Truseltiq™ (infigratinib)
(Oral)

Document Number: IC-0608

Last Review Date: 05/02/2022
Date of Origin: 07/01/2021
Dates Reviewed: 07/2021, 05/2022

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]:

- Truseltiq 1 blister pack per 28-day supply

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

- 125 mg daily for 21 days of each 28-day cycle

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1]

- Patient has received a comprehensive ophthalmic examination including optical coherence tomography at baseline and repeated periodically (months 1, 3, and every 3 months thereafter) throughout therapy; **AND**
- Patient serum phosphate level is measured at baseline and periodically throughout therapy; **AND**
- Therapy will not be used concomitantly with other selective FGFR-inhibitors (e.g., erdafitinib, pemigatinib, etc.); **AND**
- Patient will not be on concomitant therapy with any of the following:
  - Acid-reducing agents (if therapy with H2-antagonists or locally acting antacids is unavoidable, stagger the administration); **AND**
  - Strong or moderate CYP3A-Inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole, etc.); **AND**

Cholangiocarcinoma † Φ [1,2]

- Must be used as a single agent; **AND**
- Patient has unresectable locally advanced or metastatic disease; **AND**
- Patient has a susceptible gene mutation rearrangement or fusion in the fibroblast growth factor receptor 2 (FGFR2) gene, as determined by an FDA-approved or CLIA-compliant test §; **AND**
- Used as subsequent therapy after systemic treatment

§ *If confirmed using an FDA approved assay* - http://www.fda.gov/companiondiagnostics

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication specific criteria as identified in section III; **AND**
- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include retinal pigment epithelial detachment (RPED), severe hyperphosphatemia, etc.; **AND**
- Patient serum phosphate level is ≤ 7.5 mg/dL

V. Dosage/Administration

Indication	Dose
Cholangiocarcinoma	The recommended dosage of Truseltiq is 125 mg (one 100 mg capsule and one 25 mg capsule) orally once daily for 21 consecutive days followed by 7 days off therapy, in 28-day cycles. Continue treatment until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS code:

- J8999 – Prescription drug, oral, chemotherapeutic, not otherwise specified

NDC:

- Truseltiq 50 mg daily dose blister pack:
  - Each carton contains 1 blister card containing a 21-day supply (42 capsules; 25 mg infigratinib per capsule). [NDC: 72730-506-01].
- Truseltiq 75 mg daily dose blister pack:
  - Each carton contains 2 blister cards containing a 21-day supply (63 capsules; 25 mg infigratinib per capsule). [NDC: 72730-202-01].
- Truseltiq 100 mg daily dose blister pack:

- Each carton contains 1 blister card containing a 21-day supply (21 capsules; 100 mg infigratinib per capsule). [NDC: 72730-111-01].
- Truseltiq 125 mg daily dose blister pack:
  - Each carton contains 1 blister card containing a 21-day supply (21 capsules, 100 mg infigratinib per capsule and 21 capsules; 25 mg infigratinib per capsule). [NDC: 72730-101-01].

VII. References

1. Truseltiq [package insert]. Brisbane, CA; QED Therapeutics, Inc.; May 2021. Accessed March 2022.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) infigratinib. National Comprehensive Cancer Network, 2022. 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 March 2022.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hepatobiliary Cancers. Version 5.2021. National Comprehensive Cancer Network, 2022. 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 March 2022.
4. Javle M, Lowery M, Shroff RT,. Phase II Study of BGJ398 in Patients With FGFR-Altered Advanced Cholangiocarcinoma. J Clin Oncol. 2018 Jan 20;36(3):276-282. doi: 10.1200/JCO.2017.75.5009. Epub 2017 Nov 28.
5. Borad MJ, Gores GJ, Roberts LR. Fibroblast growth factor receptor 2 fusions as a target for treating cholangiocarcinoma. Curr Opin Gastroenterol. 2015 May;31(3):264-8. doi: 10.1097/MOG.0000000000000171. Review.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C22.1	Intrahepatic bile duct carcinoma
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified

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), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/ 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/LCA): 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.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC