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PHARMACY UTILIZATION MANAGEMENT GUIDELINE – 5.01.560 Excessively High Cost Drug Products with Lower Cost Alternatives

Effective Date:	July 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	June 24, 2024	10.01.511 Medical Policy and Clinical Guidelines: Definitions and Procedures
Replaces:	N/A	

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Introduction

Often, several very similar drugs are available to treat the same condition. In some cases, a drug will be very expensive, while much lower cost drugs that are appropriate therapeutic alternatives may be prescribed instead and will work just as well. This policy defines the criteria that must be met and the drugs that must be tried first before specific excessively high cost drugs can be approved.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

The drug products listed in this medical policy will be reviewed on a case-by-case basis and are subject to the criteria outlined **below**. These products are excessively high priced and have much lower cost alternatives that are equally safe and effective. Suggested alternatives are listed in the table below.

Note: Documentation in the form of chart notes is required with every prior authorization request for the drugs listed in this policy.

High Cost Drug Product	Suggested Alternatives
Absorica (isotretinoin), Absorica LD (isotretinoin)	Trial and failure of two of the following medications: Claravis, Zenatane, or Myorisan
Alcortin-A	Generic prescription topical corticosteroids
Allzital	Bultalbital with acetaminophen (generics)
Amrix (cyclobenzaprine extended-release) **Cyclobenzaprine extended-release**	Generic cyclobenzaprine AND generic tizanidine or generic methocarbamol
Auvi-Q	Epinephrine Auto-Injector (generic Epipen and generic Adrenaclick)
Brand name EpiPen	EpiPen Authorized Generic, Adrenaclick Authorized Generic
Lorzone (chlorzoxazone) **Chlorzoxazone 250 mg, 375 mg and 750 mg**	Generic chlorzoxazone 500 mg
Pennsaid	Generic topical diclofenac gel 1% AND generic topical diclofenac solution 1.5%
Evzio	Narcan (nasal spray), generic naloxone solution for injection
Bethkis, Kitabis, TOBI	Generic tobramycin solution
Tobi Podhaler	Generic tobramycin solution, Bethkis, Kitabis
Fluoxetine	Three tablets or capsules of generic fluoxetine 20mg.
Fortamet **Generic for Fortamet** **Glumetza** **Generic for Glumetza**	Generic metformin extended-release (generic for Glucophage XR)
Metformin 625 mg (brand)	Generic metformin immediate-release
Jublia **Kerydin**	Generic ciclopirox AND generic tavaborole AND either generic terbinafine OR generic itraconazole
Tavaborole	Generic ciclopirox AND either generic terbinafine OR generic itraconazole
Mytesi	Trial and failure of two of the following medications: bismuth subsalicylate, diphenoxylate/atropine, or loperamide
Natpara (parathyroid horomone)	Calcium supplements and active forms of vitamin D (e.g., calcitriol, cholecalciferol, doxercalciferol, ergocalciferol)
Northera	Generic midodrine
Kits	Non-kit version of the active ingredients found within the kit. (such as: Livixil (lidocaine 2.5%/prilocaine 2.5% cream),

High Cost Drug Product	Suggested Alternatives
	Dermacinrx Silapak (triamcinolone acetonide cream 0.1% +dimethicone cream) etc.)
Topical lidocaine products: Adazin Ldo Plus L.E.T. Lidocaine 3.88% Lidocaine HCl Lidocaine-Tetracaine Lidopin Lidotrex Nynutey Pain Relief Pliaglis Regenecare Scar Synvexia TC Vexasyn	Generic lidocaine HCL cream and generic lidocaine ointment
Lidoderm Patches **Synera** **ZTlido**	Generic lidocaine patch, AND generic lidocaine HCL cream, AND generic lidocaine ointment
Paingo KFT	Generic lidocaine/prilocaine cream, AND generic lidocaine HCL cream, AND generic lidocaine ointment
Rayos	Generic prednisone AND generic methylprednisolone
Riomet **Riomet ER**	Generic metformin tablet
Sitavig	Generic acyclovir
Zyflo CR & Zileuton ER, Zyflo & Zileuton	Generic montelukast

