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# External Review of Coverage Denials by Managed Care Organizations in California

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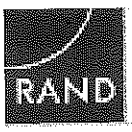


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# PREFACE

This study examines a large sample of cases in which patients in California contested their health plan's denial of coverage through the state's external review program. We describe the specific services involved in the case and the outcome of the external review process and analyze the roots of disagreement in cases in which the health plan's coverage denial was overturned. We explore the implications of our findings for policymakers. This research is forthcoming in the November 2005 edition of the *Journal of Empirical Legal Studies*.

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# TABLE OF CONTENTS

# LIST OF TABLES

# ABSTRACT

External review programs have been adopted in nearly every state to give managed care enrollees the opportunity to have certain denials of health insurance coverage reviewed by physicians who are unaffiliated with their health plan. This study explores in depth a sample of cases adjudicated in California's external review program. We abstracted information from hard copy files of several hundred cases adjudicated during 2001–02. We describe the specific services involved in external review and the outcomes of review, analyzing the roots of disagreement in cases in which the health plan's coverage denial was overturned. We find that a subset of overturns illuminate tension in the relationship between the external review program's adjudication rules and the terms of the health insurance agreements that exist between plans and enrollees. Two critical questions face designers of external review programs: (1) What deference will be paid to specific coverage exclusions in the insurance contract between plans and enrollees? and (2) How should external review handle cases that blend medical necessity and contractual issues?

# INTRODUCTION

During years of Congressional deadlock on a patients' bill of rights, one policy aimed at protecting managed care enrollees has flourished. By the end of 2003, forty-four states and the District of Columbia had introduced external review programs, with 39 of them created since 1997.[1] External review programs are formal, state-sponsored processes for resolving disputes over health insurance coverage. Their goal is to guard against stinting by providing enrollees who experience denials with a "second look" at coverage denials that is expert and independent of the financial incentives that may inappropriately skew decisionmaking.

The proliferation of external review systems reflects broad consensus about their policy wisdom. Leading stakeholder groups, including patients, providers, attorneys, even the managed care industry itself, have endorsed this type of independent scrutiny as a method for safeguarding quality of care and averting expensive litigation.[2] Reforms bolstering external review procedures have been a staple component of successive patients' rights bills at the federal level. The legal reach of state programs was somewhat uncertain until a 2002 US Supreme Court decision confirmed that they applied to enrollees in employer-sponsored health plans.[3]

The body of research into external review is small but growing. Previous studies have documented the frequency of requests for external review, estimated rates of requests among managed care enrollees, and analyzed variation across states in key design features of external review programs.[4] A few studies have provided descriptive information about programs in

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[1] K. Pollitz, J. Crowley, K. Lucia, E. Bangit, *Assessing State External Review Programs And The Effects Of Pending Federal Patients' Rights Legislation.* Prepared for the Kaiser Family Foundation (May 2002), http://www.kff.org/insurance/externalreviewpart2rev.pdf, accessed February 21, 2005; F. Sloan, M.A. Hall, "Market failures and the evolution of state regulation of managed care," *Law and Contemporary Problems* 2002; 65:169–06; Kaiser Family Foundation State Health Facts, External Review 2003, http://www.statehealthfacts.kff.org/cgi-bin/healthfacts.cgi?action=compare&category=Managed+Care+%26+Health+Insurance&subcategory=Patients'+Rights+Requirements&topic=External+Review, accessed March 30, 2005.

[2] Commission on Health Care Dispute Resolution, *Final Report.* American Arbitration Association, American Bar Association, and American Medical Association (July 27, 1998), http://www.adr.org/si.asp?id=1588 accessed February 21, 2005; American Medical Association, *External Grievance Review Procedures 2002,* Policy H–320.952; American Association of Health Plans (AAHP), *Independent Medical Review Of Health Plan Coverage Decisions: Empowering Consumers With Solutions* (April 2001); M. Andrews , "Health Care Appeals Are No Snap," *New York Times,* July 21, 2002, p. 11.

[3] Rush Prudential HMO v. Moran, 2002. 536 U.S. 355.

[4] Pollitz, Crowley, et. al, supra note 1; G. Dallek, K. Pollitz. *External Review Of Health Plan Decisions: An Update.* Prepared for the Kaiser Family Foundation (May 2000); AAHP, supra note 2; K. Pollitz, G. Dallek, N. Tapay, *External Review Of Health Plan Decisions: An Overview Of Key Program Features In States And Medicare.* Prepared for the Kaiser Family Foundation (November 1998).

particular states.[5] Previous research has also analyzed the population from which cases brought to external review emerge: enrollees' appeals to their health plans' internal review processes[6]. This is the first study to undertake an in-depth analysis of external review.

Our data consist of several hundred cases adjudicated in the California external review process during a period of just over a one year, beginning in July 2001. Because of the state's large population and substantial managed care penetration, California's program processes a relatively large volume of cases (though available estimates suggest that the rate of appeal among managed care enrollees in California is similar to rates in other states).[7]) We used an explicit case file review methodology to abstract detailed information from the hard-copy administrative files associated with external review cases. This approach allowed us to gather data on specific services, issues, and outcomes, and permitted analysis of what happened when the external review program's statutorily-defined standards for decision making confronted the contractual terms of coverage which define the plans' legal obligations to their enrollees. This tension between market forces and consumer protection laws has received little attention during the rise of external review programs over the last decade, but all programs must grapple with it in defining the scope of their intervention in the coverage decisions managed care organizations make.

