Using a Budget Impact Model Framework to Evaluate Antidiabetic Formulary Changes and Utilization Management Tools

Anna Hung, PharmD, PhD, MS; C. Daniel Mullins, PhD; Julia F. Slejko, PhD; Stuart T. Haines, PharmD; Fadia Shaya, PhD; and Amy Lugo, PharmD

ABSTRACT

BACKGROUND: Traditional budget impact models predict the financial consequences of a new drug entering the market. This study provides an example of applying the budget impact framework to a new research question of interest to managed care organizations—what is the budget impact of our formulary and utilization management (UM) policy changes?

OBJECTIVE: To predict the 3-year annual budgetary impact of TRICARE's antidiabetic formulary and UM policy changes using TRICARE claims data.

METHODS: A budget impact model was built in Microsoft Excel using health plan claims data for a 3-year time horizon. Model outcomes included spending on antidiabetic medications and medications used for side effect treatment. In sensitivity analyses, medical costs from inpatient, outpatient, and emergency room visits were also estimated. Model inputs included health plan antidiabetic medication utilization, as well as publicly available drug cost, rebate, dispensing fee, and patient cost-sharing estimates. Type of enrollee and pharmacy were also incorporated into the model. Sensitivity analyses varied estimates for utilization switch rates between preferred and nonpreferred agents, drug costs, rebates, and dispensing fees, as well as predicted impact from implementation delays.

RESULTS: For the 623,827 affected by the formulary and UM policy changes, the model predicted annual savings that increased from \$24 million in the first year to \$43 million in the third year after the changes. The majority of savings came from drug acquisition costs, as opposed to rebates, copays, and dispensing fees. Sensitivity analyses found savings across all varied parameters and scenarios except an unlikely scenario when 0% of utilization switched from nonpreferred to preferred agents. The model also predicted that the formulary and UM policy changes would lead to \$529,439 in savings from medical visit costs in Year 3.

CONCLUSIONS: This budget impact model predicted cost savings from the payer's formulary and UM policy changes.

J Manag Care Spec Pharm. 2019;25(3):342-49

Copyright© 2019, Academy of Managed Care Pharmacy. All rights reserved.

What this study adds

- This study used health plan data to predict that the formulary and UM policy changes would save the health plan \$24 million in the first year, \$35 million in the second year, and \$43 million in the third year after the changes.
- This study serves as an example for future health plans and managed care organizations desiring quantitative estimates as they make decisions around their formularies and UM strategies.

Traditional budget impact models are built to predict a payer's financial consequences from a new drug or technology entering the market.^{1,2} In the United States, the majority of published budget impact models are sponsored by biopharmaceutical companies.³ There are often barriers to payers using these models because of lack of transparency, model complexity, lack of time and understanding on the payer side, and perceived bias because of sponsorship.⁴⁻⁶ As a result, these published budget impact models are not widely and extensively used by payers.

While traditional budget impact analyses often predict the impact of a manufacturer's new drug or technology entering the market (i.e., a supply-side view), we propose a budget impact analysis approach that predicts the impact of a payer's set of interventions to manage new or existing drug utilization (i.e., a demand-side view). When there are changes to the drug market (e.g., new drugs are launched, new evidence arises), many payers use formulary coverage and tiers, along with other utilization management (UM) tools such as step therapy, prior authorization, and quantity limits to manage the health and costs of their populations.^{7,8} Often, the real-world application of these tools can become complicated, and as a result, payers are interested in the financial consequences of these tools. Hence, this study partnered with a payer and adapted the traditional budget impact framework to the payer's question—what are the financial consequences of our formularies and UM tools?

Case Study: Antidiabetic Formulary Management for TRICARE

TRICARE is the military's health plan administered by the Defense Health Agency for active-duty military, retirees, and their dependents. Of the 9.4 million beneficiaries around the world, the majority fall into 1 of 4 categories: 1.4 million are

What is already known about this subject

- Managed care organizations commonly oversee their population's health and costs using formulary coverage and tiers, as well as prior authorization, step therapy, and other utilization management (UM) tools.
- Budget impact models predict the financial consequences of a new drug or technology entering the market; however, few published budget impact models are built by health plans to predict the budget impact of their UM policies around new drugs or technologies entering the market.

FIGURE 1 SGLT2I and GLP1RA Formulary and UM Policy Changes

^aIncludes SU, TZD, DPP4I, AGI, and GLN.

