
2. Physician name, phone number and fax number
3. Drug, strength and dosage form
4. Duration of therapy
5. Documentation of medical necessity

A Prior Authorization request form must be faxed to (608) 758-7726.

If you need a copy of the Prior Authorization request form, please visit our website at www.mercycarehealthplans.com, or contact customer service at (800) 895-2421.

Prior Authorization (PA) Drugs

***Indicates the drug has a specific prior authorization form

For copies to print go to www.mercycarehealthplans.com or call customer service for a written copy.

Abiraterone (Zytiga)
Acitretin (Soriatane)
Actimmune
Addyi
Adempas
Afinitor
Albendazole (Albenza)
Alecensa
Alinia
Alunbrig
Anzemet
Apokyn
Aptiom
Aranesp
Armodafinil (Nuvigil) or modafinil (Provigil)
Atypical antipsychotics (Fanapt, Invega, Latuda, Rexulti, Saphris)
Banzel
Benlysta***
Benznidazole
Bexarotene cap (Targretin)
Biologics, Dermatology (Humira, Enbrel, Cosentyx, Otezla, Cimzia)
Biologics, Gastroenterology (Humira, Cimzia)
Biologics, Rheumatoid Arthritis (Enbrel, Humira, Orencia, Actemra, Cimzia, Kevzara, Olumiant)
Biologics, Rheumatoid, Other Indications (Enbrel, Humira, Cosentyx, Otezla, Orencia, Cimzia, Kineret, Actemra)
Bosulif
Botox (medical benefit)
Budesonide (Entocort, Uceris)
Cabometyx
Calcipotriene (Calcitrene, Dovonex)
Calcipotriene/betamethasone (Taclonex)
Calcitriol ointment (Vectical)
Calquence
Capecitabine (Xeloda)
Caprelsa
Cayston
CGRP inhibitor (Aimovig, Emgality)
Cholbam
Cometriq
Corlanor
Cotellic
Cystagon
Cystic Fibrosis (Kalydeco, Orkambi, Symdeko)
Denavir
Dificid
Digestive enzymes (Pancreaze, Pancrelipase, Pertyze, Ultresa, Zenpep)
Dofetilide (Tikosyn)
Dupixent
Emsam
Entresto
Erivedge
Esbrient or Ofev
Exjade
Farydak
Fentanyl (Abstral, Actiq, Lazanda, Onsolis, Subsys)
Fentora (fentanyl tablet)
Ferriprox
Fetzima
Flucytosine (Ancobon)
Fondaparinux (Arixtra)
Fragmin
Fycompa
Genotropin (somatropin)
Gilotrif
Hemlibra
Hycamtin
Ibrance
IBS-C or Constipation (Amitiza, Linzess)***
IBS-D (Lotronex or Xifaxan)
Iclusig
Idhifa
Imatinib (Gleevec)
Imbruvica
Infergen
Inlyta
Intron-A
Iressa
Itraconazole (Sporanox)
Jakafi
Jynarque
Kisqali
Ledipasvir/sofosbuvir (Harvoni)
Lenvima
Leukine
Lonsurf
Lynparza
Lyrica***
Makena (medical benefit)
Mavyret
Mekinist
Mesnex
Movantik
Natpara
Nerlynx
Neupogen (medical benefit)
Neupro
Nexavar
Ninlaro
Noxafil
NPlate
Nucala (medical benefit)
Nuedexta
Ocaliva
Odactra
Odomzo
Overactive Bladder (Darifenacin SR [Enablex], Oxytrol, Toviaz, Trospium SR [Sanctura XR])
Oxsoralen Ultra, 8-MOP
Oxycodone ER,
Oxycodone IR***
PCSK9 inhibitor (Repatha or Praluent)
Picato
Prolia (medical benefit)
Promacta
Pulmonary Arterial Hypertension (PAH) (Adcirca, Letairis, Opsumit, Tracleer)
Quillivant XR
Regranex
Relistor
Restasis
Revlimid
Riluzole (Rilutek)
Rydapt
Sabril
Samsca
Sancuso
Savella
Sildenafil (Revatio)
Sirturo
Sivextro
Sklice
Sofosbuvir/velpatasvir (Epclusa)
Sprycel
Stivarga
Sublingual immunotherapy (Grastek, Oralair, Ragwitek)
Sutent
Sylatron
Symlin
Synarel
Tacrolimus ointment (Protopic)
Tadalafil (Cialis)
Tafinlar
Tagrisso
Tarceva
Tasigna
Tavalisse
Tazarotene (Tazorac)
Temozolomide (Temodar)
Testosterone***
Tetrabenazine (Xenazine)
Thalomid
Tobramycin (TOBI)
Tranexamic acid (Lysteda)
Tretinoin cap
Trintellix
Truvada
Tykerb
Tyvaso
Tyzeka
Uloric
Uptravi
Valchlor
Valganciclovir (Valcyte)
Veltassa
Venclexta
Ventavis
Verzenio
Vimpat
Voriconazole (Vfend)
Vosevi
Votrient
Xadago
Xalkori
Xolair*** (medical benefit)
Xopenex
Xtandi
Xultophy
Xyrem
Zarxio
Zejula
Zelboraf
Zoledronic acid (Reclast; medical benefit)
Zolinza
Zontivity
Zortress
Zycadia
Zydelig
Zyflo or zileuton ER (Zyflo CR)

Prior Authorization Criteria

Drug	Prior Authorization Criteria

Abiraterone (Zytiga)	• Prescribed by oncologist
	• One of the following:
	  • Diagnosis of metastatic castrate-resistant prostate cancer
	  • Prescribed in combination with prednisone twice daily
	  • Diagnosis of metastatic high-risk castration-sensitive prostate cancer
	  • Prescribed in combination with prednisone once daily
	  • Patient has at least one of the following high-risk factors associated with a poor prognosis:
	  • Gleason score ≥8
	  • Presence of ≥3 bone lesions
	  • Presence of measurable visceral metastasis

Acitretin (Soriatane)	• Diagnosis of moderate to severe plaque psoriasis >10% BSA • Prescribed by dermatologist • Failure (6-month trials) or contraindications to therapies in two of the following categories: topical agents (corticosteroids, tazarotene, calcipotriene), suppressive agents (cyclosporine, methotrexate), and remitting agents (PUVA or UVB)

Actemra	• Prescribed by rheumatologist for one of the following:
	  • Diagnosis of moderate-to-severe, active, adult-onset Still's disease (AOSD) and a trial of anakinra (Kineret) was ineffective, contraindicated, or not tolerated
	  • Diagnosis of rheumatoid arthritis (RA) and a trial of adalimumab (Humira) was ineffective, not tolerated or contraindicated
	  • Diagnosis of Polyarticular Juvenile Idiopathic Arthritis (PJIA) and a trial of adalimumab (Humira) was ineffective, not tolerated or contraindicated
	  • Diagnosis of Systemic Juvenile Idiopathic Arthritis (SJIA)
	  • Diagnosis of Giant Cell Arteritis (GCA) confirmed by one of the following:
	  • Temporal artery biopsy
	  • Doppler ultrasound
	  • Magnetic resonance angiography (MRA)
	  • Positron emission tomography (PET)
	  AND meets one of the following:
	  • GCA has relapsed while on methotrexate and corticosteroids
	  • Corticosteroids and methotrexate are unable to achieve remission
	  • Member has experienced unacceptable side effects with corticosteroids
	  OR continued use is required to prevent relapse

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Actimmune	• Prescribed by specialist according to FDA indication • Failure of preferred agents

Addyi	• Diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
	  ◦ A co-existing medical or psychiatric condition
	  ◦ Problems with the relationship
	  ◦ The effects of a medication or other drug substance
	• Patient is a premenopausal woman
	• Patient abstains from alcohol use
	• Is not on moderate to strong cytochrome P450 3A4 (CYP3A4) inhibitors or inducers
	• No hepatic impairment
	• Prescriber is certified with the Risk Evaluation and Mitigation Strategy (REMS) Program
	• Treatment is discontinued after 8 weeks if no improvement

Adempas	• Prescribed by pulmonologist or cardiologist • Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO group 4) to improve exercise capacity and WHO functional class, and patient had surgical treatment or has inoperable CTEPH, OR • Pulmonary arterial hypertension diagnosed by right heart catheterization, and failure of vasodilators, calcium channel blockers, and sildenafil (Revatio)

Afinitor	• Prescribed by oncologist for one of the following:
	  ◦ Advanced hormone receptor-positive (HR+), HER2-negative breast cancer in a postmenopausal woman in combination with exemestane (Aromasin) AND failed letrozole (Femara) or anastrazole (Arimidex)
	  ◦ Progressive neuroendocrine tumors of pancreatic origin (PNET) in an adult
	  ◦ Progressive well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal or lung origin that are unresectable, locally advanced or metastatic in an adult
	  ◦ Advanced renal cell carcinoma (RCC) with a failed trial of sorafenib (Nexavar) or sunitinib (Sutent)
	  ◦ Noncancerous kidney tumors (renal angiomyolipomas) not requiring immediate surgery in patients with tuberous sclerosis complex
	  ◦ Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) in a patient who is not a candidate for surgical resection

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria

Aimovig	• Prescriber meets one of the following criteria:
	  • Prescriber is, or has consulted, a neurologist
	  • United Council for Neurologic Subspecialties (UCNS)-certified headache medicine specialist
	  • Member of the American Headache Society
	  • Member of the National Headache Foundation
	  • Member of the International Headache Society
	  • Has a Certificate of Added Qualification in Headache Medicine
	  • American Board of Headache Management Certified
	• Patient has four (4) or more migraine days per month for at least the previous three (3) months
	• Patient has tried and failed, is intolerant to, or is contraindicated from trying a minimum three (3) month trial from TWO (2) of the following drug classes:
	  • Anticonvulsants (such as topiramate, sodium valproate, etc.)
	  • Vasoactive agents (such as propranolol, metoprolol, etc.)
	  Antidepressants (such as amitriptyline, venlafaxine, etc.)
	• Patient will NOT continue to receive onabotulinumtoxinA (BOTOX) injections for migraine
	• Patient has experienced a meaningful improvement in frequency and/or severity of migraine
	• Erenumab (AIMOVIG) will NOT be used concomitantly with onabotulinumtoxinA (BOTOX) injections for migraine
	AND erenumab (AIMOVIG) was initially approved by the current or previous plan
	OR If therapy was initiated using manufacturer samples or any other mechanism, indicate ALL of the following:
	AND Prescriber meets any one (1) of the following:
	• Prescriber is, or has consulted, a Neurologist
	• United Council for Neurologic Subspecialties (UCNS)-certified headache medicine specialist
	• Member of the American Headache Society
	• Member of the National Headache Foundation
	• Member of the International Headache Society
	• Has a Certificate of Added Qualification in Headache Medicine
	• American Board of Headache Management Certified
	AND Member had four (4) or more migraine days per month for at least three (3) months prior to starting treatment with erenumab (AIMOVIG)
	AND Member has tried and failed, is intolerant to, or is contraindicated from trying a minimum three (3) month trial from TWO (2) of the following drug classes:
	• Anticonvulsants (such as topiramate, sodium valproate, etc.)
	• Vasoactive agents (such as propranolol, metoprolol, etc.)
	• Antidepressants (such as amitriptyline, venlafaxine, etc.)

