# Prior Authorization Criteria

This is NOT an all-inclusive list of medications that require prior authorization. If you are looking for a medication that requires prior authorization that is not on this list, please see:

- The Preferred Drug List (PDL) and navigate to the most current year and version
- The preferred dosage forms list at the end of this document
- Other documents explaining limitations that may cause a prior authorization denial:
  - Preferred Diabetic Supply List (PDSL)
  - o Coverage Rules on Medications
- Drug Utilization Management List

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## **ARBs (Angiotensin Receptor Blockers)**

**General Prior Authorization Form** 

**ENTRESTO:** Please see "Heart Failure-Neprilysin Inhibitor/Angiotensin Receptor Blocker" category on PDL. <a href="http://www.hidesigns.com/ndmedicaid/pdl/">http://www.hidesigns.com/ndmedicaid/pdl/</a>

#### Criteria for non-preferred agents:

- The patient must have had a 30-day trial, at the highest tolerable therapeutic dose, of 3 preferred agents, as evidenced by paid claims or pharmacy print-outs.
- Combination agents: Clinical justification must be provided explaining why the patient is unable to use a preferred combination product or the individual agents separately (subject to clinical review).

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Amlodipine-olmesartan	Amlodipine-Valsartan-Hydrochlorothiazide
Amlodipine-valsartan	ATACAND (Candesartan)
Candesartan 4mg, 32mg	ATACAND HCT (Candesartan-Hydrochlorothiazide)
EDARBI (azilsartan)	AVALIDE (Irbesartan-Hydrochlorothiazide)
EDARBYCLOR (azilsartan/chlorothalidone)	AVAPRO (irbesartan)
Irbesartan	AZOR (Amlodipine/Olmesartan)
Irbesartan-hydrochlorothiazide	Candesartan 8mg, 16mg
Losartan	Candesartan-hydrochlorothiazide
Losartan-hydrochlorothiazide	COZAAR (Losartan)
Olmesartan	DIOVAN HCT (Valsartan-Hydrochlorothiazide)
Olmesartan-hydrochlorothiazide	Eprosartan
Telmisartan	EXFORGE (Amlodipine-Valsartan)
Valsartan	EXFORGE HCT (Amlodipine-Valsartan-Hydrochlorothiazide)
Valsartan-hydrochlorothiazide	HYZAAR (Losartan-Hydrochlorothiazide)
	Telmisartan-Amlodipine
	Telmisartan-Hydrochlorothiazide
	TRIBENZOR (Olmesartan-Amlodipine-Hydrochlorothiazide)

## **Renin Inhibitors**

**General Prior Authorization Form** 

#### **Criteria for non-preferred agents:**

• The patient must have had 30-day trials, at the highest tolerable therapeutic dose, of 2 different ACE-inhibitors and 2 different ARBs, as evidenced by paid claims or pharmacy print-outs.

PREFERRED AGENTS	NON-PREFERRED AGENTS
Aliskirin – Labeler 66993	Aliskirin – Labeler 49884
TEKTURNA (aliskiren)	TEKTURNA HCT (aliskiren-hydrochlorothiazide)

#### Acne

**General Prior Authorization Form** 

#### **Criteria for ALL agents:**

The patient must be between 12 and 35 years of age

#### Additional criteria for non-preferred agents:

 Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review)

CLINDAMYCIN-BENZOYL PEROXIDE	
PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)

Clindamycin-benzyl peroxide 1.2%-5%	ACANYA (Clindamycin-benzoyl peroxide) 1.2%-2.5%
	BENZACLIN (Clindamycin/benzoyl peroxide without
Clindamycin/benzoyl peroxide 1%-5% without pump	pump) 1%-5%
ONEXTON (Clindamycin/benzoyl peroxide) 1.2%-3.75%	BENZACLIN (Clindamycin/benzoyl peroxide with pump) 1%-5%
, , , , , , , , , , , , , , , , , , , ,	Clindamycin/benzoyl peroxide 1%-5% with pump
	Clindamycin-benzoyl peroxide 1.2%-2.5%
	DUAC (clindamycin/benzoyl peroxide) 1.2%-5%
	NEUAC (Clindamycin/benzoyl peroxide) 1.2%-5%
TRETINOIN MICROSPHERES	
PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
	RETIN-A MICRO (Tretinoin Microsphere) GEL WIHOUT
RETIN-A MICRO PUMP (Tretinoin Microsphere) 0.06%	PUMP
RETIN-A MICRO PUMP (Tretinoin Microsphere) 0.08%	RETIN-A MICRO PUMP (Tretinoin Microsphere) 0.04%
	RETIN-A MICRO PUMP (Tretinoin Microsphere) 0.10%
	tretinoin microsphere without pump
	tretinoin microsphere with pump
TRETINOIN	
PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ALTRENO (tretinoin) LOTION	ATRALIN (Tretinoin) 0.05% GEL
AVITA (tretinoin) CREAM (brand preferred)	Clindamycin-tretinoin 1.2%-0.025%
RETIN-A (tretinoin) CREAM (brand preferred)	Tretinoin cream
RETIN-A (tretinoin) 0.01%, 0.025% GEL (brand preferred)	Tretinoin gel
ZIANA (Clindamycin-tretinoin 1.2%-0.025%) (brand	
preferred)	
ADAPALENE	
PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
DIFFERIN (adapalene) CREAM (brand preferred)	Adapalene 0.1% cream
Adapalene gel	Adapalene 0.3% gel with pump
DIFFERIN (adapalene) GEL W/ PUMP (brand preferred)	Adapalene/Benzoyl Peroxide 0.1%-2.5%
DIFFERIN (adapalene) LOTION	
EPIDUO (adapalene/benzoyl peroxide) 0.1%-2.5% (brand	
preferred)	
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EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER	NON-PREFFERED AGENTS (PA REQUIRED)
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED) ACZONE (Dapsone) GEL WITHOUT PUMP 5%
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5%	
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid)	ACZONE (Dapsone) GEL WITHOUT PUMP 5%
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule	ACZONE (Dapsone) GEL WITHOUT PUMP 5% CLEOCIN T (Clindamycin) GEL
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule Clindamycin gel	ACZONE (Dapsone) GEL WITHOUT PUMP 5% CLEOCIN T (Clindamycin) GEL CLEOCIN T (Clindamycin) LOTION
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule Clindamycin gel Clindamycin lotion	ACZONE (Dapsone) GEL WITHOUT PUMP 5%  CLEOCIN T (Clindamycin) GEL  CLEOCIN T (Clindamycin) LOTION  CLEOCIN T (Clindamycin) MED SWAB
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule Clindamycin gel Clindamycin lotion Clindamycin solution	ACZONE (Dapsone) GEL WITHOUT PUMP 5% CLEOCIN T (Clindamycin) GEL CLEOCIN T (Clindamycin) LOTION CLEOCIN T (Clindamycin) MED SWAB CLINDACIN P (Clindamycin) MED SWAB
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule Clindamycin gel Clindamycin lotion Clindamycin solution Clindamycin med. swab	ACZONE (Dapsone) GEL WITHOUT PUMP 5%  CLEOCIN T (Clindamycin) GEL  CLEOCIN T (Clindamycin) LOTION  CLEOCIN T (Clindamycin) MED SWAB  CLINDACIN P (Clindamycin) MED SWAB  CLINDACIN ETZ (Clindamycin) MED SWAB
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule Clindamycin gel Clindamycin lotion Clindamycin solution Clindamycin med. swab	ACZONE (Dapsone) GEL WITHOUT PUMP 5%  CLEOCIN T (Clindamycin) GEL  CLEOCIN T (Clindamycin) LOTION  CLEOCIN T (Clindamycin) MED SWAB  CLINDACIN P (Clindamycin) MED SWAB  CLINDACIN ETZ (Clindamycin) MED SWAB  CLINDAGEL (Clindamycin) GEL DAILY
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule Clindamycin gel Clindamycin lotion Clindamycin solution Clindamycin med. swab	ACZONE (Dapsone) GEL WITHOUT PUMP 5%  CLEOCIN T (Clindamycin) GEL  CLEOCIN T (Clindamycin) LOTION  CLEOCIN T (Clindamycin) MED SWAB  CLINDACIN P (Clindamycin) MED SWAB  CLINDACIN ETZ (Clindamycin) MED SWAB  CLINDAGEL (Clindamycin) GEL DAILY  Clindamycin Gel Daily
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule Clindamycin gel Clindamycin lotion Clindamycin solution Clindamycin med. swab	ACZONE (Dapsone) GEL WITHOUT PUMP 5%  CLEOCIN T (Clindamycin) GEL  CLEOCIN T (Clindamycin) LOTION  CLEOCIN T (Clindamycin) MED SWAB  CLINDACIN P (Clindamycin) MED SWAB  CLINDACIN ETZ (Clindamycin) MED SWAB  CLINDAGEL (Clindamycin) GEL DAILY  Clindamycin Gel Daily  Clindamycin foam  Dapsone gel without pump 5%
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule Clindamycin gel Clindamycin lotion Clindamycin solution Clindamycin med. swab	ACZONE (Dapsone) GEL WITHOUT PUMP 5%  CLEOCIN T (Clindamycin) GEL  CLEOCIN T (Clindamycin) LOTION  CLEOCIN T (Clindamycin) MED SWAB  CLINDACIN P (Clindamycin) MED SWAB  CLINDACIN ETZ (Clindamycin) MED SWAB  CLINDAGEL (Clindamycin) GEL DAILY  Clindamycin Gel Daily  Clindamycin foam
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule Clindamycin gel Clindamycin lotion Clindamycin solution Clindamycin med. swab	ACZONE (Dapsone) GEL WITHOUT PUMP 5%  CLEOCIN T (Clindamycin) GEL  CLEOCIN T (Clindamycin) LOTION  CLEOCIN T (Clindamycin) MED SWAB  CLINDACIN P (Clindamycin) MED SWAB  CLINDACIN ETZ (Clindamycin) MED SWAB  CLINDAGEL (Clindamycin) GEL DAILY  Clindamycin Gel Daily  Clindamycin foam  Dapsone gel without pump 5%  EVOCLIN (Clindamycin) FOAM
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule Clindamycin gel Clindamycin lotion Clindamycin solution Clindamycin med. swab Sulfacetamide suspension	ACZONE (Dapsone) GEL WITHOUT PUMP 5%  CLEOCIN T (Clindamycin) GEL  CLEOCIN T (Clindamycin) LOTION  CLEOCIN T (Clindamycin) MED SWAB  CLINDACIN P (Clindamycin) MED SWAB  CLINDACIN ETZ (Clindamycin) MED SWAB  CLINDAGEL (Clindamycin) GEL DAILY  Clindamycin Gel Daily  Clindamycin foam  Dapsone gel without pump 5%  EVOCLIN (Clindamycin) FOAM  FABIOR (Tazarotene) FOAM
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% OTHER PREFFERED AGENTS (NO PA REQUIRED) ACZONE (Dapsone) GEL WITH PUMP 7.5% AZELEX (Azelaic Acid) Clindamycin capsule Clindamycin gel Clindamycin lotion Clindamycin solution Clindamycin med. swab Sulfacetamide suspension	ACZONE (Dapsone) GEL WITHOUT PUMP 5%  CLEOCIN T (Clindamycin) GEL  CLEOCIN T (Clindamycin) LOTION  CLEOCIN T (Clindamycin) MED SWAB  CLINDACIN P (Clindamycin) MED SWAB  CLINDACIN ETZ (Clindamycin) MED SWAB  CLINDAGEL (Clindamycin) GEL DAILY  Clindamycin Gel Daily  Clindamycin foam  Dapsone gel without pump 5%  EVOCLIN (Clindamycin) FOAM