AGI=alpha-glucosidase inhibitor; DPP4I=dipeptidyl peptidase-4 inhibitor; GLN=meglitinide; GLP1RA=glucagon-like peptide-1 receptor agonist; MET=metformin; SGLT2I=sodium-glucose cotransporter-2 inhibitor; SU=sulfonylurea; TZD=thiazolidinedione; UM=utilization management.

active duty; 1.8 million are family members of active duty; 2.2 million are retired service members; and 2.6 million are family members of retired service members.⁹ Members receive their medications at 1 of 3 pharmacy points of service, including military treatment facility pharmacies, mail order pharmacies, and retail (network and non-network) pharmacies.¹⁰ Different formularies and copay amounts are associated with the different pharmacy points of service.

The prevalence of diabetes in the TRICARE beneficiary population is similar to the national prevalence of diabetes (approximately 8.5%-10%).¹¹ Because of the large membership and high prevalence of diabetes, TRICARE spends a significant amount on diabetes treatment. For instance, excluding the cost of direct medical care, TRICARE spent \$311 million on non-insulin antidiabetic drug classes in 2010.¹²

In February 2016, TRICARE implemented changes to its formularies and UM policies for 2 antidiabetic medication classes: sodium-glucose cotransporter-2 inhibitors (SGLT2Is) and glucagon-like peptide-1 receptor agonists (GLP1RAs).¹³ These changes occurred after clinical and cost considerations through the formulary management process previously described.¹⁰ For the SGLT2Is, 2 changes were implemented:

(1) a change in the step-therapy requirements and (2) an addition of preferred agents (Figure 1). Before these changes, new users of SGLT2Is were required to try metformin and a dipeptidyl peptidase-4 inhibitor (DPP4I) before receiving an SGLT2I. After the changes, new users of SGLT2Is were required to try metformin and at least 2 additional unique noninsulin antidiabetic drug classes before receiving an SGLT2I. Additionally, a preferred SGLT2I was chosen, requiring all users, current and new, to use a preferred agent before a nonpreferred agent would be authorized.

For the GLP1RAs, 2 changes were implemented: (1) an addition of preferred agents and (2) an addition to the basic core formulary (Figure 1). Before the changes, none of the medications in the GLP1RA drug class were preferred. After the changes, 2 medications were chosen as preferred agents. Additionally, after the changes, 1 agent was added to the basic core formulary, which requires that this drug be on the formulary at all military treatment facilities. These changes applied to all users, current and new, of GLP1RAs.

The objective of this study was to predict the 3-year budgetary impact of TRICARE's antidiabetic formulary and UM policy changes using TRICARE claims data.

FIGURE 2 Analytical Framework of Model

Note: I1-I9 represent input tabs in the Excel workbook; O1-O3 represent output tabs in the Excel workbook; blue font indicates sensitivity analysis.

^aPoint of service affects most variables.

ER = emergency room; SE = side effects.

Methods

A budget impact model was built in Microsoft Excel (Microsoft Corp., Redmond, WA) using budget impact analysis guidelines from the International Society for Pharmacoeconomics and Outcomes Research.^{1,2} The time horizon was 3 years, and the perspective was that of the payer. Because the TRICARE medical and pharmacy benefits are managed separately, only pharmacy costs—consisting of medication costs, rebates, dispensing fees, and cost sharing—were included in the base-case scenario (Figure 2). Medical costs were included in the sensitivity analyses.

The study population included any TRICARE member who could be affected by the formulary and UM policy changes. This population was defined as a member who received at least 1 prescription of any medication included in the 8 affected antidiabetic drug classes in the year before the formulary and UM policy changes. These 8 antidiabetic drug classes included SGLT2Is, GLP1RAs, biguanides, DPP4Is, thiazolidinediones (TZD), sulfonylureas (SU), alpha-glucosidase inhibitors (AGI), and meglitinides (GLN). A static model was assumed because

the size and disease severity mix of the population were not expected to significantly change in the time horizon (Appendix A, available in online article).

