Clinical Policy Title:	durvalumab
Policy Number:	RxA.393
Drug(s) Applied:	Imfinzi®
Original Policy Date:	03/06/2020
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 one of the following (a or b):
   a. Unresectable stage II- III NSCLC; AND
      i Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy;
   b. Metastatic NSCLC and all of the following (i-iii):
      i Will be used in combination with tremelimumab-actl and platinum-based chemotherapy;
      ii Member must have tumors that lack activating EGFR mutations and ALK fusion;
      iii No prior chemotherapy or any other systemic therapy;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request is for one of the following (a, b or c):*
   a. Unresectable stage II- III NSCLC (i or ii):
      i For body weight < 30 kg, dose does not exceed 10 mg/kg every 2 weeks;
      ii For body weight ≥ 30 kg, dose does not exceed 10 mg/kg every 2 weeks or 1,500 mg every 4 weeks;
   b. Metastatic NSCLC (i or ii):
      i For body weight < 30 kg, dose does not exceed 20 mg/kg every 4 weeks;
      ii For body weight ≥ 30 kg, dose does not exceed 1,500 mg intravenously every 4 weeks;
   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: 6 months
Medicaid: 6 months

B. Extensive-Stage Small Cell Lung Cancer (must meet all):

1. Diagnosis of ES-SCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Durvolumab is being used as first line therapy and is prescribed in combination with etoposide and either carboplatin or cisplatin for 4 cycles followed by maintenance with durvolumab as monotherapy;

5. Request meets one of the following (a or b):*
   a. For body weight < 30 kg, dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy for 4 cycles, then 10 mg/kg every 2 weeks as a single agent;
   b. For body weight ≥ 30 kg, dose does not exceed 1,500 mg every 3 weeks in combination with chemotherapy for 4 cycles, then 1,500 mg every 4 weeks as a single agent;
   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: 6 months
Medicaid: 6 months

C. Biliary Tract Cancer (must meet all):

1. Diagnosis of locally advanced, unresectable, recurrent (> 6 months after surgery and/or completion of adjuvant therapy), or metastatic BTC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with gemcitabine and cisplatin;
5. Member has not received any prior systemic therapy for BTC;
6. Request meets one of the following (a, b, or c):*
   a. For body weight < 30 kg, dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy, then 20 mg/kg every 4 weeks as a single agent;
   b. For body weight ≥ 30 kg, dose does not exceed 1,500 mg every 3 weeks in combination with chemotherapy, then 1,500 mg every 4 weeks as a single agent;
   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: 6 months
Medicaid: 6 months

D. Hepatocellular Carcinoma (must meet all):

1. Diagnosis of unresectable, liver-confined, or metastatic hepatocellular carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with tremelimumab;
5. Request meets one of the following (a, b, or c):*
   a. For body weight < 30 kg, dose does not exceed 20 mg/kg on day 1 of cycle 1 in combination with tremelimumab followed by 20 mg/kg once every 4 weeks as a single agent;
   b. For body weight ≥ 30 kg, dose does not exceed 1,500 mg on day 1 of cycle 1 in combination with tremelimumab followed by 1,500 mg once every 4 weeks as a single agent;
   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: 6 months
Medicaid: 6 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 member has previously met initial approval criteria listed in this policy;
2. Member is currently receiving durvalumab for a covered indication and has received this medication for at least 30 days;
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a, b, c, d, e or f):*
   a. NSCLC (i or ii):
      i. For body weight < 30 kg, new dose does not exceed 10 mg/kg every 2 weeks;
      ii. For body weight ≥ 30 kg, new dose does not exceed 10 mg/kg every 2 weeks or 1,500 mg every 4 weeks;
   b. Metastatic NSCLC (i or ii):
      i. For body weight < 30 kg, dose does not exceed 20 mg/kg every 4 weeks;
      ii. For body weight ≥ 30 kg, dose does not exceed 1,500 mg intravenously every 4 weeks;
   c. ES-SCLC: (i or ii):
      i. For body weight < 30 kg, new dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy for 4 cycles, then 10 mg/kg every 2 weeks as a single agent;
      ii. For body weight ≥ 30 kg, new dose does not exceed 1,500 mg every 3 weeks in combination with chemotherapy for 4 cycles, and then 1,500 mg every 4 weeks as a single agent;
   d. BTC (i or ii):
      i. For body weight < 30 kg, new dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy, then 20 mg/kg every 4 weeks as a single agent;
      ii. For body weight ≥ 30 kg, new dose does not exceed 1,500 mg every 3 weeks in combination with chemotherapy, then 1,500 mg every 4 weeks as a single agent;
   e. uHCC (i or ii):
      i. For body weight < 30 kg, new dose does not exceed 20 mg/kg on day 1 of cycle 1 in combination with tremelimumab followed by 20 mg/kg once every 4 weeks as a single agent;
      ii. For body weight ≥ 30 kg, dose does not exceed 1,500 mg on day 1 of cycle 1 in combination with tremelimumab followed by 1,500 mg once every 4 weeks as a single agent;
   f. New 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. National Comprehensive Cancer Network. Bladder Cancer Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed November 18, 2022.
2. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 5.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed November 18, 2022.
3. National Comprehensive Cancer Network. Small Cell Lung Cancer Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed November 18, 2022.
4. National Comprehensive Cancer Network. Hepatobiliary Cancers Version 3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed November 18, 2022.
5. Antonia SJ, Villegas A, Daniel D, et al. Durvalumab after chemoradiotherapy in stage III non-small cell lung cancer. N Engl J Med 2017; 377: 1919-1929. Doi: 10.1056/NEJMoa1709937. Available at:

https://www.nejm.org/doi/full/10.1056/nejmoa1709937. Accessed November 18, 2022.
6. Hui R, Ozguroglu M, Villegas A, et al. Patient-reported outcomes with durvalumab after chemoradiotherapy in stage III, unresectable non-small cell lung cancer (PACIFIC): A randomised, controlled, phase 3 study. Lancet Oncol 2020; 20: 1670-180. Doi: 10.1016/S1470-2045(19)30519-4. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8412232/. Accessed November 18, 2022.
7. Gray JE, Villegas A, Daniel D, et al. Three-year overall survival with durvalumab after chemoradiotherapy in stage III NSCLC-Update from PACIFIC. J Thorac Oncol 2020; 15: 288-293. Doi: 10.1016/j.jtho.2019.10.002. Available at: https://pubmed.ncbi.nlm.nih.gov/31622733/. Accessed November 18, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy updated. 1. Formatting updated. 2. Policy Title updated. 3. New indication and criteria added. 4. Continued criteria for approval updated. 5. Approval duration updated. 6. Reference updated.	07/23/2020	09/14/2020
Policy was reviewed: 1. Clinical Policy title was updated. 2. Initial Approval criteria was updated. 3. Continued Therapy approval criteria was updated. 4. Continued Therapy criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance”…" 5. References were reviewed and updated.	03/31/2021	06/10/2021
Policy was reviewed: 1. Continued Therapy Criteria approval durations for Commercial and Medicaid were updated from “up to but not exceed 12 months” to “12 months”. 2. References were reviewed and updated.	06/01/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	03/23/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of unresectable stage II- III NSCLC to Diagnosis of one of the following (a or b): a. Unresectable stage II- III NSCLC; AND i. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; b. Metastatic NSCLC and all of the following (i-iii): i. Will be used in combination with tremelimumab-actl and platinum-based chemotherapy;	11/18/2022	1/17/2023

ii. Member must have tumors that lack activating EGFR mutations and ALK fusion; iii. No prior chemotherapy or any other systemic therapy. 2. Initial Approval Criteria, I.A.4.b: Updated to include new dosing criteria Metastatic NSCLC: a. For body weight < 30 kg, dose does not exceed 20 mg/kg every 4 weeks; b. For body weight ≥ 30 kg, dose does not exceed 1,500 mg intravenously every 4 weeks. 3. Initial Approval Criteria, I.C and I.D: Updated to include approval criteria for indication: a. Biliary Tract Cancer; b. Hepatocellular Carcinoma. 4. Continued Therapy Approval, II.A.4.b: Update to include new maximum dose criteria for Metastatic NSCLC a. For body weight < 30 kg, dose does not exceed 20 mg/kg every 4 weeks; b. For body weight ≥ 30 kg, dose does not exceed 1,500 mg intravenously every 4 weeks. 5. Continued Therapy Approval, II.A.4.d: Updated to include new maximum dose criteria for BTC a. For body weight < 30 kg, new dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy, then 20 mg/kg every 4 weeks as a single agent; b. For body weight ≥ 30 kg, new dose does not exceed 1,500 mg every 3 weeks in combination with chemotherapy, then 1,500 mg every 4 weeks as a single agent. 6. Continued Therapy Approval, II.A.4.e: Updated to include new maximum dose criteria for uHCC a. For body weight < 30 kg, new dose does not exceed 20 mg/kg on day 1 of cycle 1 in combination with tremelimumab followed by 20 mg/kg once every 4 weeks as a single agent; b. For body weight ≥ 30 kg, dose does not exceed 1,500 mg on day 1 of cycle 1 in combination with tremelimumab followed by 1,500 mg once every 4 weeks as a single agent. 7. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023