

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



DATE: February 19, 2016

ALL PLAN LETTER 16-004 (SUPERSEDES ALL PLAN LETTER 03-004)

TO: ALL MEDI-CAL MANAGED CARE HEALTH PLANS

SUBJECT: MEDI-CAL MANAGED CARE HEALTH PLANS CARVED-OUT DRUGS

PURPOSE:

The purpose of this All Plan Letter (APL) is to clarify for Medi-Cal managed care health plans (MCPs) how carved-out (non-capitated) drugs are managed by the Department of Health Care Services (DHCS), and how new combinations of carved-out and capitated drugs must be treated.

POLICY:

DHCS refers to drugs as carved-out, capitated, and parent drugs. A carved-out drug is a drug that is not covered by the MCPs and is not included in the MCPs' capitation rates. Although an MCP provider may write a prescription for a carved-out drug, when dispensed, the pharmacy provider bills Medi-Cal fee-for-service (FFS), not the MCP. The term carved-out is synonymous with non-capitated when referring to these drugs. Certain categories of drugs are currently carved-out, or non-capitated, unless otherwise specified in the MCP's contract with DHCS, or in the Provider Manual.¹

Drugs are carved-out by categories or classes as well as by ingredients and by the generic name, not by individual brand name, dose form, or indications for treatment (e.g. hepatitis B virus or HIV), except for drugs used to treat erectile dysfunction (ED). ED drugs are capitated for all indications except ED, which is not a Medi-Cal benefit and, therefore, is not a covered service. Additional categories may be added to the list of carved-out drugs in the future. MCPs will be notified of any additions or deletions to the carved-out drug list.

A drug that is capitated is a drug that is covered by MCPs and is included in MCPs' capitation rates. When dispensed, the pharmacy bills the MCP for the covered drug, not Medi-Cal FFS.

¹ The links to the Provider Manual for the different MCP models are: <u>http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part1/mcpcohs_z01.doc;</u> <u>http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part1/mcpgmc_z01.doc;</u> and <u>http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part1/mcptwoplan_z01.doc.</u>

A parent drug is a molecular entity, as defined by the Food and Drug Administration (FDA), already marketed in this country, which has a new chemical derived from its active ingredient. New dosage forms, strengths, routes of administration, and salts of drugs are categorized the same as the parent form of the drug and will be treated in the same manner as the parent drug.

DHCS will apply the terms carved-out, capitated, and parent drugs when rendering a decision about whether a new drug, approved by the FDA, is to be carved-out or covered:

- 1. Any new combination of a currently carved-out/non-capitated drug, which is marketed as one drug, will be treated as a carved-out/non-capitated drug;
- Any new combination of a carved-out/non-capitated drug and a capitated drug, which is marketed as one drug, may be treated as carved-out or covered. This will be determined by the DHCS's Pharmacy Benefits Division. Unless DHCS notifies the MCPs that the new combination is carved-out, MCPs must treat the new combination as a capitated drug;
- 3. Any new combination of drugs, all of which are capitated, but marketed as one drug, will be treated as a capitated drug;
- 4. Any new HIV/AIDS, heroin or alcohol detoxification treatment, blood and coagulation factor, and antipsychotic medication which are approved by the FDA may be carved-out if they represent a new molecular entity; and
- 5. Any new strength, formulation, route of administration, or salt approved by the FDA of a currently carved-out/non-capitated parent drug may be carved out.

A complete list of carved-out or non-capitated drugs is maintained by the DHCS Pharmacy Benefits Division and is distributed to the MCPs on a regular basis. This list is also posted in the Provider Manual and providers are notified of any updates via Provider Bulletins. In addition, every month, DHCS will provide MCPs with a file that contains Medi-Cal carved-out drug pharmacy claims from the previous year for the MCPs' current members. These files are designed to help MCPs better understand and coordinate the care of their members.

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If you have any questions regarding this APL, please contact your Managed Care Operations Division contract manager.

Sincerely,

Oríginal Sígned by Nathan Nau

Nathan Nau, Chief, Managed Care Quality and Monitoring Division Department of Health Care Services