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UM NETRESULTS (PREAUTHORIZATION REQUIRED)

X.75

X.75 UM NETRESULTS (PREAUTHORIZATION REQUIRED)

ADDYI (FIBANSERIN)

Addyi™ (flibanserin)	Indications Treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to: • A co-existing medical or psychiatric condition • Problems within the relationship • The effects of a medication or other drug substance. Limitations of Use: • Not indicated for the treatment of HSDD in postmenopausal women or in men. Not indicated to enhance sexual performance	Dosage and Administratio Recommended dosage is daily at bedtime Flibanserin is dosed at bed administration during wak risks of hypotension, syncc and central nervous systen Discontinue treatment afte improvement

The efficacy of flibanserin for the treatment of hypoactive sexual desire disorder (HSDD) in premenopausal women was established in three 24- week, randomized, double-blind, placebo-controlled trials (Studies 1, 2, and 3). The three trials included premenopausal women with acquired, generalized HSDD of at least 6 months duration. In all three trials, ADDYI resulted in statistically significant improvement compared to placebo in the change from baseline in monthly satisfying sexual events (SSE) at Week 24. In Study 1 and 2, there were no statistically significant differences between ADDYI and placebo for the eDiary sexual desire endpoint (change in baseline to Week 24). In contrast, in Study 3 there was statistically significant improvement in the change from baseline to Week 24 in sexual desire (using the female sexual function index (FSFI) Desire Domain) with ADDYI compared to placebo. The FSFI Desire Domain findings were consistent across all three trials as were the findings for the secondary endpoint that assessed distress using Question 13 of the FSDS-R.

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

Initial Evaluation

Addyi will be approved when **ALL** of the following are met:

- The patient's benefit plan covers the requested agent; **AND**
- The patient is female; **AND**
- The patient is premenopausal; **AND**
- The patient has had a diagnosis of hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty, for at least 6 months; **AND**

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- Problems within the relationship; **OR**
- The effects of a medication or other drug substance; **AND**

- The patient does NOT have any FDA labeled contraindication(s) to the requested agent; **AND**

- The requested quantity (dose) is NOT greater than the program quantity limit

- **Length of Initial Approval:** 3 months

Renewal Evaluation

Addyi will be approved when ALL of the following are met:

- The patient has been previously approved through the Prime Therapeutics prior authorization process for the requested agent; **AND**
- Patient's HSDD symptoms have improved after 8 weeks of therapy with the requested agent; **AND**

- The patient does NOT have any FDA labeled contraindication(s) to the requested agent; **AND**

- The requested quantity (dose) is NOT greater than the proram quantity limit

Length of Renewal Approval: 12 months

Dates

Original Effective
01-01-2017
Last Review
11-06-2024
Next Review
11-09-2025

TOPICAL ANTIBIOTICS

The intent of the Topical Antibiotics/Combinations Step Therapy (ST) program is to encourage the use of the cost-effective preferred and generic topical antibiotic products prior to the use of nonpreferred brand topical antibiotic products and to accommodate for use of brand nonpreferred topical antibiotic products when the preferred products cannot be used due to previous trial, documented intolerance, FDA labeled contraindication, or hypersensitivity. The program allows continuation of therapy when there is documentation that the patient is receiving the requested agent. Requests for nonpreferred topical antibiotic products will be reviewed when patient-specific documentation has been provided.

TARGET DRUGS

Acanya (clindamycin/benzoyl peroxide)
Aczone® (dapsone)
Akne-Mycin (erythromycin)[a]
Azelex® (azelaic acid)
Benzaclin (clindamycin/benzoyl peroxide)[a]
Benzamycin (erythromycin/benzoyl peroxide)[a]
Cleocin-T (clindamycin)[a]
Clindagel (clindamycin)[a]
Duac (clindamycin/benzoyl peroxide)[a]
Epiduo® (adapalene/benzoyl peroxide)
Epiduo® Forte (adapalene/benzoyl peroxide)
Erygel® (erythromycin)[a]

Metrolotion (metronidazole)[a]
Neuac (clindamycin-benzoyl peroxide gel)
Noritate (metronidazole)
Onexton™ (clindamycin/benzoyl peroxide)
Veltin™ (clindamycin/tretinoin)
Ziana® (clindamycin/tretinoin)
BRAND Benzoyl peroxide products/combinations, including but not limited to benzoyl peroxide, Benzac, and Panoxyl products[a]

BRAND Sulfacetamide products/combinations, including but not limited to Klaron[a]

a – available as a generic; included aAs a prerequisite in the step therapy program

b – brand not available

Prior Authorization criteria for approval

I. Nonpreferred brand topical antibiotic may be considered medically necessary when the following criteria are met:

A. The patient's medication history includes use of two preferred topical antibiotic products **OR**

B. There is documenation that the patient is curently using the requested agent **OR**

C. The prescriber states the patient is currently using the requested agent AND is at risk if therapy is changed **OR**

D. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least two preferred topical

antibiotic products

Length of Appr oval: 12 months

ANTIDEPRESSANT AGENTS

The intent of the Antidepressant Agents Step Therapy program is to encourage the use of generic antidepressant agents - selective serotonin reuptake inhibiting agents (SSRIs), serotonin norepinephrine reuptake inhibiting agents (SNRIs), bupropion/bupropion extended-release, or mirtazapine [or generic trazodone extended-release if it becomes available] - prior to brand antidepressant agents and to accommodate for use of brand antidepressant agents when generic prerequisite agents cannot be used due to previous trial, documented intolerance, FDA labeled contraindication, or hypersensitivity. The criteria for Cymbalta also encourage its use for neuropathic pain after trial of amitriptyline, nortriptyline, imipramine, desipramine, or gabapentin; for fibromyalgia (FM) after a trial of amitriptyline, nortriptyline, imipramine, desipramine, cyclobenzaprine, tramadol, or gabapentin; and for chronic musculoskeletal pain (CMP; for example, osteoarthritis or chronic low back pain) after a trial of acetaminophen, oral NSAID, topical NSAID, or any other prerequisite for FM or neuropathic pain already listed. The criteria for duloxetine (delayed release capsule, brand product) and Irenka also encourage its use for neuropathic pain after trial of amitriptyline, nortriptyline, imipramine, desipramine, or gabapentin; and for chronic musculoskeletal pain (CMP; for example, osteoarthritis or chronic low back pain) after a trial of acetaminophen, oral NSAID, topical NSAID, amitriptyline, nortriptyline, imipramine, desipramine,

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TARGET DRUGS

Aplenzin™ (bupropion)

Brintellix™, Trintellix™ (vortioxetine)

Celexa® (citalopram)[a]

Cymbalta® (duloxetine)[a]

Desvenlafaxine (ER tablets, brand product)

Desvenlafaxine fumarate (ER tablets, brand product)

Duloxetine (delayed release capsule, brand product)

Effexor® (venlafaxine)[a]

Effexor XR® (venlafaxine extended release)[a]

Fetzima™ (levomilnacipran extended release)

Fluoxetine 60 mg (tablets, brand product)

Forfivo XL® (bupropion extended release)

Irenka™ (duloxetine delayed release)

Khedezla™ (desvenlafaxine extended release)

Lexapro® (escitalopram)[a]

Luvox CR® (fluvoxamine extended release)[a]

Maprotiline (tablets, brand product)

Oleptro™ (trazodone extended release)[b]

Paxil® (paroxetine hydrochloride)[a]

Paxil CR® (paroxetine extended release)[a]

Pexeva® (paroxetine mesylate)

Pristiq® (desvenlafaxine succinate)

Prozac® (fluoxetine)[a]

Prozac® Weekly™ (fluoxetine delayed release)[a]

Remeron® (mirtazapine)[a]

RemeronSolTab® (mirtazapine)[a]

Venlafaxine ER (tablets, brand product)[a]

Viibryd™ (vilazodone)

Wellbutrin® (bupropion)[a]

Wellbutrin SR® (bupropion extended release)[a]

Wellbutrin XL® (bupropion extended release)[a]

Zoloft® (sertraline)[a]

a - available as a generic; generic included as a *prerequisite* in step therapy program

b – generic product anticipated

PRIOR AUTHORIZATION CRITERIA FOR APPROVA

1. The patient has not filled a prescription for a monoamine oxidase (MAO) inhibitor in the past 30 days **AND**
2. **ONE** of the following:
   a. The patient's medication history includes use of a generic antidepressant agent - SSRI, SNRI, bupropion, or mirtazapine [or generic trazodone extended-release if it becomes available] in the past 365 days **OR**
   b. There is documentation that the patient is currently using the requested brand antidepressant **OR**
   c. The prescriber states that the patient is using the requested brand antidepressant **AND** is at risk if therapy is changed **OR**
   d. The patient has a history of a documented intolerance, FDA labeled contraindication, or hypersensitivity to a generic antidepressant agent - SSRI, SNRI, bupropion, or mirtazapine [or generic trazodone extended-release if it becomes available]

Cymbalta, Duloxetine (delayed release capsule, brand product), and Irenka will be approved when BOTH of the following are met:

1. The patient has not filled a prescription for a monoamine oxidase (MAO) inhibitor in the past 30 days **AND**
2. ONE of the following:
   a. The patient's medication history includes use of a generic antidepressant agent - SSRI, SNRI, bupropion, or mirtazapine [or generic trazodone extended-release if it becomes available] in the past 365 days **OR**
   b. The patient has a diagnosis of neuropathic pain and the medication history includes use of amitriptyline, nortriptyline, desipramine, imipramine, or gabapentin in the past 90 days **OR**
   c. For Cymbalta only, the patient has a diagnosis of fibromyalgia and the medication history includes use of amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, gabapentin, or tramadol in the past 90 days **OR**
   d. The patient has a diagnosis of chronic musculoskeletal pain and the medication history includes use of acetaminophen, oral NSAID, topical NSAID, tramadol, amitriptyline, nortriptyline, desipramine, imipramine, cyclobenzaprine, or gabapentin in the past 90 days **OR**
   e. There is documentation that the patient is currently using the requested agent **OR**
   f. The prescriber states that the patient is using the requested agent AND is at risk if therapy is changed **OR**
   g. The patient has a history of a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prerequisite for the requested diagnosis

Length of approval: 12 months

ANTIFUNGAL AGENTS

FDA APPROVED INDICATIONS AND DOSAGE[1-3,19-23]

Drug	FDA Indication(s)	Dosing
Jublia (efinaconazole) topical solution	Onychomycosis of the toenails due to Trichophyton rubrum and Trichophyton mentagrophytes	Apply to affected toenail once daily for
Kerydin™ (tavaborole) topical solution	Onychomycosis of the toenails due to Trichophyton rubrum or Trichophyton mentagrophytes.	Apply to affected toenail once daily for

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tablets, oral granules	Tinea capitis	**Fingernail –** treat 6 weeks **Toenail –** treat 12 weeks **Tinea capitis** – 125 mg -250 mg daily table) *Dosage by body weight:* <25 kg: 125 mg/day 25-35 kg: 187.5 mg/day >35 kg: 250 mg/day
Onmel (itraconazole) tabs	Onychomycosis of the toenail due to *Trichophyton rubrum* or *T. mentagrophytes* in non-immunocompromised patients	**Onychomycosis toenail-**200 mg once
Penlac (ciclopirox) topical solution	Onychomycosis of the toenail or fingernail (topical treatment in immunocompetent patients with mild to moderate onychomycosis without lunula involvement, due to *Trichophyton rubrum*)	Apply daily to affected area
Sporanox (itraconazole) capsules, oral solution	Blastomycosis, histoplasmosis, aspergillosis, onychomycosis of the toenail or fingernail	**Blastomycosis-**200 mg daily (up to 4(mg not effective) **Histoplasmosis-**200 mg daily (up to 4 mg not effective) **Aspergillosis-**200-400 mg daily **Onychomycosis toenail-**200 mg daily **Onychomycosis fingernail-**200 mg t week, then 3 weeks off, then 200 mg t more week
Terbinex Kit (terbinafine) tabs	Onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium)	**Onychomycosis -** 250 mg daily **Fingernail –** treat 6 weeks **Toenail –** treat 12 weeks

OBJECTIVE

The intent of the Itraconazole, Terbinafine Prior Authorization (PA) Criteria is to assure appropriate selection of patients for treatment according to product labeling and/or clinical trials and/or guidelines and to discourage cosmetic utilization. The PA defines appropriate use for the treatment of onychomycosis as a confirmed fungal nail infection that is considered medically necessary to treat. Brand products are included in this program and generics targeting to be determined by client. Topical terbinafine products are not included. For brand agents, the program requires the trial of a generic antifungal onychomycosis agent or that the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one generic antifungal onychomycosis agent. Approval will not be granted to patients who have any FDA labeled contraindication(s) to the requested agent. The program will approve for doses within the set limit. Doses above the set limit will be approved if the requested quantity is below the FDA limit and cannot be dose optimized or when the quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Requests will be reviewed when patient specific documentation is provided.

TARGET DRUGS

Lamisil® (terbinafine)[a] – tablets,[b] granules

Onmel™ (itraconazole) - tablets

Sporanox® (itraconazole) – capsules,[b] oral solution

Terbinex™ (terbinafine) - tablets

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PROGRAM PRIOR AUHTORIZATION AND QUANTITY LIMITS

Brand (generic)	GPI	Quantity Per Day (Or As Noted)
Lamisil (terbinafine)[a]		
250 mg tablet[b]	11000080100310	1 tablet
125 mg granules packet	11000080103020	1 packet
187.5 mg granules packet	11000080103030	1 packet
Onmel (itraconazole)		
200 mg tablet	11407035000330	1 tablet
Sporanox (itraconazole)		
100 mg capsule[b]	11407035000120	4 capsule
10 mg/mL oral solution	11407035002020	40 mL
Terbinex (terbinafine)		
250 mg tablet	11000080506420	1 tablet

a - Lamisil cream and spray not included in the program

b - available as a generic; designated target as determined by client

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Lamisil (terbinafine), Onmel (itraconazole), Sporanox (itraconazole), or Terbinex (terbinafine) will be approved when ALL of the following are met:

1. The patient does not have any FDA labeled contraindication(s) to the requested agent
   AND
2. ONE of the following:
   a. The patient has a diagnosis for fungal infection other than onychomycosis (tinea unguium)
      OR
   b. The patient has a diagnosis of onychomycosis (tinea unguium)
      AND ALL of the following:
      i. No evidence of prior authorization for the requested drug is seen in the past 12 months of claims history
         AND
      ii. The patient has one of the following: diabetes mellitus, peripheral vascular insufficiency, immune deficiency due to medical condition or treatment (e.g. cancer chemotherapy, HIV/AIDS, anti-rejection therapy post organ transplant), pain limiting normal activity, or secondary bacterial infection in the surrounding skin or systemic dermatosis with impaired skin integrity
         AND
      iii. Treatment of the patient's onychomycosis (tinea unguium) is medically necessary and not entirely for cosmetic reasons
         AND

v. If the requested agent is a brand agent, ONE of the following:

1. The patient's medication history includes use of a generic antifungal onychomycosis agent (e.g. itraconazole, terbinafine, ciclopirox) in the past 90 days
   OR
2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one generic antifungal onychomycosis agent

AND

1. ONE Of the following:
   a. The requested quantity (dose) is NOT greater than the program quantity limit
      OR
   b. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) is less than or equal to the FDA labeled dose
         AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit
         OR
   c. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) is greater than the FDA labeled dose
         AND
      iii. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of approval for onychomycosis*
Lamisil/Terbinex/terbinafine: 6 weeks for fingernail infection, 12 weeks for toenail infection
Sporanox/Onmel/itraconazole: 2 weeks of pulse therapy for fingernail infection only, 12 weeks for toenail infection with or without fingernail involvement

*Lamisil/Terbinex/terbinafine and Sporanox/Onmel/itraconazole are limited to one

approval per 12 month period for onychomycosis (tinea unguium)

Length of approval for diagnosis other than onychomycosis:

Lamisil or terbinafine for 6 weeks for tinea capitis or other fungal infections

Sporanox or itraconazole for 4 weeks for oropharyngeal or esophageal candidiasis or cutaneous fungal infections;

Sporanox or itraconazole for 12 months for other fungal infections

ANTIEMETIC AGENTS QUANTITY LIMIT CRITERIA

Antiemetic Agents Quantity Limit Criteria

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with Akynzeo, Anzemet, Cesamet, Emend, Granisol, granisetron, Sancuso, Varubi, Zofran/Zofran ODT/ondansetron, or Zuplenz for up to 7 days of cancer chemotherapy or radiotherapy per month. Emend 40 mg tablets, Kytril, and Zofran injection are not included in the program. The criteria will also evaluate Cesamet for additional quantities after conventional antiemetics have been shown to give an inadequate response. Requests for larger quantities of Akynzeo, Anzemet, Emend, Granisol, granisetron, Sancuso, Varubi, Zofran/Zofran ODT/ondansetron, and Zuplenz may be approved if prescriber provides documentation indicating chemotherapy or radiation treatment extending beyond 7 days per month, delayed emesis to highly emetogenic chemotherapy, or hyperemesis gravidarum.

QUANTITY LIMIT TARGET DRUGS - RECOMMENDED LIMITS

Brand (generic)	GPI	Quantity Per 30 Day Limit
Akynzeo® (netupitant/palonosetron)		
300 mg / 0.5 mg	50309902290120	2 capsules
Anzemet® (dolasetron)		
50 mg tablet	50250025200320	7 tablets
100 mg tablet	50250025200330	7 tablets
Cesamet® (nabilone)		
1 mg capsule	50300040000110	42 capsules
Emend® (aprepitant)		
80 mg capsule	50280020000120	4 capsules
125 mg capsule	50280020000130	2 capsules
Emend Therapy Pack (1x125 mg capsule, 2x80 mg capsules)	50280020006320	2 therapy packs
Granisol® (granisetron)		
2 mg/10 mL oral solution	50250035102060	60 mL (2 bottles)
granisetron		
1 mg tablet[a]	50250035100310	14 tablets
Sancuso® (granisetron)		
3.1 mg/24 hours patch	50250035005920	1 patch
Varubi™ (rolapitant)		
90 mg tablet	50280050200320	4 tablets
Zofran® (ondansetron)		
4 mg tablet[a]	50250065050310	21 tablets
8 mg tablet[a]	50250065050320	21 tablets
24 mg tablet[ab]	50250065050340	1 tablet
4 mg/5 mL oral solution[a]	50250065052070	100 mL (2 bottles)
Zofran® ODT (ondansetron)		
4 mg orally disintegrating tablet[a]	50250065007220	21 tablets

300 mg / 0.5 mg	50309902290120	2 capsules
8 mg orally disintegrating tablet[a]	50250065007240	21 tablets
Zuplenz® (ondansetron)		
4 mg oral soluble film	50250065008220	20 films (2 boxes of 10)
8 mg oral soluble film	50250065008240	20 films (2 boxes of 10)

a - generic available and included in quantity limit program

b - 24 mg tablet available as generic only

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Quantities above the program set limit for **Anzemet, Granisol, granisetron, Sancuso, Zofran/Zofran ODT/ondansetron, or Zuplenz** will be approved when ONE of the following is met:

- The patient has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 7 days per month; **OR**
- The patient has delayed emesis in highly emetogenic chemotherapy; **OR**
- The patient has hyperemesis gravidarum; **OR**
- The patient has radiation therapy induced nausea and vomiting and radiation treatment that extends beyond 7 days per month; **OR**
- The prescriber has submitted documentation in support of the requested therapeutic use and quantity for the requested medication which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: 12 months

Quantities above the program set limit for **Akynzeo**, **Emend, or Varubi** will be approved when **ONE** of the following is met:

- The patient has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 7 days per month; **OR**
- The prescriber has submitted documentation in support of the requested therapeutic use and quantity for the requested agent which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: 12 months

Quantities above the program set limit for **Cesamet** will be approved when **ONE** of the following is met:

- BOTH of the following:
  - The patient has a documented history of failure to respond adequately to one conventional antiemetic treatment (Akynzeo, Anzemet, Emend, Granisol, granisetron, Sancuso, Varubi, or Zofran/Zofran ODT/ondansetron); **AND**
  - The patient has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 7 days per month; **OR**
- The prescriber has submitted documentation in support of the requested therapeutic use and quantity for Cesamet which has been reviewed and approved by the Clinical Review pharmacist.

Length of Approval: 12 months

ANTI-INFLUENZA AGENT QUANTITY LIMIT

OBJECTIVE

in a 120 day period. Requests for larger quantities will be evaluated through the Clinical Review process when the prescriber provides evidence that dosing with higher quantities is appropriate for the patient.

PROGRAM QUANTITY LIMITS

Brand (generic)	GPI	Multisource Code	Quantity per 120 days
Relenza (zanamivir)			
5 mg blister	12504080008020	M, N, O, or Y	40 blisters
Tamiflu (oseltamivir)			
30 mg capsule	12504060200110	M, N, O, or Y	20 capsules
45 mg capsule	12504060200115	M, N, O, or Y	20 capsules
75 mg capsule	12504060200120	M, N, O, or Y	20 capsules
6 mg/ml suspension	12504060201910	M, N, O, or Y	360 ml
12 mg/ml suspension	12504060201920	M, N, O, or Y	150 ml

QUANTITY LIMIT AUTHORIZATION CRITERIA FOR APPROVAL

Requests above the set quantity limit will be approved when BOTH of the following are met:

- **ONE** of the following:
  - The patient requires additional courses of therapy due to additional episodes of acute influenza infection; **OR**
  - The patient requires additional courses or increased duration of therapy for prophylaxis after exposure to an influenza infected person; **AND**
- ONE of the following:
  - **BOTH** of the following:
    - The requested quantity (dose) is less than or equal to the FDA labeled dose; **AND**
    - The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit; **OR**
  - **BOTH** of the following:
    - The requested quantity (dose) is greater than the FDA labeled dose; **AND**
    - The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 4 months

OBJECTIVE

The intent of the Atopic Dermatitis Step Therapy program is to encourage the use of topical corticosteroid or topical corticosteroid combination preparations prior to, or concurrent with, Elidel or Protopic. The program allows use of Elidel or Protopic when the patient has had a trial, documented intolerance, FDA labeled contraindication, or hypersensitivity to a topical corticosteroid or topical corticosteroid combination preparation, or when the requested agent is for use on the face, neck or skin folds. Requests for Elidel or Protopic will be reviewed when patient-specific documentation has been provided.

TARGET DRUGS

Elidel® (pimecrolimus cream)

Eucrisa (criaborole ointmen 2%)

Protopic® (tacrolimus ointment)*

* generic available, targeted in program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agents will be approved when ONE of the following is met:

1. The patient is requesting the requested agent for use on the face (including eyelids), neck, or skin folds (e.g. groin, armpit/under arm); **OR**

2. The patient's medication history includes use of any topical corticosteroid or topical corticosteroid combination preparation in the past 120 days; **OR**

3. There is documentation that the patient is currently using the requested agent **OR**

4. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to topical corticosteroids or topical corticosteroid combination preparations **OR**

5. The prescriber states the patient is currently using the requested agen AND is at risk if therapy is changed.

Length of approval: 12 months

ATYPICAL ANTIPSYCHOTICS STEP THERAPY

OBJECTIVE

The intent of the Atypical Antipsychotic Step Therapy (ST) program is to encourage the use of cost-effective generic atypical antipsychotic agents over brand atypical antipsychotic agents and to accommodate for use of brand atypical antipsychotic agents when generic atypical antipsychotic agents cannot be used due to previous trial, documented intolerance, FDA labeled contraindication, or hypersensitivity. The criteria for Abilify and Abilify Discmelt encourage the use of cost-effective generic atypical antipsychotic agents or generic FDA approved agents for Tourette's Disorder, and accommodate for the use of Abilify and Abilify Discmelt when generic atypical antipsychotic agents or generic FDA approved Tourette's Disorder agents cannot be used due to previous trial, documented intolerance, FDA labeled contraindication, or hypersensitivity. The use of these agents for the off-label use "dementia-related psychosis" will be accommodated for shorter approval timeframes, due to concerns with safety of their use in the dementia population and based on published regulations and guidelines. The program also allows for continuation of therapy if a patient has been previously stabilized on the requested brand atypical antipsychotic. All dosage forms of the brand atypical antipsychotics listed will be included as targets in the step therapy program.

Abilify Discmelt® (aripiprazole)

Abilify Maintena™ (aripiprazole)

Aripiprazole ODT

Aristada™ (aripiprazole lauroxil injection)

Clozaril® (clozapine)[a]

Fanapt® (iloperidone)

FazaClo®, clozapine ODT[a,b] (clozapine)

Geodon® (ziprasidone)[a]

Invega® (paliperidone)[a]

Invega® Sustenna™ (paliperidone)

Invega Trinza™ (paliperidone injection)

Latuda® (lurasidone)

Rexulti® (brexpiprazole)

Risperdal® (risperidone)[a]

Risperdal® M-Tab® (risperidone)[a]

Risperdal® Consta® (risperidone)

Saphris® (asenapine)

Seroquel® (quetiapine)[a]

Seroquel XR® (quetiapine)

Versacloz™ (clozapine)

Vraylar™ (cariprazine)

Zyprexa® (olanzapine)[a]

Zyprexa® Zydis® (olanzapine)[a]

Zyprexa® Relprevv™ (olanzapine)

a – generic available; not a target in step therapy program

b – MSC M product available; included as target in step therapy program

PRIOR AUTHORIZATION CRITERIA FOR INITIAL APPROVAL AND RENEWAL

Brand Atypical Antipsychotics will be approved when ONE of the following is met:

- The patient is requesting Abilify OR Abilify Discmelt for Tourette's Disorder **AND** ONE of the following:
    - The patient's medication history includes the use of haloperidol OR pimozide in the past 90 days; **OR**
    - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to either generic haloperidol OR pimozide; **OR**
- The patient's medication history includes use of a generic atypical antipsychotic agent in the past 90 days; **OR**
- There is documentation that the patient is currently using the requested brand atypical antipsychotic agent; **OR**

- The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one generic atypical antipsychotic agent

Length of approval:

- dementia-related psychosis: 3 months for initial approval; 3 months for renewals
- all other indications: 12 months

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

ORAL ANTICOAGULANT

OBJECTIVE

The intent of the Oral Anticoagulant - Bevyxxa (betrixaban), Eliquis (apixaban), Pradaxa (dabigatran), Savaysa (edoxaban), Xarelto (rivaroxaban) quantity limit program is to encourage appropriate prescribing quantities as recommended by FDA approved product labeling or as otherwise clinically appropriate. Limits for Eliquis and Savaysa based on FDA labeling are reflective of the maximum recommended in that labeling. Limits for Pradaxa and Xarelto based on FDA labeling are reflective of the doses recommended for each approved indication in that labeling. Determination of quantity limits takes into account the lowest number of dosage units required to achieve the maximum dose (dose optimization).

