

# Iowa Medicaid Enterprise

## Revisions to the Iowa Medicaid Preferred Drug List (PDL) Regarding Papain Containing Products

*Notification Date: January 21, 2009*

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The U.S. Food and Drug Administration (FDA) has ordered companies to stop marketing unapproved drug products that contain papain in a topical dosage form. Under the notice firms marketing any unapproved topical papain products had to stop manufacturing these products by November 24, 2008. Companies or others engaged in shipping these products must stop shipping them by January 21, 2009. After these dates, all topical products containing papain must have FDA approval to be manufactured or shipped interstate.

Topical drug products containing papain have historically been marketed without approval; there are no approved topical drug products containing papain. The FDA is taking this action because adverse events with use of topical papain drug products reported to the agency raise serious safety concerns regarding these products. These drugs can produce harmful or near fatal effects including hypersensitivity resulting in anaphylactic reactions.

Most papain-containing drugs are marketed under trade names. The names of these products include Accuzyme, Allanfil, Allanzyme, Ethezyme, Gladase, Kovia, Panafil, Pap Urea, and Ziox. Some are marketed under the names of the active ingredients, for instance papain-urea ointment. There are approximately 35 unapproved topical products containing papain on the market.

Please visit <http://www.fda.gov/CDER/new/papain/qa.htm> for more information.

**Effective January 23, 2009 the following product will be preferred on the Iowa Medicaid Preferred Drug List (PDL):**

Santyl Ointment

**Effective January 23, 2009 the following products will be noncovered by Iowa Medicaid and removed from the Iowa Medicaid Preferred Drug List (PDL):**

Accuzyme Ointment  
Allanfill Ointment  
Allanzyme Ointment  
Ethezyme Ointment  
Gladase Ointment  
Kovia Ointment  
Panafil Ointment  
Pap Urea Ointment  
Ziox Ointment