Novartis cannot guarantee insurance coverage or reimbursement. Coverage or reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements made in seeking coverage and reimbursement for an individual patient.

**Indications**

AFINITOR is indicated for the treatment of adult patients with renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery.

AFINITOR and AFINITOR DISPERZ are indicated in adult and pediatric patients 1 year and older with tuberous sclerosis complex (TSC) for the treatment of subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.

AFINITOR DISPERZ is indicated for the adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures.

Please see Important Safety Information on pages 22-24.

Click here for full Prescribing Information.
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Please see Important Safety Information on pages 22-24. Click here for full Prescribing Information.
The sample letters in this guide are provided for informational purposes only to assist you, your office staff, your patient, and/or his or her caregiver in writing and submitting an appeal or exemption request for AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension). They are examples of the type of information usually required by a health plan and are not intended to provide all necessary information. If your patient is also writing a letter of appeal, you may want to help ensure the information is presented consistently in all letters.

**PRIOR AUTHORIZATION (PA) REQUIRED**
Submit all relevant forms as required by your patient’s health plan.

**APPEAL REQUIRED**
You may appeal the denial by submitting justification for why your patient requires treatment with AFINITOR or AFINITOR DISPERZ, supported by evidence.

**NEXT-LEVEL APPEAL REQUIRED**
You may pursue second- and third-level appeals according to the individual plan’s procedures. These appeals may include reviews by external review boards not affiliated with the health plan.

**IF AFINITOR or AFINITOR DISPERZ IS COVERED**
on a high-formulary tier, or if it is not on the health plan’s formulary, you may consider submitting a tiering or formulary exception request to demonstrate that AFINITOR or AFINITOR DISPERZ is medically necessary for your patient and that not receiving an exception would cause him or her financial hardship.

*Novartis cannot guarantee insurance coverage or reimbursement. Coverage or reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements made in seeking coverage and reimbursement for an individual patient.*

Please see Important Safety Information on pages 22-24. [Click here](#) for full Prescribing Information.
**IF A PA IS REQUIRED, YOUR EFFORTS MAY HELP WITH THE PA PROCESS**

Suggested steps for filing a PA for AFINITOR® (everolimus) Tablets and AFINITOR DISPERZ® (everolimus tablets for oral suspension):

1. **VISIT** the health plan’s health care provider (HCP) formulary portal as soon as the prescription is written to see if a PA is required for your patient’s plan.

2. **COMPLETE** the clinical rationale, sign all documents, and submit the PA form and other required information to the health plan.

3. **FOLLOW UP** regularly with the health plan until a decision is made.

Common reasons for PA denials:

**ADMINISTRATIVE**—the health plan lacks the information or documentation it requires to approve coverage.

Examples include:

- No prescriber signature
- Insufficient, incomplete, or incorrect information

**CLINICAL**—the health plan decides AFINITOR or AFINITOR DISPERZ is not:

- Medically appropriate for your patient
- Indicated for your patient’s diagnosis

While the PA is under review, you might consider:

- Telling your patient that the health plan’s review usually takes a few days
- Providing our **7-Day Free Trial** offering with refills so your patient can begin taking AFINITOR or AFINITOR DISPERZ immediately while the PA is under review
- Once the health plan approves the PA, calling the specialty pharmacy to ensure the prescription is filled and notifying your patient that the prescription is available

*For more details regarding our **7-Day Free Trial** offer, please refer to page 20 of this guide.

Please see Important Safety Information on pages 22-24. Click here for full Prescribing Information.
Suggested steps for filing an appeal:

1. CONTACT your patient about the PA denial and discuss the appeal process.

2. DETERMINE the reason for denial and use the samples provided in this guide to assist you in writing an appeal letter if appropriate for your patient’s situation.

3. CONSIDER incorporating the appropriate ICD-10 codes on the documentation.

4. SUBMIT the letters and other required documents to the health plan and follow up regularly.

Novartis associates are not permitted to complete any PA form or Coverage Determination Request Form, coach or guide a health care provider (HCP) or HCP staff member about what to write on these forms, provide PA criteria for AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension) if it is not publicly available, or talk to an HCP about a patient’s personal health information.

Please see Important Safety Information on pages 22-24. Click here for full Prescribing Information.
PROVIDING THE PROPER DIAGNOSIS CODES MAY ASSIST IN THE REVIEW PROCESS

Include primary diagnosis, such as **Q85.1 tuberous sclerosis**, and potential secondary ICD-10 code(s). This coding information may assist you as you complete the payer forms for AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension). These tables are provided for informational purposes only.

