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Redefining Medical Necessity: A Consumer-Driven Solution To The U.S. Health Care Crisis

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REDEFINING MEDICAL NECESSITY: A CONSUMER-DRIVEN SOLUTION TO THE U.S. HEALTH CARE CRISIS

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The American health care system is plagued by high costs and poor public health outcomes, due in part to the overuse of costly diagnostic tests and treatments. In 2009, the Institute of Medicine estimated that unnecessary care wastes $750 billion, equivalent to about 30 percent of health care spending. Moreover, overtreatment can directly harm patients as a result of surgical complications, drug toxicity, and hospital-acquired infections.

Yet while the problem of medical waste has long been recognized, solving the problem has proven elusive. In part, this difficulty is due to perverse economic incentives for physicians and hospitals, which still primarily receive reimbursement on a fee-for-service basis. Providers are financially motivated under this system to generate a higher volume of invasive procedures independent of their likely benefits. Patients generally lack the information needed to decline unnecessary services, even when they wish to actively share in medical decision-making, and a strong cultural bias pushes both patients and physicians to "do more," even when evidence suggests that doing more may result in harm. In the 1990s, managed health care organizations attempted to rein in health care waste by stringently reviewing and prospectively denying payment for unnecessary tests and treatments, but that experiment was a political failure. Similarly, attempts to reduce overuse by shifting financial risk directly onto providers through capitated payment mechanisms have had limited success. The ability of these mechanisms to limit waste is compromised by the real or perceived incentive to also reduce spending on appropriate care.

We propose a new conception of medical necessity that will reduce inappropriate care by allowing informed consumers to actively participate in decisions about their medical care. Where evidence-based guidelines are available, medical necessity should be determined

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on the basis of an objective, multi-level Matrix of Appropriateness rather than the subjective binary decision of an insurance company's medical reviewer. Such Matrices have already been created by systematically combining published evidence with expert judgment to create clinically detailed, evidence-based, multi-level medical necessity ratings for elective procedures based on individual patient characteristics. In our proposed system, if a patient desires a service proposed by a physician under clinical circumstances that receive low medical necessity ratings, the third-party payer would offer to cover the service but at a sliding co-payment scale imposing greater patient cost sharing based on the service's appropriateness. This system would preserve patient choice while discouraging the overuse of costly treatments that provide little marginal value, reducing medical waste and improving the overall value of medical care.

Americans pay far more for their health care than citizens of other developed countries, while receiving less value.[1] Despite a recent decrease in growth rate, overall expenditures in the U.S. health care sector approached $2.7 trillion in 2012.[2] On a per capita basis and as a percentage of gross domestic product, the United States ranks first among the world's nations in health spending by a substantial margin,[3] yet population-level health outcome statistics place the United States in the middle of the pack of developing nations, with life expectancy ranking thirty-fourth in the World Health Organization's most recent statistics, just above Barbados, Colombia, and Croatia.[4] Assessments of health care quality in the United States find even more alarming results: as much as 30 percent of U.S. health spending represents waste, paying for services that offer no net health benefits to the recipient and often result in harm.[5] Medical errors and treatment complications have risen to become one of the nation's leading causes of death.[6] A broad range of interventions undertaken by public and private entities to rein in spending, reduce waste, improve quality and safety, and enhance value have yet to yield substantial gains in costs or system performance.[7]

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1. Ryan Abbott, *Treating the Health Care Crisis: Complementary and Alternative Medicine for PPACA*, 14 DEPAUL J. HEALTH CARE L. 35, 36 (2011); *see also* Barbara Starfield, Commentary, *Is US Health Really the Best in the World?*, 284(4) JAMA 483 (2000).

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURE PROJECTIONS 2011–2021 *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2011PDF.pdf.

3. *OECD Health Data: Economic References*, OECD iLIBRARY, http://www.oecd-ilibrary.org/social-issues-migration-health/data/oecd-health-statistics/oecd-health-data-economic-references_data-00548-en;jsessionid=2hsy3us5g6883.x-oecd-live-01?isPartOf=/content/datacollection/health-data-en (last visited Oct. 8, 2014); *see also* Jason Kane, *Health Costs: How the U.S. Compares with Other Countries*, PBS NEWSHOUR THE RUNDOWN (Oct. 22, 2012, 10:30 AM), http://www.pbs.org/newshour/rundown/2012/10/health-costs-how-the-us-compares-with-other-countries.html.

4. *Life Expectancy at Birth*, WORLD HEALTH ORGANIZATION (2013), http://gamapserver.who.int/gho/interactive_charts/mbd/life_expectancy/atlas.html.

5. INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES 74 (Pierre L. Yong et al. eds., 2010), *available at* http://books.nap.edu/openbook.php?record_id=12750.

6. *See generally* LINDA T. KOHN ET AL., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 26 (Nat'l Research Council ed., 2000) (stating the results of studies revealing that medical errors are the eighth leading cause of death in the United States).

7. In 2003, health care costs grew while barriers to access increased after health plans loosened restrictions on care in response to consumer backlash toward managed care. Cara S. Lesser & Paul B. Ginsburg, CTR. FOR STUDYING HEALTH SYS. CHANGE, HEALTH CARE COSTS

The root cause of overspending and underperformance in the U.S. health care system lies in our mechanisms for paying providers of medical services, devices, and drugs.[8] The problem is twofold. First, we rely on free-market forces to ensure value despite fundamental structural features that defeat free-market functioning in the sector as a whole.[9] Chief among these structural features that inhibit free-market performance is the inability of purchasers of health services to prospectively judge the comparative effectiveness of alternative treatment strategies, and to base management choices on these judgments.[10] This limitation applies equally, regardless of whether the service purchaser is an individual or a third-party payer operating under a contractual obligation to cover the costs of all "necessary" treatments in exchange for premium payments.[11] Second, our payment mechanisms shield individuals from the financial consequences of their treatment choices, while attaching payment to each service rendered by providers, regardless of outcomes, incentivizing patients and physicians to maximize service utilization.[12]

AND ACCESS PROBLEMS INTENSIFY: INITIAL FINDINGS FROM HSC'S RECENT SITE VISITS (2003), *available at* http://www.hschange.com/CONTENT/559/559.pdf; Cara S. Lesser & Paul B. Ginsburg, *Healthcare Cost and Access Problems Intensify: Initial Findings from HSC's Recent Site Visits*, 63 JAMA 483 (2000). Seven years later, the United States ranked low in comparison to other nations in terms of health system performance despite having the most costly health system in the world. KAREN DAVIS ET AL., MIRROR, MIRROR ON THE WALL—HOW THE PERFORMANCE OF THE U.S. HEALTH CARE SYSTEM COMPARES INTERNATIONALLY 2010 UPDATE, THE COMMONWEALTH FUND (2010), *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2010/Jun/1400_Davis_Mirror_Mirror_on_the_wall_2010.pdf. And in 2013, high costs and poor system performance of the health care system remain serious issues in the United States. *See generally* CATHY SCHOEN ET AL., THE COMMONWEALTH FUND, CONFRONTING COSTS—STABILIZING U.S. HEALTH SPENDING WHILE MOVING TOWARD A HIGH PERFORMANCE HEALTH CARE SYSTEM (2013), *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2013/Jan/1653_Commission_confronting_costs_web_FINAL.pdf.

