

Drug Coverage Policy

Effective Date.....7/1/2025 Coverage Policy Number1407

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 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 quidelines. In certain markets, delegated vendor quidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

Policy Statement

This policy supports the following drug medical necessity review:

- Drugs requiring Pharmacy or Medical Prior Authorization for Employer Group Plans and/or Individual and Family Plans where no other coverage policy or criteria are specified
- Individual and Family Plans non-formulary drug exception criteria

- I. Drugs requiring pharmacy or medical prior authorization where no other coverage policy or criteria are specified are considered medically necessary when BOTH of the following is met (1 and 2):
 - **1. ONE** of the following (A <u>or</u> 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 according to 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)
 - **2.** And where available, use of therapeutic alternatives unless otherwise specified or clinically inappropriate.

<u>Note</u>: 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.

Approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered not medically necessary.

II. Individual and Family Plan non-formulary drug criteria. Non-formulary drugs are considered medically necessary when the product-specific criteria are met:

Refer to: <<u>Drugs Requiring Medical Necessity Review for Individual and Family</u> <u>Plans</u>>

This is an up-to-date list of products alphabetized by *Therapy Class* and *Brand Name*.

Conditions Not Covered

Any other exception is considered not medically necessary (criteria will be updated as newly published data are available).

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.

Background

OVERVIEW

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 Administrationapproved labeling¹, the standard medical reference compendia²⁻⁴ and peer-reviewed, evidencebased 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
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	7/15/2024
Selected Revision	 medical necessity criteria for: Blue Link glucose test strips 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 	8/1/2024
Selected Revision	medical necessity criteria for: Zituvio tablets 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	9/1/2024

	Removed Individual and Family Plan product-specific medical necessity criteria for: Glucose Test Strips, Lancets	
Selected Revision	Added Individual and Family Plan product-specific medical necessity criteria for: Libervant, Rextovy.	9/15/2024
Selected Revision	Added Individual and Family Plan product-specific medical necessity criteria for: Carac, Klisyri, imiquimod 3.75%, Zyclara 3.75%, Zyclara 2.5%, ondansetron ODT 16mg, carbinoxamine maleate 4 mg/ 5 mL suspension, Karbinal ER suspension, Innopran XL, Inderal LA, Inderal XL, Kapspargo, Katerzia, Norliqva, hydrocortisone 2% lotion, sitagliptin- metformin, Estratest FS, Furoscix, Clinpro 5000, Fraiche 5000 Previ, Fraiche 5000 Sensitive, Just Right 5000, Prevident 1.1%, Prevident Kids 5000 PPM, Prevident 5000 Booster Plus, Prevident Dry Mouth, Prevident Orthodefens, Prevident 5000 Plus, Prevident Rinse 0.2%, Prevident 5000 Sensitive, Prevident 5000 Enamel.	10/15/2024
	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 propionate and salmeterol 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)	3/1/2025

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	Updated Individual and Family Plan product-specific	
	medical necessity criteria: Differin lotion, Epiduo Forte,	
Colortad Davisian	Ergomar	4/1/2025
Selected Revision	Added Individual and Family Plan product-specific medical	4/1/2025
	necessity criteria: insulin aspart (NovoLog generic),	
	Novolog, Eucrisa Added Individual and Family Plan product-specific medical	E (1 /202E
Selected Revision	necessity criteria: Azelex cream; clonidine 0.17 mg	5/1/2025
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	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;	
	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; Voguezna Dual Pak; Voguezna 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	
Selected Revision	Updated Individual and Family Plan product-specific	5/15/2025
	medical necessity criteria: Posfrea, Focinvez, dapagliflozin	0, 10, 2020
	metformin extended-release tablet	
Selected Revision	Updated Individual and Family Plan product-specific	6/1/2025
	medical necessity criteria: Myrbetriq, Gemtesa	-, -,
	, , ,	
	Removed Individual and Family Plan product-specific	
	medical necessity criteria: mirabegron, Posfrea, Focinvez	
Selected Revision	Added Individual and Family Plan product-specific	7/1/2025
	medical necessity criteria: Angeliq, Duavee,	
	Premphase, Prempro, Veltassa, Onapgo, Xromi, GlucaGen,	
	GlucaGen Hypokit, Gvoke, Zegalogue, Twiist, Fulvicin P/G,	
	griseofulvin ultramicrosize 165mg, Journavx, Tezruly,	
	metaxolone, clobetasol propionate cream, Zunveyl, Inzirgo,	
	meclizine, ferric citrate, Auryxia, Raldesy, Auranofin,	
	meclizine, ferric citrate, Auryxia, Raldesy, Auranofin, Ridaura, Aptiom, Briviact, carbamazepine chewable, Elepsia	
	meclizine, ferric citrate, Auryxia, Raldesy, Auranofin, Ridaura, Aptiom, Briviact, carbamazepine chewable, Elepsia XR, Eprontia, Fycompa, Motpoly XR,	
	meclizine, ferric citrate, Auryxia, Raldesy, Auranofin, Ridaura, Aptiom, Briviact, carbamazepine chewable, Elepsia XR, Eprontia, Fycompa, Motpoly XR, Oxtellar XR, oxcarbazepine ER, Spritam, topiramate,	
	meclizine, ferric citrate, Auryxia, Raldesy, Auranofin, Ridaura, Aptiom, Briviact, carbamazepine chewable, Elepsia XR, Eprontia, Fycompa, Motpoly XR,	
	meclizine, ferric citrate, Auryxia, Raldesy, Auranofin, Ridaura, Aptiom, Briviact, carbamazepine chewable, Elepsia XR, Eprontia, Fycompa, Motpoly XR, Oxtellar XR, oxcarbazepine ER, Spritam, topiramate,	

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

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