MEDICAL COVERAGE POLICY	
SERVICE:	**Medications Covered Under Medical Insurance Policy**
Policy Number:	**215**
Effective Date:	**1/1/2024**
Last Review:	**12/13/2023**
Next Review:	**12/13/2024**

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.

For all other lines of business, this policy is applicable for a requested medication that does not have a more specific medical policy. This policy provides information about the indications and maximum dosage per administration of medications administered by a medical professional.

Baylor Scott & White Health Plan, and its wholly owned subsidiaries (together, "Plan") considers the use of medications medically necessary when used consistent with the member's coverage document and based on the following criteria:

1) The medication is prescribed by or in consultation with a specialist that has expertise in the applicable disease or condition.
2) The indicated diagnosis supplied in the request (including any applicable labs and/or tests) and medication usage is supported by documentation from the patient's medical records.
3) The drug is approved by the FDA for at least ONE indication.
4) One of the following:
   a) The member meets the applicable criteria set in InterQual® if the medication requires prior authorization.
      i) Applicable criteria set is defined as a drug subset with clinical criteria for the requested indication or condition
      ii) **NOTE**: All InterQual® subsets with a final recommendation requiring additional review must be reviewed by a clinical pharmacist and medical director

   OR

b) If no applicable criteria set in InterQual®, then the diagnosis supplied for use of the medication is a medically accepted FDA approved indication or an accepted off-label use defined as either:
   i) Use of the drug for the diagnosis is supported in a standard drug reference compendium, such as:
      (a) American Hospital Formulary Service Drug Information (AFHS-DI) with supportive narrative text
      (b) National Comprehensive Cancer Network (NCCN) Drugs and Biologics CompendiumTM (listed as 1-2a)
      (c) Thomson Micromedex DrugDex with a Strength of Recommendation Class IIb or better and Strength of Efficacy Class IIa or better (i.e. “effective” or “evidence favors efficacy.”)
      (d) Clinical Pharmacology with supportive narrative text

      OR
   ii) The safety and effectiveness of use for this indication has been demonstrated by at least 2 well-designed controlled clinical trials (i.e., a Phase III or “so called” Phase IIb [single center controlled] trial) published in a nationally recognized peer-reviewed medical journal.
      (a) **NOTE**: Clinical trials supporting use for indications outside of FDA labeling or compendia must be supplied as part of the request for consideration
   iii) **NOTE**: BSWHP has determined that not every indication found in the above resources, including the FDA Label, for a particular drug is medical necessary because some are not supported by published, well-designed, controlled, clinical trials. They are thus considered unproven, or experimental and investigational.
   iv) **NOTE**: Medications used for accelerated approval indications subsequently withdrawn by the FDA are not considered medically necessary as clinical benefit has not been established regardless of compendia or peer-reviewed medical literature status.

5) The medication is being used within an FDA-approved dosing regimen as stated within the FDA product labeling, including recommended dosage for initiation.
   a) Following initial dosing, patient must have tried, and failed, standard FDA-approved dosing and frequency as documented in the patient’s medical records in order to qualify for the use of increased doses per the product labeling (dose increases or more frequent dosing).
   b) Medications given beyond FDA labeling maximum dosages based on patient body size or a set maximal dosage independent of patient body size, not supported by package labeling, pharmacy compendia, or peer-reviewed published clinical evidence, are unproven and may not be medically necessary.
6) For medications with a non-preferred status, member must have failure of an adequate trial of or clinically significant intolerance or contraindication to preferred drugs 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**).
7) Authorization renewal requires clinical documentation submitted showing:
   a) Continued use of the drug and dosing is consistent with criteria above

b) Improvement, stabilization of disease, or a reduction in normal decline seen in the applicable population
c) Manageable or no side effects

Approval duration is the shortest of clinically appropriate duration, one year, or requested duration.

For oncology medications and other select medications and interventions used for oncologic conditions, please refer to BSWHP medical policy 219 Cancer Chemotherapy/Therapy Guidelines.

BACKGROUND: Most medications have dosing parameters that support an initial and maximum dosage per patient body size or a set maximal dosage independent of patient body size. These dosing parameters are product-specific, and in some cases, disease-state specific and are defined by the Food and Drug Administration (FDA) approved product prescribing information and/or national compendia and other peer-reviewed resources.

Off-label or unlabeled drug use is the use of a drug approved by the FDA for other uses or in treatment regimens or patient populations that are not included in approved labeling.

The FDA approves drugs for specific indications that are included in the drug's labeling. When a drug is used for an indication other than those specifically included in the labeling, it is referred to as an off-label use. Many off-label uses are effective, well-documented in the literature, and widely used.

Unapproved or unlabeled uses of drugs include a variety of situations ranging from completely unstudied to thoroughly investigated drug uses where the FDA has not been asked for approval, whereas approved uses of drugs have been proved to be safe and effective by the FDA after the review of adequate and controlled clinical trials that have documented their uses.

The 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.

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:	

ICD10 codes:	
ICD10 Not covered:	

POLICY HISTORY:

Status	Date	Action
New	05/28/2015	New policy
Review	07/07/2016	No changes
Review	06/13/2017	No changes
Update	01/23/2018	Move definition of medical necessity to policy 243
Update	05/22/2019	Minor language clarification
Update	06/25/2020	Clarified policy application, merged with policy 062 Off-label Use of FDA Approved Drugs, added specialist and renewal authorization criteria
Update	08/27/2020	Added: “For medications with a non-preferred status, member must have failure of an adequate trial of or clinically significant intolerance or contraindication to preferred drugs in the same class”
Update	09/24/2020	Updated criteria 3
Update	10/22/2020	Updated renewal authorization criteria
Update	04/22/2021	Medicaid instructions added.
Update	05/27/2021	Referred to policy 219 for oncology drugs and indications
Update	10/28/2021	Updated criteria 3 and 4
Update	09/01/2022	Updated criteria 4 for Interqual, updated criteria 6 to include HB1584 information, and added 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, clarified criteria 4 regarding Interqual
Update	04/27/2023	Clarified failure of preferred biosimilars will not meet medical necessity for non-preferred drug requests. Added language regarding FDA accelerated pathway.
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	10/26/2023	Clarified InterQual criteria only apply for prior authorization
Update	12/13/2023	Updated preferred drug therapy language and moved Appendix A and B to separate policies. Applied new layout and format.

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. AMA House of delegates Health and Ethics Policies, H-120.988 Patient Access to Treatments Prescribed by Their Physicians. https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.amaassn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-120.988.HTM Accessed 05/22/2013
2. Dresser, R., At Law: The Curious case of Off-Label Use. The Hastings Center Report. 6/7/2007. http://www.thehastingscenter.org/Publications/HCR/Detail.aspx?id=806 Accessed 05/22/2013.
3. "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet. FDA: Guidance for Institutional Review Boards and Clinical Investigators. http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm. Access 05/22/2013.
4. Off-Label Drug Use. Wellmark Blue Cross and Blue Shield Medical Policy: 5.01.09. Reviewed: September 2012.
5. Medicare Benefit Policy Manual. Chapter 15 – Covered Medical and Other Health Services. 50 – Drugs and Biologicals. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Accessed online 05/28/2020.
6. Medicare.gov Glossary https://www.medicare.gov/glossary/m.html. Accessed online 05/28/2020.
7. Texas Administrative Code. Title 28, Insurance. Part 1, Texas Department of Insurance. Chapter 21, Trade Practices. Subchapter V, Pharmacy Benefits. Rule §21.3011 Minimum Standards of Coverage for Off-Label Drug Use

***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 plans are offered through Scott and White Health Plan in the Central 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.