Pharmaceutical Industry Effectiveness in the Department of Defense

Part III of III
TRICARE Tier 4
What Industry Needs to Know

For:
Clients and Friends of D2 Pharma Consulting, LLC

About the Author

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David W. Bobb is a pharmacist, attorney, and retired United States Air Force Colonel with over 40 years of experience in both the civilian and federal healthcare sectors, and a deep understanding of Department of Defense pharmacy operations. Immediately before joining D2 Consulting, he served as the Chief of Pharmacy Operations at the Defense Health Agency where he led, managed, and shaped the $9.7 billion Department of Defense TRICARE Pharmacy Program, providing exceptional pharmacy services for 9.4 million beneficiaries worldwide. In this role he served as the principal advisor to the Assistant Secretary of Defense, Health Affairs, and Director, Defense Health Agency (DHA) on all aspects of policy and priority development related to Military Health System (MHS) pharmacy benefits and operations. He also gave presentations to individual Senators, Congressional representatives, and senior staffers of both the Senate and House Armed Services Committees.

Col. Bobb's widely varied career has placed him in such practice settings as independent pharmacies, large retail chain pharmacies, United States Air Force pharmacies, industry, and the Department of Health and Human Services in the Office of the National Coordinator for Health IT. He has had the opportunity to manage and execute multi-billion dollar budgets, integrate and consolidate diverse healthcare systems, build cohesive high-performing teams, and develop effective medication safety and quality assurance programs across the spectrum of pharmacy operations to optimize patient care.

In addition, Col. Bobb provide sound legal advice to federal pharmacists in respect to changing Food and Drug Administration policies, Drug Enforcement Administration laws, and federal and state pharmacy-focused legislative initiatives. He has been an integral member of several Boards of Directors, including the American Society for Pharmacy Law, Department of Defense Pharmacy Advisory Board, and the San Antonio Uniformed Services Health Education Consortium. Lastly, Mr. Bobb has provided over 35 ACPE-accredited pharmacy law presentations and authored over 20 publications for federal pharmacists and technicians.

Forward

My Time in the Capsule

Despite the fact that the title of this article may evoke memories of the 1960s Mercury, Gemini, and Apollo United States space programs, I can assure you nothing regarding my purpose for writing these articles is further from the truth. I simply was looking for a term that is relatable to the practice and business of pharmacy and thought that "capsule" provides a nice imagery.

Rather than writing about the space program, my intent is to pen a series of short articles to share some insights I discovered during my 2+ years as the Chief of the Pharmacy Operations Division (POD) at the Defense Health Agency (DHA). More specifically, I will focus on items, issues, and changes that impact how the pharmaceutical industry does business with the Department of Defense (DoD). Now that I think about it, maybe in some ways, it was similar to being strapped to the top of a rocket and heading into the unknown of space, but bear with me and I'll ensure we all return safely.

This 3-part series includes:

Part I - A Time of Change & Transition

Part II - New Market Structure

Part III - TRICARE Formulary Tier 4 - What Industry Needs to Know

Tier 4 - What Industry Needs to Know

Department of Defense (DoD) Tier 4 Formulary Status
The Initial 18 Months

This article will discuss how Tier 4 status became part of the TRICARE formulary process, as well as examine how it has been applied by the DoD Pharmacy & Therapeutics Committee since it was first incorporated at the February 2019 DoD Pharmacy & Therapeutics Committee (P&T) meeting. First however, it is important to note that the establishment of a non-covered drug list or tier is not a new concept within the pharmacy benefit industry. In fact, although it is hard to state definitively due to constant formulary changes, it is believed that no Medicare Part D drug plans, nor any commercial drug plans cover every drug that is on the market. The fact that TRICARE did cover nearly all medications for such a long period, was an anomaly within the industry.

Prior to the February 2019 P&T meeting, the DoD TRICARE pharmacy benefit covered nearly all prescription drugs. The only exceptions were drugs used to treat a non-covered condition, drugs prescribed for cosmetic purposes, homeopathic and herbal preparations, dietary supplements, most multivitamins, and most over-the-counter (OTC) products (or combination drugs containing an OTC product). While some drugs could only be obtained after prior authorization or step therapy requirements were met, still the vast majority of prescription medications were available to beneficiaries. However, with the passage of Section 702 of the National Defense Authorization Act of 2018, Congress permitted the DoD to create a new non-covered (Tier 4) classification on the formulary. This benefit-changing section of the NDAA stated:

> TREATMENT OF CERTAIN PHARMACEUTICAL AGENTS.— (1) PHARMACY BENEFITS PROGRAM.—Such section is amended by adding at the end the following new paragraph: "(10) Notwithstanding paragraphs (2), (5), and (6), in order to encourage the use by covered beneficiaries of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and the Department of Defense (as determined by the Secretary, including considerations of better care, healthier people, and smarter spending), the Secretary may, upon the recommendation of the Pharmacy and Therapeutics Committee established under subsection (b) and review by the Uniform Formulary Beneficiary Advisory Panel established under subsection (c)— "(A) exclude from the pharmacy benefits program any pharmaceutical agent that the Secretary determines provides very little or no clinical effectiveness to covered beneficiaries and the Department under the program; and "(B) give preferential status to any non-generic pharmaceutical agent on the uniform formulary by treating it, for purposes of cost-sharing under paragraph (6), as a generic product under the TRICARE retail pharmacy program and mail order pharmacy program.". (ital. added)

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While most of the attention on this legislation has focused on the exclusion portion, note that the law also says non-generic (brand name) medications may receive preferential status and be placed in the lower copay, Tier 1 category. Moreover, it is important to note that any recommendations made by the DoD P&T committee regarding Tier 4 status or preferential formulary status must be reviewed by the Uniform Formulary Beneficiary Advisory Panel and approved by the DHA Director (or designee) before implementation.

Note too that the language in the Act is very broad ("better care, healthier people, and smarter spending") when providing guidance to the P&T committee in respect to how medications should be evaluated. In order to supplement this and provide more objective criteria, the P&T committee has adopted the following guiding principles for Tier 4 placement:

1. The drug has very little or no additional clinical effectiveness relative to similar agents in the class
2. There are significant safety risks associated with the drug relative to others in the class
3. The needs of TRICARE beneficiaries are met by available alternative agents
4. The drug contains at least one ingredient that is not covered under the TRICARE benefit
5. Negative concerns have been identified by FDA Advisory Committees, other regulatory agencies, or other nationally recognized expert clinical organizations
6. Other factors that may arise

How Tier 4 Has Been Implemented to Date

Starting with the first time medications were placed on Tier 4 in February 2019, the P&T Committee has exercised its due diligence to consider the full range of criteria when determining if a drug should be placed on Tier 4. For example, there have been several medications placed on Tier 4 that were unquestionably clinically effective, but in the eyes of the committee offered no real advantages when compared to medications already on the formulary. Likewise, some brand name drugs have been placed in Tier 4 when generically equivalent drugs have become available.

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Perhaps more interesting have been the drugs placed on Tier 4 that were newer formulations of older drugs or newer formulations of drugs currently on the formulary. Even though the manufacturers may have believed the new formulation provided advantages when compared to comparable drugs already on the formulary, the committee must not have felt those advantages were significant, the increased cost of the new formulation did not warrant inclusion on the formulary, or a combination of both. In other words, even if the new formulation of the drug, the new delivery mechanism, or other factors may indicate some slight advantage when compared to current products, price may then inform the decision. If the new drug is priced much higher than the currently available products, the committee may decide to place the drug in Tier 4. In cases such as this, a competitive pricing strategy can make the difference between Tier 1, 2, or 3 placement and ending up on Tier 4.

As can be seen, the DoD Pharmacy & Therapeutics Committee has quickly adapted to using the new Tier 4 status and is employing it to its full extent.

Key Takeaways for Industry

1. While price is not specifically listed as a selection principle for Tier 4, industry needs to be aware that if it brings a drug to market that, in the committee's view, offers little or no additional clinical benefit, but is priced much higher than similar agents, it may very well land in Tier 4. Similarly, if the committee believes beneficiary needs are already covered by the drugs currently on formulary, the new drug could be placed in Tier 4.

2. Simply put, drugs placed in Tier 4 are not covered by TRICARE. They are not available at MTFs or through mail order, and can only be obtained if a patient wants to pay 100% of the cost at a retail pharmacy.

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Key Takeaways for Industry

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3. To date, the DoD P&T committee has taken a methodical approach to placing medications in Tier 4. Starting with the February 2019 P&T meeting when 3 drugs were added, through the May 2020 P&T meeting when no drugs were added, approximately 38 drugs have been placed on Tier 4. This includes several brand name drugs for which generic alternatives became available, and higher cost drugs that have multiple lower cost, similarly effective alternatives available. However, industry needs to understand that this could change as Tier 4 placement becomes a more accepted and normal part of the formulary process.

4. Also, on an annual basis the DoD P&T committee will review all drugs that have been placed in Tier 4 to determine if there is new or additional cost and/or clinical data that will warrant moving the drug to a lower tier.

5. Lastly, industry needs to understand that the possibility of a medication being placed in excluded, non-covered Tier 4 status is no longer limited to cosmetic drugs and the like. If anything, the first 18 months of Tier 4 implementation has shown the DoD P&T committee evaluates the full spectrum of criteria when evaluating drugs for Tier 4 placement. Ensure that the ramifications of Tier 4 placement are clear within your company. In short, it means that for at least one year, your drug will essentially be unavailable to TRICARE's 9.4 million beneficiary population.

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