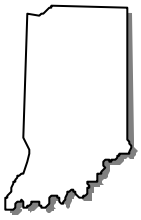
Indiana Health Coverage Programs



P R O V I D E R B U L L E T I N

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To: All Indiana Health Coverage Programs Physicians, Podiatrists, Dentists, Hospitals, Clinics, Mental Health Providers, and Pharmacies

Subject: Implementation of Prior Authorization Requirement for Brand Medically Necessary Drugs

Note: The information in this bulletin about prior authorization and payment methodology, may vary for practitioners and providers rendering services to members enrolled in the risk-based managed care (RBMC) delivery system.

Policy Change

Effective September 4, 2001, a prescriber's indication of "brand medically necessary" for a prescribed drug will require prior authorization. What this means is that, if a prescriber chooses to specify "brand medically necessary" for a drug, he or she must obtain prior authorization for that brand name drug before the pharmacist can be paid for the brand name drug. This action implements Medicaid rule *405 IAC 5-24-8, Prior Authorization; brand name drugs.*

405 IAC 5-24-8 Prior authorization; brand name drugs

Authority: IC 12-8-6-5: IC 12-15-1-10: IC 12-15-21-2

Affected: IC 12-13-7-3: IC 12-15

Sec. 8. a) Prior authorization is required for a brand name drug that:

(1) Is subject to generic substitution under Indiana Law; and

(2) The prescriber has indicated is "brand medically necessary" either orally or in writing on the prescription or drug order.

(b) In order for prior authorization to be granted for a brand name drug in such instances, the prescriber must:

(1) indicate on the prescription or drug order, in the prescriber's own handwriting, the phrase "brand medically necessary"; and

(2) seek prior authorization by substantiating the medical necessity of the brand name drug as opposed to the less costly generic equivalent.

The prior authorization number assigned to the approved request must be included on the prescription or drug order issued by the prescriber or relayed to the dispensing pharmacist by the prescriber if the prescription is orally transmitted. The office may exempt specific drugs or classes of drugs from the prior authorization requirement, based on cost or therapeutic considerations. Prior authorization will be determined in accordance with the provisions of 405 IC 5-3 and 42 U.S.C. 1396r-8(d)(5). *(Office of the Secretary of Family and Social Services; 405 IAC 5-24-8; filed Jul 25, 1997, 4:00 p.m.: 20 IR 3346: filed Sep 27, 1999, 8:55 a.m.: 23 IR 319)*

Background Information

The basis for this action is the Food and Drug Administration (FDA)'s position that therapeutically equivalent generic drugs have the same effect in the body as their more expensive brand name counterparts. Therefore, it does not make sense for a tax-funded drug benefit to subsidize the additional cost of brand-name drugs when less expensive, equally effective, generic equivalents can be used. The prior authorization system will be used to allow prescribers to substantiate what constitutes the *medical necessity* of a given brand name drug, when the prescriber chooses to write "brand medically necessary."

The Office of Medicaid Policy and Planning (OMPP) strives to employ prior authorization only in circumstances in which it is clearly warranted to do so. That would include utilization control, cost control, or ensuring quality of care. Over the past two years, Indiana Medicaid reimbursed an estimated extra three million dollars associated with uncontrolled "brand medically necessary." That is three million dollars of additional tax dollars expended for brand name drugs, when therapeutically equivalent, less expensive generics could have been used, simply because "brand medically necessary" overrode otherwise applicable payment levels to the pharmacy. At a time when Medicaid faces unsustainable cost increases, we would be remiss not to implement this reasonable and practical program policy that many other states have already adopted.

Prior Authorization is required only for those drugs that have an established federal upper limit (FUL), maximum allowable cost (MAC), and an "AA" or "AB" rated generic equivalent. The following drugs are excluded from the PA requirement:

- Coumadin®
- Dilantin®

- Lanoxin®
- Premarin®
- Provera®
- Synthroid®
- Tegretol®

How The Process Will Work

Prescribers

In the past, if you wrote a prescription for a substitutable brand name drug for an Indiana Medicaid beneficiary signed on the "Dispense as Written" line, and wrote "brand medically necessary" across the face of the prescription, the pharmacist dispensed the prescribed brand name drug and was paid for it. You were not asked what constituted the medical necessity of the more expensive brand name drug as opposed to generic equivalents. As of September 4, 2001, should you chose to continue to write "brand medically necessary" for such drugs, you will have to document the medical necessity for the brand name drug (as opposed to the generic) through the prior authorization process. A description of that process, and how it meets applicable state and federal requirements for drug prior authorization programs, is found below.

Pharmacists

If after September 4, 2001, you receive a prescription for a substitutable brand name drug that is subject to federal MAC limits and that prescription has "brand medically necessary" specified, you will not be able to get paid for the prescribed brand name drug unless the prescriber has obtained prior authorization. If your request is filed point-of-sale (POS) you will know whether or not prior authorization has been obtained if the claim denied. You may receive a call from a prescriber asking you for the National Drug Code (NDC) of the drug for which he or she is seeking prior authorization; if you can assist the member by providing this information, it will facilitate his or her being able to obtain prior authorization for the drug, and thus assist you in getting paid for what is being prescribed. Bear in mind that, ultimately, it is the prescribing physician's responsibility to initiate and obtain prior authorization for instances in which he or she opts to specify "brand medically necessary."

