

**Medication Policy Manual**

**Policy No:** dru150

**Topic:** Medication Policy Manual Introduction

**Date of Origin:** September 7, 2007

**Revised/Effective Date:** September 11, 2009

**Next Review Date:** September 2010

## **Medication Policy Development and Review Process**

### *Purpose of the Manual*

The purpose of Regence medication policy is to provide criteria and guidelines for determining coverage of specific medications. In order to be eligible for coverage, all medications must be medically necessary (unless otherwise provided in the member's benefits contract). To the extent there are any conflicts between Regence medication policy guidelines and applicable contract language, the contract language prevails. Regence medication policy is not intended to override the health insurance policy that defines the insured's benefits, nor is it intended to dictate to providers how to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care. The policies are not intended to constitute medical advice and do not guarantee any results or outcomes. They are meant to be consistent statements of medical necessity criteria for coverage through available benefits.

### *Policy Development*

#### **SELECTION OF MEDICATIONS FOR POLICY DEVELOPMENT**

Issues are selected for medication policy development through referrals from Regence staff, the physician and provider community, and members. Priority may be given to the following:

- New medications for which there are scientifically-proven, safe, effective alternatives.
- Medications that have generated a high level of interest for members and/or providers.
- Medications that may be prescribed for conditions that are not a covered benefit.
- Medications that are controversial with respect to their ability to improve net health outcome.
- New information available in the peer-reviewed scientific literature that may change the status of an indication for a medication from investigational to medically necessary.

The following sources are considered in the development and revision of Regence medication policies:

- Current published medical literature from peer-reviewed publications.
- Evidence-based guidelines developed by national organizations and recognized authorities.
- Generally accepted standards of medical practice.

- External practicing physician review.
- Government approval status.
- National medication compendia, including, but not limited to *AHFS (American Hospital Formulary Service) Drug Information*, *Thomson Micromedex DrugDex*, *National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium*, and *U.S. Pharmacopeia Drug Information*.
- Policies and technology assessments published by the BlueCross BlueShield Association and the BlueCross BlueShield Association Technology Evaluation Center (TEC).

### *Definition of Medical Necessity*

Medically necessary or medical necessity means health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating illness, injury, disease or its symptoms, and that are:

- (a) in accordance with generally accepted standards of medical practice;
- (b) clinically appropriate in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
- (c) not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

### *Generally Accepted Standards of Medical Practice*

Generally accepted standards of medical practice means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations and the views of physicians practicing in relevant clinical areas and any other relevant factors.

### *Definition of Investigational Services*

In this manual, the term "investigational" means that the medical technology does not meet Regence's technology assessment criteria, as defined below. If any one or more of the criteria are not met, the technology will be determined to be investigational. In addition, all services specifically associated with the investigational technology, including, but not limited to, associated procedures, treatments, supplies, devices, equipment, facilities or drugs, will also be considered investigational.

### *Technology Assessment Process*

The technology assessment process is applied to both the development of new medication policies and the updating of existing policies. In order to determine whether a medication may be considered medically necessary, literature searches are conducted and the published scientific evidence related to each medication is reviewed against five technology assessment criteria. In order for a medication to be considered medically necessary for an indication, all five criteria must be met. As noted above, if any one or more of the following criteria are not met, then the medication is considered investigational:

1. The medication must have final approval from the appropriate government regulatory body, specifically, the Food and Drug Administration (FDA). Any approval that is granted as an interim step (i.e., Treatment IND) in the FDA regulatory process is not sufficient.
2. The scientific evidence must permit conclusions concerning the effect of the medication on health outcomes.  
The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence. Scientific evidence and expert opinion provide the basis for summarizing the potential net health outcome. The evidence should demonstrate that the medication can alter the physiological changes related to a disease, injury, illness or condition. In addition, there should be evidence or a convincing argument based on established medical facts that such alteration affects the health outcomes.  
Opinions and evaluations by national medical associations, consensus panels or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.
3. The medication must improve the net health outcome.
4. The medication should improve the net health outcome as much as or more than established alternatives.
5. The improvement must be attainable outside the investigational settings.

#### *External Physician Review*

All new and revised Regence medication policies are sent for review in draft form to external practicing physicians. Physicians who wish to participate in this process may contact Regence Medical Policy at: [www.regence.com/trg/contact/](http://www.regence.com/trg/contact/).

#### *Approval Process*

All policy drafts, including analyses of the scientific evidence and summaries of the external expert opinion, are presented to the Regence Medication Policy Group (MPG) for final approval. MPG consists of professional medication policy staff and physician medical directors from Idaho, Oregon, Utah and Washington.

#### *Medication Policy Updates*

Medication policies are re-evaluated and updated regularly. Policies may be reviewed prior to their scheduled annual review date if new scientific evidence that would alter the policy criteria becomes available sooner.

*Medication Policy Dissemination*

- Medication policies are published on-line and available to members, providers and the general public at <http://blue.regence.com/policy/medication/contents.html>.
- Significant policy changes are communicated through provider newsletters and are noted on-line at <http://blue.regence.com/trgmedpol/drugs/PolicyUpdates.pdf>.