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## Following the Value of Drugs in AMD and Osteoporosis

### Summary

- As the cost of drugs continues to rise in the U.S., The Center for Value Based Medicine has built a broad framework for assessing value in medical treatments. Drs. Melissa and Gary Brown presented this framework, which is based on patient-assessed cost per QALY (quality-adjusted life year).
- Allowing comparisons across therapeutic areas, the framework points to good value of Bausch and Lomb's AREDS vitamins for dry age-related macular degeneration (AMD) and predicts increasing use of QLT's Visudyne for wet AMD.
- In osteoporosis, existing drugs have a high cost/QALY. Generic alendronate (replacing Merck's Fosamax) will increase value, but will put pressure on other branded bisphosphonates and on Amgen's denosumab.

### A Value-Based Framework

Although pharmacoeconomic analyses are routinely performed for individual therapeutics, Drs. Gary and Melissa Brown have developed a framework that allows all marketed drugs in the U.S. to be compared for value and economic costs. Their system, the Pharmaceutical Value Index, uses a patient questionnaire, clinical data, and cost-of-care data. The assessment numerically quantifies quality of life (QoL) and cost per QALY.

The Value-Based Medicine framework is used by drug developers to determine pricing, and to make a case with the FDA or with CMS for approval and reimbursement of drugs. According to Drs. Brown, their index is not yet widely adopted by payers, although some pharmacy benefit managers are beginning to inquire about the data. Dr. Melissa Brown expects CMS and Medicare to lead the way for value to enter the U.S. healthcare system in a way that is modeled after the U.K.'s NICE.

### Applying the Framework: AMD

As both Melissa and Gary Brown are ophthalmologists, Value-Based Medicine has focused some of its initial work on AMD therapeutics. For the more common dry AMD, Dr. Melissa Brown sees good value in Bausch and Lomb's AREDS vitamin formulation, which has been shown to have an impact on dry AMD progression and is available at relatively low cost to patients. According to Dr. Brown, vitamins are underused by AMD patients.

For the more severe but less common wet form of AMD, Dr. Gary Brown reviewed current use and value in Macugen (OSI), Visudyne (QLT), Lucentis (Genentech), and Avastin (Genentech). Lucentis and Avastin win out on value. Even as an expensive drug, Lucentis' efficacy trumps its cost. Avastin is much cheaper, but Dr. Brown defers a relative measure of its quality until a head-to-head comparison, currently ongoing, is completed.

Interestingly, QLT's Visudyne scores relatively highly on the value index. Dr. Brown notes that Visudyne may find use in decreasing the frequency of Lucentis administration when the two treatments are used in combination.

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### Applying the Framework: Osteoporosis

In contrast to medicines for AMD, the Pharmaceutical Value Index yields high costs per QALY for most osteoporosis medicines. Bisphosphonates, including Merck's Fosamax, Sanofi-Aventis' Actonel, Novartis' Reclast, and Roche's Boniva, cost about \$150,000 per QALY, although those costs are decreasing with the introduction of generic alendronate (Fosamax). Other osteoporosis drugs, such as Eli Lilly's Forteo and Evista, score even more poorly. Gary Brown discussed the nature of osteoporosis, a disease that is

#### Companies Mentioned

Bold Ticker/company name indicates the company is in our work database

Bausch and Lomb (BOL.F)

**QLT (QLTI)**

**Genentech (DNA)**

OSI (OSIP)

**Merck (MRK)**

**Novartis (NVS)**

**Sanofi Aventis (SNY)**

**Amgen (AMGN)**

**Eli Lilly (LLY)**

#### Expert Opinion:

*The Center for Value-Based Medicine is a healthcare economic research organization that amalgamates evidence based medical data with patient preferences to quantify the value of healthcare interventions.*

***Melissa Brown, MD, MN, MBA** is the Director of the Center, and also a Professor of Ophthalmology at the University of Pennsylvania School of Medicine. **Gary Brown, MD, MBA** is co-director of the center and is also Chief and Director of the Wills Eye Institute Retina Service and Professor of Ophthalmology at Jefferson Medical College.*

silent in many patients, in these assessments.

Because of the high cost / QALY associated with osteoporosis drugs, generic alendronate is likely to be rapidly adopted, and is likely to impact sales of not only Fosamax but also of Actonel and other bisphosphonates. However, Reclast's unique dosing regimen may allow it to avoid loss of market share. New drugs, notably Amgen's denosumab, will enter an increasingly value-sensitive market.

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### **The Future of Value**

Dr. Melissa Brown and Dr. Gary Brown agree that Medicare and other government payers are likely to lead the charge in evaluating value in drug pricing. Comparative effectiveness is already a buzzword in Washington, and a Democratic administration next year would accelerate the trend of taking drug value into account. Although a watchdog similar to U.K.'s NICE would face significant opposition in the U.S., any traction of such an agency would signal a change in drug pricing.