Transdermal Gel Offers New Option for Gout

By Alesia Wagner

May is recognized each year as National Arthritis Awareness Month. Arthritis is a disease that impacts more than 50 million Americans, making it the No. 1 cause of disability in the country. That means one in every five adults, 300,000 children and count- less families are affected by different forms of arthritis.

Gout, an extremely painful form of inflammatory arthritis, affects more than 4% of Americans and about 10% of men over the age of 60. It is more common in women after menopause. The disease occurs due to an excess of the bodily waste uric acid. The acid is deposited as needle-like crystals in the joints or in soft tissue. These crystals cause redness, swelling, stiffness and intense pain in the joints, which in turn can create gout flares.

ColciGel is a new prescription medication for the treatment of acute flares of gout. It is a transdermal gel that contains homeopathic colchicine (colchicum 4X) that is applied directly to the sites of a flare. ColciGel penetrates the dermal layer, resulting in the reduction of inflammation and pain associated with the flare.

Clinical experience has demonstrated the effectiveness of ColciGel in mitigating the symptoms of acute flares. ColciGel patients report a significantly higher dose of colchicine, has demonstrated only sub-clinically relevant systemic absorption, serum levels less than 50 pg/mL. This is a 100-fold lower peak concentrations of colchicine than that typically observed (about 6 mg/mL or 6,000 pg/mL) thereby significantly reducing the potential for drug-drug interactions.

The drug costs for the two treatments are very similar; however, oral colchicine therapy has the potential for large hidden costs associated with poor tolerability, serious adverse events (AEs), drug-drug interactions (DDIs), and treatment failures. ColciGel, without these hidden costs, should be a much more cost-effective treatment.

Cost of gout From 2001 to 2004, employees with gout incurred almost double the direct annual health care costs per year compared to employees without gout ($6,870 versus $3,705). With 8 million people with gout in the U.S., the extra health care costs for people with gout are likely to be over $20 billion per year. Moreover, these costs are growing and are expected to be significantly higher in 2016.

All cause-direct costs related to gout have been estimated to be between $11,080 and $13,170 per person per year. Indirect costs related to gout are estimated to be as high as $4,341 per person. A key contributing factor to the indirect costs is that employed individuals with gout miss more work days than individuals without gout.

In 2008, there were 174,623 emergency room visits in the U.S. where the primary cause for the visit was gout, with the cost of these visits reaching $182 million. An estimated 7 million ambulatory visits occurred annually in the U.S. associated with gout between 2002 and 2008, with total ambulatory costs associated with gout estimated at $933 million.

Cost of oral colchicine treatment The recommended treatment for ColciGel is 1.2 mg (two pills, 0.6 mg each) at first sign of flare and 0.6 mg (one pill) one hour later, for a total of three pills total per treatment. This can be repeated on the second day. The cost of treatment is approximately $6.00 per pill, so the range of costs (three to six pills) for treatment of a flare is $18 to $36. AEs from oral colchicine will contribute to the cost of treating patients with acute flares. Some AEs will warrant other medications (to treat diarrhoea, for example), and some AEs will lead to office visits or other care. The percent of patients with side effects is quite high, with the high dose (80%) and still significant with the low dose. Previous experience with these AEs can result in patients avoiding oral colchicine usage altogether at the early stages of ER visits. This is a 100-fold less than the peak concentrations of colchicine that contains homeopathic colchicine (about 6 mg/mL or 6,000 pg/mL) thereby significantly reducing the potential for drug-drug interactions.

Severe AEs can occur with oral colchicine, particularly those that occur because of DDIs. The costs of AEs that could arise from DDIs could be very high. Although a dose-reduction algorithm has been devised to reduce the risk of these DDIs, there are a large number of potential drugs that can induce DDIs with oral colchicine. Thus, there is a real potential that serious side effects is quite high, with the high dose (80%) and still significant with the low dose. Previous experience with these AEs can result in patients avoiding oral colchicine usage altogether at the early stages of ER visits. This is a 100-fold less than the peak concentrations of colchicine that contains homeopathic colchicine (about 6 mg/mL or 6,000 pg/mL) thereby significantly reducing the potential for drug-drug interactions.

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More than 4% of Americans suffer from gout, a highly painful form of inflammatory arthritis

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