

**Notice to 340B Covered Entities Regarding PALYNZIQ™
(NDCs 68135-0058, 68135-0673, and 68135-0756)**

June 10, 2020

This notice provides information for eligible 340B covered entities about how to acquire PALYNZIQ (*pegvaliase-pqpz*) injection at the 340B price.

PALYNZIQ (*pegvaliase-pqpz*) injection is the first FDA-approved enzyme substitution therapy designed to address the underlying cause of phenylketonuria ("PKU"), a rare and genetic brainthreatening condition marked by an inability to break down phenylalanine ("Phe"). PALYNZIQ is a once-daily self-administered therapy, clinically proven to reduce blood Phe levels in adults with PKU who have uncontrolled blood Phe levels on existing management of Phe levels over 600 micromol/L.

Due to the risk of patient anaphylaxis, PALYNZIQ is subject to an FDA-approved Risk Evaluation and Mitigation Strategy ("REMS"). As a condition of the REMS, BioMarin has developed a limited distribution network that applies to 340B covered entities and non-340B covered entities alike. Under the limited distribution network, the product is available only through a limited set of specialty pharmacies, each of which must meet stringent and onerous requirements and certifications to meet the REMS requirements.

The REMS-certified network specialty pharmacies are:

1. Accredo - 1680 Century Center Pkwy, Suite 1 Memphis, TN 38134
• 1-844-492-4944
2. Caremark/CVS - 11162 Renner Blvd. Lenexa, KS 66219
• 1-888-217-4240, Option 1
3. OptumRx (Diplomat) - 4100 S. Saginaw Street Flint, MI 48507
• 1-855-242-1786
4. Fairview – 711 Kasota Ave SE Minneapolis, MN 55414
• 612-672-5260

340B covered entities with contract pharmacy relationships with one or more of the above four REMS-certified network specialty pharmacies should contact them directly for ordering instructions. One of these pharmacies will dispense and ship PALYNZIQ directly to patients consistent with the requirements of the REMS.

BioMarin takes very seriously its commitment to patient safety and its obligations under the 340B Program and seeks to ensure that PALYNZIQ is available to 340B covered entities in the same manner in which the product is available to other entities.

If you have any questions regarding the REMS-restricted distribution of PALYNZIQ, please contact SPTRADE@BMRN.COM.

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