Administrative Policy Statement
WEST VIRGINIA MARKETPLACE PLANS

Policy Name	Policy Number	Date Effective
Medical Necessity – Off Label, Approved Orphan and Compassionate Use Drugs	PAD-0064-WV-MPP	07/02/2020

Policy Type			
Medical	**ADMINISTRATIVE**	Pharmacy	Reimbursement

Administrative Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

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Table of Contents

treatment, the therapy can be given safely outside the clinical trial setting, no other alternative therapy is available, and the drug developer agrees to provide access to the drug. The FDA refers to such a program as an expanded access program (EAP). EAPs can be used in a wide range of therapeutic areas including HIV/AIDS and other infectious diseases, cancer, rare diseases, and cardiovascular diseases. There are several types of EAPs allowed in the United States. Treatment protocols and treatment INDs provide large numbers of patient's access to investigational drugs. A single-patient IND is a request from a physician to the FDA that an individual patient be allowed access to an investigational drug on an emergency or compassionate use basis.

D. Policy

	01/11/2018	Updated format
	06/12/2020	Policy moved to a new template
Date Effective	**07/02/2020**	Approved by VAC
Date Archived		

H. References

1. U.S. Food and Drug Administration (FDA). Off-label and investigational use of marketed drugs, biologics, and medical devices. Available at: www.fda.gov
2. U.S. Food and Drug Administration (FDA). Orphan Product Designations and Approval Search. Available at: www.accessdata.fda.gov
3. U.S. Food and Drug Administration (FDA). Developing Orphan Products: FDA and Rare Disease Day. Last updated February 16, 2016. Available at: www.fda.gov
4. National Comprehensive Cancer Network®. NCCN D7 (at)3eC 0 g0.001 Tc4 (N)-1.inis5 (o(e)0.6 2r1.52 (,