AMERICAN RE HEALTHCARE
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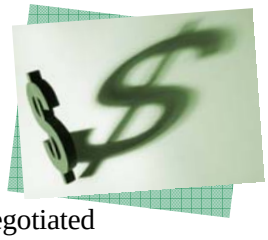
Coverage Decisions: Experimental *Versus* Standard of Care

Research, technology and medical trend continue to drive healthcare spending, and the insurance industry has responded to the need for affordable health insurance by excluding coverage for treatment that may not be effective. As a result, language that excludes experimental treatment is commonplace in the healthcare insurance business. The policy language provides the legal framework for making coverage decisions, but this language often requires a claims administrator to decide what procedures and therapies are clinically 'experimental'. *[See page 2]*

Care Management Success: Vendors Report Dramatic Savings Increase

American Re HealthCare strongly believes that both proactive quality medical care and financial discounts are required to provide the greatest impact on the burden of illness and downstream costs for a population. Our strategy, which relies upon the expertise of care management service providers, has helped clients dramatically increase their savings each year. We share examples of these success stories made possible by our clients' partnerships with our care management service providers. *[See page 3]*

Network Discounts May Be Misleading



Nearly everyone in our business has learned that some hospitals charge more than others for the same services. The Dartmouth Atlas has compiled many of these cost differentials using Medicare data. The facilities that charge more also have more leeway to offer impressive-looking discounts. Thus, we have to look at the final negotiated price itself in addition to any discount figure. Only then can one really assess the better deal. *[See page 5]*

Presentation summaries & more photos available at our website.

Click here

- Many thanks to all of our clients, business partners and speakers for making our 2005 Symposium so successful. See the summaries at http://www.americanrehealthcare.com

- Diagnostic imaging, at $100 billion annually, is among the fastest-growing cost areas in U.S. healthcare. Because cost-effectiveness varies markedly across the nation, many insurers have launched programs to develop quality guidelines and curb utilization.

- A health benefits administrator in Michigan announced that it would no longer employ smokers, citing costs upwards of $4,000 each year, per smoker, due to elevated medical bills and absenteeism. Alaska Airlines and Union Pacific Corp have made similar decisions, and the trucking firm Navistar International cites $1,000 each year in additional healthcare costs for smokers. The Surgeon General has declared that smoking is the leading preventable cause of illness and death for our country, causing 440,000 (nearly 1 in 5) deaths annually and $75.5 billion in extra medical care.

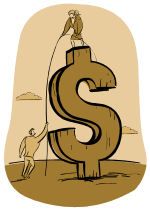
- A recent study in the Journal of the American Medical Association found that those severely obese in young adulthood to middle age will develop nearly twice the annual medical cost after age 65.

Coverage Decisions: *Experimental* Versus *Standard of Care*

The gold standard for the expected level of clinical care has been traditionally termed the "standard of care." Standard of care refers to the level of service that is commonly rendered and therefore expected in a given community. The concept of standard of care is an important benchmark in the determination of cases of medical malpractice, for instance. However, standard of care also comes into play in determining if a therapy should no longer be deemed experimental.

For example, many prescription drugs are used for effectively managing illnesses for which they were not originally approved. This is termed "off-label use." Nearly half of all prescriptions today are written for uses other than the ones for which the drug was approved. When deciding to prescribe a drug off-label, doctors tap into a network of information resources. Evidence of effective off-label uses may be derived from studies in scientific journals, presentations at professional meetings, experience that colleagues have shared, as well as a physician's own experiences with the medication. When economics are in alignment for the pharmaceutical manufacturer to pursue additional labeling, these off-label uses may ultimately achieve FDA approval as well.

Similarly, the identification of a specific intended use for a medical device may be the result of the evolution of medical practice once a device is marketed. However, when a majority of the provider community embraces common usage of any diagnostic test or therapy, it becomes a de facto standard of care. As a result, although FDA approval serves as one gold standard for particular therapies that have progressed beyond experimental use, so does general medical practice. The greatest impediment toward determining the standard of care at any one time is that there is often a continuum of practice over which therapies gain wider acceptance, meaning there is no one point in time at which a treatment magically attains status as accepted care. In contrast, sometimes a single event provides an additional standard to catalyze changes in clinician behavior and practice patterns. Such was the case in November, 1992, when the New England Journal of Medicine published an article that provided clinical trial results indicating that use of the anticoagulant drug warfarin should become standard practice to prevent stroke in patients with non-rheumatic atrial fibrillation.



