MEDICAL COVERAGE POLICY	
SERVICE:	**Cancer Chemotherapy / Therapy Guidelines**
Policy Number:	**219**
Effective Date:	**3/1/2025**
Last Review:	**2/10/2025**
Next Review:	**2/10/2026**

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 Chemotherapy/Therapy Guidelines

PRIOR AUTHORIZATION: Varies

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

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). Medicare NCD or LCD specific InterQual criteria may be used when available. 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 HB154 is applicable for Medicaid plans.

This policy provides criteria for medical benefit coverage of oncology medications (A9600 - A9699 and J9000 - J9999) and other select medications and interventions used for oncologic conditions.

Baylor Scott & White Health Plan (BSWHP) may consider cancer therapy and chemotherapy regimens medically necessary when ALL of the following criteria are met:

1. The requested drug is being used for a medically accepted indication as defined by one of the following:
    a. United States Food and Drug Administration (FDA) labeling with drugs or regimens (combinations of drugs) consistent with all components of the product labeling; **OR**
    b. National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium with Category 1 or 2A as proven and medically necessary.
        i. Note: Category 2B will be subject to a detailed review of the medical literature by BSWHP before a coverage determination is made as to whether the medication is proven and medically necessary.
        ii. Note: Category 3 is unproven and not medically necessary.

    OR

    c. Indication is not included in the official FDA labeling or recommended by NCCN (Category 1 or 2A) and meets one of the following:
        i. Thomson Micromedex DrugDex with a Recommendation Class IIb or better and Efficacy Class IIa or better (i.e. "effective" or "evidence favors efficacy."); **OR**

ii. Clinical Pharmacology with a "Strong For" recommendation; **OR**
iii. American Hospital Formulary Service - Drug Information (AHFS-DI) with supportive narrative text; **OR**
iv. Wolters Kluwer Lexi-Drugs - medically necessary if listed as "Use: Off-Label" and rated as "Evidence Level A";

OR

d. Peer-reviewed medical literature demonstrating that a particular use of a drug or drugs is safe and effective, published in full text within one of the following journals:
   i. American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association; Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; or Radiation Oncology
   ii. Note: Abstracts and case reports are excluded from consideration
   iii. Note: Any peer-reviewed medical literature supporting use for indications outside of FDA labeling, NCCN, or compendia must be supplied as part of the request for consideration.

2. For oncology medications with a non-preferred status, member must have failure of an adequate trial of or clinically significant intolerance or contraindication to preferred medications in the same class that can also be used for the requested indication (**refer to BSWHP medical policies 306 Step Therapy – Commercial and 307 Step Therapy - Medicare**).
3. Dose and frequency should be consistent with FDA labeling, NCCN, compendia listed in this policy, or indication specific peer-reviewed literature.
   a. See Appendix A for drug/class specific limits on authorization (e.g. PD-1/PD-L1 inhibitors for the treatment of metastatic non-small cell lung cancer).
4. In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high-quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

Approval duration is the shortest of clinically appropriate duration, 6 months, or requested duration.

Oncology medications and therapies used for accelerated approval indications and uses subsequently withdrawn by the U.S. Food and Drug Administration (FDA) are not considered medically necessary as clinical benefit has not been established regardless of NCCN, additional compendia, or peer-reviewed medical literature status.

For oncology drugs being used for non-oncology indications, please refer to BSWHP medical policy 215 Medications Covered Under Medical Insurance Policy.

BACKGROUND: The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a comprehensive set of treatment guidelines applicable to about 97% of all patients with cancer. They also address supportive care issues. The guidelines are developed and updated by 48 individual panels, composed of more than 950 clinicians and oncology researchers from the 26 NCCN member institutions and their affiliates.

NCCN Categories of Evidence and Consensus

- Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions.
- Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so panel members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based opinions provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent.
- Category 2B: The recommendation is based on lower level evidence, and there is non-uniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This non-uniform consensus does not represent a major disagreement rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data.
- Category 3: The recommendation has engendered a major disagreement among the panel members. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in

a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy.

The U.S. Food and Drug Administration's (FDA's) accelerated approval pathway allows drugs for serious conditions that filled an unmet medical need to be approved based on a surrogate or an intermediate clinical endpoint. Approval of a drug may be withdrawn or the labeled indication of the drug changed if trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug. 2021 saw an increase in treatment options being withdrawn following accelerated approval compared to previous years. Manufacturers announcing market withdrawal of 8 cancer indications in 2021 originally approved under the accelerated approval pathway compared to 8 total in the prior years since the accelerated approval regulations were instituted in 1992.