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[5] M. Thrailkill, *IROs-Independent Review Organizations: Consumers Gain Needed Care When Unaffiliated Medical Experts Review Health Plan Denials.* Consumers Union Southwest Regional Office, Public Policy Series, May 2002:5(2); California Department of Managed Health Care, *California HMO Help Center Annual Report* (2000, 2001, 2002, 2003), accessed February 21, 2005, http://www.dmhc.ca.gov/library/reports/

[6] D.M. Studdert, C.R. Gresenz, "Enrollee Appeals of Pre-service Coverage Denials at Two Health Maintenance Organizations," *Journal of the American Medical Association,* 289(7): 864–870, February 19, 2003; C.R. Gresenz and D.M. Studdert, "Health Care Consumers and Exposure to Financial Risk for Emergency Medical Services," *Annals of Emergency Medicine,* 43(2):155–162, February 2004. Some appeals (in California, for example, appeals involving experimental treatments) bypass the internal review process.

[7] The California external review program adjudicated between 3.5 and 4 eligible appeals per 100,00 covered lives in 2001/2002 (California Department of Managed Health Care, supra note 5), compared to the 2–17 external appeals filed per 100,000 covered lives in 11 other states (AAHP, supra note 2).

# EXTERNAL REVIEW IN CALIFORNIA

The structure of external review programs varies across states. Legislatures have made different decisions with respect to the profile of eligible disputes, the applicable decision criteria, the timeframe within which reviews must be completed, fees, and a variety of other design features.[8] Such design decisions affect the volume and types of cases that proceed to external review, as well as the outcomes of the review process. In this section, we briefly describe key features of external review in California.

In 1998 California initiated an external review program focused exclusively on experimental and investigational (EI) treatments for terminally ill patients.[9] Subsequent legislation expanded substantially its scope, and the redesigned "Independent Medical Review (IMR)" program began receiving requests on January 1, 2001. The program is open to managed care enrollees in health maintenance organization (HMO) or point-of-service (POS) plans, including enrollees in Medicaid managed care plans.[10] Enrollees in employer-sponsored plans that are "self-insured"—that is, the employer maintains significant financial risk for the cost of health care services—are widely perceived to be ineligible for external review, although the federal insurance law that underpins such eligibility rules is controversial and evolving.[11]

Plans must notify enrollees who are denied coverage of the option to proceed to external review. External review is free to enrollees; plans cover the costs of review. Enrollees lodge their requests by completing a written application form. Unless the denial is of an EI treatment, enrollees must first either exhaust options for review within the health plan or participate in these internal review processes for at least 30 days. Enrollees have six months from the date of the health plan's denial to file a request.

The California Department of Managed Health Care (DMHC) coordinates the program, receiving requests and screening them to determine eligibility. Coverage denials qualify for external review if they involve: (1) a decision to deny, delay or modify treatment on the grounds that it is not medically necessary; (2) an EI treatment for a life-threatening or seriously debilitating condition; or (3) a refusal to reimburse the costs of emergency services on medical

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[8] For a state-by-state review of the structure of external review programs, see Pollitz, Crowley et al, supra note 1.

[9] California Health and Safety Code §§1368, 1370.4.

[10] Medicare enrollees have a separate review system sponsored by the federal government and are ineligible. Center for Medicare and Medicaid Services, *Medical+Choice Organizations Appeals Process* (accessed February 21, 2005, http://www.cms.hhs.gov/healthplans/appeals/appeal1.asp).

[11] W.M. Sage, "Managed Care's Crimea: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance. 53 Duke Law J 597 (2003); M.G. Bloch and D.M.. Studdert, "A Quiet Revolution: Law as an Agent of Health Systems Chang, "Health Affairs 2004; 23(2):29–42.

necessity grounds. Eligibility of cases for external review thus depends on DMHC's classification of them into one of the foregoing categories. Although denials based on contractual exclusions in the plan's insurance contract are ostensibly ineligible for external review, they may still qualify if the DMHC determines that the dispute also raises medical necessity issues.

The DMHC itself adjudicates cases involving reimbursement for emergency services. All other eligible requests are forwarded to a private medical review company, MAXIMUS Center for Health Dispute Resolution (MAXIMUS CHDR), which is effectively the sole contractor to California's external review program. The company maintains a pool of actively practicing clinicians in major clinical specialties and subspecialties, many of whom have with faculty appointments at academic medical centers. Cases are matched to reviewers in appropriate specialties, and reviewers then receive a standard file that includes the medical record. The external review program requires one reviewer for medical necessity cases and three reviewers for EI cases, with the outcome determined by majority decision. DMHC returns decisions within 30 days for standard reviews and more quickly for expedited (urgent) reviews.

The statute prescribes the general standards to be applied in conducting external reviews.[12] Medical necessity must be determined according to "the specific medical needs of the enrollee and any of the following: (1) peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service; (2) nationally recognized professional standards; (3) expert opinion; (4) generally accepted standards of medical practice; and (5) treatments that are likely to provide a benefit to a patient for conditions for which other treatments are not clinically efficacious." For EI cases, external reviewers determine whether "the requested therapy is more likely to be beneficial for the enrollee than any available standard therapy."[13]

The plan's rationale for denying coverage for the requested service determines whether the case is channeled into the EI or medical necessity process of adjudication.

