



# Pharmacy Providers

## Gabapentin and Pregabalin Claims Require Diagnosis Code

Effective with dates of service on and after January 10, 2006, an ICD-9-CM diagnosis code will be required on all gabapentin (Neurontin<sup>®</sup>) and pregabalin (Lyrica<sup>®</sup>) claims. It is recommended that prescribing physicians supply the diagnosis on the prescription. The pharmacy will need to contact the prescribing provider if no diagnosis is noted on the prescription. Beginning January 10, 2006, gabapentin and pregabalin will be covered only for the conditions or diagnoses that are listed below.

1. Neuropathic pain: for a diagnosis indicating neuropathic pain, submit diagnosis code 3569
2. Epilepsy: for a diagnosis of epilepsy, submit the most appropriate one of the following diagnosis codes (**KMAP will accept 34500 for epilepsy diagnoses within the range of 34500 to 34591**):
  - a. 34500 – generalized nonconvulsive epilepsy without mention of intractable epilepsy
  - b. 34501 – generalized nonconvulsive epilepsy with intractable epilepsy
  - c. 34510 – generalized convulsive epilepsy without mention of intractable epilepsy
  - d. 34511 – generalized convulsive epilepsy with intractable epilepsy
  - e. 3452 – generalized convulsive epilepsy, petit mal status
  - f. 3453 – generalized convulsive epilepsy, grand mal status
  - g. 34540 – partial epilepsy, with impairment of consciousness without mention of intractable epilepsy
  - h. 34541 – partial epilepsy, with impairment of consciousness with intractable epilepsy
  - i. 34550 – partial epilepsy, without mention of impairment of consciousness without mention of intractable epilepsy
  - j. 34551 – partial epilepsy, without mention of impairment of consciousness with intractable epilepsy
  - k. 34560 – infantile spasms without mention of intractable epilepsy
  - l. 34561 – infantile spasms with intractable epilepsy
  - m. 34570 – epilepsy partialis continua without mention of intractable epilepsy
  - n. 34571 – epilepsy partialis continua with intractable epilepsy
  - o. 34580 – other forms of epilepsy without mention of intractable epilepsy
  - p. 34581 – other forms of epilepsy with intractable epilepsy
  - q. 34590 – epilepsy, unspecified without mention of intractable epilepsy
  - r. 34591 – epilepsy, unspecified with intractable epilepsy
  - s. 78039 – other convulsions
  - t. 9070 – epilepsy due to late effects of intracranial injury

## **Additional Pregabalin Limitations**

In addition to the diagnosis requirement described above, effective with dates of service on and after January 10, 2006, pregabalin (Lyrica) will only be covered for ages 18 and older. There will also be a quantity limit of no more than three units (capsules) per day, not to exceed 600 mg per day. Prior authorization will not override these limitations.

Information about the Kansas Medical Assistance Program as well as provider manuals and other publications are on the KMAP Web site at <https://www.kmap-state-ks.us>. For the changes resulting from this provider bulletin, select the *Pharmacy Provider Manual*, pages 8-10 through 8-24.

For a hard copy of the revised manual pages, send a request to Publications Coordinator, 3600 SW Topeka Blvd, Suite 204, Topeka, KS 66611 or send an e-mail to [publications@ksxix.hcg.eds.com](mailto:publications@ksxix.hcg.eds.com). Specify the bulletin by number, provider type and date, and include your mailing address with a specified individual or office if possible.

If you have any questions, please contact the KMAP Customer Service Center at 1-800-933-6593 (in state providers) or 785-274-5990 between 7:30 a.m. and 5:30 p.m., Monday through Friday.

**Gabapentin (Neurontin®)**

An ICD-9-CM diagnosis code is required on all gabapentin claims. The pharmacy will need to contact the prescribing provider if no diagnosis is noted on the prescription. Gabapentin is only covered for the following conditions or diagnoses not listed below:

