Drug Coverage Policy

Effective Date..... 11/1/2024
Coverage Policy Number 1407

Pharmacy Prior Authorization

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for drugs and biologics for the following:

- Prior Authorization for Employer Group Plans and/or Individual and Family Plans where no other criteria or polices are specified
- Non-Formulary product-specific exception criteria for Individual and Family Plans

Cigna maintains individual and/or group topic Coverage Policies describing medical necessity criteria under pharmacy benefit plans. Use the Pharmacy Index search box with a specific product name to locate additional coverage policies and clinical criteria.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Drugs and biologics (not otherwise specified), in accordance with benefit plan specifications, are considered medically necessary when ONE of the following is met:

1. **BOTH** of the following criteria are met:
   A. **ONE** of the following:
      i. Indication for use is approved and listed in the FDA product information (Label) and the dosage, frequency, site of administration, and duration of therapy is not contraindicated or otherwise not recommended in the Label, OR
      ii. Use is supported according to standard medical reference compendia [for example, American Hospital Formulary Service (AHFS) compendium, and is not contraindicated in the Label

B. And where available, use of therapeutic alternatives unless otherwise specified or clinically inappropriate

   Prior use of all formulary or covered alternatives meets criteria, unless there are more than five alternatives available, where five will be the maximum required number of alternatives.

2. **Individual and Family Plan** product-specific criteria is met in below table

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When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Individual and Family Plan Product-Specific Criteria

Therapeutic Category	Product	Criteria
Actinic Keratosis Agents (Topical)	**Carac** (fluorouracil 0.5% cream)	**Carac cream** is considered medically necessary when the following criteria are met: **1.** Patient has tried **ONE** of the following: a. fluorouracil 2% solution b. fluorouracil 5% solution c. fluorouracil 5% cream
	Klisyri (tirbanibulin 1% ointment)	**Klisyri ointment** is considered medically necessary when the following criteria are met: **1.** Patient has tried **TWO** of the following: **a.** a fluorouracil-containing product (e.g., fluorouracil cream, Carac, fluorouracil topical solution) [may require prior authorization] **b.** an imiquimod-containing product (e.g., imiquimod 5% cream, Zyclara) [may require prior authorization] **c.** diclofenac 3% gel [may require authorization]
	imiquimod 3.75% (Zyclara authorized generic cream and cream pump)	**Imiquimod 3.75% (Zyclara authorized generic)** is considered medically necessary when the following criteria are met: **1.** Patient has tried imiquimod 5% cream

Therapeutic Category	Product	Criteria
	Zyclara (imiquimod 3.75% cream and cream pump)	**Zyclara 3.75%** is considered medically necessary when the following criteria are met: **1.** Patient has tried imiquimod 5% cream
	Zyclara (imiquimod 2.5% cream pump)	**Zyclara 2.5%** is considered medically necessary when the following criteria are met: **1.** Patient has tried imiquimod 5% cream
Acne Vulgaris Agents (Topical)	**adapalene** 0.1% cream	**Adapalene cream** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease).
	adapalene 0.1% lotion	**Adapalene lotion** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease).
	adapalene 0.1% solution	**Adapalene solution** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease).
	adapalene 0.1% swab	**Adapalene swab** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease).
	adapalene 0.3% gel, gel pump	**Adapalene gel** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease).
	adapalene-benzoyl peroxide 0.1-2.5% gel pump	**Adapalene-benzoyl peroxide 0.1-2.5% gel pump** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease).

Therapeutic Category	Product	Criteria
	adapalene-benzoyl peroxide 0.3-2.5% gel pump	**Adapalene-benzoyl peroxide 0.3-2.5% gel pump** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). **2.** Tried adapalene-benzoyl peroxide 0.1-2.5% gel pump [may require prior authorization]
	Altreno (tretinoin 0.05% lotion)	**Altreno** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). **2.** Tried to one topical tretinoin product [examples include: tretinoin gel/cream - may require prior authorization]
	Cabtreo™ (clindamycin/adapalene/benzoyl peroxide 1.2%/0.15%/3.1% gel)	**Cabtreo** is considered medically necessary when **BOTH** of the following are met: 1. Inability to use all **THREE** of the following products concurrently a. a topical benzoyl peroxide product b. a topical tretinoin-containing or adapalene-containing product c. a topical clindamycin-containing product concurrently 2. According to the prescriber, there is significant clinical concern such that the patient is unable to continue to use the products in criterion [1] above
	Differin (adapalene lotion 0.1%)	**Differin 0.1% lotion** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). **2.** Tried adapalene 0.1% gel, adapalene 0.3% gel, or adapalene 0.1% cream [may require prior authorization]
	Epiduo Forte (adapalene-benzoyl peroxide 0.3-2.5% gel pump)	**Epiduo Forte gel pump** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example,

Therapeutic Category	Product	Criteria
		ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). **2.** Tried adapalene-benzoyl peroxide 0.1-2.5% gel pump [may require prior authorization]
	Retin-A Micro Pump (tretinoin 0.06% gel)	**Retin-A Micro Pump 0.06% gel** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). **2.** Tried tretinoin micro 0.04% or 0.1% gel [may require prior authorization]
	tretinoin 0.025%, 0.05%, 0.1% cream	**Tretinoin cream** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease).
	tretinoin 0.01%, 0.025%, 0.05% gel	**Tretinoin gel** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease).
	tretinoin gel micro 0.04%, 0.1% pump	**Tretinoin micro gel** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease).
	tretinoin gel micro 0.08% pump	**Tretinoin gel micro 0.08% pump** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). **2.** Tried tretinoin micro 0.04% or 0.1% gel [may require prior authorization]