8. *See generally* THE COMMONWEALTH FUND, THE PATH TO A HIGH PERFORMANCE U.S. HEALTH SYSTEM: A 2020 VISION AND THE POLICIES TO PAVE THE WAY (2009), *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2009/Feb/The%20Path%20to%20a%20High%20Performance%20US%20Health%20System/1237_Commission_path_high_perform_US_hlt_sys_WEB_rev_03052009.pdf (discussing the need to change the way the United States delivers and pays for health care to reduce health care costs and increase access).

9. *See* Paul Krugman, Op-Ed., *Why Markets Can't Cure Healthcare*, N.Y. TIMES (July 25, 2009, 5:07 PM), http://krugman.blogs.nytimes.com/2009/07/25/why-markets-cant-cure-healthcare/.

10. *See id.*

11. *See id.*

12. *See, e.g.*, Toby Gosden et al., *Capitation, Salary, Fee-for-Service and Mixed Systems of*

In contrast to most other economically advanced nations whose citizens have elected to include medical care within a package of social benefits defined by national statutes,[13] U.S. citizens receive medical goods and services through a complex web of legal contracts between individuals and a broad array of public and private entities.[14] In the most common model, firms contract with commercial third-party health insurance entities to pay for health services, devices, and pharmaceuticals needed by their employees.[15] For citizens older than sixty-five, the federally funded Medicare program effectively contracts with individual hospitals, physicians, and pharmacies to pay for professional services, facility costs, and prescription medicines.[16] A hybrid arrangement in which Medicare purchases private health insurance on behalf of members represents a smaller segment of the over sixty-five market, and creates contractual relationships between Medicare members and third-party health plans that mirror employee benefit coverage.[17]

All of the contractual relationships between health care

Payment: Effects on the Behaviour of Primary Care Physicians (Review), 3 COCHRANE DATABASE OF SYSTEMATIC REVIEW (2000), *available at* onlinelibrary.wiley.com/doi/10.1002/14651858.CD002215/pdf (evidencing that a fee-for-service payment system resulted in primary care physicians providing, and patients using, a higher quantity of care). In addition to direct financial incentives, providers are also motivated to provide medically unnecessary services for defensive medical purposes. *See, e.g.*, Daniel Kessler & Mark McClellan, *Do Doctors Practice Defensive Medicine*, 111 Q. J. OF ECON. 353, 388 (1996). For example, an emergency room physician may order a head computerized tomography (CT) scan on a patient who reports head trauma, even in the absence of a clear medical indication. This may be because the physician is concerned about malpractice liability, and there is little downside to the physician for ordering the imaging. However, a CT scan and analysis by a radiologist represents a substantial medical expense, and the test also exposes the patient to unnecessary radiation. *Choosing Wisely: Imaging Tests For Lower-Back Pain*, CONSUMER REPORTS (2012), http://consumerhealthchoices.org/wp-content/uploads/2012/06/ChooseWiselyBackPainAAFP-ER.pdf. Similarly, doctors may order imaging to satisfy patients. If a patient with lower back pain desires an MRI in the absence of a clear medical indication, there is again little downside to the physician for ordering such a test and making the patient happy. Cultural norms also promote "doing more," even when there is evidence that doing more may be harmful. *See generally* OTIS WEBB BRAWLEY, HOW WE DO HARM: A DOCTOR BREAKS RANKS ABOUT BEING SICK IN AMERICA (2011) (providing real-life examples of various scenarios where additional procedures may harm patients).

13. Max Fisher, *Here's a Map of the Countries That Provide Universal Health Care (America's Still Not in It)*, THE ATLANTIC (June 28, 2012, 6:09 PM), http://www.theatlantic.com/international/archive/2012/06/heres-a-map-of-the-countries-that-provide-universal-health-care-americas-still-not-on-it/259153/.

14. William Sage, *Managed Care's Crimea: Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance*, 53 DUKE L.J. 597, 609–12 (2003).

15. *See id.*

16. Robert B. Friedland, *How Medicare Works*, 29 GENERATIONS 1, 30 (2005).

17. *Id.*

purchaser and third-party plans, as well as those between the plans and their individual beneficiaries, revolve around the crucially important but loosely defined concept of "medical necessity."[18] Medical necessity is a term of art in the health insurance industry that may be used to determine whether insurance will cover an intervention for an individual patient.[19] All purchasers of health benefits, including federal and state governments, Employee Retirement Income Security Act (ERISA) covered health plans, smaller firms that purchase health benefits for employees in the commercial insurance market, and the small minority of citizens who purchase individual policies from private health plans, enter into contracts that legally entitle each member to all medically necessary services.[20] Since working definitions of medical necessity remain vague, typically referring to generally accepted practice standards or to services deemed necessary by a qualified physician or other health care provider, risk-bearing payers face essentially unlimited exposure to utilization and costs, which are largely at the discretion of providers reimbursed on a fee-for-service basis that incentivizes maximal utilization of all types of health services.[21]

Existing contracts deploy medical necessity as a binary or dichotomous variable: for any given patient under a particular clinical circumstance, each service is either "medically necessary" or unnecessary, without any acknowledged middle ground to reflect variability and uncertainty in the expected benefits, costs and harms

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18. *See generally* Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1637–51 (1992) (discussing insurers' use of medical necessity in determining payment for health care services).

19. *See id.* at 1663–65 (describing a trend among insurers, since the mid-1970s, to control costs by scrutinizing medical necessity).

20. 15 AM. JUR. 3D *Proof of Facts* § 355 (1992).

21.

> [T]he excess baggage of "medical necessity" is not its pejorative connotation, but rather its multiplicity of meanings. In today's health care system, parties with a range of backgrounds and biases are involved in medical necessity decisions. To many physicians, the phrase "not medically necessary" means "not clinically indicated," which makes them question why a seemingly nonprofessional party such as a health plan has the right to challenge their professional opinion. To many health plans, it means "not covered even though not expressly excluded from coverage," which gives them a degree of comfort issuing denials based on established insurance practice even though such decisions outrage physicians. Consequently, decisions involving medical necessity are frequently characterized by inconsistent administration, poor communication, distrust and, if disputes arise, relatively unprincipled, results-oriented judicial resolution.

