Stem Cell Policies: Health Care Coverage

US275 Scientific Ethics John R. Hoffman Arcadia University



The billing of medical procedures is based on a common coding system.

- Level I Healthcare Common Procedure Coding System (HCPCS) codes
 - Centers for Medicare & Medicaid Services
- Current Procedural Terminology (CPT)
 - American Medical Association



Payment of medical procedures by Government or Private insurers based on coverage decisions.

- Is the procedure approved for reimbursement?
- Is the procedure medically necessary?
- Other factors...



In clinical studies, the costs directly associated with the testing of the treatment is covered by the sponsor.

- Experimental drug or treatment
- tests performed solely for research purposes
- does not routinely cover other medical costs associated with the condition.



Most current health insurance policies exclude coverage of <u>experimental</u> medical treatments, including off-label uses of approved drugs.

- Definition of experimental is difficult
 - Approved by appropriate government regulatory body
 - Scientific evidence
 - Number of procedures completed



Medicare currently covers treatments that are "reasonable and necessary."

- considered "safe and effective" by the FDA
- June 7, 2000 Executive memorandum
 - "explicitly authorize [Medicare] payment for routine patient care costs...and costs due to medical complications associated with participation in clinical trials."



Some states require health plans to cover patient care costs in clinical trials

- "Routine patient care costs" are not consistently covered once a patient enrolls in a clinical study
- Medicare and some states require
 - that coverage outside of a clinical trial be provided to patients within the trial.



States in blue have legislation or instituted special arrangements requiring health care plans to pay the cost of routine medical care you receive as a participant in a clinical trial. http://www.cancer.gov/clinicaltrials/payingfor/laws

to be continued

• in the video lecture:

Stem cell policies: Legal rules