BlueCross BlueShield of Illinois

# Blue Cross and Blue Shield of Illinois Provider Manual

## HMO Scope of Benefits Section



Blue Cross and Blue Shield of Illinois, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company, an Independent Licensee of the Blue Cross and Blue Shield Association

# Investigational Procedures, Drugs, Devices, Services, and/or Supplies

## Benefit

Procedures, drugs, devices, services and/or supplies which are investigational are generally excluded from coverage by the Certificate of Coverage. However, certain of these services, are in benefit, reflecting provisions of Federal (Patient Protection and Affordable Care Act (PPACA) – Section 2709) and Illinois state (Public Act 097-0091) law. This benefit includes clinical trials in Phase I, II, III or IV.

## Interpretation

A procedure, drug, device, service and/or supply (referred to as a service in the following document) are defined as investigational if it meets the following criteria:

1. It is provided or performed in special settings for research purposes or under a controlled environment and which are being studied for safety, efficiency and effectiveness, and/or
2. It is awaiting endorsement by the appropriate National Medical Specialty College or federal government agency for general use by the medical community at the time they are rendered to the member, and
3. Specifically, with respect to drugs, combination of drugs and/or devices, are not finally approved by the Food and Drug Administration at the time used or administered to the member.

There are certain services that are in benefit:

1. Applied behavior analysis used for the treatment of Autism Spectrum Disorder(s)
2. Services provided within the context of a clinical trial

Clinical trial services are in benefit if all of the following are met:

1. The PCP has determined medical necessity and has referred the member to the clinical trial that is designed to address a potentially life-threatening condition. This is not limited to a cancer diagnosis, AND
2. It is a qualified clinical trial - determined by meeting at least one of the following criteria:
    a. The trial is approved or funded by one or more of the following:
        i. The National Institutes of Health
        ii. The Centers for Disease Control and Prevention
        iii. The Agency for Health Care Research and Quality
        iv. The Centers for Medicare & Medicaid Services
        v. A cooperative group or center of any of the entities described in clauses (i) through (iv) above or the Department of Defense or the Department of Veterans Affairs
        vi. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants
        vii. The Department of Veterans Affairs
        viii. The Department of Defense
        ix. The Department of Energy
    b. OR it is conducted under an investigational new drug application reviewed by the Food and Drug Administration
    OR it is a drug trial that is exempt from having such an investigational new drug application
3. AND, the services would normally be covered for members who are not enrolled in a clinical trial.

    The clinical trial can be Phase I, II, III or IV.

    Coverage of routine care for members in a qualified clinical trial is subject to the same requirements, such as authorization and utilization management. An IPA can require the member to use an in-network provider if one is available to provide routine care in connection with the clinical trial.

There are certain services that are not in benefit. These include:

- Services which are experimental, investigational, or of unproven efficacy and which do not meet the definitions of coverage as described above
- Out-of-network services, that are not approved by the PCP
- A service provided solely to satisfy data collection and analysis needs for the clinical trial that is not used in the direct clinical management of the member
- A non-health care service that the member is required to receive as a result of participation in the clinical trial
- A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis
- An investigational drug or device that has not been approved for market by the United States Food and Drug Administration
- Services provided to members of an employer group that meets the grandfathered status under the Affordable Care Act (ACA)

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| **Paid by** | Professional Charges (not covered by clinical trial) | **IPA** |
| | Inpatient and/or Outpatient Surgical Facility Charges (not covered by clinical trial) | **HMO** |

Note: It is strongly recommended that the IPA contact the clinical trial/research facility in advance, to establish the coverage for any anticipated services.

See related benefits interpretations: ASD