GEORGIA DEPARTMENT OF COMMUNITY HEALTH

# GEORGIA MEDICAID FEE-FOR-SERVICE
# ONCOLOGY, ORAL - HEMATOLOGIC PA SUMMARY

| Preferred | Non-Preferred |
|---|---|
| Bosulif (bosutinib)<br>Brukinsa (zanubrutinib)<br>Calquence (acalabrutinib tablets)<br>Copiktra (duvelisib)<br>Daurismo (glasdegib)<br>Iclusig (ponatinib)<br>Idhifa (enasidenib)<br>Imbruvica (ibrutinib)<br>Inqovi (decitabine/cedazuridine)<br>Inrebic (fedratinib)<br>Jakafi (ruxolitinib)*<br>Jaypirca (pirtobrutinib)<br>Mercaptopurine tablets generic*<br>Ninlaro (ixazomib)<br>Ojjaara (momelotinib)<br>Onureg (azacitidine)<br>Pomalyst (pomalidomide)<br>Revlimid (lenalidomide)*<br>Rezlidhia (olutasidenib)<br>Rydapt (midostaurin)<br>Scemblix (asciminib)<br>Sprycel (dasatinib)<br>Tasigna (nilotinib)<br>Thalomid (thalidomide)*<br>Tibsovo (ivosidenib)<br>Vanflyta (quizartinib)<br>Venclexta (venetoclax)<br>Xospata (gilteritinib)<br>Xpovio (selinexor)<br>Zolinza (vorinosta)<br>Zydelig (idelalisib) | Purixan (mercaptopurine suspension)<br>Vonjo (pacritinib) |

*PA not required

**LENGTH OF AUTHORIZATION:** 1 year

**NOTES:**

- Jakafi, Mercaptopurine generic, Revlimid and Thalomid do not require prior authorization.
- Special consideration taken for members with stage IV advanced metastatic cancer.

**PA CRITERIA:**

*Bosulif*

- Approvable for members with a new diagnosis of chronic-phase or diagnosis of accelerated-phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML).
- Approvable for members with a previous diagnosis of chronic-phase Ph+ CML or with a diagnosis of blast-phase Ph+ CML who are resistant, refractory, relapsed or intolerant to prior therapy.
- Approvable for members with a diagnosis of Ph+ acute lymphoblastic leukemia (ALL) who are resistant. refractory, relapsed or intolerant to prior therapy.

*Brukinsa*

- Approvable for members with a diagnosis of mantle cell lymphoma (MCL) who have received at least one prior therapy.
- Approvable for members with a diagnosis of Waldenstrom's macroglobulinemia.
- Approvable for members with a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.
- Approvable for members with a diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL).
- Approvable for members with a diagnosis of relapsed or refractory follicular lymphoma (FL) who have received at least two or more prior lines of systemic therapy when used in combination with obinutuzumab (Gazyva).

*Calquence Tablets*

- Approvable for members with a diagnosis of mantle cell lymphoma (MCL) who have received at least one prior therapy.
- Approvable for members with a diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL).

*Copiktra*

- Approvable for members with a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have relapsed after or are refractory to at least two prior therapies.

*Daurismo*

- Approvable for members 74 years of age or younger with newly diagnosed acute myeloid leukemia (AML) when used in combination with low-dose cytarabine who have a comorbidity that precludes use of intensive induction chemotherapy.
- Approvable for members 75 years of age or older with newly diagnosed AML when used in combination with low-dose cytarabine.

*Iclusig*

- Approvable for members with a diagnosis of chronic-phase CML who are resistant, refractory, relapsed or intolerant to at least 2 prior kinase inhibitors indicated for CML.
- Approvable for members with a diagnosis of accelerated- or blast-phase CML who are resistant, refractory, relapsed or intolerant to all kinase inhibitors indicated for CML.
- Approvable for members with a diagnosis of Ph+ ALL who have the T3151-postive BCR-ABL mutation or who are resistant, refractory, resistant or intolerant to all kinase inhibitors indicated for Ph+ ALL when used in combination with chemotherapy.

*Idhifa*

- Approvable for members with a diagnosis of relapsed or refractory acute myeloid leukemia (AML) who have an isocitrate dehydrogenase-2 (IDH2) mutation.