QUANTITY LIMIT TARGET DRUGS - RECOMMENDED LIMITS

Brand (generic)	GPI	Quantity Limit
Bevyxxa (betrixaban)		
40mg capsule	83370018200120	43 capsules/42 days
80mg capsule	83370018200140	43 capsules/42 days
Eliquis (apixaban)		
2.5 mg tablet	83370010000320	2 tablets/day
5 mg tablet	83370010000330	4 tablets/day
Pradaxa? (dabigatran)		
75 mg capsule	83337030200120	2 capsules/day
110 mg capsule	83337030200130	71 capsules/90 days
150 mg capsule	83337030200140	2 capsules/day
Savaysa™ (edoxaban)		
15 mg tablet	83370030200315	1 tablet/day
30 mg tablet	83370030200330	1 tablet/day
60 mg tablet	83370030200350	1 tablet/day
Xarelto? (rivaroxaban)		
Starter Pack	8337006000B720	51 tablets/30 days
10 mg tablets	83370060000320	35 tablets/90 days
15 mg tablets	83370060000330	2 tablets/day
20 mg tablets	83370060000340	1 tablet/day

Quantities above the program set limit for **Bevyaxxa,Eliquis and Savaysa** will be approved when **ONE** of the following is met:

- The quantity (dose) requested is within FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength; **OR**
- The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Pradaxa

- Quantities above the program set limit for **Pradaxa** will be approved when **ONE** of the following is met:
- The indicated use is prophylaxis of DVT and PE following hip replacement surgery **AND** the prescriber has submitted documentation in support of therapy with a higher quantity (duration) which has been reviewed and approved by the Clinical Review pharmacist; **OR**
- The indicated use is to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation OR treatment of DVT/PE OR reduction in the risk of recurrence of DVT and PE **AND BOTH** of the following:
    - The requested dosage form is not 110 mg; **AND**
    - **ONE** of the following:
        - The quantity (dose) requested is within FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength; **OR**
        - The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist;

OR

- The indicated use is other than those listed above **AND** the prescriber has submitted documentation in support of therapy with a higher quantity for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Xarelto

- Quantities above the program set limit for **Xarelto** will be approved when **ONE** of the following is met:
- The indicated use is prophylaxis of DVT following hip or knee replacement surgery **AND** the prescriber has submitted documentation in support of therapy with a higher quantity (duration) which has been reviewed and approved by the Clinical Review pharmacist; **OR**
- The indicated use is nonvalvular atrial fibrillation **OR** treatment/prophylaxis of DVT/PE **AND BOTH** of the following:
    - The requested dose is not less than or equal to 10 mg daily; **AND**
    - **ONE** of the following:

- The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

OR

- The indicated use is other than those listed above **AND** the prescriber has submitted documentation in support of therapy with a higher quantity for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of approval: 12 months or as requested by the prescriber, whichever is shorter

BUPRENORPHINE AND BUPRENORPHINE/NALOXONE FOR OPIOID DEPENDENCE PRIOR AUTHORIZATION WITH QUANTITY LIMIT

FDA APPROVED INDICATIONS AND DOSAGE[1-3,15-17]

Agent	Treatment of opioid dependence and induction; should be used as part of a complete treatment plan to include counseling and psychosocial support.	Maintenance treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support
buprenorphine sublingual tablet[ac]	✓	
Bunavail™ (buprenorphine/naloxone buccal film)		✓
Suboxone® (buprenorphine/naloxone sublingual tablet)[ab]		✓
Suboxone® (buprenorphine/naloxone sublingual film)	✓	✓
Zubsolv® (buprenorphine/naloxone sublingual tablet)	✓	✓

a – Generic available.

b –Brand Suboxone tablets discontinued by manufacturer but may still be available.

c – Brand Subutex no longer available.

Under the Drug Addiction Treatment Act of 2000 (DATA) codified at 21 U.S.C. 823(g), prescription use of this product in the treatment of opioid dependence is limited to

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OBJECTIVE

The intent of the Buprenorphine and Buprenorphine/Naloxone for Opioid Dependence Prior Authorization (PA) program is to ensure appropriate selection of patients for treatment of opioid dependence in appropriate quantities according to product labeling and/or clinical guidelines and/or clinical studies. For opioid dependence, the PA criteria encourage proper physician certification, appropriate age, abstinence from illicit drug use, patient compliance with all elements of the treatment plan (including recovery-oriented activities, psychotherapy, and/or other psychosocial modalities), state prescription drug monitoring program reporting (not applicable to Montana and Nebraska) and appropriate quantities of buprenorphine tablets, Bunavail, Suboxone, buprenorphine/naloxone, and Zubsolv. PA criteria will review to approve for an initial 6 month period and renewal periods of up to 6 months. Requests for buprenorphine tablets, Bunavail, Suboxone, buprenorphine/naloxone, and Zubsolv, including quantities above the allowed limit, will be reviewed when patient-specific documentation has been provided. For increased quantities, the quantity requested up to a maximum buprenorphine dose of 16.8 mg as Bunavail; 32 mg buprenorphine as Suboxone, buprenorphine/naloxone, or buprenorphine tablets; or 22.8 mg as Zubsolv per day may be approved.

TARGET DRUGS

buprenorphine

Bunavail™ (buprenorphine/naloxone)

Suboxone® (buprenorphine/naloxone)

Zubsolv® (buprenorphine/naloxone)

PROGRAM QUANTITY LIMIT

Brand (generic)	**GPI**	**Multisource Code**	**Quantity Limit per 90 Days– Subutex** **Quantity Limit per Day - Suboxone, Zubs**
buprenorphine[ac]			
2 mg sublingual tablet	65200010100760	M, N, O, or Y	15 tablets/90 days
8 mg sublingual tablet	65200010100780	M, N, O, or Y	15 tablets/90 days
Bunavail (buprenorphine/naloxone)			
2.1 mg/0.3 mg buccal film	65200010208260	M, N, O, or Y	3 film/day
4.2 mg/0.7 mg buccal film	65200010208270	M, N, O, or Y	2 film/day
6.3 mg/1 mg buccal film	65200010208280	M, N, O, or Y	2 film/day
Suboxone (buprenorphine/naloxone)			
2 mg/0.5 mg sublingual tablet[ab]	65200010200720	M, N, O, or Y	4 tablets/day
8 mg/2 mg sublingual tablet[ab]	65200010200740	M, N, O, or Y	3 tablets/day
2 mg/0.5 mg sublingual film	65200010208220	M, N, O, or Y	4 films/day
4 mg/1 mg sublingual film	65200010208230	M, N, O, or Y	1 film/day
8 mg/2 mg sublingual film	65200010208240	M, N, O, or Y	2 films/day
12 mg/3 mg sublingual film	65200010208250	M, N, O, or Y	2 films/day
Zubsolv (buprenorphine/naloxone)			

1.4 mg/0.36 mg sublingual tablet	65200010200715	M, N, O, or Y	3 tablets/day
2.9 mg/0.71 mg sublingual tablet	65200010200725	M, N, O, or Y	1 tablet/day
5.7 mg/1.4 mg sublingual tablet	65200010200732	M, N, O, or Y	1 tablets/day
8.6 mg/2.1 mg sublingual tablet	65200010200745	M, N, O, or Y	2 tablets/day
11.4 mg/2.9 mg sublingual tablet	65200010200760	M, N, O, or Y	1 tablet/day

a - Available as a generic and included in the quantity limit program.

b – Brand Suboxone tablets discontinued by manufacturer but may still be available.

c – Brand Subutex no longer available.

CARBAGLU (CARGLUMIC ACID) PRIOR AUTHORIZATION CRITERIA

FDA APPROVED INDICATIONS AND DOSAGE

Acute hyperammonemia in patients with NAGS deficiency

Carbaglu is indicated as an adjunctive therapy in pediatric and adult patients for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). During acute hyperammonemic episodes concomitant administration of Carbaglu with other ammonia lowering therapies such as alternate pathway medications, hemodialysis, and dietary protein restriction are recommended.

Maintenance therapy for chronic hyperammonemia in patients with NAGS deficiency

Carbaglu is indicated for maintenance therapy in pediatric and adult patients for chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). During maintenance therapy, the concomitant use of other ammonia lowering therapies and protein restriction may be reduced or discontinued based on plasma ammonia levels.

Initial Criteria:

I. Carbaglu will be approved for use when **ALL** of the following are met:

A. **ALL** of the following:

1. plasma ammonia level of 150 umol/L (>250 ug/dl) or higher if a neonate or >100 umol/L (>175 ug/dl) if an older child or adult **AND**

2. the patient has a normal anion gap **AND**

3. the patient has a normal blood glucose level **AND**

B. the patient has a diagnosis of N-acetylglutamate synthase (NAGS) deficiency confirmed by either enzyme analysis (via liver biopsy) or genetic testing **AND**

C. the patient is unable to maintain a plasma ammonia level within the normal range with the use of a protein restricted diet and essential amino acid supplementation **AND**

D. the patient does not have any FDA labeled contraindications to therapy with the requested agent **AND**

E. the dose is within the FDA labeled dosing

Lengeth of Approval: 12 months

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I. Carbaglu will be revewed when the following are **ALL** met:

A. the patient has been previously been approved through BCBS of Nebraska **AND**

B. the patient has been able to achieve a plasma ammonia level with the normal range **AND**

C. the patient does not have any FDA labeled contraindication(s) to therapy with the requested agent **AND**

D. the dose is within the FDA labeled dosing

Length of Approval: 12 months

Diagnosis	Dosage
Acute hyperammonemia with NAGS deficiency	100 mg/kg/day to 250 mg/kg/day
Maintenance therapy for chronic hyperammonemia in patients with NAGS deficiency	The recommended maintenance dose should be titrated to target normal plasma ammonia level for age. Maintenance doses in a retrospective case series were usually less than 100 mg/kg/day. Total daily dose should be divided into 2 to 4 doses

OBJECTIVE

The intent of the colony stimulating factor (CSF) Prior Authorization criteria is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines.

TARGET AGENTS

Preferred and Nonpreferred Agents – to be determined by client

Granix® (tbo-filgrastim)
Leukine® (sargramostim)
Neupogen® (filgrastim)
Nivestym™ (filgrastim-aafi)
Zarxio™ (filgrastim-sndz)

**Netresults RX Formularies (PDL 20, 30, 40) Only; Not applicable to medical benefit

Brand (generic)	GPI	Multisource Code
Granix (tbo-filgrastim)		
300 mcg/0.5 mL prefilled syringe	8240152070E530	M, N, O, or Y
300 mcg/mL vial	82401520702020	M, N, O, or Y
480 mcg/0.8 mL prefilled syringe	8240152070E540	M, N, O, or Y
480 mcg/1.6 mL	82401520702030	M, N, O, or Y
Leukine (sargramostim)		
250 mcg injection	82402050002120	M, N, O, or Y
Neupogen (filgrastim)		

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480 mcg/0.8 mL prefilled syringe	8240152000E550	M, N, O, or Y
300 mcg/mL injection	82401520002010	M, N, O, or Y
480mcg/1.6 mL injection	82401520002012	M, N, O, or Y
Nivestym (filgrastim-aafi)		
300 mcg/0.5 mL prefilled syringe	8240152010E520	M, N, O, or Y
480 mcg/0.8 mL prefilled syringe	8240152010E530	M, N, O, or Y
Zarxio (filgrastim-sndz)		
300 mcg/0.5 mL prefilled syringe	8240152060E530	M, N, O, or Y
480 mcg/0.8 mL prefilled syringe	8240152060E540	M, N, O, or Y

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

The Target agent **mayb be considered medically necessary** when **ALL** of the following are met:

1. The requested agent is not being given for prophylactic use if the patient is receiving BOTH concurrent chemotherapy and radiation

AND

2. **ONE** of the following:

A. The requested agent is Leukine (sargramostim) AND ONE of the following:
   i. The patient has a diagnosis of acute myeloid leukemia (AML) AND is receiving or has had induction or consolidation chemotherapy
   OR
   ii. The patient has undergone an allogeneic or autologous BMT and has a delayed or failed engraftment
   OR
   iii. The patient has a non-myeloid malignancy AND is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplantation (BMT)
   OR
   iv. The requested agent is being used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   OR
   v. The patient was acutely exposed to myelosuppressive doses of radiation to increase survival [hematopoietic syndrome of acute radiation syndrome (H-ARS)]
   OR
   vi. The patient has another FDA labeled indication for the requested agent
   OR
   vii. The patient has another indication that is supported in compendia (AHFS, NCCN 1 or 2a recommended use, DrugDex 1 or 2a level of evidence) for the requested agent

OR

B. The requested agent is Granix (tbo-filgrastim), Neupogen (filgrastim), Nivestym (filgrastim-aafi), or Zarxio (filgrastim-sndz) AND ONE of the following:
   i. The patient has acute myeloid leukemia (AML) AND is receiving or has had induction or consolidation

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undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplantation (BMT)
OR

iii. The patient was acutely exposed to myelosuppressive doses of radiation [hematopoietic syndrome of acute radiation syndrome (H-ARS)] AND the requested agent will be used to increase survival
OR

iv. The requested agent is being used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
OR

v. The requested agent is being used for therapeutic use for febrile neutropenia (FN) AND BOTH of the following:
    1. The requested agent is NOT Granix (tbo-filgrastim)
    AND
    2. The patient has at least one risk factor for infection-related complications or poor clinical outcome (e.g., old age [> 65 years], sepsis syndrome, severe [ANC < 100 neutrophils/mcL] or anticipated prolonged [> 10 days] neutropenia, pneumonia, invasive fungal infections or clinically documented infections, hospitalization, or prior episode of FN)
OR

vi. The patient has a diagnosis of myelodysplastic syndrome AND ONE of the following:
    1. The patient has an ANC ≤ 500/mm^3 AND a history of recurrent or resistant bacterial infections
    OR
    2. The requested agent will be used for enhancement of erythropoietic activity for the treatment of refractory anemia AND ALL of the following:
        a. The requested agent will be used concurrently with an erythropoietin stimulating agent (e.g., Epogen, Procrit)
        AND
        b. The patient has a serum erythropoietin level ≤ 500 mU/mL
        AND
        c. The patient currently has adequate iron stores (i.e., ≥ 20% transferrin saturation or serum ferritin ≥ 100 ng/ml)
OR

vii. The patient has a diagnosis of severe chronic neutropenia (i.e., congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia) AND BOTH of the following:
    1. The patient has at least one symptom (e.g., fever, infections, oropharyngeal ulcers)
    AND
    2. Diagnostic labs have been evaluated (e.g., CBC with differential, platelet counts, and bone marrow morphology and karyotype)
OR

viii. The requested agent will be used as secondary prophylaxis in patients who had a neutropenic episode or dose-limiting neutropenic event from a prior chemotherapy cycle AND a reduced dose or change in treatment regimen may compromise disease or overall survival or treatment outcomes

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neutropenia (FN) in patients receiving a chemotherapy regimen who have an overall risk of > 20%
OR

x. The requested agent will be used as primary prophylaxis for prevention of FN in patients receiving a chemotherapy regimen who have an overall risk of 10 to 20% AND the prescriber has assessed the patient risk factors and determined that the patient has greater than 1 risk factor (e.g., prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction [bilirubin > 2.0], renal dysfunction [creatinine clearance < 50], age > 65 years receiving full chemotherapy dose intensity, poor performance status, HIV infection, etc)
OR

xi. The patient has another FDA labeled indication for the requested agent
OR

xii. The patient has another indication that is supported in compendia (AHFS, NCCN 1 or 2a recommended use, DrugDex 1 or 2a level of evidence) for the requested agent

AND

3. ONE of the following:

A. The requested agent is a preferred agent (Preferred and Nonpreferred Agents to be determined by client)
OR

B. The patient has tried and had an inadequate response to a preferred agent
OR

C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL of the preferred agent(s) that is not expected to occur with the requested agent
OR

D. The prescriber has submitted documentation in support of the use of the non-preferred agent over the preferred agent(s)

AND

4. The patient does NOT have any contraindications to therapy with the requested agent

Length of approval: 6 months

CRESEMBA (ISAVUCONAZONIUM), NOXAFIL? (POSACONAZOLE), AND VFEND (VORICONAZOLE) PRIOR AUTHORIZATION

FDA APPROVED INDICATIONS AND DOSAGE[1,2,14]

Drug	FDA Indication(s)	Dosing
Cresemba (isavuconazonium) capsules, injection	Treatment of invasive aspergillosis and invasive mucormycosis	**Loading Dose -** 372 mg every 8 hours for 6 doses. **Maintenance Dose -** 372 mg once daily starting 12-24 hours after the last loading dose.
Noxafil (posaconazole)	Prophylaxis against invasive aspergillosis or candida in patients at high risk	**Prophylaxis against invasive aspergillosis or candida**

	oropharyngeal candidiasis refractory to itraconazole or fluconazole	tablets, injection - 300 mg twice daily first day, then 300 mg once a day **Oropharyngeal candidiasis, non refractory -** 100 mg twice on day one then 100 mg daily **Refractory oropharyngeal candidiasis -** 400 mg twice daily
Noxafil (posaconazole) delayed-release tablet, injection	Prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised	**Loading dose -** 300 mg IV/delayed-release tablet twice a day on the first day. **Maintenance dose -** 300 mg IV/delayed release tablet once a day thereafter. Duration of therapy is based on recovery from neutropenia or immunosuppression.
Vfend (voriconazole) Tablets*, oral suspension*, injection*	Treatment of invasive aspergillosis, candidemia, esophageal candidiasis, serious fungal infections caused by Scedosporium and Fusarium	200 mg every 12 hours for all indications

* – available as generic

OBJECTIVE

The intent of the Cresemba (isavuconazonium), Noxafil (posaconazole), and Vfend (voriconazole) Prior Authorization (PA) program is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or clinical practice guidelines. The PA process allows for approval for labeled indications and may require trial and failure of another antifungal agent when Cresemba, Noxafil, and Vfend are indicated in clinical practice guidelines as an alternative agent for the diagnosis, unless the patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to the recommended initial treatment choice. Cresemba, Noxafil, or Vfend may also be evaluated for a nonlabeled indication if recommended in clinical practice guidelines or if the prescriber submits documentation in support of the requested therapeutic use.

TARGET DRUGS

Cresemba® (isavuconazonium)

Noxafil® (posaconazole)

Vfend® (voriconazole)*

* – available as generic; included as target in PA program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation:

Cresemba (isavuconazonium) will be approved when **BOTH** of the following are met:

- **ONE** of the following:
    - The patient has a diagnosis of invasive aspergillosis; **OR**
    - The patient has a diagnosis of invasive mucormycosis; **OR**
    - The prescriber has submitted documentation supporting use of the requested agent for the intended diagnosis for this patient which has been reviewed and approved by the Clinical Review pharmacist

Length of approval: 6 months

Noxafil (posaconazole) will be approved when **BOTH** of the following are met:

- The patient does **NOT** have any FDA labeled contraindication(s) to the requested agent; **AND**
- **ONE** of the following:
    - The patient has a diagnosis of oropharyngeal candidiasis AND patient has tried fluconazole or an alternative antifungal agent or patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to fluconazole or an alternative antifungal agent; **OR**
    - The patient is severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient; or a patient with a hematologic malignancy with prolonged neutropenia from chemotherapy; or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient AND the requested agent is prescribed for prophylaxis of invasive *Aspergillus* or *Candida;* **OR**
    - The patient has an infection caused by *Scedosporium* or *Zygomycetes;* **OR**
    - The patient has a diagnosis of invasive *Aspergillus* AND patient has tried an alternative antifungal agent or patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to an alternative antifungal agent; **OR**
    - The prescriber has submitted documentation supporting use of the requested agent for the intended diagnosis for this patient which has been reviewed and approved by the Clinical Review pharmacist

Length of approval: one month for oropharyngeal, 6 months for all other indications

Vfend (voriconazole) will be approved when **BOTH** of the following are met:

- The patient does NOT have any FDA labeled contraindication(s) to the requested agent; **AND**
- **ONE** of the following:
    - The patient has a diagnosis of invasive *Aspergillus, Scedosporium apiospermum, or Fusarium;* **OR**
    - The patient has a diagnosis of esophageal candidiasis or candidemia in nonneutropenic patient AND patient has tried fluconazole or an alternative antifungal agent or patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to an alternative antifungal agent; **OR**
    - The patient has a diagnosis of blastomycosis AND patient has tried itraconazole OR patient has documented intolerance, FDA

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- The patient is severely immunocompromised, such as a hematopoietic stem cell transplant [HSCT] recipient; or a patient with a hematologic malignancy with prolonged neutropenia from chemotherapy; or is a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant patient; **OR**
- The prescriber has submitted documentation supporting use of the requested agent for the intended diagnosis for this patient which has been reviewed and approved by the Clinical Review pharmacist

Length of approval: one month for oropharyngeal and esophageal candidiasis, 6 months for all other indications

Renewal Evaluation

Cresemba (isavuconazonium) will be approved when ALL of the following are met:

- The patient has been previously approved for the requested agent through the Prime Therapeutics Prior Authorization process; **AND**
- The patient does NOT have any FDA labeled contraindication(s) to the requested agent **AND**
- **ONE** of the following:
  - The patient has a diagnosis of invasive aspergillosis and the patient has continued indicators of active disease (e.g. continued radiologic findings, positive cultures, positive serum galactomannan assay); **OR**
  - The patient has a diagnosis of invasive mucormycosis and the patient has continued indicators of active disease (e.g. continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay); **OR**
  - The prescriber has submitted documentation supporting continued use of the requested agent for the intended diagnosis for this patient which has been reviewed and approved by the Clinical Review pharmacist

Length of approval: 6 months

Noxafil (posaconazole) will be approved when ALL of the following are met:

- The patient has been previously approved for the requested agent through the Prime Therapeutics Prior Authorization process; **AND**
- The patient does NOT have any FDA labeled contraindication(s) to the requested agent;' **AND**
- **ONE** of the following:
  - The requested agent is being prescribed for prophylaxis of invasive *Aspergillus* or *Candida* and the patient continues to be severely immunocompromised as indicated by: neutropenia, ongoing graft versus host disease, and/or long term use of high dose corticosteroids (> 1 mg/kg/day of prednisone or equivalent); **OR**
  - The patient has a diagnosis of invasive *Aspergillus* or has an infection caused by *Scedosporium*, or *Zygomycetes* and the patient has continued indicators of active disease (e.g. continued radiologic findings, positive cultures, positive serum galactomannan assay for *Aspergillus;)* **OR**

approved by the Clinical Review pharmacist

-For patients with a diagnosis of oropharyngeal candidiasis see Initial Evaluation criteria

Length of approval: 6 months

Vfend (voriconazole) will be approved when **ALL** of the following are met:

- The patient has been previously approved for the requested agent through the Prime Therapeutics Prior Authorization process; **AND**
- The patient does NOT have any FDA labeled contraindication(s) to the requested agent; **AND**
  - **ONE** of the following:
    - The patient has a diagnosis of invasive *Aspergillus, Scedosporium apiospermum, Fusarium*, esophageal candidiasis, candidemia in nonneutropenic patient or blastomycosis and the patient has continued indicators of active disease (e.g. continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus); **OR**
    - The requested agent is being prescribed for prophylaxis and the patient continues to be severely immunocompromised as indicated by: neutropenia, ongoing graft versus host disease, and/or long term use of high dose corticosteroids (> 1 mg/kg/day of prednisone or equivalent); **OR**
    - The prescriber has submitted documentation supporting continued use of the requested agent for the intended diagnosis for this patient which has been reviewed and approved by the Clinical Review pharmacist

Length of approval: one month for esophageal candidiasis, 6 months for all other indications

TOPICAL DICLOFENAC, FLUOROURACIL, IMIQUIMOD & INGENOL

FDA APPROVED INDICATIONS AND DOSAGE

Topical Diclofenac Gel Agent	**Indication**	**Dosing**
Solaraze (diclofenac gel 3%)[a]	Topical treatment of actinic keratosis	Apply to lesion areas twice daily. Normally 0.5 g of gel is used on each 5 cm x 5 cm lesion site. The recommended duration of therapy is from 60 days to 90 days.

[a] generic available

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Carac, Fluorouracil Cream 0.5%	Topical treatment of multiple actinic or solar keratosis of the face and anterior scalp	Apply once a day to the skin where actinic keratosis lesions appear, using enough to cover the entire area with a thin film. Fluorouracil agent should be applied up to 4 weeks as tolerated. Continued treatment up to 4 weeks results in greater lesion reduction
Efudex (fluorouracil cream 5%)[a]	Topical treatment of multiple actinic or solar keratosis.	Apply twice daily in an amount sufficient to cover the lesions. The usual duration of therapy is from 2 to 4 weeks. Complete healing of the lesions may not be evident for 1 to 2 months following cessation of therapy.
	Treatment of superficial basal cell carcinomas when conventional methods are impractical, such as with multiple lesions or difficult treatment sites.	Apply twice daily in an amount sufficient to cover the lesions. Treatment should be continued for at least 3 to 6 weeks. Therapy may be required for as long as 10 to 12 weeks before the lesions are obliterated.
Fluoroplex (fluorouracil cream 1%)	Topical treatment of multiple actinic (solar) keratosis	Apply sufficient medication to cover the entire face or other affected areas twice daily. Increasing the frequency of application and a longer period of administration may be required on areas other than the head and neck. A treatment period of 2-6 weeks is usually required.

