09-J1000-95

Original Effective Date: 06/15/13

Reviewed: 06/12/19

Revised: 01/15/20

Subject: Pomalidomide (Pomalyst®) Capsule

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Pomalidomide (Pomalyst), a thalidomide analogue, was approved by the US Food and Drug Administration (FDA) in February 2013 for treatment of multiple myeloma (MM) in persons who have received at least two prior therapies, including lenalidomide (Revlimid) and bortezomib (Velcade), and have demonstrated disease progression on or within 60 days of completion of last therapy. Pomalyst was previously granted orphan designation by the FDA for the treatment of MM in 2003. Pomalyst, as sponsor by the innovator drug company, also has an orphan designation for the treatment of Kaposi sarcoma granted by the FDA in April 2018. The FDA-approved indication was expanded in April 2015 to allow one of the prior therapies to be any proteasome inhibitor [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), or ixazomib (Ninlaro)]. Although the mechanism by which pomalidomide exerts its cytotoxic activity has not been fully elucidated, it is thought to inhibit the proliferation of hematopoietic tumor cells and induce apoptosis. In clinical trials, pomalidomide inhibited proliferation of MM cell lines that were resistant to lenalidomide.

Multiple myeloma is a malignant neoplasm of plasma cells that accumulate in bone marrow, leading to bone destruction and marrow failure. Although MM is typically sensitive to a variety of cytotoxic drugs, both as initial treatment or as treatment of relapsed disease, the durability of the response is transient and a cure for MM remains elusive. Persons diagnosed with MM are classified as either having smoldering (asymptomatic) disease or active (symptomatic) disease. Those classified with active MM are initially treated with primary therapy and in select cases primary therapy is followed by high-dose chemotherapy with stem cell transplant (SCT). Therapy for previously treated MM will eventually be required for persons with relapsed disease after allogeneic or autologous SCT, primary progressive disease after initial allogeneic or autologous SCT, or persons who are non-transplant candidates who have progressive or relapsing disease after primary therapy.

As therapy for previously treated MM, the National Comprehensive Cancer Network (NCCN) Guidelines for MM (Version 2.2019) list the following seven pomalidomide-containing regimens under "Other Recommended Regimens": pomalidomide + dexamethasone (category 1 recommendation), pomalidomide + bortezomib + dexamethasone (category 2A), pomalidomide + carfilzomib + dexamethasone (category 2A), pomalidomide + cyclophosphamide + dexamethasone (category 2A), ixazomib + pomalidomide + dexamethasone (category 2A), elotuzumab (Empliciti) + pomalidomide + dexamethasone (category 2A), and daratumumab (Darzalex) + pomalidomide + dexamethasone (category 2A). There is a footnote stating single-agent pomalidomide can be considered for steroid-intolerant individuals. All of the listed regimens, except the daratumumab and elotuzumab regimens, include a footnote stating, "Indicated for the treatment of patients who have received at least two prior therapies including an immunomodulatory agent and a proteasome inhibitor and who have demonstrated disease progression on or within 60 days of completion of the last therapy." The daratumumab and elotuzumab regimens include a footnote stating, "Indicated for the treatment of patients who have received at least two prior therapies including an immunomodulatory agent and a proteasome inhibitor." The NCCN also supports use of pomalidomide + dexamethasone as a category 2A recommendation for the treatment relapsed or refractory systemic light chain amyloidosis (Version 1.2019), and use of pomalidomide monotherapy as the "Preferred regimen" (category 2A) for third-line or later treatment of relapsed or refractory AIDS-related Kaposi sarcoma in patients who have had disease progression or lack of response to separate lines of treatment with both liposomal doxorubicin and paclitaxel (Version 2.2019). The NCCN guidelines for central nervous system (CNS) cancers (Version 1.2019) list treatment with pomalidomide as a category 2A recommendation for relapsed or refractory primary CNS lymphoma.

