Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information.

Category: Medicine
***Current Policy Effective Date: 11/1/06**

Title: Cellular Therapy

Procedure Code(s): M0075

Description / Background

Cellular therapy – also called live cell therapy, cellular suspensions, glandular therapy, fresh cell therapy, sicca cell therapy, embryonic cell therapy, and organotherapy – refers to various procedures in which processed tissue from animal embryos, fetuses or organs is injected or taken orally. Products are obtained from specific organs or tissues said to correspond to the unhealthy organs or tissues of the recipient. The organs and glands used in cell treatment include brain, pituitary, thyroid, adrenals, thymus, liver kidney, pancreas, spleen, heart, ovary, testis and parotid. Proponents claim that the recipient's body automatically transports the injected cells to the target organs, where they supposedly strengthen them and regenerate their structure. Several different types of cells or cell extracts may be given simultaneously; some practitioners routinely give up to 20 or more at once.

The American Cancer Society has strongly advised people not to seek cellular therapy. Under ordinary circumstances cells from the organs of one species cannot replace the cells from the organs of other species. When foreign proteins are injected, the immune system attacks them. In addition, an injection of animal cells can spread viral disease and trigger severe allergic reactions. When taken by mouth, animal cells are digested and are not absorbed intact into the body.

CPT / HCPCS Level II Codes and Description *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:
N/A

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Other codes (investigational, not medically necessary, etc.):

M0075 Cellular therapy

Diagnoses / Medical Conditions

N/A

Medical Policy Statement

Cellular therapy remains investigational. Its safety and effectiveness have not been proven.

Rationale

There is insufficient medical literature available to support the safety and effectiveness of cellular therapy. Some medical sources (e.g., American Cancer Society and Medicare) strongly advise individuals not to seek cellular therapy.

Medical Policy Position Summary (Non-clinical summary statement for customer use)

Cellular therapy involves the use of processed tissues from animal embryos and fetuses. They are injected into the corresponding damaged or diseased organs of the recipient. The purpose of this therapy is to supposedly strengthen and regenerate the diseased organs. This therapy remains investigational. Its safety and effectiveness have not been proven.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

Related Policies

N/A

Medicare Information

"NCD for Cellular Therapy (30.8)," Publication Number 100-3

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"Cellular therapy involves the practice of injecting humans with foreign proteins like placenta or lungs of unborn lambs. Cellular therapy is without scientific or statistical evidence to document its therapeutic efficacy and, in fact, is considered a potentially dangerous practice."

"Accordingly, cellular therapy is not considered reasonable and necessary within the meaning of section 1862(a) (1) of the Act."

This is a longstanding national coverage determination. The effective date of this version has not been posted.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

References

- Barrett, Stephen, MD, "Cellular Therapy," Quackwatch, December 6, 1999, Revised August 21, 2003, http://www.quackwatch. com/01QuackeryRelatedTopics/Cancer/cellular.html.
- Centers for Medicare and Medicaid Services (CMS), Medicare Coverage Database, "NCD for Cellular Therapy," Manual Section Number 30.8, Original Effective Date Not posted.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 8, 2006, the date the research was completed.

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Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
6/25/02	6/25/02	6/25/02	Joint policy established
2/16/04	2/16/04	3/1/04	Routine maintenance
4/11/05	4/11/05	4/11/05	Routine maintenance
11/1/06	8/28/06	10/24/06	Routine maintenance; policy retired

Next Review: This is an obsolete policy and will no longer be subject to periodic review

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: N/A	Revised: N/A

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BLUE CARE NETWORK
POLICY: CELLULAR THERAPY

I. Coverage Determination:

BCN does not cover cellular therapy. This procedure remains investigational. Its safety and effectiveness have not been proven. Benefits are not provided for care, services, supplies, devices, drugs or procedures that are experimental or research in nature.

II. Benefit Information:

N/A

III. Benefit Exclusions:

N/A

IV. Administrative Guidelines:

N/A

V. Effective Date:

Policy updated and retired: 11/1/06
Policy updated: 4/11/05
Joint policy effective date: 2/16/04
Supersedes benefit information of: 6/25/02

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