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PHARMACY MONTHLY NEWSLETTER

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In The News:

FDA approved **Valturna® (aliskiren/valsartan)**, a combination antihypertensive medication used for the treatment of hypertension in patients not adequately controlled with monotherapy alone, or in patients initially requiring multiple drugs to achieve BP goals. The combination consists of Tekturna (aliskiren), a direct renin inhibitor, and Diovan (valsartan), an ARB. [\[Link\]](#)

- ⊕ **Valturna®** was approved after the results from an 8-week, randomized double-blind study demonstrated aliskiren/valsartan (150mg/160mg titrated to 300/320mg) more effectively reduced blood pressure as compared to either drug alone or placebo.
- ⊕ Valturna® decrease of 17.2/12.2 mmHg (SBP/DBP) vs. Valsartan 12.8/9.7 mmHg vs. Aliskiren 13/9 mmHg vs. placebo 4.6/4.1

Controlling hypertension in elderly may slow cognitive dysfunction caused by Alzheimer disease. [\[Link\]](#)

- ⊕ The American Journal of Hypertension published an observational study done in 321 Alzheimer patients (mean age was 78 yrs) over the course of 3 years. 21% used beta-blockers, 16% diuretics, 16% CCBs, 14% ACEs and 6% ARBs (20% ACE or ARB). Among those treated for hypertension (HTN), 72% used monotherapy, 22% used dual therapy, 6% used 3 or more HTN drugs.
- ⊕ Progressive declines in Mini-Mental State Examination (MMSE) were consistent w/uncontrolled HTN (specifically high SBP).
- ⊕ Also, it found that patients using HTN drugs had significantly higher MMSE scores compared w/those not taking medication.
- ⊕ **Note:** Treated group were 'sicker' patients—had more co-morbid disease states—receiving more non-HTN drugs (statins, etc)

Current research shows potential for a new vaccine to prevent urinary tract infections [\[Link\]](#)

- ⊕ Researchers at the University of Michigan have been testing thousands of bacterial proteins over the past 20 years in order to isolate a suitable vaccine to target Escherichia coli (E. coli), the main bacteria found in uncomplicated UTIs.
- ⊕ A vaccine could save \$6.8 million in office visit costs, 1.3 million ER visits, and 245,000 hospitalizations per year.

Hormone replacement therapy (HRT) and risk of lung cancer? Results from a post- hoc analysis of the Women's Health Initiative trial showed that women in the estrogen plus progestin arm were more likely to die from instances of non-small cell lung carcinoma than women in the placebo arm. [\[Link\]](#)

- ⊕ Given that the data was from a post hoc analysis in a small number of women with lung cancer, results cannot be extrapolated to other hormone replacement treatments.
- ⊕ It is recommended that the risks and benefits be heavily weighed in women with a high likelihood for developing lung cancer including women with a significant family history and women who smoke.

Pharmacy—Clinical Sound Bytes:

- ⊕ FDA approved **Zirgan® (ganciclovir ophthalmic gel) 0.15%**, the first commercially available ophthalmic antiviral gel for the treatment of acute herpetic keratitis in adults and children >2 years old. [\[Link\]](#)
- ⊕ FDA approved **Stelara® (ustekinumab)**, a biologic agent indicated for moderate-severe psoriasis in adults 18 yrs and older. [\[Link\]](#)

Safety Updates:

[Submit ADR^s to MedWatch Online!](#)

Januvia® (sitagliptin) and Janumet® (sitagliptin/metformin) The FDA is requiring the manufacturer to update prescribing information for both medications after several post-marketing cases of acute pancreatitis have been reported. [\[Link\]](#)

- ⊕ From October 16, 2006 to February 9, 2009 there have been 88 reported cases of acute pancreatitis, 2 of which were classified as hemorrhagic or necrotizing pancreatitis. (vs. 36 cases for Byetta (exenatide) up through 8/08)
- ⊕ These drugs should be discontinued at onset of signs/symptoms of pancreatitis.

[Ask RPh to submit ADR to Medwatch](#)



Mylan Inc. issued an advisory on 9/11/09 regarding **stolen cases of albuterol sulfate solution 0.083% unit dose vials and ipatropium bromide inhalation solution 0.02%**. A portion of each lot was sold a few weeks before the theft. For the safety of patients, the manufacturer is asking that any vials with the same lot numbers not be dispensed. [\[Link\]](#)

Ipratropium: NDC 49502-685-31 LOT # F0908 and NDC 49502-685-62 LOT # C09119/C09120

Albuterol: NDC 49502-697-29 LOT # 9G04 and NDC 49502-697-61 LOT # 9FD8/9FD9/9FE1

- Link to ALL June 2009 [labeling changes](#) (i.e., post-marketing ADR updates) [\[Link\]](#)

* **Example:** *Amaryl® (glimepiride)* updated drug information to include 'Drugs that may potentiate the hypoglycemic action of sulfonylureas: disopyramide, fluoxetine, and quinolones' in drug interactions section.

