Pharmacy Policy

Chronic Myelogenous Leukemia (CML) Agents – Unified Formulary

Policy Number: 9.709
Version Number: 2.0
Version Effective Date: 9/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth- MCO
	☒ MassHealth- ACO
	☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct
	☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Reference Table:

Drugs that require PA	No PA
Bosulif® (bosutinib) PD	Gleevec® # (imatinib)
Iclusig® (ponatinib)	Sprycel® (dasatinib)
Synribo® (omacetaxine mepesuccinate)	Tasigna® (nilotinib)

This is a brand-name drug with FDA "A"-rated generic equivalents. Prior authorization is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. **Please note, for CML agents, a trial with a preferred agent is not required prior to approval of a non-preferred agent.**

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Procedure:

Approval Diagnosis:	• **Chronic Myelogenous Leukemia (Bosulif®, Iclusig® Synribo® (omacetaxine mepesuccinate[j])** • **Acute Lymphoblastic Leukemia (Iclusig®)**
Approval Criteria: **Bosulif®** (bosutinib)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is a hematologist or oncologist 3. Appropriate dosing 4. **ONE** of the following: a. Member has chronic phase Philadelphia chromosome-positive (Ph+) CML b. Inadequate response or adverse reaction to **ONE** prior therapy for CML or contraindication to **ALL** other therapies for CML (*History of claims is sufficient*)* ***Notes:*** • **Please see Appendix I for examples of recommended agents for the treatment of CML.*
Approval Criteria: **Iclusig®** (ponatinib)	*For Chronic Myelogenous Leukemia* Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is a hematologist or oncologist 3. Appropriate dosing 4. **ONE** of the following: a. Inadequate response or adverse reaction to **TWO** of the following or a contraindication to **ALL** of the following (*History of claims is sufficient*): a. Bosulif® (bosutinib) b. imatinib c. Sprycel® (dasatinib) d. Tasigna® (nilotinib) b. Confirmed T315I mutation *For Acute Lymphoblastic Leukemia* Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is a hematologist or oncologist 3. Appropriate dosing 4. Inadequate response or adverse reaction to **ONE** of the following or a contraindication to **ALL** of the following (*History of claims is sufficient*)*: a. imatinib b. Sprycel® (dasatinib) c. Tasigna® (nilotinib) ***Notes:*** • **Documentation of contraindication to imatinib and dasatinib is sufficient for approval if request notes ponatinib to be used with hyper-CVAD regimen (nilotinib trial is not required)*

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Approval Criteria: Synribo® (omacetaxine mepesuccinate)	Prescriber provides documentation of ALL of the following: 1. Appropriate diagnosis 2. Prescriber is a hematologist or oncologist 3. Appropriate dosing 4. ONE of the following: a. Inadequate response or adverse reaction to TWO of the following or a contraindication to ALL of the following (History of claims in POPS is sufficient): i. Bosulif® (bosutinib) ii. imatinib iii. Sprycel® (dasatinib) iv. Tasigna® (nilotinib) b. Documentation of confirmed T315I mutation
Denial Criteria:	Cases that do not meet the approval criteria will be denied.
	If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Duration/Quantity of Authorization:	Prior authorization may be issued for **6 months**
Recertification Criteria:	Resubmission by prescriber will infer a positive response to therapy and request can be recertified for **up to 6 months**

Appendix:

Stability

Stability alone on Bosulif® (bosutinib) or Iclusig® (ponatinib) is not a reason to bypass approval criteria. However, requests for members who have already started treatment on these agents should be reviewed with clinical review and approval is strongly considered for any member with any FDA-approved indication.

Grandfathering

Information is not applicable.

Appendix I: First-line therapy for CML

The NCCN Guidelines for the treatment of CML breaks down recommendations for first-line therapy based on three different phases, chronic, accelerated, and blast. Recommendations for each category are listed below. Please note these lists may not be all inclusive.

Chronic phase-low-risk or high-risk score

a. Imatinib
b. Bosutinib
c. Dasatinib
d. Nilotinib

Accelerated phase

a. Bosutinib
b. Dasatinib
c. Nilotinib
d. Ponatinib
e. Imatinib
f. Omacetaxine

Blast phase-lymphoid

a. ALL-type induction chemotherapy plus a TKI
    a. Examples of ALL-type induction chemotherapy:
        i. Hyper-CVAD (hyperfractionated cyclophosphamide, vincristine, doxirubinin, and dexamethasone) alternating with high-dose methotrexate and cytarabine
        ii. Multiagent chemotherapy (daunorubicin, vincristine, prednisone, and cyclophosphamide)
        iii. Vincristine and dexamethasone
        iv. CALGB 10701 chemotherapy regimen (dexamethasone, vincristine, daunorubicin, methotrexate, etoposide, and cytarabine)
    b. Examples of TKIs
        i. Imatinib
        ii. Bosutinib
        iii. Dasatinib
        iv. Nilotinib
        v. Ponatinib
b. TKI plus steroids
    a. Examples of TKIs
        i. Imatinib
        ii. Bosutinib
        iii. Dasatinib
        iv. Nilotinib
        v. Ponatinib

Blast phase-myeloid

a. Acute myeloid leukemia (AML)-type induction chemotherapy plus a TKI
    a. Examples of AML-type induction chemotherapy
        i. Cytarabine plus idarubicin or daunorubicin
        ii. Cytarabine plus daunorubicin and gemtuzumab ozogamicin
        iii. Cytarabine plus daunorubicin and midostaurin
        iv. Liposomal daunorubicin plus cytarabine
        v. Cytarabine plus daunorubicin and cladribine
        vi. High-dose cytarabine plus idarubicin or daunorubicin
        vii. High-dose cytarabine, fludarabine, idarubicin, and granulocyte colony stimulating factor (GCSF)
    b. Examples of TKIs
        i. Imatinib
        ii. Bosutinib
        iii. Dasatinib
        iv. Nilotinib
        v. Ponatinib
b. TKI

a. Examples of TKIs
   i. Imatinib
   ii. Bosutinib
   iii. Dasatinib
   iv. Nilotinib
   v. Ponatinib

Members may receive other lines of therapy not indicated in the latest update of the NCCN guidelines.

Additional Information

Applicable Coding

HCPCS Code	Description
J9262	omacetaxine mepesuccinate, 0.01 mg

Clinical Background Information and References

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	New policy created to align with MH Unified Formulary Policy	1/1/2021	P&T Committee
1/20/2021	Updated policy to reflect PUF changes as of 9/29/20	1/20/2021	P&T Committee
5/13/20121	Synribo and related criteria added to policy by MH. No changes to any other criteria.	9/1/2021	P&T Committee

Next Review Date

5/2022

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.