Therapeutic Category	Product	Criteria
	tretinoin gel micro 0.04%, 0.1% tube	**Tretinoin micro gel** is considered medically necessary when the following criteria are met: **1. Treatment of Acne Vulgaris or Other <u>Non</u>-Cosmetic Conditions** (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease).
Antibiotics (Oral)	**Likmez**™ (metronidazole oral suspension)	**Likmez** is considered medically necessary when the individual meets **ONE** of the following: 1. Intolerance to metronidazole tablets 2. Inability to swallow tablets
	tetracycline 250 mg oral tablet	**Tetracycline 250 mg tablet** is considered medically necessary when there is intolerance to tetracycline 250 mg capsules.
	tetracycline 500 mg oral tablet	**Tetracycline 500 mg tablet** is considered medically necessary when there is intolerance to tetracycline 500 mg capsules.
Antidepressants - Other	**Aplenzin®** (bupropion hydrobromide extended-release tablets)	**Aplenzin tablets** are considered medically necessary when the following criteria are met: 1. Patient has tried one bupropion hydrochloride extended release tablets product (Wellbutrin XL, generics)
	Auvelity® (dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets)	**Auvelity tablets** are considered medically necessary when **ONE** of the following criteria are met: 1. Patient has tried at least two different antidepressants, one of which is bupropion and one additional antidepressant 2. Patient has suicidal ideation 3. Patient is currently taking or has taken Auvelity at any time in the past
	Forfivo® XL (bupropion hydrochloride extended-release tablets)	**Forfivo XL tablets** are considered medically necessary when the following criteria are met: 1. There is a significant clinical concern such that the patient is unable to use the buproprion hydrochloride XL 150 mg and/or 300 mg tablets (Wellbutrin XL, generics).
	bupropion hydrochloride 450 mg extended-release tablets	**Bupropion hydrochloride 450 mg extended-release tablets** are considered medically necessary when the following criteria are met: 1. There is a significant clinical concern such that the patient is unable to use the buproprion hydrochloride XL 150 mg

Therapeutic Category	Product	Criteria
		and/or 300 mg tablets (Wellbutrin XL, generics).
Antiemetics - Serotonin (5-HT3) Receptor Antagonists (Oral)	**ondansetron ODT** 16 mg	**Ondansetron ODT 16 mg** is considered medically necessary when the patient is unable to obtain ondansetron ODT 4 mg **AND** ondansetron ODT 8 mg.
Antiemetics - Serotonin (5-HT3) Receptor Antagonists (Injectable)	**Posfrea™** (palonosetron intravenous injection)	**Posfrea** is considered medically necessary when the patient has tried and cannot take generic palonosetron injection.
Antiemetic Agents - Substance P/Neurokinin-1 (NK1) receptor antagonists (Injectable)	**Focinvez™** (fosaprepitant injection)	**Focinvez** is considered medically necessary when **ONE** of the following is met: 1. Patient has tried generic fosaprepitant dimeglumine injection (IV) (generic for Emend for injection) 2. Patient has hypersensitivity to polysorbate 80 3. Patient has already started Focinvez IV to complete all cycles in the current course of chemotherapy.
Antihistamines (oral) - First-generation	**carbinoxamine** maleate 4 mg/5 ml oral suspension	**Carbinoxamine** is considered medically necessary when **EITHER** the following criteria are met: 1. Patient has tried **FIVE** oral antihistamines (e.g., clemastine, diphenhydramine, chlorpheniramine, hydroxyzine, cetirizine, loratadine) Note: OTC products count toward meeting the requirement. 2. Patient is unable to swallow or has difficulty swallowing solid dosage forms **AND** has tried at least two oral liquid antihistamines (e.g., diphenhydramine solution, hydroxyzine solution or syrup, clemastine syrup, cetirizine solution, or loratadine solution or syrup).
Antihistamines (oral) - First-generation	**Karbinal ER** (carbinoxamine maleate 4 mg/5 ml oral suspension)	**Karbinal ER** is considered medically necessary when **EITHER** the following criteria are met: 1. Patient has tried **FIVE** oral antihistamines (e.g., clemastine, diphenhydramine, chlorpheniramine, carbinoxamine (generic), hydroxyzine, cetirizine, loratadine) Note: OTC products count toward meeting the requirement.

Therapeutic Category	Product	Criteria
		2. Patient is unable to swallow or has difficulty swallowing solid dosage forms **AND** has tried at least two oral liquid antihistamines (e.g., diphenhydramine solution, hydroxyzine solution or syrup, clemastine syrup, cetirizine solution, or loratadine solution or syrup).
Antiparasitic	**Xdemvy**™ (lotilaner ophthalmic solution)	**Xdemvy** is considered medically necessary for a documented diagnosis of Demodex blepharitis.
Antiseizure Medications - Buccal	**Libervant**™ (diazepam buccal film strips)	**Libervant** is considered medically necessary when **EITHER** of the following criteria are met: 1. Patient has tried diazepam rectal gel (Diastat generics) Note: If the patient has tried a benzodiazepine nasal spray (e.g., Valtoco or Nayzilam), this would satisfy the requirement for approval 2. Patient's caregiver is unable to administer diazepam rectal gel (Diastat generics)
Antiseizure Medications	**Xcopri** (cenobamate tablets)	**Xcopri** is considered medically necessary when ONE of the following criteria are met: 1. Patient has tried (3) other antiepileptic agents. Note: Examples include lacosamide (Vimpat tablets or oral solution), topiramate (Topamax, generics), lamotrigine (Lamictal, generics), gabapentin (Neurontin, generics), zonisamide (Zonegran, generics), pregabalin (Lyrica), oxcarbazepine (Trileptal, generics), levetiracetam (Keppra, Keppra XR, generics), divalproex sodium (Depakote, Depakote ER, generics), carbamazepine (Tegretol, Tegretol XR, generics), Spritam, Fycompa, Briviact, Qudexy XR, Trokendi XR, Oxtellar XR. 2. Patient has been started on Xcopri or has taken Xcopri in the past
Beta-Blocker and Beta-Blocker Combination Products	**Innopran® XL** (propranolol hydrochloride capsule, extended release)	**Innopran XL** is considered medically necessary when **EITHER** of the following criteria are met: 1. Patient has tried propranolol extended-release capsules 2. According to the prescriber, there is a significant clinical concern such that the patient is unable to use generic propranolol extended-release capsules.

Therapeutic Category	Product	Criteria
	Inderal® LA (propranolol HCl ER capsules)	**Inderal LA** is considered medically necessary when the patient has tried the bioequivalent generic product, **propranolol HCl ER capsules**, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction.
	Inderal® XL (propranolol hydrochloride capsule, extended release)	**Inderal XL** is considered medically necessary when **EITHER** of the following criteria are met: 1. Patient has tried propranolol extended-release capsules 2. According to the prescriber, there is a significant clinical concern such that the patient is unable to use generic propranolol extended-release capsules.
	Kapspargo™ Sprinkle (metoprolol succinate extended-release capsules)	**Kapspargo Sprinkle** is considered medically necessary when **EITHER** of the following criteria are met: 1. Patient has tried metoprolol succinate extended-release tablets **2.** Patient requires a dosage form which can be opened and sprinkled for alternative administration (e.g., for patients unable to swallow capsules, for nasogastric tube administration), approve.
Bowel Evacuants – Low Volume – Polyethylene Glycol (PEG)-based Preparations	**Suflave™** (polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride for oral solution)	**Sulfave** is considered medically necessary when there is documentation of **EITHER** of the following: 1. Failure, contraindication or intolerance to either PEG3350/Ascorbic Acid powder pack (generic Moviprep) **OR** Sodium Sulfate-Potassium Sulfate-Magnesium prep kit (generic Suprep) [prior authorization may be required] 2. Use is for bowel preparation as part of a colorectal screening procedure in an individual between the ages of 45 and 75 years of age **AND** neither PEG3350/Ascorbic Acid powder pack (generic Moviprep) **OR** Sodium Sulfate-Potassium Sulfate-Magnesium prep kit (generic Suprep) [prior authorization may