New Generic Approvals*:

[Each have a Medicare exception from Tier changes until 1/1/2010]

Nateglinide, generic Starlix®; **levonorgestrel**, generic Plan B®; **Sumatriptan succinate**, generic Imi-trex® *injection*.; **Tacrolimus** generic Prograf®; **zaleplon**, generic Sonata®; **levofloxacin**, generic Quixin® 0.5% *ophthalmic*

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Emerging Therapies & the Drug Pipeline:

Osteoporosis – Cyclic therapy with **Forteo® (teriparatide)**, a recombinant parathyroid hormone, was shown to be just as effective in the treatment of osteoporosis as weekly bisphosphonate therapy. [[Link](#)]

Teriparatide offers a unique approach to treating osteoporosis involving 2 phases; the first phase (about 3 months) is anabolic and promotes osteoblast formation and osteogenesis while the second phase is dependent on osteoclast activity. [[Link](#)]

- ✦ Early evidence after 15 months into a 2-year trial shows that the use of teriparatide 25mg daily for 3 months followed by 3 months of no medication was equally effective as treatment with weekly alendronate.
- ✦ This study was only able to show short term benefits; long term benefits including decrease in fractures will need to be assessed in trials with a greater follow up period.
- ✦ The results still hold promise for an alternative osteoporosis therapy in women who cannot tolerate bisphosphonates.

Pharm.D. Monthly Q&A Review:

Incoming e-mail Question: “Are fibrates effective in raising HDL-C even when TGs are NOT also elevated?”

[Rader, 1999](#)
[Goldberg, 1989](#)
[BIP Trial, 2009](#)

Excerpt of Outgoing e-mail Answer:

- **NO**, fibrates are NOT expected to significantly raise HDL when TGs are not elevated. Fibrates increase plasma catabolism and the clearance of TG-rich particles by lipoprotein lipase induction and activation of PPARs (and some other mechanisms). Clinically, a marked reduction in plasma TGs and VLDL is observed, as is an increase in HDL cholesterol levels. Note that many trials support that the most benefit with fibrates is seen when TGs high and greatest HDL rise observed (e.g., BIP Trial).

Disease State Or Literature Update:

Guideline Update: Re: Use of Psychotropic Medications in Children

The AACAP released new practice parameter regarding the use of psychotropic medications in children. AACAP Treatment Algorithms: [[Link](#)]

Key Updates Include:

- ✦ Over last 15-20 yrs there has been a significant amount of newly developed information regarding psychiatric disorders in children.
- ✦ Reports of increased psychotropic medication used has lead to the belief that some children are being over-diagnosed with psychiatric disorders and as a result are being treated with inappropriate medications.
- ✦ The new FDA black box warnings: **WARNING: SUICIDAL IDEATION IN CHILDREN AND ADOLESCENTS** were aimed at controlling overuse. However, they are actually creating patient and parent treatment barriers.
- ✦ **A psychiatric evaluation should always be performed before initiation of pharmacotherapy in order to determine which patients are best treated with medications and which patients require psychosocial intervention.**
- ✦ Emphasis on using the correct dose and duration of treatment that defines an adequate trial for a specific medication.
- ✦ Appropriateness for using **combination therapy**; established before initiation of 2 medications. Common combinations include:
 - ◆ Two medications for two different psychiatric diagnoses
 - ⇒ An SSRI for anxiety and a stimulant for ADHD
 - ◆ Combinations that offer unique treatment for a single diagnosis
 - ⇒ Addition of lithium to antidepressant therapy
 - ◆ Additional medications to manage side effects of another medication
 - ⇒ Benztropine for extrapyramidal side effects of an antipsychotic
- ✦ There is little to no support for the *use of two medications in the same class* to treat refractory illnesses.
- ✦ Taper doses slowly when discontinuing a medication, even if the medication does not always require tapering.

Formulary Updates:

IHA Continues Value Initiative

[Link to IHA Formulary](#)

IHA has begun an initiative they are referring to as “**Value Prescribing**” which aims to help control the rising costs of prescription drugs by finding the best combination of quality (efficacy) & cost for various therapies. The program will focus on statin therapy because despite many cost reduction programs they still represent the best opportunity to achieve ‘value prescribing’ and help reduce costs.

Patients WANT guidance from their physicians Providers do NOT appear to be asking

“Most wanted providers to ask about medication affordability (81%), consider cost (86%), offer choices (70%), and to persuade them or decide for them which medication to use (88%)” — “Few said providers asked about affordability (17%), usually or always discussed prices (19%), or offered choices (45%) — [[Journal of the American Geriatrics Society 2007, 1974,1977.](#)]

	Drug	Average Annual Co-pay	Average Retail Cost of Drug	Average Annual Retail Cost of Drug
Tier 1	Lovastatin	\$48	\$156	\$108
	Pravastatin			
	Simvastatin			
Tier 2	Crestor®	\$300	\$1,596	\$1,296
Tier 3	Lipitor®	\$420	\$1,860	\$1,440
	Vytorin®			

*All meds tier 1 unless otherwise specified; §ADR = Adverse Drug Reaction; PAR = Prior Auth Req'd; † NDA = New Drug Application