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8.325.6 EXPERIMENTAL OR INVESTIGATIONAL PROCEDURES, TECHNOLOGIES OR NON-DRUG THERAPIES

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TITLE 8 SOCIAL SERVICES
CHAPTER 325 SPECIALTY SERVICES
PART 6 EXPERIMENTAL OR INVESTIGATIONAL PROCEDURES, TECHNOLOGIES OR NON-DRUG THERAPIES

8.325.6.1 ISSUING AGENCY: New Mexico Human Services Department.
[2/1/95; 8.325.6.1 NMAC - Rn, 8 NMAC 4.MAD.000.1, 6-1-03]

8.325.6.2 SCOPE: The rule applies to the general public.
[2/1/95; 8.325.6.2 NMAC - Rn, 8 NMAC 4.MAD.000.2, 6-1-03]

8.325.6.3 STATUTORY AUTHORITY: The New Mexico medicaid program is administered pursuant to regulations promulgated by the federal department of health and human services under Title XIX of the Social Security Act, as amended and by the state human services department pursuant to state statute. See Section 27-2-12 et seq. NMSA 1978 (Repl. Pamp. 1991).
[2/1/95; 8.325.6.3 NMAC - Rn, 8 NMAC 4.MAD.000.3, 6-1-03]

8.325.6.4 DURATION: Permanent
[2/1/95; 8.325.6.4 NMAC - Rn, 8 NMAC 4.MAD.000.4, 6-1-03]

8.325.6.5 EFFECTIVE DATE: February 1, 1995
[2/1/95; 8.325.6.5 NMAC - Rn, 8 NMAC 4.MAD.000.5, 6-1-03]

8.325.6.6 OBJECTIVE: The objective of these regulations is to provide policies for the service portion of the New Mexico medicaid program. These policies describe eligible providers, covered services, noncovered services, utilization review and provider reimbursement.
[2/1/95; 8.325.6.6 NMAC - Rn, 8 NMAC 4.MAD.000.6, 6-1-03]

8.325.6.7 DEFINITIONS: [RESERVED]

8.325.6.8 MISSION STATEMENT: The mission of the New Mexico medical assistance division (MAD) is to maximize the health status of medicaid-eligible individuals by furnishing payment for quality health services at levels comparable to private health plans.
[2/1/95; 8.325.6.8 NMAC - Rn, 8 NMAC 4.MAD.002, 6-1-03]

8.325.6.9 EXPERIMENTAL OR INVESTIGATIONAL PROCEDURES, TECHNOLOGIES OR THERAPIES: The New Mexico medicaid program (medicaid) pays only for medically necessary services furnished by medicaid providers to eligible recipients. Medicaid does not cover experimental or investigational medical, surgical, or other health care procedures or treatments, including the use of drugs, biological products, other products or devices, except for the following: Medicaid covers routine patient care costs associated with certain Phase I, II, III, and IV cancer clinical trials. The following sections describe the process used to assess the nature of these procedures, technologies or therapies.
[2/1/95; 12/1/99; 8.325.6.9 NMAC - Rn, 8 NMAC 4.MAD.765 & A, 6-1-03]

8.325.6.10 NONCOVERED SERVICES: Except as specified in sections 11 and 14 of this part, medicaid does not cover experimental or investigational medical, surgical, or other health care procedures or treatments, including the use of drugs, biological products, other products or devices. Medicaid does not reimburse providers for furnishing these experimental or investigational services and products.
[2/1/95; 12/1/99; 8.325.6.10 NMAC - Rn, 8 NMAC 4.MAD.765.1 & A, 6-1-03]

8.325.6.11 COVERED SERVICES: Medicaid provides coverage for routine patient care costs incurred as a result of the patient's participation in a Phase I, II, III, or IV cancer trial that meets the following criteria. The clinical trials can only be performed in New Mexico.

A. The cancer clinical trial is being conducted with approval of at least one of the following:
(1) one of the federal national institutes of health;

(2) a federal national institutes of health cooperative group or center;
(3) the federal department of defense;
(4) the federal food and drug administration in the form of an investigational new drug application;
(5) the federal department of veteran affairs; or
(6) a qualified research entity that meets the criteria established by the federal national institutes of health for grant eligibility.

