

This Computes!



Department of Health Care Services
Children's Medical Services Network
(CMS Net) - Information Bulletin #362

Active Pharmaceutical Ingredients (APIs) - Revised

It has come to the attention of CMS Branch that, beginning March 16, 2011, active pharmaceutical ingredients (APIs) classified as "bulk chemicals" in the payment system will become a non-benefit item within the Medi-Cal Program (applies to CCS and GHPP also). An API is a bulk drug substance, often the main active ingredient(s) in a compounded prescription. This action is being taken as Federal CMS does not recognize that APIs "meet the definition of a covered outpatient drug as defined in section 1927(k) (2) of the Social Security Act."

After additional review by the Department of Health Care Services, it has been determined that:

- Reimbursement for excipients (typically, inert ingredients that are added to a compound prescription to give it a more uniform and stable consistency and may include flavoring agents) is allowable.
- Bulk drug products/ingredients remain non-reimbursable.
- Non-drug APIs, such as amino acids, are reimbursable.
- Bulk nutritional products (non-drug) shown to not be investigational nor experimental when used as part of a therapeutic regimen to prevent serious disability or death are reimbursable with a SAR.
- Products considered to be a non-benefit of the Medi-Cal program may be reimbursed through the EPSDT program if the clinical circumstances warrant approval.

CCS Counties that have been issuing 01 or 02 SARs to cover the compounding of prescriptions using APIs should inform their pharmacies that APIs used in a compound prescription will no longer be payable.

Pharmacies may still be able to compound a prescription using the FDA-approved formulation of the same drug, in place of the bulk **drug** ingredient, as the FDA approved form remains payable.

The Department of Health Care Services has retroactively restored excipients, amino acids, and non-drug nutritional products used in compounding prescriptions payable in the system. Pharmacies that have claims denied for non-payment of these ingredients may rebill the claim. If the pharmacy has received any payments from CCS clients, they should reimburse the CCS client after receiving retroactive payment of the claim.

If you have any questions, please contact:

Edan Lum, Pharm D., CMS Branch Pharmaceutical Consultant,
916-327-1902 or 510-286-0722, edan.lum@dhcs.ca.gov