Sage, *supra* note 14, at 601.

of diagnostic tests or treatments.[22] Indeed, providers function under a de facto presumption of medical necessity for the services they render to patients, only rarely facing challenges on the need for services either before or after they were rendered.[23] During the 1990s, payer organizations tried to control costs by engaging in detailed prospective case review and mandatory precertification for elective surgical and diagnostic procedures.[24] This brief experiment failed following a political backlash from both consumers and providers contending undue interference by financially motivated third parties in the doctor-patient relationship.[25] With few exceptions, payers have now retreated from attempts to second-guess front-line providers on the medical necessity of procedures they perform, unleashing yet another round of steady increases in the volume of complex imaging procedures, elective surgeries, and overall health care costs.[26]

Viewed from a clinical perspective, the insurance industry's construction of medical necessity as a dichotomous variable bears little resemblance to the realities of medical decision-making and practice. Although financially it stacks the deck dramatically in favor of providers, who can justify nearly any intervention under the tautological principle that any procedure frequently performed by licensed physicians is medically necessary because it represents "standard practice."[27] In clinical settings, the medical necessity or appropriateness of any given test or treatment for a particular patient

22. *See, e.g.*, *Medically Necessary/Medical Necessity*, HEALTHPARTNERS (2013), http://www.healthpartners.com/public/coverage-criteria/medically-necessary; *Shield Savings and Spectrum PPO Savings Plan*, BLUE SHIELD OF CALIFORNIA LIFE AND HEALTH INSURANCE COMPANY (2013), https://www.blueshieldca.com/producer/documentlibrary/A16490-8_7-9.pdf (discussing plan coverage of services that are deemed medically necessary).

23. Timothy P. Blanchard, *"Medical Necessity" Determinations—A Continuing Healthcare Policy Problem*, 37 J. HEALTH L. 599, 618–19 (2004).

24. James C. Robinson, *The End of Managed Care*, 285 JAMA, 2622, 2622–23 (2001).

25. *Id.*

26. *Id.*

27. Furthermore, additional deference may be given to the opinion of a treating physician, as the party presumably most familiar with an individual patient's clinical needs. "The 'treating physician rule', as adopted by some courts, dictates that the treating physician's determination that a service is medically necessary is binding unless contradicted by substantial evidence, and is entitled to some extra weight, even if contradicted by substantial evidence, because the treating physician is inherently more familiar with the patient's medical condition." Andrew B. Wachler, *The New Audit Landscape: MICs, MACs, and RACs (Medicaid Integrity Contractors, Medicare Administrative Contractors, and Recovery Audit Contractors)*, AMERICAN HEALTH LAWYERS ASSOCIATION, http://www.healthlawyers.org/Events/Programs/Materials/Documents/HHs10/wachler.pdf (citations omitted) (last visited Feb. 20, 2014).

depends on a complex set of clinical circumstances, and rarely reflects a simple dichotomous or binary judgment.[28] Instead, depending in part on individual patient circumstances, any given intervention falls somewhere between the following categories: (a) unequivocally necessary; (b) desirable on balance but not entirely necessary; (c) unnecessary because expected benefits to the patient do not justify the costs, time, or risk; or (d) unnecessary and contraindicated due to the greater likelihood of net harm to the patient. While these determinations are made routinely by practicing clinicians based on their training, personal experience, and implicit judgment, a well-developed scientific approach also exists for the quantitative assessment of medical necessity. Thus, a more nuanced approach to judging the need for procedures is feasible, and the requisite methodology has been broadly applied and described in detail in the peer-reviewed medical literature.

Beginning in the early 1980s, Robert Brook led a group of health services researchers at RAND in an ambitious scientific initiative to quantitatively determine the medical necessity of commonly performed elective diagnostic and therapeutic procedures.[29] These researchers used explicit methods that combined published evidence from the peer-reviewed medical literature with

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28. Marc A. Koopmanschap et. al., *Dear Policy Maker: Have You Made Up Your Mind? A Discrete Choice Experiment Among Policy Makers and Other Health Professionals*, 26:2 INT'L J. TECH. ASSESSMENT IN HEALTH CARE 198, 203–04 (2010); *see also*, Linda A. Bergthold, *Medical Necessity: Do We Need It?* 14 HEALTH AFFAIRS, 180–81 (1998) (tracing the history and use of the term "medical necessity").

29. The RAND/UCLA Appropriateness Method (RAM) is "only one of several methods that have been developed to identify the collective opinion of experts." KATHRYN FITCH ET AL., THE RAND/UCLA APPROPRIATENESS METHOD USER'S MANUAL (2001), http://www.rand.org/content/dam/rand/pubs/monograph_reports/2011/MR1269.pdf. The RAM

> was developed in the mid-1980s, as part of the RAND Corporation/University of California Los Angeles (UCLA) Health Services Utilization Study, primarily as an instrument to enable the measurement of the overuse and underuse of medical and surgical procedures. In the RAM, the concept of appropriateness refers to the relative weight of the benefits and harms of a medical or surgical intervention. An appropriate procedure is one in which 'the expected health benefit (e.g., increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeds the expected negative consequences (e.g., mortality, morbidity, anxiety, pain, time lost from work) by a sufficiently wide margin that the procedure is worth doing, exclusive of cost[.]' Robert H. Brook, who identified the need for a tool to measure the appropriateness of care, explained that 'it was motivated by the concern that the increasing complexity of medical care was resulting in some patients not undergoing procedures that they needed, and others undergoing procedures that they did not need[.]'

Id. at 1 (internal quotation marks and citations omitted).

the balanced judgment of multi-disciplinary expert clinician panels in a nominal group process that limited the impact of any individual panel member on final results.[30] Using a multi-round modified Delphi method,[31] panelists rated the medical necessity of each procedure in hundreds of individual, detailed clinical scenarios using a nine-point Likert scale.[32] A rating of one on the Likert scale indicated a clinical circumstance in which the procedure was deemed both unnecessary and inappropriate, a five reflected an equivocal rating, and a nine anchored the upper end of the scale, denoting a clinical scenario in which panelists deemed the intervention in question to be both appropriate and necessary.[33] Of note, panelists were explicitly instructed to ignore monetary costs in their judgments of medical necessity and adhere to a strict definition deeming a procedure necessary to the extent that its expected medical benefits sufficiently exceeded the likely medical risks to make the procedure worthwhile.[34] These methods developed at RAND were later adopted by other academic institutions, private firms, and publicly funded delivery systems in Europe to more precisely assess the necessity of specific procedures based on detailed clinical scenarios.[35]

The quantitative construction of medical necessity combining published evidence with expert consensus invented at RAND holds that medical necessity represents a multi-level, ordinal variable, anchored on the high end by life-saving procedures such as appendectomy for acute appendicitis or immediate surgery to control hemorrhage resulting from trauma, and on the low end by any

30. *Id*.

