PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/31/2023

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 or intolerance to prior therapy that included imatinib.
- **CML**, Ph+, chronic phase and accelerated phase, in pediatric patients ≥ 1 year of age with resistance or intolerance to prior TKI therapy.

Guidelines

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

- **Acute Lymphoblastic Leukemia (ALL):** NCCN guidelines for adults and adolescents (version 1.2022 – April 4, 2022) recommend Tasigna for Ph+ disease in many different clinical circumstances (e.g., induction, consolidation therapy, maintenance, or relapsed or refractory disease) [category 2A].[2,8] TKIs in combination with other agents (e.g., chemotherapy or corticosteroids) are recommended for induction therapy for Ph+ ALL. TKIs have also been incorporated into consolidation and maintenance therapy, as well as in the relapsed/refractory setting (category 2A). TKI options include: Bosulif® (bosutinib tablets), Sprycel® (dasatinib tablets), imatinib, Tasigna, or Iclusig® (ponatinib tablets) [category 2A]. NCCN panel notes that not all TKIs have been directly studied within the context of each specific regimen and there are limited data for Bosulif in Ph+ ALL. Use of a specific TKI should account for anticipated/prior TKI intolerance and disease-related features. For adults and adolescents, Iclusig has activity against T315I mutations and/or in whom no other TKI is indicated (category 2A).
- **CML:** NCCN guidelines (version 2.2023 – April 13, 2023) recommend Tasigna as a preferred primary treatment for newly diagnosed chronic phase Ph+ CML patients with a low-, intermediate-, or high-risk score (category 1).[3,8] Tasigna is also recommended as an alternative TKI treatment (after primary treatment with imatinib, Bosulif® [bosutinib tablets], or Sprycel® [dasatinib tablets]) for BCR-ABL1 transcript levels (category 2A). Tasigna is also recommended in a variety of other situations, including post-allogeneic hematopoietic stem cell transplant (category 2A).
- **Gastrointestinal Stromal Tumor (GIST):** NCCN guidelines (version 1.2023 – March 13, 2023) recommend Tasigna 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 (excluding platelet-derived growth factor receptor alpha (*PDGFRA*) exon 18 mutations that are insensitive to imatinib including D842V 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. Second-line therapies include sunitinib as "preferred" (category 1) and Sprycel as "other recommended regimen" (category 2A). Stivarga® (regorafenib tablets) is a "preferred" third-line therapy (category 1). Qinlock™ (ripretinib tablets) is a "preferred" fourth-line therapy (category 1).
- **Melanoma: Cutaneous**: NCCN guidelines (version 2.2023 – March 10, 2023) recommend Sprycel as "useful in certain circumstances" for metastatic or unresectable disease with an

activating *KIT* mutation as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with *BRAF*-targeted therapy.[5]

- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions:** NCCN guidelines (version 1.2023 – May 19, 2023) recommend Tasigna as a preferred agent as "other recommended regimens" for *ABL1* rearrangements (category 2A).[6] It is also recommended as treatment in combination with ALL- or acute myeloid leukemia-type induction chemotherapy followed by allogeneic hematopoietic stem cell transplantation (HSCT) [if eligible] for lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and *ABL1* rearrangement in blast phase (category 2A).[8]
- **Soft Tissue Sarcomas:** NCCN guidelines (version 2.2023 – April 25, 2023) recommend Tasigna as "useful in certain circumstances" as single-agent therapy for the treatment of pigmented villonodular synovitis/tenosynovial giant cell tumor (category 2A).[7] 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 criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia.

3. **Gastrointestinal Stromal Tumor.** Approve for 1 year if the patient meets the following criteria (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.** Sunitinib or Sprycel (dasatinib tablets); AND
     - **iii.** Stivarga (regorafenib tablets); AND
     - **iv.** Qinlock (ripretinib tablets).

4. **Melanoma, Cutaneous.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND

B) Patient has metastatic or unresectable disease; AND
C) Patient has an activating *KIT* mutation; AND
D) Patient has tried at least one systemic regimen.
Note: Examples of a systemic regimen include: Opdivo (nivolumab intravenous infusion) + Yervoy (ipilimumab intravenous infusion), Opdivo + Opdualag (nivolumab/relatlimab-rmbw intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Opdivo, Tafinlar (dabrafenib capsules) + Mekinist (trametinib tablets), Zelboraf (vemurafenib tablets) + Cotellic (cobimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets).

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

6. **Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor.** Approve for 1 year if the patient meets one of the following criteria (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. Available at: http://www.nccn.org. Accessed on May 11, 2023.
3. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2023 – April 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
4. The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (version 1.2023 – March 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
5. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
6. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2023 – May 19, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
7. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2023 – April 15, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
8. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Search term: nilotinib. Accessed on May 10, 2023.