QUARTERLY TREND ADVISORY

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Keep on Your Radar: Value-Based Pricing of Drugs

One of the major tenets of healthcare reform in the U.S. has been the shift from volume-based reimbursement towards value-based reimbursement; however, the same has not been true for pharmaceuticals. In 2014, prescription drugs were the most rapidly escalating cost sector in U.S. healthcare, driving an increasing interest in value-based drug pricing. Value-based pricing for drugs is predicated upon determining measurable clinical (safety and efficacy) and/or financial outcomes for drug therapies. A survey conducted in 2014 revealed that only 10% of responding commercial health plans had an outcomes-based contract in place but more than double that number, 26%, stated they planned to implement such a contract over the next year or two. There have been several recently publicized examples, including a performance-based pricing contract between Harvard Pilgrim and Amgen regarding their PCSK9 inhibitor evolocumab (Repatha®), as well as a pay for performance contract for valsartan/sacubitril (Entresto®) signed by Aetna and Cigna. On November 20, 2015 the U.S. Department of Health and Human Services (HHS) held a pharmaceutical forum where the topic of value-based pricing agreements was discussed. The HHS panel participants discussed obstacles to arriving at such contracts. Most importantly, there is an administrative challenge of agreeing upon and then tracking what constitutes value. The agreed upon outcomes should be measurable and clinically relevant metrics, which will require pharmacy and medical data sharing to track these outcomes. As such, the panel recommended that an independent third party with transparent methodology needs to define value. One of these independent third parties is discussed in another article of this newsletter, the Institute for Clinical and Economic Review (ICER). A leading medical journal, JAMA, also recently published an article supporting the concept of performance-based pricing. Rather than setting price mandates, the authors suggest providing incentives to pharmaceutical manufacturers to encourage value-based pricing, including high tier placement and nominal copayments for new, high value drugs. The FDA could also increase the exclusivity period for high value drugs, while decreasing the exclusivity period for drugs priced above value-driven prices or offer incentives such as priority review.

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One of the authors has also advocated for a model where drug pricing is recalibrated after time on the market, utilizing "real world" data. He argues this would spur manufacturers to work with providers and insurers encouraging development of adherence programs, as well as curtailing off-label use of medications. Although some are skeptical that the pharmaceutical industry will ever move away from the current pricing model, the authors point out that until the 1950s, 1980s, and late 1990s, hospitals, physicians, and nursing homes, respectively, were paid based on what they chose to charge and those days have certainly passed.

INSIDE THIS ISSUE

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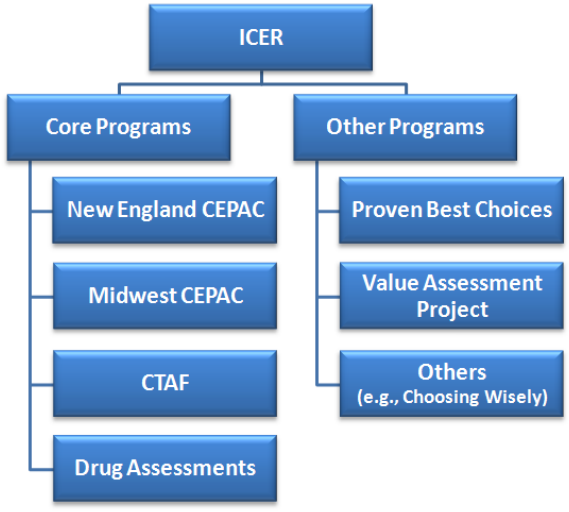
Magellan Rx MANAGEMENT

Meet the Watchdog: Institute for Clinical and Economic Review (ICER)

ICER, a Boston-based non-profit organization consisting of over 20 experts in clinical and business fields, evaluates evidence on prescription drugs, tests, and delivery systems to improve the efficacy, efficiency, and impartiality of the healthcare system. Similar to the National Institute for Health and Care Excellence (NICE) in England, ICER assesses efficacy, performs cost analyses, and develops reports to aid in decision-making that affect U.S. practice and policy to reduce wasteful care.

Core programs of ICER are the New England Comparative Effectiveness Public Advisory Council (CEPAC), Midwest CEPAC, and the California Technology Assessment Forum (CTAF), nationally-recognized community forums where independent panels debate the evidence, vote on effectiveness and value, and develop recommendations for policy development and practice. The analysis is transparent and solicits public comments as part of the process. The published reports describe the cost of drugs based on the likely outcomes achieved and aim to answer what price might be reasonable for a drug, potentially helping payers support value-based coverage decisions and design benefits.



ICER recently launched a *drug assessment* program to develop public reports for new high-impact drugs. These reports include data on comparative effectiveness, cost-effectiveness, and predicted budget impact, including a calculation of a benchmark price based on presumed patient benefit. Completed reports evaluate the newest class of agents for high cholesterol, two interventions for heart failure, and hepatitis C drugs. Scheduled reviews for 2016 include a new agent for asthma and a new insulin, as well as class reviews of agents for non-small cell lung cancer, multiple sclerosis, and psoriasis/psoriatic arthritis. ICER is also in development of a *value assessment* project to guide insurers in assessing the value of new services, medications, devices, and procedures.