Doxycycline monohydrate 25 mg/5mL suspension	DORYX MPC (Doxycycline hyclate) TABLET DR
Doxycycline monohydrate tablet 50 mg, 100mg	Doxycycline monohydrate capsule 75mg, 150mg
Doxycycline monohydrate capsule 50 mg, 100mg	Doxycycline hyclate tablet 75mg, 150 mg
Minocycline capsule	Doxycycline monohydrate tablet 75mg, 150 mg
Minocycline tablet	Doxycycline hyclate tablet DR
VIBRAMYCIN (Doxycycline calcium) 50 mg/5mL SYRUP	MINOCIN (Minocycline) CAPSULE
	Minocycline Tablet ER
	MINOLIRA ER (Minocycline) TABLET
	MORGIDOX (Doxycycline hyclate) CAPSULE
	SOLODYN ER (Minocycline) TABLET
	Tetracycline
	VIBRAMYCIN (Doxycycline) 25mg/5mL SUSPENSION
	XIMINO (Minocycline) CAPSULE ER

## **Actinic Keratosis**

**General Prior Authorization Form** 

#### **Criteria for non-preferred agents:**

- The patient must have a diagnosis of an FDA-approved indication for use.
- The patient must have had a 6-month trial of imiguimod, as evidenced by paid claims or pharmacy print-outs.

PREFERRED AGENTS	NON-PREFERRED AGENTS
Diclofenac 3% sodium gel	Imiquimod 3.75% cream pump
Imiquimod 5% cream packet	PICATO (ingenol mebutate)
	SOLARAZE (Diclofenac 3%) GEL
	ZYCLARA (imiquimod) 3.75% CREAM PUMP
	ZYCLARA (imiquimod) 3.75% CREAM PACKET
	ZYCLARA (imiquimod) 2.5% CREAM PUMP

## **Albuterol/Levalbuterol Rescue Inhalers**

<u>General Prior Authorization Form</u> MedWatch Form

#### Criteria for Albuterol HFA, ProAir Respiclick:

• The patient must currently be receiving an inhaled corticosteroid product, as evidenced by paid claims or pharmacy print-outs (see Coverage Rules for Medications).

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Albuterol HFA – Labeler 66993***	Albuterol HFA – Labeler 00933 and 00254
PROAIR (albuterol) HFA – Brand Preferred	PROVENTIL (albuterol) HFA
PROAIR RESPICLICK (albuterol)***	VENTOLIN (albuterol) HFA***
XOPENEX (levalbuterol) HFA - Brand Preferred	

## **Antibiotics - Resistance Prevention**

#### **Criteria for non-preferred agents:**

- **Initial Criteria:** Approval Duration = 5 days
  - o Patient must have an FDA-approved indication for use (meets label recommendations for diagnosis & age)
    - Diagnosis must be proven to be caused by a susceptible microorganism by culture and susceptibility testing
  - Medication must be prescribed by an infection disease specialist, an antibiotic stewardship program, or protocol.

- One of the following criteria must be met (A or B)
  - A. Prescriber must provide evidence-based medical justification for use, explaining why a preferred antibiotic is not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)
  - B. The patient is continuing treatment upon discharge from an acute care facility
- Renewal Criteria: Approval Duration = 5 days
  - o Prescriber must attest that the patient's condition is improving and that it is medically necessary to continue treatment course after re-evaluation of the patient's condition.
  - The total requested duration of use must not be greater than manufacturer labeling or treatment guideline recommendations (whichever is greater).

### Methicillin-Resistant *Staphylococcus aureus* (MRSA):

PREFERRED AGENTS	NON-PREFERRED AGENTS
Clindamycin	BAXDELA (Delafloxacin)
Doxycycline	NUZYRA (Omadacycline)
Linezolid	SIVEXTRO (Tedizolid)
Minocycline	
Trimethoprim-Sulfamethoxazole	

## **Anticoagulants - Injectable**

**General Prior Authorization Form** 

#### **Criteria for non-preferred agents:**

- The patient must have a diagnosis of an FDA-approved indication for use.
- One of the following must be met (A or B)
  - A. The patient must have had a 30-day trial of enoxaparin, as evidenced by paid claims or pharmacy print-outs.
  - B. The request must be for fondaparinux and the patient must have a diagnostic history of heparin-induced thrombocytopenia (HIT)

PREFERRED AGENTS	NON-PREFERRED AGENTS
enoxaparin	fondaparinux
	FRAGMIN (dalteparin)

## **Antifungals - Topical**

**General Prior Authorization Form** 

<u>Criteria for non-preferred agents:</u> Approval Duration = 12 months (unless for onychomycosis)

- The patient must have a diagnosis of an FDA approved indication for use
  - o Diagnosis must be confirmed by potassium hydroxide (KOH) preparation
- The patient must have had a trial of 3 preferred agents, including at least one oral agent (terbinafine, fluconazole, or itraconazole), for the length of recommended treatment time for patient's particular infection, as evidenced by paid claims or pharmacy print-outs
- One of the following must be met (A or B):
  - A. Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review)
  - B. The active ingredient of the requested product is not available in a preferred formulation

Additional criteria for treatment of onychomycosis: Approval Duration = 1 month

• Adequate time must have passed since treatment cessation to accurately assess healthy toenail outgrow (at least 6 months)

PREFERRED AGENTS	NON-PREFERRED AGENTS
Ciclopirox cream	CICLODAN (Ciclopirox) CREAM
Ciclopirox gel	CICLODAN (Ciclopirox) SOLUTION
Ciclopirox shampoo	EXTINA (Ketoconazole) FOAM
Ciclopirox solution	JUBLIA (efinaconazole) SOLUTION
Clotrimazole cream	KERYDIN (tavaborole) SOLUTION
Clotrimazole solution	Ketoconazole foam
Econazole cream	LOPROX (Ciclopirox) CREAM
ERTACZO (sertraconazole) CREAM	LOPROX (Ciclopirox) SHAMPOO
EXELDERM CREAM (sulconazole)	LOPROX (Ciclopirox/Skin Cleanser) KIT
EXELDERM SOLUTION (sulconazole)	LOPROX (Ciclopirox) SUSPENSION
Ketoconazole cream	LUZU (Luliconazole) Cream
Ketoconazole shampoo	Naftifine cream
Luliconazole cream	NAFTIN (Naftifine) CREAM
MENTAX (butenafine) CREAM	NAFTIN (Naftifine) GEL
Miconazole	NIZORAL (Ketoconazole) SHAMPOO
Miconazole/zinc oxide/white petrolatum ointment	NYAMYC (Nystatin) POWDER
Nystatin cream	NYSTOP (Nystatin) POWDER
Nystatin ointment	Oxiconazole cream
Nystatin powder	OXYSTAT (Oxiconazole) CREAM
Nystatin – triamcinolone cream	OXISTAT (oxiconazole) LOTION
Nystatin – triamcinolone ointment	PENLAC (Ciclopirox) SOLUTION
	VUSION (Miconazole/Zinc/White Petrolatum) OINTMENT

## **Antihemophilic Factor Products**

Prior Authorization Form - Antihemophilic Factors

#### **Criteria for ALL agents:**

- The provider must attest that the patient visits an accredited Hemophilia Treatment Center once per year
- The date of the patient's last appointment with treatment center must be provided
- Contact information for treatment center must be provided

#### Additional criteria for non-preferred agents:

- Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review).
- The patient may qualify for non-preferred product if they are stable on current therapy (have had a paid claim for requested therapy in the past 45 days)

FACTOR VIIa	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
NOVOSEVEN RT (Coagulation Factor VIIa recombinant)	
FACTOR VIII – HEMOPHILIA A	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ADVATE (factor VIII recombinant)	ADYNOVATE (factor VIII recombinant, PEGylated)
HEMOFIL M (factor VIII plasma derived; mAb-purified)	AFSTYLA (factor VIII recombinant, single chain)
HELIXATE FS (factor VIII recombinant)	ELOCTATE (factor VIII recombinant, Fc fusion protein)
KOATE (factor VIII plasma derived, chromatography purified)	JIVI (factor VIII recombinant, pegylated-aucl)
KOGENATE FS (factor VIII recombinant)	KOVALTRY (factor VIII recombinant)

NOVOEIGHT (factor VIII recombinant)	OBIZUR (recombinant, B domain-deleted porcine factor VIII)
NUWIQ (factor VIII recombinant)	
RECOMBINATE (factor VIII recombinant)	
XYNTHA (factor VIII recombinant)	
XYNTHA SOLOFUSE (factor VIII recombinant)	
FACTOR VIII – HEMOPHILIA A/vWF	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
HUMATE-P (Factor VIII/von Willebrand Factor (human))	VONVENDI (Recombinant human vWF)
WILATE (Factor VIII/von Willebrand Factor (human))	
FACTOR IX – HEMOPHILIA B	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ALPHANINE SD (factor IX, plasma-derived)	ALPROLIX (factor IX recombinant, Fc fusion)
BENEFIX (factor IX recombinant)	IDELVION (factor IX recombinant, albumin fusion)
IXINITY (factor IX recombinant)	REBINYN (factor IX recombinant, glycol-PEGylated)
MONONINE (factor IX, plasma-derived mAb purified)	
PROFILNINE (factor IX complex)	
RIXUBIS (factor IX recombinant)	
FACTOR IXa/IX	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
HEMLIBRA (emicizumab-kxwh)	
ANTI-INHIBITOR COAGULANT COMPLEX	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
FEIBA NF (Anti-Inhibitor Coagulant Complex)	

## **Antihyperuricemics**

**General Prior Authorization Form** 

#### **Criteria for colchicine tablets:**

 Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review)

#### **Criteria for Uloric**

• The patient must have had a 30-day trial of allopurinol, as evidenced by paid claims or pharmacy printouts

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PREFERRED AGENTS	NON-PREFERRED AGENTS
allopurinol tablet	Colchicine tablets
colchicine capsule	ULORIC (febuxostat) TABLET
probenecid-colchicine	
probenecid	

## **Antimalarial Agents**

**General Prior Authorization Form** 

#### **Criteria for ALL agents:**

• The request must be for TREATMENT of malaria (NOT covered for prophylaxis)

#### Additional criteria for non-preferred agents:

- The patient must have had a trial of a generic quinine in the last 30 days, as evidenced by paid claims or pharmacy print outs
- The patient must be less than 18 years old to qualify for atovaquone/proguanil 62.5-25 MG

PREFERRED AGENTS	NON-PREFERRED AGENTS

daraprim	atovaquone/proguanil
hydroxychloroquine	chloroquine
quinine	COARTEM (artemether/lumefantrine)
	KRINTAFEL (tafenoquine)
	MALARONE (atovaquone/proguanil)
	mefloquine
	primaguine

## **Antipsoriatics - Topical**

**General Prior Authorization Form** 

#### **Criteria for non-preferred agents:**

#### • For Foams and Sprays:

 Patient must have failed 30-day trials of the preferred solution and shampoo formulations, as evidenced by paid claims or pharmacy print outs

