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Subject: Ibrutinib (Imbruvica®)

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DESCRIPTION:

Ibrutinib (Imbruvica) was initially approved by the U.S. Food and Drug Administration (FDA) in November 2013 for treatment of mantle cell lymphoma (MCL) in individuals who have received at least one prior therapy, and, in February 2014, for chronic lymphocytic leukemia (CLL) in individuals who have received at least one prior therapy (with or without a 17p deletion). Ibrutinib was later FDA approved for the treatment of CLL in individuals with a 17p deletion (July 2014), including those who are treatment naïve, and for the treatment of patients with Waldenström's Macroglobulinemia (January 2015). In March 2016, the indication was expanded to include first-line treatment of CLL in patients without a 17p deletion. Previously, first-line CLL treatment was limited to patients with a 17p deletion. In May 2016, the labeling was updated to include clinical trial results (Study 4) and dosing information for the use of ibrutinib in combination with bendamustine. In January 2017, ibrutinib was FDA approved for the treatment of patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy. In August 2017, ibrutinib was FDA approved for the treatment of adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy. In January 2019, the indication of CLL/SLL was expanded to include combination treatment with obinutuzumab (Gazyva) based on the positive results of the iLLUMINATE trial in treatment naïve patient, and became the first non-chemotherapy combination regimen for this indication. Prior to FDA approval ibrutinib received orphan drug status for the treatment of MCL (December 2012), CLL (February 2012), WM (October 2013), nodal MZL (February 2015), splenic MZL (February 2015), extranodal MZL (mucosa associated lymphoid tissue [MALT type] lymphoma) (February 2016), and cGVHD (June 2016). Ibrutinib, as sponsored by the innovator drug company, also has orphan designations for diffuse large B-cell lymphoma (October 2013), follicular lymphoma (September 2014), pancreatic cancer (June 2017), and gastric cancer, including gastroesophageal junction adenocarcinoma (February 2018). Ibrutinib inhibits Bruton’s tyrosine kinase to inhibit enzymatic activity and malignant B-

cell proliferation and survival. Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) is a mature B-cell lymphoma and comprises approximately 7% of newly diagnosed cases of Non-Hodgkin's Lymphoma (NHL). CLL and SLL are different manifestation of the same disease and are managed in much the same way. The main difference is that in CLL the abnormal lymphocytes are found in bone marrow and blood, while in SLL they are predominately found in the lymph nodes and bone marrow.

Ibrutinib's safety and effectiveness were first evaluated in a single-arm, open-label clinical trial of 111 patients with previously treated (median of 3 previous treatments) mantle cell lymphoma in which patients received ibrutinib 560 mg/day. Complete response occurred in 17.1% of patients and partial response in 48.6%, with a median duration of response of 17.5 months. Lymphocytosis (temporary increase of 50% or greater in lymphocyte count) occurred in 33% of patients and resolved by a median of 8 weeks. The most common adverse reactions (≥20%) in patients with MCL were thrombocytopenia, diarrhea, neutropenia, anemia, fatigue, musculoskeletal pain, peripheral edema, upper respiratory tract infection, nausea, bruising, dyspnea, constipation, rash, abdominal pain, vomiting and decreased appetite. Ibrutinib carries a warning of embryo-fetal toxicity. Bleeding events including bruising of any grade occurred in 48% of patients.

National Comprehensive Cancer Network (NCCN) Guidelines for B-cell Lymphoma (Version 4.2019), Central Nervous System Cancers (Version 1.2019), CLL/SLL (Version 5.2019), Hairy Cell Leukemia (Version 3.2019), and Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (Version 2.2019) recommend ibrutinib for mantle cell lymphoma, various marginal zone lymphomas, certain diffuse large B-cell lymphomas (DLBCL), primary CNS lymphoma, certain post-transplant lymphoproliferative disorders, CLL/SLL, hairy cell leukemia, and Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma when first-line treatment has failed. For CLL/SLL, combination therapy of ibrutinib + bendamustine + rituximab is listed as treatment option for patients without a del(17p) mutation (category 2B). The NCCN also recommends use as a first-line therapy option for CLL/SLL with or without a del(17p) mutation, certain cases of mantle cell lymphoma, and for Waldenström's macroglobulinemia/lymphoplasmacytic 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 ibrutinib (Imbruvica) **meets the definition of medical necessity** for members diagnosed with **ANY** of the following conditions when **ALL** associated criteria are met ("1" to "14"):

1. Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)
    a. If used first-line for previously untreated disease - **EITHER** of the following ("i" or "ii"):
        i. Ibrutinib will be used as monotherapy
        ii. Ibrutinib will be used in combination with obinutuzumab (Gazyva) or rituximab
    b. If used second-line or later for previously treated disease - **EITHER** of the following ("i" or "ii"):

i. Ibrutinib will be used as monotherapy

ii. **BOTH** of the following:

- Ibrutinib will be used in combination with both bendamustine (Treanda, Bendeka) and rituximab (Rituxan)
- The member does **NOT** have a del(17p) mutation – lab documentation of the fluorescence in situ hybridization (FISH) cytogenetic test results must be submitted

c. Dosage does not exceed 420 mg*

2. Chronic graft-versus-host disease (cGVHD)
   a. The member is diagnosed with cGVHD following an allogeneic hematopoietic stem cell (bone marrow) transplant
   b. Member's disease is refractory to an adequate trial of combination therapy with a systemic corticosteroid **AND** a calcineurin inhibitor (i.e., cyclosporine or tacrolimus). Corticosteroid monotherapy is acceptable for members who have an intolerance or contraindication to a calcineurin inhibitor (the specific intolerance or contraindication must be provided)
   c. Dosage does not exceed 420 mg*
3. Diffuse large B-cell lymphoma (DLBCL) [includes AIDS-related DLBCL and DLBCL transformed from follicular lymphoma or transformed from marginal zone lymphoma]
   a. Ibrutinib is used as second-line or later therapy for relapsed or refractory disease
   b. Member has non-germinal center B-cell like DLBCL (non-GCB DLBCL) as determined by immunophenotyping or genetic testing – the confirmatory laboratory documentation must be submitted
   c. Member is **NOT** a candidate for stem cell transplant
   d. Member will use ibrutinib as monotherapy
   e. Dosage does not exceed 560 mg/day*
4. Gastric MALT (mucosa-associated lymphoid tissue) lymphoma (a type of extranodal marginal zone lymphoma of MALT)
   a. Ibrutinib is used as second-line or later therapy for relapsed or refractory disease
   b. Member will use ibrutinib as monotherapy
   c. Dosage does not exceed 560 mg/day*
5. Hairy cell leukemia
   a. Ibrutinib is used as third-line or later therapy for previously treated disease
   b. Member is experiencing disease progression
   c. Member will use ibrutinib as monotherapy
   d. Dosage does not exceed 420 mg/day*
6. High-Grade B-Cell Lymphomas
   a. Ibrutinib is used as second-line or later therapy for relapsed or refractory disease
   b. Member is **NOT** a candidate for stem cell transplant
   c. Member will use ibrutinib as monotherapy
   d. Dosage does not exceed 560 mg/day*
7. Mantle cell lymphoma (MCL)

a. The diagnosis has been confirmed by tissue biopsy with appropriate histology and immunophenotyping

b. **EITHER** of the following ("i" or "ii"):

i. **BOTH** of the following ("1" and "2"):

1. Ibrutinib is used as second-line or later therapy for relapsed or refractory disease

2. Member will use ibrutinib as either monotherapy or in combination with rituximab

ii. **ALL** of the following ("1", "2", and "3"):

1. Member has newly diagnosed, previously untreated MCL

2. Ibrutinib will be used in combination with rituximab (Rituxan)

3. Use is for pre-treatment to limit the number of cycles of therapy with a R-hyper-CVAD regimen (rituximab, cyclophosphamide, doxorubicin, vincristine, and dexamethasone)

c. Dosage does not exceed 560 mg/day*

8. Nodal marginal zone lymphoma

a. Ibrutinib is used as second-line or later therapy for relapsed or refractory disease

b. Member will use ibrutinib as monotherapy

c. Dosage does not exceed 560 mg/day*

9. Non-gastric MALT lymphoma (a type of extranodal marginal zone lymphoma of MALT)

a. Ibrutinib is used as second-line or later therapy for relapsed or refractory disease

b. Member will use ibrutinib as monotherapy

c. Dosage does not exceed 560 mg/day*

10. Post-transplant lymphoproliferative disorder (PTLD)

a. Ibrutinib is used as second-line or later therapy for relapsed or refractory disease