**INDICATION**

AFINITOR and AFINITOR DISPERZ are indicated in adult and pediatric patients 1 year and older with tuberous sclerosis complex (TSC) for the treatment of subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.

**SECONDARY ICD-10 CODES AND DESCRIPTIONS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D43.0</td>
<td>NEOPLASM OF UNCERTAIN BEHAVIOR OF BRAIN, SUPRATENTORIAL</td>
</tr>
<tr>
<td>D43.2</td>
<td>BRAIN AND SPINAL CORD FRONTAL GANGLIOGLIOMA</td>
</tr>
<tr>
<td>D33.2</td>
<td>BENIGN NEOPLASM OF THE BRAIN</td>
</tr>
<tr>
<td>D33.3</td>
<td>BENIGN NEOPLASM OF CRANIAL NERVES</td>
</tr>
</tbody>
</table>

**INDICATION**

AFINITOR is indicated for the treatment of adult patients with renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery.

**SECONDARY ICD-10 CODES AND DESCRIPTIONS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D17.71</td>
<td>BENIGN LIPOMATOUS NEOPLASM OF KIDNEY</td>
</tr>
<tr>
<td>D30.00</td>
<td>ANGIOMYOLIPOMA OF THE KIDNEY</td>
</tr>
<tr>
<td>D30.01</td>
<td>ANGIOMYOLIPOMA OF THE KIDNEY (RIGHT)</td>
</tr>
</tbody>
</table>

These codes are not all-inclusive. Coding may vary by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Please see Important Safety Information on pages 22-24. Click here for full Prescribing Information.
PROVIDING THE PROPER DIAGNOSIS CODES MAY ASSIST IN THE REVIEW PROCESS (continued)

Include primary diagnosis, such as **Q85.1 tuberous sclerosis**, and potential secondary ICD-10 code(s). This coding information may assist you as you complete the payer forms for AFINITOR DISPERZ® (everolimus tablets for oral suspension). These tables are provided for informational purposes only.

**INDICATION**
AFINITOR DISPERZ is indicated for the adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures.

**SECONDARY ICD-10 CODES AND DESCRIPTIONS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>R56.9</td>
<td>UNSPECIFIED CONVULSIONS</td>
</tr>
<tr>
<td>G40.009</td>
<td>LOCALIZATION-RELATED (FOCAL) (PARTIAL) IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SEIZURES OF LOCALIZED ONSET, NOT INTRACTABLE, WITHOUT STATUS EPILEPTICUS</td>
</tr>
<tr>
<td>G40.019</td>
<td>LOCALIZATION-RELATED (FOCAL) (PARTIAL) IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SEIZURES OF LOCALIZED ONSET, INTRACTABLE, WITHOUT STATUS EPILEPTICUS</td>
</tr>
<tr>
<td>G40.109</td>
<td>LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SIMPLE PARTIAL SEIZURES, NOT INTRACTABLE, WITHOUT STATUS EPILEPTICUS</td>
</tr>
<tr>
<td>G40.119</td>
<td>LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SIMPLE PARTIAL SEIZURES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS</td>
</tr>
<tr>
<td>G40.209</td>
<td>LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH COMPLEX PARTIAL SEIZURES, NOT INTRACTABLE, WITHOUT STATUS EPILEPTICUS</td>
</tr>
<tr>
<td>G40.219</td>
<td>LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH COMPLEX PARTIAL SEIZURES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS</td>
</tr>
</tbody>
</table>

Please see Important Safety Information on pages 22-24. Click here for full Prescribing Information.
HEALTH PLANS OFTEN REQUIRE SPECIFIC CLINICAL INFORMATION FOR APPEALS

Consider including the following information when submitting an appeal for AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension). Additional information could include, for example, a summary of the patient’s diagnosis, medical history, and clinical rationale for treatment.

Patient and prescriber information

- Patient’s age
- Documented TSC
- Prescriber’s specialty (oncologist or neurologist may be a requirement)

Specific TSC diagnosis

- **SEGA**
  - Your patient has a diagnosis of SEGA associated with TSC
  - Your patient requires therapeutic intervention but is not a candidate for curative surgical resection

- **Renal angiomyolipoma**
  - Your patient has a diagnosis of renal angiomyolipoma with TSC
  - AFINITOR is not being used to prevent kidney transplant rejection
  - Monitoring
    - Blood pressure
    - Glomerular filtration rate
    - MRI of the abdomen

