VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tasigna Prior Authorization Policy
- Tasigna® (nilotinib capsules – Novartis)

REVIEW DATE: 04/14/2021; selected revision 06/23/2021

OVERVIEW

Tasigna, a tyrosine kinase inhibitor (TKI), is indicated for the following uses:[1]

- **Chronic myeloid leukemia (CML)**, chronic phase, newly diagnosed and Philadelphia chromosome positive (Ph+), in adult and pediatric patients ≥ 1 year of age.
- **CML**, Ph+, chronic phase and accelerated phase, in adults with resistance to or intolerance to prior therapy that included imatinib.
- **CML**, Ph+, chronic phase, in pediatric patients ≥ 1 year of age with resistance or intolerance to prior TKI therapy.

Guidelines

Tasigna is addressed in a few guidelines from National Comprehensive Cancer Network (NCCN):

- **Acute Lymphoblastic Leukemia (ALL):** The NCCN guidelines for ALL (version 1.2021 – April 6, 2021) [adults] recommend Tasigna as an option for patients with relapsed or refractory ALL (category 2A).[2]
- **CML:** NCCN guidelines for CML (version 3.2021 – January 13, 2021) state that for patients with chronic phase CML with a low-risk score, the primary treatment recommended includes a first-generation TKI (imatinib [brand or generic]), or a second-generation TKI (Bosulif® [bosutinib tablets], Sprycel® [dasatinib tablets], or Tasigna [all category 1]).[3] For patients with chronic phase CML with an intermediate- or high-risk score, a second-generation TKI is preferred (Bosulif [category 1], Sprycel [category 1], or Tasigna [category 1]). A first-generation TKI (imatinib [brand or generic]) is an alternative (category 2A). Iclusig® (ponatanib tablets) is an option for patients with a T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs or for patients with accelerated-phase CML or blast-phase CML for whom no other TKI is indicated (category 2A).
- **Gastrointestinal Stromal Tumor (GIST):** According to the NCCN GIST guidelines (version 1.2021 – October 30, 2020), Tasigna is recommended as useful in certain circumstances after failure on approved therapies (category 2A).[4] Imatinib is a preferred regimen for first-line therapy (category 1). Ayvakit® (avapritinib tablets) is also a preferred regimen (category 2A) for GIST with platelet-derived growth factor receptor alpha *(PDGFRA)* exon 18 mutations, including the *PDGFRA* D842V mutation. Sutent® (sunitinib capsules) is a preferred regimen (category 1) for second-line therapy (progressive disease after imatinib). Stivarga® (regorafenib tablets) is a preferred regimen (category 1) for third-line therapy (progressive disease after imatinib and Sutent). Qinlock™ (ripretinib tablets) is a preferred regimen (category 1) for fourth-line therapy (progressive disease after imatinib, Sutent, and Stivarga). Besides Tasgina, other additional options after failure on approved therapies that are useful in certain circumstances include Ayvakit, Sprycel (for patients with the *PDGFRA* D842V mutation), Nexavar® (sorafenib tablets), Votrient® (pazopanib tablets), and everolimus plus TKIs (all category 2A).
- **Myeloid/Lymphoid Neoplasms with Eosinophilia:** The NCCN guidelines for myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes (version 3.2021 – August 21, 2020) note that Tasigna is a TKI with activity against *ABL1* rearrangements (category 2A) and it may have a role for use in patients with this condition.[5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tasigna. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tasigna is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Chronic Myeloid Leukemia.** Approve for 3 years if the patient has Philadelphia chromosome-positive chronic myeloid leukemia.

Other Uses with Supportive Evidence

2. **Acute Lymphoblastic Leukemia.** Approve for 3 years if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia; AND
   - **C)** Patient has tried at least one other tyrosine kinase inhibitor for Philadelphia chromosome-positive acute lymphoblastic leukemia.
     Note: Examples include Gleevec (imatinib tablets) and Sprycel (dasatinib tablets).

3. **Gastrointestinal Stromal Tumor.** Approve for 3 years if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried each of the following (i, ii, iii, and iv):
     - **i.** Imatinib or Ayvakit (avapritinib tablets); AND
     - **ii.** Sutent (sunitinib capsules); AND
     - **iii.** Stivarga (regorafinib tablets); AND
     - **iv.** Qinlock (ripretinib tablets).

4. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 3 years if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The tumor has an *ABL1* rearrangement.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tasigna is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tasigna® capsules [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals, Inc.; December 2020.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2021 – April 6, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 9, 2021.
3. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2021 – January 13, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 9, 2021.
4. The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (Version 1.2021 – October 30, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 06/14/2021.
5. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 3.2021 – August 21, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 1, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Acute Lymphoblastic Leukemia:** The condition of approval was changed to move the notation that the disease is "Philadelphia chromosome-positive" to the criteria section. The requirement that the patient is ≥ 18 years of age was added. **Chronic Myeloid Leukemia:** The condition of approval was changed to move the notation that the disease is "Philadelphia chromosome-positive" to the criteria section. **Gastrointestinal Stromal Tumor:** The requirement was removed that the patient has tried Gleevec (imatinib tablets), Sutent (sunitinib capsules), and Stivarga (regorafenib tablets). The requirements that the patient is ≥ 18 years of age and that the patient has tried at least three other medications were added. The examples of medications are provided in a Note. **Myeloid/Lymphoid Neoplasms with Eosinophilia:** This was added as a new condition of approval.	04/14/2021
Selected Revision	**Gastrointestinal Stromal Tumor:** Patient has tried at least three other medications was reworded to "Patient has tried each of the following: imatinib or Ayvakit; Sutent (sunitinib capsules); Stivarga (regorafinib tablets); AND Qinlock (ripretinib tablets). The note of examples of medications was removed.	06/23/2021