31. The "Delphi method" was developed at RAND in the 1950s as a tool to predict the future, and it has come to be used in a variety of health and medical settings. "The method generally involves multiple rounds, in which a questionnaire is sent to a group of experts who answer the questions anonymously. The results of the survey are then tabulated and reported back to the group, and each person is asked to answer the questionnaire again. This iterative process continues until there is a convergence of opinion on the subject or no further substantial changes in the replies are elicited." *Id*.

32. "A Likert scale is an ordered scale from which respondents choose one option that best aligns with their view. It is often used to measure respondents' attitudes by asking the extent to which they agree or disagree with a particular question or statement. A typical scale might be 'Strongly disagree, Disagree, Neutral, Agree, Strongly agree.'" Jan Losby & Anne Wemore, *CDC Coffee Break: Using Likert Scales in Evaluation Survey Work*, NAT'L CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION (2013), http://www.cdc.gov/dhdsp/pubs/docs/CB_February_14_2012.pdf.

33. Fitch, *supra* note 29.

34. *Id.* at 4.

35. *See generally id.*

procedures whose medical risks outweigh their benefits, including entirely elective surgical interventions for cosmetic or lifestyle enhancement.[36] Between these two extremes, the RAND method recognizes intermediate levels of necessity that balance the likely benefits of a procedure against its possible harms, as well as the comparative benefits of alternative, less invasive interventions.[37] While methodologically demanding to produce and deploy, this multi-level conception of medical necessity reflects much more closely the approach applied daily by practicing physicians than does the dichotomous model enshrined in existing contracts between payers and health plans on the one hand, and between health plans and their members on the other. Some examples will help illustrate how this more nuanced conception of medical necessity works in practice.[38] The RAND method was applied to hysterectomy, the surgical removal of the uterus (and often the ovaries), a common procedure performed for a variety of indications and complaints.[39] The expert panels charged with determining the clinical circumstances under which hysterectomy is medically necessary focused their attention on indications where the surgery might yield symptomatic improvement, but also entails significant risks and represents one of a range of alternative treatment options (such as medical management or less invasive surgical interventions).[40] The panel deemed hysterectomy performed to treat gynecologic cancer to be unequivocally necessary and was not included in this study.[41]

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36. *See generally id.*

37. *Id.* at 2.

38.

> Many procedures have been the subject of appropriateness studies in the United States, among them, coronary angiography, coronary artery bypass graft surgery, percutaneous transluminal coronary angioplasty, carotid endarterectomy, abdominal aortic aneurysm surgery, diagnostic upper gastrointestinal endoscopy, cataract surgery, colonoscopy, cholecystectomy, hysterectomy, tympanostomy and spinal manipulation for lower back pain. The method has since been applied to some of these as well as other conditions and procedures—benign prostatic hyperplasia, laminectomy, breast cancer and total hip replacement—in a wide variety of countries, including Canada, Israel, Italy, The Netherlands, Spain, Sweden, Switzerland, and the United Kingdom. Use continues to expand to other countries, particularly in Western Europe.

Id. at 2 (internal citations omitted).

39. Michael S. Broder, et al., *The Appropriateness of Recommendations for Hysterectomy*, 95 OBSTET GYNECOL 199, 199–205 (2000), http://media.redding.com/media/static/The_Appropriateness_of_Recommendations_for.7.pdf.

40. *Id.* at 200.

41. *Id.* at 202.

Instead, the experts focused their attention on the most common indications for elective hysterectomy such as abnormal uterine bleeding and pelvic pain.[42] For these indications, the panelists rated the medical necessity on the nine-point scale, based on balancing the expected benefits against the likely risks of surgery, as well as the availability of effective nonsurgical alternatives.[43]

For example, a forty-two-year-old woman proposed for a hysterectomy to control abnormal uterine bleeding, who had not received a trial of hormonal treatment or more limited surgeries such as dilation and curettage[44] and whose daily functioning was not dramatically impacted by her bleeding symptoms, received low medical necessity ratings in the one to three range, because of the availability of less invasive alternative treatments that often yield acceptable outcomes in these circumstances.[45] In contrast, if the same patient had failed the trial of hormonal treatment, did not respond to less invasive procedures, and was frequently limited in her daily activities due to bleeding or required multiple transfusions to replace blood loss, hysterectomy received high necessity ratings in the seven to nine range.[46] In other words, by combining evidence from published outcomes studies with multidisciplinary expert opinion, the RAND researchers were able to define a range of necessity for a common procedure based on the detailed clinical circumstances under which it was undertaken.[47]

To illustrate, an excerpt of the Matrix[48] for evaluating hysterectomy (here only in a subset of patients with cervical dysplasia) is listed, along with an interpretation guide.[49]

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42. *Id.* at 200–03.

43. *Id.* at 200.

44. *Dilation and Curettage: Frequently Asked Questions*, THE AM. C. OF OBSTETRICIANS AND GYNECOLOGISTS (2012), http://www.acog.org/~/media/For%20Patients/faq062.pdf?dmc=1&ts=20131219T0414505549. "D&C [dilation and curettage] is a surgical procedure in which the *cervix* is opened (dilated) and a thin instrument is inserted into the *uterus*. This instrument is used to remove tissue from the inside of the uterus (curettage) . . . D&C is used to diagnose and treat many conditions that affect the uterus, such as abnormal bleeding." *Id.*

45. Broder et al., *supra* note 39, at 202.

46. *Id.*

47. *Id.* at 201–03.

48. STEVEN J. BERNSTEIN, RAND, S. CAL. HEALTH RESEARCH CONSORTIUM, HYSTERECTOMY RATINGS OF APPROPRIATENESS 9 (1997).

49. *Id. at* 12.