Several features of external review in California warrant emphasis because they bear significantly on the landscape of case types and outcomes observed. First, the program has a special track and adjudication standard for review of cases involving EI treatments. Second, EI cases aside, eligibility for review is premised on the existence of a medical necessity issue. Denials based solely on contractual coverage exclusions are ineligible, but those that blend medical necessity and contractual issues may be. (In practice, the distinction can be very difficult to draw.[14]) Third, decision makers in California's external review process must apply

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[12] California Health and Safety Code §1374.33(b).
[13] California Health and Safety Code §1370.4(c)(3).
[14] *Bedrick v. Travelers Insurance Co.*, 93 F.3d 149 (4th Cir. 1996); *McGraw v. Prudential Insurance Co. of America*, 137 F.3d 12353 (10th Cir. 1998); D.M. Studdert, C.R. Gresenz, supra note 6.

the statutory definition of medical necessity, regardless of whether it differs from the plan's own definition of this term.

# DATA AND METHODS

We abstracted data from the hard-copy administrative files of all external review cases handled by MAXIMUS CHDR between July 23, 2001 and August 31, 2002.[15] The California external review program adjudicated approximately 3.5 eligible appeals per 100,00 covered lives in 2001 and about 4 eligible appeals per 100,000 covered lives in 2002.[16] During our study time frame, the external review program rendered 740 decisions on 724 medical necessity and EI cases (10 cases involved 2 distinct services, 1 case involved 3, and 1 case involved 5). The cases were filed by enrollees from 26 different health plans.[17]

The hard-copy case file compiles all documentation associated with the external review and includes a standard set of forms as well as supplemental material such as correspondence from the enrollee, the enrollee's physician, or plan affiliates.[18] We designed an abstraction instrument to collect a broad range of variables from the files, including: the service, equipment, or procedure requested; the specialty and network status of requested provider; the enrollee's diagnosis; evidence provided by the enrollee in support of their case; information about the plan's decision; excerpts of the provision in the coverage contract that the plan asserts justified the denial (e.g., medical necessity clause, stated policy regarding coverage of EI treatments, specific coverage exclusions); and the external reviewer's assessment of available evidence.

Five abstractors familiar with the external review files were trained in the use of the review instrument and abstracted data from the case files. To test the reliability of the process, 10% of cases were independently abstracted by two different abstractors. Among the re-reviewed cases, service, outcome, and reason for overturn were consistent across reviewers in

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[15] Resources available for the study allowed us to abstract data from slightly more than our goal of one year's worth of cases.

[16] California Department of Managed Health Care, supra note 5.

[17] Several plans had only one or two cases while the majority of appeals came from enrollees of five health plans. The distribution of cases across plans is likely to in part reflect differences in the size of the enrollee population across plans.

[18] Specifically, the file includes: a form and/or letter submitted (usually by the enrollee) to request the review, together with any letters of support from third parties; the DMHC's request for all relevant information from the health plan; the health plan's response, typically consisting of a letter describing the case, pertinent medical records, documentation arising from clinical and non-clinical evaluations of the case to date; medical literature the plan deems relevant to its decision; standardized forms completed by the physicians who make the external reviewer decision which document the physicians' decision and reasoning, and any evidence relied upon in reaching the decision.

all but one case in which one reviewer recorded an uphold and the other recorded a partial overturn.[19]

We first categorized cases according to their general and specific service type and reported outcomes of the external review by specific service type. There are four possible outcomes of external review. Reviewers may: (1) uphold the plan's coverage denial; (2) overturn the denial; (3) partially overturn the denial by deciding that part of the requested service should be covered; or (4) make an overturn contingent upon results from further clinical testing. The external review outcome was treated as binomial variable in our analyses (uphold versus overturn), with the 23 cases resulting in partial or contingent overturns collapsed into the overturn category.

Second, we categorized overturns according to the reason for the difference between the plan's coverage decision (denial) and the external review's coverage decision in favor of the enrollee. The data used to categorize overturns were the plan's stated reason for the coverage denial, relevant portions of the plan's evidence of coverage document (including the plan's definition of medical necessity and any relevant, specific contractual exclusions), and reviewers' stated rationale for their departure from the plan's decision. MAXIMUS CHDR collects this information on all reviews and maintains the data in the administrative file.

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[19] Further investigation showed that the outcome was a partial overturn. In three additional cases, data were consistent but reviewers differed in the level of detail provided about either the service or reason for overturn. We used the more detailed information in our analysis.

# RESULTS

Table 1 shows the general and specific service types at issue in the sample of external review cases. Surgical procedures (21%), prescription drugs (20%), and EI services (20%) were the most frequently disputed services, followed by clinical consultations (8%), durable medical equipment (7%), and ancillary therapies (6%). Closer analysis of the specific services within each of these general categories reveals that the external review program reviewed denials of coverage related to a diffuse range of services. Approximately 350 different therapies were represented in the 740 cases we examined.

