

DoD Formulary Placement of FDA-Approved Innovator Drugs

The Final Rule, *Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: TRICARE Pharmacy Benefits Program*, published on 27 July 2015 in the Federal Register, Vol. 80, No. 143, , pages 44269 – 44274, with effective date of 26 August 2015, clarifies the process for formulary placement of Food and Drug Administration (FDA) newly approved innovator drugs, giving the Pharmacy and Therapeutics (P&T) Committee up to 120 days to recommend tier placement on the uniform formulary. The Final Rule is available at <http://www.gpo.gov/fdsys/pkg/FR-2015-07-27/content-detail.html>

Innovator drugs that will be evaluated by the P&T Committee are FDA-approved medications under a biologic license application (BLA) or a new drug application (NDA), chemical types; Type 1 (new molecular entity) (NME), Type 2 (new active ingredient), Type 3 (new dosage form), and Type 4 (new combinations). The P&T Committee, at its discretion, may select other NDA chemical type innovator drugs to evaluate.

Market entrant innovator drugs approved by the FDA on 26 August 15 and thereafter would be assigned a pending status and be available under the terms applicable to non-formulary drugs. Innovator drugs approved by the FDA 30 days or less prior to a scheduled P&T Committee meeting would be considered at subsequent quarterly P&T Committee meeting. The DHA Director is the final approval authority for all P&T Committee formulary placement recommendations. In addition, tier status review may be deferred to the subsequent P&T Committee meeting if the innovator drug price is not available approximately 30 days prior to the next P&T Committee meeting.

For cost-effectiveness evaluation purposes, the relative cost effectiveness of the agent will be reviewed by the Committee using available pricing. The government is not soliciting Uniform Formulary Blanket Purchase Agreement (UF BPA) or Uniform Formulary Voluntary Agreements for Retail Refund (UF VARR) quotes for innovator drugs. Pharmaceutical manufacturers are under no obligation to obtain or provide a Distribution and Pricing Agreement (DAPA) for innovator drugs. For additional information on establishing a DAPA, contact Defense Logistics Agency (DLA) at PharmDAPA@dla.mil. See also: <https://www.medical.dla.mil/Portal/DapaMS/DapaMS.aspx>

TRICARE beneficiaries have access to innovator drugs at military treatment facility pharmacies, at 2nd tier cost-share at TRICARE Mail Order Pharmacy (TMOP) and network retail points of service, if they meet TRICARE's medical necessity criteria, or at 3rd tier cost-share at TMOP and retail without meeting TRICARE's medical necessity criteria.

DoD will not entertain innovator drug clinical presentations due to the quarterly volume for review. Industry partners may schedule a clinical presentation when the innovator drug is being re-evaluated in conjunction with a DoD Uniform Formulary Class review.