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Albendazole (Albenza)	• Prescribed according to FDA indication • Documentation of diagnosis
Alecensa	• Prescribed by oncologist • Diagnosis of anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) • Documentation of mutation as detected by FDA-approved test
Alinia	• Diagnosis of giardiasis with trial of metronidazole OR diagnosis of Cryptosporidium parvum infection • Maximum 3 days of therapy • Suspension use limited to patients under 12 years old
Alunbrig	• Prescribed by, or in consultation with, an oncologist • Diagnosis of ALK-positive metastatic non-small cell lung cancer (NSCLC) • Patient has tried and failed or is intolerant to any other ALK inhibitor
Amitiza	
Anzemet	• Request from oncology • Diagnosis of cancer with the treatment of a highly emetogenic (HEC) or moderately emetogenic (MEC) chemotherapeutic regimen as defined by the ASCO or MASCC • Failure of preferred agents, promethazine, metoclopramide & ondansetron • Quantity limit 9 tablets per month
Apokyn	• Diagnosis of advanced Parkinson's disease • Prescribed by a neurologist
Aptiom	• Diagnosis of partial-onset seizures • Prescribed by a neurologist or epilepsy specialist • Trial and failure or contraindication to lacosamide (Vimpat) and topiramate
Aranesp	• Chemotherapy for a minimum of 2 months • Malignancy indications other than myeloid malignancy • Hemoglobin is <10 g/dL • Trial of Retacrit required
Armodafinil (Nuvigil) or modafinil (Provigil)	• Diagnosis of narcolepsyc onfirmed by sleep studies, such as polysomnogram (PSG) and multiple sleep latency test (MSLT), OR • Diagnosis of sleep apnea and continue to have residual sleepiness despite effective CPAP use and therapy

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Atypical antipsychotics (Fanapt, Invega, Latuda, Rexulti, Saphris)	• Prescribed according to the FDA indication • Consulted or prescribed by psychiatry • Trial and failure or contraindication to risperidone (Risperdal) • Trial and failure or contraindication to other preferred formulary atypical antipsychotics, such as ziprasidone, quetiapine, olanzapine
Banzel	• Diagnosis of Lennox-Gastaut Syndrome • Prescribed by or consulted with neurologist • Recurrent seizures despite trial of 2 or more concurrent medications • Prior use (including current use) of the following formulary alternatives: lamotrigine, topiramate, felbamate, clonazepam, and valproic acid

Benlysta* ** (Medical or Pharmacy Benefit)	• Prescribed by or in consultation with a rheumatologist or dermatologist
	• Diagnosis of active, autoantibody-positive, systemic lupus erythematosus (SLE) in an adult patient who is receiving standard therapy
	• Patient is anti-double stranded DNA (anti-dsDNA) positive (concentration ≥ 30 IU/ml) and/or anti-nuclear antibody (ANA) titer positive, with measurements at two different points in time [Documentation Required] OR
	  ◦ Patient has low complement (C3/C4) [Documentation Required with reference range and patient values]
	• Requires daily use of corticosteroids, unless contraindicated
	• Trial and failure of or contraindication to all of the following therapies: hydroxychloroquine, methotrexate, azathioprine, mycophenolate mofetil, and cyclophosphamide
	• Patient does not have severe active lupus nephritis or severe active central nervous system (CNS) Lupus
	• Belimumab will not be given in combination with other biologics or intravenous (IV) cyclophosphamide
	• Continuation of therapy or IV to SC Transition
	  ◦ Prescribed according to FDA indication by or in consultation with a rheumatologist or dermatologist
	  ◦ Documentation of disease stabilization and improvement
	  ◦ Patient does not have severe active lupus nephritis or severe active CNS Lupus
	  ◦ Belimumab will not be given in combination with other biologics or intravenous cyclophosphamide

Benznidazole	• Prescribed by or in consultation with an infectious disease specialist • Patient has serologically confirmed T. cruzi infection • Patient does not have congestive heart failure (Kuschnir Class III) due to Chagas cardiomyopathy • Not recommended for patients over 50 years of age

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Bexarotene cap (Targretin)	• Prescribed by oncologist according to FDA indication

Biologics, Dermatology (Humira, Enbrel, Cosentyx, Otezla, Cimzia)	Cosentyx, Enbrel, Humira, Otezla – Psoriasis
	• Prescribed by a dermatologist
	• Patient has at least one of the following:
	  • Diagnosis of moderate to severe plaque psoriasis ≥10% BSA (body surface area) and significant functional disability
	  • Debilitating palmoplantar psoriasis
	• Failed a minimum of 15 sessions of phototherapy, or phototherapy is contraindicated
	• Failed methotrexate (minimum dose of 15 milligrams/week) or failed acitretin (Soriatane)
	• Supporting chart notes or documentation submitted with this request, such as:
	  • Documentation of disease severity and progression
	  • Medication dose, duration, response, adverse reactions or contraindications
	  • Phototherapy type, duration, response, adverse reactions or contraindications
	• Otezla will NOT be used in combination with biologic therapy
	• Continuing therapy:
	  • Prescribed by a dermatologist
	  • Patient has demonstrated a significant improvement in their condition
	  • Documented (written explanation accepted) improvement within the past year submitted with this request
	  • Otezla will NOT be used in combination with biologic therapy
	Cimzia – Psoriasis
	• Prescribed by a dermatologist
	• Diagnosis of moderate to severe plaque psoriasis
	• Trials of two of the following were ineffective, contraindicated, or not tolerated: Cosentyx,
	Enbrel, Humira, Otezla
	• Continuing therapy:
	  • Prescribed by a dermatologist
	  • Patient has demonstrated a significant improvement in their condition
	  • Documented (written explanation accepted) improvement within the past year submitted with this request
	Humira – Hidradenitis Suppurativa
	• Prescribed by a dermatologist
	• Diagnosis of severe hidradenitis suppurativa (total abscess or inflammatory nodule count ≥ 3)

Drug	Prior Authorization Criteria

	• Tried and failed at least one oral antibiotic (documentation including trial and dates is required)
	• Continuing therapy:
	  • Patient has demonstrated a significant improvement in their condition
	  • Documentation is required for approval (based on abscess/ nodule size and/or number)

Biologics, Gastroenterology (Humira, Cimzia)	Humira – Crohn's Disease
	• Prescribed by a gastroenterologist
	• Diagnosis of moderately to severely active Crohn's disease
	• Patient is 6 years of age or older
	• Inadequate/lost response to conventional therapy such as corticosteroids, azathioprine, methotrexate, or 6-mercaptopurine
	Cimzia – Crohn's Disease
	• Prescribed by a gastroenterologist
	• Diagnosis of moderately to severely active Crohn's disease
	• A trial of Humira was ineffective, contraindicated, or not tolerated
	Humira– Ulcerative Colitis
	• Prescribed by a gastroenterologist
	• Diagnosis of moderately to severely active ulcerative colitis
	• Inadequate response to immunosuppressants such as corticosteroids, azathioprine, methotrexate, or 6-mercaptopurine
	• Initial therapy is approved for 8 weeks
	• Continuing therapy:
	  • Patient has demonstrated a significant improvement in their condition
	  • Documented (written explanation accepted) improvement within the past year submitted with this request (documentation required for approval)

Biologics, Rheumatoid Arthritis (Enbrel, Humira, Orencia, Actemra, Cimzia, Kevzara, Olumiant)	Enbrel or Humira • Prescribed by a rheumatologist • Diagnosis of rheumatoid arthritis • Tried one or more conventional disease-modifying antirheumatic drugs (DMARDs) alone (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide, corticosteroids) or in combination, and must have included methotrexate ≥20 mg/week for at least 8 weeks. • Optimal therapeutic dosing of sulfasalazine is at least 2 g/day; of hydroxychloroquine is 400 mg/day; and of leflunomide is 20mg/ day. • Provide dates and doses of conventional DMARD therapy, dates of utilization of methotrexate ≥20 mg/week, dose-limiting side effect(s), if applicable, and contraindications to the use of methotrexate, if applicable

Drug	Prior Authorization Criteria

Biologics, Rheumatoid, Other Indications (Enbrel, Humira, Cosentyx, Otezla, Orencia, Cimzia, Kineret, Actemra)	• A contraindication to methotrexate does NOT cancel the requirement of a 3-6 month trial of conventional DMARDS.
	• Indicate one of the following:
	  • No response after 3 months. Must have used methotrexate ≥20 mg/week for 8 weeks during that 3 month period. No response is defined as no change in the Simple Disease Activity Index (SDAI) or Clinical Disease Activity Index (CDAI) score.
	  • Did not reach goal at 6 months. Goal at 6 months is defined as remission (SDAI score of 0.0-3.3, CDAI score of 0.0-2.8) or low disease activity (SDAI score of 3.4- 11.0, CDAI score of 2.9-10.0)
	Orencia
	• Prescribed by a rheumatologist
	• Diagnosis of rheumatoid arthritis
	• Patient experienced ineffectiveness, a contraindication to, or did not tolerate Enbrel or Humira
	Acemtra, Cimzia, Kevzara
	• Prescribed by a rheumatologist
	• Diagnosis of rheumatoid arthritis
	• Trials of both Humira and Enbrel were ineffective, contraindicated, or not tolerated
	• 162 mg every other week for weight <100 kg; 162 mg every week for weight ≥100 kg
	Olumiant
	• Confirmed Diagnosis
	• Rheumatology Specialist
	• Trial and Failure of preferred biologic DMARDs
	• Humira AND Enbrel for RA (current preferred products)
	
	Cosentyx, Enbrel, Humira, Otezla – Psoriatic Arthritis
	• Prescribed by a rheumatologist
	• Diagnosis of psoriatic arthritis
	• Intolerant to or failed therapy with sulfasalazine or methotrexate
	• Otezla will not be used in combination with biologic therapy
	Orencia – Psoriatic Arthritis
	• Prescribed by a rheumatologist
	• Diagnosis of psoriatic arthritis
	• Experienced ineffectiveness, a contraindication to, or did not tolerate one of the following: Enbrel or Humira
	Cimzia – Psoriatic Arthritis
	• Prescribed by a rheumatologist
	• Diagnosis of psoriatic arthritis
	• Trials of two of the following were ineffective, contraindicated, or not tolerated: Cosentyx, Enbrel, Humira, Otezla
	Enbrel or Humira – Peripheral Ankylosing Spondylitis or Reactive

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
	Arthritis • Prescribed by a rheumatologist • Diagnosis of peripheral ankylosing spondylitis or reactive arthritis: • Intolerant to or failed therapy with sulfasalazine or methotrexate Cosentyx, Enbrel, or Humira – Ankylosing Spondylitis with Predominant Axial Involvement • Prescribed by a rheumatologist • Diagnosis of ankylosing spondylitis with predominant axial involvement Cimzia – Ankylosing Spondylitis • Prescribed by a rheumatologist • Diagnosis of ankylosing spondylitis • Trials of two of the following were ineffective, contraindicated, or not tolerated: Cosentyx, Enbrel, Humira Cosentyx – Peripheral Spondyloarthritis • Prescribed by a rheumatologist • Diagnosis of peripheral spondyloarthritis • Intolerant to or failed therapy with sulfasalazine or methotrexate Enbrel or Humira – Polyarticular Juvenile Idiopathic Arthritis • Prescribed by a rheumatologist • Diagnosis of polyarticular juvenile idiopathic arthritis • Intolerant to or failed monotherapy with methotrexate ≥15mg/m2/week for > 3 months Orencia – Polyarticular Juvenile Idiopathic Arthritis • Prescribed by a rheumatologist • Diagnosis of polyarticular juvenile idiopathic arthritis • Experienced ineffectiveness, a contraindication to, or did not tolerate Enbrel or Humira • Or, stable on medication and switching route of administration (intravenous to/from subcutaneous) Actemra – Polyarticular Juvenile Idiopathic Arthritis • Prescribed by a rheumatologist • Diagnosis of polyarticular juvenile idiopathic arthritis • Experienced ineffectiveness, a contraindication to, or did not tolerate Enbrel or Humira • 162 mg every 3 weeks for weight <30 kg; 162 mg every 2 weeks for weight ≥30 kg Actemra - Systemic Juvenile Idiopathic Arthritis (SJIA) • Prescribed by a rheumatologist • 162 mg every other week for weight <100 kg; 162 mg every week for weight ≥100 kg Kineret • Prescribed by a rheumatologist • One of the following diagnoses: • Adult-Onset Still's Disease (ICD 10 Code: M06.1)

Drug	Prior Authorization Criteria
	• Systemic Juvenile Idiopathic Arthritis (ICD 10 Code: M08.2) • Neonatal-Onset Multisystem Inflammatory Disease (ICD 10 Code: M04.2) • Rheumatoid arthritis and polyarticular juvenile idiopathic arthritis are excluded indications for Kineret. Kineret will NOT be approved for these indications. Actemra – Giant Cell Arteritis • Prescribed by a rheumatologist • Diagnosis of giant cell arteritis confirmed by temporal artery biopsy • One of the following: • Giant cell arteritis has relapsed while on methotrexate and corticosteroids • Corticosteroids and methotrexate are unable to achieve remission • Experienced unacceptable side effects w/corticosteroids • 162 mg every week • Continuing therapy: Patient requires continued use to prevent relapse of giant cell arteritis Humira Criteria for Non-Infectious Intermediate, Posterior, or Pan-Uveitis: • Prescribed by, or in consultation with, an ophthalmologist or rheumatologist • Non-infectious intermediate, posterior, or pan-uveitis diagnosed by an ophthalmologist • Experienced an inadequate response to systemic corticosteroids in combination with immunosuppressants (methotrexate, mycophenolate mofetil, azathioprine, or cyclosporine) • Corticosteroid and immunosuppressant used, dosages, and date(s) of use or contraindication provided
Bosulif	• Prescribed by oncology or hematology specialist for one of the following: • Newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in an adult • Chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy in an adult
Botox (medical benefit)	• Diagnosis of chronic migraine in an adult patient • At least 15 headache days per month with headache lasting at least 4 hours per day for at least 3 months • The headaches are not due to acute medication overuse or another disorder • Moderate or severe disability from the headaches • Patient has tried non-drug treatment options, such as behavioral therapies, physical therapies, acupuncture, and lifestyle changes • Failure of two-month trials of three or more preventative medications from at least two of the following drug categories:

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
	• Anticonvulsants (topiramate, divalproex, carbamazepine) • Antidepressants (amitriptyline, venlafaxine) • Beta blockers (propranolol, timolol, metoprolol, atenolol, nadolol) • Other antihypertensive drugs (lisinopril, candesartan, clonidine, guanfacine) • The total dose does not exceed 200 units per treatment • For continuation of therapy, substantial clinical response to treatment since starting therapy, such as 50% reduction in monthly headache frequency, less usage of acute medications, fewer urgent care/emergency visits, improved ability to participate in activities of daily living (ADLs), ability to return to work, etc.
Budesonide (Entocort, Uceris)	• Reserved for members with Crohn's disease or ulcerative colitis and one of the following issues apply: • At high risk for complications from traditional corticosteroids • Currently taking immunomodulating drugs (e.g. azathioprine) • Have documented side effects with traditional corticosteroids, or • Unable to taper chronic traditional corticosteroid
Cabometyx	• Prescribed by oncologist for one of the following: • Advanced renal cell carcinoma with non-clear cell histology • Failure or contraindication to sunitinib (Sutent) • Advanced renal cell carcinoma with predominantly clear cell histology • Patient has poor- or intermediate-risk classification per the International Metastatic Renal Cell Carcinoma Database Consortium Criteria OR has failed one or more prior anti-angiogenic therapies • Hepatocellular carcinoma (HCC) • Previous treatment with sorafenib (Nexavar) • No Child-Pugh class B or C disease
Calcipotriene (Calcitrene, Dovonex)	• Prescribed or consulted by dermatology • Plaque psoriasis • Required failure or contraindication to topical corticosteroids
Calcipotriene/ betamethasone (Taclonex)	• Prescribed or consulted by dermatology • Moderate to severe plaque psoriasis • Required failure or contraindication to topical corticosteroids
Calcitriol ointment (Vectical)	• Prescribed or consulted by dermatology • Moderate to severe plaque psoriasis • Required failure or contraindication to topical corticosteroids, calcipotriene, Taclonex, and Tazorac

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Calquence	• Prescribed by an oncologist or hematologist • Limited to NCCN recommended indications • Relapsed/refractory to at least one prior therapy • Intolerant to ibrutinib (Imbruvica), but not refractory
Capecitabine (Xeloda)	• Prescribed by oncologist according to FDA indication and/or NCCN guidelines
Caprelsa	• Prescribed by oncologist • Diagnosis of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease
Cayston	• Diagnosis of cystic fibrosis • Pseudomonas aeruginosa

CGRP inhibitor (Aimovig, Emgality)	• Specialist – 1 of the following:
	  • Prescribed by, or in consultation with a neurologist
	  • United Council for Neurologic Subspecialties (UCNS)- certified headache medicine specialist
	  • Member of the American Headache Society
	  • Member of the National Headache Foundation
	  • Member of the International Headache Society
	  • Has a Certificate of Added Qualification in Headache Medicine
	  • American Board of Headache Management certified
	• Diagnosis of ≥ 4 migraine days per month for previous three months or longer
	• Failure of ≥ 3 month trials from two of three drug classes
	  • Anticonvulsants (topiramate, sodium valproate, etc.)
	  • Vasoactive agents (metoprolol, propranolol, etc.)
	  • Antidepressants (amitriptyline, venlafaxine, etc.)
	• Continuation
	  • Meaningful improvement in frequency and/or severity of migraine
	  • Will not be used concomitantly with onabotulinumtoxinA (Botox)

Cholbam	• Treatment of bile acid synthesis disorder OR adjunctive treatment of peroxisomal disorder • Prescribed by Hepatologist or Pediatric Gastroenterologist • Continuation requires documentation of improved or sustained liver function
Cometriq	• Prescribed by oncologist • Diagnosis of progressive, metastatic medullary thyroid cancer

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Corlanor	• Prescribed by cardiologist • Diagnosis of stable, symptomatic CHF with LVEF ≤35%, in sinus rhythm with resting HR ≥70 bpm • Failure of maximally tolerated doses of beta-blockers or contraindication to beta-blocker use
Cotellic	• Prescribed by oncologist • Diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation • Documentation of the presence of an approved mutation as detected by an FDA-approved test is provided • Used in combination with vemurafenib (Zelboraf)
Cystagon	• Prescribed according to the FDA indication
Cystic Fibrosis (Kalydeco, Orkambi, Symdeko)	• Prescribed by a pulmonologist at a Cystic Fibrosis Center of Excellence • Age ≥ 12 years • Homozygous for the F508del CFTR mutation or has at least one mutation in the CFTR gene that is responsive based on in vitro data/ clinical evidence; documented by an FDAcleared Cystic Fibrosis mutation test followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use • Continuation ◦ Prescriber attests that patient has been adherent to therapy
Denavir	• Prescribed according to the FDA indication • Failure of preferred agents
Dificid	• Documented Clostridium difficile infection in adults ≥18 years of age • Failure of metronidazole and oral vancomycin, or a documented contraindication/intolerance to metronidazole and vancomycin
Digestive enzymes (Pancreaze, Pancrelipase, Pertyze, Ultresa, Zenpep)	• Failure of Creon
Dofetilide (Tikosyn)	• Authorized Tikosyn prescriber • Failure of appropriate formulary alternatives (e.g. digoxin, amiodarone, sotalol)

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria

Dupixent	• Prescribed by or in consultation with an allergist, immunologist, or dermatologist
	• Patient is 18 years of age or older
	• Diagnosis of chronic severe atopic dermatitis (eczema) at baseline
	  • ≥10% BSA affected (with the exception of involvement in sensitive areas which would require chart note documentation of severity)
	  • Level of severity documented via SCORAD ≥40 or Eczema Area and Severity Index (EASI) score ≥21
	  • Or, submission of supporting documentation of continued disease severity and impaired activities of daily living while on most successful treatment regimen
	• Required documentation of trial and failure of the following:
	  • Medium-to-very high potency topical steroid
	  • Topical calcineurin inhibitors (tacrolimus, Elidel), including concomitant use with a topical steroid where appropriate
	  • Narrow band UVB phototherapy
	  • Immunosuppressants (cyclosporine, azathioprine, methotrexate, mycophenolate mofetil)
	• If disease was previously stabilized from the treatments above and then subsequently flared, documentation of flare prevention attempts through proactive, intermittent use as maintenance therapy of either topical steroid (1 to 2 times per week) or topical calcineurin inhibitor (2 to 3 times per week) on areas that commonly flare to help prevent relapse
	• Documentation of nonpharmacologic interventions, such as moisturizers being applied daily
	• For continuation of therapy, documentation with chart notes of positive clinical response and documentation of flare prevention and nonpharmacologic interventions for maintenance to prevent relapse

Emsam	• Prescribed according to the FDA indication • Failure of first-line agents
Entresto	• Prescribed by cardiologist • Diagnosis of chronic heart failure (NYHA Class II-IV) and reduced ejection fraction • Usage compatible with FDA approval
Erivedge	• Prescribed by oncologist or dermatologist • Patient is at least 18 years old • Diagnosis of locally advanced basal cell carcinoma or metastatic basal cell carcinoma • Recurrence after surgery OR not a candidate for surgery or radiation • If prescribed for locally advanced basal cell carcinoma, a trial of sonidegib (Odomzo) was ineffective, contraindicated, or not tolerated

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Esbrient or Ofev	• Prescribed by pulmonologist • Definitive diagnosis of IPF defined by: • No known cause of lung fibrosis • One of the following: Surgical lung biopsy revealing histopathological pattern of unspecified interstitial pneumonia (UIP), high-resolution computer tomography indicates definite UIP pattern, or high-resolution computer tomography indicates possible UIP pattern AND surgical lung biopsy reveals a histopathological pattern of probable UIP • Will not be used in combination with other agents to treat IPF • Prescriber attests that member is a nonsmoker or has ceased tobacco use for at least 6 weeks
Exjade	• Prescribed by a hematologist • Failure of deferoxamine or contraindication
Farydak	• Prescribed by oncologist • Diagnosis of multiple myeloma • Failure of at least 2 prior regimens, including Velcade (bortezomib) and an immunomodulatory agent • Used in combination with Velcade and dexamethasone
Fentanyl (Abstral, Actiq, Lazanda, Onsolis, Subsys)	• Diagnosis of cancer • Tolerant to opioid therapy (taking around-the-clock oral morphine 60 mg/day or more, transdermal fentanyl 25 mcg/h, oral oxycodone 30 mg/day, oral hydromorphone 8 mg/day, oral oxymorphone 25 mg/day, or an equianalgesic dose of another opioid daily for 1 week or longer) • Uncontrolled breakthrough pain • Member, prescriber, and pharmacy registered with TIRF REMS program • Failure of Fentora
Fentora (fentanyl tablet)	• Diagnosis of cancer • Tolerant to opioid therapy (taking around-the-clock oral morphine 60 mg/day or more, transdermal fentanyl 25 mcg/h, oral oxycodone 30 mg/day, oral hydromorphone 8 mg/day, oral oxymorphone 25 mg/day, or an equianalgesic dose of another opioid daily for 1 week or longer) • Uncontrolled breakthrough pain • Member, prescriber, and pharmacy registered with TIRF REMS program
Ferriprox	• Prescribed by hematology specialist • Diagnosis of transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate
Fetzima	• Prescribed by psychiatrist according to FDA indication • Failure of preferred agents

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Flucytosine (Ancobon)	• Prescribed by ID specialist according to FDA indication • Failure of preferred agents
Fondaparinux (Arixtra)	• Prescribed according to FDA indication • Failure of first-line agents
Fragmin	• Prescribed according to FDA indication • Failure of first-line agents

Fycompa	• Prescribed by a neurologist or epilepsy specialist for one of the following:
	  • Treatment of partial-onset seizures with or without secondarily generalized seizures
	  • Trial and failure or contraindication to lacosamide (Vimpat) and topiramate
	  • Adjunctive treatment for primary generalized tonic-clonic seizures
	  • Trial and failure of two of the following: lamotrigine, levetiracetam, primidone, topiramate

Genotropin (somatropin)	Adult PA criteria
	• Prescriber is, or has consulted with, an endocrinology specialist
	• Diagnosis of growth hormone deficiency (GHD):
	  • And one of the following:
	  • Presence of pituitary disease or condition affecting pituitary function, such as pituitary tumor, surgical damage, hypothalamic disease, irradiation or trauma
	  • Continuing treatment of childhood onset GHD
	  • And one of the following:
	  • Two (2) Growth Hormone (GH) stimulation tests <5 ng/mL (mcg/L)
	  • Two (2) pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement, such as TSH, ACTH, Gonadotropins, and ADH and one growth hormone stimulation test < 5 ng/mL
	  • Three (3) pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement and IGF-1 level below 80 ng/mL
	• Continuation of coverage
	  • Original documentation confirmed a diagnosis of GH deficiency
	  • Medication adherence is adequate
	Pediatric PA Criteria
	• Prescriber is, or has consulted with, a pediatric endocrinology specialist
	• Diagnosis of growth hormone deficiency (GHD)
	  • And one of the following:
	  • Two (2) growth hormone (GH) stimulation tests < 10 ng/mL

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
	(mcg/L) • One (1) GH stimulation test < 15ng/mL AND IGF-I and IGF-BP3 levels below normal (<2.5th percentile) as determined by the laboratory reference range for age • One (1) GH stimulation test < 10 ng/mL for child with defined CNS pathology, history of irradiation or genetic conditions associated with GHD • Multiple pituitary hormone deficiencies exist (at least two other in addition to GHD) • And both of the following: • Open epiphyses (when prescribed to promote growth and increase height) • Height is less than 3rd percentile (-1.88 SD) OR one-year growth velocity is less than 3rd percentile (-1.88 SD) as specified for age and sex • Diagnosis of Turner's Syndrome and both of the following: • Open growth plates • Height is less than the 5th percentile (-1.65 SD) OR projected height is less than 3rd percentile as specified for age and sex • Diagnosis of Prader-Willi Syndrome (PWS) confirmed through genetic testing and open growth plates • Diagnosis of small for gestational age (SGA) and both of the following: • Birth weight and/or length were more than 2 standard deviations (SD) below the mean for gestational age, and failed to show catch-up growth by age 2 • Height is less than the 3rd percentile (>1.88 SD) specified for age and sex • Continuation of coverage • All of the following: • Annual growth velocity is > 4.5 cm/year in a pre-pubertal child or > 2.5 cm/year in a post-pubertal child • Expected final adult height has not been achieved • Epiphyses remain open • Medication adherence is adequate • Additional consideration: • For the first year of therapy only - increase in growth velocity is > 50 percent • For members with Prader-Willi Syndrome only - if prescribed GH to improve body composition: body composition (lean body mass) has significantly improved
Gilotrif	• Prescribed by oncologist • Diagnosis of metastatic non-small cell lung cancer (mNSCLC) with non-resistant epidermal growth factor receptor (EGFR) mutations • Presence of mutation detected by FDA-approved test

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria

Hemlibra	• Prescribed by or in consultation with a hematologist
	• Diagnosis of Hemophilia A (congenital Factor VIII deficiency)
	• One of the following:
	  • Confirmation of high-titer inhibitors to Factor VIII (≥ 5 Bethesda Units)
	  • Moderate hemophilia (Factor VIII level <5%) with 2 or more prior episodes of spontaneous bleeding into joints with evidence of joint disease OR severe hemophilia (Factor VIII level <1%)
	  • Patient is NOT a suitable candidate for treatment with standard half-life Factor VIII recombinant products at a total weekly dose of ≤90 IU/kg
	• Continuing therapy: Documentation of positive clinical response to therapy