Nonetheless, several pockets of concentration were evident. The single most commonly disputed item was gastric bypass surgery (accounting for 26% of surgeries and 6% of all cases). This procedure has previously been identified as a source of conflict between health insurers and patients nationwide.[20] Services related to the treatment of obesity or obesity-related diagnoses—which, besides gastric bypass surgery, included breast reduction, panniculectomy, abdominoplasty, and wheelchairs or power-operated vehicles—accounted for 12% of requests.[21] Coverage for speech therapy, medical consults, and surgical consults each accounted for at least 3% of external review cases.

Among disputes over prescription drugs, one quarter centered on Lamisil (for nail fungus infections), Viagra (for erectile dysfunction), or Vioxx (for pain relief). Disputes over pharmaceuticals frequently centered on the coverage status of non-formulary medications (17% of prescription drug cases) and off-label usage (19%).

Intradiscal electrothermal therapy (IDET), uterine artery embolization (UAE), and gastric bypass with duodenal switch were the leading treatments at issue in EI cases.[22] Together, these three medical services accounted for more than a quarter of all reviews in this

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[20] Studdert and Gresenz, supra note 6; M. Mitka, "Surgery For Obesity–Demand Soars Amid Scientific, Ethical Questions," *Journal of the American Medical Association*, 2003; 289:1761–62; M.A. Hall, "State Regulation of Medical Necessity: The Case Of Weight-Reduction Surgery," 53 *Duke L. J.* 653, 2003.

[21] Panniculectomy is a surgical procedure to remove an "apron" of excess fat and skin that hangs down from the lower abdomen. Abdominoplasty is known more commonly as a "tummy tuck." It is a major surgical procedure to remove excess skin and fat from the middle and lower abdomen and to tighten the muscles of the abdominal wall.

[22] IDET is a treatment for chronic low back pain. The procedure involves the application of high heat directly to the inside of the spinal disc. UAE is used primarily for the treatment of fibroid tumors of the uterus. The treatment involves insertion of a catheter into the uterine arteries, and injection of small particles, with the goal of obstructing blood supply to the fibroids. In the gastric bypass with duodenal switch procedure, the surgeon removes approximately 60 percent of the stomach and the lower intestine is divided much further downstream than with gastric bypass so that more intestine is bypassed. See http://www.columbiasurgery.org/divisions/obesity/surgical_duodenal.html.

category. Thalidomide (commonly requested for the treatment of cancer) and Botox (usually for migraine

**Table 1**

**Medical Service in Coverage Dispute in External Review Cases**

| Category | N | All Reviews (%) | Category (%) |
|---|---|---|---|
| *Surgery* | *159* | *21* | *100* |
| Gastric bypass | 42 | 6 | 26 |
| Breast reduction | 16 | 2 | 10 |
| Dermatologic | 11 | 1 | 7 |
| Breast reconstruction/alteration | 7 | 1 | 4 |
| Nasal | 7 | 1 | 4 |
| Blepharoplasty/Brow lifts | 7 | 1 | 4 |
| *Prescription drugs* | *146* | *20* | *100* |
| Lamisil | 16 | 2 | 11 |
| Viagra | 10 | 1 | 7 |
| Vioxx | 9 | 1 | 6 |
| Pegylated interferon | 7 | 1 | 5 |
| *Experimental/investigational services* | *145* | *20* | *100* |
| Intradiscal electrothermal therapy (IDET) | 19 | 3 | 13 |
| Uterine artery embolization (UAE) | 11 | 1 | 8 |
| Gastric bypass with duodenal switch | 9 | 1 | 6 |
| Thalidomide | 8 | 1 | 6 |
| Botox | 7 | 1 | 5 |
| Stem cell transplant | 7 | 1 | 5 |
| *Consult/Evaluations* | *56* | *8* | *100* |
| Medical | 26 | 4 | 46 |
| Surgical | 19 | 3 | 34 |
| Other | 11 | 1 | 20 |
| *Durable medical equipment/medical supplies* | *50* | *7* | *100* |
| Wheelchair/power operated vehicle | 17 | 2 | 34 |
| CPAP | 6 | 1 | 12 |
| *Ancillary therapies* | *43* | *6* | *100* |
| Speech therapy | 22 | 3 | 51 |
| Physical therapy | 10 | 1 | 23 |
| Rehabilitation | 7 | 1 | 16 |
| *Imaging* | *30* | *4* | *100* |
| MRI | 12 | 2 | 40 |
| PET scan | 6 | 1 | 20 |
| *Laboratory/Testing* | *28* | *4* | *100* |
| Cancer screening | 6 | 1 | 21 |
| Genetic testing | 6 | 1 | 21 |

**Table 1 (Continued)**

| Category | N | All Reviews (%) | Category (%) |
|---|---|---|---|
| *Behavioral Health* | *25* | *3* | *100* |
| Residential care | 16 | 2 | 64 |
| *Other procedures/treatments* | *22* | *3* | *100* |
| Radiofrequency / radiation therapies | 12 | 2 | 55 |
| *Dental/Orthodontic* | *17* | *2* | *100* |
| Orthognathic surgery | 8 | 1 | 47 |
| *Alternative Medicine* | *11* | *1* | *100* |
| Chiropractry | 6 | 1 | 55 |
| *Home Health/Skilled Nursing Facility* | *8* | *1* | *100* |
| TOTAL | 740 | 100 | |

headaches) were the most commonly requested experimental prescription drug treatments, representing 10% of EI cases.