Policy Coverage Criteria

Drug	Medical Necessity
Absorica (isotretinoin), Absorica LD (isotretinoin)	**Brand Absorica and Absorica LD may be considered medically necessary when the provider submits documentation in the form of medical records to show the following:**

Drug	Medical Necessity
	• Individual has severe, recalcitrant, nodular acne and is 12 years of age or older **AND** • Individual has documented trial and failure (at least 3-month trial) of two of the following generic medications: Amnesteem, Claravis, Isotretinoin, Myorisan or Zenatane
Alcortin-A (iodoquinol, hydrocortisone, aloe polysaccharides)	**Alcortin-A may be considered medically necessary when provider submits documentation in the form of medical records to show that the individual had an adequate trial and failure with two generic prescription topical corticosteroids.**
Allzital (butalbital/ acetaminophen)	**Allzital may be considered medically necessary for individuals age 16 and above when:** • Individual has documented trial and failure of at least two generic butalbital/acetaminophen products
Amrix (cyclobenzaprine extended-release) Cyclobenzaprine extended-release	**Brand Amrix and generic cyclobenzaprine extended-release may be considered medically necessary when provider submits documentation in the form of medical records to show that the individual had an adequate trial and failure (at least 3 months) of generic cyclobenzaprine AND an additional muscle relaxant: tizanidine or methocarbamol**
Auvi-Q (epinephrine injection)	**Auvi-Q 0.15 mg/0.15 mL and Auvi-Q 0.3 mg/0.3 mL may be considered medically necessary when ONE of the following is true:** • Individual or caregiver lacks the manual dexterity or visual acuity needed to use Epinephrine Auto-Injector (generic Epipen and generic Adrenaclick) **OR** • The individual or caregiver lacks the mental capacity to be trained on how to use Epinephrine Auto-Injector (generic Epipen and generic Adrenaclick) **Auvi-Q 0.1 mg/0.1 mL may be considered medically necessary when the following is true:** • Individual body weight is between 16.5 to 33 pounds (7.5 to 15 kilograms) **AND**

Drug	Medical Necessity
	• Caregiver lacks the manual dexterity or visual acuity needed to use Epinephrine Auto-Injector (generic Epipen and generic Adrenaclick) **OR** • The caregiver lacks the mental capacity to be trained on how to use Epinephrine Auto-Injector (generic Epipen and generic Adrenaclick)
Brand name EpiPen (epinephrine injection)	**Brand EpiPen (epinephrine injection) may be considered medically necessary when provider submits documentation in the form of medical records to explain why individual is not a candidate for the use of the following preferred options:** • Generic epinephrine auto-injector **OR** • EpiPen authorized generic* **OR** • Adrenaclick authorized generic* **Note:** ***An authorized generic is defined by the Food and Drug Administration as: "The term "authorized generic" drug is most commonly used to describe an approved, brand name drug that is marketed as a generic product without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. It may be marketed by the brand name drug company, or another company with the brand company's permission. In some cases, even though it is the same as the brand name product, the authorized generic may be sold at a lower cost than the brand name drug."
Lorzone (chlorzoxazone), chlorzoxazone 250 mg, 375 mg and 750 mg	**Brand Lorzone 750 mg tablets and generic chlorzoxazone 250 mg or 750 mg tablets may be considered medically necessary when:** • Provider submits documentation that the individual has tried and did not tolerate chlorzoxazone 500 mg tablets or achieve therapeutic response with chlorzoxazone 500 mg tablets **AND** • Individual or caregiver lacks the manual dexterity or visual acuity needed to cut chlorzoxazone 500 mg tablets