Therapeutic Category	Product	Criteria
		be required] will be as medically appropriate as Suflave
Calcium Channel Blockers (CCBs)	**Katerzia®** (amlodipine oral suspension)	**Katerzia** is considered medically necessary when the patient is unable to swallow or has difficulty swallowing amlodipine tablets.
	Norliqva® (amlodipine oral solution)	**Norliqva** is considered medically necessary when the patient is unable to swallow or has difficulty swallowing amlodipine tablets.
Cardiovascular Medications - Other	**Multaq®** (dronedarone tablets)	**Multaq** is considered medically necessary when there is documentation of **ONE** of the following: 1. Patient has tried **ONE** of the following: dofetilide capsules (Tikosyn generics), flecainide (generics), propafenone ER (generics) 2. According to the prescriber, patient is not a candidate for dofetilide capsules (Tikosyn generics), flecainide (generics), propafenone ER (generics) 3. Patient has tried **ONE** of the following: sotalol or amiodarone 4. Patient is currently taking Multaq
Central Nervous System/Autonomic Drugs	**Opvee®** (nalmefene nasal spray)	**Opvee** is considered medically necessary when there is documentation of failure, contraindication or intolerance to **ONE** naloxone-containing product (for example, naloxone syringes, naloxone nasal spray).
Central Nervous System/Autonomic Drugs – Naloxone nasal sprays	**Rextovy™** (naloxone hydrochloride 4 mg nasal spray)	**Rextovy** is considered medically necessary when **EITHER** of the following criteria are met: 1. Patient has tried one product from the following list: naloxone nasal spray (Narcan nasal spray, generics) or naloxone syringes (without a needle concentrated at 1 mg/mL or greater) used with a nasal/mucosal atomizer Note: If the patient tried a prescription or over the counter (OTC) naloxone nasal spray (e.g., naloxone nasal spray, Narcan, or ReVive), this would count toward an approval of the requested agent. 2. If a nasal/mucosal atomization device is not available from the pharmacy OR the patient or caregiver is unable to use a naloxone syringe (either as an injection or nasally with an atomizer), approve if the

Therapeutic Category	Product	Criteria
		patient has tried naloxone nasal spray (Narcan nasal spray, generics). Note: If the patient tried a prescription or over the counter (OTC) naloxone nasal spray (e.g., naloxone nasal spray, Narcan, or ReVive), this would count toward an approval of the requested agent.
Constipation Agents – Chronic Idiopathic Constipation Agents	**Trulance®** (plecanatide tablets)	**Trulance** is considered medically necessary when there is documentation of **ALL** of the following: 1. Age 18 years or older 2. Documented diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) 3. Documentation of failure, contraindication or intolerance to linaclotide (Linzess®)
Corticosteroids (Topical)	**Hydrocortisone** 2% lotion	**Hydrocortisone 2% lotion** is considered medically necessary when the patient has tried **BOTH** of the following: 1. hydrocortisone 2.5% lotion 2. hydrocortisone cream or ointment (1% or 2.5%)
Diabetes Agents – Insulin (Basal)	**Insulin glargine, Insulin Glargine SoloStar** 100 units/ mL	**Insulin glargine, Insulin Glargine SoloStar 100 units/ mL** are considered medically necessary when the patient has tried Basaglar (insulin glargine).
	Insulin glargine-YFGN 100 units/ mL (Semglee-YFGN authorized generic)	**Insulin glargine-yfgn 100 units/ mL (Semglee-yfgn authorized generic)** is considered medically necessary when the patient has tried Basaglar (insulin glargine).
	Insulin glargine Max SoloStar U300 300 units/ mL (Toujeo Max SoloStar authorized generic)	**Insulin glargine Max Solostar U300 300 units/mL (Toujeo Max SoloStar authorized generic)** is considered medically necessary when **ONE** of the following is met (1, 2, 3, or 4): 1. Type 2 Diabetes, (initial user) **OR** taking Insulin glargine U300 < 100 Units/injection (and all others taking < 100 units/injection) **AND** the patient has tried Basaglar (insulin glargine) 2. Type 2 Diabetes, Continuation of Therapy with Insulin glargine U300 ≥ 100 units per injection (and all others taking ≥ 100 units per injection)

Therapeutic Category	Product	Criteria
		3. Type 1 Diabetes (initial user) AND the patient has tried Basaglar (insulin glargine) 4. Type 1 Diabetes, Continuation of Therapy with Insulin glargine U300 and patient meets ONE of the following (a or b): a. Patient has tried Basaglar (insulin glargine) b. Patient is currently receiving an Insulin glargine U300 dose of ≥ 100 units per injection
	Lantus, Lantus SoloStar (insulin glargine U-100)	**Lantus, Lantus SoloStar (insulin glargine U-100)** are considered medically necessary when the patient has tried Basaglar (insulin glargine).
	Rezvoglar Kwikpen (insulin glargine-aglr 100 units/ mL)	**Rezvoglar Kwikpen** is considered medically necessary when the patient has tried Basaglar (insulin glargine).
	Semglee-yfgn (insulin glargine U-100)	**Semglee-yfgn (insulin glargine U-100)** is considered medically necessary when the patient has tried Basaglar (insulin glargine).
	Toujeo SoloStar, Toujeo Max SoloStar (insulin glargine U-300)	**Insulin glargine Max Solostar U300 300 units/mL (Toujeo Max SoloStar authorized generic)** is considered medically necessary when **ONE** of the following is met (1, 2, 3, or 4): 1. Type 2 Diabetes, (initial user) **OR** taking Insulin glargine U300 < 100 Units/injection (and all others taking < 100 units/injection) **AND** the patient has tried Basaglar (insulin glargine) 2. Type 2 Diabetes, Continuation of Therapy with Insulin glargine U300 ≥ 100 units per injection (and all others taking ≥ 100 units per injection) 3. Type 1 Diabetes (initial user) AND the patient has tried Basaglar (insulin glargine) 4. Type 1 Diabetes, Continuation of Therapy with Insulin glargine U300 and patient meets ONE of the following (a or b): a. Patient has tried Basaglar (insulin glargine)

