CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Imbruvica (ibrutinib)
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 allogenic 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 2nd 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. 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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