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The mission of the ISPOR Drug Cost Standards Task Force 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 U.S. 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. Due to the complex nature of the pharmaceutical purchase process within the U.S., 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.

This report will 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.

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 co-pay 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. These include, for example, type of drug (single versus multisource), dispensing site (retail versus mail order), and site of administration (self-administered versus 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 prior to 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. The percent discount is negotiated between the MCO, or its pharmacy benefit manager (PBM), and the retail and mail order pharmacies in its network. PBMI, an organization that annually surveys health benefit managers in employer provided health plans, indicates that the discounts were 16% for retail pharmacies and 23% for mail order pharmacies during 2007. The dispensing fee is also negotiated between the MCO (or its PBM) and pharmacies. PBMI indicates that for 2007 mean dispensing fees were $1.88 for retail pharmacies and $1.62 for those mail order pharmacies that charged dispensing fees. About 80% of mail order pharmacies did not charge dispensing fees.
Retail pharmacy fees are for a one month supply while mail order dispensing fees cover a three month supply. Over the past several years, ingredient cost discounts have been increasing and reimbursements for dispensing fees have been decreasing.4

The MCO’s drug cost excludes the portion of the ingredient cost and dispensing fee that is paid by the patient, as well as any reimbursement made to the MCO in the form of a manufacturer rebate. The size of the patient co-pay 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. 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 co-pays for retail purchases averaged $23 and $40 in 2007.4 The size of co-pays, as well as the difference between those for second and third-tier drugs, has been increasing over time.4,5 In addition, payers have increased their use of coinsurance in recent years as an alternative to fixed dollar co-pays.4 The size of the co-pay 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 co-pays. However, in recent years there has been a trend to use somewhat higher mail order co-pays.4

The Federal Trade Commission has estimated that the average manufacturer rebate paid to an MCO for a single source drug is about 7.5% of catalog price, also known as Wholesale Acquisition Cost (WAC). 6,7 However, the rebate usually depends on the formulary status granted to the drug as well as the degree of in-class competition. 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.8 If that product were placed on the third tier, a smaller rebate would typically be granted by the manufacturer. If the drug had no in-class competitors, then assuming a rebate of 0% to 10% 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 – probably in the range of 15% to 35%. 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.9 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 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". However, there are important differences in the estimation of the drug cost components. MCOs usually do not earn rebates on multisource drugs. 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. Most generics are listed on the first formulary tier and, thus, are subject to the lowest co-pay. Average first-tier co-pays for retail pharmacies in 2007 were between $9 and $11.5 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.

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.10 MCOs typically deal with this situation by establishing maximum allowable cost (MAC) lists for multisource products. These lists base the price of a multisource product on the lowest prices at which the product appears to be available. 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.

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. Consequently, pharmacies’ prices to cash customers represent an alternative source of cost information. For many pharmacies, these prices are available on-line. 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 co-pay.

It is worth noting that the costs of multisource products are small relative to the costs of single source “brand name” products or other health care costs. As a result, less precise estimates of these 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. However, 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%. ASP is a relatively new pricing concept developed by 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 website. With co-insurance 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. 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. However, 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 co-pays. 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 done from an MCO perspective should reflect as carefully as possible the prices actually paid by the MCOs net of all rebates, co-pays or other adjustments. This is not easy since these prices are currently in a state of flux; AWP amounts may not be available in the future, or may not be available in a format that is easily accessible to researchers. 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.

