Effective Date **2/15/2024**
Next Review Date… **2/15/2025**
Coverage Policy Number **1407**

Pharmacy Prior Authorization

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

Overview

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

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

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

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

Medical Necessity Criteria

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

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

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

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

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

Authorization Duration

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

Individual and Family Plan Product-Specific Criteria

Therapeutic Category	Product	Criteria
Antiparasitic	**Xdemvy**™ (lotilaner ophthalmic solution)	**Xdemvy** is considered medically necessary for a documented diagnosis of Demodex blepharitis.
Bowel Evacuants – Low Volume – Polyethylene Glycol (PEG)-based Preparations	**Suflave**™ (polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride for oral solution)	**Sulfave** is considered medically necessary when there is documentation of **EITHER** of the following: 1. Failure, contraindication, or intolerance to either PEG3350/Ascorbic Acid powder pack (generic Moviprep) **OR** Sodium Sulfate-Potassium Sulfate-Magnesium prep kit (generic Suprep) [prior authorization may be required] 2. Use is for bowel preparation as part of a colorectal screening procedure in an individual between the ages of 45 and 75 years of age **AND** neither PEG3350/Ascorbic Acid powder pack (generic Moviprep) **OR** Sodium Sulfate-Potassium Sulfate-Magnesium prep kit (generic Suprep) [prior authorization may be required] will be as medically appropriate as Suflave

Therapeutic Category	Product	Criteria
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).
Constipation Agents – Chronic Idiopathic Constipation Agents	**Trulance®** (plecanatide tablets)	**Trulance** is considered medically necessary when there is documentation of **ALL** of the following: 1. Age 18 years or older 2. Documented diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) 3. Documentation of failure, contraindication, or intolerance to linaclotide (Linzess®)
Dermatologic: Local anesthetics, topical	**Lidocan II** (lidocaine 5% topical patch)	Documented trial of **lidocaine 5% topical patch** (generic for Lidoderm) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.
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.
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
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

Therapeutic Category	Product	Criteria
	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

Conditions Not Covered

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

Background

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