

Good Research Practices for Measuring Drug Costs in Cost-Effectiveness Analyses: A Managed Care Perspective: The ISPOR Drug Cost Task Force Report—Part III

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ABSTRACT

Objectives: The objective of this report is to provide guidance and recommendations on how drug costs should be measured for cost-effectiveness analyses conducted from the perspective of a managed care organization (MCO).

Methods: The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis (DCTF) was appointed by the ISPOR Board of Directors. Members were experienced developers or users of CEA models. The DCTF met to develop core assumptions and an outline before preparing a draft report. They solicited comments on drafts from external reviewers and from the ISPOR membership at ISPOR meetings and via the ISPOR Web site.

Results: The cost of a drug to an MCO equals the amount it pays to the dispenser for the drug's ingredient cost and dispensing fee minus the patient copay and any rebates paid by the drug's manufacturer. The

amount that an MCO reimburses for each of these components can differ substantially across a number of factors that include type of drug (single vs. multisource), dispensing site (retail vs. mail order), and site of administration (self-administered vs. physician's office). Accurately estimating the value of cost components is difficult because they are determined by proprietary and confidential contracts.

Conclusion: Estimates of drug cost from the MCO perspective should include amounts paid for medication ingredients and dispensing fees, and net out copays, rebates, and other drug price reductions. Because of the evolving nature of drug pricing, ISPOR should publish a Web site where current DCTF costing recommendations are updated as new information becomes available.

Keywords: costs, cost-effectiveness analysis, drug costs, economic analysis, managed care.

Background to the Task Force

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis (DCTF) was recommended by the ISPOR Health Science Policy Council on December 13, 2004 and was approved by the ISPOR Board of Directors on May 15, 2005. Because how drug costs should be measured for CEAs depends on the perspectives, five Task Force subgroups were created to develop drug costs standards from the societal, managed care, US government, industry, and international perspective. This report is part III: a managed care perspective (one of six reports from this ISPOR Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis [DCTF]). The other reports (part I: issues and recommendations; part II: a societal perspective; part IV: US government perspective; part V: industry perspective; and part VI: international perspective) are also published in this issue of *Value in Health*. This DCTF subgroup met to develop core assumptions and an outline before preparing a draft report. The Task Force subgroups held open forums and/or group leader breakfast meetings at the ISPOR Annual International Meetings and European Congresses. The draft report was circulated to 174 Task Force primary reviewers (who were self-identified from a broad range of perspectives). After this review, a new draft was prepared and

made accessible for broader review by all ISPOR members. Comments for these reports by Task Force primary reviewers and ISPOR membership are published at the ISPOR Web site. All opinions reflect those of the authors and not necessarily their affiliations.

Introduction

The objective of the ISPOR Task Force on Good Research Practices—Use of Drug Costs for Cost Effectiveness Analysis (DCTF) is to develop standards for using drug costs in pharmacoeconomic studies. The managed care subgroup focused on estimating drug costs to a managed care organization (MCO) within the US health-care context. An MCO is an organization that is paid to manage the accessibility, financing, provision, quality, and cost of health care delivered to a specific population of individuals [1–3]. Because of the complex nature of the pharmaceutical purchase process within the United States, the actual cost faced by an MCO is generally lower than that suggested by published prices. It is also usually different than the cost faced by patients, providers, and government agencies [4,5].

The following sections will explain the process by which the report was developed, identify and explain the components and considerations that determine the cost of a drug to an MCO, and, where possible, identify potential sources for estimates of those components. It will also provide recommendations on standards that should be employed when doing pharmacoeconomic assessments from an MCO perspective.

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10.1111/j.1524-4733.2009.00661.x

Drug Cost Components

Generally speaking, the cost of a drug to an MCO equals the amount it pays to the dispenser (usually a pharmacy) to cover the drug's "ingredient cost" and dispensing fee minus the patient copay and any rebates paid to the MCO by the manufacturer of the drug (the "ingredient cost" refers to the cost of the medicine, whereas the dispensing fee refers to the cost of pharmacists' services rendered in dispensing the prescription). The value of each of these components can differ substantially across a number of factors [4,5]. These include, for example, type of drug (single vs. multisource), dispensing site (retail vs. mail order), and site of administration (self-administered vs. physician's office). Adding to the complexity is a lack of transparency in pricing. The value of most components is determined by a proprietary and confidential contract. Finally, the nature of drug pricing and reimbursement is constantly evolving. Hence, recommendations for MCO drug costing should be applied thoughtfully, with adjustments made for new developments that occur before the time that a pharmacoeconomic analysis is conducted.

