Clinical Policy Title:	infigratinib
Policy Number:	RxA.691
Drug(s) Applied:	Truseltiq®
Original Policy Date:	08/16/2021
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Cholangiocarcinoma (must meet all):

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma;
2. Positive result of FDA-approved test to determine fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement;
3. Member has not previously received a selective fibroblast growth factor receptor (FGFR) inhibitor (e.g., Stivarga®, Pemazyre™).

Approval Duration

All Lines of Business (except Medicare): 3 months

II. Continued Therapy Approval

A. Cholangiocarcinoma (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Javle M, Lowery M, Shroff RT, et al. Phase ii study of bgj398 in patients with FGFR-altered advanced cholangiocarcinoma. JCO. 2018;36(3):276-282. Available at: https://ascopubs.org/doi/10.1200/JCO.2017.75.5009. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/16/2021	09/14/2021
Policy was reviewed: 1. Continued Therapy Approval has been reviewed and updated. 2. References were reviewed and updated.	4/19/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.5: Updated to remove NCCN recommended prior therapy	5/30/2023	7/13/2023

criteria "Member must have received at least one prior line of systemic therapy recommended by NCCN (e.g. gemcitabine + cisplatin, gemcitabine + oxaliplatin, 5-fluorouracil, capecitabine, gemcitabine and others)." 2. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. Reference was reviewed and updated.	08/28/2024	9/13/2024