

Corporate Medical Policy

Melanoma Vaccines

File Name:	melanoma_vaccines
Origination:	4/1981
Last CAP Review:	4/2012
Next CAP Review:	4/2013
Last Review:	4/2012

Description of Procedure or Service

Tumor vaccines are a type of active immunotherapy that attempts to stimulate the patient's own immune system to respond to tumor antigens. Although vaccines using crude preparations of tumor material were first studied by Ehrlich over 100 years ago, the first modern report suggesting benefit using these in cancer patients appeared in 1967. Melanoma has been viewed as a particularly promising tumor for this type of treatment because of its immunologic features, which include the prognostic importance of lymphocytic infiltrate at the primary tumor site, the expression of a wide variety of antigens, and the occasional occurrence of spontaneous remissions. Melanoma vaccines can be generally categorized or prepared in the following ways:

- **Whole-cell vaccines** prepared using melanoma cells or crude sub-cellular fractions of melanoma cell lines
 - **Autologous whole-cell vaccines**, in which tumor cells are harvested from the tissue of excised cancers, irradiated, and potentially modified with antigenic molecules to increase immunogenicity and made into patient-specific vaccines (e.g., M-Vax, AVAX Technologies)
 - **Autologous heat-shock protein-peptide complexes vaccines** in which a patient's tumor cells are exposed to high temperatures and then purified to make patient-specific vaccines (e.g., Oncophage®, Vitaspin, Antigenics, Inc.), and
 - **Allogeneic whole-cell vaccines** in which intact or modified allogeneic tumor cell lines from other patients are lysed by mechanical disruption or viral infection and used to prepare vaccine (e.g., Canvaxin®, CancerVaxCorp. or Melacine®, University of Southern California)
- **Dendritic cell vaccines** in which autologous dendritic cells are pulsed with tumor-derived peptides, tumor lysates, or antigen encoding RNA or DNA to produce immunologically enhanced vaccines.
- **Peptide vaccines** consisting of short, immunogenic peptide fragments of proteins (e.g., melanoma antigen E or MAGE; B Melanoma antigen or BAGE) used alone or in different combinations to create vaccines of varying antigenic diversity, depending on the peptide mix.
- **Ganglioside vaccines** in which glycolipids present in cell membranes are combined with an immune adjuvant (e.g. GM2) to create vaccines.
- **DNA vaccines** created from naked DNA expression plasmids.
- **Viral vectors** in which DNA sequences are inserted into attenuated viruses for gene delivery to patient immune systems.
- **Anti-idiotype vaccines** made from monoclonal antibodies with specificity for tumor antigen-reactive antibodies.

Related Policies:
Adoptive Immunotherapy

Melanoma Vaccines

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Melanoma Vaccines are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Some patients may be eligible for coverage under Clinical Trials. Refer to the policy on Clinical Trial Services for Life-Threatening Conditions.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Melanoma Vaccines are covered

Not applicable.

When Melanoma Vaccines are not covered

Melanoma vaccines are considered investigational. BCBSNC does not provide coverage for investigational services.

Policy Guidelines

Despite considerable interest and numerous studies over the past 20 years, to date no melanoma vaccine has been shown to demonstrate safety and efficacy in a well-controlled published Phase III clinical trial and no vaccine treatment for this cancer has been approved by FDA. A wide range of vaccine choices are available including use of autologous tumor cells, allogeneic tumor cells, and tumor-specific moieties including peptides, gangliosides, and DNA plasmids. A variety of mechanisms appear to exist as possible obstacles to successful active immunotherapy using vaccines. Current studies are focused on the use of new and different vaccine preparations, as well as various forms of immune-modulation as potential techniques for enhancing vaccine effectiveness.

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.

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Applicable codes: There is no specific code for this service.

Physicians may submit 86849 for this 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.

Scientific Background and Reference Sources

Tumor Vaccines

BCBSA Medical Policy Reference Manual - 3/96

European Journal of Cancer, Vol. 30A, No. 7, pp. 1029-1035. 1994-Feature Article - "Cancer Vaccines", A.G. Dalgleish

BCBSA Medical Policy Reference Manual - 4/1/98 - 2.03.04

Medical Policy Advisory Group Review 3/99

Specialty Matched Consultant Advisory Panel 11/1999

Medical Policy Advisory Group 12/2/1999

Specialty Matched Consultant Advisory Panel 11/2001

BCBSA TEC Assessment, Special Report, Volume 16, No. 4, May, 2001

BCBSA Medical Policy Reference Manual, 2.03.04; 5/15/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.03.04, 10/9/2003.

Specialty Matched Consultant Advisory Panel - 5/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.03.04, 3/15/2005.

Specialty Matched Consultant Advisory Panel - 3/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.03.04. 6/14/07

Specialty Matched Consultant Advisory Panel - 3/2008

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.03.04, 7/9/2009

Specialty Matched Consultant Advisory Panel – 5/2010

Title Changed to Melanoma Vaccines

Specialty Matched Consultant Advisory Panel – 3/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.03.04, 6/9/2011

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Medical Director – 8/2011

Specialty Matched Consultant Advisory Panel – 4/2012

Policy Implementation/Update Information

Tumor Vaccines

- 4/81 Original policy.
- 6/83 Reaffirmed.
- 12/92 Archived: Little activity (name changed to Vaccination Therapy for Cancer).
- *3/96 Re-evaluate: Policy being re-evaluated. Reactivated and remains investigational. Name changed back to Immunotherapy for Malignant Disease.
- 3/97 Reaffirmed.
- 3/99 Reaffirmed.
- 6/99 Reformatted, Medical Term Definition Added.
- 12/99 Reaffirmed, Medical Policy Advisory Group
- 3/01 System change.
- 11/01 Specialty Matched Consultant Advisory Panel. Policy revised per recommendations. Renamed from Immunotherapy for Malignant Disease. Format changes. Coding changes.
- 8/02 Reaffirmed. Source added to Scientific Reference Sources section.
- 6/10/04 Specialty Matched Consultant Advisory Panel review. Updated Benefit Application and Billing/Coding sections for consistency. No policy changes. References added. Notification given 6/10/2004. Effective 8/12/2004.
- 4/10/06 Specialty Matched Consultant Advisory Panel review. No changes to policy. Added rationale to "Policy Guidelines" section. Names of specific tumor vaccines added to "Key Words" section. References added.
- 6/2/08 Specialty Matched Consultant Advisory Panel review 3/17/2008. No changes to policy statement. Reference to the Clinical Trials policy added to "Policy" section. References added. (btw)
- 6/22/10 Policy Number(s) removed. (amw)
- 7/6/10 Specialty Matched Consultant Advisory Panel review 5/24/2010. No changes to policy statement. "Policy Guidelines" section updated. References added. (btw)

Title Changed to Melanoma Vaccines

- 5/24/11 Title changed from Vaccine Tumors to Melanoma Vaccines. Specialty Matched Consultant Advisory Panel review 4/27/11. No changes to policy intent. References added. (btw)

Melanoma Vaccines

8/16/11 “Description” section revised. References added. Medical Director review 8/6/2011. (btw)

5/15/12 Specialty Matched Consultant Advisory Panel review 4/18/2012. Policy Guidelines updated. No change to policy intent. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.