

## Apellis Limited Distribution Notice

May 2021

Apellis Pharmaceuticals, Inc. (“Apellis,” labeler code 73606) is committed to compliance with all aspects of the 340B Drug Discount Program. By this Limited Distribution Notice, we want to make clear how covered entities may access Apellis’s product pegcetacoplan 1080mg/20ml vial at the 340B price.

Pegcetacoplan is anticipated to be approved by FDA May 14, 2021, and launched immediately thereafter. It is anticipated to be indicated for paroxysmal nocturnal hemoglobinuria. Pegcetacoplan will also be subject to an FDA-imposed REMS that requires, among other things, certification by healthcare providers. To avoid degradation, stringent conditions for cold storage and dispensing are also necessary.

To ensure that patients being treated with pegcetacoplan receive the best possible care, and to ensure adherence to the FDA-imposed REMS, Apellis has developed a limited distribution arrangement through (i) a closed network of qualified pharmacies, and (ii) a dedicated and trained specialty pharmacy. All prescribers of pegcetacoplan – 340B-eligible and otherwise – are subject to this limited distribution plan.

**First**, covered entities that meet certain criteria may join a group of pharmacies that may themselves purchase, possess, and dispense pegcetacoplan (the “pegcetacoplan closed network”). The criteria were developed to ensure compliance with pegcetacoplan’s REMS and cold storage requirements. Covered entities that wish to enter the pegcetacoplan closed network must agree to each of these conditions. Applications to join the closed network can be requested here: [distribution@apellis.com](mailto:distribution@apellis.com). Covered entities in the pegcetacoplan closed network may purchase pegcetacoplan directly from Apellis’s specialty distribution partners at the 340B ceiling price. Upon launch, Apellis’s specialty distribution partners will be: ASD Healthcare, Cardinal Health, McKesson Plasma & Biologics LLC, and McKesson Specialty Care Distribution LLC.

**Second**, pegcetacoplan is also available through PANTHERx Rare Specialty Pharmacy. Pegcetacoplan may only be dispensed by PANTHERx Rare Specialty Pharmacy directly to patients. The main number for PANTHERx Rare Specialty Pharmacy is 855-726-8479; prescriptions may be submitted via facsimile at 855-246-3986.

A covered entity with a contract pharmacy relationship with PANTHERx Rare Specialty Pharmacy may place bill to/ship to replenishment orders for pegcetacoplan at the 340B price through Apellis’s third party logistics provider, Cardinal Health, pursuant to its contract pharmacy agreement with PANTHERx Rare Specialty Pharmacy. To place orders with Cardinal Health, customers may use the fax 614-553-9784 or email [GMB-SPS-APELLIS@cordlogistics.com](mailto:GMB-SPS-APELLIS@cordlogistics.com).

***Third***, 340B covered entities that do not meet the conditions of the closed network, and do not have a contract pharmacy relationship with PANTHERx Rare Specialty Pharmacy, may submit prescriptions for pegcetacoplan that will be filled by PANTHERx Rare Specialty Pharmacy directly to the covered entity's patients.

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