



# Brand Name Products with Bioequivalent Generics

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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.*

**New Brand name drugs may be added to this policy as generics become available.**

## National Formulary Medical Necessity

**Cigna covers Brand Name Products with Bioequivalent Generics [\[see Table 1 below\]](#) as medically necessary when the following criteria is met:**

1. Approve if the Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., 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 **[documentation required]**.

**Cigna covers Brand Name Products with Bioequivalent Generics [\[see Table 2 below\]](#) as medically necessary when ONE of the following criteria is met (1 or 2):**

Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is NOT required.

1. Approve if the Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., 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 **[documentation required]**.

OR

Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is required.

2. Approve if the individual meets one of the following criteria (i or ii):
  - i. The requested brand non-formulary drug is being prescribed primarily for the prevention of pregnancy AND, according to the prescriber, the brand product is being requested because the preferred bioequivalent generic product would not be as medically appropriate for the individual as the requested brand non-formulary drug; OR
  - ii. The requested brand non-formulary drug is being prescribed for a use OTHER THAN primarily for the prevention of pregnancy AND the Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., 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 **[documentation required]**.

**Cigna covers Brand Name Products with Bioequivalent Generics [\[see Table 3 below\]](#) as medically necessary when ONE of the following criteria is met (1 or 2):**

Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is NOT required.

1. **Note:** A multisource Brand product is being requested. The patient should use the preferred bioequivalent generic product.  
**Criteria:** Approve if the Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., 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 **[documentation required]**.

OR

Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is required.

2. Approve if the individual meets one of the following criteria (i or ii):
  - i. The requested brand non-formulary drug is being prescribed for HIV Pre-Exposure Prophylaxis (PrEP) in a patient at high risk for HIV infection according to the prescriber AND, according to the prescriber, the brand product is being requested

- because the preferred bioequivalent generic product would not be as medically appropriate for the patient as the requested brand non-formulary drug; OR
- ii. The requested brand non-formulary drug is being prescribed for a use OTHER THAN HIV Pre-Exposure Prophylaxis (PrEP) in a patient at high risk for HIV infection according to the prescriber AND the Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., 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 **[documentation required]**.

**Cigna covers Brand Name Products with Bioequivalent Generics [\[see Table 4 below\]](#) as medically necessary when ONE of the following criteria is met (1 or 2):**

Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is NOT required.

1. Approve if the Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., 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 **[documentation required]**.

OR

Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is required.

2. Approve one of the following (A or B):
  - A. The patient meets both of the following (i and ii):
    - i. The requested brand non-formulary drug is being prescribed for the primary prevention of cardiovascular disease (CVD) for an adult aged 40 to 75 years who has one or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year CVD event risk of 10% or greater and who does NOT have a history of (or signs or symptoms of) CVD (for example: symptomatic coronary artery disease, ischemic stroke); AND
    - ii. According to the prescriber, the brand product is being requested because the preferred bioequivalent generic product would not be as medically appropriate for the patient as the requested brand non-formulary drug; OR
  - B. The patient meets both of the following (i and ii):
    - i. The requested brand non-formulary drug is being prescribed for a use OTHER THAN the primary prevention of cardiovascular disease (CVD) for an adult aged 40 to 75 years who has one or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year CVD event risk of 10% or greater and who does NOT have a history of (or signs or symptoms of) CVD (for example: symptomatic coronary artery disease, ischemic stroke); AND
    - ii. The Brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., 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 **[documentation required]**.

**Cigna covers the following drug(s) or biologic(s) as medically necessary when the following criteria are met:**

- [\[see Table 5 below\]](#) for Product-Specific Exception Criteria]

Approval duration is 12 months unless otherwise noted.

