RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Velcade targets proteasomes inside cells and blocks or slows down the action of these cells. Proteasomes break down proteins in both healthy and cancerous cells. Once this activity is blocked or slowed down then the proteins build up causing an imbalance within the cell. Cancer cells divide and multiply faster than most other cells. Velcade slows this process and causes cancer cell death (1).

Regulatory Status
FDA-approved indications: Velcade is a proteasome inhibitor indicated for the treatment of patients with multiple myeloma and patients with mantle cell lymphoma (1).

Velcade is contraindicated for intrathecal administration. Fatal events have occurred with intrathecal administration of Velcade (1).

Patients should be monitored for cardiac toxicity, pulmonary toxicity, thrombocytopenia or neutropenia, tumor lysis syndrome, and hepatic toxicity. Caution should be used when prescribing for patients with peripheral neuropathy, hypotension, and gastrointestinal toxicity. Patients with posterior reversible encephalopathy syndrome should consider MRI imaging for onset of visual or neurological symptoms. Women should avoid getting pregnant while on this medication (1).

The safety and effectiveness of Velcade in pediatric patients have not been established (1).

Summary
Velcade is indicated for the treatment of patients with multiple myeloma and patients with mantle cell lymphoma. Velcade targets proteasomes inside cells and blocks or slows down the action of these cells. Once this activity is blocked or slowed down then the proteins build up causing an imbalance within the cell. This disruption of normal homeostatic mechanisms can lead to cell death. The safety and effectiveness of Velcade in patient under the age of 18 have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of
Velcade while maintaining optimal therapeutic outcomes.

References