ICER has other programs and collaborations. In partnership with Families USA, ICER is developing a series of guides called Proven Best Choices℠ to help patients and clinicians determine high-value healthcare choices in patient-friendly formats. ICER has also assisted in the Choosing Wisely® initiative.

Utilization of the information produced by ICER may assist prescribers, payers, and patients to make more prudent decisions regarding the use of healthcare resources.

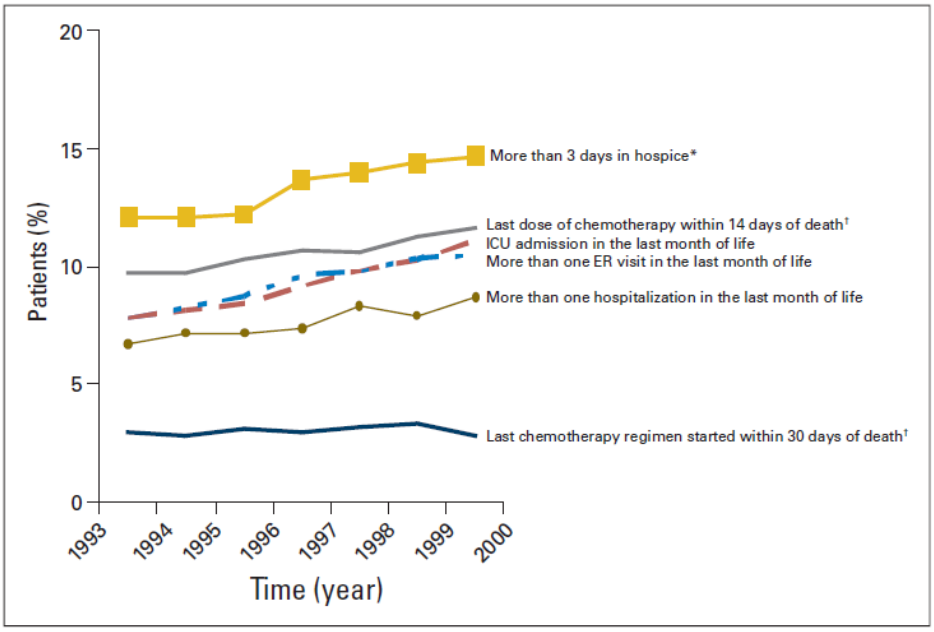
Struck by a Macaw? Bitten by a Sea Lion? There's a Code for That!

In the unfortunate event you have either been struck by a macaw or bitten by a sea lion, rest assured the information will now be adequately captured, thanks to the implementation of the International Classification of Disease Systems, 10th Revision, Clinical Modification (ICD-10-CM). After a two-year delay, the use of ICD-10-CM codes is now required by the Center for Medicare and Medicaid Services (CMS) to determine reimbursement for healthcare services. ICD-10-CM, a more detailed and specific system, replaces ICD-9-CM, utilized in the U.S. since 1979. While some have pointed to a few perceived absurdities in the coding such as "struck by a macaw" or "bitten by a sea lion," these subtleties are part of the overall aim of increasing the specificity of coding. This increased specificity will allow clinicians to more precisely describe the anatomical site and timing of certain disease processes. In addition to billing and reimbursement issues, ICD-10-CM will also be utilized to track quality of care measures and improve clinical and epidemiologic research. Many groups voiced concerns over the costs associated with implementing such a drastically expanded coding system, and there were predictions of chaos and disruption following the mandated implementation date of October 1, 2015. That, however, was not the case. A recent survey conducted a month after the implementation deadline by KPMG, an audit, tax and advisory services firm, indicated nearly 80% of organizations were reporting a successful transition to ICD-10. The use of ICD-10 promises to expand the ability to monitor usage and delivery of healthcare, potentially improving patient outcomes.

A Step in the Right Direction: Empowering Patients, Improving End of Life Care

Effective January 1, 2016, healthcare providers are eligible to be reimbursed for counseling their patients regarding advance care planning and end of life preferences. Until now, healthcare providers were not compensated for these conversations with their patients. A recent report from the Institute of Medicine (IOM) states promoting clinician-patient communication regarding advance care planning is a critical opportunity to improve quality of care. Research has demonstrated that 90% of adults say they would prefer to receive end of life care in their home, yet Medicare data indicate only about one third of Medicare recipients' deaths occur at home. In addition, roughly 25% of all Medicare healthcare expenditures are attributable to services provided to Medicare recipients in their last year of life. The American Society of Clinical Oncology (ASCO) has noted that when physicians have these discussions, patients are more likely to understand their prognosis, more likely to seek hospice care, and less likely to receive futile, aggressive therapy late in the course of their illness (refer to graph below). Encouraging patients and providers to utilize the opportunity for advanced care planning will hopefully lead to reduced healthcare expenditures and better quality of care.

