

## **DHCF Recommendation Brand Medically Necessary**

Require paper prior authorization (PA) for prescriptions for brand name drugs requested where there is a generic available that is on the Medicaid Maximum Allowable Cost (MAC) list and the prescription is not for a drug with a narrow therapeutic index. Also, require a prescriber to complete and submit the Food and Drug Administration (FDA) MedWatch form (see attachment) to the federal agency and provide a copy to the Department.

- The FDA form requires a prescriber to indicate the reason for ordering a brand drug and would provide the criteria necessary to approve a PA request for the brand drug. Approval criteria under the proposed policy include:
  - a.) a therapeutic failure of the generic drug(s)
  - b.) an adverse reaction to the generic drug(s)
  - c.) an allergic reaction to the generic drug(s)

To obtain PA for Brand Medically Necessary (BMN), the physician would be required to: (1) submit the FDA MedWatch form to the federal agency; (2) place a copy of the MedWatch form in the medical record and (3) submit a copy of the MedWatch form to the pharmacy to be sent to the Medicaid fiscal agent with the standard PA form. Approval of the PA would be granted upon submittal of the MedWatch form to the FDA and the state, given the reasons and criteria cited on the MedWatch form. Other BMN requirements would not change, e.g., physicians writing BMN in their own handwriting on the prescription. Approval would be granted based on documentation provided to the FDA on its brand drug criteria and information

- The PA process for drugs selected for brand medically necessary PA would be subject to a step PA process that will allow an initial 34-day supply via electronic (STAT) PA to allow paper PA time to be adjudicated.
  - The Medicaid program will develop a process to collect, review and retain the MedWatch form.
  - Drugs with a narrow therapeutic index, and drugs in therapeutic classes already requiring prior authorization (PA) would be exempt from this policy.
- Currently, more than 50 drugs require "brand medically necessary" documentation. Initially, the recommended policy would be applied to the drugs with the greatest number of brand medically necessary overrides, with exceptions for drugs with a narrow therapeutic index. Drugs subject to the BMN recommendation would include:
  - Clozaril
  - M.S.Contin
  - Xanax
  - Klonopin
  - Oxycontin
- Pharmacists would be allowed to submit claims for pharmaceutical care services under the category 'Therapeutic Interchange' to facilitate the use of generic drugs that are subject to the new BMN policy.
- In addition, the program would explore the use of physician profiling and face-to-face medical interventions – 'prescriber education' - with physicians who routinely write a significant volume of prescriptions with significant program expenditures for "brand medically necessary" drugs for which a generic version is available.