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Formulary & Pharmaceutical Management Procedures

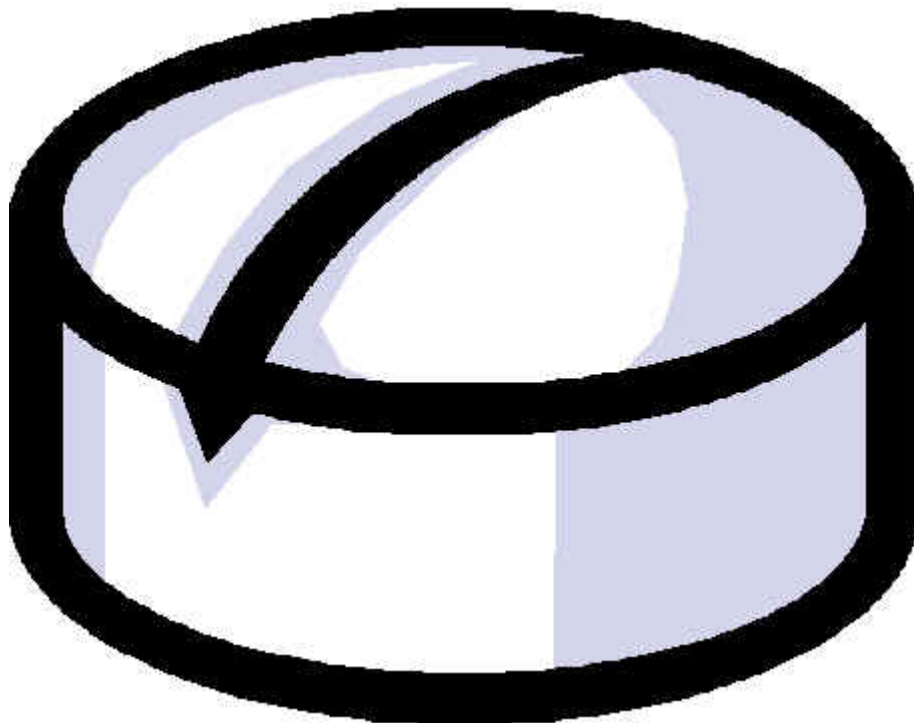


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INTRODUCTION

MercyCare Health Plans (MCHP) maintains a Drug Formulary as a guide for providers to prescribe ambulatory medications. The formulary contains medication listed for both the Two-Tiered (Closed) formulary and the Three-Tiered (Open) formulary. The MercyCare Pharmacy and Therapeutics Committee of physicians and pharmacists endorse the agents listed based on product selection criteria (pg 16). 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.

CONTACT INFORMATION

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MercyCare will honor all requests for paper copies of any an 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material on our website, however, we cannot take responsibility for notifying you when those paper copies have become outdated.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, following our P&T committee meeting.

Prior authorization/Exception forms should be faxed to:

Quality Health Management Dept.
MercyCare Health Plans
Fax (608) 758-7726

FORMULARY KEY

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 this book.

Drug coverage is based on the formulary tier status of the drug

The co-payment structure for the closed formulary drug plan is a lower amount for a generic (first-tier) and a higher amount for a brand product (second-tier). For example, many of the two-tier plans have a \$5.00 co-payment for generic products and a \$15.00 co-payment for brand products. If approved, co-pays for non-formulary drugs or exceptions will be based on the brand/generic status of the drug. If a non-formulary drug is Brand then it will be second tier co-pay. If the non-formulary drug is a generic then it will be tier-one co-pay.

EXAMPLE:

One example of a three-tier (open) plan is a \$7 first tier co-pay, \$15-\$40 (20% of the cost) second tier preferred drug co-pay and \$25-\$75 (40% of the cost) coinsurance (third-tier) for non-preferred drugs

* **Underline Drug Name**: the best economic choice.

* **Advisory**: The Pharmacy and the Therapeutics (P&T) Committee suggests these agents are only used in specified circumstances. No actions are required for coverage.

* **PA-Drug** - 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. (e.g. Celebrex)

- * 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 a 100% of the medication cost.

See policy page 40

* **Drug Exception Procedure**: Please see the Drug Exception Section for more detail. If the physician believes that a drug 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 Drug Exception Fax Form to MercyCare Health Plans at (608) 758-7726. Forms are available at:
See policy page 40

* **NTI** = Narrow Therapeutic Index medications all both the brand and the generic medication to be considered formulary (e.g. Dilantin/phenytoin, Coumadin/ warfarin).

* **SP** = Specialty Pharmacy. Specialty pharmacy will be used to dispense selected medications. Members will select a Mercy Health System pharmacy to obtain the prescribed medication.

* **TS** = Voluntary Tablet Splitting Program. Members who choose to tablet split and use # 15 tablets per month will pay HALF of the co-pay for these drugs.

FORMULARY KEY Continued

* **LL** = Lifetime Limitation. Some benefit plans offer coverage for medications with a lifetime limit.

* **DD** = Daily Dose Limitations. These medications are available in several strengths. For example, members may receive up to 1.5 tablet daily (or 45 tablets per month) of the lower dose. If the dose is raised, they must use the higher strength tablet if available (e.g. Paxil 10 mg #120 - not covered. Use Paxil 40 mg #30).

* **AL** = Age Limits apply for medications covered for a specific age group. Details by drug are listed in the formulary book. Examples of age limits are as follows:

Vitamin A Derivatives (Retin-A) - Not covered for members over age 40 years

Pulmicort Respules Covered for members \leq 8 years of age

* **QL** = Quantity Limits are established to promote safe and appropriate cost-effective use of specific 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 by quantity limits.

* **Limitations below specify the maximum amount of tablets allowed per co-pay per month:**

Zolpidem	10 tablets per co-pay per month
Amerge, Frova	9 tablets per co-pay per month
Axert	6 tablets per co-pay per month
Celebrex	200 mg 30 capsules per co-pay per month
Dalmane	10 capsules per co-pay per month
DDAVP	2-2.5 ml spray bottles per co-pay per month
Fentanyl Patches	10 patches per co-pay per month
Exelon Patches	30 patches per copay per month
Ear & Eye Drops	30-day supply or 2 containers per month
Glucagon Kit	One kit per co-pay
Triazolam	10 tablets per co-pay per month
Imitrex Injection	6 syringes per co-pay per month
Imitrex Spray	6 spray devices per co-pay

FORMULARY KEY Continued

Imitrex Tablets	9 tablets per co-pay per month
Inhalers	1 inhaler per co-pay per month
Lunesta	10 tablets per co-pay per month
Maxalt	12 tablets per co-pay per month
Maxalt MLT	12 tablets per co-pay per month
Regranex	One co-pay per 15 gram tube
Relpax, Zomig	6 tablets per co-pay, per month
Temazepam	10 capsules per co-pay per month
Rozerem	10 capsules per co-pay per month
Tamiflu	1 course - 10 tabs or 75 ml suspension per co-pay, 2 courses per year
Terbinafine	90 days per year.
Treximet	9 tablets per co-pay
Toradol	20 tablets per co-pay per month

PILL SPLITTING PROGRAM

MCHP offers a pill-splitting program, for targeted medications. Members who participate in this program reduce their medication costs. Members who receive prescriptions for #15 tablets with directions of 1/2 tablet daily (a 30 day supply) will have a reduction of their normal co-pay or coinsurance. Co-pay/coinsurance amounts vary, but the member should save between 40-50% in co-pays or coinsurance.

