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A Comparison of Coverage Restrictions for Biopharmaceuticals and Medical Procedures

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ABSTRACT

Background: Differences in payer evaluation and coverage of pharmaceuticals and medical procedures suggest that coverage may differ for medications and procedures independent of their clinical benefit. We hypothesized that coverage for medications is more restricted than corresponding coverage for nonmedication interventions. **Methods:** We included top-selling medications and highly utilized procedures. For each intervention–indication pair, we classified value in terms of cost-effectiveness (incremental cost per quality-adjusted life-year), as reported by the Tufts Medical Center Cost-Effectiveness Analysis Registry. For each intervention–indication pair and for each of 10 large payers, we classified coverage, when available, as either "more restrictive" or as "not more restrictive," compared with a benchmark. The benchmark reflected the US Food and Drug Administration label information, when available, or pertinent clinical guidelines. We compared coverage policies and the benchmark in terms of step edits and clinical restrictions. Finally, we regressed coverage restrictiveness against intervention type (medication or nonmedication), controlling for value (cost-effectiveness more or less favorable than a designated threshold). **Results:** We identified 392 medication and 185 procedure coverage decisions. A total of 26.3% of the medication coverage and 38.4% of the procedure coverage decisions were more restrictive than their corresponding benchmarks. After controlling for value, the odds of being more restrictive were 42% lower for medications than for procedures. Including unfavorable tier placement in the definition of "more restrictive" greatly increased the proportion of medication coverage decisions classified as "more restrictive" and reversed our findings. **Conclusions:** Therapy access depends on factors other than cost and clinical benefit, suggesting potential health care system inefficiency.

Keywords: cost-effectiveness, biopharmaceuticals, economic analysis, value for money.

Background

Health insurers have traditionally reviewed and managed self-administered medications and medical procedures differently, with medications handled under a pharmacy benefit and provider-administered care under a medical benefit. Insurers have typically managed the different benefit categories with different types of staff and often with different processes. Key differences include the tendency for medical procedures to have less efficacy and safety evidence because of significantly different regulatory requirements. Moreover, insurers typically subject self-administered medications to more utilization management policies (e.g., prior utilization requirements and step edits).

These differences suggest the possibility that payers systematically restrict some types of interventions more than others, independent of their value. The more intensive review and management of the pharmacy benefit may indicate that medications face higher thresholds for demonstrating value and thus more restrictive levels of coverage and access. Inconsistent coverage standards for value across therapeutic classes raises the possibility that resources are being used inefficiently; in particular, resources may be diverted from higher-return therapies in one class and toward lower-return therapies in another, less stringently evaluated class. Understanding the existence and magnitude of differences is hence important, given the ever more intensive efforts to manage constrained health budgets. This study aimed to assess systematically the restrictiveness of therapies as a function of benefit category, controlling for value expressed in terms of cost-effectiveness. We hypothesized that coverage for medications is more restricted than corresponding coverage for nonmedication interventions.

Methods

This analysis investigated the extent to which payer coverage decisions are associated with intervention type (pharmaceutical vs nonpharmaceutical procedures and associated devices).

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Data

The unit of analysis for this investigation is a payer's coverage decision for an intervention–indication pair. We developed the dataset by (1) identifying top pharmaceutical and procedure interventions for the US population, (2) identifying incremental cost-effectiveness ratios (ICERs) for each intervention, (3) classifying the ICERs for each intervention by indication subgroup and selecting a single ICER value category for each indication, and (4) for each of 10 top payers, characterizing coverage of each intervention–indication pair.

Identifying top interventions

We identified candidate medications and ranked them by annual aggregate spending in the United States [1]. To identify 25 medications, we had to expand our review to consider the top 38 medications because a number of medications (13 of the top 38) lacked adequate cost-effectiveness information (see step #2, below).

Candidate procedures came from four sources: (1) operating room procedures most frequently during hospital stays [2]; (2) common hospital operating room procedures in nonfederal community hospitals [3]; (3) the 25 most common ambulatory surgeries performed in community hospitals [4]; and (4) the 20 most common principal procedures during hospital stays [5]. In addition to eliminating duplicate procedures across these lists and procedures lacking adequate cost-effectiveness information (see step #2, below), we eliminated one procedure because we could not find any US Food and Drug Administration (FDA) label or guideline information against which to benchmark the coverage (echocardiogram) and two more procedures (cholecystectomy and colorectal resection) because we found no relevant insurance coverage information (see step #4, below).