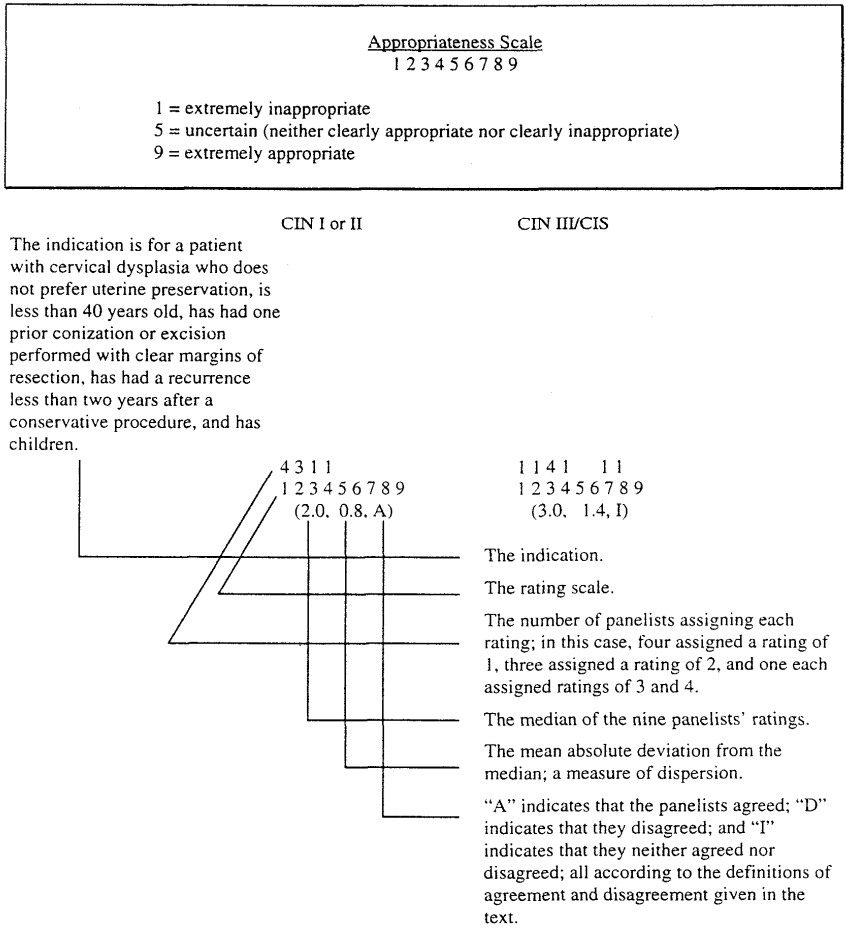

Figure 3—A Key to Reading the Final Results of Appropriateness Ratings for Each Indication

Hysterectomy is Indicated In Patients with Cervical Dysplasia Who State They:	**Degree of Dysplasia CIN I or II**	**Degree of Dysplasia CIN III/CIS**
PREFER UTERINE PRESERVATION	9 1 2 3 4 5 7 8 9 (1.0, 0.0, A)	9 1 2 3 4 5 7 8 9 (1.0, 0.0, A)
DO NOT PREFER UTERINE PRESERVATION, ARE <40 YEARS OLD AND HAVE:		
No prior conization or excision:		
No Children	9 1 2 3 4 5 6 7 8 9 (1.0, 0.0, A)	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.2, A)
Children	9 1 2 3 4 5 6 7 8 9 (1.0, 0.0, A)	6 2 1 1 2 3 4 5 6 7 8 9 (1.0, 0.4, A)
One prior conization or exision performed with clear margins of resection:		
No Recurrence		
No Children	9 1 2 3 4 5 6 7 8 9 (1.0, 0.0, A)	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.1, A)
Children	9 1 2 3 4 5 6 7 8 9 (1.0, 0.0, A)	7 2 1 2 3 4 5 6 7 8 9 (1.0, 0.2, A)
Recurrence 2 or more years after conservative procedure		
No Children	5 3 1 2 3 4 5 6 7 8 9 (1.0, 0.4, A)	2 3 1 1 1 1 2 3 4 5 6 7 8 9 (2.0, 1.4, A)
Children	6 3 1 2 3 4 5 6 7 8 9 (1.0, 0.3, A)	2 2 2 2 1 1 2 3 4 5 6 7 8 9 (3.0, 1.4, I)
Recurrence < 2 years after conservative procedure		
No Children	4 3 1 1 1 2 3 4 5 6 7 8 9 (2.0, 0.8, A)	1 3 3 1 1 1 2 3 4 5 6 7 8 9 (3.0, 1.6, A)
Children	4 3 1 1 1 2 3 4 5 6 7 8 9 (2.0, 0.8, A)	1 1 4 1 1 1 1 2 3 4 5 6 7 8 9 (3.0, 1.4, I)
One prior conization or excision performed with margins of resection showing dysplasia		
No repeat sampling or no dysplasia on repeat sampling		
No Children	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.1, A)	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.1, A)
Children	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.1, A)	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.2, A)
Repeat sampling shows dysplasia		
No Children	4 3 2 1 2 3 4 5 6 7 8 9 (2.0, 0.7, A)	1 1 4 2 1 1 2 3 4 5 6 7 8 9 (3.0, 1.1, I)

Children	3 3 3 1 2 3 4 5 6 7 8 9 (2.0, 0.7, A)	1 1 3 2 1 1 1 2 3 4 5 6 7 8 9 (3.0, 1.3, I)
Two or more prior conizations or excisions performed with clear margins of resection on last procedure		
No recurrence		
No Children	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.1, A)	7 2 1 2 3 4 5 6 7 8 9 (1.0, 0.2, A)
Children	9 1 2 3 4 5 6 7 8 9 (1.0, 0.0, A)	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.1, A)
Recurrence 2 or more years after conservative procedure		
No Children	4 3 2 1 2 3 4 5 6 7 8 9 (2.0, 0.7, A)	3 2 1 1 1 1 1 2 3 4 5 6 7 8 9 (4.0, 1.8, D)
Children	3 3 3 1 2 3 4 5 6 7 8 9 (2.0, 0.7, A)	1 3 2 1 2 1 2 3 4 5 6 7 8 9 (5.0, 1.6, I)
Recurrence < 2 years after conservative procedure		
No Children	3 2 3 1 1 2 3 4 5 6 7 8 9 (2.0, 0.9, A)	1 3 2 1 2 1 2 3 4 5 6 7 8 9 (5.0, 1.7, I)
Children	2 3 3 1 1 2 3 4 5 6 7 8 9 (2.0, 0.9, A)	1 3 1 1 1 2 1 2 3 4 5 6 7 8 9 (5.0, 1.8, I)
More than one prior conization or excision with margins of resection showing dysplasia		
No repeat sampling or no dysplasia on repeat sampling		
No Children	6 2 1 1 2 3 4 5 6 7 8 9 (1.0, 0.4, A)	4 2 2 1 1 2 3 4 5 6 7 8 9 (2.0, 1.3, A)
Children	6 2 1 1 2 3 4 5 6 7 8 9 (1.0, 0.4, A)	4 1 3 1 1 2 3 4 5 6 7 8 9 (2.0, 1.4, A)
Repeat sampling shows dysplasia		
No Children	3 3 1 2 1 2 3 4 5 6 7 8 9 (2.0, 0.9, A)	1 1 1 1 1 1 2 1 2 3 4 5 6 7 8 9 (6.0, 2.3, I)
Children	3 3 2 1 1 2 3 4 5 6 7 8 9 (2.0, 0.8, A)	1 1 1 2 1 1 2 1 2 3 4 5 6 7 8 9 (5.0, 2.3, I)
DO NOT PREFER UTERINE PRESERVATION, ARE 40 YEARS OR OLDER, AND HAVE:		
No prior conization or excision	9 1 2 3 4 5 6 7 8 9 (1.0, 0.0, A)	7 1 1 1 2 3 4 5 6 7 8 9 (1.0, 0.6, A)
One prior conization or excision performed with clear margins of resection		

