

Louisiana Medicaid Oncology Agents – Oral – Renal Cell

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization for non-preferred oral renal cell oncology agents.

Additional Point-of-Sale edits may apply.:-

~~Some medications in this therapeutic class~~ *These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria for Initial and Reauthorization Requests

- For everolimus tablet (generic for Afinitor®), there has been a treatment failure or intolerable side effect with or contraindication to brand Afinitor®; OR
- For sunitinib capsule (generic for Sutent®), there has been a treatment failure or intolerable side effect with or contraindication to brand Sutent®; OR
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
 - The recipient has had a *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
 - The prescriber states that the recipient is currently using the requested medication; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.
 - ~~The recipient has no inappropriate concomitant drug therapies or disease states.~~

Duration of ~~authorization approval, both~~ initial and reauthorization approval:
Up to 12 months based upon patient-specific factors and the condition being treated.

References

Afinitor (everolimus) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; ~~April 2021~~ March 2020. ~~HYPERLINK~~

"~~<https://www.novartis.us/sites/www.novartis.us/files/afinitor.pdf>~~"

~~<https://www.novartis.us/sites/www.novartis.us/files/afinitor.pdf>~~

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; ~~Retrieved from~~ <https://www.clinicalkey.com/pharmacology/>

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill; ~~Retrieved from~~ <https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861>

<u>Revision / Date</u>	<u>Date Implementation Date</u>
Single PDL Implementation	May 2019
Reviewed current criteria and no changes made / September 2019	September 2019 <u>January 2020</u>
Separated "Oncology Agents" into individual therapeutic class documents / November 2019	November 2019 <u>January 2020</u>
Added preferred brand wording for Afinitor®, added reference, formatting changes / <u>November 2020</u>	November 2020 <u>January 2021</u>
<u>Formatting changes, removed reference, added specific wording for use of Sutent® -/ October 2021</u>	<u>January 2022</u>