Drug Coverage Policy

Effective Date.....5/1/2025
Coverage Policy Number 1407

Pharmacy and Medical 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.

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.

Documentation: Documentation is required where noted in the criteria. Documentation may include, but not limited to, chart notes, laboratory tests, medical test results, claims records, prescription receipts, and/or other information.

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]

Therapeutic Category	Product	Criteria
	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
	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).

Therapeutic Category	Product	Criteria
	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).
	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]
	Azelex® (azelaic acid cream 20%)	**Azelex cream** is considered medically necessary when **EITHER** of the following criteria are met: 1. **Patients with rosacea.** Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with **THREE** other topical agents for rosacea. Note: Examples include: metronidazole 0.75% or 1% products such as gels, creams, and lotions (MetroGel, generics; MetroLotion, generics; MetroCream, generics; Noritate), Finacea 15% gel (generics) 2. **Patients with acne vulgaris.** Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with three other prescription topical products for acne.

Therapeutic Category	Product	Criteria
		Note: Examples include: topical antibiotic products (e.g., clindamycin, erythromycin); topical retinoids (tretinoin [Atralin/generics, Avita/generics, Retin-A/generics, Retin-A Micro]), adapalene (Differin/generics), tazorotene (Tazorac 0.1% cream or 0.1% gel); Finacea 15% gel (generics); sulfacetamide-containing products; combination products (clindamycin-benzoyl peroxide gel [Acanya, Veltin generics]); clindamycin/tretinoin gel [Ziana, Veltin generics], erythromycin-benzoyl peroxide gel [Benzamycin generics], other generics).
	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 patient meets **ALL** the following (1, 2, and 3): 1. Acne vulgaris in a patient ≥ 12 years of age. 2. Patient has tried and cannot take one other topical adapalene product [may require prior authorization] Note: Examples of topical adapalene products include Differin cream/gels and adapalene cream/gels 3. Patient has tried and, according to the prescriber, has experienced inadequate efficacy or significant intolerance with one topical tretinoin product [may require prior authorization] Note: Examples of topical tretinoin products include Retin-A, Retin-A Micro, tretinoin, Altreno, Atralin, Avita
	Epiduo® Forte (adapalene/ benzoyl	**Epiduo Forte** is considered medically necessary if the patient has tried and cannot take generic

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	peroxide 0.3-2.5% gel pump)	adapalene 0.3%-benzoyl peroxide 2.5% gel [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]
	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).

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	Twyneo® (tretinoin/benzoyl peroxide cream)	**Twyneo cream** is considered medically necessary when the patient meets **BOTH** the following criteria: 1. Acne vulgaris in a patient ≥ 9 years of age. 2. Tried and cannot take **BOTH** a benzoyl peroxide- AND a tretinoin- containing product [products may require prior authorization]. Note: Examples of topical tretinoin product include: tretinoin gel/cream, Retin-A gel/cream, Retin-A Micro gel, Atralin, Altreno, Avita.
Alpha-Adrenergic Agonist	**clonidine 0.17 mg extended-release** tablets (authorized generic for Nexiclon XR)	**Clonidine 0.17 mg extended-release** is considered medically necessary when the patient tried and is unable to use both clonidine immediate-release tablets and clonidine transdermal patches.
	Nexiclon™ XR (clonidine 0.17 mg extended-release tablet)	**Nexiclon** is considered medically necessary when the patient tried and is unable to use both clonidine immediate-release tablets and clonidine transdermal patches.
Alzheimer's Disease Agents	**Adlarity®** (donepezil transdermal system)	**Adlarity** is considered medically necessary when the patient meets **EITHER** of the following: 1. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with donepezil tablets. 2. Patient has difficulty swallowing tablets, approve if the patient has tried, and according to the prescriber, has experienced inadequate efficacy OR significant intolerance with donepezil orally disintegrating tablet (ODT)
	donepezil and extended-release memantine capsule (generic for Namzaric®)	**Donepezil and extended-release memantine capsule** is considered medically necessary when patient has tried donepezil (tablet, ODT) AND memantine (tablet, oral solution) [taken concomitantly].

Therapeutic Category	Product	Criteria
	Namzaric® (donepezil and extended-release memantine capsule)	**Namzaric capsule** is considered medically necessary when patient has tried donepezil (tablet, ODT) AND memantine (tablet, oral solution) [taken concomitantly].
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
	metronidazole 125 mg oral tablet	**Metronidazole 125 mg oral tablet** is considered medically necessary when **ONE** of the following criteria are met: 1. Patient has tried one of metronidazole 250 mg tablets or 500 mg tablets. 2. Prescribed dose cannot be obtained with whole tablets of the higher metronidazole strengths (i.e., 250 mg, 500 mg tablets). 3. According to the prescriber, there is a significant clinical concern such that the patient is unable to use metronidazole 250 mg or 500 mg tablets. 4. Patient has already started metronidazole therapy, and the requested medication is being used to complete the course of therapy.
	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/ 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

Therapeutic Category	Product	Criteria
	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 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.
Antifungals (Topical)	**sulconazole nitrate 1%** (cream)	**Sulconazole nitrate 1% (cream)** is considered medically necessary when **EITHER** the following criteria are met: 1. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with four topical antifungals. 2. Patient has an occluded fungal infection, such as intertrigo or erosio interdigitalis blastomycetica, and has tried and,

Therapeutic Category	Product	Criteria
		according to the prescriber has experienced inadequate efficacy OR a significant intolerance with two topical antifungals. Note: Example of topical antifungals include: naftifine 1% or 2% cream, naftifine 2% gel, clotrimazole 1% cream, econazole 1% cream, ketoconazole 2% cream, oxiconazole 1% cream, ciclopirox 0.77% cream or gel.
Antifungals (Topical)	**sulconazole nitrate 1%** (solution)	**Sulconazole nitrate 1% (solution)** is considered medically necessary when **EITHER** the following criteria are met: 1. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with four topical antifungals. 2. Patient has an occluded fungal infection, such as intertrigo or erosio interdigitalis blastomycetica, and has tried and, according to the prescriber has experienced inadequate efficacy OR a significant intolerance with two topical antifungals. Note: Example of topical antifungals include: naftifine 1% or 2% cream, naftifine 2% gel, clotrimazole 1% cream, econazole 1% cream, ketoconazole 2% cream, oxiconazole 1% cream, ciclopirox 0.77% cream or gel.
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).

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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. 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).
Antimalarial Agents	**Arakoda™** (tafenoquine tablets)	**Arakoda** is considered medically necessary when **ONE** of the following criteria are met: 1. Patient has tried atovaquone-proguanil (Malarone, generics), chloroquine, doxycycline, mefloquine, or primaquine. 2. Patient has been started on a current course of therapy with Arakoda.
	Coartem® (artemether/ lumefrantrine tablets)	**Coartem** is considered medically necessary when use is for the treatment of malaria.
	Krintafel™ (tafenoquine tablets)	**Krintafel** is considered medically necessary when the patient has tried primaquine.
Antimigraine Agent	**Ergomar® Sublingual** (ergotamine 2 mg sublingual tablet)	**Ergomar** is considered medically necessary when **BOTH** of the following criteria are met: 1. Patient has tried dihydroergotamine nasal spray (Migranal generics) [may require prior authorization] 2. Patient meets **ONE** of the following: a. Patient has tried **ONE** oral triptan product (for example, almotriptan, eletriptan [may require prior authorization], frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan) b. Patient has already experienced inadequate efficacy or a contraindication with triptan product(s)
Antiparasitic	**Xdemvy™** (lotilaner ophthalmic solution)	**Xdemvy** is considered medically necessary for a documented diagnosis of Demodex blepharitis.

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Antiparkinson Drugs -Carbidopa and Levodopa Extended-Release Agents	**Crexont®** (carbidopa and levodopa extended-release capsules)	**Crexont** is considered medically necessary when **EITHER** of the following are met: 1. Patient has tried carbidopa-levodopa extended-release tablets 2. Patient has already been started on therapy with Crexont
Antipsychotics (Oral)	**Fanapt®** (iloperidone tablets and titration pack)	**Fanapt** is considered medically necessary when **EITHER** of the following criteria are met: 1. Patient has tried **TWO** oral antipsychotics (e.g., aripiprazole, asenapine maleate, olanzapine, paliperidone, quetiapine fumarate, risperidone, or ziprasidone HCl). 2. Patient is currently taking or has history of taking Fanapt.
	Opipza™ (aripiprazole oral film)	**Opipza** is considered medically necessary when the patient has tried and cannot take **ONE** of aripiprazole ODT or aripiprazole oral solution.
Antipsychotics (Oral) [Muscarinic Agonist and Muscarinic Antagonist]	**Cobenfy™** (xanomeline and trospium chloride capsules)	**Cobenfy** is considered medically necessary when **ONE** of the following is met: 1. Patient has tried TWO other novel (atypical) antipsychotics. Note: Examples of novel (atypical) antipsychotics include risperidone tablets/orally disintegrating tablets (ODT) [Risperdal, generics], lurasidone tablets (Latuda generic), olanzapine tablets/ODT (Zyprexa/Zydis, generics), quetiapine tablets (Seroquel, generics), quetiapine extended-release tablets (Seroquel XR, generics), aripiprazole tablets (Abilify, generics), paliperidone ER tablets (Invega, generics), ziprasidone capsules (Geodon, generics), asenapine sublingual tablets (Saphris, generics). 2. Patient has already started therapy with Cobenfy. 3. Patient has taken Cobenfy at any time in the past.
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