#### • For Lotions:

 Patient must have failed a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy print outs

#### For Ointments:

 Patient must have failed 30-day trials of the preferred ointment formulations, as evidenced by paid claims or pharmacy print outs

PREFERRED AGENTS	NON-PREFERRED AGENTS
calcipotriene ointment	calcipotriene/betamethasone ointment
calcipotriene solution	Calcitriol ointment
calcipotriene cream	DOVONEX (Calcipotriene) CREAM
SORILUX (calcipotriene) FOAM	DUOBRII (halobetasol/tazarotene) LOTION
TACLONEX (calcipotriene/betamethasone) SUSPENSION	ENSTILAR (calcipotriene/betamethasone) FOAM
TAZORAC (Tazarotene) CREAM 0.05%	TACLONEX (calcipotriene/betamethasone) OINTMENT
TAZORAC (Tazarotene) GEL	Tazarotene cream
VECTICAL (Calcitriol) OINTMENT	TAZORAC (Tazarotene) CREAM 0.1%

## **Benign Prostatic Hyperplasia**

**General Prior Authorization Form** 

#### **Criteria for non-preferred agents:**

- The patient must have diagnosis of benign prostatic hyperplasia (BPH)
- The patient must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS	NON-PREFERRED AGENTS
alfuzosin ER	sildenafil
CARDURA XL (doxazosin)	
doxazosin	
dutasteride	
finasteride	
prazosin	
RAPAFLO (silodosin) – brand required	
tamsulosin	
terazosin	

## **Biosimilar Agents**

**General Prior Authorization Form** 

#### **Criteria for ALL agents:**

- The patient must have a diagnosis of an FDA-approved indication for use.
- Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review)

## **Dispense as Written (DAW1)**

<u>Prior Authorization Form - Dispense As Written (DAW1)</u> MedWatch Form

#### <u>Criteria for ALL DAW requests</u> (must meet one of the following (A or B):

- A. Primary insurance requires a ND Medicaid non-preferred branded product
- B. All of the following are met (1-3):
  - 1. The requested brand-name product must not have an authorized generic available
  - 2. The patient must have failed a 30-day trial of each pharmaceutically equivalent generic product from each available manufacturer, as evidenced by paid claims or pharmacy print outs
    - a. A failure is defined as product was not effective at maximum tolerated dose or caused adverse reaction where the branded product is expected to have a different result and other alternatives (e.g. medications in same class) are not an option for the patient
    - b. The patient or prescriber preference is NOT criteria considered for approval
  - 3. A MedWatch form for each trial of each product from the available manufacturer(s) must be filled out and attached to request

## **Dificid**

**General Prior Authorization Form** 

#### **Criteria for non-preferred agents**: Approval Duration = 5 days

- The patient must have diagnosis of Clostridium difficile-associated diarrhea (CDAD)
- The patient must be 18 years of age or older
- The patient must have failed a 10-day trial with Firvang, as evidenced by paid claims or pharmacy print-outs

#### <u>Additional Renewal Criteria for Dificid</u>: Approval Duration = 5 days

Request must be for treatment of the first recurrence for a patient whose initial episode was treated with Dificid

PREFERRED AGENTS	NON-PREFERRED AGENTS
FIRVANQ (vancomycin)	DIFICID (fidaxomicin)
	VANCOCIN (vancomycin)

## Dihydroergotamine

**General Prior Authorization Form** 

#### Criteria for non-preferred agents:

- Non-preferred step 1 agents:
  - o The patient must have a diagnosis of migraine or cluster headache
  - Within the past 2 years, the patient must have had 30-day trials of at least two 'Preferred Agents', as evidenced by paid claims or pharmacy print-outs
- Non-preferred step 2 agents:

- o The patient must meet criteria for Step 1 agents
- Within the past 2 years, the patient must have had 30-day trials of at least two 'Non-Preferred Step 1
  Agents', as evidenced by paid claims or pharmacy print-outs

PREFERRED AGENTS	NON-PREFERRED STEP 1 AGENTS	NON-PREFERRED STEP 2 AGENTS
RELPAX (eletriptan)	ONZETRA XSAIL (sumatriptan) NASAL SPRAY	CAFERGOT (ergotamine/caffeine) TABLET
rizatriptan	ZOMIG (zolmitriptan) NASAL SPRAY	D.H.E.45 (dihydroergotamine) INJECTION
Rizatriptan ODT	zolmitriptan ODT	dihydroergotamine injection
sumatriptan		ERGOMAR (ergotamine) SL TABLET
		MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY
		MIGRANAL (dihydroergotamine) SPRAY

### **Edecrin**

**General Prior Authorization Form** 

#### Criteria:

- One of the following must be met (A or B)
  - A. The patient must have a documented sulfa allergy
  - B. The patient must have failed a 30-day trial of all preferred agents, as evidenced by paid claims or pharmacy print outs

PREFERRED AGENTS	NON-PREFERRED AGENTS
furosemide	ethacrynic acid
bumetanide	
torsemide	

## **Emflaza**

Prior Authorization Form - Emflaza

#### **Initial Criteria:** Approval Duration = 6 months

- The patient must be 5 years of age or older
- The patient must have diagnosis of Duchenne muscular dystrophy (DMD) confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- Onset of weakness must have occurred before 5 years of age
- The medication must be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- The patient must have serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) prior to initiating treatment
- The patient must have failed a 6-month trial of prednisone due to inadequate treatment response, intolerance, or contraindication, as evidenced by paid claims or pharmacy print-outs
- The provider must submit baseline motor milestone score results from at least ONE the following assessments:
  - i. 6-minute walk test (6MWT)
  - ii. North Star Ambulatory Assessment (NSAA)
  - iii. Motor Function Measure (MFM)
  - iv. Hammersmith Functional Motor Scale (HFMS)
- The patient must have ONE of the following significant intolerable adverse effects supported by documentation:
  - i. Cushingoid appearance
  - ii. Central (truncal) obesity
  - iii. Undesirable weight gain (>10% of body weight gain increase over 6-month period)

- iv. Diabetes and/or hypertension that is difficult to manage
- v. Severe behavioral adverse effect

#### Renewal Criteria: Approval Duration = 12 months

- The patient must have ONE of the following (A or B)
  - A. Improvement in motor milestone score from baseline from ONE the following assessments:
    - i. 6MWT improvement of 20 meters from baseline
    - ii. NSAA improvement of 2 points from baseline
    - iii. MFM improvement of 2 points from baseline
    - iv. HFMS improvement of 2 points from baseline
  - B. The patient must have had improvement of adverse effects experienced on prednisone supported by documentation:
    - i. Cushingoid appearance
    - ii. Central (truncal) obesity
    - iii. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    - iv. Diabetes and/or hypertension that is difficult to manage
    - v. Severe behavioral adverse effect

## **Eosinophilic Asthma**

#### **Prior Authorization Form - Dupixent**

#### Initial Criteria: Approval Duration = 3 months

- The patient must have a diagnosis of an FDA-approved indication for use
- The patient must be 12 years of age or older
- The patient must have had 2 or more asthma exacerbations in previous year despite continued compliant use of a moderate to high dose inhaled steroid in combination with a long-acting beta agonist (LABA) or long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy print-outs
- One of the following must be met (A or B):
  - A. The patient must have baseline eosinophil level of ≥ 300 cells/mcL within past 12 months
  - B. The patient must have oral corticosteroid dependent asthma and has required at least 30 days of oral steroid use in past 120 days, as evidenced by paid claims or pharmacy print-outs

#### **Renewal Criteria:** Approval Duration = 3 months

• The prescriber must be provide documentation showing that the patient has achieved a significant reduction in asthma exacerbations and utilization of rescue medications since treatment initiation

PREFERRED AGENTS	NON-PREFERRED AGENTS
DUPIXENT (Dupilumab)	
NUCALA (Mepolizumab)	

## **Estrogens**

#### **Criteria for non-preferred agents:**

 The patient must have failed 30-day trials of at least two preferred products, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS	NON-PREFERRED AGENTS
CLIMARA PRO (estradiol-levonorgestrel) PATCH	Estradiol patch
COMBIPATCH (Estradiol- Norethindrone)	Estradiol vaginal cream
DIVIGEL (estradiol) GEL	Estradiol vaginal tablet
ELESTRIN (estradiol) GEL	FEMRING (estradiol)
Estradiol- Norethindrone tablet	MENEST (estrogens, esterified) TABLET
Estradiol tablet	MINOSTAR (estradiol) PATCH

ESTRING (estradiol)	PREFEST (estradiol-norgestimate) TABLET
EVAMIST (estradiol) SPRAY	
Norethindrone-Ethinyl Estradiol tablet	
PREMARIN (estrogens, conjugated) TABLET	
PREMARIN (estrogens, conjugated) VAGINAL CREAM	
PREMPHASE (estrogen, conj.,m-progest) TABLET	
PREMPRO (estrogen, conj.,m-progest) TABLET	
VAGIFEM (estradiol) VAGINAL TABLET	
YUVAFEM (estradiol) VAGINAL TABLET	

## **Glyburide**

**General Prior Authorization Form** 

#### **Criteria for coverage:**

- The patient must have failed a 30-day trial of glipizide, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the patient is unable to use the preferred agents and other classes of medication (subject to clinical review).

PREFERRED AGENTS	NON-PREFERRED AGENTS
Glipizide	Glimepiride
Glipizide/Metformin	Glyburide
Glipizide ER	Glyburide/Metformin

## Hemangeol

Prior Authorization Form - Hemangeol

#### **Criteria for coverage:**

- The patient must have a diagnosis of proliferating infantile hemangioma requiring systemic therapy
- The patient must be between 5 weeks and 1 year of age
- The patient must weigh at least 2 kg
- The provider must attest that the patient does not have any of the following contraindications to treatment:
  - o Asthma or history of bronchospasm
  - Bradycardia (<80 beats per minute)</li>
  - o Greater than first-degree heart block
  - o Decompensated heart failure
  - Blood pressure <50/30 mmHg</li>
  - o Pheochromocytoma

## **Hereditary Angioedema**

Prior Authorization - Hereditary Angioedema

#### **Criteria for ALL agents:**

• The patient must have diagnosis of hereditary angioedema, confirmed by a specialist.

