DoD Formulary Placement of FDA Newly 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 an effective date of 26 August 2015, clarifies the process for formulary placement of Food and Drug Administration (FDA) newly approved innovator drugs (i.e., "newly approved 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 the following 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 2015 and thereafter will 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 will be considered at the 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 will solicit Uniform Formulary Blanket Purchase Agreement (UF BPA) and Additional Discount Program (UF ADP) quotes for all newly approved drugs. There will be three solicitation windows leading up to the meeting during which manufacturers can submit price concessions. Drugs will be considered for Tier 1, Tier 2, Tier 3 and Tier 4/Not Covered designation based on the clinical and cost effectiveness information available at the time of the quarterly meeting. Drugs that are to be reviewed at the quarterly meeting will be posted at the health.mil/pandt page, approximately 30 days before the meeting date. 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.

Innovator drugs are designated as Tier 3 and therefore not generally available at MTFs unless the prescriber provides information that meets the criteria for medical necessity established by the P&T Committee. Innovator drugs are available through TMOP and retail pharmacies at the Tier 3 copay unless the prescriber provides information that meets the criteria for medical necessity established by the P&T Committee in which case they will be made available at the 2nd tier copay.

DoD will not entertain innovator drug clinical presentations due to the quarterly volume of newly approved drugs.