Medications in the pill splitting program:

**Abilify, Actos, Avandia, Benicar, Cozaar, Lexapro, Lipitor,
Risperdal, Seroquel, Zyprexa**

	FIRST TIER Preferred Generic & OTC LOW Co-pay	SECOND TIER Preferred Brand INTERMEDIATE Co-pay
2-TIER DRUG PLAN	1/2 Usual Generic Co-pay \$2.50 - \$5	Usual Brand Co-pay \$5 - \$12.50
3-TIER DRUG PLAN	Usual Generic Co-pay \$3.50	Usual Brand Co-pay \$7.50 min / \$20 Max (20% coinsurance)

COVERED DRUGS

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

1. Any prescription drug or insulin in the MercyCare Drug Formulary
2. Insulin syringes
3. Any medication compounded by the participating pharmacy that contains a covered prescription drug

The medication must also be:

1. Medically necessary for patients medical condition and appropriate given the patient's medical history; and
2. Prescribed in a manner consistent with its FDA approval 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 the MercyCare P&T Committee.

COVERED DRUGS-continued

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. Co-payment amounts vary, depending on the plan selected by the employer group.

Limited additional coverage exists under the medical benefit for drugs administered on an outpatient basis or 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 and exclusion criteria for MercyCare are:

- * Most members can receive a supply of medications not exceeding 30 days for one co-pay.
- * For certain groups the supply can be up to 34 days for one co-pay.
- * Some members have enhanced benefit allowing them to receive up to a 90-day supply of certain medications for three co-pays.
- * 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. (A limited list of OTC's is covered as listed).
- * Insulin, diabetes monitoring products, and associated syringes and needles are covered. Selected diabetic monitoring products are available at no co-pay through a special program; contact customer service for further details.
- * Generally, there is no coverage for other injectable medications unless the medication is included under the prior authorization process.
 - Investigational drugs, which bear the label, Caution: New Drug - Limited by Federal (or United States) law to investigational use are not covered.

Covered Over-the-counter (OTC) drugs

A prescription written by a participating provider allows coverage of these formulary OTC products:

Loratadine, Loratadine-D 12 hr & 24 hr
Nephazoline/pheniramine (Naphcon-A, Opcon)
Niacin
Nicotine cessation products
Prilosec OTC
Zaditor
Cetirizine, Cetirizine - D

NON-COVERED DRUGS

Birth Control and Fertility Drugs

- Contraceptives, other than oral contraceptives and diaphragms.

Miscellaneous (non-covered 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 prescriber.
- Any drug or medicine which is taken by or administered while in 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, or experimental drugs, even though a charge is made to you, except that meets the following criteria:
 1. Prescribed for the treatment of HIV infection or an illness or medical condition arising from or related to HIV infection, AND
 2. Approved by the Federal Food and Drug Administration, including phase –3 investigational drugs, AND
 3. If the drug is an investigational new drug, is prescribed and administered in accordance with the treatment protocol approved by the FDA for the investigational new drugs.
- Anabolic steroids.
- Anti-obesity and anorexients.
- Growth hormones.
- Any prescription drug for a non-covered procedure.
- Any drug for a sickness or bodily injury not covered by the plan.
- Medication other than prescription drugs with or without a prescription order.
- Prescription drugs, which the eligible person is entitled to receive without charge from any Worker's Compensation laws or any municipal state or federal program.
- Nutritional supplements.
- Any prescription drugs dispensed to a member prior to the member's effective date of coverage under the plan or after the member's termination date.

Miscellaneous (non-covered drugs) continued

- Any drug when used for cosmetic treatment of the aging process.
- Any drug when used for treatment of hair loss.
- Any medication or device used to obtain, treat, or enhance sexual performance and/or function. This includes dysfunction caused by organic diseases.
- Any prescription drugs administered by injection, except for insulin injections approved by the Plan's Pharmacy and Therapeutics Committee to be covered under the Pharmacy Benefit.
- Any brand name drug when it is available as a generic.
- Any generic or brand name drug when it is covered as OTC.
- Any specialty drug that is not obtained from the designated Specialty Pharmacy
- Homeopathic medications.
- Special formulations of covered drugs such as sustained release intended primarily for convenience of the patient; as deemed by MercyCare, are not covered.
- Special packaging of covered drugs intended primarily for convenience of the patient; as deemed by MercyCare, are not covered.
- Most Over-The-Counter (OTC) drugs.
- Tretinoin topical (example: Retin A), for members over the age of 40.

CO-PAY STRUCTURE EXPLANATION

	FIRST TIER Preferred Generic & OTC LOW Co-pay	SECOND TIER Preferred Brand INTERMEDIATE Co-pay	THIRD TIER Non-Preferred Brand & Generic 3-Tier=\$25-100, 2-Tier =PA
	Lovastatin	Lipitor	Crestor
2-TIER DRUG PLAN	Usual Generic Co-pay \$5 - \$10	Usual Brand Co-pay \$10 - \$25	* Formulary Exception denial, member pays 100% of cost. Formulary Exception approval then second tier-2 co pays apply
3-TIER DRUG PLAN	Usual Generic Co-pay \$10	Usual Brand Co-pay \$15 min / \$50 Max (20% coinsurance)	50% coinsurance Exceptions to co-pays are not made. Formulary exception is not necessary

For complete benefit explanation please review your certificate of coverage and your drug rider. If you or your patient is concerned about coverage of a particular drug on a MercyCare Health Plans (MCHP) drug plan, you may call customer service at:

**MercyCare Health Plans
Customer Service
(800) 895 - 2421**

PRIOR AUTHORIZATION PROCEDURE

Prior Approval - PA

Drugs indicated with a PA are not covered unless they have been pre approved by MercyCare Health Plans. The physician must apply for prior approval for a specific patient and a specified drug and dose. The request must fulfill PA criteria. This 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 PA:

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

The PA request form must be faxed to 608-758-7726

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

For copies to print go to

<http://www.mercycarehealthplans.com/index.asp?menuid=255>
or call customer service for a written copy.

PA-drugs:

Accutane	Itraconazole	Relistor
Adcira	Kadian***	Remicade*** (Med Ben)
Advair	Kineret	Restasis***
Ambien CR	Kytril	Revatio
Amitiza***	Leukine	Rilutek
Ampyra	Lotronex	Roferon-A
Apokyn	Lupron	Sabril
Avinza	Lyrica***	Samsca
Banzel	Neulesta	Sancuso
Betaseron	Neupogen	Savella
Byetta	Noxafil	Simponi***
Celebrex***	NPlate	Symlin
Cellcept	Nuvigil	Taclonex
Cimzia***	Orencia*** (Med Ben)	Tazorac
Cymbalta***	Oxycondone-ER***	Tarceva
Fentanyl,*** Transdermal Patch	Oxycontin***	Temodar
Effexor XR***	Pegasys	Tikosyn
Embeda	Pristiq	Tracleer
Emend	Procrit***	Uloric
Enbrel***	Protopic	Vectical
ExJade	Provigil	
Extavia	Promacta	Vefend
Famvir	Raptiva***	Vimpat
Forteo	Rebetron	Xenazine
Gleevec	Rebif	Xolair*** (Med Ben)
Humira	Regranex	Zetia
Infergen		Zyvox
Intron-A		