Therapeutic Category	Product	Criteria
		or Nayzilam), this would satisfy the requirement for approval 2. Patient's caregiver is unable to administer diazepam rectal gel (Diastat generics)
Antiseizure Medications Antiseizure Medications	**carbamazepine 200 mg** chewable tablet	**Carbamazepine chewable tablet** is considered medically necessary when the patient has tried carbamazepine 100 mg/ 5 mL oral suspension.
	topiramate 50 mg oral sprinkle capsule	**Topiramate 50 mg oral sprinkle capsule** is considered medically necessary when **EITHER** of the following criteria are met: 1. Patient has tried topiramate 25 mg sprinkle capsules. 2. According to the prescriber, there is a significant clinical concern such that the patient is unable to use topiramate 25 mg oral sprinkle capsules.
	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
Bacterial Vaginosis Agents	**Clindesse®** (clindamycin phosphate vaginal cream)	**Clindesse** is considered medically necessary when **ONE** of the following criteria are met: 1. **Patient is ≥ 18 years of age.** Patient has tried a vaginal metronidazole-containing product AND a vaginal clindamycin-containing product. 2. **Patient is post-menarchal and < 18 years of age.** Patient has tried one of a vaginal metronidazole-containing product OR a vaginal clindamycin-containing product.

Therapeutic Category	Product	Criteria
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.
	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.
	labetalol 400 mg oral tablets	**Labetalol 400 mg oral tablets** is considered medically necessary when **EITHER** of the following criteria are met: 1. Patient tried labetalol 100 mg, 200 mg, or 300 mg oral tablets. 2. According to the prescriber, there is a significant clinical concern such that the patient is unable to use labetalol 100 mg, 200 mg, or 300 mg oral tablets.

Therapeutic Category	Product	Criteria
Bowel Evacuants – Low Volume – Polyethylene Glycol (PEG)-based Preparations	**MoviPrep®** (PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid for oral solution)	**MoviPrep** is considered medically necessary when the following is met: **Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.** Approve if according to the prescriber, the brand product is being requested because the preferred bioequivalent generic product would not be as medically appropriate for the patient as the requested brand non-formulary drug.
	Plenvu® (PEG 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride powder for oral solution)	**Plenvu** is considered medically necessary when the following is met: **Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.** Approve if according to the prescriber, other formulary alternative(s) would not be as medically appropriate for the patient as the requested non-formulary drug.
	Suflave™ (polyethylene glycol 3350/ sodium sulfate/ potassium chloride/ magnesium sulfate/ sodium chloride for oral solution)	**Sulfave** is considered medically necessary when the following is met: **Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.** Approve if according to the prescriber, other formulary alternative(s) would not be as medically appropriate for the patient as the requested non-formulary drug.
Bowel Evacuants – Low Volume – Sodium Picosulfate-based Preparations	**Clenpiq®** (sodium picosulfate, magnesium oxide, and anhydrous citric acid oral solution)	**Clenpiq** is considered medically necessary when the following is met: **Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.** Approve if according to the prescriber, other formulary alternative(s) would not be as medically appropriate for the patient as the requested non-formulary drug.
Bowel Evacuants – Low Volume – Sodium Sulfate-based Preparations	**Suprep®** (sodium sulfate, potassium sulfate, and magnesium sulfate oral solution)	**Suprep** is considered medically necessary when the following is met: **Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.**

Therapeutic Category	Product	Criteria
		Approve if according to the prescriber, the brand product is being requested because the preferred bioequivalent generic product would not be as medically appropriate for the patient as the requested brand non-formulary drug.
	Sutab® (sodium sulfate, magnesium sulfate, and potassium chloride tablets)	**Sutab** is considered medically necessary when the following is met: **<u>Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.</u>** Approve if according to the prescriber, other formulary alternative(s) would not be as medically appropriate for the patient as the requested non-formulary drug.
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.
	nimodipine 60 mg/ 20 mL oral solution (generic for Nymalize®)	**Nimodipine 60 mg/ 20 mL oral solution** is considered medically necessary when patient tried nimodipine oral capsules or is unable to have the nimodipine oral capsules appropriately administered.
	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	**Aspruzyo Sprinkle™** (ranolazine extended-release granules)	**Aspruzyo Sprinkle™** is considered medically necessary when **EITHER** of the following criteria are met: 1. Patient is unable to or has difficulty swallowing ranolazine extended-release tablets (Ranexa, generics). 2. Patient requires administration by nasogastric or gastrostomy/gastric tube.
	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)

Therapeutic Category	Product	Criteria
		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 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	**prucalopride 1 mg, 2 mg** oral tablet (generic for Motegrity®)	**Prucalopride 1 mg, 2 mg oral tablet** is considered medically necessary when the patient meets **ALL** of the following criteria: 1. Diagnosis of chronic idiopathic constipation. 2. Patient is >/= 18 years of age. 3. Patient has tried and, according to the prescriber, experience inadequate efficacy or significant intolerance with Linzess.
	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)

Therapeutic Category	Product	Criteria
		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%)
	hydrocortisone 2.5% topical solution	**Hydrocortisone 2.5% topical solution** is considered medically necessary when the patient has tried and, according to the prescriber, has experienced inadequate efficacy or significant intolerance to **ALL** of the following: 1. hydrocortisone 2.5% lotion 2. betamethasone valerate 0.05% lotion 3. fluocinolone acetonide 0.01% solution
Diabetes Agents - Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	**alogliptin** tablet (Nesina authorized generic)	**Alogliptin** is considered medically necessary when the patient has tried **ALL** of the following: 1. Januvia 2. saxagliptin (Onglyza generic) 3. Tradjenta
	Nesina® (alogliptin tablet)	**Nesina** is considered medically necessary when the patient has tried **ALL** of the following: 1. Januvia 2. saxagliptin (Onglyza generic) 3. Tradjenta
	Onglyza® (saxagliptin tablets)	**Onglyza** is considered medically necessary when the patient has tried the bioequivalent generic product, **saxagliptin tablets**, 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.
	sitagliptin 100 mg, 50 mg, 25 mg tablets	**Sitagliptin** is considered medically necessary when the patient has tried Januvia.
	Zituvio™ (sitagliptin tablets)	**Zituvio** is considered medically necessary when the patient has tried Januvia.
Diabetes Agents - Dipeptidyl Peptidase-4 (DPP-	**alogliptin and metformin** tablets	**Alogliptin and metformin tablet** is considered medically necessary when the patient has tried **ALL** of the following:

Therapeutic Category	Product	Criteria
4) Inhibitor Combination Products	(Kazano authorized generic)	1. Janumet OR Janumet XR 2. Jentadueto OR Jentadueto XR 3. saxagliptin plus metformin extended release tablets
	alogliptin and pioglitazone tablets (Oseni authorized generic)	**Alogliptin and pioglitazone tablet** is considered medically necessary when the patient has tried pioglitazone and **TWO** of the following: 1. Januvia 2. saxagliptin (Onglyza generic) 3. Tradjenta
	Kazano® (alogliptin/ metformin tablets)	**Kazano** is considered medically necessary when the patient has tried **ALL** of the following: 1. Janumet OR Janumet XR 2. Jentadueto OR Jentadueto XR 3. saxagliptin plus metformin extended release tablets
	Kombiglyze® XR (saxagliptin plus metformin extended-release tablets)	**Kombiglyze XR** is considered medically necessary when the patient has tried the bioequivalent generic product, **saxagliptin plus metformin extended-release tablets**, 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.
	Oseni® (alogliptin/ pioglitazone tablets)	**Oseni** is considered medically necessary when the patient has tried pioglitazone and **TWO** of the following: 1. Januvia 2. saxagliptin (Onglyza generic) 3. Tradjenta
	sitagliptin-metformin oral tablet	**Sitagliptin-metformin tablet** is considered medically necessary when the patient has tried Janumet.
	Zituvimet™ (sitagliptin/ metformin hydrochloride tablets)	**Zituvimet** is considered medically necessary when the patient has tried Janumet.
	Zituvimet™ XR (sitagliptin/ metformin hydrochloride tablets)	**Zituvimet XR** is considered medically necessary when the patient has tried Janumet XR.

