

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

<input type="checkbox"/> Initial Request		<input type="checkbox"/> Renewal		<input type="checkbox"/> Appeal/Redetermination¹	
<input type="checkbox"/> Urgent²		<input type="checkbox"/> Non-Urgent			
Requested Drug Name: Afinitor® Disperz (everolimus) – Medicare Part D					
Patient Information:			Prescribing Provider Information:		
Patient Name:			Prescriber Name:		
Member/Subscriber Number:			Prescriber Fax:		
Policy/Group Number:			Prescriber Phone:		
Patient Date of Birth (MM/DD/YYYY):			Prescriber Pager:		
Patient Address:			Prescriber Address:		
Patient Phone:			Prescriber Office Contact:		
Patient Email Address:			Prescriber NPI:		
			Prescriber DEA:		
Prescription Date:			Prescriber Tax ID:		
			Specialty/Facility Name (If applicable):		
			Prescriber Email Address:		
Prior Authorization Request for Drug Benefit					
Patient Diagnosis and ICD Diagnostic Code(s):					
Drug(s) Requested (with J-Code, if applicable):					
Strength/Route/Frequency:					
Unit/Volume of Named Drug(s):					
Start Date and Length of Therapy:					
Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:					
Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:					
<p>Afinitor® Disperz (everolimus)</p> <p>Diagnosis for AFINITOR DISPERZ ONLY (documentation supportive of diagnosis is required) <i>* See Afinitor Prior Authorization form for other indications</i></p> <p><input type="checkbox"/> Pediatric or Adult with tuberous sclerosis complex (TSC) who has Subependymal Giant Cell Astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected</p> <p>Clinical Consideration:</p> <p><i>*Note:</i></p> <ul style="list-style-type: none"> • The effectiveness is based on demonstration of durable objective response, as evidenced by reduction in SEGA tumor volume. • Improvement in disease related symptoms and overall survival in patients with SEGA and TSC has not been demonstrated. 					

Physician Specialty (diagnosis made by):		
<input type="checkbox"/> Oncology <input type="checkbox"/> Other (please state): _____		
<input type="checkbox"/> For use in clinical trial? (If yes, provide trial name and registration number):		
Drug Name (Brand Name and Scientific Name)/Strength:		
Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to: <input type="checkbox"/> Patient's Home <input type="checkbox"/> Physician Office		Other:
Prescriber or Authorized Signature:		Date:
Dispensing Pharmacy Name and Phone Number:		
<input type="checkbox"/> Approved		<input type="checkbox"/> Denied
If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:		

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Afinitor[®] Disperz (everolimus)

CLASSIFICATION

- Antineoplastic

DESCRIPTION

- Inhibits mammalian target of rapamycin kinase activity which reduces the activity of S6 ribosomal protein kinase, eukaryotic elongation factor 4E-binding protein, inhibits the expression of hypoxia-inducible factor, and reduces vascular endothelial growth factor expression.
- Everolimus is an analogue of rapamycin (sirolimus) with immunosuppressive and antiproliferative activity. It was developed to improve upon the wide inter-individual variation in pharmacokinetic parameters observed with oral sirolimus in animal and human studies. Everolimus is not a prodrug of sirolimus; it exhibits metabolic stability in that hydrolytic cleavage of the side chain does not occur to a significant extent in vivo.
- Everolimus (Afinitor tablets and Afinitor Disperz) is indicated for the treatment of **subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis** in adults and children 1 year or older who are not candidates for curative surgical resection. Treatment with everolimus for 6 months resulted in a significant decrease in the volume of the primary subependymal giant cell astrocytoma compared with baseline in patients with tuberous sclerosis, according to a phase 1-2, prospective, open-label study (n=28). Clinical benefit such as improvement in disease related symptoms or increase in overall survival has not been demonstrated.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	T3
Commercial Formulary:	T3
Medicare Part D coverage:	T5 (Part D)

COVERAGE CRITERIA

Afinitor[®] Disperz (everolimus tablets for oral suspension) meets the definition of **medical necessity** for all FDA-approved indications not otherwise excluded from Part D, including the following:

- Adults and children ≥ 1 year of age with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) that requires therapeutic intervention but cannot be curatively resected (supporting documentation required).
- Requests meeting criteria will be approved in 12 month increments.

Afinitor[®] Disperz (everolimus tablets for oral suspension) is considered **experimental** for the following:

- Any indication that is not FDA approved or Compendia supported.