Description Of The Prior Authorization Process

Prior Authorization for Brand Medically Necessary will be granted in cases where documentation indicates the following.

- *Allergic reaction to excipients in the generic products* – If multiple generics are available, a history of trials of generics from multiple companies must exist.
- *A therapeutic failure to the generic product* – A history of documented previous purchases will be reviewed to determine dosing and compliance issues.
  - Prescribers and pharmacists are encouraged to report experiences with generic drug products that create concerns in product quality, performance, or safety.
  - When a physician or pharmacist observes differences in the pharmacologic effect of a generic drug over its branded drug product in a patient, the health professional is asked to report this concern to the Federal Drug Administration, using the MEDWatch form.
  - If the concern immediately above is the rationale for request of a branded drug, a copy of the MEDWatch form or alternative reporting system submitted to the Federal Drug Administration (FDA) must accompany the prior authorization (PA) request. (One may also call 1-800-FDA-1088 to obtain MedWatch forms.)

Note: Patient requests for brand name drugs will not be approved.

Drugs subject to FUL are listed in the *Indiana Health Coverage Programs (IHCP) Provider Manual* in *Chapter 9*. Additions and deletions are published in IHCP banner page articles and bulletins.

Prior Authorization Process

To obtain approval, the physician must send the following.

- An *Indiana Prior Authorization Request* form (PA Request). A form may be downloaded from www.indianamedicaid.com. The following must be included on or with the form:
  - The 11-digit NDC for the requested drug must be included as the "Service Code Required."
  - The medical necessity for a brand name drug must be documented in the "Clinical Summary." Alternatively, a letter explaining the need for generic substitution exemption may be attached to the prior authorization request.
  - A copy of the MEDWatch form or alternate reporting system submitted to the FDA, if applicable.
- Prior authorization approval generally effective for a one-year supply.

The PA Request and other documentation or letters should be mailed or faxed to the Health Care Excel (HCE) Prior Authorization (PA) Department. PA requests also be called to the HCE Department. However, telephone approvals can only be given for one month and a PA Request will need to be completed as described above and faxed or mailed to the HCE PA Department.

Health Care Excel, Prior Authorization Department
P.O. Box 531520
Indianapolis, IN 46253-1520
Fax Number: (317) 347-4537
Telephone: (317) 347-4511 or (800) 457-4518

Pharmacy Claims Processing

Prescription claims for brand name drugs requiring prior authorization will deny by the Indiana*AIM* claims processing system with a message that prior authorization is required. The pharmacist may then take three possible courses of action.

- Contact the prescriber to get the order changed so a generic drug may be substituted.
- Contact the prescriber and ask he or she submit a PA request.
- Give the prescription back to the patient so he or she can return to the prescribing practitioner.

If the claim is denied and there is an emergency, the prescriber cannot be reached, or the prescription is presented after normal business hours at the HCE PA Department (including week-ends and holidays), a 72-hour supply (*Sec. 1927 (d) 42 USC 1396r-8, "OBRA '90"*) of the drug may be dispensed by the pharmacy at no risk to the pharmacy. Prescriptions meeting these criteria may be dispensed in a sufficient amount to provide medication to the patient until the HCE PA Department can review the PA request.

Claim instructions for emergency situations, situations when the prescribing physician is unavailable, or instances when the HCE PA Department is closed are as follows:

- The pharmacist may use the "06" indicator in the Brand Field Locator on the Drug Claim Form if the prescriber has written "brand medically necessary" in his or her own hand-writing or met other requirements of *IC 16-42-22-10* for "Brand Medically Necessary" Medicaid or Medicare prescriptions.
- The correct number of day's supply (less than or equal to three) would need to be included on the pharmacy claim form.
- If the package size is for greater than three days and cannot be broken, the pharmacist may also dispense the medication at no risk to the pharmacy. However, the claim must be held until PA is obtained for the package size. Prescriptions presented on holiday weekends and filled for more than three days will need to be handled in the same manner.
  - Information may be placed on the PA Request accompanied by the prescription and faxed to the HCE PA Department. A PA number will then be faxed back to the pharmacy.

- Alternatively, the PA Department may be called during business hours, 7:30 a.m. – 6 p.m., Central Standard Time, Monday through Friday.

Prescribers should bear in mind that if they choose to write "brand medically necessary" on their prescriptions and do not initiate the required prior authorization request, it could result in the patient encountering difficulties in obtaining their medication. The mutual goal should be to ensure that patients receive less expensive, therapeutically equivalent generic products whenever feasible and reasonable, while allowing for payment of more expensive brand name products if there are true and valid, documented medical reasons for use of the brand name product.

Further Information

Questions about this bulletin may be directed to the Health Care Excel Medical Policy Department at (317) 347-4500.