Therapeutic Category	Product	Criteria
Diabetes Agents - Dipeptidyl Peptidase-4 (DPP-4) Inhibitor and Sodium Glucose Co-Transporter-2 (SGLT-2) Inhibitor Combination Product	**Glyxambi®** (empagliflozin/ linagliptin tablets)	**Glyxambi** is considered medically necessary when **ONE** of the following criteria are met: 1. Patient has tried and, according to the prescriber, has experienced inadequate efficacy or significant intolerance to **ALL** of the following: A. Farxiga B. Januvia C. Jardiance D. saxagliptin E. Tradjenta 2. History of heart failure or history of renal impairment **AND** patient has tried and, according to the prescriber, has experienced inadequate efficacy or significant intolerance to **BOTH** of the following: A. Farxiga OR Jardiance B. Tradjenta OR Januvia 3. Estimated glomerular filtration rate is less than 45 mL/ minute/ 1.73 m^2 AND patient has tried and, according to the prescriber, has experienced inadequate efficacy or significant intolerance to Jardiance
	Qtern® (dapagliflozin/ saxagliptin)	**Qtern** is considered medically necessary when the patient has tried, and according to the prescriber, has experienced inadequate efficacy or a significant intolerance to **ALL** of the following: A. Farxiga B. Januvia C. Jardiance D. saxagliptin E. Tradjenta
	Steglujan™ (ertugliflozin/ sitagliptin tablets)	**Steglujan** is considered medically necessary when the patient meets **ONE** of the following: 1. Patient has tried and, according to the prescriber, has experienced inadequate efficacy or significant intolerance to **ALL** of the following: A. Farxiga B. Januvia C. Jardiance D. saxagliptin E. Tradjenta 2. History of heart failure or renal impairment AND patient has tried and, according to the prescriber, has experienced inadequate efficacy or significant intolerance to **BOTH** of the following:

Therapeutic Category	Product	Criteria
		A. Farxiga OR Jardiance B. Tradjenta OR Januvia
	Trijardy® XR (empagliflozin/ linagliptin/ metformin extended release)	**Trijardy XR** is considered medically necessary when the patient meets **ONE** of the following: 1. Patient has tried and, according to the prescriber, has experienced inadequate efficacy or significant intolerance to **ALL** of the following: A. Farxiga with metformin OR Xigduo XR B. Januvia with metformin OR Janumet C. Jardiance with metformin OR Synjardy D. Saxagliptin with metformin OR saxagliptin-metformin ER E. Tradjenta with metformin OR Jentadueto 2. History of heart failure or renal impairment AND patient has tried and, according to the prescriber, has experienced inadequate efficacy or significant intolerance to **BOTH** of the following: A. Farxiga with metformin OR Xigduo XR OR Jardiance with metformin OR Synjardy B. Tradjenta with metformin OR Jentadueto OR Januvia with metformin OR Janumet
Diabetes Agents – Insulin (Basal)	**insulin aspart** (authorized generic for NovoLog®)	**Insulin aspart** is considered medically necessary when the patient meets **ONE** of the following: 1. Patient has tried **ONE** of insulin lispro, Humalog, Admelog [may require prior authorization] or Lyumjev [may require prior authorization] 2. Patient is using an insulin pump that is not compatible with the formulary alternative(s).
	insulin aspart protamine-insulin aspart (NovoLog® 70/30 mix generic)	**Insulin aspart protamine-insulin aspart** is considered medically necessary when the patient has tried Humalog Mix 75/25.
	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.

Therapeutic Category	Product	Criteria
	insulin glargine-YFGN 100 units/ mL (Semglee-YFGN authorized generic)	**Insulin Glargine-YFGN 100 units/ mL** is considered medically necessary when the patient has tried Basaglar.
	insulin glargine Max SoloStar U300 300 units/ mL (Toujeo Max SoloStar authorized generic)	**Insulin Glargine Max Solostar U300 300 units/mL** is considered medically necessary when **ONE** of the following criteria are met: 1. **Type 1 Diabetes** and **ONE** of the following: A. Initial user and **BOTH** of the following: i. Patient has tried Tresiba. ii. Patient has tried Basaglar. B. Continuation of therapy and **ONE** of the following: i. Patient has tried Basaglar. ii. Patient is currently receiving insulin glargine Max Solostar U300 (300 units/mL) or Toujeo Max Solostar U300 dose >/= 100 units per injection. 2. **Type 2 Diabetes** and **ONE** of the following: A. Initial user **OR** taking insulin glargine Max Solostar U300 < 100 units/ injection and **BOTH** of the following: i. Patient has tried Tresiba. ii. Patient has tried Basaglar. B. Continuation of therapy with insulin glargine Max Solostar U300 (300 units/mL) or Toujeo Max Solostar U300 >/= 100 units per injection and the patient has tried Tresiba.
	Lantus®, Lantus SoloStar (insulin glargine U-100)	**Lantus, Lantus SoloStar (insulin glargine U-100)** are considered medically necessary when the patient has tried Basaglar.
	Levemir® (insulin detemir U-100 vial and FlexTouch pen)	**Levemir** is considered medically necessary when **ONE** of the following criteria are met: 1. Type 2 Diabetes (initial user and a patient currently receiving Levemir); **OR** Type 1 Diabetes (initial user) and **ONE** of the following: A. Patient meets **BOTH** of the following: i. Patient has tried Tresiba.

Therapeutic Category	Product	Criteria
		ii. Patient has tried Basaglar. B. Patient is less than 6 years of age and has tried Tresiba. C. Patient is pregnant. 2. Type 1 Diabetes and the patient is currently taking Levemir.
	NovoLog® (insulin aspart injection)	**NovoLog** is considered medically necessary when the patient meets **ONE** of the following: 1. Patient has tried **ONE** of insulin lispro, Humalog, Admelog [may require prior authorization] or Lyumjev [may require prior authorization] 2. Patient is using an insulin pump that is not compatible with the formulary alternative(s).
	Rezvoglar™ Kwikpen (insulin glargine-aglr 100 units/ mL)	**Rezvoglar** is considered medically necessary when the patient has tried Basaglar.
	Semglee® (non YFGN) (insulin glargine U-100 vial and pen)	**Semglee (non YFGN)** is considered medically necessary when the patient has tried Basaglar.
	Semglee-YFGN (insulin glargine U-100)	**Semglee-YFGN** is considered medically necessary when the patient has tried Basaglar.
	Toujeo® SoloStar, Toujeo Max SoloStar (insulin glargine U-300)	**Toujeo** is considered medically necessary when **ONE** of the following criteria are met: 1. **Type 1 Diabetes** and **ONE** of the following: A. Initial user and **BOTH** of the following: i. Patient has tried Tresiba. ii. Patient has tried Basaglar. B. Continuation of therapy and **ONE** of the following: i. Patient has tried Basaglar. ii. Patient is currently receiving Toujeo or insulin glargine U300 dose >/= 100 units per injection. 2. **Type 2 Diabetes** and **ONE** of the following: A. Initial user **OR** taking Toujeo/ insulin glargine U300 < 100 units/

Therapeutic Category	Product	Criteria
		injection and **BOTH** of the following: i. Patient has tried Tresiba. ii. Patient has tried Basaglar. B. Continuation of therapy with Toujeo OR insulin glargine U300 >/= 100 units per injection and the patient has tried Tresiba.
Diabetes Agents – Insulin (Basal) and Glucagon-Like Peptide-1 (GLP-1) Agonist Combination	**Soliqua®** (insulin glargine/ lixisenatide injection)	**Soliqua** is considered medically necessary when **EITHER** of the following criteria are met: 1. Patient has tried **BOTH** of the following: A. TWO basal insulins: Basaglar AND Tresiba B. THREE glucagon-like peptide (GLP-1) agonists: an exenatide product (Bydureon BCise, Byetta), liraglutide, Ozempic, OR Trulicity Note: Lantus, insulin glargine (YFGN), Semglee (YFGN), Basalgar, Toujeo, and insulin glargine U300 would count as one alternative for a trial of basal insulins. Note: Tresiba and insulin degludec would count as one alternative for a trial of basal insulins. Note: Bydureon BCise and Byetta would count as one alternative for a trial of GLP-1 agonists. Note: Victoza and its generic would count as one alternative for a trial of GLP-1 agonists. Note: A trial of Rybelsus or Mounjaro would also count as a trial of a GLP-1 agonist. 2. Patient with a personal or family history of medullary thyroid carcinoma or a patient with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) and **BOTH** of the following: A. TWO basal insulins: Basaglar AND Tresiba B. Patient has tried Byetta

Therapeutic Category	Product	Criteria
		Note: If the patient has tried Bydureon or Bydureon BCise, this would satisfy the requirement for a trial of Byetta. Note: Lantus, insulin glargine (YFGN), Semglee (YFGN), Basalgar, Toujeo, and insulin glargine U300 would count as one alternative for a trial of basal insulins. Note: Tresiba and insulin degludec would count as one alternative for a trial of basal insulins.
	Xultophy® (insulin degludec/liraglutide injection)	**Xultophy** is considered medically necessary when the following criteria are met: 1. Patient has tried **BOTH** of the following: A. TWO basal insulins: Basaglar AND Tresiba B. TWO glucagon-like peptide (GLP-1) agonists: an exenatide product (Bydureon BCise, Byetta liraglutide, Ozempic, OR Trulicity Note: Lantus, insulin glargine (YFGN), Semglee (YFGN), Basalgar, Toujeo, and insulin glargine U300 would count as one alternative for a trial of basal insulins. Note: Tresiba and insulin degludec would count as one alternative for a trial of basal insulins. Note: Bydureon BCise and Byetta would count as one alternative for a trial of GLP-1 agonists. Note: Victoza and its generic would count as one alternative for a trial of GLP-1 agonists. Note: A trial of Rybelsus or Mounjaro would also count as a trial of a GLP-1 agonist.
Diabetes Agents - Other	**metformin 750 mg** immediate release oral tablet	**Metformin immediate release 750 mg oral tablet** is considered medically necessary when the patient has had inadequate efficacy or significant intolerance with metformin 500 mg, 850 mg, or 1000 mg immediate-release tablets.
Diabetes Agents - Sodium Glucose	**dapagliflozin-metformin**	**Dapagliflozin and metformin extended release tablet** is considered medically necessary

