GUIDE TO SCORING
PD-L1 EXPRESSION
USING COMBINED
POSITIVE SCORE
(CPS)

PD-L1 = programmed death ligand 1.
Severe and Fatal Immune-Mediated Adverse Reactions

SELECTED SAFETY INFORMATION

Cancer

Indication

PD-L1 Expression

KEYTRUDA, as a single agent, is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC) whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved assay. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

CPS ≥1

KEYTRUDA, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

No testing required

KEYTRUDA, as a single agent, is indicated for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

No testing required

KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC) who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (CPS ≥1), as determined by an FDA-approved test. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

CPS ≥1

KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC) who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (CPS ≥1), as determined by an FDA-approved test. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

CPS ≥1

KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC) who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (CPS ≥1), as determined by an FDA-approved test. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

CPS ≥1

KEYTRUDA is indicated for the treatment of patients with recurrent locally advanced or metastatic gastric or GEJ cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test, with disease progression after or more prior lines of therapy, including fluoropyrimidine- and platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

CPS ≥10

KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy.

CPS ≥1

KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

No testing required

KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

No testing required

KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

CPS ≥1

KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma of the esophagus whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy.

No testing required

KEYTRUDA is indicated for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

No testing required

KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

No testing required

KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

No testing required

KEYTRUDA can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis.

SELECTED SAFETY INFORMATION (continued)

Severe and Fatal Immune-Mediated Adverse Reactions

- Immune-Mediated Pneumonitis:
  - KEYTRUDA can cause immune-mediated pneumonitis. The incidence is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.4% (94/2789) of patients receiving KEYTRUDA, including fatal (0.1%), Grade-4 (0.3%), Grade 3 (0.5%), and Grade 2 (1.2%) reactions. Systemic corticosteroids were required in 67% (94/140) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.3% (36) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 25% had recurrence. Pneumonitis resolved in 58% of the 94 patients.

- Immune-Mediated Colitis:
  - KEYTRUDA can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis.

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**PD-L1 expression status helps inform treatment decisions with KEYTRUDA**

**Examples of HNSCC tumor specimens using PD-L1 IHC 22C3 pharmDx**

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**Examples of urothelial tumor specimens using PD-L1 IHC 22C3 pharmDx**

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**SELECTED SAFETY INFORMATION (continued)**

**Severe and Fatal Immune-Mediated Adverse Reactions (continued)**

KEYTRUDA may cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2799) of patients receiving KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients; additional immunosuppressant therapy was required in 11% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% and withholding in 0.3% of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients.

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**Severe and Fatal Immune-Mediated Adverse Reactions (continued)**

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KEYTRUDA may cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2799) of patients receiving KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients; additional immunosuppressant therapy was required in 11% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% and withholding in 0.3% of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients.

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**Severe and Fatal Immune-Mediated Adverse Reactions (continued)**

KEYTRUDA may cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2799) of patients receiving KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients; additional immunosuppressant therapy was required in 11% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% and withholding in 0.3% of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients.

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**SELECTED SAFETY INFORMATION (continued)**

**Severe and Fatal Immune-Mediated Adverse Reactions (continued)**

KEYTRUDA may cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2799) of patients receiving KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients; additional immunosuppressant therapy was required in 11% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% and withholding in 0.3% of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients.
IDENTIFY PATIENTS WITH PD-L1 EXPRESSION USING CPS

PD-L1 expression status helps inform treatment decisions with KEYTRUDA

Examples of gastric tumor specimens using PD-L1 IHC 22C3 pharmDx

PD-L1 IHC 22C3 pharmDx: A qualitative immunohistochemical assay used in clinical trials with KEYTRUDA

Examples of ESCC tumor specimens using PD-L1 IHC 22C3 pharmDx

SELECTED SAFETY INFORMATION (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Adrenal Insufficiency

Adrenal insufficiency occurred in 0.8% (22/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 77% (17/22) of patients; of these, the majority remained on systemic corticosteroids. Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.3% (8) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

Before prescribing KEYTRUDA, please read the accompanying Prescribing Information. The Medication Guide also is available.

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CPS – PD-L1 staining on both tumor cells and certain tumor-associated immune cells are evaluated when determining the CPS numerator\(^1\)

- **Tumor cells** with convincing partial or complete linear membrane staining (at any intensity) that is distinct from cytoplasmic staining.
- **Lymphocytes and macrophages (MICs)** within the tumor nests and/or adjacent supporting stroma with convincing membrane and/or cytoplasmic staining (at any intensity). MICs must be directly associated with the response against the tumor.

Tumor cells and immune cells demonstrating convincing partial or complete linear membrane staining at any intensity (including weak [1+] should be included in the CPS numerator (gastric specimen). Note that MICs can have membrane and/or cytoplasmic staining. © Agilent Technologies, Inc. 2018 Reproduced with Permission, Courtesy of Agilent Technologies, Inc.