Single-Source Products

For products that are branded and still under patent protection (single-source products), the amount that an MCO pays a pharmacy for ingredient cost has traditionally been based on the average wholesale price (AWP) minus some percentage [4,5]. The percent discount is negotiated between the MCO, or its pharmacy benefit manager (PBM), and the retail and mail-order pharmacies in its network. The Pharmacy Benefit Management Institute (PBMI), an organization that annually surveys health benefit managers in employer-provided health plans, indicates that mean discounts were 16% for retail pharmacies and 23% for mail-order pharmacies during 2008 [6]. The dispensing fee is also negotiated between the MCO (or its PBM) and pharmacies. PBMI indicates that for 2008, mean dispensing fees were \$1.73 for retail pharmacies and \$2.17 for those mail-order pharmacies that charged dispensing fees; however, only about 20% of mail-order pharmacies charged dispensing fees [6]. Note that retail pharmacy fees are for a 1-month supply, whereas mail-order dispensing fees cover a 3-month supply. Over the past several years, ingredient cost discounts have been increasing and reimbursements for dispensing fees have been decreasing [6].

The MCO's drug cost is reduced by the portion of the ingredient cost and dispensing fee that is paid by the patient, i.e., the patient copay, as well as any reimbursement made to the MCO in the form of a manufacturer rebate. The size of the patient copay depends on the formulary tier to which the drug is assigned and on whether the drug is dispensed by a retail or mail-order pharmacy [6]. Most single-source drugs are given second or third-tier formulary status. Exceptions typically include lifestyle drugs, specialty pharmaceuticals, and products administered by a physician (which generally receive special formulary status). PBMI indicates that second and third-tier copays for retail purchases averaged \$24 and \$42, respectively, in 2008 [6]. The size of copays, as well as the difference between those for second and third-tier drugs, has been increasing over time [6,7]. In addition, payers have increased their use of coinsurance in recent years as an alternative to fixed dollar copays [6]. The size of the copay also depends on whether the drug is dispensed at a retail or mail-order pharmacy. Historically, MCOs have offered patients the option of getting a 3-month supply at mail order for the equivalent of two retail monthly copays. Nevertheless, in recent years, there has been a trend to use somewhat higher mail-order copays [6]. Mail copays for 2008 for second and third-tier drugs were \$49 and \$84, respectively [6].

The Federal Trade Commission has estimated that the average manufacturer rebate paid to an MCO for a single-source drug in 2003 was about 7.5% of catalog price, also known as wholesale acquisition cost (WAC) [4,8]. Nevertheless, the rebate usually varies with the formulary status granted to the drug as well as the degree of in-class competition [5]. Based on the limited information that we were able to gather, an analyst can reasonably assume a base-case rebate of 15%, with a range from 5% to 25% for a second-tier drug with in-class competitors, none of which is available generically [9]. If that product were placed on the third tier, a significantly smaller rebate would typically be granted by the manufacturer. If the drug had no in-class competitors, then a much smaller rebate, or no rebate, would be reasonable for both second and third-tier drugs. Drugs that have a generic in-class competitor that is clinically similar to the branded medicine may earn much higher rebates. Note that the rebate percentage applies to the manufacturer's catalog price for the drug (i.e., WAC).

Using industry sources, one author estimated that approximately 20% of manufacturer rebates are retained by PBMs, the organizations that administer the drug benefit for the MCOs [10]. In most cases, PBMs are independent external organizations, but in some cases, they are internal subsidiaries of the MCO. Either way, the services they provide are a necessary part of the drug acquisition and delivery process. As such, the portion of the rebate that they retain should be considered part of the MCOs' drug cost. For this reason, when subtracting the manufacturer rebate to arrive at the final net cost to the MCO, the analyst should exclude that portion of the rebate retained by the PBM. For example, if the total rebate is \$100 and the PBM keeps 20% of it, then only \$80 should be subtracted to arrive at the final cost to the MCO.