Tolak (fluorouracil cream 4%)	Topical treatment of actinic keratosis lesions of the face, ears, and scalp	Apply once daily in an amount sufficient to cover the lesions of the face, ears, and/or scalp with a thin film, using the fingertips to gently massage the medication uniformly into the skin Cream should be applied for a period of 4 weeks as tolerated

[a] generic available

Topical Imiquimod Agent	Indication	Dosing
Aldara (imiquimod 5% cream)*[a]	Clinically typical nonhyperkeratotic, nonhypertrophic actinic keratosis (AK) of face or scalp for immunocompetent adults	Apply 2 times per week for a full 16 weeks. Treatment area is defined as a 25cm^2 (5 cm x 5 cm) area on face or scalp.[cdf]
	Biopsy confirmed primary Superficial basal cell carcinoma (BCC) for immunocompetent adults[b]	Apply 5 times per week for full 6 weeks.[cdf] Tumor diameter / Diameter of cream droplet (mg imiquimod) 0.5 to <1.0 cm / 4 mm (10 mg) ≥1.0 to <1.5 cm / 5 mm (25 mg) ≥ 1.5 to 2.0 cm / 7 mm (40 mg)
	External genital and perianal warts (condyloma acuminata) for patients age ≥12	Apply a thin layer to wart area 3 times per week until total clearance of warts or for a maximum of 16 weeks[cd]
Zyclara (imiquimod 3.75% cream)[e]	Clinically typical, visible or palpable AK of the full face or balding scalp for immunocompetent adults	Apply a thin film (up to two packets) to treatment area once daily before bedtime to the skin of the affected area (either the face or balding scalp) for two 2-week treatment cycles separated by a 2 week no treatment period.[cdg]
	External genital and perianal warts (condyloma acuminata) for patients age ≥12	Apply a thin layer (up to one packet) once a day to the external genital/perianal warts until total clearance or for up to 8 weeks. [cd]

Zyclara (imiquimod 2.5% cream)[e]	Clinically typical, visible or palpable AK of the full face or balding scalp for immunocompetent adults	Apply a thin film (up to two packets) to treatment area once daily before bedtime to the skin of the affected area (either the face or balding scalp) for two 2-week treatment cycles separated by a 2 week no treatment period.[cdg]

*generic available

Topical Ingenol	Indication	Dosing
Picato® (ingenol gel 0.015%, 0.05%))	Topical treatment of actinic keratosis	Face or scalp with 0.015%: apply once daily for 3 consecutive days Trunk or extremities with 0.05%: apply once daily for 2 consecutive days For application of up to one contiguous skin area of approximately 25 cm^2 (5 cm x 5 cm) using one unit dose tube

OBJECTIVE

The intent of the Topical Diclofenac Gel, Fluorouracil Cream, Imiquimod Cream, and Ingenol Gel Prior Authorization with Quantity Limit program is to encourage appropriate selection of patients for treatment according to product labeling, clinical studies, and/or guidelines, and to promote the use the cost effective generics. The PA program defines appropriate use as therapy for a Food and Drug Administration (FDA) approved label indication. In addition, the PA program will review for quantities and duration of therapy consistent with FDA labeled recommended dosing, clinical studies, and/or guidelines.

TARGET DRUGS

Diclofenac Gel

Solaraze (diclofenac gel)[b]

Fluorouracil Cream

Carac (fluorouracil cream)

Fluorouracil cream

Fluoroplex (fluorouracil cream)

Efudex (fluorouracil cream)[a]

Tolak (fluorouracil cream)

Imiquimod Cream

Aldara (imiquimod cream)[a]

Zyclara (imiquimod cream)

Ingenol Gel

Picato (ingenol gel)

a – generic available and not included in prior authorization program

b – generic available and included in prior authorization program

PROGRAM PRIOR AUTHORIZATION, QUANTITY AND DURATION LIMIT

		Authorization	all MSC Codes)
Diclofenac Gel			
Solaraze (diclofenac gel)[b] 3% gel	90374035304020	M, N, O, Y	Actinic keratosis: one 100 gram tube per month for up to 90 days
Fluorouracil Cream			
Carac (fluorouracil cream), Fluorouracil Cream 0.5% cream	90372030003705	M, N, O, Y	Multiple actinic or solar keratosis: one 30 gram tube per month for up to 4 weeks
Efudex (fluorouracil cream)[a], 5% cream	90372030003730	M, N, O	Multiple actinic or solar keratosis: one 40 gram tube per month for up to 4 weeks Superficial basal cell carcinomas when conventional methods are impractical, such as with multiple lesions or difficult treatment sites: two 40 gram tubes per month for up to 12 weeks
Fluoroplex (fluorouracil cream) 1% cream	90372030003710	M, N, O, Y	Multiple actinic or solar keratosis: one 30 gram tube per month for up to 6 weeks
Tolak (fluorouracil cream) 4%	90372030003725	M, N, O, Y	Actinic Keratosis: one 40 gram tube per month for up to 4 weeks
Imiquimod Cream			

		Authorization	all MSC Codes)
Aldara (imiquimod cream)[a] 5% cream	90773040003720	M, N, O	External genital and perianal warts or Actinic keratosis: 12 packets per month for up to 4 months Superficial basal cell carcinoma: 24 packets per month for up to 2 months
Zyclara (imiquimod cream) 2.5%	90773040003710	M, N, O, Y	Actinic keratosis: 56 packets for up to 6 weeks two 7.5 gm pumps for up to 6 weeks one 15 gm pump for up to 6 weeks
Zyclara (imiquimod cream) 3.75%	90773040003715	M, N, O, Y	Actinic keratosis: 56 packets for up to 6 weeks two 7.5 gm pumps for up to 6 weeks one 15 gm pump for up to 6 weeks External genital or perianal warts (condyloma acuminata): 56 packets for up to 8 weeks two 7.5 gm pumps for up to 8 weeks one 15 gm pump for up to 8 weeks
Ingenol Gel			
Picato (ingenol gel) 0.015%	90378035204020	M, N, O, Y	Actinic keratosis (face or scalp): 3 tubes for up to 90 days

		Authorization	all MSC Codes)
Picato (ingenol gel) 0.05%	90378035204040	M, N, O, Y	Actinic keratosis (trunk or extremities): 2 tubes for up to 90 days

a – generic available and not included in prior authorization program

b – generic available and included in prior authorization program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Solaraze, diclofenac gel will be approved when BOTH of the following are met:

1. ONE of the following:
   a. The patient's medication history includes at least one generic fluorouracil cream or generic imiquimod cream in the past 90 days **OR**
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream or generic imiquimod cream
   AND

1. The patient has a diagnosis of actinic keratosis **AND** ONE of the following:
   a. The quantity prescribed does not exceed one 100 gram tube per month for up to 90 days.
   OR
   b. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Carac, Fluorouracil Cream will be approved when BOTH of the following are met:

1. ONE of the following:
   a. The patient's medication history includes generic fluorouracil cream in the past 90 days
   OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream
   AND
2. The patient has diagnosis of multiple actinic or solar keratosis **AND** ONE of the following:
   a. The quantity prescribed does not exceed one 30 gram tube over 4 weeks
   OR
   b. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Efudex will be approved when ALL of the following is met:

1. ONE of the following:
   a. The patient's medication history includes generic fluorouracil cream in the past 90 days
   OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic

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a. The patient has a diagnosis of multiple actinic or solar keratosis **AND** ONE of the following:
   i. The quantity prescribed does not exceed one 40 gram tube over 4 weeks
   OR
   ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist
   OR
b. The patient has a diagnosis of superficial basal cell carcinoma **AND** ONE of the following:
   i. The quantity prescribed does not exceed two 40 gram tubes per month over 12 weeks
   OR
   ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Fluoroplex will be approved when BOTH of the following are met:

1. ONE of the following:
   a. The patient's medication history includes generic fluorouracil cream in the past 90 days
   OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream
   AND
2. The patient has a diagnosis of multiple actinic or solar keratosis **AND** ONE of the following:
   a. The quantity prescribed does not exceed one 30 gram tube over 6 weeks
   OR
   b. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Tolak will be approved when BOTH of the following are met:

1. ONE of the following:
   a. The patient's medication history includes generic fluorouracil cream in the past 90 days
   OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream
   AND
2. The patient has a diagnosis of actinic keratosis **AND** ONE of the following:
   a. The quantity prescribed does not exceed one 40 gram tube over 4 weeks
   OR
   b. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Aldara will be approved when BOTH of the following are met:

imiquimod cream in the past 90 days
OR
b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic imiquimod cream
AND

2. ONE of the following:
   a. The patient has a diagnosis of external genital and/or perianal warts/condyloma acuminata **AND** ONE of the following:
      i. The quantity prescribed does not exceed 12 packets/month over 4 months
      OR
      ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist
      OR
   b. The patient has a diagnosis of actinic keratosis **AND** ONE of the following:
      i. The quantity prescribed does not exceed 12 packets/month over 4 months
      OR
      ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist
      OR
   c. The patient has a diagnosis of superficial basal cell carcinoma **AND** ONE of the following:
      i. The quantity prescribed does not exceed 24 packets/month over 2 months
      OR
      ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Zyclara 2.5% will be approved when BOTH of the following are met:

1. ONE of the following:
   a. The patient's medication history includes generic imiquimod cream in the past 90 days **OR**
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic imiquimod cream
   AND

1. The patient has a diagnosis of actinic keratosis **AND** ONE of the following:
   a. The quantity prescribed does not exceed 56 packets, two 7.5 gm pumps, or one 15 gm pump over 6 weeks
   OR
   b. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

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1. ONE of the following:
   a. The patient's medication history includes generic imiquimod cream in the past 90 days
   OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic imiquimod cream
   AND
2. ONE of the following:
   a. The patient has a diagnosis of actinic keratosis **AND** ONE of the following:
      i. The quantity prescribed does not exceed 56 packets, two 7.5 gm pumps, or one 15 gm pump over 6 weeks
      OR
      ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist
      OR
   b. The patient has a diagnosis of external genital or perianal warts/condyloma acuminata **AND** ONE of the following:
      i. The quantity prescribed does not exceed 56 packets, two 7.5 gm pumps, or one 15 gm pump over 8 weeks
      OR
      ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Picato 0.015% will be approved when BOTH of the following are met:

1. ONE of the following
   a. The patient's medication history includes generic fluorouracil cream or generic imiquimod cream in the past 90 days
   OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream or generic imiquimod cream
   AND
2. ONE of the following:
   a. The patient has a diagnosis of actinic keratosis of the face or scalp **AND** ONE of the following:
      i. The quantity prescribed does not exceed 3 tubes over 90 days
      OR
      ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

      Picato 0.05% will be approved when BOTH of the following are met:

1. ONE of the following
   a. The patient's medication history includes generic fluorouracil cream or generic imiquimod cream in the past 90 days
   OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream or generic imiquimod cream

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of extremities **AND** ONE of the following:

i. The quantity prescribed does not exceed 2 tubes over 90 days
OR

ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: up to 12 months

BONJESTA, DICLEGIS

TARGET AGENTS FOR PRIOR AUTHORIZATION AND QUANTITY LIMIT(S)

Brand (generic)	GPI	Multisource Code	Quantity Limit Per Day
Bonjesta (doxylamine/pyridoxine ER)			
20 mg / 20 mg	50309902100430	M, N, O, Y	2 tablets
Diclegis (doxylamine/pyridoxine delayed release)*			
10 mg / 10 mg	50309902100620	M, N, O, Y	4 tablets

generic available

I. Target agent(s) **may be considered medically necessary** when **ALL** of the following are met:

A. The requested agent is being used to treat pregnancy related nausea or vomiting (not including hyperemesis gravidarum) **AND**

B. The prescriber has provided documentation that the use of the individual ingredients within the target combination agent as separate dosage forms is not clinical appropriate for the patient **AND**

C. The patient does **NOT** have any FDA labeled contraindications to the requested agent **AND**

D. **ONE** of the following:

1. The requested quantity dose does **NOT** exceed the program quantity limit **OR**

2. **ALL** of the following:

a. the requested quantity dose is greater than the program quantity limit **AND**

b. the requested quantity dose does **NOT** exceed the maximum FDA labeled dose (for the requested indication) **AND**

c. The requested quantity dose cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

3. **ALL** of the following:

a. The requested quantity dose is greater than the program quantity limit **AND**
b. The requested quantity dose is greater than the maximum FDA labeled dose (for the requested indication)

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of therapy with a higher dose for the requested indication

Length of Approval: 12 months

CABLIVI QUANTITY LIMIT

TARGET AGENT

Cablivi® (caplacizumab-yhdp)

Brand (generic)	GPI	Multisource Code	Quantity Limit
Cablivi (caplacizumab-yhdp)			
11 mg single dose vial	85151020806420	M, N, O, or Y	58 vials/365 days

I. Quantities above the program quantity limit for the Target Agent may be considered medically necessary when ONE of the following is met:

A. BOTH of the following:

1. The patient had at least one occurrence of acquired thrombotic thrombocytopenic purpura (aTTP) during the current course of therapy AND

2. The patient has NOT had more than 2 occurrences of aTTP while using the requested agent during the current course of therapy

OR

B. The patient had a relaspe/recurrence of aTTP after completion of a course of therapy and requires an additional course of therapy

Length of Approval:

For patients having occurrence(s) of aTTP on current course of therapy: approve number of vials requested up to 58 vials/365 days

Relapse of aTTP: approve 58 vials/365 days

EGRIFTA® (TESAMORELIN) PRIOR AUTHORIZATION

FDA Indication[1]: The reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

OBJECTIVE

The intent of the Egrifta (tesamorelin) Prior Authorization (PA) program is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines and according to dosing recommended in product labeling (2mg per day). The PA program will consider Egrifta appropriate for HIV infected patients with lipodystrophy (defined as a waist circumference of ≥95 cm [37.4 inches] and a waist-to-hip ratio of ≥0.94 for men, and ≥94 cm [37.0 inches] and ≥0.88 for women, respectively) who are between the ages of 18 and 65, currently on anti-retroviral therapy and have a CD4 cell count of >100 cells/mm^3 and a viral load <10,000 copies/mL. The PA criteria will not approve Egrifta for patients with disruption of the hypothalamic-pituitary axis, an active malignancy or for women who are pregnant, planning to become pregnant or are breastfeeding. Additionally, the PA criteria will not

factor products, insulin-like growth factor (IGF)-1, or IGF-binding protein-3. The dose of Egrifta will be limited to the FDA labeled dosage of 2 mg injected subcutaneously once daily. Renewal requires patients to achieve and/or maintain at least an 8% reduction in VAT from baseline or maintain or improve waist circumference to show clinically significant efficacy.

TARGET DRUGS

Egrifta® (tesamorelin)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation

Egrifta will be approved when ALL of the following are met:

- The patient has a diagnosis of HIV infection; **AND**
- The patient has lipodystrophy, defined as the following:
    - Men: Waist circumference of ≥95 cm [37.4 inches] and waist-to-hip ratio of ≥0.94
    - Women: Waist circumference of ≥94 cm [37.0 inches] and waist-to-hip ratio of ≥0.88

    AND
- The patient has a CD4 cell count >100 cells/mm^3 and a viral load <10,000 copies/mL; **AND**
- The patient is between 18 and 65 years of age; **AND**
- The patient is currently on anti-retroviral therapy (ART); **AND**
- The patient has a BMI> 20 kg/$m^{2;}$ **AND**
- The patient does not have any FDA labeled contraindications; **AND**
- The patient is not planning to become pregnant or currently breastfeeding; **AND**
- The patient does not have a diagnosis of diabetes mellitus or a fasting blood glucose of >150 mg/dL; **AND**
- The patient is not currently being treated with growth hormone(GH), GH secretagogues, GH-releasing hormone/GH-releasing factor products, insulin-like growth factor (IGF)-1, or IGF-binding protein-3; **AND**
- The prescribed dosage is 2 mg injected subcutaneously once daily

Length of Approval: 6 months

Renewal Evaluation

Egrifta will be approved when **ALL** the following are met:

- The patient has been approved for Egrifta previously through the Prime Therapeutics PA process; **AND**
- The patient has achieved or maintained an 8% decrease in visceral adipose tissue (VAT) OR maintained or decreased waist circumference from baseline; **AND**
- The patient has a CD4 cell count >100 cells/mm^3 and a viral load <10,000 copies/mL; **AND**
- The patient is between 18 and 65 years of age; **AND**
- The patient is currently on anti-retroviral therapy (ART); **AND**
- The patient has a BMI>20 kg/$m^{2;}$ **AND**
- The patient does not have any FDA labeled contraindications; **AND**· The patient is not planning to become pregnant or currently breastfeeding; **AND**
- The patient does not have a diagnosis of diabetes mellitus or a fasting blood glucose of >150 mg/dL; **AND**
- The patient is not currently being treated with growth hormone (GH), GH secretagogues, GH-releasing hormone/GH-releasing factor products, insulin-like growth factor (IGF)-1, or IGF-binding protein-3; **AND**

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ELMIRON (PENTOSAN POLCYSULFATE SODIUM)

Target Agent

Elmiron® (pentosan polysulfate sodium

Initial Evaluation

I. Target Agent **may be considered medically necessary** for initial use when **ALL** of the following are met:

A. The patient has a diagnosis of interstitial cystitis (IC) or interstitial cystitis/bladder pain syndrome (IC/BPS) or interstitial cystitis/painful bladder syndrome (IC/PBS) **AND**

B. The patient has tried and had an inadequate response to behavioral modification or self care practices **AND**

C. **ONE** of the following:

1. The patient has tried and had an inadequate response to phenazopyridine, hydroxyzine, cimetidine, or amitriptyline **OR**
2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to phenazopyridine, hydroxyzine, cimetidine, or amitriptyline

AND

D. The patient does not have any FDA labeled contraindication, or hypersensitivity to phenazopyridine, hydroxyzine, cimetidine, or amitriptyline

AND

F. The requested quantity dose does not exceed the FDA labeled dos.

Length of Approval: 6 months

Renewal Evaluation

I. The Target Agent **may be considered medically necessary** for renewal when **ALL** of the following are met:

A. The patient has been approved for the requested agent through the Prime Therapeutics Prior Authorization process **AND**

B. The patient has received benefit from the requested agent (e.g., decreased bladder pain, decreased frequency or urgency of urination) **AND**

C. The patient does not have any FDA labeled contraindications to the requested agent **AND**

D. The requested dose does not exceed the FDA labeled dose

Length of Approval: 12 months

FDA APPROVED INDICATIONS AND DOSAGE[1-3,31,36]

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Aranesp (darbepoetin alfa) May be administered either IV or SC.	Anemia due to Chronic Kidney Disease (CKD), including patients on dialysis and patients not on dialysis.[c,g,h]	**Adult:** Dialysis patient dosing is 0. body weight IV or SC once weekly mcg/kg IV or SC every 2 weeks. Ir not receiving dialysis, the recomn starting dose is 0.45 mcg/kg body SC may be administered at 4 weel **Pediatric:** Dialysis patient dosing body weight SC or IV once weekly patients not on dialysis may be ini dose of 0.75 mcg/kg once every 2
	Anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.[a,b,c,g,h]	2.25 mcg/kg SC weekly **or** 500 mcg every 3 weeks. May be increased to 4.5 mcg/kg S
Epogen® /Procrit (epoetin alfa) May be administered either IV or SC.	Anemia due to Chronic Kidney Disease (CKD), in patients on dialysis and those not on dialysis to decrease the need for red blood cell (RBC) transfusion.[c,f,g,h]	**Adult:** 50-100 Units/kg 3 times we Individualize maintenance dose. **Pediatric:** starting 50 Units/kg 3 ti (children on dialysis). Individualiz dose.
	Anemia in patients with non-myeloid malignancies, where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of 2 additional months of planned chemotherapy.[a,b,c,d,g,h]	**Three times weekly dosing** Initial dose: 150 Units/kg SC 3 times weekly. May increase dos maximum of 300 Units/kg 3 times **Weekly Dosing** **Adults:** 40,000 Units SC Max: 60,000 Units SC. **Pediatrics (≥5 years old):** 600 Unit (maximum 40,000 Units) Max: 900 Units/kg IV weekly (max Units).
	Treatment of anemia due to zidovudine administered at ≤ 4200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL .[c,d,g,h]	**Initial dosing:** 100 Units/kg 3 times weekly. **Maximum dose**: 300 Units/kg 3 ti
	Reduce the need of allogeneic RBC transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery.[c,e,h]	300 Units/kg/day SC for 10 days b on the day of surgery, and for 4 da surgery (15 days total). **OR** 600 Units/kg SC once weekly dose 7 days before surgery) plus a fourt day of surgery.
Mircera (methoxy polyethylene glycol – epoetin beta)	Anemia associated with chronic kidney disease (in adult patients on dialysis and not on dialysis)[c,g,h,j]	**Initial:** 0.6 mcg/kg body weight SC every two weeks **Conversion from another ESA:** do monthly or once every two weeks

		total weekly epoetin alfa or darbe dose at time of conversion.
Retacrit (epoetin alfa-epbx) May be administered either IV or SC.	• Treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion. • Treatment of anemia due to zidovudine administered at ≤ 4,200 mg/week in patients with HIV-infection with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL. • Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy. • To reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. RETACRIT is not indicated for patients who are willing to donate autologous blood pre-operatively.	**Initial:** 50-100u/kg 3 times weekly of Retacrit sufficient to reduce the transfusion **Dose adjustments:** Do not increas more frequently than once every dosing adjustments in response to response

IV – intravenous; SC-subcutaneous

Notes on Indications, Dosing and Administration

a - Not indicated for use in patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless also receiving concomitant myelosuppressive chemotherapy.

b - Not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure due to the absence of studies that adequately characterize the impact of erythropoiesis-stimulating agents (ESAs) on progression-free and overall survival.

c - Has not been shown to improve quality of life, fatigue, or patient well-being.

d - Not indicated for the treatment of anemia in cancer patients or HIV-infected patients due to other factors such as iron or folate deficiencies, hemolysis, or gastrointestinal bleeding.

e - Not indicated for anemic patients who are willing to donate autologous blood pre-operatively.

f - Non-dialysis patients with symptomatic anemia considered for therapy should have hemoglobin less than 10 g/dL.

g - Is not intended for patients who require immediate correction of severe anemia. May obviate the need for maintenance transfusions but is not a substitute for emergency transfusion.

h - Prior to initiation of therapy, the patient's iron stores should be evaluated. Transferrin saturation should be at least 20% and ferritin at least 100 mcg/L. Blood pressure should be adequately controlled prior to initiation of ESA therapy, and must be closely monitored and controlled during therapy.

i – Not indicated and is not recommended for use: in patients with CKD not on dialysis, in patients receiving treatment for cancer and whose anemia is due to CKD nor as a substitute for RBC transfusions in patients who require immediate correction of anemia.

J – Not indicated for treatment of anemia due to cancer chemotherapy

OBJECTIVE

and/or clinical studies. The PA process will approve use of erythropoietins (or erythropoiesis-stimulating agents, also called ESAs) when prescribed appropriately for FDA approved indications. All agents will also be approved when there is supporting clinical evidence or prescriber-provided documentation supporting the unlabeled use. The PA program requires the patient's hemoglobin levels to be within the limits defined in labeling or guidelines for the intended use.

TARGET DRUGS

Aranesp (darbepoetin alfa)

Epogen (epoetin alfa)

Mircera (methoxy polyethylene glycol – epoetin beta)

Procrit (epoetin alfa)

Retacrit (epoetin alfa-epbx)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Aranesp, Epogen, Mircera, Procrit, or Retacrit (ESAs) will be approved when the following are met:

- ONE of the following:
    - The ESA is being prescribed to reduce the possibility of allogeneic blood transfusion in a surgery patient **AND** the patient's hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL; **OR**
    - The ESA (all agents except Mircera) is being prescribed for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy **AND** ALL of the following:
        - The patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy or stabilized on therapy (measured within the previous four weeks); **AND**
        - The patient is being concurrently treated with chemotherapy (with or without radiation) (treatment period extends to six weeks post chemotherapy);**AND**
        - The intent of the chemotherapy is non-curative

        OR
    - The ESA is being prescribed for a patient with anemia associated with chronic kidney disease in a patient on dialysis, **AND** the patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy or stabilized on therapy (measured within the previous 4 weeks); **OR**
    - The ESA is being prescribed for a patient with anemia associated with chronic kidney disease in a patient NOT on dialysis **AND** the patient's hemoglobin level is less than 10 g/dL for patients initiating ESA therapy or stabilized on therapy (measured within the previous 4 weeks) **AND** BOTH of the following:
        - The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion; **AND**

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OR

- The ESA is being prescribed for a patient with anemia due to myelodysplastic syndrome, or a patient with anemia resulting from zidovudine treatment of HIV infection **AND** the patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy or less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks); **OR**
- The ESA is being prescribed for another indication **AND** BOTH of the following**:**
  - The prescriber has submitted documentation in support of the use of the prescribed ESA for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist; **AND**
  - The patient's hemoglobin level is less than 12 g/dL for patients initiating ESA therapy or less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous 4 weeks); **AND**

- BOTH of the following:
  - The patient's transferrin saturation and serum ferritin have been evaluated within the previous 4 weeks;**AND**
  - Supplemental iron therapy has been started if the serum ferritin was <100 mcg/L or if serum transferrin saturation was less than 20%; **AND**
- The patient does not have any FDA labeled contraindications to therapy with the requested agent

Length of Approval:

1 month for allogenic blood transfusion in a surgery patient;

6 months for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy; 12 months for all other diagnoses: anemia associated with chronic kidney disease in patients on/not on dialysis, anemia due to myelodysplastic syndrome, anemia resulting from zidovudine treatment of HIV infection, or other diagnosis

GABAPENTIN EXTENDED-RELEASE (HORIZANT, GRALISE) STEP THERAPY

OBJECTIVE

The intent of the Gabapentin ER (extended-release) [Horizant and Gralise] Step Therapy (ST) program is to encourage the use of cost-effective generic prerequisites over the more expensive brand Horizant or Gralise and to accommodate for use of Horizant or Gralise when the prerequisites cannot be used due to previous trial, documented intolerance, FDA labeled contraindication, or hypersensitivity. The program allows use of Horizant or Gralise when the patient has had a trial, documented intolerance, FDA labeled contraindication, or hypersensitivity to generic gabapentin. Requests for Horizant or Gralise will be reviewed when patient-specific documentation has been provided.

TARGET AGENTS

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Horizant (gabapentin enacarbil) or Gralise (gabapentin) will be approved when ONE of the following is met:

- The patient's medication history includes use of generic gabapentin in the past 90 days; **OR**
- The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to generic gabapentin

Length of Approval: 12 months

HYPERPOLARIZATION-ACTIVATED CYCLIC NUCLEOTIDE-GATED (HCN) CHANNEL BLOCKER (CORLANOR) PRIOR AUTHORIZATION AND QUANTITY LIMIT

FDA APPROVED INDICATIONS AND DOSAGE[1]

	Indication	Dosage & Administration
Corlanor® (ivabradine)	To reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta blockers or have a contraindication to beta-blocker use.	Starting dose is 5 mg twice daily. After 2 weeks of treatment, adjust dose based on heart rate. The maximum dose is 7.5 mg twice daily. In patients with conduction defects or in whom bradycardia could lead to hemodynamic compromise, initiate dosing at 2.5 mg twice daily.