In the base-case scenario, the intervention mix included all medications in the 8 antidiabetic drug classes directly affected by the formulary and UM policy changes. This consisted of 95 unique drug products, including brand and generic medications, as well as single-agent and combination medications. New brands (e.g., Adlyxin, Xultophy, and Soliqua) and generic medications expected to enter the market during the study time horizon were also included. Based on expert opinion from TRICARE benefit administrators, we anticipated very small market share shifts from other drugs within the same drug class to the new drug (Appendix A). We assumed natural changes in utilization from 2 years before to 1 year before the formulary and UM policy changes would continue forward.

The intervention mix also included drugs used to treat side effects from new use of 1 of the 8 antidiabetic drug classes. These drugs include antifungals to treat genital mycotic infection after SGLT2I use, antibiotics to treat urinary tract infection after SGLT2I use, and glucagon to treat hypoglycemia after SU

FIGURE 3 Impact on Annual Pharmacy Budget for Antidiabetic Drugs Directly Affected by Formulary and UM Policy Changes

or GLN use. We decided on these drugs by creating a list of all side effects reported in the guidelines from the American Diabetes Association for the 8 antidiabetic drug classes directly affected by the formulary and UM policy changes.¹⁴ We then consulted with 2 clinical pharmacists to remove any side effects that were considered rare, unlikely to occur within 3 years, weakly associated with the drug, or uncommonly treated with prescription medication. We assumed that if a patient switched drugs within a drug class, there would be no change in rates of side effects (Appendix A). Changes in utilization of drugs used to treat side effects were based on an estimate of the difference in utilization 6 months after versus 6 months before new use of antidiabetic drug classes seen in TRICARE claims.

The baseline utilization and market share of the intervention mix were based on TRICARE claims data in the year before the formulary and UM policy changes. Based on TRICARE expert opinion through a process of considering similar past scenarios, the disease state, drug classes of interest, and loyalty to drug products, we made the following assumptions: (a) due to the formulary and UM policy changes, between 65% and 80% of utilization would switch from nonpreferred to preferred agents in the GLP1RA and SGLT2I drug classes, respectively, at each pharmacy point of service, and (b) 30% of potential new use of SGLT2Is would try a third antidiabetic drug to meet the step-therapy requirements (Appendix A).

Drug unit costs were based on publicly available pricing benchmarks, including federal supply schedule and wholesale acquisition cost. Federal supply schedule was used for

most pharmacy points of service, except retail non-network pharmacies and for nonformulary drugs at retail network pharmacies. Constant drug costs were used (Appendix A), meaning that changes in price per the National Drug Code number over time were not included. We chose not to change drug costs over time because of our short time horizon, complicated contracting agreements, and difficulty in accurately predicting individual drug price fluctuations over time. However, costs per unique drug could change based on the utilization of more or less expensive National Drug Code numbers for a given drug over time. TRICARE copays and coinsurance were also included and varied by point of service and plan type.¹⁵ Rebates and dispensing fees were estimated based on publicly available literature (Appendix B, available in online article).^{16,17} Dispensing fees were set as \$1.66 per prescription for brand drugs and \$1.68 for generic drugs at the retail point of service, and \$0.74 per prescription for all drugs at the mail order point of service.¹⁷ Copays, coinsurance, rebates, and dispensing fees were static (Appendix A), except for a known copay change that occurred in February 2016. Additionally, we assumed that TRICARE would pay 30% of total drug costs if members had other health insurance (Appendix A).¹⁸

Sensitivity Analysis

In one-way sensitivity analyses, switch rates for nonpreferred to preferred SGLT2I and GLP1RA, as well as the SGLT2I step therapy, were varied from 0% to 100%, to mimic a worst-case and best-case scenario. Additionally, rebates were varied based on generic status, formulary tier, and pharmacy point of service

FIGURE 4 Summary Impact on Medical and Pharmacy Benefits

AntiDM_dir = antidiabetic drugs directly affected by the formulary and utilization management policy changes; SE = side effect; Tx = treatment.

(Appendix B). Dispensing fees varied from \$0 per prescription as the lowest possible fee to \$25 per prescription as the highest. The \$25 upper bound was based on the highest dispensing fee found per prescription for Medicaid in March 2017.¹⁹

Sensitivity analyses were also conducted. In one scenario, the national average drug acquisition cost (NADAC) was substituted for the wholesale acquisition cost because the NADAC may provide a closer estimate to true drug acquisition costs.²⁰ In a second scenario, the implementation of the formulary and UM policy changes was delayed by 5 months. In a third scenario, we removed the natural trend assumption, which stated that the change in utilization from one year to the next would continue forward.

