



# Drug Coverage Policy

Effective Date.....11/01/2024  
Coverage Policy Number.....IP0011  
Policy Title....Brands with Bioequivalent  
Generics

## Brands with Bioequivalent Generics

### 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.

## Cigna Healthcare Coverage Policy

### OVERVIEW

The FDA Office of Generic Drugs follows a rigorous review process to make sure that, compared to the brand-name (or innovator) medications, the proposed generic medications:

- Contain the same active/key ingredient;
- Have the same strength;
- Use the same dosage form (for instance, a tablet, capsule, or liquid); and
- Use the same route of administration (for instance, oral, topical, or injectable).

FDA's review process ensures that generic medications perform the same way in the human body and have the same intended use as the name brand medication. Health care professionals and consumers can be assured that FDA-approved generic drug products have met the same rigid

standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity, and stability as brand-name drugs. In addition, FDA inspects facilities to make certain the generic manufacturing, packaging, and testing sites pass the same quality standards as those of brand-name drugs.<sup>1</sup>

A multi-sourced brand drug is a brand-name drug that is marketed or sold by two or more manufacturers or labelers, is no longer protected under patent exclusivity, and has a therapeutically equivalent generic available.

This Coverage Policy supports medical necessity review for brands with bioequivalent generic drugs available, not addressed in any other policy.

## Medical Necessity Criteria

**Brands with bioequivalent generic products listed in the below table are considered medically necessary when the following criteria are met:**

The patient has tried the bioequivalent generic product AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

Any other exception is considered not medically necessary.

All products are approved for a duration of 12 months unless otherwise noted.

Non-Covered Brand	Bioequivalent Generic
Abilify	aripiprazole
Aciphex tablet	<b>EFFECTIVE 1/1/2025</b> rabeprazole sodium tablets
Accupril	quinapril tablet
Accuretic	quinapril/hydrochlorothiazide
Actos	pioglitazone
Acular 0.5% solution	ketorolac 0.5% solution
Acular LS 0.4% solution	ketorolac 0.4% solution
Aczone (5% gel and 7.5% gel pump)	<b>EFFECTIVE 1/1/2025</b> dapson topical gel
Aldactone	spironolactone
Alphagan P 0.15% ophthalmic solution	brimonidine tartrate ophthalmic solution
Altace	ramipril capsule
Amitiza	lubiprostone
Anafranil	clomipramine capsules
Analpram-HC	pramoxine and hydrocortisone cream
Ancobon	flucytosine capsules
Anusol-HC 2.5% cream	hydrocortisone acetate 2.5% cream
Anusol-HC 25 mg suppository	hydrocortisone acetate, Anucort-HC (hydrocortisone), Hemmorex-HC (hydrocortisone) 25 mg suppository

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
Atacand	<b>EFFECTIVE 1/1/2025</b> candesartan cilexetil tablets
Atacand HCT	<b>EFFECTIVE 1/1/2025</b> candesartan/hydrochlorothiazide tablets
Avalide	<b>EFFECTIVE 1/1/2025</b> irbesartan/hydrochlorothiazide tablets
Avapro	irbesartan tablets
Avodart	dutasteride
Ativan	lorazepam tablets
Atralin	tretinoin gel (0.05%)
Augmentin tablet	amoxicillin/clavulanate potassium tablet
Augmentin XR tablet	amoxicillin/clavulanate potassium extended-release tablet
Augmentin suspension	amoxicillin/clavulanate potassium suspension
Augmentin ES suspension	amoxicillin/clavulanate potassium suspension
Avapro	<b>EFFECTIVE 1/1/2025</b> irbesartan tablets
Azopt 1% solution	brinzolamide 1% solution
AZOR	<b>EFFECTIVE 1/1/2025</b> amlodipine besylate/olmesartan medoxomil tablets
Azulfidine	sulfasalazine
Baciguent ophthalmic ointment	bacitracin ophthalmic ointment
Baraclude	entecavir
Benicar	<b>EFFECTIVE 1/1/2025</b> olmesartan medoxomil tablets
Benicar HCT	<b>EFFECTIVE 1/1/2025</b> olmesartan/hydrochlorothiazide tablets
Bepreve 1.5% solution	bepotastine 1.5% solution
Betapace	sotalol
Betapace AF	sotalol
BiDil	<b>EFFECTIVE 1/1/2025</b> isosorbide dinitrate and hydralazine tablets
Bromfed DM	brompheniramine, dextromethorphan and pseudoephedrine syrup
Brovana 15 mcg/2 mL solution	arformoterol 15 mcg/2 mL solution
Bystolic	nebivolol
Canasa	mesalamine rectal suppository
Carafate suspension	sucralfate oral suspension
Carafate tablet	sucralfate tablet
Carbatol	carbamazepine ER
Cardizem	diltiazem hcl tablet
Cardizem CD	diltiazem extended-release capsules
Cardizem LA	<b>EFFECTIVE 1/1/2025</b> diltiazem extended-release tablets
Carnitor	levocarnitine
Carnitor SF	levocarnitine
Cellcept 200mg/ml oral suspension	<b>EFFECTIVE 1/1/2025</b> mycophenolate mofetil oral suspension
Cellcept 250mg capsule	<b>EFFECTIVE 1/1/2025</b>