OBJECTIVE

The intent of the Hyperpolarization-Activated Cyclic Nucleotide-Gated (HCN) prior authorization (PA) and Quantity Limit (QL) program is to appropriately select patients for therapy according to product labeling and/or clinical guidelines and according to dosing recommended in product labeling. Corlanor will be approved for use in patients with stable, symptomatic chronic heart failure; who have a baseline or current left ventricular ejection fraction of ≤35%; who are in sinus rhythm with a resting heart rate of ≥70 beats per minute; who is on maximally tolerated dose of beta blocker or the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to beta blockers. The program will also approve for patients with a diagnosis of inappropriate sinus tachycardia (IST), also called chronic nonparoxysmal sinus tachycardia, who are symptomatic. The program will approve for doses within the set limit. Doses above the set limit will be approved if the requested quantity is below the FDA limit and cannot be dose optimized or when the quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Requests for an HCN agent will be reviewed when patient specific documentation is provided.

Corlanor® (ivabradine)

Brand (generic)	GPI	Multisource Code	Quantity Limit Per Day
Corlanor (ivabradine)			
5 mg tablet	40700035100320	M, N, O, or Y	2 tablets
7.5 mg tablet	40700035100330	M, N, O, or Y	2 tablets

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Corlanor will be approved when ALL of the following are met:

- **ONE** of the following:
  - **ALL** of the following:
    - The patient has stable, symptomatic chronic heart failure (e.g. NYHA Class II, III, IV; ACCF/AHA Class C, D); **AND**
    - The patient has a baseline OR current left ventricular ejection fraction of ≤35%; **AND**
    - The patient is in sinus rhythm with a resting heart rate of ≥70 beats per minute; **AND**
    - **ONE** of the following:
      - The patient is on a maximally tolerated dose of beta blocker (e.g. atenolol, bisoprolol, carvedilol, metoprolol); **OR**
      - The patient has a history of a documented intolerance, FDA labeled contraindication, or hypersensitivity to a beta blocker (e.g. atenolol, bisoprolol, carvedilol, metoprolol); **OR**
  - **BOTH** of the following:
    - The patient has a diagnosis of inappropriate sinus tachycardia (IST) or chronic nonparoxysmal sinus tachycardia; **AND**
    - The patient's IST is symptomatic; **AND**
- The patient does NOT have any FDA labeled contraindication(s) to the requested agent; **AND**

- **ONE** of the following:
  - The quantity requested is less than or equal to the program quantity limit; **OR**
  - The quantity (dose) requested is above the program limit, less than or equal to the maximum dose recommended in FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength; **OR**
  - The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

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HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA AGENTS PRIOR AUTHORIZATION WITH QUANTITY LIMIT

FDA APPROVED INDICATIONS AND DOSAGE[8,9]

Available products	Indication	Strength(s)	Dosing (maximum labeled dose) and Administration
Kynamro (mipomersen)**	Adjunct therapy to lipid lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)	200 mg/mL	Recommended dose is 200 mg once weekly as a subcutaneous injection^
Juxtapid (lomitapide)	Adjunct therapy to a low-fat diet and other lipid lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B) and non-high density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).	5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 60 mg capsules	Initial dose starts at 5 mg/day, (titrate dose based on acceptable safety/tolerability) after at least 2 weeks increase to 10 mg/day, dose then can be increased every 4 weeks to 20 mg/day, 40 mg/day, and up to the maximum recommended dose of *60 mg/day orally. Take with glass of water, without food, at least 2 hours after evening meal. See Table 1 below.

*Patients with end-stage renal disease on dialysis or with baseline mild hepatic impairment should not exceed 40 mg daily; dose should not exceed 30 mg/day when there is concomitant use of weak CYP3A4 inhibitors.

**Use with apheresis is NOT recommended

^If dose is missed, the missed dose should be given at least 3 days before the next weekly dose is due.

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hypercholesterolemia agents is to encourage appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines and according to dosing recommended in product labeling. Criteria will limit the approved doses for homozygous familial hypercholesterolemia agents to at or below the maximum FDA labeled dose.

TARGET DRUGS

Juxtapid (lomitapide)

Kynamro (mipomersen)

Brand (generic)	GPI	Multisource Code	Quantity Limit
Juxtapid (lomitapide)			
5 mg capsule	39480050200120	M, N, O, or Y	1 capsule/day
10 mg capsule	39480050200130	M, N, O, or Y	1 capsule/day
20 mg capsule	39480050200140	M, N, O, or Y	1 capsule/day
30 mg capsule	39480050200150	M, N, O, or Y	1 capsule/day
40 mg capsule	39480050200160	M, N, O, or Y	1 capsule/day
60 mg capsule	39480050200170	M, N, O, or Y	1 capsule/day
Kynamro (mipomersen)			
200 mg/mL injection	3950004010E520	M, N, O or Y	One injection/week

INITIAL PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

The requested agents will be approved when the following are met:

ONE of the following:

- The patient has the diagnosis of homozygous familial hypercholesterolemia (HoFH) and ALL of the following:
  - The patient has a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH), through **ONE** of the following:
    - Genetic confirmation of two mutant alleles at the *LDLR, Apo-B, PCSK9, ARH* adaptor protein 1/*LDLRAP1* gene locus; **OR**
    - Untreated LDL-C >13 mmol/L (>500 mg/dL) or treated LDL-C ≥7.76 mmol/L (≥300 mg/dL) with ONE of the following:
      - Cutaneous or tendon xanthoma before age 10 years; **OR**
      - Untreated elevated LDL-C levels consistent with heterozygous FH in both parents [untreated total cholesterol >290 mg/dL (7.5 mmol/L) or untreated LDL-C >190 mg/dL]

    AND
  - ONE of the following:

ezetimibe); **OR**

- The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to all of these therapies (i.e. rosuvastatin in combination with ezetimibe AND atorvastatin in combination with ezetimibe)

AND

- ONE of the following:
  - The patient has recently tried and failed (adherent for at least the last 3 months) a PCSK9 inhibitor (e.g. Repatha, Praluent) AND will continue combination therapy with the PCSK9 inhibitor and the requested medication; **OR**
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to all PCSK9 inhibitors

AND

- d. If Juxtapid (lomitapide), BOTH of the following:
- The patient will be maintained on a low fat diet with <20% of calories from fat

AND

- The patient is receiving a dietary supplement providing approximately 400 IU vitamin E, 210 mg alpha-linolenic acid (ALA), 200 mg linoleic acid, 110 mg eicosapentaenoic acid (EPA), and 80 mg docosahexaenoic acid (DHA) per day

AND

- If the request is for Kynamro (mipomersen), the patient will not be receiving apheresis while on therapy with mipomersen

OR

- B. The patient has another FDA approved diagnosis

AND

- The patient does NOT have any FDA labeled contraindications to therapy with the requested agent

AND

- The requested agent will not be used with any other agent included in the program

AND

ONE of the following:

- The quantity requested (dose) is less than or equal to the program quantity limit

OR

- ALL of the following:
  - The requested quantity (dose) is greater than the program quantity limit

labeled dose

AND

- The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

Length of Approval: 12 months for lomitapide

6 months for mipomersen

Renewal Evaluation

These agents will be approved for renewal when the following criteria are met:

- The patient has been previously approved for therapy through Prime Therapeutics PA process

  AND

- The patient has shown a reduction from baseline in at least ONE of the following metrics:
  - LDL-C
  - Apo B
  - Total cholesterol (TC)
  - Non-HDL-C
  - Triglycerides (TG)

  AND

- ONE of the following:
  - The patient is on a maximally tolerated lipid-lowering regimen (i.e. rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe)

    OR

  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to these therapies (i.e. rosuvastatin in combination with ezetimibe AND atorvastatin in combination with ezetimibe)

  AND

- ONE of the following:
  - The patient is currently on a PCSK9 inhibitor (e.g. Praluent, Repatha)

    OR

  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to all PCSK9 inhibitors

  AND

- The patient does NOT have any FDA labeled contraindications to therapy with the requested agent

  AND

- If the request is for Juxtapid (lomitapide), BOTH of the following:
  - The patient will be maintained on a low fat diet with <20% of calories from fat

(ALA), 200 mg linoleic acid, 110 mg eicosapentaenoic acid (EPA), and 80 mg docosahexaenoic acid (DHA) per day

AND

- If the request is for Kynamro (mipomersen), the patient will not be receiving apheresis while on therapy with mipomersen
- **AND**
- The requested agent will not be used with any other agent included in the program

AND

- ONE of the following:
  - The quantity requested (dose) is less than or equal to the program quantity limit

    OR
  - ALL of the following:
    - The requested quantity (dose) is greater than the program quantity limit

      AND
    - The requested quantity (dose) is less than or equal to the FDA labeled dose

      AND
    - The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of approval: 12 months

INSULIN COMBINATION AGENTS (SOLIQUA, XULTOPHY) STEP THERAPY

OBJECTIVE

The intent of the Insulin Combination (Soliqua, Xultophy) Step Therapy (ST) program is to ensure appropriate selection of patients based on product labeling, and/or clinical guidelines, and/or clinical studies. The program will approve for patients who have tried an agent containing metformin and an agent containing either basal insulin or GLP-1. The step edit allows continuation of therapy. Patients without prerequisite agents in claims history or those who are unable to take a prerequisite agent due to documented intolerance, FDA labeled contraindication, or hypersensitivity will be reviewed when patient-specific documentation has been provided.

TARGET AGENTS

Soliqua (insulin glargine/lixisenatide)

Xultophy (insulin degludec/liraglutide)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Insulin Combination Agents will be approved when ONE of the following is met:

- There is documentation that the patient is currently using the requested agent; **OR**

- **BOTH** of the following:
    - **ONE** of the following:
        - The patient's medication history includes an agent containing metformin in the past 180 days

          OR

        - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to metformin or the patient has failed metformin

          AND

    - **ONE** of the following:
        - The patient's medication history includes the use of at least one of the agents included as a combination in the requested agent (e.g., basal insulin, GLP-1 for diabetes) in the past 180 days

Length of approval: 12 months

KEVEYIS PRIOR AUTHORIZATION AND QUANTITY LIMIT

OBJECTIVE

For initial therapy, the program will be approved for members who have a diagnosis of primary hypokalemic periodic paralysis, primary hyperkalemic periodic paralysis, or a related variant; who have implemented and maintained dietary and lifestyle changes to help prevent episodes; and who have a documented intolerance, FDA-labeled contraindication, or hypersensitivity to acetazolamide, or have previously tried acetazolamide and did not achieve a successful response. The program will also be approved for use in another FDA approved indication.

For continued therapy, the program requires that the member be previously approved for initial therapy through Prime's prior authorization and quantity limit program; the member has continued to maintain dietary and lifestyle changes to help prevent episodes; and that the prescriber has indicated that the patient's periodic paralysis symptoms have improved with the requested therapy.

PROGRAM PRIOR AUTHORIZATION AND QUANTITY LIMITS

Brand (generic)	GPI	Quantity Limit Per Day or As Noted
Keveyis™ (dichlorphenamide)	37100020000305	4 tablets

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

Keveyis will be approved when **ALL** of the following are met:

Initial Criteria

- **ONE** of the following:
    - **ALL** of the following:
        - The patient has a diagnosis of primary hypokalemic periodic paralysis, primary hyperkalemic periodic paralysis, or a related variant; **AND**

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- **ONE** of the following:
    - The patient has a documented intolerance, FDA-labeled contraindication, or hypersensitivity to acetazolamide; **OR**
    - The patient has previously tried acetazolamide and did not achieve a successful response

OR

- Another FDA approved indication

AND

- The patient does not have any FDA labeled contraindications to the requested agent

AND

- **ONE** of the following:
    - The requested quantity (dose) is NOT greater than the program quantity limit

OR

- **ALL** of the following:
    - The requested quantity is greater than the program quantity limit; **AND**
    - The requested quantity (dose) is less than or equal to the FDA labeled dose; **AND**
    - The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

OR

- **ALL** of the following:
    - The requested quantity is greater than the program quantity limit; **AND**
    - The requested quantity (dose) is greater than the FDA labeled dose; **AND**
    - The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 3 months

Renewal Criteria

- The patient has been previously approved for therapy through Prime Therapeutics Prior Authorization Review process; **AND**
- The patient has continued to maintain dietary and lifestyle changes to help prevent episodes; **AND**
- The prescriber has indicated that the patient's periodic paralysis symptom(s) have improved under therapy with the requested agent; **AND**
- The patient does not have any FDA labeled contraindications to the requested agent; **AND**

quantity limit

OR

- **ALL** of the following:
  - The requested quantity is greater than the program quantity limit; **AND**
  - The requested quantity (dose) is less than or equal to the FDA labeled dose; **AND**
  - The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

OR

- **ALL** of the following
  - The requested quantity is greater than the program quantity limit; **AND**
  - The requested quantity (dose) is greater than the FDA labeled dose; **AND**
  - The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 12 months

KUVAN (SAPROPTERIN) PRIOR AUTHORIZATION

OBJECTIVE

The intent of the Kuvan (sapropterin) Prior Authorization (PA) program is to appropriately select patients for treatment according to product labeling and/or clinical studies and/or clinical practice guidelines. The PA criteria consider Kuvan appropriate for use in patients who: a) have been diagnosed with PKU, b) have a baseline blood Phe measured within 2 weeks prior to initiating therapy, c) are unable to maintain Phe levels within the recommended range despite compliance with dietary restrictions, and d) are able to maintain a consistent Phe-restricted diet during a Kuvan (sapropterin) trial period. The PA criteria require that the prescriber be a specialist with knowledge and expertise in metabolic diseases or genetic diseases or has consulted with a specialist in metabolic or genetic diseases. Initial approval will be for two months of therapy if the initial dose is 5 mg/kg/day to less than 20 mg/kg/day; it will be for one month if the initial dose is 20 mg/kg/day. Additional (renewal) approvals for continued use will be for 6 months if patient response is seen. Patient response is defined as a ≥30% decrease in blood Phe level from baseline or the maintenance of blood Phe level within recommended range.

TARGET DRUGS

Kuvan (sapropterin)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Kuvan will be approved for INITIAL USE when **ALL** of the following are met:

- The patient has NOT been previously treated with Kuvan (sapropterin); **AND**

- The prescriber has submitted a baseline blood Phe level measured within 2 weeks prior to initiation of Kuvan therapy which is above the recommended levels [all ages: 2-6 mg/dL (120-360 mcmol/L)]; **AND**
- The prescriber has verified that the patient's diet will NOT be modified in any way during the initial 1-month or 2-month trial of Kuvan (sapropterin) therapy; **AND**
- The prescriber is a specialist with knowledge and expertise in metabolic diseases or genetic diseases or has consulted with a specialist in metabolic or genetic diseases; **AND**
- The patient does not have any FDA labeled contraindication(s) to the requested agent; **AND**
- The dose is within the FDA-labeled dose range of 5 to 20 mg/kg/day

Length of Approval: 2 months if initial dose is 5 mg/kg/day to <20 mg/kg/day;

1 month if initial dose is 20 mg/kg/day.

Kuvan will be approved for RENEWAL when **ALL** of the following are met:

- The patient has been successfully treated with Kuvan previously (sapropterin) as defined by one of the following:
  - The patient's blood Phe levels are being maintained within the acceptable range [all ages: 2-6 mg/dL (120-360 mcmol/L)]; **OR**
  - The patient has had a ≥30% decrease in blood Phe level from baseline; **AND**
- The prescriber has verified that the patient's diet was NOT modified in any way during the initial 1-month or 2-month trial of Kuvan (sapropterin) therapy; **AND**
- The prescriber is a specialist with knowledge and expertise in metabolic diseases or genetic diseases or has consulted with a specialist in metabolic or genetic diseases; **AND**
- The patient does not have any FDA labeled contraindication(s) to the requested agent; **AND**
- The dose is within the FDA-labeled dose range of 5 to 20 mg/kg/day

Length of Approval: 6 months

TOPICAL LIDOCAINE PRIOR AUTHORIZATION WITH QUANTITY LIMIT

OBJECTIVE

The intent of the Topical Lidocaine Prior Authorization (PA) criteria is to promote appropriate use for patients based on product labeling and/or clinical practice guidelines. The program will approve topical lidocaine agents for doses within the set limit. Doses above the set limit will be approved if the requested quantity is above the FDA limit and the prescriber has submitted documentation in support of

when patient-specific documentation is provided.

TARGET DRUGS

lidocaine ointment 5%*
Lidoderm (lidocaine patch 5%)*
* – generic available

PROGRAM QUANTITY LIMIT

Brand (generic)	GPI	Quantity per Day Limit
Lidoderm (lidocaine patch) 5%	90850060005930	3 patches
lidocaine ointment 5%	90850060004210	20 grams

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

lidocaine ointment will be approved when ALL of the following are met:

- The patient has at least ONE of the following diagnosis:
  - Anesthesia of accessible mucous membranes of the oropharynx
    OR
  - Anesthetic lubricant for intubation
    OR
  - Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites
    OR
  - Other FDA approved diagnosis
    AND
- The patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent
  AND
- ONE of the following:
  - The requested quantity (dose) is NOT greater than the program quantity limit
    OR
  - ALL of the following:
    - The requested quantity (dose) is greater than the program quantity limit
      AND
    - The requested quantity (dose) is greater than the FDA labeled dose
      AND
    - The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the BCBS of Nebraska Clinical Review pharmacist)

Length of Approval: 12 months

- ONE of the following:
  - The patient has a diagnosis of pain associated with post-herpetic neuralgia (PHN)
    OR
  - The patient has a diagnosis of neuropathic pain associated with cancer
    OR
  - The patient has another FDA approved diagnosis
    AND
- The patient does NOT have any FDA labeled contraindication(s) to therapy with the requested medication
  AND
- ONE of the following:
  - The requested quantity (dose) is NOT greater than the program quantity limit
    OR
  - ALL of the following:
    - The requested quantity (dose) is greater than the program quantity limit
      AND
    - The requested quantity (dose) is greater than the FDA labeled dose
      AND
    - The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 12 months

LYRICA® (PREGABALIN CR)

TARGET AGENT

Lyrica® CR (pregabalin ER)

Prior Authorization and Quantity Limit Target

Agent	GPI	Multisource Code	Quantity Limit per day
Lyrica CR (pregabalin ER)			
82.5 mg tablet	62540060007520	M, N, O, or Y	1 tablet
165 mg tablet	62540060007530	M, N, O, or Y	1 tablet
330 mg tablet	62540060007540	M, N, O, or Y	2 tablets

I. Target Agent **may be considered medically necessary** when **ALL** of the following are met:

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neuropathy (DPN) **OR**

2. Postherpetic neuralgia (PHN)

AND

B. **ONE** of the following:

1. The patient has tried and had inadequate response to **ONE** of the following generic agents: duloxetine, amitriptyline, nortriptyline, imipramine, desipramine, venlafaxine, or gabapentin **OR**
2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to **ALL** prerequisite agents

AND

C. **ONE** of the following:

1. The patient has tried and had inadequate response to pregabalin immediate release **OR**

2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to pregabalin immediate release that is not expected to occur with the requested agent

AND

D. The patient does **NOT** have any FDA labeled contraindication(s) to the requested agent

AND

E. **ONE** of the following:

1. The requested quantity dose does NOT exceed the program quantity limit **OR**
2. **ALL** of the following:

   a. The requested quantity dose is greater than the program quantity limit **AND**

   b. The requested quantity dose does not exceed the maximum FDA labeled dose **AND**

   c. The requested quantity dose cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

3. **ALL** of the following:

   a. The requested quantity dose is greater than the program quantity limit **AND**

   b. The requested quantity dose is greater than the maximum FDA labeled dose **AND**

   c. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

MYALEPT (METRELEPTIN)

Myalept Prior Authorization
TARGET AGENT

Myalept® (metreleptin)

Brand (generic)	GPI	Multisource Code

Prior Authorization Criteria for Approval

Initial Evaluation

I. The target agent **may be considered medically necessary** when **ALL** of the following are met:

A. The patient has a diagnosis of either congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL) AND

B. The patient has a diagnosis of leptin deficiency **AND**

C. The patient does Not have any of the following: partial lipodystrophy, liver disease (including non alcoholic steatohepatitis), HIV related lipodystrophy, or generalized metabolic disease without generalized lipodystrophy **AND**

D. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

E. The patient has baseline HbA1c, triglycerides, and fasting insulin levels prior to initiating he requested agent **AND**

F. The patient has complications related to lipodystrophy [e.g., diabetes mellitus, hypertriglyceridemia (≥200mg/dL), and/or high fasting insulin (≥30µU/mL)] **AND**

G. The patient has had inadequate response to maximally tolerable conventional agent for complications related to lipodystrophy **AND**

H. The patient does **NOT** have any FDA labeled contraindications to the requested agent **AND**

I. The requested quantity dose does not exceed the maximum FDA labeled dose

Length of Approval: 12 months

Renewal Evaluation

I. The target agent **may be considered medically necessary** when **ALL** of the following are met:

A. The patient has been previously approved for the requested agent through the plan's prior authorization process **AND**

B. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

C. The patient has had stabilization and/or reduction from baseline in at least ONE of the following: HbA1c, triglycerides and/or fasting insulin **AND**

D. The patient will continue with lifestyle modifications (ee, diet and exercise) with the requested agent **AND**

E. The patient does **NOT** have any FDA labeled contraindications to the requested agent **AND**

F. The requested quantity dose does not exceed the maximum FDA labeled dose

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NEUROTROPHIC KERATITIS- OXERVATE (CENEGERMIN-BKBJ)

Oxervate (cenegermin-bkbj)

Brand (generic)	GPI	Multisource Code	Quantity Limit
Oxervate (cenegermin-bkbj) ophthalmic solution			
20 mcg/mL vials	86770020202020	M, N, O, or Y	56 vials/ 8 weeks

Evaluation

I. The Target Agent **may be considered medically necessary** when **ALL** of the following are met:

A. the patient has a diagnosis of neurotrophic keratitis (NK) **AND**

B. the patient has stage 2 (persistent epithelial defect [PED]) or stage 3 (corneal ulcer) NK **AND**

C. **ONE** of the following:

1. the patient has **NOT** been previously treated with the requested agent in the affected eye(s) and **ALL** of the following:

a. the patient's PED and/or corneal ulcer have been present for at least 2 weeks **AND**

b. **ONE** of the following:

i. the patient's NK has been refractory to at least **ONE** conventional non-surgical treatment (i.e., preservative-free lubricant eye drops or ointment, discontinuation of preserved topical agents that can decrease corneal sensitivity, therapeutic soft contact lenses, topical autologous serum application) **OR**

ii. the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL conventional non-surgical treatments for NK.

AND

c. the patient has decreased corneal sensitivity (≤4 cm using the Cochet-Bonnet esthesiometer) within the area of the PED or ulcer and outside the area of defect in at least one corneal quadrant

OR

2. the patient has been previously treated with the requested agent in the affected eye(s) and **BOTH** of the following:

a. the patient had complete corneal healing in the previously treated eye(s) **AND**

b. the patient has recurrence of neurotrophic keratitis (NK) that requires another treatment course

1. the patient does **NOT** have ocular surfaced disease associated with or in conjunction with NK **OR**

2. BOTH of the following:

a. the patient has ocular surface disease associated with or in conjunction with NK **AND**

b. the ocular surface disease has been properly treated

AND

E. **ONE** of the following:

1. the patient is not currently being treated with a topical ophthalmic NSAID **OR**

2. the patient is currently being treated with a topical ophthalmic NSAID and will discontinue prior to starting the requested agent

AND

F. The patient does **NOT** have any of the following:

1.active ocular infection or active ocular inflammation not related to NK in the affected eye **OR**

2. Schirmer test without anesthesia ≤3 mm/5min in the affected eye **OR**

3. severe blepharitis and/or severe Meibomian gland disease in the affected eye **OR**

4. history of ocular surgery in the affected eye within the past 90 days that has not been determined to be the cause of NK **OR**

5. corneal perforation, ulceration involving the posterior third of the corneal stroma, or corneal melting

AND

G. The patient does **NOT** have any FDA labeled contraindications to the requested agent

AND

H. **ONE** of the following:

1. the requested quantity dose dose NOT exceed the program quantity limit **OR**

2. **BOTH** of the following:

a. the patient has bilateral NK **AND**

b. the requested quantity dose does **NOT** exceed Twice the program quantity limit

Length of approval: 8 weeks

TOPICAL NSAID (FLECTOR, PENNSAID, VOLTAREN GEL) STEP THERAPY AND QUANTITY LIMIT CRITERIA

FDA APPROVED INDICATIONS AND DOSAGE[1-3,13]

BlueCross BlueShield Nebraska

Flector (diclofenac epolamine) 180 mg topical patch (1.3% in aqueous base)	Topical treatment of acute pain due to minor strains, sprains, and contusions	One patch to the most painful area twice a day
Pennsaid (diclofenac sodium) 1.5% topical solution[a] 2% topical solution	Treatment of signs and symptoms of osteoarthritis of the knee(s) Treatment of pain of osteoarthritis of the knee(s)	40 drops per knee, 4 times daily; apply 10 drops at a time; 40 mg (2 pump actuations) per knee, 2 times Application of Pennsaid in an amount exceedi than the recommended dose has not been stu therefore not recommended
Voltaren Gel (diclofenac sodium) 1% topical gel[a]	Relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands. Voltaren Gel has not been evaluated for use on the spine, hip, or shoulder	Apply gel to affected area 4 times daily Lower extremities: (knees, ankles, feet) Dose is 4 grams per joint; Maximum daily dose is 16 grams to any single joint Upper extremities: (elbows, wrists, hands) Dose is 2 grams per joint; Maximum daily dose is 8 grams to any single joint Total dose should not exceed 32 grams/day ov affected joints

a – available as generic

OBJECTIVE

The intent of the Topical NSAID (Flector, Pennsaid, Voltaren Gel) Step Therapy (ST) criteria is to encourage the use of cost-effective generic oral non-steroidal anti-inflammatory drug (NSAID) products before the target topical agents, and to accommodate for the use of target topical agents due to previous trial, documented intolerance, FDA labeled contraindication or hypersensitivity to generic oral NSAIDs. Patients younger than 75 years of age will be required to fulfill step therapy criteria before approval for target topical NSAIDs; step therapy criteria will not be applied to patients 75 years of age or over, due to their higher risk of GI adverse events with oral nonselective NSAIDs. Requests for target topical NSAIDs will be reviewed when patient-specific documentation has been provided.

TARGET DRUGS – STEP THERAPY

Flector® (diclofenac patch)

Pennsaid® 1.5% (diclofenac solution)[a]

Pennsaid® 2% (diclofenac solution)

Voltaren Gel® (diclofenac gel)[a]

a –available as generic, included in step therapy program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Flector, Pennsaid, and Voltaren Gel will be approved when ONE of the following are met:

2. The patient's medication history includes use of any generic oral NSAID (non-steroidal anti-inflammatory drug) product in the past 90 days
   OR
3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a generic oral NSAID product

Length of approval: 12 months

NUVIGIL (ARMODAFINIL), PROVIGIL (MODAFINIL) PRIOR AUTHORIZATION WITH QUANTITY LIMIT

OBJECTIVE

The PA criteria will approve modafinil or armodafinil when prescribed according to product labeling for patients 17 years and older. Requests for modafinil or armodafinil will be reviewed when patient-specific documentation has been provided. The PA criteria will approve only one of these agents at a time. Brand and generic products are included in this program.

