



A Public Entity

Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

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Important Notice:

Acetaminophen (APAP) combination products

As of September 1, 2011, IEHP will be implementing new quantity limits and restrictions related to acetaminophen combination products (see below for affected products). This decision was based on the recent APAP safety warnings and new restrictions placed on combination analgesics by the FDA. On 1/13/2011, the FDA announced that all prescription acetaminophen products (includes all combination products) will be limited to 325mg per dosage. This decision will be phased in over 3 years. The FDA is also requiring all manufacturers to update warnings on labels with a box warning detailing the risk of liver injury. More information can be found at: <http://www.fda.gov/Drugs/DrugSafety/ucm239821.htm>.

New IEHP Restrictions:

- Percocet (oxycodone/apap):
 - Quantity limit increased to 240 tabs per 30 days
 - All Pharmacy Exception Requests (PERs) for dosing above the quantity limit or APAP restriction will be required to be provide by the prescribing physician only. Online PER requests for these medications will be blocked at the pharmacy level.
- Vicodin, Norco, Lorcet (hydrocodone/apap):
 - Quantity limit increased to 240 tabs per 30 days
 - All Pharmacy Exception Requests (PERs) for dosing above the quantity limit or APAP restriction will be required to be provide by the prescribing physician only. Online PER requests for these medications will be blocked at the pharmacy level.
- New Global Quantity limits of 4 grams of APAP per day

- This new quantity limit will affect all APAP containing products. The system will automatically calculate the daily dose of APAP and restrict requests exceeding 4 grams of APAP

Impact to Pharmacy and Members

This safety edit enhancement will help Pharmacists to identify Members who are receiving high dose of APAP daily. The temporary increase in the quantity limitation allows IEHP and Pharmacists to focus on the requests that exceed 4g APAP daily. There should be no clinical condition that warrants the use of APAP at dosage exceeding 4g/day, hence, Pharmacists should explain to the Members the safety concerns and consult with the Physician regarding the prescription.

Background

Acetaminophen is one of the most commonly used drugs in the United States, yet it is also an important cause of serious liver injury. Acetaminophen is the generic name of a drug found in many common brand name over-the-counter (OTC) products, such as Tylenol, and Prescription (Rx) products, such as Vicodin and Percocet. Acetaminophen is effective in relieving pain and fever, but unlike other commonly used drugs to reduce pain and fever (e.g. nonsteroidal anti-inflammatory drugs (NSAIDs), such as aspirin, ibuprofen, and naproxen), at recommended doses acetaminophen does not cause adverse effects, such as stomach discomfort and bleeding. However, taking more than the recommended amount can cause liver damage, ranging from abnormalities in liver function blood tests, to acute liver failure, and even death. Many cases of overdose are caused by patients inadvertently taking more than the recommended dose (i.e. 4 grams a day) of a particular product, or by taking more than one product containing acetaminophen (e.g. an OTC product and an Rx drug containing acetaminophen).

The mechanism of liver injury is due to the production of a toxic metabolite. The toxic metabolite binds with liver proteins, which cause cellular injury. The ability of the liver to remove this metabolite before it binds to liver protein influences the extent of liver injury. In a study that combined data from 22 specialty medical centers in the United States, acetaminophen-related liver injury was the leading cause of acute liver failure for the years 1998 through 2003. Patients in this study were found to have taken too much acetaminophen from OTC, Rx products, or both. Almost half of these cases involved overdose in which the patient had not intended to take too much acetaminophen (unintentional overdoses). The high percentage of cases of liver failure related to unintentional acetaminophen overdose was also observed in a study published in 2007. The extent of liver failure cases reported in the medical literature provides an important signal of concern.

Please feel free to contact IEHP Pharmaceutical Services Department at 909-890-2049, if you have questions.

Sincerely,

IEHP Pharmaceutical Services Team