



JENNIFER KENT
DIRECTOR

State of California—Health and Human Services Agency
Department of Health Care Services



EDMUND G. BROWN JR.
GOVERNOR

October 29, 2015

CCS Information Notice: 15-11

TO: ALL LOCAL COUNTY CALIFORNIA CHILDREN'S SERVICES (CCS) PROGRAM AND GENETICALLY HANDICAPPED PERSONS PROGRAM (GHPP) STAFF, CCS PROGRAM MEDICAL CONSULTANTS, COUNTY MEDICAL STAFF, AND SYSTEMS OF CARE DIVISION (SCD) STAFF

SUBJECT: PRESCRIPTION EAR PRODUCTS NO LONGER PAYABLE

The purpose of this Information Notice is to communicate that specific prescription otic (for the ear) products which are currently payable in the Medi-Cal billing system and where found to be not approved by the Federal Food and Drug Administration (FDA), will no longer be payable in the Medi-Cal billing system effective for dates of service beginning December 1, 2015 (See Attachment A). An approved SAR will not allow payment.

This action is being taken due to enforcement action by the FDA against companies that manufacture and/or distribute products to relieve ear pain, infection, and inflammation containing the following active ingredients:

- benzocaine
- benzocaine and antipyrine
- benzocaine, antipyrine, and zinc acetate
- benzocaine, chloroxylenol, and hydrocortisone
- chloroxylenol and pramoxine
- chloroxylenol, pramoxine, and hydrocortisone

According to the FDA, the above products have not been evaluated for safety, effectiveness, and quality.

More information on FDA's decision:

[FDA takes action against unapproved prescription ear drop products](#)

[Unapproved and Misbranded Otic Prescription Drug Products; Enforcement Action Dates](#)

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Otic products that have been approved by the FDA remain payable in the billing system.

If you have any questions, please contact Edan Lum, Pharm D., Pharmaceutical Consultant, at (916) 322-1543 or (510) 286-0708, or via e-mail at edan.lum@dhcs.ca.gov.

Sincerely,

ORIGINAL SIGNED BY LOUIS R. RICO

Louis R. Rico, Chief
Systems of Care Division

Attachment

Attachment A: List of Otic Products Not Approved by FDA

The following products will no longer be payable beginning December 1, 2015:

NDC	Label Name	Generic Name
24208056162	ANTIPYRINE-BENZOCAINE EAR DROP	ANTIPYRINE/BENZOCAINE
42192070810	ANTIPYRINE-BENZOCAINE EAR DROP	ANTIPYRINE/BENZOCAINE
42192071015	ANTIPYRINE-BENZOCAINE EAR DROP	ANTIPYRINE/BENZOCAINE
42192071214	AURAX OTIC SOLUTION	ANTIPYRINE/BENZOCAINE
43199001615	ANTIPYRINE-BENZOCAINE EAR DROP	ANTIPYRINE/BENZOCAINE
58657048014	ANTIPYRINE-BENZOCAINE OTIC SOL	ANTIPYRINE/BENZOCAINE
58980020010	ANTIPYRINE-BENZOCAINE EAR DROP	ANTIPYRINE/BENZOCAINE
58980020015	ANTIPYRINE-BENZOCAINE EAR DROP	ANTIPYRINE/BENZOCAINE
59088086402	OTIC CARE OTIC SOLUTION	ANTIPYRINE/BENZOCAINE
64376043815	ANTIPYRINE-BENZOCAINE EAR DROP	ANTIPYRINE/BENZOCAINE
66424052035	AUROGUARD OTIC SOLUTION	ANTIPYRINE/BENZOCAINE
76439030414	ANTIPYRINE-BENZOCAINE OTIC SOL	ANTIPYRINE/BENZOCAINE
76439030510	ANTIPYRINE-BENZOCAINE EAR DROP	ANTIPYRINE/BENZOCAINE
76439030515	ANTIPYRINE-BENZOCAINE EAR DROP	ANTIPYRINE/BENZOCAINE
28595042020	OTOZIN EAR DROPS	ANTIPYRINE/BENZOCAIN/GLY/ZINC
67877026911	PRAMOXINE-HC OTIC DROPS	HC/PRAMOXINE HCL/CHLOROXYLENOL