The external review decision overturned the health plan's decision in 42% of medical necessity cases and 20% of EI cases (Table 2). However, enrollee win-rates varied dramatically by service type. Compared to the mean overturn rate of 42% for medical necessity cases, overturns were more likely for Viagra, gastric bypass surgery, orthognathic surgery, and breast reduction surgery.[23] On the other hand, overturns were less likely for cases involving power-operated vehicles or wheelchairs, Vioxx, and pegylated interferon (commonly requested for the treatment of hepatitis). Among EI cases, all IDET and UAE denials were upheld, whereas virtually all of the stem cell transplant denials and nearly half of the Botox denials were overturned.

Table 3 categorizes external review cases that resulted in overturns according to the reason for the overturn. In all of the overturned cases, the external reviewer determined that the services were medically necessary or, in the case of EI services, that the services met the statutory threshold for coverage. In the majority of overturned cases (57%), the health plan denial was based on a determination that the services were not medically necessary, and thus, the reversal at external review is attributable to a difference in judgment between the external reviewer and health plan about the medical necessity of the services. Such variability is not unexpected, given the amorphous nature of the standard; to an extent, it reflects underlying disagreement about clinical appropriateness in circumstances where definitive answers may not exist.

[23] Orthognathic surgery is corrective facial and jaw surgery used to treat a variety of facial and jaw abnormalities.

**Table 2**

**Outcome of External Review Cases by Type of Case and Specific Medical Service**

| | N | Percent Overturned | Deviation from mean overturn rate** |
|---|---|---|---|
| All medical necessity cases | 595 | 42 | 0 |
| Viagra | 8 | 100 | 58** |
| Orthognathic surgery | 10 | 100 | 58** |
| Gastric bypass surgery | 42 | 76 | 34** |
| Breast reduction surgery | 16 | 75 | 33** |
| Blepharoplasty/brow Lift | 7 | 71 | 29 |
| Consult-surgical | 19 | 63 | 21* |
| Speech therapy | 22 | 59 | 17 |
| Nasal surgery | 7 | 57 | 15 |
| Dermatologic surgery | 11 | 55 | 12 |
| Consult-nonmedical, nonsurgical | 11 | 55 | 12 |
| Chiropractic care | 6 | 50 | 8 |
| CPAP | 6 | 50 | 8 |
| Lamisil | 16 | 50 | 8 |
| MRI | 12 | 50 | 8 |
| Consult-medical | 26 | 38 | -4 |
| Cancer screening | 6 | 33 | -9 |
| Physical therapy | 10 | 30 | -12 |
| Breast reconstruction/alteration surgery | 7 | 29 | -14 |
| Rehabilitative care | 7 | 29 | -14 |
| Radiofrequency/radiation therapies | 12 | 25 | -17 |
| Residential behavioral health care | 16 | 25 | -17 |
| Wheelchair/power operated vehicle | 17 | 18 | -25* |
| Genetic testing | 6 | 17 | -26 |
| PET scan | 6 | 17 | -26 |
| Pegylated interferon | 6 | 0 | -42* |
| Vioxx | 7 | 0 | -42 |
| All experimental/investigational cases | 145 | 20 | 0 |
| Stem cell transplant | 7 | 86 | 66** |
| Botox | 7 | 43 | 23 |
| Thalidomide | 8 | 38 | 18 |
| Gastric bypass with duodenal switch | 9 | 11 | -9 |
| Uterine artery embolization (UAE) | 19 | 0 | -20** |
| Intradiscal electrothermal therapy (IDET) | 11 | 0 | -20* |

*Only specific services with at least 5 cases shown.

**Deviation from case-type specific overturn rate (42% for MN and 20% for EI); ** p<.01, *p<.05

**Table 3**

**Basis for External Review Overturn of Health Plan Coverage Denial: Frequency and Clinical Examples**

| | *Frequency (n=281*)* | *Percent* |
|---|---|---|
| *A. Different judgment of medical necessity* | 159 | 57 |
| Clinical Examples | | |
| 1. Coverage of gastric bypass surgery denied for 43-year-old female with BMI of 48.4 because she did not meet the health plan's stated criteria: BMI ≥50 or BMI 40–50 with two serious comorbidities. Overturned based on NIH consensus standards:** BMI ≥40 or BMI 35–40 with significant health problems. | | |
| 2. Coverage of Lamisil denied for 64-year-old male with dermatophytosis of nail because of absence of functional impairment and pain. Overturned based on finding of functional impairment and pain. | | |
| 3. Coverage denial of Botox injection for 63-year-old female with migraine headaches because Botox not indicated for treatment of headaches; overturned based on finding that treatment was likely to provide a benefit. | | |
| *B. Coverage exclusion not applicable* | 63 | 22 |
| Clinical Examples | | |
| 4. Coverage of speech therapy denied for 9-year-old girl because of exclusion in cases of developmental articulation and language disorders. Overturned based on external review determination that girl's speech impediment due to multiple bouts of *otitis media.* | | |
| 5. Coverage for surgical removal of multiple seborrheic keratoses denied for 53-year-old female because of exclusion relating to cosmetic services and supplies. Overturn stated procedure not cosmetic in this instance because irritation and bleeding were present. | | |
| *C. Coverage exclusion not considered* | 54 | 19 |
| Clinical Examples | | |
| 6. Coverage of speech therapy for a 7-year-old girl with speech apraxia denied because speech therapy "not a covered benefit under enrollee's health plan." Overturned because speech therapy was "the recommended and established treatment for the enrollee's condition, and should be helpful for the child." | | |
| 7. Coverage of Viagra for a 48-year-old male denied because drugs for sexual dysfunction only covered for organically based sexual dysfunction. Overturn stated, "standard therapy for erectile dysfunction is producing desired outcome, not finding cause." | | |

*Reason for 5 overturns could not be ascertained.