TARGET DRUGS

Nuvigil (armodafinil)*

Provigil (modafinil)*

* – generic available, subject to prior authorization program

PROGRAM QUANTITY LIMIT

Brand (generic)	GPI	Quantity Per Day Limit
Nuvigil/armodafinil		
50 mg tablet*	61400010000310	1 tablet
150 mg tablet*	61400010000330	1 tablet
200 mg tablet*	61400010000335	1 tablet
250 mg tablet*	61400010000340	1 tablet
Provigil/modafinil*		
100 mg tablet	61400024000310	1 tablet
200 mg tablet	61400024000320	1 tablet

* – generic available, subject to quantity limit

PRIOR AUTHORIZATION WITH QUANTITY LIMIT CRITERIA FOR APPROVAL

Nuvigil or Provigil will be approved when **ALL** of the following are met:

- The patient is 17 years of age or older; **AND**
- The patient has a diagnosis of narcolepsy, obstructive sleep apnea, or shift work disorder; **AND**
- The patient does not have any FDA labeled contraindications to the requested agent; **AND**

- **ONE** of the following:
    - The quantity requested is less than or equal to the program quantity limit; **OR**
    - The quantity (dose) requested is above the program limit, less than or equal to the maximum dose recommended in FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength; **OR**
    - The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: 12 months

OCALIVA (OBETICHOLIC ACID) PRIOR AUTHORIZATION WITH QUANTITY LIMIT

OBJECTIVE

The intent of the Ocaliva Prior Authorization (PA) program is to ensure that patients prescribed therapy meet the selection requirements defined in product labeling and/or clinical guidelines and/or clinical studies. The PA defines appropriate use as the Food and Drug Administration (FDA) labeled indication or as supported by guidelines and/or clinical evidence.

QUANTITY LIMIT TARGET DRUG- RECOMMENDED LIMIT

Brand (generic)	GPI	Quantity per Day Limit
Ocaliva (obeticholic acid)		
5 mg tablet	52750060000320	1 tablet
10 mg tablet	52750060000330	1 tablet

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Ocaliva (obeticholic acid) will be approved when the following criteria are met:

Initial Evaluation

Obeticholic acid will be approved when following are met:

- The patient does NOT have any FDA labeled contraindications to therapy with the requested agent; **AND**
- The patient has the diagnosis of Primary Biliary Cholangitis (PBC) as evidenced by **TWO** of the following three criteria at the time of diagnosis:
    - There is biochemical evidence of cholestasis with an alkaline phosphatase elevation of at least 1.5 times the upper limit of normal
    - Presence of antimitochondrial antibody (AMA): a titer of 1:40 or higher

AND

- The prescriber has documented the patient's baseline (prior to treatment) phosphatase (ALP) level

AND

- **ONE** of the following:
    - **BOTH** of the following:
        - The patient has tried treatment with ursodeoxycholic acid (UDCA) for at least 1 year and had an inadequate response; **AND**
        - The patient will continue treatment with ursodeoxycholic acid (UDCA) with the requested agent

        OR
    - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ursodeoxycholic acid (UDCA)

AND

- **ONE** of the following:
    - The requested quantity (dose) is NOT greater than the program quantity limit; **OR**
    - **ALL** of the following
        - The requested quantity (dose) is greater than the program quantity limit; **AND**
        - The requested quantity (dose) is less than or equal to the FDA labeled dose; **AND**
        - The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

Length of Approval: 12 months

Renewal Evaluation

- The patient has been previously approved for therapy through the Blue Cross Blue Shield of Nebraska Prior Authorization Review process; **AND**
- The patient does NOT have any FDA labeled contraindications to therapy with the requested agent; **AND**
- **ONE** of the following:
    - The patient is currently on AND will continue treatment with ursodeoxycholic acid (UDCA) with the requested agent; **OR**
    - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ursodeoxycholic acid (UDCA)

    AND
- The patient has had an alkaline phosphatase (ALP) decrease of at least 15% AND is less than 1.67-times the upper limit of normal (ULN); **AND**

quantity limit **OR**

- **ALL** of the following
  - The requested quantity (dose) is greater than the program quantity limit; **AND**
  - The requested quantity (dose) is less than or equal to the FDA labeled dose; **AND**
  - The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

Length of Approval: 12 months

OPHTHALMIC PROSTAGLANDINS (STEP THERAPY)

FDA APPROVED INDICATIONS AND DOSAGE[1-7]

Drug	Treatment of elevated IOP in patients with OHT or OAG[a]	Dosage and Administration
Lumigan®, Bimatoprost[c] 0.01%, 0.03% 2.5 mL, 5.0 mL, & 7.5 mL bottle	?	One drop in affected eye(s) once daily in the evening
Rescula® (unoprostone) 0.15% 5.0 mL bottle	?	One drop in affected eye(s) twice daily
Travatan Z® (travoprost, benzalkonium free) 0.004% 2.5 mL, 5.0 mL bottle	?	One drop in affected eye(s) once daily in the evening
Travoprost 0.004% 2.5 mL, 5.0 mL bottle	?	One drop in affected eye(s) once daily in the evening
Xalatan®[b] (latanoprost) 0.005% 2.5 mL bottle	?	One drop in affected eye(s) once daily in the evening
Xelpros™ (latanoprost emulsion) 2.5 mL bottle	?	One drop in the affected eye(s) once daily in the evening
Vyzulta® (latanoprostene bunod) 0.024% 2.5 mL, 5 mL bottle	?	One drop in affected eye(s) once daily in the evening
Zioptan® (tafluprost) 0.0015% 0.3 mL single-use container	?	One drop in affected eye(s) once daily in the evening

a – IOP = intraocular pressure; OHT = ocular hypertension; OAG = open angle glaucoma
b – Available as a generic
c – Available as generic only

Objective

The intent of the Ophthalmic Prostaglandin Step Therapy (ST) program is to encourage use of cost effective generic products over the more expensive brand products. This program will accommodate for use of

continuation of therapy when there is documentation that the patient is receiving the requested agent. Requests for brand products will be reviewed when patient specific documentation is provided.

TARGET AGENTS

Bimatoprost

Lumigan® (bimatoprost)

Rescula® (unoprostone)

Travatan Z® (travopost)

Travoprost

Vyzulta™ (latanoprostene bunod)

Xalatan® (latanoprost)

Xelpros™ (latanoprost emulsion)

Zioptan™ (tafluprost)

a – Available as a generic; prerequisite in step therapy program
b – Available as generic only and is prerequisite in step therapy program

Prior authorization criteria for approval

I. Bimatroprost, Lumigan, Rescula, Travatan Z, Travoprost, Vyzulta, Xalatan, Xelpros, and Zioptan **may be considered Medically Necessary** when **ONE** of the following criteria are met:

A. The patient's medication history includes previous use of a generic ophthalmic prostaglandin in the past 90 days **OR**

B. There is documentation that the patient is currently using the requested agent **OR**

C. The prescriber states the patient is currently using the requested agent **AND** is at risk if therapy is changed **OR**

D. The patient had documented intolerance, FDA labeled contraindication, or hypersensitivity to generic ophthalmic prostaglandin(s)

Length of approval: 12 months

OPIOIDS IR NEW TO THERAPY

Objective

the intent of this Opioids IR quantity limit is to encourage FDA approved dosing regimen and if the patient is new to therapy, the patient will be restricted to <50 MME per day and ≤7 days of therapy. The program will check if a patient is new to opioid therapy as defined as having no prior opioid use in the past 120 days. Requests for exception will be approved upon reviewed.

QUANTITY LIMIT TARGET AGENTS – RECOMMENDED LIMITS

BlueCross BlueShield Nebraska

			Availability		
butorphanol	10 mg/mL nasal spray	65200020102050	G	2.9167 mL	M,N,O,Y
Codeine	15 mg tablet	65100020200305	B	6 tablets	M,N,O,Y
Codeine	30 mg tablet	65100020200310	BG	6 tablets	M,N,O,Y
Codeine	60 mg tablet	65100020200315	B	6 tablets	M,N,O,Y
Dilaudid (hydromorphone)	2 mg tablet	65100035100310	BG	6 tablets	M,N,O,Y
Dilaudid (hydromorphone)	4 mg tablet	65100035100320	BG	6 tablets	M,N,O,Y
Dilaudid (hydromorphone)	8 mg tablet	65100035100330	BG	6 tablets	M,N,O,Y
Dilaudid (hydromorphone)	1 mg/mL liquid	65100035100920	BG	48 mL	M,N,O,Y
Levorphanol	2 mg tablet	65100040100305	G	4 tablets	M,N,O,Y
Levorphanol	3 mg tablet	65100040100310	B	4 tablets	M,N,O,Y
Meperidine	50 mg tablet	65100045100305	B	8 tablets	M,N,O,Y
Meperidine	100 mg tablet	65100045100310	B	8 tablets	M,N,O,Y
Meperidine	50 mg/5 mL solution	65100045102060	B	80 mL	M,N,O,Y
Dolophine (methadone)	5 mg tablet	65100050100305	BG	3 tablets	M,N,O,Y
Dolophine (methadone)	10 mg tablet	65100050100310	BG	3 tablets	M,N,O,Y
Methadose (methadone)	40 mg soluble tablet	65100050107320	G	3 tablets	M,N,O,Y
methadone	5 mg/5mL solution	65100050102010	BG	30 mL	M,N,O,Y
methadone	10 mg/5 mL solution	65100050102015	BG	15 mL	M,N,O,Y
methadone	10 mg/mL concentrate	65100050101310	BG	3 mL	M,N,O,Y
Morphine	15 mg tablet	65100055100310	BG	8 tablets	M,N,O,Y
Morphine	30 mg tablet	65100055100315	BG	6 tablets	M,N,O,Y
Morphine	10 mg/5 mL solution	65100055102065	G	90 mL	M,N,O,Y
Morphine	20 mg/5 mL solution	65100055102070	G	45 mL	M,N,O,Y

BlueCross BlueShield Nebraska

			(G) Availability	Limit	
Morphine	20 mg/mL concentrate	65100055102090	G	9 mL	M,N,O,Y
oxycodone	5 mg capsule	65100075100110	G	12 capsules	M,N,O,Y
Oxaydo, (oxycodone)	5 mg tablet	6510007510A510	B	6 tablets	M,N,O,Y
Oxaydo (oxycodone)	7.5 mg tablet	6510007510A520	B	6 tablets	M,N,O,Y
oxycodone	10 mg tablet	65100075100320	G	6 tablets	M,N,O,Y
oxycodone	20 mg tablet	65100075100330	G	6 tablets	M,N,O,Y
oxycodone	5 mg/5mL solution	65100075102005	G	180 mL	M,N,O,Y
oxycodone	20 mg/mL concentrate	65100075101320	G	9 mL	M,N,O,Y
Roxicodone (oxycodone)	5 mg tablet	65100075100310	BG	12 tablets	M,N,O,Y
Roxicodone (oxycodone)	15 mg tablet	65100075100325	BG	6 tablets	M,N,O,Y
Roxicodone (oxycodone)	30 mg tablet	65100075100340	BG	6 tablets	M,N,O,Y
Opana (oxymorphone)	5 mg tablet	65100080100305	BG	6 tablets	M,N,O,Y
Opana (oxymorphone)	10 mg tablet	65100080100310	BG	6 tablets	M,N,O,Y
Nucynta (tapentadol)	50 mg tablet	65100091100320	B	6 tablets	M,N,O,Y
Nucynta (tapentadol)	75 mg tablet	65100091100330	B	6 tablets	M,N,O,Y
Nucynta (tapentadol)	100 mg tablet	65100091100340	B	6 tablets	M,N,O,Y
Ultram (tramadol)	50 mg tablet	65100095100320	BG	8 tablets	M,N,O,Y
Tramadol	100 mg tablet	65100095100340	B	4 tablets	M,N,O,Y

Combination Ingredient Agents	**Strength**	**GPI**	**Brand (B)/ Generic (G)Availability**	**Daily Quantity Limit**
Oxycodone/Ibuprofen	5 mg/400 mg tablet	65990002260320	B	4 tablets
Reprexain (hydrocodone/ibuprofen)	2.5 mg/200 mg tablet	65991702500310	DC	5 tablets

Reprexain, Ibudone (hydrocodone/ibuprofen)	5 mg/200 mg tablet	65991702500315	G	5 tablets
Reprexain, Ibudone, Xylon (hydrocodone/ibuprofen)	10 mg/200 mg tablet	65991702500330	BG	5 tablets
Vicoprofen (hydrocodone/ibuprofen)	7.5 mg/200 mg tablet	65991702500320	G	5 tablets
Ultracet (tramadol/acetaminophen)	37.5 mg/325 mg tablet	65995002200320	BG	8 tablets
Oxycodone/Aspirin	4.8355 mg/325 mg tablet	65990002220340	B	12 tablets
Synalgos-DC, Aspirin/Caffeine/Dihydrocodeine	356.4 mg/30 mg/16 mg capsule	65991303100115	B	12 capsules
Apadaz (benzhydrocodone/acetaminophen)	4.08/325 mg tablet	65990002020310	B	12 tablets
Apadaz (benzhydrocodone/acetaminophen)	6.12/325 mg tablet	65990002020320	B	12 tablets
Apadaz (benzhydrocodone/acetaminophen)	8.16/325 mg tablet	65990002020330	B	12 tablets
Percocet, Endocet (oxycodone/acetaminophen)	2.5 mg/325 mg tablet	65990002200305	BG	12 tablets
Percocet, Endocet, Roxicet (oxycodone/acetaminophen)	5 mg/325 mg tablet	65990002200310	BG	12 tablets
Percocet, Endocet (oxycodone/acetaminophen)	7.5 mg/325 mg tablet	65990002200327	BG	8 tablets
Percocet, Endocet (oxycodone/acetaminophen)	10 mg/325 mg tablet	65990002200335	BG	6 tablets
Nalocet (oxycodone/ acetaminophen)	2.5 mg/300 mg tablet	65990002200303	G	12 tablets
Primlev (oxycodone/ acetaminophen)	5 mg/300 mg tablet	65990002200308	B	12 tablets
Primlev (oxycodone/ acetaminophen)	7.5 mg/300 mg tablet	65990002200325	B	8 tablets
Primlev (oxycodone/ acetaminophen)	10 mg/300 mg tablet	65990002200333	B	6 tablets

Roxicet (oxycodone/ acetaminophen)	5 mg/325 mg/5 mL solution	65990002202005	B	60 mL
Acetaminophen/ Codeine	120 mg/12 mg/5 mL solution	65991002052020	G	90 mL
Tylenol w/Codeine (acetaminophen/ codeine)	300 mg/15 mg tablet	65991002050310	BG	12 tablets
Tylenol w/Codeine (acetaminophen/ codeine)	300 mg/30 mg tablet	65991002050315	BG	12 tablets
Tylenol w/Codeine (acetaminophen/ codeine)	300 mg/60 mg tablet	65991002050320	BG	6 tablets
Hycet (hydrocodone/ acetaminophen)	7.5 mg/325 mg/15 mL solution	65991702102015	G	90 mL
Hydrocodone/ Acetaminophen	2.5 mg/325 mg tablet	65991702100302	G	12 tablets
Norco (hydrocodone/ acetaminophen)	5 mg/325 mg tablet	65991702100356	BG	8 tablets
Norco (hydrocodone/ acetaminophen)	7.5 mg/325 mg tablet	65991702100358	BG	6 tablets
Norco (hydrocodone/ acetaminophen)	10 mg/325 mg tablet	65991702100305	BG	6 tablets
Xodol (hydrocodone/ acetaminophen)	5 mg/300 mg tablet	65991702100309	BG	12 tablets
Xodol (hydrocodone/ acetaminophen)	7.5 mg/300 mg tablet	65991702100322	BG	6 tablets
Xodol (hydrocodone/ acetaminophen)	10 mg/300 mg tablet	65991702100375	BG	6 tablets

hydrocodone/ acetaminophen solution	10 mg/325 mg/15 mL solution	65991702102025	B	90 mL
Zolvit/Lortab (hydrocodone/ acetaminophen)	10 mg/300 mg/15 mL solution	65991702102024	B	67.5 mL
Trezix (acetaminophen/ caffeine/ dihydrocodeine)	320.5 mg/30 mg/16 mg capsule	65991303050115	B	10 capsules
Dvorah (acetaminophen/ caffeine/ dihydrocodeine)	325 mg/30 mg/16 mg tablet	65991303050320	BG	10 tablets
butalbital/ acetaminophen/ caffeine/codeine	50 mg/325 mg/40 mg/30 mg capsule	65991004100115	G	6 capsules
Fioricet w/Codeine (butalbital/ acetaminophen/ caffeine/codeine)	50 mg/300 mg/40 mg/30 mg capsule	65991004100113	BG	6 capsules
Fiorinal w/Codeine (butalbital/aspirin/ caffeine/codeine)	50 mg/325 mg/40 mg/30 mg capsule	65991004300115	BG	6 capsules
pentazocine/naloxone	50 mg/0.5 mg tablet	65200040300310	G	12 tablets

Prior Authorization Criteria for Approval

I. Quantities of Opioid Immediate Release agents above the program quantity limit but less than or equal to the program maximum daily dose (maximum mg allowed with highest dosage strength) **may be considered medically necessary** when **ALL** of the following are met:

A. The requested quantity dose cannot be achieved using a lesser quantity of a higher strength **AND**
B. The prescriber has submitted information in support of therapy with a higher dose (quantity) for the requested indication **AND**

C. **ONE** of the following:

1. The requested opioid dose not contain tramadol or codeine **OR**

2. The requested opioid contains tramadol or codeine **AND ONE** of the following:

a. The patient is between 12 and 18 years of age AND the requested opioid will NOT be used for post-operatie pain management following a tonsillectomy and/or adenoidectomy **OR**

D. **ONE** of the following

1. The requested agent does **NOT** contain acetaminophen **OR**

2. The requested agent does contain acetaminophen **AND** the requested dose (quantity) of acetaminophen does **NOT** exceed 4 g/day.

Length of Approval: 1 month for dose titration requested and up to 6 months for all other requests

I. Quantities of Opioids Immediate Release agents which are greater than the program maximum daily dose (maximum mg allowed with highest dosage strength) **may be considered medically necessary** when **ALL** of the following are met:

A. The requested quantity (dose) requested cannot be achieved using a lesser quantity of a higher strength **AND**

B. **ONE** of the following:

1. The member has a diagnosis of active cancer pain due to an active malignancy **OR**
2. The member is eligible for hospice care **OR**

3. The member is undergoing treatment of pain and **ALL** of the following are met:

a. The prescriber has provided information that a formal, consultative evaluation which includes **ALL** of the following was conducted:

i. diagnosis **AND**

ii. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy **AND**

iii. The need for continued opioid therapy has been assessed.

AND

C. The prescriber has submitted information in support of therapy with a higher dose (quantity) for the requested indication

AND

D. **ONE** of the following:

1. The requested opioid does not contain tramadol or codeine **OR**

2. The requested opioid contains tramadol or codeine **AND** **ONE** of the following:

a. The patient is between 12 and 18 years of age **AND** the requested opioid will **NOT** be used for post-operatie pain management following a tonsillectomy and/or adenoidectomy **OR**

b. the patient is 18 years of age or over

AND

E. **ONE** of the following

1. The requested agent does **NOT** contain acetaminophen **OR**

2. The requested agent does contain acetaminophen **AND** the requested dose (quantity) of acetaminophen does **NOT** exceed 4 g/day.

New To Therapy Authorization Criteria for Approval

I. Agents **may be considered medically necessary** when **ONE** of the following are met:

A. The request exceeds the 7 day supply limit and/or the 50 morphine milligram equivalent per day limit **AND BOTH** of the following:

1. **ONE** of the following:

a. The requested agent does **NOT** contain acetaminophen **OR**

b. The requested agent does contain acetaminophen **AND** the requested dose (quantity) of acetaminophen does **NOT** exceed 4 g/day

AND

2. **ONE** of the following:

a. The requested agent contains tramadol or codeine **AND ONE** of the following:

i. The patient is between 12 and 18 years of age **AND** the requested agent will **NOT** be used for post operative pain management following a tonsillectomy and/or adenoidectomy **OR**

ii. The patient is 18 years of age or older **OR**

iii. The requested agent does not contain tramadol or codeine

AND

3. **ONE** of the following:

a. the requested quantity dose does **NOT** exceed the program daily quantity limit and **ONE** of the following:

i. There is information that the patient is not new to opioid therapy in the past 120 days **OR**

ii. The prescriber states the patient is **NOT** new to opioids therapy **AND** is at risk if therapy is changed **OR**

iii. The patient has a claim for oncology agent in the past 120 days **OR**

iv. **BOTH** of the following:

a). **ONE** of the following:

i). the patient has a diagnosis of chronic cancer pain due to an active malignancy OR

ii). the patient is eligible for hospice care **OR**

iii). **ALL** of the following:

aa). the prescriber has provided information in support of use of immediate release single or combination opioids for an extended duration (>7 days) and/or greater than 50 morphine milligram equivalents (MME) per day **AND**

following was conducted:

i. diagnosis **AND**

ii. a complete medical history which includes previous and current pharmacological and non-pharmacological therapy

AND

cc). The prescriber has confirmed that a patient specific pain management plan is on file for the patient

AND

dd). The prescriber has confirmed that the patient is not diverting the requested medication, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable

b). **ONE** of the following:

i. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment **OR**

ii. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

OR

b. The requested quantity dose is greater than the program daily quantity limit **AND ALL** of the following:

i. **ONE** of the following:

a). There is information that the patient is not new to opioid therapy in the past 120 days OR

b). The prescriber states the patient is **NOT** new to opioids therapy **AND** is at risk if therapy is changed OR

c). The patient has a claim for oncology agent in the past 120 days **OR**

d). The prescriber has provided information in support of use of immediate release single or combination opioids for

an extended duration (>7 days) and/or greater than a 50 morphine milligram equivalents (MME) per day

AND

ii. **ONE** of the following:

a). The patient has a diagnosis of chronic cancer pain due to an active malignancy **OR**

b). The patient is eligible for hospice care **OR**

c). **ALL** of the following:

conducted:

aa. diagnosis **AND**

bb. a complete medical history which includes previous and current pharmacological and non-pharmacological therapy

AND

ii. The prescriber has confirmed that a patient specific pain management plan is on file for the patient **AND**

iii. The prescriber has confirmed that the patient is not diverting the requested medication, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable

iii. **ONE** of the following:

i. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment **OR**

ii. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

AND

iv. The quantity dose requested cannot be achieved using a lesser quantity of a higher strength **AND**

v. The prescriber has submitted information in support of therapy with a higher dose quantity for the intended diagnosis.

OR

B. The requested does **NOT** exceed the 7 day supply limit nor the 50 morphine milligram equivalent per day limit; but the requested dose is greater than the program quantity daily limit **AND ALL** of the following:

1. **ONE** of the following:

a. The patient has a diagnosis of chronic cancer pain due to an active malignancy **OR**

b. The patient is eligible for hospice care **OR**

c. **ALL** of the following:

i. The prescriber has provided information that a formal, consultative evaluation which includes **ALL** of the following was conducted:

a). Diagnosis **AND**

b). A complete medical history which includes previous and current pharmacological and non pharmacological therapy

AND

ii. The prescriber has confirmed that a patient specific pain management plan is on file for the patient

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diverting the requested medication, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable

2. **ONE** of the following:

   a. The patient is not concurrently using a buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment **OR**

   b. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

AND

3. **ONE** of the following:

   a. The requested agent does **NOT** contain acetaminophen **OR**

   b. The requested agent does contain acetaminophen **AND** the requested soe quantity of acetaminophen does **NOT** exceed 4 g/day.

4. **ONE** of the following:

   a. The requested agent contains tramadol or codeine **AND** **ONE** of the following

      i. The patient is between 12 and 18 years of age AND the requested agent will **NOT** be used for post operative pain management following a tonsillectomy and/or adenoidectomy **OR**

      ii. The patient is 18 years of age or older

   OR

   b. The requested agent does not contain tramadol or codeine

5. **BOTH** of the following:

   a. The quantity dose requested cannot be achieved using a lesser quantity of a higher strength **AND**

   b. The prescriber has submitted information in support of therapy with a higher dose quantity for the intended diagnosis

Length of approval: 6 months

NOTE: if other programs (e.g. step therapy) also applies, please refer to program specific documents.

