



Indiana Medicaid Drug Utilization Review Board Newsletter

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Indiana Medicaid DUR Board

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Center, South

402 West Washington
Street

Indianapolis, Indiana 46204

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Inside this Issue

- The Value of Generics
- Program Assistance and PDL Listing Information
- Top 20 Drugs for 3Q2007

The Value of Generics

What is considered a generic medication? Once a patent expires on a brand name medication, other manufacturers are able to make a “generic” formulation of the product. Generic medications are required by the Food and Drug Administration (FDA) to be pharmaceutically equivalent and bioequivalent to the brand name product. Pharmaceutical equivalence indicates that medications are identical in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.¹ Bioequivalence is defined by the FDA as pharmaceutically equivalent products whose rate and extent of absorption are not statistically different when administered to patients or subjects at the same dose under similar experimental conditions.²

For approval of a generic medication, the FDA requires that the medication must:

- Contain the same active ingredient as the innovator medication
- Be identical in strength, dosage form, and route of administration
- Have the same indications for use, bioequivalence, and batch requirements for identity, strength, purity, and quality
- Be manufactured under the same good manufacturing practice standards.

How are generic medications less expensive? According to the Congressional Budget Office, generics save consumers an estimated 8-10 billion dollars a year at retail pharmacies. When a generic medication first appears on the U.S. market it typically has a 6 month exclusivity period and usually has only a slightly lower price than the brand name product. As more generic manufacturers obtain approval from the FDA to sell the same medication product, the market becomes more competitive and the generic price begins to fall.³ This price reduction can be quite substantial, as illustrated in Table 1

on page 2; which shows a comparison of the average monthly cost of some common generics vs. the cost of the brand name medication.

Which medications can be substituted? The FDA provides a resource that is helpful in the context of generic substitution. It is entitled *Approved Drug Products with Therapeutic Equivalency Evaluations*, also referred to as “The Orange Book”. This compendia contains two-letter therapeutic equivalency evaluation codes for most generic medications. Medications having a therapeutic equivalency evaluation code commencing with the letter “A” (e.g., AA, AB) are, according to the FDA, products for which there are no known or suspected bioequivalence problems, or actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence.⁴ Indiana law is such that only generics with a therapeutic equivalency rating of “A” can be legally substituted.

It is important that healthcare providers understand the importance of generic substitution and are able to access the available resources to assist them in making the appropriate substitution choices. Patient adherence and proper disease state management has been directly correlated with the expense of the medication regimen and copay. Many patients cannot afford to take their medication as prescribed and skip doses or decrease their doses by taking half the prescribed dose. Medicare Part D participants have been known to discontinue their therapy once they have encountered a gap, also known as the “donut hole”, in benefit coverage. Non-adherence may lead to increased hospitalizations and mortality among the disabled and senior populations. Generic utilization is one way to help prevent or delay expenses related to non-adherence. Prescribers should discuss the utilization of generic products with their patients.

Continued on Page 2

Table 1. Cost Comparison of Generic vs. Brand Name Agents⁵ for Indiana Medicaid's Fee-for-Service Program