Medical benefit costs were also examined separately in the sensitivity analyses. These costs included inpatient, emergency room, and outpatient visits. Similar to drug costs, costs of medical visits were assumed to be constant (Appendix A). We also assumed that TRICARE would only pay 20% of medical costs if members had other health insurance.²¹

This study received approval by institutional review boards from the University of Maryland Baltimore and the Defense Health Agency.

Results

In 2015, there were 9,438,123 TRICARE beneficiaries.¹⁷ Of these, 623,827 beneficiaries received a prescription claim for at least 1 of the 8 antidiabetic drug classes directly affected by the formulary and UM policy changes in the year before the formulary

and UM policy changes. The majority of our study population was older, with 53% of patients aged between 65 and 84 years, and 36% aged between 45 and 64 years. Approximately 50% were retired, and 57% of the population was enrolled in the TRICARE for Life plan, which provides secondary coverage to those who have Medicare Parts A and B. Only 1.4% of the population were active-duty service members. The population had equal proportions male and female.

The base-case model predicted that 3 years after the formulary and UM policy changes, the annual budget for antidiabetic drugs directly affected by the changes would be \$837 million with formulary and UM policy changes and \$880 million without the formulary and changes. Hence, the model predicted that the formulary and UM policy changes would lead to \$43 million in savings in the third year after the changes. The \$43 million in estimated savings consisted of \$38 million in savings from drug acquisition costs, \$9 million in savings from rebates, \$4 million in copay losses, and \$10,843 in additional dispensing fees (Figure 3). The \$43 million in savings in the third year was an increase from the \$24 million in the first year and \$35 million in the second year after the formulary and UM policy changes (Figure 3).

Additional model predictions at Year 3 included the following: \$12,601 in savings from spending on treatment of side effects (Figure 4); 1,791 fewer days of side effect treatment in the scenario with formulary and UM policy changes versus without changes; 3,165 fewer days of utilization of fluconazole (potential treatment for genital mycotic infection); and 691

FIGURE 5 Year 3 Impact on Annual Budget for Antidiabetic Drugs Directly Affected by Formulary and UM Policy Changes After Varying Parameter and Structural Assumptions

GLP1RA=glucagon-like peptide-1 receptor agonist; NADAC=national average drug acquisition cost; SGLT2I=sodium-glucose cotransporter-2 inhibitor; UM=utilization management.

more days of utilization of glucagon (potential treatment for hypoglycemia).

In one-way sensitivity analyses, the budget impact was most sensitive to switch rates, especially the switch from nonpreferred to preferred agents in the GLP1RA drug class (Figure 5). If there was no change in nonpreferred and preferred GLP1RA drug utilization rates, the cost savings from the formulary and UM policy changes was \$13 million. When all utilization switched from nonpreferred to preferred GLP1RA drugs, the cost savings from the formulary and UM policy changes was \$60 million. When the natural trend assumption was removed, the predicted savings decreased to \$15 million.

When medical costs were included in the sensitivity analyses, the model predicted that the formulary and UM policy changes would lead to \$529,439 in savings from medical visit costs (Figure 4). The majority of these savings came from fewer inpatient visits (leading to \$535,209 in savings) followed by fewer outpatient visits (leading to \$42,260 in savings). The lower utilization of medical visits resulted in a copay loss of \$45,865. The number of emergency room visits was predicted to increase (leading to \$2,176 in additional costs).

Discussion

With health care costs continuing to rise in the United States, there is increasing pressure on payers to manage utilization and high drug costs.²² To aid in the formulary decision-making process, payers need accurate and relevant budget impact models that reliably predict what, if any, influence their UM tools may have on cost. For this purpose, we have presented

an example of how a budget impact model could be built using payer data for a specific health plan.

Although the vast majority of published budget impact models predict the financial consequences of a new drug entering the market, there is growing interest to expand the budget impact model framework beyond the traditional context.^{3,23-26} A recent study evaluated the budget impact of a transition-of-care program, also using claims data from a health plan in the United States.²⁷ In our study, we applied the budget impact model framework to a set of payer formulary and UM policy changes. To our knowledge, our study is one of the first published budget impact analyses that evaluates a payer's formulary and UM policy changes using its own claims data. In an era of value frameworks, budget impact models can be a second step that payers use to determine if the UM strategies around the technologies they perceive to be of high value are affordable.²⁸⁻³¹

Our budget impact model predicted that the formulary and UM policy changes TRICARE implemented for the SGLT2I and GLP1RA drug classes would lead to savings for both the pharmacy and medical benefits. The majority of the cost savings came from spending on the antidiabetic drugs directly impacted by the formulary and UM policy changes. These findings are consistent with original expectations. However, savings may not be possible for all UM policy changes.