1. Neuropathic pain: for a diagnosis indicating neuropathic pain, submit diagnosis code 3569
2. Epilepsy: for a diagnosis of epilepsy, submit the most appropriate one of the following diagnosis codes (**KMAP will accept 24500 for epilepsy diagnoses within the range of 34500 to 34591**):
  - a. 34500 – generalized nonconvulsive epilepsy without mention of intractable epilepsy
  - b. 34501 – generalized nonconvulsive epilepsy with intractable epilepsy
  - c. 34510 – generalized convulsive epilepsy without mention of intractable epilepsy
  - d. 34511 – generalized convulsive epilepsy with intractable epilepsy
  - e. 3452 – generalized convulsive epilepsy, petit mal status
  - f. 3453 – generalized convulsive epilepsy, grand mal status
  - g. 34540 – partial epilepsy, with impairment of consciousness without mention of intractable epilepsy
  - h. 34541 – partial epilepsy, with impairment of consciousness with intractable epilepsy
  - i. 34550 – partial epilepsy, without mention of impairment of consciousness without mention of intractable epilepsy
  - j. 34551 – partial epilepsy, without mention of impairment of consciousness with intractable epilepsy
  - k. 34560 – infantile spasms without mention of intractable epilepsy
  - l. 34570 – epilepsy partialis continua without mention of intractable epilepsy
  - m. 34571 – epilepsy partialis continua with intractable epilepsy
  - n. 34580 – other forms of epilepsy without mention of intractable epilepsy
  - o. 34581 – other forms of epilepsy with intractable epilepsy
  - p. 34590 – epilepsy, unspecified without mention of intractable epilepsy
  - q. 34591 – epilepsy, unspecified with intractable epilepsy
  - r. 78039 – other convulsions
  - s. 9070 – epilepsy due to late effects of intracranial injury.

**Influenza Treatment:**

Prescription drug claims for neuraminidase inhibitors zanamivir (Relenza®) and oseltamivir (Tamiflu®) will be paid for dates of service during the influenza (flu) season only (October 1 through April 30) and will be limited to one course of therapy per beneficiary per flu season. According to the Kansas Department of Health and Environment, the Centers for Disease Control consider the flu season in Kansas to be from mid-October through mid-April. One course of therapy for both Relenza® and Tamiflu® are defined by the company in the package insert as five days of therapy.

**Ketorolac (Toradol®)**

Claims submitted for greater than a 5 days supply will be denied.

**Long-Term Care Units (LTCU):**

Hospitals approved by SRS with long-term care units may bill for covered drugs dispensed for use by Medicaid beneficiaries. The following guidelines apply only to LTCUs, where automatic stop orders in the acute care area might result in an unreasonable number of billings for drugs used on a continuing basis by LTCU residents.

<b>Therapeutic Class</b>	<b>Days Supply Payable</b>
Antibiotics	7 days
Anticoagulants	7 days
Narcotics, Stimulants, and Depressants	7 days
Steroids	7 days
Other drugs given on an irregular or PRN basis	30 days
Drugs given on a continuing maintenance schedule	31 days
Injectable drugs normally supplied in single dose ampules	7 days
Injectable drugs normally supplied in multiple dose vials	vial size

When the quantity of medication ordered by the physician conflicts with the hospital's policy regarding automatic stop orders or maximum dispensing quantities, the days supply guidelines as described above should be used for billing.

Medication used on a continuing or permanent basis should be billed for a 31 day supply.

When a physician orders a short course of drug therapy, the quantity of medication should be billed on a single claim form.

Billing for medication for LTCU patients must be done: 1) monthly, or 2) upon discharge of the patient (using the date medication was **dispensed** rather than date of administration).

**Maintenance Drug Allowable Criteria:**

Covered drugs designated as “maintenance drugs” by KMAP must be dispensed in a 31 day supply if the physician’s order is written for a 31 day supply or greater. This criteria are for all pharmacy providers, including Adult Care Home providers.

An override is allowed if the beneficiary meets one of the following criteria:

- A single unit dispensed, such as DepoProvera® 150 mg, for contraceptive purposes, exceeds a 31 days supply.
- A child's school requires a separate medication supply
- Primary insurance requires more than 31 days supply, AND primary made a payment. (If primary payment is identified on the claim, the system will automatically override.)

The allowable override is a value of "02" (other override) in the NCPDP submission clarification override code field. For web claims, the allowable override is the text option “Other Override” in the Submission Clarification Code field. Providers utilizing the override code must keep written documentation of the reason for use.

Unauthorized reduction of prescription quantities is considered prescription splitting and is not allowed.

Schedule II, III, IV, and V drugs are exempt from minimum quantity limitation requirements, but should be prescribed and dispensed in reasonable quantities.