b. Member has monomorphic PTLD that is of non-germinal center B-cell type origin as determined by immunophenotyping or genetic testing – the confirmatory laboratory documentation must be submitted

c. Member is **NOT** a candidate for stem cell transplant

d. Member will use ibrutinib as monotherapy

e. Dosage does not exceed 560 mg/day*

11. Primary central nervous system (CNS) lymphoma

a. Ibrutinib is used as second-line or later therapy for relapsed or refractory disease

b. Member will use ibrutinib as monotherapy

c. Dosage does not exceed 560 mg/day*

12. Splenic marginal zone lymphoma

a. Ibrutinib is used as second-line or later therapy for relapsed or refractory disease

b. Member will use ibrutinib as monotherapy

c. Dosage does not exceed 560 mg/day*

13. Waldenström's macroglobulinemia (a.k.a. lymphoplasmacytic lymphoma)

a. Member is symptomatic (e.g., hyperviscosity, neuropathy, symptomatic adenopathy or organomegaly, amyloidosis, cryoglobulinemia, cold agglutinin disease, presence of cytopenia)

b. The member's baseline (i.e., within 90 days prior to initiating treatment with ibrutinib) serum IgM level is provided

c. Member will use ibrutinib as either monotherapy or combination with rituximab

d. Dosage does not exceed 420 mg/day*

14. Other FDA-approved or NCCN supported diagnosis (not previously listed above)

    a. When **ONE** 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. Dosage does not exceed 560 mg/day*

**The following tablet/capsule regimens must be used for the various dosages of ibrutinib:*

- *70 mg once daily – one 70 mg **capsule** once daily*
- *140 mg once daily – one 140 mg **capsule** once daily*
- *280 mg once daily – two 140 mg **capsules** once daily*
- *420 mg once daily – one 420 mg **tablet**, or three 140 mg **capsules***
- *560 mg once daily – one 560 mg **tablet***

Duration of approval: 6 months

Continuation of ibrutinib (Imbruvica) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Authorization or reauthorization for ibrutinib has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of MCL, CLL/SLL, cGVHD, DLBCL, hairy cell leukemia, gastric or non-gastric MALT lymphoma, nodal or splenic marginal zone lymphoma, PTLD, primary CNS lymphoma, or Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma, high-Grade B-cell lymphomas, or other FDA-approved or NCCN-supported diagnosis, **OR** the member previously met **ALL** indication-specific initiation criteria.
2. The member did **NOT** have progressive disease during treatment with ibrutinib
3. Dosage does not exceed the following:
    a. CLL/SLL, cGVHD, hairy cell leukemia, and Waldenström's macroglobulinemia - 420 mg/day*
    b. Other indications - 560 mg/day*

**The following tablet/capsule regimens must be used for the various dosages of ibrutinib:*

- *70 mg once daily – one 70 mg **capsule** once daily*
- *140 mg once daily – one 140 mg **capsule** once daily*
- *280 mg once daily – two 140 mg **capsules** once daily*
- *420 mg once daily – one 420 mg **tablet**, or three 140 mg **capsules***
- *560 mg once daily – one 560 mg **tablet***

Duration of approval: 1 year

Ibrutinib (Imbruvica) **meets the definition of medical necessity** when used to treat any of the following designated orphan indications, the member has relapsed or refractory disease, the member has received at least two prior lines of therapy, and the dosage does not exceed 560 mg daily*

1. Follicular lymphoma
2. Gastric cancer, including gastroesophageal junction adenocarcinoma
3. Multiple myeloma
4. Pancreatic cancer

**The following tablet/capsule regimens must be used for the various dosages of ibrutinib:*

- *70 mg once daily – one 70 mg **capsule** once daily*
- *140 mg once daily – one 140 mg **capsule** once daily*
- *280 mg once daily – two 140 mg **capsules** once daily*
- *420 mg once daily – one 420 mg **tablet**, or three 140 mg **capsules***
- *560 mg once daily – one 560 mg **tablet***

Duration of approval: 1 year.