A recent study found that payers perceive budget impact models as only moderate in strength as economic evidence for their formulary decisions.³² This, in addition to the perceived sponsorship bias and low transparency of many budget impact models, leads to limited use of budget impact models by payers

in their formulary decisions and reveals a need to improve the credibility of budget impact models.⁴⁻⁶

To increase credibility and use of the model, this study was built in collaboration with a payer, which has important advantages. One key strength is the use of actual payer utilization data as an input, which increases the accuracy and relevance of the model. For example, we found that after accounting for a delay in implementation, the predicted switch rates were close (differences of 3 to 5 percentage points) to what was provided based on expert opinion. A future publication will provide extensive detail regarding the validation of this budget impact model. Another key strength is the ability to validate the model by comparing payer utilization and cost data with what the model had predicted. There is scarce literature on the validation of budget impact models. A formal and systematic validation process examining various aspects of the model, such as face validity and internal verification, as well as comparing the model's predictions to what is observed in realized costs, increases the credibility of the model.

A third key strength of this study is that we incorporated specific health system features that were most important to the payer. In our case, these features included pharmacy points of service and plan types, as well as accounting for other health insurance. In a rapidly changing environment, an adaptable model as described here is critical when policies change, unexpected delays in implementation occur, and drugs enter and exit the market.

There are many opportunities for budget impact models. Beyond informing decisions on UM policies, budget impact models could provide quantitative estimates that aid in rebate negotiations. Additionally, these models could be used as part of performance-based risk-sharing agreements, which are increasingly being explored and adopted.³³⁻³⁵

Limitations

This study has some limitations to consider. One limitation was use of publicly available estimates for many of the cost parameters, including drug prices, rebates, dispensing fees, and medical visit prices. Actual costs were limited for proprietary reasons. Future budget impact models should be flexible enough to include true payer costs for internal reporting and publicly available cost estimates for publication.

Although patient copays and coinsurance were included, we did not include deductibles and additional patient cost sharing when using non-network pharmacies and medical services. We do not think that the formulary and UM policy changes of interest would significantly impact the utilization and costs from these deductibles and extra patient cost sharing. However, future research focused on patient spending could include these potential patient costs.

Finally, we did not explore what proportion of antidiabetic drug utilization was for diabetes treatment as opposed to off-label

use. However, since the payer paid for antidiabetic drug utilization regardless of indication, any utilization was of interest.

Conclusions

In this study, the budget impact model estimated that TRICARE's antidiabetic formulary and UM policy changes would lead to savings for the pharmacy and medical benefits. These savings were robust to varying individual switch rates for preferred agents and step therapies.

Authors

ANNA HUNG, PharmD, PhD, MS, Duke Clinical Research Institute, Durham, North Carolina. C. DANIEL MULLINS, PhD; JULIA F. SLEJKO, PhD; and FADIA SHAYA, PhD, University of Maryland School of Pharmacy, Baltimore. STUART T. HAINES, PharmD, University of Mississippi School of Pharmacy, Jackson, and AMY LUGO, PharmD, Defense Health Agency, San Antonio, Texas.

AUTHOR CORRESPONDENCE: Anna Hung, PharmD, PhD, MS, Duke Clinical Research Institute, 200 Morris St., Durham, NC 27713. Tel.: 301.412.7396; E-mail: anna.hung@duke.edu.

DISCLOSURES

This project was supported by grant number F32HS024857 from the Agency for Healthcare Research and Quality (AHRQ), which contracted with the University of Maryland School of Pharmacy to conduct this study. The content is solely the responsibility of the authors and does not necessarily represent the official views of the AHRQ, which had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or design to submit the manuscript for publication. The findings discussed in this manuscript represent the views of the authors and do not necessarily reflect the views of the Department of Defense, the Defense Health Agency, nor the Departments of the Army, Navy, and Air Force.