Drug	Medical Necessity
	Brand Lorzone 375 mg tablets and generic chlorzoxazone 375 mg tablets may be considered medically necessary when: • Provider submits documentation that the individual has tried and did not tolerate chlorzoxazone 500 mg tablets **Note:** Chlorzoxazone 500 mg tablets are scored and can be cut in half to deliver a 250 mg dose or a 750 mg dose.
Pennsaid (diclofenac sodium topical solution)	**Pennsaid(diclofenac sodium topical solution) may be considered medically necessary when:** • Individual has a documented diagnosis of osteoarthritis of the knee(s) **AND** • Individual has a documented trial* and failure of both, generic diclofenac topical gel 1% AND generic topical diclofenac solution 1.5% **Note:** *Trial is defined as 3 months of continuous therapy.
Bethkis (tobramycin inhalation solution), Kitabis Pak (tobramycin inhalation solution), TOBI (tobramycin inhalation solution), TOBI Podhaler (tobramycin inhalation powder)	**Bethkis (tobramycin inhalation solution), Kitabis Pak (tobramycin inhalation solution) and TOBI (tobramycin inhalation solution) may be considered medically necessary for the management of cystic fibrosis when:** • Individual has tried generic tobramycin inhalation solution and had an inadequate response after 1-month of treatment or had intolerance to generic tobramycin inhalation solution **TOBI Podhaler (tobramycin inhalation powder) may be considered medically necessary for the management of cystic fibrosis when:** • Individual has tried generic tobramycin inhalation solution and had an inadequate response after 1-month of treatment or had intolerance to generic tobramycin inhalation solution **AND** • Individual has tried Bethkis (tobramycin inhalation solution) or Kitabis Pak (tobramycin inhalation solution) **Initial approval will be for 3-years.**

Drug	Medical Necessity
	Reauthorization criteria: • Continued therapy will be approved for 3-years as long as the medical necessity criteria are met and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.
Fluoxetine 60mg	**Fluoxetine 60mg tablets may be considered medically necessary when BOTH (1 and 2) of the following criteria are met:** 1. Individual has **ONE** of the following conditions, as documented by the chart notes: o Major Depressive Disorder (MDD)* in those 8 years of age or older o Obsessive Compulsive Disorder (OCD)* in those 7 years of age or older o Bulimia Nervosa in an adult individual o Panic Disorder with or without agoraphobia in an adult individual **AND** 2. Individual is non-adherent** on therapy with 3 tablets or capsules of generic fluoxetine 20mg, as documented by the chart notes. **Note:** *Fluoxetine 60mg is FDA-approved for use in pediatric individuals only for MDD and OCD. The safety and efficacy in those < 8 and < 7 years of age, respectively has not been established. **Note:** **Non-adherence is defined as less than 50% adherence over a 6-months period.
Glumetza, Fortamet (metformin extended release) and their generic	**Glumetza and Fortamet, as well as the generic version of these medications may be considered medically necessary, when ALL of the following criteria are met:** • Individual has tried and failed generic metformin immediate release **AND** • Individual has tried and failed generic metformin extended release (generic for Glucophage XR):

Drug	Medical Necessity
	○ In an event such that individual experiences intolerance to a generic metformin extended release (generic for Glucophage XR), documentation of the attempts to minimize the adverse effects where appropriate is necessary to qualify for Glumetza and/or its generic version. ○ Dose de-escalation, in addition to taking the drug with meals before attempting a re-challenge of the preferred agent, metformin extended release (generic for Glucophage XR) are required to establish and confirm intolerance to the preferred agent. ▪ Metformin extended release should be started at a low dose with gradual dose escalation over 4 to 8 weeks ▪ Re-challenge period should last at a minimum of ≥3 months.
Brand metformin 625 mg	**Brand metformin 625 mg tablets may be considered medically necessary when ALL of the following criteria are met:** • Individual is 10 years of age or older **AND** • Diagnosed with type 2 diabetes mellitus **AND** • Tried* and failed or had intolerance with two of the following generic metformin immediate-release products (documentation required): ○ Metformin 500 mg tablets ○ Metformin 850 mg tablets ○ Metformin 1,000 mg tablets **AND** • The dose prescribed is ≤ 2,500 mg per day **Note:** *Defined as 2 months of continuous therapy for each metformin product.
Mytesi (crofelemer)	**Mytesi (crofelemer) may be considered medically necessary for the symptomatic relief of non-infectious diarrhea when ALL of the following criteria have been met:** • Individual is 18 years of age or older

Drug	Medical Necessity

	AND
	• Diagnosed with HIV/AIDS and on anti-retroviral therapy
	AND
	• Tried* and failed or had intolerance with two of the following (documentation required):
	  ○ Bismuth subsalicylate
	  ○ Diphenoxylate/atropine
	  ○ Loperamide
	AND
	• The dose is limited to 250 mg per day (taken as 125 mg twice daily)
	
	Note: *Defined as 1 month of continuous therapy for each drug.