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
	mycophenolate mofetil capsules
Cellcept 500mg tablet	<b>EFFECTIVE 1/1/2025</b> mycophenolate mofetil tablets
Celexa	citalopram
Celontin	<b>EFFECTIVE 1/1/2025</b> methsuximide
Chantix	varenicline
Ciloxan 0.3% solution	ciprofloxacin 0.3% solution
Ciprodex	ciprofloxacin / dexamethasone otic suspension
Cleocin vaginal cream	clindamycin vaginal cream
Clobex 0.05% Shampoo	clobetasol 0.05% shampoo
Clobex 0.05% Spray	clobetasol 0.05% spray
Clozaril	clozapine
Colcrys	colchicine tablet
Combigan ophthalmic solution	brimonidine tartrate/timolol maleate ophthalmic solution
Coreg	carvedilol tablet
Coreg CR	carvedilol extended-release capsule
Corgard	nadolol
Cortef	hydrocortisone tablet
Cosopt solution	dorzolamide and timolol solution
Cosopt PF solution	dorzolamide and timolol preservative free solution
Coumadin	warfarin
Cozaar	<b>EFFECTIVE 1/1/2025</b> losartan tablet
Cymbalta	duloxetine delayed-release capsules
Cytomel	liothyronine
DDAVP injection	desmopressin acetate injection
DDAVP tablet	desmopressin acetate tablet
Delestrogen intramuscular injection	estradiol valerate intramuscular injection
Depakote	divalproex sodium
Depakote ER	divalproex sodium ER
Depakote sprinkle	divalproex sodium
Detrol	tolterodine tablets
Detrol LA	tolterodine ER capsules
Diastat, Diastat Acudial	diazepam
Diclegis	<b>EFFECTIVE 1/1/2025</b> doxylamine succinate and pyridoxine hydrochloride delayed-release tablets
Differin 0.1% cream	adapalene 0.1% cream
Differin 0.3% gel pump	adapalene 0.3% gel pump
Diflucan suspension	fluconazole suspension
Diflucan tablet	fluconazole tablet
Dilantin, Dilantin-125, Phenytek	phenytoin
Diovan	<b>EFFECTIVE 1/1/2025</b> valsartan tablets
Diovan HCT	<b>EFFECTIVE 1/1/2025</b> valsartan/hydrochlorothiazide tablets
Durezol 0.05% emulsion	difluprednate 0.05% emulsion

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
Dyrenium	triamterene
E.E.S. 200 mg/5 mL	erythromycin ethylsuccinate 200 mg/5 mL granules for suspension
Effexor XR	venlafaxine hydrochloride extended-release capsule
Elidel	pimecrolimus
Elixophyllin	theophylline 80 mg/15 mL solution
Emend capsules and Emend Trifold Pack	<b>EFFECTIVE 1/1/2025</b> aprepitant oral capsules
Epaned	<b>EFFECTIVE 1/1/2025</b> enalapril maleate powder for oral solution, enalapril maleate oral solution
EryPed 400	erythromycin 400 mg/5 mL suspension
Estrace tablets	<b>EFFECTIVE 1/1/2025</b> estradiol tablets
Estrace cream	<b>EFFECTIVE 1/1/2025</b> estradiol cream
Exforge	amlodipine and valsartan
Exforge HCT	amlodipine, valsartan and hydrochlorothiazide
Felbatol	felbamate
Flomax	<b>EFFECTIVE 1/1/2025</b> tamsulosin hydrochloride capsules
FML	fluorometholone
FML Liquifilm 0.1% suspension	fluorometholone 0.1% suspension
Fosrenol Chewable Tablet	lanthanum carbonate chewable tablet
Furadantin 25 mg/5 mL oral suspension	nitrofurantoin 25 mg/5 mL oral suspension
Gabitril	tiagabine hydrochloride
Geodon	ziprasidone
Gralise 300mg and 600mg tablets	<b>EFFECTIVE 1/1/2025</b> gabapentin extended-release tablets
Halog 0.1% cream	halcinonide 0.1% cream
Hyzaar	<b>EFFECTIVE 1/1/2025</b> losartan/hydrochlorothiazide tablets
Inderal LA	propranolol extended-release capsule
Inspra	eplerenone
Intuniv	guanfacine ER
Istalol 0.5% solution	timolol maleate 0.5% solution
Isordil Titradose 5mg	isosorbide dinitrate 5mg tablet
Jalyn	dutasteride / tamsulosin
Kapvay	clonidine ER tablet
Keppra	levetiracetam
Keppra XR	levetiracetam extended release
Klonopin	clonazepam
Lamictal	lamotrigine
Lamictal ODT	lamotrigine ODT
Lamictal XR	lamotrigine
Lanoxin	digoxin
Lasix	furosemide
Latuda	lurasidone