Hung reports a grant from the AHRQ, during the conduct of the study, and personal fees from CVS Health and BlueCross BlueShield Association, outside the submitted work. Mullins reports grants and personal fees from Bayer and Pfizer and personal fees from Boehringer-Ingelheim, Janssen/J&J, Regeneron, and Sanofi, outside the submitted work. Mullins, Slejko, and Shaya are employed by the University of Maryland School of Pharmacy. Haines and Lugo have nothing to disclose.

Part of this content was previously presented as a poster at the 2017 AMCP Managed Care & Specialty Pharmacy Annual Meeting; March 27-30, 2017; Denver, CO, and as poster and oral presentations at the 2017 AMCP Nexus Meeting; October 16-19, 2017; Dallas, TX. Part of this content was published as Hung's PhD dissertation.

ACKNOWLEDGMENTS

The authors thank Alexander Rittel, Lee Ann Zarzabal, and Alan Sim of the Defense Health Agency for their contributions to this study.

REFERENCES

1. Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysis—principles of good practice: report of the ISPOR 2012 budget impact analysis good practice II task force. *Value Health*. 2014;17(1):5-14.

2. Mauskopf JA, Sullivan SD, Annemans L, et al. Principles of good practice for budget impact analysis: report of the ISPOR task force on good research practices—budget impact analysis. *Value Health*. 2007;10(5):336-47.
3. Mauskopf J, Earnshaw S. A methodological review of US budget-impact models for new drugs. *Pharmacoeconomics*. 2016;34(11):1111-31.
4. van de Vooren K, Duranti S, Curto A, Garattini L. A critical systematic review of budget impact analyses on drugs in the EU countries. *Appl Health Econ Health Policy*. 2014;12(1):33-40.
5. Orlewska E, Gulácsi L. Budget-impact analyses: a critical review of published studies. *Pharmacoeconomics*. 2009;27(10):807-27.
6. Neumann PJ. Budget impact analyses get some respect. *Value Health*. 2007;10(5):324-25.
7. Shoemaker SJ, Dengelis J; Abt Associates. Academy of Managed Care Pharmacy (AMCP): an annotated bibliography of managed care pharmacy interventions. January 15, 2010. Available at: <http://amcp.org/WorkArea/DownloadAsset.aspx?id=9276>. Accessed January 31, 2019.
8. Academy of Managed Care Pharmacy. Formulary management. November 2009. Available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9298>. Accessed January 31, 2019.
9. Military Health System. Patients by beneficiary category. Available at: <https://health.mil/I-Am-A/Media/Media-Center/Patient-Population-Statistics/Patients-by-Beneficiary-Category>. Accessed January 30, 2019.
10. Trice S, Devine J, Mistry H, Moore E, Linton A. Formulary management in the Department of Defense. *J Manag Care Pharm*. 2009;15(2):133-46. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2009.15.2.133>.
11. Chao SY, Zarzabal LA, Walker SM, et al. Estimating diabetes prevalence in the Military Health System population from 2006 to 2010. *Mil Med*. 2013;178(9):986-93.
12. Department of Defense. Quarterly DoD P&T committee meeting minutes. November 2010. Available at: <https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/Operations/Pharmacy-Division/DoD-Pharmacy-and-Therapeutics-Committee/Meeting-Minutes>. Accessed January 30, 2019.
13. Department of Defense. Quarterly DoD P&T committee meeting minutes. August 2015. Available at: <https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/Operations/Pharmacy-Division/DoD-Pharmacy-and-Therapeutics-Committee/Meeting-Minutes>. Accessed January 30, 2019.
14. American Diabetes Association. Standards of medical care in diabetes—2016. *Diabetes Care*. 2016;39(Suppl 1):S1-S112.
15. TRICARE. Costs. Available at: <https://tricare.mil/prescriptioncosts>. Accessed February 12, 2019.
16. Congressional Budget Office. A CBO paper: prices for brand-name drugs under selected federal programs. June 2005. Available at: <https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/64xx/doc6481/06-16-prescriptdrug.pdf>. Accessed January 30, 2019.
17. Academy of Managed Care Pharmacy. AMCP guide to pharmaceutical payment methods-2013 (version 3.0). Available at: <http://www.amcp.org/pharmaceutical-payment-guide/>. Accessed January 31, 2019.
