

b. Cancer.

History: Effective September 1, 2003; amended effective July 26, 2004; July 1, 2006.

General Authority: NDCC 50-24.6-10

Law Implemented: NDCC 50-24.6; 42 USC 1396r-8

75-02-02-28. Drug use review board, grievances, and appeals.

1. The department shall implement a prospective and retrospective drug use review program for outpatient prescription drugs and determine which drugs shall be subject to prior authorization before payment will be approved. The department shall consider the advice and recommendations of the drug use review board before requiring prior authorization of any drug.
2. The drug use review board shall:
 - a. Cooperate with the department to implement a drug use review program;
 - b. Receive and consider information regarding the drug use review process which is provided by the department and interested parties, including prescribers who treat significant numbers of recipients;
 - c. Review and make recommendations to the department regarding drugs to be included on prior authorization status;
 - d. Review no less than once each year the status of the drugs that have been deemed to require prior authorization and make recommendations to the department regarding any suggested changes;
 - e. Review and approve the prior authorization program process used by the department, including the process to accommodate the provision of a drug benefit in an emergency situation;
 - f. Advise and make recommendations to the department regarding any rule proposed for adoption by the department to implement the provisions of state and federal law related to drug use review; and
 - g. Propose remedial strategies to improve the quality of care and to promote effective use of medical assistance program funds or recipient expenditures.
3. The drug use review board may establish a panel of physicians and pharmacists to provide guidance and recommendations to the board in considering specific drugs or therapeutic classes of drugs to be included in the prior authorization program.

4. The drug use review board shall make a recommendation to the department regarding prior authorization of a drug based on:
 - a. Consideration of medically and clinically significant adverse side effects, drug interactions and contraindications, assessment of the likelihood of significant abuse of the drug, and any other medically and clinically acceptable analysis or criteria requested by the drug use review board; and
 - b. An assessment of the cost-effectiveness of the drug compared to other drugs used for the same therapeutic indication and whether the drug offers a clinically meaningful advantage in terms of safety, effectiveness, or clinical outcome over other available drugs used for the same therapeutic indication.
5. Drug use review board meeting procedures.
 - a. Any interested party may address the drug use review board at its regular meetings if the presentation is directly related to an agenda item.
 - b. The drug use review board may establish time limits for presentations.
 - c. The department shall post on its web site the proposed date, time, location, and agenda of any meeting of the drug use review board at least thirty days before the meeting.
6. Within thirty days of the date the drug use review board's recommendation is received by the department, the department shall review the recommendations and make the final determination as to whether a drug requires prior authorization and, if so, when the requirement for prior authorization will begin. If the department's final determination is different from the recommendation of the drug use review board, the department shall present, in writing, to the drug use review board at its next meeting the basis for the final determination.
7. The department shall post on its web site the list of drugs subject to prior authorization and the date on which each drug became subject to prior authorization.
8. Grievances.
 - a. An interested party may file a grievance with the department regarding a decision of the department to place a drug on prior authorization. In order to be considered by the department, the grievance must:
 - (1) Be in writing;

- (2) State the specific reasons the interested party believes the decision to be erroneous or not, based on the facts available to the department at the time of the decision;
 - (3) Provide any supporting documentation; and
 - (4) Be received by the department within forty-five days of the department's final determination to include the drug on prior authorization.
 - b. The department shall consider all grievances that were filed in a timely manner. Within thirty days after the time for filing grievances has expired, the department shall determine whether to change its decision regarding placing a drug on prior authorization. The requirement for prior authorization shall not be suspended during the department's review of timely filed grievances.
9. A recipient may appeal the department's denial, suspension, reduction, or termination of a covered drug based upon application of this section as authorized under North Dakota Century Code chapter 28-32.

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