Pharmaceutical Horizons

Engineering Efficient and Effective Drug Therapy

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Our summary of news concerning medications and prescription drug benefit programs

Clinical Literature Digest

Impact of Zanamivir (Brand Name = Relenza) on Antibiotic Use for Respiratory Events Following Acute Influenza in Adolescents and Adults

A recently published meta analysis of 7 randomized, double-blind, placebo controlled trials evaluated the impact of Zanamivir use on subsequent upper and lower respiratory tract infections. The analysis demonstrated that 17% of placebo controlled patients but only 11% of Zanamivir treated patients went on to develop upper or lower respiratory tract infections. Zanamivir demonstrated a statistically significant reduction in lower respiratory tract infections only. There was not a statistically significant difference in upper respiratory tract infections between the two groups. *Arch Intern Med. 2000;160:3234-3240*

Commentary: This new study, the lay press focus on the "shortage" of influenza vaccine, the clinical focus on appropriate use of antibiotics, and the FDA approval of Tamiflu for prevention of influenza (see related story under FDA Approvals in this newsletter) significant increases in prescribing of Relenza and Tamiflu are expected later this month and next quarter.

Nicotine Inhaler and Nicotine Patch Combination Therapy for Smoking Cessation

In this trial, the combination of inhaler plus patch resulted in significantly higher cessation rates than inhaler plus placebo patch. In this double blind, randomized, placebo controlled trial of 400 subjects who had smoked 10 or more cigarettes (at least ½ pack) per day for 3 years or longer, the combination therapy demonstrated statistically significant reduction in complete abstinence at both 6 and 12 weeks, but failed to demonstrate statistical significance at 6 and 12 months. *Arch Intern Med. 2000;160:3128-3134*

Commentary: The use of chemical supplements to reduce physical withdrawal symptoms must be complemented with a strong behavior modification program for long term quit rates.

Role of Aspirin Therapy in the Primary Prevention of Myocardial Infarction

Aspirin therapy provides significant benefit in preventing a "first" myocardial infarction. A recent review of the four primary prevention trials of aspirin therapy affirms the conclusion arrived at by the four different studies. While this review concludes the benefits related to primary prevention of myocardial infarction, there remains debate not only on this issue but also on the role of aspirin therapy in the primary prevention of stroke and other vascular disease.

Long Term Assessment of Psychological Well-being in a Randomized Placebo-Controlled Trial of Cholesterol Reduction with Pravastatin

A recent study concluded that long-term reduction of serum cholesterol with pravastatin has no adverse effect on psychological well-being. In the recent past there have been reports that aggressive lipid lowering may result in increased mortality due to non-cardiovascular causes. This has been called the "J Curve Phenomenon". The aim of this recent study was to objectively evaluate psychological well-being in patients undergoing lipid lowering therapy with Pravastatin. For those persons whose baseline serum cholesterol was 178 mg/dL, there was no evidence of increased anxiety, depression, anger, or impulsiveness indicating at least for psychological purposes aggressive reduction in serum cholesterol does not have a negative effect.

FDA Updates

Tamiflu Approved by the FDA for the Prevention of Influenza

On November 20, the FDA approved Tamiflu (oseltamivir phosphate), a neuraminidase inhibitor, for the prevention of influenza in adults and children 13 years and older. Tamiflu 75mg taken once daily for 42 days during a community outbreak reduced the incidence of laboratory confirmed influenza from 4.8% in the placebo group to 1.2% in the Tamiflu group. In a study of post-exposure prevention in households utilizing Tamiflu 75mg daily within two days of onset of symptoms and continued for seven days reduced the incidence of laboratory confirmed influenza from 12% in the placebo group to 1% in the Tamiflu group.

Continued Expansion of New Drug Approvals

Not only are more drugs coming to market, but they are doing it at ever increasing rates. In 1990, there were a total of 69 new drug approvals with an average review time of 31.7 months. In 2000, there have been a total of 106 new drug approvals, an increase of 53%, while the average approval time has decreased to 14.6 months, a decrease of 54%.

Trizivir Approved for the Treatment of HIV

Trizivir, a combination product containing the Abcavir Sulfate, Lamivudine, and Zidovudine, has been approved by the FDA for use either alone or in combination with other antiretroviral agents for the treatment of HIV-1 infection. All three active ingredients are currently available individually from Glaxo Wellcome. This new product is simply a fixed dose combination product. The product is being priced equivalently to the combined cost of the products being purchased separately. From a managed care standpoint, this product will be equivalent from an acquisition drug cost standpoint, but there will be a loss of member contribution and therefore a slight increase over the e xisting products when purchased separately.

Generic Drug Approvals

Extension of Pepcid Market Exclusivity

Pepcid was to lose its market exclusivity in the fourth quarter of 2000. On November 21, the FDA granted a six-month extension of market exclusivity for Pepcid based upon a supplemental new drug application related based on pediatric studies. Generic equivalents to Pepcid will now not be available until April 15, 2001.

Sotolol Hydrochloride

Impax Pharmaceuticals has received FDA approval of Sotolol Hydrochloride, the generic equivalent of name brand Betapace used in the treatment of certain cardiac arrythmias.

Nizatidine

Mylan pharmaceuticals Nizatidine, generic equivalent for Axid, was approved on November 16.