No recurrence	9 1 2 3 4 5 6 7 8 9 (1.0, 0.0, A)	9 1 2 3 4 5 6 7 8 9 (1.0, 0.0, A)
Recurrence 2 or more years after conservative procedure	5 4 1 2 3 4 5 6 7 8 9 (1.0, 0.4, A)	2 1 5 1 1 2 3 4 5 6 7 8 9 (3.0, 1.2, A)
Recurrence < 2 years after conservative procedure	4 2 3 1 2 3 4 5 6 7 8 9 (2.0, 0.8, A)	1 1 3 1 1 1 1 1 2 3 4 5 6 7 8 9 (3.0, 1.8, I)
One Prior conization or excision performed with margins of resection showing dysplasia		
No repeat sampling or no dysplasia on repeat sampling	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.1, A)	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.2, A)
Repeat sampling shows dysplasia	3 2 4 1 2 3 4 5 6 7 8 9 (2.0, 0.8, A)	1 1 1 2 2 1 1 1 2 3 4 5 6 7 8 9 (4.0, 1.7, I)
Two or more prior conizations or excisions performed with clear margins of resection on last procedure		
No recurrence	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.1, A)	8 1 1 2 3 4 5 6 7 8 9 (1.0, 0.3, A)
Recurrence 2 or more years after conservative procedure	4 5 1 2 3 4 5 6 7 8 9 (3.0, 0.9, A)	1 2 1 1 1 1 1 1 1 2 3 4 5 6 7 8 9 (5.0, 2.1, D)
Recurrence < 2 years after conservative procedure	3 1 4 1 1 2 3 4 5 6 7 8 9 (3.0, 1.0, A)	2 2 1 1 2 1 1 2 3 4 5 6 7 8 9 (5.0, 1.9, I)
More than one prior conization or excision with margins of resection showing dysplasia		
No repeat sampling or no dysplasia on repeat sampling	7 2 1 2 3 4 5 6 7 8 9 (1.0, 0.4, A)	6 1 2 1 2 3 4 5 6 7 8 9 (1.0, 1.1, A)
Repeat sampling shows dysplasia	3 1 3 1 1 1 2 3 4 5 6 7 8 9 (3.0, 1.1, A)	1 2 1 2 2 1 1 2 3 4 5 6 7 8 9 (6.0, 1.9, I)

The use of advanced imaging in the setting of low back pain offers another example of the same principle. Acute low back pain represents one of the most common indications for patients to seek medical care in the United States.[50] The vast majority of these episodes resolve within a few days to weeks without specific treatment beyond short-term symptom control with appropriate analgesics.[51] Some of these episodes result from specific anatomic

50. *See* Steven J. Atlas & Richard A. Deyo, *Evaluating and Managing Acute Low Back Pain in the Primary Care Setting*, 16 J. GEN. INTERNAL MED. 120, 120 (2001) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1495170/pdf/jgi_91141.pdf.

51. Barbara S. Webster et al., *Iatrogenic Consequences of Early Magnetic Resonance*

derangements such as lumbar disc herniation, but even these episodes resolve without surgical intervention in approximately 60 to 70 percent of cases.[52] Despite this, patients presenting with low back pain often receive advanced imaging, such as magnetic resonance imaging (MRI), early in the course of their illness.

These imaging tests may reveal abnormalities, such as disc herniations, that arouse concern for both patient and practitioner despite the well-documented fact that herniated disc symptoms, while initially severe, generally improve rapidly with non-operative measures and most often resolve spontaneously in the course of a few weeks.[53] The presence of the radiographic abnormality, in combination with severe symptoms, often leads to unnecessary lower back surgery.[54] Applying the RAND approach, a patient with acute low back pain, even with features strongly suggestive of lumbar disc herniation, such as radiation of pain to the lower extremity, would receive a low rating of medical necessity for MRI early in the course of the illness in the absence of signs of serious neurologic compromise.[55] However, following a trial of conservative treatment, which might include physical therapy and other non-operative treatments, if this same patient remained limited by back and leg pain after several weeks then imaging could be used to determine the likely benefit from disc surgery. This would move the determination of medical necessity toward the high end of the scale, since the failure of symptoms to resolve with non-operative measures on balance favors surgical intervention for patients who desire more rapid relief of symptoms.[56] Moving from a binary or dichotomous definition of medical necessity to a more nuanced, multi-level rating based on detailed clinical circumstances offers a number of intriguing possibilities for reducing unnecessary care and controlling

Imaging in Acute, Work-Related, Disabling Low Back Pain, 32 SPINE 1939 (2013) ("Early MRI without indication has a strong iatrogenic effect in acute LBP, regardless of radiculopathy status. Providers and patients should be made aware that when early MRI is not indicated, it provides no benefits, and worse outcomes are likely.").

52. Alessandra Splendiani et. al., *Spontaneous Resolution of Lumbar Disk Herniation: Predictive Signs for Prognostic Evaluation*, 46 NEURORADIOLOGY 916, 919 (2004).

53. *Id.*

54. Derek J. Emery et al., *Overuse of Magnetic Resonance Imaging*, 173 JAMA INTERNAL MED. 823, 824 (2013) (finding "evidence of substantial overuse of lumbar spine MRI scans" where "[o]ver half the requests (55.7%) were inappropriate (28.5%) or of uncertain value (27.2%)").

55. *See id.* at 823–24.

56. *Id.*

costs.[57] At the same time, this multi-level rating system can improve value from both the patient's and the payer's perspectives.[58] Validated multi-level ratings of medical necessity, based on clinical circumstances for a majority of commonly performed and costly diagnostic and therapeutic procedures, could be deployed in a variety of ways to ensure that patients who stand to substantially benefit retain access to these procedures[59] while those who might benefit more from alternative and less complex interventions are offered both an opportunity and an incentive to select them. Here, we explore only one possible application of multi-level medical necessity: varying the patient's co-payment for the procedure based on experts' ratings of medical necessity under specific, detailed clinical circumstances.

