Drug Coverage Policy

Effective Date……6/1/2025
Coverage Policy Number…… 1701
Policy Title….. Unassigned Drug Code Outpatient Medical Precertification

Unassigned Drug Code Outpatient Medical Precertification

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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

Coverage Policy

Policy Statement
This policy addresses outpatient use of drugs with unassigned Healthcare Common Procedure Coding System (HCPCS) code that require medical precertification. This policy does not address the use of drugs in hospitalized patients.

Refer to Oncology Medications (1403) located on the Drug Policy A-Z Index for medical necessity criteria requirements for unassigned HCPCS code J9999 (not otherwise classified antineoplastic drugs).

HCPCs Code	Product	Criteria
J3490 (Unclassified Drug) **J3590** (Unclassified Biologics)	**Non-specified Product**	Absence of product-specific criteria, drugs with an unassigned Healthcare Common Procedure Code System (HCPCS) code requiring outpatient medical precertification are considered medically necessary when the following are met: 1. Approve for up to 12 months if the patient meets **ONE** of the following: (A or B) A. 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 B. Use is supported by standard medical reference compendia (for example: Clinical Pharmacology, MicroMedex, Wolters Kluwer Facts and Comparisons) and is not contraindicated or otherwise not recommended in the FDA product information (Label) or compendia. **Conditions Not Covered** Any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available): 1. Dose, duration of therapy, frequency or quantity exceeding generally accepted medical practice standards
J3490	**Isuprel** (isoproterenol)	Isuprel is considered medically necessary for outpatient use when **ONE** of the following criteria are met (1 or 2): Note: Use of Isuprel (isoproterenol) in hospitalized patients is not addressed in this policy. **Other Outpatient Uses with Supportive Evidence**

HCPCs Code	Product	Criteria
		1. Provocation during tilt table testing for syncope. **2. Provocation of arrhythmia during electrophysiologic testing, includes pre- and post-ablation.** **Conditions Not Covered** Isuprel for any other outpatient use is considered not medically necessary.
J3490	**Ketalar®** (ketamine intravenous)	**Conditions Not Covered** Ketalar for any outpatient use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available): Note: Use of Ketalar (ketamine) in hospitalized patients is not addressed in this policy. **1. Bipolar Disorder.** **2. Major Depressive Disorder.** **3. Chronic Pain.** **4. Complex Regional Pain Syndrome.**

Background

Health benefit plans vary, drugs that are not part of the covered drug list may be approved for coverage when medical necessity criteria are met through the coverage review process. Doctors and health care professionals can log in to CignaForHCP.com to learn more about which medications require prior authorization. Customers can log in to the myCigna App or myCigna.com, or check plan materials, to learn more about how medications are covered.

In general, to be eligible for coverage, a drug must be approved by the Food and Drug Administration (FDA), prescribed by a health care professional, purchased from a licensed pharmacy and be medically necessary. In developing medical necessity exception criteria within coverage policies criteria incorporate information from U.S. Food and Drug Administration-approved labeling[1], the standard medical reference compendia[2-4] and peer-reviewed, evidence-based scientific literature or guidelines.

References

1. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.
2. Clinical Pharmacology powered by ClinicalKey. Philadelphia (PA): Elsevier. c2021- [cited 2025 March 24]. Available from: http://www.clinicalkey.com.
3. Individual Drug Name Entries. Drug Facts and Comparisons. eFacts [online] 2025. Available from Wolters Kluwer Health, Inc.

4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Policy Title.** **Added** "outpatient" and **removed** "biologic" to state "Unassigned Drug Code Outpatient Medical Precertification" **Non-specified Product.** **Added J3590** **Added** "and the dosage, frequency, site of administration, and duration of therapy is not contraindicated or otherwise not recommended in the Label" to "Use is approved and listed in the FDA product information (Label)..." **Added** "Clinical Pharmacology, MicroMedex, Wolters Kluwer Facts and Comparisons, Wolters Klewer UpToDate)" as compendia examples and **removed** "American Hospital Formulary Service-Drug Information [AHFS-DI]" as a compendia example **Defitelio, Dsuvia, Macrilen.** **Removed** as drugs are primarily for inpatient use. **DefenCath.** **Removed** DefenCath as product received unique Healthcare Common Procedure Coding System (HCPCS) code. **Isuprel, Ketalar.** **Updated** to address outpatient use only. **Regiocit**. **Removed** as Emergency Use Authorization was revoked on 1/16/2025.	6/1/2025

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