



Notice to Covered Entities Regarding PEMAZYRE™
Limited Distribution Network
June 2020

This notice provides information to 340B covered entities about how to acquire PEMAZYRE™ (pemigatinib) at 340B ceiling prices.

PEMAZYRE is an orphan drug approved on April 17, 2020 for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement as detected by an FDA-approved test. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Incyte offers the 340B price to all covered entities, except those that are ineligible for 340B pricing for orphan drugs as PEMAZYRE is designated for orphan use by the FDA.¹

In light of the very small patient population anticipated to be treated with PEMAZYRE, PEMAZYRE is available to 340B covered entities through the sole specialty distributor for the product, ASD Healthcare. If a 340B covered entity does not have an in-house pharmacy capable of dispensing PEMAZYRE, then Incyte will support a contract pharmacy arrangement for that covered entity with Biologics by McKesson, the only designated specialty pharmacy dispensing PEMAZYRE.

Incyte takes seriously both its obligations to protect patient safety and to comply with the 340B statute, and has designed this distribution network accordingly. This distribution network may change from time-to-time. If a covered entity has any questions regarding how it may access PEMAZYRE at the 340B price, please contact Incyte at Incyte_TradeandDistribution@incyte.com.

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¹ These covered entities are free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. See 42 U.S.C. § 256b(e).