POSITION STATEMENT:

Comparative Effectiveness

The Food and Drug Administration has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Initiation of pomalidomide (Pomalyst) **meets the definition of medical necessity** for treatment of **ANY** of the following indications ("1" to "5") and **ALL** associated criteria are met:

1. Relapsed or refractory multiple myeloma (MM) when **ALL** of the following criteria are met ("a" to "e"):
    a. **EITHER** of the following ("i" or "ii"):
        i. **ALL** of the following:
            - Member has received at least **TWO** prior therapies including an immunomodulatory agent (e.g., lenalidomide, thalidomide) **AND** a proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib)
            - The member's MM is refractory (i.e., disease progression on treatment, or progression within 60 days after the last dose of their most recent therapy)
            - **ANY** of the following drug regimens will be used:
                - Pomalidomide as triplet therapy in combination with both bortezomib + dexamethasone
                - Pomalidomide as triplet therapy in combination with both carfilzomib (Kyprolis) + dexamethasone

- Pomalidomide as triplet therapy in combination with both cyclophosphamide + dexamethasone
- Pomalidomide as triplet therapy in combination with both ixazomib (Ninlaro) + dexamethasone
- Pomalidomide as doublet therapy in combination with dexamethasone
- Pomalidomide as monotherapy (if the member is steroid-intolerant)

ii. **BOTH** of the following:

- Member has received at least **TWO** prior therapies including an immunomodulatory agent (e.g., lenalidomide, thalidomide) **AND** a proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib)
- **EITHER** of the following drug regimens will be used:
  - Pomalidomide as triplet therapy in combination with both daratumumab (Darzalex) + dexamethasone
  - Pomalidomide as triplet therapy in combination with both elotuzumab (Empliciti) + dexamethasone

b. The member's MM was **NOT** previously refractory (i.e., disease progression on treatment, or progression within 60 days after the last dose of a given therapy) to a pomalidomide-containing treatment regimen

c. Pomalidomide will **NOT** be used in combination with another immunomodulatory agent (i.e., thalidomide or lenalidomide)

d. The member's baseline (i.e., within 90 days prior to initiating treatment with pomalidomide) serum monoclonal protein (M-protein) level, as detected by serum protein electrophoresis (SPEP), is provided*

**If the M-protein is undetectable by SPEP, baseline serum free light chain (SFLC) levels (kappa and lambda), as detected by serum free light chain assay (SFLCA), must also be provided*

e. The dosage does not exceed 4 mg daily for 21 days of a 28-day cycle and will be obtained using the fewest number of capsules possible.

2. Relapsed or refractory systemic light chain amyloidosis (SLCA) when **ALL** of the following criteria are met ("a" to "f"):

   a. The diagnosis has been validated by confirming the presence of amyloid deposits in tissue **AND** the deposits are composed of light chains

   b. Member has received one or more prior lines of NCCN-recommended therapy for their for their disease

   c. Pomalidomide will be used in combination with dexamethasone

   d. The member's baseline (i.e., within 90 days prior to initiating treatment with pomalidomide) serum free light chain (SFLC) levels (kappa and lambda), as detected by serum free light chain assay (SFLCA), is provided

   e. Pomalidomide will **NOT** be used in combination with another immunomodulatory agent (i.e., thalidomide or lenalidomide)

   f. The dosage does not exceed 4 mg daily and will be obtained using the fewest number of capsules possible

3. Relapsed or refractory AIDS-related Kaposi sarcoma when **ALL** of the following criteria are met ("a" to "e"):

   a. Pomalidomide will be used as third-line or later systemic therapy

b. Member has had disease progression or lack of response to separate lines of systemic treatment with **BOTH** liposomal doxorubicin **AND** paclitaxel

c. Pomalidomide will **NOT** be used in combination with another immunomodulatory agent (i.e., thalidomide or lenalidomide) or in combination with systemic chemotherapy

d. Treatment will be given in combination with appropriate antiretroviral therapy (ART)

e. The dosage does not exceed 5 mg daily for 21 days of a 28-day cycle and will be obtained using the fewest number of capsules possible

4. Primary central nervous system (CNS) lymphoma when **ALL** of the following criteria are met ("a" to "d"):

   a. The member has relapsed or refractory disease

   b. Pomalidomide will be used in combination with dexamethasone or as single-agent systemic therapy (with or without radiation therapy)

   c. Pomalidomide will **NOT** be used in combination with another immunomodulatory agent (i.e., thalidomide or lenalidomide)

   d. The dosage does not exceed 5 mg daily for 21 days of a 28-day cycle and will be obtained using the fewest number of capsules possible.

