

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

<b>DRUG NAME</b>	<b>Imbruvica (ibrutinib)</b>
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Imbruvica is indicated for the treatment of adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy. GVHD, a common complication following allogeneic hematopoietic stem cell transplant (HSCT), occurs in about 50% of HSCT patients. Prednisone is the mainstay of initial therapy but at least half of patients require at least 2 lines of therapy. Clinical guidelines do not come to a consensus regarding optimal 2<sup>nd</sup> line therapy but describe a variety of options.

Imbruvica is a small molecule inhibitor of Bruton’s tyrosine kinase (BTK). BTK is a signaling molecule of the B-cell antigen receptor (BCR) and cytokine receptor pathways. Imbruvica can exert its effects on B cells and T cells, both of which are thought to be involved in cGVHD pathogenesis. Approval was based on a phase 1b/2 study of 42 patients with cGVHD after failure of first line corticosteroid therapy and requiring additional therapy.

Imbruvica (ibrutinib) will be considered for coverage when the following criteria are met:

#### Chronic Graft-Versus-Host Disease (cGVHD)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a transplant or hematology/oncology specialist; AND
3. Member has a documented diagnosis of active cGVHD that is steroid-dependent or steroid-refractory; AND
4. Member does NOT have a known bleeding disorder or hemophilia.
5. **Dosage allowed/Quantity limit:** 420 mg orally once daily (until progression, recurrence of underlying malignancy, or unacceptable toxicity). QL: 28 tablets per 28 days.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must show improvement of signs and symptoms of disease in at least 1 organ/site, without progression in any other organ/site.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

#### Mantle Cell Lymphoma, Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Waldenstrom’s Macroglobulinemia, Marginal Zone Lymphoma

Any request for cancer must be submitted through [NantHealth/Eviti](#) portal.

**CareSource considers Imbruvica (ibrutinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
10/04/2021	New policy created for Imbruvica.

References:

1. Imbruvica [prescribing information]. Pharmacyclics LLC and Janssen Biotech, Inc.; 2020.
2. Miklos D, Cutler CS, Arora M, et al. Ibrutinib for chronic graft-versus-host disease after failure of prior therapy. *Blood*. 2017;130(21):2243-2250. doi:10.1182/blood-2017-07-793786
3. Waller EK, Miklos D, Cutler C, et al. Ibrutinib for Chronic Graft-versus-Host Disease After Failure of Prior Therapy: 1-Year Update of a Phase 1b/2 Study. *Biol Blood Marrow Transplant*. 2019;25(10):2002-2007. doi:10.1016/j.bbmt.2019.06.023
4. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (HCT): Pre-Transplant Recipient Evaluation and Management of Graft-Versus-Host Disease. (Version 5.2021). [https://www.nccn.org/professionals/physician\\_gls/pdf/hct.pdf](https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf). Accessed October 4, 2021.
5. Wolff D, Fatobene G, Rocha V, Kröger N, Flowers ME. Steroid-refractory chronic graft-versus-host disease: treatment options and patient management. *Bone Marrow Transplant*. 2021;56(9):2079-2087. doi:10.1038/s41409-021-01389-5
6. Penack O, Marchetti M, Ruutu T, et al. Prophylaxis and management of graft versus host disease after stem-cell transplantation for haematological malignancies: updated consensus recommendations of the European Society for Blood and Marrow Transplantation. *Lancet Haematol*. 2020;7(2):e157-e167. doi:10.1016/S2352-3026(19)30256-X

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