Prior Authorization Criteria for PA Drugs

PA Medication	Criteria
Accutane	PA Accutane: 1) Prescribed by a dermatologist, 2) diagnosis of severe nodular acne
Adcira	PA Adcira: 1) Prescribed by a pulmonologist, 2) diagnosis of pulmonary arterial hypertension including a 6 minute walk distance between 150 and 450 meters.
Advair	PA Advair: 1) Diagnosis of moderate or severe persistent Asthma or COPD, 3) Failure of preferred agents Asmanex, Qvar, Pulmicort, monotherapy or combination therapy with Foradil, Singulair,
Ambien CR	PA Ambien CR: 1) A diagnosis of chronic insomnia with sleep maintenance disorder, and after failure or contraindication to Ambien or 1 other formulary alternative
Anzemet	PA Anzemet: 1) request from oncology, 2) diagnosis of cancer with the treatment of a highly emetogenic (HEC) or moderately emetogenic (MEC) chemotherapeutic regimen as defined by the ASCO or MASCC. 3. Failure of preferred agents, promethazine, metoclopramide & ondansetron. 4) Quantity limit 9 tablets per month.
Apokyn	PA Apokyn: 1) Diagnosis of advanced Parkinson's disease, 2) prescribed by a neurologist
Ampyra	PA Ampyra: 1) Diagnosis of end stage MS
Avinza	PA Avinza: 1) Diagnosis of chronic pain, 2) Current pain contract, 3) random urine toxicology screens, 4) coordination of care with surgery, pain management, addictions, rehabilitation medicine, 5) preferred agents failed or contraindicated (MsContin)
Banzel	PA Banzel: 1) Prescribed by or consulted with a Neurologist, 2) A diagnosis of Lennox Gastaut syndrome, 3) failed first line agents such as Lamotrigine and Topiramate
Betaseron	PA Betaseron: Failure of Avonex or Copaxone.
Byetta	PA Byetta: 1) Diagnosis of Type-2 diabetes, 2) No evidence of end stage renal disease, 3) Good historical medication adherence, 4) A1c > 10 but less than 12, 5) concurrent metformin, sulfonylurea or a combination of the two.
Celebrex	PA COX II Criteria: 1) History/risk of GI ulcer, 2) Concomitant warfarin, 3) Chronic corticosteroid use or 4) Age > 60 years.
Cellcept	PA CellCept: 1) diagnosis of post renal, cardiac, or hepatic transplant, 2) prescribed by transplant specialist
Cimzia	PA Cimzia: 1) Rheumatology consult dictation is submitted with request, 2) Included Diagnosis, 3) Patient failed a trial of methotrexate or leflunomide (Arava) in combination with one other DMARD or there is a clinical reason these options are inappropriate. 4) Failure of Enbrel & Humira
Cymbalta	PA Cymbalta 1) Diagnosis of MDD or Diabetic Neuropathic Pain, with no HX of ETOH abuse 2) MDD behavioral health provider consult, failure of 2 SSRI and 1 second line agent, 6 cognitive psychotherapy visits in last 3 months. 3) DNP, diagnosis of Diabetic neuropathy, failure of 2 first line agents. 4) Diagnosis of Fibromyalgia, failure of first line agents
Duragesic	PA Duragesic: Treatment of chronic pain after failure of other formulary options
Effexor XR	PA Effexor XR 1) Diagnosis of MDD no HX of HTN 2) Behavioral health provider consult, failure of 2 SSRI and 2 second line agents and Venlafaxine ER, 6 cognitive psychotherapy visits in last 3 months
Embeda	PA Embeda: 1) Diagnosis of chronic pain, 2) Current pain contract, 3) random urine toxicology screens, 4) coordination of care with surgery, pain management, addictions, rehabilitation medicine
Emend	PA Emend QL-5 Criteria: : 1) request from oncology, 2) diagnosis of cancer with the treatment of a highly emetogenic (HEC) or moderately emetogenic (MEC) chemotherapeutic regimen as defined by the ASCO or MASCC. Quantity limit 5 tablets per month. If a greater quantity is required, prior authorization is required.
Enbrel	PA Enbrel, Humira and Kineret: 1) Rheumatology consult dictation is submitted with request, 2) Included Diagnosis, 3) Patient failed a trial of methotrexate or leflunomide (Arava) in combination with one other DMARD or there is a clinical reason these options are inappropriate.

Entocort EC	PA Entocort Criteria: Reserved for members with Crohn's Disease or Ulcerative Colitis and one of the following issues apply: 1) at high risk for complications from traditional corticosteroids, 2) Currently taking immunomodulating drugs (e.g. Azathioprine), 3) have documented side effects with traditional corticosteroids or 4) Unable to taper chronic traditional corticosteroid.
Epogen/Procrit/Aranesp	PA Criteria: 1) Chemotherapy for a minimum of 2 months 2) Epogen & Procrit are preferred agents, 3) Malignancy indications other than myeloid malignancy, 4) Hemoglobin is <12 g/dl
Exjade	PA Criteria: 1 Prescribed by a hematologist 2) failure of deferoxamine or contraindication
Extavia	PAExtavia: Failure of Avonex or Copaxone.
Famvir	PA Criteria: 1) A diagnosis consistent with FDA indication, Herpes zoster, HIV infection - Recurrent herpes simplex, Recurrent genital herpes simplex, Recurrent herpes simplex labialis 2) Failure or contraindication to preferred agents such as acyclovir
Forteo	PA Forteo: 1) Rheumatology or endocrinology consult dictation is submitted with request, 2) fracture history, Submit most recent BMD T-score by DXA, 3) Previous /current osteoporosis therapies and reasons regimen must change
Gleevec	Pa Gleevec: 1) Diagnosis of CML or Gastric Stromal tumors
Humira	PA Enbrel, Humira and Kineret: 1) Rheumatology consult dictation is submitted with request, 2) Included Diagnosis, 3) Patient failed a trial of methotrexate or leflunomide (Arava) in combination with one other DMARD or there is a clinical reason these options are inappropriate.
Infergen	PA Infergen: 1) detectable levels of hepatitis C virus RNA in serum, 2) persistently elevated ALT, 3) Signs of hepatitis on liver biopsy, approve for 6 months to assess response
Intron-A	PA Intron-A: 1) detectable levels of hepatitis C virus RNA in serum, 2) persistently elevated ALT, 3) Signs of hepatitis on liver biopsy, approve for 6 months to assess response
Itraconazole	PA Itraconazole: 1) Invasive Aspergillosis or 2) Patient is intolerant or refractory to other therapy (Fluconazole, Itraconazole). Onychomycosis 1) Documented/probable candida or mold species or 2) have failed previous Lamisil treatment.
Kadian	PA Kadian: 1) Diagnosis of chronic pain, 2) Current pain contract, 3) random urine toxicology screens, 4) coordination of care with surgery, pain management, addictions, rehabilitation medicine, 5) preferred agents failed or contraindicated (MsContin)
Kineret	PA Enbrel, Humira and Kineret: 1) Rheumatology consult dictation is submitted with request, 2) Included Diagnosis, 3) Patient failed a trial of methotrexate or leflunomide (Arava) in combination with one other DMARD or there is a clinical reason these options are inappropriate.
Kytril	PA Kytril: 1) request from oncology, 2) diagnosis of cancer with the treatment of a highly emetogenic (HEC) or moderately emetogenic (MEC) chemotherapeutic regimen as defined by the ASCO or MASCC. 3. Failure of preferred agents, promethazine, metoclopramide & ondansetron. 4) Quantity limit 9 tablets per month.
Leukine	PA Leukine: 1) Diagnosis of AML or Bone Marrow Transplant
Lupron	PA Lupron: 1) Diagnosis of advanced prostatic cancer, endometriosis, uterine fibroids
Lotronex	PA Lotronex: 1) Patients with severe diarrhea predominate-IBS who have failed other treatments, 2) Physician participation in the GSK-Lotronex prescribing program.
Lyrica	PA Lyrica: 1) Diagnosis of epilepsy, Diabetic Peripheral Neuropathy, Post Herpetic Neuralgia, or Fibromyalgia 2) failed at least one antidepressant and 1 anticonvulsant.
Neupogen/Neulasta	PA Neupogen/Neulasta: 1) Oncology patients receiving myelosuppressive chemotherapy, BMT or severe chronic neutropenia, 2) prescribed by oncologist
Neupro	PA Neupro: 1) Early stage Parkinson's 2) Difficulty swallowing tablets
Noxafil	PA Noxafil: 1) Febrile neutropenia prophylaxis and/or 2) Patients with serious fungal infections who are intolerant or refractory to other therapy
NPlate	PA Criteria: 1) A 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