Natpara (parathyroid hormone)	**Natpara (parathyroid hormone) may be considered medically necessary when ALL of the following criteria have been met:** • Individual is 18 years of age or older and diagnosed with hypocalcemia with hypoparathyroidism within the last year **AND** • Individual is using calcium supplements **AND** • Individual is using an active form of vitamin D (e.g., calcitriol, cholecalciferol, ergocalciferol) **AND** • Albumin-corrected serum calcium is at least 7.5 mg/dL **AND** • Individuals does not have acute post-surgical hypoparathyroidism **AND** • Prescribed by or in consultation with an endocrinologist **AND** • The quantity prescribed is limited to two cartridges per 28 days **Initial approval will be for 1-year.** **Reauthorization criteria:**

Drug	Medical Necessity
	• Continued therapy will be approved for 1-year when documentation shows the albumin-corrected total serum calcium concentration is between 7.5 mg/dL and 10.6 mg/dL
Northera (droxidopa)	**Northera (droxidopa) may be considered medically necessary when ALL of the following criteria have been met:** • Individual is 18 years of age or older and diagnosed with symptomatic neurogenic orthostatic hypotension **AND** • Individual has tried and failed non-pharmacologic therapy (e.g., adjusting salt intake, drinking adequate water, avoiding alcohol, reducing meal size, elevating the head of bed, use of compression stockings) **AND** • Individual has tried and failed one-month of therapy with the maximum tolerated dose of midodrine unless there is a contraindication to use of midodrine **AND** • Northera is prescribed by a neurologist or cardiologist **Initial approval will be for 1 month.** **Reauthorization criteria:** • Continued therapy will be approved for 12 months when documented evidence shows the individual experienced improvement in symptoms for neurogenic orthostatic hypotension.
Kits	**Excessively high cost kits (containing one or more drugs, often packaged with medical supplies such as sterile gloves) may be considered medically necessary when:** • Individual has a documented trial and failure on continuous use, for at least 3 months with ALL dosage forms of ALL active ingredients in the kit **AND** • There is a documented specific clinical rationale for the individual not being able to use each of the ingredients within the kit separately

Drug	Medical Necessity
	The use of excessively high cost kits solely for the convenience of either provider or individual is considered not medically necessary.

Jublia (efinaconazole) and Kerydin (tavaborole) (topical antifungal agents)	**Jublia (efinaconazole) and Kerydin (tavaborole) may be considered medically necessary when:**
	• Individual has a documented diagnosis of onychomycosis confirmed by a positive KOH (potassium hydroxide) test AND a fungal culture
	  ○ Copy of the KOH test and culture results are required
	AND
	• Individual has a documented trial* and failure of:
	  ○ Generic ciclopirox (topical)
	  AND
	  ○ Generic tavaborole (topical)
	  AND
	  ○ Generic terbinafine OR itraconazole, unless such are contraindicated or not tolerated
	AND
	• Total duration of therapy is not to exceed 48 weeks
	
	Note: *Trial is defined as 3 months of continuous therapy.

Generic tavaborole (topical antifungal solution)	**Generic tavaborole (topical) may be considered medically necessary when:**
	• Individual has a documented diagnosis of onychomycosis confirmed by a positive KOH (potassium hydroxide) test AND a fungal culture
	  ○ Copy of the KOH test and culture results are required
	AND
	• Individual has a documented trial* and failure of:
	  ○ Generic ciclopirox (topical)
	  AND
	  ○ Generic terbinafine OR itraconazole, unless such are contraindicated or not tolerated
	AND
	• Total duration of therapy is not to exceed 48 weeks

