



**BRAND NAME (Generic)** **Afinitor (everolimus)**

**IMPORTANT NOTE:**

*The purpose of this policy is to provide general information applicable to the administration of outpatient prescription drug benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. **Outpatient prescription drugs are not covered under all Horizon benefit plans.** If the member's contract benefits differ from the pharmacy guideline, the contract prevails. Although a service, supply drug or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply drug or procedure is not covered and the member proceeds to obtain the service, supply drug or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's or pharmacist's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.*

**FDA-APPROVED INDICATION**

Afinitor (everolimus) is indicated for the treatment of patients with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib.<sup>1-3</sup>

**CRITERIA FOR APPROVAL**

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|----|--|-----|----|
| 1. | Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?<br>[If the answer to this question is no, then no further questions.]  | Yes | No |
| 2. | Has the patient tried and failed previous treatment with either Sutent (sunitinib) or Nexavar (sorafenib)?<br>[If the answer to this question is no, then no further questions.]   | Yes | No |
| 3. | If applicable, are the physician and patient aware that this drug must not be taken if the patient is pregnant or may become pregnant?<br>[If this question is not applicable, please answer "yes" and proceed to question 4.] | Yes | No |
| 4. | Is the patient currently receiving Afinitor?<br>[If the answer to this questions is no, then skip to question 6.]  | Yes | No |
| 5. | Has the patient's disease stabilized and there are no detectable adverse events associated with Afinitor therapy?  | Yes | No |
| 6. | Is the request for MORE THAN the following dispensing limits of:<br>-Afinitor 5mg - 1 tablet per day<br>-Afinitor 10mg - 1 tablet per day  | Yes | No |



Duration of Approval		6 months	
Set 1: Initial		Set 2: Renewal	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	4	1	6
2	6	2	
3		3	
		4	
		5	

**Horizon BCBSNJ Pharmacy Guideline Development Process:** This Horizon BCBSNJ Pharmacy Guideline (the “Pharmacy Guideline”) has been developed by Horizon BCBSNJ’s Pharmacy Drug Policy Subcommittee, Clinical Issues Subcommittee, and Quality Improvement Committee which include practicing physicians and pharmacists. This guideline is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ’s view of the subject health care services, supplies drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Guideline also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Guideline considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

**Rationale**

The intent of the criteria is to ensure that patients follow selection elements established by Horizon BCBS New Jersey’s medical policies.

Afinitor (everolimus) is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib.<sup>1-3</sup>

In 2008, it was estimated that there were about 53,000 new cases of kidney cancer diagnosed and about 13,000 deaths. RCC is the most common type of kidney cancer. It comprises of approximately 2% of all malignancies.

In the past, cytokines such as interleukin-2 (IL-2) and interferon α (IFN α) were the mainstay of treatment for advanced RCC until recent therapies known as tyrosine kinase inhibitors have been approved as first and second-line treatments. Examples of tyrosine kinase inhibitors are Sutent (sunitinib malate), Nexavar (sorafenib tosylate), and Torisel (temsirolimus). Avastin (bevacizumab) has also shown benefit in a phase III, pivotal clinical trial.

Afinitor is also classified as a kinase inhibitor and acts by inhibiting mammalian Target of Rapamycin (mTOR), a protein in the cancer cell that controls tumor cell division and blood vessel growth. Afinitor is intended as second-line treatment for those patients with advanced RCC who have already tried another kinase inhibitor, Sutent (sunitinib) or Nexavar (sorafenib).<sup>1,3</sup> Sutent and Nexavar are considered as first-line therapies for advanced RCC. NCCN defines “advanced” as relapsed or medically unresectable stage IV RCC.<sup>1,3</sup>

Hypersensitivity reactions have been observed in patients taking Afinitor or other rapamycin derivatives (e.g., Torisel). There are no additional contraindications listed in the product labeling. However, it should be noted

that Afinitor is labeled as pregnancy category D. While receiving treatment with Afinitor, women of childbearing potential should be advised to avoid becoming pregnant.

Treatment with Afinitor should be continued until unacceptable toxicities occur or the patient is not experiencing any further clinical benefit.<sup>1-4</sup>

## **REFERENCES**

1. Afinitor [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2009.
2. Klasko RK (ed): DRUGDEX® System (electronic version). Thomson Micromedex, Greenwood Village, Colorado, USA. Available at: <http://www.thomsonhc.com>. (cited May 13, 2009).
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: <http://www.nccn.org>. Accessed May 13, 2009.
4. The prior authorization criteria have been derived from the Horizon Blue Cross Blue Shield of New Jersey website. Available at: <https://services3.horizon-bcbsnj.com/hcm/MedPol2.nsf>. Accessed May 21, 2009.

*Pharmacy Guidelines can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.*

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