Hycamtin	• Prescribed by oncologist according to FDA indication

Ibrance	• Prescribed by oncologist
	• Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with one of the following:
	  • An aromatase inhibitor as initial endocrine based therapy in postmenopausal women
	  • Fulvestrant in women with disease progression following endocrine therapy

IBS-C or Constipation (Amitiza, Linzess)***	• Diagnosis of chronic constipation or irritable bowel syndrome with constipation
	• Serious attempts at symptomatic care over 6 months with the following agents have clearly failed to give relief:
	  • Bulking agents, specifically ispaghula husk
	  • Tricyclic antidepressants
	  • Laxatives
	• Prescribed by a GI specialist or has been consulted
	• Colonoscopy performed to rule out other causes
	• Evaluation and screening for psychological co-morbidities

IBS-D (Lotronex or Xifaxan)	• Prescribed by gastroenterologist
	• Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)
	• Usage compatible with the FDA (Food and Drug Administration) approval
	• Failure of the following medications:
	  • Anti-diarrheal medications, such as loperamide and diphenoxylate/atropine (Lomotil)
	  • Antispasmodic agents, such as dicyclomine and hyoscyamine
	  • Tricyclic antidepressants, such as amitriptyline
	• Failure of dietary modification, including lactose restricted diet, if lactose-

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
	intolerant; exclusion of gas-producing foods; low carbohydrate diet and elimination of fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs) • The patient has been evaluated and screened for psychological comorbidities

Iclusig	• Prescribed by hematology/oncology specialist for one of the following:
	  • Treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) or Ph+ ALL for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated
	  • Treatment of adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-pos

Idhifa	• Prescribed by or in consultation with an oncologist or hematologist • Diagnosis of relapsed/refractory AML with IDH2 mutation OR patient ≥ 60 years old and declines/not a candidate for intensive induction therapy and AML with IDH2 mutation • Documentation of IDH2 mutation required

Imatinib (Gleevec)	• Prescribed by hematology/oncology specialist for one of the following:
	  • Philadelphia chromosome positive chronic myeloid leukemia
	  • Unresectable and/or metastatic gastrointestinal stromal tumor
	  • Philadelphia chromosome positive acute lymphoblastic leukemia
	  • Myelodysplastic/ myeloproliferative disease
	  • Aggressive systemic mastocytosis
	  • Hypereosinophilic syndrome
	  • Chronic eosinophilic leukemia, or
	  • Unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans

Imbruvica	• Prescribed by oncologist according to FDA indication
Infergen	• Detectable levels of hepatitis C virus RNA in serum • Persistently elevated ALT • Signs of hepatitis on liver biopsy, approve for 6 months to assess response
Inlyta	• Prescribed by oncology/hematology specialist • Diagnosis of advanced renal cell carcinoma after failure of 1 prior systemic therapy, with documentation of the prior therapy tried

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Intron-A	• Detectable levels of hepatitis C virus RNA in serum • Persistently elevated ALT • Signs of hepatitis on liver biopsy, approve for 6 months to assess response
Iressa	• Prescribed by oncologist according to FDA indication
Itraconazole (Sporanox)	• Invasive Aspergillosis OR patient is intolerant or refractory to other therapy (fluconazole) OR onycomycosis, with documented/probable candida or mold species, or failed previous Lamisil treatment

Jakafi	• Prescribed by oncologist for one of the following:
	  • Polycythemia vera
	  • A trial of hydroxyurea was ineffective, contraindicated, or not tolerated
	  • Intermediate or high-risk myelofibrosis, including primary myelofibrosis, postpolycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis
	  • Platelet count is provided and is greater than 50,000 per µL
	• For continuation of treatment, documentation of improvement in debilitating symptoms (abdominal discomfort, pain under left ribs, early satiety, night sweats, itching, bone or muscle pain, inactivity) and/or weight gain

Jynarque	• Prescribed by a nephrologist
	• Autosomal dominant polycystic kidney disease (ADPKD) is rapidly progressing, defined by at least one of the following:
	  • Estimated glomerular filtration rate (eGFR) has declined >5 mL/min/1.73m^2 in the past year
	  • eGFR has declined ≥2.5 mL/min/1.73m^2 per year for the past 5 years
	  • Total kidney volume has increased >5% per year by repeated measurements
	• Patient is ≥18 years old and has an eGFR ≥25 mL/min/1.73 m^2

Kisqali	• Prescribed by, on in consultation with, an oncologist • Prescribed as initial endocrine-based therapy in combination with an aromatase inhibitor for the treatment of HR+/HER2- advanced metastatic breast cancer in postmenopausal women
Ledipasvir/ sofosbuvir (Harvoni)	• Prescribed by GI, ID, hepatology, or transplant specialist • Diagnosis of chronic HCV genotype 1 in an adult • Current HCV-RNA titer within past 3 months is <6 million • Patient does NOT have cirrhosis

Drug	Prior Authorization Criteria
	• Patient is treatment naïve • Patient is HIV-uninfected • Usage compatible with FDA approval • Duration of therapy is 8 weeks

Lenvima	• Prescribed by oncologist for one of the following:
	  • Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC)
	  • Unresectable hepatocellular carcinoma

Leukine	• Prescribed for one of the following indications:
	  • To shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections and infections resulting in death following induction chemotherapy in a patient ≥55 years old with acute myelogenous leukemia (AML)
	  • The mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation in an adult
	  • For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation in a patient ≥2 years old
	  • For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation in a patient ≥2 years old
	  • The treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation in a patient ≥2 years old
	  • To increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS])
	  • Trials of BOTH of the following were ineffective, contraindicated, or not tolerated: tbofilgrastim (Granix) and filgrastim-sndz (Zarxio)

Lonsurf	• Diagnosis of metastatic colorectal cancer (mCRC) • Previously tried the following: a) Fluoropyrimidine-based chemotherapy, b) Oxaliplatinbased chemotherapy, c) Irinotecan-based chemotherapy, d) Anti-VEGF therapy, e) AntiEGFR therapy (if RAS wild-type) • Prescribed by oncologist • Limited to 15-day supply for each fill for the first 3 months

Lynparza	• Prescribed by oncologist for one of the following:
	  • Deleterious or suspected deleterious germline BRCA mutated advanced ovarian cancer
	  • Documentation of deleterious or suspected deleterious germline BRCA mutation confirmed by FDA-approved test

Drug	Prior Authorization Criteria
	and provided with the request • Patient is platinum-refractory • First-line maintenance treatment of an adult with epithelial ovarian, fallopian tube, or primary peritoneal cancer • Documentation of deleterious or suspected deleterious germline BRCA mutation confirmed by FDA-approved test and provided with the request • Patient has advanced (Stage III or IV) disease • Patient has been treated with and exhibited a complete or partial response to platinum-based chemotherapy • Continuing therapy: 2 years of therapy if complete response • Maintenance treatment of recurrent disease of an adult with epithelial ovarian, fallopian tube, or primary peritoneal cancer • Patient has been treated with ≥2 lines of prior chemotherapy • Patient has platinum-sensitive disease (recurrence >6 months after penultimate platinum regimen) • Patient is in a complete or partial response to their most recent platinum based chemotherapy, which was administered within the past 8 weeks • Deleterious or suspected deleterious germline BRCA mutated human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer • Documentation of deleterious or suspected deleterious germline BRCA mutation confirmed by FDA-approved test and provided with the request • Patient has been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting • Patient has hormone receptor positive (HR+) disease AND has been treated with or it is inappropriate to use endocrine therapy, OR patient has hormone receptor negative (HR-) disease • Limited to 15-day supply for each fill for the first 3 months
Lyrica* **	• Diagnosis of epilepsy, partial onset seizures, and not adequately controlled with 1 to 3 concomitant antiepileptic drugs OR • Diagnosis of diabetic peripheral neuropathy (DPN), failure of 12-week trials of first-line agents (gabapentin, valproic acid, amitriptyline, venlafaxine, tramadol), max dose 300 mg/day OR • Diagnosis of postherpetic neuralgia (PHN) for at least 3 months following the healing of herpes zoster rash, failure of 12-week trials of first-line agents (gabapentin, amitriptyline, nortriptyline, desipramine), max dose 300 mg twice daily OR • Fibromyalgia (see Savella listing for fibromyalgia criteria)

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Makena (medical benefit)	• Prescribed by OB-GYN specialist • Pregnancy is a singleton • Has had a previous spontaneous pre-term delivery (singleton before 37 weeks) • Treatment is started between 16 weeks, 0 days and 20 weeks, 6 days of gestation • Once-weekly treatment is continued until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever comes first

Mavyret	• Prescribed by GI, ID, hepatology, or transplant specialist
	• Diagnosis of one of the following:
	  • HCV genotype 1, 2, 3, 4, 5, or 6, without cirrhosis or with compensated cirrhosis (Child-Pugh class A)
	  • HCV genotype 1 and previously treated with an NS5A inhibitor or NS3/4A protease inhibitor, but not both
	• Current HCV-RNA titer within past 3 months
	• Indicate if patient has or does not have cirrhosis
	• Indicate if patient is treatment naïve or has been previously treated for HCV
	  • If previously treated, indicate ALL prior treatments used
	• Usage compatible with FDA approval for each genotype
	  • 8-week treatment
	  • Patient does NOT have cirrhosis
	  • Patient has NOT been treated with an NS5A inhibitor or NS3/4A protease inhibitor
	  • If HCV genotype 3, patient is treatment naïve
	  • 12-week treatment
	  • Patient has either compensated cirrhosis, OR HCV genotype 1 and has failed prior treatment with an NS3/4A protease inhibitor
	  • Patient has NOT been treated with an NS5A inhibitor
	  • If HCV genotype 3, patient is treatment naive
	  • 16-week treatment
	  • Patient has one of the following:
	  • HCV genotype 1 and has failed prior treatment with an NS5A inhibitor (without an NS3/4A protease inhibitor)
	  • HCV genotype 3 and has failed prior treatment with an interferon, ribavirin, and/or sofosbuvir

Mekinist	• Prescribed by oncologist • Documentation of mutation as detected by an FDA-approved test • Prescribed in combination with Tafinlar for one of the following: • Diagnosis of unresectable or metastatic melanoma with BRAF

Drug	Prior Authorization Criteria
	V600E or BRAF V600K mutation • Prescribed for the adjuvant treatment of melanoma with BRAF V600E or V600K mutations and lymph node involvement, following complete resection • Diagnosis of metastatic NSCLC with a BRAF V600E mutation • Diagnosis of locally advanced or metastatic ATC with a BRAF V600E mutation and with no satisfactory locoregional treatment options
Mesnex	• Prescribed by oncologist for prevention of ifosfamide-induced hemorrhagic cystitis

Movantik	• Diagnosis of opioid-induced constipation
	• Serious attempts at symptomatic care over 6 months with the following agents have clearly failed to give relief:
	  • Bulking agents, specifically ispaghula husk
	  • Tricyclic antidepressants
	  • Laxatives
	• Prescribed by a GI specialist or has been consulted
	• Colonoscopy performed to rule out other causes
	• Evaluation and screening for psychological co-morbidities

Natpara	• Prescribed by specialist • Diagnosis of hypoparathyroidism with hypocalcemia • Hypocalcemia is not well-controlled on calcium supplements and active forms of vitamin D alone • Hypoparathyroidism is not caused by calcium-sensing mutations and is not acute postsurgical

Nerlynx	• Prescribed by or in consultation with an oncologist
	• Patient has early-stage HER2+ breast cancer
	• Patient has HR+ disease
	  • OR Patient has inflammatory breast cancer
	• Patient has a high-risk for recurrence defined by one of the following:
	  • Heavy nodal burden
	  • Age ≤ 35 years at diagnosis
	  • Locally advanced disease at diagnosis
	• Patient has completed trastuzumab therapy and will be starting neratinib within one year of completion

Neupogen (medical benefit)	• Oncology patients receiving myelosuppressive chemotherapy, BMT, or severe chronic neutropenia • Prescribed by oncologist

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Neupro	• Early-stage Parkinson's and difficulty swallowing tablets, OR • Restless legs syndrome (RLS) and failure of preferred agents
Nexavar	• Prescribed by oncologist according to FDA indication
Ninlaro	• Prescribed by oncologist or hematology specialist • Diagnosis of multiple myeloma • History of at least one prior therapy • Used in combination with lenalidomide (Revlimid) and dexamethasone
Noxafil	• Febrile neutropenia prophylaxis and/or • Patients with serious fungal infections who are intolerant or refractory to other therapy
NPlate	• Diagnosis of chronic idiopathic thrombocytopenia purpura of at least 6 months duration, failed at least 2 prior immunosuppressive therapies, age >18 years of age • Approval duration should be no longer than 8 weeks with reauthorization required demonstrating platelet response above 50,000/ml

Nucala (medical benefit)	• Ordered by a pulmonologist, allergist, or immunologist
	• Indicated for patients ≥12 years old
	• Has a diagnosis of eosinophilic asthma with a documented blood eosinophil count of:
	  • ≥150 cells/mm3 (cells per cubic millimeter) at therapy initiation
	  • ≥300 cells/mm3 in the previous 12 months
	• Other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease have been ruled out
	• Symptoms have not been adequately controlled by high dose inhaled corticosteroids with a long-acting bronchodilator and leukotriene inhibitor after at least 6 months of adherent therapy. Inadequate control demonstrated by hospitalization for asthma, systemic corticosteroids, and increasing need for short-acting inhaled beta2-agonists.

