

Clinical Policy Title:	selpercatinib
Policy Number:	RxA.636
Drug(s) Applied:	Retevmo®
Original Policy Date:	09/14/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of recurrent, advanced, or metastatic Non-Small Cell Lung Cancer (NSCLC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of RET fusion-positive disease (e.g., KIF5B-RET);
5. Member has not received prior RET targeted therapy (e.g., Gavreto®);
6. Prescribed as a single agent;
7. Request meets one of the following (a, b, or c):*
 - a. Weight < 50 kg: Dose does not exceed 120 mg twice daily;
 - b. Weight ≥ 50 kg: Dose does not exceed 160 mg twice daily;
 - c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration

Commercial: 12 months

Medicaid: 12 months

B. Thyroid Cancer (must meet all):

1. Diagnosis of one of the following (a or b):
 - a. RET- mutant medullary thyroid cancer (MTC);
 - b. RET fusion-positive thyroid cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Disease is recurrent, advanced, or metastatic;
5. For Medullary thyroid cancer (MTC): Disease requires treatment with systemic therapy;
6. For Thyroid cancer : Member meets one of the following (a or b):
 - a. Disease has progressed on or following prior systemic treatment (e.g, chemotherapy);
 - b. There are no satisfactory alternatives available;
7. Member has not received prior RET targeted therapy (e.g., Gavreto®);
8. Prescribed as a single agent;
9. Request meets one of the following (a, b, or c):*
 - a. Weight < 50 kg: Dose does not exceed 120 mg twice daily;

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.

- b. Weight \geq 50 kg: Dose does not exceed 160 mg twice daily;
- c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration

Commercial: 12 months

Medicaid: 12 months

C. RET Fusion-Positive Solid Tumors (must meet all):

- 1. Diagnosis of a locally advanced or metastatic solid tumor;
- 2. Age \geq 18 years;
- 3. Prescribed by or in consultation with an oncologist;
- 4. Documentation of RET fusion-positive disease;
- 5. One of the following (a or b):
 - a. Disease has progressed on or following prior systemic treatment;
 - b. Member has no satisfactory alternative treatment options;
- 6. Member has not received prior RET targeted therapy (e.g., Gavreto®);
- 7. Prescribed as a single agent;
- 8. Request meets one of the following (a, b, or c):*
 - a. Weight $<$ 50 kg: Dose does not exceed 120 mg (2 capsules) twice daily;
 - b. Weight \geq 50 kg: Dose does not exceed 160 mg (2 capsules) twice daily;
 - c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration:

Commercial: 12 months or duration of request, whichever is less

Medicaid: 12 months

D. Histiocytic Neoplasms - Langerhans Cell Histiocytosis (off -label) (must meet all):

- 1. Diagnosis of Langerhans Cell Histiocytosis;
- 2. Prescribed by or in consultation with an oncologist;
- 3. Age \geq 12 years;
- 4. Request is for first-line or subsequent therapy for RET fusion target for single agent;
- 5. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration

Commercial: 12 months

Medicaid: 12 months

E. Histiocytic Neoplasms- Erdheim-Chester Disease (off -label) (must meet all):

- 1. Diagnosis of Erdheim-Chester Disease;
- 2. Prescribed by or in consultation with an oncologist;
- 3. Age \geq 12 years;
- 4. Request is for first-line or subsequent therapy for RET fusion target as a single agent;
- 5. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration

Commercial: 12 months

Medicaid: 12 months

F. Histiocytic Neoplasms - Rosai-Dorfman Disease (off -label) (must meet all):

1. Diagnosis of Rosai-Dorfman Disease;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Request if for first-line or subsequent therapy for RET fusion target as a single agent;
5. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. The member is responding positively to therapy;
3. Age ≥ 12 years;
4. Maximum Dose does not exceed (a, b or c):
 - a. 240 mg per day for < 50 kg weight;
 - b. 320 mg per day for ≥ 50 kg weight;
 - c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration

Commercial: 12 months

Medicaid: 12 months

References

1. Bongarzone I, et al. RET/NTRK1 Rearrangements in Thyroid Gland Tumors of the Papillary Carcinoma Family: Correlation with Clinicopathological Features. Available at: <https://pubmed.ncbi.nlm.nih.gov/9516975/>. Accessed April 6, 2022.
2. National Comprehensive Cancer Network Guidelines. Histiocytic Neoplasms. Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf. Accessed May 8, 2023.
3. National Comprehensive Cancer Network Guidelines. Occult Primary. Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/occult.pdf. Accessed May 8, 2023.
4. National Comprehensive Cancer Network Guidelines. Neuroendocrine and Adrenal Tumors. Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed May 8, 2023.
5. National Comprehensive Cancer Network Guidelines. Cervical Cancer. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed May 8, 2023.
6. National Comprehensive Cancer Network Guidelines. Small Bowel Adenocarcinoma. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/small_bowel.pdf. Accessed May 8, 2023.
7. National Comprehensive Cancer Network Guidelines. Head and Neck Cancers. Version 1.2023. Available

