Pharmacy Drug Policy

SUBJECT: Low Clinical Impact Drugs - Rx
POLICY NUMBER: PHARMACY-122
EFFECTIVE DATE: 01/2025
LAST REVIEW DATE: 09/11/2026

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

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ 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.

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)
Amrix, Fexmid and equivalent generic cyclobenzaprine
Allopurinol 200mg tablets
Aplenzin
Arbli
Arynta
Atmeksi
Baclofen 15mg tablets
Baclofen oral solution 5mg/5mL (generic of Ozobax)
Baclofen oral solution 10mg/5mL (generic of Ozobax DS)
Bafiertam
Beclomethasone dipropionate HFA 40mcg and 80mcg inhalers
Bisoprolol 2.5mg tablets
Brekiya
Bucapsol capsules
Buspirone 2.5mg and 12.5mg tablets
Butalbital/acetaminophen/caffeine 50-325mg/15mL oral solution
Byqlovi ophthalmic suspension
Bynfezia
Bysanti
Cabtreo
Carbinoxamine 6mg and Ryvent tablets
Cefixime 400mg tablets
Citalopram 30 mg capsules
Chlorzoxazone 250mg, 375mg and 750mg tablets
Clemastine fumarate syrup
Clonidine 0.05mg tablet
Clonidine ER tablets
Clotic
Combogesic
Corphena
Coxanto
Dartisla ODT
Desloratadine 0.5mg/mL oral solution
Desmoda 0.05mL/mL oral solution
Desvenlafaxine ER tablets (generic Khedezla)
Dexlyt
Diclofenac 2% topical solution
Dicyclomine hcl 40mg tablets
Dolobid 250mg, 375mg tablets
Duloxetine 40, 80, 90, 120mg capsules
Escitalopram 10mg/10mL oral solution, 15mg capsule
Enbumyst
Exxua
Ezetimibe/atorvastatin
Fenofibrate 30mg, 40mg, 50mg, 90mg, 120mg, 130mg, 150mg
Fenofibric acid 35mg, 105mg

Fenoprofen capsules and fenoprofen tablets
Fenopron
Fibricor
Fulvicin P-G 165mg tablets
Furoscix, Furoscix Readyflow
Gabapentin 200mg capsules
Gabarone
Glimepiride 3mg tablets
Glycate
Glycopyrrolate 1.5mg tablets
Granisol 1mg/5 mL oral solution
Griseofulvin ultramicrosize 165mg tablets
Halcinonide 0.1% cream
Hydrocortisone 2.5% topical solution (generic of Texacort)
Ibuprofen 300mg tablets
Ibuprofen/famotidine tablets
Inderal XL
Indocin and indomethacin 25 mg/5ml Suspension
Indocin and Indomethacin 50mg rectal suppositories
InnoPran XL
Javadin
Kiprofen
ketoprofen 25 mg capsules
Labetalol 400mg tablets
Lactulose (10g, 20g) powder for solution packets
Lasix ONYU
Tridacaine II and Tridacaine XL patches
Lipofen
Lofena and diclofenac 25mg tablets
Lopressor 10mg/mL oral solution
Lopressor 12.5mg tablets and metoprolol tartrate 12.5mg tablets
Loreev XR
Meclizine 25mg chewable tablet
Meclofenamate Sodium 50 mg, 100 mg capsules
Meloxicam oral suspension and meloxicam capsules
Metaxalone 400 mg, 640mg tablets
Metformin 625mg, 750mg tablets
Metronidazole 125mg tablets, 375mg capsules
Methocarbamol 1000mg tablets
Micort-HC
Nalfon
Naprelan, Naprosyn suspension, naproxen ER, naproxen suspension
Nereus
Nexiclon XR
Niacin 500 mg tablets
Omlonti 0.002% ophthalmic drop
Ondansetron ODT 16 mg tablets

Ontralfy
Opipza
Orudis
Oxaprozin 300 mg capsules
Pexeva
Pokonza 10mEq, 15mEq packets and 10mEq/15mL oral liquid
Potassium chloride 40mEq packets
Prednisone 1mg, 2mg and 5mg enteric coated tablets (generic Rayos)
Ranitidine 150mg and 300mg tablets
Relafen DS
Relgaabi
Risedronate sodium 30mg tablets
Sdamlo
Semglee-yfgn
Sertraline capsules
Sitagliptin tablets (authorized generic for Zituvio)
Sitagliptin-metformin and sitagliptin-metformin ER (authorized generic for Zituvimet)
Soaanz
Soma 250mg and carisoprodol 250mg tablets
Sovuna
Tanlor 1000mg tablets
Texacort 2.5%
Tizanidine 8mg capsule
Tetracycline tablets
Tobramycin 0.3%/loteprednol etabonate 0.5% ophthalmic suspension (generic of Zylet)
Tolectin DS 400mg capsules
Tolectin 600 mg tablets
Tolmetin
Tonmya
Topiramate 50mg sprinkle capsules
Trudhesa nasal spray
Umeclidinium ellipta
Vevye
Vimovo and naproxen/esomeprazole tablets
Vivlodex
Vybrique
Vyscoxa
Xtoro otic suspension
Zanaflex
Zituvimet and Zituvimet XR
Zituvio
Zolpidem 7.5 mg caps
Zorvolex and diclofenac 35 mg capsules
Zybic

