**INTRODUCTION**: Eculizumab is currently the only treatment available for paroxysmal nocturnal hemoglobinuria (PNH). It was recently incorporated by Conitec and listed in the specialized component of SUS, making it necessary to develop a Clinical Protocol and Therapeutic Guidelines (PCDT), so that the medicine can be distributed to the population within 180 days. In this context, the challenge arises of rapidly developing a robust, evidence-based and society-validated PCDT for a rare disease with major financial impact on SUS.

**METHOD**: The scope of the PCDT was directed by the incorporation of eculizumab, which defined the beneficiary population and the criteria for its use. The research questions were elaborated and systematic searches were made in the literature. In order to identify the main HPN medical specialists and to validate the scope of the PCDT, the snowball method was used. Then, a panel was held to present the draft of the PCDT with a group of experts, medical societies and patient representatives, to validate the text, clarify critical points and finalize the elaboration of the PCDT.

**RESULTS**: After searching for evidence, eligibility and treatment interruption criteria were established. Through the snowball method, five PNH experts were contacted, representing all five regions of Brazil, and their contributions were used to prepare the draft version of the PCDT. The text was presented and discussed in a 9-member panel to define the final version of the PCDT, which was presented to Conitec and approved by the plenary. In the Public Consultation, of the 309 contributions received, 85% considered the PCDT to be very good or good.

**CONCLUSION**: The HPN PCDT was elaborated and validated with agility, in approximately 60 days, with good acceptance by society.