5. Other FDA-approved or NCCN supported diagnosis (not previously listed above), and **BOTH** of the following ("a" and "b"):

   a. **EITHER** of the following is met ("i or "ii"):

      i. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)

      ii. Indication **AND** usage is recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation

   b. The dosage of pomalidomide does not exceed the maximum recommended in the FDA-approved prescribing information or the maximum recommended by the applicable NCCN guidelines for the diagnosis

Approval duration: 6 months

Continuation of pomalidomide (Pomalyst) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "5"):

1. Authorization or reauthorization for pomalidomide has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of multiple myeloma, AIDS-related Kaposi sarcoma, primary CNS lymphoma, systemic light chain amyloidosis, or other FDA-approved or NCCN-supported diagnosis; **OR** the member previously met **ALL** indication-specific initiation criteria.
2. Documentation of a favorable response to treatment is provided (see indication-specific criteria below):

   a. AIDS-related Kaposi sarcoma, primary CNS lymphoma, or other FDA-approved or NCCN-supported diagnosis (not listed below) - provider attestation that the member has not had disease progression during pomalidomide treatment

b. Multiple myeloma:

i. If less than18 months of treatment – a serum M-protein level decrease of 25% or more* compared to baseline, or M-protein is undetectable, **AND** no increase in the size or number of lytic bone lesions after at least two cycles of treatment with pomalidomide[†,#]

ii. 18 or more months of treatment - provider attestation that the member has not had disease progression during pomalidomide treatment

**If the M-protein was undetectable by SPEP at baseline and a baseline SFLC level is available, a decrease of 25% or more in the difference between the light chain produced by the myeloma cells (lambda or kappa) and the other light chain must be achieved*

[†]If the M-protein was undetectable by SPEP at baseline and a baseline SFLC level is available, a follow-up SFLC level must be provided

*[#]An exception is permitted if a baseline M-protein level **AND** SFLC level are unavailable. In these cases the physician may provide an attestation of a beneficial clinical response which must include no increase in the size or number of lytic bone lesions.*

c. Systemic light chain amyloidosis:

i. If less than18 months of treatment - there has been a reduction (improvement) in the member's SFLC level as compared to baseline[¥] after at least two cycles of treatment with pomalidomide

ii. If 18 or more months of treatment - provider attestation that the member has not had disease progression during pomalidomide treatment

[¥]*An exception is permitted if a baseline SFLC value is unavailable. A follow-up SFLC level still must be* provided*. The physician* also *must provide an attestation of a beneficial clinical response.*

2. Pomalidomide is **NOT** being used in combination with another immunomodulatory agent (i.e., thalidomide or lenalidomide)
3. Member is using **ANY** of the following drug regimens based on the indication:

a. AIDS-related Kaposi sarcoma – pomalidomide monotherapy with appropriate background antiretroviral therapy

b. Multiple myeloma

i. Pomalidomide as triplet therapy in combination with both bortezomib + dexamethasone

ii. Pomalidomide as triplet therapy in combination with both carfilzomib + dexamethasone

iii. Pomalidomide as triplet therapy in combination with both cyclophosphamide + dexamethasone

iv. Pomalidomide as triplet therapy in combination with both ixazomib + dexamethasone

v. Pomalidomide as triplet therapy in combination with both daratumumab + dexamethasone

vi. Pomalidomide as triplet therapy in combination with both elotuzumab + dexamethasone

vii. Pomalidomide as doublet therapy in combination with dexamethasone

viii. Pomalidomide as monotherapy (if the member is steroid-intolerant)

c. Primary CNS lymphoma – pomalidomide as doublet therapy in combination with dexamethasone or pomalidomide monotherapy (with or without radiation therapy)

d. Systemic light chain amyloidosis – pomalidomide as doublet therapy in combination with dexamethasone

e. Other FDA-approved or NCCN-supported diagnosis (not previously listed above) - pomalidomide is used in a treatment regimen in accordance with the FDA-approved prescribing information or NCCN guideline recommendation

4. The dosage does not exceed the following based on the indication:

   a. AIDS-related Kaposi sarcoma and primary CNS lymphoma – 5 mg daily for 21 days of a 28-day cycle and will be obtained using the fewest number of capsules possible.

   b. Multiple myeloma - 4 mg daily for 21 days of a 28-day cycle and will be obtained using the fewest number of capsules possible.

   c. Systemic light chain amyloidosis - 4 mg daily and will be obtained using the fewest number of capsules possible.

