

# Pharmacy Management Drug Policy

**SUBJECT: Low Clinical Impact Drugs - Rx**

**POLICY NUMBER: PHARMACY-122**

**EFFECTIVE DATE: 01/2025**

**LAST REVIEW DATE: 03/06/2025**

*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. This drug policy applies to the following line/s of business:*

## Policy Application

Policy Application		
<b>Category:</b>	<input checked="" type="checkbox"/> Commercial Group (e.g., EPO, HMO, POS, PPO)	<input type="checkbox"/> Medicare Advantage
	<input checked="" type="checkbox"/> On Exchange Qualified Health Plans (QHP)	<input type="checkbox"/> Medicare Part D
	<input checked="" type="checkbox"/> Off Exchange Direct Pay	<input checked="" type="checkbox"/> Essential Plan (EP)
	<input type="checkbox"/> Medicaid & Health and Recovery Plans (MMC/HARP)	<input checked="" type="checkbox"/> Child Health Plus (CHP)
	<input type="checkbox"/> Federal Employee Program (FEP)	<input type="checkbox"/> Ancillary Services
	<input type="checkbox"/> Dual Eligible Special Needs Plan (D-SNP)	

## DESCRIPTION:

Low clinical impact drugs are medications manufactured with slight modifications to existing drugs, such as changes in dosage, form, or strength, without offering significant therapeutic advantages or improvements in patient outcomes. These drugs typically work in the same way as their existing counterparts, providing no new mechanism of action or therapeutic benefit and serving as redundant options in the treatment landscape. Clinical studies and real-world evidence usually show that these drugs have similar efficacy profiles to their predecessors, with no significant improvement in health outcomes or substantial enhancements in managing specific conditions.

The modifications in these drugs, such as dosage adjustments or form alterations, do not result in better therapeutic outcomes or improved patient adherence. Additionally, there is often a lack of robust clinical trials demonstrating superior outcomes or meaningful improvements in patient quality of life, leading to unchanged treatment protocols and no impact on clinical guidelines. The introduction of low clinical impact drugs can lead to unnecessary complexity in prescribing practices and potential confusion for patients and healthcare providers, resulting in medication errors or misuse.

In conclusion, the drugs included in the "Drugs with Local Clinical Impact" policy are identified as having low therapeutic value because they do not provide significant clinical advantages over existing therapies. The Pharmacy & Therapeutics Committee supports the focus on drugs that truly enhance patient outcomes to ensure that our healthcare resources are directed toward treatments that offer real, measurable benefits.

## POLICY:

New-to-market products and new variations of products already in the marketplace are evaluated for clinical appropriateness and meaningful therapeutic values. Drugs identified as low clinical impact drugs will be non-preferred and will not be approved for any other non-FDA approved indications.

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### 1. Low Clinical Impact Drugs that are considered Not Medically Necessary

The health plan has determined the medications listed are not medically necessary due to the availability of lower costing options that are likely to produce equal therapeutic results and, as such, will not be covered.

Drug
Amcinonide 0.1% ointment)
Allopurinol 200 mg tablets
Baclofen 15mg tablets
Baclofen oral solution 5mg/5mL (generic of Ozobax)
clonidine ER tablets
Coxanto
Dolobid 250 mg tablet
Duloxetine 40 mg capsules
ezetimibe/atorvastatin
fenofibrate 30 mg, 40mg, 50 mg, 90 mg, 120 mg, 130 mg, 150 mg
fenofibric acid 35 mg, 105 mg
Fibricor
Fulvicin P-G 165mg tablets
Furoscix
Glimepiride 3mg tablets
Griseofulvin ultramicrosize 165mg tablets
Hydrocortisone 2.5% topical solution
Labetalol 400mg tablets
Lactulose (10g, 20g) powder for solution packets
Lidocan III, IV, and V patches and Tridacaine II and Tridacaine XL patches
Lipofen
Meclofenamate Sodium 50 mg, 100 mg capsules
Metaxalone 400 mg tablets
Metformin 650mg, 750mg tablets
Metronidazole 125mg tablets
Methocarbamol 1000mg tablets
Nexiclon XR
Niacin 500 mg tablets
Ondansetron ODT 16 mg tablets
Opipza
oxaprozin 300 mg capsules
Seglantis
Semglee-yfgn
sitagliptin tablets
Sitagliptin-Metformin
Soaanz
Sovuna
Tanlor 1000mg tablets
Tetracycline tablets
Tolectin 600 mg tablets
Tolmetin

