



Submitted by:  
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Date of Request: September 1, 2020

Dear NCCN Acute Myeloid Leukemia Guidelines Panel:

On behalf of Bristol-Myers Squibb Company, we respectfully request that the NCCN Guidelines Panel for Acute Myeloid Leukemia (AML) review the enclosed Prescribing Information for ONUREG® (azacitidine) tablets.

**Specific Changes:**

We respectfully request the panel's consideration of the enclosed data and inclusion of ONUREG within the AML guidelines for post-remission therapy with a Category 1 recommendation.

**FDA Clearance:**

On September 1, 2020 the US Food and Drug Administration (FDA) granted approval of ONUREG for the treatment of patients with AML. The indication is as follows:

ONUREG is a nucleoside metabolic inhibitor indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.<sup>1</sup>

Please see the enclosed full Prescribing Information.

**Rationale:**

This information is being submitted in response to a standing request from NCCN for new data.

A previous submission to NCCN regarding clinical data from the QUAZAR® AML-001 study on the use of CC-486 for maintenance therapy in patients with newly-diagnosed AML in first complete remission (CR) or CR with incomplete blood count recovery (CRi) following induction with intensive chemotherapy, with or without consolidation, which was published in *Blood*, was submitted on July 7, 2020.

As part of this submission, the following resources are included for your review:

1. Product information, ONUREG® (azacitidine) tablets, for oral use. Bristol Myers Squibb Company, Summit, NJ. September 2020.

Your consideration of this submission is greatly appreciated.

Sincerely,

A handwritten signature in black ink, appearing to read 'Albert Kodersha', with a long horizontal flourish extending to the right.

Albert Kodersha, PharmD  
Associate Director, US Medical

A handwritten signature in black ink, appearing to read 'Michael S. Ondovik', with a long horizontal flourish extending to the right.

Michael S. Ondovik, PharmD, MBA  
Senior Director, US Medical Affairs, Hematology