   d. Other FDA-approved or NCCN-supported diagnosis (not previously listed above) - the maximum recommended in the FDA-approved prescribing information or the maximum recommended by the applicable NCCN guidelines for the diagnosis

Approval duration: 12 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved: pomalidomide is indicated in combination with dexamethasone for treatment of multiple myeloma in persons who have received at least two prior therapies including lenalidomide (Revlimid) and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of last therapy. The recommended dose is 4 mg daily on days 1 to 21 of repeated 28-day cycles until disease progression. View the package insert for dexamethasone dosage recommendations. Pomalidomide should be taken **without** food (at least 2 hours before or 2 hours after a meal) and capsules should be administered intact. Women of childbearing age must have negative pregnancy testing and use contraception methods prior to pomalidomide initiation.

Dose Adjustments in MM Treatment

- **Hematologic Toxicity**: Table 1 denotes dose modification instructions for hematologic toxicities.

Table 1

Pomalidomide Dose Modification Instructions for Hematologic Toxicities		
Toxicity	**Dose Modification**	**Re-initiation Instructions**
Neutropenia		
1st episode: ANC less than 500/mcL **OR** fever† plus ANC less than 1,000/mcL	Interrupt treatment, follow CBC weekly	Once ANC returns to 500/mcL or more, resume at 3 mg daily
Subsequent episodes of ANC less than 500/mcL	Interrupt treatment, follow CBC	Once ANC returns to 500/mcL or more, resume at 1 mg less than previous dose

Thrombocytopenia		
1st episode: PLT less than 25,000/mcL	Interrupt treatment, follow CBC weekly	Once PLT return to 50,000/mcL or more, resume at 3 mg daily
Subsequent episodes of PLT less than 25,000/mcL	Interrupt treatment, follow CBC	Once PLT return to 50,000/mcL or more, resume at 1 mg less than previous dose
ANC, absolute neutrophil count; CBC, complete blood count; PLT, platelets [†]Fever: temperature more than or equal to 38.5°C (101.3°F)		

To initiate a new cycle of pomalidomide, the ANC must be at least 500/mcL and the PLT must be at least 50,000/mcL. If toxicities occur after dose reductions to 1 mg, then discontinue.

- Dermatologic: Permanently discontinue pomalidomide for angioedema, skin exfoliation, bullae, or any other severe dermatologic reaction.
- Other Grade 3 or 4 toxicities: Hold treatment and restart treatment at 1 mg less than the previous dose when toxicity has resolved to less than or equal to Grade 2 at the physician's discretion.
- Strong CYP1A2 Inhibitors in the Presence of Strong CYP3A4 and P-gp Inhibitors: Avoid co-administration of strong inhibitors of CYP1A2. If necessary to co-administer strong inhibitors of CYP1A2 in the presence of strong inhibitors of CYP3A4 and P-gp, reduce pomalidomide dose by 50%.
- Renal and Hepatic Impairment: Avoid use in patients with a serum creatinine greater than 3 mg/dL; these patients were excluded from clinical studies. Avoid use in patients with serum bilirubin greater than 2 mg/dL and AST/ALT greater than 3 x ULN; these patients were excluded from clinical studies.

Drug Availability: pomalidomide is supplied as 1, 2, 3, and 4 mg capsules. Because of the embryo-fetal risk, pomalidomide is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) program called "Pomalyst REMS". Further information about the REMS program is available at celgeneriskmanagement.com or by telephone at 1-888-423-5436.

PRECAUTIONS:

Boxed Warning

- **Embryo-fetal toxicity**: Pomalidomide is a thalidomide analogue. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. In women of child-bearing potential, pregnancy should be ruled out (i.e., 2 negative pregnancy tests) prior to pomalidomide initiation. During therapy and for 4 weeks after discontinuation, two forms of reliable methods of contraception or abstaining from sex should be used to prevent pregnancy.
- **Venous thromboembolism**: Deep vein thrombosis (DVT), myocardial infarction, stroke, and pulmonary embolism (PE) may occur in persons with multiple myeloma treated with pomalidomide. Prophylactic anti-thrombotic measures were used in clinical trials. Thromboprophylaxis is recommended and the choice of regimen should be based on assessment of the individual's underlying risk factors.

