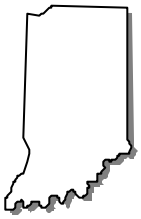
Indiana Health Coverage Programs



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

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To: All Indiana Medicaid Prescribers and Pharmacy Providers

Subject: Indiana Rational Drug Program

Note: The information in this bulletin regarding prior authorization payment methodology does not apply to practitioners and providers rendering services to members enrolled in the risk-based managed care (RBMC) delivery system.

Overview

The Prior Authorization (PA) Department of Health Care Excel (HCE) will initiate a new Rational Drug Program effective January 7, 2002. The Drug Utilization Review Board, after careful review of this initiative, approved moving forward with the Indiana Rational Drug Program at the October 2001 meeting. This program has been approved by the Indiana Health Coverage Programs (IHCP) and is modeled after the successful West Virginia Rational Drug Therapy Program. Prior authorization services will be provided for the following two drugs and three drug classes: Stadol-NS®, Ultram® (tramadol and products containing tramadol), non-steroidal anti-inflammatory drugs (including COX-2 inhibitors), peptic acid disease drugs, and growth hormones. This program is designed for fee-for-service, Primary Care Case Management (PCCM), and Package C members. The intent of the program is to promote quality of care and control costs.

The Indiana Rational Drug Program will be carried out in compliance with all applicable provisions of both state and federal law. Prescribing practitioners will be responsible for initiating and obtaining prior authorization (PA) for all prescriptions they issue that require prior authorization.

Attached to this bulletin are the required forms for non-steroidal anti-inflammatory drugs (including COX-2 inhibitors), UltramÒ (tramadol and products containing tramadol), peptic acid disease drugs, growth hormones, and Stadol-NSÒ.

Current rules and procedures will remain in effect regarding appeals of denied PA requests. The prescriber may request an administrative review by telephone, followed by a written request, or by faxing to the PA department.

Health Care Excel
Prior Authorization Department
Attn: Indiana Rational Drug Program
2629 Waterfront Parkway East Drive, Suite 200
Indianapolis, IN 46214
Telephone: (317) 347-4511
Fax: (317) 347-4537
Toll Free: (800) 457-4518

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

Prior Authorization Process

PA review operations consist of the following components.

Prior authorization will be given to drug categories related to the prior authorization program, and not by national drug codes (NDCs). Prescribers and their authorized office personnel may submit requests via telephone, fax, or mail using the following address, and telephone and fax numbers.

Health Care Excel
Prior Authorization Department
Attn: Indiana Rational Drug Program
2629 Waterfront Parkway East Drive, Suite 200
Indianapolis, IN 46214
Telephone: (317) 347-4511
Fax: (317) 347-3593
Toll Free: (800) 457-4518

Each request will be entered into Indiana*AIM* and will be given a unique PA number. There will be a 24-hour response by telephone, fax, or mail on all pharmacy requests. Telephone authorizations are only given for one month, and then a written prior authorization request must be completed and faxed or mailed to the HCE PA department. The 24-hour response by mail will begin on the date and time the mail has been received by HCE. When the PA office is closed, provisions will be made within the Indiana*AIM* system to authorize a minimum 72-hour supply of medications. Business hours for the PA department are 7:30 a.m. – 6:00 p.m. Indianapolis Time, Monday through Friday. A recorded message on the telephone line will instruct those who call after hours, on weekends or holidays, that when the office is closed, the pharmacist may issue a supply of drugs that will cover a

minimum of 72 hours. During long holiday weekends, larger quantity supplies will be available.

Criteria for Stadol-NSÒ, UltramÒ (tramadol and products containing tramadol), non-steroidal anti-inflammatory drugs (including COX-2 inhibitors), peptic acid disease drugs, and growth hormones

Criteria for the Indiana Rational Drug Program are based on national standards and have been approved for use in the IHCP.

Stadol-NS® Criteria

Stadol-NS® will only be authorized for the short-term control of acute pain.

Migraine Pain: two (2) vials per month maximum therapy

Non-Migraine Pain: one (1) vial per month maximum therapy

Initial dose of one vial (2.5 ml) per 30-day period does not require prior authorizations.