## Hyperkalemia

#### **Criteria for non-preferred agents:**

• Initial criteria: Approval Duration = 3 months

- The patient must be 18 years of age or older.
- o Medication must be prescribed by, or in consultation with, a nephrologist
- The patient's current serum potassium level must be exceeding the upper limit of normal, as evidenced by documentation from at least two separate lab values, submitted with the request
- The patient must not have gastrointestinal motility disorders (e.g. severe constipation, bowel obstruction or impaction, abnormal postoperative bowel motility disorders)
- o One of the following criteria must be met:
  - The patient must have failed a 30-day trial with at least one preferred product
  - The provider must submitted evidenced-based, medical justification explaining why the patient is unable to use all available preferred agents.
- The patient must not be receiving the medications known to cause hyperkalemia listed below, OR medical
  justification must be provided explaining why discontinuation of these agents would be clinically
  inappropriate in this patient:
  - angiotensin-converting enzyme inhibitor
  - angiotensin II receptor blocker
  - aldosterone antagonist
  - nonsteroidal anti-inflammatory drugs (NSAIDs)
- Renewal Criteria: Approval Duration = 6 months
  - The patient's current serum potassium level is within normal limits or has been significantly reduced from baseline, as evidenced by lab documentation submitted with the request

•	·
PREFERRED AGENTS	NON-PREFERRED AGENTS
Bumetanide	LOKELMA (Sodium Zirconium Cyclosilicate)
Chlorothiazide	VELTASSA (Patiromer)
Fludrocortisone	
Furosemide	
Hydrochlorothiazide	
Indapamide	
Metolazone	
Torsemide	

## **Idiopathic Pulmonary Fibrosis**

Prior Authorization Form - Idiopathic Pulmonary Fibrosis

#### **Criteria for ALL agents:**

- The patient must be 18 years of age or older
- The patient must have documented diagnosis of idiopathic pulmonary fibrosis
- The patient must have a specialist involved in therapy
- The patient must have forced vital capacity (FVC) ≥ 50% of predicted within prior 60 days

## **Immune Globulins**

Prior Authorization Form - Immune Globulins

#### **Criteria for ALL NON-preferred agents:**

- If the patient's BMI > 30, adjusted body weight must be provided along with the calculated dose
- The patient must have a diagnosis of an FDA-approved indication for use
- The patient may qualify for non-preferred product if they are stable on current therapy (have had a paid claim for requested therapy in the past 45 days)

#### Additional product-specific criteria:

#### Gammagard S/D:

• The patient must be intolerant to IgA (i.e., treatment of an autoimmune process in a patient with undetectable levels of igA)

#### • Cuvitru, Hizentra, or Hygvia:

- o The patient must be unable to tolerate IV administration
- The patient must have failed a trial of at least two of the following, as evidenced by paid claims or pharmacy print-outs:
  - Gamunex-C
  - Gammaked
  - Gammagard

#### • Other Products:

- The patient must have failed a trial of at least two of the following, as evidenced by paid claims or pharmacy print-outs:
  - Gammagard
  - Gamunex-C
  - Privigen

PREFERRED AGENTS	NON-PREFERRED AGENTS
BIVIGAM (human immunoglobulin gamma)	CUTAQUIG (human immune globulin G solution)
FLEBOFAMMA DIF (human immunoglobulin gamma)	CUVITRU (human immunoglobulin gamma)
GAMANEX-C (human immunoglobulin gamma)	GAMMAGARD S-D (human immunoglobulin
Character of (contracting contracting cont	gamma)
GAMASTAN S-D	HIZENTRA (human immunoglobulin gamma)
GAMMAGARD LIQUID (human immunoglobulin gamma)	HYQVIA (human immune globulin G and
	hyaluronidase
GAMMAKED (human immunoglobulin gamma)	
GAMMAPLEX (human immunoglobulin gamma)	
OCTAGAM (human immunoglobulin gamma)	
PANZYGA (Immune Globulin- IFAS)	
PRIVIGEN (human immunoglobulin gamma)	

## **Juxtapid**

Prior Authorization Form - Juxtapid

#### **Criteria for coverage:**

- The patient must have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)
- The patient must be 18 years of age or older
- The patient must have LDL levels of >130 mg/dL after a 90-day trial of the following, as evidenced by paid claims or pharmacy print-outs:
  - A lipid lowering agent other than a statin combined with either Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
- The patient must meet one of the following (A, B, or C):
  - A. The patient must have genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus
  - B. The patient's current untreated LDL and total cholesterol level is > 500 mg/dl or >300 mg/dl with cutaneous or tendon xanthoma before 10 years of age
  - C. The patient has a current untreated LDL level consistent with Heterozygous Familial Hypercholesterolemia (HeFH) in both parents

## Lidocaine-Prilocaine topical cream

Prior Authorization Form – Topical Anesthetics

#### **Criteria for coverage:**

• The request must be for patient home use of cream, prior to injection pain from a medically necessary procedure

## Lucemyra

**General Prior Authorization Form** 

#### **Criteria for coverage:**

- The patient must have a diagnosis of an FDA-approved indication for use
- Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review)

PREFERRED AGENTS	NON-PREFERRED AGENTS
Clonidine	LUCEMYRA (Lofexidine)
Guanfacine	

## Medications that cost over \$3000/month

**General Prior Authorization Form** 

#### **Criteria for coverage:**

• The patient must have a diagnosis of an FDA-approved indication for use in line with label recommendations

DOPTELET (avatrombopag)	
GATTEX (teduglutide)	
INCRELEX (mecasermin)	
MULPLETA (lusutrombopag)	
OXERVATE (cenegermin-bkbj)	
TAVALISSE (fostamatinib)	

## **Mifeprex**

**Prior Authorization Form - Mifeprex** 

Criteria for coverage: Approval Duration = 1 month

- Gestational age must be less than or equal to 70 days
- One of the following criteria must be met (A or B):
  - A. Pregnancy must have resulted from an act of rape or incest, and one of the following (I or II)
    - I. The provider has provided a signed written statement indicating that the rape or act of incest has been reported to the appropriate law enforcement agency, or in the case of a minor who is a victim of incest, to an agency authorized to receive child abuse and neglect reports. The statement must indicate to whom the report was made.
    - II. The provider has provided written statement signed by the recipient and the provider that the recipient's pregnancy resulted from rape or incest and by professional judgement, the provider agrees with the woman's statement.
  - B. Both of the following must be met (I and II)

- I. The woman must suffer from a physical disorder, physical injury, or physical illness, including a lifeendangering physical condition caused by or arising from the pregnancy itself, that would as certified by a provider, place the woman in danger of death unless an abortion is performed
- II. The provider must provide a signed written statement indicating why, in the provider's professional judgement, the life of a woman would be endangered if the fetus were carried to term

## **Naloxone Rescue Medications**

Prior Authorization Form - Naloxone Rescue Medications

#### **Initial Criteria:**

Narcan Nasal Spray does NOT require prior authorization for the initial dose

#### **Renewal Criteria:**

- The provider must attest that it is known that the previous dose was taken by the patient (and not diverted or given to another patient)
- One of the following criteria must be met (A, B, or C)
  - A. The previous dose has expired
  - B. The dose was used by patient for illicit drug use
  - C. The patient is currently taking opioids and meets one of the following criteria:
    - The opioid dose must have been decreased
    - The provider has provided medical justification why the opioid dose as not been decreased

PREFERRED AGENTS	NON-PREFERRED AGENTS
Naloxone injection	
NARCAN (naloxone) NASAL SPRAY	

## Nausea/Vomiting

Prior Authorization Form - Nausea/Vomiting

#### Chemo Induced

Criteria for ALL non-preferred agents: Approval Duration = 6 months or until last day of chemotherapy

- The patient must have diagnosis of nausea and/or vomiting
- Prescriber must be an oncologist
- The patient must be receiving a moderately or highly emetogenic chemotherapy
- The final date of chemotherapy treatment must be provided with the request
- Patient must have failed a 3-day trial of each preferred product(s) in the same class within the last 6 months, as evidenced by paid claims or pharmacy print outs
- Patient must not have failed a preferred chemical entity with same active ingredient as requested product due to side effects

#### **Additional Criteria for coverage of SYNDROS**

- The patient must be less than 7 years of age, or unable to ingest solid dosage form as evidenced by swallow study documentation
- The patient must have one of the following diagnoses and meet required trial for their diagnosis:
  - Loss of appetite due to HIV/AIDS:
    - The patient must have tried and failed a 3-month trial with Megace, as evidenced by paid claims or pharmacy printouts

- Chemotherapy-induced nausea and vomiting:
  - The patient must have tried and failed a 3-day trial of ondansetron ODT in combination with aprepitant suspension and a glucocorticoid, as evidenced by paid claims or pharmacy printouts

NK1 RECEPTOR ANTAGONISTS	
PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
VARUBI (Rolapitant) TABLET	Aprepitant Capsule
	EMEND (Aprepitant) CAPSULE
	EMEND (Aprepitant) SUSPENSION
5-HT3 RECEPTOR ANTAGONISTS	
PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Granisetron tablet	SANCUSO (Granisetron) PATCH
Ondansetron ODT	ZOFRAN (Ondansetron) TABLET
Ondansetron solution	ZUPLENZ (Ondansetron) FILM
Ondansetron tablet	
CANNABINOIDS	
PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Dronabinol Capsule	CESAMET (Nabilone) CAPSULE
	MARINOL (Dronabinol) CAPSULE
	SYNDROS (Dronabinol) SOLUTION

#### Pregnancy

<u>Criteria for ALL non-preferred agents:</u> Approval Duration = 2 weeks past the patients estimated date of delivery

- The patient must have diagnosis of nausea and vomiting of pregnancy
- The patient must have failed 3-day trials of all preferred products, as evidenced by paid claims or pharmacy printouts
- The patient's due date must be provided

#### Additional Criteria for coverage of Bonjesta:

• The prescriber must submit medical justification explaining why the patient cannot use a preferred product or Diclegis (subject to clinical review)

PREFERRED AGENTS	NON-PREFERRED AGENTS
meclizine	BONJESTA (doxylamine/vitamin B6)*
metoclopramide	DICLEGIS (doxylamine/vitamin B6)*
ondansetron	
*: Diclegis and Bonjesta have not been studied in women with hyperemesis gravidarum	

## **Noxafil & Tolsura**

**General Prior Authorization Form** 

#### <u>Criteria for ALL non-preferred agents:</u> Approval Duration = 2 weeks

- The request must be for use as prophylaxis of invasive Aspergillus and Candida infections or Oropharyngeal Candidiasis
- The patient must have documented history of failure to all preferred agents in last 30-days, as evidenced by paid claims or pharmacy print-outs

PREFERRED AGENTS	NON-PREFERRED AGENTS
Clotrimazole	NOXAFIL (posaconazole)
Fluconazole	TOLSURA (itraconazole)
Itraconazole	
Nystatin	
ORAVIG (miconazole)	

## **NSAIDS**

**Prior Authorization Form - NSAIDs** 

#### Oral solid dosage forms

#### **Criteria for coverage:**

 The patient must have failed a 30-day trial of 3 different oral generic NSAIDs, as evidenced by paid claims or pharmacy print outs

#### Additional criteria for coverage of Mefanemic acid:

The patient must have diagnosis of dysmenorrhea

#### Additional criteria for coverage of branded NSAIDs and non-preferred strengths

• Clinical justification must be provided explaining why the patient is unable to use other NSAID agents (subject to clinical review)

#### Additional criteria for coverage of combination products:

 Clinical justification must be provided explaining why the patient is unable to use the individual agents separately (subject to clinical review)

SOLID ORAL DOSAGE FORMS	
PREFERRED AGENTS	NON-PREFERRED AGENTS
Celecoxib 50mg, 100mg, 200mg	ARTHOTEC (Diclofenac/Misoprostol)
Diclofenac potassium	Celecoxib 400mg
Diclofenac sodium 50mg, 75mg	CELEBREX (Celecoxib)
Etodolac	DAYPRO (Oxaprozin)
Fenoprofen 600mg	Diclofenac sodium ER 100mg
Flurbiprofen	Diclofenac sodium 25mg
Ibuprofen	DUEXIS (Famotidine/Ibuprofen)
Indomethacin	Etodolac ER
Indomethacin ER	FELDENE (Piroxicam)
Ketoprofen 50mg, 75mg	Fenoprofen 400mg
Ketorolac	INDOCIN (Indomethacin)
Meloxicam	Ketoprofen 25mg
Nabumetone	Ketoprofen ER 200mg
Naproxen 220mg, 250mg, 500mg CR, 550mg,	Meclofenamate
Piroxicam	Mefenamic acid
Sulindac	MOBIC (Meloxicam)
Tolmetin 200mg, 400mg	NALFON (Fenoprofen)
ZIPSOR (diclofenac)	NAPRELAN (Naproxen)
	Naproxen ER 375 mg
	Naproxen 275mg
	Oxaprozin
	QMIIZ ODT (meloxicam)

