

Subject: Antineoplaston Therapy
Policy #: MED.00085
Status: Reviewed

Current Effective Date: 11/17/2006
Last Review Date: 09/14/2006

Description/Scope

Antineoplastons are a group of medium and small size synthetic peptides and amino acid derivatives thought to be components of a biochemical defense system which functions by inducing differentiation in neoplastic cells. Antineoplastons A10 and AS2-1 have been most commonly researched as a treatment for a wide variety of malignancies and HIV infection.

Policy Statement

Investigational/Not Medically Necessary:

Antineoplaston therapy, including, but not limited to, antineoplaston A10 and AS2-1, is considered **investigational/not medically necessary** for all conditions, including but not limited to any malignancy or HIV infection.

Rationale

A search of the literature did not identify any controlled studies of antineoplaston therapy. The bulk of the literature consists of case reports, case series and data from single institution phase II trials. In summary, there is inadequate published data to permit scientific conclusions regarding the efficacy of antineoplaston therapy.

Background/Overview

Antineoplastons are a group of synthetic compounds originally isolated from human blood and urine by Stanislaw Burzynski, M.D., Ph.D., in Houston, Texas. Dr. Burzynski has used antineoplastons to treat patients with a variety of cancers. In 1991, the National Cancer Institute (NCI) conducted a review to evaluate the clinical responses in a group of patients treated with antineoplastons at the Burzynski Research Institute in Houston.

The medical records of seven brain tumor patients who were thought to have benefited from treatment with antineoplastons were reviewed by NCI. This did not constitute a clinical trial but, rather, was a retrospective review of medical records, called a "best case series." The reviewers of this series found evidence of antitumor activity, and NCI proposed that formal clinical trials be conducted to further evaluate the response rate and toxicity of antineoplastons in adults with advanced brain tumors.

Investigators at several cancer centers developed protocols for two phase II clinical trials with review and input from NCI and Dr. Burzynski. These NCI-sponsored studies began in 1993 at the Memorial Sloan-Kettering Cancer Center, the Mayo Clinic, and the Warren Grant Magnuson Clinical Center at the National Institutes of Health. Patient enrollment in these studies was slow, and by August 1995 only nine patients had entered the trials. Attempts to reach a consensus on proposed changes to increase accrual could not be reached by Dr. Burzynski, NCI staff, and investigators, and on August 18, 1995, the studies were closed prior to completion. Because of the small number of patients in these trials, the NCI concluded that no definitive conclusions can be drawn about the effectiveness of treatment with antineoplastons.

At present, the Burzynski Research Institute is conducting trials using antineoplastons for a variety of cancers. Information about these trials is available from the Cancer Information Service or on the NCI's <http://www.cancer.gov> web site at http://www.cancer.gov/clinical_trials on the Internet. Currently, no antineoplaston product is approved for use by the Food and Drug Administration (FDA).

Definitions

HIV: Human Immunodeficiency Virus

Malignancy: a neoplasm or tumor that is cancerous

Synthetic peptides: a compound containing two or more amino acids that are produced artificially

Coding

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational/Not Medically Necessary:

CPT
No specific code for administration of antineoplastons

HCPCS
No specific code for antineoplastons

ICD-9 Diagnosis
All diagnoses

References

1. Burzynski SR, Weaver RA, Janicki T, et al. Long-term survival of high-risk pediatric patients with primitive neuroectodermal tumors treated with antineoplastons A10 and AAS2-1. *Integr Cancer Ther* 2005; 4:168-77.
2. Buckner JC, Malkin MG, Reed E, Cascino TL, et al. Phase II study of antineoplaston A10 and AS2-1 in patients with recurrent glioma. *Mayo Clin Proc* 1999; 74:137-45.
3. Burzynski SR, Lewy RI, Weaver R, et al. Long-term survival and complete response of a patient with recurrent diffuse intrinsic brain stem glioblastoma multiforme. *Integr Cancer Ther* 2004; 3:257-61.
4. Burzynski SR. The present state of antineoplaston research. *Integr Cancer Ther* 2004;3:1999.

Web Sites for Additional Information

1. American Cancer Society: Antineoplaston Therapy: Making Treatment decisions: Available at: http://www.cancer.org/docroot/ETO/content/ETO_5_3X_Antineoplaston_Therapy.asp?sitearea=ETO. Accessed on May 30, 2006.
2. NCI Cancer Facts. http://cis.nci.nih.gov/fact/7_43 Accessed May 30, 2006.

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Policy History

Status	Date	Action
Reviewed	09/14/2006	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated references. No change to policy position.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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