## Brands with Bioequivalent Generics

**Table 1**

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
Abilify	aripiprazole tablets and oral solution
Abilify Discmelt	aripiprazole orally disintegrating tablets (ODT)
Acanya Gel	benzoyl peroxide 2.5% and clindamycin phosphate 1.2% gel
Aciphex	rabeprazole sodium tablets
Adcirca	tadalafil tablets
Adderall	dextroamphetamine/amphetamine tablets
Adderall XR	dextroamphetamine/amphetamine extended-release capsules
Afinitor Disperz	everolimus tablets for oral suspension
Afinitor tablet	everolimus tablets
Alinia tablets	nitazoxanide tablets
Ambien	zolpidem tablets
Ambien CR	zolpidem extended-release tablets
Amitiza	lubiprostone capsules
Ampyra	dalfampridine extended-release tablets
Androgel	testosterone 1% gel packets and pump, 1.62% (2021)
Anusol-HC cream	hydrocortisone acetate cream
Aptensio XR	methylphenidate hydrochloride XR capsule
Arimidex	anastrozole tablets
Asacol HD	mesalamine 800 mg delayed release tablet
Atacand	candesartan cilexetil tablets
Atacand HCT	candesartan/hydrochlorothiazide tablets
Atralin	tretinoin gel (0.05%)
Atripla	efavirenz 600 mg, emtricitabine 200 mg, tenofovir disoproxil fumarate 300 mg tablets
Avalide	irbesartan/hydrochlorothiazide tablets
Avapro	irbesartan tablets
Avodart	dutasteride capsules
Azopt	brinzolamide 1% ophthalmic suspension
AZOR	amlodipine besylate/olmesartan medoxomil tablets
Banzel	rufinamide tablets and oral suspension
Baraclude tablets	entecavir tablets
Benicar	olmesartan medoxomil tablets
Benicar HCT	olmesartan/hydrochlorothiazide tablets
Bepreve	bepotastine besilate ophthalmic solution
BiDil	isosorbide dinitrate and hydralazine tablets
BromSite	bromfenac 0.075% ophthalmic solution
Butrans	buprenorphine transdermal system
Bystolic	nebivolol tablets
Canasa	mesalamine rectal suppository
Carafate	sulfacalfate tablets and oral suspension
Celebrex	celecoxib capsules
Celexa	citalopram tablets

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
Cialis	tadalafil tablets
Clindagel 1% gel	clindamycin 1% gel
Colcrys	colchicine tablets
Concerta	methylphenidate hcl extended-release tablets
Coreg	carvedilol tablet
Cosopt/Cosopt PF	dorzolamide 2%/timolol 0.5% ophthalmic solution
Cozaar	losartan tablet
Cuprimine	penicillamine capsules
Cuvposa	glycopyrrolate oral solution
Cymbalta	duloxetine HCl capsules
Cystadane	betaine trimethylglycine powder for solution
Cytomel	liothyronine sodium tablets
Daliresp	roflumilast tablets
Delzicol	mesalamine delayed-release capsule
Detrol	tolterodine tablets
Detrol LA	tolterodine, extended-release capsules
Diovan	valsartan tablets
Diovan HCT	valsartan/hydrochlorothiazide tablets
Divigel	estradiol gel 0.1%
Doryx 50 mg, 200 mg	doxycycline hyclate delayed-release tablets
Duexis	ibuprofen and famotidine tablets
Durezol	difluprednate 0.05% ophthalmic emulsion
Effexor XR	venlafaxine HCl extended-release capsules
Elidel	pimecrolimus cream
Emend capsules and Emend Trifold Pack	aprepitant oral capsules
Epaned	enalapril maleate powder for oral solution, enalapril maleate oral solution
Esbriet	pirfenidone tablets and capsules
Estrace Cream	estradiol cream
Evekeo	amphetamine sulfate tablet
Exforge	valsartan/amlodipine tablets
Exforge HCT	valsartan/amlodipine/hydrochlorothiazide tablets
Exjade	deferasirox tablets for oral suspension
Feraheme	ferumoxytol injection
Focalin and Focalin XR	dexmethylphenidate tablets and extended-release capsules
Fosrenol chewable tablets	lanthanum carbonate chewable tablets
ganirelix injection	ganirelix acetate injection
Generess FE	norethindrone - ethinyl estradiol -iron chewable tablets
Gilenya 0.5 mg	fingolimod capsule
Gleevec	imatinib tablets
Hyzaar	losartan/hydrochlorothiazide tablets
Imitrex injection	sumatriptan succinate solution for injection (injectable pen/cartridges)
Imitrex nasal spray	sumatriptan nasal spray
Imitrex tablets	sumatriptan succinate tablets
Inderal LA	propranolol HCl capsules
Intuniv	guanfacine HCl tablets
Istalol	timolol maleate 0.5% ophthalmic solution

