PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/01/2024; selected revision 06/12/2024

OVERVIEW

Tasigna, a tyrosine kinase inhibitor (TKI), is indicated for the following uses:[1]
Chronic myeloid leukemia (CML), Philadelphia chromosome positive (Ph+), that is newly diagnosed in adult and pediatric patients ≥ 1 year of age in chronic phase.

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 4.2023 – February 5, 2024) 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 The guidelines state that the ALL panel considers adolescents to be within the age range of 15-39 years. 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 2.2024 – December 5, 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]) (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 1.2024 – March 8, 2024) 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) or Qinlock® (ripretinib tablets) [for patients intolerant or sunitinib] 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 2.2024 – April 3, 2024) recommend Tasigna 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 (category 2A).5

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions: NCCN guidelines (version 1.2024 – December 21, 2023) recommend Tasigna as a "preferred" agent for ABL1 rearrangements in chronic or blast phase (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 1.2024 – April 26, 2024) 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

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

Other Uses with Supportive Evidence

Acute Lymphoblastic Leukemia. Approve for 1 year if the patient meets BOTH of the following (A and B):

Patient is ≥ 15 years of age; AND

Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia.

Gastrointestinal Stromal Tumor. Approve for 1 year if the patient meets BOTH of the following (A and B):

Patient is ≥ 18 years of age; AND

Patient has tried ALL of the following (i, ii, iii, and iv):

Imatinib or Ayvakit (avapritinib tablets); AND

Sunitinib or Sprycel (dasatinib tablets); AND

Stivarga (regorafenib tablets); AND

Qinlock (ripretinib tablets).

Melanoma, Cutaneous. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

Patient is ≥ 18 years of age; AND

Patient has metastatic or unresectable disease; AND

Patient has an activating KIT mutation; AND

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 and tablets for suspension) + Mekinist (trametinib tablets), Zelboraf (vemurafenib tablets) + Cotellic (cobimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets).

Myeloid/Lymphoid Neoplasms with Eosinophilia. Approve for 1 year if the patient meets the BOTH of following (A and B):

Patient is ≥ 18 years of age; AND

The tumor has an ABL1 rearrangement.

Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. Approve for 1 year if the patient meets ONE of the following (A or B):

Patient has tried Turalio (pexidartinib capsules); OR

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:

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

References

Tasigna® capsules [prescribing information]. East Hanover, NJ: Novartis; February 2024.

The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 4.2023 – February 5, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2024 – December 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (version 1.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 29, 2024.

The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Search term: nilotinib. Accessed on April 29, 2024.