**Maximum Allowable Quantities:**

No more than a 31 day supply of medication per prescription may be dispensed at one time.

**Modafinil (Provigil®):**

Modafinil (Provigil®) is covered for the following diagnosis/ICD-9 code:  
Cataplexy and Narcolepsy      347

NOTE: KMAP does not cover Provigil® (modafinil) when used to treat diagnoses other than the above mentioned.

**Narcotic Analgesics, Tramadol, and Skeletal Muscle Relaxants:**

Medicaid will not reimburse drug claims that exceed maximum recommended dosing during any thirty-day period for scheduled narcotic analgesics, narcotic analgesic combination products, tramadol, and skeletal muscle relaxants.

For medically necessary conditions which require more than the maximum approved dosage, the dose may be approved through the prior authorization process. The claim must be supported with documentation in the consumer's medical records.

Medications included are:

- Acetaminophen, Aspirin, or Ibuprofen combination products containing any of the following:
  - Butalbital, Codeine, Dihydrocodone, Hydrocodone, Oxycodone, Pentazocine, Propoxyphene, or Tramadol (also included are single ingredient narcotic analgesic, and skeletal muscle relaxant products)
- Carisoprodol (Soma®), Cyclobenzaprine (Flexeril®), Metaxalone (Skelaxin®), Methocarbamol (Robaxin®), Orphenadrine (Norflex®), Tizanidine (Zanaflex®)
- Hydromorphone (Dilaudid®)
- Meperidine (Demerol®)
- Narcotic Agonist/Antagonist combinations of Pentazocine (Talwin NX®, Talwin Compound®, Talacen®)
- Tramadol (Ultram®)
- Oxycodone (Oxycontin®)

**Nursing Services Requirements for IV Medication/Nutrition:**

Pharmacy services provided for parenteral administration of total nutritional replacements and intravenous medication in the consumer's home require that nursing services from a local home health agency be provided. Areas not serviced by a home health agency may utilize the local health department or an advanced registered nurse practitioner.

Postpayment reviews of pharmacy provider charges and reimbursement include verification that required nursing services were provided.

**Parenteral & Irrigation Solution Reimbursement:**

All sterile irrigation solutions, large volume parenteral, and small volume parenteral (SVP) fluid replacements for intravenous drug administration are reimbursed the Average Wholesale Price (AWP) less 50%.

**Partial Fills of C-II Drugs:**

Kansas Medicaid will reimburse for partial fills of prescriptions for C-II drugs in accordance with Kansas Pharmacy Regulations (Article 20, Controlled Substances, 68-20-19), for beneficiaries in long-term care facilities, or with a medical diagnosis documenting terminal illness, when the claims contain the applicable diagnosis code. To indicate a diagnosis of terminal illness, the ICD-9 diagnosis code V667 must be entered on the pharmacy claim.

NOTE: KMAP does not cover partial fills of prescriptions for C-II drugs when used in circumstances other than the above mentioned.

**Pregabalin (Lyrica®)**

An ICD-9-CM diagnosis code is required on all gabapentin claims. the pharmacy will need to contact the prescribing provider if no diagnosis is noted on the prescription. Gabapentin is only covered for the following conditions or diagnoses not listed below:

1. Nueropathic pain: for a diagnosis indicating neuropathic pain, submit diagnosis code 3569
2. Epilepsy: for a diagnosis of epilepsy, submit the most appropriate one of the following diagnosis codes (**KMAP will accept 24500 for epilepsy diagnoses within the range of 34500 to 34591**):
  - a. 34500 – generalized nonconvulsive epilepsy without mention of intractable epilepsy
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  - i. 34550 – partial epilepsy, without mention of impairment of consciousness without mention of intractable epilepsy
  - j. 34551 – partial epilepsy, without mention of impairment of consciousness with intractable epilepsy
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  - m. 34571 – epilepsia partialis continua with intractable epilepsy
  - n. 34580 – other forms of epilepsy without mention of intractable epilepsy
  - o. 34581 – other forms of epilepsy wit intractable epilepsy
  - p. 34590 – epilepsy, unspecified without mention of intractable epilepsy
  - q. 34591 – epilepsy, unspecified with intractable epilepsy
  - r. 78039 – other convulsions
  - s. 9070 – epilepsy due to late effects of intracranial injury.