TIVODDEV (in domesthesis, submissessized)
TIVORBEX (indomethacin, submicronized)
Tolmetin 600mg
VIMOVO (Naproxen/Esomeprazole)
VIVLODEX (meloxicam, submicronized)
ZORVOLEX (diclofenac, submicronized)

#### **Oral Solutions**

#### Criteria for coverage of Indomethacin oral solution:

- The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation
- The patient must have failed a 30-day trial of naproxen oral solution, as evidenced by paid claims or pharmacy print outs

NON-SOLID ORAL DOSAGE FORMS		
PREFERRED AGENTS NON-PREFERRED AGENTS		
Ibuprofen	Indomethacin	
Naproxen		

#### Nasal

#### **Criteria for coverage of Sprix**:

- The patient must be 18 years of age or older
- The patient must have a diagnosis of postoperative nausea and vomiting
- The patient must not have a documented history of gastric or duodenal ulcer or comorbidities of GI bleed, perforation, or obstruction

## Non-solid dosage preparations

**General Prior Authorization Form** 

#### **Criteria for coverage:**

• The patient must have failed treatment with a more cost-effect dosage form in the last 30 days, as evidenced by paid claims or pharmacy print-outs

OR

• The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

## **Nuedexta**

#### Prior Authorization Form - Nuedexta

#### **Initial Criteria**: Approval Duration = 3 months

- The patient must be 18 years of age or older
- The patient must not have a diagnosis of any of the following: prolonged QT interval, heart failure, or complete atrioventricular (AV) block
- The prescriber must provide the following information:
  - o Baseline Center for Neurological Studies lability (CNS-LS) score
  - Baseline weekly PBA episode count
- The patient must have diagnosis of pseudobulbar affect (PBA) due to one of the following neurologic conditions and meet additional criteria for diagnosis:
  - Amytrophic Lateral Sclerosis (ALS)
  - o Multiple Sclerosis (MS)

- Alzheimer's Disease
- o Stroke

#### Additional initial criteria for a diagnosis of PBA due to Alzheimer's disease or stroke:

- Neurologic condition must have been stable for at least 3 months
- Patient must have failed\*\* a 3-month trial of at least one medication from each of the classes listed below (A and B),
   as evidenced by paid claims or pharmacy print outs:
  - A. **SSRIs**: sertraline, fluoxetine, citalopram and paroxetine
  - B. Tricyclic Antidepressants: nortriptyline and amitriptyline
- A PBA episode count and CNS-LS score must be provided for before and after each trial
  - \*\*A failure is defined as one of the following:
    - PBA count decreased less than 75 percent, stayed the same, or increased from baseline in each trial
    - CHS-LS score decreased less than 7 points, stayed the same, or increased from baseline in each trial

#### Renewal Criteria: Approval Duration = 6 months

- Benefit of continued therapy must be assessed
- Baseline and current PBA episode count must be included with request
- Current PBA episode must be reduced by at least 75% from baseline

#### Additional renewal criteria for a diagnosis of PBA due to Alzheimer's disease or stroke:

- Baseline and current Center for Neurological Studies lability (CNS-LS) must be included with request
- Current CNS-LS score must be reduced by at least 30% from baseline

## **Opioid Analgesic - Short Acting**

Prior Authorization Form - Short Acting Opioids

#### Criteria for coverage of Subsys, Fentora, Lazanda, Actiq, and Abstral:

- The patient's age must be within label recommendations
- The patient must have a diagnosis of cancer pain
- The patient must currently be on around the clock opioid therapy for at least a week, as evidenced by paid claims or pharmacy print-outs
  - The around the clock opioid therapy must be equivalent to 60 mg oral morphine daily, 25 mcg transdermal fentanyl/hour, 30mg oxycodone daily, 8 mg of oral hydromorphone daily, or equianalgesic dose of another opioid daily

#### **Criteria for coverage of Oxycodone IR:**

- The patient must have a diagnosis of chronic pain
- The patient must currently be on a long-acting opioid analgesic, as evidenced by paid claims or pharmacy print-outs
- The prescriber must confirm that they have reviewed the North Dakota PDMP reports for the patient
- The Morphine Equivalent Dose (MED) provided by the long-acting opioid analgesic must meet the requirements based on oxycodone IR strength below (Please use an <u>Opioid Dose Calculator</u> to find the MED for specific products):
  - Oxycodone 15 mg tablet: long-acting opioid analgesic must provide at least 150mg MED per day
  - o Oxycodone 20 mg tablet: long-acting opioid analgesic must provide at least 200mg MED per day
  - Oxycodone 30 mg tablet: long-acting opioid analgesic must provide at least 300mg MED per day

## **Orilissa**

#### Initial Criteria: Approval Duration = 6 months

- The patient must be 18 years of age or older
- The patient must have a diagnosis of moderate to severe pain associated with endometriosis
- Must be prescribed by or in consult with an obstetrician/gynecologist or endocrinologist
- Documented pain scores must be attached.
- Pregnancy test must be performed prior to initiation of treatment, and a non-combination hormone birth control
  method must be used throughout treatment
- The patient must not have osteoporosis or severe liver disease (Child-Pugh Class C).
- The patient must have failed the following trials (A and B), as evidenced by paid claims or pharmacy print-outs:
  - A. A 3-cycle trial of two different types of Non-Steroidal Anti-Inflammatory agent (NSAIDs):
    - A phenylproprionic acid derivative at the upper end of the dose range (e.g. ibuprofen 400mg -800mg every 6 hours)
    - A fenamate (such as mefenamic acid)
  - B. A 3-cycle trial of two oral estrogen-progestin or progestin contraceptives

#### **Renewal Criteria**: Approval Duration = 18 months

- Prescriber must submit documentation of improvement in pain score from baseline
- Request must be for maintenance dosing (150 mg strength).

## **Osteoporosis**

#### Initial Criteria for ALL non-preferred agents: Approval Duration = 2 years

- The patient must have a diagnosis of an FDA-approved indication for use
- The patient must have a current BMD T-score ≤ -2.5 OR new fracture after a 6-month trial of each of the following, as evidenced by paid claims or pharmacy print-outs:
  - o Alendronate or Risedronate
  - o Denosumab
- Patient must be at high risk of fracture, confirmed by at least one of the following:
  - o The patient with a history of hip or vertebral fracture
  - o The patient with a T-score of −2.5 or lower at the femoral neck or spine
  - The patient who have a T-score of between -1.0 and -2.5 at the femoral neck or spine and a ten-year hip fracture risk of  $\geq 3\%$  as assessed with the FRAX
  - o 10-year risk of a major osteoporosis-related fracture of ≥20% as assessed with the FRAX

#### **Additional Criteria for Forteo and Miacalcin:**

- The patient must have a current BMD T-score ≤ -2.5 OR new fracture after a 6-month trial of each of the following, as evidenced by paid claims or pharmacy print-outs:
  - Tymlos (Abaloparatide)

PREFERRED AGENTS	NON-PREFERRED AGENTS
Alendronate	FORTEO (Teriparatide)
Calcitonin, Salmon Nasal Spray	MIACALCIN (Calcitonin, Salmon)
Ibandronate	TYMLOS (Abaloparatide)
PROLIA (Denosumab)	
Risedronate	

## Parkinson's disease

#### **Initial Criteria for ALL non-preferred agents:**

- The patient must have a diagnosis of an FDA-approved indication for use
- The patient must be currently taking carbidopa levodopa, as evidenced by paid claims or pharmacy print-outs, and will continue taking carbidopa levodopa concurrently with requested agent

#### Additional Criteria for Gocovri, Osmolex ER, Rytary, and Pramipexole ER:

- The patient is must not be currently residing in a facility with skilled nursing care
- Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review).

#### Additional Criteria for apomorphine, Duopa and Inbrija

• The provider must submit documentation of a swallow study or other medical documentation (e.g. chart notes) indicating that the patient has a proven inability to ingest solid dosage formulations.

#### **Additional Criteria for Xadago**

- Medication must be prescribed by, or in consultation with, a psychiatrist or neurologist
- The patient must be currently experiencing intermittent hypomobility or "off" episodes
- The patient must be exhibiting deterioration in quality of response to during levodopa/carbidopa therapy for intermittent hypomobility, or "off" episodes
- The patient must have had inadequate response to rasagiline and selegiline, as evidenced by paid claims or pharmacy print-outs

#### **Additional Criteria for Nuplazid**

- Medication must be prescribed by, or in consultation with, a psychiatrist or neurologist
- The patient must be experiencing recurrent or continuous hallucinations and/or delusions for the past 30 days
- The patient must have experienced an inadequate response to a 30-day trial of quetiapine or clozapine, as evidenced by paid claims or pharmacy print-outs
- The patient must not have experienced a reduction in symptoms of psychosis, despite documented medication dosage reduction and discontinuation trials (with a goal of levodopa monotherapy)

#### **Additional Criteria for Tolcapone**

The patient must have failed a 30-day trial of entacapone, as evidenced by paid claims or pharmacy print-outs

#### Renewal Criteria:

• The patient has experienced disease stabilization or improvement in disease since initiation of treatment

PREFERRED AGENTS	NON-PREFERRED AGENTS
Amantadine	DUOPA (levodopa/carbidopa)
AZILECT (Rasagiline)	APOKYN (Apomorphine)
Benztropine	GOCOVRI (amantadine ER)
Bromocriptine	INBRIJA (Levodopa)
Carbidopa-levadopa-entacapone	Pramipexole ER
Carbidopa-Levadopa	NUPLAZID (pimavanserin)
Carbidopa-Levadopa ER	OSMOLEX ER (amantadine ER)
Entacapone	Rasagiline
Levodopa	RYTARY (levodopa/carbidopa)
NEUPRO (rotigotine) PATCH	Tolcapone
Pramipexole	XADAGO (Safinamide)
Ropinirole	
Ropinirole ER	

Selegiline	
Trihexyphenidyl	

## Phenylketonuria

Prior Authorization Form - Phenylketonuria

#### Kuvan:

#### <u>Criteria for initial requests: Approval Duration = 2 months</u>

- The patient must have a diagnosis of hyperphenylalaninemia
- The patient must be following a PHE restricted diet
- The patient's weight must be provided
- The patient must be 4 years of age or older
- The patient must not have been known to have two null mutations in TRANS
- Baseline PHE levels must be attached
  - o For females of child bearing potential: PHE levels must be above 360 micromoles/liter
  - o For males or females unable to bear children: PHE levels must be above 600 micromoles/liter
- Requested initial dose must be 10 mg/kg or less

#### <u>Criteria for renewal requests: Approval Duration = 12 months</u>

- The patient's weight must be provided
- If dose is the same or less than previous trial:
  - o PHE level must be between 60 and 360 micromoles per liter
- For a dose increase from previous trial:
  - o PHE levels must be attached that were taken after 1 month of previous trial
  - o The patient's PHE level must be greater than 360 micromoles per liter
  - o For increase > 10 mg/kg patient must have failed a trial of 1 month of 10 mg/kg

#### Palynziq:

#### Criteria for initial requests: Approval Duration = 6 months

- The patient must have a diagnosis of hyperphenylalaninemia
- The patient must be following a PHE restricted diet
- The patient must be 18 years of age or older
- PHE levels must be above 600 micromoles/liter
- The patient must have been compliant with diet and medication management for past 6 months.

