

Empliciti® (elotuzumab) – New indication

- On November 6, 2018, [Bristol-Myers Squibb](#) announced the FDA approval of [Empliciti \(elotuzumab\)](#), in combination with [Pomalyst® \(pomalidomide\)](#) and [dexamethasone](#) for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including [Revlimid® \(lenalidomide\)](#) and a proteasome inhibitor.
 - Empliciti is also approved in combination with Revlimid and dexamethasone for the treatment of adult patients with multiple myeloma who have received one to three prior therapies.
- Multiple myeloma is a blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow. The [National Cancer Institute](#) estimates there will be 30,770 new cases of multiple myeloma and 12,770 related deaths in the U.S. this year.
- The approval of Empliciti's new indication was based on a randomized, open-label study in 117 patients with relapsed or refractory multiple myeloma. Patients were randomized to receive either Empliciti in combination with Pomalyst and low-dose dexamethasone or Pomalyst and low-dose dexamethasone. The efficacy of Empliciti was evaluated by progression-free survival (PFS) and overall response rate (ORR).
 - Median PFS was 10.25 months (95% CI: 5.59, not-estimable) and 4.67 (95% CI: 2.83, 7.16) for patients in the Empliciti and comparator arms, respectively (HR 0.54, 95% CI: 0.34, 0.86; p = 0.0078).
 - ORR was 53.3% (95% CI: 40.0, 66.3) and 26.3% (95% CI: 15.5, 39.7) for patients in the Empliciti and comparator arms, respectively (p = 0.0029).
- The most common adverse reactions (≥ 20%) with Empliciti in combination with Pomalyst and dexamethasone use were constipation and hyperglycemia.
- The recommended dose for Empliciti when used in combination with Pomalyst and dexamethasone is 10 mg/kg administered intravenously every week for the first two cycles and 20 mg/kg every 4 weeks thereafter until disease progression or unacceptable toxicity.
 - To reduce the risk of infusion reactions, patients should be premedicated with dexamethasone, [diphenhydramine](#), [ranitidine](#), and [acetaminophen](#).
 - Refer to the Pomalyst and dexamethasone drug labels for additional dosing information.
- Refer to the Empliciti drug label for dosing recommendations when Empliciti is used in combination with Revlimid and dexamethasone.