When making the difficult coverage decisions, there are several tools and consulting resources that may provide additional guidance. Increasingly, even the Internet provides a deep resource of medical coverage content, made public by various health plans and plan administrators (see the 'Web Links' box below). Medicare also provides a leading benchmark (***http://www.cms.hhs.gov/coverage/***). Additional information can be found on the websites of Medicare benefits administrators. These websites provide additional guidelines for local coverage decisions (i.e. ***http://www.hqsa.com/***). In fact, Medicare invests so much into medical coverage resources and guidelines (mostly via outsourcing review of the medical literature to specialized researchers) that many health plans follow Medicare's lead in determining what to cover.

Web Links – A Fertile Research Resource

Practice Guidelines for General Areas:

Heart:
- *The American College of Cardiology Foundation*
- *American Society of Clinical Oncology*®

Lung:
- *American Lung Association*®

Cancer:
- *National Comprehensive Cancer Network, Inc.*®
- *American Cancer Society*®

Practice Guidelines for More Specialized Conditions:
- *Cystic Fibrosis*
- *Multiple Sclerosis*
- *Brain Trauma*

Private Plan Coverage Documents:
- *Aetna*®
- *The Regence Group*

These web links illustrate sites with rich content to inform coverage decisions, but this is not a comprehensive list, nor are these necessarily the best resources, nor can we warrant their accuracy.

An additional source of standard of care can be found in various forms within clinical guidelines. These are published by various special interest groups such as the American Cancer Society®, the American Heart

Association® and the American Lung Association®. Similarly, particular societies dedicate resources to form guidelines to achieve excellence in patient care for particular diseases (see the Web Links box above for examples). There is also the federal repository of guidelines at ***http://www.guidelines.gov/***, providing perhaps the most comprehensive compilation of multidisciplinary guidelines on the web.

Coverage decisions are frequently based upon effectiveness or standards of care. Therefore, policy wording may be designed exclude coverage for experimental practices. Given the difficulty for a small claims staff to maintain up-to-date knowledge on current evidence for the vast library of medical advancements, various private companies now employ research staff to monitor the medical literature for effectiveness of therapies or standard of care. This information provides yet another objective tool for determining what is experimental.

Examples of such companies include the Emergency Care Research Institute (***http://www.ecri.org/***), a non-profit company that began by evaluating emergency room equipment and techniques, but today provides a broad array of reference materials covering various diagnostic tests and therapies with respect to their effectiveness for specific medical conditions and diseases. They offer this information, as well as specific research as needed, for a fee. Because of their broadened focus across all of medical care, ECRI also administrates ***http://www.guidelines.gov/***, the federal website for evidence-based medical practice guidelines. A competing for-profit company is Hayes, Inc (***http://www.hayesinc.com/***). Hayes also provides medical information that summarizes the consensus of medical literature for various therapies.

Yet other companies provide a more consultative approach to assist with coverage decisions. Case management companies may be able to provide appropriate clinical assessments. Other fee-based consulting services, like the Specialty Physician Review service at URN, or Best Doctors®, provide an opinion from a panel of several physician experts in the area in question. The staff at American Re HealthCare may also help identify particular resources.

There are many useful benchmarks for assessing the experimental nature of a given therapy. When making these determinations, it may be helpful to validate your coverage decision with several sources for determining clinical efficacy, accepted standard practice, FDA or Medicare approval, as well as various other plan resources or consulting expertise.

However, coverage decisions should first and foremost be grounded in the legal framework of the policy language. Exclusions and limitations for experimental or investigational treatments vary considerably among policies. Some simply use general wording to exclude experimental procedures, investigational procedures or procedures that are not considered medically necessary. Others may further define these terms or make specific reference to Medicare, the FDA or other governmental bodies. The data used to support the decision should be specific to the wording in the policy.

Care Management Success: *Vendors Report Dramatic Savings Increase*

American Re HealthCare is committed to improving the quality of patient care and reducing claims cost for the various risk takers involved by providing access to case management, bill negotiation, and network service provider relationships. By leveraging the purchase power of covered lives across all of our clients, American Re HealthCare achieves a superior standard of excellence in customer service and the most competitive pricing.

