



Drug Quantity Management – Per Rx Oncology – Afinitor®/Afinitor® Disperz (everolimus tablets and tablets for oral suspension) Dispensing Limit

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Product Identifier(s)

94698

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- Afinitor® (everolimus tablets)
- Afinitor® Disperz (tablets for oral suspension)

Afinitor Disperz 2 mg, 3 mg, 5 mg tablets

Maximum quantity per RX = 30 tablets

Afinitor 2.5 mg, 5 mg, 7.5 mg tablets (generics)

Maximum quantity per RX = 30 tablets

Afinitor 10 mg tablets

Maximum quantity per RX = 30 tablets

Indication	Afinitor Dose	Afinitor Disperz dose
Hormone Receptor-Positive, HER2-Negative Breast Cancer	10 mg daily	N/A
Neuroendocrine Tumors (NET)	10 mg daily	N/A
Renal Cell Carcinoma (RCC)	10 mg daily	N/A
Tuberous Sclerosis Complex (TSC)-Associated Renal Angiomyolipoma	10 mg daily	N/A
Tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA)	4.5 mg/m ² daily. Titrate to maintain blood trough concentrations of 5 ng/mL to 15 ng/mL.	4.5 mg/m ² daily. Titrate to maintain blood trough concentrations of 5 ng/mL to 15 ng/mL.
Tuberous Sclerosis Complex (TSC)-Associated Partial-Onset Seizures	N/A	5 mg/m ² daily. Titrate to maintain blood trough concentrations of 5 ng/mL to 15 ng/mL.

Dose interruption and/or dose reduction may be required in the event of intolerable grade 2 toxicity, grade 3 or 4 toxicities, other toxicities. Dose reduction ranging from one 2.5 mg, 5 mg or 7.5 mg tablet daily is also required for mild to severe hepatic impairment or when Afinitor is co-administered with moderate CYP3A4 and/or P-glycoprotein (PgP) inhibitors.

Co-administration with the CYP3A4 inducer rifampicin decreased everolimus area under the curve (AUC) by approximately 63%. Use of alternative treatments lacking CYP3A4-inducing activity is strongly recommended. If an alternative treatment is unavailable, double the dose of Afinitor using 5 mg increments or less. If the strong inducer is discontinued, the Afinitor dose should be returned to the dose used prior to the initiation of the strong CYP3A4 inducer, once all inducers are discontinued for 5 days. Other CYP3A4 inducers include, but are not limited to, carbamazepine, phenobarbital, phenytoin, rifabutin, rifapentine. St. John's Wort should be avoided as it may decrease everolimus exposure unpredictably.

Cigna covers quantities as medically necessary when the following criteria are met:

All approvals are provided for 1 year in duration unless otherwise noted below.

Afinitor 2.5 mg, 5 mg, 7.5 mg tablets (generics)

Afinitor 10 mg tablets

Afinitor 2.5 mg tablets, generics

- For patients with Tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA) who need to increase their dose to maintain blood trough concentrations between 5 ng/mL and 15 ng/mL, the following quantities may be approved for the designated doses in the table below:

Dose	# of 2.5 mg tablets to approve per dispensing
12.5 mg	150 tablets
17.5 mg	210 tablets

Afinitor 5 mg tablets, generics

- For patients with Tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA) who need to increase their dose to maintain blood trough concentrations between 5 ng/mL and 15 ng/mL, the following quantities may be approved for the designated doses in the table below:

Dose	# of 5 mg tablets to approve per dispensing
25 mg	150 tablets

Afinitor 7.5 mg tablets, generics

1. For patients taking a strong CYP3A4 inducer (e.g., rifampicin, carbamazepine, phenobarbital, phenytoin, rifabutin, rifapentine) at the same time as Afinitor and may require a dose of 15 mg per day, approve a quantity of 60 of the 7.5 mg tablets per dispensing.
2. For patients with Tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA) who need to increase their dose to maintain blood trough concentrations between 5 ng/mL and 15 ng/mL, the following quantities may be approved for the designated doses in the table below:

Dose	# of 7.5 mg tablets to approve per dispensing
15 mg	60 tablets
22.5 mg	90 tablets

Afinitor 10 mg tablets

1. Approve up to 60 tablets per dispensing if the patient is taking a strong CYP3A4 inducer (e.g., rifampicin, carbamazepine, phenobarbital, phenytoin, rifabutin, and rifapentine).
2. For patients with Tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA) who need to increase their dose to maintain blood trough concentrations between 5 ng/mL and 15 ng/mL, the following quantities may be approved for the designated doses in the table below:

Dose	# of 10 mg tablets to approve per dispensing
20 mg	60 tablets
30 mg	90 tablets

Afinitor Disperz 2 mg, 3 mg, 5 mg tablets***Afinitor Disperz 2 mg tablets***

2. For patients with Tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA) or Tuberous Sclerosis Complex (TSC)-Associated Partial-Onset Seizures who need to increase their dose to maintain blood trough concentrations between 5 ng/mL and 15 ng/mL, the following quantities may be approved for the designated doses in the table below:

Dose	# of 2 mg tablets to approve per dispensing
4 mg	60 tablets
8 mg	120 tablets
14 mg	210 tablets
16 mg	240 tablets
22 mg	330 tablets

Afinitor Disperz 3 mg tablets

3. For patients with Tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA) or Tuberous Sclerosis Complex (TSC)-Associated Partial-Onset Seizures who need to increase their dose to maintain blood trough concentrations between 5 ng/mL and 15 ng/mL, the following quantities may be approved for the designated doses in the table below:

Dose	# of 3 mg tablets to approve per dispensing
6 mg	60 tablets
9 mg	90 tablets
12 mg	120 tablets
18 mg	180 tablets
21 mg	210 tablets
24 mg	240 tablets

Afinitor Disperz 5 mg tablets

4. For patients with Tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA) or Tuberous Sclerosis Complex (TSC)-Associated Partial-Onset Seizures who need to increase their dose to maintain blood trough concentrations between 5 ng/mL and 15 ng/mL, the following quantities may be approved for the designated doses in the table below:

Dose	# of 5 mg tablets to approve per dispensing
10 mg	60 tablets
15 mg	90 tablets
20 mg	120 tablets
25 mg	150 tablets
30 mg	180 tablets

Conditions Not Covered

Any other exception is considered not medically necessary.

References

1. Afinitor®/Afinitor Disperz [prescribing information]. East Hanover, NJ: Novartis; March 2020.

Revision History

Type of Revision	Summary of Changes	Approval Date
New Policy	Reviewed and approved at TAC.	06/02/2021

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