Pharmacy Management Drug Policy

SUBJECT: Medicaid Managed Care (MMC) Step Therapy
POLICY NUMBER: PHARMACY-28
ANNUAL REVIEW DATE: 11/11/2020
EFFECTIVE DATE: 10/11
LAST REVIEW DATE: 3/15/2020

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

DESCRIPTION:

Step therapy encourages use of safe, cost-effective medications within different therapeutic drug categories. The entry of new generics and cost-effective therapeutic alternatives has provided an opportunity to promote these therapies as first-line.

This policy applies only to Managed Medicaid members with a closed formulary prescription drug benefit.

POLICY:

Step Therapy requires members try certain first-line options before other medications will be considered medically necessary for treatment of a specific condition. Step therapy requirements may apply to both brand and generics. Typically, first-line medications are classified as generics, but there are instances where brand-name medications may be preferred.

Based upon our review and assessment of the peer-reviewed literature, these medications have been medically proven to be effective and therefore **medically necessary** for medical treatment if the request meets the following criteria:

ANALGESICS	
Drug	**Requirement**
Cambia	Coverage requires documentation of serious side effects or drug failure with TWO generic NSAIDs **and** ONE generic triptan. **Exception:** requirement is bypassed when requested by a neurologist

ANTIPSYCHOTICS		
Drug	**Diagnosis**	**Requirement**
Fanapt	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole, paliperidone ER)
Latuda	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole, paliperidone ER)

	Bipolar Depression	Coverage requires documentation of serious side effects or drug failure with TWO alternative therapies (lamotrigine, lithium, quetiapine, olanzapine, valproate)
Rexulti	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole, paliperidone ER)
	Major Depressive Disorder	Coverage requires documentation of serious side effects or drug failure with TWO different antidepressants (with different mechanisms of action) used in combination or an antidepressant in combination with one other augmentation therapy (such as an atypical antipsychotic, lithium, buspirone)
Saphris	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole, paliperidone ER)
	Bipolar Disorder	

BLOOD GLUCOSE REGULATORS

Drug	Requirement
Alogliptin	Coverage requires documentation of serious side effects or drug failure with generic metformin
Alogliptin/Metformin	
Alogliptin/Pioglitazone	
Steglatro	
Segluromet	
Byetta	
Bydureon	
Victoza	

CARDIOVASCULAR AGENTS

Drug	Requirement
Entresto	Coverage requires documentation of serious side effects or drug failure with TWO first-line medications from 2 of the 3 the following classes: Angiotensin-Converting Enzyme Inhibitors (ACEI), Angiotensin II Receptor Antagonists (ARB) or Beta Blockers. The two medication trials documented, however, cannot be from the same drug class. For example, approval would not be granted for a patient who had tried two ARBs, but no other agents from the ACEI or Beta-Blocker categories.

HORMONAL AGENTS, STIMULANT/REPLACEMENT/MODIFYING (ADRENAL)

Drug	Requirement
Cloderm	Coverage requires documentation of serious side effects or drug failure with TWO of the following generic topical steroids: aclometasone, amcinonide, betamethasone, clobetasol, desonide, desoximetasone, diflorasone, fluocinolone, fluocinonide–E, fluticasone, halobetasol, hydrocortisone 2.5%, hydrocortisone valerate, hydrocortisone butyrate, mometasone, prednicarbate, triamcinolone
Halcinonide	

IMMUNOLOGICAL AGENTS

Prograf Granules	Must have documentation of serious side effects or drug failure with generic tacrolimus capsules Exception: age less than 9 years old

RESPIRATORY TRACT / PULMONARY AGENTS	
Drug	**Requirement**
Levalbuterol Tartrate HFA	Coverage requires documentation of serious side effects or drug failure with albuterol inhaler or nebulizer solution
Xopenex HFA	

SLEEP DISORDER AGENTS	
Drug	**Requirement**
Silenor	Coverage requires documentation of serious side effects or drug failure with zolpidem
Doxepin HCL	

POLICY GUIDELINES:

1. Unsupported physician statement of hypersensitivity reaction, severe drug intolerance or clinical ineffectiveness without clear clinical history, reaction and resolution will not be considered adequate documentation.

2. Supportive documentation of previous drug use must be submitted for any criteria that require trial of a preferred agent, if the preferred drug is not found in claims history.

3. Approved formulary exceptions will allow the requested medication to be processed at the formulary brand copayment/coinsurance.

4. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.

    a. The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;

    b. The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;

    c. The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

    d. The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;

e. The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.

f. The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.

5. Initial approval will be granted for a period of 1 year.

UPDATES:

Date	Revision
3/20	Revised
2/20	Revised
10/19	Revised
5/19	Revised/P&T Approval
11/18	Revised
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11/16	Revised
10/16	Revised
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