**National Institutes of Health, supra note 24.

Two other categories of overturns were traceable to the fact that a coverage exclusion in the enrollee's health insurance policy, as opposed to a determination on the merits of medical necessity, formed the basis of the plan's denial. These cases were eligible for external review if they contained a medical necessity component. For example, a plan may deny coverage for Viagra for an enrollee because of a contractual exclusion of treatment for sexual dysfunction

that is non-organic in origin. While the denial is based on a coverage exclusion, the case could be eligible for external review if the etiology of the enrollees' erectile dysfunction (whether its roots are in fact non-organic) is unclear.

These kinds of cases can be thought of as "blended" in nature, combining a mix of contractual coverage and medical necessity issues. In overturns of blended cases, the external reviewer's decision that the services should be covered differed from the health plan's decision to deny coverage for one of two reasons: (1) A difference in judgment about the medical necessity component of the case and consequently the applicability of the coverage exclusion; or (2) a difference in the basis on which the determinations were made—in particular, the external reviewer's sole reliance on medical necessity versus the plan's consideration of contractual coverage exclusions.

In what follows, we elaborate on each of these three reasons for overturn (different judgment of medical necessity, different judgment of applicability of coverage exclusion; different consideration of coverage exclusion). We use the examples shown in Table 3 to illustrate each.

## A. Different Judgments of Medical Necessity

Examples 1–3 in Table 3 exemplify a range of cases where an overturn can be attributed to a difference in the plan's versus the external reviewer's judgment of medical necessity. Example #1 describes a case where the plan and external reviewer diverge in their translation of the medical necessity into clinical criteria. The health plan denied coverage of gastric bypass surgery for a 43-year-old female because she did not meet the plan's clinical criteria for coverage; but the denial was overturned because the enrollee did meet the National Institutes of Health (NIH) consensus standard for coverage of gastric bypass surgery.[24]

Overturns were the rule when plans employed coverage thresholds for gastric bypass that deviated from the NIH standard. In other gastric bypass cases, external reviewers and plans differed in the extent to which they made efforts at "conservative" treatment a precondition for the surgery. For example, a plan denied surgery for a 42-year-old obese female with a body mass index (BMI) of 46 and hypertension on the grounds that "the enrollee has not attempted medically supervised weight loss in past." The external reviewer disagreed with the need for further attempts at weight loss and overturned the denial, stating, "the enrollee has obesity-related co-morbidities and a BMI greater than 46…she meets nationally accepted criteria for gastric bypass." Breast reduction surgery was another service where overturns often

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[24] National Institutes of Health, "Gastrointestinal Surgery For Severe Obesity: Consensus Development Conference Statement," *American Journal of Clinical Nutrition* 1992; 55: 615S–619.

reflected a difference in opinion over when such surgery was medically indicated. For example, one plan denied coverage of breast reduction surgery for a 34-year-old woman because the enrollee did not meet the plan's criteria: "within 20% of ideal body weight and failure of pain to be relieved by 3 month course of conservative therapy." The external reviewer, in contrast, judged that the surgery was clinically indicated because "the enrollee suffers from pain and is limited in function because of the size of her breasts."

Example 2 illustrates a case where the difference in judgment of medical necessity stems from divergent views about the clinical facts of the case—in this particular example, the dispute concerns whether the enrollee has functional impairment and/or pain. In another case, the plan and external reviewer differed in their respective assessments of a 60-year-old woman's ability to ambulate. The plan denied coverage for an electric wheelchair after concluding that the enrollee "is able to independently self-propel and manage a manual wheelchair in her home environment," whereas the reviewer determined, on the basis of the information before him, that "the enrollee is not able to drive a manual wheelchair for any distance" and overruled the plan.

Finally, Example #3 illustrates different judgments in medical necessity stemming from a difference in the definition or standard used to determine medical necessity: A plan denied coverage for Botox injections to a 63-year-old woman suffering from migraine headaches. The denial hinged on lack of medical necessity, with the plan indicating that Botox was not considered an effective treatment for migraine headaches. In overturning the denial, the external reviewer bypassed the issue of whether the treatment met generally accepted standards for effectiveness and ruled, in line with statutory directives, that the "patient benefited" from this treatment in the past and "studies support" its use. As described earlier, one consideration among those prescribed by California statute as compelling in rendering external review decisions on medical necessity cases is whether a service is "likely to provide a benefit." This standard may be interpreted more permissively than medical necessity formulations developed and applied by plans in their coverage decisionmaking activities. Typical formulations of plans' coverage language specified that medically necessary services were those rendered for the treatment, diagnosis or prevention of injury or illness that were, "in accordance with professionally recognized standards," "in accordance with generally accepted standards," "furnished in the most cost-effective manner which may be provided safely and effectively to the enrollee," "known to be safe and effective in improving a medical condition," or whose "omission would adversely affect health."

