

<b>Clinical Policy Title:</b>	infigratinib
<b>Policy Number:</b>	RxA.691
<b>Drug(s) Applied:</b>	Truseltiq®
<b>Original Policy Date:</b>	08/16/2021
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	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

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>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 )."</p> <p>2. References were reviewed and updated.</p>		
Policy was reviewed.	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed age restrictions.</li> <li>2. Removed prescriber restrictions.</li> <li>3. Removed dose restrictions.</li> <li>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li> <li>5. Removed reauthorization requirement for positive response to therapy.</li> <li>6. Updated approval duration verbiage.</li> <li>7. Reference was reviewed and updated.</li> </ol>	08/28/2024	9/13/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025