- **Partial-onset seizures**
  - Your patient has a diagnosis of TSC-associated partial-onset seizures
  - Your patient is 2 years of age or older
  - Recurrent seizures (uncontrolled after use of ≥2 first-line AEDs)
  - AFINITOR DISPERZ is being used as adjunctive therapy in combination with AED(s)
  - List reasons why your patient could not tolerate previous therapies, with supporting clinical evidence of the severity and duration of the reaction

AEDs, antiepileptic drugs; MRI, magnetic resonance imaging.
Consider including the following documentation, if applicable, to support an appeal for AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension):

**MEDICAL RECORDS**

**LABORATORY VALUES**

**IMAGING RESULTS**

**PROOF OF PREVIOUS THERAPIES**

**OTHER CLINICAL INFORMATION**
(eg, clinical study data from the AFINITOR or AFINITOR DISPERZ Prescribing Information)

**YOUR RESPONSE TO PREVIOUS DENIAL LETTERS**
(if filing a second- or third-level appeal)

Please see Important Safety Information on pages 22-24. Click here for full Prescribing Information.
SAMPLE LETTER FOR APPEALING A PA DENIAL
for AFINITOR and AFINITOR DISPERZ

Use when the health plan denies the initial PA request
• Include a Letter of Medical Necessity and your patient’s relevant medical records

[Physician Practice letterhead]
[Date]

[Name of insurance company]
[Address]
[City, State, ZIP code]

Re: Appeal for denial of [drug name]

[Patient’s name]
[Policy number]
[Case ID number]
[Date of birth]

To Whom It May Concern:

I am writing to request you reconsider your denial of coverage for [AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension)] [dose and frequency] that I prescribed for my patient, [patient’s full name]. Your reason for denial was [insert health insurance plan’s reason for denying coverage].

I still believe [AFINITOR or AFINITOR DISPERZ] is appropriate for my patient. Listed below are my patient’s diagnosis, medical history, treatment plan, and other supporting information, which confirm the medical necessity and appropriateness of [AFINITOR or AFINITOR DISPERZ].

Patient’s diagnosis, medical history, treatment plan, and other supporting information

[Insert information regarding your patient’s diagnosis to include:
• Brief description of the patient’s diagnosis, including the ICD-10 code. Please refer to sample ICD-10 codes on pages 6-7
• History of TSC and:
  – Serial radiologic evidence of subependymal giant cell astrocytoma (SEGA) tumor growth
  – Tuberous sclerosis complex–associated seizures
  – Noncancerous tumors growing in the kidney
• Previous therapies and results
• Treatment plan
• Other supporting information.

Refer to page 8 of this guide for examples of information commonly required by health insurance plans for AFINITOR or AFINITOR DISPERZ coverage.]
I hope you will agree [AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension)] is appropriate and medically necessary for [patient’s name] and provide coverage for this treatment. Enclosed in support of this appeal are [insert description of supporting documents. Refer to page 9 of this guide for examples of documentation that may help support an appeal for AFINITOR or AFINITOR DISPERZ coverage].

Thank you in advance for your consideration. Please contact me at [office phone number] for any additional information you may require regarding this request. I look forward to your timely approval of this appeal.

Sincerely,

[Prescriber’s name and signature]

[Attachments: Enclose denial letter and supporting documentation]
SAMPLE LETTER FOR YOUR PATIENT TO APPEAL A PA DENIAL for AFINITOR and AFINITOR DISPERZ

Give to your patient who wants to file an appeal when the initial PA request is denied

- Talk to your patient and offer to help with writing the letter
- Provide a Letter of Medical Necessity and your patient’s relevant medical records
- This letter can be modified for caregivers to write an appeal on behalf of your patient

---

[Date]

[Name of insurance company]
[Address]
[City, State, ZIP code]

Re: [Patient’s name]
[Policy number]
[Date of birth]

To Whom It May Concern:

I am writing to request that you reconsider your denial of coverage for AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension) for [insert patient’s name]. I understand the reasons for the denial are [include the reasons from the letter you received from the insurance company].

Listed below are the reasons why [my/her/his] doctor prescribed AFINITOR or AFINITOR DISPERZ:

[Insert information the doctor gave you about the diagnosis to include:
  - History of TSC and:
    - Serial radiologic evidence of subependymal giant cell astrocytoma tumor growth
    - Tuberous sclerosis complex–associated seizures
    - Noncancerous tumors growing in the kidney
  - Previous therapies and results
  - Treatment plan
  - Other supporting information.]

I have also enclosed [insert descriptions of supporting documents the doctor gave you] outlining why [my/his/her] doctor believes [I/he/she] should be treated with AFINITOR or AFINITOR DISPERZ.