Nuvigil	PA Criteria: 1) Diagnosis of Narcolepsy, 2) Diagnosis of sleep apnea and continue to have residual sleepiness despite effective CPAP use and therapy
Orencia	PA Orencia: 1) Rheumatology consult dictation is submitted with request, 2) Included Diagnosis, 3) Patient failed a trial of methotrexate or leflunomide (Arava) in combination with one other DMARD or there is a clinical reason these options are inappropriate. 4) Failure of Enbrel & Humira
Oxycodone ER/Oxycontin	PA Oxycontin: 1) Diagnosis of chronic pain, 2) Current pain contract, 3) random urine toxicology screens, 4) coordination of care with surgery, pain management, addictions, rehabilitation medicine, 5) preferred agents failed or contraindicated (MsContin)
Pegasys	PA Pegasys: 1) detectable levels of hepatitis C virus RNA in serum, 2) persistently elevated ALT, 3) Signs of hepatitis on liver biopsy, approve for 6 months to assess response
Pristiq	PA Pristiq 1) Diagnosis of MDD no HX of HTN 2) Behavioral health provider consult, failure of 2 SSRI and 2 second line agents and Venlafaxine ER, 6 cognitive psychotherapy visits in last 3 months
Prograf	PA Prograf: 1) diagnosis of post renal, or hepatic transplant, 2) prescribed by transplant specialist
Promacta	PA Criteria: 1) A 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
Protopic	PA Protopic: Reserved for members who have failed or have contraindications to topical corticosteroids and pimecrolimus (Elidel)
Provigil	PA Criteria: 1) Diagnosis of Narcolepsy, 2) Diagnosis of sleep apnea and continue to have residual sleepiness despite effective CPAP use and therapy
Raptiva	PA Raptiva: 1) Moderate to Severe Plaque Psoriasis (>10% BSA involvement) 2) Prescribed by a Dermatologist, 3) Required failure or contraindication to therapies in each category of topical, suppressive and remitting agents Topical corticosteroids(tazarotene (Tazorac), calcipotriene (Dovonex), Acitretin,, Cyclosporine, Methotrexate, PUVA, UVB
Rebif	PA Rebif: Failure of Avonex or Copaxone.
Rebetron	PA Rebetron: 1) detectable levels of hepatitis C virus RNA in serum, 2) persistently elevated ALT, 3) Signs of hepatitis on liver biopsy, approve for 6 months to assess response
Regranex	PA Regranex: 1) Prescribed by wound management specialist, 2) diagnosis of severe diabetic neuropathic ulcers of the lower extremities that extend into the subcutaneous tissue or beyond and have an adequate blood supply
Relistor	PA Criteria: 1) Opioid induced constipation in patients with advanced illness receiving palliative care, 2) Documentation of failure or intolerance to other laxative agents (osmotic, stimulant and bulk laxatives
Remicade	PA Remicade: 1) Rheumatology consult dictation is submitted with request, 2) Included Diagnosis, 3) Patient failed a trial of methotrexate or leflunomide (Arava) in combination with one other DMARD or there is a clinical reason these options are inappropriate. 4) Failure of Enbrel & Humira
Restasis	PA Restasis: 1) Usage compatible with its FDA approval: Keratoconjunctivitis Sicca (Chronic Dry Eye Syndrome) 2) Prescribed by a Ophthalmologist or Optometrist, 3) No History of Recent/Scheduled LASIK or refractive surgery, 4) Reasonable attempt to minimize environmental factors- Smoking cessation, wind, heat, dust exposure. Use of humidifier or other attempts to moisten the surrounding air, 5) Failure or contraindicated (failure is after a 6 month trial) to the following agents: Tear Replacement Products: Hypotonic agents (Hypotears), Surface Tension Agents, Lubricants (Lacri-Lube), Demulcents (hydroxypropylmethylcellulose), Punctual Plugs, 6) Discontinuation of contact lenses
Revatio	PA Adcira: 1) Prescribed by a pulmonologist, 2) diagnosis of pulmonary arterial hypertension including a 6 minute walk distance between 150 and 450 meters, 3) failure of Adcira.
Ribavirin	PA Ribavirin: 1) detectable levels of hepatitis C virus RNA in serum, 2) persistently elevated ALT, 3) Signs of hepatitis on liver biopsy, approve for 6 months to assess response

Rilutek	PA Rilutek: 1) Diagnosis of Amyotrophic lateral sclerosis
Roferon-A	PA Roferon-A: 1) detectable levels of hepatitis C virus RNA in serum, 2) persistently elevated ALT, 3) Signs of hepatitis on liver biopsy, approve for 6 months to assess response
Sabril	PA Sabril 1) Diagnosis of complex partial seizures, 2) trial of all formulary alternatives or documentation explaining why some formulary options are not medically appropriate, 3) copies of SHARE enrollment materials, 4) documentation of ophthalmic examinations according to SHARE program requirements. Or a diagnosis of infantile spasms, 2) age-restricted <2 years of age, 3) if approved, for an initial coverage duration of 30 days.
Samsca	PA Samsca: 1) Diagnosis that matches the FDA-approved labeling, Excluding the coverage for use in the outpatient management of congestive heart failure, 2) Laboratory confirmed hyponatremia, 3) therapy should be initiated in hospital, 4) limited to a maximum of 30 days of therapy.
Sancuso	PA Criteria: 1) Request from oncology 2.) Diagnosis of cancer with treatment using a highly emetogenic or moderately emetogenic chemotherapy regimen
Savella	PA Criteria: 1) Diagnosis of Fibromyalgia, failure of first line agents
Simponi	PA Simponi: 1) Rheumatology consult dictation is submitted with request, 2) Included Diagnosis, 3) Patient failed a trial of methotrexate or leflunomide (Arava) in combination with one other DMARD or there is a clinical reason these options are inappropriate. 4) Failure of Enbrel & Humira
Sporanox (Preferred agent is Lamisil)	PA Sporanox Onychomycosis: 1) Documented/probable candida or mold species or 2) have failed previous Lamisil treatment.
Symlin	PA Symlin: 1) Endocrinologist/Diabetologist consult 2) Inadequate response optimal insulin therapy: 3) Quantity limit of 0.7 ml per day (20 ml per month).
Tarceva	PA Tarceva: 1) Diagnosis of nonsmall cell lung cancer, pancreatic cancer, 2) prescribed by an oncologist
Taclonex	PA Criteria: : 1) Prescribed or dermatology consult 2) Moderate to Severe Plaque Psoriasis 3) Required failure or contraindication Topical corticosteroids
Tazorac	PA Tazorac: 1) Moderate to Severe Plaque Psoriasis 3) Required failure or contraindication Topical corticosteroids
Temodar	PA Temodar: 1) Diagnosis of Glioblastoma multiforme or anaplastic astrocytoma, 2) prescribed by an oncologist
Tikosyn	PA Tikosyn: 1) Authorized Tikosyn prescriber and 2) Failure of appropriate formulary alternatives (e.g. Digoxin, Amiodarone, Sotalol).
Tracleer	PA Tracleer: 1) Cardiology or Pulmonology consult, 2) Dx of Pulmonary Arterial Hypertension and 3) Failed vasodilators and calcium channel blockers.
Tyvaso	PA Tyvaso: 1) Diagnosis of PAH, 2) Used as add-on therapy to phosphodiesterase inhibitors or endothelin receptor antagonists, and 3) Require cardiology or pulmonology consult.
Uloric	PA Criteria: 1) Prescribed or consultation by rheumatology, 2) Joint changes based on X-ray, 3) failure of first line agents, 3) A dietary consult.
Vectical	PA Criteria: 1) Prescribed by dermatologist or consultation
Vimpat	PA Criteria: 1) Prescribed by or consulted with a Neurologist, 2) A diagnosis of Partial onset Seizures, 3) failed first line agents such as Levetiracetam, Gabapentin and Zonisamide
Vfend	PA Vfend: 1) Invasive Aspergillosis or 2) Patient is intolerant or refractory to other therapy (Fluconazole, Itraconazole).
Xenazine	PA Criteria: 1) Prescribed by a specialist in treating Huntington chorea patients, 2) failure of at least 2 drugs, 3) medical statement regarding what limitations chorea has imposed on the member, 4) no depression, no schizophrenia, no underlying arrhythmias, no history of dysphagia or aspiration pneumonia