Therapeutic Category	Product	Criteria
		b. Patient is currently receiving an Insulin glargine U300 dose of ≥ 100 units per injection
Diabetes Agents - Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	**sitagliptin** 100 mg, 50 mg, 25 mg tablets	**Sitagliptin** is considered medically necessary when **ONE** of the following is met: 1. Patient has tried saxagliptin (Onglyza) 2. Patient with a history of heart failure or history of renal impairment
		EFFECTIVE 1/1/2025 **Sitagliptin** is considered medically necessary when the patient has tried Januvia.
	sitagliptin-metformin oral tablet	**Sitagliptin-metformin tablet** is considered medically necessary when **ONE** of the following criteria are met: 1. Patient has tried saxagliptin-metformin ER (Kombiglyze XR generic) 2. Patient with a history of heart failure (HF) or renal impairment and has tried metformin.
		EFFECTIVE 1/1/2025 **Sitagliptin-metformin tablet** is considered medically necessary when **ONE** of the following criteria are met: 1. Patient has tried ALL of the following: a. saxagliptin-metformin ER (Kombiglyze XR generic) b. Janumet XR c. Jentadueto or Jentadueto XR 2. Patient with a history of heart failure (HF) or renal impairment and has tried Janumet XR.
	Zituvio™ (sitagliptin tablets)	**Zituvio** is considered medically necessary when **ONE** of the following is met: 1. Patient has tried saxagliptin (Onglyza) 2. Patient with a history of heart failure or history of renal impairment
		EFFECTIVE 1/1/2025 **Zituvio** is considered medically necessary when the patient has tried Januvia.
Diabetes Agents – Sulfonylurea	**glipizide** 2.5mg IR tablet	**Glipizide 2.5mg IR tablet** is considered medically necessary when there is documentation that the individual cannot obtain the prescribed dose with glipizide 5mg IR tablet.

Therapeutic Category	Product	Criteria
Direct Muscle Relaxants – Baclofen Agents	**baclofen** 15 mg tablet	**Baclofen** is considered medically necessary, when according to the prescriber, there is significant clinical concern such that the individual is unable to use baclofen 5 mg, 10 mg, or 20 mg tablets.
Estrogen Combination Products (Oral)	**Bijuva** (estradiol and progesterone capsules)	**Bijuva** is considered medically necessary when there is documentation of **ALL** of the following: 1. For the treatment of moderate to severe vasomotor symptoms due to menopause 2. Failure, contraindication or intolerance to **BOTH** of the following: a. **ONE** of the following: Amabelz, estradiol-norethindrone, or Mimvey b. **ONE** of the following: Jinteli, Fyavolv, or norethindrone-ethinyl estradiol
	Estratest FS (esterified estrogens 1.25 mg and methyltestosterone 2.5 mg tablets)	**Estratest FS** is considered medically necessary when the following are met: 1. Patient has tried **TWO** equivalent products (Covaryx, EEMT DS 1.25 mg-2.5 mg, and Esterified Estrogens and Methyltestosterone FS) AND cannot take due to a formulation difference in the inactive ingredients (for example, difference in dyes, fillers, preservatives) between the Estratest FS and the equivalent strength products which, per the prescriber, would result in a significant allergy or serious adverse reaction. Note: A non-covered product is being requested. The patient should use the preferred equivalent strength products.
Gabapentin and Gabapentin-Like Medications	**gabapentin** extended-release tablets 300 mg, 600 mg	**Gabapentin extended-release tablet** is considered medically necessary when there is the following: 1. Tried **ONE** of the following: gabapentin capsules/ tablets (Neurontin generics), pregabalin capsules (Lyrica generics)
	Gralise (gabapentin extended-release tablets)	**Gralise** is considered medically necessary when there is the following: 1. Tried **ONE** of the following: gabapentin capsules/ tablets (Neurontin generics), pregabalin capsules (Lyrica generics)
Gout Medications	**allopurinol 200 mg** tablet	**Allopurinol 200 mg tablet** is considered medically necessary when, when according to the

Therapeutic Category	Product	Criteria
		prescriber, there is a significant clinical concern such that the patient is unable to use allopurinol 100 mg or 300 mg tablets.
Immunosuppressant Agents	**Myhibbin™** (mycophenolate mofetil oral suspension)	**Myhibbin** is considered medically necessary when the patient has tried **mycophenolate mofetil oral suspension (Cellcept powder for oral suspension generic)** AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between Myhibbin and mycophenolate mofetil oral suspension (Cellcept powder for oral suspension generic) which, per the prescriber, would result in a significant allergy or serious adverse reaction.
Immunosuppressant Agents – Oral Methotrexate Agents	**Jylamvo®** (methotrexate 2 mg/mL oral solution)	**Jylamvo** is considered medically necessary when there is documentation of **ONE** of the following: 1. Inability to swallow, or has difficulty swallowing, oral generic methotrexate tablets 2. The dose prescribed cannot be obtained using whole generic methotrexate 2.5 mg tablets
	Trexall® (methotrexate tablets)	**Trexall** is considered medically necessary when there is documentation of failure, contraindication or intolerance to generic methotrexate 2.5 mg tablets.
	Xatmep® (methotrexate 2.5 mg/mL oral solution)	**Xatmep** is considered medically necessary when there is documentation of **ONE** of the following: 1. Inability to swallow, or has difficulty swallowing, oral generic methotrexate tablets 2. The dose prescribed cannot be obtained using whole generic methotrexate 2.5 mg tablets
Inflammatory Conditions	**Sovuna™** (hydroxychloroquine sulfate 200 mg tablet)	**Sovuna** is considered medically necessary when the patient has tried generic hydroxychloroquine sulfate 200 mg tablets.
Isotretinoin Products	**Absorica®** (isotretinoin 10 mg, 20 mg, 30 mg, 40 mg capsules)	The patient has tried the bioequivalent generic product, **isotretinoin**, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic

Therapeutic Category	Product	Criteria
		product which would result, per the prescriber, in a significant allergy or serious adverse reaction.
	Absorica® (isotretinoin 25 mg, 35 mg capsules)	**Absorica capsules** are considered medically necessary when the following criteria are met: 1. Patient has tried **THREE** of the following: a. Accutane b. Amnesteem c. Claravis d. Myorisan e. Zenatane
	Absorica LD® (isotretinoin low dose 8 mg, 16 mg, 20 mg, 24 mg, 28 mg, 32 mg capsules)	**Absorica LD capsules** are considered medically necessary when the following criteria are met: 1. Patient has tried **THREE** of the following: a. Accutane b. Amnesteem c. Claravis d. Myorisan e. Zenatane
	isotretinoin 25 mg, 35 mg capsules	**Isotretinoin capsules** are considered medically necessary when the following criteria are met: 1. Patient has tried **THREE** of the following: a. Accutane b. Amnesteem c. Claravis d. Myorisan e. Zenatane
Loop Diuretics	**Furoscix®** (furosemide subcutaneous injection by on-body infusor)	**Furoscix** is considered medically necessary when the following are met: 1. For the treatment of congestion due to fluid overload in a patient ≥ 18 years of age with chronic heart failure. 2. Patient has tried at least one loop diuretic, or the patient is currently taking a loop diuretic. Note: Examples of loop diuretics include furosemide, bumetanide, torsemide.
Neurokinin-3 Antagonists	**Veozah™** (fezolinetant tablets)	**Veozah** is considered medically necessary when there is documentation of **BOTH** of the following: 1. **ONE** of the following: A. Failure or intolerance to one oral or topical estrogen-containing product (for example, estradiol tablets, estradiol patches, estradiol gel) B. Contraindication to hormone therapy (current or history of an

Therapeutic Category	Product	Criteria
		estrogen-dependent cancer, current or history of deep vein thrombosis or pulmonary embolism, current or history of thrombophilic disorders, current or history of cardiovascular disorders) 2. **ONE** of the following: A. Failure or intolerance to paroxetine 7.5 mg (formerly Brisdelle) [prior authorization may be required] B. Individual is already taking either a selective serotonin reuptake inhibitor OR a serotonin and norepinephrine reuptake inhibitor C. Contraindication to a selective serotonin reuptake inhibitor
NSAIDs (Oral)	**Indocin** (indomethacin) 25 mg/ 5 mL oral suspension	**Indocin oral suspension** is considered medically necessary when there is **BOTH** of the following: 1. Inability to swallow indomethacin 25 mg or 50 mg capsules 2. Tried ibuprofen 100 mg/5 mL oral suspension (e.g., Motrin, generics)
	indomethacin 25 mg/ 5 mL oral suspension	**Indomethacin oral suspension** is considered medically necessary when there is **BOTH** of the following: 1. Inability to swallow indomethacin 25 mg or 50 mg capsules 2. Tried ibuprofen 100 mg/5 mL oral suspension (e.g., Motrin, generics)
	Kiprofen™ (ketoprofen 25mg capsules)	**Kiprofen** is considered medically necessary when there is the following: 1. Failure, contraindication, or intolerance to **FIVE** generic prescription-strength non-steroidal anti-inflammatory drugs (NSAIDs) [examples include: ketoprofen 50 mg or 75 mg, meloxicam, diclofenac, ibuprofen, naproxen]
Ophthalmic Anti-Allergics	**Alrex®** (loteprednol etabonate 0.2% ophthalmic suspension)	**Alrex** is considered medically necessary when there is **ONE** of the following: 1. Patient has tried **THREE** of the following: A. azelastine 0.05% ophthalmic solution B. epinastine 0.05% ophthalmic solution C. cromolyn ophthalmic drops D. olopatadine ophthalmic solution E. bepotastine ophthalmic drops [may require prior authorization]

Therapeutic Category	Product	Criteria
		2. Patient requires concurrent use of Alrex with an H1 antagonist or an H1 antagonist/ mast cell stabilizer (e.g., azelastine [generics], bepotastine, epinastine solution [generics], Lastacaft, olopatadine ophthalmic solution [generics], Zerviate)
	loteprednol etabonate 0.2% ophthalmic suspension	**Loteprednol** is considered medically necessary when there is **ONE** of the following: 1. Patient has tried **THREE** of the following: A. azelastine 0.05% ophthalmic solution B. epinastine 0.05% ophthalmic solution C. cromolyn ophthalmic drops D. olopatadine ophthalmic solution E. bepotastine ophthalmic drops [may require prior authorization] 2. Patient requires concurrent use of loteprednol with an H1 antagonist or an H1 antagonist/ mast cell stabilizer (e.g., azelastine [generics], bepotastine, epinastine solution [generics], Lastacaft, olopatadine ophthalmic solution [generics], Zerviate)
Ophthalmic Anti-Inflammatory Agents -NSAIDs	**bromfenac** 0.07% ophthalmic solution	**Bromfenac 0.07% ophthalmic solution** is considered medically necessary when the patient has had failure, contraindication, or intolerance to **TWO** of the following: 1. diclofenac 0.1% ophthalmic solution 2. ketorolac 0.5% ophthalmic solution 3. bromfenac 0.09% ophthalmic solution
	bromfenac 0.075% ophthalmic solution	**Bromfenac 0.075% ophthalmic solution** is considered medically necessary when there is **EITHER** of the following: 1. Failure, contraindication, or intolerance to **TWO** of the following: A. diclofenac ophthalmic solution B. ketorolac ophthalmic solution C. bromfenac 0.09% ophthalmic solution 2. Patient has sulfite hypersensitivity **AND** has failure, contraindication, or intolerance to **TWO** of the following: A. diclofenac ophthalmic solution B. ketorolac ophthalmic solution
	BromSite (bromfenac) 0.075% ophthalmic solution	**Bromsite** is considered medically necessary when there is **EITHER** of the following: 1. Failure, contraindication, or intolerance to **TWO** of the following: A. diclofenac ophthalmic solution