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Trudhesa nasal spray
Veveye
Zituvimet and Zituvimet XR
Zituvio
Zolpidem 7.5 mg caps

## 2. Low Clinical Impact Drugs with Specific Criteria

Drug-specific criteria as listed below; *these drugs will not be approved for any other non-FDA approved indications.*

<b>Airsupra – albuterol/budesonide inhaler</b>
<ol style="list-style-type: none"> <li>Based on comparable indications, efficacy, and safety profile, the member will be required to use a budesonide/formoterol formulation (such as Breyna) unless there is adequate justification as to why a budesonide/formoterol formulation cannot be used</li> <li>Please see the Quantity Limit Policy (Pharmacy-43) for specific quantity limitations for this product.</li> </ol>
<b>Aplenzin – bupropion hydrobromide ER tablets</b>
<ol style="list-style-type: none"> <li>Due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results, patients must use the lower cost generic alternatives such as bupropion HCl SR, bupropion HCl XL 150 mg, bupropion HCl XL 300 mg, escitalopram, fluoxetine, citalopram, sertraline, paroxetine, mirtazapine, and venlafaxine unless the patient has tried and failed or had severe intolerance to all lower cost alternatives.</li> <li>Quantity limit of 30 tablets per 30 days.</li> </ol>
<b>Azasan and azathioprine 75 mg and 100 mg tablets</b>
<ol style="list-style-type: none"> <li>Based on comparable indications, efficacy, safety profiles, and available strength that allows for equivalent dosing, the patient will be required to use generic azathioprine 50 mg tablets unless there is adequate justification as to why this formulation is not appropriate.</li> <li>Quantity limit: 30 tablets/30 days. Additional quantities will be granted based on FDA-approved dosing.</li> </ol>
<b>Cardizem CD 360 mg and diltiazem CD 360 mg capsules</b>
<ol style="list-style-type: none"> <li>Due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results, patients must use the lower cost generic alternatives such as diltiazem LA and diltiazem ER unless there is adequate justification as to why these formulations are not appropriate. In addition, there must be documentation of serious side effects or drug failure of diltiazem CD 180 mg (daily dose of 360 mg diltiazem CD may be obtained by ordering diltiazem CD 180 mg capsules, taken as 2 capsules once daily)</li> </ol>
<b>Citalopram 30 mg capsules</b>
<ol style="list-style-type: none"> <li>Based on comparable indications, efficacy, safety profiles, and available strengths that allow for equivalent dosing, the patient will be required to use generic citalopram tablets or solution unless there is adequate justification as to why these formulations are not appropriate <b>AND</b></li> <li>If the member is unable to use generic citalopram tablets or solution, the member must try and fail or have severe intolerance to all lower cost generic alternatives such as escitalopram, fluoxetine, paroxetine, sertraline, and venlafaxine <b>AND</b></li> <li>Citalopram 30 mg capsules will not be authorized as initial citalopram treatment as the package labeling notes that another citalopram product must be used for initial dosage and titration</li> <li>Quantity limit of 30 capsules per 30 days</li> </ol>