B. The clinical trial has been reviewed and approved by an institutional review board that has a multiple project assurance contract approved by the office of protection from research risks of the federal national institutes of health.

[8.325.6.11 NMAC – N, 6-1-03]

8.325.6.12 EXPERIMENTAL OR INVESTIGATIONAL INTERVENTIONS: Any medical, surgical, or other healthcare procedure or treatment, including the use of drug(s), biological product(s), other product(s) or device(s), is considered experimental or investigational if it meets any of the following conditions:

A. Current, authoritative medical and scientific evidence regarding the medical, surgical, or other health care procedure or treatment, including the use of drug(s), biological product(s), other product(s) or device(s) for a specific condition shows that further studies or clinical trials are necessary to determine benefits, safety, efficacy and risks, especially as compared with standard or established methods or alternatives for diagnosis and/or treatment outside an investigational setting;

B. The drug, biological product, other product, device, procedure or treatment (the "technology") lacks final approval from the food and drug administration (FDA) or any other governmental body having authority to regulate the technology;

C. The medical, surgical, other health care procedure or treatment, including the use of drug(s), biological product(s), other product(s) or device(s) is the subject of ongoing phase I, II, or III clinical trials or under study to determine safety, efficacy, maximum tolerated dose or toxicity, especially as compared with standard or established methods or alternatives for diagnosis and/or treatment outside an investigational setting.

[2/1/95; 12/1/99; 8.325.6.12 NMAC - Rn, 8 NMAC 4.MAD.765.2 & A, 6-1-03]

8.325.6.13 REVIEW OF CONDITIONS: On request of MAD or its designee, providers of a particular service can be required to present current, authorative medical and scientific evidence that the proposed technology is not considered experimental or investigational.

[2/1/95; 12/1/99; 8.325.6.13 NMAC - Rn, 8 NMAC 4.MAD.765.3, 6-1-03]

8.325.6.14 REIMBURSEMENT:

A. Except as specified below in subsection B, medicaid does not reimburse for medical, surgical, other health care procedures or treatments, including the use of drugs, biological products, other products or devices that are considered experimental or investigational.

B. Medicaid will reimburse providers for routine patient care services, which are those medically necessary services that would be covered if the patient were receiving standard cancer treatment, rendered during the patient's participation in Phase I, II, III, or IV cancer clinical trials.

[2/1/95; 12/1/99; 8.325.6.14 NMAC - Rn, 8 NMAC 4.MAD.765.4 & A, 6-1-03]

HISTORY OF 8.325.6 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed with the State Records Center:
ISD 310.0200, Hospital Services, filed 1/9/80.
ISD 310.0200, Hospital Services, filed 12/8/80.
ISD 310.0200, Hospital Services, filed 12/30/81.
ISD 310.0200, Hospital Services, filed 4/2/82.
ISD 310.0200, Hospital Services, filed 7/8/82.
ISD Rule 310.0200, Hospital Services, filed 4/5/83.
ISD Rule 310.0200, Hospital Services, filed 2/15/84.
ISD Rule 310.0200, Hospital Services, filed 4/26/84.
ISD Rule 310.0200, Hospital Services, filed 2/21/86.
MAD Rule 310.02, Hospital Services, filed 12/1/87.
MAD Rule 310.02, Hospital Services, filed 4/27/88.

MAD Rule 310.02, Hospital Services, filed 5/23/88.
MAD Rule 310.02, Hospital Services, filed 8/18/88.
MAD Rule 310.02, Hospital Services, filed 7/2/90.
MAD Rule 310.02, Hospital Services, filed 3/27/92.
MAD Rule 310.02, Hospital Services, filed 4/21/92.
MAD Rule 310.02, Hospital Services, filed 5/1/92.
MAD Rule 310.02, Hospital Services, filed 7/14/93.
MAD Rule 310.02, Hospital Services, filed 3/10/94.
MAD Rule 310.02, Hospital Services, filed 6/15/94.
MAD Rule 310.02, Hospital Services, filed 12/8/94.

History of Repealed Material:
MAD Rule 310.02, Hospital Services, filed 12/8/94 - Repealed effective 2/1/95.