Policies Repository

Independence Blue Cross

Policy Title	Experimental/Investigational/Off-label Drug Use
Policy Number	FS.CLIN.52

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

All prescription pharmaceutical agents available in the United States have FDA approved labeling. The label specifies which disease states a drug can be used to treat. However, use of a pharmaceutical agent may expand past the approved labeling and into what is known as off-label use. Coverage for off-label or experimental use will require Prior Authorization. This policy will be used unless otherwise directed by FutureScripts.

Policy Description

The US Food and Drug Administration (FDA) approves labeling that details all indications for which a pharmaceutical agent can be marketed. The approved indications identify the specific disease states that the agent has been shown to be safe, efficacious and meet all clinical requirements set forth by the FDA. An off-label or unlabeled use of a prescription drug or biologic is a use that has not been approved by the US Food and Drug Administration (FDA) and which is not identified in package labeling. Use of a drug for any indication, patient population, or route of administration other than those approved by the FDA and listed on the label or packaging insert is considered an off-label or unlabeled use.

Off-label use of prescription drugs and biologics not meeting the medical necessity criteria is considered experimental/investigational and may not be a covered pharmacy benefit.

In determining whether there is clinical evidence to support a medical necessity determination, FutureScripts will consider the quality of the published evidence as well as an assessment of the following information as submitted by the requesting physician.

Reliable evidence must demonstrate that the proposed off-label use for the specified medical condition is safe and effective and that the treatment's beneficial effects outweigh its risks.

Policy Guideline Inclusion	Consideration for coverage of off-label use must meet **one** of the following criteria:
	• Documentation of accepted off-label use in one of the following compendia:
	  ○ American Hospital Formulary Service (AHFS) Drug Information
	  ○ US Pharmacopoeia Drug Information (USP DI Volume 1-now known as DrugPoints)
	  ○ MicroMedex® DRUGDEX
	• The requested off-label use is supported by adequate submitted clinical research published in major peer-reviewed medical journals. For example:
	  ○ The requested off-label use must have been studied in at least two clinical trials and must be, when possible, randomized, blinded, multi-centered and controlled. The results must have been published in national peer-reviewed journals with an editorial committee comprised of physicians.
	  ○ Peer reviewed medical literature includes scientific, medical, and pharmaceutical publications. It does not include in-house publications of pharmaceutical manufacturing companies, abstracts (including meeting abstracts), poster presentations or published case studies.

Policy Guideline Exclusion	Coverage for off-label use is denied when **any** of the following are present: • The FDA determines a prescription drug or biologic to be contraindicated for specific conditions. • The drug has not received FDA approval for any indication. • The compendia lists the drug as "not indicated." • The compendia has a recommendation of IIb or lower for specific conditions requested. • The requested off-label use is not supported by adequate clinical research or research as determined by FutureScripts.
Policy List of Applicable Drugs	This policy applies to all drugs that have clinical managment policies addressing them.
Dosing and Administration	Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.
Policy References	N/A
Policy Link to Related Policies	
Printed	08/16/2010 09:59:08