> *Note: A PA form is **required** and must be filled out completely for processing PA requests. You can obtain this form from this bulletin, or on the IHCP Web site at www.indianamedicaid.com.*

Ultram® (tramadol and products containing tramadol) Criteria

1. Authorized only for chronic pain of moderate or moderately severe intensity. Tramadol will be considered a second-line drug of choice behind nonsteroidal anti-inflammatory drug (NSAID) pain therapy.
2. Authorized for patients with chronic pain and are greater than 70 years of age. (300 mg/day maximum dose.)
3. Authorized for patients with a previous therapeutic failure of full-dose NSAIDs.
4. Authorized for patients who have high risk of adverse effects from NSAIDs.
   a) History of risk of GI bleed
   b) Current drug therapy causing high risk
      1) Warfarin
      2) Cyclosporine
      3) Lithium
      4) Ace Inhibitor/beta blocker with diagnosis of congestive heart failure.
   c) Other conditions (e.g., renal disease).
5. Not authorized for short-term acute pain or emergency use.
6. Not authorized for patients with previous or suspected substance abuse unless benefit outweighs the risk. (Benefit/risk justification must be stated.)
7. Not authorized for patients with a diagnosis of seizure disorder unless the benefit outweighs the risk. (Benefit or risk justification must be stated.)

8. Not authorized for patients with concomitant opioid use.
9. Not authorized for patients with a recent therapeutic failure of a stronger opioid.
10. Maximum of 8 tablets (400mg) per day for any condition or diagnosis.

> *Note: A PA form and the tramadol PA form are **required** and must be filled out completely for processing PA requests. You can obtain these forms from this bulletin, or on the IHCP Web site at www.indianamedicaid.com.*

Nonsteroidal Anti-Inflammatory Drug (NSAID) Criteria

All brand-name non-steroidal anti-inflammatory medications and COX-2 inhibitors require prior authorization.

- Step therapy between classes of NSAIDs is recommended before authorization of brand-name drug products.
- Patient should be treated with different CLASSES of NSAIDs before going to brand name agent.
- Criteria state that a patient must fail two (2) trials of generic source agents that last at least two (2) weeks in duration, before a brand name NSAID can be authorized.
- COX-2 inhibitors or brand name NSAIDs containing a combination of an NSAID and misoprostol will be authorized by utilizing the NSAID risk scale.
- The following is the policy for the authorization of COX-2 inhibitors or misoprostol/NSAID combinations.
  - Any patient greater than 75 years of age that has been prescribed a full dose prescription NSAID.
  - Any patient with a history of serious NSAID gastrointestinal complications (e.g., GI bleed requiring hospitalization) that has been prescribed a full dose prescription NSAID.
  - Any patient using a full dose prescription NSAID and NOT falling into the above two (2) categories must have a total point score of thirteen (13) points or more from Chart 1 below.

Table 1 – Patient Points Determination

Patient's Age/Issue Points Patient's Points	**Points**	**Patient's Points**
<25	0	
26-30	1	
31-35	2	
36-40	3	
41-45	4	
46-50	5	
51-55	6	
56-60	7	
61-65	8	
66-70	9	
71-75	10	
Concurrent Oral Steroid	Use No = 0 Yes = 4	
History of NSAID GI Side Effects	None = 0 Occasional = 4 Frequent = 5	
Current NSAID	Use OTC or PRN Rx = 0 RX – 1	

Patient's Age/Issue Points Patient's Points	Points	Patient's Points
General Health Status (Select only one limitation category)	No function limitation = 0 Patient limited in recreational activities = 1 Patient limited in vocational activities = 2 Patient limited in self-care activities = 3	
	SUM OF POINTS	

*Note: A PA form and the COX-2 Inhibitor (COX-1 Sparing) Brand Name NSAID authorization form are **required** and must be filled out completely for processing PA requests. You can obtain these forms from this bulletin, or on the IHCP Web site at www.indianamedicaid.com.*

Peptic Acid Disease Drugs Criteria

Peptic Acid Disease Medication Use Chart

H2-Antagonists	Cimetidine Famotidine Nizatidine Ranitidine Ranitidine/bismuth citrate
All Proton Pump Inhibitors (PPIs)	Esomeprazole Lansoprazole Omeprazole Pantaprazole Rabeprazole
Other Agents	Sulcralfate Cisapride Misoprostol

Basic Criteria

Goal of program is to get the patient to the lowest sustainable acid suppression dosing.

Prior authorization is required for any treatment consisting of full therapeutic doses of an acid suppression agent beyond an acute treatment period of 90 days.

Full therapeutic dosing is considered.

