

# Pharmacy Benefit News

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## Specialty Spotlight

Pro Pharma Perspectives

We expect to hear a significant dialog about the cost of new drugs in 2015, especially the specialty medications. The dialog will surely surround the high cost of specialty medications and the potential for biosimilars to reduce those costs. However, there is a limit to how much can be saved from purchasing decisions -- probably about 10-15% on average. Biosimilars may be less expensive, but it is not expected the cost of medications will be reduced by 50% or more as historically occurred with small molecules when they went generic. (See our article on Biosimilars soon to be published in the California Pharmacist Journal.) As a result, the discussion of specialty will have to include utilization methods and their impact, as well as an emphasis on research into alternative therapies and their comparative effectiveness. Marketing claims will have to be scrutinized as will prescribing practices comparing clinical and behavioral outcomes.

To lend to this dialog Pro Pharma will include a "Specialty Spotlight" section of Pharmacy Benefit News in future editions. Our goal is to provide clarity of the therapies and perspectives into the various arguments. As always, we are data analytical experts. Whatever the data demonstrates, or equivocates, we will discuss the results. When, and if, we have opinions we will make those clear and discuss the assumptions and options.

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### Botox: Forever 21

Originally developed to potentially treat crossed eyes, Allergan's Botox has become a sensation with multiple indications from cosmetic to migraine therapy. Because it requires continued injection therapy for efficacy, the safety of frequent injections of Botox remains a problem. Botulinum toxin is FDA approved for a variety of disease states including dermatological, ophthalmic, neurological, and urological conditions. Specifically approved indications are as follows: blepharospasm (abnormal spasm of eyelids), strabismus (eye muscle problems), cervical

### To Give or Not to Give: Bisphosphonates

Bisphosphonates are a class of medication used to treat osteoporosis (e.g. Boniva, Fosamax ect.) The protective benefits of bisphosphonates reach its ceiling effect at age 78, and individuals older than 78 do not seem to benefit regardless of adherence rates. This is consistent with findings that Risedronate had no beneficial effect of decreasing risk of hip fractures among elderly women of age 80 and older diagnosed with osteoporosis. Furthermore, bisphosphonates come with a whole array of

dystonia, axillary hyperhidrosis, muscle stiffness with upper limb spasticity (i.e. elbow, wrist, and fingers), chronic migraines, and urinary incontinence. According to a study published in the Journal of Clinical, Cosmetic and Investigational Dermatology, patients receiving Botox injections experienced secondary treatment failure as they developed neutralizing antibodies to botulinum toxin type A.

**Commentary:**

Although the neurotoxin is approved for a wide range of indications and has been shown to be safe and effective with long-term use, patients need to take precautions for potential adverse events. This prescription does have a good duration of action as it lasts several weeks/ months, however it should not be repeated at high doses or more frequently than 3-4 months in order to avoid decreasing effects of the medication.

Source:

1. Torres, S et. al. Neutralizing antibodies to botulinum neurotoxin type A in aesthetic medicine: five case reports. Clin Cosmet Investig Dermatol. 2014; 7: 11-17
2. BOTOX Cosmetic. Irvine, CA: Allergan, Inc; 2013.

adverse effect profile, including but not limited to hypocalcemia, headache, acid regurgitation, nausea, GERD, esophageal ulcer, and osteonecrosis of the jaw.

**Commentary:**

The recommendation is to consider the risk vs. benefit of giving bisphosphonates in the elderly population older than 78 years of age and weigh its use against its impact on quality of life, adverse effect profile, and the possibility of no benefit, at all. It may be more prudent to educate the patient and their family regarding healthy eating habits, adequate intake of vitamin D and calcium, weight bearing exercises, and fall prevention.

Source: 1Curtis, J. R., Westfall, A. O., Cheng, H., Lyles, K., Saag, K. G. and Delzell, E. (2008), Benefit of Adherence With Bisphosphonates Depends on Age and Fracture Type: Results From an Analysis of 101,038 New Bisphosphonate Users. J Bone Miner Res, 23: 1435-1441. doi: 10.1359/jbmr.080418  
2Mcclung, M., Geusens, P., Miller, P., Zippel, H., Bensen, W., Roux, C., ... Reginster, J. (2001). Effect of Risedronate on the Risk of Hip Fracture in Elderly Women. Obstetric and Gynecologic Survey, 423-424.

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