Achieving high value care for all and the perverse incentives of 340B price agreements

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Abstract

Section 340B of the Public Health Service Act requires drug manufacturers to enter into price agreements with the Department of Health and Human Services. These agreements result in variation in the price paid to acquire a drug by sector, which complicates the price used in cost-effectiveness analyses. We describe the transactions and sectors in a 340B agreement using a multiple sclerosis drug. Cost-effectiveness estimates were calculated for the drug using drug prices from the manufacturer and payer perspective. We found the amount paid to the manufacturer (340B price) was a good value ($118,256 per quality-adjusted life-year); however, from the payer drug cost perspective, good value ($196,683 per quality-adjusted life-year) was not achieved. Given that emerging value frameworks incorporate cost-effectiveness, these price variations may have downstream negative consequences, including inaccurate coverage and reimbursement policy recommendations. Upcoming policy changes to the 340B program should incentivize pricing schemes hinged on transparency and value.

Section 340B of the Public Health Service Act requires drug manufacturers to enter into a price agreement with the Secretary of the Department of Health and Human Services with the goal of extending scarce financial resources to more patients.[1] The 340B price agreement requires pharmaceutical companies to provide outpatient drugs to "eligible covered entities" at considerable up-front discounts.[1] These prescription drugs include biologics (vaccines excluded), approved prescription drugs, and prescribed over-the-counter drugs.[1] Typical 340B price discounts range from 30% to 50%,[2] whereas price discounts outside of these agreements often range from 20% to 30% for brand name drugs.[3] Evidence suggests the 340B program is shifting away from providing discounted prescription drugs to vulnerable populations to providing major revenue to hospitals and their affiliated clinics. The 340B program does not require hospitals to pass on these savings to uninsured and vulnerable populations.[4] While the perverse incentives of the 340B pricing program have been discussed in detail in relation to market transactions among manufacturers, hospitals, and affiliated clinics,[2,4–6] none has discussed the downstream consequences for assessing the value of these pharmaceuticals. Perverse incentives resulting from 340B pricing agreements potentially limit the policy implications of emerging US value assessments that incorporate cost-effectiveness analyses. The objective of this evaluation is to estimate the price paid to acquire fingolimod, a disease-modifying therapy for relapsing-remitting multiple sclerosis, for sectors

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(e.g., manufacturers, hospitals, third-party payers) involved in the 340B arrangement and illustrate the influence of this price variation on estimates of value.

Details of fingolimod example

Because there are different prices of fingolimod for different sectors involved in the 340B agreement, separate cost-effectiveness estimates were calculated for fingolimod using the different drug prices. Informed by previous evidence suggesting discounts of 30%–50% off of the list price,[2,7] we assumed the 340B price was a 50% discount from the wholesale acquisition cost (i.e., the price at which brand manufacturers sell to wholesalers and chain warehouses). Further, informed by previous evidence suggesting price discounts outside of these 340B agreements often range from 20% to 30% for brand name drugs,[3] the negotiated rate between the third-party payer and the contract pharmacy was assumed to be 20% off the wholesale acquisition cost. The negotiated rate between the manufacturer and the wholesaler was also assumed to be 20% off the wholesale acquisition cost. The fees charged by the contract pharmacy, split-billing vendor, and wholesaler were assumed to be $100 each.

Estimates for incremental cost and incremental effect between fingolimod and supportive care were retrieved from

the final evidence report on disease-modifying therapies for relapsing-remitting and primary-progressive multiple sclerosis generated by the Institute for Clinical and Economic Review (table E12 from their report).[8] Incremental cost estimates were adjusted based on different drug price perspectives and the incremental cost-effectiveness ratios were calculated.

Sectors and transactions in a 340B pricing agreement

The steps and transactions for a 340B pricing agreement for fingolimod are as follows (figure):

1. A drug wholesaler (e.g., McKesson Corporation) purchases a 30-day supply of 0.5 mg fingolimod pills from the drug manufacturer (e.g., Novartis Pharmaceuticals). The wholesaler and manufacturer have an agreement of a 20% discount from the wholesale acquisition unit cost of $6,743.[8,9] Therefore, the drug wholesaler pays the manufacturer $5,394 in exchange for the 30 pills. This negotiation is not related to 340B.
2. The wholesaler transfers the product to the contract pharmacy.
3. A patient fills a prescription for a 30-day supply of 0.5 mg fingolimod pills at a contract pharmacy. The patient receives the product from the pharmacy after paying a $20 copayment.
4. The contract pharmacy (e.g., Walgreens) is paid the remaining amount for the 30-day supply of 0.5 fingolimod pills by the patient's insurance. The third-party payer and contract pharmacy have an agreement of a 20% discount from the wholesale acquisition cost; therefore, the third-party payer (e.g., UnitedHealth) reimburses the contract pharmacy $5,394 less the patient's copayment. Therefore, the third-party payer pays the contract pharmacy $5,374.
5. The contract pharmacy transfers the payment to a split-billing vendor (e.g., consultancy). The contract pharmacy