Multisource Products

The same factors govern the cost of multisource drugs—those that are available from multiple manufacturers or repackagers. These are commonly referred to as "generics." Nevertheless, there are important differences in the estimation of the drug cost components. MCOs usually do not earn rebates on multisource drugs [5]. Because the decision of which multisource products to dispense is made at the pharmacy level, price considerations usually accrue to the pharmacy rather than to the MCO [4]. Most generics are listed on the first formulary tier and, thus, are subject to the lowest copay [5]. Average first-tier copays in 2008 averaged about \$10 for retail pharmacies and about \$19 for mail-order purchases [6].

Ingredient costs for multisource products are more difficult to determine because most are distributed by a large number of companies at a wide range of prices. Furthermore, list prices are typically much higher than what pharmacies actually pay [11]. MCOs typically deal with this situation by establishing maximum allowable cost (MAC) lists for multisource products. These lists establish a maximum amount that the MCO will reimburse a pharmacy for a multisource product. MCOs and PBMs consider their MAC lists to be proprietary and confidential. As a further complication, MCOs may use MAC pricing for retail pharmacies and discounted AWP for mail-order pharmacies [6]. Dispensing fees for multisource products are typically the same as those for branded products, although MCOs will occasionally provide higher dispensing fees to encourage pharmacists to dispense them.

Most contracts specify that the MCO will pay the pharmacy the lesser of the contract price (i.e., MAC plus dispensing fee) or the pharmacy's usual and customary price to cash patients [5].

Consequently, pharmacies' prices to cash customers represent an alternative source of cost information. For many pharmacies, these prices are available online. Examples include *costco.com*, *drugstore.com*, and *cvs.com*. The lists of "\$4 generics" posted by Wal-Mart, Kroger, and Target stores represent yet another source of information. Whether pharmacies are reimbursed at the usual and customary price, or at the contract price, the cost to the MCO is reduced by the amount of the patient copay.

It is worth noting that the costs of multisource products are small relative to the costs of single-source products or other health-care costs. As a result, less precise estimates of generic prices do not typically have a large impact on pharmacoeconomic analyses.

Physician-Administered Drugs

Some drugs are not delivered to patients through pharmacies but are administered via infusion or injection in physician offices or hospital outpatient clinics. MCOs have tended to follow Medicare Part B in their compensation for physician-administered drugs. Until recently, Medicare reimbursement for such medicines was 85% of AWP [12,13]. Nevertheless, that included the 20% patient coinsurance. Medicare thus paid 80% of 85%, equal to 68% of AWP. Thus, 68% of AWP was a reasonable basis from which to estimate the cost of these drugs to MCOs.

The federal government recently changed its reimbursement from 85% of AWP to average sales price (ASP) plus 6% [5,14]. ASP is a relatively new pricing concept developed by the Centers for Medicare and Medicaid Services (CMS) for the reimbursement of drugs covered under Medicare Part B. Although the ASP amounts are not made public, the amounts representing 106% of ASP are available publicly via the CMS Web site (<http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>). With coinsurance of 20%, the new net Medicare reimbursement for a drug would be 80% of 106% of ASP, or 84.8% of ASP. Note, however, that not all managed care payers have adopted this new reimbursement level [15–17]. They have, however, become more aggressive in demanding and extracting rebates. Therefore, when estimating the cost of physician-administered drugs, the analyst should consider using the smaller of 68% of AWP or 84.8% of ASP. Nevertheless, given the pluralism of managed care payment levels, we also recommend performing sensitivity analysis using the higher of the two options, thus enabling readers to choose the estimate that is closest to their own experience.

Conclusion

Drug prices paid by MCOs are based on ingredient cost and dispensing fee reimbursements, less manufacturer rebates and patient copays. Each of these components can vary based on such factors as dispensing site, site of administration, type of product, and formulary placement. Further, drug pricing is dynamic. Consideration of the factors discussed in this report should lead the analyst to a price that is considerably more accurate than the published list prices, such as AWP, typically used in pharmacoeconomic analyses.

Task Force Recommendations

Pharmacoeconomic analyses, as well as budget impact analyses, done from an MCO perspective should reflect as carefully as possible the prices actually paid by the MCOs net of all rebates, copays, or other adjustments. This is not easy because these prices are currently in a state of flux; AWP amounts may not be available in the future. One alternative benchmark, ASP + 6%, is

currently available through CMS, but only for drugs covered under Medicare Part B. Yet another benchmark, the average manufacturer's price (AMP), may eventually be published by CMS as mandated by law, but this is currently being challenged in court and the outcome is uncertain [18,19].