Xolair	<p>PA Xolair: 1) Ordered by a pulmonologist or allergist, 2) > 12 years of age, 3) IgE value of > 30, 4) Positive skin test or in vitro testing (blood test for allergen-specific IgE antibodies such as the RAST) for one or more perennial aeroallergens (ie, house dust mite, animal dander, cockroach, feathers, mold spores), 5) Symptoms have not been adequately controlled by high dose inhaled corticosteroids after at least 6 months of therapy. , 6) Inadequate control demonstrated by: hospitalization for asthma, systemic corticosteroids, increasing need for short acting inhaled beta 2 agonists, 7) Compliant use of a leukotriene inhibitor, 8) Reasonable attempt to minimize environmental factors, 9) 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</p>
Zetia	<p>PA Zetia: 1) reserved for patients that have failed or intolerant to Statins and Niacin.</p>
Zyvox	<p>PA Zyvox: 1) Documented or suspected infection with VRE, MRSA or Strep and 2) Documentation of resistance to Penicillins, Cephalosporins or Quinolones (not including Vancomycin).</p>

Drug Exception

If the physician believes that a drug not found on MercyCare formulary is necessary for the patient then they must apply for a DRUG EXCEPTION. For more information see policy page 40.

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 classes) are inappropriate for the patient, or have failed.

In addition the drug must be:

1. Medically necessary for patients medical condition, and appropriate given the patient's medical history; and
2. Prescribed in a manner consistent with its FDA approved indications 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; and
5. Not listed as an exclusion in the member's drug rider

All exceptions are subject to approval from the Plan.

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 pharmaco-economic 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 Managed Care Pharmacist 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 page 40.

FIRST TIER	SECOND TIER	THIRD TIER
Preferred Generic & OTC LOW CO-PAY	Preferred Brand INTERMEDIATE CO-PAY	NON Preferred Brand & Generic: 3-Tier = \$50 - \$100

KEY: Underline = Best Economic Choice, () = Generic Covered Only, **PA** = Prior Authorization, for criteria see PA table pg 12-15, ***Advisory** = Recommendation, **AL** = Age Limit, **NR** = Not reviewed by P&T not covered, **NTI** = brand & generic product covered, **QL** = Daily dose > 1 tablets/day, use higher strength if possible, **NC** = Not Covered, **OTC** = Over-the-counter, **TS** = Tab Splitting Half-Co-pay #15/month.

ANTI - INFECTIVES

Penicillins	<u>Penicillin vk</u> <u>Amoxicillin (250,500mg)</u> Dicloxacillin Amox/Clav (Augmentin, ES)	Augmentin XR	<i>Moxatag</i>
Cephalosporins	<u>Cefadroxil caps only</u> <u>Cephalexin</u> Cefuroxime Cephadrine Cefaclor Cefprozil Cefadroxil Cefdinir	Suprax	<i>Cedax</i>
Quinolones	<u>Ciprofloxacin</u>	Levaquin	<i>Penetrex, Cipro XR, Maxaquin, Noroxin, Floxin Oral, Avelox</i>
Macrolide	<u>Erythromycin</u> (EryC, generic basis Erythrocin & salts E.E.S.) <u>Azithromycin</u> <u>Clarithromycin, XL</u>	Ery-Tab	<i>Dynabac, Tao</i> <i>Z-Max</i>
Sulfa	<u>Dapsone</u> <u>SMZ/TMP (Bactrim DS)</u> <u>Sulfisoxazole</u> <u>Sulfisoxaz/erythromycin</u>		
Tetracycline	<u>Doxycycline</u> <u>Minocycline</u> <u>Tetracycline</u>		
Other	<u>Clindamycin</u> (Cleocin) <u>Mebendazole</u> (Vermox) <u>Methenamine</u> <u>Metronidazole</u> (Flagyl) <u>Nitrofurantoin</u> <u>Trimethoprim</u> <u>Chloroquine</u> <u>Mefloquine</u> (Lariam)	<u>Zyvox PA-2 SP</u> Lamprene Alina AL Furoxone Biltricide Malarone, Vivotif Berna	<i><u>Monurol</u></i> <i><u>Tindamax</u></i> <i><u>Xifaxan</u></i>

AL Alina: 1) Indicated for the treatment of diarrhea caused by *Cryptosporidium parvum* or *Giardia lamblia* in pediatric patients 1 through 11 years of age.

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ANTI-Invectives, Continued

Anti - TB	Isoniazid (INH) Pyrazinamide Rifampin (Rifadin)	Myambutol Mycobutin Priftin	<i>All anti-TB agents are on formulary</i>
Antifungals, oral	Nystatin Fluconazole Ketoconazole (Nizoral) Tablet Itraconazole (Sporanox) PA-1 Terbinafine QL-90 Griseofulvin	Nizoral Shampoo Grispeg, Grifulvin Sporanox Soln PA-2 Noxafil PA-2 Vfend PA-2 Mycelelex Troche	

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Antivirals

Flu	<u>Amantadine</u> (Symmetrel) <u>Rimantadine</u> (Flumadine)	Tamiflu QL-10 Relenza	
Hepatitis	Ribavirin	Hepsera Infergen PA-2, SP Epivir – HBV Peg-Intron SP Intron-A PA-2, SP Roferon-A PA-2, SP Pegasys PA-2, SP	<i>All Hep-C Agents Are Formulary</i>
Herpe	Acyclovir (Zovirax) Famciclovir (Famvir)		<i>Denavir Topical Zovirax</i>
NNRTI's	All HIV Antivirals Are Formulary	All HIV Antivirals Are Formulary	<i>All HIV Antivirals Are Formulary</i>
Protease Inhibs	All HIV Antivirals Are Formulary	All HIV Antivirals Are Formulary	<i>All HIV Antivirals Are Formulary</i>
Other & Combo	All HIV Antivirals Are Formulary	All HIV Antivirals Are Formulary	<i>All HIV Antivirals Are Formulary</i>

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ANTINEOPLASTICS & IMMUNOSUPPRESSIVES

MISC.	Cyclosporine NTI	Sandimmune, Neoral NTI	<i>Cellcept</i>
	Azathioprine	Temodar PA-2, SP Tarceva PA-2, SP	
	Mycophenolate (Cellcept)	Gleevec PA-2 Rapamune Purinethol	

NTI = Narrow therapeutic index. Both brand and generic are covered.

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CARDIOVASCULAR DRUGS

Ace Inhib	Captopril Enalapril Benzapril Lisinopril Fosinopril Quinapril Trandolapril Moexipril Amlodipine/Bhenazepril (Lotrel)		
Antiadrenergic	Clonidine tabs only MD Prazosin Doxazosin (Cardura) Guanfacine (Tenex) Methyldopa (Aldomet) Ramipril (Altace) Terazosin (Minipres) Tamulosin (Flomax)	Uroxatral* Catapres TTS	<i>Rapaflo</i>

Angiotensin II AT	Losartan (Cozaar) Losartan/ HCTZ (Hyzaar)	Benicar* 20,40 mg TS Benicar HCT*	<i>Atacand, Avapro, Avalide, Diovan Micardis, Teveten, Tekturna Valturna Azor Exforge Twynsta</i>
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* Advisory – Reserve for ACE Inhibitor intolerance associated cough or andioedema

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Cardiovascular Drugs, Continued

Lipid Reduction	Cholestyramine Colestipol Fenofibrate Gemfibrozil Lovastatin Niacin OTC \$0 co-pay (Prescriber must order a prescription for fomulary OTC to be covered) Simvastatin \$0.00 Copay Pravastatin	Niaspan Advicor Lipitor Simcor Zetia PA-2 Trilipix Welchol	<i>Atromid –S</i> <i>Lescol, Lescol XL</i> <i>Altacor</i> <i>Crestor</i> <i>Tricor</i> <i>Antara</i> <i>Vytorin</i>
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TS = Voluntary targeted tab splitting program. If member uses #15 tablets per month, they pay HALF-co-pay. **Free Tab Splitters (800-895-2421)**

