



Drug Coverage Policy

Effective Date.....9/1/2024
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.¹

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
Actos	pioglitazone
Acular 0.5% solution	ketorolac 0.5% solution
Acular LS 0.4% solution	ketorolac 0.4% solution
Aldactone	spironolactone
Alphagan P 0.15% ophthalmic solution	brimonidine tartrate ophthalmic solution
Amitiza	lubiprostone
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
Avodart	dutasteride
Atralin	tretinoin gel (0.05%)
Augmentin tablet	amoxicillin/clavulanate potassium tablet
Augmentin XR tablet	amoxicillin/clavulanate potassium extended-release tablet

Non-Covered Brand	Bioequivalent Generic
Augmentin suspension	amoxicillin/clavulanate potassium suspension
Augmentin ES suspension	amoxicillin/clavulanate potassium suspension
Azopt 1% solution	brinzolamide 1% solution
Azulfidine	sulfasalazine
Baciguent ophthalmic ointment	bacitracin ophthalmic ointment
Baraclude	entecavir
Bepreve 1.5% solution	bepotastine 1.5% solution
Betapace	sotalol
Betapace AF	sotalol
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	sucralfate
Carbatol	carbamazepine ER
Cardizem	diltiazem hcl tablet
Carnitor	levocarnitine
Carnitor SF	levocarnitine
Celexa	citalopram
Chantix	varenicline
Ciloxan 0.3% solution	ciprofloxacin 0.3% solution
Ciprodex	ciprofloxacin / dexamethasone otic suspension
Cleocin vaginal cream	clindamycin vaginal cream
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
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
Diastat, Diastat Acudial	diazepam
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

Non-Covered Brand	Bioequivalent Generic
Dilantin, Dilantin-125, Phenytek	phenytoin
Durezol 0.05% emulsion	difluprednate 0.05% emulsion
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
Exforge	amlodipine and valsartan
Exforge HCT	amlodipine, valsartan and hydrochlorothiazide
Felbatol	felbamate
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
Inderal LA	propranolol extended-release capsule
Inspra	eplerenone
Intuniv	guanfacine ER
Istalol 0.5% solution	timolol maleate 0.5% solution
Isordil Titrados 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
Lialda	mesalamine delayed-release tablet
Librax	chlordiazepoxide hydrochloride; clidinium bromide
Lidoderm 5% topical patch	lidocaine 5% topical patch
Lithobid	lithium
Lopressor	metoprolol tartrate

Non-Covered Brand	Bioequivalent Generic
Lotemax 0.5% ophthalmic gel	loteprednol 0.5% ophthalmic gel
Lotemax 0.5% ophthalmic suspension	loteprednol 0.5% ophthalmic suspension
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
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
Neoral capsule	cyclosporine capsule
Neoral oral solution	cyclosporine oral solution
Neurontin	gabapentin
Norpace	disopyramide phosphate
Norpramin	desipramine
Noxafil	posaconazole
Ocuflox 0.3% solution	ofloxacin 0.3% solution
Onfi	clobazam
Pacerone	amiodarone
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
Pristiq	Desvenlafaxine succinate extended-release tablet
Procardia XL	nifedipine extended-release
Proglycem suspension	diazoxide oral suspension
Prograf capsule	tacrolimus
Prometrium	progesterone
Protopic	tacrolimus ointment
Prozac	fluoxetine
Qualaquin	quinine sulfate
Qudexy XR	topiramate

Non-Covered Brand	Bioequivalent Generic
Ranexa	ranolazine
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
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
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
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

Non-Covered Brand	Bioequivalent Generic
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
Trileptal	oxcarbazepine
Trusopt 2% solution	dorzolamide 2% solution
Uloric	febuxostat
Valcyte solution	valganciclovir hydrochloride solution
Valcyte tablet	valganciclovir hydrochloride tablet
Vancocin	vancomycin hydrochloride
Vigamox 0.5% solution	moxifloxacin 0.5% solution
Viiibryd	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
Zarontin	ethosuximide
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
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Annual Revision	<p>Removed 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 both Employer Plans and Individual and Family Plans for medical necessity review.</p> <p>Added to the policy 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>Removed Taytulla</p> <p>Added Moviprep, Mepron (Mepron effective 9/1/2024)</p>	8/15/2024
Selected Revision	<p>Added Myrbetriq to support Employer plans for medical necessity review.</p> <p>Added Ancobon to support Individual and Family Plans medical necessity review.</p>	9/1/2024

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

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