

May 3, 2019

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## NCCN Chemotherapy Order Template

Dear NCCN Template® Committee,

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed OPDIVO® (nivolumab) prescribing information that reflects the new recommended dosage for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) and recommended dosages tables<sup>1</sup>. This information is being sent to the NCCN Template® Committee for your consideration.

### **Specific Changes:**

#### Chemotherapy Order Template: Colon Cancer (MSI-H/dMMR)

- Regimen Name: Nivolumab (Template ID COL 64)
  - Request for the inclusion of the following: nivolumab 480mg intravenously (IV) every 4 weeks administered over 30 minutes until disease progression or unacceptable toxicity<sup>1</sup>
- Regimen Name: Nivolumab + Ipilimumab followed by Nivolumab (Template ID COL 68)
  - Request for the inclusion of the following: nivolumab 3mg/kg IV administered over 30 minutes, followed by ipilimumab 1mg/kg IV administered over 30 minutes on the same day, every 3 weeks for 4 doses followed by nivolumab 480mg IV every 4 weeks administered over 30 minutes until disease progression or unacceptable toxicity<sup>1</sup>

#### Chemotherapy Order Template: Rectal Cancer (MSI-H/dMMR)

- Regimen Name: Nivolumab (Template ID REC75)
  - Request for the inclusion of the following: nivolumab 480mg IV every 4 weeks administered over 30 minutes until disease progression or unacceptable toxicity<sup>1</sup>
- Regimen Name: Nivolumab + Ipilimumab followed by Nivolumab (Template ID REC 80)
  - Request for the inclusion of the following: nivolumab 3mg/kg IV administered over 30 minutes, followed by ipilimumab 1mg/kg IV administered over 30 minutes on the same day, every 3 weeks for 4 doses followed by nivolumab 480mg IV every 4 weeks administered over 30 minutes until disease progression or unacceptable toxicity<sup>1</sup>

Additionally, I respectfully request you to consider the inclusion of the following diseases and regimens to the library of chemotherapy order templates:

- Head and Neck Cancers
  - Regimen Name: Nivolumab
    - Nivolumab 240mg IV every 2 weeks or 480mg IV every 4 weeks administered over 30 minutes until disease progression or unacceptable toxicity<sup>1</sup>
- Hodgkin Lymphoma
  - Regimen Name: Nivolumab
    - Nivolumab 240mg IV every 2 weeks or 480mg IV every 4 weeks administered over 30 minutes until disease progression or unacceptable toxicity<sup>1</sup>

**FDA Clearance of OPDIVO® (nivolumab) for the treatment of patients with (indication in metastatic colorectal cancer, squamous cell carcinoma of the head and neck, and Hodgkin lymphoma):**

**Metastatic Colorectal Cancer**

- Adult and pediatric (12 years and older) patients with MSI-H or dMMR metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, as a single agent or in combination with ipilimumab.

**Squamous Cell Carcinoma of the Head and Neck:**

- Patients with recurrent or metastatic SCCHN with disease progression on or after platinum-based therapy

**Hodgkin Lymphoma**

- Adult patients with classical Hodgkin lymphoma that has relapsed or progressed after
  - autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or
  - 3 or more lines of systemic therapy that includes autologous HSCT

**Rationale:** This data is being submitted in response to a standing request from NCCN for new clinical data. The OPDIVO® prescribing information was updated to reflect the new recommended dosage for MSI-H/dMMR CRC and recommended dosages tables.

The following resource is included for your review:

1. Product Information, OPDIVO® (nivolumab) injection for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. May 2019

Thank you for your consideration of this request.

Sincerely,



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