Beta Blockers	Acebutolol Atenolol Labetalol Metoprolol, XL Nadolol Pindolol Sotalol Propranolol & SR Betaxolol Bisoprolol Carvedilol	Inderal LA Innopran XL	<i>Betapace AF</i> <i>Cartrol</i> <i>Bystolic</i> <i>Levatol</i> <i>Coreg XR</i> <i>Ziac</i>
Calcium CH Blockers	Diltiazem Diltia XT (Dilacor XR) Diltiazem ER (Cardizem CD) Nifedipine ER (Adalat CC & Procardia XL) Felodipine (Plendil) Verapamil Verapamil SR tablets Amlodipine Nimodipine	Sular Caduet	<i>Cardizem CD</i> <i>Cardizem LA</i> <i>Procardia XL</i> <i>Dynacirc, Cardene</i>
Duretics & Combo	Furosemide Bumetanide Hydrochlorothiazide Torsemide Metolazone Amiloride/HCTZ Triamterene Triamterene/		<i>Edecrin</i> <i>Lozol</i> <i>Dyrenium</i> <i>Inspra</i> <i>Samsca PA-3</i>

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Cardiovascular Drugs, Continued

Antiarrhythmics	Amiodarone 200 mg (Cordarone) Digoxin (Lanoxin) Disopyramide (Norpace) Disopyramide ER (Norpace CR) Flecainide NTI Mexilitine (Mexitil) Procainamide ER (Procainamide) Propafenone (Rythmol) Quinidine gluc (Quinaglute) Quinidine sulf ER (Quinidex) Sotalol (Betapace)	Tambocor NTI Tikosyn PA-2 Procanbid	<i>Amiodarone 400 mg Multaq</i> <i>Betapace AF</i>	
	Isosorbid dinit & ER (Isordil, Isochron) IsosorbidmononitER (Imdur) Hydralazine Midodrine Minoxidil (Loniten) NTG Patch (Nitro Dur, Transderm Nitro) NTG SL (Nitrostat) NTG Caps ER (Nitroglycerin)	Catapres TTS Monoket Tracleer PA-2, SP Tyvaso PA-2 Ranexa Nitro-Dur 0.8 & 0.3	<i>Bidil</i>	
	PAH		<i>Adcira PA-3</i> <i>Revatio PA-3</i>	
	GOUT	Allopurinol (Zyloprim) Colchicine Colchicine / probenecid probenecid	Uloric PA-2	
	Blood Modifiers	Warfarin- NTI (Coumadin) Dipyridamole (Persantine) Ticlopidine (Ticlid) Pentoxifylline (Trental)	Coumadin NTI Mephyton Plavix Effient Epogen PA-2, SP Procrit PA-2, SP Aranesp PA-2, SP Neupogen PA-2, SP Neulasta PA-2, SP Leukine PA-2, SP Lovenox PA-2, SP Promacta PA-2, SP NPlate PA-2, SP	<i>Exjade PA-3, SP</i>

FIRST TIER	SECOND TIER	THIRD TIER
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CNS Drugs

Migraine	Butalbital/ APAP/ Caff (Fioricet) But/ASA/caff (Fiorinal) Erotamine/caff (Wigraine) Isomet/dichlor/ APAP (Midrin) Propranolol SR (Inderal LA) Sumatriptan QL-9 Sumatriptan inj. QL-6 Sumatriptan NS QL-6 Divalproex, ER	Migranal Inderal LA Maxalt QL-12 Maxalt MLT QL-12 Innopran XL	<i>Amerge QL-9</i> <i>Axert QL-6/12</i> <i>Axert QL-6</i> <i>Frova QL-9</i> <i>Zomig QL-6</i> <i>Replax QL-6</i> <i>Treximet QL-9</i> Depakote, Depakote ER
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QL-6 = Quantity Limit. Max 6 dose units/co-pay.

QL-9 = Quantity Limit. Max 9 tablets/co-pay.

Skeletal Muscle relaxants	Baclofen (Lioresal) Diazepam (Valium) Carisoprodol (Soma) Chlorzoxazone (Parafon Forte) <u>Cyclobenzaprine</u> (Flexeril) Methocarbamol (Robaxin) Orphenadrine (Norflex) Tinazidine (Zanaflex)	Dantrium <i>Skelaxin</i>
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Narcotic/APAP	Propoxyphene/APAP (Darvocet N 100) Codeine/APAP (Tylenol #2,3,4) Hydrocodone 10/APAP 650 (Lorcet 10) Hydrocodone/ APAP 500 (Lortab 2.5,7.5) Hydrocodone 5/APAP 500 (Vicodin, Lortab) Hydrocodone 7.5/APAP 750 (Vicodin E.S.) Oxycodone 5/ APAP 325 (Percocet 5-325) Oxycodone 7.5/ APAP 325 Oxycodone 10/ APAP 325 Oxycodone / ASA (Percodan)		
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FIRST TIER	SECOND TIER	THIRD TIER
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CNS Drugs, Continued

ADHD/Anorexiant/Narcolepsy	Methylphenidate & ER (Ritalin & SR, Metadate ER) Amphet mixed (Adderall) Adderall XR d-amphet & SR (Dexedrine & spansule) Phentermine	Concerta Metadate CD Vyvanse Daytrana Intuniv Provigil PA-2 Nuvigil PA-2	<i>Focalin</i> <i>Focalin XR</i> <i>Ritalin LA, Xyrem</i> <i>Not Covered: Meridia, Adipex – P</i> <i>Xenical</i>
Bipolar	Lithium Generic Eskalith CR Lamotrigine (Lamictal)	Depakote & ER	<i>Stavzor</i>
Neuroleptics	Chlorpromazine (Thorazine) Fluphenazine (Prolixin) Haloperidol (Haldol) Loxapine (Loxitane) Perphenazine (Trilafon) Thioridazine (Mellaril) Trifluoperazine (Stelazine) Clozapine (Clozaril) Risperidone	Abilify TS Geodon Seroquel, XR Zyprexa TS Saphris	<i>Invega</i> <i>Fanapt</i>
Rheumatoid	Hydroxychloroquine (Plaquenil) Azathioprine (Imuran) Methotrexate 2.5md Only (Rheumatrex) Leflunomide (Avara)	Cuprimine Ridaura Enbrel PA-2, SP Humira PA-2, SP Kineret PA-2, SP	<i>Cimzia PA-3, SP</i> <i>Simponi PA-3, SP</i>

* Advisory Arava – Second line to methotrexate and sulfasalazine

Nicotine	Nicotine (Nicotrol) (OTC & RX) (Habitrol) Nicotine Gum (OTC) Bupropion IR, SR	Nicotrol nasal spray Nicotrol Inhaler Chantix QL	
MS		Avonex SP Copaxone SP Betaseron PA-2, SP Extavia PA-2, SP Rebif PA-2, SP Rilutek PA-2, SP	<i>Ampyra PA-3, SP</i>

MISC	Naltrexone Disulfran	Campral Evoxac Salagen Ana-Kit Epipen JR. Epipen	<i>Xenazine – PA-3</i>
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FIRST TIER	SECOND TIER	THIRD TIER
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Preferred Generic & OTC LOW CO-PAY	Preferred Brand INTERMEDIATE CO-PAY	NON Preferred Brand & Generic: 3-Tier = \$50 - \$100
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GASTROINTESTINAL DRUGS