## B. Coverage Exclusion Not Applicable

As described earlier, a subset of overturns occur in cases that blend contractual coverage and medical necessity issues. In some of these overturns of blended cases, the reversal of the health plan denial arose because of a difference in judgment about the medical necessity component of the case and, consequently, the applicability of the coverage exclusion. In Example #4, the plan denied a nine-year-old girl coverage for speech therapy, citing an exclusion in her health policy for coverage of speech therapy for developmental articulation and language disorders. The external reviewer judged that the girl's speech impediment was due to an alternative cause—specifically, multiple bouts of *otitis media* that she had experienced. Consequently, he determined that the exclusion did not apply and the services were medically necessary. In Example #5, a 53-year-old female sought external review of her plan's denial of coverage for surgical removal of multiple seborrheic keratoses.[25] In refusing coverage for the procedure, the plan cited specific exclusions of cosmetic services and supplies in the coverage contract. The subsequent overturn was premised on the external reviewer's judgment that the procedure was not cosmetic in this instance because irritation and bleeding were present.

## C. Coverage Exclusion Not Considered

In other blended cases, the external review reversal reflects a difference in the basis on which the determinations were made; specifically, the external review relied solely on medical necessity considerations while the health plan decision reflected contractual coverage considerations. Example #6 relates the denial of speech therapy coverage for a 7-year-old girl with speech apraxia.[26] In justifying the coverage denial, the plan's medical director explicitly noted that even though "speech therapy was medically appropriate and necessary, it is not a covered benefit under the enrollee's plan." The decision was overturned in external review not because of a disagreement about the diagnosis of speech apraxia but because speech therapy was "the recommended and established treatment for the enrollee's condition, and should be helpful for the child." Thus, the medical necessity threshold was met, the coverage exclusion was essentially disregarded, and the divergent coverage decisions arose because of the different bases of decisionmaking. The reviewers' approach to these cases—unfettered consideration of medical necessity—is demanded by the statutes governing the California external program.

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[25] Seborrheic keratoses are raised growths on the skin.

[26] Children with speech apraxia have trouble saying what they want to say correctly and consistently. The principal form of this condition in children is developmental apraxia of speech (DAS), which is present at birth and manifests within 2 to 3 years. The etiology of DAS is unknown. DAS differs from other types of developmental speech delays in which the child follows a normal path of speech development but at a pace that is slower than normal.

Overturns of denials of coverage for Viagra often followed the same path (Example #7). Plans' denials were typically grounded in an exclusion of coverage for drugs treating sexual dysfunction, unless the dysfunction was organically based. In the time period covered by our data, external reviewers reversed these coverage denials every time. In one case, the reviewer remarked that, while the cause of dysfunction was non-organic, the "origin of dysfunction does not change the fact that Viagra can treat the condition," and thus, Viagra was deemed medically necessary. In another case, the reviewer was silent on the issue of etiology, holding simply that the "standard treatment for erectile dysfunction is producing the desired outcome, not finding the cause."

Overturns of EI services tended to follow the same logic. External reviewers' charge was to determine whether services meet the statutory threshold for EI coverage—namely, are the services more likely to be beneficial than any standard therapy? This decision was made without regard to plans' contractual coverage exclusion of this class of services. In one EI case, for example, a 47-year-old man sought coverage for the prescription drug Enbrel for the treatment of ankylosing spondylitis.[27] The following rationale accompanied one reviewer's decision to overturn: "Although Enbrel for the treatment of ankylosing spondylitis remains investigational, in this enrollee it has provided beneficial results."

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[27] Ankylosing spondylitis is a form of inflammatory arthritis.

# DISCUSSION

A variety of administrative mechanisms now exist for adjudicating disputes over coverage between health plans and their enrollees. The prevalence and visibility of these forums have grown significantly in recent years as policymakers, prompted by the managed care "backlash," have moved to establish consumer safeguards. Most states mandate administrative review options within health plans for enrollees who are denied coverage of desired services. These mandates typically specify minimum requirements for the internal review programs, such as notice to the patient, timeframes for review, and annual reporting to the state of outcomes of review. The U.S. Department of Labor has extended such requirements to employment-based health insurance plans.[28]

Many states also have a second layer of administrative review: external review programs. External review provides several additional benefits to enrollees. First, although health plan appeals processes are regulated and enrollees who use them often win reversals of the denial, there are ongoing concerns about potential for conflicts of interest to color coverage decisionmaking when a health plan reviews its own denial.[29] By comparison, external review furnishes consumers with a coverage decision made by an adjudicator with no financial conflict of interest—actual or perceived—in the outcome of the decision. Many regard this as an effective way to guard against inappropriate decisions by managed care organizations. Reviewer objectivity may be especially valuable in situations where existing clinical evidence does not place decisions squarely on one side or the other of the medical necessity line. Is abdominoplasty after gastric bypass surgery a cosmetic therapy? Has progress from speech therapy plateaued or is there more to be gained from additional services? When is breast reduction surgery clinically indicated? These are vexing questions in clinical medicine; the answers to them call for judgments about appropriateness that are both controversial and evolving.