In addition to the diagnosis requirement, pregabalin (Lyrica) is only covered for ages 18 and older. There is also a quantity limit of no more than three units (capsules) per day, not to exceed 600 mg per day. PA will not override these limitations.

**Prenatal Vitamins:**

Legend prenatal vitamins are covered for pregnant women only and up to three months postpartum for lactating women. To indicate a condition of pregnancy or that of a lactating woman for up to 3 months postpartum, submit a diagnosis code of 650.

NOTE: KMAP does not cover prenatal vitamins when used to treat diagnoses other than the above mentioned.

**Prior Authorization:**

PA's approved by SRS or EDS (using state established criteria) for prescriptions which list providers other than pharmacies are accepted by EDS for claims processing. (Refer to Section 4300 in the General Special Requirements Manual for further information.)

Approved PA numbers will have a specified duration, not to exceed one year. The end date for the approved PA is noted on the letter identifying the approved PA number.

PA forms are available at:

<http://www.da.state.ks.us/hpf>

**Routine Services and Supplies for NFs, NF/MH and ICF/MRs:**

"Routine services and supplies", are those services and supplies commonly stocked for use by nursing facilities (NFs), nursing facilities for mental health (NF/MH), and intermediate care facilities for the mentally retarded (ICF/MR) or provided to any nursing facility resident. These services/supplies (listed on page 8-12) are included in the facility's per diem reimbursement.

**Smoking Cessation Products:**

Kansas Medicaid will provide coverage for nicotine patches and bupropion SR (Zyban®). The medication coverage is limited to a maximum of one twelve-week course of therapy per 365 days based upon manufacturers' recommended dosing. Nicotine gum, nicotine oral, and nasal inhalers will not be covered.

**Triptans:**

Any combination of Triptans in excess of 18 units in a 31 day period will be denied.

**Adult Care Homes:****Routine Services/Supplies Provided by Adult Care Homes:**

The adult care home reimbursement rate includes but is not limited to the following durable medical equipment, medical supplies and other items and services as routine for each resident to attain and maintain the highest practicable physical and psychosocial well-being in accordance with the comprehensive assessment and plan of care and shall not be billed or reimbursed separately from the per diem rate :

Alternating pressure pads and pumps	Laxatives
Analgesics (OTC)	Lifts
Antacids (OTC)	Lotions, creams and powders
Armboards	Mouthwash
Bedpans, urinals, basins	Nebulizers
Bedrails, beds & mattress and mattress covers	Nutritional supplements
Blood glucose monitors and supplies	Orthotics and splints to prevent or correct contractures
Canes	Oxygen Masks, stands, tubing, regulators, hoses,
Commodes	catheters, cannulas and humidifiers
Compressors	Parenteral, enteral infusion pumps
Crutches	Patient gowns, pajamas, bed linens
Denture cups	Restraints
Dialysis & maintenance	Sheepskins, foam pads
Dressing items (applicators, tongue blades, tape, gauze, bandages, bandaids, pads and compresses, ace bandages, vaseline gauze, cotton balls, slings, triangle bandages, pressure pads, and tracheostomy care kits)	Skin antiseptic
Emesis basins, bath basins	Sphygmomanometer, stethoscopes, & other examination equipment
Enemas and enema equipment	Stool softeners
Extra nursing care and supplies	Stretchers
Facial tissues & toilet paper	Suction pumps and tubing
First aid type ointments	Syringes & needles (except insulin syringes & needles for diabetics that are covered by pharmacy program)
Footboards	*Therapy (occupational speech, physical)
Foot cradles	Thermometers
Gel pads or cushion (example: Action Cushion)	Traction apparatus & equipment
Geri-chairs	Transportation (non-emergent)
Gloves, rubber or plastic	Stretchers
Heating pads	Suction pumps and tubing
Heat lamps, examination light	Syringes & needles (except insulin syringes & needles for diabetics that are covered by pharmacy program)
Humidifiers and stands	
Ice bags, hot water bottles	
Intermittent Positive Pressure Breathing (IPPB) machines	*ICF/MR payments are limited to the quantity of services that exceed Medicaid's allowed amounts.
Irrigation solution (i.e., H <sub>2</sub> O, normal saline)	
I.V. stands, clamps	
Laundry (including personal laundry)	

## **8400 Updated 12/05**

### **DME/Medical Supplies for NF Residents:**

These services must be billed through DME provider.