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
Jadenu	deferasirox tablets
Jadenu Sprinkles	deferasirox oral granules
Keppra	levetiracetam tablets and solution
Keppra XR	levetiracetam extended-release tablets
Kerydin	tavaborole topical solution, 5%
Klonopin	clonazepam tablets
Kuvan	sapropterin tablet and powder packet
Lamictal	lamotrigine tablets and chewable tablets
Lamictal ODT	lamotrigine oral disintegrating tablets
Lamictal XR	lamotrigine extended-release tablets
Letairis	ambrisentan tablets
Lexapro	escitalopram oxalate tablets and oral solution
Lialda	mesalamine delayed-release tablet
Lidoderm	lidocaine 5% patch
Locoid	hydrocortisone butyrate cream, lotion, ointment, solution
Locoid Lipocream	hydrocortisone butyrate 0.1% cream
Lotrel	amlodipine/benazepril capsules
Lotronex	alosetron tablets
Lovaza	omega-3 acid ethyl esters capsules
Lovenox	enoxaparin sodium injection (syringe/vial)
Lunesta	eszopiclone tablets
Lyrica	pregabalin capsules
Lyrica CR	pregabalin controlled-release capsules
Maxalt	rizatriptan tablets
Maxalt MLT	rizatriptan orally disintegrating tablets
Mestinon	pyridostigmine tablet, solution, extended-release tablet
Micardis	telmisartan tablets
Micardis HCT	telmisartan/hydrochlorothiazide tablets
Minivelle	estradiol transdermal patch
MoviPrep	PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, ascorbic acid
Nalfon	fenoprofen capsules
Namenda XR	memantine extended-release capsule
Natroba	spinosad topical suspension
Neurontin	gabapentin tablet, capsule and solution
Nexium capsules	esomeprazole delayed-release capsules
Nexium packet (granules for oral suspension) 10 mg, 20 mg, 40 mg packet	esomeprazole delayed-release granules for oral suspension (packet)
Norvasc	amlodipine tablets
Noxafil tablets	posaconazole delayed-release tablets
Nuvigil	armodafinil tablets
Onfi	clobazam tablets and suspension
Oxistat Cream	oxiconazole nitrate cream
Pennsaid	diclofenac sodium topical solution 2.0% pump
Percocet	oxycodone/acetaminophen tablets
Perforomist	formoterol fumarate inhalation solution
Plaquenil	hydroxychloroquine sulfate tablets
Plavix	clopidogrel bisulfate tablets
Prevacid	lansoprazole delayed-release (DR) capsules

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
Prevacid SoluTab	lansoprazole orally disintegrating tablets
Pristiq	desvenlafaxine succinate tablets
ProAir HFA	albuterol sulfate inhalation aerosol
Protonix	pantoprazole sodium delayed-release (DR) tablets and intravenous (IV) injection
Protonix oral suspension	pantoprazole delayed-release oral suspension (granules)
Proventil HFA	albuterol sulfate inhalation aerosol
Provigil	modafinil tablets
Prozac	fluoxetine HCl pulvules
Pulmicort	budesonide respules
Pyridium	phenazopyridine tablets
Ranexa	ranolazine tablets
Rapaflo	silosodin capsules
Relpax	eletriptan tablets
Renagel	sevelamer hydrochloride tablet
Retin-A Micro 0.1% & 0.04% gel	tretinoin 0.1% & 0.04% gel
Ritalin	methylphenidate tablets
Ritalin LA	methylphenidate long-acting capsules
Rozerem	ramelteon tablets
Sabril	vigabatrin tablets and powder packet
Samsca	tolvaptan tablets
Saphris	asenapine sublingual tablets
Sensipar	cinacalcet tablets
Seroquel	quetiapine fumarate tablets
Seroquel XR	quetiapine fumarate extended-release tablets
Singulair tablets	montelukast sodium tablets, chewable tablets, granules
Strattera	atomoxetine HCl capsules
Suboxone	buprenorphine/naloxone sublingual film
Suprep	magnesium sulfate; potassium sulfate; sodium sulfate solution
Synthroid	levothyroxine tablets
Targretin capsule	bexarotene capsule
Tazorac 0.1% cream	tazarotene 0.1% cream
Tazorac gel	tazarotene gel 0.05% and 0.1%
Tekturna	aliskiren tablets
Testim	testosterone gel
Thiola	tiopronin tablets
Tikosyn	dofetilide capsules
TOBI	tobramycin solution for inhalation
Topamax	topiramate tablets
Topicort spray	desoximetasonone spray
Toprol XL	metoprolol succinate extended-release tablets
Toviaz	fesoterodine fumarate extended-release tablets
Transderm-Scop	scopolamine patches
Travatan Z	travoprost 0.004% ophthalmic solution (benzalkonium chloride-free)
Tribenzor	olmesartan/amlodipine/hydrochlorothiazide tablets
Tricor	fenofibrate tablets
Trileptal	oxcarbazepine tablets and suspension
Uloric	febuxostat tablets

