Public Statement:

Tumor (or Cancer) Vaccines claim to arm the immune system and shrink specific cancers. Unlike traditional vaccines, tumor (or cancer) vaccines do not prime the immune system to prevent illness. They combat existing tumors and they also work in the same way as traditional vaccines, by activating disease-fighting white blood cells of the immune system to mount a counterattack. The only FDA approved tumor vaccine to date is sipuleucel-T (Provenge®). All other such vaccines are still in investigational trials, and are not covered services.

Medical Policy Statement:

Tumor vaccines, other than the use of Provenge® for its FDA approved use, are considered investigational and are not covered.

Background:

Numerous clinical trials are ongoing with over 170 phase I and II trials of melanoma vaccines listed in the NIH clinical trials database.

One vaccine has recently shown a statistically significant improvement in outcomes. Schwartzentruber et al reported the initial findings of their phase III trial of gp100:209-217(210M) peptide plus high-dose IL-2 (Vacc) vs. high-dose IL-2 alone (Ctl). The Vacc arm showed significant improvement in response rate (p=0.02), progression-free survival (PFS; p=0.01), but not median overall survival (p=0.09). Complete evaluation of the results awaits full publication.

A trial testing M-Vax™ (AVAX Technologies, Inc.) is currently recruiting subjects with Stage IV melanoma. M-Vax™ consists of autologous tumor cells conjugated to dinitrophenyl, a highly immunogenic hapten. AVAX Technologies is also sponsoring a
Phase I/II trial of O-Vax®, an autologous, hapten-modified vaccine for patients with ovarian cancer.

Schuster et al, reported results of a phase III randomized trial of BiovaxID, a tumor-specific protein vaccine for patients with advanced follicular lymphoma with complete response to chemotherapy (Schuster et al, 2009). The results indicated that BiovaxID prolonged disease free survival in patients that received the vaccine to 44 months compared to 31 months for those who received the control vaccine. However, the trial was terminated early due to difficulty with patient accrual. This was due in part because rituximab became the standard of care for patients with follicular lymphoma.

In a recent systematic review of medical treatments in melanoma, two pending studies were highlighted (Garbe, 2011). The first is a Phase III vaccine trial of patients with stage IIIIB melanoma whose tumors express MAGE-A3 antigen in lymph node metastasis. This allogeneic vaccine is unique in targeting a specific cancer germline family antigen. The second is a Phase III trivalent vaccine prepared using 3 peptides (GP100, MART-1/Melan, and tyrosine HLA-A2). Preliminary reports suggest patients exhibiting antibodies to any of the 3 peptides had insignificantly improved survival. More definitive results from both studies are pending.

References:


Application to Products

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This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

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