One way to enhance the likelihood of achieving the clinical and cost benefits of an early referral is to make sure that those who are in a position to effect timely referrals understand the benefits of an early referral. In this spirit, we present several recent case examples to illustrate how our vendors have been successful in the mitigation of catastrophic claims.

Specialized Networks Save Real Dollars

A bone marrow transplant patient was referred by his physician to a transplant center, which happened to be U.R.N. approved, thereby facilitating immediate access to that network. Treatment required the patient to travel from his home in Las Vegas to Los Angeles. The health plan covered the travel expenses. The patient received the transplant and did well, yielding 42% off $584,472 in billed charges, saving $244,878 net of access fees.

While assessing one of our clients for quality of care and loss mitigation opportunities with the Wellington Health Group (WHG) Renal Care Management and Network Access Program, a review of renal dialysis claims identified a claim of $50,803 that spanned two months of service. The provider was part of the WHG Renal Network, so a pre-negotiated WHG discount of 25% resulted in an immediate savings of $12,701. As chronic renal failure requires ongoing dialysis, they will continue to achieve this 25% discount for future claims.

Bill Review and Negotiation: A Cure for Large Bills or Weak Discounts

A 46-year-old woman with congestive heart failure was urgently transferred out-of-network in Ohio from another hospital. Although the TPA negotiated a prompt pay discount of 5%, the payment was not released in the designated time frame, so the discount was lost. The patient was now receiving balance bills. Asert Benefits performed a bill screening that challenged $158,115 or 26.56% of the bill. The challenge consisted of $59,126 in pharmacy costs and $98,989 in other utilization overages. The facility was initially uncooperative, rejecting the settlement agreement proposed by Asert, but after repeated reengagements, they agreed to settle the case for a discount of $109,160 or 18.33% of savings.

Don't Dismiss the Prospect for Discounts above those of the PPO

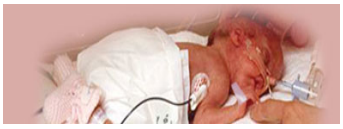
A 57-year old male was admitted with acute vascular insufficiency of the intestine (insufficient blood flow that threatened his life). Asert reviewed the bill and challenged 14.13%, $58,862 in pharmacy charges and $4,260 in excess services and supplies. A corrected bill yielded a savings of $86,230 or 19.30%, 4.3% more than the 15% PPO discount.

Case Management is Just What the Good Doctor would have Ordered

A 21-year-old pregnant woman was in danger of premature delivery due to a condition called "cervical incompetence" in her second trimester, and she was hospitalized for the second time in her pregnancy. This mother would probably have stayed in the hospital until delivery, but case management by EnvisionCare Alliance™ facilitated her discharge to home with bed rest and increased hydration instructions. She delivered a full-term healthy infant at 37 weeks, and both were discharged home three days after delivery. The intervention provided a more comfortable environment to await delivery as well as a savings of $162,768 due to shortened hospital stay.

A 55-year-old man sustained a C2 spinal cord injury, leaving him ventilator-dependent. Case management helped to effect a timely and appropriate discharge to acute inpatient rehabilitation (including air transport) and then ultimately to his home. Case Management arranged an extensive home-care plan involving private duty nursing to avoid further inpatient costs and achieved $31,800 in savings. They also negotiated his DME (Daily Medical Expense), power wheelchair and medical supplies for $28,113 in savings. Negotiations with the rehabilitation facility yielded an additional $50,695 in savings, and negotiating his home-care plan saved $27,268. Finally, a review of claims found daily charges of $1,306 for a specialty mattress that was never used. EnvisionCare achieved a total net savings of $115,411 for this case.

Fragile Neonates Require Oversight with Specialized Expertise



Neonates are a major source of catastrophic claims for any insurer, however, significant opportunities exist to enhance the quality and efficiency of care by providing clinical oversight to better manage the sickest and most expensive neonates in the NICU. American Re HealthCare offers access to CareAssist to achieve these objectives, and the following cases illustrate some of their successes with our clients.

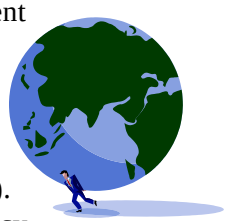
With shortages for NICU beds, it often requires multiple calls per day to transfer an NICU baby to an in-network facility. CareAssist facilitated one such transfer to achieve an average cost-per-day difference of $3,911 for 66 days. Without CareAssist, this baby would have completed her confinement out-of-network. The transfer saved over $250,000.