Contraindications:

- Pregnancy

Warnings

- **Hematologic toxicity**: Neutropenia and other hematologic toxicities may occur; monitor CBC weekly for the first 8 weeks and then monthly thereafter.
- **Hepatotoxicity**: Hepatic failure including fatalities; monitor liver function tests monthly.

- **Hypersensitivity reactions**: Angioedema and severe dermatologic reactions have been reported. Persons with a history of serious hypersensitivity associated with either thalidomide or lenalidomide were excluded from clinical trials and may be at higher risk of hypersensitivity.
- **Tumor Lysis Syndrome (TLS)**: Monitor patients at risk of TLS (i.e., those with high tumor burden) and take appropriate precautions.

BILLING/CODING INFORMATION:

HCPCS Coding:

C9399	Unclassified drugs or biologicals (Hospital Outpatient Use ONLY)
J8999	Prescription drug, oral, chemotherapeutic, Not otherwise specified

ICD-10 Diagnosis Codes That Support Medical Necessity:

C46.0 – C46.9	Kaposi's sarcoma
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C83.80	Other non-follicular lymphoma, unspecified site
C83.81	Other non-follicular lymphoma, lymph nodes of head, face, and neck
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
E85.81	Light chain (AL) amyloidosis
E85.89	Other amyloidosis
E85.9	Amyloidosis, unspecified

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

Medicare Part D: BCBSF has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

DEFINITIONS:

Heavy chain – the larger component of an immunoglobulin. There are five types: IgG, IgA, IgM, IgD, and IgE.

Immunoglobulins (a.k.a., antibodies) – proteins made by normal plasma cells that have an important role in fighting infection as part of the humoral immune response. Antibodies are composed of two heavy chains and two light chains that form a larger complex. Each plasma cell produces only one type of heavy chain and one type of light chain.

Light chain – the smaller component of an immunoglobulin. There are two types: kappa and lambda.

Minimal response (MR) (according to the Revised Uniform Response Criteria by the International Myeloma Working Group) – **ALL** of the following:

- ≥25% but ≤49% reduction of serum M-protein
- Reduction in 24-hour urine M-protein by 50% to 89%
- In addition, if present at baseline, 25% to 49% reduction in size of soft tissue plasmacytomas is also required
- No increase in size or number of lytic bone lesions (development of compression fractures dose not exclude response).

Myeloma Protein (M-Protein) – a nonfunctional immunoglobulin protein or protein fragment produced by malignant plasma cells (or myeloma cells). Since myeloma cells are monoclonal, the M-proteins for a given patient are structurally identical. Both portions of an immunoglobulin (the heavy chain and light chain) can be found in the serum, while only light chains can be found in the urine.

Plasma cell - a fully differentiated B lymphocyte (a type of white blood cell) that is specialized for immunoglobulin production and is found primarily in bone marrow.

Primary refractory MM - patients who never achieve at least a MR to initial induction therapy and progress while on therapy

Progressive MM - at least a 25% increase from nadir in the serum M-protein (absolute increase must be ≥0.5 g/dL) or urine M-protein (absolute increase must be ≥200mg/24 hours), or in the difference between involved and uninvolved serum-free light-chain (FLC) levels (with an abnormal FLC ratio and FLC difference >100 mg/L).

Relapsed and refractory MM - patients who never achieve at least a MR or who progress within 60 days of their last therapy

Serum free light chain assay (SFLCA) – a test that detects the amount of unbound or free light chains (i.e., not attached to a heavy chain) in the serum. Normal values - kappa: 3.3 to 19.4 mg/L, lambda: 5.71 to 26.3 mg/L, kappa/lambda ratio: 0.26–1.65 (0.37–3.1 if renal impairment).

Serum Protein Electrophoresis (SPEP) – a test that detects and quantifies the amount of M-protein in the serum. An serum M-protein of greater than 30 g/L is consistent with a diagnosis of MM.

Smoldering (Asymptomatic) myeloma: defined as M-protein in serum of 30 g/dL or more AND/OR bone marrow clonal plasma cells of 10% or more and no related organ or tissue impairment (no end organ damage, including bone lesions) or symptoms.