APPENDIX:

Appendix A – Drug/Class Limits on Authorization

Drug/Class	Drugs Applicable	Limits
PD-1/PD-L1's	Bavencio (Avelumab) Imfinzi (Durvalumab) Jemperli (Dostarlimab) Keytruda (Pembrolizumab) Libtayo (Cemiplimab) Loqtorzi (Toripalimab) Opdivo (Nivolumab) Opdualag (Nivolumab and Relatimab-rmbw) Tecentriq (Atezolizumab) Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs) Tevimbra (Tislelizumab) Zynyz (Retifanlimab-dlwr)	Maximum total length of initial therapy with PD-1/PD-L1 Inhibitor for metastatic non-small cell lung cancer is 2 years

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:	
HCPCS Codes:	A9600 - A9699 J9000 - J9999
ICD10 codes:	
ICD10 Not covered:	

POLICY HISTORY:

Status	Date	Action
New	12/17/2015	New policy
Updated	09/29/2016	Corrected Prior Authorization statement
Reviewed	11/17/2016	No changes
Reviewed	10/24/2017	Redefined coverage criteria.
Reviewed	03/20/2018	Added resource list
Reviewed	04/25/2019	Changed coverage criteria to include NCCN categories 1 & 2A
Reviewed	04/24/2020	No changes
Updated	04/22/2021	Medicaid instructions added
Updated	05/27/2021	Refer to policy 215 for non-oncology indication review
Updated	01/27/2022	Added information regarding FDA accelerated pathway
Updated	09/01/2022	Added preferred and non-preferred medication information, Appendix A and B
Update	09/22/2022	Updated Appendix A to add trastuzumab
Update	01/26/2023	Added Appendix B drugs. Added Stimufend to Appendix A.
Update	03/30/2023	Added targeted therapy for recurrence of platinum-resistant ovarian cancer to Appendix A and B
Update	04/27/2023	Clarified failure of preferred biosimilars will not meet medical necessity for non-preferred drug requests.
Update	05/25/2023	Added injectable lipid lowering therapy to Appendix A and B
Update	06/28/2023	Removed injectable lipid lowering therapy from Appendix A – added in error. Removed targeted therapy for recurrence of platinum-resistant ovarian cancer from Appendix A and B.
Update	10/09/2023	Added VEGF inhibitor classes to Appendix A and B. Removed asthma biologics from Appendix B.

Update	12/13/2023	Updated preferred drug therapy language and moved Appendix A and B to separate policies. Applied new layout and format.
Update	10/14/2024	Updated format. Added dosing, approval duration, sequential therapy criteria, and Appendix A. Added hyperlinks to other BSWHP policies.
Update	12/09/2024	Removed OncoHealth exclusion language
Update	02/10/2025	Added Tecentriq Hybreza to Appendix A.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and make modifications 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 BSWHP 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.

1. Herbst RS, Baas P, Kim DW, et al. Pembrolizumab versus docetaxel for previously treated, PD-L1 positive, advanced non-small cell lung cancer (KEYNOTE-010): a randomized controlled trial. The Lancet. 2016;387(10027):1540-1550.
2. Medicare Benefit Policy Manual. Medicare Benefit Policy Manual Chapter 15 – Covered medical and other health services [Internet]. Medicare Benefit Policy Manual. 2024 Jun. Available from: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf
3. NCCN Guidelines at http://www.nccn.org/professionals/default.aspx
4. Office of the Commissioner. "Accelerated Approval." U.S. Food and Drug Administration, 2018, www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval. Accessed 5 Jan. 2022.
5. Research, Center for Drug Evaluation and. "Withdrawn | Cancer Accelerated Approvals." FDA, 23 Dec. 2021, www.fda.gov/drugs/resources-information-approved-drugs/withdrawn-cancer-accelerated-approvals. Accessed 5 Jan. 2022.
6. Sun L, Bleiberg B, Hwang W, et al. Association Between Duration of Immunotherapy and Overall Survival in Advanced Non–Small Cell Lung Cancer. JAMA Oncol. 2023;9(8):1075–1082.

***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.