Therapeutic Category	Product	Criteria
		B. ketorolac ophthalmic solution C. bromfenac 0.09% ophthalmic solution 2. Patient has sulfite hypersensitivity **AND** has failure, contraindication, or intolerance to **TWO** of the following: A. diclofenac ophthalmic solution B. ketorolac ophthalmic solution
	Ilevro® (nepafenac ophthalmic suspension 0.3%)	**Ilevro** is considered medically necessary when there is **ONE** of the following: 1. Patient has tried **TWO** of the following: A. diclofenac ophthalmic solution B. ketorolac ophthalmic solution C. bromfenac 0.09% ophthalmic solution 2. Patient has sulfite hypersensitivity AND has tried TWO of the following: A. diclofenac ophthalmic solution B. ketorolac ophthalmic solution 3. Patient is less than age 18 years AND has tried ketorolac ophthalmic solution
	Nevanac® (nepafenac ophthalmic suspension 0.1%)	**Nevanac** is considered medically necessary when there is **ONE** of the following: 1. Patient has tried **TWO** of the following: A. diclofenac ophthalmic solution B. ketorolac ophthalmic solution C. bromfenac 0.09% ophthalmic solution 2. Patient has sulfite hypersensitivity AND has tried TWO of the following: A. diclofenac ophthalmic solution B. ketorolac ophthalmic solution 3. Patient is less than age 18 years AND has tried ketorolac ophthalmic solution
Oral Agents for Rosacea	**doxycycline monohydrate** IR 40 mg capsules	**Doxycycline monohydrate IR 40 mg capsules** are considered medically necessary when the following criteria are met: 1. **Rosacea**. Approve if the patient meets **BOTH** of the following (A and B): A. Patient has failure, contraindication, or intolerance to **TWO** of the following: 1) a topical metronidazole-containing product, 2) a topical azelaic acid-containing product or 3) topical ivermectin; AND B. Patient meets **ONE** of the following (i or ii): i. Patient has tried, and according to the prescriber, has

Therapeutic Category	Product	Criteria
		experienced failure with one other generic, oral doxycycline product after a 4-week duration with the product; OR ii. Patient has tried, and according to the prescriber, has experienced a significant intolerance with one other generic, oral doxycycline product.
	Oracea (doxycycline 40 mg capsules)	**Oracea capsules** are considered medically necessary when the following criteria are met: 1. **Rosacea**. Approve if the patient meets **BOTH** of the following (A and B): A. Patient has failure, contraindication, or intolerance to **TWO** of the following: 1) a topical metronidazole-containing product, 2) a topical azelaic acid-containing product or 3) topical ivermectin; AND B. Patient meets **ONE** of the following (i or ii): i. Patient has tried, and according to the prescriber, has experienced failure with one other generic, oral doxycycline product after a 4-week duration with the product; OR ii. Patient has tried, and according to the prescriber, has experienced a significant intolerance with one other generic, oral doxycycline product.
Oral Fluoride Preparations	**Clinpro 5000** (1.1% sodium fluoride toothpaste)	**Clinpro 5000** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste, sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect

Therapeutic Category	Product	Criteria
		1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Fraiche 5000 Previ (1.1%-3% sodium fluoride/ hydroxyapatite gel)	**Fraiche 5000 Previ** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste, sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect 1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Fraiche 5000 Sensitive (1.1%-4.5% sodium fluoride/ potassium nitrate gel)	**Fraiche 5000 Sensitive** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste, sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect 1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Just Right 5000 (1.1% sodium fluoride toothpaste)	**Just Right 5000** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste, sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect

Therapeutic Category	Product	Criteria
		1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Prevident (1.1% sodium fluoride gel)	**Prevident** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste, sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect 1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Prevident Kids 5000 PPM (sodium fluoride paste)	**Prevident Kids 5000 PPM** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste, sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect 1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Prevident 5000 Booster Plus (sodium fluoride)	**Prevident 5000 Booster Plus** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste,

Therapeutic Category	Product	Criteria
		sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect 1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Prevident Dry Mouth (sodium fluoride)	**Prevident Dy Mouth** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste, sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect 1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Prevident Orthodefense (sodium fluoride)	**Prevident Orthodefense** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste, sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect 1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Prevident 5000 Plus (sodium fluoride)	**Prevident 5000 Plus** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste,

Therapeutic Category	Product	Criteria
		sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect 1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Prevident Rinse 0.2% (sodium fluoride)	**Prevident Rinse 0.2%** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste, sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect 1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Prevident 5000 Sensitive (sodium fluoride/ potassium nitrate paste)	**Prevident 5000 Sensitive** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream, sodium fluoride 1.1% cream, gel, paste, sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect 1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
	Prevident 5000 Enamel (sodium fluoride/ potassium nitrate paste)	**Prevident 5000 Enamel** is considered medically necessary when the following criteria are met: 1. Patient has tried **FIVE** generic formulations of covered fluoride sodium products (for example, Dentagel 1.1% gel, Denta 5000 Plus 1.1% cream, Fluoridex 1.1% paste, Fluoridex Sensitivity Relief 1.1%-5% paste, SF 1.1%, SF 5000 Plus 1.1% cream,

Therapeutic Category	Product	Criteria
		sodium fluoride 1.1% cream, gel, paste, sodium fluoride 5000 Dry Mouth 1.1% paste, sodium fluoride enamel protect 1.1%-5% paste, sodium fluoride sensitive 1.1%-5% paste) AND cannot take due to a formulation difference in the inactive ingredient(s) which resulted in a significant allergy or serious adverse reaction.
Overactive Bladder Agents – Selective Beta-3 Adrenergic Receptor Agonists	**mirabegron** extended- release tablets	**Mirabegron** is considered medically necessary when **ONE** of the following criteria are met: 1. Patient is greater than age 65 years 2. Patient is less than age 18 years and has tried **ONE** of oxybutynin solution/ syrup/ tablet 3. Patient has tried, and according to the prescriber, inadequate efficacy, or significant intolerance to **ONE** of the following: A. darifenacin ER B. oxybutynin ER C. solifenacin D. tolterodine ER Note: If patient has tried an immediate-release version of an extended-release product, then trial of an extended-release product is not required.
	Myrbetriq (mirabegron extended-release tablets)	**Myrbetriq** is considered medically necessary when the patient has tried the bioequivalent generic product, **mirabegron extended-release tablets [may require prior authorization]**, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result , per the prescriber, in a significant allergy or serious adverse reaction.
	Myrbetriq granules (mirabegron for extended-release oral suspension)	**Myrbetriq granules** are considered medically necessary when **ONE** of the following criteria are met: 1. Patient is less than age 5 years 2. Patient has tried oxybutynin solution/ syrup Note: If patient has tried any oxybutynin-containing product (for example, immediate-release or extended-release