Please approve this request so [I/he/she] can start treatment with AFINITOR or AFINITOR DISPERZ as prescribed by [my/his/her] doctor.

[My/His/Her] doctor may be contacted at [insert the doctor’s phone number] for any additional information you may require regarding this request. You can also contact me at [insert your phone number]. I look forward to your timely approval of this appeal.

Sincerely,

[Sign and print your name here]

[Attachments: Enclose the denial letter from the insurance company and supporting documents given to you by the doctor.]
Health plans often request this letter to justify the need to prescribe AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension)

- It is usually submitted to support a PA denial appeal, formulary exception request, or a tiering exception request

[Physician Practice letterhead]
[Date]

[Name of insurance company]
[Address]
[City, State, ZIP code]

Re: [Patient’s name]
[Policy number]
[Date of birth]

To Whom It May Concern:

I am writing on behalf of my patient, [patient’s name], to document the medical necessity of [AFINITOR or AFINITOR DISPERZ] for treatment of [subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC); or tuberous sclerosis complex (TSC)–associated renal angiomyolipomas; or tuberous sclerosis complex (TSC)–associated partial-onset seizures] and to provide information about my patient’s medical history and treatment.

Listed below are my patient’s diagnosis, medical history, treatment plan, and other supporting information, which confirm the medical necessity and appropriateness of [AFINITOR or AFINITOR DISPERZ].

Patient’s diagnosis, medical history, treatment plan, and other supporting information

[Insert information regarding your patient’s diagnosis to include:
  • Brief description of the patient’s diagnosis, including the ICD-10 code. Please refer to sample ICD-10 codes on pages 6-7
  • History of TSC and:
    – Serial radiologic evidence of SEGA growth
    – TSC-associated seizures
    – Noncancerous tumors growing in the kidney
  • Previous therapies and results
  • Treatment plan
  • Other supporting information.

Refer to page 8 of this guide for examples of information commonly required by health insurance plans for AFINITOR or AFINITOR DISPERZ coverage.]

Enclosed in support of this matter are [insert description of supporting documents. Refer to page 9 of this guide for examples of documentation that may help support an appeal for AFINITOR or AFINITOR DISPERZ coverage]. Please contact me at [insert office phone number] for any additional information you may need to ensure prompt approval of [AFINITOR or AFINITOR DISPERZ] for my patient.

Sincerely,

[Prescriber’s name and signature]

[Attachments: Enclose supporting documentation]
SAMPLE LETTER FOR FILING A TIERING EXCEPTION REQUEST
for AFINITOR and AFINITOR DISPERZ

Use for government-insured patients (eg, Medicaid or Medicare) when AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension) is placed on the health plan’s formulary at a tier with a high co-pay or percent coinsurance. Commercially insured (non-government) patients may be eligible to receive a $0 co-pay per month for AFINITOR or AFINITOR DISPERZ. See page 19 for more details.

- This exception attempts to reduce a co-pay or coinsurance to an amount that will be affordable for your patient
- Include a written statement of financial hardship from your patient
- Include a Letter of Medical Necessity and your patient’s relevant medical records

[Physician Practice letterhead]
[Date]

[Name of insurance company]
[Address]
[City, State, ZIP code]

Re: [Patient’s name]
[Policy number]
[Date of birth]

To Whom It May Concern:

I am writing to request a tiering exception for [AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension)] [dose and frequency] that I prescribed for my patient, [patient’s full name].

Listed below are my patient’s diagnosis, medical history, treatment plan, and other supporting information, which confirm the medical necessity and appropriateness of [AFINITOR or AFINITOR DISPERZ].

**Patient's diagnosis, medical history, treatment plan, and other supporting information**

[Insert information regarding your patient’s diagnosis to include:
- Brief description of the patient’s diagnosis, including the ICD-10 code. Please refer to sample ICD-10 codes on pages 6-7
- History of TSC and:
  - Serial radiologic evidence of subependymal giant cell astrocytoma tumor growth
  - Tuberous sclerosis complex-associated seizures
  - Noncancerous tumors growing in the kidney
- Previous therapies and results
- Treatment plan
- Other supporting information.

Refer to page 8 of this guide for examples of information commonly required by health insurance plans for AFINITOR or AFINITOR DISPERZ coverage.]

Please see Important Safety Information on pages 22-24.
Click here for full Prescribing Information.
Without a tiering exception, the co-pay/coinsurance requirement for [AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension)] at its currently assigned tier will create a significant financial burden for my patient. Enclosed in support of this request are [insert description of supporting documents. Refer to page 9 of this guide for examples of documentation that may help support an appeal for AFINITOR or AFINITOR DISPERZ coverage.]