- Any dose of a Proton Pump Inhibitor
- H-2 Antagonist doses as follows:
  - Ranitidine, Nizatidine > 150 mg per day
  - Famotidine > 20 mg per day
  - Cimetidine > 400 mg per day

Alternating regimens of different drugs beyond the 90 days will require renewed prior authorization. Repeating a full therapeutic regimen of any of the drugs at any time will need renewed prior authorization.

Maintenance doses (doses less than those stated above) of H-2 receptor antagonist within the guidelines do not need prior authorization.

Therapeutic exemption from future prior authorization will be granted for the following conditions (maximum authorization time is one year before another review).

- Hypersecretory conditions (Zollinger-Ellison, systemic mastocytosis, multiple endocrine adenomas)
- Symptomatic Gastroesophageal Reflux, not responding to or failure to adequate therapeutic trials of H-2 Antagonist
- Barrett's esophagus
- Esophageal Stricturing
- Erosive Esophagitis
- Other conditions will be considered on an individual basis.

Initial therapeutic doses of H-2 antagonists or proton pump inhibitors will be prior authorized if they are being utilized for a diagnosis authorized by the Drug Utilization and Review Board. After initial therapy, of 90 days, guidelines require that the dosing of the agent be stepped down in increments of 90 days to try to achieve the lowest sustainable maintenance dosing.

Authorization for treatment of symptomatic relapses on maintenance therapy, after a previous diagnosis of duodenal or peptic ulcer, will require documentation of H. pylori testing. (>90% of recurring duodenal ulcers are caused by H. pylori infection.)

After the documentation of H. pylori testing, the medication may be re-authorized for therapeutic dosing that is based on the results of the H. pylori testing and patient results.

Sulcralfate Criteria

Sulcralfate is indicated for the healing of open wounds within the GI tract.

Sulcralfate prescribed with another peptic acid disease drug for a period exceeding 30 days will be considered duplicative therapy and will not be authorized.

Sulcralfate prescribed for GERD will not be authorized. Maintenance dosing of 1 gram twice daily does not require prior authorization.

Misoprostol and Misoprostol Containing Product Guidelines

Misoprostol is indicated for the prevention of GI side effects associated with the use of non-steroidal anti-inflammatory drugs. Justification is required for treatment with any dose of misoprostol. When used as adjunctive therapy with a NSAID it will be authorized upon request based on the patient risk scale. When used concurrently with other peptic acid drugs, it will be considered as duplicative therapy and drug choice will have to be made.

> *Note: A PA form is **required** and must be filled out completely for processing PA requests. You can obtain these forms from this bulletin, or on the IHCP Web site at www.indianamedicaid.com.*

Growth Hormone Criteria

Growth hormone therapy for growth hormone deficiency or supplementation in adults will not be authorized.

Growth Hormone Deficiency in Children

1. Standard deviation of 2.0 or more below mean height for chronological age.
2. No expanding intracranial lesion or tumor diagnosed.
3. Growth rate below five centimeters per year.
4. Failure of any two stimuli test to raise the serum growth hormone level above 10 nanograms/milliliter.
5. Bone age 14-15 years or less in females and 15-16 years or less in males.
6. Epiphyses open.

Growth Retardation of Chronic Renal Insufficiency

1. Standard deviation of 2.0 or more below mean height for chronological age.
2. No expanding intracranial lesion or tumor diagnosed.
3. Growth rate below five centimeters per year.
4. Irreversible renal insufficiency with a creatinine clearance <75 ml/min per 1.73m^2 but pre-renal transplant.
5. Bone age 14-15 years or less in females and 15-16 years or less in males.
6. Epiphyses open.

Turner's Syndrome

1. Chromosomal abnormality showing Turner's syndrome.
2. Standard deviation of 2.0 or more below mean height for chronological age.
3. No expanding intracranial lesion or tumor diagnosed.
4. Growth rate below five centimeters per year.
5. Bone age 14-15 years.
6. Epiphyses open.

Neurosecretory Growth Retardation

1. Standard deviation of 2.0 or more below mean height for chronological age.
2. No expanding intracranial lesion or tumor diagnosed.
3. Growth rate below five centimeters per year.
4. Bone age 14-15 years or less in females and 15-16 years or less in males.
5. Epiphyses open.
6. Mixed or normal response to any two stimuli test in raising serum growth hormone above 10 nanograms/milliliter.
7. IGF-1 levels less than 50th percentile for chronological age.

*Note: A PA form is **required** and must be filled out completely for processing PA requests. You can obtain these forms from this bulletin, or on the IHCP Web site at www.indianamedicaid.com*