Generic	Generic Cost for Quantity Specified <small>(Allowable ingredient amount that could be paid to the dispensing pharmacy as of 11/29/2007, does not include dispensing fee)</small>	Brand Name	Brand Cost for Quantity Specified <small>(Allowable ingredient amount that could be paid to the dispensing pharmacy as of 11/29/2007, does not include dispensing fee)</small>
Antidepressants (SSRIs/SNRIs)			
Citalopram 20mg	\$3.66 (60 tabs)	Celexa 20mg	\$167.38 (60 tabs)
Duloxetine 60mg	Generic unavailable	Cymbalta 60mg	\$111.30 (30 caps)
Escitalopram 10mg	Generic unavailable	Lexapro 10mg	\$74.96 (30 tabs)
Fluoxetine 20mg	\$0.81 (30 caps)	Prozac 20mg	\$140.24 (30 caps)
Paroxetine 20mg	\$10.82 (30 tabs)	Paxil 20mg	\$97.05 (30 tabs)
Sertraline 50mg	\$3.03 (30 tabs)	Zoloft 50mg	\$87.81 (30 tabs)
Venlafaxine 75mg	\$55.25 (30 tabs)	Effexor 75mg	\$58.02 (30 tabs)
Cardiovascular Agents			
Amlodipine 5mg	\$3.40 (30 tabs)	Norvasc 5mg	\$52.13 (30 tabs)
Carvedilol 6.25mg	\$4.68 (60 tabs)	Coreg 6.25mg	\$119.66 (60 tabs)
Carvedilol 40mg 24HR	Generic unavailable	Coreg CR 40mg	\$105.09 (30 caps)
Diltiazem CD 240mg	\$14.84 (30 caps)	Dilacor XR 240mg	\$64.59 (30 caps)
Sleep Agents			
Eszopiclone 2mg	Generic unavailable	Lunesta 2mg	\$120.96 (30 tabs)
Ramelteon 8mg	Generic unavailable	Rozerem 8mg	\$92.97 (30 tabs)
Temazepam 15mg	\$2.10 (30 caps)	Restoril 15mg	\$160.59 (30 caps)
Zaleplon 10mg	Generic unavailable	Sonata 10mg	\$97.30 (30 tabs)
Zolpidem Tartrate 10mg	\$1.37 (30 tabs)	Ambien 10mg	\$129.51 (30 tabs)
Zolpidem Tartrate ER	Generic unavailable	Ambien CR 12.5mg	\$114.41 (30 tabs)
Statins			
Atorvastatin 10mg	Generic unavailable	Lipitor 10mg	\$80.28 (30 tabs)
Fluvastatin 20mg	Generic unavailable	Lescol 20mg	\$65.38 (30 tabs)
Lovastatin 40mg	\$26.41 (60 tabs)	Mevacor 40mg	\$239.20 (60 tabs)
Pravastatin 40mg	\$6.52 (30 tabs)	Pravachol 40mg	\$77.42 (30 tabs)
Rosuvastatin 10mg	Generic unavailable	Crestor 10mg	\$90.34 (30 tabs)
Simvastatin 40mg	\$3.01 (30 tabs)	Zocor 40mg	\$137.77 (30 tabs)
Miscellaneous Agents			
Acyclovir 800mg	\$6.83 (30 tabs)	Zovirax 800mg	\$242.18 (30 tabs)
Ciprofloxacin 500mg	\$1.97 (20 tabs)	Cipro 500mg	\$107.87 (20 tabs)
Cyclobenzaprine 5mg	\$7.16 (90 tabs)	Flexeril 5mg	\$137.97 (90 tabs)
Diclofenac Sodium 75mg	\$3.82 (60 tabs)	Voltaren 75mg	\$138.68 (60 tabs)
Meloxicam 7.5mg	\$1.08 (30 tabs)	Mobic 7.5mg	\$93.16 (30 tabs)
Omeprazole 20mg	\$14.05 (30 caps)	Prilosec 20mg	\$116.28 (30 caps)
Ondansetron 4mg	\$7.72 (12 tabs)	Zofran 4mg	\$279.07 (12 tabs)

Continued from Page 2

Recent FDA Generic Approvals^{6,7}

Brand Name	Generic
Ambien [®] Tablets	Zolpidem Tartrate Tablets
Cefotan [®] Injection	Cefotetan Injection
Cerebyx [®] Injection	Fosphenytoin Injection
Dantrium [®] Injection	Dantrolene Injection
Diprolene [®] Lotion	Betamethasone Dipropionate Lotion
Lamisil [®] Tablets	Terbinafine Tablets
Lexapro [®] Tablets	Escitalopram Capsules
Lotrel [®] Capsules	Amlodipine/Benazepril Capsules
Maxipime [®] Injection	Cefepime Injection
Nimotop [®] Capsules	Nimodipine Capsules
Omnicef [®] Capsules and Oral Suspension	Cefdinir Capsules and Oral Suspension
Paxil [®] CR Extended Release	Paroxetine Extended Release
Protonix [®] Tablets	Pantoprazole Tablets
Toprol XL [®] Extended Release	Metoprolol Extended Release
Vesanoid [®] Capsules	Tretinoin Capsules
Zofran [®] ODT	Ondansetron ODT

