Change in Procedures for Brand Medically Necessary Pharmacy Prior Authorizations

The purpose of this bulletin is to notify providers of an upcoming change to the Brand Medically Necessary (BMN) pharmacy Prior Authorization (PA) process for members of the Connecticut Medical Assistance Program (please note: CADAP is not subject to BMN PA requirements). Effective July 1, 2012, the Department of Social Services (DSS) will require providers seeking BMN PA to submit a completed federal MedWatch form (FDA 3500) along with the Pharmacy PA form for instances where the patient has a reported allergic reaction to the generic product.

A brand name drug currently requires PA if there are at least two (2) therapeutically equivalent “A-rated” drugs in existence. (Please note: claims on which Medicare Part D is the primary payer, and claims for brand-name multi-source medications that are on the Preferred Drug List (PDL), are not subject to BMN PAs.) BMN authorization must be obtained if a prescriber has a documented clinical reason for a member to receive a brand name drug (i.e., the brand is medically necessary). The length of a BMN authorization approval for a non-controlled medication is for a period of twelve (12) months. For controlled substances, including Schedule II medications, approved authorizations carry an approval period of six (6) months.

The provider must complete and submit both the MedWatch form and DSS’ Pharmacy PA form in order for the request to be approved. The MedWatch form must document that the outcome attributed to the adverse reaction to the generic product met one of the following four criteria:

- **Life Threatening:** Check if suspected that:
  - The patient was at substantial risk of dying at the time of the adverse event, or
  - Use or continued use of the generic product might have resulted in the death of the patient

- **Hospitalization – initial or prolonged:** Check if admission to the hospital or prolongation of hospitalization was a result of the adverse event:
  - Do not check if:
    - A patient in the hospital received a generic product and subsequently developed an otherwise non-serious adverse event, unless the adverse event prolonged the hospital stay
  - Do check if:
    - A patient is admitted to the hospital for one or more days, even if released on the same day
    - An emergency room visit results in admission to the hospital. Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage)

- **Disability or Permanent Damage:** Check if the adverse event resulted in a substantial disruption of a person’s ability to conduct normal life functions. Such would be the case if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage, or disruption in the patient’s body function/structure, physical activities, and/or quality of life.

- **Required Intervention to Prevent Permanent Impairment/Damage:** Check if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a generic product.

The submitted MedWatch form must document the dates and clinical details of the therapeutic failure including the names of specific companies and the generic medications involved. The provider will be
required to provide a copy of the member’s record showing that other drug products within the same therapeutic class have been ruled out because previous clinical trials with that member produced ineffective or unsafe results (e.g. allergic response).

The MedWatch form and the Pharmacy PA form (and associated field completion instructions) can be obtained from the Connecticut Medical Assistance Program Web site at [www.ctdssmap.com](http://www.ctdssmap.com). From the Home page: navigate to Pharmacy Information; and under “Pharmacy Program Publications,” select the “MedWatch Form FDA 3500” link and/or the “Pharmacy Prior Authorization Form” to access the desired form(s). These forms can also be obtained by navigating to Information > Publications, and selecting the appropriate link within the “Authorization / Certification Forms” section.

Providers are reminded to complete all applicable fields on both the Pharmacy PA form as well as the MedWatch form and to include documentation to support the clinical statement when submitting their request to the Pharmacy Prior Authorization Assistance Center via fax at 1-866-759-4110.

Additionally, if assistance is needed with completing the MedWatch form, providers should indicate so when submitting their request to the Pharmacy PA Assistance Center.