CONSISTENCY OF END-OF-LIFE MEASURES



Updated trends in the aggressiveness of cancer care near the end of life, all cancer types, all durations of disease among 215,484 Medicare enrollees in Surveillance, Epidemiology, and End Results (SEER) areas who died as a result of cancer.
(*) Among patients admitted to hospice.
(†) Among patients who received chemotherapy. ER = emergency room; ICU = intensive care unit

Originally published by the American Society of Clinical Oncology [Earle, C et al: 26(23) 2008:3860-3866].

Did You Know? Off-Label Drug Use and Freedom of Speech

One mission of the Office of Prescription Drug Promotion (OPDP), a division within the FDA, is to protect the public through surveillance, enforcement, education, and improvement of labeling and promotional materials. This oversight ensures that information presented to healthcare professionals and consumers is truthful, balanced, and accurately communicated.

The FDA mandates that drugs may only be marketed for their FDA-approved usages; however, as long as the request is unsolicited, manufacturers may provide off-label information to healthcare providers. Despite this accommodation, some manufacturers have challenged the FDA's restrictions on promoting off-label use.

In August 2015, the manufacturer of icosapent ethyl (Vascepa®), Amarin Pharma, won a case against the FDA in federal court citing that the FDA had limited their First Amendment right to freedom of speech. Vascepa consists of a specific component of omega-3 fatty acids and is approved in select patients with extremely high triglyceride levels; however, the manufacturer wanted to promote its use (off-label) for patients with less elevated

triglycerides based on information from a clinical trial. In this case, the judge ruled the FDA cannot restrict Amarin's right to disseminate such information as it was considered neither false nor misleading.

Unnecessary off-label use increases drug spending and may negatively impact patient safety, which in turn can lead to subsequent costs. A recent report evaluated off-label use and its impact on adverse events in a cohort of 46,021 Canadian adults. When the data was broken down by labeled and off-label use, a higher rate of adverse events was seen with off-label use than with labeled use (19.7 events versus 12.5 events per 10,000 person-months, respectively).

As a result of the ruling in the Vascepa case, it will be interesting to see how off-label use—based on data obtained from clinical trials—may be used by pharmaceutical manufacturers to influence prescribing habits and the public's use of their drug, particularly since off-label use may incur additional costs and adverse effects.

Pipeline Report: 1st/2nd Quarter 2016

Drug/Manufacturer	Clinical Use	Anticipated Date	Projected Market Impact
Select Branded Pipeline Agents: Potential New Emerging Expenses for Health Plans			
tofacitinib modified-release (Xeljanz MR) Pfizer	Rheumatoid arthritis	February 2016	Product line-extension; Xeljanz MR will be available as an 11 mg tablet taken once-daily compared to a twice-daily Xeljanz 5 mg tablet
emtricitabine/ rilpivirine/ tenofovir alafenamide Gilead; Janssen emtricitabine/ tenofovir alafenamide Gilead	HIV-1	March 1, 2016 April 7, 2016	• Identical to Gilead's Complera® and Truvada®, respectively, with substitution of tenofovir alafenamide (TAF) for tenofovir disoproxil fumarate (TDF) • TAF – improved side effect profile compared to TDF in some patients, less risk of renal injury and less negative impact on bone mineral density • First TAF-based product (Genvoya®), (similar to TDF-based Stribild®) was approved November 2015 • Gilead's Genvoya wholesale price was nearly identical to Stribild wholesale price • Question of similar pricing strategy for these 2 products compared to Complera and Truvada to be determined • Generic TDF is expected in late 2017/early 2018 • Forecasted U.S. sales of $176 million and $320 million in 2016, respectively
pimavanserin (Nuplazid) Acadia	Parkinson's disease (PD) psychosis	May 1, 2016	First in class selective serotonin 5-HT2A inverse agonist with antipsychotic benefits without negatively impacting motor symptoms in PD patients; forecasted U.S. sales of $74 million in 2016
Select New Generics/Patent Expirations			
darifenacin – generic for Actavis' Enablex®	Overactive bladder, urinary incontinence	March 15, 2016	Joins generic oxybutynin products and generic tolterodine in otherwise brand-heavy class; $109 million in sales in 2014; 2 generic entrants expected at launch
rosuvastatin – generic for AstraZeneca's Crestor®	Atherosclerosis, hypercholesterolemia, hyperlipoproteinemia, hypertriglyceridemia, myocardial infarction prophylaxis, stroke prophylaxis	May 2, 2016	Rosuvastatin dosed at 20–40 mg daily is 1 of only 2 drugs considered "high intensity" statins, which are recommended for patients with the most high risk features for clinical heart disease (the other being atorvastatin, which is already available as a generic); Crestor had sales of over $5.6 million in 2014