Nuedexta	• Diagnosis of pseudobulbar affect with ALS or MS, • Prescribed or consulted by neurology • Previous failed trial of one antidepressant
Ocaliva	• Prescribed by hepatologist or gastroenterologist • Diagnosis of primary biliary cholangitis (PBC) • At least 1 year history of and concurrent ursodiol treatment with documentation of ALP>2x ULN or TBIL>ULN, or documentation of ursodiol intolerance • Used in combination with ursodiol if inadequate response to ursodiol, or as monotherapy if intolerant to ursodio

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Odactra	• Prescribed by an allergist, immunologist, or ENT physician • Will not be used in combination with another sublingual or subcutaneous immunotherapy regimen
Odomzo	• Diagnosis of locally advanced basal cell carcinoma (laBCC) • Prescribed by oncologist or dermatologist • Patient is 18 years of age or older • Recurrence following surgery OR is not candidate for surgery or radiation therapy • Limited to 15-day supply for each fill for the first 3 months
Overactive Bladder (Darifenacin SR [Enablex], Oxytrol, Toviaz, Trospium SR [Sanctura XR])	• Failure of preferred formulary agents such as oxybutynin (ER), tolterodine (ER), and Vesicare
Oxsoralen Ultra, 8-MOP	• Diagnosis of moderate to severe plaque psoriasis >10% BSA • Prescribed by dermatologist • Failure (6-month trials) or contraindications to therapies in one of the following categories: topical agents (corticosteroids, tazarotene, calcipotriene), suppressive agents (cyclosporine, methotrexate)
Oxycodone ER, Oxycodone IR* **	• Diagnosis of chronic pain • Current pain contract • Random urine toxicology screens • Coordination of care with surgery, pain management, addictions, rehabilitation medicine • Preferred agents failed or contraindicated (MS Contin, fentanyl patches)

PCSK9 inhibitor (Repatha or Praluent)	• Homozygous familial hypercholesterolemia (HoFH):
	  • Prescribed by, or in consultation with, a cardiologist, lipidologist, or endocrinologist
	  • Prescriber is, has consulted with, or is affiliated with, a Familial Hypercholesterolemia Specialist (https://thefhfoundation.org/find-fh-specialist)
	  • Patient has:
	  • Two parents diagnosed with HeFH OR genetic confirmation of LDL receptor mutation
	  • Two of the following:
	  • Xanthomas present ≤ 10 years of age
	  • Atherosclerotic disease ≤ 20 years of age (written

Drug	Prior Authorization Criteria
	documentation required) • Untreated total cholesterol > 290 mg/dL or LDL-C > 190 mg/dL • Most recent full lipid panel, including Apo-B, and 2 previous lipid panels • Not being used in combination with Juxtapid, Kynamro or apheresis • Clinical atherosclerotic cardiovascular disease (ASCVD) or Heterozygous familial hypercholesterolemia (HeFH) and unable to meet LDL goal: • Prescribed by, or in consultation with, a cardiologist, lipidologist, or endocrinologist • Patient has one of the following: • Clinical atherosclerotic cardiovascular disease (ASCVD) defined by one of the following: • Acute coronary syndromes (ACS) • History of myocardial infarction (MI) • Ongoing angina (stable or unstable) • Prior coronary or other arterial revascularization • Prior stroke or transient ischemic attack (TIA) • Peripheral arterial disease of atherosclerotic origin • Heterozygous familial hypercholesterolemia, defined by one of the following: • DNA-based evidence of mutation in the LDLR, Apo B, PCSK9 mutation • Untreated LDL-C > 190 mg/dl AND Tendon xanthomas in patient or first/second degree relative • Untreated LDL-C > 190 mg/dl AND either first degree relative <60 years of age or second degree relative <50 years of age with premature heart disease • Untreated LDL-C > 190 mg/dl AND First or second degree relative with total cholesterol >290 mg/dl • Recent fasting lipid panel (< 3 months) provided • Patient has failed an 8 week trial of high-intensity statin (atorvastatin ≥ 40 mg OR rosuvastatin ≥ 20 mg) in combination with ezetimibe • Prescriberatteststhatpatientwasadherenttotherapy • LDLlevelremains>100mg/dLOR • LDLlevelremains>70mg/dLANDpatienthasdiabetes. • Documentation of trial attempts must be submitted, including trial dates and LDL levels before and after. • Clinical ASCVD or Heterozygous Familial Hypercholesterolemia (HeFH) and unable to tolerate statins: • Prescribed by, or in consultation with, a cardiologist, lipidologist, or endocrinologist

Drug	Prior Authorization Criteria

	• Patient has one of the following:
	  • Clinical atherosclerotic cardiovascular disease (ASCVD) defined by one of the following:
	  • Acute coronary syndromes (ACS)
	  • History of myocardial infarction (MI)
	  • Ongoing angina (stable or unstable)
	  • Prior coronary or other arterial revascularization
	  • Prior stroke or transient ischemic attack (TIA)
	  • Peripheral arterial disease of atherosclerotic origin
	  • Heterozygous familial hypercholesterolemia, defined by one of the following:
	  • DNA-based evidence of mutation in the LDLR, Apo B, PCSK9 mutation
	  • Untreated LDL-C > 190 mg/dl AND Tendon xanthomas in patient or first/second degree relative
	  • Untreated LDL-C > 190 mg/dl AND either first degree relative <60 years of age or second degree relative <50 years of age with premature heart disease
	  • Untreated LDL-C > 190 mg/dl AND First or second degree relative with total cholesterol >290 mg/dl
	  • Recent fasting lipid panel (<3 months) provided
	  • Patient has failed 3 attempts with statins in combination with ezetimibe, including an attempt with a low or alternatively-dosed statin (twice weekly low-dose rosuvastatin or atorvastatin, low-intensity pitavastatin or pravastatin) in combination with ezetimibe
	  • LDL level remains >100 mg/dL OR
	  • LDL level remains >70 mg/dL AND patient has diabetes.
	  • Documentation of trial attempts must be submitted, including trial dates, LDL levels before and after, and description of adverse events leading to discontinuation.
	• Continuation criteria (all indications):
	  • Patient has demonstrated adherence to therapy via claims data
	  • Both recent (within 3 months) and pre-PCSK-9 therapy baseline LDL levels provided.

Picato	• Diagnosis of actinic keratosis Picato • Prescribed by dermatology • Failure of first-line agents
Prolia (medical benefit)	• Usage compatible with the FDA (Food and Drug Administration) approval • Diagnosis of osteoporosis • Failure of oral bisphosphonate therapy and intravenous bisphosphonate therapy (Reclast) for at least one of the following reasons:

Drug	Prior Authorization Criteria
	• Diagnosis of gastrointestinal conditions such as Barrett's esophagus, esophageal erosions, or delayed esophageal emptying • Progression of boneloss as documented by bone density measurements after at least 12 months of adherent therapy • Occurrence of osteoporotic fracture or atypical femur fracture while on treatment • Change in treatment plan after completing 3 to 5 years of bisphosphonate therapy for a patient who is at high risk of fracture • Or, diagnosis of breast cancer with aromatase inhibitor-induced bone loss • Or, diagnosis of prostate cancer with androgen deprivation-induced bone loss
Promacta	• Prescribed by hematology specialist for one of the following: • Diagnosis of chronic idiopathic thrombocytopenia purpura of at least 6 months duration • Failed at least 2 prior immunosuppressive therapies • Age>18yearsofage • Approval duration should be no longer than 8 weeks with reauthorization required demonstrating platelet response above 50,000/ml • Diagnosis of hepatitis C associated thrombocytopenia • Patient needs to initiate interferon-based therapy • Diagnosis of severe aplastic anemia • Patient has had an insufficient response to immunosuppressive therapy or will be using first-line in combination with immunosuppressant therapy
Pulmonary Arterial Hypertension (PAH) (Adcirca, Letairis, Opsumit, Tracleer)	• Prescribed by pulmonologist or cardiologist • Pulmonary arterial hypertension diagnosed by right heart catheterization and includes a 6 minute • Walk distance between 150 and 450 meters • Failure of vasodilators, calcium channel blockers, and sildenafil (Revatio)
Quillivant XR	• Diagnosis of ADHD • Inability to swallow pills • Requires long-acting preparation
Regranex	• Prescribed by wound management specialist • Diagnosis of severe diabetic neuropathic ulcers of the lower extremities that extend into the subcutaneous tissue or beyond and have an adequate blood supply

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Relistor	• Opioid-induced constipation in patients with advanced illness receiving palliative care • Documentation of failure or intolerance to other laxative agents (osmotic, stimulant and bulk laxatives
Restasis	• Prescribed by an ophthalmologist or optometrist
Revlimid	• Prescribed by oncologist according to FDA indication and/or NCCN guidelines
Riluzole (Rilutek)	• Diagnosis of amyotrophic lateral sclerosis

Rubraca	• Prescribed by oncologist or OB/GYN for one of the following:
	  • Deleterious BRCA mutated advanced ovarian cancer
	  • Documentation of deleterious BRCA mutation by an FDA-approved test is provided
	  • Previous treatment with ≥ 2 lines of chemotherapy
	  • Maintenance treatment of diagnosed recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer
	  • Previous treatment with ≥2 lines of prior chemotherapy
	  • Platinum-sensitive disease(recurrence >6months after penultimate platinum regimen)
	  • In a complete or partial response to most recent platinum-based chemotherapy, which was administered within the past 8 weeks

Rydapt	• Prescribed by, or in consultation with, an oncologist or hematologist
	• FDA indication
	  • Newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
	  • Aggressive systemic mastocytosis (ASM
	  • One or more C-Findings
	  • Systemic mastocytosis with associated hematological neoplasm (SM-AHN)
	  • SM diagnostic criteria plus clonal hematologic nonmast cell lineage disorder
	  • Mast cell leukemia (MCL)
	  • Bone marrow biopsy shows a diffuse infiltration, usually compact, by atypical, immature mast cells
	  • Bone marrow aspirate smears show 20% or more mastcells

Sabril	• Diagnosis of complex partial seizures

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
	• Trial of all formulary alternatives or documentation explaining why some formulary options are not medically appropriate • Copies of SHARE enrollment materials • Documentation of ophthalmic examinations according to SHARE program requirements. • Or a diagnosis of infantile spasms • Age-restricted <2 years of age • If approved, for an initial coverage duration of 30 days
Samsca	• Diagnosis that matches the FDA-approved labeling, excluding the coverage for use in the outpatient management of congestive heart failure • Laboratory confirmed hyponatremia • Therapy should be initiated in hospital • Limited to a maximum of 30 days of therapy
Sancuso	• Request from oncology • Diagnosis of cancer with treatment using a highly emetogenic or moderately emetogenic chemotherapy regimen
Savella	• Diagnosis of fibromyalgia by ACR criteria of widespread pain/symptoms for at least 3 months using the Widespread Pain Index (WPI) and Symptom Severity (SS) scale • Failure of 12-week trials of first-line agents (amitriptyline, cyclobenzaprine, duloxetine, gabapentin, SSRI +/- NSAID, tramadol +/- acetaminophen) • Non-pharmacologic therapies (documented exercise plan, cognitive behavioral therapy, complementary therapies)
Sildenafil (Revatio)	• Prescribed by pulmonologist or cardiologist • Diagnosis of pulmonary arterial hypertension including a 6 minute walk distance between 150 and 450 meters • Failure of vasodilators and calcium channel blockers
Sirturo	• Prescribed by ID specialist • As part of combination therapy in adults with pulmonary multi-drug resistant tuberculosis (MDR-TB)
Sivextro	• Prescribed by infectious disease specialist • Diagnosis of acute bacterial skin and skin structure infection (ABSSSI) caused by designated susceptible bacteria in an adult patient • Limited to 6 days of treatment
Sklice	• Tried and failed or was intolerant to an over-the-counter lice treatment for current infestation (including medication tried and trial date)

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria

Sofosbuvir/ velpatasvir (Epclusa)	• Prescribed by GI, ID, hepatology, or transplant specialist
	• Diagnosis of chronic HCV genotype 2 or 3 in an adult
	• Current HCV-RNA titer within past 3 months
	• Indicate if patient has compensated (Child-Pugh A), decompensated (Child-Pugh B and C), or no cirrhosis
	  • If patient has decompensated cirrhosis, weight-based ribavirin will be coadministered
	• Indicate if patient is treatment naïve or has been previously treated for HCV
	  • If previously treated, indicate ALL prior treatments used
	• Usage compatible with FDA approval for each genotype
	• Duration of therapy is for 12 weeks