### **Legend and Non-Legend Drug Items for NF Residents:**

A legend drug is any medication which requires a prescription in order to be dispensed.

Non-legend drugs are those items essential to the health, safety and welfare of the residents that can be purchased over-the-counter.

Non-legend nutritional supplements such as calcium supplements, vitamins, and minerals are not considered drugs. Therefore these are non-covered under the Kansas Medicaid Pharmacy Program.

While it is true a physician can write a prescription to have some drugs/items dispensed by the pharmacy, products of like nature can be purchased over-the-counter and included in the facility's cost report at a much lower cost without a charge to the consumer.

### **Nutritional Therapy:**

Nutritional supplement products used for a nursing facility resident should be included in the facility's cost report submitted to the Kansas Department of Social and Rehabilitation Services (SRS).

Total nutritional replacement therapy is covered if prior authorized and billed through a DME Provider.

In either case, do not billed the nursing facility resident for any nutritional supplements or replacements.

### **Over-The-Counter Items for NF Residents:**

Over-the-counter drugs/supplies or personal comfort items which are regularly available without prescription at a commercial pharmacy or medical supply outlet and which may be stocked by the facility are considered routine and the responsibility of the nursing facility to provide within the bounds of reasonable accommodation.

Depending on how physicians prescribe a particular medication, there are instances when an over-the-counter product may be either the responsibility of the nursing facility or paid through the pharmacy program. Those prescribed on a scheduled basis and covered by the beneficiary's medical card may be billed to KMAP.

### **Urinary Catheters and Accessories (KAR 30-10-15a(b)(2):**

Urinary catheters and accessories shall be covered services in the Medicaid/MediKan program when billed through the durable medical equipment or medical supply provider. This expense shall not be reimbursed in the per diem rate of the nursing facility cost report.

**Prospective Drug Utilization Review (PDUR)**

KMAP is required through OBRA to perform PDUR. An incoming pharmacy claim goes through certain checks within the pharmacy system to determine if any potential problems exist by dispensing a medication. That information is then returned to the provider. The provider utilizes this information to determine the best course of therapy for the patient.

In the past the PDUR alerts only reported to the provider. As of October 2, 2000, KMAP has PDUR alerts that pay-but-report and auto-deny claims. For purposes of simplification, only the auto-deny DUR alerts are discussed. A list of the pay-but-report alerts can be obtained by contacting the Kansas Medical Assistance Customer Service Center.

**Auto Deny DUR Alerts : (These alerts are in hierarchy order.)**

**Refill Too Soon:**

DUR alert that will auto-deny when the same medication has been filled by the same provider, or by a different provider and less than 80% of supply has been used.

**Pregnancy Alert:**

DUR alert that will auto-deny when a female is flagged as pregnant on the pharmacy claim and the drug submitted is a category X, or a First Data Bank value of 1.

**Above Maximum Dose**

This DUR alert occurs when the daily dose is greater than the recommended maximum dose for the beneficiary's age.

**Therapeutic Duplication:**

DUR alert that will auto-deny when a prescription is filled within 80% of the remaining supply of another prescription which is considered therapeutically equivalent by KMAP. Including:

- (a) H2 Antagonists vs. PPIs
- (b) NSAIDS vs. Cox II Inhibitors

**Allowed Exceptions for Auto-Deny DUR Alerts:**

In order to override an auto-deny DUR alert, the provider must determine if the prescription meets the criteria in the following chart for the highest ranking alert listed in order under "Auto-Deny DUR Edits". Patients that do not meet the criteria for the highest ranking auto-deny alert set may pay for the medication out-of-pocket. The provider must maintain documentation for the reason the denial was overridden and input the proper override values on the claim in the NCPDP DUR Reason for Service code, Professional Service code, and Result of Service code fields.