Thank you in advance for your consideration. Please contact me at [office phone number] for any additional information you may require regarding this matter. I look forward to your timely approval of this tiering exception request.

Sincerely,

[Prescriber’s name and signature]

[Attachments: Enclose supporting documentation]
SAMPLE LETTER FOR FILING A FORMULARY EXCEPTION REQUEST
for AFINITOR and AFINITOR DISPERZ

Use if AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension) is not listed on a health plan’s formulary or if the health plan blocks all prescriptions for AFINITOR or AFINITOR DISPERZ

• Include a Letter of Medical Necessity and your patient’s relevant medical records

[Physician Practice letterhead]
[Date]

[Name of insurance company]
[Address]
[City, State, ZIP code]

Re: [Patient’s name]
[Policy number]
[Date of birth]

To Whom It May Concern:

I am writing to request an exception to your formulary for [AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension)] [dose and frequency] that I prescribed for my patient, [patient’s full name].

Listed below are my patient’s diagnosis, medical history, treatment plan, and other supporting information, which confirm the medical necessity and appropriateness of [AFINITOR or AFINITOR DISPERZ].

Patient’s diagnosis, medical history, treatment plan, and other supporting information

[Insert information regarding your patient’s diagnosis to include:

• Brief description of the patient’s diagnosis, including the ICD-10 code. Please refer to sample ICD-10 codes on pages 6-7

• History of TSC and:
  – Serial radiologic evidence of subependymal giant cell astrocytoma tumor growth
  – Tuberous sclerosis complex–associated seizures
  – Noncancerous tumors growing in the kidney

• Previous therapies and results

• Treatment plan

• Other supporting information.

Refer to page 8 of this guide for examples of information commonly required by health insurance plans for AFINITOR or AFINITOR DISPERZ coverage.]

Please see Important Safety Information on pages 22-24. Click here for full Prescribing Information.
I hope you will agree [AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension)] is appropriate and medically necessary to treat my patient’s condition and will support this request for a formulary exception. Enclosed in support of this request are [insert description of supporting documents. Refer to page 9 of this guide for examples of documentation that may help support an appeal for AFINITOR or AFINITOR DISPERZ coverage].

Thank you in advance for your consideration. Please contact me at [office phone number] for any additional information you may require regarding this matter. I look forward to your timely approval of this formulary exception request.

Sincerely,

[Prescriber’s name and signature]

[Attachments: Enclose supporting documentation]
FILING TIERING AND FORMULARY EXCEPTION REQUESTS WITH MEDICARE PLANS

TIERING EXCEPTION

- **The same form** can be used to file for a tiering exception
- The prescriber will need to provide a **statement supporting this request**

FORMULARY EXCEPTION

- Many Medicare Part D plans use a standard process for requesting a medication that is not on formulary, which includes completing a Coverage Determination Request Form
- Contact your patient’s health plan first—most have a customized version of this form available for you to complete and submit
- You will need to provide the clinical rationale for the formulary exception. The plan may request additional information, and prior treatment with medications on the plan’s formulary may be required

Please see Important Safety Information on pages 22-24. 
[Click here](#) for full Prescribing Information.
Novartis Pharmaceuticals Corporation is committed to providing support to meet the needs of patients and caregivers.

Universal Co-pay Card

Patients may be eligible for immediate co-pay savings on their next prescription of AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension)

- Eligible patients with private insurance may pay $0 per month
- Novartis will pay the remaining co-pay, up to $15,000 per calendar year, per product*

*Limitations apply. This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Novartis reserves the right to rescind, revoke, or amend this program without notice.

Encourage your patients to find out if they are eligible to enroll in the Universal Co-pay Program by visiting www.Copay.NovartisOncology.com or calling 1-877-577-7756.
AFINITOR PATIENT RESOURCES AND ACCESS SUPPORT (continued)

AfniTRAC®: The Patient Support Program
AfniTRAC provides 1:1 phone support to help appropriate patients start and stay on AFINITOR® (everolimus) Tablets or AFINITOR DISPERZ® (everolimus tablets for oral suspension). The program includes a Case Manager for the HCP and a dedicated Care Champion Nurse for your patient.

AfniTRAC Care Champion Nurses provide comprehensive educational support, including help with an AFINITOR treatment routine and reminders to patients to take medication as prescribed. Each Care Champion is a registered nurse (RN).

