MEDICAL COVERAGE POLICY	
SERVICE:	**Medications Covered Under Medical Insurance Policy**
Policy Number:	**215**
Effective Date:	**12/01/2021**
Last Review:	**10/28/2021**
Next Review Date:	**10/28/2022**

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: Medications Covered Under Medical Policy

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.

For Medicare plans, please refer to appropriate Medicare coverage policies at CMS.gov (e.g. Local Coverage documents and articles, national coverage documents and articles, etc.). If there is no applicable Medicare coverage policy, more specific medical policy, or applicable Interqual® criteria set, then use this policy.

For all other lines of business, this policy is applicable for a requested medication that does not have a more specific medical policy or when there is no applicable criteria set in Interqual®. This policy provides information about the indications and maximum dosage per administration of medications administered by a medical professional.

Scott & White Health Plan, and its wholly owned subsidiaries (together, "Plan") considers the use of medications medically necessary when used consistent with the members 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 has been approved by the FDA for at least ONE indication.
4) The diagnosis supplied for use of the medication is a medically accepted FDA approved indication or an accepted off-label use defined as either:
   a) Use of the drug for the diagnosis is supported in a standard drug reference compendium, such as:

(1) American Hospital Formulary Service Drug Information (AFHS-DI) with supportive narrative text
(2) National Comprehensive Cancer Network (NCCN) Drugs and Biologics CompendiumTM (listed as 1-2a)
(3) 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.")
(4) Clinical Pharmacology with supportive narrative text

OR

b) 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.
(1) **NOTE**: Clinical trials supporting use for indications outside of FDA labeling or compendia in 3.b.ii must be supplied as part of the request for consideration
c) **NOTE**: SWHP 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.

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 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
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 policy 219 Cancer Chemotherapy/Therapy Guidelines.

Definition of Medical Necessity: (see policy 243 Medical Necessity Definition)

OVERVIEW: 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.

SUPPORTING DATA:

From the Scott & White Health Plan Provider Contract:

II. Obligations of Group Provider - A. Provision of Covered Service

… Group Provider understands that SWHP or a Payor may be entitled to deny payment for services rendered to a Covered Person which it determines are not Medically Necessary, are not Covered Services, or are not otherwise provided in accordance with the Plan.

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.

CPT Codes:	
CPT Not Covered:	
ICD10 codes:	
ICD10 Not covered:	

CMS:

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

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP 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 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