



Everolimus

DESCRIPTION

Everolimus, an antineoplastic agent, has antiproliferative and antiangiogenic properties. It reduces protein synthesis and cell proliferation by binding to an intracellular protein, FKBP-12, resulting in inhibition of mTOR (mammalian target of rapamycin) serine-threonine kinase activity. Everolimus also reduces angiogenesis by inhibiting vascular endothelial growth factor (VEGF) and hypoxia-inducible factor (HIF-1) expression.

An example of a preparation of everolimus is Afinitor[®].

REFER TO DECISION SUPPORT TREE

POLICY

- Everolimus for the treatment of renal cell carcinoma is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Everolimus for the treatment of other conditions/diseases is considered **investigational**.

MEDICAL APPROPRIATENESS

- Everolimus for the treatment of renal cell carcinoma is considered **medically appropriate** if **ALL** of the following criteria are met:
 - The individual has advanced renal cell carcinoma
 - Has failed treatment with sunitinib or sorafenib therapy

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

Tennessee State law requires coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is relative to life-threatening illnesses, such as cancer, AIDS, and coronary heart disease and recognized in one of the standard reference compendia (As defined in the statute: The United States Pharmacopoeia Drug Information, The American Medical Association Drug Evaluations, & The American Hospital Formulary Service Drug Information) or in the medical literature. This law is applicable to all fully insured members. The law is not applicable to self-funded accounts, but coverage for off-label uses may be provided based on the contractual agreement.

ADDITIONAL INFORMATION

For appropriate dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., The American Hospital Formulary Service Drug Information).

Clinical data supporting the potential role for everolimus in the treatment of other conditions/diseases is lacking.

SOURCES

National Comprehensive Cancer Network. (2009). NCCN Drugs & Biologics Compendium[™]. *Everolimus*. Retrieved February 4, 2009 from http://www.nccn.org/professionals/drug_compendium/mainpage.aspx.



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Policy

Medical Policy Manual

Approved: Do Not Implement Until 12/12/09

MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2009). *Everolimus*. Retrieved April 23, 2009 from MICROMEDEX Healthcare Series.

U. S. Food and Drug Administration. (2009, March). Center for Drug Evaluation and Research. Label and Approval History. *Afinitor*[®]. Retrieved April 23, 2009 from <http://www.fda.gov/cdrh/pma/pmafeb01.html>.

EFFECTIVE DATE 12/12/2009

ID_BT



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Pharmaceutical Decision Support Tree

Everolimus (Afinitor®)

1. Does the individual have a diagnosis of renal cell carcinoma?

If yes, go to question # 2

If no, this does not meet medical necessity and/or medical appropriateness criteria

2. Does the individual show evidence of **ALL** the following?

- Advanced renal cell carcinoma
- Has failed treatment with sunitinib or sorafenib therapy

If yes, this satisfies medical necessity and medical appropriateness criteria

If no, this does not meet medical necessity and/or medical appropriateness criteria