



Corporate Medical Policy

Investigational (Experimental) Services

File Name: investigational_(experimental)_services
Origination: 1/1996
Last Review: 09/28/2009

Active policy, no longer scheduled for routine review.

Description of Procedure or Service

BCBSNC defines the terms "investigational" or "experimental" as the use of a service, procedure or supply that is not recognized by the Plan as standard medical care for the condition, disease, illness or injury being treated. A service, procedure or supply includes, but is not limited to the diagnostic service, treatment, facility, equipment, drug or device.

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

1. The services, procedures 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) or final approval from any other governmental regulatory body 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 final or unrestricted market approval.
2. There is insufficient or inconclusive [medical and scientific evidence](#) to permit the Plan to evaluate the therapeutic value of the service, procedure or supply. (Adequate evidence is defined as **at least two** documents of [medical and scientific evidence](#) that indicate that the proposed treatment is likely to be beneficial to the member.)
3. There is inconclusive [medical and scientific evidence](#) in peer-reviewed medical literature that the service, procedure or supply has a beneficial effect on health outcomes.
4. The service, procedure or supply under consideration is not as beneficial as any established alternatives.
5. There is insufficient information or inconclusive scientific evidence that, when used in a non-investigational setting, the service, procedure or supply has a beneficial effect on health outcomes or is as beneficial as any established alternatives.

Refer to Clinical Trial Services for Life-Threatening Conditions for additional information.

Policy

BCBSNC will **not** provide coverage for Investigational (Experimental) Services, except for covered clinical trial services (see Clinical Trial Services for Life-Threatening Conditions policy). Investigational (Experimental) Services do not meet the criteria for "medically necessary services" because these services are not standard medical practice (see Medical Necessity policy).

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Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

This policy will apply to all product lines of business unless otherwise indicated by the member's certificate/contract (e.g., self-funded groups).

When Investigational (Experimental) Services are covered

Investigational (Experimental) Services are not covered except as delineated in the Clinical Trial Services for Life-Threatening Conditions medical policy.

When Investigational (Experimental) Services are not covered

Investigational (Experimental) Services are not covered. BCBSNC does not cover investigational (experimental) services, procedures or supplies.

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

1. The services, procedures 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) or final approval from any other governmental regulatory body 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 final or unrestricted market approval.
2. There is insufficient or inconclusive **medical and scientific evidence** to permit the Plan to evaluate the therapeutic value of the service, procedure or supply. (Adequate evidence is defined as **at least two** documents of **medical and scientific evidence** that indicate that the proposed treatment is likely to be beneficial to the member.)
3. There is inconclusive **medical and scientific evidence** in peer-reviewed medical literature that the service, procedure or supply has a beneficial effect on health outcomes.
4. The service, procedure or supply under consideration is not as beneficial as any established alternatives.
5. There is insufficient information or inconclusive scientific evidence that, when used in a non-investigational setting, the service, procedure or supply has a beneficial effect on health outcomes or is as beneficial as any established alternatives.

Note: BCBSNC does not cover investigational, cosmetic or not medically necessary services and will not reimburse for any services, procedures, drugs or supplies **associated with those** investigational, cosmetic or not medically necessary services.

Policy Guidelines

Determinations are made by the Plan after BCBSNC's review of available scientific data. 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 or conclusive.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes:

See procedure code for specific procedure or service.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Policy Key Words

Key Words: Investigational Procedures, Investigational, Experimental, FDA, Food and Drug Administration, Clinical Trial Services for Life-Threatening Conditions, Clinical Trials

Medical Term Definitions

Medical and Scientific Evidence

is defined by BCBSNC as one of the following:

1. Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.
2. Peer-reviewed literature or biomedical compendia from such sources as the National Institute of Health's National Library of Medicine or The Cochrane Library.
3. An accepted indication for treatment in one of the following standard reference compendia:
 - The American Hospital Formulary Service-Drug Information,
 - The American Medical Association Drug Evaluations,
 - The American Dental Association Accepted Dental Therapeutics, and
 - The United States Pharmacopoeia Drug Information.
4. Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the:
 - U.S. Department of Health and Human Services,
 - Federal Agency for Healthcare Research and Quality,
 - National Institutes of Health,
 - National Cancer Institute,
 - National Academy of Sciences,
 - Center for Medicare and Medicaid Services, and

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- Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual
Specialty Matched Consultant Advisory Panel - 11/1999
Medical Policy Advisory Group - 12/2/1999
Medical Policy Advisory Group - 9/2001
Medical Policy Advisory Group - 2/2002
Medical Policy Advisory Group - 3/2002
Medical Policy Advisory Group - 10/2003
Medical Policy Advisory Group - 9/2005

Policy Implementation/Update Information

1/96 Original Policy issued

8/96 Revised: Updated list with removal of the following policies: Laser Prostatectomy, Terbutaline Infusion Pump, and TIPS.

6/97 Policy revised to include non-FDA approved drugs, devices, equipment, and supplies.

11/98 Revised to remove the list of procedures considered investigational. Check specific policy for proper coverage guidelines.

9/99 Reformatted, Medical Term definitions added.

12/99 Reaffirmed, Medical Policy Advisory Group

4/01 S9990, S9991 removed from coding section.

9/01 Medical Policy Advisory Group review. No change to policy.

4/02 Medical Policy Advisory Group review 2/02 and 3/02. Policy revised based on clinical trials mandate and medical consultant recommendations. Revised the definition for Medical and Scientific Evidence to include review from The Cochrane Library.

10/03 Medical Policy Advisory Group review. Information added in Benefits Application and Billing and Coding sections of the policy. No change in criteria. Format change.

11/03 Corrected Benefit Application Section.

3/04 Policy Number changed from ADM9060 to MED1263.

10/8/05 Medical Policy Advisory Group review on 09/08/2005. No changes to policy coverage criteria.

4/9/07 Policy Number changed from MED1263 to ADM9051.

05/05/08 Policy reviewed 4/4/2008 by Vice President and Senior Medical Director of Provider Partnerships, Medical and Reimbursement Policy. No changes to policy criteria.

09/28/09 Under the section, "When Investigational (Experimental) Services are not covered" added the following:
Note: BCBSNC does not cover investigational, cosmetic or not medically necessary services and will not reimburse for any services, procedures, drugs or supplies **associated with those** investigational, cosmetic or

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not medically necessary services.” for clarification purposes. Active policy, no longer scheduled for routine review.

6/22/10 Policy Number(s) removed (amw)