#### <u>Criteria for renewal requests: Approval Duration = 12 months</u>

- If dose is the same or less than previous trial:
  - o PHE level must be between 60 and 360 micromoles per liter
- For a dose increase to 40 mg:
  - o PHE levels must be attached that were taken after 24 weeks of 20 mg
  - The patient's PHE level must be greater than 360 micromoles per liter

## **Proton Pump Inhibitor**

**General Prior Authorization Form** 

**Criteria for ALL non-preferred agents:** Approval Duration = 6 months

#### Solid Dosage Forms

#### Criteria for ALL non-preferred Step 1 Agents (Esomeprazole Magnesium, Lansoprazole 15mg, rabeprazole):

Patient must have failed a 25-day trial of at least one of the preferred or Step 1 Solid Dosage Form agents in the past
 90 days, as evidenced by paid claims or pharmacy print-outs

# <u>Criteria for ALL non-preferred Step 2 Agents (Esomeprazole strontium, Esomeprazole magnesium/glycerin, Omeprazole-sodium bicarbonate):</u>

• Clinical justification must be provided explaining why the patient is unable to use the other agents (subject to clinical review).

SOLID DOSAGE FORMS		
PREFERRED AGENTS	NON-PREFERRED STEP 1 AGENTS	NON-PREFERRED STEP 2 AGENTS
DEXILANT (dexlansoprazole)	Esomeprazole magnesium	Esomeprazole magnesium/glycerin
Lansoprazole 30mg	Lansoprazole 15mg	Esomeprazole strontium
omeprazole	Rabeprazole	omeprazole-sodium bicarbonate
pantoprazole		

#### Non-Solid Dosage Forms

#### **Criteria for ALL non-preferred agents:**

- The patient must have feeding tube in place
- The patient must have failed a 30-day trial of all Preferred Non-Solid Dosage form agents (Nexium Packet and Protonix Packet) in the past 2 years, as evidenced by paid claims or pharmacy printouts

#### **Criteria for coverage of Prilosec Packet:**

• The patient must have had a 30-day trial of lansoprazole ODT in the past 2 years, as evidenced by paid claims or pharmacy print-outs

#### <u>Criteria for coverage of Omeprazole-sodium bicarbonate packet/Aciphex Sprinkle:</u>

• Clinical justification must be provided explaining why the patient is unable to use the other proton-pump inhibitor agents (subject to clinical review)

NON-SOLID DOSAGE FORMS		
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
NEXIUM (esomeprazole) PACKET	Lansoprazole 15mg ODT	ACIPHEX SPRINKLE (rabeprazole)
PROTONIX (pantoprazole) PACKET	PRILOSEC PACKET (omeprazole)	Lansoprazole 30mg ODT
		Omeprazole-Sodium Bicarbonate Packet
		PREVACID (Lansoprazole) SOLUTAB

## Rosiglitazone

**General Prior Authorization Form** 

#### **Criteria for coverage:**

- The patient must have failed a 30-day trial of pioglitazone, as evidenced by paid claims or pharmacy printouts
- Clinical justification must be provided explaining why the patient is unable to use the preferred agents and other classes of medication (subject to clinical review)

PREFERRED AGENTS	NON-PREFERRED AGENTS
Pioglitazone	Rosiglitazone

## **Sedatives/Hypnotics**

Prior Authorization Form - Sedative/Hypnotics

#### **Initial Criteria**: Approval Duration = 1 month

- Criteria for coverage of Zolpidem 10mg (prior authorization required for females only):
  - The patient must have failed a 25-day trial of zolpidem 5 mg within the last 30 days, as evidenced by paid claims or pharmacy print outs

#### • Criteria for coverage of Zolpidem ER:

- o The patient's insomnia must be characterized by difficulty with sleep maintenance
- The patient must have failed a 25-day trial of eszopiclone within the last 30 days, as evidenced by paid claims or pharmacy print-outs

#### • Criteria for coverage of Belsomra:

- o The patient's insomnia must be characterized by difficulty with sleep onset and maintenance
- The patient must have had the following 25-day trials with the most recent failure within the last 30 days, as evidenced by paid claims or pharmacy print-outs
  - Silenor (doxepin)
  - Eszopiclone
  - Zolpidem ER

#### Criteria for coverage of Temazepam, zolpidem SL:

- o The patient's insomnia must be characterized by difficulty with sleep onset and maintenance
- The patient must have had the following 25-day trials with the most recent failure within the last 30 days, as
   evidenced by paid claims or pharmacy print-outs
  - Zolpidem ER
  - Eszopiclone
  - Silenor (doxepin)
  - Belsomra

#### Criteria for coverage of Edluar (Zolpidem):

- The patient's insomnia must be characterized by difficulty with sleep onset
- The patient must have had the following 25-day trials with the most recent failure within the last 30 days, as evidenced by paid claims or pharmacy print-outs
  - Zolpidem IR
  - Zaleplon
  - Eszopiclone

#### • Criteria for coverage of Triazolam, fluazepam, estazolam, Seconal sodium, Zolpimist:

 Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review)

#### Renewal Criteria for ALL agents: Approval Duration = 6 months (2 weeks for benzodiazepines)

The rpescriber has provided confirmation that other conditions causing sleep issues have been ruled out

#### Additional renewal criteria for benzodiazepines (temazepam, triazolam, flurazepam, estazolam):

o The patient must be undergoing dose tapering

NON-SCHEDULED (NON-ADDICTIVE) OPTIONS:	
PREFERRED AGENTS	NON-PREFERRED AGENTS
mirtazapine	
ROZEREM (ramelteon)	
SILENOR (doxepin)	
trazodone	

PREFERRED AGENTS	NON-PREFERRED AGENTS
eszopiclone	BELSOMRA (suvorexant)
zaleplon	EDLUAR (zolpidem)

zolpidem 5mg	flurazepam
zolpidem 10mg (for males)	SECONAL SODIUM (secobarbital)
	temazepam
	triazolam
	zolpidem CR
	zolpidem 10mg (for females)
	ZOLPIMIST (zolpidem)
	Zolpidem SL tab

#### Serostim

Prior Authorization Form - Growth Hormone

#### **Initial Criteria:**

- The patient must not have an active malignancy
- The patient must have a diagnosis of treatment of HIV with wasting cachexia
- Prescriber must be experienced in the diagnosis and management of HIV infection
- The patient must be on concomitant antiretroviral therapy
- The patient must have failed a 3-month trial with Megace, as evidenced by paid claims or pharmacy print-outs

#### **Renewal Criteria:**

- The patient must meet the initial criteria
- Lean body mass and body weight must be provided and show an increase within the past 12 weeks
- Physical endurance must have increased in past 12 weeks
- The patient must not have completed 48 weeks of continuous treatments

## **Skeletal Muscle Relaxants**

**General Prior Authorization Form** 

#### <u>Criteria for ALL non-preferred agents:</u> Approval Duration = 3 months

 The patient must have failed two 30-day trials of other skeletal muscle relaxants, as evidenced by paid claims or pharmacy print-outs.

#### Additional criteria for coverage of metaxalone: Approval Duration = 1 week

 Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review)

#### <u>Additional criteria for coverage of carisoprodol:</u> Approval Duration = 3 months

• One of the required 30-day trials must be methocarbamol, as evidenced by paid claims or pharmacy print-outs.

PREFERRED AGENTS	NON-PREFERRED AGENTS
Baclofen	Chlorzoxazone 375mg and 750mg
Chlorzoxazone 500mg	Cyclobenzaprine 7.5mg
Cyclobenzaprine 5mg and 10mg	cyclobenzaprine ER
Dantrolene	carisoprodol
Methocarbamol	carisoprodol-aspirin
Orphenadrine ER	carisoprodol-aspirin-codeine
Tizanidine tablets	metaxalone
	Tizanidine capsules

## Spiriva Respimat 1.25 mcg

**General Prior Authorization Form** 

#### **Criteria for coverage:**

- The patient must have a diagnosis of asthma
- The patient must have failed a 30-day trial of a steroid inhaler and a long acting beta agonist

### **Statins**

#### **General Prior Authorization Form**

#### **Criteria for coverage of Livalo:**

- Statin intensity treatment goal must be "moderate" or "low"
- The patient must have failed the following 3-month trials, based on their intensity treatment goal, as evidenced by paid claims or pharmacy print outs:
  - "Moderate" treatment goal
    - atorvastatin 10-20mg, rosuvastatin 5-10mg, and one of the following:
      - Simvastatin 20 40mg a day
      - Pravastatin 40 80mg a day
      - Lovastatin 40mg a day
      - Fluvastatin XL 80mg a day
      - Fluvastatin 40mg twice a day
  - "Low" treatment goal
    - Two of the following:
      - Simvastatin 10mg a day
      - Pravastatin 10 20mg a day
      - Lovastatin 20mg a day
      - Fluvastatin 20 40mg a day

#### Criteria for coverage of Ezetimibe-simvastatin/amlodipine-atorvastatin

• Please prescribe individual medication separately or use a different medication combination

#### Criteria for coverage of Altoprev (Iovastatin) ER/Fluvastatin/Fluvastatin ER/Zypitamag:

 Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review)

PREFERRED AGENTS	NON-PREFERRED AGENTS
atorvastatin	ALTOPREV (lovastatin) ER
lovastatin	Amlodipine-atorvastatin
pravastatin	Ezetimibe-simvastatin
rosuvastatin	fluvastatin
simvastatin	fluvastatin ER
	LIVALO (pitavastatin)
	ZYPITAMAG (pitavastatin)

## **Steroids - Nasal**

**General Prior Authorization Form** 

#### **Criteria for ALL non-preferred agents:**

- The patient must have failed a 30-day trial (within the past 2 years) of 1 preferred agent, as evidenced by paid claims or pharmacy print-outs
- Additional Criteria for coverage of Xhance and Zetonna (Ciclesonide):

 Clinical justification must be provided explaining why the patient is unable to another product with the same active ingredient (subject to clinical review)

PREFERRED AGENTS	NON-PREFERRED AGENTS
BECONASE AQ (beclomethasone)	flunisolide
Fluticasone	mometasone
QNASL (beclomethasone)	OMNARIS (ciclesonide)
	QNASL CHILDREN'S (beclomethasone)
	XHANCE (fluticasone)
	ZETONNA (ciclesonide)

## **Steroids - Topical**

**General Prior Authorization Form** 

#### Criteria for coverage of non-preferred Step 1 agents (not labeled as "STEP 2"):

• The patient must have failed a 2-week trial of all preferred drug entities within the same potency category and dosage form group within the last 3 months, as evidenced by paid claims or pharmacy print-outs

#### Criteria for coverage of non-preferred agents labeled as "STEP 2":

• The patient must have failed a 2-week trial of all preferred and non-preferred drug entities within the same potency category and dosage form group within the last 3 months.

