

**CAUTION: Read the [ICD-9 Policy Holding Library](#) page about policy in this document.**

## Drugs: Contract Drugs List Part 8 – Step Therapy

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**Sections *Drugs: Contract Drugs List Part 1 – Prescription Drugs (A through D)* through *Drugs: Contract Drugs List Part 7 – Preferred Prior Authorization Drug List* may be found in the *Part 2 Pharmacy* manual but are not applicable to providers who receive the *Part 2* manual, *Medical Services for General Medicine*.**

Step Therapy is an enhanced utilization management process, or set of drug use protocols, intended to promote safe and cost-effective drug use based on nationally accepted standards of care or well-documented clinical drug studies. On December 1, 2004, Step Therapy protocols will be implemented to determine if therapies considered as first-line, or “Step 1,” have been used before a claim can be processed for a second-line, or “Step 2,” therapy. If one or more Step 1 drugs exist in the claims history and/or a valid clinical exception is documented, the Step 2 drug claim will process automatically. These claims will be subject to the usual utilization controls, such as the monthly claim line limit or “six-prescription limit.” In specific circumstances, the dispensing pharmacist will be asked to provide information to determine if the Step 2 drug meets established use criteria. If a medical diagnosis is required, the treatment-associated ICD-9-CM code (that is, the diagnosis being treated) must be entered in the *Primary ICD-CM* field (Box 21) or *Secondary ICD-CM* field (Box 22) on the claim. Step 2 or higher drugs will be reimbursable without prior authorization only if a diagnosis matches those listed in the protocol and a valid clinical exception is present. To facilitate claims submission and reduce unnecessary phone calls, physicians and others that prescribe medications should write the diagnosis codes on the prescriptions.

When a valid diagnosis and clinical exception are present, a Step 2 drug will be automatically reimbursable. If the diagnosis does not match one listed in the protocol, or a health care provider wants to prescribe a Step 2 drug without first using the recommended Step 1 drug, and the patient does not qualify for a clinical exception, then the prescribing provider or pharmacy provider must submit a *Treatment Authorization Request* (TAR). The request must include information on why the Step 1 drug cannot be used and/or the medical necessity for use in the diagnosis listed. When creating an electronic TAR, the *Special Handling* value, “Step Therapy Exemption,” must be used. The TAR may be rejected if this is left blank or another value is used.

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The following are therapeutic drugs subject to Step Therapy:

**Note:** It is the intent of the Department of Health Care Services (DHCS) to allow claims for COX-2 inhibitors for patients with a diagnosis of rheumatoid arthritis to pay without meeting any of the clinical exceptions described below or first requiring the use of two Step 1 drugs. Due to system limitations, this will not happen on the December 1, 2004 implementation date. As soon as the Medi-Cal system is updated, providers will be notified.

| Category   | Step 1   | Step 2                             | Clinical Exceptions   |
|--|--|------------------------------------|---|
| <p>Selective COX-2 Inhibitors</p> <p>Code 1: Arthritis<br/>A diagnosis code must be submitted on a pharmacy claim using ICD-9-CM codes 714.xx, 715.xx or 720.xx</p> <p><b>Note:</b> A patient must try at least two Step 1 drugs before receiving a Step 2 drug.</p> | <p>Diclofenac Sodium *</p> <p>Etodolac</p> <p>Fenoprofen *</p> <p>Ibuprofen *</p> <p>Indomethacin *</p> <p>Ketoprofen *</p> <p>Meclofenamate Sodium</p> <p>Mefenamate</p> <p>Meloxicam *</p> <p>Nabumetone *</p> <p>Naproxen Sodium</p> <p>Naproxen *</p> <p>Oxaprozin</p> <p>Piroxicam *</p> <p>Sulindac *</p> <p>Tolmetin *</p> <p>* These drugs are currently covered under the <i>Medi-Cal List of Contract Drugs</i> and should be used first, if possible.</p> | <p>Celecoxib</p> <p>Valdecoxib</p> | <p>Beneficiaries with one of the following:</p> <ul style="list-style-type: none"> <li>• age ≥ 65 years</li> <li>• a history of ulcer</li> <li>• concurrent use of oral corticosteroids</li> <li>• concurrent use of anticoagulants</li> <li>• rheumatoid arthritis (ICD-9-CM code 714.xx)</li> </ul> |

**Note:** Patients currently receiving a COX-2 Inhibitor, and have a paid claim within the last 120 days, may continue to receive their medication.