MEDICAL COVERAGE POLICY	
SERVICE:	**Cancer Treatment Vaccines**
Policy Number:	**050**
Effective Date:	**06/01/2025**
Last Review:	**05/12/2025**
Next Review:	**05/12/2026**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

SERVICE: Cancer Treatment Vaccines

PRIOR AUTHORIZATION: Not applicable

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). Texas Mandate HB1584 is applicable for Medicaid plans.

BSWHP considers vaccine therapy in the treatment of the following cancers experimental, investigational, and unproven and not medically necessary 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.

BACKGROUND:

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. Earlier melanoma vaccines were 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.

The current emphasis and progress in melanoma vaccine development are largely centered on personalized neoantigen vaccines delivered through platforms like mRNA and their integration with checkpoint blockade.

NOTE: At the present time, only T-VEC (Imlygic) and Amtagvi (Lifileucel) have received approval from the U.S. Food and Drug Administration (FDA). For coverage of T-VEC (Imlygic) and Amatagvi (Lifileucel) please refer to our Medical Coverage Policy 219 – Cancer Chemotherapy / Therapy Guidelines.

CODES:

Important note: *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.*

CPT Codes	

CPT Codes Not Covered	
HCPCS Codes	
HCPCS Codes Not Covered	
ICD-10 Codes	C00.0-C14.8 - Malignant neoplasm of lip, oral cavity and pharynx C16.0-C16.9 - Malignant neoplasm of stomach C18.0-C21.8 - Malignant neoplasm of colon, rectum, rectosigmoid junction, and anus C22.0-C22.9 - Malignant neoplasm of liver and intrahepatic bile ducts C23 - Malignant neoplasm of gallbladder 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 penis 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 C79.81 - Secondary malignant neoplasm of breast D03.52 - Melanoma in situ of breast (skin) (soft tissue) D03.59 - Melanoma in situ of other part of trunk Z23 - Encounter for immunization

POLICY HISTORY:

Status	Date	Action
New	12/28/2010	New policy
Reviewed	12/6/2011	Reviewed.
Reviewed	10/25/2012	No changes
Reviewed	10/3/2013	No changes.
Reviewed	07/24/2014	Updated, changed name and added ovarian cancer vaccine
Reviewed	08/11/2015	No changes
Reviewed	09/08/2016	No changes
Updated	08/29/2017	Change status for Sipuleucel-T to “medically necessary”
Updated	06/26/2018	Update coverage for Imlygic® to medically necessary
Updated	12/04/2018	Removed Imlygic® and Sipuleucel-T to separate policies
Reviewed	01/23/2020	No changes

Reviewed	01/28/2021	Additional E&I vaccines added
Updated	04/22/2021	Medicaid instructions added
Reviewed	04/21/2022	No changes
Reviewed	04/27/2023	No changes
Reviewed	05/13/2024	Formatting changes, Added hyperlinks to TMPPM and Texas Mandate HB1584, Beginning and ending note sections updated to align with CMS requirements and business entity changes, Added guidance on FDA approved melanoma vaccine therapies, T-VEC (Imlygic) and Amtagvi (Lifleucel), in “BACKGROUND” section
Update	05/12/2025	Updated Medicaid language to align with standard language, Updated background, Updated ending note sections to align with business entity changes, Updated references to AMA style, Added references
Update	08/11/2025	Removed, Medicare NCD/LCD Interqual statement for clarity.

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.

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***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 Plan.

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.