



Coverage of New-to-Market Drug Entities

Overview:

When a new drug entity enters the U.S. drug market, there can be enthusiasm among prescribers and patients to begin prescribing and using the new therapy option. For drugs subject to prior authorization under MedTrak's Specialty or Enhanced Management programs, this can result in the necessity to make a coverage determination before a thorough review of the drug product can be performed.

A complete product evaluation includes:

- Review of the approved product labeling and relevant literature
- Assessment of the medication's appropriate place in therapy
- Analysis of the price of the medication relative to other treatment modalities for the labeled indications

Performing a comprehensive drug product evaluation allows for development of appropriate prior authorization criteria as well as creation of a Benefit Assessment Form which collects all the information necessary to make a benefit determination.

MedTrak Clinical Care Center Position Statement:

New-to-market products and new variations of products already in the marketplace will be excluded from benefit coverage until the product has been evaluated, deemed clinically appropriate, considered cost effective, and assessed for place in therapy. In order to allow adequate time for the Clinical Care Center to perform a full evaluation, it is MedTrak's policy that new drug entities not be eligible for benefit coverage for a period of 90 days after market entry. Requests for coverage made prior to 90 days after market entry will be declined.

Exceptions to this policy can be made on a one-on-one basis after taking into consideration the medication, clinical justification, and the specific characteristics of the member for whom it is being requested.