PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/04/2022; selected revision 06/22/2022

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 1.2022 – April 4, 2022) [adults] recommend Tasigna as an option for patients with relapsed or refractory ALL (category 2A).[2]
- **CML:** NCCN guidelines for CML (version 3.2022 – January 27, 2022) 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). Scemblix® (asciminib tablets) is a treatment option for chronic phase CML in patients with the T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs (category 2A).
- **Gastrointestinal Stromal Tumor (GIST):** According to the NCCN GIST guidelines (version 1.2022 – January 21, 2022), 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) for sensitive mutations or for platelet-derived growth factor receptor alpha (*PDGFRA*) exon 18 mutations (excluding the D842 mutation). Ayvakit® (avapritinib tablets) is also a preferred regimen (category 2A) for GIST with *PDGFRA* exon 18 mutations that are insensitive to imatinib, including the *PDGFRA* D842V mutation. Sutent® (sunitinib capsules) is a preferred regimen (category 1) for second-line therapy (progressive disease after imatinib). Sprycel is recommended as a preferred second-line therapy after treatment with imatinib (category 1) or Ayvakit (category 2A) [both first-line therapies] for unresectable, progressive or metastatic disease in patients with platelet-derived growth factor receptor alpha *[PDGFRA]* exon 18 mutations that are insensitive to imatinib (including the PDGFRA D842V mutation). Sprycel reintroduction may be considered for symptom palliation as supportive care. Stivarga® (regorafenib tablets) is a preferred regimen (category 1) for third-line therapy. Qinlock™ (ripretinib tablets) is a preferred regimen (category 1) for fourth-line therapy. Besides Tasgina, other additional options after failure on approved

therapies that are useful in certain circumstances include Ayvakit, 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 1.2022 – April 14, 2022) 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]
- **Soft Tissue Sarcomas:** The NCCN guidelines on soft tissue sarcoma (version 1.2022 – March 29, 2022) cite Tasigna as useful in certain circumstances as single-agent therapy for the treatment of pigmented villonodular synovitis/tenosynovial giant cell tumor (category 2A).[6] Turalio® (pexidartinib capsules) is the preferred regimen (category 1) and imatinib is also cited as useful in certain circumstances (category 2A).

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 one of the following criteria:

FDA-Approved Indication

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

Other Uses with Supportive Evidence

2. **Acute Lymphoblastic Leukemia.** Approve for 1 year 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 imatinib and Sprycel (dasatinib tablets).

3. **Gastrointestinal Stromal Tumor.** Approve for 1 year 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) or Sprycel (dasatinib tablets); AND
     - **iii.** Stivarga (regorafinib tablets); AND
     - **iv.** Qinlock (ripretinib tablets).

4. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The tumor has an *ABL1* rearrangement.

5. **Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor.** Approve for 1 year if the patient meets one of the following (A or B):
   A) Patient has tried Turalio (pexidartinib capsules); OR
   B) Patient cannot take Turalio, according to the prescriber.
   Note: Examples of reasons for not being able to take Turalio include patients with elevated liver enzymes or concomitant use of medications that are associated with hepatotoxicity.

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; September 2021.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – April 4, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 28, 2022.
3. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2022 – January 27, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 27, 2022.
4. The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (Version 1.2022 – January 21, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 27, 2022.
5. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2022 – April 14, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 28, 2022.
6. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2022 – March 29, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 29, 2022.