Another infant remained hospitalized with a complicated birth defect that required surgery, but the surgeon's schedule could not accommodate the case until weeks later. CareAssist determined that the baby met all of the hospital's criteria for discharge and that the family was able and motivated to bring her home if they could be provided with appropriate supplies, equipment and support. The infant was discharged home on her 175th day of life. This was 17 days earlier (at an average cost $9,357/day) than the day the tracheal surgery was to take place. Over $150,000 was saved in addition to helping the baby return home to her family, in a much more comfortable environment.

Specialty Drugs are Ripe for Savings

Within days of our announcement that LDI joined our offering of preferred vendors, one of our clients contacted LDI for assistance on a Hemophilia case. Our client achieved a monthly savings of $22,500.00 for 7500 injectable units of Monoclate P daily and an additional monthly savings of $8,250.00 for 7500 injectable units of Febia every 3 days. This generated a combined monthly savings of $30,750 to the HMO. Assuming 10 months of treatment, over $300,000 would be saved. LDI's Specialty case management also made recommendations to improve the patient's compliance with therapy. The patient has responded very well to treatment, and the antibody levels are rapidly declining.

In another case, Asert Benefits was managing a patient receiving a four-month treatment of Gamunex, an IVIG medication. Asert successfully negotiated an inpatient discount of 20% less than the drug's average wholesale price (AWP). Because the hospital pharmacy could not obtain enough of the medication to handle this particular patient, Asert was faced with the dilemma of having this patient moved to a non-participating facility and losing the discount. By creatively leveraging LDI to provide medication to the hospital, Asert was able not only to keep, but also to slightly improve, the hospital discount. The pharmacy director was so impressed with LDI that he requested that LDI supply this medication for other patients needing Gamunex.



The Responsibility to Manage Success

Our care management service providers have increasingly managed cost and quality for our clients' claims over recent years. The key to care management success involves the assembly of best-in-class services, the knowledge of when interventions are appropriate, and volume-discounted rates.

American Re HealthCare is pleased to facilitate successful relationships between our clients and our vendors, which have achieved impressive results. We also realize that by providing more referral resources, even further savings are possible. We will continue our efforts to identify the best service providers available, and to achieve the highest quality medical care and cost efficiency for your clients.

Network Discounts May Be Misleading

Imagine you are underwriting a case that is moving from one PPO to another. To simplify matters, you are told that each PPO has a single participating hospital, and their respective discounts are 15% and 25%. Does the case deserve a rate reduction for switching to the PPO with the better discount?

Interestingly, if one knew that the billed charges at Hospital B were always 125% of the billed charges for the same service at Hospital A, then a switch to PPO B would warrant a 10% rate increase. Why?

- The 15% discount with Hospital A pays 85% of Hospital A billed charges
- The 25% discount at Hospital B pays 93.75% (125% x 75%) of Hospital A billed charges
- (93.75% / 85%) – 1 = 10%

These billed charge differentials can create major discrepancies, particularly in situations where:

- Networks use a single hospital system within an area that has two or more hospital systems
- Networks do not have similar discounts with every tertiary hospital in an area

One method of comparing billed charges across various hospitals would be to simply compare the "chargemasters" for those hospitals. Unfortunately, with the exception of their recent public availability in California, this information is otherwise almost never publicly available. Given information that is readily available, however, we believe that two components are needed for proper comparison of billed charges across hospitals.

First, a *large volume of claims* from a (relatively) homogenous population is required to determine a reasonable average billed charge per inpatient admit. Without a large volume (hundreds, if not thousands, of admits per hospital), a single high-cost admit can distort the average charge. Secondly, a *severity adjustment factor* must be used to prevent punishing hospitals that tend to admit more complicated (and therefore more expensive) patients for their higher average charges. A common factor used for this is the CMS definition of Case Mix Index, which is the average of the CMS DRG weights across all admits at the hospital.

Interestingly, many network analyses that we have reviewed, both commercially available and client performed, appear to ignore this important issue. However, we feel that it is of such key importance to analyzing networks that we have gathered billed charges data from multiple external sources. This helps us fulfill our desire to reward truly cost-efficient networks, rather than those that show large discounts off of inflated billed charges.

Please call us for assistance in evaluating of your network options.

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Questions/ Comments

We welcome questions and comments on the newsletter and the topics covered.

To make comments, please contact the editor, Mark G. Schippits, MD

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