18. Defense Health Agency. Evaluation of the TRICARE program: access, cost, and quality-fiscal year 2016 report to Congress. May 19, 2016. Available at: <http://www.health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Health-Care-Program-Evaluation/Annual-Evaluation-of-the-TRICARE-Program?type=Reports>. Accessed January 30, 2019.
19. Medicaid.gov. Medicaid covered outpatient prescription drug reimbursement information by state. Quarter ending September 2017. Available at: <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxreimbursement-chart-current-qtr.pdf>. Accessed January 30, 2019.
20. Levy J, Rosenberg M, Vanness D. A transparent and consistent approach to assess U.S. outpatient drug costs for use in cost-effectiveness analyses. *Value Health*. 2018;21(6):677-84.
21. TRICARE. 2017 TRICARE for Life cost matrix. Fiscal year 2017. Available at: <https://tricare.mil/Costs/HealthPlanCosts/TFL>. Accessed January 30, 2019.
22. National Academies of Sciences, Engineering, and Medicine. *Making Medicines Affordable: A National Imperative*. Consensus study report. Washington, DC: National Academies Press; 2017.
23. Bly CA, Molife C, Brown J, et al. The budget impact of including necitumab on the formulary for first-line treatment of metastatic squamous non-small cell lung cancer: U.S. commercial payer and Medicare perspectives. *J Manag Care Spec Pharm*. 2018;24(6):534-43. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2018.24.6.534>.
24. Graham J, Earnshaw S, Burslem K, Lim J. Budget impact analysis of afatinib for first-line treatment of patients with metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or exon 21 substitution mutations in a U.S. health plan. *J Manag Care Spec Pharm*. 2018;24(6):544-53. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2018.24.6.544>.
25. Bui CN, O'Day K, Flanders S, et al. Budget impact of enzalutamide for chemotherapy-naïve metastatic castration-resistant prostate cancer. *J Manag Care Spec Pharm*. 2016;22(2):163-70. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2016.22.2.163>.
26. Perk S, Wielage RC, Campbell NL, et al. Estimated budget impact of increased use of mirabegron, a novel treatment for overactive bladder. *J Manag Care Spec Pharm*. 2016;22(9):1072-84. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2016.22.9.1072>.
27. Ni W, Colayco D, Hashimoto J, et al. Budget impact analysis of a pharmacist-provided transition of care program. *J Manag Care Spec Pharm*. 2018;24(2):90-96. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2018.24.2.90>.
28. Ben-Aharon O, Magnezi R, Leshno M, Goldstein DA. Association of immunotherapy with durable survival as defined by value frameworks for cancer care. *JAMA Oncol*. 2018;4(3):326-32.
29. Schafer J, Galante D, Shafrin J. Value tools in managed care decision making: current hurdles and future opportunities. *J Manag Care Spec Pharm*. 2017;23(6-a Suppl):S21-S27. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2017.23.6-a.s21>.
30. Shah-Manek B, Wong W, Ravelo A, DiBonaventura M. Oncologists' perceptions of drug affordability using NCCN evidence blocks: results from a national survey. *J Manag Care Spec Pharm*. 2018;24(6):565-71. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2018.17449>.
31. Bentley TGK, Cohen JT, Elkin EB, et al. Measuring the value of new drugs: validity and reliability of 4 value assessment frameworks in the oncology setting. *J Manag Care Spec Pharm*. 2017;23(6-a Suppl):S34-S48. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2017.23.6-a.s34>.
32. Choi Y, Navarro RP. Assessment of the level of satisfaction and unmet data needs for specialty drug formulary decisions in the United States. *J Manag Care Spec Pharm*. 2016;22(4):368-75. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2016.22.4.368>.
33. AMCP partnership forum: advancing value-based contracting. *J Manag Care Spec Pharm*. 2017;23(11):1096-02. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2017.17342>.
34. Nazareth T, Ko JJ, Sasane R, et al. Outcomes-based contracting experience: research findings from U.S. and European stakeholders. *J Manag Care Spec Pharm*. 2017;23(10):1018-26. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2017.23.10.1018>.
35. Goble JA, Ung B, van Boemmel-Wegmann S, Navarro RP, Parece A. Performance-based risk-sharing arrangements: U.S. payer experience. *J Manag Care Spec Pharm*. 2017;23(10):1042-52. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2017.23.10.1042>.