Therapeutic Category	Product	Criteria
Co-Transporter-2 (SGLT-2) Inhibitor Combination Products	extended-release tablet	when there is documented inability to obtain Xigduo® XR (the brand name product) due to market availability.
	Invokamet (canagliflozin and metformin tablets)	**Invokamet** is considered medically necessary when the patient has tried **BOTH** of the following: 1. Synjardy **OR** Synjardy XR 2. Xigduo XR
	Invokamet XR (canagliflozin and metformin extended-release tablets)	**Invokamet XR** is considered medically necessary when the patient has tried **BOTH** of the following: 1. Synjardy **OR** Synjardy XR 2. Xigduo XR
	Segluromet (ertugliflozine and metformin tablets)	**Segluromet** is considered medically necessary when the patient has tried **BOTH** of the following: 3. Synjardy **OR** Synjardy XR 4. Xigduo XR
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.
	Glimepiride 3 mg (brand)	**Glimepiride 3 mg (brand)** is considered medically necessary when the patient cannot use one of the following: generic glimepiride 1mg, 2mg, or 4 mg
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.
Epinephrine Nasal Spray	**Neffy®** (epinephrine nasal spray)	**Neffy** is considered medically necessary when the patient or patient's caregiver is unable to use a self-injectable epinephrine product.
Estrogen and Estrogen Combination Products (Topical)	**estradiol** gel 0.06%	**Estradiol gel 0.06%** is considered medically necessary when the patient has tried one estradiol patch product (for example, Alora, estradiol patch [Climara, Vivelle Dot generics], Minivelle [generics]).
Estrogen Combination Products (Oral)	**Bijuva®** (estradiol/ 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:

Therapeutic Category	Product	Criteria
		A. **ONE** of the following: Amabelz, estradiol-norethindrone, or Mimvey B. **ONE** of the following: Jinteli, Fyavolv, or norethindrone-ethinyl estradiol
	Estratest® F.S. (esterified estrogens 1.25 mg/ methyltestosterone 2.5 mg tablets)	**Estratest F.S.** 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.
	Estratest® H.S. (esterified estrogens 0.625 mg/ methyltestosterone 1.25 mg oral tablets)	**Estratest H.S.** is considered medically necessary when the patient has tried **TWO** equivalent strength products [Covaryx H.S., EEMT HS 0.625 mg -1.25 mg, Esterified Estrogens and Methyltestosterone H.S.] **AND** cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the Estratest HS 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.
Estrogen Products (Vaginal)	**Femring®** (estradiol vaginal ring (0.05 mg and 0.10 mg)	**Femring** is considered medically necessary when the patient has tried **TWO** of the following estrogen products: estradiol cream, estradiol patch, estradiol tablets, or estradiol vaginal tablet.
	Imvexxy® (estradiol vaginal insert)	**Imvexxy** is considered medically necessary when there is **ONE** of the following: 1. Patient has tried both of the following estrogen products: estradiol cream, estradiol vaginal tablet.

Therapeutic Category	Product	Criteria
		2. According to the prescriber, patient requires a low-dose vaginal product and has tried estradiol vaginal tablets.
	Premarin® (conjugated estrogens, cream)	**Premarin** is considered medically necessary when the patient has tried both of the following estrogen products: estradiol cream, estradiol vaginal tablet.
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)
	Gabarone 100 mg, 400 mg (gabapentin oral tablets)	**Gabarone 100 mg, 400 mg oral tablets** are considered medically necessary when the patient has tried and **CANNOT TAKE** gabapentin capsules.
	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 prescriber, there is a significant clinical concern such that the patient is unable to use allopurinol 100 mg or 300 mg tablets.
Helicobacter Pylori Agents	**bismuth subcitrate 140 mg/ metronidazole 125 mg/ tetracycline 125 mg capsules** (generic for Pylera)	**Bismuth subcitrate 140 mg/ metronidazole 125 mg/ tetracycline 125 mg capsules** are considered medically necessary when **ONE** of the following criteria are met (1 or 2): 1. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with TWO different regimens of single-entity products (e.g., clarithromycin + amoxicillin + proton pump inhibitor [e.g., omeprazole, lansoprazole]; bismuth-containing product + tetracycline + metronidazole + proton pump inhibitor [e.g., omeprazole, lansoprazole]; OR 2. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with any

Therapeutic Category	Product	Criteria
		ONE pre-packaged products (e.g., amoxicillin/clarithromycin/lansoprazole [Prevpac, generics]).
	Omeclamox®-Pak (amoxicillin 500 mg/ clarithromycin 500 mg/ omeprazole 20 mg capsules)	**Omeclamox-Pak** is considered medically necessary when **ONE** of the following criteria are met (1 or 2): 1. Patient meets **ONE** of the following: A. Patient has tried and according to the prescriber, has experienced inadequate efficacy OR significant intolerance with TWO different regimens of single-entity products (e.g., clarithromycin + amoxicillin + proton pump inhibitor [e.g., omeprazole, lansoprazole]; bismuth-containing product + tetracycline + metronidazole + proton pump inhibitor [e.g., omeprazole, lansoprazole]; OR B. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with any ONE pre-packaged products (e.g., amoxicillin/clarithromycin/lansoprazole [Prevpac, generics]). 2. Patient has already been started on Omeclamox-Pak in order to complete the course of therapy.
	Pylera® (bismuth subcitrate 140 mg/ metronidazole 125 mg/ tetracycline 125 mg capsules)	**Pylera** is considered medically necessary when **ONE** of the following criteria are met (1 or 2): 1. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with TWO different regimens of single-entity products (e.g., clarithromycin + amoxicillin + proton pump inhibitor [e.g., omeprazole, lansoprazole]; bismuth-containing product + tetracycline + metronidazole + proton pump inhibitor [e.g., omeprazole, lansoprazole]; OR 2. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with any ONE pre-packaged products (e.g., amoxicillin/clarithromycin/lansoprazole [Prevpac, generics]).

Therapeutic Category	Product	Criteria
	Talicia® (omeprazole 10 mg/ amoxicillin 250 mg/ rifabutin 12.5 capsules)	**Talicia** is considered medically necessary when **ONE** of the following criteria are met (1 or 2): 1. Patient meets **ONE** of the following: A. Patient has tried and according to the prescriber, has experienced inadequate efficacy OR significant intolerance with ONE different regimens of single-entity products (e.g., clarithromycin + amoxicillin + proton pump inhibitor [e.g., omeprazole, lansoprazole]; bismuth-containing product + tetracycline + metronidazole + proton pump inhibitor [e.g., omeprazole, lansoprazole]; OR B. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with ONE pre-packaged products (e.g., amoxicillin/clarithromycin/lansoprazole [Prevpac, generics]). 2. Patient has already been started on Talicia in order to complete the course of therapy.
	Voquezna™ Dual Pak (vonoprazan 20 mg/ amoxicillin 1000 mg)	**Voquezna Dual Pak** is considered medically necessary when **ONE** of the following criteria are met (1 or 2): 1. Patient meets **ONE** of the following: A. Patient has tried and according to the prescriber, has experienced inadequate efficacy OR significant intolerance with ONE different regimens of single-entity products (e.g., clarithromycin + amoxicillin + proton pump inhibitor [e.g., omeprazole, lansoprazole]; bismuth-containing product + tetracycline + metronidazole + proton pump inhibitor [e.g., omeprazole, lansoprazole]; OR B. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with ONE pre-packaged products (e.g., amoxicillin/clarithromycin/lansoprazole [Prevpac, generics]). 2. Patient has already been started on Voquezna in order to complete the course of therapy.

