**Vermont Department of Banking, Insurance, Securities and Health Care Administration**
**Division of Health Care Administration**

# HCA Bulletin 121: Off-Label Use of Prescription Drugs for Cancer
**July, 2006**

The 2006 session of the Vermont legislature passed, and Governor James Douglas signed into law, Senate Bill 22 relating, in relevant part, to insurance coverage for "off-label" use of prescription drugs to treat cancer. In summary form, the law requires all health insurance plans doing business in Vermont[1] that provide coverage for prescription drugs, to also provide coverage for "off-label" uses of pharmaceuticals to treat cancer where the drug is: (1) prescribed by a treating oncologist and (2) the "off-label" use is a "medically accepted indication for the treatment of cancer" The law prohibits insurers from denying coverage for such off-label uses as investigational.

An "off label" use of a pharmaceutical is a prescribed use that has not been approved by the federal Food and Drug Administration as reflected in the product labeling. The insurer's contract may not exclude coverage for any drugs used to treat cancer solely because the drug has not been approved by the federal Food and Drug Administration for the particular use for which it is prescribed. This prohibition may require insurers to amend their contract language and/or internal operating policies. Insurers may continue to apply provisions related to maximum benefits and coinsurance, deductibles and exclusions for prescription drug benefits so long as they are not inconsistent with this law and are otherwise permissible.

When a treating oncologist prescribes an off-label use of a pharmaceutical to treat cancer, the health insurer must determine if that use is for a "medically accepted indication" and, if so, the insurer must provide coverage. A "medically accepted indication" is one that is **supported** by "medical or scientific evidence." "Medical or scientific evidence" can be found in one or more of the following sources:

A. peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;

B. peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline and MEDLARS database Health Services Technology Assessment Research (HSTAR);

[1] This includes Medicaid, the Vermont health access plan, VScript and other public health care assistance programs.

C. medical journals recognized by the federal Secretary of Health and Human Services, under Section 1861(t)(2) of the federal Social Security Act;

D. the following standard reference compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluation, and the United States Pharmacopoeia-Drug Information;

E. findings, studies, or research conducted by or under auspices of federal government agencies and nationally recognized federal research institutes, including the Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Center for Medicare and Medicaid Services and any national board recognized by the National Institutes of Health for the purposes of evaluating the medical value of health services; and

F. peer-reviewed abstracts accepted for presentation at major medical association meetings.

In general, materials contained on the online research site, Medline, meet the criteria of "medical or scientific evidence."

The Department interprets the word "**supported**" to mean that there is corroborating evidence or information for the prescribed use. The language is not intended to require clinical trials finding the prescribed use efficacious. Denials based on a lack of clinical trials for the prescribed use will not meet the standards of this law, rather, insurers must evaluate each available source of "medical or scientific evidence" and determine whether any contain corroborating evidence for the prescribed use. If one or more of the sources contain such corroborating evidence, the off-label use must be covered.

The required coverage under the law includes medically necessary services associated with the administration of the drug. Insurers should refer to Division of Health Care Administration Rule 10, or any successor rule, for the definition of medically necessary care.

Off-label uses of pharmaceuticals to treat cancer prescribed by treating oncologists may be denied coverage where: (1) the federal Food and Drug Administration has determined the use of the pharmaceutical to be contraindicated for the prescribed use; or (2) the prescribed use is not for a medically accepted indication as set forth above.

If an insurer denies a claim for coverage of an off-label use of pharmaceuticals to treat cancer, any appeal of that claim must be treated as an emergency appeal and determined within the applicable time limits for emergency appeals. Those time limits are 72 from the receipt of the grievance or appeal for first level appeals and 48 hours from receipt of the grievance or appeal for second level appeals. Please refer to Division of Health Care Administration Rule 10 Implementation Manual, Sections 203(D)(2)(a); 10.203(5)(a).

To the extent those timeframes may be amended in the future, insurers shall be bound by the applicable time limits for expedited or emergency internal appeals.

If an insured is dissatisfied with the results of the internal appeals process, he/she may seek an independent external review of the denial of coverage for the off label use of a pharmaceutical to treat cancer pursuant to 8 V.S.A. §4089f. The Department will handle all such appeals on an expedited basis.

Date: ____8/1/06_____ _____s/JPC_____

John P. Crowley, Commissioner