Pomalyst (pomalidomide)

Background
Pomalyst is an immunomodulatory agent used to treat patients with multiple myeloma who have not improved after being treated with other cancer drugs. Multiple myeloma is a form of blood cancer that primarily affects older adults and arises from plasma cells in the bone marrow. Pomalyst modulates the body's immune system to destroy cancerous cells and inhibit their growth. It is intended for patients who have received at least two prior therapies for multiple myeloma and whose disease has not responded to treatment and has worsened within 60 days of the last treatment (1).

Regulatory Status
FDA-approved indication: Pomalyst is a thalidomide analogue indicated, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy (2).

Pomalyst is a thalidomide analogue and carries a boxed warning regarding the risk of embryo-fetal toxicity. Pomalyst is classified as pregnancy category X and is contraindicated in pregnancy. Females of reproductive potential must avoid pregnancy while taking Pomalyst and for at least 4 weeks after completing therapy. Two negative pregnancy tests must be obtained prior to initiating therapy. Pomalyst is present in the semen of male patients receiving the drug. Males must be advised of using condoms during any sexual contact with females of
reproductive potential, even if they have undergone a successful vasectomy. Male patients taking Pomalyst must not donate sperm (2).

Pomalyst has an additional boxed warning regarding the risk of venous thromboembolism. Deep venous thrombosis (DVT) and pulmonary embolism (PE) may occur in patients treated with Pomalyst (2).

Patients must not donate blood during treatment with Pomalyst and for 1 month following discontinuation of the drug because the blood might be given to a pregnant female patient whose fetus must not be exposed to Pomalyst (2).

Safety and effectiveness of Pomalyst in patients below the age of 18 have not been established (2).

Because of Pomalyst’s embryo-fetal risk, it is available only through the Pomalyst Risk Evaluation and Mitigation Strategy (REMS) Program. Prescribers must be certified with the Pomalyst REMS Program. Patients must sign a Patient-Physician agreement form and comply with the REMS requirements (2).

Related policies
Revlimid

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Pomalyst may be considered medically necessary in patients that are 18 years of age and older with multiple myeloma and if the conditions indicated below are met.

Pomalyst is considered investigational in patients that are under 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age or older

Diagnosis

Patient must have the following:
Multiple myeloma

AND ALL of the following:
1. The patient has received at least TWO prior therapies for multiple myeloma including:
   a. Lenalidomide (Revlimid)
   b. Proteasome inhibitor
2. Used in combination with dexamethasone
3. Patient has demonstrated disease progression on or within 60 days of completion of the last therapy for multiple myeloma
4. Blood counts for neutropenia, thrombocytopenia, and anemia will be monitored weekly for the first 8 weeks and monthly thereafter
5. If female of childbearing potential: pregnancy has been excluded prior to initiation of therapy and physician agrees to monitor throughout therapy
6. Physician, patient, and pharmacy are registered with the REMS program

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Multiple myeloma

AND ALL of the following:
1. Blood counts for neutropenia, thrombocytopenia, and anemia will be monitored monthly
2. If female of childbearing potential: pregnancy has been excluded and physician agrees to monitor throughout therapy

Policy Guidelines

Pre - PA Allowance
None
Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Duration 12 months

Rationale

Summary
Pomalyst is a thalidomide analogue indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Pomalyst is classified as pregnancy category X and is contraindicated in pregnancy. Pomalyst is available only through the Pomalyst Risk Evaluation and Mitigation Strategy (REMS) Program (2).

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

References

Policy History

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<td>April 2013</td>
<td>Addition to PA</td>
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<tr>
<td>September 2014</td>
<td>Annual review and reference update</td>
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<td>June 2015</td>
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<td>September 2016</td>
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Section: Prescription Drugs
Subsection: Antineoplastic Agents
Subject: Pomalyst

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June 2018 Annual editorial review and reference update
June 2019 Annual review and reference update

Keywords

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