Therapeutic Category	Product	Criteria
		tablets), then this meets the requirement for a trial of an oxybutynin product.
	Gemtesa (vibegron tablets)	**Gemtesa** is considered medically necessary when **ONE** of the following criteria are met: 1. Patient is greater than age 65 years **and** has tried mirabegron [may require prior authorization] 2. Patient has inadequate efficacy or significant intolerance to **ONE** of the following: A. darifenacin ER B. fesoterodine ER [may require prior authorization] C. oxybutynin ER D. solifenacin E. tolterodine ER Note: If patient has tried an immediate-release version of an extended-release product, then trial of an extended-release product is not required.
Potassium Sparing Diuretics	**Carospir®** (spironolactone 25mg/5 mL oral suspension)	**Carospir** is considered medically necessary when there is documentation of **ONE** of the following: 1. Failure, contraindication or intolerance to spironolactone tablets 2. Inability to swallow spironolactone tablets
	spironolactone 25mg/mL oral suspension	**Spironolactone 25mg/5 mL oral suspension** is considered medically necessary when there is documentation of **ONE** of the following: 1. Failure, contraindication or intolerance to spironolactone tablets 2. Inability to swallow spironolactone tablets
Potassium Supplement	**Pokonza™** (potassium chloride powder, for solution)	Documented inability to use **ONE** other oral potassium chloride product (for example, potassium chloride powder for oral solution, potassium chloride oral solution)
Respiratory - Corticosteroid/Beta-Agonist Combination Inhalers	**Airsupra™** (albuterol and budesonide inhalation aerosol)	**Airsupra** is considered medically necessary when there is documentation of **BOTH** of the following: 1. Failure, contraindication or intolerance to **ONE** of the following: A. Breyna (budesonide/formoterol) B. budesonide/formoterol (Symbicort generic) C. Dulera (mometasone/formoterol)

Therapeutic Category	Product	Criteria
		2. Failure, contraindication or intolerance to **ONE** albuterol-containing inhaler **OR** levalbuterol-containing inhaler taken concomitantly with one single-entity inhaled corticosteroid
Thyroid Supplements	**Ermeza**™ (levothyroxine sodium oral solution)	**Ermeza** is considered medically necessary when there is **ONE** of the following: 1. Tried **FIVE** formulary levothyroxine products: a. levothyroxine (Synthroid generics) b. Levoxyl (generics) c. Unithroid (generics) d. Euthyrox (generics) e. Levo-T (generics) 2. Patient has an inability to swallow tablets/ capsules.
	levothyroxine capsules (Tirosint® generic)	**Levothyroxine** is considered medically necessary when there is the following: 1. Tried **FIVE** formulary levothyroxine products: A. levothyroxine (Synthroid generics) B. Levoxyl (generics) C. Unithroid (generics) D. Euthyrox (generics) E. Levo-T (generics)
	Thyquidity® (levothyroxine sodium oral solution)	**Thyquidity** is considered medically necessary when there is **ONE** of the following: 1. Tried **FIVE** formulary levothyroxine products: A. levothyroxine (Synthroid generics) B. Levoxyl (generics) C. Unithroid (generics) D. Euthyrox (generics) E. Levo-T (generics) 2. Patient has an inability to swallow tablets/ capsules.
	Tirosint® (levothyroxine capsules)	**Tirosint** is considered medically necessary when there is the following: 1. Tried **FIVE** formulary levothyroxine products: A. levothyroxine (Synthroid generics) B. Levoxyl (generics) C. Unithroid (generics) D. Euthyrox (generics) E. Levo-T (generics)

Therapeutic Category	Product	Criteria
	Tirosint®-SOL (levothyroxine oral solution)	**Tirosint-SOL** is considered medically necessary when there is **ONE** of the following: 1. Tried **FIVE** formulary levothyroxine products: A. levothyroxine (Synthroid generics) B. Levoxyl (generics) C. Unithroid (generics) D. Euthyrox (generics) E. Levo-T (generics) 2. Patient has an inability to swallow tablets/ capsules
Thyroid Supplements - Desiccated Thyroid Supplements	**Adthyza®** (thyroid tablets, USP) 15mg, 16.25 mg, 30 mg, 32.5 mg, 60 mg, 65 mg, 90 mg, 97.5 mg, 120 mg, 130 mg	**Adthyza** is considered medically necessary when there is **ONE** of the following: 1. Tried **ONE** levothyroxine product (e.g., levothyroxine, Levoxyl) AND **ONE** other desiccated thyroid product (e.g., Armour Thyroid, NP Thyroid) 2. Patient currently receiving Adthyza AND has failure, contraindication or intolerance to ONE other desiccated thyroid product (e.g., Armour Thyroid, NP Thyroid)
Topical agents for Condyloma acuminatum	**Condylox** (podofilox 0.5% topical gel)	**Condylox** is considered medically necessary when there is documentation of **EITHER** of the following: 1. Failure, contraindication or intolerance to **TWO** of the following: A. podofilox 0.5% topical solution B. imiquimod cream (Aldara generic) C. Veregen 15% ointment [may require prior authorization] 2. For treatment of perianal warts and there is failure, contraindication or intolerance to **ONE** of the following: A. podofilox 0.5% topical solution B. imiquimod cream (Aldara generic) C. Veregen 15% ointment [may require prior authorization]
	podofilox 0.5% topical gel	**Podofilox** is considered medically necessary when there is documentation of **EITHER** of the following: 1. Failure, contraindication or intolerance to **TWO** of the following: A. podofilox 0.5% topical solution B. imiquimod cream (Aldara generic) C. Veregen 15% ointment [may require prior authorization]

Therapeutic Category	Product	Criteria
		2. For treatment of perianal warts and there is failure, contraindication or intolerance to **ONE** of the following: A. podofilox 0.5% topical solution B. imiquimod cream (Aldara generic) C. Veregen 15% ointment [may require prior authorization]
Topical Corticosteroid-containing Agents – Halobetasol Agents	**halobetasol propionate** topical foam 0.05%	**Halobetasol propionate topical foam 0.05%** is considered medically necessary when there is the following: 3. Failure, contraindication, or intolerance to **FIVE** generic prescription-strength topical corticosteroid products: A. betamethasone dipropionate, augmented 0.05% (gel, lotion, ointment) B. clobetasol propionate 0.05% (cream, foam, gel, lotion, ointment, shampoo, solution, spray) C. diflorasone diacetate 0.05% (ointment) D. fluocinonide 0.1% (cream) E. halobetasol propionate 0.05% (cream, ointment)
	Lexette (halobetasol propionate) topical foam 0.05%	**Lexette** is considered medically necessary when there is the following: 1. Failure, contraindication, or intolerance to **FIVE** generic prescription-strength topical corticosteroid products: A. betamethasone dipropionate, augmented 0.05% (gel, lotion, ointment) B. clobetasol propionate 0.05% (cream, foam, gel, lotion, ointment, shampoo, solution, spray) C. diflorasone diacetate 0.05% (ointment) D. fluocinonide 0.1% (cream) E. halobetasol propionate 0.05% (cream, ointment)

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW

Coverage for certain Prescription Drug Products prescribed require prior authorization. The reason for prior authorization is to determine whether the prescription drug product is medically necessary in accordance with Cigna's coverage criteria. Coverage criteria for a prescription drug product may vary based on the clinical use for which is submitted, and may change periodically based on changes in, without limitation, clinical guidelines or practice standards, or market factors.