- Pharmacoeconomic researchers should keep current as to which data source (WAC, AWP, ASP, AMP, etc.) provides the most comprehensive and transparent basis for establishing drug prices used by MCOs.
- When doing a pharmacoeconomic assessment from the MCO perspective, to the extent possible, the drug cost should include amounts paid for medication ingredients and dispensing fees, and net out rebates, patient copays, volume discounts, or any other drug price reductions that are relevant to the MCO environment.
- In estimating drug costs, analysts should make adjustments for the proportion of medication dispensed through retail and mail-order pharmacies, and any resulting variation in dispensing fees or reimbursement for ingredient costs.
- In estimating drug costs, analysts should make adjustments for whether the medication is administered by a physician or has other special characteristics that make its coverage different from the typical medication dispensed in a retail pharmacy or by mail order.
- Recognizing that different MCOs may face somewhat different rebates and pricing structures, pharmacoeconomic researchers should include, in sensitivity analyses, pricing variation that reflects reasonable ranges in fully discounted MCO prices.
- For drugs that are off patent or likely to be off patent in the near future, particularly when looking at treatments for chronic diseases, it is appropriate to consider multisource drug prices in either the base-case or sensitivity analyses of pharmacoeconomic models.
- ISPOR should publish a Web site where current DCTF recommendations for managed care drug costing are updated as important new information becomes available.

Source of financial support: The article was prepared without a contract or funding from a sponsor.

References

- 1 Folland S, Goodman AC, Stano M. *The Economics of Health and Health Care*, (5th ed.). Upper Saddle River, NJ: Pearson Prentice Hall, 2007.
- 2 Nash DB. *The Managed Care Manual*. Boston: TLC Medical Publishing, 1997.
- 3 Berger L, Binglefors K, Hedblom E, et al., eds. *Health Care Cost, Quality, and Outcomes: ISPOR Book of Terms*. Princeton, NJ: International Society for Pharmacoeconomics and Outcomes Research, 2003.
- 4 Congressional Budget Office. *Prescription Drug Pricing in the Private Sector*. Washington, DC: Congressional Budget Office, 2007.
- 5 AMCP Task Force on Drug Payment Methodologies. *AMCP Guide to Pharmaceutical Payment Methods*. Alexandria, VA: Academy of Managed Care Pharmacy, 2007.
- 6 Pharmacy Benefit Management Institute. *The Takeda Prescription Drug Benefit Cost & Plan Design Survey Report: 2008–2009 Edition*. Scottsdale, AZ: Pharmacy Benefit Management Institute, Inc., 2008.
- 7 Claxton G, DiJulio B, Finder B, et al. *Employer Health Benefits: 2007 Annual Survey*. Menlo Park, CA: Henry J. Kaiser Family Foundation, 2007.
- 8 Wroblewski M, Schmidt D, Schultheiss P, et al. *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*. Washington, DC: Federal Trade Commission, 2005.

- 9 Health Strategies Group. Best Practices, Reimbursement and Contracting Outlook 2007. Lambertville, NJ: Health Strategies Group, 2005.
- 10 Smith C. Retail prescription drug spending in the National Health Accounts. *Health Aff* 2004;23:161–7.
- 11 Office of the Inspector General. Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products A-06-01-00053. Washington, DC: Department of Health and Human Services, 2002.
- 12 Gencarelli DM. Average wholesale price for prescription drugs: is there a more appropriate pricing mechanism? *NHPF Issue Brief* 2002;1–19.
- 13 Gencarelli DM. One pill, many prices: variation in prescription drug prices in selected government programs. *NHPF Issue Brief* 2005;1–20.
- 14 Centers for Medicare and Medicaid Services. Overview Medicare Part B drug average sales price. Center for Medicare and Medicaid Services Website, 2009. Available from: <http://www.cms.hhs.gov/mcrpartbdrugavgsalesprice/> [Accessed September 24, 2009].
- 15 EMD Serono Injectables Digest (4th ed.). Rockland, MA: EMD Serono, Inc., 2008.
- 16 Mullen P. The arrival of average sales price. *Biotechnol Healthc* 2007;4:48–53.
- 17 Butcher L. Insurers and oncologists forge a better cancer drug policy. *Manag Care* 2008;17:28–30.
- 18 Paul R. Bracing for a showdown. *Drug Topics* 2008;152:30–7.
- 19 Latebreakers: AWP is back from the dead. *Drug Topics* 2008;152:8.