Care Champion RNs support patients in:
- Understanding insurance coverage
- Personal phone calls
- Finding financial support information
- Finding pharmacies covered by their plan
- Education about medications
- Translation services in more than 160 languages
- Creating a customized dosing and mealtime routine

For assistance, HCPs and patients can call 1-888-923-4648 or visit www.AFINITOR.com

AFINITOR and AFINITOR DISPERZ 7-Day Free Trial

The AFINITOR and AFINITOR DISPERZ 7-Day Free Trial helps eligible patients start therapy quickly.

Eligible patients can receive an introductory 7-day supply. This program is available and shipped directly to all patients prescribed AFINITOR or AFINITOR DISPERZ for a US Food and Drug Administration–approved indication without regard to purchase of AFINITOR or AFINITOR DISPERZ or any other product. Medications are dispensed directly from the AFINITOR Tablets or AFINITOR DISPERZ Support Program (at no cost to patient).

- For more information and access to the enrollment form, providers can call 1-888-923-4648 or visit https://www.hcp.novartis.com/products/afinitor/sega/access/
- Both formulations available, including AFINITOR Tablets and AFINITOR DISPERZ
- Shipped directly to patient’s home

Please see Important Safety Information on pages 22-24. Click here for full Prescribing Information.
The Novartis Patient Assistance Foundation, Inc. (NPAF) is committed to providing access to Novartis medications for those most in need. If your patient is experiencing financial hardship and has limited or no prescription coverage, he or she may be eligible to receive Novartis medications for free.

**To be eligible for NPAF assistance, a patient must:**

- Be a US resident
- Meet the income requirements listed below
- Have limited or no private or public prescription coverage*

**Income requirements for NPAF eligibility**

<table>
<thead>
<tr>
<th>Current Criteria</th>
<th>Alaska</th>
<th>Hawaii</th>
</tr>
</thead>
<tbody>
<tr>
<td>Household size: 1</td>
<td>≤ $75,000</td>
<td>$90,360</td>
</tr>
<tr>
<td>Household size: 2</td>
<td>≤ $100,000</td>
<td>$121,740</td>
</tr>
<tr>
<td>Household size: 3</td>
<td>≤ $125,000</td>
<td>$153,120</td>
</tr>
<tr>
<td>Household size: 4</td>
<td>≤ $150,000</td>
<td>$184,500</td>
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*Exceptions exist for individuals with limited prescription coverage.

Please see Important Safety Information on pages 22-24. Click here for full Prescribing Information.
Important Safety Information

AFINITOR® (everolimus) Tablets and AFINITOR DISPERZ® (everolimus tablets for oral suspension) are contraindicated in patients with hypersensitivity to everolimus, to other rapamycin derivatives, or to any of the excipients.

**Noninfectious Pneumonitis:** Noninfectious pneumonitis is a class effect of rapamycin derivatives. Noninfectious pneumonitis was reported in up to 19% of patients treated with AFINITOR/AFINITOR DISPERZ in clinical trials, some cases reported with pulmonary hypertension (including pulmonary arterial hypertension) as a secondary event. The incidence of grade 3 and 4 noninfectious pneumonitis was up to 4.0% and up to 0.2%, respectively. Fatal outcomes have been observed. Consider a diagnosis of noninfectious pneumonitis in patients presenting with nonspecific respiratory signs and symptoms. Consider opportunistic infections such as *Pneumocystis jiroveci* pneumonia (PJP) in the differential diagnosis. Advise patients to report promptly any new or worsening respiratory symptoms. Continue AFINITOR/AFINITOR DISPERZ without dose alteration in patients who develop radiological changes suggestive of noninfectious pneumonitis and have few or no symptoms. Imaging appears to overestimate the incidence of clinical pneumonitis. For grade 2 to 4 noninfectious pneumonitis, withhold or permanently discontinue AFINITOR/AFINITOR DISPERZ based on severity. Corticosteroids may be indicated until clinical symptoms resolve. Administer prophylaxis for PJP when concomitant use of corticosteroids or other immunosuppressive agents are required. The development of pneumonitis has been reported even at a reduced dose.

**Infections:** AFINITOR/AFINITOR DISPERZ has immunosuppressive properties and may predispose patients to bacterial, fungal, viral, or protozoal infections, including those with opportunistic pathogens. Localized and systemic infections, including pneumonia, mycobacterial infections, other bacterial infections; invasive fungal infections, such as aspergillosis, candidiasis, or PJP; and viral infections, including reactivation of hepatitis B virus, have occurred. Some of these infections have been severe (eg, sepsis, sepsis shock, or resulting in multisystem organ failure) or fatal. The incidence of grade 3 and 4 infections was up to 10% and up to 3%, respectively. The incidence of serious infections was reported at a higher frequency in patients <6 years of age. Complete treatment of preexisting fungal infections prior to starting treatment. Monitor for signs and symptoms of infection. Withhold or permanently discontinue AFINITOR/AFINITOR DISPERZ based on severity of infection. Administer prophylaxis for PJP when concomitant use of corticosteroids or other immunosuppressive agents are required.

