Clinical Policy Title:	cobimetinib
Policy Number:	RxA.361
Drug(s) Applied:	Cotellic®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Metastatic or Unresectable Melanoma (must meet all)**:**

1. Diagnosis of metastatic or unresectable melanoma;
2. Disease is positive for the BRAF V600E or V600K mutation;
3. Prescribed in combination with Zelboraf®;

Approval duration

All Lines of Business (except Medicare): 12 months

B. Central Nervous System (CNS) Cancers (off -label) (must meet all):

1. Disease is positive for the BRAF V600E mutation;
2. Used as adjuvant treatment in combination with vemurafenib;
3. Member has incomplete resection, biopsy, or surgically inaccessible location;
4. Member meets one of the following: (a or b):
   a. Adjuvant treatment of one of the following conditions (i, ii, or iii):
      i. Pilocytic astrocytoma;
      ii. Pleomorphic xanthoastrocytoma;
      iii. Ganglioglioma;
   b. Recurrent disease for one of the following conditions (i, ii, iii, iv, or v):
      i. Low-grade glioma;
      ii. Anaplastic glioma;
      iii. Glioblastoma;
      iv. Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma;
      v. Oligodendroglioma

Approval duration

All Lines of Business (except Medicare): 12 months

C. Histiocytic Neoplasms (must meet all):

1. Diagnosis of one of the following histiocytic neoplasms (a, b or c):
   a. Langerhans Cell Histiocytosis
   b. Rosai-Dorfman Disease
   c. Erdheim-Chester Disease
2. Disease meets one of the following (a or b):
   a. As preferred first-line or subsequent therapy for mitogen-activated protein (MAP) kinase pathway

mutation;
b. As a single agent for non-detectable mutation or testing not available.

Approval duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All indications in section I (must meet all)**:**
1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration
All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Cutaneous Melanoma Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Central Nervous System Cancers Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed August 28, 2024.
3. National Comprehensive Cancer Network. Histiocytic Neoplasms Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf. Accessed August 28, 2024.
4. National Comprehensive Cancer Network. Cutaneous Melanoma Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed. 1. Policy title table was updated 2. Line of Business policy was updated to 'All lines of business'. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Initial therapy criteria I.A.6 clarified dosing is limited to the first 21 days of each 28-day cycle. 5. Continued therapy approval duration for Medicaid updated to 12 months. 6. Approval duration for commercial was updated from length of benefit to 12 months. 7. Reference reviewed and updated.	07/14/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.A was updated from "Melanoma" to "Metastatic or Unresectable Melanoma." 2. Initial Approval Criteria I.B was updated to include off-label indication, "Central Nervous System (CNS) Cancers (off -label)."	06/24/2021	09/14/2021

Review/Revision History	Review/Revised Date	P&T Approval Date
3. Initial Approval Criteria I.C was updated to include off-label indication, “Cutaneous Melanoma (off-label).” 4. Initial Approval Criteria I.D was updated to include off-label indication, “Histiocytic Neoplasms - Langerhans Cell Histiocytosis (off -label).” 5. Initial Approval Criteria I.E was updated to include off-label indication, “Histiocytic Neoplasms- Erdheim-Chester Disease (off -label).” 6. Initial Approval Criteria I.F was updated to include off-0lable indication, “Histiocytic Neoplasms - Rosai-Dorfman Disease (off -label).” 7. Continued Therapy Approval Criteria II.A was updated from “Melanoma” to “All Indications in Section I.” 8. Continued Therapy Approval Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…” 9. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.B.6: Updated diagnostic criteria from Patient has one of the following: (a, b or c): a. Pilocytic astrocytoma; b. Pleomorphic xanthoastrocytoma (PXA); c.Ganglioglioma; to Member has one of the following situations: (a or b):a. Adjuvant treatment of one of the following conditions (i, ii, or iii):i. Pilocytic astrocytoma; ii. Pleomorphic xanthoastrocytoma (PXA); iii. Ganglioglioma; b. Recurrent disease for one of the following conditions (i, ii, or iii): i. Low-grade glioma; ii. Anaplastic glioma; iii. Glioblastoma. 2. Initial Approval Criteria, I.C :Updated to be removed as it was covered under I.A. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.	03/22/2022	07/18/2022
Policy was reviewed:	11/21/2022	01/17/2023

Review/Revision History	Review/Revised Date	P&T Approval Date
1. Initial Approval Criteria, I.B.6.b.iv and I.B.6.b.v: Updated to include new diagnostic criteria: a. Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma; b. Oligodendroglioma. 2. Initial Approval Criteria, I.B and I.C: Updated approval duration length from 6 months to 12 months for Commercial. 3. Initial Approval criteria, I.C.2: Updated prescriber criteria from Prescribed by or in consultation with an oncologist to Prescribed by or in consultation with an oncologist or hematologist. 4. Initial Approval Criteria, I.D and I.E: Updated to merge the Histiocytic Neoplasms- Erdheim-Chester Disease and Rosai-Dorfman Disease criteria into one as Histiocytic Neoplasms (I.C). 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024