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
Lexapro	escitalopram tablets
Lialda	mesalamine delayed-release tablet
Librax	chlordiazepoxide hydrochloride; clidinium bromide
Lidoderm 5% topical patch	lidocaine 5% topical patch
Lithobid	lithium
Lomotil	<b>EFFECTIVE 1/1/2025</b> diphenoxylate/atropine
Lopressor	metoprolol tartrate
Lotemax 0.5% ophthalmic gel	loteprednol 0.5% ophthalmic gel
Lotemax 0.5% ophthalmic suspension	loteprednol 0.5% ophthalmic suspension
Lotensin	benazepril tablet
Lotensin HCT	benazepril/hydrochlorothiazide
Lotrel	amlodipine/benazepril capsule
Lovaza	omega-3-acid ethyl esters capsule
Lunesta	eszopiclone
Lyrica	pregabalin
Malarone	atovaquone / proguanil
Marinol	dronabinol
Maxitrol ointment	neomycin, polymyxin B, and dexamethasone ointment
Maxitrol suspension	neomycin, polymyxin B, and dexamethasone suspension
Mepron	atovaquone
Mestinon	pyridostigmine
Metrogel vaginal	Metronidazole vaginal
Micardis	<b>EFFECTIVE 1/1/2025</b> telmisartan tablets
Micardis HCT	<b>EFFECTIVE 1/1/2025</b> telmisartan/hydrochlorothiazide tablets
Minivelle	estradiol transdermal patch
MoviPrep	PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, ascorbic acid
Mycobutin	rifabutin
Myfortic	mycophenolic acid
Myrbetriq tablets	mirabegron extended-release tablets
Mysoline	primidone
Nardil	phenelzine
Natroba	<b>EFFECTIVE 1/1/2025</b> spinosad topical suspension
Neoral capsule	cyclosporine capsule
Neoral oral solution	cyclosporine oral solution
Neurontin	gabapentin
Norpace	disopyramide phosphate
Norpramin	desipramine
Noxafil 40mg/ml (200mg/5ml) oral suspension	<b>EFFECTIVE through 12/31/2024 for Employer Plans</b> posaconazole 40mg/ml (200mg/5ml) oral suspension  <b>EFFECTIVE 1/1/2025 for Employer Plans and Individual and Family Plans</b> posaconazole 40mg/ml (200mg/5ml) oral suspension