Second, even if the internal health plan and external review decisions are equally objective, patients may also benefit from reconsideration in external review because some degree of natural variability would be expected in "close call" situations. A second look is a second chance for the desired outcome. Third, the expert consultation

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[28] US Department of Labor, Federal Register, "Employee Retirement Income Security Act of 1974; Rules and Regulations for Administration and Enforcement; Claims Procedure." November 21, 2000; 65(225): 70245–70271

[29] Studdert and Gresenz, supra note 6; Gresenz and Studdert, supra note 6.

used in external review provides an opportunity for dissemination of information to plans about the latest evidence and opinion in selected clinical areas, a benefit that plans themselves have acknowledged (Silverman et al, 2003).

However, some significant and unresolved tensions permeate external review—anomalies that many legislators almost certainly did not envision in their push to establish these programs in the late 1990s as a method of curbing the perceived excesses of managed care. A fundamental tension is the relationship between coverage standards imposed by external reviewers and those specified in the terms of the coverage agreement between plans and their enrollees. What deference is owed to plans' coverage exclusions? And how should external review handle cases that blend medical necessity and contractual issues?

In California, once a case has screened eligible for external review, coverage exclusions are not considered in the decisionmaking process. The fact that the exclusion was agreed to as part of the health insurance contract, and the service in question is not formally prohibited as an exclusion by state law through a statutory mandate or common law standard of care requirements, is immaterial. But this is not a frontal infringement on commercial choices in insurance markets. The letter of California law dictates that denials based on contractual exclusions are excluded. The infringement springs from the intrinsically intertwined nature of contractual and medical necessity issues in denials of care. The practice of having reviewers focus exclusively on medical necessity considerations is consistent with the US Supreme Court's characterization of external review programs as "akin" to a mandatory (and binding) second medical opinion.[30]

The lack of deference to coverage exclusions has given rise to legal battles between plans and the external review program in California. The managed care industry recently challenged the program's decisions requiring coverage of contractually excluded-prescription drugs, and won.[31] The California legislature quickly responded with a mandate requiring managed care organizations to cover "life-saving" medications.[32] Although the program's lack of deference to contractual coverage exclusions also drives many of the overturns among experimental and investigational therapies, to the best of our knowledge, there has been no litigation to date in this area. Nevertheless, further legal battles seem likely.

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[30] Rush Prudential HMO v. Moran, 2002.
[31] Kaiser Foundation Health Plan v Zingale, 99 Cal. App. 4th 1018 (2002).
[32] California Senate Bill 842.

A second type of infringement of plan-enrollee coverage agreements in California is the eschewal of the plan's definition of medical necessity in favor of the statutory definition. The latter appears to set a lower bar, presenting external reviewers a looser series of considerations, including whether the services at issue are "likely" to provide a benefit when other treatment options are not effective. In practice, the difference in definitions may have little effect on reviewers' determinations in most cases, but we find evidence that at least in some cases, the definitional differences do matter.

Our findings point to several key areas for consideration by policymakers involved in the design and regulation of state external review programs. First, policy choices about eligibility rules and coverage standards indirectly impact the sovereignty of health insurance contracts. Deference to the terms of plans' contractual relationships with their enrollees requires that one of two conditions be met: (1) eligibility for external review must be limited to cases in which the plan denial was based solely on the medical necessity of the services (which would, in theory, render blended and EI cases ineligible), or; (2) if blended cases are eligible, the review must be attentive to both the merits of the medical necessity strand and the reasonableness of the coverage exclusion asserted. In addition, replacing the plan's definition of medical necessity with one prescribed by the state may also undermine contractual freedoms, especially when the latter sets a higher or lower threshold for coverage. Ensuring deference to enrollee-plan coverage contracts requires that external reviewers render their judgments against the same formulation of medical necessity as was used by the plan to make the initial denial. Some states have followed this course.[33]

Virtually all of the characteristics of external review that we have highlighted strike in the direction of providing enrollees with a reconsideration of their coverage decision under a more liberal standard than was applied in the original review. In other words, over and above the statistical reality of "second look-second chance" phenomenon, managed care enrollees in California are more likely to get the service they seek when the decision is made at external review. There is a significant equity issue here for policymakers to consider. Case-by-case determinations in external review protect the disputing enrollees' interests, but they do not universalize the logic of the resultant decisions across populations. Enrollees who respond passively to a denial miss out. This is true even in situations where a previous overturn may have attacked

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[33] Pollitz, Crowley, et al, supra note 1; Pollitz, Dallek, et al, supra note 4; Tenn. Code Ann. § 56–32–227(b)(6).

the very foundations of the coverage denial. Explicit, ex *ante* regulation of plans' contractual exclusions, rather then *ex post* auditing through consumer-initiated external review, is an obvious solution to the equity concern, but of course such regulation would likely entail weighty political and economic costs, and plans in California (and other states) already face an impressive array of benefits mandates.[34]

[34] J. Cubanski, H.H. Schauffler, "Mandated Health Insurance Benefits: Tradeoffs Among Benefits, Coverage, And Cost?" Center for Health and Public Policy Studies, University of California, Berkeley. Issue Brief, July 2002.