Sprycel	• Prescribed by a hematology/oncology specialist for one of the following:
	  • Adult member with newly diagnosed with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
	  • Adult member with chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy
	  • Pediatric member with Ph+ CML in chronic phase
	  • Adult member with Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy
	  • Pediatric member 1 year of age or older with newly diagnosed Ph+ ALL (to be used in combination with chemotherapy)

Stivarga	• Prescribed by oncologist, AND • Diagnosis of locally advanced, unresectable, or metastatic GI stromal tumor with trial and failure of imatinib (Gleevec) and sunitinib (Sutent) OR diagnosis of metastatic colorectal cancer with trial and failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and an anti-VEGF therapy, and if KRAS wild type, an anti-EGFR therapy OR diagnosis of hepatocellular carcinoma (HCC) with previous treatment of sorafenib (Nexavar)
Sublingual immunotherapy (Grastek, Oralair, Ragwitek)	• Prescribed by allergist • Positive skin test or in vitro testing for pollen-specific IgE antibodies

Sutent	• Prescribed by oncologist for one of the following:
	  • Unresectable locally advanced or metastatic pancreatic Neuroendocrine Tumor (pNET)
	  • Advanced Renal Cell Carcinoma (RCC)
	  • Gastrointestinal Stromal Tumor (GIST) with documented disease

Drug	Prior Authorization Criteria
	progression or contraindication with imatinib (Gleevec) • Patient is 18 years of age or older
Sylatron	• Prescribed by oncologist • For the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection, including complete lymphadenectomy
Symlin	• Endocrinologist/diabetologist consult • Inadequate response optimal insulin therapy • Quantity limit of 0.7 ml per day (20 ml per month)
Synarel	• Prescribed by specialist according to FDA indication • Failure of preferred agents
Tacrolimus ointment (Protopic)	• Dermatology consult • Failure or contraindication to topical corticosteroids
Tadalafil (Cialis)	• Prescribed by urologist • Diagnosis of moderate to severe benign prostatic hyperplasia (BPH) • Failure of alpha blockers (doxazosin, terazosin, tamsulosin, alfuzosin, silodosin) • Failure of androgen hormone blockers (finasteride, dutasteride) • No diagnosis of erectile dysfunction
Tafinlar	• See Mekinist listing for criteria

Tagrisso	• Prescribed by oncologist
	• Diagnosis of metastatic non-small cell lung cancer (NSCLC) with one of the following:
	  • Epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations
	  • EGFR T790M mutation-positive after prior use of afatinib (Gilotrif), gefitinib (Iressa), or erlotinib (Tarceva)
	• Mutation detected by an FDA-approved test

Tarceva	• Diagnosis of nonsmall cell lung cancer, pancreatic cancer • Prescribed by oncologist
Targretin gel	• Prescribed by oncologist or dermatologist • Diagnosis of Stage IA or IB cutaneous T-cell lymphoma in patients who have refractory or persistent disease after other therapies or who have not tolerated other therapies

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
	• Failure of Valchlor and non-drug therapies (PUVA, UVB, radiation, phototherapy)
Tasigna	• Prescribed by oncology/hematology specialist • Diagnosis of chronic phase (CP) or accelerated phase (AP) Ph+ CML
Tavalisse	• Prescribed by hematologist • Diagnosis of chronic immune thrombocytopenia • Relapsed/refractory to at least one treatment • Platelet count <30,000/µl)
Tazarotene (Tazorac)	• Prescribed or consulted by dermatology • Moderate to severe plaque psoriasis • Required failure or contraindication to topical corticosteroids
Temozolomide (Temodar)	• Diagnosis of glioblastoma multiforme or anaplastic astrocytoma • Prescribed by oncologist

Testosterone* **	• PSA <4 ng/ml OR if high risk for prostate cancer, PSA <3 ng/ml
	• Does not have sleep apnea OR is compliant with CPAP (submit last 60 days of machine use
	• Failure or contraindication to testosterone IM injections
	• AND one of these criteria:
	  ◦ Two laboratory-confirmed low total testosterone tests
	  ◦ One total testosterone tests near the lower limit of normal AND one low free testosterone level
	  ◦ One low total testosterone test AND elevated FSH and/or LH
	• AND three of the following signs/symptoms:
	  ◦ Eunuchoidism, hypogonadism, castration
	  ◦ Breast discomfort/gynecomastia
	  ◦ Mild anemia
	  ◦ Height loss, low trauma fracture, or low bone mineral density
	  ◦ Depressed mood
	  ◦ Sleep disturbance

Tetrabenazine (Xenazine)	• Prescribed by specialist in treating Huntington chorea patients • Failure of at least 2 drugs • Medical statement regarding what limitations chorea has imposed on the member • No depression, no schizophrenia, no underlying arrhythmias, no history of dysphagia or aspiration pneumonia
Thalomid	• Prescribed by oncologist according to FDA indication and/or NCCN guidelines

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Tobramycin (TOBI)	• Prescribed by pulmonologist according to FDA indication
Tranexamic acid (Lysteda)	• Diagnosis of heavy menstrual bleeding • Failure or contraindication to oral contraceptives • Limited to 3 courses of therapy each year
Tretinoin cap	• Prescribed by oncologist according to FDA indication
Trintellix	• Prescribed by psychiatrist according to FDA indication • Failure of preferred agents

Truvada	• Prescribed by infectious disease specialist for one of the following:
	  • Active treatment of Human Immunodeficiency Virus (HIV)
	  • Post-exposure prophylaxis following suspected or confirmed HIV or Hepatitis B Virus (HBV) for needle stick
	  • Duration of treatment is 1 month
	  • Pre-exposure prophylaxis
	  • Patient is at high risk for contracting HIV due to sexual transmission
	  • Patient is an adult or adolescent weighing ≥35 kg
	  • Patient is HIV negative with the last test occurring within the previous 3 months
	  • Prescriber has completed the REMS Prescriber Checklist
	  • Patient and prescriber have signed the REMS Agreement Form and it is saved in the member's medical chart
	  • Provide expected duration of treatment
	  • Continuing therapy: Patient continues to be tested every 3 months

Tykerb	• Prescribed by oncologist/hematologist and one of the following criteria must be met:
	  • Prescribed in combination with capecitabine (Xeloda), for the treatment of a patient with advanced or metastatic breast cancer that overexpresses HER2 and who has received prior therapy including an anthracycline, a taxane, and trastuzumab (Herceptin) OR
	  • Prescribed in combination with letrozole (Femara), for the treatment of patient with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor OR
	  • Prescribed in combination with trastuzumab, for the treatment of a patient with advanced or metastatic breast cancer that overexpresses HER2 and who has received prior therapy including

Drug	Prior Authorization Criteria
	an anthracycline, a taxane, and more than 2 prior courses of trastuzumab
Tyvaso	• Prescribed by pulmonologist or cardiologist • Diagnosis of pulmonary arterial hypertension • Failure of vasodilators, calcium channel blockers, and sildenafil (Revatio) • Used as add-on therapy to phosphodiesterase inhibitors or endothelin receptor antagonists
Tyzeka	• Prescribed by GI or ID specialist according to FDA indication
Uloric	• Prescribed or consultation by rheumatology • Joint changes based on X-ray • Failure of first-line agents • A dietary consult
Uptravi	• Prescribed by pulmonologist or cardiologist • Diagnosis of pulmonary arterial hypertension (PAH, WHO Group 1) • Failure of vasodilators, calcium channel blockers, and sildenafil (Revatio)
Valchlor	• Prescribed by oncologist or dermatologist • Diagnosis of Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy
Valganciclovir (Valcyte)	• Prescribed by ID or transplant specialist according to FDA indication
Veltassa	• Prescribed by nephrologist, cardiologist, or endocrinologist • Diagnosis of hyperkalemia • K+ ≥ 5.5 mmol/L

Venclexta	• Prescribed by oncologist or hematologist for one of the following:
	  • Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
	  • Documentation of at least one prior therapy
	  • Diagnosis of acute myeloid leukemia
	  • Patient is at least 60 years of age or prescriber attests that intensive chemotherapy is NOT an option for this member

Ventavis	• Prescribed by cardiologist or pulmonologist • Diagnosis of PAH confirmed by right heart catheterization
Verzenio	• Prescribed by or in consultation with an oncologist • Patient has not progressed on prior CDK4/6 therapy

Drug	Prior Authorization Criteria

	• Prescribed for:
	  • Initial endocrine-based therapy in combination with an aromatase inhibitor for the treatment of HR+, HER2- advanced metastatic breast cancer in a postmenopausal woman OR
	  • Second-line endocrine-based therapy in combination with fulvestrant for the treatment of HR+, HER2- advanced/metastatic breast cancer in a woman OR
	  • Monotherapy treatment of HR+, HER2- advanced/metastatic breast cancer in an adult with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

Vimpat	• Diagnosis of partial-onset seizures • Prescribed by or consulted with neurologist • Failed first-line agents such as divalproex, gabapentin, lamotrigine, levetiracetam, topiramate, and zonisamide
Voriconazole (Vfend)	• Invasive Aspergillosis, or • Patient is intolerant or refractory to other therapy (fluconazole, itraconazole)

Vosevi	• Prescribed by GI, ID, hepatology, or transplant specialist
	• Diagnosis of one of the following:
	  • HCV genotype 1, 2, 3, 4, 5, or 6 without cirrhosis or with compensated cirrhosis (Child-Pugh class A) and previously treated with an NS5A inhibitor
	  • HCV genotype 1a or 3 without cirrhosis or with compensated cirrhosis (Child-Pugh class A) and previously treated with sofosbuvir without an NS5A inhibitor
	• Current HCV-RNA titer within past 3 months
	• Indicate if patient has or does not have cirrhosis
	• Indicate ALL prior treatments used
	• Usage compatible with FDA approval for each genotype
	• Duration of therapy is 12 weeks

Votrient	• Prescribed by oncologist according to FDA indication
Xadago	• Prescribed by neurologist • Diagnosis of Parkinson's disease • Patient continued to experience "off" episodes or experienced intolerable adverse effects while using levodopa/carbidopa in combination with rasagiline AND • Patient continued to experience "off" episodes or experienced intolerable adverse effects while using levodopa/carbidopa in combination with entacapone

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
Xalkori	• Prescribed by oncologist • Anaplastic lymphoma kinase (ALK)-positive or ROS1-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test
Xolair*** (medical benefit)	Asthma: • Ordered by pulmonologist or allergist • ≥6 years of age • IgE value of >30 • Positive skin test or in vitro testing (blood test for allergen-specific IgE antibodies such as the RAST) for one or more perennial aeroallergens (i.e., house dust mite, animal dander, cockroach, feathers, mold spores) • Symptoms have not been adequately controlled by high-dose inhaled corticosteroids after at least 6 months of therapy • Inadequate control demonstrated by hospitalization for asthma, systemic corticosteroids, increasing need for short-acting inhaled beta2-agonists • Compliant use of a leukotriene inhibitor • Reasonable attempt to minimize environmental factors • Approvals are limited to a 3-month period and will be reevaluated. Prescriber must provide medical records to document response. Rx history review for compliance and rescue medication use. Decrease in corticosteroid use. CIU: • Diagnosis of chronic idiopathic urticaria (CIU) in a patient 12 years and older • Ordered by allergist, immunologist, or dermatologist. • Patient continues to have symptoms despite compliant use of the following: • Scheduled, high dose antihistamines • Immunomodulators (cyclosporine, hydroxychloroquine, mycophenolate, tacrolimus) • For continuation, clinically documented improvement from prior to initiating Xolair from an office visit in the preceding 12 months including at least one of the following: • Reduction in exacerbation frequency • Reduction in exacerbation intensity
Xopenex	• Failure of Ventolin • Adherence to asthma-control medications

Xtandi	• Prescribed by oncologist for one of the following:
	  • Diagnosis of metastatic castration-resistant prostate cancer (mCRPC)
	  • Failure or contraindication to abiraterone (Zytiga)

Drug	Prior Authorization Criteria
	• Diagnosis of non-metastatic castration-resistant prostate cancer (non-mCRPC) • Documentation of prostate surface antigen doubling-time (PSADT) in ≤10 months

Xultophy	• Patient failed to achieve A1c ≤ 7.0 after 3 months of either:
	  • Maximally dosed glucagon-like peptide-1 receptor agonist OR
	  • Basal insulin of 30 units per day or greater
	• OR patient is currently using basal insulin in combination with a GLP-1 RA

Xyrem	• Prescribed by sleep medicine specialist • Diagnosis of narcolepsy • Failure of first-line agents
Zarxio	• Oncology patients receiving myelosuppressive chemotherapy, BMT, or severe chronic neutropenia • Prescribed by oncologist
Zejula	• Prescribed by, or in consultation with, an oncologist • Diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer • Previous treatment with at least 2 lines of chemotherapy • Platinum-sensitive disease (recurrence > 6 months after penultimate platinum regimen) • In a complete or partial response to their most recent platinum-based chemotherapy, which was administered within the past 8 weeks