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<b>Clemastine fumarate syrup</b>
<ol style="list-style-type: none"> <li>1. Due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results, patients must use other antihistamine alternatives (such as clemastine tablets, diphenhydramine, carbinoxamine, cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine)</li> <li>2. If unable to use the above alternatives, the following criteria must be met:               <ol style="list-style-type: none"> <li>a. Clemastine fumarate syrup is being requested to treat allergic rhinitis or mild uncomplicated allergic skin manifestations of urticaria or angioedema <b>AND</b></li> <li>b. Evidence of a swallowing disorder is provided documenting an inability to take clemastine tablets <b>AND</b></li> <li>c. There is a clinically valid medical reason why <b>ALL</b> the following cannot be used: diphenhydramine, carbinoxamine, cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine</li> </ol> </li> <li>3. Quantity limit is 120 mL/30 days               <ol style="list-style-type: none"> <li>a. Additional quantities will be granted based on FDA-approved dosing</li> </ol> </li> </ol>
<b>Consensi – amlodipine/celecoxib tablets</b>
<ol style="list-style-type: none"> <li>1. The member must have a diagnosis of hypertension <b>AND</b> osteoarthritis</li> <li>2. Must be 18 years of age or older</li> <li>3. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic amlodipine and celecoxib, the member will be required to use generic amlodipine and celecoxib (as separate pills) unless there is adequate justification as to why these are not appropriate.</li> <li>4. Quantity limit of 30 tablets per 30 days.</li> </ol>
<b>Dapagliflozin tablets</b>
<ol style="list-style-type: none"> <li>1. Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Farxiga, the member will be required to use brand name Farxiga unless there is adequate justification as to why it will not work for you.</li> </ol>
<b>Dapagliflozin/Metformin tablets</b>
<ol style="list-style-type: none"> <li>1. Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Xigduo, the member will be required to use brand name Xigduo unless there is adequate justification as to why it will not work for you.</li> </ol>
<b>Desvenlafaxine ER tablets (generic Khedezla)</b>
<ol style="list-style-type: none"> <li>1. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic desvenlafaxine succinate extended-release tablets (generic Pristiq) the patient will be required to use generic desvenlafaxine succinate extended-release tablets (generic Pristiq) unless there is adequate justification as to why this formulation is not appropriate <b>AND</b></li> <li>2. If unable to use generic desvenlafaxine succinate extended-release tablets (generic Pristiq), patient must have tried and failed or have severe intolerance to all lower cost generic alternatives such as escitalopram, fluoxetine, citalopram, sertraline, and venlafaxine</li> </ol>
<b>Duobrii – halobetasol and tazarotene lotion</b>
<ol style="list-style-type: none"> <li>1. Must be prescribed by a dermatologist</li> <li>2. The member must have a diagnosis of plaque psoriasis</li> <li>3. Must be 18 years of age or older</li> <li>4. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic tazarotene and halobetasol, the member will be required to use generic tazarotene and halobetasol unless there is adequate justification as to why these are not appropriate.</li> <li>5. Quantity limit of 200 mL per 28 days</li> </ol>
<b>Dymista and generic azelastine/fluticasone combination spray</b>
<ol style="list-style-type: none"> <li>1. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic azelastine and fluticasone, the member will be required to use azelastine and fluticasone as separate products unless they have tried azelastine and fluticasone as separate products and</li> </ol>

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have a valid medical reason for requiring combination therapy
2. Quantity limit of 23 grams per 30 days
<b>Fleqsuvy and baclofen 5 mg/1mL oral suspension, Ozobax and baclofen 5 mg/5 mL oral solution, Ozobax DS, and baclofen 10 mg/5 mL oral solution, and Lyvispah (baclofen oral granules)</b>
1. Must be 12 years of age or older
2. Must have documentation of a swallowing disorder which prevents the use of all oral pills (a speech and swallow evaluation is required)
3. The following criterion applies to requests for Ozobax, Ozobax DS, Fleqsuvy, baclofen 10 mg/5 mL oral solution and baclofen 5 mg/5 mL oral solution:
a. Based on comparable indications, efficacy, safety profiles, and available strengths that allows for equivalent dosing, the patient will be required to use Lyvispah unless there is adequate justification as to why this formulation is not appropriate
4. Requests for brand Fleqsuvy will also require serious side effects or drug failure to baclofen 5 mg/1 mL oral suspension (generic Fleqsuvy)
5. Quantity limits are as follows:
a. Ozobax and baclofen 5 mg/5 mL oral solution quantity limit is 2,400 mL per 30 days
b. Fleqsuvy and baclofen 5 mg/1 mL quantity limit is 480 mL per 30 days
c. Ozobax DS and baclofen 10 mg/5 mL quantity limit is 1,200 mL per 30 days
d. Lyvispah quantity limit is 30 packets per 30 days
i. Additional quantities will be granted based on FDA approved dosing
<b>Fluticasone-Salmeterol HFA</b>
1. Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Advair HFA, the member will be required to use brand name Advair HFA unless there is adequate justification as to why it will not work for you.
<b>Fluticasone-Vilanterol</b>
1. Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Breo, the member will be required to use brand name Breo unless there is adequate justification as to why it will not work for you.
<b>Indocin 25 mg/5ml Suspension</b>
1. Must have an indication of rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, acute painful shoulder bursitis and/or tendonitis, or gouty arthritis
2. Based on comparable indications, efficacy, safety profiles, and available strengths that allow for equivalent dosing, the member will be required to use generic indomethacin capsules unless there is adequate justification as to why this formulation is not appropriate <b>AND</b>
3. If unable to use generic indomethacin capsules, the member must try and failed or have severe intolerance to all lower cost generic alternatives such as ibuprofen, naproxen, celecoxib, diclofenac, etodolac, flurbiprofen, ketoprofen, and nabumetone.
4. Requests for brand name Indocin suspension must have has serious side effects to generic indomethacin suspension.
<b>InnoPran XL and Inderal XL – propranolol ER capsule</b>
1. Must be used for the treatment of hypertension
2. Due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results, patients must use other beta blocker alternatives (such as propranolol ER capsules, Inderal LA capsules, propranolol tablets, metoprolol succinate, metoprolol tartrate, or atenolol) unless there is a clinically valid medical reason why ALL other oral beta blockers are unable to be used
3. Quantity limit is 1 capsule per day
a. An exception to this quantity limit will not be granted as doses above 120 mg per day were shown to have no additional effects on lowering blood pressure

