WEA trust
P.O. Box 21538 | Eagan, Minnesota 55121-5038
800.279.4000 WEAtrust.com

Medication Policy

General Medication Policy

Policy Number: 1096

Policy History			
Approve Date:	02/06/2019	Effective Date:	04/01/2019
Reviewed/Revised Date:	02/01/2020		

Preauthorization	
All Plans	Benefit plans vary in coverage and some plans may not provide coverage for certain service(s) listed in this policy. Decisions for authorization are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations as well as applicable state and/or federal laws. Please review the benefit plan descriptions for details. We utilize a combination of MCG and internally developed evidence-based clinical guidelines to support our prior authorization work. All internally developed prior authorization guidelines follow a rigorous process including, but not limited to, review by clinical pharmacist, clinical nurse manager, Chief Medical Officer, independent 3rd party physician review agency and WEA Trust's Medical Advisory Committee. Prior authorization guidelines are reviewed at least annually, or when there are significant labeling changes made by FDA or peer-reviewed clinical outcomes (via Cochrane or Hayes).

Section I—Approval Criteria

I. Any new specialty drugs subsequent to FDA approval and from date of availability shall be excluded for six months.

II. Any FDA drug unless otherwise excluded may be considered medically necessary for its FDA approved indication when all criteria A – G below are met:
   - A. The patient's diagnosis is consistent with:
     - i. FDA approved labeling OR
     - ii. An off-label/unproven indication when the drug is already FDA approved and all the below:
       1. The patient's diagnosis is a chronic and seriously debilitating condition
       2. At least one nationally recognized compendia (such as DRUGDEX System by Micromedex®) clinically supports its use
       3. Two articles from major peer reviewed medical journals (such as New England Journal of Medicine) support its use
   - B. All necessary lab tests, including applicable genetic tests to verify diagnosis
   - C. The diagnosis must be made be a relevant specialist in that field
   - D. The patient will be monitored as recommended per FDA labeling
   - E. The patient must try and fail all conventional, standard therapies unless contraindicated or not tolerated
   - F. The patient must try and fail all preferred therapy unless contraindicated or not tolerated
   - G. Both physician and patient must attest that the patient will be adherent to treatment.

III. Quantity limit, authorization period, and renewal criteria for approvals
   A. When prior authorization is approved, the requested drug may be authorized in quantities as recommended per package labeling for no greater than six months.
   B. Authorization shall be reviewed initially at no greater than six months then at least every 12 months to confirm that current medical necessity criteria are met, and that the patient has had an objective clinical response or is meeting the goals of therapy of the medication.

IV. Investigational or non-medically necessary
   A. All FDA approved drugs are considered investigational when used for any condition that does not meet the criteria listed above.

Background

More than 1500 drugs have been approved by the Food and Drug Administration (FDA) in its history.

Since 1990 many of the new drugs approved have been specialty and/or covered on the medical benefit. Utilization management ensures that for high-cost drugs on both pharmacy and medical benefits that there is a proper review to confirm that the patient is being prescribed the most safe and cost-effective drug therapy for them.

The scope of this policy includes any FDA approved drug that is currently on the market or will be in the future, unless otherwise excluded by the plan. For drugs that have their own policy, please refer to the drug specific policy.

References

1. American Cancer Society. Just the Facts: Prescription Drug Utilization Management. February 2014.Available at: https://www.acscan.org/policy-resources/just-facts-prescription-drug-utilizationmanagement. Accessed April 17, 2018.
2. Brown L. Gain a solid understanding of compendia and its impact on patient access. *Formulary*. 2012;47(7): 252-256.
3. Cooperman T. Trends in FDA approval of Specialty Drugs 1990 through 2017. RJ Health. December 2017. Available at: http://rjhealthsystems.com/2017/12/15/trends-fda-approval-specialty-drugs-1990-q3-2017/. Accessed April 17, 2018.
4. Kinch MS, Haynesworth A, Kinch SL, Hoyer D. An overview of FDA approved new molecular entities: 1827-2013. *Drug Discov Today*. 2014;19(8):1033-9.