Therapeutic Category	Product	Criteria
	Voquezna™ Triple Pak (vonoprazan 20 mg/ amoxicillin 1000 mg/ clarithromycin 500 mg)	**Voquezna Triple Pak** is considered medically necessary when **ONE** of the following criteria are met (1 or 2): 1. Patient meets **ONE** of the following: A. Patient has tried and according to the prescriber, has experienced inadequate efficacy OR significant intolerance with ONE different regimens of single-entity products (e.g., clarithromycin + amoxicillin + proton pump inhibitor [e.g., omeprazole, lansoprazole]; bismuth-containing product + tetracycline + metronidazole + proton pump inhibitor [e.g., omeprazole, lansoprazole]; OR B. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with ONE pre-packaged products (e.g., amoxicillin/clarithromycin/lansoprazole [Prevpac, generics]) 2. Patient has already been started on Voquezna in order to complete the course of therapy.
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®	**Trexall** is considered medically necessary when there is documentation of failure, contraindication,

Therapeutic Category	Product	Criteria
	(methotrexate tablets)	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 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

Therapeutic Category	Product	Criteria
Leukotriene Pathway Inhibitors	**zileuton** extended-release tablet	**Zileuton extended-release tablet** is considered medically necessary when **EITHER** of the following criteria are met: 1. Patient has tried **ONE** of the following: montelukast **OR** zafirlukast. 2. Patient has already been started on therapy with a zileuton-containing product.
	Zyflo® (zileuton tablet)	**Zyflo tablet** is considered medically necessary when **EITHER** of the following criteria are met: 3. Patient has tried **ONE** of the following: montelukast **OR** zafirlukast. 4. Patient has already been started on therapy with a zileuton-containing product.
Long-Acting Beta-Agonists (Inhalers)	**Serevent® Diskus®** (salmeterol xinafoate inhalation powder)	**Serevent Diskus** is considered medically necessary when **ONE** the following criteria are met: 1. Patient has tried Striverdi® Respimat®. 2. Patient is unable to coordinate breath and actuation with a metered-dose inhaler (MDI). 3. Patient with asthma and is using Serevent Diskus concomitantly with an inhaled corticosteroid or an inhaled corticosteroid-containing product. 4. Patient with exercise-induced bronchospasm without asthma.
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.
Muscle Relaxants – Baclofen Agents	**baclofen 5 mg/ 5 mL** oral solution	**Baclofen 5 mg/ 5 mL oral solution** is considered medically necessary when **EITHER** OF the following criteria are met: 1. Patient tried oral baclofen tablets. 2. Patient is unable or has difficulty swallowing oral tablets.
Nasal Steroids	**Xhance®**	**Xhance** is considered medically necessary when

Therapeutic Category	Product	Criteria
	(fluticasone propionate nasal spray)	the patient has tried **THREE** of the following nasal steroids: 1. flunisolide 25 mcg/ spray nasal solution 2. fluticasone 50 mcg/ spray nasal suspension 3. mometasone furoate 50 mcg/ spray nasal suspension 4. triamcinolone acetonide 55 mcg/spray nasal spray suspension Note: Over the counter (OTC) nasal steroids would count as a trial of an alternative.
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 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)	**Dolobid** (diflunisal tablets)	**Dolobid tablets** are 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]
	Fenopron™ 300 mg oral capsules (fenoprofen calcium)	**Fenopron 300 mg oral capsules** is considered medically necessary when the patient has tried **FIVE** prescription-strength, oral NSAIDs.

Therapeutic Category	Product	Criteria
		Note: For example: fenoprofen (tablets/generic), etodolac (generics), flurbiprofen (Ansaid, generics), ibuprofen (e.g., Motrin, generics), ketoprofen (generics), meloxicam (Mobic, generics), nabumetone (generics), naproxen (e.g., Naprosyn, Naprelan, generics), oxaprozin (Daypro, generics), diclofenac (Voltaren XR, generics), piroxicam (Feldene, generics), indomethacin (generics) Note: Over-the-counter (OTC) NSAIDs would count if prescription-strength doses were used. Note: Five unique NSAIDs should be tried.
	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: 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]
	naproxen sodium controlled-release/ extended-release 375 mg	**Naproxen sodium CR/ ER 375 mg** is considered medically necessary when the patient has tried **FIVE** prescription-strength non-steroidal anti-inflammatory drugs (NSAIDs).
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:

Therapeutic Category	Product	Criteria
		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 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

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
	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 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

Therapeutic Category	Product	Criteria
Ophthalmic Corticosteroids	**clobetasol propionate** 0.05% ophthalmic suspension	**Clobetasol propionate 0.05% ophthalmic suspension** is considered medically necessary when **ONE** of the following criteria are met: 1. Patient has tried **THREE** formulary ophthalmic corticosteroids from the following list: A. fluorometholone 0.1% drops B. prednisolone AC 1% drops or prednisolone sodium phosphate 1% drops C. difluprednate 0.05% [may require prior authorization] D. loteprednol 0.5% drops [may require prior authorization] 2. **BOTH** of the following: A. Patient has elevated intraocular pressure (IOP) or glaucoma after a trial of another corticosteroid (i.e., topical, inhaled, oral, ophthalmic) B. Patient has tried **ONE** of the following: i. fluorometholone 0.1% drops ii. difluprednate 0.05% [may require prior authorization] iii. loteprednol 0.5% drops [may require prior authorization]
Ophthalmic Drugs for Glaucoma - Alpha-Adrenergic Agonist	**Iopidine®** (apraclonidine 1% ophthalmic solution)	**Iopidine** is considered medically necessary when the patient meets **EITHER** of the following criteria: 1. Patient has tried one product from the following list: brimonidine 0.1%, brimonidine 0.15%, or brimonidine 0.2% ophthalmic solution. 2. Patient is undergoing argon laser trabeculoplasty, argon laser iridotomy or Nd: YAG posterior capsulotomy.
Ophthalmic Drugs for Glaucoma - Beta-Adrenergic Blocker	**Betimol®** (timolol hemihydrates 0.25% and 0.5% ophthalmic solution)	**Betimol** is considered medically necessary when the patient has tried **FOUR** of the following: 1. levobunolol ophthalmic solution 2. a timolol ophthalmic product (timolol maleate, timolol gel-solution) 3. betaxolol ophthalmic solution 4. carteolol ophthalmic solution Note: If the patient tried the brand version of a generic equivalent product, then this trial would count towards the requirement.

Therapeutic Category	Product	Criteria
	timolol hemihydrates 0.25% and 0.5% ophthalmic solution	**Timolol hemihydrates ophthalmic solution** is considered medically necessary when the patient has tried **FOUR** of the following: 1. levobunolol ophthalmic solution 2. a timolol ophthalmic product (timolol maleate, timolol gel-solution) 3. betaxolol ophthalmic solution 4. carteolol ophthalmic solution Note: If the patient tried the brand version of a generic equivalent product, then this trial would count towards the requirement.
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 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-

Therapeutic Category	Product	Criteria
		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 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

Therapeutic Category	Product	Criteria
		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 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

Therapeutic Category	Product	Criteria
		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, 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 Dry 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

Therapeutic Category	Product	Criteria
		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, 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

Therapeutic Category	Product	Criteria
		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, 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

Therapeutic Category	Product	Criteria
		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 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 has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with **ONE** formulary product from the following list: A. darifenacin ER B. oxybutynin ER C. solifenacin D. tolterodine ER E. trospium ER 2. For the treatment of overactive bladder symptoms in a patient with benign prostatic hyperplasia. 3. Patient greater than 65 years of age AND has tried and, according to the prescriber, has experienced inadequate efficacy OR

Therapeutic Category	Product	Criteria
		significant intolerance with mirabegron [may require prior authorization].
Pancreatic Enzymes	**Creon®** (amylase/ lipase/ protease capsule)	**Creon** is considered medically necessary when there is documentation the patient has tried Pancreaze.
	Pertzye® (pancrelipase delayed-release capsules)	**Pertzye** is considered medically necessary when there is documentation the patient has tried Pancreaze.
	Zenpep® (pancrelipase delayed-release capsules)	**Zenpep** is considered medically necessary when there is documentation the patient has tried Pancreaze.
Plaque Psoriasis Topical Agents	**Vtama®** (tapinoraf 1% cream)	**Vtama** is considered medically necessary when **ONE** of the following is met: 1. **Plaque Psoriasis.** Patient meets ALL of the following criteria (a, b, c, and d): a. Patient is ≥ 18 years of age; AND b. Patient has psoriasis involvement estimated to affect ≤ 20% of the body surface area; AND c. Patient meets one of the following criteria (i or ii): i. Patient meets all of the following criteria (1, 2, and 3): 1. Patient has tried at least one medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid; AND 2. This topical corticosteroid was applied daily for at least 4 consecutive weeks; AND 3. Inadequate efficacy was demonstrated with this topical corticosteroid, according to the prescriber; OR ii. Patient is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia; AND d. Patient meets ALL of the following criteria (i, ii, and iii):

Therapeutic Category	Product	Criteria
		i. Patient has tried at least one topical vitamin D analog; AND Note: Examples of topical vitamin D analogs include calcipotriene 0.005% foam (Sorilux, authorized generic), calcipotriene 0.005% cream (Dovonex, generic), calcipotriene 0.005% ointment (generic only), calcitriol 3 mcg/g ointment (Vectical, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% foam (Enstilar), calcipotriene 0.005% and betamethasone dipropionate 0.064% cream (Wynzora), calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment (Taclonex, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% suspension (Taclonex, generic). Note: Concomitant use of a topical vitamin d analog and a topical corticosteroid would meet the requirement. ii. This topical vitamin D analog was applied daily for at least 4 consecutive weeks; AND iii. Inadequate efficacy was demonstrated with this topical vitamin D analog, according to the prescriber. 2. **Atopic Dermatitis in a patient ≥ 2 years of age.** Patient meets **ONE** of the following (a or b): a. Patient is ≥ 6 years of age and has tried **BOTH** of the following: i. pimecrolimus cream (Elidel cream, generics) ii. tacrolimus ointment b. Patient is ≥ 2 years of age and < 6 years of age and has tried **ONE** of the following: i. pimecrolimus cream (Elidel cream, generics) ii. tacrolimus ointment