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<b>Kiprofen and ketoprofen 25 mg capsules</b>
<ol style="list-style-type: none"> <li>1. Must have a diagnosis of osteoarthritis, rheumatoid arthritis, or primary dysmenorrhea</li> <li>2. Must have had serious side effects or drug failure with a different strength of ketoprofen and two other generic oral NSAIDs</li> </ol>
<b>Kristalose and lactulose (10g, 20g) powder for solution packets</b>
<ol style="list-style-type: none"> <li>1. Must have a diagnosis of constipation or hepatic encephalopathy</li> <li>2. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of lactulose formulations available in a solution, the member will be required to use a lactulose solution unless there is adequate justification as to why these are not appropriate <ol style="list-style-type: none"> <li>a. To determine that lactulose solution is not appropriate, all formulations of lactulose solution (Constulose, Enulose, Generlac and lactulose solution) must be attempted with serious side effects or drug failure prior to the approval of Kristalose or lactulose (10g, 20g) packets. Documentation of each trial will be required in progress notes for review</li> </ol> </li> <li>3. If packets are determined to be required, Kristalose packets will be the product authorized. Lactulose (10g, 20g) packets will not be authorized</li> </ol>
<b>Loreev XR – lorazepam extended-release capsules</b>
<ol style="list-style-type: none"> <li>1. Based on comparable indications, dosing, efficacy, and safety profiles the patient will be required to use generic lorazepam tablets, administered three times daily in evenly divided doses, unless there is adequate justification why this formulation is not appropriate <b>AND</b></li> <li>2. Patient must have tried and failed or had severe intolerance to lower cost generic alternatives such as alprazolam, clonazepam, diazepam, sertraline, escitalopram, fluoxetine, paroxetine, duloxetine, and venlafaxine extended- release</li> <li>3. For patients unable to swallow whole tablets or capsules, there must be adequate justification as to why lorazepam concentrate cannot be used <b>AND</b> a speech and swallow evaluation is required to confirm a swallowing disorder</li> <li>4. Loreev XR will only be approved for the treatment of anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets. Loreev XR will not be approved for any non-FDA approved indications</li> <li>5. Quantity limit: 30 capsules/30 days. Requests in excess of this amount will be reviewed in accordance with FDA-approved dosing and as such, will be limited to the minimum number of capsules required to obtain the appropriate daily dose/day supply</li> </ol>
<b>Meloxicam oral suspension</b>
<ol style="list-style-type: none"> <li>1. Must have a diagnosis of osteoarthritis, rheumatoid arthritis, or juvenile rheumatoid arthritis <ol style="list-style-type: none"> <li>a. Requests will not be approved for any other indication</li> </ol> </li> <li>2. Based on comparable indications, efficacy, safety profiles, and available strengths that allow for equivalent dosing, the member will be required to use generic meloxicam tablets unless there is adequate justification as to why this formulation is not appropriate <b>AND</b></li> <li>3. If unable to use generic meloxicam tablets, the member must try and failed or have severe intolerance to all lower cost generic alternatives such as ibuprofen, naproxen, celecoxib, diclofenac, etodolac, fenoprofen, flurbiprofen, indomethacin, ketoprofen, and nabumetone.</li> </ol>
<b>Pexeva – paroxetine mesylate tablets</b>
<ol style="list-style-type: none"> <li>1. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic paroxetine hydrochloride tablets the patient will be required to use generic paroxetine hydrochloride tablets unless there is adequate justification as to why this formulation is not appropriate <b>AND</b></li> <li>2. If unable to use generic paroxetine hydrochloride tablets, patient must have tried and failed or have severe intolerance to all lower cost generic alternatives such as escitalopram, fluoxetine, citalopram, sertraline, and venlafaxine</li> </ol>

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**Pokonza – potassium chloride 10 mEq packets**

1. Based on comparable indications, efficacy, safety profiles, and available strength that allows for equivalent dosing, the patient will be required to use generic potassium chloride tablets, potassium chloride capsules, potassium chloride 20 mEq packets, or potassium chloride solution unless there is adequate justification as to why all of these formulations are not appropriate
2. Quantity limit of 30 packets per 30 days
  - a. Additional quantities can be granted if generic potassium chloride tablets, potassium chloride capsules, potassium chloride 20 mEq packets, and potassium chloride solution have been used to obtain the same daily dose or there is adequate justification as to why all of these formulations are not appropriate

