

**Mountain State Blue Cross Blue Shield
(Otherwise referred to as the Plan)**

CORPORATE POLICY AND PROCEDURES

TITLE: INVESTIGATIONAL (EXPERIMENTAL) SERVICES

No: MP 03 Supersedes No.: N/A Original Effective Date: 11/15/01
Standards: Date of Last Review: 07/09/04
**Related Policies: CM 02 - Medical Director/
Physician Advisor Referral Date of Last Revision: 04/03/03**

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DRAFT () INTERIM () FINAL (X)

Lines of Business:

Applies To: FEP (X) PPO (X) POS (X) INDEMNITY (X)

Variation for: (N/A)

**Intended Distribution: Standard List (X) Secondary Review List () Secondary
Distribution List:()**

DESCRIPTION

The term investigational (experimental) is defined by the Plan as the use of any treatment, procedure, facility, equipment, drug, device, supply or technology that does not meet all of the following criteria as determined by Mountain State Blue Cross Blue Shield:

- Final approval from the appropriate government regulatory bodies for the application proposed.
- The scientific evidence provides conclusive evidence regarding the effect on outcomes.
- Must improve the net health outcome; as shown in published peer-reviewed medical literature.
- Must be as beneficial as any established available alternatives.
- Improvement must be attainable in other investigational settings.

These criteria apply even if there is no available alternative to treat an injury, ailment, condition, disease, disorder, or illness. This determination will be made by Mountain State Blue Cross Blue Shield, in its sole discretion, and will be conclusive.

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POLICY

A service is considered investigational (experimental) if any of the following criteria are met:

- The services or supplies requiring Federal or other Governmental body approval, such as drugs and devices, do not have unrestricted market approval from the Food and Drug Administration (FDA) for use in treatment of a specified condition. Any approval that is granted as an interim step in the regulatory process is not a substitute for unrestrictive market approval. The state of the FDA approval may be obtained by contacting the Project Manager, Medical Information Services at the BCBSA at 888-832-4321.
- There is insufficient or inconclusive *evidence in peer-reviewed medical literature to permit the Plan to evaluate the therapeutic value of the service or supply.
- There is insufficient or inconclusive *evidence in peer-reviewed medical literature that the service or supply has a beneficial effect on health outcomes.
- The service or supply under consideration is not as beneficial as any established alternatives.
- There is insufficient or inconclusive *evidence that, when used in a non-investigational setting, the service or supply has a beneficial effect on health outcomes or is as beneficial as any established alternatives.

*** *Evidence* as noted above is defined as at least two peer-reviewed documents of medical/scientific evidence that treatment is likely to be beneficial.**

Opinions of experts in a particular field and opinions and assessments of nationally recognized review organizations may also be considered by the Plan but are not determinative nor conclusive. All services or procedures determined as or potentially considered Investigational (Experimental) would be referred to the Medical Director/Physician Advisor for review (Refer to Policy CM 02 – Medical Director/Physician Advisor Referral).

BENEFIT APPLICATIONS

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State or federal mandates may dictate that all FDA approved devices/procedures may not be considered investigational and thus coverage eligibility may be assessed only on the basis of medical necessity.

REFERENCES

1. BCBSA Medical Policy Manual
2. BCBS of North Carolina Medical Policy ADM9060
3. MSBCBS Medical Policy Committee, July 2001
4. Highmark Medical Policy 2003, Policy G-15

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances may warrant individual consideration, based on review of applicable medical records.

Medical policies are designed to supplement the terms of a member's contract. The member's contract defines the benefits available; therefore, medical policies should not be construed as overriding specific contract language. In the event of conflict, the contract shall govern.

Medical policies do not constitute medical advice, nor the practice of medicine. Rather, such policies are intended only to establish general guidelines for coverage and reimbursement under Mountain State Blue Cross Blue Shield plans. Application of a medical policy to determine coverage in an individual instance is not intended and shall not be construed to supercede the professional judgment of a treating provider. In all situations, the treating provider must use his/her professional judgment to provide care he/she believes to be in the best interest of the patient, and the provider and patient remain responsible for all treatment decisions.

Mountain State Blue Cross Blue Shield (MSBCBS) retains the right to review and update its medical policy guidelines at its sole discretion. These guidelines are the proprietary information of MSBCBS. Any sale, copying or dissemination of the medical policies is prohibited; however, limited copying of medical policies is permitted for individual use.

SIGNATURE PAGE

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Approval: _____

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