Drug	Medical Necessity
	Note: *Trial is defined as 3 months of continuous therapy.
Topical lidocaine products • **Adazin** • **Ldo Plus** • **L.E.T.** • **Lidocaine 3.88%** • **Lidocaine HCl** • **Lidocaine-Tetracaine** • **Lidopin** • **Lidotrex** • **Nynutey** • **Pain Relief** • **Pliaglis** • **Regenecare** • **Scar** • **Synvexia TC** • **Vexasyn**	**Adazin, Elenza Patch, Ldo Plus, L.E.T., Lidocaine 3.88%, Lidocaine-Epinephrine-Tetracaine, Lidocaine HCl, Lidocaine-Tetracaine, Lidodextrapine, Lidopin, Lidotrex, Lidozion, Pain Relief, Pliaglis, Regenecare, Relyyks, Scar, Synvexia TC, and Vexa may be considered medically necessary when the individual has a documented trial* and failure of generic lidocaine HCL cream AND generic lidocaine ointment.** **Note:** *Trial is defined as 3 months of continuous therapy.
Lidoderm Patches **Synera** **ZTlido**	**Lidoderm patches, Synera, and ZTlido may be considered medically necessary when the individual has a documented trial* and failure of generic lidocaine patch, AND generic lidocaine HCL cream, AND generic lidocaine ointment.** **Note:** *Trial is defined as 3 months of continuous therapy.
Paingo KFT	**Paingo KFT may be considered medically necessary when the individual has a documented trial* and failure of generic lidocaine/prilocaine cream, AND generic lidocaine HCL cream, AND generic lidocaine ointment.** **Note:** *Trial is defined as 3 months of continuous therapy.
Rayos (prednisone delayed-release)	**Rayos may be considered medically necessary when the individual has a documented trial* and failure of both generic prednisone AND methylprednisolone.** **Note:** *Trial is defined as 3 months of continuous therapy.
Riomet (metformin oral solution), Riomet ER	**Riomet and Riomet ER may be considered medically necessary when one of the following documented reasons is provided as**

Drug	Medical Necessity
(metformin extended-release oral suspension)	**to why the oral tablet of the generically available metformin is not appropriate for the individual:** • Individual is unable to swallow tablets **OR** • Individual has compromised ability to absorb tablets
Sitavig (acyclovir buccal tablets)	**Sitavig (acyclovir buccal tablets) may be considered medically necessary for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults when all the following criteria are met:** • Individual is 18 years of age or older **AND** • Documented trial and failure or intolerance with topical acyclovir or Denavir (penciclovir topical) **AND** • Documented trial and failure or intolerance with two of the following oral drugs: o acyclovir o famciclovir o valacyclovir **AND** • The quantity is limited to 4 tablets per 30 days
Zileuton extended-release; Zyflo (zileuton) & zileuton	**Zileuton extended-release, Zyflo (zileuton), or zileuton may be considered medically necessary when provider submits documentation in the form of medical records to show that the individual had an adequate trial and failure (at least 3 months) of generic montelukast.**

Drug	Not Medically Necessary
As listed	**All other uses of the drugs listed in this policy are considered not medically necessary.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Unless noted otherwise for specific drugs under the medical necessity criteria the drugs listed in policy may be approved up to 12 months.**
Re-authorization criteria	**Unless noted otherwise for specific drugs under the medical necessity criteria future re-authorization of the drugs listed may be approved up to 12 months as long as the medical necessity criteria are met, and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation and medication history

Coding

N/A

Related Information

Definition of Medical Necessity

Those covered services and supplies that a physician, exercising prudent clinical judgment, would provide to an individual for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and

2. Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the individual's illness, injury or disease; and

3. Not primarily for the convenience of the individual, physician, or other health care provider, and

4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that individual's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on reliable scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and the views of physicians practicing in relevant clinical areas and any other relevant factors.

A recent disturbing trend threatens to drive substantial increases in pharmaceutical expenditures. Opportunistic pharmaceutical companies are buying up products and raising the prices by 500% or more overnight. In addition, these companies are marketing kits, which combine a prescription medication with a medical supply or OTC products. These kits far exceed the cost of each individual product alone. These companies do not do research to originate new products and add no value to what they purchase. Unfortunately, some of these products are one of a kind, and thus have a captive audience. Recent media attention has been drawn to Daraprim (pyrimethamine), an antiprotozoal drug for which there are no comparable alternatives that was purchased by Turing Pharmaceuticals (now Vyera Pharmaceuticals), who raised the price overnight from $13.50 per tablet to $750.

