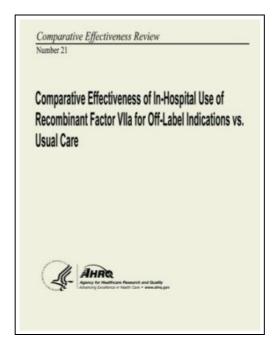
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COMPARATIVE EFFECTIVENESS OF IN-HOSPITAL USE OF RECOMBINANT FACTOR VIIA FOR OFF-LABEL INDICATIONS VS. USUAL CARE: COMPARATIVE EFFECTIVENESS REVIEW NUMBER 21



CreateSpace Independent Publishing Platform. Paperback. Condition: New. This item is printed on demand. 332 pages. Dimensions: 11.0in. x 8.5in. x 0.8in.This report evaluates the level of evidence currently available to support the effectiveness and safety of using recombinant activated coagulation factor VII (rFVIIa) for clinical indications not approved by the U. S. Food and Drug Administration (FDA). rFVIIa is approved for a variety of uses in hemophilia patients who have developed antibody inhibitors that compromise the use of standard factor replacement. Use of this costly biologic product has expanded beyond these hemophilia-related indications to encompass a range of off-label uses, most of which are in-hospital uses. These uses differ substantially from the drugs FDA approved label. The purpose of this report is two-fold: (1) To document the full range of clinical indications for which rFVIIa is being used and the types of studies available to evaluate these uses and (2) To provide a comparative effectiveness review of rFVIIa vs. usual care for several in-hospital clinical indications: intracranial hemorrhage, massive bleeding secondary to trauma, and the selected surgical procedures of cardiac surgery, liver transplantation, and prostatectomy. Off-label drug use refers to any use of a medication that deviates from the product labeling approved and required by the FDA. The FDA drug approval process mandates randomized clinical trials that demonstrate efficacy and safety for specific indications prior to marketing. Once approval is given, however, the FDA does not regulate whether drugs are prescribed for off-label indications. In most instances, the data supporting off-label drug use falls short of the rigor that accompanies FDA review. This uncertainty may be acceptable, as when a drugs use is infrequent. Nevertheless, concerns increase when off-label use is clinically distinct from approved indications, when off-label use becomes frequent, when a drug is costly, or when a drug...

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