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Coverage Policy Number IP0011

Multi-Source Brand Name Drugs

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Related Coverage Resources

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. 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.

Overview

This Coverage Policy supports medical necessity review for multi-source brand (MSB) named drugs not addressed in any other policy.

Coverage Policy Statement

Multi-Source Brand (MSB) name drugs [see tables below] are medically necessary when the following criteria is met:

- Documentation that individual 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 prescribing physician, would result in a significant allergy or serious adverse reaction

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 as applicable.

Documentation: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts.

Refer to Specific Additional Criteria section below if applicable.

Specific Additional Criteria

Multi-Source Brand Drug	Bioequivalent Generic	Specific Additional Criteria
Armour Thyroid	NP Thyroid	Approve in individuals with Thyroid Cancer.
Cytomel	liothyronine	
Synthroid	levothyroxine	
Unithroid	levothyroxine	

Conditions Not Covered

Any other exception is considered not medically necessary.

Multi-Source Brand Name Drugs

Table 1

Multi-Source Brand Drug	Bioequivalent Generic
Absorica	isotretinoin
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
Apriso	mesalamine
Armour Thyroid (15 mg, 30 mg, 60 mg, 90 mg, 120 mg) tablet	NP Thyroid (15 mg, 30 mg, 60 mg, 90 mg, 120 mg) tablet
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
Baraclude	entecavir
Betapace	sotalol
Carafate	sucralfate
Cardizem	diltiazem hcl tablet
Cortef	hydrocortisone tablet
Cytomel	liothyronine
DDAVP tablet	desmopressin acetate tablet
Diflucan suspension	fluconazole suspension
Diflucan tablet	fluconazole tablet
E.E.S. 200 mg/5 mL	erythromycin ethylsuccinate 200 mg/5 mL granules for suspension
Elidel	pimecrolimus
FML	fluorometholone
Humatin	paromomycin sulfate capsule
Intuniv	guanfacine ER
Isordil Titrados 5mg	isosorbide dinitrate 5mg tablet
Librax	chlordiazepoxide hydrochloride; clidinium bromide
Lotemax	loteprednol

Multi-Source Brand Drug	Bioequivalent Generic
Lovaza	omega-3-acid ethyl esters capsule
Lyrica	pregabalin
Marinol	dronabinol
Mepron	atovaquone
Minivelle	estradiol transdermal patch
Mycobutin	rifabutin
Myfortic	mycophenolic acid
Noxafil	posaconazole
Pepcid	famotidine
Prenatabs FA	prenatal vitamin, iron 29 mg/folic acid 1 mg
Prograf capsule	tacrolimus
Ranexa	ranolazine
Rowasa	mesalamine rectal suspension
Salex 6% cream kit	salicylic acid 6% cream
Salex 6% lotion kit	salicylic acid 6% lotion
Salex 6% shampoo	salicylic acid 6% shampoo
Sensipar	cinacalcet
Sporanox capsule	itraconazole capsule
Sporanox solution	itraconazole solution
Sulfatrim	sulfamethoxazole/trimethoprim (co-trimoxazole; TMP-SMZ)
Strattera	atomoxetine
Synthroid	levothyroxine
Tamiflu	oseltamivir phosphate
Uloric	febuxostat
Unithroid	levothyroxine
Valcyte solution	valganciclovir hydrochloride solution
Valcyte tablet	valganciclovir hydrochloride tablet
Vancocin	vancomycin hydrochloride
Vitatrue	prenatal vitamin, iron 30 mg/folic acid 1.4 mg/DHA 300 mg
Vivelle-DOT	estradiol transdermal patch
Wellbutrin XL	bupropion extended-release
Zyflo CR 600mg extended-release tablet	zileuton 600mg extended-release tablet
Zovirax capsule	acyclovir capsule
Zovirax suspension	acyclovir suspension
Zovirax tablet	acyclovir tablet

Table 2 (Therapeutic Categories Requiring Prior Authorization)

Therapeutic Categories	Multi-Source Brand Drug	Bioequivalent Generic
Antipsychotics	Abilify	aripiprazole
	Geodon	ziprasidone
	Lithobid	lithium
	Zyprexa	olanzapine
	Zyprexa Zydis	olanzapine
Blood Thinners	Coumadin	warfarin
Cardiovascular	Lanoxin	digoxin
	Norpace	disopyramide phosphate
	Pacerone	amiodarone
	Rythmol SR	propafenone HCL ER

Therapeutic Categories	Multi-Source Brand Drug	Bioequivalent Generic
	Tikosyn	dofetilide
Seizure Disorders	Carbatol	carbamazepine ER
	Depakote	divalproex sodium
	Depakote ER	divalproex sodium ER
	Depakote sprinkle	divalproex sodium
	Diastat, Diastat Acudial	diazepam
	Dilantin, Dilantin-125, Phenytek	phenytoin
	Felbatol	felbamate
	Gabitril	tiagabine hydrochloride
	Keppra, Keppra XR	levetiracetam
	Klonopin	clonazepam
	Lamictal, Lamictal XR, Lamictal ODT	lamotrigine
	Mysoline	primidone
	Neurontin	gabapentin
	Onfi	clobazam
	Tegretol, Tegretol XR	carbamazepine
	Topamax	topiramate
	Trileptal	oxcarbazepine
	Zarontin	ethosuximide
	Zonegran	zonisamide

Background

Generics

The FDA's generic drug approval process does not require the drug sponsor to repeat costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness. Generic drugs must establish the following for approval:

- contain the same active ingredients as the innovator drug (inactive ingredients may vary)
- be identical in strength, dosage form, and route of administration
- have the same use indications
- be bioequivalent
- meet the same batch requirements for identity, strength, purity, and quality
- be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products

A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used. FDA requires generic drugs have the same high quality, strength, purity and stability as brand-name drugs. Not every brand-name drug has a generic drug. When new drugs are first made they have drug patents. Most drug patents are protected for 20 years. The patent, which protects the company that made the drug first, doesn't allow anyone else to make and sell the drug. When the patent expires, other drug companies can start selling a generic version of the drug. But, first, they must test the drug and the FDA must approve it.

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.

References

1. U.S Food and Drug Administration. Generic Drugs Questions and Answers:
<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100>.

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