RELATED GUIDELINES:

Allogeneic Bone Marrow and Stem Cell Transplantation, 02-38240-01

Bortezomib (Velcade) IV, 09-J0000-92

Carfilzomib (Kyprolis), 09-J1000-81

Daratumumab (Darzalex) IV, 09-J2000-49

Doxorubicin HCl Liposome (Doxil) IV, 09-J0000-91

Elotuzumab (Empliciti) IV, 09-J2000-50

Ixazomib (Ninlaro), 09-J2000-51

Lenalidomide (Revlimid), 09-J0000-80

Panobinostat (Farydak), 09-J2000-37

Thalidomide (Thalomid) Capsules, 09-J1000-56

OTHER:

None

REFERENCES:

1. Baz RC, Martin TG 3rd, Lin HY, et al. Randomized multicenter phase 2 study of pomalidomide, cyclophosphamide, and dexamethasone in relapsed refractory myeloma. Blood. 2016 May 26;127(21):2561-8.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: www.clinicalpharmacilogy-ip.com. Accessed 5/24/19.
3. Dispenzieri A, Buadi F, Laumann K, et al. Activity of pomalidomide in patients with immunoglobulin light-chain amyloidosis. Blood 2012; 119(23):5397-5404.
4. Gertz M and Merlini G. Definition of organ involvement and response to treatment in AL amyloidosis: an update consensus opinion [abstract]. Amyloid 2010 17(Suppl 1):48-49. (Abstract CP-B).
5. Micromedex Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 5/24/19.
6. National Comprehensive Cancer Network. Cancer Guidelines. Cancer Guidelines and Drugs and Biologics Compendium. Accessed 5/24/19.
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Version 2.2019. AIDS-Related Kaposi Sarcoma. Available at https://www.nccn.org/professionals/physician_gls/pdf/kaposi.pdf. Accessed 5/29/19.
8. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Version 1.2019. Central Nervous System Cancers. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed 5/29/19.
9. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Version 2.2019. Multiple Myeloma. Available at http://www.nccn.org/professionals/physician_gls/PDF/myeloma.pdf. Accessed 5/29/19.

10. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Version 1.2019. Systemic Light Chain Amyloidosis. Available at http://www.nccn.org/professionals/physician_gls/pdf/amyloidosis.pdf. Accessed 5/29/19.
11. Polizzotto MN, Uldrick TS, Wyvill KM, et al. Pomalidomide for Symptomatic Kaposi's Sarcoma in People With and Without HIV Infection: A Phase I/II Study. J Clin Oncol. 2016 Dec;34(34):4125-4131.
12. Pomalyst (pomalidomide) [package insert]. Celgene Corporation. Summit (NJ): March 2018.
13. Shah JJ, Stadtmauer EA, Abonour R, et al. Carfilzomib, pomalidomide, and dexamethasone for relapsed or refractory myeloma. Blood. 2015 Nov 12;126 (20):2284-90.
14. Tun HW, Johnston PB, DeAngelis LM, et al. Phase 1 study of pomalidomide and dexamethasone for relapsed/refractory primary CNS or vitreoretinal lymphoma. Blood. 2018 Nov 22;132(21):2240-2248. Epub 2018 Sep 27.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 06/12/19.

GUIDELINE UPDATE INFORMATION:

06/15/13	New Medical Coverage Guideline.
07/15/14	Review and revision to guideline; consisting of updating position statement, references, and coding.
07/15/15	Review and revision to guideline; consisting of updating description, position statement, dosage/administration, precautions, billing/coding, definitions, and references.
11/01/15	Revision: ICD-9 Codes deleted.
07/15/16	Review and revision to guideline consisting of updating description section, position statement, billing/coding information, definitions, related guidelines, and references.
12/15/16	Revision to guideline consisting of updating the description section, position statement, and references based on updated NCCN guidelines for multiple myeloma.
02/16/17	Revision: Update to Position Statement.
07/15/17	Review and revision to guideline consisting of updating the description section, position statement, and references.
11/15/17	Revision to guideline consisting of updating the description section, position statement, and references.
07/15/18	Review and revision to guidelines consisting of updating the description section, position statement, billing/coding information, and references.
01/15/19	Revision to guideline consisting of updating the description section, position statement, and references based on updated NCCN guidelines for multiple myeloma.
5/15/19	Revision to guideline consisting of updating the description, position statement, billing/coding, and references based on a new NCCN recommended indication.
07/15/19	Review and revision to guidelines consisting of updating the description section, position statement, billing/coding information, related guidelines, and references.
01/15/20	Revision to guideline consisting of updating the position statement.