Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Cancer Treatment Vaccines

PRIOR AUTHORIZATION: Not applicable.

POLICY:

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM. Texas Mandate HB1584 is applicable for Medicaid plans.

BSWHP considers vaccine therapy in the treatment of the following cancers experimental and investigational because the clinical evidence is not sufficient to permit conclusions on the health outcome effects of vaccine therapy:

- Breast cancer
- CNS cancers (e.g., glioblastoma and neuroblastoma)
- Colorectal cancer
- Gallbladder cancer
- Gastric cancer
- Glioma
- Head and neck cancer
- Hepatic cancer
- Lung cancer
- Oral squamous cell carcinoma
- Ovarian cancer
- Pancreatic cancer.

BSWHP considers the use of melanoma vaccines, e.g., Theraccine, Oncophage, experimental, investigational and unproven and not medically necessary because of insufficient evidence regarding its safety and effectiveness.

BSWHP considers helper multi-peptide (6MHP) vaccine for metastatic melanoma experimental, investigational and unproven and not medically necessary because of insufficient evidence regarding its safety and effectiveness.
OVERVIEW: Tumor vaccines are a type of immunotherapy that attempts to stimulate the patient’s own immune system to respond to tumor antigens. Tumor vaccines have been principally investigated as a treatment of melanoma, due to the recognition that melanoma can induce an immune response, and the overall ineffectiveness of chemotherapy. Melanoma vaccines can be generally categorized or prepared in the following ways:

- Purified antigen vaccines, consisting of single, purified proteins or gangliosides, or short, immunogenic peptide fragments of proteins (e.g., GMK (ganglioside) vaccine, Progenics);
- Cell lysate vaccines, in which allogeneic tumor cell lines are lysed by mechanical disruption or viral infection;
- Whole cell vaccines, consisting of whole killed allogeneic cells from tumor cell lines. Autologous whole-cell vaccines, in which tumor cells are harvested from the patients, irradiated, and potentially modified with antigenic molecules to increase immunogenicity (e.g., M-Vax®, AVAX Technologies).
- Heat-shock protein-peptide complexes purified from autologous tumor cells (e.g., Oncophage®, Antigenics, Inc.).
- Shed antigen vaccines, consisting of a mixture of cell surface antigens shed into tissue culture supernatant by melanoma cell lines.
- Dendritic cell vaccines, consisting of autologous, dendritic cells pulsed with tumor-derived peptides, tumor lysates, antigen encoding Ribonucleic acid (RNA) or Deoxyribonucleic acid (DNA).
- Genetically modified tumor vaccines, consisting of autologous or allogeneic tumor cell lines transduced with retroviral vectors containing cytokine genes, tumor antigen genes, co-stimulatory molecules, or human leukocyte antigen (HLA) proteins.
- Anti-idiotype vaccine, consisting of monoclonal antibodies with specificity for tumor antigen-reactive antibodies.

NOTE: At the present time, no melanoma vaccine has received approval from the U.S. Food and Drug Administration (FDA).

CODES:

Important note: CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

<table>
<thead>
<tr>
<th>CPT Codes:</th>
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<tbody>
<tr>
<td>CPT Not Covered:</td>
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<td>HCPCS Covered:</td>
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<tr>
<td>HCPCS Not Covered:</td>
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<tr>
<td>ICD-10 Codes:</td>
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<tr>
<td>C00.0-C14.8 - Malignant neoplasm of lip, oral cavity and pharynx</td>
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<tr>
<td>C16.0-C16.9 - Malignant neoplasm of stomach</td>
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<tr>
<td>C18.0-C21.8 - Malignant neoplasm of colon, rectum, rectosigmoid junction, and anus</td>
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<tr>
<td>C22.0-C22.9 - Malignant neoplasm of liver and intrahepatic bile ducts</td>
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<tr>
<td>C23 - Malignant neoplasm of gallbladder</td>
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C25.0-C25.9 - Malignant neoplasm of pancreas  
C34.00-C34.92 - Malignant neoplasm of bronchus and lung  
C43.0-C44.99 - Malignant melanoma of skin  
C50.011-C50.929 - Malignant neoplasm of breast  
C51.0-C51.9 - Malignant neoplasm of vulva  
C52 - Malignant neoplasm of vagina  
C53.0-C53.9 - Malignant neoplasm of cervix uteri  
C56.1-C56.9 - Malignant neoplasm of ovary  
C60.0-C60.9 - Malignant neoplasm of cervix uteri  
C64.1-C64.9 - Malignant neoplasm of kidney, except renal pelvis  
C70.0-C70.9, C72.0-C72.9 - Malignant neoplasm of meninges, spinal cord, cranial nerves and other parts of central nervous system  
C71.0-C71.9 - Malignant neoplasm of brain [glioma]  
C76.0 - Malignant neoplasm of head, face, and neck  
D03.52 - Melanoma in situ of breast (skin) (soft tissue)  
D03.59 - Melanoma in situ of other part of trunk  
Z23 - Encounter for immunization  

CMS: There are no NCDs or LCDs related to this coverage.

POLICY HISTORY:

<table>
<thead>
<tr>
<th>Status</th>
<th>Date</th>
<th>Action</th>
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<tr>
<td>New</td>
<td>12/28/2010</td>
<td>New policy</td>
</tr>
<tr>
<td>Reviewed</td>
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<td>Reviewed</td>
<td>10/3/2013</td>
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<td>Updated, changed name and added ovarian cancer vaccine</td>
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<tr>
<td>Reviewed</td>
<td>09/08/2016</td>
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<td>Updated</td>
<td>08/29/2017</td>
<td>Change status for Sipuleucel-T to “medically necessary”</td>
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<tr>
<td>Updated</td>
<td>06/26/2018</td>
<td>Update coverage for Imlygic® to medically necessary</td>
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<td>12/04/2018</td>
<td>Removed Imlygic® and Sipuleucel-T tp separate policies</td>
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<td>04/22/2021</td>
<td>Medicaid instructions added</td>
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<tr>
<td>Reviewed</td>
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REFERENCES:
The following scientific references were utilized in the formulation of this medical policy. SWHP/FirstCare will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP/FirstCare so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.


Note: Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plans.

STAR Medicaid plans are offered through Scott and White Health Plan in the Central RightCare Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs. Individual HMO plans are offered through FirstCare in West Texas.