Definition of Kit

Kits are defined as a combination of a prescription medication with a medical supply or OTC product, in which the combination of these products far exceeds the cost of each individual product.

Consideration of Age

The ages noted in the policy statements are based on the FDA labeling for these agents.

2019 Update

Reviewed prescribing information and updated drug lists documented for each therapeutic class. No new evidence was identified that require changes to existing criteria.

2020 Update

Reviewed prescribing information and added Absorica LD to policy with same criteria as Absorica. Updated criteria for Alcortin-A to require trial of two generic prescription topical corticosteroids first.

2021 Update

Reviewed prescribing information and generic availability for drugs referenced in policy. Updated brand name EpiPen (epinephrine injection) and Adrenaclick (epinephrine injection) to include generic epinephrine auto-injector as one of the preferred options prior to brand EpiPen or Adrenaclick.

2022 Update

Reviewed product availability for all drugs referenced in policy. Removed Vanatol LQ (butalbital/acetaminophen) and Vanatol S (butalbital/acetaminophen) from policy as products are no longer available. Removed from topical lidocaine products Reciphexamine, Silvera, and Velma as products are no longer available

2023 Update

Reviewed product availability for all drugs referenced in policy. Removed from topical lidocaine products eLenzaPatch, Lidodextrapine, Relyyks, and lidocaine-epinephrine-tetracaine as products are no longer available.

2024 Update

Reviewed product availability for all drugs referenced in policy. Removed Adrenaclick (epinephrine injection), Evzio (naloxone), and Zyflo CR (zileuton extended-release) from the policy as these products are no longer available.

References

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History

Date	Comments
02/09/16	New Utilization Management Guideline, add to Prescription Drug section. Excessively high cost drug products with lower cost alternatives are considered not medically necessary for all indications.
05/01/16	Annual Review, approved April 12, 2016. Addition of a new agent, Evzio, and its criteria to the policy. Revision of the criteria for Glumetza and its generic agent.
11/01/16	Interim Review, approved October 11, 2016. Inclusion of new agents and their associated criteria to the policy: DermacinRx Lexitral PharmaPak, Diclotral Pak, Pennsaid, Xrylix, Rayos, Jublia, Kerydin, and Zegerid.
12/01/16	Interim Review, approved November 8, 2016. Adding Zegerid's generic to the edit.

Date	Comments
01/01/17	Interim Review, approved December 13, 2016. Criteria for fluoxetine 60mg tablets has been added to the policy.
01/26/17	Interim Update. Added Auvi-Q and its related criteria.
02/01/17	Annual Review, approved January 10, 2017. Added Xelitral, Sure Result DSS Premium Pack, and Diclo Gel with Xrylix Sheets 1% kit to the topical NSAIDs criteria.
03/01/17	Interim Review, approved February 14, 2017. Addition of brand name EpiPen, Adrenaclick, Fortamet, and its generic, Riomet, and Alcortin-A.
04/01/17	Interim Review, approved March 14, 2017. Addition of brand drug Differen and its generic version adapalene.
08/01/17	Interim Review, Approved July 25, 2017. Addition of excessively high cost kits.
09/01/17	Interim Review, approved August 22, 2017. Addition of Amrix ER, omeprazole ODT, and Zyflo CR/Zileuton ER & Zyflo/Zileuton. Addition of Absorica and new criteria for Differin.
10/01/17	Interim Review, approved September 21, 2017. Changed criteria for Differin, clarified criteria for auvi-q, added criteria for omePPi.
01/01/18	Interim Review, approved December 20, 2017. Updated drugs targeted by topical NSAIDs edit.
03/01/18	Annual Review, approved February 27, 2018. Addition of various topical lidocaine products to policy as well as criteria for these products.
07/01/18	Interim Review, approved June 5, 2018. Addition of various topical lidocaine products and generic Alcortin-A to existing criteria. Generic Daraprim name was corrected.
09/12/18	Interim Review, approved September 11, 2018. Added Consideration of Age information. Added Vexasyn, removed Differin/Adapalene criteria from this policy as it was moved to policy 5.01.605.
11/01/18	Interim Review, approved October 26, 2018. Added Allzital, Vanatol LQ, Vanatol S, and multiple topical lidocaine products.
02/01/19	Interim Review, approved January 4, 2019. Added Suvicort as topical lidocaine product.
03/01/19	Interim Review, approved February 25, 2019. Updated Absorica criteria. Updated Glumetza, Fortamet and their generic criteria.
05/01/19	Annual Review, approved April 9, 2019. Added ZTlido to policy and generic cyclobenzaprine extended-release. Added criteria for Natpara (parathyroid horomone) to policy. Added Auvi-Q 0.1 mg/0.1 mL criteria.
06/01/19	Interim Review, approved May 23, 2019. Added L.E.T. as topical lidocaine product. Added criteria for Lorzone and generic chlorzoxazone to policy.