- 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 co-pays, 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 rebates.
• 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 website where current DCTF recommendations for managed care drug costing are updated as important new information becomes available.
<table>
<thead>
<tr>
<th>Price Term</th>
<th>Definition / Explanation</th>
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<tr>
<td>Catalog Price</td>
<td>This price, posted by the manufacturer in its price catalog, is the amount to be paid by customers that buy directly from it (e.g., wholesalers). Catalog Price is sometimes alternatively referred to as the &quot;Direct Price&quot; or the &quot;Wholesale Acquisition Cost (WAC)&quot;.</td>
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<tr>
<td>Wholesale Acquisition Cost (WAC)</td>
<td>WAC is a commonly used alternative name for the manufacturer's Catalog Price. As such, it is a fixed amount and does not reflect the actual average price paid by wholesalers. The average cost to wholesalers is less than this amount because they typically receive small discounts off of the catalog price for such things as prompt payment. (See Average Manufacturer's Price).</td>
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<tr>
<td>Average Wholesale Price (AWP)</td>
<td>AWP is not an actual average price, but instead, is a suggested list price that is created by adding 20% or 25% to the manufacturer's Catalog Price. It is supplied by several drug information companies including First DataBank (via their National Drug Data File Plus™ database), Thomson Healthcare (via their Drug Topics Red Book), and Wolters Kluwer (via their Medi-Span Electronic Drug File). AWP has traditionally been the benchmark from which PBMs and MCOs begin price negotiations with pharmacies.</td>
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<tr>
<td>Maximum Allowable Cost (MAC)</td>
<td>A maximum amount that a health plan determines that it will pay for a particular medication that is available from multiple sources. Multi-source drugs are commonly referred to as &quot;generics&quot;. The term generally does not apply to drugs that still have patent protection.</td>
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<tr>
<td>Dispensing Fee</td>
<td>A relatively small additional amount that pharmacies are paid for the service of dispensing a prescription.</td>
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<td>Patient Co-payment (co-pay)</td>
<td>The co-pay is the portion of drug cost that the patient is responsible for paying. It generally varies according to the drug's formulary status within the patient's insurance plan (e.g., first, second, or third tier).</td>
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<tr>
<td>Average Manufacturer's Price (AMP)</td>
<td>AMP is the average amount paid by wholesalers for drugs ultimately distributed via the retail channel. This is calculated by the manufacturer on a quarterly basis and reported to the Centers for Medicare and Medicaid Services (CMS). It is used to calculate the rebate amount for purchases of the drug through the Medicaid program. AMP amounts have not yet been made public.</td>
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<tr>
<td>Best Price</td>
<td>The lowest price, net of all discounts and rebates, charged by a manufacturer to a purchaser in the private market. Like AMP, it is calculated by the manufacturer and reported to CMS for the purpose of establishing the Medicaid rebate. Given that this rebate partly depends on Best Price, which in turn depends on the level of rebates to MCOs, pricing concessions to MCOs are somewhat constrained.</td>
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<tr>
<td>Average Sales Price (ASP)</td>
<td>This relatively new pricing concept, introduced as part of the Medicare Modernization Act of 2003, is meant to replace AWP as the benchmark from which reimbursements are calculated for drugs covered under Medicare Part B, such as those that are administered by a physician on an outpatient basis (e.g., chemotherapy). ASP for a particular drug is the weighted average of the manufacturer's sales prices across all direct purchasers (excluding some public entities). Unlike AMP, it is not limited to purchases by wholesalers, nor limited to drugs distributed via the retail channel. However, ASP is only calculated for drugs covered under Medicare Part B. Although ASP amounts have not been made public, the new agree-upon reimbursement amounts, equal to 106% of ASP, have been published online by CMS.</td>
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<tr>
<td>Federal Supply Schedule (FSS)</td>
<td>FSS is a list of prices available to Federal purchasers who purchase directly from the manufacturer, such as the Veteran's Administration (VA). Prices on the list, which are based on actual transaction data reported to the VA by manufacturers, are equal to or lower than those given to any non-federal purchaser. FSS prices are publicly available and sometimes used by researchers, but likely understate the average cost to MCOs.</td>
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Sources:


Academy of Managed Care Pharmacy (AMCP). A Guide to Understanding Common Prescription Drug Pricing Terms. AMCP, Alexandria VA.


Reference List