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
Uroxatral	alfuzosin tablets
Vagifem	estradiol vaginal tablet
Valium	diazepam tablets
Valtrex	valacyclovir HCl caplets
Vanos	fluocinonide 0.1% cream
Veltin	clindamycin phosphate and tretinoin gel
Vesicare	solifenacin succinate tablets
Viagra	sildenafil tablets
Viibryd (non- starter pack) 10 mg, 20 mg, 40 mg	vilazodone tablets
Vimovo	naproxen and esomeprazole magnesium delayed-release tablets
Vimpat	lacosamide tablets and oral solution
Vivelle-Dot	estradiol transdermal patch
Vytorin	ezetimibe/simvastatin tablets
Welchol packets and tablets	colesevelam packets and tablets
Wellbutrin SR	bupropion HCl tablets
Wellbutrin XL	bupropion XL tablets
Xalatan	latanoprost 0.005% ophthalmic solution
Xanax	alprazolam tablets
Xanax XR	alprazolam extended-release tablets
Xenazine	tetrabenazine tablets
Zetia	ezetimibe tablets
Zioptan	tafluprost 0.0015% ophthalmic solution
Zipsor	diclofenac potassium capsule
Zoloft	sertraline HCl tablets and oral solution
Zomig	zolmitriptan tablets
Zonegran	zonisamide capsule
Zovirax ointment	acyclovir 5% ointment
Zytiga	abiraterone acetate tablets

**Table 2**

<b>Non-Covered Brand</b>	<b>Bioequivalent Generic</b>
Generess FE	norethindrone - ethinyl estradiol -iron chewable tablets
Loestrin and Loestrin FE	ethinyl estradiol/norethindrone and ferrous fumarate tablets
Loseasonique	levonorgestrel/ethinyl estradiol and ethinyl estradiol tablets
Minastrin 24 FE	norethindrone - ethinyl estradiol - iron chewable tablets
Mircette	desogestrel - ethinyl estradiol and ethinyl estradiol tablets
NuvaRing	etonogestrel/ethinyl estradiol vaginal ring
Quartette	levonorgestrel-ethinyl estradiol and ethinyl estradiol tablets
Safyral	drospirenone/ethinyl estradiol-levomefolate tablets
Seasonique	levonorgestrel-ethinyl estradiol and ethinyl estradiol tablets
Taytulla	norethindrone and ethinyl estradiol and ferrous fumarate capsules



Non-Covered Brand	Bioequivalent Generic
Yasmin	ethinyl estradiol/ drospirenone tablets

**Table 3**

Non-Covered Brand	Bioequivalent Generic
Truvada	emtricitabine/ tenofovir tablets

**Table 4**

Non-Covered Brand	Bioequivalent Generic
Crestor	rosuvastatin tablets
Lipitor	atorvastatin tablets
Zocor	simvastatin tablets

**Table 5 – Product-Specific Exception Criteria**

Non-Covered Product	Bioequivalent Generic	Exception Criteria
Zavesca	miglustat capsules	<p><b>NOTE:</b> A multisource Brand product is being requested.</p> <p>See standard Gaucher Disease – <i>Substrate Reduction Therapy Preferred Specialty Management Policy</i> criteria</p>

## Conditions Not Covered

Any other exception is considered not medically necessary.

## 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/>

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