In the examples offered above, a woman desiring a hysterectomy for bleeding prior to a trial of conservative treatment would not be denied coverage based on a failure to meet a medical necessity threshold. Instead, she might be offered the procedure with a 30 to 40 percent co-pay prior to undergoing the surgery, perhaps amounting to several thousand dollars. However, the same patient, after failing an adequate trial of alternative non-operative treatments, might receive the surgery with a low or even no co-pay since the failure of alternative therapy increases the appropriateness of a surgical intervention. In the low back pain example, a patient desiring an MRI during the first week of his symptoms could be offered the procedure with a 50 percent co-pay. Alternatively, should he elect to delay the imaging and try non-operative treatments, but remain symptomatic and disabled by his back and leg symptoms after a period of six to eight weeks, he would receive imaging with a nominal or no co-pay since the failure of symptoms to follow the usual pattern of spontaneous resolution places the patient in a different clinical category where the benefits of imaging and decompressive surgery of a disc herniation begin to outweigh the potential risks.

57. Anthony J. Culyer & Yvonne Bombard, *An Equity Framework for Health Technology Assessments*, 32 MED. DECISION MAKING 428, 429 (2012) ("The framework is primarily intended for high-level decision makers who specify the criteria to be used by HTA advisory committees."); *see* Sara Rosenbaum et al., *Who Should Determine When Health Care Is Medically Necessary?*, 340 NEW ENG. J. MED. 229, 230 (1999).

58. Culyer & Bombard, *supra* note 57, at 429.

59. *Id.* at 429–31.

Varying the co-payment to reflect the level of medical necessity determined by published evidence and expert opinion has several advantages. This variation retains an element of patient choice in accessing complex or invasive treatments, while incentivizing patients to try less invasive and costly alternatives in circumstances where these treatments are likely to result in similar outcomes. Properly executed by an impartial body, detailed medical necessity criteria could serve as the basis for overcoming a principal cause of market failure in the health care sector, namely the inability of the typical consumer to judge on his or her own the relative merits of different diagnostic and treatment approaches. It would provide patients, as well as payers and providers, with expert input on the comparative effectiveness of different treatment strategies.[60] In comparison to outright denials of service based on adverse medical necessity decisions attempted by health plans during the 1990s, which resulted in a public opinion backlash that scuttled the first round of managed care reforms,[61] the variable co-payment approach may more closely reflect societal values favoring freedom of choice among treatment options by individuals and their physicians,[62] while at the same time giving consumers access to evidence-based guidance on the relative costs and advantages of the different treatments available to them.

However, the variable co-pay approach proposed here has several important limitations. Chief among these limitations is the challenge of developing multi-level medical necessity ratings for common or costly treatments based on an unbiased and broadly representative interpretation of existing published data on the comparative effectiveness of different treatments, using validated methods to combine expert opinion with published evidence. The RAND approach offers one example of how this can be accomplished,[63] and advances in information technology allowing broader input from a larger, geographically dispersed panel of experts would further enhance adaptation of these proven methods to current circumstances.[64] Strict avoidance of any conflict of interest

60. *See* sources cited *supra* note 57.

61. *See* Sage, *supra* note 14, at 609–12.

62. RJ Belndon et al., *Understanding the Managed Care Backlash*, 17 HEALTH AFF., 80, 81 (1998).

63. *See supra* notes 27–34.

64. Referring to the importance of a varied panel of experts, the article states that "[t]he

between those involved in developing medical necessity ratings and entities applying them in variable co-payment contracts would be critical to the ethical and sustainable implementation of this approach.

Independent, non-profit organizations such as the Patient-Centered Outcomes Research Institute (PCORI) and the Institute of Medicine (IOM) may be the most appropriate parties to generate Matrices of Appropriateness.[65] While health insurance companies could internally develop Matrices, their financial incentives to limit spending on necessary as well as unnecessary care,[66] and the public perception that insurers do not always act in the best interests of their enrollees,[67] may limit the effectiveness of insurer-developed Matrices. Alternately, a government agency, such as the Centers for Medicare and Medicaid Services (CMS), might develop Matrices for internal use or to disseminate for use by private insurers. Government agencies would have the advantage of being mission-driven to benefit the public but the disadvantage of being potentially captive to political interests.[68] Political interests have already been a significant barrier, for example, to government initiatives in the Affordable Care Act (ACA) designed to promote comparative effectiveness research (CER), resulting in

> [m]any Republicans, private institutions, and conservative pundits [going] into "rhetorical overdrive," with claims of government interference in patient care and rationing of services. Town hall meetings resonated with concerns over

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decision as to which specialty or specialties to include will depend on the particular procedure under study and the way clinical decisions are made in each country," followed by a discussion of different approaches employed in the United States, Sweden, Spain, Switzerland, and the Netherlands. Fitch, *supra* note 29, at 23.

65. *Patient-Centered Outcomes Research*, PATIENT-CENTERED OUTCOMES RES. INST., http://www.pcori.org/research-we-support/pcor/ (last updated Nov. 7, 2013); *see Our Study Process*, INSTITUTE OF MEDICINE, http://www.iom.edu/About-IOM/Study-Process.aspx (last updated June 26, 2012).

66. *See Containing Health Care Costs*, THE MERCK MANUAL, http://www.merckmanuals.com/professional/special_subjects/financial_issues_in_health_care/containing_health_care_costs.html (last updated Oct. 2013) (stating that "[i]nsurance companies have limited access to care by denying coverage to people likely to need care").

67. *See* Tanzina Vega, *Insurers Seek to Soften Their Image, No Matter How Court Rules on Health Act*, N.Y. TIMES, June 22, 2012, at A14 (quoting Harvard Business School professor Regina E. Herzlinger as stating that insurance providers "are among the most disliked industries in the United States").

68. Ryan Abbott, *Big Data and Pharmacovigilance: Using Health Information Exchanges to Revolutionize Drug Safety*, 99 IOWA L. REV. 225, 257 (2013).

