



Society of Interventional Radiology Position Statement on Off-Label Use

The Society of Interventional Radiology (SIR) confirms its strong support for the autonomous clinical decision-making authority of a physician. This includes the lawful use by a physician of an FDA approved medical device or drug product for an unlabeled indication when such use is based upon sound scientific evidence and/or sound medical opinion. The SIR affirms the position that, when the “off label” use of a device or prescription of a drug represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as clinically appropriate (reasonable and necessary) medical care, irrespective of labeling, and should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate "off-label" uses of drugs on their formulary.

To support the highest quality of clinical decision-making and patient care, the SIR strongly supports the important need for physicians to have access to accurate and unbiased information about unlabeled uses of drugs and devices, while ensuring that manufacturer-sponsored promotions remain under FDA regulation. The SIR supports the dissemination of generally available information about off label uses by manufacturers to physicians. This information should be derived from peer-reviewed independent sources with full disclosure by the authors, based on adequate and well-controlled investigations, be truthful and not misleading, provided in its entirety, not edited or altered by the manufacturer, inclusive of any known risks not discussed in the publication, and clearly distinguished from manufacturer-sponsored materials. Any material supporting “off-label” use provided by the manufacturer should also be accompanied by the approved product labeling and disclosure regarding the lack of FDA approval for such uses.

The SIR strongly supports the development of Level I evidence to support the use of devices and drugs in “off-label” applications whenever possible, but does not consider the absence of this data a reason to restrict “off-label” use when it is supported by lower levels of evidence, based on sound medical opinion, and, in the opinion of the physician, in the best interest of the patient.

The SIR fully endorses the AMA statement on “off-label” use of devices and drugs: Resolution 218-I-13, FDA Regulation of Off-Label Drug Promotion (2014).

Approved by the SIR Executive Council November 18, 2007. Revised and approved by the SIR Operations Committee November 2, 2015.