
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-10-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.

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.

«Table of Therapeutic Drugs Subject to Step Therapy»

Category	Step 1	Step 2	Clinical Exceptions
Selective COX-2 Inhibitors Code 1: Arthritis A diagnosis code must be submitted on a pharmacy claim using ICD-10-CM codes M05.XX, M06.XX, M07.XX, M08.XX, M13.XX, M15.XX, M45.XX or M46.XX Note: A patient must try at least two Step 1 drugs before receiving a Step 2 drug.	Diclofenac Sodium * Etodolac Fenoprofen * Ibuprofen * Indomethacin * Ketoprofen * Meclofenamate Sodium Mefenamate Meloxicam * Nabumetone * Naproxen Sodium Naproxen * Oxaprozin Piroxicam * Sulindac * Tolmetin *	Celecoxib Valdecoxib	Beneficiaries with one of the following: <ul style="list-style-type: none"> • «65 years or age or older» • a history of ulcer • concurrent use of oral corticosteroids • concurrent use of anticoagulants • rheumatoid arthritis (ICD-10-CM code M05.XX, M06.XX)

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

<<Legend>>

<<Symbols used in the document above are explained in the following table.>>

Symbol	Description
<<	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
>>	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.
*	These drugs are currently covered under the <i>Medi-Cal List of Contract Drugs</i> and should be used first, if possible.