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## Antineoplaston Therapy

Policy Number: HS-183

Original Effective Date: 8/5/2010

Revised Date(s): 8/2/2011

### DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

### APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

**BACKGROUND**

Originally isolated from human blood and urine by Stanislaw Burzynski, M.D., Ph.D., in Houston, Texas, antineoplastons are synthetic compounds made up of naturally occurring peptides, amino acid derivatives and organic acids. For many years, Dr. Burzynski has utilized antineoplaston therapy to treat patients with a variety of cancers. In 1991, the clinical responses in a group of patients treated with antineoplastons at the Burzynski Research Institute in Houston were reviewed by the National Cancer Institute (NCI, 2008).

The NCI performed a retrospective review of medical records of seven brain tumor patients who were thought to have benefited from treatment with antineoplastons. This "best case series" analysis did not constitute a clinical trial. After the reviewers found some evidence of antitumor activity, the NCI proposed that formal clinical trials be conducted on adult patients with advanced brain tumors, to further evaluate the response rate and toxicity of antineoplastons.

The NCI sponsored two phase II clinical trials at several cancer centers which included Memorial Sloan-Kettering Cancer Center, the Mayo Clinic, and the Warren Grant Magnuson Clinical Center at the National Institutes of Health. These NCI-sponsored studies were developed with review and input from Dr. Burzynski and the trials began in 1993. However, by 1995, only nine patients had enrolled in the trials. On August 18, 1995, the studies were closed prior to completion when attempts to reach a consensus on proposed changes to increase accrual could not be reached by Dr. Burzynski, NCI staff, and investigators. The NCI concluded that no definitive conclusions can be drawn about the effectiveness of treatment with antineoplastons as a result of the small number of patients enrolled in the studies.

In 2006, Burzynski and colleagues reported data on antineoplaston therapy for high-grade, recurrent and progressive brainstem gliomas consolidated from four trials. The resulting non-randomized, uncontrolled case studies involved 18 evaluable patients and only three patients were alive at the last evaluation. Larger, randomized, controlled studies are needed to demonstrate the efficacy of antineoplaston therapy.

Presently, the Burzynski Research Institute is conducting multiple phase II trials using antineoplastons for a variety of cancers. Information about many of these trials is available from the National Cancer Institute's web site of clinical trials. Currently, there are no antineoplaston products approved for use by the U.S. Food and Drug Administration (FDA).

**POSITION STATEMENT**

Antineoplaston therapy, including, but not limited to, antineoplaston A10 and AS2-1, **is considered experimental and investigational** for all conditions, including, but not limited to, any malignancy.

**CODING**

**Non-covered CPT® Code** - All CPT codes related to injection or infusion

**Non-covered ICD-9-CM Procedure Code** - All ICD-9-CM procedure codes related to injection or infusion

**HCPCS Level II® Code** - Not applicable

**Non-covered ICD-9-CM Diagnosis Codes**

All ICD-9-CM diagnoses including:

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<b>140.0 - 239.9</b>	Neoplasms; malignant, benign, uncertain behavior and unspecified nature
<b>282.41 - 282.49</b>	Thalasseмии
<b>282.60 - 282.69</b>	Sickle-cell disease
<b>335.10 - 335.19</b>	Spinal muscular atrophy
<b>V58.0</b>	Encounter for radiotherapy
<b>V58.11</b>	Encounter of chemotherapy
<b>V58.12</b>	Encounter for immunotherapy

\*Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.®©

## REFERENCES

### Peer Reviewed

1. 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; 74:137-145.
2. Burzynski SR. The present state of antineoplaston research. *Integr Cancer Ther.* 2004; 3(1):47-58.
3. Burzynski SR, Janicki TJ, Weaver RA, Burzynski B. Targeted therapy with antineoplastons A10 and AS2-1 of high-grade, recurrent, and progressive brainstem glioma. *Integr Cancer Ther.* 2006; 5(1):40-47.
4. 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; 3:257-261.
5. 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; 4:168-177.

### Government Agencies, Professional and Medical Organizations

1. American Cancer Society: Antineoplaston Therapy. Revised on November 1, 2008.
2. National Cancer Institute. Antineoplastons PDQA<sup>®</sup>. Last Modified on March 13, 2008.

## HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none"><li>• New template design approved by MPC.</li></ul>
8/2/2011	<ul style="list-style-type: none"><li>• Approved by MPC. No changes.</li></ul>