

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Imbruvica (ibrutinib)
BILLING CODE	Must use valid NDC
STATUS	Prior Authorization Required

Imbruvica is indicated for the treatment of 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 2nd line therapy but describe a variety of options.

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.
09/23/2022	Updated age limit from 18 years to 1 year per label change; added pediatric dosing.

References:

1. Imbruvica [prescribing information]. Pharmacyclics LLC and Janssen Biotech, Inc.; 2022.
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
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