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.*

Airsupra – albuterol/budesonide inhaler
1. Based on comparable indications, efficacy, and safety profile, and consistent with the recommendations from the 2025 Global Initiative for Asthma (GINA) guidelines, 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. 2. Please see the Quantity Limit Policy (Pharmacy-43) for specific quantity limitations for this product
Atoncy (atomoxetine) 4mg/mL oral solution
1. Must be 6 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. Quantity limit: 100mL (1 bottle) per 30 days
Azasan and azathioprine 75 mg and 100 mg tablets
1. 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. 2. Quantity limit: 30 tablets/30 days. Additional quantities will be granted based on FDA-approved dosing
Cardizem CD 360 mg and diltiazem CD 360 mg capsules
1. 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)
Consensi – amlodipine/celecoxib tablets
1. The member must have a diagnosis of hypertension **AND** osteoarthritis 2. Must be 18 years of age or older 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. 4. Quantity limit of 30 tablets per 30 days.
Duobrii – halobetasol and tazarotene lotion
1. Must be prescribed by a dermatologist 2. The member must have a diagnosis of plaque psoriasis 3. Must be 18 years of age or older 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. 5. Quantity limit of 200 mL per 28 days
Dymista and generic azelastine/fluticasone combination spray
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 have a valid medical reason for requiring combination therapy 2. Quantity limit of 23 grams per 30 days
Fleqsuvy and baclofen 25mg/5mL oral suspension, Ozobax DS, and baclofen 10mg/5 mL oral solution
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 DS, Fleqsuvy, baclofen 10mg/5 mL oral

solution and baclofen 5 mg/5 mL oral solution:
   a. Based on comparable indications, efficacy, safety profiles, and available strengths allows for equivalent dosing, the patient will be required to use baclofen 25mg/5 mL oral suspension (generic Fleqsuvy) unless there is adequate justification as to why this formulation is not appropriate
4. Quantity limits are as follows:
   a. Baclofen 5 mg/5 mL oral solution quantity limit is 2,400 mL per 30 days
   b. Fleqsuvy and baclofen 25 mg/5 mL oral suspension 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

Fluticasone Furoate Ellipta Inhalation Powder

1. Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Arnuity Ellipta, the member will be required to use brand name Arnuity Ellipta unless there is adequate justification as to why it is not appropriate
2. Quantity limit of 30 blisters per 30 days

Fluticasone-Salmeterol HFA

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.

Fluticasone-Vilanterol

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.

Kristalose and lactulose (10g, 20g) powder for solution packets

1. Must have a diagnosis of constipation or hepatic encephalopathy
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
   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
3. If packets are determined to be required, Kristalose packets will be the product authorized. Lactulose (10g, 20g) packets will not be authorized

Quiofic – folic acid oral solution

1. Based on comparable indications, dosing, efficacy, and safety profiles the patient will be required to use generic folic acid tablets unless the patient requires small weight-based doses only Quiofic oral solution can provide.
   Quantity limit: 1 Bottle (30 mL)/30 days.

Reltone, generic ursodiol 200 mg and 400 mg capsules, and Ursolign

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 to 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
Symbravo
1. Must be 18 years of age or older 2. Must be used for the acute treatment of migraine headaches 3. Must have had serious side effects or drug failure of ALL the following: a. TWO different triptans with different active ingredients (as acute monotherapy) b. One oral triptan in combination with an NSAID (as separate pills) c. Sumatriptan-naproxen tablet 4. Quantity Limit: 9 tablets per 30 days [refer to Quantity Limit Policy (PHARMACY-43)]
Subvenite – lamotrigine 10mg/mL oral suspension
1. Based on comparable indications, dosing, efficacy, and safety profiles the patient will be required to use generic lamotrigine tablets/chewable tablets/orally disintegrating tablets unless the patient requires small weight-based doses only Subvenite oral suspension can provide. 2. Quantity limit: 1 Bottle (240 mL)/30 days.
Tezruly
1. Must have one of the following diagnoses (**a or b**): a. Benign prostatic hyperplasia (BPH) or b. Hypertension 2. Documentation must be provided why member is unable to use terazosin capsules 3. Quantity Limit: 1 bottle (150 mL) per 30 days.
Umeclidinium-vilanterol
1. Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Anoro Ellipta, the member will be required to use brand name Anoro Ellipta unless there is adequate justification as to why it will not work for you.

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 is 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 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.
- 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.
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:

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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