Reference number(s)
6350-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☑

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Bruton Tyrosine Kinase (BTK) Inhibitors

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), and Value Formulary (VF).

Plan Design Summary

This program applies to the oncology products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Bruton Tyrosine Kinase Inhibitors

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• Brukinsa (zanubrutinib) • Calquence (acalabrutinib)

	Products
Target	• Imbruvica (ibrutinib) • Jaypirca (pirtobrutinib)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

- Coverage for Imbruvica is provided when any of the following criteria are met:
    - Member is currently receiving treatment with Imbruvica, excluding when Imbruvica is obtained as samples or via manufacturer's patient assistance programs.
    - Member has a documented inadequate response or intolerable adverse event with both of the preferred products.
    - For Waldenström's macroglobulinemia, member has a documented inadequate response or intolerable adverse event with Brukinsa.
    - Imbruvica will be used as aggressive induction therapy as a component of TRIANGLE regimen (alternating RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) + covalent BTK inhibitor (ibrutinib)/RDHA (rituximab, dexamethasone, and cytarabine) + carboplatin, cisplatin, or oxliplatin) or as maintenance therapy in combination with rituximab for mantle cell lymphoma.
- Coverage for Jaypirca is provided when any of the following criteria are met:
    - Member is currently receiving treatment with Jaypirca, excluding when Jaypirca is obtained as samples or via manufacturer's patient assistance programs.
    - Member has a documented inadequate response or intolerable adverse event with both of the preferred products.
    - Jaypirca will be used to treat histologic (Richter's) transformation to diffuse large b-cell lymphoma (clonally related or unknown clonal status) as a single agent in patients with del(17p)/TP53 mutation or who are chemotherapy refractory or unable to receive chemoimmunotherapy.
    - Member has chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and documented BTK C481 mutation with disease progression (resistance) on a covalent BTK inhibitor (e.g., zanubrutinib, acalabrutinib, or ibrutinib).

References

1. Brukinsa [package insert]. San Mateo, CA: BeiGene USA, Inc.; June 2024.
2. Calquence [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2024.
3. Imbruvica [package insert]. South San Francisco, CA: Pharmacyclics LLC; May 2024.
4. Jaypirca [package insert]. Indianapolis, IN: Eli Lilly and Company; June 2024.

5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed October 18, 2024.