> the creation of "death panels" and fear that the United States would adopt a "British-style" model of health care.[69]

Efforts by government agencies to limit unnecessary care have also failed in the past. One of the highest profile historical examples occurred when the Agency for Health Care Policy and Research (AHCPR), which was created in 1989 to carry out outcomes studies, develop practice guidelines, and conduct and coordinate health services research, was criticized by the North American Spine Society (NASS) (an association of back surgeons), with the support of a number of Republican politicians, after the AHCPR reported that "there was no evidence to support spinal-fusion surgery and that such surgery commonly had complications."[70] The agency ultimately survived the incident, but with a new name that removed the word "policy": the Agency for Healthcare Research and Quality (AHRQ).[71] The incident also resulted in the abandonment of the agency's practice guideline program and a 21 percent budget cut.[72]

Regardless of what party develops Matrices of Appropriateness, private health insurance companies utilizing Matrices would gain a competitive advantage from being able to minimize spending on unnecessary care, which would provide a market-driven impetus to adopt a multi-level medical necessity rating system. As a general matter, medical necessity is defined in insurance contracts, and judicial interpretation of the language in policies is governed by the rules established for the construction and interpretation of written contracts generally.[73] Some state laws specify a standard definition of medical necessity that health plans are required to use, but these states are in the minority.[74] Other states have general legislation that might impact plans' definitions of medical necessity[75] even though there is no state-mandated definition, while yet a third set of states

69. Corinna Sorenson et al., *The Politics of Comparative Effectiveness Research: Lessons from Recent History*, 39.1 J. HEALTH POL. POL'Y & L. 139, 140 (2014) (internal citation omitted).

70. *Id.* at 147–48 (internal citation and quotation marks omitted).

71. *Id.* at 149.

72. *Id.*

73. 15 AM. JUR. 3D, *supra* note 20, § 355.

74. CENTER FOR HEALTH POLICY, STANFORD UNIVERSITY, STATE-BY-STATE COMPENDIUM OF MEDICAL NECESSITY REGULATION: SURVEY OF STATE MANAGED CARE REGULATORS 12 (2001), *available at* http://www.hcfo.org/files/hcfo/stanford.pdf. (indicating that 11 states have any legislation that might impact plans' definitions).

75. *Id.*

have no legislation that might impact a definition.[76] While a state-by-state analysis is beyond the scope of this Article, insurers should be free to adopt a multi-level definition in most markets. The ACA does not define medical necessity.[77]

The ACA does, however, significantly strengthen the external review process,[78] and this represents an even stronger reason for insurers to adopt an unbiased, third-party Matrix of Appropriateness when making medical necessity determinations. The ACA establishes a set of rules for consumers to appeal a health insurance plan directly with the insurer (an internal appeal), as well as a right to have an independent review organization decide whether to uphold or overturn the plan's decision (an external review).[79] The conventional wisdom about external, or judicial, reviewers is that they tend to promote access to sympathetic patients.[80] However, determinations adverse to insurers would probably be less likely when an insurer could demonstrate a medical necessity determination was made on the basis of an independently generated, non-biased, and evidence-based Matrix. The ACA also limits the upper bound of patient cost sharing; out-of-pocket limits for health plans are approximately $6,350 in 2014.[81]

Unavoidably, variable co-pays for elective procedures would disproportionately affect low-income individuals, necessitating measures to balance the impact of co-pays according to each patient's ability to pay them. This balancing could be accomplished through scaling co-pay amounts to a percentage of annual income. Extreme caution would be needed when applying this approach to potentially life-saving treatments for serious conditions such as cancer, despite the fact that the same basic principles govern medical

76. *Id.*

77. Daniel Skinner, *Defining Medical Necessity under the Patient Protection and Affordable Care Act*, 73 PUB. ADMIN. REV. S49, S50 (2013); *see also* Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified at various sections) (failing to provide a definition for "medical necessity").

78. *See* 42 U.S.C. § 300gg-19 (2014).

79. *Id.*; The Ctr. for Consumer Info. & Ins. Oversight, *HHS-Administered Federal External Review Process for Health Insurance Coverage*, CENTERS FOR MEDICARE AND MEDICAID SERVICES, http://www.cms.gov/CCIIO/Programs-and-Initiatives/Consumer-Support-and-Information/csg-ext-appeals-facts.html (last visited Jan. 26, 2014).

80. Sage, *supra* note 14, at 610–11.

81. *Focus on Health Reform: Patient Cost-Sharing Under the Affordable Care Act*, THE HENRY J. KAISER FAM. FOUND. 1, 3 (2012), http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8303.pdf.

necessity determinations in these circumstances. For example, before high-dose chemotherapy followed by bone marrow transplant was proven not to extend the lives of patients suffering from metastatic breast cancer, many such procedures were performed. The procedures were, at the time, deemed medically necessary by virtue of the fact that practitioners were willing to undertake them and they held some hope on biological grounds of extending life or even curing the disease.[82] Now, payers have stopped covering this costly and risky treatment for disseminated breast cancer because it does not meet current, dichotomous criteria for medical necessity, lacking proof of benefit after multiple clinical trials.[83]

In many instances, however, similar clarity on the efficacy of emerging treatments for life-threatening conditions is not yet available, and it would be unethical to expose patients to high co-pays in circumstances where the science is not yet sufficiently clear to make a reasoned, balanced judgment of the relative risks and benefits of alternative approaches. However, the technique could be ethically applied to expand choice at the boundaries of current, dichotomous guidelines for managing potentially fatal illnesses. For example, the U.S. Preventive Services Task Force (USPSTF) recently recommended CT screening for lung cancer in heavy smokers between the ages of fifty-five and eighty.[84] For patients with a strong preference for screening outside of these age and risk guidelines, variable co-pays could be offered to lower the cost of access to this potentially life-saving screening test, as long as a mechanism for balancing income disparities was in place.

In conclusion, applying proven scientific methods to create detailed, multi-level ratings of medical necessity for the most commonly performed elective procedures, as well as for costly interventions with a variable likelihood of benefit, offers a strategy for reining in the overuse of diagnostic and therapeutic technologies. This strategy would improve the quality and value of medical care while maintaining an element of patient and consumer choice that balances preferences for alternative treatments with a willingness to

82. Sage, *supra* note 14, at 611.

83. *Id.*

84. *Screening for Lung Cancer: U.S. Preventative Services Task Force Recommendation Statement*, U.S. PREVENTIVE SERVICES TASK FORCE, http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanfinalrs.htm#summary (last updated Dec. 2013).

share in their costs. Because this strategy would be deployed in the insurance industry, which remains under the legal purview of each state, a variety of models could be tested. The principal challenges entailed by this approach include ensuring the objectivity and avoiding conflicts of interest in the development of the necessity ratings, and scaling co-pays to income to blunt a disproportionate impact on choice among lower-income individuals. Enshrined in the contracts that bind health plans and their members, as well as those between purchasers and health plans, variable co-pays for elective procedures based on objective, multi-level medical necessity ratings could offer a powerful tool for improving value while controlling costs.