Subject: **Drug, Device or Biologic (Off-Label Use)***

Effective Date: **August 1, 1994**

Department(s): **Utilization Management**

Policy: All requests for certification of coverage for off label use of a FDA approved drug, device or biologic must be reviewed by QualCare's Utilization Management Medical Director and/or a Medical Advisor in the specialty area in question for usage.

Procedure:

A. The use of drugs, devices, or biologics not approved by the FDA will **NOT** be reimbursed.

B. A physician requesting certification for off-label use of a drug, device or biologic must submit the following information to QualCare's Utilization Management Department:

1. A complete past and present history regarding prior course of treatment that addresses failure of treatment of this individual with interventions approved by the FDA or other agencies for the individual's diagnosis.

2. Documentation, including but not limited to peer-reviewed articles, regarding the success or failure of the drug, device or biologic for the intended off-label use.

3. Acknowledgement that the patient is aware of the off-label use and any known potential side effects.

C. Off-label use of a drug, device, or biologic that is not supported by a satisfactory body of peer-reviewed literature will be denied as experimental, investigational, and unproven.

References

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*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.