See <u>Topical Corticosteroids Preferred Medication List</u>

## Steroid/Long Acting Beta Agonist (LABA) Combination Inhalers

**General Prior Authorization Form** 

#### Criteria for coverage:

- The patient must have had 30-day trials of each preferred agent, as evidenced by paid claims or pharmacy print-outs
- The patient must have a diagnosis of an FDA-approved indication for use and meet the criteria for that diagnosis
  - o For COPD diagnosis: one of the following must be met (A or B):
    - A. The patient must have failed 30-day trials of at least 1 agent from each of the below lists (I and II)
      - Tudorza Pressair, Spiriva, Spiriva Respimat, Incruse Ellipta, or Seebri Neohaler
      - II. Brovana, Arcapta Neohaler, Striverdi Respimat, Perforomist, or Serevent.
    - B. The patient must have failed 30-day trials of at least 1 of the following agents below:
      - Anoro Ellipta, Stiolto Respimat, Utibron NeoHaler, Bevespi Aerosphere, or Trelegy Ellipta
  - o For asthma diagnosis:
    - The patient must have been reviewed for step down therapy for all renewal requests.

PREFERRED AGENTS	NON-PREFERRED AGENTS
ADVAIR HFA (fluticasone/salmeterol)	ADVAIR DISKUS (fluticasone/salmeterol)
DULERA (mometasone/formoterol)	AIRDUO RESPICLICK (fluticasone/salmeterol)
Fluticasone/Salmeterol – Labeler 66993	BREO ELLIPTA (fluticasone/vilanterol)
SYMBICORT (budesonide/formoterol)	Fluticasone/Salmeterol – Labeler - 00093
	WIXELA INHUB (fluticasone/salmeterol)

## **Tobacco Cessation**

North Dakota Medicaid has joined forces with the Department of Health to provide free, confidential, telephone-based cessation coaching to recipients interested in quitting tobacco. Beginning November 15, 2008, to receive smoking cessation products (patches, gum, lozenges, bupropion, or Chantix®), Medicaid recipients must be signed up with NDQuits (1-800-QUIT-NOW or 1-800-784-8669). Once a recipient is enrolled in coaching, they will work with their coach to determine which medications they wish to use. The complete process is described below:

- 1. Patient calls NDQuits and enrolls in coaching.
- 2. Coaches guide patient through quitting process.
- 3. Individualized treatment plan (including medications if used) is developed.
- 4. The patient will receive an NDQuit's Enrollment Letter which will include the NDQuit's recommendation for specific medication(s)
- 5. The HID Prior Authorization form will be included with the NDQuit's Enrollment Letter.
- 6. The client must bring the HID Prior Authorization form and enrollment letter to their physician or pharmacy
- 7. The client must contact their physician and obtain the prescription.
- 8. The physician or pharmacy must complete and fax the HID Prior Authorization form and NDQuit's Enrollment Letter to HID.
- 9. If prior authorization is approved, prior authorization letter is faxed to physician and/or pharmacy
- 10. Pharmacy fills prescription and the claim is paid.

Patients will be limited to a 90 consecutive days supply of therapy for nicotine inhalers, patches, gum, lozenges, and bupropion, every two years.

Chantix is limited to the initial 12 weeks of therapy with an additional 12 weeks (24 consecutive weeks) allowed if the patient has continuously quit for a minimum of one month (since day 56 of therapy). The Chantix regimen will be allowed once every two years.

Nicotrol inhaler requires a smoking cessation trial with nicotine gum, lozenges, or nasal spray.

Prior authorizations will be entered based upon the recipient's Quit Date. This means that the approval date range will be sufficient to allow recipients to pick up medications at least one week prior to their Quit Date. Compliance will be an important aspect of the patient's success.

Please contact Health Information Designs, Inc. at (334) 502-3262 or toll free at 1-800-225-6998, with questions regarding the smoking cessation prior authorization process.

#### **Uceris Rectal Foam**

**General Prior Authorization Form** 

#### **Criteria for coverage:**

- The patient has a diagnosis of ulcerative colitis
- The patient must have failed a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy print-outs

PREFERRED AGENTS	NON-PREFERRED AGENTS
CANASA (mesalamine) RECTAL SUPPOSITORY	Mesalamine enema kit
Mesalamine enema	UCERIS (budesonide) RECTAL FOAM

## Vecamyl

**General Prior Authorization Form** 

#### **Criteria for coverage:**

• The patient must have documented history of failure to achieve blood pressure goals (using maximum tolerated doses) of all first- and second-line agents as defined by the most recent JNC report.

## **Xyrem**

**General Prior Authorization Form** 

#### **Criteria for coverage:**

- The patient must be 7 years of age or older
- The patient must have failed a 2-month trial of modafinil, as evidenced by paid claims or pharmacy print-outs
- The patient must have one of the following diagnoses and additional criteria for diagnosis:
  - o Cataplexy in Patient's with Narcolepsy

## **Zorbtive**

#### Prior Authorization Form - Growth Hormone

#### **Criteria for coverage:**

- The patient must not have active malignancy
- The patient must have diagnosis of short bowel syndrome
- The patient must be receiving specialized nutritional support
- Treatment must not be longer than 4 weeks

## **Preferred Dosage Forms List:**

Prior Authorization Form - Non-Preferred Dosage Form

#### Criteria for coverage:

- Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review).
- The patient must have a diagnosis of an FDA-approved indication for use
- The patient must not have any contraindication to the requested product
- The patient must have failed\* a therapeutic course\*\* of each preferred agent (listed in boxes below) within the past 2 years, as evidenced by paid claims or pharmacy print-outs.
  - \*: A failure is defined as product was not effective at maximum tolerated dose or patient has a documented intolerance or adverse reaction to inactive ingredients where the non-preferred product is expected to have a different result and other alternatives (e.g. medications in same class) are not an option for the patient
  - \*\*: Trials must have been at least 30 days in duration unless otherwise indicated

#### Altoprev (lovastatin) ER

Required trial duration: 3 months

PREFERRED AGENTS	NON-PREFERRED AGENTS
lovastatin	ALTOPREV (lovastatin) ER

#### Amoxicillin ER

PREFERRED AGENTS	NON-PREFERRED AGENTS
Amoxicillin IR	Amoxicillin ER

#### **Bowel Prep Agents**

Required trial duration: 1 complete dose

PREFERRED AGENTS	NON-PREFERRED AGENTS
GAVILYTE-G	CLENPIQ
GOLYTELY 227.1-21.5	COLYTE
GOLYTELY 236-22.74G	GAVILYTE-C
MOVIPREP	GAVILYTE-N
OSMOPREP	NULYTELY
PEG-3350 AND ELECTROLYTES 236-22.74G	PEG 3350-ELECTROLYTE 240-22.72G
	PEG 3350-ELECTROLYTE 420 G
	PLENVU
	PREPOPIK
	SUPREP

TDII VTE	
INILTIE	

## Brisdelle (paroxetine)

PREFERRED AGENTS	NON-PREFERRED AGENTS
Paroxetine tablets	BRISDELLE (paroxetine) CAPSULES

## Daxbia (Cephalexin)

PREFERRED AGENTS	NON-PREFERRED AGENTS
Cephalexin	Daxbia (Cephalexin)

## Durlaza (aspirin ER)

• Please see "Platelet Aggregation Inhibitor" category on PDL. <a href="http://www.hidesigns.com/ndmedicaid/pdl/">http://www.hidesigns.com/ndmedicaid/pdl/</a>

## Envarsus ER (tacrolimus)

PREFERRED AGENTS	NON-PREFERRED AGENTS
Tacrolimus	ASTAGRAF XL (Tacrolimus)
	Envarsus ER (tacrolimus)

## Fortamet (metformin) & Glumetza (metformin)

PREFERRED AGENTS	NON-PREFERRED AGENTS
Metformin ER	FORTAMET (metformin)
	GLUMETZA (metformin)

## Gocovri (amantadine ER) & Osmolex ER (amantadine ER)

PREFERRED AGENTS	NON-PREFERRED AGENTS
Amantadine IR	Gocovri (amantadine ER)
	Osmolex ER (amantadine ER)

## Gralise (gabapentin)

PREFERRED AGENTS	NON-PREFERRED AGENTS
gabapentin	GRALISE (gabapentin)

## Horizant (gabapentin)

PREFERRED AGENTS	NON-PREFERRED AGENTS
gabapentin	HORIZANT (gabapentin)
pramipexole	
ropinirole	

## Jadenu (deferasirox)

PREFERRED AGENTS	NON-PREFERRED AGENTS
Deferasirox tablet for suspension	JADENU (deferasirox)

#### Kits

PREFERRED AGENTS	NON-PREFERRED AGENTS
FDA approved products prescribed separately	DERMACINRX ARM PAK (lidocaine/dimethacone)
	DERMACINRX CINLONE-I CPI (triamcinolone/lidocaine/prilocaine)
	DERMACINRX PHN PAK (lidocaine/emollient cmb No. 102)
	DERMACINRX SILAZONE (triamcinolone/silicones)
	TRIXYLITRAL (diclofenac/lidocaine/tape)
	ELLZIA PAK (triamcinolone/dimethicone)

INFAMMACIN (diclofenac/capsicum)	
LOPROX (ciclopirox/skin cleanser No. 40)	
MIGRANOW (sumatriptan/menthol/camphor)	
MORGIDOX (doxycycline/skin cleanser No. 19)	
PRO DNA MEDICATED COLLECTION (lidocaine/glycerin)	
QUTENZA (capsaicin/skin cleanser)	
SILAZONE-II (triamcinolone/silicones)	
TICANSE (fluticasone/sodium chloride/sodium bicarbonate)	
XRYLIX (diclofenac/kinesiology tape)	

#### Methotrexate

Required trial duration: 6 weeks

PREFERRED AGENTS	NON-PREFERRED AGENTS
methotrexate	OTREXUP (methotrexate)
	RASUVO (methotrexate)
	TREXALL (methotrexate)

## Mupirocin

PREFERRED AGENTS	NON-PREFERRED AGENTS
Mupirocin Ointment	Mupirocin Calcium Cream

## Narcotic/APAP Criteria

PREFERRED AGENTS	NON-PREFERRED AGENTS
hydrocodone-acetaminophen 5-325 MG	hydrocodone-acetaminophen 2.5-325 MG
hydrocodone-acetaminophen 7.5-325 MG	hydrocodone-acetaminophen 10MG-300MG
hydrocodone-acetaminophen 10-325 MG	hydrocodone-acetaminophen 5 MG-300MG
oxycodone-acetaminophen 5-325 MG	hydrocodone-acetaminophen 7.5-300 MG
oxycodone-acetaminophen -325 MG	oxycodone-acetaminophen 2.5-325 MG
	oxycodone-acetaminophen7.5-325 MG
	PRIMLEV (oxycodone-acetaminophen) 5 MG-300MG
	PRIMLEV (oxycodone-acetaminophen) 7.5-300 MG
	PRIMLEV (oxycodone-acetaminophen) 10MG-300MG

## Nitroglycerin Spray

Required trial duration: 1 dose while on preventative medication

<u> </u>	
PREFERRED AGENTS	NON-PREFERRED AGENTS
Nitroglycerin sublingual tablets	Nitroglycerin Spray