For a "not covered" product, an individual must try the covered alternative drug(s) before Cigna will approve coverage for the identified drug unless the plan's exception criteria are satisfied. A "Covered Alternative Drug" is a drug or biologic in the same therapeutic or pharmacological class and usually can be expected to have similar outcomes and adverse reaction profiles when administered in therapeutically equivalent doses as, another prescription drug product, medical pharmaceutical, or over-the-counter medication. The number of covered alternative drugs tried may vary by Prescription Drug List.

Drugs intended for human use are evaluated by FDA's Center for Drug Evaluation and Research (CDER) to ensure that drugs marketed in the United States are safe and effective.[1] Biological products are evaluated by FDA's Center for Biologics Evaluation and Research (CBER).[2] Federal law generally requires that prescription drugs in the U.S. be shown to be both safe and effective prior to marketing for all indications or uses. FDA's review of the applicant's labeling insures that health care professionals and patients have the information necessary to understand a drug product's risks and its safe and effective use.[1,2] Once FDA-approved, the Human prescription drug labeling (1) contains a summary of the essential scientific information needed for the safe and effective use of the drug; and (2) includes the Prescribing Information, FDA-approved patient labeling (Medication Guides, Patient Package Inserts, and/or Instructions for Use), and/or carton and container labeling.[3]

Unapproved use of an approved drug is often called "off-label" use. Once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient.[4]

Standard Medical Reference Compendia
Standard medical reference compendia utilized to establish frequency limitations include, but not limited to: American Hospital Formulary Service-Drug Information (AHFS), Elsevier Gold Standard's Clinical Pharmacology, Thomson Micromedex/DrugDEX, and Wolters Kluwer Facts & Comparisons eAnswers.

References

1. U.S. Food & Drug Administration Center for Drug Evaluation and Research (CDER). Accessed 10/19/2023. Available at https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder.
2. U.S. Food & Drug Administration Center for Biologics Evaluation and Research (CBER). Accessed 10/19/2023. Available at https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber.
3. U.S. Food & Drug Administration: Drugs@FDA: FDA-Approved Drugs. Accessed 10/19/2023. Available at https://www.accessdata.fda.gov/scripts/cder/daf/.
4. U.S. Food & Drug Administration: Understanding Unapproved Use of Approved Drugs "Off Label". Accessed 10/19/2023. Available at https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria for: Airsupra, Bijuva, Bromfenac 0.07%, Cabtreo, Condylox, Jylamvo, Likmez, podofilox 0.5%, Pokonza, Trexall, Xatmep, Zituvio	5/1/2024
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria for: tetracycline, gabapentin, Gralise, Blue Link glucose test strips, Indocin, indomethacin, bromfenac, BromSite, Adthyza, halobetasol, Lexette	6/1/2024
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria for: Kiprofen, Sovuna, Ermeza, levothyroxine, Thyquidity, Tirosint, Tirosint-SOL, Glucose Test Strips, Lancets, Altreno, Retin-A Micro Pump 0.06% gel, tretinoin 0.025%, 0.05% 0.1% cream, tretinoin 0.01%, 0.025%, 0.05% gel, tretinoin gel micro 0.04%, 0.08%, 0.1% pump, tretinoin gel micro 0.04%, 0.1% tube, adapalene 0.1% cream/ lotion/ solution/ swab, adapalene 0.3% gel/ gel pump, Differin 0.1% lotion, adapalene-benzoyl peroxide 0.1-2.5% gel pump, adapalene-benzoyl peroxide 0.3-2.5% gel pump, Epiduo Forte 0.3-2.5% gel pump **Removed** Individual and Family Plan product-specific medical necessity criteria for: Blue Link glucose test strips	7/15/2024
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria for: Absorica 10 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg capsules, Absorica LD capsules, Aplenzin tablets, Auvelity tablets, baclofen 15 mg tablets, bupropion hydrochloride 450 mg extended-release tablets, doxycycline monohydrate IR 40 mg capsules, Forfivo XL tablets, isotretinoin 25 mg, 35 mg capsules, Multaq tablets, Oracea 40 mg capsules, sitagliptin tablets **Updated** Individual and Family Plan product-specific medical necessity criteria for: Zituvio tablets	8/1/2024
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria for: Gemtesa tablets, insulin glargine, insulin glargine SoloStar, insulin glargine-yfgn, insulin glargine Max SoloStar, Lantus, Lantus SoloStar, mirabegron extended-release tablets, Myrbetriq granules, Myrbetriq tablets, Nevanac ophthalmic suspension 0.1%, Rezvoglar, Semglee-yfgn, Toujeo SoloStar, Toujeo Max SoloStar, Xcopri **Removed** Individual and Family Plan product-specific medical necessity criteria for: Glucose Test Strips, Lancets	9/1/2024
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria for: Libervant, Rextovy.	9/15/2024
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria for: Carac, Klisyri, imiquimod 3.75%, Zyclara 3.75%, Zyclara 2.5%, ondansetron ODT 16mg, carbinoxamine maleate 4 mg/ 5 mL suspension, Karbinal ER suspension, Innopran XL, Inderal LA, Inderal XL, Kapspargo, Katerzia, Norliqva, hydrocortisone 2% lotion, sitagliptin-metformin, Estratest FS, Furoscix, Clinpro 5000, Fraiche 5000 Previ, Fraiche 5000 Sensitive, Just Right 5000, Prevident 1.1%, Prevident Kids 5000 PPM, Prevident 5000	10/15/2024

	Booster Plus, Prevident Dry Mouth, Prevident Orthodefens, Prevident 5000 Plus, Prevident Rinse 0.2%, Prevident 5000 Sensitive, Prevident 5000 Enamel. **Updated** Individual and Family Plan product-specific medical necessity criteria for: Rextovy, loteprednol etabonate 0.2%	
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria for: Focinvez, Myhibbin, allopurinol 200 mg oral tablet, Posfrea IV injection	11/1/2024

The policy effective date is in force until updated or retired.