*Imbruvica*

- Approvable for members with a diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL).
- Approvable for members with a diagnosis of Waldenstrom's macroglobulinemia.
- Approvable for members with a diagnosis of chronic graft versus host disease (cGVHD) who have failed one or more lines of systemic therapy.
- Approvable for members with a diagnosis of diffuse large B-cell lymphoma who have progressed on first-line therapy and are not a candidate for high-dose therapy.

*Inqovi*

- Approvable for members with a diagnosis of myelodysplastic syndrome (MDS) who have an absolute neutrophil count (ANC) $\geq$ 500/µL and a platelet count $\geq$ 50,000/µL.

*Inrebic*

- Approvable for members with a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) who are not a transplant candidate and have a platelet count $\geq 50 \times 10^9$/L.

*Jaypirca*

- Approvable for member with a diagnosis of relapsed or refractory mantle cell lymphoma (MCL) who have received at least two prior lines of therapy, including a bruton tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, zanubrutinib).
- Approvable for member with a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least two prior lines of therapy, including a bruton tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, zanubrutinib) and a B-cell lymphoma-2 (BCL-2) inhibitor (e.g., venetoclax).

*Ninlaro*

- Approvable for members with a diagnosis of multiple myeloma who have been previously treated with at least 1 prior therapy
- Ninlaro must be given in combination with lenalidomide (Revlimid) and dexamethasone.

*Ojjaara*

- Approvable for members with a diagnosis of anemia with intermediate or high-risk myelofibrosis (MF), including primary or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)] who have a platelet count $\geq 50 \times 10^9$/L and an absolute neutrophil count (ANC) $\geq 0.5 \times 10^9$/L.

*Onureg*

- Approvable for members with a diagnosis of acute myeloid leukemia (AML) who have achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and is not able to complete intensive curative therapy and who have an ANC $\geq$ 500/µL.

*Pomalyst*

- Approvable for members with a diagnosis of multiple myeloma who have been previously treated with at least 2 prior therapies, including lenalidomide (Revlimid) and a proteasome inhibitor (bortezomib [Velcade], ixazomib [Ninlaro] or carfilzomib [Kyprolis]), and have experienced disease progression on or within 60 days of completion of the last therapy and when given in combination with dexamethasone.
- Approvable for members with HIV-negative Kaposi sarcoma (KS).
- Approvable for members with AIDS-related Kaposi sarcoma who are taking highly active antiretroviral therapy (HAART).
- Prescriber, pharmacy and member must be enrolled in the Pomalyst REMS program and the member must be on antithrombotic therapy.

*Purixan*

- Approvable for members with a diagnosis of acute lymphoblastic leukemia (ALL), acute myeloid leukemia (AML) or chronic myeloid leukemia (CML) who are unable to swallow solid oral dosage forms or require a dose that is not obtainable with mercaptopurine tablets.

*Rezlidhia*

- Approvable for members with a diagnosis of relapsed or refractory acute myeloid leukemia (AML) that is relapsed or refractory who have an isocitrate dehydrogenase-1 (IDH1) mutation.

*Rydapt*

- Approvable for members with a diagnosis of newly-diagnosed acute myeloid leukemia (AML) who have an FMS-like tyrosine kinase 3 **(**FLT3) mutation when used in combination with cytarabine and daunorubicin induction as well as cytarabine consolidation chemotherapy.
- Approvable for members with a diagnosis of advanced or aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN) or mast cell leukemia (MCL).

*Scemblix*

- Approvable for members with a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase.

*Sprycel*

- Approvable for members with a diagnosis of chronic-phase Ph+ CML.
- Approvable for members with a diagnosis of accelerated- or blast-phase Ph+ CML who are resistant or intolerant to imatinib (Gleevec), bosutinib (Bosulif) or nilotinib (Tasigna).
- Approvable for members with a diagnosis of Ph+ acute ALL.
- Approvable for members with a diagnosis of gastrointestinal stromal tumor (GIST) who are resistant or intolerant to imatinib (Gleevec), sunitinib (Sutent) or regorafenib (Stivarga).

*Tasigna*

- Approvable for members with a diagnosis of chronic-phase Ph+ CML.