Therapeutic Category	Product	Criteria
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)
	potassium chloride extended-release tablet	**Potassium chloride extended-release tablet** is considered medically necessary when the patient has tried generic **potassium chloride ER 15mEq tablet (generic for Klor-Con M15)**, 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.
Respiratory - Corticosteroid Inhalers	**ArmonAir® Digihaler** (fluticasone propionate powder, metered)	**ArmonAir Digihaler** is considered medically necessary when there is documentation of **ONE** the following (by diagnosis, age, and/or ability to use device type): 1. **12 years of age, or older**. Tried **ALL** of the following: A. Alvesco (ciclesonide) B. Arnuity Ellipta (fluticasone furoate inhalation powder) C. Qvar Redihaler (beclomethasone) D. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler (mometasone) [step therapy may apply] 2. **Less than 12 years of age.** Tried **ALL** of the following: A. Arnuity Ellipta (fluticasone furoate inhalation powder) B. Qvar Redihaler (beclomethasone) C. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler

Therapeutic Category	Product	Criteria
		(mometasone) [step therapy may apply] 3. **Unable to coordinate breath and actuation with a conventional metered-dose inhaler**. Tried **ALL** of the following: A. Arnuity Ellipta (fluticasone furoate inhalation powder) B. Qvar Redihaler (beclomethasone) C. Asmanex Twisthaler (mometasone) [step therapy may apply] 4. **4 years of age to less than 5 years of age**. Tried **BOTH** of the following: A. Qvar Redihaler (beclomethasone) B. Asmanex Twisthaler (mometasone) [step therapy may apply]
	Flovent® Diskus (fluticasone inhalation powder)	**Flovent Diskus** is considered medically necessary when there is documentation of **ONE** the following (by diagnosis, age, and/or ability to use device type): 1. **12 years of age, or older**. Tried **ALL** of the following: A. Alvesco (ciclesonide) B. Arnuity Ellipta (fluticasone furoate inhalation powder) C. Qvar Redihaler (beclomethasone) D. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler (mometasone) [step therapy may apply] 2. **Less than 12 years of age**. Tried **ALL** of the following: A. Arnuity Ellipta (fluticasone furoate inhalation powder) B. Qvar Redihaler (beclomethasone) C. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler (mometasone) [step therapy may apply] 3. **Unable to coordinate breath and actuation with a conventional metered-dose inhaler.** Tried **ALL** of the following: A. Arnuity Ellipta (fluticasone furoate inhalation powder) B. Qvar Redihaler (beclomethasone) C. Asmanex Twisthaler (mometasone) [step therapy may apply] 4. **4 years of age to less than 5 years of age**. Tried **BOTH** of the following:

Therapeutic Category	Product	Criteria
		A. Qvar Redihaler (beclomethasone) B. Asmanex Twisthaler (mometasone) [step therapy may apply]
	Flovent HFA (fluticasone inhalation aerosol HFA)	**Flovent HFA** is considered medically necessary when there is documentation of **ONE** the following (by diagnosis, age, and/or ability to use device type): 1. **12 years of age, or older**. Tried **ALL** of the following: A. Alvesco (ciclesonide) B. Arnuity Ellipta (fluticasone furoate inhalation powder) C. Qvar Redihaler (beclomethasone) D. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler (mometasone) [step therapy may apply] 2. **12 years of age, or older and has a low inspiratory flow rate who are unable to use a dry powder inhaler (DPI).** Tried **ALL** of the following: A. Alvesco (ciclesonide) B. Qvar Redihaler (beclomethasone) C. Asmanex HFA [step therapy may apply] 3. **Less than 12 years of age**. Tried **ALL** of the following: A. Arnuity Ellipta (fluticasone furoate inhalation powder) B. Qvar Redihaler (beclomethasone) C. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler (mometasone) [step therapy may apply] 4. **Less than 12 years of age and has a low inspiratory flow rate who are unable to use a dry powder inhaler (DPI).** Tried **BOTH** of the following: A. Qvar Redihaler (beclomethasone) B. Asmanex HFA [step therapy may apply] 5. **Less than 12 years of age and is unable to use both a DPI and a breath-actuated metered-dose inhaler (MDI).** 6. **4 years of age to less than 5 years of age.** Tried **BOTH** of the following: A. Qvar Redihaler (beclomethasone) B. Asmanex Twisthaler (mometasone) [step therapy may apply]

Therapeutic Category	Product	Criteria
		7. **4 years of age to less than 5 years of age and has a low inspiratory flow rate and is unable to use a dry powder inhaler**. Tried the following: A. Qvar Redihaler (beclomethasone) 8. **Less than 4 years of age.** 9. **Eosinophilic esophagitis.**
	fluticasone propionate HFA	**Fluticasone propionate HFA** is considered medically necessary when there is documentation of **ONE** the following (by diagnosis, age, and/or ability to use device type): 1. **12 years of age, or older**. Tried **ALL** of the following: A. Alvesco (ciclesonide) B. Arnuity Ellipta (fluticasone furoate inhalation powder) C. Qvar Redihaler (beclomethasone) D. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler (mometasone) [step therapy may apply] 2. **12 years of age, or older and has a low inspiratory flow rate who are unable to use a dry powder inhaler (DPI).** Tried **ALL** of the following: A. Alvesco (ciclesonide) B. Qvar Redihaler (beclomethasone) C. Asmanex HFA [step therapy may apply] 3. **Less than 12 years of age**. Tried **ALL** of the following: A. Arnuity Ellipta (fluticasone furoate inhalation powder) B. Qvar Redihaler (beclomethasone) C. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler (mometasone) [step therapy may apply] 4. **Less than 12 years of age and has a low inspiratory flow rate who are unable to use a dry powder inhaler (DPI).** Tried **BOTH** of the following: A. Qvar Redihaler (beclomethasone) B. Asmanex HFA [step therapy may apply] 5. **Less than 12 years of age and is unable to use both a DPI and a breath-actuated metered-dose inhaler (MDI).** 6. **4 years of age to less than 5 years of age.** Tried **BOTH** of the following:

Therapeutic Category	Product	Criteria
		A. Qvar Redihaler (beclomethasone) B. Asmanex Twisthaler (mometasone) [step therapy may apply] 7. **4 years of age to less than 5 years of age and has a low inspiratory flow rate and is unable to use a dry powder inhaler**. Tried the following: A. Qvar Redihaler (beclomethasone) 8. **Less than 4 years of age.** 9. **Eosinophilic esophagitis.**
	fluticasone inhalation powder	**Fluticasone inhalation powder** is considered medically necessary when there is documentation of **ONE** the following (by diagnosis, age, and/or ability to use device type): 1. **12 years of age, or older**. Tried **ALL** of the following: A. Alvesco (ciclesonide) B. Arnuity Ellipta (fluticasone furoate inhalation powder) C. Qvar Redihaler (beclomethasone) D. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler (mometasone) [step therapy may apply] 2. **Less than 12 years of age**. Tried **ALL** of the following: A. Arnuity Ellipta (fluticasone furoate inhalation powder) B. Qvar Redihaler (beclomethasone) C. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler (mometasone) [step therapy may apply] 3. **Unable to coordinate breath and actuation with a conventional metered-dose inhaler.** Tried **ALL** of the following: A. Arnuity Ellipta (fluticasone furoate inhalation powder) B. Qvar Redihaler (beclomethasone) C. Asmanex Twisthaler (mometasone) [step therapy may apply] 4. **4 years of age to less than 5 years of age**. Tried **BOTH** of the following: A. Qvar Redihaler (beclomethasone) B. Asmanex Twisthaler (mometasone) [step therapy may apply]
	Pulmicort® Flexhaler®	**Pulmicort Flexhaler** is considered medically necessary when there is documentation of **ONE**

Therapeutic Category	Product	Criteria
	(budesonide inhalation powder)	the following (by diagnosis, age, and/or ability to use device type): 1. **12 years of age, or older**. Tried **ALL** of the following: A. Alvesco (ciclesonide) B. Arnuity Ellipta (fluticasone furoate inhalation powder) C. Qvar Redihaler (beclomethasone) D. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler (mometasone) [step therapy may apply] 2. **Unable to coordinate breath and actuation with a metered-dose inhaler (MDI).** Tried **ALL** of the following: A. Arnuity Ellipta (fluticasone furoate inhalation powder) B. Qvar Redihaler (beclomethasone) C. Asmanex Twisthaler (mometasone) [step therapy may apply] 3. **Less than 12 years of age**. Tried **ALL** of the following: A. Arnuity Ellipta (fluticasone furoate inhalation powder) B. Qvar Redihaler (beclomethasone) C. Asmanex HFA [step therapy may apply] or Asmanex Twisthaler (mometasone) [step therapy may apply]
Respiratory - Corticosteroid/Beta-Agonist Combination Inhalers	**Airsupra**™ (albuterol/ 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) **2.** Failure, contraindication, or intolerance to **ONE** albuterol-containing inhaler **OR** levalbuterol-containing inhaler taken concomitantly with one single-entity inhaled corticosteroid
Respiratory - Corticosteroid/Long -Acting Beta-Agonist Combination Inhalers	**Advair® Diskus** (fluticasone propionate/salmeterol powder)	**Advair Diskus** is considered medically necessary when the patient has tried the bioequivalent generic product, **fluticasone propionate and salmeterol powder**, 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.
	Advair® HFA (fluticasone propionate/salmeterol inhalation aerosol)	**Advair HFA** is considered medically necessary when there is documentation of **ONE** the following (by diagnosis, age, and/or ability to use device type): 1. **Age 18 years or older.** Tried **FOUR** of the following: A. Breo Ellipta (fluticasone/ vilanterol) B. budesonide/ formoterol (generic for Symbicort) OR Breyna C. Dulera (mometasone/ formoterol) D. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) 2. **Less than 18 years of age.** Tried **THREE** of the following: A. Breo Ellipta (fluticasone/ vilanterol) B. budesonide/ formoterol (generic for Symbicort) OR Breyna C. Dulera (mometasone/ formoterol) D. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) 3. **Patient with a low inspiratory flow rate who are unable to use a dry powder inhaler (DPI):** Tried **BOTH** of the following: A. budesonide/ formoterol (generic for Symbicort) OR Breyna B. Dulera (mometasone/ formoterol)
	AirDuo® Digihaler® (fluticasone/ salmeterol inhalation powder)	**AirDuo Digihaler** is considered medically necessary when there is documentation of **ONE** the following (by diagnosis, age, and/or ability to use device type): 1. **Age 18 years or older.** Tried **FOUR** of the following: A. Breo Ellipta (fluticasone/ vilanterol) B. budesonide/ formoterol (generic for Symbicort) OR Breyna C. Dulera (mometasone/ formoterol) D. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) 2. **Age 18 years or older and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).** Tried **BOTH** of the following:

Therapeutic Category	Product	Criteria
		A. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) B. Breo Ellipta (fluticasone/vilanterol) 3. **Less than 18 years of age.** Tried **THREE** of the following: A. Breo Ellipta (fluticasone/ vilanterol) B. budesonide/ formoterol (generic for Symbicort) OR Breyna C. Dulera (mometasone/ formoterol) D. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) 4. **Less than 18 years of age and unable to coordinate breath and actuation with a metered-dose inhaler (MDI)**. Tried **ONE** of the following: A. Breo Ellipta (fluticasone/ vilanterol) B. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)
	AirDuo® RespiClick® (fluticasone propionate/ salmeterol inhalation powder)	**AirDuo RespiClick** is considered medically necessary when there is documentation of **ONE** the following (by diagnosis, age, and/or ability to use device type): 1. **Age 18 years or older.** Tried **FOUR** of the following: A. Breo Ellipta (fluticasone/ vilanterol) B. budesonide/ formoterol (generic for Symbicort) OR Breyna C. Dulera (mometasone/ formoterol) D. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) 2. **Age 18 years or older and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).** Tried **BOTH** of the following: A. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) B. Breo Ellipta (fluticasone/vilanterol) 3. **Less than 18 years of age.** Tried **THREE** of the following: A. Breo Ellipta (fluticasone/ vilanterol) B. budesonide/ formoterol (generic for Symbicort) OR Breyna C. Dulera (mometasone/ formoterol)

Therapeutic Category	Product	Criteria
		D. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) 4. **Less than 18 years of age and unable to coordinate breath and actuation with a metered-dose inhaler (MDI)**. Tried **ONE** of the following: A. Breo Ellipta (fluticasone/ vilanterol) B. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)
	fluticasone propionate/ salmeterol inhalation powder (AirDuo Respiclick authorized generic)	**Fluticasone propionate/ salmeterol inhalation powder** is considered medically necessary when there is documentation of **ONE** the following (by diagnosis, age, and/or ability to use device type): 1. **Age 18 years or older.** Tried **FOUR** of the following: A. Breo Ellipta (fluticasone/ vilanterol) B. budesonide/ formoterol (generic for Symbicort) OR Breyna C. Dulera (mometasone/ formoterol) D. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) 2. **Age 18 years or older and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).** Tried **BOTH** of the following: A. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) B. Breo Ellipta (fluticasone/vilanterol) 3. **Less than 18 years of age.** Tried **THREE** of the following: A. Breo Ellipta (fluticasone/ vilanterol) B. budesonide/ formoterol (generic for Symbicort) OR Breyna C. Dulera (mometasone/ formoterol) D. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) 4. **Less than 18 years of age and unable to coordinate breath and actuation with a metered-dose inhaler (MDI)**. Tried **ONE** of the following: A. Breo Ellipta (fluticasone/ vilanterol) B. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)

Therapeutic Category	Product	Criteria
	fluticasone furoate and vilanterol inhalation powder	**Fluticasone furoate and vilanterol inhalation powder** is considered medically necessary when there is documentation of **BOTH** of the following: 1. Documented inability to obtain Breo Ellipta inhaler (the brand name product) 2. **ONE** of the following (by diagnosis, age, and/or ability to use device type): A. Tried **ALL** of the following: i. budesonide/ formoterol (generic for Symbicort) OR Breyna ii. Dulera (mometasone/formoterol) iii. fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol) B. **Less than 12 years of age.** Tried **ONE** of the following: i. budesonide/ formoterol (generic for Symbicort) OR Breyna ii. Dulera (mometasone/formoterol) iii. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) C. **Age 5 years or less.** Tried **ONE** of the following: i. Dulera (mometasone/formoterol) ii. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) D. **Unable to coordinate breath and actuation with a metered-dose inhaler (MDI).** Tried fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol) E. **COPD.** Tried **BOTH** of the following: i. budesonide/ formoterol (generic for Symbicort)

Therapeutic Category	Product	Criteria
		ii. fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol) F. **COPD and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).** Tried fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol).
	fluticasone propionate/salmeterol HFA oral inhalation	**Fluticasone propionate/ salmeterol HFA** is considered medically necessary when there is documentation of **BOTH** of the following: 1. Documented inability to obtain Advair HFA (the brand name product) 2. **ONE** the following (by diagnosis, age, and/or ability to use device type): A. **Age 18 years or older.** Tried **FOUR** of the following: i. Breo Ellipta (fluticasone/ vilanterol) ii. budesonide/ formoterol (generic for Symbicort) OR Breyna iii. Dulera (mometasone/formoterol) iv. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) B. **Less than 18 years of age.** Tried **THREE** of the following: i. Breo Ellipta (fluticasone/ vilanterol) ii. budesonide/ formoterol (generic for Symbicort) OR Breyna iii. Dulera (mometasone/formoterol) iv. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol) C. **Low inspiratory flow rate and unable to use a dry powder**

Therapeutic Category	Product	Criteria
		inhaler (DPI): Tried **BOTH** of the following: i. budesonide/ formoterol (generic for Symbicort) OR Breyna ii. Dulera (mometasone/formoterol)
	Symbicort® (budesonide/ formoterol fumarate dihydrate)	**Symbicort** is considered medically necessary when the patient has tried the bioequivalent generic product, **budesonide and formoterol fumarate dihydrate**, 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.
Respiratory – Inhaled Corticosteroid (ICS)/ Long-Acting Muscarinic Antagonist (LAMA)/Long-Acting Beta-Agonist (LABA) Combination Inhaler	**Breztri® Aerosphere** (budesonide/ glycopyrrolate/ formoterol fumarate inhalation aerosol)	**Breztri Aerosphere** is considered medically necessary when the patient has tried Trelegy Ellipta.
Respiratory - Inhaled Phosphodiesterase (PDE)-3 and PDE-4 Inhibitor	**Ohtuvayre™** (ensifentrine inhalation suspension)	**Ohtuvayre** is considered medically necessary when the following criteria are met: 1. Chronic obstructive pulmonary disease (COPD) in a patient ≥ 18 years of age AND the patient has tried, and according to the prescriber, experienced inadequate efficacy, OR significant intolerance with BOTH of the following products used concurrently: A. A Long-Acting Muscarinic Antagonist (LAMA) product AND B. A Long-Acting Beta-Agonist (LABA) product. <u>Note: Examples of LAMA/LABA Inhalers:</u> Anoro Ellipta <u>Note: Examples of LAMA Inhalers:</u> Incruse Ellipta, Tudorza Pressair [may require prior authorization].

Therapeutic Category	Product	Criteria
		Note: Examples of LABA Inhalers/Nebulized: formoterol fumarate inhalation solution, Striverdi Respimat [may require prior authorization]. Note: Examples of ICS/LABA Inhalers: Breo Ellipta, budesonide-formoterol, Dulera, fluticasone-salmeterol diskus, Wixela.
Rosacea Agents (Topical)	**Finacea®** (azelaic acid 15% foam)	**Finacea 15% foam** is considered medically necessary when **EITHER** of the following criteria are met: 1. **Patients with rosacea.** Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with three other topical agents for rosacea. Note: Examples include: metronidazole 0.75% or 1% products such as gels, creams, and lotions (MetroGel, generics; MetroLotion, generics; MetroCream, generics; Noritate), azelaic acid 15% gel (Finacea 15% gel, generics). 2. **Patients with acne vulgaris.** Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with three other prescription topical products for acne. Note: Examples include: topical antibiotic products (e.g., clindamycin, erythromycin); topical retinoids (tretinoin [Atralin/generics, Avita/generics, Retin-A/generics, Retin-A Micro, Tretin-X/generics], adapalene [Differin/generics], tazorotene [Tazorac 0.1% cream or 0.1% gel generics]; azelaic acid 15% gel (Finacea 15% gel, generics); sulfacetamide-containing products; combination products (Acanya generics), clindamycin/tretinoin gel [Ziana, Veltin generics], other generics).

