FDA Approved Indications and Contraindications

VELCADE® (bortezomib) is indicated for the treatment of patients with multiple myeloma. VELCADE for injection is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.

VELCADE is contraindicated in patients with hypersensitivity to bortezomib, boron, or mannitol. VELCADE is contraindicated for intrathecal administration.

Please contact the VELCADE Reimbursement Assistance Program (RAP) at 1-866-VELCADE (835-2233), OPTION 2 for specific payer coverage information relating to VELCADE.

MEDICARE Coding and Billing

In both the physician office and hospital outpatient setting, multiple units of the J-code for VELCADE may need to be billed depending on the specifics of each situation. For example, if 3.5 mg of VELCADE are administered, 35 billing units of J9041 (bortezomib) for Injection may be billed.

Please see accompanying full Prescribing Information, also available at www.VELCADEHCP.com.
INDICATIONS: VELCADE® (bortezomib) is indicated for the treatment of patients with multiple myeloma. VELCADE is indicated for the treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy.

CONTRAINDICATIONS: VELCADE is contraindicated in patients with hypersensitivity to bortezomib, boron, or mannitol. VELCADE is contraindicated for intramuscular administration.

WARNINGS AND PRECAUTIONS: VELCADE is for subcutaneous or intravenous (IV) administration only. Because each route of administration has a different reconstituted concentration, caution should be used when calculating the volume to be administered. Complete blood counts should be monitored frequently during treatment with VELCADE.

• Peripheral Neuropathy, including severe cases, may occur. Patients should be monitored for symptoms and managed with dose modification or discontinuation. Patients with pre-existing symptoms may experience worsening peripheral neuropathy (including grade 3). Starting with VELCADE subcutaneously may be considered for patients who either have pre-existing symptoms or are at high risk for peripheral neuropathy.

• Hypotension can occur. Caution should be used when treating patients receiving antihypertensives, those with a history of syncope, and those who are dehydrated.

• Cardiac Disorders, including acute myocardial infarction or exacerbation of congestive heart failure and new onset of decreased left ventricular ejection fraction, have been reported. Isolated cases of QT-interval prolongation have been reported. Patients with risk factors for cardiac disease should be monitored during treatment with VELCADE.

• Pulmonary Disorders, some fatal—including pneumonitis, interstitial pneumonia, lung infiltration, and acute respiratory distress syndrome (ARDS)—have been reported. Pulmonary hypertension in the absence of left heart failure or significant pulmonary disease has also been reported.

• Gastrointestinal Adverse Events, including nausea, diarrhea, constipation, and vomiting, have occurred and may require use of anticholinergic and antidiarrheal medications or fluid replacement.

• Thrombocytopenia/Neutropenia can occur—manage with dose and/or schedule modifications. Platelets should be monitored prior to each dose of VELCADE. There have been reports of gastrointestinal and intracranial hemorrhage. Transfusions may be considered.

• Patients with Hepatic Impairment: Exposures to VELCADE is increased in patients with moderate or severe hepatic impairment. Start these patients at a lower dose of VELCADE and adjust after cycle 1, depending on tolerability.

• Patients with Diabetes: Hypoglycemia and hyperglycemia have been reported with use of VELCADE. Patients may require close monitoring and adjustment of the diabetic medications.

• Tumor Lysis Syndrome, Reversible Posterior Leukoencephalopathy Syndrome (RPLS), and Acute Hepatic Failure have been reported.

• Pregnancy and Nursing: Women should avoid breastfeeding or becoming pregnant while on VELCADE.

DRUG INTERACTIONS: Close monitoring patients receiving VELCADE in combination with strong CYP3A4 inhibitors. Concomitant use of strong CYP3A4 inducers is not recommended.

ADVERSE REACTIONS

• Previously untreated Multiple Myeloma (MM): In the phase 3 study of VELCADE administered IV with melphalan and prednisone (MP) vs MP alone, the most commonly reported adverse events were thrombocytopenia (52% vs 47%), neutropenia (74% vs 69%), nausea (71% vs 59%), peripheral neuropathy (41% vs 5%), diarrhea (46% vs 17%), anemia (43% vs 55%), constipation (37% vs 16%), neutropenia (36% vs 31%), leukopenia (33% vs 30%), and vomiting (33% vs 16%).

• Relapsed MM and Mantle Cell Lymphoma (MCL): In the integrated results of 1163 patients in phase 2 and 3 studies of VELCADE administered IV, the most commonly reported adverse events were anemia (including fatigue, malaise, and dyspnea) (47%), nausea (41%), diarrhea (40%), vomiting (40%), and peripheral neuropathy (25%). A total of 50% of patients experienced at least one grade 3-4 adverse event (AE). The most commonly reported AEs included peripheral neuropathy (30%), anemia (24%), infection (23%), and pyrexia (12%).

• Relapsed MM Subcutaneous vs IV: In the phase 3 study of VELCADE administered subcutaneously vs IV in relapsed MM, safety data were similar between the 2 treatment groups. The most commonly reported adverse events in this study were nausea (38% vs 35%), peripheral neuropathy (44% vs 51%), diarrhea (40% vs 27%), anemia (37% vs 37%), constipation (38% vs 36%), and peripheral neuropathy (including peripheral sensory neuropathy and peripheral neuropathy aggravated) (39%). trombocytopenia and appetite decreased (including anorexia) each 36%), pyrexia (34%), and vomiting (33%). A total of 50% of patients experienced serious adverse events (SAEs). The most commonly reported SAEs included pneumonia (7%); pyrexia (6%); diarrhea (5%); viremia (4%); deep vein thrombosis (4%); and acute respiratory distress syndrome (ARDS) (3%).

• Relapsed MM Subcutaneous vs IV: In the phase 3 study of VELCADE administered subcutaneously vs IV in relapsed MM, safety data were similar between the 2 treatment groups. The most commonly reported adverse events in this study were nausea (38% vs 35%), peripheral neuropathy (44% vs 51%), diarrhea (40% vs 27%), anemia (37% vs 37%), constipation (38% vs 36%), and peripheral neuropathy (including peripheral sensory neuropathy and peripheral neuropathy aggravated) (39%). thrombocytopenia and appetite decreased (including anorexia) each 36%), pyrexia (34%), and vomiting (33%). A total of 50% of patients experienced serious adverse events (SAEs). The most commonly reported SAEs included pneumonia (7%); pyrexia (6%); diarrhea (5%); viremia (4%); deep vein thrombosis (4%); and acute respiratory distress syndrome (ARDS) (3%).

Please see following full Prescribing Information, also available at www.VELCADEHCP.com.
Please see full Prescribing Information at

velcade.com/Files/PDFs/VELCADE_PREScribing_INFORMATION.pdf