Vutrisiran: Surgical Procedures

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SUMMARY

- In the HELIOS-A study, patients who had a major surgery planned within 3 months or anticipated surgery during the study (through Month 18) were excluded from enrollment. Patients who had a liver transplant or were likely to undergo liver transplantation during the study were also excluded from enrollment.[1]
- In the HELIOS-B study, patients who had a prior or anticipated (during the first 12 months after randomization) heart, liver, or other organ transplant or implantation of left-ventricular assist device were excluded from enrollment. There were no additional exclusion criteria regarding surgical procedures.[2]
- A cumulative post-marketing review of Alnylam Pharmaceuticals' global safety database did not identify any safety concerns involving surgical procedures related to the use of vutrisiran.[3]
- No additional information is available regarding the incidence of surgical procedures, including orthopedic procedures, in the HELIOS-A and HELIOS-B studies.

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REFERENCES

1. Alnylam Pharmaceuticals. Data on file. MED-ALL-TTRSC02-2300015.
2. Protocol for: Fontana M, Berk JL, Gillmore JD, et al. Vutrisiran in patients with transthyretin amyloidosis with cardiomyopathy. *N Engl J Med*. 2025;392(1):33-44. doi:10.1056/NEJMoa2409134
3. Alnylam Pharmaceuticals. Data on file. MED-ALL-VUTRI-2500021.