



Compliance Alert

June 1, 2009

Formulary Update – CellCept® Capsules and Tablets

Issue

On May 4, 2009, the U.S. Food and Drug Administration (FDA) approved generics to Roche's CellCept® (mycophenolate mofetil) capsules and tablets. This drug is approved to prevent rejection in people who have received a kidney, heart or liver transplant. Generic CellCept is now available from several manufacturers in both the 250mg capsule and 500mg tablet formulations.

Now that generics are established in the marketplace, Express Scripts will enact a procedure that will result in the removal of the brand CellCept capsules and tablets from Express Scripts formularies, replacing them with equivalent generic mycophenolate mofetil product. This procedure is being enacted because CellCept is marked with an '*' on the formularies, indicating a potential conversion to non-formulary status with the availability of generics.

Take-Away Points

- Generic mycophenolate mofetil capsules and tablets are AB-rated generics to CellCept® capsules and tablets, respectively, and are now available in the marketplace.
- The brand-name product, CellCept capsules and tablets, will be converted to non-formulary status on July 1, 2009.
- This procedure is being enacted because CellCept is marked with an '*' on the formularies, indicating a potential for conversion to non-formulary status with the availability of generics.

In addition to CellCept capsules and tablets, 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 exclusivities.

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

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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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