Required Provider Specialty:

- Approval is limited to Oncology

DOSAGE/ADMINISTRATION:

SEGA with TSC (not indicated in pediatric patients less than 1 year of age):

- Do NOT combine tablets and tablets for oral suspension to achieve the desired dose; administer only 1 dosage form.
- 4.5 mg/m² once daily; adjust dose to attain trough concentrations of 5-15 ng/mL.
- Assess trough concentrations approximately 2 weeks after initiation of treatment, a change in dose, a change in co-administration of CYP3A4 and/or PgP inducers or inhibitors, a change in hepatic function, or a change in dosage form between AFINITOR Tablets and AFINITOR DISPERZ.
- For patients with severe hepatic impairment reduce the starting dose of AFINITOR Tablets or AFINITOR DISPERZ.
- If concomitant use of moderate inhibitors of CYP3A4 and/or PgP is required, reduce the dose of AFINITOR Tablets or AFINITOR DISPERZ by 50%.
- If concomitant use of strong inducers of CYP3A4 is required, double the dose of AFINITOR Tablets or AFINITOR DISPERZ.
- Use therapeutic drug monitoring to guide subsequent dosing. Adjust dose at 2 week intervals as needed to achieve and maintain trough concentrations of 5 to 15 ng/mL.
- Continue treatment until disease progression or unacceptable toxicity occurs. The optimal duration of therapy is unknown.

Dose reduction or treatment interruption may be needed to manage adverse drug reactions. See prescribing information for complete dosing and dose adjustment information.

PRECAUTIONS:

- Contraindicated if hypersensitivity to everolimus, other rapamycin derivatives (ego, sirolimus), or any other components of the product.
- Adverse reactions, severe and/or intolerable, including death; may require dose adjustment, interruption or withdrawal; risk greater in elderly 65 years of age and older.
- Hematologic aberrations (decreases in hemoglobin, lymphocytes, neutrophils, platelets) have been reported; monitoring recommended.
- Preexisting severe hepatic impairment (Child-Pugh class C): use not recommended.
- Hepatic impairment due to increased exposure to everolimus may require dose adjustment.
- Hyperglycemia, hyperlipidemia and hypertriglyceridemia have been reported; monitoring is recommended and dose reduction, interruption, or withdrawal may be required.
- Hypersensitivity reactions, including anaphylaxis and angioedema have been reported.
- Localized or systemic opportunistic infections, sometimes severe including fatalities have been reported; monitoring recommended; interruption or discontinuation of therapy may be required.
- Mouth ulcers, oral mucositis, and stomatitis have been reported and may require dose reduction, interruption, or withdrawal.
- Noninfectious pneumonitis has been reported; monitoring and dose adjustments recommended; discontinuation of therapy may be required in severe cases.
- Concomitant use with live vaccines should be avoided; close contact with live vaccine recipients should also be avoided.
- Concomitant use with strong CYP3A4 or P-glycoprotein inducers (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital), including St John's wort or grapefruit, should be avoided. Dosage adjustment recommended if alternative therapies are unavailable.
- Impaired wound healing: Increased risk of wound-related complications. Monitor for signs and symptoms. Exercise caution in the peri-surgical period.
- Female infertility may occur.
- Embryo-fetal toxicity: Fetal harm can occur when administered to a pregnant woman. Apprise women of potential harm to the fetus.
- Nephrotoxicity, including serum creatinine elevations, proteinuria, and acute renal failure with fatalities, has been reported. Monitoring recommended.

COST

- AWP (July 2013): Afinitor Disperz 2mg tablets (1): \$330.05
- AWP (January 2014): Afinitor Disperz 2mg tablets (1): \$362.73
- AWP (July 2013): Afinitor Disperz 3mg tablets (1): \$333.36
- AWP (January 2014): Afinitor Disperz 3mg tablets (1): \$366.36
- AWP (July 2013): Afinitor Disperz 5mg tablets (1): \$337.98
- AWP (January 2014): Afinitor Disperz 5mg tablets (1): \$381.31

COMMITTEE APPROVAL:

- January 26, 2011 – Afinitor® tablets
 - Afinitor Disperz – line extension coverage for new formulation for FDA approved indication.

GUIDELINE UPDATE INFORMATION:

May 2013	Medicare Prior Authorization and Coverage Policy created for Afinitor Disperz

REFERENCES:

- DRUGDEX®, accessed 05/24/2013, 3/10/2014
- Product Information: Afinitor Disperz® (everolimus tablets for oral suspension). Novartis Pharmaceutical Corporation, East Hanover, NJ, 2/2014.