When positioning the tumor cells in the approximate center of a 20× field, PD-L1–staining MICs that are present within the same field should be included in the numerator (20x magnification, urothelial specimen).© Agilent Technologies, Inc. 2018 Reproduced with Permission, Courtesy of Agilent Technologies, Inc.

**Hypophysitis**

- **KEYTRUDA** can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA depending on severity. Hypophysitis occurred in 0.6% (17/2799) of patients receiving KEYTRUDA, including Grade 3 (0.3%) and Grade 2 (0.2%) reactions.

**CPS calculation**

Evaluate the number of PD-L1–staining cells (tumor cells, lymphocytes, and macrophages) relative to all viable tumor cells.

\[
\text{CPS} = \frac{\# \text{ of PD-L1-positive cells}}{\# \text{ of viable tumor cells}} \times 100
\]

CPS is reported as a whole number. Although the result of the calculation can exceed 100, the maximum score is defined as CPS 100.

**SELECTED SAFETY INFORMATION (continued)**

**Systemic corticosteroids** were required in 94% (16/17) of patients; of these, the majority remained on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% and withholding in 0.3% of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

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PD-L1 expression in clinical trials with KEYTRUDA^®

**Mi/uR HNSCC**

| CPS in the KEYNOTE-048 study | ≥10 in 784/982 (79.4%) of treatment-naive patients with Mi/uR HNSCC | 85% |

**Cisplatin-eligible patients with locally advanced or mUC**

| CPS 2+ in the KEYNOTE-052 study | ≥10 in 150/370 (40.5%) of patients with locally advanced or mUC who were not eligible for cisplatin-containing chemotherapy had tumors that expressed CPS ≥10. |

| CPS 2+ in the KEYNOTE-053 study | ≥10 in 143/205 (70.0%) of patients with advanced gastric or GEJ cancer who had PD-L1 expression. |

Advanced gastric or GEJ cancer

| CPS 2+ in the KEYNOTE-181 study | ≥10 in 77/98 (78.5%) of patients with advanced cervical cancer had PD-L1 expression and received at least 1 prior line of chemotherapy in the metastatic setting. |

PD-L1 expression was determined using the PD-L1 IHC 22C3 pharmDx kit.

**SELECTED SAFETY INFORMATION (continued)**

**Thyroid Disorders**

KEYTRUDA can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Immune-mediated thyroid disorders can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or initiate medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA depending on severity. Thyroiditis occurred in 0.4% (10/2799) of patients receiving KEYTRUDA, including Grade 4 (0.2%) patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Patients that expressed CPS ≥10.

Advanced cervical cancer

| CPS 2+ in Cohort E of the KEYNOTE-158 study | (n=7708) of patients with advanced cervical cancer had PD-L1 expression and received at least 1 prior line of chemotherapy in the metastatic setting. |

Additional exclusions included patients with anti–PD-L1/PD-1 treatment or those with anti–PD-1/PD-L1 treatments, other immunosuppressive medications, prior radiotherapy, use of anti–PD-1/PD-L1 treatment within 4 weeks of enrollment, or a history of severe or systemic autoimmune diseases. The majority of patients with advanced cervical cancer had PD-L1 expression.

Cohort E of the KEYNOTE-158 study

| CPS 2+ in Cohort E of the KEYNOTE-158 study | (n=7708) of patients with advanced cervical cancer had PD-L1 expression and received at least 1 prior line of chemotherapy in the metastatic setting. |

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Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Adverse Reactions (continued)

In KEYNOTE-046, KEYTRUDA monotherapy was discontinued due to adverse events in 12% of 360 patients with NSCLC; the most common adverse reactions leading to permanent discontinuation were rash (7.1%) and pneumonitis (1.3%). The most common adverse reactions (≥2%) were fatigue (33%), constipation (23%), and diarrhea (20%).

In KEYNOTE-048, when KEYTRUDA was administered in combination with platinum (carboplatin or cisplatin) and FU chemotherapy, KEYTRUDA was discontinued due to adverse reactions in 16% of 278 patients with NSCLC. The most common adverse reactions resulting in permanent discontinuation of KEYTRUDA were pneumonia (3.5%), pneumonitis (1.4%), and septic shock (1.4%). The most common adverse reactions (≥2%) were nausea (15%), fatigue (14%), constipation (12%), vomiting (12%), mucosal inflammation (11%), diarrhea (22%), decreased appetite (20%), stomatitis (24%), and cough (22%).
Prepare a report that includes CPS as a number between 0 and 100 to help inform treatment decisions with KEYTRUDA.¹

Before prescribing KEYTRUDA, please read the accompanying Prescribing Information. The Medication Guide is also available.

References:

¹Biomarker status can be a road map for personalizing treatment.