Commercial/Healthcare Exchange PA Criteria

Effective: November 2, 2016

Prior Authorization: Pomalyst

Products Affected: Pomalyst (pomalidomide) oral capsules

Medication Description:

Pomalyst is a thalidomide analogue indicated, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (Velcade [bortezomib], Kyprolis [carfilzomib]) and have demonstrated disease progression on or within 60 days of completion of the last therapy.

Pomalyst, an analogue of thalidomide, is an immunomodulatory agent with antineoplastic activity. In in vitro cellular assays, Pomalyst inhibited proliferation and induced apoptosis of hematopoietic tumor cells. Additionally, Pomalyst inhibited the proliferation of lenalidomide-resistant multiple myeloma cell lines and synergized with dexamethasone in both lenalidomide-sensitive and lenalidomide-resistant cell lines to induce tumor cell apoptosis. Pomalyst enhanced T cell- and natural killer (NK) cell-mediated immunity and inhibited production of pro-inflammatory cytokines (e.g., TNF-α and IL-6) by monocytes. Pomalyst demonstrated anti-angiogenic activity in a mouse tumor model and in the in vitro umbilical cord model.

Pomalyst is part of a Restricted Evaluation and Mitigation Strategy (REMS) program to prevent the risk of embryo-fetal exposure.

Covered Uses:

1. Multiple Myeloma
2. Kaposi Sarcoma

Exclusion Criteria:

1. Pregnancy

Required Medical Information:

1. Diagnosis
2. Pregnancy status
3. Previous therapies tried and failed

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an Oncologist

Coverage Duration: 3 years

Other Criteria:

Multiple Myeloma

A. Patient has a diagnosis of multiple myeloma; AND
B. Patient has tried two previous therapies including Revlimid and a proteasome inhibitor (Velcade or Kyprolis); AND
C. Patient is using in combination with dexamethasone; AND
D. Patient has demonstrated disease progression on or within 60 days of completion of the last therapy.

Kaposi sarcoma

A. Patient has a diagnosis with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART); OR
B. Patient has a diagnosis of Kaposi Sarcoma and is HIV negative

References:

1.Pomalyst [prescribing information]. New York, NY: Celgene Corporation August 2016.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 3.2016). © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 9, 2016

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	Updated to new template – updated indications to match FDA label Removed Pomalyst from CCI oncology policy	All	5/20/2020