**Reltone and generic ursodiol 200 mg and 400 mg capsules**

1. Due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results, patients must use the closest equivalent dose of the lower cost generic alternatives (such as ursodiol 300 mg capsules, ursodiol 250 mg tablets, and ursodiol 500 mg tablets)
2. If unable to use the above alternatives, the following requirements must be met:
  - a. Must be prescribed to treat gallbladder stones <20 mm in diameter
    - i. Must be unable to undergo surgery due increased surgical risk due to systemic disease, advanced age, or idiosyncratic reaction to general anesthesia **OR**
  - b. Must be prescribed for prevention of gallstone formation in obese patients experiencing rapid weight loss **AND**
  - c. There is a clinically valid medical reason why ursodiol 300 mg capsules, ursodiol 250 mg tablets, and ursodiol 500 mg tablets cannot be used **AND**
3. If all the above are met, brand name Reltone will be required to be used
  - a. Coverage of generic ursodiol 200 mg or 400 mg capsules will require serious side effects or drug failure to brand name Reltone
4. Requests will not be approved for any other non-FDA approved indications

**Rezvoglar**

1. Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Lantus, insulin glargine, and insulin glargine-yfgn, the member will be required to use brand name Lantus, insulin glargine, and insulin glargine-yfgn unless there is adequate justification as to why it will not work for you.

**Ryaltris – mometasone and olopatadine nasal spray**

1. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic mometasone and olopatadine, the member will be required to use generic mometasone and olopatadine as separate products unless they have tried mometasone and olopatadine as separate products and have a valid medical reason for requiring combination therapy.
2. Quantity limit of 29 grams per 30 days

**Sertraline capsules**

1. Based on comparable indications, efficacy, safety profiles, and available strengths that allow for equivalent dosing, the member will be required to use generic sertraline tablets unless there is adequate justification as to why this formulation is not appropriate **AND**
2. If unable to use generic sertraline tablets, the member must try and failed or have severe intolerance to all lower cost generic alternatives such as escitalopram, fluoxetine, citalopram, paroxetine, and venlafaxine.

**Vimovo and naproxen/esomeprazole tablets**

1. Must have a diagnosis of Osteoarthritis, Rheumatoid Arthritis, or Ankylosing Spondylitis
2. Must have documentation of being at high risk for gastric ulcer.
  - Risk factors include Patient greater than 65 years of age, previous history of peptic ulcer

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disease
3. Must have had serious side effects or drug failure to 3 different PPIs with each PPI trial used in combination with naproxen
4. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic naproxen and esomeprazole, the member will be required to use generic naproxen and esomeprazole unless there is adequate justification as to why these are not appropriate.
<b>Vivlodex and meloxicam capsules</b>
1. Must have a diagnosis of osteoarthritis <b>AND</b>
2. Must have documentation of serious side effects or drug failure to 3 different generic oral NSAIDs, one of which is meloxicam tablets
3. In addition, coverage of brand name Vivlodex capsules will require serious side effects or drug failure to generic meloxicam capsules (generic Vivlodex)
4. Quantity limit is 30 capsules / 30 days

### **POLICY GUIDELINES:**

1. This policy is applicable to drugs that are included on a specific drug formulary. Specific approval criteria refer to drug policies wherever applicable. Example: Quantity Limit Policy (Pharmacy-43), Non-Formulary Medication Exception Review Policy (Pharmacy-69)
2. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to criteria being added to the policy. Utilization Management are contract dependent and coverage criteria may be dependent on contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
3. 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.
  - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member
  - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen
  - 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
  - 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
  - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rationale for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
  - 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.
4. Supportive documentation of previous drug use must be submitted for any criteria that require a trial of a preferred agent if the preferred drug is not found in claims history.

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5. Unless otherwise stated above within the individual drug criteria, approval time-period will be for 1 year
6. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
7. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
8. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.

#### **UPDATES:**

<b>Date</b>	<b>Revision</b>
03/06/2025	Revised
03/01/2025	Revised
01/31/2025	Revised
01/06/2025	Revised
01/01/2025	Revised
11/21/2024	P&T Committee Approval

#### **REFERENCES:**

1. Glaus CEG, et al. Defining 'therapeutic value' of medicines: a scoping review. *BMJ Open* 2023;13:e078134. doi:10.1136/bmjopen-2023-078134