**NOTE:** Overrides are not allowed for stolen or vacation medications.

<u>DUR Alert</u>	<u>Allowed Exceptions</u>
Refill Too Soon	<ul style="list-style-type: none"> <li>* Therapy change, all consumers</li> <li>* Lost/spilled medications, KBH ONLY</li> </ul>
Pregnancy Alert	<ul style="list-style-type: none"> <li>* Beneficiary is not pregnant</li> <li>* Physician and beneficiary are aware of the drug’s teratogenic effects and authorization to dispense has been given after the pharmacist consults with the physician.</li> </ul>
Above Maximum Dose	<ul style="list-style-type: none"> <li>* Physician contacted and has approved dosage</li> </ul>
Therapeutic Duplication	<ul style="list-style-type: none"> <li>* Drug/dosage change verified by the physician</li> </ul>

**Guidelines To Help Identify DUR Alerts:**

Claims setting DUR alerts can auto-deny or pay-but-report. Any set will return pertinent information to the provider, including the DUR Reason for Service code, in the DUR Response Data fields. The first alert returned to the provider in the DUR Response Data fields is considered the most significant. The provider may contact the Medical Assistance Customer Service Center for further DUR information. Also, any auto-deny alert set will cause an NCPDP Reject Code to be returned to the provider. This reject code along with the DUR Response helps a provider determine what alert set.

The following table contains information to help a provider determine what auto-deny DUR alert was set, and if provider intervention is necessary. Remember, provider action requires certain criteria to be met as explained on the previous page.

DUR EXCEPTION	DUR REASONS FOR SERVICE	DUR PROFESSIONAL SERVICE CODE	DUR RESULT OF SERVICE
Refill Too Soon	ER	M0 P0 R0	1A 1B 1C 1D 1E 1F 1G 2A 2B
Pregnancy, Category X, D, or FDB value 1	PG	M0 P0 R0	1A 1B 1C 1D 1E 1F 1G 2A 2B
Therapeutic Duplication	TD	M0 P0 R0	1A 1B 1C 1D 1E 1F 1G 2A 2B
Above Maximum Dose	HD	M0 P0 R0	1A 1B 1C 1D 1E 1F 1G 2A 2B

**Benefits Non-Covered:**

The consumer is allotted money for miscellaneous expenditures within their monthly budget; consequently, some pharmacy items are not covered. The following represent examples of items that are not covered:

- Medical supplies (as determined by FDA)
- Over-the-counter laxatives and stool softeners
- Over-the-counter nutritional supplements such as vitamins and minerals
- Routine feminine hygiene products
- Topical antiseptic and first aid preparations

Therapeutic categories of drugs generally not covered are:

- DESI less-than-effective drugs and their Identical, Related, and Similar (IRS) drugs
- Benzodiazepines
- Cosmetic purposes
- Symptomatic relief of cough and colds
- Drugs designated by the Secretary of Health and Human Services
- Drugs with a manufacturer imposed restricted distribution system which requires the additional purchase of associated tests or services from the manufacturer or its designee
- Promotion of fertility
- Gender-specific medications if prescribed to the gender for which they are not FDA-approved or medically necessary
- Hair growth
- Non legend (OTC)
- Weight reduction with exception of those requiring prior authorization
- Weight gain

**Single -source prescription claim limitations:**

Effective with DOS on or after April 1, 2003, there will be a limit of 5 single -source prescription drug claims allowed per beneficiary per calendar month. The following will be excluded from the limit edit:

KBH beneficiaries  
Antiretroviral drugs  
State specified preferred drugs only on the preferred drug list  
State-specified anti-rejection drugs used for transplant patients  
State-specified anti-emetics  
State-specified chemotherapy drugs  
Interferons  
Immune Globulins  
Antihemophilic drugs  
Most drugs used to treat mental illness  
All covered contraceptives

Note: All prescriptions for insulin will price as single -source but may or may not be counted as multi-source for this policy.

Note: **PRESCRIPTION LIMIT OVERRIDE CRITERIA**

Pharmacists should submit the prescription limit override code only if both of the following are met:

- 1) Medical necessity has been obtained from the physician
- 2) The monthly prescription limit of 5 single source claims per month has been met.

If a beneficiary meets the above criteria, the pharmacy provider should enter a value of "07" (Medical Necessary) in the NCPDP Submission Clarification Override Code field. For web claims, the allowable override is the text option "Medically Necessary" in the Submission Clarification Code field. Documentation of the medical necessity must be kept.

Pharmacists must not use the override code for a prescription until after the monthly prescription limit has been reached and medical necessity has been shown. Pharmacists will be audited for appropriate utilization of the prescription limit override code.

