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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF MEDICAID SERVICES

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Pediatric Medical and Psychiatric Off-Label Drug Usage Project  
Decision Making Matrix  
August 10, 2017

Off-label use of a drug is a common practice representing approximately 50-75% of pediatric medication use. Prescribing of an off-label drug does not constitute a contraindication for the use of the drug in children. (Source: Child and Adolescent Psychiatry and Mental Health, 2008, 2:24). The purpose of this document is to provide instructions for decision making in accordance with state and federal regulations.

Use of the Health Plan pharmacy criteria for review of requests for prior authorization of off-label drugs is the first decision point. If the drug is denied based on those criteria, then Early Periodic, Screening, Diagnosis, and Treatment (EPSDT) federal provisions must be applied before a final decision can be rendered.

EPSDT entitles Medicaid enrolled infants, children, and adolescents to any treatment or procedure that fits within any of the categories of Medicaid covered services listed in 42 USC 1396(a) [1905(r) of the Social Security Act]. Prescription drugs are a treatment service per 42 USC 1396d (a) (12). The provision of services under EPSDT are for those members under 21 years of age (until their 21<sup>st</sup> birthday).

Determination of whether a treatment is medically necessary must be made on a case by case basis taking into consideration a child's particular needs. The definition of medically necessary comes from DHHS Administrative rule He-W 546 and states:

*Medically necessary "means reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent the worsening of conditions that endanger life, cause pain, result in illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction, and no other equally effective course of treatment is available or suitable for the EPSDT recipient requesting a medically necessary service."*

Community Mental Health Centers (CMHCs) should provide documentation to assure the Health Plans have sufficient information to apply the provisions of EPSDT in making a final decision about drug coverage. CMHCs should include answers to the following questions for Health Plan consideration under EPSDT. These questions should also be discussed in any peer to peer consultations:

- Is the treatment determined to be medical in nature?
- Does the treatment requested meet the definition of medical necessity? How will the requested treatment maintain or improve the child's condition and help with symptoms the medication is meant to target?
- Is the treatment requested generally recognized as appropriate under acceptable standards of medical practice or treatment protocols based on the physician's recommendation for the treatment? Are there peer review articles, results of clinical trials or expert opinion available to support the request?
- What are the risks for denying the treatment?
- Is there an equally effective course of treatment available? If so, why is that treatment not appropriate?

- Has the parent/guardian/individual 18 and older consented to the treatment?

Health Plans in their final decision to deny off-label drug coverage must include in the denial letter a statement indicating why off-label pharmacy criteria was not met and a statement indicating why medical necessity criteria under EPSDT was not met.