APPENDIX A Assumptions

1	Constant population size and disease severity mix (static model).
2	“Natural” change in utilization from one year to the next determined by fitting a linear trend using February 2014-January 2015 to February 2015-January 2016 utilization data. Floor of 0 (negative values not allowed). If quantity, day supply, or number of prescription were 0, then the rest (and number of 30-day prescription) were set to 0. If there was no utilization at Year 1 but utilization at Year 0 (and vice versa), then the other value was continued forward.
3	No change in side effect or medical treatment when switching within a drug class.
4	Shifts in market share because of formulary and UM policy changes —65% for GLP1RA, 80% for SGLT2I nonpreferred to preferred, and 30% for SGLT2I step therapy.
5	Shifts in market share to new drugs on the market —3% starting in Year 2 for lixisenatide (Adlyxin), 0% for insulin degludec and liraglutide (Xultophy) and insulin glargine and lixisenatide injection (Soliqua), and 1% starting in Year 3 for generic exenatide.
6	Constant drug prices per NDC (pulled from February-March 2017). However, drug prices per day change based on the market share of NDC numbers used from one year to the next, as well as the average quantity per day supply. Specifically, the “natural” change in drug price (weighted average) per day (based on utilization of NDC numbers per drug) is predicted by fitting a linear trend to February 2014-January 2015 and February 2015-January 2016 data. Note: If drug price per day is missing one year because of lack of use, no change is assumed. WAC per day and FSS per day cannot go lower than the lowest seen for each category (antidiabetic drugs: \$0.64 WAC per day and \$0.02 FSS per day; drugs used to treat side effects: \$0.70 WAC per day and \$0.08 FSS per day; and medical supplies: \$0.14 WAC per day and \$0.08 FSS per day). No future adjustment for inflation.
7	Constant rebates, copays, coinsurance, and dispensing fees throughout the time horizon. Copays increased February 1, 2016, and these copays were continued forward. No dispensing fees at military treatment facilities.
8	Constant medical visit prices. Percentage of purchased claims that are in network as seen in Excel workbook tab 18—average of 90%. No future adjustment for inflation.
9	If other health insurance member, TRICARE pays 30% of drug costs and 20% of medical costs. TRICARE does not pay dispensing fees and does not receive rebates, copays, or coinsurance.

FSS=federal supply schedule; GLP1RA=glucagon-like peptide-1 receptor agonist; NDC=National Drug Code; SGLT2I=sodium-glucose cotransporter-2 inhibitor; WAC=wholesale acquisition cost.

APPENDIX B Drug Price and Rebates by Point of Service, Generic Status, and Formulary Tier

Point of Service	Generic Status and Formulary Tier	Drug Price Benchmark		Rebate, %		
		Base Case	Scenario Analysis	Base Case	Lower Bound	Upper Bound
Military treatment facility	Brand drug					
	BCF	FSS ^a	FSS ^a	23 ^b	20	50
	Neither BCF nor NF			11	5	20
	NF			0	0	5
	Generic drug					
	BCF	FSS ^a	FSS ^a	13 ^c	10	25
Mail order/retail (network)	Neither BCF nor NF			6	3	10
	NF			0	0	3
	Tier 1 (UF and generic)	FSS ^a	FSS ^a	23 ^b	20	50
	Tier 2 (UF and branded)			13 ^c	10	25
	Tier 3 (NF)			0	0	15
	Tier 1 (UF and generic)	WAC	NADAC	0	0	15
Retail (non-network)	Tier 2 (UF and branded)			0	0	10
	Tier 3 (NF)			0	0	5

^aFSS includes lower of FSS and Big 4 FSS (when available).

^bBased on the Congressional Budget Office. A CBO paper: prices for brand-name drugs under selected federal programs.¹⁵ The Department of Defense's military treatment facility average price is 41% of the average wholesale price (AWP) versus the FSS price, which is 53% of AWP (and the Big 4 FSS, which is 49% of AWP): 41%/53%=77%; 100%-77%=23%.

^cBased on the Academy of Managed Care Pharmacy. AMCP guide to pharmaceutical payment methods-2013 (version 3.0).¹⁶ Medicaid rebates are 13% of the average manufacturer price (AMP), whereas brand drugs are 23.1% of AMP.

BCF=basic core formulary; FSS=federal supply schedule; NADAC=national average drug acquisition cost; NF=nonformulary; UF=uniform formulary; WAC=wholesale acquisition cost.