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
Noxafil tablet	posaconazole tablet
Ocuflox 0.3% solution	ofloxacin 0.3% solution
Onfi	clobazam
Pacerone	amiodarone
Pamelor	nortriptyline capsules
Parnate	tranylcypromine tablets
Patanol 0.1% solution	olopatadine 0.1% solution
Paxil	paroxetine hydrochloride
Paxil CR	paroxetine hydrochloride extended-release tablet
Pentasa 500 mg	mesalamine 500 mg extended-release capsule
Perforomist 20 mcg/2 mL solution	formoterol 20 mcg/2 mL solution
Plaquenil	hydroxychloroquine sulfate
Polytrim solution	trimethoprim and polymyxin B solution
Pred Forte 1% suspension	prednisolone 1% suspension
Prenatabs FA	prenatal vitamin, iron 29 mg/folic acid 1 mg
Prezista 600mg and 800mg tablets	<b>EFFECTIVE 1/1/2025</b> darunavir oral tablets
Pristiq	Desvenlafaxine succinate extended-release tablet
Procardia XL	nifedipine extended-release
Proglycem suspension	diazoxide oral suspension
Prograf capsule	tacrolimus
Prometrium	progesterone
Protopic	tacrolimus ointment
Provera	<b>EFFECTIVE 1/1/2025</b> medroxyprogesterone acetate tablet
Prozac	fluoxetine
Qualaquin	quinine sulfate
Qudexy XR	topiramate
Ranexa	ranolazine
Rapamune	<b>EFFECTIVE 1/1/2025</b> sirolimus
Remeron	mirtazapine
Renagel tablet	sevelamer hydrochloride tablet
Renvela tablet	sevelamer carbonate tablet
Renvela powder packet	sevelamer carbonate powder packet
Retin-A cream (0.025%, 0.05%, 0.1%)	tretinoin cream (0.025%, 0.05%, 0.1%)
Retin-A gel (0.025%, 0.01%)	tretinoin gel (0.025%, 0.01%)
Retin-A Micro gel (0.04% & 0.1%)	tretinoin microsphere gel (0.04% & 0.1% gel)
Retin-A Micro Pump gel (0.04%, 0.08%, 0.1%)	tretinoin microsphere pump gel (0.04%, 0.08%, 0.1%)
Rilutek	riluzole
Risperdal	risperidone
Risperdal Consta	risperidone intramuscular injection
Rowasa	mesalamine rectal suspension
Rozerem	ramelteon

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
Rythmol SR	propafenone HCL ER
Salex 6% cream kit	salicylic acid 6% cream
Salex 6% lotion kit	salicylic acid 6% lotion
Salex 6% shampoo	salicylic acid 6% shampoo
Samsca	tolvaptan
Sandimmune	cyclosporine
Sensipar	cinacalcet
Silenor	doxepin tablet
Soma	<b>EFFECTIVE 1/1/2025</b> carisoprodol
Sporanox capsule	itraconazole capsule
Sporanox solution	itraconazole solution
Strattera	atomoxetine
Sulfatrim	sulfamethoxazole/trimethoprim (co-trimoxazole; TMP-SMZ)
Suprep oral solution	Sodium sulfate-potassium sulfate-magnesium sulfate oral solution
Symbyax	olanzapine and fluoxetine capsule
Synthroid	levothyroxine tablets
Tamiflu	oseltamivir phosphate
Tasmar	tolcapone
Tekturna	aliskiren
Tegretol	carbamazepine
Tegretol XR	carbamazepine extended release
Tenoretic	atenolol and chlorthalidone
Tenormin	atenolol
Tikosyn	dofetilide
Timoptic 0.25% solution	timolol maleate 0.25% solution
Timoptic 0.5% solution	timolol maleate 0.5% solution
Timoptic 0.5% OcuDose solution	timolol maleate 0.5% solution
Timoptic XE 0.25% gel solution	timolol maleate 0.25% gel forming solution
Timoptic XE 0.5% gel solution	timolol maleate 0.5% gel forming solution
Tobradex suspension	tobramycin and dexamethasone suspension
Tobrex 0.3% solution	tobramycin 0.3% solution
Topamax	topiramate
Toprol XL	metoprolol succinate extended-release tablet
Toviaz	fesoterodine fumarate
Tranxene T-tab	Clorazepate dipotassium tablet
Tribenzor	<b>EFFECTIVE 1/1/2025</b> olmesartan/amlodipine/hydrochlorothiazide tablets
Trileptal	oxcarbazepine
Trusopt 2% solution	dorzolamide 2% solution
Uloric	febuxostat
Unithroid	levothyroxine tablets
Vagifem	<b>EFFECTIVE 1/1/2025</b> estradiol vaginal tablet
Valcyte solution	valganciclovir hydrochloride solution
Valcyte tablet	valganciclovir hydrochloride tablet
Valium	<b>EFFECTIVE 1/1/2025</b>



