



Compliance Alert

May 13, 2009

Formulary Update – Topamax® Sprinkle Capsules

Issue

On April 15, 2009, the U.S. Food and Drug Administration (FDA) approved generics to Ortho-McNeil-Janssen Pharmaceuticals Topamax® (topiramate) Sprinkle Capsules, a medication commonly prescribed for the treatment of seizures and prevention of migraines. Generics to Topamax Sprinkle Capsules now join generics to Topamax tablets in the market, which have been available since late March 2009.

Now that generics are established in the marketplace, Express Scripts will enact a procedure that will result in the removal of the brand Topamax Sprinkle Capsules from Express Scripts formularies, replacing them with equivalent generic topiramate capsules. This procedure is being enacted because Topamax is marked with an ‘*’ on the formularies, indicating a potential conversion to non-formulary status with the availability of generics.

Take-Away Points

- Generic topiramate capsule are AB-rated generics to Topamax® Sprinkle Capsules and are now available in the marketplace.
- The brand-name product, Topamax Sprinkle Capsules, will be converted to non-formulary status on June 1, 2009.
- This procedure is being enacted because Topamax is marked with an ‘*’ on the formularies, indicating a potential for conversion to non-formulary status with the availability of generics.

In addition to Topamax Sprinkle Capsules, several other drugs are scheduled to lose patent protection in 2009. The drugs listed in the table below are some of the drugs that will also be designated as ‘non-formulary’ when generics are established in the market. However, keep in mind that although a key drug patent expires, generic products are not always readily available. There are many issues that may delay their availability, including litigation, patent settlements, final approval from FDA, and additional patents and granted exclusives.

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CellCept (mycophenolate – Roche)	Transplant	May 3
Prandin (repaglinide – Novo Nordisk)	Diabetes	September 14
Alphagan P (brimonidine – Allergan)	Glaucoma	September 15
Allegra-D (fexofenadine/pseudoephedrine - sanofi-aventis)	Allergies	November 1
Acular (ketorolac – Allergan)	Anti-inflammatory	November 5
Prevacid Naprapac (lansoprazole/naproxen – Takeda)	Ulcers	November 10
Activella (estradiol/noreth ac – Novo Nordisk)	Hormone Replacement Therapy	December 28
Valtrex (valacyclovir – GlaxoSmithkline)	Viral Infections	4 th Quarter
Ambien CR (zolpidem e.r. – sanofi-aventis)	Sleep	Litigation
Cardizem LA (diltiazem e.r. – Biovail)	High Blood Pressure	Settlement
Concerta (methylphenidate e.r. – Johnson & Johnson)	AHDH	Litigation
Dynacirc CR (isradipine e.r. – GlaxoSmithKline)	High Blood Pressure	Expired*
Lovenox (enoxaparin – sanofi-aventis)	Anticoagulant	Citizen's
Petition		
Protopic (tacrolimus – Astellas)	Atopic Dermatitis	Expired*

*Generics not available

If you have any questions regarding this information, please contact your Group Benefit Services Account Manager at 1.800.638.6085.

This communication is not intended to be legal advice and should not be construed as legal advice. If you have any legal questions or concerns about your plan, GBS recommends seeking counsel from an ERISA attorney.

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