**Section 140.442 Drug Product Prior Approval and the Preferred Drug List**

a) The Department may require prior approval for the reimbursement of any drug product, except as provided in this Section. Determinations of whether a drug product is listed as preferred on the Preferred Drug List (PDL) and when prior approval for any drug product is required shall be made in the following manner:

1) The Department shall consult with the Drug and Therapeutics Advisory Board (the Board), comprised of individuals that possess appropriate expertise in the areas of pharmacology and medicine, when determining which drug products to list as preferred on the PDL, as well as which drug products outside of the PDL require prior approval.

2) Board Members. The Board shall be compromised of voting members appointed by the Governor in accordance with Section 5-30.11 of the Public Aid Code.

3) Board Advisors. The Department will select nonvoting clinicians to advise the Board in accordance with Section 5-30.11.

4) Board members shall serve 3 year terms without compensation. Board advisors are appointed by the Department to serve 3 years terms without compensation.

5) Board members and advisors shall disclose conflicts of interest and shall not participate in matters in which they have a potential conflict of interest.

6) The Board shall meet not less than one time per calendar quarter. The recommendations of the Board shall be non-binding upon the Department and can in no way bind or otherwise limit the Department's right to determine, in its sole discretion, those drugs that shall be available with or without prior approval, or as preferred or non-preferred products.

7) Upon U.S. Food and Drug Administration approval of a new drug product, the new drug product shall require prior approval until the Department determines otherwise. When a newly approved drug product enters the market, or when post-marketing information becomes available for existing drug products requiring prior approval, the drug manufacturer shall be responsible for submitting materials to the Department that the Department and the Board will consider in determining whether reimbursement for the drug product will require prior approval.

8) New dosage strengths and new dosage forms of drug products already available without prior approval (see Section 140.440(e)) shall be available without prior approval upon the request of the manufacturer, unless otherwise designated by the Director. In such a case, the Director shall submit the new dosage strength, or new form, to the prior approval procedures described in this Section.

9) To ensure all Board members and the Department have the same information regarding drug products, drug manufacturers shall provide, in writing, all relevant drug product information to the Department and the Board in its entirety. The Board shall only consider information given to both the entire Board and the Department when reviewing a drug product.

10) The Board shall evaluate drug products in an impartial manner, and base recommendations on clinical and cost effectiveness factors.

11) Board members shall make motions and take votes during the meeting, and the Department shall record the results in the meeting minutes.

12) The Department shall make a final determination on the status of drug products reviewed by the Board. Final determinations will be made using complete clinical and financial information received by the Department. The Department shall notify the Board and the affected manufacturers of all final determinations within 30 business days after receipt of a recommendation from the Board.

13) Drug manufacturers shall be afforded an opportunity to request reconsideration of products recommended for prior approval or non-preferred status. The drug manufacturers may submit any information they deem appropriate to support their request for reconsideration of the drug product. All reconsideration requests must be submitted in writing to the Department for inclusion on the agenda at a subsequent meeting.

14) The Department shall require that contraceptive drugs and products are available without prior approval.

b) Prior approval shall be given for drug products if:

1) The drug is a legend item; and

2) The drug product is used in accordance with predetermined standards consistent with the compendia consisting of the American Hospital Formulary Service Drug Information, the United States Pharmacopeia, as well as the peer-reviewed medical literature; and

3) Either:

A) The drug is necessary to prevent a higher level of care, such as institutionalization; or

B) The prescriber has determined that the drug is medically necessary over other available treatments.

c) Decisions on all requests for prior approval by telephone or other telecommunications device and, upon the Department's receipt of the request, shall be made by the same time of the Department's next working day. In an emergency situation, the Department shall provide for the dispensing of at least a 72-hour supply of a covered prescription drug.

d) In accordance with subsection (d)(2), the Department may require approval prior to reimbursement for a brand name prescription drug if the patient for whom the drug is prescribed has already received three brand name prescription drugs in the preceding 30-day period and is 21 years of age or older.

1) For purposes of this subsection (d), brand name prescription drugs in the following therapeutic classes shall not count towards the limit of three brand name prescription drugs and shall not be subject to prior approval requirements because a patient has received three brand name prescription drugs in the preceding 30 days.

A) Antiretrovirals;

B) Antineoplastics; and

C) Anti-Rejection Drugs.

2) Brand name prescription drugs are exempt from the prior approval requirements of this subsection (d) if:

A) there are no generic therapies for the condition treated within the same therapeutic drug class; or

B) the Department determines that the brand name prescription drug is cost effective.

e) Effective July 1, 2012, the Department may require prior approval prior to reimbursement for a prescription drug if the patient for whom the drug is prescribed has already received four prescription drugs in the preceding 30-day period. For purposes of this subsection (e), prescription drugs in the following therapeutic classes shall not count towards the limit of four prescription drugs and shall not be subject to prior approval requirements because a patient has received four prescription drugs in the preceding 30 days:

1) Antiretrovirals;

2) Antineoplastics;

3) Anti-Rejection Drugs; and

4) Effective July 1, 2014, Antipsychotics.

(Source: Amended at 44 Ill. Reg. 13678, effective August 7, 2020)