Non-Covered Brand	Bioequivalent Generic
	diazepam tablets
Vancocin	vancomycin hydrochloride
Vanos 0.1% cream	fluocinonide 0.1% cream
Vaseretic	enalapril/hydrochlorothiazide tablet
Vasotec	enalapril tablet
Vesicare	solifenacin tablets
Vigamox 0.5% solution	moxifloxacin 0.5% solution
Viibryd	vilazodone
Vimpat	lacosamide
Vitatrue	prenatal vitamin, iron 30 mg/folic acid 1.4 mg/DHA 300 mg
Vivelle-DOT	estradiol transdermal patch
Wellbutrin SR	bupropion hydrochloride extended-release tablet
Wellbutrin XL	bupropion extended release
Welchol packet	colesevelam packet
Welchol tablet	colesevelam tablet
Xanax	<b>EFFECTIVE 1/1/2025</b> alprazolam tablets
Xanax XR	<b>EFFECTIVE 1/1/2025</b> alprazolam extended-release tablets
Zarontin	ethosuximide
Zestoretic	lisinopril/hydrochlorothiazide tablet
Zestril	lisinopril tablet
Ziac	bisoprolol and hydrochlorothiazide
Zoloft	sertraline
Zonegran	zonisamide
Zovirax capsule	acyclovir capsule
Zovirax suspension	acyclovir suspension
Zovirax tablet	acyclovir tablet
Zyloprim	allopurinol tablet
Zymaxid 0.5% solution	gatifloxacin 0.5% solution
Zyprexa	olanzapine
Zyprexa Zydis	olanzapine

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.

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

## References

1. U.S Food and Drug Administration. Generic Drugs Overview & Basics: <http://www.fda.gov/drugs/generic-drugs/overview-basics>. Accessed on 4/2/2024.

## Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	<p><b>Removed</b> diagnosis requirement from the following products: Felbatol, Keppra, Keppra XR, Lamictal, Lamictal ODT, Lamictal XR, Qudexy XR, Topamax, Trileptal, Vimpat, and Zonegran and to now support medical necessity review for both Employer Plans and Individual and Family Plans.</p> <p><b>Added</b> to the policy to support medical necessity review for Individual and Family Plans: Atralin, Differin 0.1% cream, Differin 0.3% gel pump, Retin-A cream, Retin-A gel, Retin-A Micro gel, Retin-A Micro Pump gel</p>	7/15/2024
Selected Revision	<p><b>Removed</b> Taytulla</p> <p><b>Added</b> Moviprep, Mepron (Mepron effective 9/1/2024)</p>	8/15/2024
Selected Revision	<p><b>Added</b> Myrbetriq to support medical necessity review for Employer plans.</p> <p><b>Added</b> Ancobon to support medical necessity review for Individual and Family Plans.</p>	9/1/2024
Selected Revision	<p><b>Added</b> to the policy to support medical necessity review for Employer Plans: Accupril, Accuretic, Altace (applies to Value/Advantage/Total Savings and Individual and Family Plans), Anafranil, Ativan, Cardizem CD, Clobex 0.05% shampoo, Clobex 0.05% Spray, Cymbalta, Detrol, Detrol LA, Elixophyllin, EryPed 400, Halog 0.1% cream, Lexapro, Lotensin, Lotensin HCT, Lotrel, Pamelor, Parnate, Toviaz, Vanos 0.1% cream, Vaseretic, Vasotec, Vesicare, Zestoretic, Zestril.</p>	10/15/2024
Selected Revision	<p>The following were added to the policy to support medical necessity review:</p> <p><b><u>Effective 11/1/2024</u></b>  <b>Added for Employer Plans:</b> Cytomel (Individual and Family plans already utilize this policy), Synthroid, Unithroid</p> <p><b><u>Effective 1/1/2025</u></b>  <b>Added for Employer Plans and Individual and Family Plans:</b>            Aciphex tablet, Altace, Atacand, Atacand HCT, Avalide, Avapro, AZOR, Benicar, Benicar HCT, Carafate tablets, Cardizem LA, Cellcept 200mg/ml oral suspension, Cellcept 250mg capsule, Cellcept 500mg tablet, Cozaar, Diovan, Diovan HCT, Emend 80mg capsule and Emend Trifold Pack, Estrace</p>	11/01/2024

	<p>cream, Exforge, Exforge HCT, Flomax, Hyzaar, Lomotil, Micardis, Micardis HCT, Natroba, Noxafil tablet (added dosage form to clarify tablet and suspension), Provera, Rapamune, Soma, Tribenzor, Vagifem, Valium, Xanax, Xanax XR, Zestril</p> <p><b>Added for Employer Plans:</b> Diclegis, BiDil, Carafate suspension, Epaned, Gralise 300mg and 600mg, Estrace tablet (Individual and Family Plans already utilize this policy), Aczone (5% gel and 7.5% gel pump)</p> <p><b>Added for Individual and Family Plans:</b> Celontin, Prezista 600mg and 800mg tablets, Noxafil 40mg/ml oral suspension (Employer plans already utilize this policy for tablet and suspension), Welchol (Employer plans already utilize this policy)</p>	
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The policy effective date is in force until updated or retired.

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