OPIOIDS EXTENDED RELEASE QUANTITY LIMIT CRITERIA

Brand/Generic Name	Strength	Dosing frequency (maximu
Narcotics		
Avinza **morphine sulfate ER**	30, 45, 60, 75, 90, 120 mg	Once daily (not to exceed 1600

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(buprenorphine buccal film)	75, 150, 300, 450, 600, 750, 900 mcg	(not to exceed 900 mcg
Butrans (buprenorphine transdermal)	5, 7.5, 10, 15, 20 mcg/hour system	1 transdermal system weekly (max
Duragesic (fentanyl transdermal patch ER)	12, 25, 50, 75, 100 mcg/hour	15 patches / m
Embeda (morphine/naltrexone ER)	20-0.8, 30-1.2, 50-2, 60-2.4, 80-3.2, 100-4 mg	Once or twice c
Exalgo (hydromorphone ER)	8, 12, 16, 32 mg	Once daily
Fentanyl transdermal patch	37.5, 62.5, 87.5 mcg/hour	15 patches / m
Hysingla ER (hydrocodone ER)	20, 30, 40, 60, 80, 100, 120 mg	Once daily
Kadian (morphine ER)	10, 20, 30, 40, 50, 60, 70, 80, 100, 130, 150, 200 mg	Once or twice
MS Contin (morphine sulfate ER)	15, 30, 60, 100, 200 mg	Twice daily (some may require three ti
Opana ER (oxymorphone ER)	5, 7.5, 10, 15, 20, 30, 40 mg	Twice daily
Opana ER crush-resistant (oxymorphone ER)	5, 7.5, 10, 15, 20, 30, 40 mg	Twice daily
Oramorph SR (morphine ER)	15, 30, 60, 100 mg	Twice daily (some may require three ti
OxyContin (oxycodone ER)	10, 15, 20, 30, 40, 60, 80 mg	Twice daily
Xartemis XR (oxycodone and acetaminophen ER)	7.5/325 mg	Twice daily
Xtampza ER (oxycodone ER)	9, 13.5, 18, 27, 36 mg	Twice daily (288
Zohydro ER (hydrocodone ER)	10, 15, 20, 30, 40, 50 mg	Twice daily
Zohydro ER Abuse Deterrent (hydrocodone ER)	10, 15, 20, 30, 40, 50 mg	Twice daily
Tramadol, Tapentadol		
Conzip (tramadol SR biphasic)	100, 200, 300 mg	Once daily
Nucynta ER (tapentadol ER)	50, 100, 150, 200, 250 mg	Twice daily
Ryzolt (tramadol extended-release)	100, 200, 300 mg	Once daily

(tramadol SR biphasic)	150 mg	Once daily
Ultram ER (tramadol extended-release)	100, 200, 300 mg	Once daily

* - Maximum dosage units in FDA-approved labeling where available. In addition, daily doses should not exceed the following limits for individual ingredients: tramadol ER - 300 mg, tapentadol ER - 500 mg

Opioids ER Quantity Limit

OBJECTIVE

The intent of the quantity limit for opioids extended-release (ER) is to allow for quantities that permit dose choices that individualize the treatment plan for chronic pain to the needs of the patient. Requests for larger quantities will be reviewed if the prescriber provides evidence that the requested dose is appropriate for the patient

QUANTITY LIMIT TARGET DRUGS - RECOMMENDED LIMITS

Brand (generic)	GPI	Quantity Per Day Limit
Narcotic Analgesics		
Avinza, morphine sulfate ER		
30 mg sustained-release capsule	65100055207020	1 capsule
45 mg sustained-release capsule	65100055207025	1 capsule
60 mg sustained-release capsule	65100055207030	1 capsule
75 mg sustained-release capsule	65100055207035	1 capsule
90 mg sustained-release capsule	65100055207040	1 capsule
120 mg sustained-release capsule	65100055207050	1 capsule
Belbuca (buprenorphine buccal film)		
75 mcg buccal film	65200010108210	2 films
150 mcg buccal film	65200010108220	2 films
300 mcg buccal film	65200010108230	2 films
450 mcg buccal film	65200010108240	2 films
600 mcg buccal film	65200010108250	2 films
750 mcg buccal film	65200010108260	2 films
900 mcg buccal film	65200010108270	2 films
Butrans (buprenorphine)		
5 mcg/hour transdermal system	65200010008820	1 system/week
7.5 mcg/hour transdermal system	65200010008825	1 system/week
10 mcg/hour transdermal system	65200010008830	1 system/week
15 mcg/hour transdermal system	65200010008835	1 system/week
20 mcg/hour transdermal system	65200010008840	1 system/week

12 mcg/hr transdermal patch	65100025008610	15 patches/month
25 mcg/hr transdermal patch	65100025008620	15 patches/month
50 mcg/hr transdermal patch	65100025008630	15 patches/month
75 mcg/hr transdermal patch	65100025008640	15 patches/month
100 mcg/hr transdermal patch	65100025008650	15 patches/month
Embeda (morphine/naltrexone)		
20 mg/0.8 mg controlled-release capsule	65100055700220	2 capsules
30 mg/1.2 mg controlled-release capsule	65100055700230	2 capsules
50 mg/2 mg controlled-release capsule	65100055700240	2 capsules
60 mg/2.4 mg controlled-release capsule	65100055700250	2 capsules
80 mg/3.2 mg controlled-release capsule	65100055700260	2 capsules
100 mg/4 mg controlled-release capsule	65100055700270	2 capsules
Exalgo (hydromorphone)		
8 mg extended-release tablet[a]	6510003510A820	1 tablet
12 mg extended-release tablet[a]	6510003510A830	1 tablet
16 mg extended-release tablet[a]	6510003510A840	1 tablet
32 mg extended-release tablet	6510003510A855	1 tablet
Fentanyl transdermal patch		
37.5 mcg/hr transdermal patch	65100025008626	15 patches/month
62.5 mcg/hr transdermal patch	65100025008635	15 patches/month
87.5 mcg/hr transdermal patch	65100025008645	15 patches/month
Hysingla ER (hydrocodone)		
20 mg extended-release tablet	6510003010A810	1 tablet
30 mg extended-release tablet	6510003010A820	1 tablet
40 mg extended-release tablet	6510003010A830	1 tablet
60 mg extended-release tablet	6510003010A840	1 tablet
80 mg extended-release tablet	6510003010A850	1 tablet
100 mg extended-release tablet	6510003010A860	1 tablet
120 mg extended-release tablet	6510003010A870	1 tablet
Kadian (morphine sulfate)		
10 mg sustained-release capsule[a]	65100055107010	2 capsules
20 mg sustained-release capsule[a]	65100055107020	2 capsules
30 mg sustained-release capsule[a]	65100055107030	2 capsules
40 mg sustained-release capsule	65100055107035	2 capsules

60 mg sustained-release capsule[a]	65100055107045	2 capsules
70 mg sustained-release capsule	65100055107047	2 capsules
80 mg sustained-release capsule[a]	65100055107050	2 capsules
100 mg sustained-release capsule[a]	65100055107060	2 capsules
130 mg sustained-release capsule	65100055107070	2 capsules
150 mg sustained-release capsule	65100055107074	2 capsules
200 mg sustained-release capsule	65100055107080	2 capsules
MS Contin (morphine sulfate)*		
15 mg sustained-release tablet	65100055100415	3 tablets
30 mg sustained-release tablet	65100055100432	3 tablets
60 mg sustained-release tablet	65100055100445	3 tablets
100 mg sustained-release tablet	65100055100460	3 tablets
200 mg sustained-release tablet	65100055100480	3 tablets
Opana ER /oxymorphone SR		
5 mg sustained-release tablet	65100080107405	2 tablets
7.5 mg sustained-release tablet[a]	65100080107407	2 tablets
10 mg sustained-release tablet[a]	65100080107410	2 tablets
15 mg sustained-release tablet[a]	65100080107415	2 tablets
20 mg sustained-release tablet[a]	65100080107420	2 tablets
30 mg sustained-release tablet[a]	65100080107430	2 tablets
40 mg sustained-release tablet[a]	65100080107440	2 tablets
Opana ER (oxymorphone SR, crush resistant)		
5 mg sustained-release tablet	6510008010A705	2 tablets
7.5 mg sustained-release tablet	6510008010A707	2 tablets
10 mg sustained-release tablet	6510008010A710	2 tablets
15 mg sustained-release tablet	6510008010A715	2 tablets
20 mg sustained-release tablet	6510008010A720	2 tablets
30 mg sustained-release tablet	6510008010A730	2 tablets
40 mg sustained-release tablet	6510008010A740	2 tablets
Oramorph SR (morphine sulfate)		
15 mg sustained-release tablet	65100055107415	3 tablets
30 mg sustained-release tablet	65100055107430	3 tablets
60 mg sustained-release tablet	65100055107445	3 tablets
100 mg sustained-release tablet	65100055107460	3 tablets
OxyContin (oxycodone ER)		
10 mg tablet	6510007510A710	2 tablets
15 mg tablet	6510007510A715	2 tablets

30 mg tablet	6510007510A730	2 tablets
40 mg tablet	6510007510A740	2 tablets
60 mg tablet	6510007510A760	4 tablets
80 mg tablet	6510007510A780	4 tablets
Xartemis XR (oxycodone/acetaminophen)		
7.5/325 mg tablet	65990002200430	4 tablets
Xtampza ER (oxycodone ER)		
9 mg capsule	6510007500A310	2 capsules
13.5 mg capsule	6510007500A315	2 capsules
18 mg capsule	6510007500A320	2 capsules
27 mg capsule	6510007500A330	2 capsules
36 mg capsule	6510007500A340	2 capsules
Zohydro ER (hydrocodone)		
10 mg sustained-release capsule	65100030106910	2 capsules
15 mg sustained-release capsule	65100030106915	2 capsules
20 mg sustained-release capsule	65100030106920	2 capsules
30 mg sustained-release capsule	65100030106930	2 capsules
40 mg sustained-release capsule	65100030106940	2 capsules
50 mg sustained-release capsule	65100030106950	2 capsules
Zohydro ER Abuse Deterrent (hydrocodone ER)		
10 mg sustained-release capsule	6510003010A310	2 capsules
15 mg sustained-release capsule	6510003010A315	2 capsules
20 mg sustained-release capsule	6510003010A320	2 capsules
30 mg sustained-release capsule	6510003010A330	2 capsules
40 mg sustained-release capsule	6510003010A340	2 capsules
50 mg sustained-release capsule	6510003010A350	2 capsules
Tramadol, Tapentadol		
ConZip (tramadol SR biphasic)		
100 mg sustained-release capsule	65100095107070	1 capsule
200 mg sustained-release capsule	65100095107080	1 capsule
300 mg sustained-release capsule	65100095107090	1 capsule
Nucynta ER (tapentadol SR)		
50 mg extended-release tablet	65100091107420	2 tablets
100 mg extended-release tablet	65100091107430	2 tablets
150 mg extended-release tablet	65100091107440	2 tablets
200 mg extended-release tablet	65100091107450	2 tablets
250 mg extended-release tablet	65100091107460	2 tablets

100 mg sustained-release tablet	65100095107560	1 tablet
200 mg sustained-release tablet	65100095107570	1 tablet
300 mg sustained-release tablet	65100095107580	1 tablet
Tramadol ER (tramadol SR biphasic)		
150 mg sustained-release capsule	65100095107075	1 capsule
Ultram ER (tramadol)*		
100 mg sustained-release tablet	65100095107520	1 tablet
200 mg sustained-release tablet	65100095107530	1 tablet
300 mg sustained-release tablet	65100095107540	1 tablet

* – generic available, included in quantity limit program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Quantities of **Opioids ER** which are above the program set limit but **less than or equal to the Program Maximum Daily Dose** (maximum mg allowed with highest dosage strength) will be approved when BOTH of the following are met:

- The quantity (dose) requested cannot be achieved using a lesser quantity of a higher strength; **AND**
- The prescriber has submitted documentation in support of therapy with a higher dose (quantity) for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Quantities of **Opioids ER** which are **greater than the Program Maximum Daily Dose** (maximum mg allowed with highest dosage strength) will be approved when ALL of the following are met:

- The quantity (dose) requested cannot be achieved using a lesser quantity of a higher strength

AND

- ONE of the following:
  - The member has a diagnosis of active cancer pain due to an active malignancy; **OR**
  - The member is eligible for hospice care; **OR**
  - The member is undergoing treatment of chronic non-cancer pain and ALL of the following are met:
    - The prescriber provides documentation of a formal, consultative evaluation including:
      - Diagnosis; **AND**
      - A complete medical history which includes previous and current pharmacological and non-pharmacological therapy; **AND**
    - The prescriber has confirmed that a patient-specific pain management plan is on file for the patient; **AND**
    - The prescriber has confirmed that the patient is not diverting the requested medication, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable

AND

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Length of Approval: 1 month for dose titration requests

Up to 6 months for all other requests

OPHTHALMIC ANTIHISTAMINE STEP THERAPY CRITERIA

FDA APPROVED INDICATIONS AND DOSAGE[1-8]

Drug	FDA Indication(s)	Administration and Dosing
Bepreve® (bepotastine) 1.5% ophthalmic solution	Treatment of itching associated with allergic conjunctivitis.	Instill one drop into the affected eye(twice a day.
Elestat® (epinastine)[a] 0.05% ophthalmic solution[a]	Prevention of itching associated with allergic conjunctivitis.	One drop in each eye twice a day.
Emadine® (emedastine) 0.05% ophthalmic solution	Temporary relief of the signs and symptoms of allergic conjunctivitis.	One drop in the effected eye up to fo times daily.
Lastacaft® (alcaftadine) 0.25% ophthalmic solution	Prevention of itching associated with allergic conjunctivitis.	Instill one drop in each eye once daily
Optivar® (azelastine)[a] 0.05% ophthalmic solution	Treatment of itching of the eye associated with allergic conjunctivitis.	One drop instilled into each affected e twice a day.
Patanol™ (olopatadine)[a] 0.1% ophthalmic solution	Treatment of the signs and symptoms of allergic conjunctivitis.	One drop in each affected eye two tin per day at an interval of 6 to 8 hours.
Pataday™ (olopatadine) 0.2% ophthalmic solution	Treatment of ocular itching associated with allergic conjunctivitis.	One drop in each affected eye once a day.
Pazeo™ (olopatadine) 0.07% ophthalmic solution	Treatment of ocular itching associated with allergic conjunctivitis.	One drop in each affected eye once a day.

OBJECTIVE

The intent of the Ophthalmic Antihistamine Step Therapy (ST) program is to encourage use of cost-effective generic products over the more expensive brand products. This program will accommodate for use of brand products when generic prerequisites cannot be used due to previous trial and failure; or the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity. The program allows continuation of therapy when there is documentation that the patient is receiving the requested agent. Requests for brand products will be reviewed when patient-specific documentation is provided.

TARGET DRUGS

Bepreve® (bepotastine)

Elestat® (epinastine)[a]

Optivar® (azelastine)[a]

Patanol™ (olopatadine)[a]

Pataday™ (olopatadine)

Pazeo™ (olopatadine)

a – generic available

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Brand Ophthalmic Antihistamine will be approved when ONE of the following is met:

1. The patient's medication history indicates previous use of a generic ophthalmic antihistamine product in the past 90 days

OR

2. There is documentation that the patient is currently using the requested agent

OR

3. The prescriber states the patient is currently using the requested agent AND is at risk if therapy is changed

OR

4. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a generic ophthalmic antihistamine product

Length of approval: 12 months

OPHTHALMIC IMMUNOMODULATORS PRIOR AUTHORIZATION & QUANTITY LIMIT CRITERIA

FDA APPROVED INDICATIONS AND DOSAGE[1,4]

Agent	Indication	Dosage and Administra
Restasis® (cyclosporine ophthalmic emulsion)	Indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.	Instill one drop of ophthal twice a day in each eye ap 12 hours apart
Xiidra™ (lifitegrast ophthalmic solution)	Treatment of the signs and symptoms of dry eye disease.	One drop twice daily in ea (approximately 12 hours a

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Ophthalmic Immunomodulators PHOP Authorization with Quantity Limit

OBJECTIVE

The intent of the Ophthalmic Immunomodulators prior authorization (PA) program is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines. The PA defines appropriate use for Restasis as treatment for patients who have tear production presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca (e.g. Sjögren's Syndrome). The program will not approve for Restasis if the patient is also using a topical ophthalmic anti-inflammatory drug or punctal plug. The program defines appropriate use for Xiidra as treatment for patients with a diagnosis of dry eye disease. The program requires patients to have previously tried or are currently using aqueous enhancements. The program will also approve members who have another FDA labeled indication for the requested agent. The program will not approve those with contraindication(s) to the requested agent. Doses above the set limit will be approved if the requested quantity is below the FDA limit or when the quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Requests will be reviewed when patient-specific documentation has been provided.

TARGET DRUG

Restasis® (cyclosporine ophthalmic emulsion)

Xiidra™ (lifitegrast ophthalmic solution)

Brand (generic)	GPI	Multisource Code	Quantit
Restasis (cyclosporine ophthalmic emulsion)	86720020001620	M, N, O, or Y	2 vials
Xiidra (lifitegrast ophthalmic solution)	86734050002020	M, N, O, or Y	2 conta

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Restasis (cyclosporine ophthalmic emulsion) will be approved when ALL of the following are met:

1. ONE of the following:
   a. ALL of the following:

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Sjögren's Syndrome)
AND
ii. ONE of the following:
1. The patient is not currently using a topical ophthalmic anti-inflammatory drug or punctal plug
OR
2. The patient's current use of topical ophthalmic anti-inflammatory drug or punctal plug will be discontinued before starting the requested agent
AND
iii. ONE of the following:
1. The patient has previously tried or is currently using aqueous enhancements (e.g. artificial tears, gels, ointments)
OR
2. The patient has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity to aqueous enhancements (e.g. artificial tears, gels, ointments)
OR

b. Other FDA approved indication
AND

2. The patient does not have any FDA labeled contraindication(s) to the requested agent
AND
3. ONE of the following:
a. The requested quantity (dose) is NOT greater than the program quantity limit

OR

a. ALL of the following:
i. The requested quantity (dose) is greater than the program quantity limit

AND

i. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 12 months

Xiidra (lifitegrast ophthalmic solution) will be approved when ALL of the following are met:

1. ONE of the following:
a. ALL of the following:
i. The patient has a diagnosis of dry eye disease
AND
ii. ONE of the following:
1. The patient has previously tried or is currently using aqueous enhancements (e.g. artificial tears,

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labeled contraindication(s), or hypersensitivity to aqueous enhancements (e.g. artificial tears, gels, ointments)

OR

b. Other FDA approved indication

AND

2. The patient does not have any FDA labeled contraindication(s) to the requested agent

AND

3. ONE of the following:
   a. The requested quantity (dose) is NOT greater than the program quantity limit

OR

a. ALL of the following:
   i. The requested quantity (dose) is greater than the program quantity limit

AND

i. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 12 months

ORAL PULMONARY ARTERIAL HYPERTENSION (PAH) AGENTS PRIOR AUTHORIZATION WITH QUANTITY LIMIT

TARGET DRUGS

Adcirca® (tadalafil)

Adempas® (riociguat)

Letairis® (ambrisentan)

Opsumit® (macitentan)

[a]Revatio® (sildenafil)

Tracleer® (bosentan)

Tyvaso® (inhaled treprostinil)

Ventavis® (iloprost)

a- generic available, subject to prior authorization with quantity limit

20 mg tablet	40143080000320	2 tablets
Adempas (riociguat)		
0.5 mg tablet	4013405000****	3 tablets
1 mg tablet	4013405000****	3 tablets
1.5 mg tablet	4013405000****	3 tablets
2.0 mg tablet	4013405000****	3 tablets
2.5 mg tablet	4013405000****	3 tablets
Letairis (ambrisentan)		
5 mg tablet	4016000700****	1 tablet
10 mg tablet	4016000700****	1 tablet
Opsumit (macitentan)		
10 mg tablet	4016005000****	1 tablet
[a]**Revatio (sildenafil)**		
20 mg tablet	40143060100320	3 tablets
10 mg/mL oral susp	40143060101920	2 bottles (224 mL)/30 days
Tracleer (bosentan)		
62.5 mg tablet	4016001500****	2 tablets
125 mg tablet	4016001500****	2 tablets
Tyvaso (inhaled treprostinil)		
0.6 mg/mL System Starter Kit (66302-206-01)	40170080002020	1 kit/180 days
0.6 mg/mL System Refill kit (66302-206-02)	40170080002020	1 package of 28 ampules/28 days
0.6 mg/mL 4 pack Carton-(66302-206-03)	40170080002020	7 packages of 4 ampules/28 days
Institutional starter kit (66302-206-04)	40170080002020	1 kit/180 days
Ventavis (iloprost)		
10 mcg/mL	40170060002020	9 packages of 30 ampules/30 days
20 mcg/mL	40170060002040	9 packages of 30 ampules/30 days

a- generic available, subject to prior authorization with quantity limit

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Adcirca, Revatio, sildenafil, Tyvaso, or Ventavis will be approved when the following are met:

- The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization and

filling, **AND**

○ The patient has a pulmonary vascular resistance > 3 Wood units; **AND**

○ The patient's World Health Organization (WHO) functional class is II or greater; **AND**

○ If Adcirca, Revatio or sildenafil, the patient will not be taking an PDE5 inhibitor (e.g. tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) at the same time as the requested therapy **AND**

○ **ONE** of the following:

▪ The request is for Adcirca (tadalafil) for use in combination with Letairis (ambrisentan) for dual therapy ONLY; **OR**

▪ The requested agent will be utilized as monotherapy; **OR**

▪ The requested agent will be utilized for add-on therapy to existing monotherapy (dual-therapy) [except combo requests for Adcirca with Letairis for dual therapy], and ALL of following:

▪ The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy; **AND**

▪ The requested agent is in a different therapeutic class; **OR**

▪ The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) and **ALL** of the following:

▪ The patient is WHO functional class III or IV; **AND**

▪ A prostanoid has been started as one of the agents in the triple therapy unless the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid; **AND**

▪ The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy; **AND**

▪ All three agents in the triple therapy are from a different therapeutic class

AND

- The patient does not have any FDA labeled contraindications to therapy with the requested agent

Length of Approval: 12 months

Initial Evaluation

Adempas (riociguat) will be approved when the following are met:

- **ONE** of the following:

selective pulmonary angiography and ALL of the following:

- The patient has both a mean pulmonary artery pressure of ≥ 25 mmHg and a pulmonary capillary wedge pressure ≤15 mmHg; **AND**
- **ONE** of the following:
  - The patient is NOT a candidate for surgery; **OR**
  - The patient has had a pulmonary endarterectomy AND has persistent or recurrent disease; **OR**

○ The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization and ALL of the following:

- The patient's World Health Organization (WHO) functional class is II or greater; **AND**
- The patient has a mean pulmonary artery pressure of ≥25 mmHg; **AND**
- The patient has a pulmonary vascular resistance > 3 Wood units; **AND**
- If the requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy), then ALL of the following:
  - The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy; **AND**
  - The requested agent is in a different therapeutic class; **AND**
- If the requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy), then ALL of the following:
  - The patient is WHO functional class III or IV; **AND**
  - A prostanoid has been started as one of the agents in the triple therapy unless the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid; **AND**
  - The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy; **AND**
  - All three agents in the triple therapy are from a different therapeutic class

AND

- The patient does not have any FDA labeled contraindications to therapy with the requested agent

Length of approval: 12 months

Initial Evaluation

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- **ONE** of the following:
  - **BOTH** of the following:
    - There is documentation that the patient is currently receiving the requested agent **OR** The prescriber states that the patient is using the requested agent AND is at risk if therapy is changed; **AND**
    - The patient has an FDA labeled indication for the requested agent

OR

- The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 as determined by right heart catheterization and ALL of the following:
  - The patient's WHO functional class is II or greater; **AND**
  - The patient has a mean pulmonary artery pressure of ≥ 25 mmHg; **AND**
  - The patient has a pulmonary vascular resistance > 3 Wood units; **AND**
  - **ONE** of the following:
    - The request is for Letairis (ambrisentan) for use in combination with Adcirca (tadalafil) for dual therapy ONLY; **OR**
    - The requested agent will be utilized as monotherapy; **OR**
    - The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy; except combo requests for Letairis with Adcirca for dual therapy), and ALL of the following:
      - The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy; **AND**
      - The requested agent is in a different therapeutic class; **OR**
    - The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) and ALL of the following:
      - The patient is WHO functional class III or IV; **AND**
      - A prostanoid has been started as one of the agents in the triple therapy unless unless the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a prostanoid; **AND**
      - The patient has unacceptable or

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- All three agents in the triple therapy are from a different therapeutic class

AND

- If **Tracleer,** the patient does not have elevated liver enzymes accompanied by signs or symptoms of liver function/injury or a bilirubin level of ≥ 2 x ULN (upper limit of normal); **AND**
- The patient does not have any FDA labeled contraindications to therapy with the requested agent

Length of Approval: 12 months

Renewal Criteria

Adcirca, **Adempas, Letairis, Opsumit, Revatio, sildenafil, Tracleer, Tyvaso or Ventavis** will be approved for renewal when the following met:

- The patient has been previously approved for therapy through BCBS of Nebraska PA process; **AND**
- The patient is responding to therapy;

AND

- If **Adempas**, ONE of the following:
  - The patient has shown improvement from baseline in the 6-minute walk distance; **OR**
  - The patient has a stable 6-minute walk distance AND improvement in at least ONE of the following:
    - pulmonary vascular resistancep; **OR**
    - WHO functional class; **OR**
    - Borg dyspnea score

AND

- If **Tracleer,** the patient does not have elevated liver enzymes accompanied by signs or symptoms of liver function/injury or a bilirubin level of ≥ 2 x ULN (upper limit of normal)

AND

- The patient does not have any FDA labeled contraindications to therapy with the requested agent

Length of Approval: 12 months

ORILISSA OR MYFEMBREE

TARGET AGENT(S)

Orilissa™ (elagolix)

Myfembree™ (relugolix, estradiol hemihydrate, nonethindrone)

PROGRAM PRIOR AUTHORIZATION AND QUANTITY LIMITS

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Orilissa (elagolix)			
150 mg tablet	30090030100320	M, N, O, Y	1 tablet
200 mg tablet	30090030100330	M, N, O, Y	2 tablets
Myfembree (relugolix,estradiol hemihydrate, norethindrone)			
Myfembree (relugolix,estradiol hemihydrate, norethindrone	24993503800320	M, N, O, Y	1 tablet

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

I. The Orilissa or Myfembree may be considered medically necessary when **ALL** of the following are met:

A. For Orilissa the patient has a diagnosis of moderate to severe pain associated with endometriosis

OR

B. For Myfembree For Orilissa the patient has a diagnosis of moderate to severe pain associated with endometriosis or the diagnosis is heavy mensttrual bleeding associated with uterine leiomyomas.

AND

C. **ONE** of the following:

1. The patient has tired and had an inadequate response to therapy with hormonal contraceptives **OR**

2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to hormonal contraceptives

AND

D. The patient does **NOT** have any FDA labeled contraindications to the requested agent **AND**

E. **ONE** of the following

1. The patient has never used the requested previously **OR**

2. **ALL** of the following

a. The prescriber has submitted information on how long the patient has already been on therapy with the requested agent **AND**

b. **ONE** of the following:

i. The patient has coexisting moderate hepatic impairment (Child-Pugh Class B) **AND** has not received 6 or more months of therapy with the requested agent **OR**

ii. The patient has received neither 24 or more months of therapy with the requested agent, nor 6 months of therapy with the requested agent at 200 mg twice daily.

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density **AND** states that the patient can continue therapy **AND**

d. The patient has NOT had a fragility fracture since starting therapy with the requested agent

F. **ONE** of the following:

1. The requested quantity dose does not exceed the program quantity limit **OR**

2. **ALL** of the following

a. The requested quantity dose is greater than the program quantity limit **AND**
b. The requested quantity dose is less than the maximum FDA labeled dose for the requested indication **AND**

c. The requested quantity dose cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of Approval:

Based on coexisting condition:

Orilissa 200 mg twice daily dosing OR moderate hepatic impairment (Child-Pudh Class B): up to at total of 6 months (inclusive of previous duration of therapy

All other requests: up to a total of 24 months (inclusive of previous duration of therapy)

PHOSPHODIESTERASE TYPE 5 INHIBITORS QUANTITY LIMIT

OBJECTIVE

The intent of the Phosphodiesterase Type 5 (PDE5) Inhibitors Quantity Limit (QL) program is to recommend the monthly quantity of thirty tablets, cumulative, for Cialis 2.5 mg and 5 mg tablets and the monthly quantity limit of six tablets, cumulative for any combination of the other products and Cialis 10 mg and 20 mg tablets for male patients, based on Food and Drug Administration (FDA) approved indications and dosing schedule and/or clinical studies of erectile dysfunction. The program will review for increased quantities for the accepted off-label uses of therapy of Raynaud's phenomenon in male and female patients and the preservation of erectile function following nerve-sparing radical retropubic prostatectomy in males. These criteria may not apply if these agents are excluded from coverage under the member's pharmacy benefit plan.