## Nocdurna (desmopressin)

PREFERRED AGENTS	NON-PREFERRED AGENTS
Desmopressin	Nocdurna (desmopressin)

## Onmel (itraconazole)

Required trial duration: 12 weeks with 6 months outgrow following treatment for onychomycosis

PREFERRED AGENTS	NON-PREFERRED AGENTS		
Itraconazole capsule	ONMEL (itraconazole) tablet		
Terbinafine			

## Oxaydo (oxycodone)

PREFERRED AGENTS	NON-PREFERRED AGENTS

Oxycodone	Oxaydo (oxycodone)	
	Roxybond (oxycodone)	

## Procysbi (cysteamine)

PREFERRED AGENTS	NON-PREFERRED AGENTS	
CYSTAGON (cysteamine)	PROCYSBI (cysteamine)	

## Ribavirin

PREFERRED AGENTS	NON-PREFERRED AGENTS	
RIBASPHERE (ribavirin)	COPEGUS (ribavirin)	
Ribavirin	MODERIBA (ribavirin)	
	RIBASPHERE RIBAPAK (ribavirin)	

## Rytary (Carbidopa/Levodopa)

Additional Criteria: Patient is not in a long-term care facility

PREFERRED AGENTS	NON-PREFERRED AGENTS	
Carbidopa/Levodopa	RYTARY (carbidopa/levodopa)	
Carbidopa/Levodopa ER		
Carbidopa/Levodopa/Entacapone		

## Siklos (Hydroxyurea)

PREFERRED AGENTS	NON-PREFERRED AGENTS		
DROXIA (Hydroxyurea capsule)	SIKLOS (Hydroxyurea tablet)		
Hydroxyurea capsule			

## Steroids - Oral

<u>Additional Criteria for coverage of Emflaza</u>: See Emflaza Criteria on this document

Rayos required trial duration: 12 weeks with 2AM dosing of prednisone

PREFERRED AGENTS	NON-PREFERRED AGENTS		
Budesonide 3mg EC	Budesonide 9 mg ER		
Cortisone	DEXPAK (dexamethasone)		
Dexamethasone	DXEVO (dexamethasone)		
Hydrocortisone	EMFLAZA (deflazacort)		
Methylprednisone	MILLIPRED (Prednisolone)		
Prednisolone sodium phosphate 5mg/5ml, 15mg/5ml, 25mg/5ml	Prednisolone sodium phosphate ODT		
Prednisone	Prednisolone sodium phosphate 10mg/5ml, 20mg/5ml solution		
	RAYOS (prednisone)		
	TAPERDEX (dexamethasone)		
	UCERIS (budesonide)		

## Tirosint (levothyroxine)

PREFERRED AGENTS	NON-PREFERRED AGENTS	
levothyroxine	TIROSINT (levothyroxine)	

## Tussicaps

PREFERRED AGENTS	NON-PREFERRED AGENTS
Hydrocodone/chlorpheniramine ER suspension	TUSSICAPS (hydrocodone/chlorpheniramine)

Promethazine/codeine	
ZODRYL AC (chlorpheniramine/codeine)	

# **Topical Corticosteroids Preferred Medication List - Page 1 of 2**

Potency	Dosage Form	Preferred		Non-Preferre	.d	
Potency	Class 1 - Very High Potency					
_		Clobetasol Propionate	0.05%	Clobetasol Emollient	0.05%	
	Cream			Halobetasol Propionate	0.05%	
				STEP2*Fluocinonide	0.10%	
,	Ointer and	Betamethasone, augmented	0.05%	Halobetasol Propionate	0.05%	
nc)	Ointment	Clobetasol Propionate	0.05%			
Class 1 - Very High Potency		Clobetasol Propionate Solution	0.05%	Betamethasone, augmented lotion Betamethasone,	0.05%	
ry Hig	Foam,	Clobex ( <i>Brand Required</i> ) Lotion Clobex ( <i>Brand Required</i> )	0.05%	augmented gel	0.05%	
- Ve	Gel, Lotion,	Shampoo	0.05%	Clobetasol emulsion foam Clobetasol propionate	0.05%	
ass 1	Shampoo, Solution,	Clobex (Brand Required) Spray	0.05%	foam Lexette (Halobetasol)	0.05%	
C	Spray,	Clobetasol Propionate Gel	0.05%	foam	0.05%	
	Tape			Desoximetasone spray  STEP2*Cordran	0.25%	
				(Flurandrenolide) Tape  STEP 2* Ultravate	4MCG/SQ CM	
				(Halobetasol) lotion	0.05%	
		Class 2	- High Poteno	cy		
		Betamethasone, augmented	0.05%	Apexicon E	0.05%	
		Desoximetasone	0.25%	Halog	0.10%	
	Cream	Diflorasone Diacetate	0.05%	Fluocinonide-E	0.05%	
>		Fluocinonide	0.05%	STEP2*Amcinonide	0.10%	
tency		Triamcinolone Acetonide	0.50%			
ote	Ointment	Betamethasone Dipropionate	0.05%	Diflorasone Diacetate	0.05%	
High Po		Betamethasone Valerate	0.10%			
lgil		Desoximetasone	0.25%			
		Fluocinonide	0.05%			
s 2		Fluticasone Propionate	0.01%			
Class 2 -		Halog	0.10%			
O		Mometasone Furoate	0.10%			
		Triamcinolone Acetonide	0.50%			
	Cal	Fluocinonide gel	0.05%	Desoximetasone gel	0.05%	
	Gel, Lotion	Fluocinonide solution	0.05%	Bryhali (halobetasol)	0.01%	
	Solution			STEP2*Amcinonide Lotion	0.10%	

# **Topical Corticosteroids Preferred Medication List - Page 2 of 2**

		Class 3 - N	Medium Po	tency	
		Betamethasone Valerate	0.10%	Betamethasone Dipropionate	0.05%
Medium Potency	Cream	Fluticasone Propionate	0.05%	Clocortolone Pivalate	0.10%
		Mometasone Furoate	0.10%	Fluocinolone Acetonide	0.025%
		Synalar	0.025%	Pandel	0.10%
		Triamcinolone Acetonide	0.10%	Prednicarbate	0.10%
				STEP2*Desoximetasone	0.05%
				STEP2*Flurandrenolide	0.05%
				STEP2*Hydrocortisone Butyrate STEP2*Hydrocortisone Butyrate	0.10%
				Emollient	0.10%
				STEP2*Hydrocortisone Valerate	0.20%
Je	Ointment	Fluocinolone Acetonide	0.025%	Desoximetasone	0.05%
1		Desonide	0.05%	Hydrocortisone Valerate	0.20%
s 3		Hydrocortisone Butyrate	0.10%	Trianex	0.05%
Class		Prednicarbate	0.10%	STEP2*Flurandrenolide	0.05%
0		Triamcinolone Acetonide	0.10%		
		Triamcinolone Acetonide	0.025%		
	Aerosol,	Mometasone Furoate Solution	0.10%	Betamethasone Valerate Foam	0.12%
		Betamethasone Dipropionate Lotion	0.05%	Triamcinolone Acetonide Aerosol	0.147MG/G
	Foam, Lotion,	Hydrocortisone Butyrate Solution	0.10%	STEP2*Flurandrenolide Lotion	0.05%
	Solution, Spray	Triamcinolone Acetonide Lotion	0.10%	STEP2*Fluticasone Propionate Lotion STEP2*Sernivo spray	0.05%
		Class 4	- Low Pote	(Betamethasone)	0.05%
Class 4 - Low Potency		Alclometasone Dipropionate	0.05%		
	Cream	Desonide	0.05%		
		Fluocinolone Acetonide	0.01%		
		Hydrocortisone	2.50%		
		Hydrocortisone	1.00%		
		Triamcinolone Acetonide	0.025%		
	Ointment	Alclometasone Dipropionate	0.05%		
		Hydrocortisone	1.00%		
		Hydrocortisone	2.50%		
	Oil,	Capex Shampoo	0.01%	Betamethasone Valerate Lotion	0.10%
		Desonide Lotion	0.05%		
		Fluocinolone Acetonide Oil	0.01%		
	Lotion, Shampoo,	Fluocinolone Acetonide Solution	0.01%		
	Solution	Hydrocortisone Lotion	2.50%		
		Texacort Solution	2.50%		
		Triamcinolone Acetonide Lotion	0.025%		

## **Clinic Administered Drugs**

#### Brineura

#### Initial Criteria: Approval Duration = 6 months

- Patient must be between 3 and 8 years of age.
- The patient must have diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency confirmed by the following:
  - A genetic test confirming CLN2 disease
  - An enzyme assay confirming deficiency of tripeptidyl peptidase 1 (TPP1)
- Brineura must be prescribed by or in consultation with a metabolic specialist, geneticist, or pediatric neurologist.
- Patient must not have ventriculoperitoneal shunts
- Baseline results of motor and language domains of the Hamburg CLN2 Clinical Rating Scale must be submitted and meet the following parameters
  - o Results must show a combined score of less than 6 in the motor and language domains
  - o Results must show a score of at least 1 in each of these domains

#### Renewal Criteria: Approval Duration = 12 months

- The patient must not have acute, unresolved localized infection on or around the device insertion site or suspected or confirmed CNS infection
- Patient maintains at a score of at least 1 in the motor domain on the Hamburg CLN2 Clinical Rating Scale
- The patient has responded to therapy compared to pretreatment baseline with stability/lack of decline\* in motor function/milestones
  - \*: Decline is defined as having an unreversed (sustained) 2-category decline or an unreversed score of 0 in the Motor domain of the CLN2 Clinical Rating Scale

### Spinraza

#### <u>Criteria</u>: Approval Duration = 12 months

- For a diagnosis of Spinal Muscular Atrophy (SMA) Type 1, 2, or 3:
  - The patient must not have respiratory insufficiency (need for invasive or noninvasive ventilation for more than 6 hours per 24-hour period)
  - o The patient must not require gastric feeding tubes for the majority of feeds
  - o The patient must not have severe contractures or severe scoliosis
  - The patient must not have wasting or cachexia
- For a diagnosis of Spinal Muscular Atrophy (SMA) Type 3:
  - The patient must be less than 2 years of age
  - The patient must be experiencing issues with ambulating (falls, trouble climbing stairs, unable to walk independently)

#### Synagis

Criteria: Approval Duration = 5 months (allows for 5 monthly doses between October 19th through April 21st)

Patient must have one of the following diagnoses (A, B, or C) and the additional criteria outlined for diagnosis:

#### A. Prematurity:

- < 29 weeks, 0 days gestational age</p>
- ≤12 months of age at start of RSV season

#### B. Chronic Lung Disease of Prematurity (CLD)

- ≤12 months of age at start of RSV season
  - < 32 weeks, 0 days gestational age</p>
  - Requires supplemental oxygen > 21% for at least the first 28 days after birth
- 13-24 months of age at start of RSV season

- < 32 weeks, 0 days gestational age</p>
- ❖ Requires supplemental oxygen > 21% for at least the first 28 days after birth
- Continues to receive medical support within six months before the start of RSV season with supplemental oxygen, diuretic, or chronic corticosteroid therapy

#### C. Congenital Heart Disease

- ≤12 months of age at start of RSV season
  - Hemodynamically significant cyanotic or acyanotic congenital heart disease with medical therapy required