



Amivantamab - In Combination with Chemotherapy for EGFR-mutated Advanced NSCLC after Osimertinib Treatment

(This form should be completed before the first dose is dispensed.)

1. Patient Profile

- * Surname: _____
- * Given Name: _____
- * OHIN: _____ * Chart Number: _____
- * Postal Code: _____
- * Height (cm): _____ * Weight (kg): _____ * BSA (m²): _____
- * Gender: ☐ Male ☐ Female ☐ Other
- * Date of Birth: _____
Day Month Year
- * Site: _____
- * Attending Physician (MRP- Most Responsible Physician): _____
- Requested Prior Approval ☐ Yes * Patient on Clinical Trial ☐ Yes ☐ No
- Other (specify): _____
- Specify Arm:
☐ Standard of care arm ☐ Experimental arm
☐ Blinded / Unknown

Prior Approval Request

- * Select the appropriate prior approval scenario:
- | | |
|---|---|
| ☐ 1-Unknown primary (submit pathology report and clinic note) | ☐ 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below) |
| ☐ 3-Regimen modification - schedule (complete questions a and b) | ☐ 4-Regimen modification - drug substitutions (complete questions a and c) |
| ☐ 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f) | ☐ 6-Maintenance therapy delay (submit clinic note) |
| ☐ 7-Prior systemic therapy clinical trials (complete question g) | ☐ 8-Modification due to supply interruption/drug shortage |
| ☐ Other (specify) | |
- _____

All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.

a. Co-morbidities / toxicity / justification:

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b. Intended regimen
schedule:

c. Intended regimen:

d. Drug(s) to be held:

e. Rationale for holding
drug(s):

f. Intention to introduce drug ☐ Yes
at a later date?

g. Prior clinical trial identifier
(e.g., NCT ID, trial name)
and treatment description
(e.g., arm, drug/regimen):

h. Anticipated date of first
treatment: Day Month Year

i. Additional comments:

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2. Eligibility Criteria

Amivantamab will be used in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced (not amenable to curative therapies) or metastatic *EGFR*-mutated non-small cell lung cancer (NSCLC) whose disease has progressed on or after osimertinib therapy. ☐ Yes

Patients must have:

- *EGFR*-mutated NSCLC (exon 19 deletion or exon 21 L858R substitution).
- Osimertinib as the most recent therapy.
- A good performance status.
- If applicable, platinum-sensitive disease (i.e., at least 6 months from completion of platinum-based chemotherapy to disease progression).

Patients must not have:

- Active interstitial lung disease.
- Unstable brain metastases.
- Squamous cell histology.

3. Baseline Information

- a. ECOG Performance Status at the time of enrolment ☐ 0 ☐ 1 ☐ 2
- b. EGFR mutation ☐ Exon 19 deletion
☐ Exon 21 L858R substitution
- c. Prior osimertinib therapy setting ☐ Adjuvant ☐ Advanced ☐ Both
- d. Date of last dose of Osimertinib
.....
Day Month Year
- e. Is the patient transitioning from a private payer or compassionate program? ☐ Yes ☐ No
- f. If yes, please indicate the funding source ☐ Private payer ☐ Manufacturer patient support program
- g. If yes, please indicate how many doses of amivantamab they have received.
- h. If yes, please indicate the date of the last administered dose.
Day Month Year

4. Funded Dose

Please select the dosing regimen:

- ☐ Patient's weight at baseline is less than 80 kg:
- Amivantamab 350 mg given intravenously (IV) on cycle 1 day 1, followed by 1050 mg IV on day 2; then,
 - Amivantamab 1400 mg IV weekly on cycle 1 days 8 and 15, and cycle 2 day 1; then,
 - Amivantamab 1750 mg IV every 3 weeks from cycle 3 day 1 onwards.
- ☐ Patient's weight at baseline is greater than or equal to 80 kg:
- Amivantamab 350 mg IV on cycle 1 day 1, followed by 1400 mg IV on day 2; then,
 - Amivantamab 1750 mg IV weekly on cycle 1 days 8 and 15, and cycle 2 day 1; then,
 - Amivantamab 2100 mg IV every 3 weeks from cycle 3 day 1 onwards.

Amivantamab is given in combination with carboplatin and pemetrexed for the first 4 cycles, followed by maintenance amivantamab and pemetrexed until disease progression or unacceptable toxicity.

[ST-QBP regimen code(s): CRBPPEME+AMIV, CISPPEME+AMIV, PEME+AMIV(MNT), AMIV(MNT)]

5. Notes

1. Cisplatin may be substituted for carboplatin.
2. The dosing selected in the "Funded Dose" section will be the dosing used for the entirety of treatment. Dose adjustments are not required for subsequent body weight changes, only for toxicity.

6. FAQs

1. My patient is currently receiving amivantamab through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding through the New Drug Funding Program (NDFP)?

Provided the eligibility criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage through the NDFP.

2. What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?

If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:

- A clinic note and imaging (if applicable) from treatment initiation, including the patient's treatment history, and
- Pathology report(s) demonstrating NSCLC with an EGFR exon 19 deletion or exon 21 L858R substitution, and
- The most recent clinic note and imaging (if applicable).

Please note: Patients who meet the NDFP eligibility criteria and are enrolled in the manufacturer's patient support program (PSP) are eligible to receive continued drug supply through the PSP until July 28, 2026, inclusive.

After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

3. My patient is awaiting EGFR mutation test results. Can we start therapy with amivantamab and chemotherapy in the interim?

Patients may only initiate chemotherapy while awaiting test results. Once an EGFR exon 19 deletion or exon 21 L858R substitution is confirmed, amivantamab can be added.

4. My patient is intolerant to carboplatin or pemetrexed. Can I continue therapy with the remaining agent(s)?

Patients who are intolerant to either carboplatin or pemetrexed may continue therapy with the other agent(s) until disease progression or unacceptable toxicity.

5. My patient's disease progressed during adjuvant osimertinib treatment. Are they eligible for amivantamab in the advanced setting?

Patients whose disease progresses during adjuvant osimertinib therapy may be eligible for amivantamab with chemotherapy, provided that they do not meet criteria to rechallenge with osimertinib, there has been at least 6 months between their last platinum chemotherapy exposure and disease progression, and all other eligibility criteria are met.

6. My patient is currently receiving an alternate second-line treatment. Can my patient be switched to amivantamab with chemotherapy?

On a time-limited basis, your patient may be eligible for funding of amivantamab under this policy, provided their disease has not progressed and all other eligibility criteria are met. At least 1 cycle of amivantamab must be given with platinum-based chemotherapy to be eligible to switch.

7. My patient is receiving pemetrexed maintenance. Are they eligible for the addition of amivantamab?

On a time-limited basis, your patient may be eligible for funding of amivantamab under this policy, provided their disease has not progressed and all other eligibility criteria are met. At least 2 cycles of amivantamab in combination with platinum-based chemotherapy must be given before proceeding with maintenance amivantamab and pemetrexed.

Supporting Documents

None required at time of enrolment.

In the event of an audit or upon request, the following should be available to document eligibility:

- Clinic notes outlining patient and treatment history/response.
- Pathology report(s) demonstrating non-squamous histology and an EGFR exon 19 deletion or exon 21 L858R substitution.
- CT scans demonstrating no disease progression.

Signature of Attending Physician (MRP-Most Responsible Physician):

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Day Month Year