Therapeutic Category	Product	Criteria
	Finacea® (azelaic acid 15% gel)	**Finacea 15% gel** is considered medically necessary when **EITHER** of the following criteria are met: 1. **Patients with rosacea.** Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with three other topical agents for rosacea. Note: Examples include: metronidazole 0.75% or 1% products such as gels, creams, and lotions (MetroGel, generics; MetroLotion, generics; MetroCream, generics; Noritate), azelaic acid 15% gel (Finacea 15% gel, generics). 2. **Patients with acne vulgaris.** Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with three other prescription topical products for acne. Note: Examples include: topical antibiotic products (e.g., clindamycin, erythromycin); topical retinoids (tretinoin [Atralin/generics, Avita/generics, Retin-A/generics, Retin-A Micro, Tretin-X/generics], adapalene [Differin/generics], tazorotene [Tazorac 0.1% cream or 0.1% gel generics]; azelaic acid 15% gel (Finacea 15% gel, generics); sulfacetamide-containing products; combination products (Acanya generics), clindamycin/tretinoin gel [Ziana, Veltin generics], other generics).
Selective Estrogen Receptor Modifiers and Antiestrogens	**Osphena®** (ospemifene tablets)	**Osphena** is considered medically necessary when the patient has tried one of the following estrogen products: estradiol cream or estradiol vaginal tablet.
Selective Serotonin Reuptake Inhibitors (SSRIs)	**Trintellix®** (vortioxetine tablets)	**Trintellix** is considered medically necessary when **ONE** of the following criteria are met: 1. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with **TWO** formulary SSRIs from the following list: A. escitalopram B. fluoxetine C. fluvoxamine

Therapeutic Category	Product	Criteria
		D. paroxetine E. sertraline 2. Patient is currently taking or has taken Trintellix at any time in the past. 3. Suicidal ideation. Note: If the patient tried the brand version of a generic equivalent product, then this trial would count towards the requirement.
Testosterone Products (Oral)	**Undecatrex**™ (testosterone undecanoate capsules)	**Undecatrex** is considered medically necessary when the patient has tried **ONE** of the following: 1. testosterone 1% gel 2. testosterone 1.62% gel pump or gel packet 3. testosterone 50 mg/ 5 gm gel 4. testosterone 12.5 mg/ 1.25 gm gel
Tetracycline-Derivatives -Oral Agents for Rosacea	**Emrosi**™ (minocycline extended-release capsules)	**Emrosi** is considered medically necessary when the patient meets both of the following (1 and 2): 1. Patient has tried **TWO** of the following: a. topical metronidazole-containing product, b. topical azelaic acid-containing product or c. topical ivermectin [may require prior authorization 2. Patient meets **ONE** of the following (a or b): a. Patient has tried, and according to the prescriber, has experienced inadequate efficacy with one other generic, oral minocycline product after a 4-week duration with the product; OR b. Patient has tried, and according to the prescriber, has experienced a significant intolerance with one other generic, oral minocycline product.

Therapeutic Category	Product	Criteria
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)
	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)

Therapeutic Category	Product	Criteria
		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 Atopic Dermatitis	**Eucrisa®** (crisaborole ointment, 2%)	**Eucrisa** is considered medically necessary when there is **ONE** of the following: 1. Patient is less than 2 years of age 2. Patient is less than 6 years of age **AND** has tried either pimecrolimus cream or tacrolimus ointment 3. Patient has tried **BOTH** of the following: pimecrolimus cream and tacrolimus ointment
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)

Therapeutic Category	Product	Criteria
		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]
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: 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)
	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)
Topical Roflumilast Agents	**Zoryve®** (roflumilast 0.15% cream)	**Zoryve 0.15% cream** is considered medically necessary when the following criteria are met: 1. **Atopic dermatitis in a patient ≥ 6 years of age.** Patient has tried **BOTH** pimecrolimus cream [may require prior authorization] and tacrolimus ointment

Therapeutic Category	Product	Criteria
	Zoryve (roflumilast 0.3% cream)	**Zoryve 0.3% cream** is considered medically necessary when the following criteria are met: 1. **Plaque Psoriasis.** Patient meets **ALL** of the following criteria: A. Patient is ≥ 6 years of age; AND B. Patient meets ONE of the following criteria: i. Patient has tried at least one medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid; OR ii. Patient is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia; AND C. Patient has tried at least one topical vitamin D analog. Note: Examples of topical vitamin D analogs include calcipotriene 0.005% cream (Dovonex, generic), calcipotriene 0.005% ointment (generic only), calcitriol 3 mcg/g ointment (Vectical, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment (Taclonex, generic). Concomitant use of a topical vitamin d analog and a topical corticosteroid would meet the requirement.
	Zoryve (roflumilast 0.3% foam)	**Zoryve 0.3% foam** is considered medically necessary when **ALL** of the following criteria are met: 1. **Seborrheic Dermatitis in a patient ≥ 9 years of age. BOTH** of the following criteria are met: A. **ONE** of the following: i. Patient has tried one of topical ketoconazole or topical ciclopirox; OR ii. Patient is ≥ 9 years of age and < 12 years of age; B. Patient has tried at least one low-, medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid.

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,	10/15/2024

	Prevident 1.1%, Prevident Kids 5000 PPM, Prevident 5000 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
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria, **EFFECTIVE on 1/1/2025** for: sulconazole nitrate 1% cream, sulconazole nitrate 1% solution, Ergomar, alogliptin tablet, Nesina, Onglyza, alogliptin and metformin tablet, alogliptin and pioglitazone tablet, Kazano, Kombiglyze XR, Oseni, sitagliptin and metformin oral tablet, Zituvimet, Zituvimet XR, Glyxambi, Qtern, Steglujan, Trijardy XR, insulin glargine, insulin glargine Solostar 100 units/ mL, insulin glargine-YFGN 100 units/ mL, insulin glargine Max Solostar U300 300 units/ mL, Lantus, Lantus SoloStar, Levemir, Rezvoglar Kwikpen, Semglee (non-YFGN), Semglee-YFGN, Toujeo Solostar, Toujeo Max SoloStar, Femring, Imvexxy, Premarin, Serevent Diskus, naproxen sodium controlled-release/ extended-release 375 mg, Creon, Pertzye, Zenpep, ArmonAir Digihaler, Flovent Diskus, Flovent HFA, fluticasone propionate HFA, fluticasone inhalation powder, Pulmicort Flexhaler, Advair Diskus, Advair HFA, AirDuo Digihaler, AirDuo Respiclick, fluticasone furoate and vilanterol inhalation powder, fluticasone propionate and salmeterol HFA oral inhalation, Symbicort, Breztri Aerosphere, Osphena	12/1/2024
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria: Fanapt, Clindesse, Glimepiride 3 mg, fluticasone propionate/ salmeterol, Ohtuvayre, Zoryve 0.15% cream, Zoryve 0.3% cream, Zoryve foam.	12/15/2024
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria: Clenpiq, Moviprep, Plenvu, Suprep, Sutab, Xhance. **Updated** Individual and Family Plan product-specific medical necessity criteria: Suflave.	1/1/2025
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria: potassium chloride ER tablet, clobetasol propionate 0.05% ophthalmic suspension, Dolobid, estradiol gel 0.06%, Estratest HS.	1/15/2025
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria: Crexont, carbamazepine chewable, Neffy, Betimol, timolol hemihydrates ophthalmic, Undecatrex.	2/15/2025
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria: Twyneo, Opipza, Emrosi, insulin aspart protamine-insulin aspart (NovoLog 70/30 mix generic) **Updated** Individual and Family Plan product-specific medical necessity criteria: Differin lotion, Epiduo Forte, Ergomar	3/1/2025
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria: insulin aspart (NovoLog generic), Novolog, Eucrisa	4/1/2025
Selected Revision	**Added** Individual and Family Plan product-specific medical necessity criteria: Azelex cream; clonidine 0.17 mg extended-release tablet; Nexiclon XR tablet; Adlarity transdermal system; donepezil and extended release memantine capsule; Namzaric; metronidazole 125 mg oral tablet; Arakoda tablet; Coartem tablet; Krintafel tablet; Cobenfy capsule; topiramate 50 mg oral sprinkle capsule;	5/1/2025

	labetalol 400 mg oral tablet; nimodipine 60 mg/ 20 mL oral solution; Aspruzyo Sprinkle; prucalopride 1 mg, 2 mg oral tablet; hydrocortisone 2.5% topical solution; Soliqua; Xultophy; metformin immediate release 750 mg; dapagliflozin-metformin extended-release tablet; Invokamet; Invokamet XR; Segluromet; Gabarone 100 mg, 400 mg tablet; bismuth subcitrate 140 mg/ metronidazole 125 mg/ tetracycline 125 mg; Omeclamox-Pak; Pylera; Talicia; Voquezna Dual Pak; Voquezna Triple Pak; zileuton extended-release tablet; Zyflo tablet; baclofen 5 mg/ 5 mL oral solution; Fenopron 300 mg; Iopidine ophthalmic solution; Vtama cream; Finacea foam; Finacea gel; Trintellix **Updated** Individual and Family Plan product-specific medical necessity criteria: Gemtesa	

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