

## 340B Distribution Notice for Nulibry™ (fosdenopterin) for injection (NDC 73129-0001-01)

February 26<sup>th</sup>, 2021

Origin Biosciences, Inc (“Origin,” labeler code 73129) markets and sells Nulibry™ (fosdenopterin) for injection, a recently-approved therapy indicated to reduce the risk of mortality in patients with molybdenum Cofactor Deficiency (MoCD) Type A,<sup>1</sup> an ultra-rare genetic disease. Origin is committed to compliance with all aspects of the 340B Drug Discount Program. By this notice, we want to make clear how 340B covered entities may access Nulibry™ at the statutory 340B ceiling price.

Origin has created a defined distribution network for Nulibry™ for several reasons. Nulibry™ is a highly specialized biological product that is very difficult to manufacture. This difficulty means that production quantity is necessarily limited. In order to ensure that there is adequate supply in the market -- including critical safety stock – Origin must closely monitor the flow of product through the distribution channel. Maintaining a defined distribution network for Nulibry™ greatly aids in that monitoring effort.

Further, Nulibry™ is particularly sensitive to environmental factors such as temperature. To ensure maintenance of biological activity, stringent conditions for storage are necessary—including cold storage of unreconstituted product between -25°C and -10°C (-13°F and 14°F). The defined distribution network for Nulibry™ helps ensure that dispensing facilities have appropriate cold storage capabilities.

Finally, preparation and dosing of Nulibry™ requires specialized training and equipment. Origin trains each dispensing pharmacist on how to handle and administer Nulibry™. Maintaining a defined distribution network for Nulibry™ facilitates Origin’s ability to train all dispensing pharmacists.

For these reasons, Origin makes Nulibry™ available to hospital inpatient facilities and through its specialty pharmacy partner Biologics by McKesson (800-850-4306 or contact Origin at [scott.denobile@bridgebio.com](mailto:scott.denobile@bridgebio.com)). This defined network applies equally to 340B covered entities and all other commercial dispensaries. Covered entities may access Nulibry™ at the 340B ceiling price through contract pharmacy arrangements with Biologics.

If you have any questions about this limited distribution or Nulibry™, please do not hesitate to contact [scott.denobile@bridgebio.com](mailto:scott.denobile@bridgebio.com).

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<sup>1</sup> Nulibry™ (fosdenopterin) Highlights of Prescribing Information, <https://www.nulibry.com/pdfs/nulibry-prescribing-information-v2.pdf>.