

Initial Public Comment Period
Abarelix for the Treatment of Prostate Cancer
CAG-00238N
June 22-July 22, 2004

Comment #1:

Submitter: Manuel Pubillones, MD

Organization: Medical Director, Medicare Part A, COSVI; FI for PR & US-VI

Date: June 23, 2004

Comment:

After reviewing the letters pertaining to the "request <<http://www.cms.hhs.gov/coverage/download/id129.zip>> and recommendations for coverage" for Plenaxis (Abarelix), I fully support the coverage of said drug under the Incident To Provision. Nevertheless, I have some concerns if an NCD or NCA is prepared solely for this drug.

Please, consider developing an NCD addressing ALL DRUGS classified as Gonadotropin Releasing Hormone (GnRH) Antagonist. Zoladex & Lupron can be included on said determination. As new ones (on the pipeline) get approval, they can be included in the NCD. On the Indications Section, the FDA approved ones can be specified per drug (prostate adenocarcinoma, endometriosis, etc).

Hope this comments are useful.