Zelboraf	• Metastatic melanoma (see Cotellic listing for criteria), or
	• Diagnosis of Erdheim-Chester disease with a BRAF V600 mutation
	  • Prescribed by oncologist
	  • NOT used in combination with cobimetinib (Cotellic)
	  • Documentation of the presence of the mutation as detected by an FDA-approved test is provided

Zoledronic acid (Reclast; medical benefit)	• Usage compatible with the FDA (Food and Drug Administration) approval
	• Diagnosis of osteoporosis
	• Failure of oral bisphosphonate therapy for one of the following reasons:
	  • Diagnosis of gastrointestinal conditions such as Barrett's esophagus, esophageal erosions, or delayed esophageal emptying
	  • Progression of bone loss as documented by bone density measurements after at least 12 months of adherent therapy
	  • Occurrence of osteoporotic fracture or atypical femur fracture while on treatment
	  • Change in treatment plan after completing 3 to 5 years of oral

Prior Authorization Criteria (continued)

Drug	Prior Authorization Criteria
	bisphosphonate therapy for a patient who is at high risk of fracture
Zolinza	• Prescribed by oncologist • Diagnosis of cutaneous manifestations of cutaneous T-cell lymphoma in a patient who has progressive, persistent or recurrent disease on or following two systemic therapies
Zontivity	• Prescribed by cardiologist • Usage compatible with FDA approval • Patient has history of myocardial infarction (MI) or has peripheral arterial disease (PAD) • Used in combination with aspirin and/or clopidogrel
Zortress	• Prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant
Zydelig	• Prescribed by oncologist • Diagnosis of relapsed chronic lymphocytic leukemia (CLL) • Must be used in combination with rituximab (Rituxan) • Failure of prior systemic therapy
Zyflo or zileuton ER (Zyflo CR)	• Prescribed by pulmonologistor allergist • Failure of first-line agents
Zykadia	• Prescribed by, or in consultation with, an oncologist • Diagnosis of ALK positive metastatic non-small cell lung cancer, as determined by an FDA-approved test

Drug Exception

This section does not apply to non-covered drugs.

If the physician believes that a drug not found on the MercyCare formulary is necessary for the patient then they must apply for the drug exception.

Drug exception criteria:

1. Patient previously treated with the drug AND it would be dangerous to the patient's health or unreasonably difficult to switch patient to formulary alternatives, or
2. The requested drug is medically necessary and ALL formulary alternatives (including drugs from other drug classes) are inappropriate for the patient, or have failed.

In addition the drug must be:

1. Medically necessary for patient's medical condition, and appropriate given the patient's medical history; and
2. Prescribed in a manner consistent with its FDA approved indication(s) and manufacturer recommendations; and
3. Prescribed in its most cost-effective dosing regimen; and
4. Used in a manner consistent with any and all guidelines and criteria developed, adopted, or researched by MercyCare.
5. Not listed as an exclusion in the member's drug rider or summary plan description.

All exceptions are subject to approval from MCHP. If you need a copy of the Non-Formulary request form, please visit our website at www.mercycarehealthplans.com, or contact customer service at (800) 895-2421.

Specialty Pharmacy Program

MercyCare Health Plans utilizes Mercy Pharmacies, which are categorized as specialty pharmacies. Only these specialty pharmacies are used to dispense select medications, which are indicated on the formulary as MSP or Tier 4. Some of the medications require prior authorization from MercyCare Health Plans. After the request has been received and approved, MercyCare members are required to select a Mercy Pharmacy to obtain the prescribed medication. These medications will be limited to either a 15 or 30 day supply per prescription fill or a specified quantity based on limits established in the formulary. Depending on the drug and the member's plan, an alternative Network Specialty Pharmacy may be designated. For more information, contact customer service at (800) 895-2421.

Mercyhealth Mall Pharmacy
1010 N. Washington St
Janesville, WI 53538
Hours: M-F 8-6, Sat 9-1
(608) 754-0286

Mercyhealth Milton Pharmacy
725 S Janesville St
Milton, WI 53563
Hours: M-F 9-6, Sat 9-1
(608) 868-6777

Mercyhealth West Pharmacy
1000 Mineral Point
Janesville, WI 53548
Hours: daily 8:30-5:30
(608) 741-6980

Mercyhealth Walworth Pharmacy
N2950 State Road 67
Lake Geneva, WI 53147
Hours: M-F 8-6, Sat 9-1
(262) 245-2319

Mercyhealth East Pharmacy
3524 E Milwaukee St
Janesville, WI 53546
Hours M-F 8:30-6, Sat 9-1
(608) 754-5194

Mercyhealth Woodstock Pharmacy
2000 Lake Ave
Woodstock, IL 60098
Hours: M-F 9-6, Sat 9-1
(815) 337-4116

Extended Supply Program

MercyCare offers an extended supply program that makes it more convenient for members to receive their prescriptions. If their prescription drug benefit allows them to receive a 90-day supply, they may be able to participate in this program. Members have the option to pick up their 90-day prescription at any Mercyhealth pharmacy. If they choose to have their 90-day supply mailed, the Mercyhealth Mall Pharmacy will be the mail order pharmacy. If you would like more information about our program please visit our website at www.mercycarehealthplans.com, or contact customer service at (800) 895-2421.

Some benefit designs require that mail order through Mercy Mall Pharmacy be used for certain medications. To identify whether your benefit design requires mandatory mail order medications, please check your drug rider or summary plan description, or contact customer service at (800) 895-2421. Customer service will provide you with a written list of mandatory mail order medications upon request.

Not all medications are good candidates for extended supply, such as antibiotics, medications that are taken on an "as needed" basis and medications that require special handling, such as refrigeration. This includes specialty drugs (SP, MSP, or Tier 4), which are only covered up to a 30-day supply for each fill.

Prescription Drug Glossary

Co-insurance
Co-insurance means the member's portion, expressed as a percentage of the fee for covered services that the member is required to pay for certain covered drugs.

Co-payment
Co-payment means the portion, expressed as a fixed dollar amount, that the member is required to pay for certain covered drugs.

Deductible
Deductible means a pre-determined amount of money that an individual member may have to pay before benefits are payable by MercyCare. The single deductible applies to each member each contract year, and the family deductible amount is the most that the employee and his or her dependents must pay each contract year.

Generic
A generic equivalent means a prescription drug available from more than one drug manufacturer that has the same active therapeutic ingredient as the brand or trade name prescription drug prescribed.

Maximum out-of-pocket
Maximum out-of-pocket means the portion of covered charges for which the member is responsible because of applicable coinsurance, co-payment, and/or deductible provisions.

MercyCare Drug Formulary
MercyCare Drug Formulary means the comprehensive listing of prescription medications available to a member.

Non-participating pharmacy
Non-participating pharmacy means any pharmacy that does not have a contractual relationship with MercyCare for the provision of pharmacy services or supplies to members.

OTC (over-the-counter)
Over-the-counter (OTC) drugs on the preferred drug list are covered only with a prescription.

Non-preferred drug
All drugs not on MercyCare's preferred drug list.

Participating pharmacy
Participating pharmacy means any pharmacy that has contracted with MercyCare to provide pharmacy services or supplies to members.

Preferred drug
Name brand, generic or OTC drugs in our preferred drug list as determined by MercyCare.

Prescription drug
Prescription drug means any medicinal substance, the label of which, under the Federal Food, Drug and Cosmetic Act, is required to bear the legend: "Caution: Federal Law prohibits dispensing without a prescription."

Usual and customary charge
Usual and customary charge is the dollar amount for a treatment, service or supply provided by a health care provider that is reasonable, as determined by the Plan, when taking into consideration, among other factors determined by MercyCare, amounts charged by health care providers for similar treatment, services and supplies when provided in the same general geographic area under similar or comparable circumstances.

Pharmacy and Therapeutics (P&T) Committee

The MercyCare P&T Committee consists of physicians and participating pharmacists whose primary purpose is to recommend policies in the evaluation, selection, and therapeutic use of and to educate members on matters related to drugs and drug use. The P&T Committee meets quarterly to determine formulary status of new-to-market and existing drugs. Updates are communicated to the MercyCare Health Plans Participating Providers through physician newsletters.

Product Selection Criteria

The MercyCare P&T Committee will consider all FDA-approved drugs for inclusion on the formulary, except those drugs in therapeutic classes excluded from coverage by MercyCare. The evaluation includes a literature review, and expert opinion may also be sought. Formal reviews are prepared which typically address the following information:

- Safety
- Efficacy
- Comparative studies
- Approved indications
- Adverse Effects
- Contraindications/Warnings/Precautions
- Pharmacokinetics
- Patient administration/compliance considerations
- Medical outcome and pharmacoeconomic studies
- Cost

When a new drug is considered for formulary inclusion, an attempt will be made to examine the drug relative to similar drugs currently on formulary. In addition, entire therapeutic classes are periodically reviewed. The class review process may result in deletion of one or more drugs in a particular therapeutic class, in an effort to continually promote the most clinically useful and cost-effective agents. If a physician requests the addition of an FDA-approved drug to the formulary, it will be reviewed for formulary addition. Such requests should be directed to the Director of Pharmacy of MercyCare Health Plans (MCHP).

All the information in the MercyCare formulary is provided as a reference for drug therapy selection. The final choice of specific drug selection for an individual rests solely with the prescriber.

For more information see policy on following page.

Pharmaceutical Management Procedure

I. Policy and Procedures

A. Criteria used to adopt pharmaceutical management procedures and new or emerging technology

1. The P&T Committee considers all FDA-approved drugs for addition to the formulary except those drugs in therapeutic classes that are excluded from coverage by MCHP.
2. A review of a specific drug or drug class is carried out within 12 months if any one of the following review triggers occur:
    a) FDA approval and subsequent market availability of a new molecular entity or new biologic product that is not specifically excluded from the MCHP prescription drug benefit.
    b) Significant new safety data or FDA safety warning that may indicate a need to review MCHP current policies regarding that medication's formulary status, restriction status, etc., including the approval of new dosage forms that have clinically meaningful advantages.
    c) Prescriber request for review.
    d) P&T committee recommendation for a review.
3. If a review is not possible or desirable within 12 months of a trigger, the P&T committee will be apprised of the situation and asked to endorse an extension.
4. Drugs or drug classes not meeting the criteria of a review trigger will be reviewed at the discretion of the HPPD (Health Plan Pharmacy Director), P&T Committee Chairperson, or request from a P&T committee member.
5. Prioritization of the timing of drug reviews within 12 months is based on a variety of factors. These factors considered in determining the timing of a review by the P&T Committee include:
    a) Breakthrough product or new mechanism of action (significant safety or efficacy differences, etc.) versus a "me-too" product
    b) Presence or absence of safety signals, depth and duration of available data on safety
    c) Depth and duration of available data on efficacy, presence of head-to-head comparisons with existing products
    d) Relevance of the indications to MCHP's membership
    e) Volume of prior authorization requests or volume of non-formulary exceptions
    f) Opportunities to improve the cost-effectiveness of care
    g) Concern of inappropriate utilization of new products from an efficacy, safety, or cost-effectiveness standpoint or utilization patterns of existing products that reflect inappropriate or less cost-effective utilization
    h) The HPPD, HPMD (Health Plan Medical Director), and Behavioral Health Medical Director will monitor a variety of information sources on an ongoing basis to identify triggers for P&T review. Sources of information include FDA email updates for approvals and safety warnings, review of table of contents of medical journals such as New England Journal of Medicine, Journal of American Medical Association, weekly new drug reports from Medispan, Medical Associations, National Commissions, CDC, NIH, peer-reviewed medical journals, and/or other authoritative compendia, and a variety of daily health news email services.
6. When a possible trigger is identified, the HPPD, HPMD, Behavioral Health Medical Director and the P&T Chairperson determine if the criteria for a review trigger has been met. If so, the review is prioritized to occur sometime in the next 12 months.
7. The evaluation includes a literature review and expert opinion. Formal reviews are prepared which address the following information: safety, effectiveness, comparison studies, approved indications, adverse effects, contraindications, pharmacokinetics, patient compliance considerations, medical outcomes, and pharmacoeconomic studies.
8. New agents are compared to formulary agents of similar type.
9. During the review process, the following criteria will be used to adopt pharmaceutical management procedures:
    a) Procedures will be determined according to the specific class of pharmaceutical
    b) Current formulary alternatives and pharmaceutical classes
    c) When limitations are put into place, prior authorization criteria, exception process, formulary alternatives will be developed, and evidence showing preferred-status pharmaceuticals can produce similar or better results for the majority of the membership.
    d) General membership demographics: to include but limited to, medical condition, prevalent disease states, age, race, gender
    e) Prescribing patterns of participating providers
    f) The impact on public safety
    g) Current medical practice standards

10. Clinical evidence from external organizations will be used and incorporated in pharmaceutical management procedures and pharmaceutical review process.
    a) External organizations include but not limited to Medical Associations, National Commissions, NCCN, CDC, NIH, peer-reviewed medical journals, and/ or other authoritative compendia
    b) Expert opinion reviewer is defined and an internal or external organization or individual practitioner, self proclaimed or otherwise noted as an expert in a specific practice of medical practice or pharmacology.
    c) External clinical evidence will be incorporated in the review process when any of the following conditions are met:
        (1) Requested by the HPMD, HPPD, or any P&T committee member.
        (2) If the committee members do not have knowledge or expertise to review a medication that is outside of their scope of practice.