- Approvable for members with a diagnosis of accelerated-or blast-phase Ph+ CML who are resistant, refractory, relapsed or intolerant to imatinib (Gleevec), bosutinib (Bosulif) or dasatinib (Sprycel).
- Approvable for members with a diagnosis of Ph+ acute ALL.
- Approvable for members with a diagnosis of GIST who are resistant, refractory, relapsed or intolerant to imatinib (Gleevec), sunitinib (Sutent) or regorafenib (Stivarga).

*Tibsovo*

- Approvable for members with a diagnosis of relapsed or refractory acute myeloid leukemia (AML) who have an isocitrate dehydrogenase-1 (IDH1) mutation.
- Approvable for members with newly diagnosed AML who have an IDH1 mutation and are 75 years of age or older or are less than 75 years of age with a comorbidity that precludes use of intensive induction chemotherapy.
- Approvable for members with a diagnosis of relapsed or refractory myelodysplastic syndromes (MDS).
- Approvable for members with a diagnosis of locally advanced or metastatic cholangiocarcinoma who have an IDH1 mutation and have been previously treated.

*Vanflyta*

- Approvable for members with a diagnosis of newly-diagnosed acute myeloid leukemia (AML) who have an FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (ITD) mutation when used in combination with cytarabine and daunorubicin induction as well as cytarabine consolidation chemotherapy or as maintenance monotherapy following consolidation chemotherapy.

*Venclexta*

- Approvable for members with a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- Approvable for members 74 years of age or younger with newly diagnosed acute myeloid leukemia (AML) when used in combination with azacitidine, decitabine or low-dose cytarabine who have a comorbidity that precludes use of intensive induction chemotherapy.
- Approvable for members 75 years of age or older with newly diagnosed AML when used in combination with azacitidine, decitabine or low-dose cytarabine.

*Vonjo*

- Approvable for members with a diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) who are not a transplant candidate and have a platelet count $\leq 50 \times 10^9$/L.

*Xospata*

- Approvable for members with a diagnosis of relapsed or refractory acute myeloid leukemia (AML) who have an FMS-like tyrosine kinase 3 (FLT3) mutation.

*Xpovio*

- Approvable for members with a diagnosis of relapsed or refractory multiple myeloma who have been previously treated with at least 4 prior therapies, including at least 2 proteasome inhibitors, at least 2 immunomodulatory agents and an anti-CD38 monoclonal antibody and when given in combination with dexamethasone.

- ❖ Approvable for members with a diagnosis of multiple myeloma who have been previously treated with at least one prior therapy and when given in combination with bortezomib (Velcade) and dexamethasone.
- ❖ Approvable for members with a diagnosis of diffuse large B-cell lymphoma (DLBCL) or transformed DLBCL arising from follicular lymphoma who been treated with at least two prior systemic therapies.

*Zolinza*

- ❖ Approvable for members with a diagnosis of progressive, persistent or recurrent cutaneous manifestations of cutaneous T-cell lymphoma (CTCL) in members who have received at least two previous systemic therapies.

*Zydelig*

- ❖ Approvable for members with a diagnosis of chronic lymphocytic leukemia (CLL) who are relapsed or refractory to at least one prior therapy when used in combination with Rituxan (rituximab).
- ❖ Approvable for members with a diagnosis of follicular lymphoma (FL) or marginal zone lymphoma (MZL) (B-cell non-Hodgkin lymphomas) who are relapsed or refractory to at least two prior therapies.
- ❖ Approvable for members with a diagnosis of small lymphocytic lymphoma (SLL) who are relapsed or refractory to at least two prior therapies.

**EXCEPTIONS:**

- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling **OptumRx at 1-866-525-5827.**

**PREFERRED DRUG LIST:**

- For online access to the Preferred Drug List (PDL), please go to http://dch.georgia.gov/preferred-drug-lists.

**PA AND APPEAL PROCESS:**

- For online access to the PA process, please go to www.dch.georgia.gov/prior-authorization-process-and-criteria and click on Prior Authorization (PA) Request Process Guide.

**QUANTITY LEVEL LIMITATIONS:**

- For online access to the current Quantity Level Limits (QLL), please go to www.mmis.georgia.gov/portal, highlight Pharmacy and click on Other Documents, then select the most recent quarters QLL list.