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

- Mantle cell lymphoma (MCL) in patients who have received at least one prior therapy: 560 mg taken orally once daily until disease progression or unacceptable toxicity.
- Chronic lymphocytic leukemia/ small lymphocytic lymphoma (with or without 17p deletion): 420 mg taken orally once daily as a single-agent, in combination with bendamustine and rituximab, or in combination with obinutuzumab until disease progression or unacceptable toxicity. When administering ibrutinib in combination with rituximab or obinutuzumab, consider administering ibrutinib prior to rituximab or obinutuzumab when given on the same day.
- Waldenström's macroglobulinemia: 420 mg taken orally once daily as a single-agent or in combination with rituximab until disease progression or unacceptable toxicity.
- Marginal zone lymphoma in patients who require systemic therapy and have received at least one prior anti-CD20-based therapy: 560 mg taken orally once daily until disease progression or unacceptable toxicity.
- Chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy: 420 mg taken orally once daily until cGVHD progression, recurrence of an underlying malignancy, or unacceptable toxicity. When a patient no longer requires therapy for the treatment of cGVHD, ibrutinib should be discontinued considering the medical assessment of the individual patient.

Dose Adjustments

Toxicity

- Interrupt ibrutinib therapy for any Grade 3 or greater non-hematological, Grade 3 or greater neutropenia with infection or fever, or Grade 4 hematological toxicities.
- Once the symptoms of the toxicity have resolved to Grade 1 or baseline (recovery), ibrutinib therapy may be reinitiated at the starting dose.
- If the toxicity reoccurs, reduce dose by 140 mg per day.
- A second reduction of dose by 140 mg may be considered as needed.
- If these toxicities persist or recur following two dose reductions, discontinue ibrutinib.

Hepatic Impairment

- For patients with mild liver impairment (Child-Pugh A), the recommended dose is 140 mg daily
- For patients with moderate hepatic impairment (Child-Pugh class B), the recommended dose is 70 mg daily
- Avoid the use in patients with severe hepatic impairment (Child-Pugh C).

Use with CYP3A Inhibitors

- A dose reduction or avoiding use of ibrutinib may be warranted for moderate or strong CYP3A4 inhibitors and depends on if use is for a B-cell malignancy or cGVHD. Refer to the product labeling for the specific recommendations. Specific dosage reductions are recommended for co-administration with voriconazole or posaconazole.

Drug Availability

- 70 mg capsule, 140 mg capsule, 140 mg tablet, 280 mg tablet, 420 mg tablet, and 560 mg tablet. The 140 mg capsule was to be discontinued May 15, 2018, but the decision was reversed by the pharmaceutical company.

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- None

Precautions/Warnings

- **Hemorrhage**: Monitor for bleeding. Ibrutinib may increase the risk of hemorrhage in patients receiving antiplatelet or anticoagulant therapies. Consider the benefit-risk of withholding treatment for at least 3 to 7 days pre and post-surgery depending upon the type of surgery and the risk of bleeding.
- **Infections**: Monitor patients for fever and infections and evaluate promptly. Cases of progressive multifocal leukoencephalopathy (PML) have occurred.
- **Myelosuppression/Cytopenias**: Check complete blood counts monthly.
- **Atrial Fibrillation**: Monitor patients for atrial fibrillation. Patients who develop arrhythmic symptoms (e.g., palpitations, lightheadedness) or new onset dyspnea should have an ECG performed.
- **Hypertension**: Monitor blood pressure and treat as needed.
- **Tumor Lysis Syndrome (TLS)**: Monitor patients at risk for TLS (e.g. high tumor burden)

- **Second Primary Malignancies**: Other malignancies have occurred in patients, including skin cancers, and other carcinomas.
- **Embryo-Fetal Toxicity**: Can cause fetal harm. Advise women of the potential risk to a fetus and to avoid pregnancy while taking the drug.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J8999	Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

ICD-10 Diagnosis Codes That Support Medical Necessity

C16.0 – C16.9	Malignant neoplasm of stomach
C25.0 – C25.2	Malignant neoplasm of head, body, or tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas
C25.7 – C25.9	Malignant neoplasm of other parts of pancreas, overlapping sites of pancreas, or unspecified part of pancreas
C82.00 – C82.09	Follicular lymphoma grade I
C82.10 – C82.19	Follicular lymphoma grade II
C82.20 – C82.29	Follicular lymphoma grade III, unspecified
C82.30 – C82.39	Follicular lymphoma grade IIIa
C82.40 – C82.49	Follicular lymphoma grade IIIb
C82.60 – C82.69	Cutaneous follicle center lymphoma
C82.80 – C82.89	Other types of follicular lymphoma
C82.90 – C82.99	Follicular lymphoma, unspecified
C83.00	Small cell B-cell lymphoma unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face, and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.10	Mantle cell lymphoma, unspecified site
C83.11	Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites

C83.30 – C83.39	Diffuse large B-cell lymphoma
C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.80	Other non-follicular lymphoma, unspecified site
C83.81	Other non-follicular lymphoma, lymph nodes of head, face, and neck
C83.82	Other non-follicular lymphoma, intrathoracic lymph nodes
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes
C83.84	Other non-follicular lymphoma, lymph nodes of axilla and upper limb
C83.85	Other non-follicular lymphoma, lymph nodes of inguinal region and lower limb
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes
C83.87	Other non-follicular lymphoma, spleen
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites
C83.90 – C83.99	Non-follicular (diffuse) lymphoma, unspecified
C85.20 – C85.29	Mediastinal (thymic) large B-cell lymphoma
C85.80 – C85.89	Other specified types of non-Hodgkin lymphoma
C88.00	Waldenström's macroglobulinemia
C88.08	Other lymphoplasmacytic lymphoma
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]
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
C91.10	Chronic lymphocytic leukemia of B-cell type, not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type, in remission
C91.12	Chronic lymphocytic leukemia of B-cell type, in relapse
C91.40	Hairy cell leukemia not having achieved remission
C91.42	Hairy cell leukemia in relapse
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
D89.811	Chronic graft-versus-host disease

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

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

DEFINITIONS:

FISH (Fluorescence In Situ Hybridization): Leukemias, lymphomas, other hematopoietic malignancies and some types of solid tumors can often be characterized by specific chromosomal and genetic abnormalities. FISH studies are used to determine the presence of a known or suspected abnormality. This is particularly useful when there are few or no dividing cells in the sample for cytogenetic analysis.

RELATED GUIDELINES:

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

Autologous Bone Marrow and Stem Cell Transplantation, 02-38241-01

Bendamustine (Treanda), 09-J2000-40

Idelalisib (Zydelig), 09-J2000-23

Interferons for Oncology Use, 09-J1000-37

Lenalidomide (Revlimid), 09-J0000-80

Obinutuzumab (Gazyva), 09-J2000-07

Procarbazine (Matulane), 09-J1000-59

Rituximab (Rituxan), 09-J0000-59

OTHER:

None

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 07/10/19.

GUIDELINE UPDATE INFORMATION:

03/15/14	New Medical Coverage Guideline.
04/15/14	Revision to guideline; consisting of description, position statement, dosing/administration, references.
10/15/14	Revision to guideline; consisting of position statement, coding
08/15/15	Review and revision to guideline; consisting of description, position statement, dosing/administration, references.
12/15/15	Revision to guideline consisting of updating the position statement and definitions section.
05/15/16	Revision to guideline consisting of updating the position statement based on expanded FDA indication and NCCN guideline updates, and updated references.
08/15/16	Review and revision to guideline consisting of updating the description section, position statement, dosing/administration section, billing/coding information, 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 CLL/SLL.
05/15/17	Revision to guideline consisting of updating the description section, position statement, dosage/administration section, billing/coding information, and references based on a new FDA approved indication and updated NCCN guidelines for non-Hodgkin lymphomas.
08/15/17	Review and revision to guideline consisting of updating the description section, position statement, dosing/administration section, and references.
10/15/17	Revision to guideline consisting of updating the description section, position statement, dosage/administration section, billing/coding information, and references based on a new FDA approved indication for chronic Graft versus Host Disease (cGVHD).
04/15/18	Revision to guideline consisting of updating the description section, position statement, dosage/administration section, billing/coding information, and references based on new NCCN guideline recommendations for B-cell lymphomas and new tablet strengths.
08/15/18	Review and revision to guideline consisting of updating the description section, position statement, dosing/administration section, and references.
11/15/18	Revision to guideline consisting of updating the description section, position statement, and references based on revised NCCN guidelines for Waldenström's Macroglobulinemia.
03/15/19	Revision to guideline consisting of updating the description section, position statement, and references based on NCCN guideline updates and a new FDA-approved combination regimen with Gazyva for CLL/SLL.
08/15/18	Review and revision to guideline consisting of updating the description section, position

	statement, and references.