

Clinical Policy Title:	everolimus
Policy Number:	RxA.008
Drug(s) Applied:	everolimus
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Breast Cancer (must meet all):

1. Diagnosis of recurrent or metastatic breast cancer;
2. Disease is HR-positive and HER2-negative;
3. Member is postmenopausal; or premenopausal receiving ovarian ablation or suppression;
4. Prior history of endocrine therapy unless contraindicated or clinically significant adverse effects are experienced;
5. Prescribed in combination with exemestane, fulvestrant or tamoxifen.

6. Approval Duration

All Lines of Business (except Medicare): 6 months, Split-fill

B. Neuroendocrine Tumors (must meet all):

1. Diagnosis of NET of one of the following origins (a – e):
 - a. Pancreatic;
 - b. GI tract;
 - c. Lung;
 - d. Bronchopulmonary (off-label);
 - e. Thymus (off-label);
2. Disease is unresectable, locally advanced or metastatic.

3. Approval Duration

All Lines of Business (except Medicare): 6 months, Split-fill

C. Renal cell carcinoma (must meet all):

1. Diagnosis of relapsed or stage IV (unresectable or metastatic) RCC;
2. If clear cell histology, failure of a prior therapy (e.g. Inlyta®, Votrient®, Sutent®, Nexavar®) unless contraindicated or clinically significant adverse effects are experienced;

*Prior authorization may be required for prior therapy

3. Approval Duration

All Lines of Business (except Medicare): 6 months, Split-fill

D. Renal Angiomyolipoma with Tuberous Sclerosis Complex (must meet all):

1. Diagnosis of renal angiomyolipoma associated with TSC, not requiring immediate surgery.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

2. Approval Duration

All Lines of Business (except Medicare): 6 months, Split-fill

E. Tuberos Sclerosis Complex with Subependymal Giant Cell Astrocytoma (must meet all):

1. Diagnosis of SEGA associated with TSC;
2. Member is not a candidate for curative surgical resection.

3. Approval duration

All Lines of Business (except Medicare): 6 months, Split-fill

F. Tuberos Sclerosis Complex-Associated Partial-Onset Seizures (must meet all):

1. Diagnosis of partial-onset seizures associated with TSC.

2. Approval duration

All Lines of Business (except Medicare): 6 months, Split-fill

G. Prophylaxis of Organ Rejection (must meet all):

1. Member has received or is scheduled for a kidney or liver transplant;
2. For kidney transplant, failure of tacrolimus unless contraindicated or clinically significant adverse effects are experienced;
3. Prescribed in combination with one of the following (a or b):
 - a. For kidney transplant: Simulect®, cyclosporine, and corticosteroids;
 - b. For liver transplant: tacrolimus and corticosteroids.

Approval duration

All Lines of Business (except Medicare): 6 months

H. Continued Therapy Approval

A. All Indications (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Kidney Cancer Version 1.2025. Available at: http://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf . Accessed August 27, 2024.
2. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors Version 2.2024. Available at: http://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed August 27, 2024.
3. National Comprehensive Cancer Network. Breast Cancer Version 4.2024. Available at: http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 27, 2024.
4. Kidney Disease Improving Global Outcomes. KDIGO clinical practice guideline for the care of kidney transplant recipients. American Journal of Transplantation 2009; 9 (Suppl 3): Si- S155. doi: 10.1111/j.1600-6143.2009.02834.x. Available at: <https://kdigo.org/wp-content/uploads/2017/02/KDIGO-2009-Transplant-Recipient-Guideline-English.pdf>. Accessed August 27, 2024.
5. Bia M, Adey DB, Bloon RD, Chan L, Kulkarni S, and Tomlanovich S. KDOQI US Commentary on the 2009 KDIGO clinical practice guideline for the care of kidney transplant recipients. Am J Kidneys Dis 2010; 56:189-218. Available at: https://www.kidney.org/sites/default/files/docs/transplant_commentary2010_ajkd.pdf. Accessed August 27, 2024.
6. Lucey MR, Terrault N, Ojo L, et al. Long-term management of the successful adult liver transplant: 2012 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation. Liver Transplantation 2013; 19:3-26. Available at: <https://pubmed.ncbi.nlm.nih.gov/23281277/>. Accessed August 27, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
2Q2020 P&T Review; Updates below, references reviewed and updated <ol style="list-style-type: none"> 1. TSC association seizures – neurologist added; 2. meningioma removed NCCN 2B; 3. NET bronchopulmonary disease added NCCN 2A; 4. specified max dose requirement in continued therapy applies to all diagnoses except partial-onset seizures associated with TSC and organ rejection prophylaxis; 5. Breast cancer: Added additional criteria of postmenopausal; or premenopausal receiving ovarian ablation or suppression. 	4/2020	05/20/2020
Policy was reviewed. <ol style="list-style-type: none"> 1. Line of Business Policy Applies to was updated to “All lines of business”. 2. Initial therapy criteria I.H.1(a) & I.H.1(b) were added. 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by Rxadvance...”. 4. References were reviewed and updated. 	02/11/2021	03/09/2021
Policy was reviewed. <ol style="list-style-type: none"> 1. Initial Approval Criteria <ol style="list-style-type: none"> a. IE3: Updated to include new age criteria Age ≥ 1 years. b. IF2: Updated to include new age criteria Age ≥ 2 years 2. Initial Approval Criteria, IH1: Updated to include new indication <ol style="list-style-type: none"> a. Histiocytic Neoplasms (Langerhans Cell Histiocytosis, Rosai-Dorfman Disease, a Erdheim-Chester Disease b. Uterine Neoplasms - Endometrial Carcinoma c. Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma - Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma 3. References were reviewed and updated. 	12/06/2021	01/17/2022
Policy was reviewed.	07/04/2022	10/19/2022

<ol style="list-style-type: none"> Continued Therapy Criteria II.A.3.a: Updated new dose does not exceed from 20 mg to 10 mg per day. References were reviewed and updated. 		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: <ol style="list-style-type: none"> Added generic everolimus to Drug(s) Applied. Removed age restrictions. Removed prescriber restrictions. Removed dose restrictions. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. Removed reauthorization requirement for positive response to therapy. Updated approval duration verbiage. References were reviewed and updated. 	8/27/2024	9/13/2024
Added “Split-fill” for Afinitor® or Afinitor Disperz to initial criteria approval duration.	11/22/2024	12/05/2024
Policy was reviewed: <ol style="list-style-type: none"> Removed Afinitor®, Afinitor Disperz® and Zortress from drug applied section. Removed off label indications 	12/05/2024	N/A
Policy reviewed	12/11/2025	12/11/2025