## 8400 Updated 12/05

The limit of 5 single-source prescription claims per calendar month has been in effect as of April 1, 2003. Since then, many questions have been raised regarding this policy. Below are several clarifications for providers:

- Documentation of 'Medical Necessity' is good for up to six (6) months.
- The form in the March 2003 bulletin does NOT have to be used. This is an example providers may use. Or, providers may develop their own form, document the information on the back of the prescription or use any other means of documenting the 'Medical Necessity' information.
- Providers may use one form documenting 'Medical Necessity' for several of a beneficiary's scheduled medications. If a new single-source prescription claim is requested and denies for this edit, the provider must get 'Medical Necessity' documentation. KEEP IN MIND the 'blanket' form with 'Medical Necessity' may be used ONLY for the beneficiary's regularly scheduled medications.
- Any time a single-source prescription claim is filled for a beneficiary within the same calendar month, regardless of whether or not it is a refill, it will count towards the limitation.
- The NCPDP Reject Code that appears when reaching this limit is "76" or "Plan Limitations Exceeded".
- Providers submitting claims on paper must document the Medical Necessity override code in the 'Remarks' section (field 16) on the paper claim form. The provider must link the line number to the code.
- Providers submitting via EMC may only resolve this edit issue via a paper claim form or POS or Web.
- There is NOT a list of NDCs considered single-source, multi-source or excluded. Providers may contact the Medical Assistance Customer Service Center at 1-800-933-6593 (between 7:30 A.M. & 5:30 P.M.) to inquire about an NDC.  
NDCs may move back and forth between single-source, multi-source and excluded at any time.

**DAW documentation required**

Effective May 28, 2004: In order for KMAP to increase patient safety, unnecessary expenditures, and assist in monitoring drug products, if a prescriber specifies Dispense As Written (DAW) on a drug which has a bioequivalent generic substitute available, the prescriber will be required to fill out the FDA MedWatch form 3500. This MedWatch form must be submitted to the dispensing pharmacy AND also to the FDA. The dispensing pharmacy will then submit this to the KMAP Prior Authorization Unit for evaluation and receive approval if medical necessity is met.

**Submitting MedWatch Documentation for review:**

The FDA MedWatch forms may be obtained online at:

<http://www.fda.gov/medwatch/getforms.htm>

1. Prescribers must mail or fax the completed FDA MedWatch forms to the FDA AND to the dispensing pharmacy.

Address: MedWatch 5600 Fishers Lane  
Rockville, MD 20852-9787

Fax: 1-800-FDA-0178

2. Pharmacists must mail or fax the completed FDA MedWatch Forms to the KMAP Prior Authorization Unit for consideration. Please include the following information when mailing or faxing the FDA MedWatch forms:

- Pharmacy Name
- Pharmacy Phone and Fax Numbers
- KMAP Provider Number

Address: Kansas Medical Assistance Program  
3600 SW Topeka Blvd, Suite 204  
Attn: Prior Authorization

Fax: 1-800-913-2229  
785-274-5956

3. The Prior Authorization Unit will contact the pharmacy to inform them of the status of the DAW request.

**CRITERIA TO MEET MEDICAL NECESSITY FOR A BRAND NAME DRUG WHEN A BIOEQUIVALENT GENERIC SUBSTITUTE IS AVAILABLE**

**A. Adverse Reaction(s) to the generic:**

Documentation by prescriber that the adverse reaction caused by the generic meets one of the following criteria:

1. life threatening
2. hospitalization
3. disability
4. required intervention to prevent impairment or damage

**OR**

**B. Allergic Reaction(s) to the generic:**

Prescriber must document the beneficiary's experience of an allergic reaction to the generic product of one or more manufacturers. The dates and clinical details with the name of specific companies and the generic versions involved must be included.

**OR**

**C. Therapeutic Failure(s) of the generic:**

Prescriber must document the clinical failure due to beneficiary's suboptimal drug plasma concentration while taking the generic drug when compared to published full pharmacokinetic profiles for the brand name drug.

The term "generic drug" means a drug that is "bioequivalent". Kansas law refers to the Federal Food and Drug Administration's definition, which says drugs are bioequivalent if:

- 1) they use the same active ingredient as the original version of the drug
- 2) the active ingredient is absorbed and available where it is needed in the body

at the same rate.