Turalio™ (pexidartinib)
(Oral)

Document Number: IC-0489

Last Review Date: 02/04/2020
Date of Origin: 09/03/2019
Dates Reviewed: 09/2019, 02/2020

I. Length of Authorization

- Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Turalio 200 mg capsules: 4 capsules per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 800 mg per day

III. Initial Approval Criteria [1, 2, 3, 4]

Coverage is provided in the following conditions:

Universal Criteria

- Patient is at least 18 years old; **AND**
- Patient does not have any pre-existing active liver or biliary tract disease; **AND**
- Patient and provider are enrolled in the Turalio Risk Evaluation and Mitigation Strategy (REMS) Program; **AND**
- Patient will avoid concomitant use with the following drugs:
  - Strong CYP3A Inducer (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **OR**
  - Acid Reducing Agents (e.g., proton-pump inhibitors, etc.); **AND**

Tenosynovial giant cell tumor (TGCT) †

- Patient has a histologically confirmed diagnosis of TGCT [also referred to as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS)]; **AND**
- Will be used as single-agent therapy

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria [1]

Coverage may be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hepatotoxicity, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread or improvement in patient symptoms and/or functional status; **AND**
- Patient does not have any of the following signs of hepatotoxicity:
  - Increased ALT and/or AST >3 times the upper limit of normal; **OR**
  - Increase in both alkaline phosphatase and GGT >2 times the upper limit of normal; **OR**
  - Increased total bilirubin above the upper limit of normal

V. Dosage/Administration

Indication	Dose
TGCT	The recommended dosage of Turalio is 400 mg taken twice daily on an empty stomach until disease progression or unacceptable toxicity. Swallow whole.
Note: Patients requiring dose reductions due to adverse reactions from Turalio should permanently discontinue therapy if they are unable to tolerate 200 mg twice daily after stepped taper	

VI. Billing Code/Availability Information

HCPCS Code:

- J8999: Prescription drug, oral, chemotherapeutic, nos

NDC:

- Turalio 200 mg capsules: 65597-0402-xx

VII. References

1. Turalio [package insert]. Basking Ridge, NJ; Daiichi Sankyo, Inc.; August 2019. Accessed January 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for pexidartinib. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2020.

3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma 4.2019. National Comprehensive Cancer Network, 2020. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2020.
4. Tap WD, Gelderblom H, Palmerini E, et al; ENLIVEN investigators. Pexidartinib versus placebo for advanced tenosynovial giant cell tumour (ENLIVEN): a randomised phase 3 trial. Lancet. 2019 Jun 19. doi: 10.1016/S0140-6736(19)30764-0. [Epub ahead of print]

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue
Z85.831	Personal history of malignant neoplasm of soft tissue

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC