

Policy Name:	Antineoplaston Therapy and Sodium Phenylbutyrate
Effective Date:	2/1/17

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member's plan document for specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Antineoplastin therapy and associated medical services are investigative and therefore NOT COVERED

Sodium phenylbutyrate for the treatment of breast cancer, prostate cancer or cancers other than acute promyelocytic leukemia or malignant glioma is investigative and therefore NOT COVERED

Description

Antineoplastons are drugs composed of chemical compounds that are naturally present in the urine and blood which are hypothesized to have anti-tumor activity. Antineoplastons are NOT approved by the U.S. Food and Drug Administration (FDA) for the prevention or treatment of any disease and are considered to be complementary and alternative medicine (CAM) by the National Cancer Institute. Case reports, phase I clinical trials, toxicity studies, and phase II clinical studies examining the effectiveness of antineoplaston therapy have been published. For the most part, these publications have been authored by the developer of the therapy, Dr. Burzynski, in conjunction with his associates at the Burzynski Research Institute located in Houston, TX. Although these studies often report remissions, other investigators have not been successful in duplicating these results. Nonrandomized clinical trials investigating the anticancer efficacy of antineoplastons are continuing at the developer's institute; however, there no controlled, peer-reviewed clinical trials to validate the effectiveness of antineoplaston therapy for any indication in the literature. The evidence for use of antineoplaston therapy as a treatment for cancer is inconclusive.

Sodium phenylbutyrate (BUPHENYL) taken orally is metabolized in the liver into a combination of phenylacetylglutamine and phenylacetate, which then enter the bloodstream. These byproducts are the prime ingredients of antineoplaston AS2-1. Sodium phenylbutyrate removes ammonia from the bloodstream and has been approved by the FDA for use in patients with urea cycle disorders. It has also received an orphan drug designation by the FDA for treatment of acute promyelocytic leukemia; as adjunctive treatment to surgery, radiation therapy, and chemotherapy for treatment of patients with primary or recurrent malignant glioma; spinal muscular atrophy; and sickle cell disorders which include S-S hemoglobinopathy, S-C hemoglobinopathy, and S-thalassemia hemoglobinopathy. There is no evidence in the peer-reviewed literature that sodium phenylbutyrate improves clinical outcomes of patients with cancers of the prostate, breast, or cancers other than acute promyelocytic leukemia and malignant glioma.

Medica Coverage Policy



FDA Approval

Antineoplastons are NOT approved by the FDA

Sodium phenylbutyrate is FDA approved for the adjunctive treatment for disorders of urea cycle metabolism including carbamylphosphate synthetase deficiency, ornithine transcarbamylase deficiency, and arginiosuccinic acid synthetase deficiency

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement. (denial)

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met. (split)

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

Original Effective Date: 04/21/2011

Re-Review Date(s): 1/30/14, 9/27/16

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