Medicare off-label drug coverage on the agenda

By ACSH Staff — March 23, 2011

On March 7, the Medicare Rights Center in New York won a lawsuit against the Department of Health and Human Services (HHS): a federal judge ruled [1] the Medicare Part D drug coverage program is responsible for covering off-label use of drugs when treatment is medically necessary.

“Off-label” use means that a drug is being used for an indication not FDA-approved. Doctors can decide to do that if they feel such treatment is in the best interests of the patient, but insurance coverage can be tricky in that circumstance. The new ruling comes on the heels of another law enacted in 2009, the Medicare Improvements for Patients and Providers Act. That Act clarified that Medicare has to cover off-label use of FDA-approved cancer drugs deemed medically acceptable based on clinical evidence in peer-reviewed journals or other publications approved by the HHS secretary.

The amended law, however, is only applicable to cancer drugs. Therefore, the Medicare Rights Center, in conjunction with Congress and other organizations, is drafting a new provision, the Part D Off-Label Prescription Parity Act, which would extend coverage to go beyond just cancer treatments. ACSH staffers applaud the new law and hope to see that the amended provision garners enough bipartisan support for Congressional approval.

ACSH’s Dr. Josh Bloom adds, “There are many drugs that fill unmet medical needs when used off-label for other conditions. Perhaps the most common is the use of both antidepressants and anti-epilepsy drugs for chronic or neuropathic pain, an area where there are often no satisfactory approved medicines.”

Links
[1] http://www.ama-assn.org/amednews/2011/03/14/gvse0318.htm