QUANTITY LIMIT TARGET DRUGS - RECOMMENDED LIMITS

Brand (generic)	GPI	Quantity per month
Cialis (tadalafil)		
2.5 mg tablets	40304080000302	30* (cumulative)
5 mg tablets	40304080000305	

Levitra (vardenafil)		
2.5 mg tablets	40304090100310	
5 mg tablets	40304090100320	
10 mg tablets	40304090100330	
20 mg tablets	40304090100340	
Staxyn (vardenafil)		6[b] (cumulative)
10 mg orally disintegrating tablets	40304090107230	
Stendra (avanafil)		
50 mg tablets	40304015000320	
100 mg tablets	40304015000330	
200 mg tablets	40304015000340	
Viagra (sildenafil)		
25 mg tablets	40304070100310	
50 mg tablets	40304070100320	
100 mg tablets	40304070100330	

* - Quantity of 30 tablets per month is cumulative for Cialis 2.5 mg and 5 mg

b – Quantity of 6 tablets per month is cumulative for Viagra, Levitra, Staxyn, Stendra, Cialis 10 and 20mg

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Increased quantities of **Phosphodiesterase Type 5 Inhibitors** will be approved when ONE of the following is met:

- The patient has a diagnosis of Raynaud's phenomenon AND BOTH of the following:
  - The patient's medication history includes use of a dihydropyridine calcium channel blocker OR the patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to dihydropyridine calcium channel blocker therapy

AND

  - **ONE** of the following:
    - The quantity requested is equal to or less than 60 tablets per month; **OR**
    - The quantity requested is greater than 60 tablets per month and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

OR

- The phosphodiesterase type 5 inhibitor has been prescribed for preservation of erectile function following a nerve-sparing radical retropubic prostatectomy AND BOTH of the following:
  - The patient has been treated with the phosphodiesterase type 5 inhibitor for less than 12 months; **AND**
  - The quantity requested is equal to or less than 30 tablets per month

Length of Approval:

Preservation of erectile function following a nerve-sparing radical retropubic prostatectomy – 30 tablets per month for a duration of up to 12 months total

PLERIXAFOR

TARGET AGENT

Mozobil® (plerixafor)

Brand (generic)	GPI	Multisource Code
Mozobil (plerixafor)		
24 mg/1.2 mL (20 mg/mL) subcutaneous injection	82502060002020	M, N, O, or Y

Prior Authorization criteria for approval

Evaluation

I. The Target Agent may be considered medically necessary when **ALL** of the following are met:

A. **ONE** of the following:

1. The patient has a diagnosis of non-Hodgkin's lymphoma or multiple myeloma **AND ALL** of the following:

a. the patient will use the requested agent to mobilize hematopoietic stem cells (HSTs) to the peripheral blood **AND**

b. The patient will have an autologous stem cell transplant **AND**

c. The patient will use the requested agent along with a granulocyte stimulating factor (G-CSF) (e.g. Neupogen, Nivestym, Zarxio)

OR

2. The patient has another FDA approved indication for the requested agent **OR**

3. The patient has another indication that is supported in compendia (AHFS or DrugDex 1 or 2a level of evidence, NCCN 1 or 2a recommendation) for the requested agent.

AND

B. The prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, hematologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

C. The patient does **NOT** have any FDA labeled contraindications to the requested agent **AND**

D. The requested quantity dose is within FDA labeled dosing or supported in compendia (AHFS or DrugDex 1 or 2a level of evidence, NCCN 1 or 2a recommendation) for the requested indication **AND**

E. The requested dose is not over 40 mg/day **AND**

F. The patient will **NOT** use the requested agent for more than 4 days.

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PROGESTERONES

TARGET AGENTS

Crinone® 4%

Crinone® 8%

Endometrin®

Brand (Generic)	GPI	Multi-source Code	Quantity limit
Crinone			
4% vaginal gel	55370060004010	M, N, O, or Y	6.75 gm (6 prefilled applicators)/30 days
8% vaginal gel	55370060004020	M, N, O, or Y	67.5 gm (60 prefilled applicators)/30 days
Endometrin			
100 mg vaginal insert	55370060009910	M, N, O or Y	84 vaginal inserts (4 cartons of 21 inserts)/28 days

I. The target agents **may be considered medically necessar**y when ALL of the following are met:

A. **ONE** of the following:

1. The requested agent is Endometrin **AND BOTH** of the following:

a. The patient's benefit plan covers agents for infertility **AND**

b. The patient is undergoing Assisted Reproductive Technology (ART)

OR

2. The requested agent if Crinone 4% gel **AND ALL** of the following:

a. The patient has a diagnosis of secondary amenorrhea **AND**

b. **ONE** of the following:

i. the patient has tried and had an inadequate response to a generic progesterone agent (e.g. oral contraceptives (combination or progestin only), micronized progesterone, intramuscular progesterone, norethindrone, medroxyprogeserone) in the las 90 days. **OR**

ii. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to **ALL** generic progesterone agents that is not expected to occur with the requested agent

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include shistory, physical examination, and estimation of follicle stimulating hormone (FSH) and thyroid stimulating hormone (TSH) **AND**

d. The patient is not pregnant **AND**

e. **ONE** of the following:

i. The underling cause of secondary amenorrhea CANNOT be corrected **OR**

ii. The underlying cause of secondary amenorrhea (e.g., weight loss/anorexia, hypo/hyperthyroidism, Cushing's syndrome, hyperprolactinemia (has been corrected)

OR

3. The requested agent is Crinone 8% **AND ONE** of the following:

a. The patient has a diagnosis of secondary amenorrhea AND ALL of the following:

i. **ONE** of the following:

aa. the patient has tried and had an inadequate response to a generic progesterone agent (e.g. oral contraceptives (combination or progestin only), micronized progesterone, intramuscular progesterone, norethindrone) **AND** Crinone 4% vaginal gel **OR**

bb. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to **ALL** generic progesterone agents **AND** Crinone 4% gel.

AND

ii. The patient has had a physical examination which include shistory, physical examination, and estimation of follicle stimulating hormone (FSH) and thyroid stimulating hormone (TSH) AND

iii. The patient is not pregnant **AND**

iv. **ONE** of the following:

aa. The underling cause of secondary amenorrhea CANNOT be corrected **OR**

bb. The underlying cause of secondary amenorrhea (e.g., weight loss/anorexia, hypo/hyperthyroidism, Cushing's syndrome, hyperprolactinemia) has been corrected

OR

b. The patient is using the requested agent as part of Assisted Reproductive TEchnology (ART) and **BOTH** of the following:

i. The patient's benefit plan covers agent for fertility **AND**

ii. **ONE** of the following:

aa. Information has been provided that indicates the patient has been treated with

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bb. The prescriber states the patient has been treated with the requested agent within the past 90 days **AND** is at risk if therapy is changed **OR**

cc. The patient has tried and had to the preferred agent Endometrin **OR**

dd. The patient has a documented intolerance, FDAlabeled contraindication or hypersensitivity that is not expected to occur with the requested agent.

AND

B. The patient does **NOT** have any FDA labeled contraindications to the requested agent **AND**

C. **ONE** of the following:

1. The requested quantity dose does not exceed the program quantity limit **OR**

2. **ALL** of the following:

a. The requested quantity dose is greater than the program quantity limit **AND**

b. The requested quantity dose does not exceed the maximum FDA labeled dose for the requested indication **AND**

c. The requested quantity dose cannot be achieved with lower quantity of a higher strength that does not exceed the program quantity limit

OR

3. **ALL** of the following:

a. The requested quantity dose is greater than the program quantity limit **AND**

b. The requested quantity dose is greater than the maximum FDA labeled dose for the requested indication **AND**

c. The prescriber has submitted information in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months for secondary amenorrhoea

4 months for ART

PSEUDOBULBAR AFFECT

TARGET AGENT

Nuedexta® (dextromethorphan hydrobromide and quinidine sulfate)

Brand (generic)	GPI	Multisource Code	Quantity Limit
Nuedexta (dextromethorphan hydrobromide and quinidine sulfate)			

Prior Authorization Criteria for Approval

Initial Evaluation:

I. The target agent may be considered medically necessary when **ALL** the following are met:

A. The patient has a diagnosis of pseudobulbar affect (PBA) **AND**

B. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS) **AND**

C. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, neruopsychologit, psychiatrist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

D. The prescriber has provided a baseline number of laughing and/or crying episodes experienced by the patient **AND**

E. **ONE** of the following:

1. The patient has tried and had inadequate response to a tricyclic antidepressant (TCA) (e.g., amitriptyline, clomipramine, desipramine, doxepin, imipramine, nortripyline) or a selective serotonin reuptake inhibitor (SSRI) (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) used for the requested indication **OR**

2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL TCAs and SSRis

AND

F. **ONE** of the following:

1. The patient is NOT currently being treated with a monoamine oxidase inhibitor (MAOI) (e.g., Marplan (isocarboxazid), Nardil (phenelzine), Parnate (tranylcypromine)) **OR**

2. The patient is currently being treated with a MAOI AND will discontinue at least 14 days prior to starting the requested agent

AND

G. The patient does **NOT** have any FDA labeled contraindications to the requested agent

AND

H. **ONE** of the following:

1. The requested quantity dose does **NOT** exceed the program quantity limit

OR

2. **ALL** of the following:

a. The requested quantity dose is greater than the program quantity limit **AND**

b. The requested quantity dose does **NOT** exceed the maximum FDA labeled dose for the requested indication **AND**

c. The requested quantity dose cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

a. The requested quantity dose is greater than the program quantity limit **AND**

b. The requested quantity dose is greater than the maximum FDA labeled dose for the requested indication **AND**

c. The prescriber has submitted information in support of therapy with a higher dose for the requested indication

Length of Approval: 6 months

Renewal Evaluation

I. The target agent may be considered medically necessary when **ALL** of the following are met:

A. The patient has been previously approved for the requested agent through the plan's prior authorization process **AND**

B. The patient has a diagnosis of pseudobulbar affect (PBA) **AND**

C. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS) **AND**

D. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, neruopsychologit, psychiatrist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

E. The patient has experienced a decrease in laughing and/or crying episodes from baseline **AND**

F. **ONE** of the following:

1. The patient is **NOT** currently being treated with a monoamine oxidase inhibitor (MAOI) (e.g., Marplan (isocarboxazid), Nardil (phenelzine), Parnate (tranylcypromine)) **OR**

2. The patient is currently being treated with a MAOI **AND** will discontinue at least 14 days prior to continuing the requested agent

AND

G. The patient does **NOT** have any FDA labeled contraindications to the requested agent

AND

H. **ONE** of the following:

1. The requested quantity dose does **NOT** exceed the program quantity limit

OR

2. **ALL** of the following:

a. The requested quantity dose is greater than the program quantity limit **AND**

b. The requested quantity dose does **NOT** exceed the maximum FDA labeled dose for the requested indication **AND**

c. The requested quantity dose cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

a. The requested quantity dose is greater than the program quantity limit **AND**

b. The requested quantity dose is greater than the maximum FDA labeled dose for the requested indication **AND**

c. The prescriber has submitted information in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

REGRANEX

TARGET AGENT

Regranex® (becaplermin)

PROGRAM PRIOR AUTHORIZATION AND QUANTITY LIMIT

Brand (generic)	GPI	Multisource Code	Quantity Limit
Regranex (becaplermin)			
0.01% gel	90945020004020	M, N, O, or Y	15 g / 30 days

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

Initial Evaluation

I. The Target Agent may be medically necessary when **ALL** of the following are met:

A. The patient has a diagnosis of lower extremity diabetic neuropathic ulcer(s) that extend into the subcutaneous tissue or beyond **AND**

B. The ulcer(s) intended for treatment has an adequate blood supply **AND**

C. The patient will practice good ulcer care (e.g. debridement, infection control, pressure relief) with the requested agent **AND**

D. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

E. ONE of the following:

1. The requested quantity (dose) is NOT greater than the program quantity limit **OR**

2. **ALL** of the following:

a. The requested quantity (dose) is greater than the program quantity limit **AND**

b. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis

Length of Approval: 6 months

Renewal Evaluation

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A. The patient has been previously approved for the requested agent through Prime Therapeutics' Prior Authorization process for the initially treated ulcer(s) **AND**

B. The request is to continue treatment of the same ulcer(s) approved through Prime Therapeutics' Prior Authorization **AND**

C. **ONE** of the following:

1. The patient has received <10 weeks of therapy with the requested agent for the treated ulcer(s) **OR**

2. The patient has received ≥10 weeks and <20 weeks of therapy with the requested agent for the treated ulcer(s) AND ONE of the following:

a. The treated ulcer(s) has decreased in size by at least 30% **OR**

b. The prescriber has provided documentation supporting the continuation of therapy with the requested

agent

OR

3. The patient has received ≥ 20 weeks of therapy with the requested agent for the treated ulcer(s) AND the prescriber has provided documentation for the continuation of therapy with the requested agent

AND

D. The patient does **NOT** have any FDA labeled contraindications to the requested agent **AND**

E. **ONE** of the following:

1. The requested quantity (dose) is **NOT** greater than the program quantity limit **OR**

2. **ALL** of the following:

a. The requested quantity (dose) is greater than the program quantity limit **AND**

b. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: 6 months

RHO KINASE INHIBITOR (STEP THERAPY)

TARGET AGENTS

Rhopressa® (netarsudil ophthalmic solution) 0.02%

BlueCross BlueShield Nebraska

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

I. The target agent **may be considered medically necessary** when **ONE** of the following is met:

A. The patient's medication history indicates use of a generic ophthalmic prostaglandin in the past 90 days **OR**

B. There is documentation that the patient is currently being treated with the requested agent **OR**

C. The prescriber states the patient is currently being treated with the requested agent **AND** is at risk if therapy is changed **OR**

D. The patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to generic ophthalmic prostaglandin(s)

Length of approval: 12 months

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

SELECTIVE SEROTONIN INVERSE AGONIST (SSIA) PRIOR AUTHORIZATION AND QUANTITY LIMIT

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent	Indication	Dosage & Administration
Nuplazid™ (pimavanserin)	Treatment of hallucinations and delusions associated with Parkinson's disease psychosis	Recommended dose is 34 mg, taken orally as two 17 mg tablets once daily, without titration

OBJECTIVE

The intent of the Selective Serotonin Inverse (SSIA) prior authorization (PA) and Quantity Limit (QL) program is to appropriately select patients for therapy according to product labeling and/or clinical guidelines and according to dosing recommended in product labeling. The program requires the trial of guideline recommended clozapine and quetiapine prior to approval of the requested agent. The program allows for approval for those who are unable to use clozapine or quetiapine due to FDA labeled contraindication, intolerance, or hypersensitivity. The program will not approve for patients who have an FDA labeled contraindication to the requested agent. The program will approve for doses within the set limit. Doses above the set limit will be approved if the requested quantity is below the FDA limit and cannot be dose optimized or when the quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Requests will be reviewed when patient specific documentation is provided.

TARGET AGENT(S)

BlueCross BlueShield Nebraska

Nuplazid (pimavanserin)		
17 mg tablet	59400028200320	2 tablets

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

TARGET AGENT(S) will be approved when ALL of the following are met:

- **ONE** of the following:
  - The patient has a diagnosis of hallucinations or delusions associated with Parkinson's disease psychosis; **OR**
  - Other FDA approved indication

    AND
- **ONE** of the following:
  - The patient's medication history includes the use of clozapine or quetiapine; **OR**
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to clozapine or quetiapine

    AND
- The patient does NOT have any FDA labeled contraindication(s) to the requested agent

    AND
- **ONE** of the following:
  - The quantity requested is less than or equal to the program quantity limit; **OR**
  - The quantity (dose) requested is above the program limit, less than or equal to the maximum dose recommended in FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength; **OR**
  - The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: 12 months

SENSIPAR

TARGET AGENT

Sensipar® (cinacalcet)[a]

[a] – generic available

BlueCross BlueShield Nebraska

30 mg tablet	30905225100320	M, N, O, or Y
60 mg tablet	30905225100330	M, N, O, or Y
90 mg tablet	30905225100340	M, N, O, or Y

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

I. The target agent **may be considered medically necessary** when **ALL** of the following are met:

1. **ONE** of the following:

a. The patient has a diagnosis of hypercalcemia due to parathyroid carcinoma

OR

b. The patient has a diagnosis of primary hyperparathyroidism (HPT) and BOTH of the following:

i. The patient has a pretreatment serum calcium level that is above the testing laboratory's upper limit of normal **AND**

ii. The patient is unable to undergo parathyroidectomy

OR

c. The patient has a diagnosis of secondary hyperparathyroidism (HPT) due to chronic kidney disease (CKD) **AND** ALL of the following:

i. The patient is on dialysis **AND**

ii. The patient has a pretreatment or current intact PTH (iPTH) level that is >300 pg/mL **AND**

iii. **ONE** of the following:

1. The patient has tried and had an inadequate response to a phosphate binder [e.g., calcium acetate, calcium carbonate, sevelamer carbonate, Fosrenol* (lanthanum carbonate), Renagel* (sevelamer hydrochloride)]

OR

2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL phosphate binder agents

AND

iv. ONE of the following:

1. The patient has tried and had an inadequate response to a vitamin D analog [e.g., calcitriol, Hectorol (doxecalciferol), Rayaldee (calcifediol), Zemplar (paricalcitol)] **OR**

2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL vitamin D analog agents

OR

AND

2. **ONE** of the following:
    a. The patient is **NOT** currently being treated with another calcium sensing receptor agonist [e.g., Parsabiv (etelcalcetide)] **OR**
    b. The patient is currently being treated with another calcium sensing receptor agonist AND will discontinue prior to starting the requested agent

AND

3. The patient does **NOT** have any FDA labeled contraindications to the requested agent

Length of approval: 12 months

*prerequisite agent may be subject to Step Therapy (ST) program

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent	Indication	Dosage
Sensipar® (cinacalcet)[a] tablets	Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis *Limitations of Use: Not indicated for use in patients with CKD who are not on dialysis	Initial dose 30mg orally once daily. Titrate no more frequently than every 2-4 weeks through sequential doses of 30, 60, 90, 120, and 180 mg once daily to target iPTH level of 150 to 300 pg/mL
	Hypercalcemia in adult patients with parathyroid carcinoma	Initial dose 30mg orally twice daily. Titrate every 2-4 weeks through sequential doses of 30mg twice daily, 60 mg twice daily, and 90 mg twice daily, and 90mg 3 or 4 times daily as necessary to normalize serum calcium level
	Hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy	

a – Generic available

SIGNIFOR (PASIREOTIDE)

TARGET AGENT

Signifor® (pasireotide)

Brand (generic)	GPI	Multisource Code	Quantity Limit

BlueCross BlueShield Nebraska

0.3 mg/1 mL ampules	30170075202020	M, N, O, or Y	ampules every 30 days
0.6 mg/1 mL ampules	30170075202030	M, N, O, or Y	60 ampules every 30 days
0.9 mg/1 mL ampules	30170075202040	M, N, O, or Y	60 ampules every 30 days

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation

I. The target agent **may be considered medically necessary** when ALL the following are met:

A. **ONE** of the following:

1. The patient has a diagnosis of Cushing's disease and **BOTH** of the following:
2. The patient has urinary free cortisol levels greater than 1.5 times the upper limit of normal **AND**
3. **ONE** of the following:
   i. The patient has had an inadequate response to pituitary surgical resection **OR**
   ii. The patient is not a candidate for pituitary surgical resection

OR

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diagnosis for the requested agent

AND

B. The prescriber is a specialist (e.g., endocrinologist) in the area of the patient's diagnosis or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

C. **ONE** of the following:

1. The patient is **NOT** currently being treated with Signifor LAR (pasireotide LAR) **OR**
2. The patient is currently being treated with Signifor LAR **AND** will discontinue prior to initiating the requested agent

AND

D. The patient does **NOT** have any FDA labeled contraindications to the requested agent **AND**

E. ONE of the following:

1. The requested quantity (dose) does not exceed the program quantity limit **OR**
2. ALL of the following:
   i. The requested quantity (dose) is greater than the program quantity limit **AND**
   ii. The requested quantity (dose) does not

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FDA labeled dose for the requested indication **AND**

iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

Length of Approval: Cushing's Disease – 6 months

All other FDA approved diagnosis – 12 months

Renewal Evaluation

I. The target agent **may be considered medically necessary** ALL the following are met:

A. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**

B. The patient has had clinical benefit with the requested agent **AND**

C. The patient has urinary free cortisol levels less than or equal to the upper limit of normal **AND**

D. The patient has shown improvement from baseline in at least **ONE** of the following are met:

1. Fasting plasma glucose **OR**
2. Hemoglobin A1c **OR**
3. Hypertension **OR**
4. Weight

AND

E. The prescriber is a specialist (e.g., endocrinologist) in the area of the patient's

F. **ONE** of the following:

1. The patient is **NOT** currently being treated with Signifor LAR (pasireotide LAR) **OR**
2. The patient is currently being treated with Signifor LAR AND will discontinue prior to continuing the requested agent

AND

G. The patient does **NOT** have an FDA labeled contraindication to the requested agent **AND**

H. **ONE** of the following:

1. The requested quantity (dose) does not exceed the program quantity limit **OR**
2. **ALL** the following:
   a. The requested quantity (dose) is greater than the program quantity limit **AND**
   b. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **AND**
   c. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

Length of Approval: 12 monthss

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent	Indication	Dosing
Signifor® (pasireotide) subcutaneous injection	Adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative	Initial dose: either 0.6 mg or 0.9 mg twice daily Maintenance dose: range 0.3 mg to 0.9 mg twice daily based on response and tolerability

STRENSIQ (ASFOTASE ALFA) PRIOR AUTHORIZATION

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Initial Evaluation
Strensiq will be approved when ALL of the following are met:

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The patient has/had clinical manifestations consistent with hypophospatasia at the age of onset prior to age 18 (e.g. vitamin B6-dependent seizures, skeletal abnormalities: such as rachitic chest deformity leading to respiratory problems or bowed arms/legs, "failure to thrive"); **AND**

- The patient has/had radiographic imaging to support the diagnosis of hypophospatasia at the age of onset prior to age 18 (e.g. infantile rickets, alveolar bone loss, craniosynostosis); **AND**
- Molecular genetic test has been completed confirming mutations in the *ALPL* gene that encodes the tissue nonspecific isoenzyme of ALP (TNSALP); **AND**
- Reduced activity of unfractionated serum alkaline phosphatase (ALP) in the absence of bisphosphonate therapy (i.e. below the normal lab reference range for age and sex); **AND**
- ONE of the following: elevated urine concentration of phosphoethanolamine (PEA), elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior, or elevated urinary inorganic pyrophosphate (PPi);

AND

- The prescriber is a specialist in the area of the patient's disease (e.g. endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's disease; **AND**

- The patient does not have any FDA labeled contraindication(s) to therapy with Strensiq (esfotase alfa); **AND**

- The requested quantity is within FDA labeled dosing (prescriber must provide patient's weight)

Length of Approval: 6 months

Renewal Evaluation
Strensiq (esfotase alfa) will be approved when ALL the following are met:

- The patient has been previously approved for Strensiq (esfotase alfa) through the Blue Cross and Blue Shield of Nebraska PA process; **AND**

- The prescriber is a specialist in the area of the patient's disease (e.g. endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's disease; **AND**

- The patient has responded to treatment with Strensiq (asfotase alfa) as evidenced by an improvement and/or stabilization (upon subsequent renewals) respiratory status, growth, or radiographic findings; **AND**

- The patient does not have any FDA labeled contraindication(s) to therapy with Strensiq (esfotase alfa); **AND**

- The requested quantity is within FDA labeled dosing (prescriber must provide patient's weight)

Length of Approval: 12 months

SUBSTRATE REDUCTION THERAPY

TARGET AGENT

Cerdelga® (eliglustat)

Zavesca® (miglustat)[a]

[a]- generic available and included in program

Brand (generic)	GPI	Multisource Code	Quantity Limit per

84 mg capsule	82700040600120	M, N, O, or Y	2 capsules
Zavesca (miglustat)[a]			
100 mg capsule	82700070000120	M, N, O, or Y	3 capsules

[a]- generic available and included in program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation

I. The target agent **may be considered medically necessary** when **ALL** the following are met:

A. The patient is 18 years of age or over **AND**

B. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

C. The patient has a diagnosis of Gaucher Disease type 1 **AND**

D. The patient does **NOT** have any neuropathic symptoms (e.g., convulsive crisis, ataxia, supranuclear horizontal ocular palsy, dementia, alteration in ocular movement, bulbar (swallowing difficulties, stridor, convergent strabismus)) **AND**

E. **ONE** of the following:

1. The patient has a baseline glucocerebrosidase activity of <15% of mean normal in fibroblasts, leukocytes, or other nucleated cells **OR**

2. Genetic analysis with two (2) disease-causing alleles on the glucocerebrosidase genome (*GBA* gene)

AND

F. The prescriber has drawn baseline levels of hemoglobin, platelets, liver volume, and spleen volume **AND**

G. The patient has at least **ONE** of the following clinical presentations at baseline:

1. Anemia defined as mean hemoglobin (Hb) level below the testing laboratory's lower limit of the normal range based on age and gender **OR**

2. Thrombocytopenia (platelet count of < 100,000/µL on at least 2 measurements) **OR**

3. Hepatomegaly **OR**

4. Splenomegaly **OR**

5. Growth failure (i.e., growth velocity is below the standard mean for age) **OR**

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H. **ONE** of the following:

1. If the requested agent is Cerdelga (eliglustat), the patient is a CYP2D6 extensive metabolizer (EMs), intermediate metabolizer (IMs), or poor metabolizer (PMs) established by an FDA-cleared test **OR**

2. If the requested agent is Zavesca (miglustat), enzyme replacement therapy is NOT a therapeutic option (e.g. contraindication, intolerance, previous ERT failure)

