Policy Number	MED203.002
Policy Effective Date	01/01/2026

Antineoplaston Cancer Therapy

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Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Antineoplaston therapy for the treatment of cancer **is considered experimental, investigational and/or unproven.** This includes, but is not limited to, the following malignancies:

- Brain,
- Head, neck and throat,
- Breast,
- Lung,
- Colon,
- Blood,

- Lymphoma,
- Melanoma,
- Myeloma, or
- Sarcoma.

Policy Guidelines

None.

Description

Antineoplaston (AN) therapy is an alternative form of cancer treatment that involves using a group of synthetic chemicals called ANs to protect the body from disease.

Background
Antineoplastons are hypothesized by proponents to have anti-tumor activity. ANs are made up mostly of peptides and amino acids originally taken from human blood and urine. The therapy can be given orally or by injection into a vein. Proponents claim AN cancer therapy has been successful in treating many forms of cancer. They claim people with cancer have a deficiency of naturally occurring ANs, and that this therapy replenishes the body's supply allowing the biochemical defense system of the body to convert cancer cells into normal cells.

AN cancer therapy is offered exclusively in the U.S. by the Burzynski Research Institute (BRI) in Houston, Texas, and has long been a controversial treatment for various types of malignancy.

Regulatory Status
Antineoplastons are not approved by the U. S. Food and Drug Administration (FDA) for the prevention or treatment of any disease. The FDA gave the developer permission to run clinical trials of antineoplaston therapy. In the United States, antineoplaston therapy can be obtained only in clinical trials at the developer's clinic.

Rationale

Antineoplastons are not approved by the U. S. Food and Drug Administration (FDA) for the prevention or treatment of any disease.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	96549
HCPCS Codes	J9999

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References

1. National Cancer Institute. Antineoplastons (PDQ®) – Health Professional Version. Updated August 15, 2019. Available at <https://www.cancer.gov> (accessed November 24, 2025).
2. National Cancer Institute. Antineoplastons (PDQ®) – Health Patient Version. Updated August 15, 2019. Available at <https://www.cancer.gov> (accessed November 24, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. Coverage unchanged. No new references added; some removed.
07/15/2025	Reviewed. No changes.
06/15/2024	Document updated with literature review. Coverage unchanged. No new references added, some references removed.
03/15/2023	Reviewed. No changes.
05/15/2022	Document updated with literature review. Coverage unchanged. No new references added.
02/15/2021	Reviewed. No changes.
10/01/2020	Document updated with literature review. Coverage unchanged. References 22-23 added, and others revised.
01/15/2019	Reviewed. No changes.
01/15/2018	Document updated with literature review. Coverage unchanged.
01/15/2017	Reviewed. No changes.

04/15/2016	Document updated with literature review. Coverage unchanged.
02/01/2015	Reviewed. No changes.
11/01/2013	Literature reviewed. No changes.
05/15/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
02/01/2007	Revised/updated entire document
10/24/2003	Revised/updated entire document
03/01/1996	New medical document