Date	Comments
08/01/19	Interim Review, approved July 9, 2019. Added criteria for the deferasirox products Exjade, Jadenu and Jadenu Sprinkle. Added criteria for the tobramycin inhaled products Bethkis, Kitabis Pak, TOBI and TOBI Podhaler.
10/01/19	Interim Review, approved September 19, 2019. Moved the deferasirox products Exjade, Jadenu and Jadenu Sprinkle to policy 5.01.613 Oral Iron Chelating Agents.
03/01/20	Annual Review, approved February 20, 2020. Added Absorica LD to policy with same criteria as Absorica. Updated criteria for Alcortin-A.
04/01/20	Interim Review, approved March 10, 2020. Added criteria for Northera (droxidopa) for treatment of symptomatic neurogenic orthostatic hypotension. Added Riomet ER to policy with same criteria as Riomet.
07/01/20	Interim Review, approved June 9, 2020. Added criteria for Sitavig (acyclovir buccal tablets) for the treatment of cold sores.
09/01/20	Interim Review, approved August 11, 2020. Changed lidocaine lotion to lidocaine ointment as part of requirement for coverage criteria for all Topical Lidocaine Products and Lidoderm, Synera, ZTlido, and Paingo KFT. Change made due to lidocaine lotion being no longer available. Added criteria for Mytesi (crofelemer) for the treatment of non-infectious diarrhea.
11/01/20	Interim Review, approved October 22, 2020. Moved omeprazole ODT, Zegerid (omeprazole/sodium bicarbonate), and generic omeprazole/sodium bicarbonate to Policy 5.01.605 Medical Necessity Criteria for Pharmacy Edits.
02/01/21	Interim Review, approved January 12, 2021. Added step therapy for generic tavaborole to Jublia and Kerydin criteria. Added new criteria for generic tavaborole. Removed from topical lidocaine products Anastia, Astero, Kamdoy, Lido-K, Lidorx, Lidotral, Lidovex, Lidtopic Max, Numbonex, Suvicort, Tranzarel, and Vexasyn as these drugs are not approved by the FDA and have coverage blocked under pharmacy benefit.
11/01/21	Annual Review, approved October 5, 2021. Updated brand name EpiPen (epinephrine injection) and Adrenaclick (epinephrine injection) to include generic epinephrine auto-injector as one of the preferred options.
06/01/22	Annual Review, approved May 9, 2022. Removed Vanatol LQ (butalbital/acetaminophen) and Vanatol S (butalbital/acetaminophen) from policy as products are no longer available. Removed from topical lidocaine products Reciphexamine, Silvera, and Velma as products are no longer available.
10/01/22	Interim Review, approved September 13, 2022. Added criteria for brand metformin 625 mg tablets. Changed the wording from "patient" to "individual" throughout the policy for standardization.
08/01/23	Annual Review, approved July 10, 2023. Added Nynutey to the topical lidocaine products. Removed from topical lidocaine products eLenzaPatch, Lidodextrapine, Relyyks, and lidocaine-epinephrine-tetracaine as products are no longer available.

Date	Comments
07/01/24	Annual Review, approved June 24, 2024. Removed Adrenaclick (epinephrine injection), Evzio (naloxone), and Zyflo CR (zileuton extended-release) from the policy as these products are no longer available.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.