Anti - Emetics/motility Agents	Diphenoxylate / Atropine (Lomotil) Metoclopramide (Reglan) Loperamide caps Atrop/scop/hyoscy/ (Donnatal) Propantheline Dicyclomine (Bentyl) Hyoscyamine ER (Levbid, Levsinex) Dronabinol PA-1 Promethazine Ondansetron (Zofran) Granisetron QL-6	Compazine Phenergan Anzemet PA-2 Emend PA-2 Cesamet	<i>Sancuso – PA-3</i>
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Digestants	Pancrelipase and ER (Viokase) (Pancrease MT) Dygase (Kutrase) Palpeon (Creon)		
H2 & Other	Cimetidine (Tagamet) Famotidine (Pepcid) Nizatidine Ranitidine tabs (Zantac) Sucralfate (Carafate)		
PPI's	Prilosec – OTC (#28 or #42 count pkg only) Omeprazole Pantoprazole	Aciphex	<i>Prevacid</i> <i>Nexium</i> <i>Dexilant (Kapidex)</i>
H. Pylori	1) <u>Triple Therapy</u> : Biaxin 500mg BID X 10 days + Amoxicillin 1000 mg BID X 10 days + Prilosec 20 mg BID X 10 days. 2) <u>Triple Therapy</u> : Biaxin 500 mg BID + Amoxicillin 1000 mg BID X 10-14 days + H2 Blocker or PPI (see options above).		<i>Helidac</i> <i>Pylera</i> <i>Prevpac</i>

Colitis	Hydrocortisone Foam (Cortifoam)	Pentasa	<i>Lialda</i>
	Sulfasalazine (Azulfidine)	Asacol, HD	
	Sulfasalazine ER (Azulfidine EN - tab)	Rowasa, Canasa	<i>Apriso</i>
	Balsalazide (colazal)	Dipentum	
		Entocort EC PA-2	
		Enbrel PA-2, SP	
		Humira PA-2, SP	

FIRST TIER	SECOND TIER	THIRD TIER
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Preferred Generic & OTC LOW CO-PAY	Preferred Brand INTERMEDIATE CO-PAY	NON Preferred Brand & Generic: 3-Tier = \$50 - \$100
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KEY: Underline = Best Economic Choice, () = Generic Covered Only, **PA** = Prior Authorization, for criteria see PA table pg 12-15, ***Advisory** = Recommendation, **AL** = Age Limit, **NR** = Not reviewed by P&T not covered, **NTI** = brand & generic product covered, **QL** = Daily dose > 1 tablets/day, use higher strength if possible, **NC** = Not Covered, **OTC** = Over-the-counter, **TS** = Tab Splitting Half-Co-pay #15/month.

GASTROINTESTINAL DRUGS, Continued

OTHER	Lactulose (Enulose)	Nulytely	<i>Visicol</i>
	Electrolyte/PEG Solution (Golytely)	Miralax	<i>Lotronex PA-3</i>
	Ursodil (Actigall)	Osmoprep	<i>Moviprep</i>
		URSO	<i>Amitiza PA-3</i>
			<i>Relistor, PA-3</i>

FIRST TIER	SECOND TIER	THIRD TIER
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Endocrine Agents & Oral Contraceptives

Monophasic (Product listed is the only one covered)

Other	Tamoxifen (Nolvadex)	Evista	<i>Boniva</i> <i>Skelid</i>
	Alendronate Calitonin (Miacalcin)	Actonel Forteo PA-2,SP	<i>Fosamax – D</i> <i>Actonel with Calcium</i> <i>Fareston</i>

Thyroid	Levothyroxine	Synthroid NTI	
	Thyroid Propylthiouracil Methimazole (Tapazole)	Armour Thyroid Cytomel	

MONOPHASIC (Product listed is only one covered.)

Monophasic	Microgestin, Junel Avine Levora Low Ogestrel Apri Cryselle		<i>Loestrin, FE</i>
	Ocella Zovia Necon or Genora Sprintec	Yaz Ortho Evra Patch Nuvaring	<i>Lo/Ovral</i> <i>Yasmin</i> <i>Seasonale</i> <i>Quazense, Tolessa</i> <i>Seasonique</i> <i>Demulen</i> <i>Loseasonique</i> <i>Lybrel</i> <i>Ovral, Ovcon</i> <i>Ogestrel</i>

MULTIPHASIC (Product listed is the only one covered)

Multiphasic	Mircette Necon		
	Trivora Tilia FE, Tri Legest FE Trinessa Velivet	Ortho Tri-Cyclen Lo	<i>Tri -Norinyl</i>

Progestin Only & Misc. (Product Listed is the only one covered)

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Endocrine Agents & Oral Contraceptives

Other	Camila, Jolivette, or Errin	Plan -B	Ovrette Preven
Androgens		Halotestine Excluded Testoderm Excluded Androderm Excluded Androgel Excluded	

Anabolic Steroids: Covered for replacement only

Adrenal Corticosteroids	Prednisone (Deltasone) Cortisone 10mg, 20mg Prednisolone (Prelone) Dexamethasone (Decadron) Fludricortisone (Florinef) Methylprednisolone (Medrol) Prednisolone (Pediapred) Triamcinolone (Aristocort)	Orapred Cortef 5 mg	Orapred ODT
Gonadotropin		Synarel Lupron, Depot PA-2 Danacrine	Humatrope Excluded Protropin Excluded Nutropin Excluded

Growth Hormone: Please see Plan Exclusions.

Pituitary		DDAVP DDAVP NasalSpray QL-2 Stimate	
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QL-2: Limit of 2 spray bottles per co-pay

Supplements	Potassium tablets (slow-K 8mEq, Mirco K) Potassium Liq (Kaochlor liquid) Potassium packet (Klor-Con 20 mEq, K-lor 20 mEq) Ergocalciferol (Drisdol) Folic acid Calcitriol Fluoride (Luride & Lozi Tab) Multivits/fluoride (Poly-VI-Flor) Vit. ADC/fluoride (Tri-Vi-Flor) Vit. ADC/fluoride (Vi-Daylin F ADC) Prenatal vit. F.A. (Natalcare Plus, various)	K-Lyte 50 mEq Micro-K 8 mEq Prenate Advance Stuartnatal Plus 3	Zemplar
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Endocrine Agents & Oral Contraceptives (continued)

Urinary	Phenazopyridine (Pyridium)	Avodart Urispas	Rapaflo
	Oxybutynin, XL (Ditropan)		
Urinary	Hyoscyamine (Cystospaz & M)	Uroxatral Detrol, Detrol LA Toviaz Sanctura, XR Urecholine Elmiron	Vesicare Enablex Oxytrol Patch Gelnique
	Doxazosin (Cardura)		
	Tamulosin (Flomax)		
	Urisepic Tablet (Urised)		
	Finasteride		
Dialysis	Sodium (Kayexalate)	Chromagen	Fosrenol
	Polystyrene		
	Polysaccharide Iron (Niferex-150 Forte)	PhosLo	

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Respiratory Drugs

Nasal	Fluticasone (Flonase)	Nasonex Astelin Astepro	<i>Beconase AQ</i> <i>Rhinocort Aqua</i> <i>Nasacort AQ</i> <i>Nasarel</i> <i>Vancenase & AQ</i> <i>Veramyst</i> <i>Patanase</i> <i>Omnaris</i> <i>Brand Atrovent Nasal</i>
Bronchodilators	Albuterol ERT (Proventil Repetab) Vospire ER Terbutaline (Brethine) Aminophylline Theophylline (Uniphyl, Slo-phyllin)	Proair QL-1 Proventil HFA- QL-1 Maxair Autohaler ONLY Serevent AL > 40 years Foradil AL > 40 years Accuneb	<i>Aminophylline Tabs</i> <i>Quibron Generics</i> <i>Theo-24 Generics</i> <i>Theo-Dur Generics</i> <i>Metaproterolol (Alupent)</i> <i>Tornalate</i> <i>Isuprel Medi-haler</i> <i>Xopenex</i> <i>Maxair MDI</i> Ventolin HFA, QL-1
Corticosteroids	QVAR Asmanex	Symbicort Pulmicort Turbuhaler Pulmicort Respules – AL < 8 years ONLY	<i>Aerobid, Aerobid- M</i> <i>Flovent</i> Advair – PA-3 Alvesco
Other	Acetylcysteine Singular	Combivent Atrovent Spiriva Intal, Tilade Accolate Xolair PA-2	<i>Zyflo</i>
Antihistamines	Loratadine-OTC 10mg (syrup & D) Fexofenadine Clemastine-syrup ONLY Cyproheptadine Diphenhydramine Promethazine Hydroxyzine (Atarax, Vistaril). Cetirizine OTC Cetirizine –D OTC	(Prescriber must order a prescription for formulary OTC to be covered)	<i>Clarinx</i> <i>Xyzal</i> <i>Clemastine tabs</i> <i>Allegra-D</i>