Figure Flow of funds for a 340B agreement for fingolimod
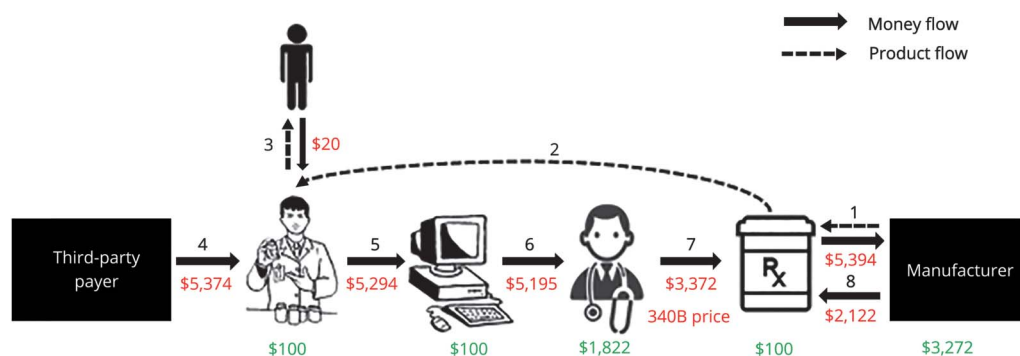
The green text denotes money that stays at each sector. The red text denotes money that is paid out by each sector. The amount the third-party payer paid for the acquisition of fingolimod equated to $5,374, which when added to the $20 copayment from the patient, equates to 20% off the wholesale acquisition cost. This assumed discount is not related to 340B. The amount the manufacturer kept for the provision of fingolimod equated to $3,272. This value was 50% off the wholesale acquisition cost less a $100 chargeback fee to the wholesaler. This discount is the result of the 340B price agreement.

keeps $100 of the payment as a fee; therefore, the contract pharmacist transfers $5,294 to the split-billing vendor and keeps $100.

6. The split-billing vendor transfers the payment to the provider (e.g., university medical center). The split-billing vendor keeps $100 of the payment as a fee; therefore, the split-billing vendor transfers $5,194 to the provider and keeps $100.

7. The provider pays the drug wholesaler at the 340B contract price, which is a 50% discount from the wholesale acquisition cost. This discount is the result of 340B agreement. Therefore, the provider reimburses the wholesaler $3,372. The difference between the 340B contract price and payment received from the split-billing vendor ($1,822) is kept at the provider's location.

8. The wholesaler submits a chargeback transaction to the manufacturer for the difference between the 340B price and their negotiated acquisition cost. The manufacturer reimburses the wholesaler the difference of $2,022 plus a $100 fee.

The figure pictorially represents the various steps and transactions characteristic to this agreement. This is a simplistic version of this process, but identifies the difference in price paid for the drug from different sectors involved in these agreements.

Cost-effectiveness and 340B pricing agreements

Separate incremental cost-effectiveness ratios (calculated by dividing the difference in cost by the difference in quality-adjusted life-years [QALYs] between fingolimod and supportive care) were calculated based on the different drug prices observed in the 340B pricing agreement (table). Cost-effectiveness ratios provide one estimate of value calculated

> Because some emerging US value assessment frameworks incorporate cost-effectiveness estimates, these price variations may have downstream negative consequences.

as the difference in costs over the difference in effectiveness (i.e., value for money). When the drug price equated to the wholesale acquisition cost, the incremental cost-effectiveness ratio was nearly $250,000 per QALY gained. However, the wholesale acquisition cost is not the price paid by any sector in these 340B price agreements. At the negotiated price the drug manufacturer has with the wholesaler (informed by previous evidence to be a 20% discount from the wholesale acquisition cost),[3] the incremental cost-effectiveness ratio dipped beneath $200,000 per QALY gained. This represents the payer drug price perspective and is above the commonly cited value threshold of $150,000 per QALY gained.[10] However, at the 340B price (informed by previous evidence to be a 50% discount from the wholesale acquisition cost),[2,7] the incremental cost-effectiveness ratio was $118,256 per QALY gained. This represents the manufacturer drug price perspective and is less than the commonly cited cost-effectiveness threshold.[10]

Discussion

This example showcases how the discounted drug prices negotiated with the 340B program generate drastically different