AND

I. The patient does **NOT** have an FDA labeled contraindication to the requested agent **AND**

J. **ONE** of the following:

1. The requested quantity (dose) does not exceed the program quantity limit **OR**

2. **ALL** the following:

   a. The requested quantity (dose) is greater than the program quantity limit **AND**

   b. The requested quantity (dose) does not exceed the maximum FDA labeled dose **AND**

   c. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

3. **ALL** the following:

   a. The requested quantity (dose) is greater than the program quantity limit **AND**

   b. The requested quantity (dose) is greater than the maximum FDA labeled dose **AND**

   c. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Renewal Evaluation

I. The targe agent **may be considered medically necessary** when the following are met:

A. The patient has been previously approved for the requested agent through Prime Therapeutics Prior Authorization Review process **AND**

B. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or has consulted with a specialist in the area of the patient's diagnosis **AND**

C. The patient has shown improvement in or stabilization from baseline of **ONE** of the following:

1. Spleen volume
2. Hemoglobin level
3. Liver volume
4. Platelet count (sufficient to decrease the risk of bleeding)
5. Growth
6. Bone pain or crisis

AND

D. The patient does **NOT** have an FDA labeled contraindication to the requested agent **AND**

E. **ONE** of the following:

1. The requested quantity (dose) does not exceed the program quantity limit **OR**
2. **ALL** the following:
   a. The requested quantity (dose) is greater than the program quantity limit **AND**
   b. The requested quantity (dose) does not exceed the maximum FDA labeled dose **AND**
   c. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

3. **ALL** the following:
   a. The requested quantity (dose) is greater than the program quantity limit **AND**

c. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent	Indication	Dosing and Administration
Cerdelga® (eliglustat) capsule	Long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test Limitations of Use: • Patients who are CYP2D6 ultra-rapid metabolizers (URMs) may not achieve adequate concentrations of Cerdelga to achieve a therapeutic effect • A specific dosage cannot be recommended for those patients whose CYP2D6 genotype cannot be determined (indeterminate metabolizers)	CYP2D6 extensive metabolizer (EM) or intermediate metabolizer (IM): 84 mg orally twice daily CYP2D6 poor metabolizer (PM): 84 mg orally once daily
Zavesca® (miglustat)[a] capsule	Monotherapy for treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g. due to allergy, hypersensitivity, or poor venous access)	100 mg administered orally three times a day at regular intervals

[a] – generic available

SUCRALFATE SUSPENSION QUANTITY LIMIT

TARGET AGENTS FOR PRIOR AUTHORIZATION AND QUANTITY LIMIT(S)

Carafate® oral suspension (sucralfate oral suspension)			
1 g/10 mL	49300010001820	M, N, O, Y	40 mL

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

I. The target agent **may be considered medically necessary** when **ANY ONE** of the following is met:

A. The prescriber has provided documentation that the use of the tablet formulation is not clinically appropriate for the patient **AND**

B. The patient does NOT have any FDA labeled contraindication(s) to the requested agent **AND**

C. **ONE** of the following:

1. The requested quantity (dose) is less than or equal to the program quantity limit **OR**

2. **ALL** the following:

a. The requested quantity (dose) is greater than the program quantity limit **AND**

b. The requested quantity (dose) is less than the maximum FDA labeled dose **AND**

c. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

3. **ALL** the following:

a. The requested quantity (dose) is greater than the program quantity limit **AND**

b. The requested quantity (dose) is greater than the maximum FDA labeled dose **AND**

c. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of approval: 12 months

FDA APPROVED INDICATIONS AND DOSAGE[1,2]

(sucralfate) Oral suspension, Tablet	• Short-term (up to 8 weeks) treatment of active duodenal ulcer Tablet: • Short-term treatment (up to 8 weeks) of active duodenal ulcer. • Maintenance therapy for duodenal ulcer patients at reduced dosage after healing of acute ulcers	• 1 gram four times daily Maintenance therapy in adults: • 1 gram twice daily

THROMBOPOIETIN RECEPTOR AND TAVALISSE PRIOR AUTHORIZATION WITH QUANTITY LIMITS

Initial Evaluation

Target Agent(s) may be considered **medically necessary** when ALL of the following are met:

I. ONE of the following:

A. The requested agent is Doptelet AND ONE of the following:

1. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following:

a. ONE of the following:

i. The patient has a platelet count less than or equal to 30 X 10^9/L **OR**

ii. The patient has a platelet count greater than 30 X 10^9/L but less than 50 X 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND**

b. ONE of the following:

i. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR**

ii. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR**

iii. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR**

iv. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Nplate, Promacta) or Tavalisse **OR**

vi. The patient has had an inadequate response to a splenectomy **OR**

vii. The patient has tried and had an inadequate response to rituximab **OR**

2. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following:

a. The patient has a platelet count less than 50 X 10^9/L **AND**

b. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND**

c. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR**

3. The patient has another FDA approved indication for the requested agent **OR**

4. The patient has another indication supported in compendia for requested agent **OR**

B. The requested agent is Mulpleta (lusutrombopag) AND ONE of the following:

1. BOTH of the following:

a. The patient has a platelet count less than 50 X 10^9/L **AND**

b. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND BOTH of the following:

i. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND**

ii. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with requested agent) **OR**

2. The patient has another FDA approved indication for the requested agent **OR**

3. The patient has another indication supported in compendia for the requested agent **OR**

C. The requested agent is Nplate (romiplostim) AND ONE of the following:

1. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **OR**

2. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ALL of the following:

a. ONE of the following:

months **OR**

ii. The patient is 18 years of age or older **AND**

b. ONE of the following:

i. The patient has a platelet count less than or equal to 30 X 10^9/L **OR**

ii. The patient has a platelet count greater than 30 X 10^9/L but less than 50 X 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND**

c. ONE of the following:

i. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR**

ii. The patient has an intolerance or hypersensitivity to ONE corticosteroid used in the treatment of ITP **OR**

iii. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR**

iv. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR**

v. The patient has had an inadequate response to splenectomy **OR**

vi. The patient has tried and had inadequate response to rituximab **OR**

3. The patient has another FDA approved indication for the requested agent **OR**

4. The patient has another indication supported in compendia for the requested agent **OR**

D. The request is for Promacta (eltrombopag) AND ONE of the following:

1. The patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following:

a. The intent of therapy with the requested agent is to increase platelet counts sufficiently to initiate pegylated interferon therapy AND the patient's platelet count is less than 75 X 10^9/L **OR**

b. The patient is on concurrent therapy with a pegylated interferon and ribavirin AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia **OR**

2. The patient has a diagnosis of severe aplastic anemia AND ALL of the following:

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i. Neutrophils less than 0.5 X 10^9/L

ii. Platelets less than 30 X 10^9/L

iii. Reticulocyte count less than 60 X 10^9/L **AND**

b. The patient has 1 of the following marrow criteria:

i. Severe hypcellularity: less than 25% **OR**

ii. Moderate hypocellularity, 25050% with hematopoietic cells representing less than 30% of residual cells **AND**

c. ONE of the following:

i. BOTH of the following:

(a) The patient will use the requested agent as first-line treatment **AND**

(b) The patient will use the requested agent in combination with standard immunosuppressive therapy (i.e., antithymocyte [ATG] AND cyclosporine) **OR**

ii. ONE of the following:

(a) The patient has tried and had an inadequate response to BOTH antithymocyte globulin [ATG] AND cyclosporine therapy **OR**

(b) The patient has an intolerance or hypersensitivity to BOTH ATG and cyclosporine **OR**

(c) The patient has an FDA labeled contraindication to BOTH ATG and cyclosporine **OR**

3. The patient has a diagnosis of persistent or chronic (defined as lasting for at least 3 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following:

a. ONE of the following:

i. The patient has a platelet count less than or equal to 30 x 10^9/L **OR**

ii. The patient has a platelet count greater than 30 x 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND**

b. ONE of the following:

i. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR**

iii. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR**

iv. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR**

v. The patient has had an inadequate response to a splenectomy **OR**

vi. The patient has tried and had an inadequate response to rituximab **OR**

4. The patient has another FDA approved indication for the requested agent **OR**

5. The patient has another indication supported in compendia for the requested agent **OR**

E. The requested agent is Tavalisse (fostamatinib disodium hexahydrate) AND ONE of the following:

1. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following:

a. ONE of the following:

i. The patient has a platelet count less than or equal to 30 X 10^9/L **OR**

ii. The patient has a platelet count greater than 30 X 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND**

b. ONE of the following:

i. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR**

ii. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR**

iii. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR**

iv. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Doptelet, Nplate, Promacta) **OR**

v. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR**

vi. The patient has had an inadequate response to a splenectomy OR

vii. The patient has tried and had an inadequate response to rituximab **OR**

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3. The patient has another indication supported in compendia for the requested agent **AND**

II. If the patient has an FDA approved indication, ONE of the following:

A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**

III. ONE of the following:

A. The patient will NOT use the requested agent in combination with another agent included in this program **OR**

B. The patient will use the requested agent in combination with another agent included in this program AND BOTH of the following:

1. The requested agent is Nplate **AND**

2. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **AND**

IV. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

V. The requested quantity (dose) does NOT exceed the program quantity limit **OR**

VI. ALL of the following:

A. The requested quantity (dose) is greater than the program quantity limit **AND**

B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**

C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit **OR**

VII. ALL of the following:

A. The requested quantity (dose) is greater than the program quantity limit AND

B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication AND

C. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence NCCN 1 or 2a recommended use

Length of Approval:

Doptelet:
ITP: 6 months
Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure: 1 month
All other indications: 6 months

Mulpleta
Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure: 1 month
All other indications: 6 months

All other indications: 6 months

Promacta
ITP: 2 months
Thrombocytopenia in Hep C: 3 months
First-Line therapy in severe aplastic anemia: 6 months
All other severe aplastic anemia: 4 months
All other indications: 6 months

Tavalisse
All indications: 6 months

Renewal Evaluation

Renewal of Target Agent(s) may be considered **medically necessary** when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process. Note: Doptelet and Mulpleta for thrombocytopenia with chronic liver disease AND Nplate for hematopoietic syndrome of acute radiation syndrome (HS-ARS) should always be reviewed under initial criteria **AND**
2. ONE of the following:
    A. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:
        1. The patient's platelet count is greater than or equal to 50 x 10^9/L **OR**
        2. The patient's platelet count has increased sufficiently to avoid clinically significant bleeding **OR**
    B. The patient has the diagnosis of hepatitis C associated thrombocytopenia AND BOTH of the following:
        1. ONE of the following:
            A. The patient will be initiating hepatitis C therapy with pegylated interferon and ribavirin **OR**
            B. The patient will be maintaining hepatitis C therapy with pegylated interferon and ribavirin **AND**
        2. ONE of the following:
            A. The patient's platelet count is greater than or equal to 90 x 10^9/L **OR**
            B. The patient's platelet count has increased sufficiently to initiate or maintain pegylated interferon based therapy for the treatment of hepatitis C **OR**
    C. The patient has another indication for the requested agent AND has shown clinical improvement (i.e., decreased symptom severity and/or frequency) **AND**
3. The patient will NOT use the requested agent in combination with another agent included in this program **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval:

ITP: 12 months

Thrombocytopenia in hepatitis C: 6 months

All other indications for the requested agent: 12 months

TOPIRAMATE ER

TARGET AGENT(S)

Qudexy XR (topiramate ER)

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PROGRAM PRIOR AUTHORIZATION AND QUANTITY LIMITS

Brand (generic)	GPI	Multisource Code	Quantity Limit (Daily Limit)
Qudexy XR, Topiramate ER			
25 mg capsule	7260007500F310	M, N, O, Y	1 capsule
50 mg capsule	7260007500F320	M, N, O, Y	1 capsule
100 mg capsule	7260007500F330	M, N, O, Y	1 capsule
150 mg capsule	7260007500F340	M, N, O, Y	1 capsule
200 mg capsule	7260007500F350	M, N, O, Y	2 capsules
Trokendi XR (topiramate ER)			
25 mg capsule	72600075007020	M, N, O, Y	1 capsule
50 mg capsule	72600075007030	M, N, O, Y	1 capsule
100 mg capsule	72600075007040	M, N, O, Y	1 capsule
200 mg capsule	72600075007050	M, N, O, Y	2 capsules

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

Initial Evaluation

I. The target agents **may be considered medically necessary** when **ALL** the following are met:

A. **ONE** of the following:

1. The patient's medication history includes an anti-seizure drug which is not topiramate **OR**
2. The patient has **ONE** of the following:
    a. Diagnosis of partial onset seizures **OR**
    b. Diagnosis of primary generalized tonic-clonic seizures **OR**
    c. Diagnosis of Lennox-Gastaut Syndrome **OR**
    d. Diagnosis of Migraine

AND

B. The patient does **NOT** have any FDA labeled contraindications to the requested agent **AND**

C. O**NE** of the following:

1. The requested quantity (dose) does not exceed the program quantity limit **OR**

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quantity (dose) is greater than the program quantity limit **AND**

b. The requested quantity (dose) does not exceed the maximum FDA labeled dose for the requested indication **AND**

c. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity

OR

3. **ALL** of the following:

a. The requested quantity (dose) is greater than the program quantity limit **AND**

b. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND**

c. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

Renewal Evaluation

Target Agents

I. The target agents **may be considered medically necessary** when **ALL** of the following are met:

A. **ONE** of the following:

a. The patient's medication history includes an anti-seizure drug which is not topiramate **OR**

b. ALL of the following:

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approved for the requested agent through Prime Therapeutics Prior Authorization Review process **AND**

ii. The prescriber has indicated that the patient has received benefit from the requested agent

AND

B. The patient does **NOT** have any FDA labeled contraindications to the requested agent **AND**

C. **ONE** of the following:

a. The requested quantity (dose) does not exceed the program quantity limit
OR

b. ALL of the following:

i. The requested quantity (dose) is greater than the program quantity limit
AND

ii. The requested quantity (dose) does not exceed the maximum FDA labeled dose (for the requested

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iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

c. **ALL** of the following:

i. The requested quantity (dose) is greater than the program quantity limit
AND

ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
AND

iii. The prescriber has submitted documentation in

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with a higher dose for the requested indication

Length of Approval: 12 months

TRELEGY ELLIPTA (STEP THERAPY)

TARGET AGENT

Trelegy Ellipta (fluticasone/umeclidinium/vilanterol)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

I. The target agent **may be considered medically necessary** when **ONE** of the following is met:

A. The patient's medication history includes use of at least ONE inhaled single or combination agent containing a long acting antimuscarinic agonist (LAMA) or long acting beta$_2$-adrengergic (LABA) in the past 90 days **OR**

B. Information has been provided that indicates the patient is currently being treated with the requested agent **OR**

C. The prescriber states the patient is currently being treated with the requested agent and is at risk if therapy is changed **OR**

D. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to **ALL** inhaled single or combination agents containing an inhaled long acting antimuscarinic agonist (LAMA) or long acting beta$_2$-adrengergic (LABA)

Length of approval: 12 months

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent	Indication	Dosage and Administration
Trelegy Ellipta (fluticasone/ umeclidinium/ vilanterol) Inhalation powder	Maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)	1 inhalation once daily

URAT1 INHIBITOR PRIOR AUTHORIZATION AND QUANTITY LIMIT

a diagnosis of gout. The program requires that the patient has not already achieved the goal uric acid level of <6.0 mg/dL; or the patient has achieved a uric acid level of <6.0 mg/dL and the prescriber has provided documentation supporting the further lowering of uric acid levels. The program also requires one of the following: the patient is currently taking at least 300 mg of allopurinol or 80 mg of febuxostat; the patient has a documented contraindication or hypersensitivity to allopurinol, and has a documented intolerance or expected intolerance to 80 mg or higher of febuxostat; the patient has a documented contraindication or hypersensitivity to febuxostat, and has a documented intolerance or expected intolerance to 300 mg or higher of allopurinol; or the patient has a documented intolerance or expected intolerance to 300 mg or higher of allopurinol and 80 mg or higher of febuxostat.

For renewal evaluation, the program requires the patient to have been previously approved through Prime Therapeutics' prior authorization program for the requested agent. The program also requires the concurrent use of allopurinol or febuxostat along with Zurampic. The program will not approve patients who have a contraindication to the requested agent. The program will approve for doses within the set limit. Doses above the set limit will be approved if the requested quantity is below the FDA limit and cannot be dose optimized or when the quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis.

Brand (generic)	GPI	Quantity Limit Per Day
Zurampic (lesinurad)		
200 mg tablet	Not Yet Available	1 tablet

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation

URAT1 Inhibitor will be approved when ALL of the following is met:

- The patient's has a diagnosis of gout; **AND**
- ONE of the following:
    - The patient's serum uric acid level is >6.0 mg/dL (either within the past 6 months OR prior to initiating therapy with the requested agent); **OR**
    - The patient's most recent (within the past 6 months) serum uric acid level is ≤6.0 mg/dL and the prescriber has provided documentation supporting the further lowering of the serum uric acid level

      AND
- **ONE** of the following:
    - The patient is currently taking at least 300 mg of allopurinol or at least 80 mg of febuxostat; **OR**
    - **BOTH** of the following:
        - The patient has a documented FDA labeled contraindication, or hypersensitivity to allopurinol; **AND**

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- **BOTH** of the following:
  - The patient has a documented FDA labeled contraindication, or hypersensitivity to febuxostat; **AND**
  - The patient has a documented intolerance or expected intolerance to 300 mg or higher of allopurinol

    OR
  - The patient has a documented intolerance or expected intolerance to 300 mg or higher of allopurinol AND has a documented intolerance or expected intolerance to 80 mg or higher of febuxostat;

AND

- The patient will be taking an xanthine oxidase inhibitor (e.g. allopurinol or febuxostat) concurrently with the requested agent; **AND**
- The patient does not have an FDA labeled contraindication to the requested agent

AND

- **ONE** of the following:
  - The requested quantity (dose) is NOT greater than the program quantity limit; **OR**
  - **ALL** of the following:
  - The requested quantity (dose) is greater than the program quantity limit; **AND**
    - The requested quantity (dose) is less than or equal to the FDA labeled dose; **AND**
    - The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

      OR
  - **ALL** of the following:
    - The requested quantity (dose) is greater than the program quantity limit; **AND**
    - The requested quantity (dose) is greater than the FDA labeled dose; **AND**
    - The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of approval: 12 months

Renewal Evaluation

URAT1 Inhibitor will be approved when **ALL** of the following are met:

- The patient has been previously approved through the Blue Cross Blue Shield of Nebraska prior authorization program for the requested agent; **AND**
- The patient will be taking an xanthine oxidase inhibitor (e.g. allopurinol or febuxostat) concurrently with the requested agent; **AND**

- **ONE** of the following:
  - The requested quantity (dose) is NOT greater than the program quantity limit
    OR
  - **ALL** of the following:
    - The requested quantity (dose) is greater than the program quantity limit; **AND**
      - The requested quantity (dose) is less than or equal to the FDA labeled dose; **AND**
      - The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

    OR
  - **ALL** of the following:
    - The requested quantity (dose) is greater than the program quantity limit; **AND**
    - The requested quantity (dose) is greater than the FDA labeled dose; **AND**
    - The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of approval: 12 months

UREA CYCLE DISORDERS PRIOR AUTHORIZATION

OBJECTIVE

The intent of the Urea Cycle Disorders Prior Authorization (PA) program is to appropriately select patients for treatment according to product labeling and/or clinical studies and/or clinical practice guidelines. The PA criteria consider these agents appropriate for use in patients who have been diagnosed with any of the following urea cycle disorders (UCD): carbamylphosphate synthetase I deficiency [CPSID], ornithine transcarbamylase deficiency [OTCD], argininosuccinic acid synthetase deficiency [ASSD], argininosuccinic acid lyase deficiency [ASLD], or arginase deficiency [ARGD]. The use of these agents in N-acetyl glutamate synthetase deficiency [NAGS] has not been evaluated. The agent may not be used in the acute setting. Patients must also not be able to manage the disease by a protein restricted diet or with essential amino acid supplementation alone. The patient may not have any FDA labeled contraindications to therapy with the requested agent and the dose must be within the FDA labeled dosing.

TARGET DRUGS

Buphenyl* (sodium phenylbutyrate)
Ravicti (glycerol phenylbutyrate)
*_generic available

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation

Buphenyl OR Ravicti will be approved for use when ALL of the following are met:

- **ALL** of the following:

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- The patient has a normal anion gap; **AND**
- The patient has a normal blood glucose level

AND

- The patient has a diagnosis of **ONE** of the following urea cycle disorders:
  - carbamylphosphate synthetase I deficiency [CPSID]
  - ornithine transcarbamylase deficiency [OTCD]
  - argininosuccinic acid synthetase deficiency [ASSD]
  - argininosuccinic acid lyase deficiency [ASLD]
  - arginase deficiency [ARGD]

  AND
- The patient does not have acute hyperammonemia; **AND**
- The patient is unable to maintain a plasma ammonia level within the normal range with the use of a protein restricted diet and essential amino acid supplementation; **AND**
- The patient does not have any FDA labeled contraindications to therapy with the requested agent; **AND**
- The dose is within the FDA-labeled dosing

Length of Approval: 12 months

Renewal Evaluation

Buphenyl or Ravicti will be renewed when the following are met:

- The patient has been previously approved through the Blue Cross Blue Shield of Nebraska Prior Authorization process; **AND**
- The patient is unable to maintain a plasma ammonia level within the normal range with the use of a protein restricted diet and essential amino acid supplementation; **AND**
- The patient does not have any FDA labeled contraindication(s) to therapy with the requested agent; **AND**
- The dose is within the FDA labeled dosing

Length of Approval: 12 months

URINARY INCONTINENCE (STEP THERAPY)

TARGET AGENTS[b]

Detrol (tolterodine)[a]

Detrol LA (tolterodine extended-release)[a]

Ditropan XL (oxybutynin extended-release)[a]

Enablex (darifenacin extended-release)[a]

Gelnique (oxybutynin topical gel)

Toviaz (fesoterodine extended-release)

VESIcare (solifenacin)[a]

a - available as a generic; included as a prerequisite in step therapy program

b – oxybutynin, trospium, and trospium ER are available as generics only and are prerequisites in step therapy program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Brand Urinary Incontinence Agents

I. The brand urinary incontinence agents **may be considered medically necessary** when **ONE** of the following is met:

A. The patient's medication history includes use of a generic urinary incontinence agent in the past 90 days **OR**

B. There is documentation that the patient is currently using the requested agent **OR**

C. The prescriber states the patient is currently using the requested agent and is at risk if therapy is changed **OR**

D. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to **ALL** generic urinary incontinence agents

Length of approval: 12 months

FDA APPROVED INDICATIONS AND DOSAGE:

Agent(s)	Indication	Dosage
Detrol® (tolterodine)[a] tablet	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency	2 mg twice daily; may reduce to 1 mg twice daily based on patient response
Detrol LA® (tolterodine)[a] extended release capsule	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency	4 mg once daily; may reduce to 2 mg once daily based on patient response
Ditropan (oxybutynin)[a,b] tablet, syrup	Relief of symptoms of bladder instability associated with voiding in patients with uninhibited neurogenic or reflex neurogenic bladder (i.e., urgency, frequency, urinary leakage, urge incontinence, dysuria)	**Adults**: 5 mg two to three times daily (maximum 5 mg four times daily) **Pediatric patients (age >5)**: 5 mg twice daily (maximum 5 mg three times daily)

(oxybutynin)[a] extended release tablet	symptoms of urge urinary incontinence, urgency, and frequency Treatment of pediatric patients 6 years and older with symptoms of detrusor overactivity associated with a neurological condition (e.g., spina bifida)	mg increments at weekly intervals to a maximum 30 mg/day **Pediatric**: 5 mg once daily; may titrate in 5 mg increments at weekly intervals to a maximum 20 mg/day
Enablex® (darifenacin)[a] extended release tablet	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency	7.5 mg once daily; may increase to 15 mg once daily
Gelnique® (oxybutynin) topical gel	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency	**10%:** one sachet (100 mg) topically once daily to abdomen, upper arms/shoulders, or thighs. **3%:** 3 pumps (84 mg) topically once daily to abdomen, upper arms/shoulders, or thighs
Oxytrol® [RX], Oxytrol for Women® [OTC] (oxybutynin) transdermal patch	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency	One 3.9 mg/day system topically to abdomen, hip, or buttock twice weekly (every 3-4 days).
Sanctura (trospium)[a,b] tablet	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency	20 mg twice daily
Sanctura XR (trospium)[a,b] extended release capsule	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency	60 mg once daily
Toviaz® (fesoterodine) extended release tablet	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency	4 mg once daily; may increase to 8 mg once daily
Vesicare® (solifenacin)[a] tablet	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency	5 mg once daily; may increase to 10 mg once daily

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(mirabegron) extended release tablet	combination with solifenacin for overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency	mg once daily if needed

XANTHINE OXIDASE INHIBITORS QUANTITY LIMIT (STEP THERAPY)

TARGET AGENT

Uloric (febuxostat)[a]

a – generic available, not a target or prerequisite

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

I. The target agent may be considered medically necessary when **ONE** of the following is met:

A. The patient's medication history includes use of allopurinol 300 mg within the past 90 days **OR**

B. Information has been provided that indicates the patient is currently being treated with the requested agent **OR**

C. The prescriber states the patient is currently being treated with the requested agent and is at risk if therapy is changed **OR**

D. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to allopurinol 300 mg

Length of approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit document.

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent	Indication	Dosage
Uloric (febuxostat)[a] tablets	Chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable Limitations of Use: Not recommended for the treatment of asymptomatic hyperuricemia	Starting dose is 40 mg once daily For patients who do not achieve serum uric acid (sUA) < 6 mg/dL after two weeks of treatment, 80 mg is recommended once daily

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REVISIONS

01-02-2025
Added new code for 01/01/2025: J2802

01-29-2024
Added Myfembree to the Orilissa section of the policy

01-04-2024
Updated criteria for Thrombopoietin receptor agonists

12-01-2023
Policy reviewed at Medical Policy Committee meeting on 11/8/2023 – no changes to policy.

11-17-2022
Addition of Retacrit

04-26-2022
Added Effective 05/01/2022: Onjesta, Cablivi, Colony Stimulating Factors, Elmiron, Lyrica, Myalept, Oxervate, Ophthalmic Prostaglandins Opioids IR, Orilissa, Plerixafor, Progesterones, Pseudobulbar Affect, Regranex, Rho Kinase Inhibitor, Sensipar, Signifor (pasireotide), Substrate Reduction Therapy, Sucralfate Suspension, Topiramate ER, Trelegy Ellipta, Urinary Incontinence, Xanthine, Oxidase Inhibitors

12-31-2019
Adding new codes for 01/01/2020: J1943 J1944

06-14-2017
Added Carbaglu and Zavesca to policy