- at: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed May 8, 2023.
8. National Comprehensive Cancer Network Guidelines. Ovarian Cancer Continue Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed May 8, 2023.
 9. National Comprehensive Cancer Network Guidelines. Esophageal and Esophagogastric Junction Cancers. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed May 8, 2023.
 10. National Comprehensive Cancer Network Guidelines. Gastric Cancer. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed May 8, 2023.
 11. National Comprehensive Cancer Network Guidelines. Thyroid Carcinoma. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed May 8, 2023.
 12. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed May 8, 2023.
 13. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer. Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed May 8, 2023.
 14. National Comprehensive Cancer Network Guidelines. Breast Cancer. Version 4.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed May 8, 2023.
 15. National Comprehensive Cancer Network Guidelines. Biliary Tract Cancer. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf. Accessed May 8, 2023.
 16. National Comprehensive Cancer Network Guidelines. Colon Cancer. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed May 8, 2023.
 17. National Comprehensive Cancer Network Guidelines. Rectal Cancer. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed May 8, 2023.
 18. National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed May 8, 2023.
 19. National Comprehensive Cancer Network Guidelines. Ampullary Adenocarcinoma. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ampullary.pdf. Accessed May 8, 2023.
 20. National Comprehensive Cancer Network Guidelines. Pancreatic Adenocarcinoma. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed May 8, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	07/07/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Line of Business was updated from “Commercial, Medicaid” to “All line of Business”. 2. Initial Approval Criteria I.A.5.a was updated to include “240 mg per day for < 50 kg weight;”. 3. Initial Approval Criteria I.A.5.b was updated to include “320 mg per day for ≥ 50 kg weight;”. 4. Initial Approval Criteria I.B was updated to include off-label indication “Histiocytic Neoplasms - Langerhans Cell Histiocytosis (off -label)...”. 5. Initial Approval Criteria I.C was updated to include off-label indication “Histiocytic Neoplasms- Erdheim-Chester Disease (off -label)...”. 	07/06/2021	09/14/2021

<ol style="list-style-type: none"> 6. Initial Approval Criteria I.D was updated to include off-label indication “Histiocytic Neoplasms - Rosai-Dorfman Disease (off -label)...”. 7. Continued Therapy Approval Criteria II.A was updated from “Non-Small Cell Lung Cancer” to “Non-Small Cell Lung Cancer or Medullary Thyroid Cancer and other off label indications (must meet all)...”. 8. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 9. Continued Therapy Criteria II.A.4.a was updated to include “240 mg per day for < 50 kg weight;”. 10. Continued Therapy Criteria II.A.4.b was updated to include “320 mg per day for ≥ 50 kg weight;”. 11. References were reviewed and updated. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial approval criteria reviewed and updated. 2. References were reviewed and updated. 	04/06/2022	07/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5 and I.B.5: Updated to remove concurrent therapy criteria Retevmo® is not prescribed concurrently with Gavreto®. 2. Initial Approval Criteria, I.A.6 and I.B.11: Updated to remove prior generic Preferred criteria For brand Retevmo® requests, member must use generic selpercatinib, if available, unless contraindicated or clinically significant adverse effects are experienced. 3. Initial Approval Criteria, I.B.1.a: Updated diagnostic criteria from Medullary thyroid cancer (MTC) to RET- mutant medullary thyroid cancer (MTC). 4. Initial Approval Criteria, I.B.1.b: Updated to include new diagnosis criteria RET fusion-positive thyroid cancer. 5. Initial Approval Criteria, I.B.1.b and I.B.1.c: Updated to remove diagnostic criteria: <ol style="list-style-type: none"> a. Differentiated thyroid carcinoma (DTC; Hurthle cell, papillary, follicular); b. Anaplastic thyroid carcinoma (ATC to RET- mutant medullary thyroid cancer (MTC). 6. Initial Approval Criteria, I.B.5: Updated prior therapy criteria from For MTC, documentation of RET mutant-positive disease (e.g., RET M918T) to For Medullary thyroid cancer (MTC) :Disease requires treatment with systemic therapy. 	05/08/2023	07/13/2023

<p>7. Initial Approval Criteria, I.B.6: Updated prior therapy criteria from For DTC, oncocytic or ATC, documentation of RET fusion-positive disease (e.g., CCDC6-RET, KIF5B-RET), member is radioactive iodine-refractory (if radioactive iodine is appropriate) to For Thyroid cancer: Member meets one of the following (a or b):</p> <ol style="list-style-type: none"> a. Disease has progressed on or following prior systemic treatment (e.g, chemotherapy); b. There are no satisfactory alternatives available; <p>8. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, RET Fusion-Positive Solid Tumors.</p> <p>9. Initial Approval Criteria, I.D.3: Updated prior therapy criteria from If the request is for first-line or subsequent therapy for RET fusion target for single agent;, useful in certain circumstances, for (i, ii, iii, iv, or v):</p> <ol style="list-style-type: none"> i. Multisystem Langerhans Cell Histiocytosis (LCH) with symptomatic or impending organ dysfunction; ii. Pulmonary LCH; iii. Multifocal single system bone disease not responsive to treatment with a bisphosphonate and >2 lesions (useful in certain circumstances); iv. CNS lesions; to Request is for first-line or subsequent therapy for RET fusion target for single agent; <p>10. Initial Approval Criteria, I.E.4: Updated to remove diagnostic criteria Request is for one of the following (a or b):</p> <ol style="list-style-type: none"> a. Erdheim-Chester Disease (ECD) with symptomatic disease; b. Relapsed/refractory disease; <p>11. Initial Approval Criteria, I.F.4: Updated the prior therapy criteria from If the request if for first-line or subsequent therapy for RET fusion target as a single agent; (a, b or c):</p> <ol style="list-style-type: none"> a. Symptomatic unresectable (bulky/site of disease) unifocal disease; b. Symptomatic multifocal disease; c. Relapsed/refractory disease; <p>to Request if for first-line or subsequent therapy for RET fusion target as a single agent</p>		
---	--	--

<p>12. Initial Approval Criteria, I.A, I.B, I.D, I.E, I.F: Updated Approval duration from 3 to 12 months for Commercial and Medicaid.</p> <p>13. Continued Therapy Approval Criteria II.A.1 was rephrased to Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy.</p> <p>14. Continued Therapy Approval Criteria, II.A: Updated Approval duration from 6 to 12 months for Commercial.</p> <p>15. References were reviewed and updated.</p>		
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>