Table Cost-effectiveness of fingolimod as compared to supportive care under different drug price perspectives

Drug price	30-Day drug cost[a]	Incremental[b] lifetime drug cost	Incremental[b] lifetime other costs	Incremental[b] lifetime QALYs	ICER
WAC	$6,743	$888,842	−$42,352	3.4	$248,968
payer drug cost[c] (assumed 20% discount from WAC)	$5,394	$711,074	−$42,352	3.4	$196,683
Manufacturer drug cost[d] (340B price—assumed 50% discount from WAC)	$3,372	$444,421	−$42,352	3.4	$118,256

Abbreviations: ICER = incremental cost-effectiveness ratio (incremental costs/incremental effect), cost per quality-adjusted life year gained; QALYs = quality-adjusted life years; WAC = wholesale acquisition cost.
Estimates for incremental cost and incremental effect were retrieved from the final evidence report on disease-modifying therapies for relapsing-remitting and primary progressive multiple sclerosis generated by the Institute for Clinical and Economic Review. Estimates were adjusted based on different drug pricing scenarios.[8]
[a] Cost for 30-day supply of 0.5 mg fingolimod pills.
[b] Incremental costs and QALYs were calculated by finding the difference between fingolimod and supportive care over a lifetime time horizon. Incremental drug costs were calculated by subtracting drug costs for supportive care ($0)[8] from drug costs for fingolimod ($888,842 for WAC price, $711,074 for payer cost, and $444,421 for manufacturer cost). Incremental other costs were calculated by subtracting other health care costs for supportive care ($341,064)[8] from other health care costs for fingolimod ($298,712).[8] Incremental effect was calculated by subtracting the QALYs gained following supportive care (5.4 QALYs)[8] from the QALYs gained following treatment with fingolimod (8.8 QALYs).[8]
[c] Commensurate with the payer perspective of payment spent for incremental patient effect.
[d] Commensurate with the drug manufacturer perspective of revenue received compared to incremental patient effect.

cost-effectiveness estimates for different sectors involved in these agreements. Although this case is hypothetical and different discount rates may generate different findings, this case may suggest that the floor price driven by 340B price agreements may be the price point that drug manufacturers are currently using to price their products (i.e., price below commonly accepted thresholds). However, payers pay much more than this floor price (i.e., price above commonly accepted thresholds). When the price varies by sector, complexities around which price to use in value assessments arise. Because some emerging US value assessment frameworks incorporate cost-effectiveness estimates, these price variations may have downstream negative consequences, including inaccurate coverage and reimbursement policy recommendations. Reforms to the 340B program have been proposed, including the recent decision by the Center for Medicare and Medicaid Services (CMS) to reduce payment for drugs acquired through the 340B program to 22.5% less than the average sales price of a drug.[11] This contrasts the average sales price plus 6% CMS was previously paying for drugs acquired through 340B.[11] Although 340B is part of the Health Resources and Services Administration, and not CMS, both agencies can administer programs and make decisions that affect health care payment practices. This CMS decision, along with other potential 340B reforms, may have implications for emerging US value assessment frameworks as long as price variation among sectors continues.

Conclusion

Agreements like 340B likely hinder the delivery of high value care due to the variation in drug price by sector. This multiple sclerosis case study provides one example of how the variation in drug prices from agreements like 340B could be large enough to provide different estimates of value. Given that some emerging US value assessment frameworks incorporate estimates of cost-effectiveness, these price variations may have downstream negative consequences, including inaccurate coverage and reimbursement policy recommendations. Future research should expand this investigation to other 340B-eligible pharmaceuticals. Upcoming policy changes to the 340B program should incentivize pricing schemes hinged on transparency and value to help achieve sustainable and high value health care for all.

Author contributions

M.D. Whittington: drafting/revising the manuscript, study concept or design, analysis or interpretation of data, statistical analysis. J.D. Campbell: drafting/revising the manuscript, study concept or design. R.B. McQueen: drafting/revising the manuscript, study concept or design, analysis or interpretation of data.

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TAKE-HOME POINTS
→ Price agreements like 340B are complex due to multisector involvement and variation in the price paid to acquire the drug by sector. This price variation likely affects the ability to assess pharmaceutical value, which could hinder the goal of achieving high value care.
→ The discounted drug costs negotiated with the 340B price agreement generate drastically different cost-effectiveness estimates for different sectors involved in these agreements. These price variations may have downstream negative consequences, including inaccurate coverage and reimbursement policy recommendations by US value assessment frameworks.
→ Upcoming policy changes to the 340B program should incentivize pricing schemes hinged on transparency and value to help achieve sustainable and high value health care for all.

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