



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMIGATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMIGATINIB	PEMAZYRE	46462		GPI-10 (2153226000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has been previously treated for unresectable locally advanced or metastatic cholangiocarcinoma
 - The patient has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test
 - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to initiation of therapy and at the recommended scheduled intervals

If yes, **approve for 12 months by HICL or GPI-10 for #14 per 21 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has a fibroblast growth factor receptor 1 (FGFR1) rearrangement
 - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to initiation of therapy and at the recommended scheduled intervals

If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEMIGATINIB (Pemazyre)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 1. Unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has spread to nearby tissue and lymph nodes and cannot be removed by surgery, or it has spread to other parts of the body)
 2. Relapsed or refractory myeloid/lymphoid neoplasms (a type of blood cancer that has returned or did not respond to treatment)

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

- B. **If you have unresectable locally advanced or metastatic cholangiocarcinoma, approval also requires:**
 1. You are 18 years of age or older
 2. You have previously been treated for unresectable locally advanced or metastatic cholangiocarcinoma
 3. You have a fibroblast growth factor receptor 2 (FGFR2: a type of protein) fusion or other rearrangement as detected by a Food and Drug Administration (FDA)-approved test
 4. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times
- C. **If you have relapsed or refractory myeloid/lymphoid neoplasms, approval also requires:**
 1. You are 18 years of age or older
 2. You have a fibroblast growth factor receptor 1 (FGFR1: a type of protein) rearrangement
 3. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pemazyre.

REFERENCES

- Pemazyre [Prescribing Information]. Wilmington, DE: Incyte Corporation; August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

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