

## DEPARTMENT OF HEALTH SERVICES

714/744 P STREET  
P.O. BOX 942732  
SACRAMENTO, CA 94234-7320



(916) 654-0499  
(916) 654-0476 TDD/Relay

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Index: Experimental/  
Investigational  
Services

To : All County California Children Services (CCS) Offices and State  
CCS Regional Offices

Subject: Coverage of Experimental and/or Investigational Services

### Introduction

There have been no clearly defined criteria which CCS medical consultants could use to determine whether or not to authorize the coverage of experimental and/or investigational services. There is a need to assist the professional consultant staff in determining when such services are a benefit of CCS. The Medi-Cal program adopted guidelines in 1988 for the authorization of such services and these appear in Sections 51056.1 and 51303 (g), Title 22, California Code of Regulations. The CCS program is adopting similar criteria.

### Policy

1. Experimental services are not benefits of CCS. These include those drugs, equipment, procedures or services that are in a testing phase undergoing laboratory or animal studies prior to testing in humans.
2. Investigational services are those drugs, equipment, procedures or services for which laboratory and animal studies have been completed and for which human studies are in progress but the testing is not complete. The efficacy and safety are not yet established and the service is not in wide usage.
3. Investigational services are only covered when ALL of the following conditions apply to a specific patient.
  - a. Conventional therapy will not adequately treat the patient's condition.
  - b. Conventional therapy will not prevent progressive disability or premature death.
  - c. The provider of the proposed service has a record of safety and success with it or equivalent to that of other providers of the investigational services.

- d. The investigational service is the lowest cost item that meets the patient's medical needs and is less costly than all conventional alternatives.
  - e. There is reasonable expectation that the investigational service will significantly prolong the patient's life or will maintain or restore a range of physical and social function suited to activities of daily living.
  - f. The service is not being performed as part of a research study protocol.
4. Authorizations for the use of an investigational new drug shall only be given after documentation that all of the criteria in (2) above are met and the drug shall be in Phase III clinical trials or have approval by the Federal Food and Drug Administration (FDA) under a treatment investigational new drug. If authorization is also being sought for hospital admission for the specific purpose of the administration of an investigational new drug, the determination shall be made whether or not the patient's medical condition requires the medical necessity of acute hospital care. If it is determined that the patient requires acute hospital care, the requested stay can be authorized. Claims for such drugs given on an outpatient basis can only be reimbursed if the drug company has permission from the FDA to charge for the drug.
5. All requests for investigational drugs and/or other services require prior authorization by CCS and shall be referred to the CCS regional medical consultant for review of the available documentation and applicability of the criteria in (2) above. Authorizations shall be issued after consultation with the other state regional medical consultants and the program director.

*Maridee Gregory MD*

Maridee A. Gregory, M.D., Chief  
Children's Medical Services Branch