Identifying incremental cost-effectiveness ratios

We searched the Tufts Medical Center CEA Registry to identify cost-effectiveness studies that evaluated each selected medication and procedure [6]. A detailed description of the methodology used for the CEA Registry is presented elsewhere [7]. In summary, a search of Medline using the keywords "quality-adjusted," "quality-adjusted life-years," "cost-utility analysis," "and 'CUAs" identifies relevant studies evaluated by trained reviewers. Because our analysis focused on contemporary coverage data from the United States (see step #4, below), we considered cost-effectiveness articles published after 2007 that reported on the United States.

For each intervention, we searched the Tufts CEA Registry for entries that mentioned the intervention in the article title, abstract, or in the ratio description field. Next, on the basis of a consensus evaluation of two members of the research team, we eliminated those ratios for which the intervention did not pertain to the intervention or the comparator did not describe a distinct alternative intervention (e.g., analyses that compare different dosages for a medication). The decision for elimination was based on consensus.

Classifying ICERs by indication

We classified the ICERs identified for each intervention by indication. We then assigned each ICER to five ordered value categories (based on cost-effectiveness standardized to 2014 dollars using the CPI): (1) cost-saving (intervention saves money and improves health); (2) ICER ratio under $50,000 per quality adjusted life year (QALY); (3) ICER greater than or equal to $50,000 to no more than $150,000/QALY; (4) ICER greater than $150,000/QALY; and (5) dominated (intervention increases costs and makes health worse). For each indication–intervention pair, we identified the median value category. (Note that these thresholds correspond to commonly referenced benchmarks in the health economics literature [8].

Coverage

We characterized coverage for each intervention–indication pair for each of the 10 largest commercial payers in terms of covered lives [9]. Payers included United Healthcare, Anthem, Aetna, Health Care Services Corporation (HCSC), Cigna, Humana, HealthNet, Highmark, Independence Blue Cross, and Blue Cross Blue Shield of Michigan. We excluded Kaiser Permanente because it does not publish the needed coverage information. We obtained information pertaining to the payers' coverage determinations from websites. Sources included the payers' medical policies, prior authorization documentation, and medication formularies. Coverage information we recorded included clinical restrictions (clinical criteria patients must satisfy, such as a minimum level of disease severity, or the presence of a particular comorbidity) and step therapy restrictions (requirements that patients must first fail an alternative treatment). For medications, we also noted whether the payer placed the medication on an unfavorable formulary tier (nonpreferred generic or nonpreferred branded medication). We note that various plans administered by a particular insurance company may differ in detail (e.g., copayment amounts). Our coverage characterization restricts attention to features generally shared across plans (which is why online documentation typically addresses those features explicitly). For each payer, we classified coverage for each intervention–indication pair as either "more restrictive" or "not more restrictive" than the FDA label or pertinent clinical guidelines. For medications, we always used the FDA label (because all FDA-approved medications have FDA labels). For procedures, we used the FDA label for the pertinent device (e.g., an artificial disk for laminectomy procedure), if available. If we could not find a pertinent FDA label, we used practice guidelines (e.g., the American Council of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions for percutaneous coronary angioplasty).

We classified coverage as "more restrictive" if (1) it imposed more clinical restrictions than the FDA label or clinical guidelines; or (2) it imposed additional step therapy restrictions.

We conducted several sensitivity analyses. A first sensitivity analysis designated coverage as "more restrictive" if either of the two criteria described above were satisfied or if, in the case of medications, the payer placed the medication on an unfavorable formulary tier. A second sensitivity analysis omitted medications covered under "pharmacy benefit" rules rather than "medical benefit" rules. This second sensitivity analysis explored the possibility that payers do not use clinical or step restrictions to tighten coverage on these medications and hence that their inclusion may reduce the estimated overall restrictiveness of coverage on medications collectively in our base case analysis.

Analysis

We used logistic regression to model the relationship between coverage ("more restrictive" vs not "more restrictive") and (1) type of intervention (medication or non-medication); and (2) cost-effectiveness, dichotomized as "favorable" or unfavorable. In our base case analysis, we classified ICERs as "favorable" if the intervention was cost-saving or under $50,000/QALY.

Sensitivity Analyses

We assessed the influence of base case assumptions by conducting a series of sensitivity analyses. The first two sensitivity analyses investigate alternative cost-effectiveness "threshold"