II. Pharmaceutical Restrictions

A. MercyCare has a clinical review process whereby medications requiring prior authorization or formulary exceptions to the formulary can be reviewed for coverage purposes on behalf of members. Requests are accepted from practitioners or members via fax or mail on the MCHP Prior Authorization or Non-Formulary Exception Form. The HPP (Health Plan pharmacist) or HPPD reviews requests and make determinations based on P&T approved prior authorization criteria and medical necessity. Requestors and members are notified of decisions via mail. The HPP or HPPD is available to members or practitioners to discuss the prior authorization criteria or the reasons for a denial at 800-895-2421.
    1. Related Documents:
        a) Prior Authorization and Non-Formulary Exception forms

B. Quantity Limits
    1. Quantity limits are established to promote safe and appropriate cost-effective use of specific classes of medications for both formulary and non-formulary agents.
    2. Quantity limits will be determined by the P&T committee during the medication review process.

C. Therapeutic Interchange
    1. The HPP under the authority and supervision of the P&T Committee and HPPD will carry out Therapeutic Interchange.
    2. The P&T committee will approve appropriate diagnosis/conditions in which to apply any pharmaceutical interchange program.
        a) Therapeutic Interchanges will occur with the physician's signed order.
        b) Members and pharmacies will be notified by phone, facsimile machine, or via the mail.

D. Step Therapy Protocols
    1. For the purposes of this policy and procedure, Step Therapy is defined as the requirement of a trial of a prerequisite therapy before the approval of coverage for Step Therapy medications.
    2. All Step Therapy protocols must be based on current scientific data and approved by the P&T Committee on an annual basis.
    3. The committee will oversee each step that defines what agents and duration are appropriate for the protocol.
    4. Exceptions to the requirements of Step Therapy protocols are included as part of the protocol. Exceptions not based on established criteria are handled on a case-by-case basis
    5. If a provider wants to bypass the step therapy then a prior authorization/exception request will be submitted.
    6. Clear communications are distributed to practitioners and members prior to implementation of Step Therapy protocols.
    7. Prerequisite therapies, or treatment algorithms, must be clearly communicated to practitioners before implementation of Step Therapy protocols. Communications will include information on the protocol, as well as instructions for how the practitioner can request continued coverage of included medications.
    8. The MercyCare Practitioner Newsletter and the MercyCare Drug Formulary (both are available on www.mercycarehealthplans.com) are used as the vehicles to communicate information on Step Therapy protocols to practitioners.
    9. Members impacted by Step Therapy protocols will receive communications regarding any changes in coverage before implementation of Step Therapy protocols. Communications will include information on the protocol, as well as instructions for how the member can request continued coverage of included medications.

III. Pharmaceutical Patient Safety Issues

A. Recalls

1. New safety information gained from post-marketing clinical trials and real world experience often leads to the recognition of previously undetected adverse effects, administration issues, drug interactions, monitoring parameters, and other issues. The recognition of these issues often leads to new black box warnings in product labeling or market withdrawal of products. Additionally, safety issues related to the manufacturing, packaging, and storage of a drug product, such as contamination, incorrect labeling, and other product specification issues, lead to lot-specific drug product recalls by the FDA. The FDA classifies such safety recalls into 3 categories:
    a) Class I recalls are for dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are a food found to contain botulism toxin, food with undeclared allergens, a label mix-up on a life-saving drug, or a defective artificial heart valve.
    b) Class II recalls are for products that might cause a temporary health problem or pose only a slight threat of a serious nature. One example is a drug that is under-strength but that is not used to treat life-threatening situations.
    c) Class III recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations. Examples might be a container defect (plastic material delaminating or a lid that does not seal); off-taste, color, or leaks in a bottled drink, and lack of English labeling in a retail food.
2. In cases of voluntary or FDA-mandated product withdrawals from the market and Class I safety recalls, both members and prescribers with claims will be notified of the withdrawal or recall within 10 days. Members who have had a claim for the affected medication in the past 6 months will be identified from claim history. For recalls, since MercyCare does not have access to the specific lot numbers that were dispensed from the pharmacy, all patients and prescribers with recent claims for the product will be notified. Included in the notification will be the statement that the recall only applies to specific lots and the patient may or may not have product from the lot number in question. The patient will be instructed to contact the pharmacy to determine if the affected lot number had been part of their stock.
3. Members and prescribers will be identified and notified when affected by medication recalls published by the FDA or Market withdrawals by mail.
4. In addition a direct link to Medwatch provided on MercyCare Health Plans web site pharmacy page.
5. When products are withdrawn with a reasonable probability that the use of the product will cause serious adverse health consequences and for class I recalls, the notification to members and prescribers will be expedited (sent within 10 calendar days).
6. With Class II recalls or withdrawals, member and prescriber notification will take place within 30 calendar days of the withdrawal notice being posted by the FDA.
7. Affected members/practitioners are identified via pharmacy claims.
8. The HPP or HPPD will stop claims for all FDA medication ordered market withdrawals, including manufacturer withdrawals that are for a medication that are not Lot or Batch number specific.

IV. Reviewing and Updating Procedures

A. The pharmaceutical management procedures will be reviewed annually.

B. The P&T committee will meet at least quarterly.

1. The committee will review relevant new information regarding pharmaceuticals
2. New information may include but not limited to:
    a) FDA warnings, notices, or publications
    b) Manufacturer warnings, notices, or publications
    c) National commissions, medical associations, or peer-reviewed journal notice orpublication

C. Entire therapeutic classes are periodically reviewed in order to maintain the most clinically useful, safe, and cost-effective agents.

V. Pharmacist and Practitioner Involvement

A. The Pharmacy & Therapeutics (P&T) Committee: Consists of diverse a group of physicians, pharmacists, nurses, and managers from a variety of specialties and general practice. Their primary purpose is to recommend policies in the evaluation, selection, and therapeutic use of drugs and to educate members on matters related to drugs, drug use, and drug interactions.

B. Any committee member may request to have an expert opinion to assist with decision-making. The P&T chair or vice person will seek a practitioner with the expertise to advise or assist the P&T committee. The P&T committee will decide if the selected expert is knowledgeable to provide the requested information.
C. Expert opinion reviewer is defined and an internal or external organization or individual practitioner, self proclaimed or otherwise noted as an expert in a specific practice of medical practice or pharmacology.
D. The HPPD or HPMD may also request feedback regarding pharmaceutical management procedures from participating practitioners, prior to presenting them to the P&T Committee.

VI. Availability of Procedures

A. Practitioners are informed when changes are made on the Formulary, Prescription Drug Benefit Design, how to request medical exceptions or prior authorizations, who to contact regarding other questions or comments, and on other pharmaceutical management procedures. This is done with an annual mailing notification, which directs practitioners to MCHP website at www.mercycarehealthplans.com. Additionally, up-to-date information regarding the formulary, Prescription Drug Benefit Design, the Prior Authorization Process and how to request exceptions, and other pharmaceutical management procedures is available at any time on MCHP website at www.mercycarehealthplans.com. Printed copies of web content can be requested by contacting Customer Service at (800) 895-2421. The availability of up-to-date pharmacy program information on the website as well as the ability to request printed copies by contacting customer service is communicated in an annual mailing.

VII. Procedure for Formulary Medications that require Prior Approval or Non-Formulary Exception Requests

A. Required Information for Medically Necessary Determination

1. MercyCare will accept medication prior authorization and formulary exception requests from members or practitioners by fax or mail.
2. MercyCare will differentiate between "Urgent" and "Non-Urgent" medication requests.
3. UM decisions will be rendered consistent with the formulary status, restriction status, and any quantity limits of a medication as designated by the P&T Committee. Decisions will be made by the HPP, HPPD or HPMD and will be in a manner consistent with Prior Authorization Criteria and the patient's benefit design. Formulary exception requests will be reviewed and evaluated for a medical necessity over formulary alternatives or an indication that the formulary alternatives are contraindicated or not appropriate for the specific patient.
4. Medical information needed to make a decision (see Prior Authorization or NonFormulary Exception Form)
    a) Member information: name, date of birth, member number
    b) Requested drug: name, (dosage form, schedule, and duration of therapy as necessary)
    c) Indication for treatment and other pertinent diagnoses
    d) Current and past treatment of medical condition including alternative medications failed and reason of failure, or contraindications to formulary alternatives
    e) The HPP or HPPD can obtain the patient's pharmacy claims history on-line to complement the information obtained directly from the requestor.
5. If required additional medical information will be requested of the provider before rendering a decision: If the appropriate medical information is not provided with the initial request, MercyCare will contact the prescriber to obtain additional information necessary before processing the request.
6. The requests are date stamped and entered in to the pharmacy database, then placed in a confidential folder for review by the HPP or HPPD.
    a) The forms are assessed for completeness, and if the appropriate medical information is not provided with the initial request, MercyCare will contact the prescriber to obtain additional information necessary before processing the request via phone/fax.
    b) If the HPP or HPPD is unable to obtain the information requested within the time frame listed for pharmacy decisions, a 45-day extension letter for nonurgent requests and 48-hour extension letter for urgent pre-service requests. The extension letter is sent to the requesting practitioner, and a copy is sent to the member. The extension letter will describe the information that we are waiting for.
    c) If MCHP is unable to make a decision due to matters beyond its control, they will notify the member (or the member's authorized representative); a copy will be sent to the requesting practitioner of the need for an extension and the date (not to exceed 15 days) by which it expects to make a decision.

d) If we have not received the additional information within the stated time frame on the extension letter, a denial based on lack of medical information letter is sent to the member with a copy to the requesting practitioner.
e) The denial/approval decision is made within the time frame for either urgent pre-service or non-urgent decisions.

B. Denied Prior Approval Drug requests
1. HPP or HPPD will state clearly on the denial letter the reason for the denial and criteria for approval.
2. The Health Plan will notify the member via letter of the denial.
a) The prescribing practitioner will get a copy of member's denial letter and a verbal notification of denial from the HPP or HPPD.
b) Information regarding the IRO appeal process is sent with the denial letter to the member and practitioner.

C. Approved Prior Approval Drug requests
1. The member and practitioner's office are notified via letter.

VIII. Required for Review of Pharmaceuticals
A. In an effort to assess the appropriateness of new technologies and new uses of existing technologies on a consistent basis, MCHP reviews documentation from:
1. Appropriate regulatory bodies (e.g., the Food and Drug Administration)
2. Hayes® Medical Technology
3. NCCN
4. Clinical literature and medical journals (including scientific evidence)
5. Professionals with expertise related to the technology such as but not limited to:
a. Professional physician organizations
b. Network providers with specialty certifications relevant to the requested new technology
c. MCHP-contracted independent review services
6. Center for Medicare and Medicaid Services (CMS) (if applicable)
7. MercyCare Health Plans Certificates of Coverage.

B. The collected documentation and evidence should prove, based on established medical facts, that:
1. The technology being requested can alter or affect the outcome of a disease, illness, injury, or condition.
2. The technology's benefits must clearly outweigh any harmful effects.
3. The technology's benefits must be equally or more beneficial than the current treatments being used.
4. The technology must be available or successful outside the investigational setting.

IX. Requests for New or Emerging Technology
A. The Quality Health Management Department receives a request for a new or emerging technology, or the Quality Health Management Department initiates a request for inclusion or consideration.
B. Requests that originate from outside the Quality Health Management Department at MCHP must be submitted in writing.
C. A pharmaceutical must have final approval from the Food and Drug Administration for the specific indications and use that are being evaluated.
D. Pharmaceutical Requests
1. Drug requests are forwarded to the HPP or HPPD
2. The HPP or HPPD through a documented process:
a. Reviews the request and if necessary seeks additional information from appropriate government regulatory bodies, published scientific evidence and documentation, or solicits opinions from professionals with expertise related to the requested drug.
b. Reviews MCHP certificates of coverage and formularies for specific benefit exclusions.
c. Reviews MCHP certificates of coverage and formularies for similar covered procedures or items.
3. The request is evaluated and voted on by the P&T Committee. Please see policy Pharmaceutical Management Procedures PH-01.
4. Drugs or biological products must have final approval from the Food and Drug Administration.
5. The P&T Committee reviews the literature, evidence, and opinions and renders a decision on the requested drug.

E. The appropriate committee will vote to make a recommendation.
F. The formulary is updated to reflect the changes. Members and providers are notified of formulary changes via the website.

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12/1/2021