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Cold & Cough Combination

Antihistamine/Decongestant	ONLY Generic Formulations are Covered	ONLY Generic Formulations are Covered	<i>All Brand Name Formulations</i>
Expectorant/Decongestant	ONLY Generic Formulations are Covered	ONLY Generic Formulations are Covered	<i>All Brand Name Formulations</i>
Anti-Tussives	ONLY Generic Formulations are Covered	ONLY Generic Formulations are Covered	<i>All Brand Name Formulations</i>

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Dermatologic Preparations

Acne	Benzol peroxide – rx only (Clearplex) Clindamycin sol'n (Cleocin -T) Erythromycin gel (Emgel, Ery-Gel) Erythromycin sol'n 2% Sulfacetamide/sulfa (Novacet, Plexion) Tretinoin AL < 40 (Retin-A AL > 35) Amnesteem (Accutane) Claravis (Accutane)	Triax Benzamycin Metrogel, MetroLotion, MetroCream Klaron, Ovace Azelex Finacea Retin – A Microgel – AL<40 Differin* AL<40 Tazorac PA-2	<i>Avita AL>40</i> <i>Avage AL>40</i> <i>Sotret</i>
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AL>40 Vitamin A Derivatives are not covered in patients > 40 years. Use for wrinkles is considered cosmetic exclusion.

***Advisory Differin** – Use if intolerance to Retin-A

Anesthetic	Lidocane viscous (Xylocaine) Lidocane/ prilocaine cream (EMLA Cream)	EMLA Patch Lidoderm QL-90	
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PA Lidoderm: Treatment of post-herpetic neuralgia

Antifungals	Nystatin/TMC (Mycolog II) Nystatin (Mycostatin) Econazole (Spectazole) Ketoconazole tab & cream Rx only-miconazole – 3 vag suppository 200 mg (Monistat-3 Rx) Terconazole	Ertaczo Oxistat Exelderm Nizoral Shampoo Mycelex Tablets	
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Anti-Infective	Metronidazole vaginal Silver sulfadizine (Silvadene)	Aldara, Noritate Bactroban Condyllox	<i>Zovirax Ointment</i> <i>Penlac</i> <i>Denavir</i>
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Psoriasis/Pruritis	Selenium Shampoo 2.5% (Selsun RX)	Capitrol, Dovonex Vectical PA-2 Elidil Protopic PA-2 Tazorac PA-2 Taclonex PA-2	
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OPHTHALMIC & OTIC AGENTS

Allergy	Naphcon A. / Opcon naphaxoline/ pheniramine (Prescriber must write a prescription for fomulary OTC to be covered at \$0 co-pay.) Zaditor OTC (Prescriber must write a prescription for fomulary OTC to be covered at \$0 co-pay.)		<i>Alamast</i> <i>Alocril</i> <i>Patanol</i> <i>Optivar</i> <i>Bepreve</i>
Anti-Infective & Anti Viral	Acetic acid OTIC (Vosol OTIC) Sulfacetamide (Salumyd) Gentamicin (Garamycin) Tobramycin (Tobrex) Erythromycin (Ilotycin) Bacitracin (AK-Tracin) Neospor/polymyx/gramic (Neosporin) Ciprofloxacin (Ciloxan)	Floxin OTIC Ocuflox Vigamox Zymar Vira-A, Viroptic Quixin	<i>Azasite</i> <i>Besivance</i>
Steroid Combo	Neomycin/dexamethasone (Neodecadron) Poly/neosp/hydrocort (Cortisporin) Prednisolone 1% (Pred Forte) Neomy/poly/dex (Maxitrol) Tobramycin/Dexamethasone (Tobradex)	Maxidex Blephamide Pred Mild Cipro HC OTIC Ciprodex OTIC	<i>Durezol</i>

* **Advisory Ciprodex:** Failure of generic cotisporin, Floxin OTIC or formulary agents are clinically inappropriate.

Glaucoma	Epinephrine (Epifrin) Pilocarpine (Isopto Carpine) Timolol & ER (Timoptic & XE) Dorzolamide (Trusopt) Drozolamide/Timolol (Cosopt) Acetazolamide (Diamox) Methazolamide (Neptazane)	Iopidine Betoptic – S Alphagan-P Xalatan Travatan	<i>Lumigan</i> <i>Betimol</i> <i>Combigan</i>
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MISC.	Benzocaine/antipyrine (Auralgan OTIC) Trolamine Polypeptide (Cerumenex OTIC)	Acular & LS Nevanac Voltaren Restasis PA-2	<i>Xibrom</i> <i>Acuvail</i>
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Policy & 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 for 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 isn't 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 HPP, 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 HPP (Health Plan pharmacist), HPMD (Health Plan Medical Director), and Behavioral Health Medical Director will monitor a variety of information sources on an on going 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 First Data Bank, 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 HPP, HPMD, Behavioral Health Medical Director and the P&T Chair person, 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, HPP, 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 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 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. **Generic Substitution**
 1. MCHP covers “A” rated generic medications, which have been approved by the FDA, for brand name medications that were already on the formulary.
 2. A member may still receive the Brand Name drug that is not on formulary under the following conditions:
 - a) For the closed formulary: if the practitioner would prescribe a generic drug, but the member chooses not to obtain a generic drug, the member is responsible for coinsurance and co-payment amount plus any dollar amount difference between the generic and the name brand drug.

- b) For the open formulary: The member will pay the non-preferred brand (3rd tier) co-pay.

D. Therapeutic Interchange

1. The HPP under the authority and supervision of the P&T Committee and HPMD 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.

E. 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 Pharmacy & Therapeutics Committee on an annual basis.
3. The committee will oversee each step that defines what agents and duration is 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 as a hard copy on www.mercycarehealthplans.com and PDA format on www.epocrates.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 that 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 was 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 website 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 1 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 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 or publication
- 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 HPP 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.mercycarehealthplan.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.mercycarehealthplan.com. Printed copies of web content can be requested by contacting Customer Service at (800) 895-2421. Another source of up-to-date formulary information for PDAs or PCs is ePocrates at www.epocrates.com. 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 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 need to make a decision (see Prior Authorization or Non Formulary 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 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:
 - 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 is unable to obtain the information requested within the time frame listed for pharmacy decisions, a 45-day extension letter for non-urgent 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 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.
 - 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 is notified via letter.

IV. 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:

- 2. Appropriate regulatory bodies (e.g., the Food and Drug Administration)
- 3. Hayes® Medical Technology
- 4. NCCN
- 5. Clinical Literature and Medical Journals (including scientific evidence)
- 6. 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.
- 7. Center for Medicare and Medicaid Services (CMS) (if applicable)
- 8. MercyCare Health Plans Certificates of Coverage.

B. The collected information shall:

- 1. Collected documentation and evidence should prove, based on established medical facts, that the technology being requested can alter or effect 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 beneficial or more than the current treatments being used.
4. The technology must be available or successful outside the investigational setting

V. 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.

D. A pharmaceutical must have final approval from the Food and Drug Administration for the specific indications and use that is being evaluated

D. Pharmaceutical Requests

1. Drug requests are forwarded to the Managed Care Pharmacist.
2. The Managed Care Pharmacist 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 and 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.