Anticipated Availability of First-Time Generics^{8,9}

Brand Name and Generic	Projected Date of Availability
Depakote [®] ER (Divalproex Extended Release)	January 2008
Kytril [®] (Granisetron)	January 2008
Zyrtec [®] (Cetirizine)	January 2008
Fosamax [®] (Alendronate)	February 2008
Sonata [®] (Zaleplon)	June 2008
Risperdal [®] (Risperidone)	July 2008
Requip [®] (Ropinirole)	November 2008
Zerit [®] (Stavudine)	December 2008
Imitrex [®] (Sumatriptan)	February 2009
Lamictal [®] (Lamotrigine)	February 2009

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Program Assistance

All prior authorization requests or questions regarding the fee-for-service PDL should be directed to the ACS Clinical Call Center at 1-866-879-0106.

PDL Listing

The fee-for-service PDL listing may be found at the following Web site:
<http://www.indianapbm.com/>

Top 20 Medications for 3Q 2007

Top 20 Medications 3 rd Quarter 2007 Ranked by Total Amount Paid		
Medication	Total Paid	Total Claims
Risperidone	\$3,533,115.80	14,443
Antihemoph.FVIII Plas/ Alb Free	\$3,045,891.01	95
Quetiapine Fumarate	\$2,965,121.54	12,831
Aripiprazole	\$2,870,543.23	8,172
Olanzapine	\$2,870,130.60	6,650
Divalproex Sodium	\$1,699,324.07	11,378
Topiramate	\$1,473,940.82	6,497
Antihemophilic Factor, Hum Rec	\$1,411,295.47	52
Lamotrigine	\$1,333,087.35	6,503
Fentanyl	\$1,171,142.01	3,825
Insulin	\$1,165,328.45	9,166
Oxycodone HCL	\$1,144,263.24	5,154
Ziprasidone HCL	\$1,131,152.37	4,193
Atorvastatin Calcium	\$954,959.69	9,249
Fluticasone / Salmeterol	\$910,320.69	5,099
Levetiracetam	\$891,117.85	3,792
Oxcarbazepine	\$884,397.03	4,815
Factor VIIA, Recomb (BHK Cells)	\$809,145.00	6
Duloxetine HCL	\$784,112.33	6,540
Methylphenidate HCL	\$761,138.88	8,559

Top 20 Medications 3 rd Quarter 2007 Ranked by Total Claims Paid		
Medication	Total Claims	Total Paid
Hydrocodone/APAP	44,640	\$381,986.28
Aspirin	39,787	\$32,327.63
Docusate Sodium	37,870	\$79,242.93
Alprazolam	32,560	\$218,299.25
Calcium Carb/Vit D	31,949	\$66,031.10
Acetaminophen	31,850	\$80,806.95
Multivitamins	26,491	\$38,639.61
Loratadine	26,696	\$248,349.16
Clonazepam	22,530	\$117,434.97
Lorazepam	21,906	\$125,843.57
Omeprazole	19,402	\$544,265.88
Multivitamins with Minerals	17,067	\$49,687.49
Albuterol	17,013	\$336,315.49
Risperidone	14,443	\$3,533,115.80
Quetiapine Fumarate	12,831	\$2,965,121.54
Levothyroxine	12,653	\$92,985.92
Diazepam	12,461	\$253,278.83
Lisinopril	12,142	\$57,195.92
Divalproex Sodium	11,378	\$1,699,324.07
Furosemide	11,037	\$39,822.64