

## MorphoSys Notice to 340B Covered Entities Regarding MONJUVI® (tafasitamab-cxix) for Injection for Intravenous Use

August 19, 2020

This notice provides information for 340B Drug Pricing Program (340B) covered entities about how to acquire MONJUVI\* (tafasitamab-cxix) for injection, for intravenous use at the 340B ceiling price. MONJUVI, which was approved by the U.S. Food and Drug Administration (FDA) under an original Biologics License Application (BLA) on July 31, 2020, is a CD19-directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). The FDA granted breakthrough therapy, fast track, and orphan drug designations to MONJUVI.

MorphoSys manufactures MONJUVI.¹ The product is available as a lyophilized powder in a single-dose vial for reconstitution, in following packaging configuration:

NDC-11	Dosage Strength	Package Size
73535-0208-01	200 mg	1

MorphoSys offers MONJUVI at the 340B ceiling price to all covered entities, except those that are ineligible for 340B pricing for drugs, like MONJUVI, that are designated by the FDA for an orphan use.<sup>2</sup> MorphoSys takes its participation under the 340B program seriously and makes every effort to ensure that MONJUVI is available to covered entities in a manner that is no more restrictive than for its non-340B customers. Accordingly, eligible 340B covered entities may purchase MONJUVI at the 340B price for delivery to the covered entities' facilities through the MorphoSys network of specialty distributors, which is available at <a href="https://www.mymissionsupport.com/pdf/monjuvi-distribution-and-ordering-flashcard.pdf">https://www.mymissionsupport.com/pdf/monjuvi-distribution-and-ordering-flashcard.pdf</a>. This network may change over time.

If a covered entity has questions about acquiring MONJUVI or experiences any difficulty obtaining MONJUVI at the 340B price, please contact MorphoSys at <a href="mailto:us.customerservice@morphosys.com">us.customerservice@morphosys.com</a>.

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<sup>&</sup>lt;sup>1</sup> In the United States, MONJUVI is co-commercialized by MorphoSys and Incyte Corporation.

These types of covered entities are critical access hospitals, rural referral centers, free-standing cancer hospitals, and sole community hospitals. See *Exclusion of orphan drugs for certain covered entities* at 42 U.S. Code § 256b(e).