**Severe Hypersensitivity Reactions:** Hypersensitivity reactions to AFINITOR/AFINITOR DISPERZ have been observed and include anaphylaxis, dyspnea, flushing, chest pain, and angioedema (eg, swelling of the airways or tongue, with or without respiratory impairment). The incidence of grade 3 hypersensitivity reactions was up to 1%. Permanently discontinue AFINITOR/AFINITOR DISPERZ for the development of clinically significant hypersensitivity.

**Angioedema With Concomitant Use of Angiotensin-Converting Enzyme (ACE) Inhibitors:** Patients taking concomitant ACE inhibitor with AFINITOR/AFINITOR DISPERZ may be at increased risk for angioedema (eg, swelling of the airways or tongue, with or without respiratory impairment). In a pooled analysis, the incidence of angioedema in patients taking everolimus with an ACE inhibitor was 6.8% compared to 1.3% in the control arm with an ACE inhibitor. Permanently discontinue AFINITOR/AFINITOR DISPERZ for angioedema.

**Stomatitis:** Stomatitis, including mouth ulcers and oral mucositis, has occurred in patients treated with AFINITOR/AFINITOR DISPERZ at an incidence ranging from 44% to 78% across the clinical trial experience. Grade 3/4 stomatitis was reported in 4% to 9% of patients. Stomatitis most often occurs within the first 8 weeks of treatment. When starting AFINITOR/AFINITOR DISPERZ, initiating dexamethasone alcohol-free oral solution as a swish and spit mouthwash reduces the incidence and severity of stomatitis. If stomatitis does occur, mouthwashes and/or

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other topical treatments are recommended, but alcohol-, hydrogen peroxide-, iodine-, or thyme-containing products should be avoided. Antifungal agents should not be used unless fungal infection has been diagnosed.

**Renal Failure:** Cases of renal failure (including acute renal failure), some with a fatal outcome, have occurred in patients taking AFINITOR. Elevations of serum creatinine and proteinuria have been reported in patients taking AFINITOR® (everolimus) Tablets/AFINITOR DISPERZ® (everolimus tablets for oral suspension). The incidence of grade 3 and 4 elevations of serum creatinine was up to 2% and up to 1%, respectively. The incidence of grade 3 and 4 proteinuria was up to 1% and up to 0.5%, respectively. Monitor renal function prior to starting AFINITOR/AFINITOR DISPERZ and annually thereafter. Monitor renal function at least every 6 months in patients who have additional risk factors for renal failure.

**Impaired Wound Healing:** AFINITOR/AFINITOR DISPERZ delays wound healing and increases the occurrence of wound-related complications like wound dehiscence, wound infection, incisional hernia, lymphocele, and seroma. These wound-related complications may require surgical intervention. Exercise caution with the use of AFINITOR/AFINITOR DISPERZ in the perisurgical period.

**Metabolic Disorders:** Hyperglycemia, hypercholesterolemia, and hypertriglyceridemia have been reported in patients taking AFINITOR/AFINITOR DISPERZ at an incidence up to 75%, 86%, and 73%, respectively. The incidence of these grade 3 and 4 laboratory abnormalities was up to 15% and up to 0.4%, respectively. In nondiabetic patients, monitor fasting serum glucose prior to starting AFINITOR/AFINITOR DISPERZ and annually thereafter. In diabetic patients, monitor fasting serum glucose more frequently as clinically indicated. Monitor lipid profile prior to starting AFINITOR/AFINITOR DISPERZ and once yearly thereafter. When possible, achieve optimal glucose and lipid control prior to starting AFINITOR/AFINITOR DISPERZ. For grade 3 to 4 metabolic events, withhold or permanently discontinue AFINITOR/AFINITOR DISPERZ based on severity.

**Myelosuppression:** Anemia, lymphopenia, neutropenia, and thrombocytopenia have been reported in patients taking AFINITOR/AFINITOR DISPERZ. The incidence of these grade 3 and 4 laboratory abnormalities was up to 16% and up to 2%, respectively. Monitor complete blood count prior to starting AFINITOR/AFINITOR DISPERZ every 6 months for the first year of treatment and annually thereafter. Withhold or permanently discontinue AFINITOR/AFINITOR DISPERZ based on severity.

**Risk of Infection or Reduced Immune Response With Vaccinations:** The safety of immunization with live vaccines during AFINITOR/AFINITOR DISPERZ therapy has not been studied. Due to the potential increased risk of infection and/or reduced immune response to the vaccine, avoid the use of live vaccines and close contact with individuals who have received live vaccines during treatment with AFINITOR/AFINITOR DISPERZ. Due to the potential increased risk of infection or reduced immune response with vaccination, complete the recommended childhood series of live vaccinations according to American Council on Immunization Practices (ACIP) guidelines prior to the start of therapy. An accelerated vaccination schedule may be appropriate.

**Embryo-Fetal Toxicity:** Based on animal studies and the mechanism of action, AFINITOR/AFINITOR DISPERZ can cause fetal harm when administered to a pregnant woman. In animal studies, everolimus caused embryo-fetal toxicities in rats when administered during the period of organogenesis at maternal exposures that were lower than human exposures at the clinical dose of 10 mg once daily. Advise pregnant women of the potential risk to a fetus. Advise female patients of reproductive potential to avoid becoming pregnant and to use effective contraception during
treatment with AFINITOR® (everolimus) Tablets/AFINITOR DISPERZ® (everolimus tablets for oral suspension) and for 8 weeks after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with AFINITOR/AFINITOR DISPERZ and for 4 weeks after the last dose.

Adverse Reactions: In patients with TSC-associated renal angiomyolipoma the most common adverse reaction (incidence ≥30%, all grades) was stomatitis (78%). The most common grade 3/4 adverse reactions (incidence ≥2%) were stomatitis and amenorrhea. Updated safety information from 112 patients treated with AFINITOR for a median duration of 3.9 years identified the following additional adverse reactions: urinary tract infection (31%), abdominal pain (16%), pruritus (12%), gastroenteritis (12%), myalgia (11%), and pneumonia (10%).

In patients with TSC-associated SEGA the most common adverse reactions (incidence ≥30%, all grades) were stomatitis (62%) and respiratory tract infection (31%). The most common grade 3/4 adverse reactions (incidence ≥2%) were stomatitis, pyrexia, pneumonia, gastroenteritis, aggression, agitation, and amenorrhea. Updated safety information from 111 patients treated with AFINITOR for a median duration of 47 months identified the following additional notable adverse reactions: decreased appetite (14%), hypertension (11%), urinary tract infection (9%), cellulitis (6%), abdominal pain (5%), and decreased weight (5%).

In patients with TSC-associated partial-onset seizures, the most common adverse reaction reported for AFINITOR DISPERZ (incidence ≥30%, all grades) was stomatitis (55% low trough, 64% high trough). The most common grade 3/4 adverse reactions (incidence ≥2%) were stomatitis, pneumonia, and irregular menstruation. Updated safety information from 357 patients treated with AFINITOR DISPERZ for a median duration of 48 weeks identified the following additional notable adverse reactions: hypersensitivity (0.6%), angioedema (0.3%), and ovarian cyst (0.3%).

Laboratory Abnormalities: In patients with TSC-associated renal angiomyolipoma, the most common laboratory abnormalities (incidence ≥50%, all grades) were hypercholesterolemia (85%), hypertriglyceridemia (52%), and anemia (61%). The most common grade 3/4 laboratory abnormality (incidence ≥3%) was hypophosphatemia (5%). Updated safety information from 112 patients treated with AFINITOR for a median duration of 3.9 years identified the following additional key laboratory abnormalities: increased partial thromboplastin time (63%), increased prothrombin time (40%), decreased fibrinogen (38%), and proteinuria (18%).

In patients with TSC-associated SEGA, the most common key laboratory abnormalities (incidence ≥50%, all grades) were hypercholesterolemia (81%) and elevated partial thromboplastin time (72%). The most common grade 3/4 laboratory abnormality (incidence ≥3%) was neutropenia (9%). Updated safety information from 111 patients treated with AFINITOR for a median duration of 47 months identified the following additional key laboratory abnormalities: hyperglycemia (13%), decreased fibrinogen (8%), elevated creatinine (5%), and azoospermia (1%).

In patients with TSC-associated partial-onset seizures, the most common laboratory abnormality (incidence ≥50%, all grades) was hypercholesterolemia (86% low trough, 85% high trough). The most common grade 3/4 laboratory abnormality (incidence ≥2%) was neutropenia.
Reference:

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